Talking about medicines (TABS): a multi-method study to understand reasons for medicines non-adherence in children and young people with chronic illness, and to improve their contribution to managing their medicines

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### Glossary of terms/abbreviations

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<tr>
<td>A&amp;E</td>
<td>Accident and Emergency Department</td>
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<tr>
<td>AAMW</td>
<td>Ask About Medicines Week</td>
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<tr>
<td>ADHD</td>
<td>Attention deficit and hyperactivity disorder</td>
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<tr>
<td>AEI</td>
<td>Adherence-enhancing intervention</td>
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<tr>
<td>AOM</td>
<td>Acute otitis media</td>
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<tr>
<td>BTEC</td>
<td>Business and Technology Education Council</td>
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<tr>
<td>CCSQ</td>
<td>Compliance/Caregiver Satisfaction Questionnaire</td>
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<tr>
<td>CCT</td>
<td>Concurrent controlled trial</td>
</tr>
<tr>
<td>CF</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>CHD</td>
<td>Congenital heart disease</td>
</tr>
<tr>
<td>CHQ-PF28</td>
<td>Child Health Questionnaire-PF28</td>
</tr>
<tr>
<td>CLoC</td>
<td>Child Locus of Control</td>
</tr>
<tr>
<td>CPAP</td>
<td>Continuous positive airways pressure</td>
</tr>
<tr>
<td>CSE</td>
<td>Certificate of Secondary Education</td>
</tr>
<tr>
<td>CYP</td>
<td>Child(ren) and young person (people)</td>
</tr>
<tr>
<td>ED</td>
<td>Emergency Department</td>
</tr>
<tr>
<td>EMSY</td>
<td>East Midlands and South Yorkshire</td>
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<tr>
<td>EOT</td>
<td>End of therapy</td>
</tr>
<tr>
<td>EOS</td>
<td>End of study</td>
</tr>
<tr>
<td>FEV₁</td>
<td>Forced expiratory volume in one second</td>
</tr>
<tr>
<td>FU</td>
<td>Follow up</td>
</tr>
<tr>
<td>GCE</td>
<td>General Certificate of Education</td>
</tr>
<tr>
<td>GCSE</td>
<td>General Certificate of Secondary Education</td>
</tr>
<tr>
<td>GP</td>
<td>General practitioner</td>
</tr>
<tr>
<td>HbA₁c</td>
<td>Glycosylated haemoglobin</td>
</tr>
<tr>
<td>HCP</td>
<td>Health care professional</td>
</tr>
<tr>
<td>HEAR</td>
<td>Helping Establish Adolescent Rapport</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>IDDM</td>
<td>Insulin-dependent diabetes mellitus</td>
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<tr>
<td>IMD</td>
<td>Index of multiple deprivation</td>
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<tr>
<td>INR</td>
<td>International normalised ratio</td>
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<tr>
<td>JIA</td>
<td>Juvenile idiopathic arthritis</td>
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<tr>
<td>LSOA</td>
<td>Lower Super Output Areas</td>
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<tr>
<td>MASRI</td>
<td>Medication Adherence Self Report Inventory</td>
</tr>
<tr>
<td>MCRN</td>
<td>Medicines for Children Research Network</td>
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<tr>
<td>MDI</td>
<td>Metered dose inhaler</td>
</tr>
<tr>
<td>MEMS</td>
<td>Medication Event Monitoring System</td>
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<tr>
<td>MRC</td>
<td>Medical Research Council</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>NSF</td>
<td>National Service Framework</td>
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<tr>
<td>NVQ</td>
<td>National Vocational Qualification</td>
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<tr>
<td>ONS</td>
<td>Office of National Statistics</td>
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<tr>
<td>OPD</td>
<td>Outpatient Department</td>
</tr>
<tr>
<td>PCAT</td>
<td>Paediatric Consultation Assessment Tool</td>
</tr>
<tr>
<td>PCP</td>
<td>Primary care provider</td>
</tr>
<tr>
<td>PCRN</td>
<td>Primary Care Research Network</td>
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<td>PCT</td>
<td>Primary Care Trust</td>
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<tr>
<td>PEF</td>
<td>Peak expiratory flow</td>
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<tr>
<td>PFM</td>
<td>Peak flow meter</td>
</tr>
<tr>
<td>pMDI</td>
<td>Pressurised metered dose inhaler</td>
</tr>
<tr>
<td>PMR</td>
<td>Patient medical record</td>
</tr>
<tr>
<td>PROSPER</td>
<td>Planning Recruitment Options: Strategies for Primary Care Research</td>
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<tr>
<td>RCPCH</td>
<td>Royal College of Paediatrics and Child Health</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>REC</td>
<td>Research Ethics Committee</td>
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<tr>
<td>SD</td>
<td>Standard deviation</td>
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<tr>
<td>SES</td>
<td>Socio-economic status</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>VHC</td>
<td>Valved holding chamber</td>
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<tr>
<td>VNS</td>
<td>Vagal nerve stimulation</td>
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Executive Summary

Background
Medicines-based self-management of longstanding illness can be suboptimal in children and young people (CYP), with medicines adherence ranging from 25 to 82%.

Aim
To develop a paediatric medicines management package involving children, parents and health care providers that will empower children to talk openly and be active partners in decisions about medicine-taking for long-term conditions.

Key objectives:
1. To use critical evidence synthesis and consensus-building methods to examine the child-parent-provider triad at individual and organisational levels to:
   a. examine expectations, experiences and concerns about medicines;
   b. explore transferring responsibility control for older adolescents, and how to facilitate honest disclosure of medicines-taking behaviours;
   c. clarify perceptions of roles, empowerment, rights and responsibilities associated with long-term medicines use;
   d. understand children’s and parents’ interaction with the health system in community, primary and secondary care from initial contact to medicines supply, and over time;
   e. identify effective interventions to improve medicines use in CYP

2. To devise a child-centred paediatric medicines management package that works across ages, social characteristics, conditions, complexity of needs and service delivery settings, informed by individual and organisational perspectives;

3. To explore operation of the package, the complexity and nature of resulting consultations, to determine feasibility and generalisability;

4. To assess methods of objective evaluation of behaviour change, clinical outcome and resource use.
This study used a range of methods, and a range of overlapping literature to address the study objectives. Objectives 1a-1e were achieved through a review of the published evidence and focus groups and interviews with CYP, parents and practitioners. Each source of evidence provided some input to each objective. By triangulating the sources of evidence, we were able to address each objective.

An Expert Advisory Panel was convened and a number of individuals and organisations were identified through a snowballing process, as key stakeholders to participate in the study from the outset. The interpretation of data was validated with the stakeholders, and the Expert Advisory Panel. Involvement of stakeholders throughout this project has enabled us to ensure that the research is relevant and accessible

Objective 1e was not in the original proposal. Our overall hypothesis was that, once real reasons for non-adherence had been disclosed and discussed within the CYP-parent-practitioner triad, we would be able to provide recommended evidence-based interventions, linked to that reason for non-adherence, from published evidence, to support the practitioner. However, the published reviews of interventions to improve adherence available did not provide us with sufficient guidance to inform the development of an evidence-based intervention. Therefore, we needed to carry out our own review of interventions.

Determinants of medicines-taking and improving adherence in children and young people

We carried out a review of the published evidence and focus groups and interviews with CYP, parents and practitioners.

Our literature review summarised current knowledge about determinants of medicines-taking in CYP. Of 197 studies, most were American, fewer than 10 percent were British, over half were in asthma, most used quantitative methods and examined parent report of factors. To identify factors relevant to the UK, increase input from CYP and obtain information on diseases beyond asthma, forty-three face-to-face interviews were conducted with 26 parents and 18 CYP with asthma, CHD, diabetes or epilepsies in the East Midlands. (In one of the interviews both parents were present, providing a total of 44 interviewees, but 43 interviews.) Three focus groups were conducted with 19 practitioners.

Similar determinants of non-adherence were identified from these sources. Where both parents’ and CYP’s views or behaviour were examined, these were likely to differ. Person-related determinants reducing adherence were reduced illness severity, increased illness duration, forgetting, reduced self-efficacy in adolescents, increased age. This was supported by the CYP in our interviews. Tiredness and a change of routine were the most common reasons for forgetting. Perceived necessity for a medicine was a key driver for adherence. High concern and/or low perceived necessity were associated with lower scores of parent-rated adherence. There is conflicting evidence of
an association of knowledge and information use with adherence. This did not emerge as a significant factor in the interviews with parents and CYP.

Regimen-related determinants reducing adherence were poor palatability or acceptability, anticipation of adverse effects, but not the experience of adverse effects, and increased complexity. Once daily regimens improved adherence over more frequent dosing, or doses taken outside the home. Some variables related to social and family context have associations with reduced adherence: lack of family routine, poor family functioning and single parent families. Socio-economic status, racial/ethnic or cultural background and school environment did not have a consistent effect.

Relationship-related determinants reducing adherence were poor parent supervision, highly levels of conflict within family relationships, perceived lack of concern from practitioners, and difficulties negotiating the health system. These findings were strengthened by our stakeholder work. The strongest theme emerging from the study with parents was the need to maintain control of their CYP’s medicines-taking, and a lack of confidence that their CYP could self-manage. Support was variable within the family setting and support from practitioners was mixed. The study CYP relied on their parents and rituals within the home to remind them to take medication, share the informational load in consultations and to liaise with schools. The study practitioners were aware that they talked over the CYP, and insufficient time was spent during consultations talking about medicines. They felt that adverse effects and problems with access at school were key barriers to adherence, (this was not reported by CYP or parents) and suspected that CYP stopped taking medicines without telling anyone.

There were key gaps and limitations in the evidence around facilitators and barriers to medicines-taking in CYP. Studies varied in quality, design, age range, measurement of adherence, knowledge or sociodemographic characteristics and there was uneven distribution of the numbers of studies examining each theme. There were few UK studies, and studies in asthma dominate. This was compounded by the general lack of use of validated measures of adherence and the use of parent report of factors rather than CYP report. Consequently, it is not often known what is important to CYP. Few studies examined the association between multiple factors and adherence behaviour. Very few of the studies, other than the 44 studies that specifically examined age, controlled for effect of age.

Our review of interventions assessed evidence about interventions to improve adherence in CYP. Of 48 studies, most were in asthma (29) and diabetes (7). Nine studies showed significant improvements in adherence and outcome. Features of effective interventions were those based on reasons for non-adherence, those taken to the patient, involving the family, convenient for CYP and parent, sensitive to age and development, sustained over time and co-ordinated with care delivery. There was no optimal approach to improving medicines-taking in CYP. Poor quality study design commonly precluded assessment of effectiveness.
From our interviews and focus groups, adherence seems best when parents and CYP work together to optimise medicines use, and homes with consistent routines are most conducive to good medicines taking routines. The use of evening doses should be minimised. Positively, schools seemed to provide good support generally, although access issues need to be improved in some places.

**TABS intervention development**

We combined the results of the consensus-building methods and interviews with the critical evidence synthesis of reasons for non-adherence to obtain an overall picture of reasons for non-adherence. We then synthesised this evidence with the findings from the systematic review of interventions to inform our intervention design.

We proposed that the TABS intervention should engender open discussion between parents, CYP and practitioners to identify, and remove, key modifiable barriers to adherence. A pre-consultation tool was proposed, to act as a prompt to facilitate discussion of medicines-taking between parent and CYP prior to the consultation. The purpose of this was to create “proactive patients” through building and supporting the partnership between the parent and CYP, to help both to engage with practitioners. In addition, the intervention proposed to support practitioners by providing a briefing on actual reasons for non-adherence in CYP derived from our work, and to facilitate a more patient-centred consultation, with the aid of a prompt. The “prepared practitioner” should understand determinants of non-adherence and be able to enhance the parents’ and CYP’s input into the discussion about medicines.

**TABS intervention feasibility study**

The TABS intervention consisted of a pre-consultation tool for the parents and CYP to complete and use as a basis for discussion around medicines with the practitioner. The practitioner had received a briefing session around barriers to medicines-taking in CYP and how to engage CYP in consultations. During the initial consultation an action plan was to be developed to form the basis of follow-up consultations. The intervention was tested in primary care, community and hospital-based secondary care, and community pharmacy, with 40 parent-CYP dyads in the East Midlands, in CYP with asthma (14), CHD (4), diabetes (11) and epilepsies (11), aged from 5 to 17, most taking one to two medicines regularly. The sample contained dyads from minority ethnic groups and low socioeconomic groups, although these were under-represented.

Assessing the use and usefulness of the preconsultation tool and practitioner prompt required combining researcher observations and parent/CYP/practitioner report.

Of the 40 parents and CYP, 31 parents and 20 CYP completed the pre-consultation form before coming to the appointment and 9 parents and 5
CYP filled it out at the clinic/practice. All parent-CYP dyads took the pre-consultation tool into the consultation and 8/40 handed it to the practitioner.

The CYP used, or found the pre-consultation tool useful in 17/40 consultations. The parent found the pre-consultation tool useful in 21/40 consultations. The practitioner found the pre-consultation tool or practitioner prompt useful in 14/40 consultations. The number of consultations where the pre-consultation tool was used either by the parent or the CYP was 26/40. In 12/40 consultations, CYP and parent used the tool. All members of the triad used the tool in 8/40 consultations.

The number of consultations where the pre-consultation tool or the practitioner prompt was used by any member of the triad was 29/40. Failure to use the tool was associated with stressful consultations, parents or practitioners feeling they did not need the tool, or forgetting to use the tool. Many of the practitioners did not attend the training session, only attended for part of it, or did not engage with the topic. It was not possible to assess either baseline knowledge or learning from the session. Of the 14 practitioners who had used the pre-consultation tool or prompt, ten had found it “useful”.

The quality of the interaction between parent, CYP and practitioner was assessed through the use of the Paediatric Consultation Assessment Tool (PCAT). The mean scores of different aspects of the consultation were high, but with variability in the scores of individual practitioners. Parents and CYP aspects were either scored very similarly within an individual consultation, or the CYP aspect scored the poorer, suggesting that consultations were often targeted at the parent.

The group reported high levels of self-reported medicines adherence as rated by CYP (mean 85%) and parents (mean 89%). Self-efficacy was high with a strong sense of personal control of medicines-taking. Child health (CHQ-PF28) scores showed that the sample had poor physical and psycho-social wellbeing.

In a post-hoc exploratory analysis, fourteen parent-CYP dyads were observed by the researchers to have used the pre-consultation tool actively during the consultation. At two month follow-up, there were no significant changes in clinical outcomes for those who did or did not use the pre-consultation tool. In the group that used it, there was a significant improvement in psycho-social well-being over time (Wilcoxon test, Z=-2.76, p=0.006) and CYP rated themselves as being more in control of their own health at follow-up compared to baseline (Z=-2.233, p=0.026). There were improvements in adherence but these failed to reach significance. There were no significant differences in outcomes in those who had not used the tool. We must not over-interpret these findings. The parents and CYP who chose to use the pre-consultation tool may well have been highly motivated and destined to succeed, with or without the tool.

The ability of the intervention to address previously encountered problems affecting adherence and promote behaviour change was examined within each case study by collecting data at both baseline and at two follow-up points (1 week and 2 months after the consultation). An evaluative
framework assessing clinical outcomes and resource consumption was also developed. Generally, we were able to collect the data we needed. In terms of evaluation, all the measures used performed well and appeared to be discriminatory. We were able to collect data for a range of resource use parameters including length of initial and subsequent consultations, NHS contact (primary and secondary care) and medicines consumption, although there were some discrepancies between CYP, parent and practitioner report.

We had no control over the selection of patients, by the clinical sites, due to R&D restrictions, although we did ask for patients with poor adherence. This significantly reduced the potential utility of the intervention. Some clinical sites sent out invitation packs to people who did not fit the inclusion criteria. We had no control over this process, due to R&D restrictions. This contributed to the increased length of time taken to recruit, the reduced relevance to the intervention, and the ultimate reduction in numbers recruited to the study. We requested that clinical sites selected patients that they suspected were not adhering to medicines but we had no control over this. We feel the high rate of reported adherence was caused by a number of factors. Lack of appropriate selection of patients by clinical sites participating in the study resulted in the selection of dyads who are already more interested in their medicines and may be more adherent. There was also likely to be social desirability bias leading to unwillingness to admit to non-adherence by patients, parents and practitioners. From our experience, it takes skill to present non-adherence as a “norm” in medicines use behaviour, such that CYP and parents feel they can disclose real behaviour. We have reviewed the literature on adherence and the adherence levels reported here are much higher. However, the sample was not unrepresentative in terms of emotional and physical wellbeing.

Conclusions: implications for healthcare, recommendations for research

CYP with long-term illnesses face challenges presented by the illness, the medicines and the family, social, cultural and healthcare context within which they function. This occurs against a background of developmental changes, and within the complex dynamics of a constantly evolving relationship with parents/caregivers. Both the literature review and the qualitative data from parents and CYP pointed to the importance of parental support in facilitating CYP’s adherence. Practitioners need to take account of this complex situation when dealing with the parent-CYP dyad. Flexibility to identify modifiable and non-modifiable reasons for non-adherence, to increase efforts to empower the CYP to voice their agenda, to promote honest disclosure of medicines-taking behaviour, together with sensitivity to the level of parental involvement wanted within a specific family, are essential. Service users in this context are both parents/caregivers and CYP. The relative rights and responsibilities of parent and CYP with regards to medicines-taking is relatively under-researched, and not explored within a practice context. CYP and their parents need to be supported to discuss medicines more openly with one another, and be supported in presenting their issues to their practitioner.
The advantage of this approach is that the different sources informed the objectives differently. For example, the use of published evidence in combination with focus group and interview data provided a much richer view of reasons for non-adherence in children and young people, and an increased relevance for the local context, given that most evidence was not based in the UK. The disadvantages of this approach are the large amount of data available, the extent to which evidence from different sources can be synthesised and the subjective nature of interpreting data of this type. The resultant interpretation was reliant upon the perspectives, experience and expertise of the research team.

Examination of the published evidence combined with primary data to determine barriers and facilitators for medicines-taking in Phase 1 provided an essential basis for intervention design, approaches for practitioner briefings, and content for intervention paperwork.

We planned an innovative, evidence-based approach to managing medicines in CYP with chronic illness, by investigating the role of the triad of parent, CYP and practitioner. This meant that we had to observe and evaluate the TABS-based intervention, which introduced a level of complexity to the research process, and artificiality to the intervention process. However, this was a successful approach and we would repeat this method in future work.

Implementing the primary research in two phases was intended to allow the interviews and focus groups to inform intervention design, before testing it in Phase 2. This was partially successful. Unfortunately, we were delayed significantly by two sets of transitional NHS R&D process changes, such that our researchers were taken away from field work in order to complete the approval processes. This has critically reduced the time spent working with clinical sites to ensure appropriate recruitment of patients, appropriate briefing of practitioners, and removed our ability to schedule a follow-up consultation. Furthermore, we had no control over which patients were recruited to the study. This has substantially reduced the ability to demonstrate the utility of this intervention.

Despite this, our study suggests that the parent/CYP pre-consultation tool was quite successful and acceptable when used, whereas the practitioner briefing and prompts were not always so successful. We have proposed an intervention that, with further development, may improve CYP’s involvement in discussions and decisions about medicines-taking, and this could lead to improved medicines-taking and associated health benefits.

The strength of this study was that we were able to investigate the applicability of the TABS tool in a range of clinical settings, being used by different practitioners, disease areas, disease severity and age groups. Any future version of the TABS intervention needs to better address the challenges of practitioner engagement and education, but from our experience in this study, ways need to be found to enable practitioners to better support medicines use in this age group. We encountered initial enthusiasm by practitioners, and acceptance that medicines use was suboptimal. This was succeeded by lack of engagement in the practice situation. This may illustrate the complexities in introducing a new tool into practice that needs new ways of working, and is trying to change the power.
dynamic between CYP, parents and practitioners. The lack of engagement by practitioners in this study appeared to result in parents becoming resigned to not being listened to. However, where the tool was used during the consultation, there was evidence of behaviour change, which is encouraging for any future work.

From this early work, we would recommend that a future version of this intervention has the following characteristics:

- Ensures all members of triad understand the purpose of the tool,
- Encourages parents and CYP to complete tool beforehand,
- Makes sure practitioner has engaged with, and had a briefing about the intervention,
- Ensures that the CYP or parent hands the pre-consultation tool to the practitioner at the beginning of the consultation,
- Does not exclude the parents of older CYP from discussions,
- Does not exclude younger CYP from discussions.
- Targeted CYP starting a new medicine for a chronic condition, or where poor adherence is suspected by practitioners (or parents).

Priorities for future research:

1. Better understanding of CYP-parent-practitioner interactions and their influence on adherence;

2. Better appreciation of the needs of CYP as they age and develop, keeping a regular dialogue with age-appropriate updates on medicines;

3. Methods for effective practitioner engagement and education;

4. Simpler design and CYP-centred delivery of the TABS pre-consultation tool, and integration in care pathways, such as incorporating the CYP responses and any resultant action plan into the GP PMR, and targeting CYP earlier in the disease;

5. Future NICE guidance should include advice relating to CYP;

6. Research governance procedures should be examined such that study design of ethically appropriate studies is not compromised unnecessarily, with associated waste of public sector research resources.
1.1 Background

Terminology in this report

Children and young people

Unless specifically stated, for brevity and clarity, we use the term "CYP" to refer to children and young people under 18 years of age and the term “parents” to include other primary caregivers. The National Institute for Health and Clinical Excellence (NICE) defines this group in the following way:¹

- neonates (0 weeks or older, and younger than 4 weeks)
- infants (4 weeks or older, and younger than 52 weeks)
- pre-school children (1 year or older, and younger than 5 years)
- primary school children (5 years or older, and younger than 11 years)
- young people (11 years or older, and younger than 18 years).

Compliance, adherence and concordance²

Compliance is the extent to which the patient’s behaviour matches the prescriber’s recommendations.

Adherence is the extent to which the patient’s behaviour matches agreed recommendations.

Compliance has been criticised because it seems to denote a relationship in which the role of the clinician is to decide on the appropriate treatment and issue the relevant instructions, whereas the role of the patient is to passively follow “the doctor’s orders”. The term adherence has been adopted by many as an alternative to compliance, in an attempt to emphasise that the patient is free to decide whether to adhere to the doctor’s recommendations and that failure to do so should not be a reason to blame the patient. However, they are generally considered synonymous measures of medicines-taking behaviour.

The term concordance is increasingly used in relation to medication-taking. It is a complex concept originally defined as:
“a new approach to the prescribing and taking of medicines. It is an agreement reached after negotiation between a patient and a health care professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken. Although reciprocal, this is an alliance in which the health care professionals recognise the primacy of the patient's decisions about taking the recommended medications”.

It is often mistakenly used instead of adherence or compliance to indicate medicines-taking behaviour.

Name of the study

The name “Talking About Medicines” (TABS) and the associated logo were developed near the beginning of the study to develop an easily recognisable “brand” for the study participants (CYP, parents and practitioners). This name reflected our perspective that the key issue for us seemed to be encouraging CYP to feel they could discuss their medicines and associated problems, with both parents and practitioners. The name and logo were developed in consultation with children of the research team and a website designer and were tested in the stakeholder workshop for acceptability to CYP, parents and practitioners. The internet was also interrogated to prevent unintended double meanings. From this process the acronym “TABS” emerged as the most appropriate. A TABS website was developed, with stakeholder consultation, including the creation of an associated “virtual family”, to prevent copyright issues. This imagery was understandable and acceptable to CYP, parents and practitioners.

Medicines are an important aspect of managing many childhood illnesses. One in five British CYP under 16 years have longstanding illnesses, and 9.5 million (13 percent) American CYP required regular prescription medicines for at least three months in 2008.

Throughout this report we focus on four key conditions in CYP:

- **Asthma:** Surveys of asthma prevalence in CYP vary widely, mainly due to differences in the definitions used. Nevertheless, asthma is the most common chronic condition affecting children. In the United Kingdom (UK) where an estimated 5.4 million people are affected by asthma, 1.1 million of those affected are children and adolescents. The estimated prevalence is 1 in 11 children under 16.

- **Diabetes:** The all England prevalence of diabetes in CYP is 209/100,000 (95% CI 180–240)/100,000. Type 1 diabetes accounts for 97% of cases. Just over half, 51.1%, are boys.

- **Epilepsy:** The incidence of paediatric epilepsy in UK is estimated to be 86/1000 at age 0-4 years, 46/1000 at age 5-9 and 94/1000 at age 10-14 years. In England and Wales, the prevalence of epilepsy in children under 16 years old is 4.4/1000 for males and 4.1/1000 for females in 1998.

- **Congenital heart disease:** In the UK there are about 4,600 babies born with congenital heart disease each year (6.9/1000 births). At
least three-quarters of babies with congenital heart disease are predicted to survive to age 18.

Asthma, diabetes, epilepsy and congenital heart disease are prevalent chronic conditions where there is evidence supporting use of medicines above other treatment options and over doing nothing, and high levels of adherence are essential to ensure efficacy.

There is evidence that medicines-based self-management of longstanding illness can be suboptimal in CYP, especially adolescents, with adherence to medicines reported to range from 25 to 82%.²⁻⁴ The term “adherence” is used to describe the extent to which a patient’s behaviour follows medical advice and recommendations from the prescriber.² Adherence in CYP and adolescents has been shown to be as variable and suboptimal as in adults.¹² Non-adherence has three types: original prescription not filled; no refill prescriptions obtained; suboptimal dosing (taking doses at the wrong time, reducing or increasing doses or dose frequency, missing doses, taking drug holidays).²

Factors causing non-adherence are likely to be different for CYP compared to adults. These include the potential influence of developmental stage and age, varying involvement of parents and carers, formulation and licensing issues, access at school and peer pressure. Poor outcomes have been associated with poor adherence in CYP, such as experiencing recurrent exacerbations and the need for the escalation of therapy in asthma.¹³¹⁴

The Royal College of Paediatrics and Child Health (RCPCH) echoes other commentators when it voices concern about the significant financial crisis in the UK, large-scale workforce pressures in many inpatient paediatric units, relatively poor health outcomes for the UK childhood population,¹⁵¹⁶ and inadequate provision in many aspects of CYP healthcare.¹⁷¹⁸ In his report, Sir Ian Kennedy described CYP healthcare as a “Cinderella” service.¹⁷

The Children’s Task Force and the Children’s National Service Framework (NSF) departs from paternalistic care models such that CYP with chronic illness are cared for in terms of medical, social and educational needs, in light of their own views and decision-making.¹⁹ Provision of paediatric services has been undergoing substantial change in the UK. This has been driven in the recent past by NSFs, the establishment of Primary Care Trusts (PCTs), and the Bristol Royal Infirmary Inquiry.²⁰ The RCPCH has led the debate on future configurations of child health services¹⁸ and the future shape of community child health.²¹²²

These reports suggest that the role of parents and CYP needs to be better developed. Self-care²³ is a cornerstone of successive Governments’ health policy, evidenced by the “Expert Patient” initiative.²⁴ Commentators assert that young people need to know more about self-care if future NHS resources are to be used appropriately.²⁵ Combined services delivering acute and community services was one proposed solution to develop better communication between primary, secondary and community care.²⁰ As community paediatric services develop, they must take account of provision of information, consent, privacy and use of information in CYP.²⁶ Any proposed intervention must take into account the evolving nature of CYP’s
services by developing solutions that will integrate into both existing and new delivery systems.

1.2 Medicines-taking in CYP

CYP are a heterogeneous group and differ from adults in terms of pharmacokinetics and pharmacodynamics. A lack of licensed products for CYP often leads to inadequate information for prescribers and a lack of suitable formulations. Unlicensed or “off label” products are often required, creating potential errors, delays in supply, absent or inappropriate patient information leaflets and confusion and anxiety for parents and CYP. The NSF has identified that CYP’s medicines should be subject to safe access, consistent, current and timely information provision for CYP and parents, and that there should be concordance and partnership in medicines-taking.27

The terms “compliance” and “adherence” are generally used synonymously to describe medicines-taking behaviour congruent with providers’ recommendations. “Concordance” is a patient-centred process where professionals make a therapeutic alliance with patients.28 Non-adherence can be “intentional” or “non-intentional”, and both types should be explored in CYP.29 Measuring adherence is problematic with no gold standard.2

Medicines non-adherence is often considered to be worse in CYP than in adults,30-34 particularly in adolescence (11 to 20 years), ranging from 10 to 96%.37 38 Poor childhood adherence increases hospitalisation, restricted activity days and deaths in asthma,33 39 relapse in leukaemia,40 seizure rates in epilepsy,41 and complications in diabetes.42 Gender, race and socio-economic status do not reliably predict adherence in CYP, but urban living, language barriers and age (adolescence) increase non-adherence.33 43-45

Adolescents have their own conceptualisation of health and medicines.46-48 Piagetian theory argues that shifts in CYP’s ability to reason occur around 5 to 7 years and 10 to 12 years and there is evidence for associated development of CYP’s understanding of illness concepts.49 50 By 15 to 17 deductive reasoning and some concepts of illness prevention should be established, but the transition to independence may be accompanied by reduced treatment adherence.33 Independence in health care decision-making occurs around 15 years of age with increased ability to consider consequences and benefits of health conditions and medicines-taking.51

1.3 Interventions to optimise medicines-taking

It seems sensible to intervene to improve medicines-taking in this population. Most interventions in CYP have been psycho-educational and
have variable effectiveness, tending to focus on disease management rather than psycho-social factors. Nevertheless, reviews of psycho-educational interventions in CYP report improved clinical outcome and increased self-efficacy. Many interventions to improve adherence stop at the patient-provider level and are criticised for lack of integration in service provision. Like many other attempts to change systems in health care provision, most interventions are not introduced using whole systems thinking. This understanding of the multi-factorial nature of introducing a change within a system is essential for implementation of a successful care package, particularly one such as paediatric medicines management that has a wide range of stakeholders.

The triad of CYP, parent and provider has not been researched extensively. CYP have been given little voice in consultations. Parents’ perceptions of their CYP’s disease may or may not reflect those of the CYP, or indeed, objective measures of severity. Providing CYP and parents with a framework in which they can voice concerns is essential for a successful consultation. People need to be empowered to ask the right questions so that they can be given the “right” information. However, this concept of the “information prescription” is not widely applied in CYP. Rights and responsibilities need to be more clearly defined within the three-way relationship of parent-CYP-provider. Furthermore, the environment of the organisation within which the service operates (both physical and human) needs to be investigated to identify and minimise barriers to empowering CYP in optimising their medicines use. CYP who are satisfied with their care appear more adherent. Teenagers are concerned about lack of respect for adolescent health concerns, poor communication skills among GPs, privacy and waiting times, and have limited knowledge of services. The role of other professional groups in supporting CYP’s medicines taking has been little investigated. Importantly, CYP’s assessment of quality of care may be different from their parents and they may have quite radically different frameworks of assessment. Current NICE guidance on medicines adherence does not provide advice for CYP.

The most recent Cochrane review on interventions to improve adherence suggests that more fundamental research is required to understand medicines-taking, as current interventions have limited, or variable, effectiveness. Existing interventions need to be examined to identify effective and affordable components that can be used in practice. It is unlikely that one intervention is appropriate for all CYP. Also, systems level thinking must be used during the development and implementation of what is effectively an additional service, within the complex multi-stakeholder world of CYP with long term medical conditions.

## 1.4 Rationale

The overarching aim of the study was to develop and pilot a paediatric medicines management package. The “Talking About Medicines (TABS)”
package was designed to work across ages, social characteristics, conditions, complexity of needs and service delivery settings. By involving the triad of CYP, parents and practitioners, we aimed to empower CYP to talk openly and be active partners in decision-taking about taking their medicines for long-term conditions.

**Key objectives were to:**

1. To use critical evidence synthesis and consensus-building methods to examine the CYP-parent-provider triad at individual and organisational levels to:
   
   a. examine expectations, experiences and concerns about medicines;
   
   b. explore transferring responsibility control for older adolescents, and how to facilitate honest disclosure of medicines-taking behaviours;
   
   c. clarify perceptions of roles, empowerment, rights and responsibilities associated with long-term medicines use;
   
   d. understand CYP’s and parents’ interaction with the health system in community, primary and secondary care from initial contact to medicines supply, and over time;
   
   e. identify effective interventions to improve medicines use in CYP.

2. To devise a CYP-centred paediatric medicines management package that works across ages, social characteristics, conditions, complexity of needs and service delivery settings, informed by individual and organisational perspectives.

3. To explore operation of the package, the complexity and nature of resulting consultations, to determine feasibility and generalisability.

4. To assess methods of objective evaluation of behaviour change, clinical outcome and resource use.

**1.5 Overview of Methods**

Development and evaluation of a complex intervention such as this has many challenges, and the intervention itself could be subject to variation in a range of factors. Problems can arise if the intervention has not been fully designed and developed. A common reason for the failure of interventions
designed to improve medicines use behaviour is the lack of a theoretical basis for the intervention and there is a need to “unpack” reasons for behaviour before designing an intervention.\textsuperscript{54}

Phases 1 and 2 of this study were designed to follow the stages in Phases 1 (“defining components of the intervention”) and 2 (“defining trial and intervention design”) of the framework for design and evaluation of complex interventions to improve health.\textsuperscript{64}

In Phase 1, objectives 1a-1e were achieved through a review of the published evidence and focus groups and interviews with CYP, parents and practitioners. Each source of evidence provided some input to each objective. By triangulating the sources of evidence, we were able to address each objective. In Phase 2, these evidence sources led the design and initial field-testing of an intervention to improve medicines-taking in CYP with asthma, congenital heart disease (CHD), diabetes and epilepsies.(see Figure 1)

**Figure 1. Overview of TABS Study**

Phase 1 combined evidence synthesis and consensus-building, to develop the pilot TABS package. We aimed to generate a list of possible reasons affecting medicines use for CYP, parents and providers, grouped into key domains, along with evidence-based solutions for these reasons using two approaches:
A critical evidence synthesis examined reasons for sub-optimal medicines use (medicines non-adherence) (Chapter 2) and evidence-based solutions for medicines non-adherence (Chapter 3).

Three focus groups of 19 providers and 43 in-depth interviews with CYP (18) and parents (26) were carried out to explore reported reasons for medicines non-adherence, and potential solutions (Chapter 4).

These sources of evidence were combined with online resources, team expertise and feedback from an expert advisory panel, repeated input from a range of stakeholders and a stakeholder day funded by Ask About Medicines Week (AAMW)(see Section 1.6).

We combined the results to obtain an overall picture of reasons for non-adherence. (see Section 4.6) We then synthesised this evidence with the findings from the systematic review of interventions to inform our intervention design. (see Section 5.3)

The TABS package comprised a:
- CYP and parent self-completion pre-consultation survey tool;
- practitioner briefing prior to initial consultations;
- practitioner prompt to use during consultation;
- resource pack to provide sources of information or referral options.

The role of each of these components is summarised in Figure 2.
Phase 2 explored operation of the package in a purposive sample of 40 in-depth case studies to determine feasibility and generalisability across a range of age groups, conditions, delivery settings, ethnicity and complexity and nature of resulting consultations.

Baseline data collection at point of consent comprised demographic information along with baseline quality of life (QoL) measurement, child medicines self-efficacy, child medicines locus of control and self-reported adherence. Consultation observation was structured around context, process and content. Documentation from the consultation was analysed looking at responses to pre-consultation tool questions, frequency with which different concerns occur, influence of decision support prompts and training on provider response. Follow-up telephone interviews (1 week & 2 months) and repeated measures of baseline, examined usefulness of pre-consultation tool and post-consultation information, recall of important points in consultation from their perspective and perceived impact upon medicine-related activities.

We assessed methods of objective evaluation of behaviour change, clinical outcome and resource use for future clinical and economic evaluation.
Feasibility of the TABS package across a range of conditions was investigated. To allow in-depth investigation, we examined four key conditions. Asthma, diabetes, epilepsy and congenital heart disease are conditions where there is evidence supporting use of medicines above other treatment options and over doing nothing, and high levels of adherence are essential to ensure efficacy. Generic issues across these conditions (age, ethnicity, service delivery setting) were investigated. Specific issues include:

- Asthma: reluctance, or inability, to use inhalers, attitudes to steroids, attitudes to smoking;
- Epilepsy: stigma, palatability and accessibility of paediatric formulations;
- Diabetes: reluctance to use needles, weight gain with insulin, attitudes to diet;
- Congenital heart disease: lack of availability of licensed paediatric preparations, management of warfarin.

The age groups were selected to represent both development and educational transitions. The age groups also offered the opportunity to explore school/work based barriers.

1.6 Stakeholder involvement

A number of individuals and organisations were identified through a snowballing process, as key stakeholders to participate in the development of the study from the outset.

Appendix 7.6 details an early piece of stakeholder engagement to allow us to develop themes for the focus groups, interviews and literature reviews. The responses provided are those given by our stakeholders, verbatim, which also helped us with language, phrasing and vocabulary.

The involvement and participation of these key stakeholders has continued throughout. Involvement has included commenting on design and development documentation through a stakeholder workshop and via electronic communication.

1.6.1 Ask About Medicines Week (AAMW) funded stakeholder workshop.

Dr Nicola Gray is part of the TABS research management team and led a submission to AAMW. We were successful in obtaining £1000 to fund a patient and health care professional stakeholder workshop. This took place on 17/2/2009, and was used to develop the design of the intervention. Further details are available on request. The workshop was carried out in Nottingham, with four parents, three CYP, four HCPs and one charity representative. The delegates spent the day working on the TABS intervention (pre-consultation survey for parents and CYP, consultation support pack), and giving feedback and opinions about it. A representative
from Digitv also attended to show how an electronic internet based version of the survey might work. The output of this day fed significantly into the development of the pre-consultation tool and provider response package. (see Appendix 7.11)

1.6.2 Expert Advisory Panel

An expert panel was set up comprising four individuals, including one based in the United States and three from across the United Kingdom. The expert involvement continued throughout the duration of the study and included input into the study design and development by means of regular telephone conferences and one face to face meeting with the US expert, as well as regular electronic communication.

A list of the expert panel contributors and their remit is provided in Appendix 7.7.

1.7 Data protection

All study staff endeavoured to protect the rights of the study’s participants to privacy and informed consent, and adhered to the Data Protection Act, 1998. We only collected the minimum required information for the purposes of the study. Study data, including signed consent forms is held securely, in a locked cabinet. Access to the information was limited to the study staff and any relevant regulatory authorities. Computer held data including the study database is held securely and password protected. All data were stored on a secure dedicated web server. Access is restricted by user identifiers and passwords (encrypted using a one way encryption method).

Information about the study in the participant’s notes is treated confidentially in the same way as all other confidential medical information.

Electronic data are backed up every 24 hours to both local and remote media in encrypted format.

1.8 Insurance and indemnity

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham has taken out an insurance policy to provide indemnity in the event of a successful litigious claim for proven non-negligent harm.

1.9 Study approvals

The process of project approval involved the following four stages:

1. University approval (as project sponsor)
2. NHS Ethical approval
3. NHS R&D approval
4. Honorary contracts / research passports/ letters of confidentiality.

All approvals were obtained prior to carrying out research. See Section 1.10.2 for more detail on this process.

1.10 Deviation from original proposal

1.10.1 Systematic review of interventions to improve adherence in CYP

Objective 1e was not in the original proposal. Our overall hypothesis was that, once real reasons for non-adherence had been disclosed and discussed within the CYP-parent-practitioner triad, we would be able to provide tailored evidence-based interventions to support the practitioner. However, the published reviews of interventions to improve adherence which were available did not provide us with sufficient guidance to inform the development of an evidence-based guideline for practitioners. Therefore, we needed to carry out our own review of interventions.

1.10.2 Impact of ethical and NHS R&D approval delays on study design, sample recruitment and follow-up

This section provides an account of the approvals process during this project. This is followed by a summary of the consequences of this process for study design, sample recruitment and follow-up. A discussion of the effect of this process on the overall quality of the resultant outputs from this study is provided in Chapter 6 (Section 6.1.2)

1. University approval (as project sponsor)

Research Innovation Services at the University of Nottingham changed their procedures in 2008, requiring a much more extensive application to be submitted, a similar level of detail to an IRAS form. Ours was one of the first projects to be subject to this process, and this application was approved in May 2008 (Month 3).

2. NHS Ethical approval

The IRAS application was completed on 30th June. (Ref 08/H0408/122). The ethics committee was held on Monday 28th July. (Nottingham 2 - chaired by Martin Hewitt.) We received the REC decision letter confirming favourable ethical opinion, subject to some conditions on 8th August 08 (Month 6). (full correspondence available on request) The Committee agreed that this study was exempt from site-specific assessment (SSA).

3. NHS R&D approval
On 2nd July IRAS R&D initial documentation submitted to (6) PCTs / Trusts. The PCTs are linked, which means that we were dealing with 4 organisations in total:

Nottingham University Hospitals Trust (NUHT)
University Hospitals Leicester (UHL)
Leicester City & Leicestershire County & Rutland PCT (LC and LR)
Nottingham City and Nottinghamshire County Teaching PCT (NCNC).

We were subject to significant delay to the project due to the apparent lack of co-ordination and staffing of the necessary departments in the Trusts. The research passport was not operating in this area, and each organisation had a different set of requirements for R&D approval. It was not made clear at the outset of application what the requirements are, and these appeared to change as correspondence developed. Details are given below for each organisation.

A site specific information form had to be completed and submitted to each Trust for review. This required information on NHS “host” sites, i.e. sites from where patients / professionals are recruited. TABS was classed originally as exempt from this requirement, (as confirmed by REC) but we were still required by individual sites to complete these forms. It is not clear why this disjoint between REC and R&D existed. One PCT also requested full pre-employment checks, and eventually withdrew the request, on our insistence that this was not necessary.

4. **Honorary contracts/ research passports/ letters of confidentiality**

As part of this process we were also given variable advice regarding the need for either a research passport or honorary contracts for research staff. All ensuing correspondence is summarised in progress reports for October 2008 and December 2008, and is also available on request.

In summary, the dates for approval are listed in Table 1 (JW, Jacky Williams; NL, Natasher Lafond). Due to the significant delays and uncertainties in the approval processes, other than University and NHS ethical approval, we started this phase five months late.
Table 1. NHS R&D Approvals Process Summary

<table>
<thead>
<tr>
<th>NHS Organisation</th>
<th>Approval dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Hospitals Leicester</td>
<td>R&amp;D Approval: 21 October 2008</td>
</tr>
<tr>
<td></td>
<td>(Month 8: 4 months from application)</td>
</tr>
<tr>
<td>Leicester City PCT</td>
<td>R&amp;D Approval: 24 November 2008</td>
</tr>
<tr>
<td></td>
<td>(Month 9: 5 months from application)</td>
</tr>
<tr>
<td>Leicester County and Rutland PCT</td>
<td>R&amp;D Approval: 24 November 2008</td>
</tr>
<tr>
<td></td>
<td>(Month 9: 5 months from application)</td>
</tr>
<tr>
<td>Nottingham University Hospitals Trust</td>
<td>R&amp;D Approval: 07 October 2008</td>
</tr>
<tr>
<td></td>
<td>JW/NL Letter of Authority/Honorary Contract: 01 October 2008</td>
</tr>
<tr>
<td></td>
<td>(Month 8: 4 months from application)</td>
</tr>
<tr>
<td>Nottingham City and Nottingham County PCT</td>
<td>R&amp;D Approval: 07 November 2008</td>
</tr>
<tr>
<td></td>
<td>JW/NL/RE Confidentiality Letter: 07 November 2008</td>
</tr>
<tr>
<td></td>
<td>(Month 9: 5 months from application).</td>
</tr>
</tbody>
</table>

Ethics approval for Phase 2 was received from Nottingham Research Ethics Committee 2 (REC reference 09/H0408/46) in April 2009. Subsequently, two substantial and four minor amendments to the original Phase 2 proposal were received relating to revisions in the design and wording of TABS documents, the addition of two researchers and changes in recruitment strategy.

Summary of the consequences of this process for study methods

Effect on study design

In Phase 1, the delays meant a lack of data to inform our intervention design. We were forced to move from focus groups with CYPs and parents to one-to-one interviews. This was approved with the LREC before continuing. We liaised with multiple sites for children-parent dyads.

Effect on sample recruitment and follow-up

We recruited 40 case studies instead of 48 and had no control over which patients were recruited to the study. Due to time constraints, we could not be selective about the patients we recruited and it was not possible to schedule a follow-up consultation.
2 Critical evidence synthesis of research to examine reasons for non-adherence to medicines in CYP with chronic illness

2.1 Background and aims of review

The most recent Cochrane review on interventions to improve adherence suggests that more fundamental research is required to understand medicines-taking. The aim of the critical evidence synthesis reported in this chapter is to summarise current knowledge about determinants of medicines-taking in CYP. Figure 3 (see below) provides a suggestion of the complexity and reciprocity of influences and interactions that influence CYP’s medicines use behaviour.

![Figure 3. Influences affecting CYP’s medicines-taking behaviour](image)

The overall aim of this critical evidence synthesis was to examine the child-parent-provider triad at individual and organisational levels to:

- examine expectations, experiences and concerns about medicines;
- explore transferring responsibility control for older adolescents, and how to facilitate honest disclosure of medicines-taking behaviours;
- clarify perceptions of roles, empowerment, rights and responsibilities associated with long-term medicines use;
• understand children’s and parents’ interaction with the health system in community, primary and secondary care from initial contact to medicines supply, and over time;

More specifically, we examine the CYP-parent-practitioner triad at individual and organisational levels to:

• Examine expectations, experiences and concerns about medicines and illnesses.
• Understand how CYP development, transition into adolescence, parenting styles and psychological functioning of parents and CYP can affect medicines-taking.
• Explore the impact of family, peers, school, socio-economic and cultural context on medicines-taking behaviour.
• Understand CYP's and parents' interaction with the health system in a range of community, primary and secondary care settings from initial contact to medicines supply, and over time.
• Explore the impact of complexity, palatability and access on medicines use.

2.1.1 Methods

To explore this large and complex field, a multi-method approach was adopted. We used evidence-scoping methods similar to those used by other SDO teams. We also analysed the literature and underwent consultation with user, academics, health professionals and managers, plus feedback from an Expert Advisory Panel of four opinion leaders whose expertise complemented and extended that of the project team. Our strategy included searches of electronic databases, and the “grey literature” obtained from other sources, such as websites of governmental, professional and user groups.

2.1.2 Systematic searches of electronic databases

Systematic searches of seven electronic databases were conducted including The Cochrane Library, MEDLINE, EMBASE, PsycINFO, (all via OVID), CINAHL (via EBSCOhost) and ePIC in June and July 2008 and Econlit (via CSA) in August 2008, to search for papers from 1970 relating to adherence to medicines in CYP with English as a language restriction. The exact search strategies can be found in Appendix 7.1. We also reviewed bibliographies in articles on patient adherence and contacted authors of relevant original and review articles that were inaccessible. Retrieved papers were downloaded into Endnote.

We expanded the search strategy developed by Horne et al. (2006) from Cochrane searches used to identify papers relating to adherence in CYP, adolescents and family/carers. We also combined Cochrane search...
strategies for: Asthma; Diabetes; Congenital heart disease; Epilepsy; Compliance; Children and adolescents; Family therapy; and Education. The search strategy had the structure outlined in Figure 4 (see below). Reviews found in the search were used to identify further primary studies.

Figure 4. Schematic representation of search strategy for research in adherence in CYP

2.1.3 Explanatory paper selection criteria

All English language studies that investigated medicines adherence in CYP were assessed for inclusion. Studies were suitable for inclusion if the study sample included CYP 18 years of age or younger with a disease requiring daily medication, with medicines use reported. We required data to be reported separately for CYP under 18 where adults were included in the study sample. Where adult and CYP data were reported together, the authors were contacted for disaggregated data and the study was excluded if the data were not obtained. Papers needed to measure adherence, and record reasons for variations in adherence, examined either quantitatively, qualitatively, or both.

Full text papers were obtained and assessed for compliance with the inclusion criteria. These were then coded according to themes based on the following potential barriers or facilitators to adherence:

Person factors:
1. Severity and duration of illness.
2. Forgetting.
3. Self-efficacy, roles, empowerment, rights and responsibilities.
4. Psychological functioning of child and parent, including presence of depression.
5. Transitional concerns and impact of age.
6. Use and sources of information, including parental knowledge.
7. Impact of educational levels.

Regimen factors:
8. Side effects (adverse events as defined by CYP or parents).
10. Ability to use medicines.
12. Access to medicines, including off-label use.

Context factors:
13. Beliefs and expectations, experiences and concerns about disease and medicines (CYP and parent), including stigma.
14. Social context (impact of family structure, friends, peer groups, media).
15. Financial context (impact of socio-economic status).
16. Cultural context (impact of racial/ethnic or cultural background).
17. Educational context (impact of school).

Relationship factors:
18. Parent-CYP dyad interaction and communication.
20. CYP and parent interaction with the health system in community, primary and hospital care from initial contact to medicines supply, and over time.

The coding framework was partially designed prior to examining the research, but the categories were developed iteratively once the analysis began.

2.1.4 Data synthesis

Data were extracted and a non-quantitative synthesis was conducted similar to methods reported by Goldsmith et al (2007). A critical account was prepared of the evidence available for each theme. Aspects of studies reviewed were: country of origin, age of study, disease under consideration, age group, qualitative or quantitative method (descriptive, univariate or multivariate analysis), sample selection, the main characteristics of the patient population, outcome measures used, adherence measures used, and the extent to which adherence behaviour could be linked to the factor under investigation within that study. For each theme, an assessment was made of the overall quality of evidence, and relevance to the UK context.

Studies were included if they examined the effect of any factor on adherence in CYP of any age. Two reviewers (RE, JW) coded the 197 studies initially according to any factor that was investigated for its effect on adherence. The studies were sent out to NG, RE, CG, ML, SC to analyse the studies in more detail. If the latter reviewers found any further factors investigated in the paper, this study was sent to the appropriate reviewer, or a new factor category was created. The reviewers developed a consensus on factor definition to create 20 categories, and NG reduced these to the four main themes. Each reviewer gave an account of the quality, relevance and key findings of studies within each factor, to assess whether that factor
could be a facilitator or barrier to adherence. All reviewers read these detailed accounts to develop a consensus on findings for each factor within each theme.

2.2 Results

2.2.1 Description of studies included in the review

We found 197 studies that examined the link between the factors listed above and adherence to medicines in CYP. Over 70 percent of the studies were from the USA, and fewer than a tenth were from the UK. Therefore, the relevance of the research found needs to be considered in the context of this. All age ranges were examined. Some studies looked across the entire age range, some looked at preschool, school age, or adolescents, and some did not report their age range at all. This makes it more difficult to compare studies with one another. Half of the studies were in asthma. Other principal diseases were ADHD, arthritis, diabetes, epilepsy, HIV, transplants, leukaemia, cystic fibrosis, sickle cell anaemia and tuberculosis. There were only three studies in CHD, two of these post heart transplant. Three quarters of the studies were under ten years old, so the research is relatively recent, however older studies should not be discounted if the disease and treatment are still relevant.

Over 70 percent used quantitative methods, a minority using multivariate or logistic regression techniques. The remainder were qualitative studies or used a mixed methodology.

2.2.2 Key findings

Key findings are summarised by theme in Table 2, and are discussed in more detail below. Details of specific studies included in each theme are detailed in Appendix 7.2. These findings need to be taken in light of the limitations described above. This project has a particular focus on the role of parents and practitioners in CYP medicines taking behaviour. Therefore, we have discussed the evidence around parent-CYP and practitioner-CYP dyads and parent-CYP-practitioner triad interaction and communication in more detail, to inform design aspects of the study.
**Table 2. Summary of evidence around factors affecting adherence to medicines in CYP**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Effect on adherence</th>
<th>Evidence gaps</th>
<th>Number of studies in TABS index diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Severity and duration of illness</td>
<td>Severity: ↑</td>
<td>Effect of different age groups</td>
<td>Asthma: 3; CHD: 0; Diabetes: 3; Epilepsies: 2</td>
</tr>
<tr>
<td></td>
<td>Duration: ↑</td>
<td></td>
<td></td>
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<tr>
<td>2. Forgetting</td>
<td>CYP’s report: ↓</td>
<td>Effect of different age groups</td>
<td>Asthma: 7; CHD: 0; Diabetes: 1; Epilepsies: 0</td>
</tr>
<tr>
<td></td>
<td>Parent’s report: ↓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Self-efficacy, roles, empowerment</td>
<td>↑ self efficacy ↑</td>
<td>Few good quality studies</td>
<td>Asthma: 6; CHD: 0; Diabetes: 9; Epilepsies: 2</td>
</tr>
<tr>
<td></td>
<td>Adolescents: ↑ self efficacy ↑</td>
<td>Strength of associations not clear</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Parent reporting of CYP’s self-efficacy ⇧</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Parent’s reporting of own self-efficacy ⇧</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Effect of “risky behaviours”</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Drinking alcohol ?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Smoking ?</td>
<td></td>
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<tr>
<td></td>
<td>Poor eating attitudes ↓</td>
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<tr>
<td></td>
<td>Lack of exercise ?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Earlier age at first marijuana use ?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sexual activity ⇧</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theme</td>
<td>Effect on adherence</td>
<td>Evidence gaps</td>
<td>Number of studies in TABS index diseases</td>
</tr>
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<td>-------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
</tbody>
</table>
| 4. Psychological functioning of CYP and parent, including presence of depression | Presence of anger in CYP ⬇️  
Anxiety ⬆️ ⬇️ (?)  
Depression ? | Few good quality studies  
Strength of associations not clear | Asthma: 0; CHD: 0; Diabetes: 1; Epilepsies: 1 |
| 5. Transitional concerns and impact of age                         | Increased age: ⬆️ (?)  
فئ Quality of relationship with parents: ⬆️  
فئ Optimism: ⬆️  
فئ Sense of normalcy: ⬆️ | Strength of associations not clear  
Effect of transition between different age groups | Asthma: 7; CHD: 2 (heart transplant); Diabetes: 5; Epilepsies: 2 |
| 6. Use and sources of information, incl knowledge                  | ⬆️ Caregiver knowledge: ⬆️  
فئ CYP knowledge: ⬆️  | Strength of associations not clear  
Effect of different age groups  
Sources of information | Asthma: 9; CHD: 1; Diabetes: 1; Epilepsies: 3 |
| 7. Impact of educational levels                                    | Low CYP educational level ⬇️  
Low parent educational level ⬇️  
School environment ⬇️ | Very poor evidence  
Effect of different age groups | Asthma: 4; CHD: 0; Diabetes: 0; Epilepsies: 1 |
| 8. Side effects                                                      | Experience: ↔️ ⬇️  
Parents’ anticipation/fear: ⬇️ | CYP’s anticipation/fear of side effects  
Effect of different age groups | Asthma: 8; CHD:0; Diabetes: 0; Epilepsies: 0 |
<table>
<thead>
<tr>
<th>Theme</th>
<th>Effect on adherence</th>
<th>Evidence gaps</th>
<th>Number of studies in TABS index diseases</th>
</tr>
</thead>
</table>
| 9. Complexity of regimen | ✦ Number of medicines: ↓, ↑ (HIV sometimes)  
✦ Number of doses per day: ✦  
Once daily dosing ✦  
✦ Inconvenience: ✦  
✦ Size of device (asthma): ✦  
✦ Time to administer ✦  
Need to take medicines at specific times in relation to meals or outside the home ✦  
Need to take large numbers of tablets/capsules each day ✦ | Conflicting evidence about effect of numbers of medicines  
Some evidence about number of doses  
Effect of different age groups | Asthma: 3; CHD: 1 (heart transplant); Diabetes: 2; Epilepsies:2 |
| 10. Ability to use medicines | ✦ Instruction from practitioner ✦  
✦ Regular follow up & assessment of technique for drug delivery devices by practitioner ✦  
✦ Ability of CYP to use device themselves ✦  
✦ Choice of device ✦ | | Asthma: 5; CHD: 0; Diabetes: 0; Epilepsies:0 |
| 11. Palatability and acceptability of regimen | Poor taste ✦  
Lack of availability of suitable formulation e.g. liquid for young CYP ✦ | Effect of route of administration e.g. inhaled vs oral – effect unclear | Asthma: 5; CHD: 1 (heart transplant); Diabetes: 0; Epilepsies:0 |
<table>
<thead>
<tr>
<th>Theme</th>
<th>Effect on adherence</th>
<th>Evidence gaps</th>
<th>Number of studies in TABS index diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Access to medicines, including off-label use</td>
<td>☐ Cost ☐</td>
<td>Effect of unlicensed and off label prescribing on access and adherence</td>
<td>Asthma: 1; CHD: 0; Diabetes:0; Epilepsies: 0</td>
</tr>
<tr>
<td></td>
<td>☐ Availability of medicines ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Length of prescription ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. beliefs and expectations, experiences about disease and medicines</td>
<td>Parental beliefs about ☐ necessity: ☐</td>
<td>CYP’s beliefs</td>
<td>Asthma: 10; CHD: 1 (Heart transplant); Diabetes: 4; Epilepsies: 3</td>
</tr>
<tr>
<td>and medicines (CYP and parent), incl stigma</td>
<td>CYP’s beliefs about ☐ necessity: ☐</td>
<td>Effect of different age groups</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Effect of stigma</td>
<td>Effect of different age groups</td>
<td></td>
</tr>
<tr>
<td>14. Social context (impact of family structure, friends, peer groups,</td>
<td>Single parent family ☐</td>
<td>Strength and direction of associations not clear</td>
<td>Asthma: 11; CHD: 1 (heart transplant); Diabetes: 10; Epilepsies: 3</td>
</tr>
<tr>
<td>media)</td>
<td>Peers ☐ ☐</td>
<td>Effect of different age groups</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Family structure ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Family routine ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Parental reminders ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Giving children space” ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other family member with same condition ☩</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theme</td>
<td>Effect on adherence</td>
<td>Evidence gaps</td>
<td>Number of studies in TABS index diseases</td>
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</tr>
<tr>
<td>15. Financial context (impact of socio-economic status)</td>
<td>Lower socio-economic status: ☕ ☕</td>
<td>Very poor evidence Effect of different age groups</td>
<td>Asthma: 2; CHD: 0; Diabetes: 1; Epilepsies: 1</td>
</tr>
<tr>
<td>16. Cultural context (impact of racial/ethnic or cultural background)</td>
<td>Ethnicity: ☕ ☕ Minority status: ☕</td>
<td>Very poor evidence Effect of different age groups Effect of specific ethnic features Effect of language barriers</td>
<td>Asthma: 7; CHD: 0; Diabetes: 3; Epilepsies: 0</td>
</tr>
<tr>
<td>17. Educational context (effect of school)</td>
<td>No clear indicators</td>
<td>No evidence on association of school to adherence</td>
<td>Asthma: 3; CHD: 0; Diabetes: 2; Epilepsies: 0</td>
</tr>
<tr>
<td>18. Parent-CYP dyad interaction and communication</td>
<td>Parental supervision ☣ Authoritative and warm parenting ☣ Conflict ☕</td>
<td>Strength of associations not clear Effect of transition between different age groups</td>
<td>Asthma: 1; CHD: 0; Diabetes: 3; Epilepsies: 0</td>
</tr>
<tr>
<td>19. Provider-CYP dyad, Parent-CYP-provider triad</td>
<td>Increased CYP satisfaction ☣ Lack of concern shown by HCP ☕</td>
<td>Very little evidence Effect of different age groups</td>
<td>Asthma: 3; CHD: 0; Diabetes: 3; Epilepsies: 2</td>
</tr>
<tr>
<td>Theme</td>
<td>Effect on adherence</td>
<td>Evidence gaps</td>
<td>Number of studies in TABS index diseases</td>
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<tr>
<td>20. CYP and parent interaction with the health system in community, primary and hospital care</td>
<td>Poor relationship with HCP †</td>
<td>Very poor evidence</td>
<td>Asthma: 2; CHD: 0; Diabetes: 0; Epilepsies: 0</td>
</tr>
</tbody>
</table>

Key

†  Evidence that factor increases adherence significantly

‡  Evidence that factor decreases adherence significantly

⇔  Evidence that factor has little or no effect on adherence

† ‡  Conflicting evidence about the effect of the factor on adherence

?  No evidence about the effect of the factor on adherence
2.2.3 Synthesis of results

Themes presented here are discussed in the following categories: Person factors; Regimen factors; Context factors; Relationship factors

**Person factors**
1. Severity and duration of illness

From 21 studies, of eight multiple regression analyses, four examined the independent effects of duration. Two of these studies concluded that duration of disease was a strong independent predictor of non-adherence, in diabetes and HIV. Two studies found no independent effect, in JIA and renal transplant. Five examined the independent effects of severity. Of these, two found that increased severity of illness was independently associated with increased medicines adherence, in ADHD and JIA. However, none of these models contain all explanatory domains.

In summary, reduced severity of illness and increased duration of disease appears to be associated with reduced adherence. Adverse health events can lead to increased adherence, or reduced adherence if the events are considered to be associated with the treatment itself.

2. Forgetting

Of 21 studies that reported forgetfulness, five reported that this was the main factor linked to non-adherence, either by parents or by CYP. CYP’s own reports appear to be a more reliable method of identifying the extent of this behaviour than parents’ reports. Parents appear to report much lower levels of forgetting than CYP, maybe due to social desirability bias. Being concerned about forgetting does not necessarily translate into forgetting behaviour. Different studies used different definitions of forgetting, or did not report the definition at all. Some people were asked to describe their forgetfulness quantitatively as number of doses missed, whilst some were asked to rank their forgetfulness on ordinal scales from “never forget” to “often forget”. None of the multivariate analyses included forgetting in their models to identify whether it had an independent effect. Three univariate analyses examined the link between forgetting and adherence, without correcting for other effects. Meyers and Zelikovsky found reports of forgetting to be associated with increased non-adherence, but Beltzer found no association. This latter study was very small, so probably underpowered. None of the qualitative studies reported examination of the importance of forgetting. Only one study, a qualitative study of adolescents with asthma, was from the UK.

Forgetting may be more of an influence for adolescents, who have less parental involvement. CYP appear to find morning doses most difficult to remember because they are often rushing to school or college.
3. Self-efficacy, roles, empowerment, rights and responsibilities

Most of the 18 studies used non-validated measures of self-efficacy and self concept and few used longitudinal designs. Five studies found a relationship between increased self-efficacy and adherence, and two studies found no association. Parental ratings of the CYP’s self-efficacy did not relate well to adherence. It may be that parents who perceive their CYP to be competent offer less support, leading to poorer adherence. Most studies looked at adolescents, suggesting a link between this age group’s self-efficacy and adherence.

Regardless of the direction of the relationship between self-efficacy and disease control, these findings do provide some evidence for the role of low self-efficacy as an indicator for poor self-management. The evidence for general attributes such as self-concept and hope is stronger and suggests that generic measures of perceived competence would be useful.

4. Psychological functioning of CYP and parent, including presence of depression

Only six studies examined this theme. The evidence concerning the relationship between cognitive function and adherence is mixed. Studies showed weak or no correlation between cognitive function and adherence. The evidence concerning the relationship between affective function and adherence is sparse, but there appeared to be some link between anger or oppositional disorder and non-adherence.

5. Transitional concerns and impact of age

Forty-four studies examined effect of age on adherence. Twenty quantitative studies showed decrease in adherence with age, 12 showed no difference, four showed increase. Reduced adherence with increase in age appears to be linked to a marked social change to more independence from their parents, less parental involvement, closer relationship with peers, breakdown in family routines. Adherence was greater when parents and adolescents agreed who was responsible for medication administration. Increased normalcy and optimism were linked to increased adherence. In some illnesses (e.g. CF) parental involvement re-emerged in later adolescence. In summary, biological age - which is non-modifiable - may be modified by other attributes, which themselves may or may not be modifiable.

Twenty quantitative papers reviewed showed a negative association between age and adherence: that is, as age increased, adherence decreased. It was notable that this included all the large-cohort studies, and
seven of the ten studies employing multivariate analysis. The study by Williams et al.\textsuperscript{81} even estimated that, for each year of increasing age through adolescence, the risk of non-adherence increased by 10 percent. Twelve quantitative studies asserted no effect of age on adherence, and four studies showed a positive association between age and adherence. One quantitative multivariate study supported a positive association between age and “goal alliance”, and another found no association between age and adherence.

6. Use and sources of information, including parental knowledge

In the 25 studies reviewed, a consistent finding across themes and conditions was the positive association of knowledge with adherence, but these findings referred to different ways of knowing and different subtle effects upon adherence. Twelve studies looked at caregiver’s knowledge, six at CYP’s knowledge, and seven at both. CYP’s age was not associated with knowledge. Parents appeared to report higher levels of knowledge than CYP, when examined. Overall knowledge about disease and medicines was generally very low.

Fourteen quantitative studies explored associations between knowledge and adherence, or proxies for adherence. The inconsistency in the variables showing associations, such as “knowledge” or “understanding”, is a challenge in trying to draw overall conclusions. Four of these studies used multivariate analysis, and there was no consistent association between knowledge and adherence in these studies. The wider group of quantitative studies reflected this mixed picture.

In summary, there is some evidence of a positive association of knowledge and information use with adherence, but these findings are complicated by reference to different ways of knowing and different subtle effects upon adherence and associated outcomes.

7. Impact of educational levels

Eleven studies examined the link between parental educational levels and adherence. Two of these studies examined the effect of the educational level of the CYP. Quality and size of studies varied. Studies used a variety of ways of recording educational levels and did not use validated measurements of adherence. Some studies did not measure educational attainment directly but inferred it from SES. Four studies found no link between educational levels and adherence. In multivariate analysis, no studies demonstrated an independent link between educational levels and adherence.

In summary, the studies examined provided varying results, some studies identifying an association between parental education level and adherence.
and not in others. In addition, due to the tools used or the population chosen these studies cannot be used to demonstrate a causal effect between adherence and educational levels.

**Regimen factors**

1. **Side effects**

From 17 studies, it appears that the effect of side effects experienced on adherence appears to be different from, and less important than anticipation and concerns about side effects. Parents’ worries were more evident than CYP’s, partly due to study design. In summary, concern about future side effects is likely to affect initial take-up of a newly prescribed medication. Perceptions and concerns about side effects are much more commonly found within groups than experience of side effects.

Actual experience of side effects appears to have little effect on medicines-taking behaviour. The reporting of side effects is generally poor, and it is not clear if parent report is reliable. CYP reporting of side effects is very rare. Many studies reported reduced adherence in groups of parents who worried more about side effects, but true or independent association was not generally investigated. Three studies examined the effect of side effects in multivariate analyses. Lloyd reported that, in univariate analysis, side effects were associated with non-adherence (P<0.001), but in logistic regression, side effects did not retain a significant effect on adherence. Berg’s model suggests that isoniazid side effects were not associated with adherence over 9 months (p=0.16). Simons’ factor analysis reported that more frequent and more intense side effects were associated with perceived barriers to adherence for both parents and adolescents. No significant effect of perceived barriers to adherence on actual adherence behaviour was found in this study.

2. **Complexity of regimen**

Most of the 32 studies e.g. in asthma, cystic fibrosis and diabetes suggested that the more complex a drug regimen the lower the adherence will be. However, in some of the studies conducted in HIV patients the opposite is found. Patients with more complex regimens may be less healthy and therefore more motivated to be adherent. Also clinicians may be more hesitant in prescribing complex regimens to those with a history of poor adherence. It is not clear which aspect of complexity affects adherence: number of doses or pills per day, number of different medications or the need to take them at specific times e.g. in relation to food. Some regimens were time-consuming for parents and CYP. Of seven studies using multiple regression analyses, two looking at ADHD therapy with methylphenidate showed that patients on once daily regimens were much more likely to be adherent than those on three times daily. Similarly, a study looking at epilepsy showed increased adherence on once daily compared to 2-3 times daily regimens. Studies on use of inhalers, injection pens, oral dosing
devices and related equipment demonstrated common poor technique, and thus unintentional non-adherence in parents and CYP. There is some suggestion that patients are more adherent to smaller devices than larger ones.

In summary, many factors are involved in the complexity of a drug regimen including: number of doses per day required; number of tablets/capsules to be taken; number of different drugs involved; timing of doses in relation to food; route of administration and the need to take medicines at school or outside the home. Studies vary in their findings. Overall however, it seems that the more complex the drug regimen the less likely the patient is to adhere particularly when there is a need to take medicines at specific times in relation to meals or outside the home. The need to take large numbers of tablets/capsules each day and the need for frequent dosing through the day are highly likely to reduce adherence. Once daily regimens are more likely to result in adherence than more frequent dosing.

3. Ability to use medicines

In the ten studies found, the evidence around the ability to use medicines generally focuses on drugs delivered by devices such as pens, pumps and inhalers. Most studies relied on self-report to assess adherence although the asthma studies did generally assess patient technique. Accurate use of the various different inhaler devices is a particular issue and adequate and regularly reinforced instruction and assessment of technique is essential. Carrying bulky devices such as spacer devices is problematic, in some cases the patient does not have their medication with them when they need it.

Two studies used multivariate analysis techniques. One examining the use of growth hormone injections showed that patients who injected themselves, those who were trained by hospital staff and those who used pen devices rather than syringes/needles were more likely to be adherent. Similarly multiple regression in a Taiwanese study of asthmatic children found that the determinants of a CYP’s skill to use their inhaler device included unaided use of inhaler and the potential for CYP to receive help from their parents. Other studies involving measurement of doses of liquid preparations similarly showed that education could strongly improve accuracy of measurement.

In summary, comprehensive instruction and regular follow up assessment of technique when using drug delivery devices seems to improve adherence. The ability of the CYP to use their device themselves rather than relying on carers also seems to improve adherence.

4. Palatability of regimen
In the 19 studies reviewed, poor taste and acceptability present a significant barrier to adherence with both oral medicines and those involving a device for administration, particularly in younger CYP.

The one study using multivariate analysis involved liver transplant patients and showed that only five percent of carers considered medicines tasting bad to be a reason for the CYP not taking their medicines – usually there was no reason or the carer had forgotten to give the medicine to the CYP. The small numbers of qualitative studies however suggested that poor taste of medicines was an important factor in adherence particularly in younger CYP.

In summary, poor taste and lack of acceptability of medicines and delivery devices seems to be an important factor influencing adherence. Giving CYP and their families a choice of these where possible may encourage adherence.

5. Access to medicines, including off-label use

Five studies examined this area. Barriers to access can be defined as lack of availability of the medicine, lack of availability of the services associated with providing the medicine, and cost associated with obtaining the medicine (medication acquisition costs, other health care costs, family travel and other out of pocket expenses). Cost and central availability of medicines are the main access barriers to adherence shown in these papers and these are unlikely to be issues relevant to the UK population.

Context factors

1. Beliefs and expectations, experiences and concerns about disease and medicines (CYP and parent), including stigma

There were 29 studies examining this theme, none correcting for age. In asthma, HIV, sickle cell and JIA, high concern and/or low perceived necessity was associated with lower scores on parent rated medication adherence measures, in both univariate and multivariate analysis. Very few studies looked at effect of CYP’s beliefs on adherence. One study carrying out multivariate analyses found beliefs accounted for additional 22 percent of variance and negative outcome expectancy was strongest predictor (beta coefficient =0.31, p<0.05). Parental beliefs about complementary and alternative medicine predicted both risks for non-adherence and asthma control.

An unrepresentative survey of 58 haematologists and paediatricians (response rate 12 percent) found that only 9 percent thought that parents beliefs that the medication was harmful was an important cause of non-adherence in CYP with sickle cell and 58 percent thought it not important suggesting that is an issue that clinicians might miss during consultation.
2. Social context (impact of family structure, friends, peer groups, media)

Social contexts are not easily reduced to a set of exclusive, non-confounding factors. The multiplicity of measures makes it difficult to compare results across the 51 papers reviewed. It is not possible to conclude that families or friends have a consistently positive or negative effect on adherence. Direction of association is also complex. Medication can affect family functioning, but can also be affected by it. Positive family roles include motivating CYP and young people, giving practical support e.g. reminders, and accepting the young person and giving them space to manage their condition in their own way. Peers can either provide support to adherent or non-adherent behaviours, depending on the context. Having only one parent in the household is a factor consistently associated with poor adherence. Other family members with the same condition can increase adherence. Family routines related to medicines use increase adherence and their breakdown is linked to poorer adherence during adolescence.

Sixteen quantitative studies examined family functioning and routine as a factor in adherence. Seven of these studies, those employing multivariate analysis, reflect the mixed findings of all 16 studies. The specific variables used to describe family functioning vary across the studies, making comparison very difficult. Four multivariate studies indicated significant positive associations between family functioning and adherence. Three studies found no significant effect.

Nine quantitative studies explored the effect of different family structures across the range of conditions. There has been interest in the impact of having only one parent in the household, as opposed to the presence of two caregivers (either of whom may, or may not, be biologically related to the CYP). Four studies, three of which used multivariate analysis, found single-parent (usually mother) homes associated with higher levels of non-adherence. Two other studies found no significant effect.

3. Financial context (impact of socio-economic status)

Poor adherence was associated with lower socio-economic status in five studies but not associated in five other studies. It was not clear if this was due to lack of association, poor design or insufficient sample size. One study found increased adherence with lower SES, but methods were not clear here. Families with a lower SES had more difficulties with timeliness and cancellations/delays of clinic appointments. We do not, however, know why this is the case. A range of methods were used to evaluate socio-economic status, (occupation, salary, private versus public insurance) and sometimes the method was not stated.
In summary, most studies that were larger or well conducted did find an association with socio-economic status measured in a number of different ways and adherence, although some studies found no association. Studies varied in how they measured adherence or socio-economic status so comparison or synthesis of results is difficult.

4. Cultural context (impact of racial/ethnic or cultural background)
All eleven studies showed some effect of cultural/ethnic background or minority status on adherence. These results are all specific to the US context so may have limited applicability to the UK. African-Americans generally had lower adherence, Hispanic-Americans reported both increased and reduced adherence, Asian-Americans had higher adherence. Speaking both English and native language led to increased adherence, and increased integration into US culture reduced adherence. Ethnicity remained significant in multivariate analysis in some studies but not others. Most studies identified a difference in attitude towards asthma medication in minority groups in the USA. A minority of studies showed no relation between ethnicity and adherence.

It is not clear whether it is ethnicity or minority status that is the mediator here. It is not clear from some studies whether race affects adherence, or whether this is a mediator for poor SES and educational levels.

5. Educational context (impact of school)
There were very few studies addressing school and adherence. Asthma and diabetes were the main illnesses addressed. None of the studies were designed to examine the relationship between school and adherence but did provide some information about problems faced by CYP who have to take medication whilst at school. No conclusion about the effect of these problems on adherence can be made.

Relationship factors

1 Parent-CYP dyad interaction and communication

Nineteen studies examined the association between parent-child dyad interaction and communication and adherence. Most studies were from the USA, so relevance to UK behaviour is not clear. Sixteen studies were quantitative, nine of these using multivariate regression techniques. Only five of the studies were ten years old or more, so the evidence base is relatively current. Most used non-validated methods to measure adherence.

A) Parenting
Despite some conflicting results, the majority of studies reviewed support the idea that quality of parenting in relation to treatment management was important to adherence. A large representative survey of children with asthma (n=266) found that adolescent perceptions of greater parental support were significantly associated with good adherence (p<0.001). However, since only univariate analyses were used and the compliance variable and all the dependent variables were self-rated it is difficult to judge the strength of this finding. Manne et al in a subset of 32 parents of children with cancer found that nurse-rated adherence correlated moderately (r=0.33, p<0.05) with parents rating of a more nurturing parenting style. Interestingly, although parental control was not related to adherence, a subcomponent which assessed the extent to which parents felt able to let a child’s behaviour go without providing consequences was strongly associated with difficulty with obtaining child cooperation with care including mouth care and central line care (r=0.57, p<0.05) so that more permissive parents had more difficulties.

A larger study of children with CF aged 9-16 years also found that the quality of the family relationship (RQ) was related to adherence to more procedural aspects of care. RQ based on ratings of taped discussions and a valid self-report measure accounted for variance in child-reported adherence to aerosolised medications (6.2%), mother reported adherence (9.6%) and father reported adherence (14.9%). RQ was not associated with adherence to medications or enzymes. A strength of this study was the validity of the RQ measure but the study had a poor response rate. Bernstein et al (2000) found that the quality of family relationships predicted adherence to medication in 63 adolescents with anxiety disorder. Adolescent perceptions of family function predicted non-compliance with medications and appointment attendance. Parental perceptions of adaptability were associated with adherence as rated by pill count (r=0.34).

The nature of the parental relationship has also been found to impact on control of diabetes, with both parent and child reports of conflict being associated with higher HbA1c (difference 8.0 vs 8.6 +/-1, p<0.01). Another cross-sectional study with 41 mothers of children with CF also found that a better relationship between child and parent was associated with a range of adherence measures including staff rated adherence. This study also found better dyadic adjustment to be strongly correlated with staff rated compliance with diet (r=-0.5, p<0.05) and family cohesion to be positively associated with ratings of compliance with various aspects of treatment including medication. One interesting finding was that parent-rated adherence to medication was associated with dyadic consensus but also with less family adaptability and a more structured family environment (r=0.31, p<0.01) which seems to confirm the importance of authoritative parenting where there are high levels of control but also high levels of warmth. In contrast staff rated adherence to medication was associated with high adaptability (r=-0.3, P<0.05). There was poor correlation between staff and parent ratings of adherence and it may be that staff ratings of compliance are influenced by their perceptions of parenting.
B) Parental supervision

Lack of parental supervision was the reason most commonly identified by health professionals for non-adherence in 112 children and adolescents following renal transplant. Feinstein et al (2005) found that child patients who were non-adherent after a kidney transplant had lower family support as assessed through medical records (7/12 vs 1/32, p<0.001). Also 5/12 in the non-adherent group compared to 0/32 in the adherent group were responsible for their own medications. Adherence was assessed by blood results and patient report in medical records. It is not clear if raters of family support were blind to adherence status.

A small study of 15 children with sickle cell found that the 3 children in adherent group shared significantly more responsibility for care than those in the non-adherent and partially adherent group (<0.05). The importance of child participation was highlighted in a large study of children with ADHD in Taiwan. A quarter of children had poor adherence and these children had poor scores for all aspects of family functioning even after controlling for age, maternal mental health and maternal education (but not severity of symptoms). The largest effect size was for the partnership subscale (0.61) with mothers of non-adherent children being more controlling.

The results from a number of studies suggest that giving children too much responsibility for treatment may have a negative impact on management of the condition. A recent survey of 56 adolescents following renal transplant found where parents held primary responsibility for medication, 60% were adherent as assessed by a standardised self-report measure, compared to only 15% of young people who managed themselves. Although this study failed to control for age, there is evidence from other studies that child management may be more risky. A much earlier study of children with IDDM aged 8-17 years found those with poorer control, as measured by glycosylated haemoglobin levels and other clinical indicators, were more likely to be giving their own insulin injections (r=0.31, p<0.035) and taking responsibility for carry sweets (r=0.32, p=0.021). A survey of adolescents aged 10-17 with CF identified that parental supervision was an important factor in predicting adherence to nebulised treatments (n=51, b=0.35, p<0.01). The effect was particularly strong for electronically monitored nebuliser treatments (b=0.6, p<0.001). The role of supervision was confirmed by Anderson and colleagues (2002) in a cross-sectional study of 104 mothers of children with diabetes aged 8-17. Higher parental involvement was significantly related to better blood glucose monitoring (p<0.01, 3.4 vs 4.0). Another small cross-sectional study of 30 inner city African American children aged 6-14 with asthma found that giving children responsibility for care too soon could have a negative effect on management. Almost all children (93%) were administering inhalers independently at time of study but only 2 had inhaler technique scores in the acceptable range. Children who had administered inhalers from an earlier age had poorer skills (mean 4.18 vs 5.29, p=0.02) and parents were found to over-estimate children’s skills compared to the objective rating of technique (7.8Vs 4.83, p<0.001).
The relationship between parental control and adherence is clearly complex, however. A longitudinal study with parents of children aged 2-18 years with juvenile arthritis found child involvement in treatment was predictive of better parent rated adherence to exercise (OR 2.12, CI 1.02-4.39) after controlling for potential confounders. Since the same effect was not evident for medication it may be that child involvement is particularly important for adherence to lifestyle changes. Another longitudinal study found that disagreement between who was responsible for treatment was predictive of worse adherence at time 2 ($r=-0.54$, $p<0.05$) but individual ratings of responsibility were not related to adherence at either time 1 or time 2. This was, however, a small study with 24 children with HIV (aged 8-18 years) and caregivers but it did have a partially objective assessment of adherence. The importance of agreement about control was confirmed in a small study of 16 children, aged 9-19 and receiving treatment for cancer. For 8/11 young people who rated themselves as compliant, parents and young people had agreed on who was responsible for medication administration. Agreement with parents about responsibility for medication was not evident for any of the 8 children in the non-complaint group ($p=0.02$).

Walders et al (2000) investigated the hypothesis that discordance between adolescents and parents concerning beliefs about who was responsible for asthma treatment in a sample of 60 African American children aged 10-18 would be associated with poorer adherence as measured by the Revised Asthma Problem Behaviour Checklist. This was completed by the adolescent and used the study composite score to rate adherence. Adolescents whose parents overestimated their child’s level of responsibility in remembering to take medications ($n=15$) reported more non-adherence (Mean 2.07 vs 1.70, $P<0.05$). However, the study conducted multiple univariate tests and failed to control for potentially confounding variables such as age. Some further support for the importance of concordance between parents and children’s perceptions of responsibility for treatment was found in another study with 56 children aged 9-17 years with asthma and their parents. Greater self-report youth involvement associated with better outcomes (e.g. fewer emergency visits $b=0.35$ & fewer hospitalizations $b=0.31$) but there was an significant interaction between youth report and parent report with low youth report and higher parent report of youth involvement being associated with increased severity of symptoms as rated by physician ($b=-0.28$) and more symptoms as rated by parents (0.362). No relationship was found between overestimation of youth involvement and adherence. This study used multivariate tests, but unfortunately did not report the amount of variance accounted for by the independent variables.

These results further support the idea that it is the partnership between parent and child which aids adherence rather than the level of control itself. Indeed Hovell and colleagues, in a large longitudinal study of 286 Latino adolescents aged 13-18 years with TB, found no relationship between level of control and adherence at 9 month follow-up. This methodology for this study was particularly strong as although adherence was self-report it was validated by...
blood levels. Control in this study might reflect an element of coercion as it encompassed parental strictness and presence of rules. A descriptive study by Kyngas et al (1998) examined how actions of family perceived were to influence compliance with treatment in adolescents aged 13-17 years with IDDM. Of 17 participants who described their parents as motivating, which included planning care together, 10 were in the good compliance group. Conversely of the 22 participants who rated their parents in the discipline control category which includes forcing adolescents to carry out self-care and giving negative feedback only 6 were in the good compliance group as rated by self-report. Related to this Gerson et al (2004) found that in families of 13 children and young people aged 2 to 20 who had undergone renal transplant, high achievement orientation was strongly associated with poor adherence ($r=-0.83$, $p=0.03$).

Three qualitative studies provided useful insight into the complexity of the relationship between child involvement in treatment and adherence. For example Slatter et al (2004) in a study of 17 parents of children with cystic fibrosis found that adherence issues tended to centre around the role of the child:

“even now she forgets her Creon and after 9 years of taking them I can’t believe she’ll sit down to eat and she won’t have them, I just get so frustrated”.

Another larger qualitative study with 71 mothers of children aged 1-18 with HIV found that 44% reported their child as being repeatedly resistant to medication. A desire for the child to be autonomous was an important theme to emerge, together with recognition of the importance of parental supervision. Some parents were reluctant to let go for fear of deterioration in the condition. A qualitative study of 42 children aged 5 to 17 years with HIV found nearly a third of the children reported poor adherence. Disclosure of HIV status was perceived as facilitating disclosure and there appeared to be particular problems where children suspected their HIV status but had not been told, reflecting the importance of supportive communication between parents and children.

The strong theme to emerge from this body of research is the importance of a supportive partnership between parent and child. Arguably the goal for adolescent management should be that they share the responsibility for following treatment advice. Parents may need help to recognise that complete autonomy may not be achievable whilst young people share a home with parents and that supporting the young persons’ attempts to self-manage may be a more effective strategy. Control is important but it seems that an authoritative approach which combines structure and control with warmth and support rather than an authoritarian approach is likely to enhance adherence. Authoritative parenting has been associated with positive outcomes in adolescence and is associated with better communication. However, authoritative parenting is more difficult when families are under stress.

Despite some conflicting results, the majority of the 19 studies reviewed support the idea that quality of parenting in relation to treatment management was important to adherence. Highly levels of conflict within family relationships are
associated with poorer adherence. More authoritative parenting appears to enhance adherence if associated with parental warmth.

Parental supervision appears to increase adherence. The results from a number of studies suggest that giving CYP more responsibility for treatment than they are ready to take on at that time may have a negative impact on management of the condition.

The strong theme to emerge from this body of research is the importance of a supportive partnership between parent and CYP. Arguably the goal for adolescent management should be that they share the responsibility for following treatment advice.

2 Practitioner-CYP dyad and parent-CYP-practitioner triad

Eight studies explored the influence of relationship with health care provider on adherence. The majority of studies were conducted in Finland (5), with one study from Taiwan, US and UK. Of the five quantitative studies only one used multivariate statistics. Only two of the studies were 10 years old or more, so the evidence base is relatively current. Most used non-validated methods to measure adherence.

Kyngas and colleagues did include relationship with health provider as an explanatory variable in their body of work on adherence in a range of chronic conditions. The four quantitative studies had good sample sizes and excellent response rates but no objective measure of adherence although some validation was possible in studies which looked at diabetes as better self-rated adherence was associated with lower HbA1c. Univariate analyses showed a strong effect of health care provider on adherence to health care regimens. For example in a study of adolescents aged 13-17 with diabetes, 39% of those reporting good support from physicians and 37% of those reporting good support from nurses were in the good adherence group compared to none in the poor adherence group, a highly significant difference. A qualitative study using content analysis with the same population (n=51) found that 12/15 young people who perceived that they had a motivating relationship with their physician and that decisions were made together had good compliance compared to 7/14 who perceived the relationship as routine and 1/10 of those with features of routine and negligence. Another qualitative study which looked at parental perceptions (n=17) of the relationship with the health care provider also found evidence of supportive relationships but issues around expertise to manage cystic fibrosis were a concern. This was a well conducted study with a good response rate. A much smaller and less methodologically rigorous study explored perceptions of health care providers in 6 older adolescents (16 -24) with HIV. An interesting issue was the extent to which participants felt they could confide about missed doses. This in-depth study provided some illuminating examples of how a good relationship with clinic staff helps adherence. The only quantitative study to use multivariate statistics explored factors influencing adherence to correct inhaler technique following
emergency admission to accident and emergency for asthma. Parents of children aged 8-13 reported better inhaler technique if they also rated themselves as satisfied with the educational programme. Other factors which entered into the regression included having experienced an asthma attack in the past year, and older age. No weights are reported so it is difficult to judge the contribution of satisfaction with the doctor’s provision of information to inhaler technique.

In summary there is some compelling qualitative evidence of the perceived importance of the relationship with healthcare providers to adherence. The evidence from quantitative studies is poor although the body of work from Finland suggests that perception of lack of concern from nurses and physicians could be a useful marker for non-adherence.

3 CYP and parent interaction with the health system in community, primary and hospital care from initial contact to medicines supply, and over time

Only five studies related health service interaction to medicines adherence. There is very little work about the interaction with the health system and its impact on adherence to medicines in children. These studies were based in the USA (4) and Germany (1). Three studies were quantitative, two of these using multivariate regression techniques. Only two of the studies were 10 years old or more, so the evidence base is relatively current. Most used non-validated methods to measure adherence.

A study of children with ADHD assessed the association of consistency of prescription fills calculated with continuity of care (COC) by using the continuity of care index. Seeing the same provider at each visit was associated with consistency of use but increased age was associated with decreased likelihood of consistent use. Among children who initiated therapy early, increased COC was associated with increased likelihood of filling more than 7 prescriptions (OR, 1.81[95%CI, 1.12-2.35])

A study of parents of Hispanic children with asthma demonstrated a fear of dependency and a fear that physicians fail to disclose side effects of drugs (80%) and that medications in the US were overused. Adherence was affected by health beliefs. HCPs do not ask about these beliefs or understand them. Families did not feel that doctors understood their beliefs and therefore did not tell them what they were thinking, i.e., physicians did not ask and families did not tell them.

A study of children post-renal transplant reported some interesting findings and reasons for non-adherence that need to be considered: insufficient information, no communication re non-adherence, not feeling they were being taken seriously, lack of time of health care providers, lack of praise from health care providers. However, this study appeared to have a biased sample so its generalisability is not clear.
Due to the lack of studies linking satisfaction with adherence, we were not able to make any conclusions based on the evidence. Two studies were found that have relevance to this patient group, despite not examining medicines adherence, so their results are reported briefly here.

A study of participants at a general adolescent clinic reported 38.1% were dissatisfied with health care they received. Females were more satisfied than males. Older patients (over 15) more satisfied than younger. If the appointment was initiated by the adolescent, 89% were satisfied. 67% dissatisfied if the parent made the appointment. 84% of satisfied patients had been seen by more senior member of the team. Reasons for not being satisfied include having to wait too long to be seen and that their physician was not thorough enough. This study did not examine medication adherence. The inference may be that if one is satisfied with care, then more likely to adhere to medication. However this cannot be presumed.

A study of parents of children with asthma suggested that they were less likely to attend appointments if there was a lack of convenient follow up appointment times or long waits at the appointments. Other barriers to follow up included children having to miss school or parents missing work. This study did not examine medication adherence. The inference may be that if one attends the follow up then more likely to adhere to medication. However this cannot be presumed.

They suggest that there is a problem between health care providers and families i.e. in the relationship and understanding about the families’ beliefs. Insufficient information, no communication about non-adherence, not feeling they were being taken seriously, lack of time of practitioners, and lack of praise from practitioners are given as reasons. One study reported continuity of care i.e. seeing same provider at each visit was associated with consistency of medicines use. Studies on reasons for poor clinic attendance suggest that parents are less likely to attend if they experience lack of convenient follow-up appointment times or long waits at the appointments, or if CYP have to miss school or parents miss work.

2.3 Key results from the critical evidence synthesis

There is a range of factors that have the potential to affect adherence in CYP and these can be related to people, the regimen, the context and relationships. From the literature we identified that generic barriers to adherence were forgetting, parents’ anticipation of side effects, perceptions of a medicine’s necessity, regimen complexity and family functioning. Disease-specific reasons included weight gain and needle phobia in diabetes, and visibility and steroid phobia in asthma. CYP may benefit from device training where appropriate.
There is little work around the parent-CYP-provider triad, and the research found here suggests that this interaction is likely to increase adherence when functional and reduce adherence when dysfunctional.

The evidence base for many of these individual factors is weak, not least because of the inconsistency of concepts and measures of adherence in the studies.

The four categories used to classify the factors described, however, bring collective strength to the description of factors affecting adherence for CYP and their families. If there are weaknesses in any of the four categories, the prospect of good adherence is reduced.

There are similarities between reasons for non-adherence in adults and CYP. As in adult populations, our review shows that non-adherence is not significantly related to a number of fixed factors (e.g. the type or severity of disease; sociodemographic variables; personality type). In adults and CYP, adherence is positively correlated with income when the patient is paying for treatment but not with general socio-economic status. Social support is linked with increased adherence. Providing clear information, although essential, is not enough to guarantee adherence. Non-adherence is also often lower for more complex regimens, but reducing the frequency of dosage administrations does not always solve the problem. In both adults and CYP perceptions, experiences and priorities, including concerns about side effects and other unwelcome effects of medicines mean that they seek to balance perceived necessity and concerns. As in adults, there is little understanding of the relative importance of intentional and unintentional non-adherence (individual constraints: memory, dexterity; environmental constraints: accessing prescriptions, cost, competing demands). There is also little understanding of the effect of the quality of communication between the patient and healthcare provider or of the wider societal contexts such as access to resources and societal policy and practice. Where reasons for non-adherence differ, they relate to the dependent nature of CYP and the pivotal role of parents and that relationship. This is also a period of life where cognitive, emotional, social and physical development is at its most rapid, and our review illustrates the effect of this on medicines-taking behaviour.

2.3.1 Key gaps and limitations of the evidence

This critical evidence synthesis has produced some important results. However there are key gaps and limitations in the evidence. Apart from variations in quality of studies, there was uneven distribution of the numbers of studies examining each theme, from over 50 examining social context (impact of family structure, friends, peer groups, media) to five looking at educational context. Most of the research is from the USA, so
application to the UK context may be variable, and studies in asthma dominate, meaning that there is less evidence for other key illnesses. There are some studies in diabetes and epilepsy, but only three in heart disease. It is not clear how research carried out in one disease type can be applied to other diseases.

Synthesis of the data is complicated by different countries of origin, study designs, use of different and overlapping age ranges, use of different measurements and estimates of adherence and other parameters such as knowledge and socio-economic status. This was compounded by the failure to use validated measures of adherence. Self-report or parent-report were the most common measures used which generally overestimate adherence.

Most studies examined parent report of factors rather than CYP report, so consequently it is not often known what is important to CYP. Where both parents’ and CYP’s views or behaviour were examined, there is a suggestion that these are likely to differ.

Few studies examined the association between multiple factors and adherence behaviour. Therefore it is difficult to assess the relative importance of individual factors. For example, very few of the studies, other than the 44 studies that specifically examined age, controlled for effect of age. Where multiple regression techniques were used studies tended to measure a subset of factors, rather than the full spectrum of possible factors.

### 2.3.2 Limitations of our search and analysis methods

The key limitation of this search is that we may have not included all research around adherence in this age group, due to the wide range of types of research and terminology used.

The disadvantages of this approach are the large amount of data available, the challenges involved in trying to synthesise evidence from different sources and the subjective nature of interpreting data of this type. In qualitative work it is important to acknowledge the perspective of the researchers undertaking the research and the impact that their specific expertise and experience could have on the selection and interpretation of data. However, we had a range of perspectives as a team and from our stakeholders so many of the themes identified complemented and enriched evidence from the literature reviews (for example the importance of perceived necessity of the medication in driving adherence). Other themes (for example the role of the school in supporting adherence) were unexpected and not evident in the literature.

### 2.3.3 Recommendations for future research

Future research examining factors affecting adherence in CYP should cover the following general gaps: UK-based studies of a full range of diseases
should be examined; studies should allow for measurement of multiple factors and correct or control for age, use validated measures of adherence; and obtain CYP’s views and reports of behaviour.

Factors particularly requiring more research are the effect of educational levels, culture, socio-economic status, school, and the effect of interaction with the health system.
3 Systematic review of interventions to improve medicines adherence in CYP and with chronic illness

3.1 Background

The overall aim of this review was to identify which interventions are effective in changing the medicines-taking behaviour of CYPs. This review is more extensive than was originally proposed for the study. The published reviews of interventions to improve adherence available did not provide us with sufficient guidance to inform the development of an evidence-based intervention. These reviews are discussed in more detail in Section 3.3.2. Therefore, we needed to carry out our own review of interventions. We also wanted to use published studies to inform methods of objective evaluation of behaviour change, clinical outcome and resource use.

Many interventions have been designed to improve medicines adherence, but not all appear to improve adherence or patient outcome.54 There are many narrative and partial reviews of adherence-enhancing interventions (AEIs), but the most rigorous available to date is the recent Cochrane review, including both adult and paediatric studies.54 It examines 79 randomized controlled trials (RCTs) that measure patient adherence and outcomes. Nine published studies were carried out in CYP but data were not assessed separately from adult studies. As adult interventions do not necessarily translate into the paediatric setting,128 the overall results from this review cannot be used to inform paediatric practice.

Horne et al developed a conceptual map of factors affecting medicines adherence and where interventions might be placed to change adherence behaviour.2 (see Figure 5)
Figure 5. Horne’s conceptual map of where interventions to improve medicines use can be targeted

This representation does not take account of the dependent nature of CYP’s decision-making or allow independent interaction between the three members of the parent-CYP-provider triad.

Figure 6 (below) is an adaptation of Horne’s model and demonstrates where interventions may be placed to affect CYP’s medicines use behaviour, taking account of the dependent nature of CYP’s decision-making and allowing independent interaction between the three members of the parent-CYP-provider triad.
Figure 6. Adaptation of Horne’s conceptual map to indicate where interventions to improve medicines use can be targeted in CYP

Two recent reviews have focused on medicines AEIs in CYP. One included 71 studies and carried out a meta-analysis. However, nearly half of the studies included were not concurrent controlled studies, and three published RCTs included in the Cochrane review were omitted. Another recent review of educational and behavioural AEIs included 17 studies, omitting six of the RCTs in the Cochrane review. These are partial, or narrative, reviews, because the search and inclusion criteria were not systematic. The optimal approach for improving medicines-taking in CYP remains unclear. We conducted a systematic review of AEIs in CYP.

3.1.1 Data sources

To explore this complex field, a multi-method approach was adopted, using evidence-scoping methods. We combined search strategies used by Haynes and Horne with specific CYP keywords. We searched seven electronic databases in August 2009 (Figure 7). Clinical and lay experts were consulted. A hand search was conducted of reference lists from relevant studies.
3.1.2 Study selection

We included RCTs and concurrent controlled studies investigating an intervention to improve medicines adherence in CYP with a long-term illness requiring regular daily medication, reporting medicines use/adherence,
published between 1980 and July 2009, in English. The aim of this review was to identify which interventions were effective at changing medicines-related behaviour. On this basis, we gave no emphasis to a particular type of intervention. Our intention was to use the published evidence on effective interventions to drive the design of our intervention, rather than assume a particular type of intervention would be more effective.

We excluded unpublished dissertations, reviews, abstracts, studies using historical controls only, studies where adult and CYP data were reported together only, adherence was only to hygiene techniques, physiotherapy, orthotics, CPAP masks, diet or exercise, or if medicines adherence was only reported as part of a composite adherence score combined with other behaviours. We excluded studies that only reported reductions in medicines use due to substitution with another treatment, such as cognitive behavioural therapy in depression. Authors of studies with combined adult and paediatric results were contacted for disaggregated data. Unfortunately, no data were provided.

3.1.3 Data extraction

We identified 48 studies for inclusion (Figure 7). Six reviewers (DC, RAE, NL, JW, HP and AS) summarised and assessed studies using standardised criteria. Each study was reviewed by at least two reviewers.

Effect sizes or odds ratios for adherence and clinical outcomes were extracted, or calculated by the review team. Where effect size could not be derived, odds ratios were derived. An effect size of >0.49 was considered clinically relevant. Due to the heterogeneity of study design, populations, interventions, adherence and outcome measures employed, a meta-analysis was not carried out.

3.1.4 Results

Table 3 summarises key study characteristics. Eight studies were published before 1990, ten between 1990 and 1999, and 30 in or after 2000. An outline of each study is presented in Appendix 7.4.

Patient groups

Most interventions were carried out in asthma (29) and diabetes (7), in a range of age groups (Figure 8). Effectiveness of the interventions was not reported separately for different age groups. Eleven studies specifically recruited patients considered at risk of non-adherence, usually defined as uncontrolled disease (Table 4).
### Table 3. Key characteristics of 48 studies included in the review

<table>
<thead>
<tr>
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<th>References</th>
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<p>| <strong>Disease group</strong> | Asthma (29) | 135-139 142 143 146-149 152 |
| | Type 1 diabetes mellitus (7) | 133 134 140 141 145 151 162 |
| | Malaria (2) | 144 160 |
| | Hypercholesterolaemia (1) | 163 |
| | CF (1) | 168 |
| | Iron deficiency anaemia (1) | 172 |
| | JIA (1) | 150 |
| | Sickle cell disease (1) | 177 |
| | TB (3) | 144 157 179 |
| | HIV (1) | 155 |
| | Epilepsy (1) | 160 |</p>
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<td>Comparing different drugs/dosing/drug delivery (7)</td>
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<td></td>
<td>Involvement of families, peers or carers (7)</td>
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<td></td>
<td>Telephone support from health care provider (2)</td>
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<td>Adherence coaching (1)</td>
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<td></td>
<td>Directly observed therapy/medication observed (1)</td>
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<td>Study had a total sample size that was</td>
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<td>fewer than 120</td>
<td>AEI had more than one component</td>
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<td>Adherence measures used</td>
<td>143 144 146-149 152 153 155 160 162 165 168-170 173 178 180</td>
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<td>Control of disease state</td>
<td>Self-report (18)</td>
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<td>Prescriptions filled / refill rates (3)</td>
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<td>Clinician checklist (1)</td>
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<td>Comparison of symptoms after treatment (1)</td>
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<td>Expert reported – Visual Analogue Scale (VAS) (1)</td>
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<td>Inspection on contents of medicine bottles so not to run out (1)</td>
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<td>Sanford et al. 1993</td>
<td>176 TB</td>
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</table>

*in studies where there were more than two intervention arms, the comparator with the largest effect is presented

**only calculated where Cohen's d could not be derived

*0-0.20: no effect; 0.21-0.49: small effect; 0.50-0.79: moderate effect; >0.79: large effect. Grey shaded cells indicate lack of mean (SD/SEM) adherence/outcome in intervention or control arms so Cohen's d could not be derived

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Project 08/1704/212
3.1.5 Quality of studies

Of the 48 studies, 47 claimed to be RCTs and one was a concurrent controlled trial. The studies included 6282 patients in total, the mean (range) number of subjects in intervention and control arms being 68 (7 to 251) and 63 (6 to 249), respectively. Studies with single intervention and control groups need at least 60 participants per group for 80 percent power.
to detect an absolute difference of 25 percent in the proportion of patients with adequate adherence.\textsuperscript{54} In 26 studies, sample size was based upon a power calculation. Only 20 had total sample sizes of 120 patients or more, suggesting that other studies lacked the statistical power to detect clinically important effects.

The Jadad\textsuperscript{182} scoring method was used to assess the quality of the 47 RCTs. Thirty-two were low quality studies(scores 0 to 2). Lack of blinding, poor randomisation schemes and failure to describe dropouts and withdrawals were common weaknesses.

A funnel plot (not shown) suggested considerable publication bias towards smaller studies with positive findings.

### 3.1.6 Intervention design

Interventions used health education or training interventions (39), drug delivery, drug dosing and regimen-focused interventions (7) and parent, family and peer-led interventions (7). Thirty-four studies reported interventions with more than one component. (Appendix 7.4).

Education was delivered by health care professionals, peers, paper and/or electronic sources, ranging from simple information-giving to complex behavioural and psychological training. It was generally unclear how homogenously interventions were delivered, in terms of content or number of contacts, and to whom in the family.

Most interventions were reported as based on previous studies,\textsuperscript{133 135-141 145 147 148 151-160 162 163 165 166 168-170 175-178} common practice or existing models of care,\textsuperscript{167 172 174} or derived from a review of literature.\textsuperscript{145 173} Nine were based explicitly on theories.\textsuperscript{144 146 149 150 152 161 171 175 176 178} One example, in Latino adolescents with tuberculosis, based their effective peer coaching intervention on learning theory and a behavioural model developed by the authors.\textsuperscript{144}. Behavioural theory was used\textsuperscript{150} to design an effective AEI in JIA, comprising strategies like cueing (e.g., pairing medication taking with an established behaviour such as brushing teeth). In some studies, justification for intervention design was not clear or not given.\textsuperscript{134 142 164 179} In one study the intervention was described as non-evidence based.\textsuperscript{143}

Few studies reported age-specific adjustment of interventions, with most targeting children/adolescents across a broad age range. One study reported generating age-specific educational materials.\textsuperscript{169} Two studies in diabetic adolescents tailored interventions to their age group, using peer support\textsuperscript{134} and focusing on the parent-adolescent relationship.\textsuperscript{133} Both studies were too small to demonstrate effect.

Interventions were conducted over varying lengths of time, from four days to over two years. Eight were “one-offs”\textsuperscript{142 145 152 158 171 172 174 176}, the rest
repeated on more than one occasion. Eight studies had follow up periods of 8 weeks or less. Five studies had follow up periods of 24 months or more.

In most studies, the comparator was “usual care”, clearly described in 34 studies, but not obvious or not described in the remainder. Nine studies had more than two arms.

3.1.7 Adherence and outcome measures

In most studies adherence measures were clearly reported (Table 3). Parent/carer report via diary or questionnaire was the most common method used. It was sometimes unclear whether parent or CYP report was used (Table 4), and whether reporting methods were tailored for age. For example, in one study of CYP aged 3 to 16 years, the authors noted, “subjects recorded taking doses on diary cards, and compliance was assessed by review of returned drug supplies and diary card.”

Many clinical outcomes were used, usually disease-specific clinical indicators. These were used explicitly by some as proxies for adherence, for example, glycaemic control.

Thirty-four studies measured both clinical outcome and medicines adherence.

3.2 Findings

3.2.1 Adherence

Nineteen studies reported statistically significant differences in adherence between intervention and control. These studies included asthma, cystic fibrosis, diabetes, epilepsy, JIA, and TB. The interventions were: adjustments to dosage regimens, health education and training, a nurse run asthma clinic, and involvement of families, peers or carers. Studies explicitly targeting patients with uncontrolled disease did not appear to demonstrate increased effectiveness.

3.2.2 Clinical outcomes

Twenty three studies reported statistically significant differences in clinical outcomes. These studies included diabetes, asthma, iron deficiency anaemia, cystic fibrosis, tuberculosis, hypercholesterolaemia, HIV and juvenile arthritis.
The interventions included drug dosing, family, carers and peers, health education and training, and a combination of educational and behavioural interventions. One study suggested a negative direction of effect, with an increase in hospitalizations in the intervention group.

### 3.2.3 Adherence and clinical outcome

Sixteen studies reported statistically significant improvements in both outcome and adherence in asthma, diabetes, TB, JIA and hypercholesterolaemia. Eleven studies used a health education and training intervention approach, four incorporated family training and three studies used drug dosing. Overall, the follow-up period ranged from 12 weeks up to 6 years.

Of these sixteen, only nine studies had large or moderate effect sizes or statistically significant odds ratios for both adherence and effect (Table 3).

### 3.2.4 What were the features of successful interventions?

Three studies focused on changing aspects of the drug regimen: formulation, medicine administration route.

Five studies took the intervention to the patient. In a small study, adding internet-based education to office-based education, followed up on multiple occasions over 24 weeks showed improvements over the office-based intervention alone. In a well-designed RCT, “The Health Buddy”, was effective. This home-based intervention was a personal and interactive communication device tailored to give support rather than education, with use driven by the CYP. A home-based intervention for adolescents with diabetes improved adherence. A school-based adolescent asthma clinic was more effective than physician-based clinics. In CYP with TB, home or telephone-based education was more effective than office-based support.

Five studies demonstrated education was effective over normal care in asthma, tuberculosis, epilepsy and CF. It is unclear whether education, or increased attention, was the cause of improved adherence. As demonstrated in another study, adherence was not improved by education alone, but CYP receiving a “caring interaction” had improved adherence.

Three studies added behavioural components to educational interventions and improved effectiveness. A coaching intervention for adolescents with
TB, based on learning theory and a behavioural model, showed a sustained improvement in adherence. A “one-off” behavioural intervention in JIA improved adherence over a standard educational intervention. In adolescents with diabetes, the intervention was more effective at improving adherence when behavioural family training was added.

Two studies demonstrated that sustained support was more effective than “one-off” interventions. One education-based study in asthma, with ongoing support as part of the intervention, demonstrated that the effect of the intervention ends if the support is stopped.

Lozano et al (2004) compared usual care versus peer leader education, versus peer leader plus multidisciplinary planned care in asthma. Planned care was effective. Peer support had no effect in this study, possibly due to the wide age range (1 to 16), as this may be effective in older age groups only.

3.3 Discussion

3.3.1 Key findings

We found 48 studies examining the effectiveness of an intervention to improve medicines adherence in CYP. Only nine studies reported clinically important increases in adherence and outcome.

3.3.2 Comparison of this review with published reviews

We used very similar search strategies to the Cochrane review, and accessed all nine published RCTs included in their review. We used the updated results from Hederos et al [2009] to supplement the original results presented in 2005. We excluded one study as it was a 10-day treatment of an infection. Similarly to Horne et al, we extended our review to include studies that only reported adherence, which provided five further studies. We included a further 34 studies of poorer design, 33 of which claimed to be RCTs, and one CCT, including six excluded from the Cochrane review due to incomplete randomisation or poor follow up. Inclusion of these studies enabled us to provide a wider view of the interventions being designed and tested, and some of these studies present potentially useful and effective interventions.

The recent review by Dean et al [2010] excluded five RCTs included in the Cochrane review, included one study that was published only as an abstract and one study that was not an intervention to improve medicines adherence. They had included ten further studies, also included in our review. Graves et al [2010] excluded two published RCTs and one unpublished dissertation included in the Cochrane review, despite
including a further eight dissertations. They had included ten further studies also included in our review, but a different ten to those included by Dean et al. Their review also included 54 studies that were historically controlled studies. Due to the heterogeneity of study design, intervention type, patient group, adherence and outcome measures used, a meta-analysis was also clearly not appropriate, and the results should be discounted.

3.3.3 Limitations of studies

The study sample was dominated by US studies, and asthma, which may limit generalisability to other diseases, countries, cultural or socio-economic contexts. We had to exclude some interventions that probably affected medicines adherence but did not report adherence.

Although some studies used robust study design criteria, many were designed sub-optimally. Hence, it was difficult assess the impact and effectiveness of interventions for the majority of studies covered by this review. Key generic design limitations included sample size, lack of randomisation, lack of outcome assessment blinding, description of comparators and short follow-up.

Many AEIs were atheoretical with a didactic educational component, with no ongoing patient contact after initial counselling and education sessions. The contribution of information to non-adherence is not fully understood. A recent meta-analysis of psychological interventions in CYP suggests that behavioural or multi-component interventions are more effective than education alone, but education does have a small effect size, and we found an independent effect in some studies.

It was often unclear how or whether the interventions were designed for the target group, or targeted towards the CYP or the parents/carers. Interventions designed for adults are not necessarily appropriate for CYP. Also, differently-aged CYP have different needs. Some studies included CYP from a wide age range, including both pre-verbal CYP and those attending high school. It seems unlikely that a single intervention will be equally effective across wide age ranges.

Understanding and changing CYP’s medicines use behaviour requires us to take account of the dependent nature of CYP’s decision-making, especially at younger ages. The interaction between the three members of the parent-CYP-practitioner triad also needs to considered, in the context of the changing relationship between CYP and parent, as the CYP moves into adolescence. Few interventions examined this, but when incorporated, this led to improved adherence.

There is no “gold standard” measurement of adherence. The most commonly used methods are self-report, using health professionals’ judgment, reviewing prescription refill patterns, electronic measurement devices, clinical outcome measures, and measurement of blood or urine
concentrations of the drug.\textsuperscript{189} Because intentional non-adherence has often perceived as a deviant behaviour,\textsuperscript{190-192} patients may conceal non-adherence. The studies in this review mostly used a range of non-validated measures of adherence, relying on self-report (although not always clear from whom), and did not assess reliability of adherence measures used.

3.3.4 Limitations of our search and analysis methods

The key limitation of this search is that we may have not included all research around adherence in this age group, due to the wide range of types of research and terminology used. However, our review has been quite inclusive, and we have included study designs that would have been excluded from an equivalent Cochrane Review. The other main limitation is that our approach to analysing the evidence we found may have been affected by our perspective.

3.3.5 Conclusions

Improving medicines adherence in CYP is an ongoing challenge, as it is in adults.\textsuperscript{127} Whilst some interventions are effective, many more do not appear to be, for a range of reasons, including poor design and not being based on reasons for non-adherence. There is insufficient evidence in many illnesses, or in CYP with complex needs. Most interventions do not address the complexities of the parent-CYP dyad, or the changing nature of the CYP’s involvement in decision-making as they develop, and stop at the patient-provider level.

This review suggests that interventions based on reasons for non-adherence, sensitive to age and development stage, sustained over time, convenient for the CYP and family, and deliverable in a local practice setting are most likely to be effective.
4 Barriers and facilitators to medicines use in CYP with chronic illness: a qualitative study of CYP, their parents, carers and practitioners

4.1 Background

The aim of the TABS study is to develop and pilot a new paediatric medicines management service delivery package. This practice model involves CYP, parents and practitioners, challenges preconceptions about rights and responsibilities, and empowers CYP to talk openly and be active partners in decisions about medicine-taking for long-term conditions.

This package has an organisational and individual level theoretical basis, was informed by users across ages (5 to 7, 10 to 12, 15 to 17), social characteristics, conditions (asthma, diabetes, epilepsy and CHD), and complexity of needs, and designed to function in community, primary, secondary (and tertiary) care. User and provider stakeholder forums and expert advisory panel were consulted to ensure validity, acceptability and feasibility.

Chapters 2 and 3 present the current state of published evidence. In this chapter, we describe the part of the TABS study that engaged with a range of stakeholders and an expert advisory panel before holding focus groups and interviews with CYP, parents and providers to examine barriers to medicines-taking and methods to overcome those barriers.

4.2 Aims and objectives

To use interview and focus group methods to examine the CYP-parent-provider triad at individual and organisational levels to:

1. Examine expectations, experiences and concerns about medicines and perceived barriers (both modifiable and non-modifiable) to adherence.
2. Explore transferring responsibility control for older adolescents, and how to facilitate honest disclosure of medicines-taking behaviours.
3. Clarify perceptions of roles, empowerment, rights and responsibilities associated with long-term medicines use.
4. Understand CYP's and parents' interaction with the health system in a range of community, primary and secondary care settings from initial contact to medicines supply, and over time.
5. Identify ways in which barriers to medicines adherence might be overcome.

4.3 Methods

Prior to the roll out of focus groups and interviews, patient, family, and health care provider stakeholders (Appendix 7.5) were surveyed for their views on a range of issues around medicines taking in CYP. The responses are listed in Appendix 7.6, and were used to inform the focus group and interview schedules. An Expert Advisory Panel was also consulted at this stage. (Appendix 7.7).

The original study planned to run a series of 14 focus groups to explore patients’ and health providers’ beliefs, expectations and priorities for medicine-taking in CYP. The purpose of this exercise was to compare the findings from this element of the study against the findings from the critical evidence synthesis, to design and develop a medicines management package that would meet the needs of patients, carers and practitioners alike.

However, whilst recruiting for three focus groups made up of a range of health professionals was achievable, recruiting groups of patients from the various approved sources (i.e. GP clinics; hospital outpatient clinics, community paediatric clinics and community pharmacies) proved extremely difficult. Clinicians were provided with packs to hand out to patients who matched the recruitment inclusion criteria, and where possible, lists of patients fitting the criteria for inclusion were identified and study information packs were posted to them. In total, more than 800 study information packs were distributed.

Responses were slow to be returned and did not meet the numbers required to facilitate focus groups in specific locations, as numbers of potential participants were low and they came from across a wide geographical area. For these reasons, an amended protocol was submitted and approved by the local ethics committee, permitting face to face interviews with parents and CYP from the selected age ranges and with the four index conditions. This revised approach led to increased levels of participation. Due to the delays associated with approvals for access (see Section 1.10), we had to make the decision to stop recruiting for interviews before we reached our original targets for numbers of parents and CYPs for the focus groups. However, the numbers achieved for one-to-one interviews were sufficient to obtain thematic saturation. See Appendix 7.8 for the information sheet for interviewees under age 18. Interviews were conducted mainly in the patients’ homes or in mutually convenient locations such as hospital clinic waiting areas or at the University of Nottingham.
A modified interview schedule / topic guide was developed to take account of the revised approach i.e. face-to-face and in people’s own homes. This also provided an opportunity to pilot a pre-consultation tool that had been developed as a result of the early findings from the critical evidence synthesis and stakeholder input.

See Appendix 7.9 and Appendix 7.10 for the practitioner focus group schedule and face-to-face interview schedule with parents of CYP. Full versions of the information, consent and assent documentation for all participant groups are available on request.

4.3.1 Study setting

Participants were recruited from the Leicester and Nottingham areas in the East Midlands. Specific practice settings targeted were secondary care paediatric services, community paediatrics and primary care services at both localities.

4.3.2 Sampling

A purposive, maximum variation sampling strategy was adopted in order to recruit participants from across social and ethnic groups as well as representing the study age groups (5 to 7 years; 10 to 12 years; 15 to 17 years) and the four index conditions (asthma, diabetes, epilepsies and congenital heart disease). Generic issues across these conditions (for example: age, ethnicity, service delivery setting) were to be investigated. Specific issues to be explored included:

- Asthma: reluctance, or inability to use inhalers, attitudes to steroids, attitudes to smoking.
- Congenital heart disease: lack of availability of licensed paediatric preparations, management of warfarin.
- Diabetes: reluctance to use needles, weight gain with insulin, attitudes to diet.
- Epilepsies: stigma, palatability and accessibility of paediatric formulations.

We also requested clinicians to identify those CYP whom they suspected were adherent and those who they suspected were non-adherent to their medication regimens. The research team were not made aware of which category the young people identified fitted in to before interview.

The age groups (5 to 7 years – starting school; 10 to 12 years - primary to secondary school and 15 to 17 years - secondary to further education / work / adult care) were selected to represent both developmental and educational transitions. We planned to talk to the parents of the 5 to 7 year old CYP, but not involve this group of CYP in interviews or focus groups, since we felt that adherence would be determined by parents. The original
ethical and R&D approval for focus groups did not include children aged 5-7 years. Due to delays in recruitment to Phase 1, we changed our methods to interviews, but did not have time to go through the process of obtaining ethical approval and R&D approval to interview 5-7 year olds. The active participation of 5 to 7 year olds has been incorporated into Phase 2 of the study, in which we piloted the medicines management package developed as a result of Phase 1. However, within Phase 1, older CYP were given the opportunity to voice their opinions, concerns and priorities regarding medicines-taking and self-management. By selecting these age groups we have had the opportunity to explore school and work-based barriers.

We aimed to achieve data saturation within our samples of parents and CYP regarding major themes within the analysis.

**Challenging cases**

We planned to conduct six interviews with parents of CYP who represent challenging medical cases, with the following characteristics:

1. CYP within the three transitional age groups identified for this study AND
2. a) CYP with at least two significant chronic medical conditions (at least one of which should be an index condition) each requiring at least one medication to ensure control (e.g. diabetes with asthma, or ADHD with asthma) OR
   2 b) CYP with one of the index conditions who are taking three or more medicines OR
   2 c) CYP with unstable index conditions.

**Exclusion criteria**

The two study exclusion criteria were:
1. Adults and CYP from whom we would be unable to gain written informed consent / assent.
2. Adults and CYP who would be unable to read the written material provided.

Participants’ postcodes were collected, to be mapped against the English Indices of Deprivation 2007. The lower the IMD score the “less” deprived the area: conversely, the higher the IMD rank, the “less” deprived the area. The least deprived area in England has an IMD score of 0.37 and an IMD rank of 32482. The most deprived area in England has an IMD score of 85.46 and an IMD rank of 1.00.
The mean IMD score for participants was only slightly less than that of England (21.67) and the East Midlands (20.01) (see Table 5). The range of IMD rank for participants was from 503 (more deprived) to 32134 (least deprived) suggesting that participants were drawn from a wide range of areas, from among the least affluent to the most affluent in the region.

### 4.3.3 Recruitment

The identification of potential (parent / children and young people) participants occurred in one of three ways.

Firstly, potential participants saw a poster or flier in their local clinical setting or local voluntary organisation meetings (e.g. Asthma UK) and had the opportunity to approach the research team directly.

Secondly, consultants, general practitioners or community pharmacists could approach potential participants in the clinical setting and provide them with an information pack containing detailed written information, a consent form and a reply slip, which was to be returned to the research team.

Finally, medicine providers or members of the care team could identify potential participants who met with the inclusion criteria from a practice / clinical dataset and send an information pack to them, including a letter from the study team inviting them to participate, along with a reply slip and a reply paid envelope.

The second and third method obtained most interviewees. The research team followed up all responses, checking that the child, young person and family met with the inclusion criteria and gaining agreement to participate by telephone where possible, or letter if required. Participants were enrolled into the study when the research staff met them in clinics, or visited their home to undertake an in-depth interview. A minimum of twenty four hours passed between inviting families to participate in the clinic setting and confirming a mutually convenient time and location for the interview to take place. The prescribed informed consent procedure was followed (assent from CYP under 16 years) at the time and location of the

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interview, along with collection of minimal demographic information, including ethnic background; family make-up and roles. In some cases, parents of non-participating CYP and young people were interviewed. Out of pocket travel expenses were reimbursed (via expenses claim forms). CYP who participated in group sessions or interviews received a High Street store voucher to the value of £5.

4.3.4 Qualitative data handling

Digital recordings from focus group sessions and interviews were transcribed verbatim by a transcription agency, assigning participant identification numbers during the checking of transcripts, to protect the anonymity of participants. Transcripts were checked for accuracy by JW and NL, and where appropriate, headings assigned to indicate the index condition of the CYP; sex and age of the CYP, before being shared amongst those members of the research team with qualitative research expertise, for initial thematic analysis and coding. NVivo 8 software was used to manage data. (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 8, 2008)

The members of the research team involved in the conduct of the qualitative work - both during data collection and analysis - represented different background disciplines (pharmacy, health services research, psychology). The combination of their input, and the ongoing iterative debate about the findings, reduced the risk of any individual being unduly influenced by their own previous experience or assumptions about the subject area.

4.3.5 Thematic analysis

Interview transcripts were analysed using theme analysis. This method was chosen for its flexibility in allowing themes to be extracted both deductively, based on previous research, and inductively from the data. Each transcript was read thoroughly by one coder (CG) to familiarise the coder with the text and the context of the text. Key themes were identified then and text linked to theme. Extracted examples of themes were grouped into sub-ordinate themes within each overarching theme. The themes were then reviewed by a second researcher (NG) We adopted this approach to enable the development of an exploratory conceptual framework, which would allow us to compare and contrast themes identified from the critical evidence synthesis (Chapters 2 and 3) and stakeholder involvement.

Each interview transcript was subjected to an iterative and in-depth analysis whereby behaviours, attitudes and experiences were identified and coded by assigning appropriate labels. Both individual and organisational domains of medicine use were examined.
Verbatim quotes and recurring ideas were listed independently by the two researchers, to illustrate the labels. The labels were then further refined through discussion (CG/NG). A detailed list of themes and sub-themes was generated from the resultant findings.

Data that related to these themes were then grouped under their appropriate theme headings. Once this inductive process was complete, the emergent themes were compared to those themes identified within the explanatory literature review (Chapter 2).

4.3.6 Reliability

The consistency of agreement between codes has been checked by two people independently coding the transcripts. Agreement confirms the reliability of the code. Where there was disagreement, the codes were further examined by a third person and the majority view prevailed.

4.4 Results

4.4.1 Recruitment

CYP and parents

One hundred and sixty-four recruitment packs were left with clinic and practice staff. Interviews were carried out between January and April 2009. Forty-three face-to-face interviews were conducted across the conurbations of Nottinghamshire and Leicestershire (see Table 6), with:

- 26 parents (of 5 to 7 year olds; 10 to 12 year olds and 15 to 17 year olds) including:
  - 22 mothers
  - 4 fathers who were interviewed or participated in the interview

- 18 CYP including:
  - 10 CYP aged 10 to 12 years old (4 female and 6 male)
  - 8 CYP aged 15 to 17 years old (5 female and 3 male)
  - 13 CYP were diagnosed with asthma
  - 4 CYP were diagnosed with congenital heart disease
  - 10 CYP were diagnosed with diabetes
  - 15 CYP were diagnosed with epilepsy.

In one of the interviews both parents were present, providing a total of 44 interviewees, but 43 interviews.

Seven families were from ethnic minority groups including Asian, Asian British, Black British and African. Three families (five interviews) constituted
challenging cases, 2 CYP were 10 to 12 with asthma, and heart disease or cystic fibrosis, on multiple medicines, and their parents, and one parent of a CYP (10 to 12) with epilepsy, who also had learning difficulties. CYP had been diagnosed with their chronic condition for a median of 6 years with a range of 2 to 17 years. The median number of medications per CYP was 2 (range 1 to 8).

The length of the interviews ranged from 15 to 90 minutes. Two interviewers (NL and JW) attended each house to undertake separate concurrent interviews with the CYP and the parent. Field notes were made during the interview, to complement the digital audio recording, and soon after the interview these were converted to 1-page summaries for each.

Table 6. Summary of CYP and parent face-to-face interviews completed

<table>
<thead>
<tr>
<th></th>
<th>Asthma</th>
<th>Diabetes</th>
<th>Epilepsies</th>
<th>CHD</th>
<th>Families from ethnic minority groups</th>
<th>Total interviews</th>
<th>Total families</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parents of 5 to 7 yr olds</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>10 to 12 year olds</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Parents of 10 to 12 yr olds</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>15 to 17 yr olds</td>
<td>2</td>
<td>0</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Parents of 15 to 17 yr olds</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td>14</td>
<td>10</td>
<td>15</td>
<td>4</td>
<td>6</td>
<td>43</td>
<td>25</td>
</tr>
</tbody>
</table>

Health professionals

Three focus groups were conducted (two in Nottingham and one in Leicester) with 19 practitioners from a range of settings (see Table 7). The length of the focus groups ranged from 60 to 90 minutes. Two moderators (NL and JW) attended each group, with assistance from at least one other member of the research team (including RE, NG and CG). Field notes were
made during each group, to complement the digital audio recording, and soon after the group these were converted to short summaries for each.

Table 7. Practitioner attendees at focus groups

<table>
<thead>
<tr>
<th>Health professional</th>
<th>Number attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant pharmacist</td>
<td>1</td>
</tr>
<tr>
<td>Paediatric advanced nurse practitioner</td>
<td>3</td>
</tr>
<tr>
<td>Community paediatric consultant</td>
<td>1</td>
</tr>
<tr>
<td>GP</td>
<td>4</td>
</tr>
<tr>
<td>GP registrars</td>
<td>2</td>
</tr>
<tr>
<td>GP Receptionist</td>
<td>1</td>
</tr>
<tr>
<td>GP practice nurses</td>
<td>2</td>
</tr>
<tr>
<td>PCT lead for children</td>
<td>1</td>
</tr>
<tr>
<td>Hospital paediatrician</td>
<td>2</td>
</tr>
<tr>
<td>School nurse lead</td>
<td>1</td>
</tr>
<tr>
<td>Health visitor lead</td>
<td>1</td>
</tr>
</tbody>
</table>

4.4.2 Summary of thematic analysis

The themes are presented from the parents’ and CYP’s perspectives in detail. The views of the parents and CYP were deemed essential to the design of the TABS tool.

The focus groups with practitioners did not allow such detailed thematic analysis, their views are presented in the context of how they relate to themes presented by CYP. The codebook for the parent interview thematic analysis is summarised in Appendix 7.12 to illustrate the analytical approach.

Data saturation was seen with regard to the major themes identified here.

4.4.3 Parental themes

Thematic analysis of interviews with 26 parents resulted in the identification of five major themes:

- Parents’ need to maintain control and supervision in medicines-taking
- CYP developing responsibility for medicines-taking
- Parents’ perceptions of available support
• Barriers and facilitators for medicines-taking
• Perceived necessity of the medication as a driver for adherence.

**Theme 1: Parents’ needs to maintain control and supervision of medication.**

This was the strongest theme which was evident in almost all interviews. It describes how parents achieve adherence by monitoring medicine taking. It includes the parent’s perception that the CYP needs to be supervised or that they need to supervise for the parent’s own peace of mind. It also describes the importance of retaining control and monitoring the regimen, being involved and the parents’ response to attempts by health professionals to reduce parental control of medicine taking.

a) Supervision of medications as part of parental responsibility

This sub-theme describes how parents accept control for the CYP’s medication as part of their parental duty and an integral part of parenting.

“No because he’s 15 and he’s still my responsibility so you know it’s my duty really to ensure that he has his medication”. (P21, mother, CYP: 15 year old boy, epilepsy, secondary care)

b) Supervision seen as safety netting.

This sub-theme illustrates how parental supervision results from the parent’s perception that the CYP can’t be relied on to manage the medication rather than a need to be in control per se. This sub-theme also includes supervision to protect the CYP and to maintain optimum management.

“I think he just relies so much on me, but I can't step back because I know if I step back he's not going to be doing it”. (P12, mother, CYP: 12 year old boy, diabetes, secondary care)

c) Perceived pressure from health professionals to let CYP take responsibility and reduce parental role in managing medication,

This sub-theme captures how parents clearly found it very difficult to be excluded from health professionals’ discussions with their CYP. They often explained this in terms of the CYP wanting them to be there or the need to be fully informed.

“We don’t believe the clinic …… is particularly welcoming of parents to teenagers. It was almost a question of why do you want to sit in and hear about it? And in some cases we’re having to ask the children what was
said, in fact with the (illness) discussions, we fully accept the children might want to go in themselves and have a chat, but we would also like to see the clinicians ourselves, we have to pick up the pieces when there are problems. So there was, there seemed to be a sense of ‘why do you want to be here to listen to this’ “? (P24, father, CYP: 16 year old girl, epilepsy, secondary care)

One mother was concerned that the hospital wouldn’t get the full picture if the CYP spoke to the doctor by himself:

“Well we’ve got no idea what they talk about, but because his memory is so bad if Dr <<name>> says well, how many fits have you had, he probably wouldn’t know would he?” (P22, father, CYP: 15 year old boy, epilepsy, secondary care)

Some parents recognised the need for the CYP to be independent but sometimes there was a discrepancy between parents’ views, with one parent more willing to allow the CYP to have more responsibility.

**Theme 2: CYP developing responsibility for medicine taking.**

The second theme reflected parents’ recognition of changes in their CYP’s level of responsibility. This theme had a number of dimensions.

a) Parental recognition that the CYP’s contribution to taking medicines is developing or changing over time

This sub-theme captured parents’ recognition that CYP’s ability to manage their medicines would change over time and that CYP develop expertise as they get older. Some parents identified the need to take into account developmental stage when giving a CYP responsibility.

“But I’ve realised that he doesn’t miss them, he’s now, because I’ve just got to at least to let him take the responsibility as well because maybe some time he is growing up now so he needs to know how to do it himself.” (P19 stepmother, CYP: 16 year old girl, epilepsy, secondary care)

Some parents identified that developmental changes can have a negative effect, reflected in comments that the CYP’s self-management had deteriorated or they expected medicine taking to get more difficult as the CYP got older.

“Although of late it has lapsed a little bit, as she's reached sort of puberty, she's not taken it quite as well, I don't think. Well we aren't going to the chemist as often as we should be, so we're suspicious she's not taking it as often as she should be.” (P03 mother, CYP: 12 year old girl, CHD and asthma, secondary care)
b) Parental role in developing the CYP’s autonomy

This sub-theme reflects parents’ identification of independence or awareness that they should help to develop independence. A few parents described specific strategies to help develop the CYP’s skills in managing their medicines and this theme includes examples of where parent negotiates or shares care with CYP.

"Well obviously I’m always there, I’m there for him to check her, when he checks her bloods and then we’ll decide together.” (P3 mother, CYP: 12 year old girl, CHD and asthma, secondary care)

c) Perception that CYP should take more responsibility

Parents describe attempts to get the CYP to take more responsibility or acknowledge the need for the CYP to be more independent.

"Yes, like yesterday, I got quite cross because he should have re-filled it, again we're trying to put the responsibility onto him, he knows it needs filling up but he didn't, so he just took them out of the foil packet.” (P21, mother, CYP: 15 year old boy, epilepsy, secondary care)

"I view it as a fact he's now 11 and he should be thinking I should be doing this and I should do it but that doesn't happen. Maybe it does with other children I don't know.” (P11 mother, CYP: 11 year old boy, diabetes, secondary care)

Theme 3: Parents’ perceptions of available support.

This theme captured beliefs about the quality and range of support available to them and their CYP in relation to medicine taking.

a) Support for medicine taking within the family

Within some families there was evidence of shared responsibility medicine taking with mothers, father and even siblings sharing responsibility. However in many families one parent took major control.

"..we just know if I sort of forget, my husband will just say "Has he taken his tablet?” and like I said if not, M will say "I haven't taken my tablet yet," so it's set in our, I mean he's been on it since last February” (P8 mother, CYP: 11 year old boy, epilepsy, secondary care)

"I think it's always mainly the mums isn't it?” (P11 mother, CYP: 11 year old boy, diabetes, secondary care)
For a few parents the lack of involvement of the other parent was seen as negative.

"I will be honest with you, his dad does forget and that does infuriate me, it really does" (P25 mother, CYP: 12 year old boy, asthma and cystic fibrosis, secondary care).

b) School as an important source of support

This striking sub-theme, which emerged inductively from the data, suggested that many parents felt the CYP’s medicines-taking was well supported at school and that there was good communication between the school, home and health service.

"literally on the induction day we actually met the nurse, they spent five minutes with us and they said look as soon as he comes here we'll have a, we'll have a care plan in place and whatever, so school's been brilliant. The actual lady responsible, the school nurse, Mrs F, I mean he's actually got a really, really close relationship with her, she watches out for him. And all the tutors, everybody is aware, you know, any tutor that teaches him is aware of his condition." (P06 father, CYP: 12 year old boy, asthma, secondary care)

"The teacher always tells us when she's had it” (P05 mother, CYP: 6 year old girl, CHD, secondary care)

One parent described how the school had tackled bullying

"D came to fetch her and the teachers had the chance to chat to the other children about her medication and that and things seemed to swing round a bit, and they seem to have been a lot kinder to her” (P11 mother, CYP: 11 year old boy, diabetes, secondary care).

c) Health professionals lack of interest and concern for medicine taking

There was evidence from some interviews that parents didn’t perceive health professionals as concerned about adherence. This sub-theme includes lack of information, poor communication hindering parents’ understanding or control of regimen and the perception health professionals provide emotional support rather than support for medicine taking. In particular GPs appeared to make very little contribution to medicines management.

"... just the last appointment I just felt nobody was listening to me” (P22 father, CYP: 15 year old boy, epilepsy, secondary care).
"Well nobody has really mentioned a one day dosage, it's always been, because that's what we were on before, that's what we went straight back onto." (P14 mother, CYP: 16 year old boy, epilepsy, secondary care)

d) Parents perceptions that medication taking was supported and facilitated by health services and pharmacists

There were examples of shared decision making and a few parents commented that pharmacists were a useful source of information and had been particularly supportive.

..“he's (CYP) had so many different combinations that we've played around with, to see which one is having the best effect. So yeah, they've explained to us, we've worked with them, trial and error, we've gone back and said hang on this ain't working, that's not working and it's evolved over time.” (P06 father, CYP: 12 year old boy, asthma, secondary care)

**Theme 4: barriers and facilitators for medicine taking.**

This deductive theme explores factors which the parents explicitly identify as impinging on the CYP’s medicine taking

a) Role of stigma

A few parents acknowledged that stigma might interfere with medicine taking.

"she says "I hate it." She just hates it and she hates people knowing about it." (P17 mother, CYP: 16 year old girl, epilepsy, secondary care)

b) Problems with regimen

This theme describes aspects of the medication or delivery of the medication that helps, hinders or potentially hinders adherence, including difficulties with supply

"Mm only when it's, like when Tom is on his prednisolone especially when like when I'm on a reducing, reducing course of prednisolone it gets a nightmare. When you're reducing, I had last, the last course was reduce it by one tablet every three days and you just can't do it without a chart or in the diary you know.” (P13 mother, CYP: 15 year old girl and 6 year old boy, asthma, primary care)

A few parents expressed difficulties with adjusting for a CYP’s dose.
"..it’s one and a half tablets, cutting it in half is a trial in itself" (P03 mother, CYP: 12 year old girl, CHD and asthma, secondary care)

c) Strategies to overcome barriers to adherence

A number of strategies were used including cues and timers. Dispensers, which are not routinely supplied for CYP, seemed to work well. The importance of routine in facilitating adherence was also emphasised by many parents.

"I don’t think he has to take them with food, but it’s just easier, it’s just a set pattern we’ve got into. (P22 father, CYP: 15 year old boy, epilepsy, secondary care)"

d) Forgetfulness as a barrier to medicine taking

Many parents found that the CYP forgot medication, with the evening dose causing particular difficulties.

"The biggest thing that’s R’s problem is she sometimes forgets in the evening." (P17 mother, CYP: 16 year old girl, epilepsy, secondary care)

e) Side effects of medication

Although parents described concerns about medicines there were very few cases in which links were made between side effects and adherence.

"... we, you know, we don’t like to use it, because obviously the steroids have had a negative impact on his growth and things like that, he’s obviously very small for his age and whatever" (P06 father, CYP: 12 year old boy, asthma, secondary care)

Theme 5: Perceived necessity of the medication as a driver for adherence.

This was a very strong theme in relation to medicine taking which has been highlighted as important in previous research.

a) Parents’ motivation to ensure adherence driven by perceived necessity of the medication.

This includes issues about the difficulty in assessing need for medication when the condition is well controlled or balancing need with unwanted effects of medication.
"Yeah, I mean it’s like I say it can’t be helped, she has to have them to control you know, to sort of like lead a normal life, control, like I say control is more important (P10 father, CYP: 11 year old girl, diabetes, primary care)."

b) Parents emphasising the necessity of the medication to encourage adherence.

This sub-theme also includes the need to balance the consequences of non-adherence with the need to avoid disturbing the CYP.

"That’s the only thing because she has to, I mean we just say to her “Look you know if you don’t take it, I know it’s horrid, but if you don’t, well if you don’t take it you’re going to be poorly and you need to probably have to go back into hospital.” (P05 mother, CYP: 6 year old girl, CHD, secondary care)

c) Perception that adherence is driven by the CYP’s understanding of the importance of the medication.

This includes the perceived negative impact of the CYP’s failure to understand the potential consequences non-adherence.

". . and I don’t think it’s anything in particular, I think he just doesn’t see or doesn’t feel it’s important enough to do it.” (P22 father, CYP: 15 year old boy, epilepsy, secondary care)

4.4.4 CYP themes and practitioner contribution to those themes

Thematic analysis of interviews with eighteen young people aged 10 to 17 years resulted in the identification of four major themes:

- Control and responsibility in medicine-taking;
- Concerns about medicines;
- Perceptions about the necessity of the medicine;
- Difficulty remembering to take medicines.

Following this analysis, the focus group transcripts from groups of health professionals were reviewed to explore their perspectives relating to themes identified by young people.

**Theme 1: control and responsibility in medicine-taking**

Many young people reported that parents checked on whether or not they had taken their medication:

"Like my mum will say “Have you had that?” and makes sure that I’ve had it.” (YP01, 17 year old girl, CHD and asthma, secondary care)
Even though many claimed that they were responsible for taking their medications, especially the older adolescents, they still often relied on their parents - and rituals within the home like mealtimes - to ensure that they remembered to take their medication:

"My mum normally helps remind me, like just asks me have I taken them, or I try and get into a routine, so I take them as soon as I've had breakfast or something." (YP09, 15 year old girl, asthma, primary care)

In most cases, the young person was relieved to have their parent with them at the consultation, as they would share responsibility for absorbing the necessary information:

"I ask the questions [during the consultation], but my mum just like actually like takes it in. Well I do take it in, but...say they [health care professionals] told me I need to change my insulin, for my mum to actually remember." (YP17, 12 year old boy, diabetes, secondary care)

Parents generally made concerted efforts to ensure that school was aware of their CYP’s condition, medication regimen, and what might be required of staff, and this reassured the young person:

"In year 7 at the start, my dad and my mum went to the medical room, because they've [secondary school] got their own medical lady and then they talked to her about what to do and if I have asthma and what to do, so then I felt safe.” (YP03, 12 year old boy, asthma, primary care)

Some of the young people in our sample were aware and mature enough to remember their medications, and some actually reminded their parents that they needed to take them:

"I remind myself, but sometimes, like quite rarely.... my parents have to like say have you done my inhaler, then I have to rush upstairs and do it.” (YP05, 11 year old girl, asthma, primary care)

Some narratives demonstrated how responsibility had transferred from the parent to the young person over time:

"When I was younger my mum made sure, and then when I got older ...it became more of my responsibility to remember.” (YP09, 15 year old girl, asthma, primary care)

There were very few examples of the young person taking their prescription and fetching their medication from the local pharmacy:

"It's me who goes and drops it off at the pharmacy, then I get the pills.” (YP15, 16 year old boy, epilepsy, secondary care)

Some young people felt that health care professionals ‘talked over’ the young person and communicated with the parents. This could have an effect of dis-empowering the young person:
"They've [health professionals] wanted me to take responsibility, wanted me to become an adult, yet they don't talk to me, they still treat me like I were when I was about nine.... I felt a bit excluded, because like my surgeon wanted to talk to my mum and dad ... on their own and I had to go into the crèche... They tell me...I've got to start being able myself to do things myself, yet in another way they still treat me like I'm young.” (YP01 17 year old girl, CHD and asthma, secondary care)

Health professionals reflected many of the issues raised by young people. They talked about the challenges of caring for CYP of different ages and how they hoped for transfer of control during adolescence. It was acknowledged that this could cause some conflict, as this exchange shows:

HP8: “Yes because that sort of you know loss of control, i.e. the parents losing the control of managing the condition now and it's over to the young person, is often quite a conflict and a battle you know…”

HP5: “But if you’re talking about 15 to 17 I think we have failed if we haven’t got them on board to manage their chronic illness.”

HP7: “But they can often go through a period of time, you know they’ve been really good, and then suddenly something happens in their life.”

HP5: "Well it's known as adolescence." [FG2]

Some felt that, in order to prepare a patient for greater responsibility during adolescence, they should engage directly with young patients at an earlier age:

HP5: “If you follow the child from 5 there’s a tendency just to talk to the parents and the child is all assuming. We are bad at switching to saying the child is the focus of the conversation. You do that when they’re 15, you should be doing it probably when they're 10.” [FG2]

There was also a feeling that each case was unique, and the provider should be tuned to the needs of the family at the point where transition started:

HP1: "I think it's important to individualise it though for each patient because certainly some of the patients who are transferred are quite happy for someone else to take full responsibility, they don't want to think about their medicines, they just want to you know, perhaps have mum still putting them into a dosette box or whatever for them and that's it. Whereas others...don't want their mothers involved...So I think it's probably important to make sure that you don’t just assume, that because they’re coming to a transitional clinic that all of a sudden they want to take all the aspects of their own self management.” [FG3]
Theme 2: concerns about medicines

There were some examples where the prescribed medication was making the young person feel unwell, rather than better:

"Before I was on my lamotrigine I was on this other tablet that was - I was taking it but it was making me throw up all the time, I couldn't keep nothing down, I was in hospital for three weeks on a drip to keep me hydrated, because I was dehydrated that much." (YP14, 17 year old girl, epilepsy, secondary care)

Other challenges related to formulation or regimen effects:

"Yeah, I was supposed to have them [tablets] in water, but it made, makes me feel sick, because it's such, it tastes so strong... So I used to have a little cup of hot chocolate - probably about that much - and just dissolve it in that and swallow it down just really quick.” (YP12, 11 year old girl, asthma and compromised immunity, secondary care)

There were a few examples of CYP experiencing difficulties in accessing their medicines during the school day:

"I used to have problems when I were younger, like I used to have to ask, go to the office and ask for my medicines.” (YP01,17 year old girl, CHD and asthma, secondary care)

This became more of a challenge when moving to secondary school, where pupils have to move round to different rooms and teachers:

"With the primary school you get like your own little drawer and you get your own peg. But with [name of secondary school].... I have a bag and carry it round with you in every class... So if you're in the lesson, you have to quickly run across the playground, grab your stuff to run all the way back.” (YP12, 11 year old girl, asthma and compromised immunity, secondary care)

Although many of the schools appeared to be facilitative, the stigma of having to drop off and collect medication, as well as using the medical facilities during the school day, could be a problem for some young people:

"When loads and loads of people are like watching, I tell them to buzz off basically.” (YP07, 11 year old boy, diabetes and coeliac disease, secondary care)
On the other hand, there were even more examples where schools were co-operative and provided as much assistance as possible:

"If I feel a bit like I'm coughing then straight away I go to the teacher and the school gave me a card that said if he shows you this card, you have to let him leave your lesson and give, tell him to...take someone with him to the medical room straight away.” (YP03, 12 year old boy, asthma, primary care)

Health professionals recognised the potential for non-adherence when a medicine produced unpleasant side-effects:

HP8: "Yes I think on the medicines related the side effects would be a big one for that age group because if they have any adverse effects then they often just don't take them don't they, you know, wouldn't tell anybody you know... Sometimes they don't, they just stop taking them and don't tell anybody.” [FG2]

They also reported challenges for young people regarding medicine-taking at school, using prescribing strategies to minimise in-school administration:

HP 4: “Certainly one of the barriers that we have within schools, is the taking of medication during school hours. And we try, if possible, to ask GPs or whoever is prescribing, to...prescribe it bd, so that they can take it before they come to school and after. The insulin unfortunately has just been changed, so they have to have a dose at lunch time, which has caused major problems in school as you can imagine.” [FG1]

The engagement and practices of different schools could help or hinder care.

Theme 3: perceptions about the necessity of the medicine

Many of the CYP understood the need for their medicines, and the possible consequences of not taking their medicines, in terms of how they might feel (for example, feeling unwell or out of breath), or what might happen to them, such as admission to hospital:

"Some of the people I know, like they've rebelled against taking medication and that - and I just think well it's helping me, so I'll take it. I'm quite good at that really.” (YP01, 17 year old girl, CHD and asthma, secondary care)
In some cases their perceptions of the possible consequences of not taking their medication were very serious, as in: “then I’ll die”:

“If I don’t take it, then I’ll like die and... I couldn’t like breathe properly.” (YP05, 11 year old girl, asthma, primary care)

For some young people, taking their medication provided them with a sense of reassurance:

“They give me reassurance, well a bit more reassurance that I might not have a fit, but that’s all.” (YP16, 16 year old boy, epilepsy, secondary care)

There were several examples of teenagers (particularly males) who had been prescribed medication for epilepsy, but who were hopeful that not having had a seizure for some time might mean that they could be weaned off the medication. One young man was almost at the point of coming off medication, when he had a seizure:

“And I got to just having one of these a day and that wasn’t enough for me. Because I thought I’d be able to come off the medication...but Christmas Day was quite stressful [at work in a hotel / restaurant] and everything and it just got the better of me.” (YP11, 16 year old boy, epilepsy, secondary care)

Successful transfer of responsibility could be hampered if the young person did not understand why they needed the medicine, and health professionals were criticised for not providing that education:

“I know I’m on them, but I don’t know the full reason why I’m on them.... I don’t think I’ve been properly educated about my medication and that, like and the reasons, if I don’t take them what would happen and stuff like that - I’ve never, I’ve just had to educate myself.” (YP01, 17 year old girl, CHD and asthma, secondary care)

Health professionals perceived that many young people did not appreciate the necessity of their medicines, or how they could benefit from them:

HP3:” It’s no good just saying 'Here you go, take it’: they’ve got to be aware of why they’re taking it and potentially what would happen if they didn’t. And the problem is they’re going to put the feelers out and and see how they feel when they don't take it...but you don't want them to fall off their perch to the point that they're having an epileptic seizure or collapse.” [FG3]
They also admitted that they might not have enough time to help a young patient to understand and appreciate their condition and the roles of medicines, and that specialist nurses might help:

HP2: "I don't think doctors are particularly good at spending that time to give the relevant information, so when we saw the change was when we actually had the epilepsy specialist nurses come in... it was spending a bit more time going through the condition, understanding the condition, what happens when you don't take the medication. It was just having that time to do it which you can't often do in a medical consultation.” [FG3]

**Theme 4: difficulty remembering to take medicines**

The main reasons reported for forgetting medication were tiredness and / or a change of routine. The night time medication was the dose most often forgotten:

"Sometimes when I’m in my grandma's house... I usually I take it and then I go to sleep or sometimes because we go like to my cousin’s house, we come back a bit late and then I fall asleep on the settee, so then I forget to take it.” (YP03, 12 year old boy, asthma, primary care)

Simply forgetting to take medication was also described, despite adherence aids like charts:

"Normally if I forget I'll forget all of them, but yeah [laughs] I've tried, I've tried like charts and things... it didn't go so well, because I just forgot to tick the chart.” (YP09, 15 year old girl, asthma, primary care)

There were some young people, however, who felt that they remembered to take/use their medicines most of the time:

"Say I do four [jabs] a day and I've probably been doing it for two years, nearly three, I've probably only forgot it probably about thirty times at max, I don't forget it very often.” (YP17, 12 year old boy, diabetes, secondary care)

Young men reported distraction from taking their medication by their desire to be out and about, playing with their friends:

"It's hard to like get it [insulin] on time and that and so like if I'm playing out and I forget what time it is and then I'm late and stuff like that.” (YP08, 12 year old boy, diabetes, secondary care)
Several young people reported that they did use prompts - such as mobile phone alarms - from time to time, but these were not effective as reminders:

"Well I started with a reminder on my phone, but I just ended up ignoring it." (YP16, 16 year old boy, epilepsy, secondary care)

Health professionals had sympathy with forgetting, not least as they too had done so, and some tried pragmatic prescribing approaches where possible:

HP2: "I find it really hard to take medicine three times a day... I do try and take a pragmatic approach... Yes, in some cases, not all the time, you know, you've got to take your epilepsy medication when it's prescribed, because that's how you've got to take it, you can't miss the afternoon one out in that case. But there are other things that you can - just the way you prescribe it, you can be a little bit more amenable to help children take it. [FG3]"

4.5 Discussion

4.5.1 Key findings

Parents

The strongest theme that emerged from the interviews with parents was the need to maintain control of their CYP’s medicines-taking, if only for “peace of mind”, and this led to general concern when practitioners attempted to reduce their involvement. Parents seem to be aware of the transitional and developmental nature of medicines-taking responsibility in CYP and often gave examples of where they attempted to hand over this responsibility to the CYP. However, observation of deteriorating medicines-taking with reduced parental control meant that parents did not seem to feel confident that they could trust their CYP to self-manage. Support was variable within the family setting, schools were generally seen as very supportive, and support from practitioners was mixed. Key barriers to medicines use seemed to be issues around routine and forgetting, rather than side effects or stigma, with evening doses often highlighted as a problem. Parents often used necessity of the medicine, or consequences of not using it, as a strategy to enhance adherence in the CYP.

Children and young people
CYP reported that they relied on their parents to remind them to take medication, share the informational load in consultations and to liaise with their school. They relied on rituals within the home to help them remember to take their medication, and tiredness and a change of routine was the most common reason for forgetting, specifically the evening dose. Those CYP who were aware of the necessity for their medicine seemed to report this as a key driver for adherence.

A significant proportion of our interviewees were CYP with epilepsy. There was a strong disease specific theme here, where the CYP was keen to attempt discontinuation of the medicine, due to lack of certainty about the continued presence of the disease, but didn’t because of the negative consequences of a seizure (driving licence, social stigma).

**Practitioners**

Practitioners were aware of the challenges associated with the transitional and developmental aspects of responsibility for medicines taking. They were aware that they talked over the CYP, and insufficient time was spent during consultations talking about medicines. They felt that the approaches used needed to be tailored to individual families. They felt that side effects and problems with access at school were key barriers to adherence. Practitioners also suspected that CYP stopped taking medicines without telling anyone.

### 4.6 Comparison of findings with critical evidence synthesis

Table 8 compares the key findings from the interviews and focus groups with those of the critical evidence synthesis reported in Chapter 2.

**Table 8. Comparison of reasons for non-adherence obtained from critical evidence synthesis and focus group and interviews with stakeholders**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Effect on adherence (published evidence)</th>
<th>Effect on adherence (interviews and focus groups)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Severity and duration of illness</td>
<td>Severity: ⬆️</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Duration: ⬆️</td>
<td></td>
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<tr>
<td>2. Forgetting</td>
<td>CYP’s report: ⬇️</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CYP’s report: ⬇️</td>
<td></td>
</tr>
</tbody>
</table>
### 3. Self-efficacy, roles, empowerment

- Parent’s report: ⬇️
  - Morning doses forgotten
- Parent’s report: ⬇️
  - Evening doses forgotten

- Self efficacy ⬆️
- Adolescents: ⬆️ self efficacy ⬆️
- Parent reporting of CYP’s self-efficacy ⬆️
- Parent’s reporting of own self-efficacy ⬆️
- Drinking alcohol ?
- Smoking ?
- Poor eating attitudes ⬇️
- Lack of exercise ?
- Earlier age at first marijuana use ?
- Sexual activity ⬇️

### 4. Psychological functioning of CYP and parent, including presence of depression

- Presence of anger in CYP ⬇️
- Anxiety ⬆️ (?)
- Depression ?

### 5. Transitional concerns and impact of age

- Increased age: ⬇️ (?)
- Quality of relationship with parents: ⬆️
- Optimism: ⬆️
- Sense of normalcy: ⬆️

### 6. Use and sources of information, incl knowledge

- Caregiver knowledge: ⬆️
- CYP knowledge: ⬆️

### 7. Impact of educational levels

- Low CYP educational level ⬇️
- Low parent educational level ⬇️
- School environment ⬇️

### Regimen factors

### 8. Side effects

- Experience: ⇔ ⬇️
- Experience: ⇔ ⬇️
<table>
<thead>
<tr>
<th>9. Complexity of regimen</th>
<th>Parents’ anticipation/fear: ◄</th>
<th>Practitioners anticipated ◄</th>
</tr>
</thead>
<tbody>
<tr>
<td>◄ Number of medicines: ◄,► (HIV sometimes)</td>
<td>◄ Number of doses per day: ◄</td>
<td>◄ Number of doses per day: ◄</td>
</tr>
<tr>
<td>◄ Once daily dosing ◄</td>
<td>◄ Inconvenience: ◄</td>
<td>◄ Inconvenience: ◄</td>
</tr>
<tr>
<td>◄ Size of device (asthma): ◄</td>
<td>◄ Time to administer ◄</td>
<td>◄ Time to administer ◄</td>
</tr>
<tr>
<td>Need to take medicines at specific times in relation to meals or outside the home ◄</td>
<td>Need to take large numbers of tablets/capsules each day ◄</td>
<td></td>
</tr>
<tr>
<td>10. Ability to use medicines</td>
<td>◄ Instruction from practitioner ◄</td>
<td>Could not make assessment</td>
</tr>
<tr>
<td>◄ Regular follow up &amp; assessment of technique for drug delivery devices by practitioner ◄</td>
<td>◄ Ability of CYP to use device themselves ◄</td>
<td></td>
</tr>
<tr>
<td>◄ Ability of CYP to use device themselves ◄</td>
<td>◄ choice of device ◄</td>
<td></td>
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<tr>
<td>11. Palatability and acceptability of regimen</td>
<td>Poor taste ◄</td>
<td>Not raised in interviews with CYP or parents. ?</td>
</tr>
<tr>
<td>Lack of availability of suitable formulation e.g. liquid for young CYP ◄</td>
<td></td>
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<tr>
<td>12. Access to medicines, including off-label use</td>
<td>◄ Cost ◄</td>
<td>Not raised in interviews or focus groups</td>
</tr>
<tr>
<td>◄ Availability of medicines ◄</td>
<td>◄ Length of prescription ◄</td>
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### Context factors

<table>
<thead>
<tr>
<th>13. Beliefs and expectations, experiences and concerns about disease and medicines (CYP and parent), incl stigma</th>
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<tbody>
<tr>
<td>Parental beliefs about ↓ necessity: ↓</td>
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<tr>
<td>CYP’s beliefs about ↓ necessity: ↓</td>
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<td>Parental beliefs about ↓ necessity: ↓</td>
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<td>CYP’s beliefs about ↓ necessity: ↓</td>
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<tr>
<th>14. Social context (impact of family structure, friends, peer groups, media)</th>
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<tbody>
<tr>
<td>Single parent family ↓</td>
</tr>
<tr>
<td>Peers ↑ ↓</td>
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<tr>
<td>Family structure ↑ ↓</td>
</tr>
<tr>
<td>Family routine ↑</td>
</tr>
<tr>
<td>Parental reminders ↑</td>
</tr>
<tr>
<td>“Giving children space” ↑</td>
</tr>
<tr>
<td>Other family member with same condition ↑</td>
</tr>
<tr>
<td>Family routine ↑</td>
</tr>
<tr>
<td>Parental reminders ↑</td>
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<tr>
<th>15. Financial context (impact of socio-economic status)</th>
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<tbody>
<tr>
<td>Lower socio-economic status: ⇆ ↓</td>
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<tr>
<td>Could not make assessment</td>
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<tr>
<th>16. Cultural context (impact of racial/ethnic or cultural background)</th>
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</thead>
<tbody>
<tr>
<td>Ethnicity: ↑ ↓</td>
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<tr>
<td>Minority status: ↓</td>
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<tr>
<td>Could not make assessment</td>
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<tr>
<th>17. Educational context (effect of school)</th>
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<tbody>
<tr>
<td>No clear indicators</td>
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<tr>
<td>Most facilitated medicines taking</td>
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### Relationship factors

<table>
<thead>
<tr>
<th>18. Parent-CYP dyad interaction and communication</th>
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<tbody>
<tr>
<td>Parental supervision ↑</td>
</tr>
<tr>
<td>Authoritative and warm parenting ↑</td>
</tr>
<tr>
<td>Conflict ↓</td>
</tr>
<tr>
<td>Parental supervision ↑</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>19. Provider-CYP dyad, Parent-CYP-provider triad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased CYP satisfaction ↑</td>
</tr>
<tr>
<td>Lack of concern shown by HCP ↓</td>
</tr>
<tr>
<td>CYP excluded from discussions with HCP ↓</td>
</tr>
<tr>
<td>Parent excluded from discussions with HCP ↓</td>
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<table>
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<tr>
<th>20. CYP and parent interaction with</th>
</tr>
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<tbody>
<tr>
<td>Poor relationship with HCP ↓</td>
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<tr>
<td>Poor relationship with HCP ↓</td>
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Key

✈Evidence that factor increases adherence significantly
✈✈Evidence that factor decreases adherence significantly
✈✈✈Evidence that factor has little or no effect on adherence
✈✈✈✈Conflicting evidence about the effect of the factor on adherence
✈✈✈✈✈No evidence about the effect of the factor on adherence

Some of the factors investigated in the literature for their effects on adherence could not be explored in the context of our methodology, for example, socio-economic status. However, comparisons can be made in a number of key areas.

There are no direct contradictions between the two sources of evidence in direction of effect of factors on adherence. Our interview and focus groups support the hypothesis that parenting quality and supervision affect adherence significantly, and that, as the CYP gets older and takes on more responsibility, adherence deteriorates. Both sources also emphasise the importance of forgetting in medicines taking and underline the positive effect that routine (and thus stable family structure and functioning) has on helping with this. The critical evidence synthesis suggests the morning dose is the most easily forgotten, whereas the interviews and focus groups suggest the evening dose is a problem. Notwithstanding, increased complexity is clearly indicated as a driver for non-adherence. Perceived necessity for the medicine by parents is a very strong factor in the literature, and from our interviews and focus groups, we can see that this is used by parents to encourage adherence in the CYP. Perceived necessity for the medicine by the CYP is a strong factor in the literature and was cited regularly by our sample as a reason for staying on the medicine. In the literature, anticipation of side effects, rather than experience of them, was a factor for non-adherence. In our sample, only the HCPs seemed to consider them a significant factor. The literature suggests poor relationships with HCPs can reduce adherence. Our interviews and focus groups provide more information on why this may be the case, in terms of lack of time, not involving the CYP, and prematurely reducing the involvement of the parent.
4.7 Limitations of methods

The sample is unlikely to be representative of the population as a whole, or of the population of parents and CYP with long term conditions. In addition, selection bias may have been introduced as the researchers have no way of knowing whether those agreeing to participate were different in any way to those who did not consider participation or refused to participate.

Implications of these results for intervention design are discussed at the beginning of Chapter 5, as part of intervention development.
5 Development and feasibility study of the TABS intervention

5.1 Background

The aim of Phase 2 of the TABS study was to pilot a medicines management (intervention) package for CYP that is applicable across a range of age groups, clinical conditions and service settings. The package was designed to support the involvement of all members of the parent-CYP-practitioner triad in the use of the TABS intervention but principally by empowering CYP to become active partners in the consultation and to encourage them openly to express their attitudes and concerns about their medication.

5.2 Objectives

The objectives of the feasibility study were to:
Evaluate the feasibility and generalisability, use and usefulness of the TABS package across a purposive sample of 48 practitioner-parent-CYP triads across a variety of clinical settings.
Develop an evaluation framework to assess the impact of the package on attitudes, behaviour, clinical outcomes and resource use.

5.3 Intervention development

5.3.1 Intervention development

The structure and content of the intervention package were derived from the theoretical and conceptual framework described in Chapters 2 and 3, and the outcomes from the engagement with stakeholders, an expert advisory panel, CYP, parents and practitioners (see Chapter 4). Initial versions of the TABS tool were presented to, and discussed by, these groups.

5.3.2 Factors affecting adherence from critical evidence synthesis, interviews and focus groups

From the literature we identified that generic barriers to adherence were forgetting, parents’ anticipation of side effects, perceptions of a medicine’s
necessity, regimen complexity, family functioning. Disease-specific reasons included weight gain and needle phobia in diabetes, and visibility and steroid phobia in asthma.

From our interviews and focus groups, parents and CYP focused mainly on routines and necessity for the medicine as factors affecting adherence, which concords with the literature. Practitioners focussed on side effects and school access, which do not appear to such main concerns for parents and CYP. This finding suggests that practitioners need to find out the reasons for non-adherence, rather than making assumptions. Problems with honest disclosure of medicines taking were not raised by CYP or parents, but were raised by practitioners. This suggests that this needs to be raised somehow during the consultation.

5.3.3 What do we know works to improve adherence to appropriately prescribed medicines in CYP

The aim of the review of interventions was to identify what interventions were effective at changing medicines-related behaviour. On this basis, we gave no emphasis to a particular type of intervention. Our intention was to use the published evidence on effective interventions to drive the design of our intervention, rather than assume a particular type of intervention would be more effective. Our hypothesis was that the reasons for non-adherence should inform the type of intervention. From the literature, we found that, whilst some interventions are effective, many more do not appear to be, for a range of reasons, including poor design and not being based on reasons for non-adherence. There is insufficient evidence in many illnesses, or in CYP with complex needs. Most interventions do not address the complexities of the parent-CYP dyad, or the changing nature of the CYP’s involvement in decision-making as they develop, and stop at the patient-provider level. This review suggests that interventions based on reasons for non-adherence, sensitive to age and development stage, sustained over time, convenient for the CYP and family, and deliverable in a local practice setting are most likely to be effective.

From our interviews and focus groups, when parents and CYP work together to optimise medicines use, this seems to work, and homes with good routines are most conducive to good medicines taking routines. The use of evening doses should be minimised if possible. Schools seemed to provide good support generally, although access issues need to be improved in some places.

Reasons for the CYP’s non-adherence is usually subsumed by the parents’ and prescribers’ agenda. The effectiveness of the practitioner in supporting the parent and CYP needs to be improved, particularly in more accurately and sensitively assessing the level of responsibility for medicines taking taken by parent or CYP, making more effort to involve the CYP. Parents were often very distressed by their CYP’s illness, and generally were very
closely involved in management, irrespective of age. Practitioners need to acknowledge that parents generally care deeply about their CYP’s health, so should not be too hasty in excluding the parent from management discussions, without assessing the individual situation.

5.3.4 How to increase the involvement of the CYP

From the critical evidence synthesis of reasons for non-adherence, it was evident that the CYP was often not involved in discussions about their medicines-taking behaviour.

A key anxiety in increasing involvement of the CYP is uncertainty about their competence, and how it can be assessed in different ages and abilities. Consequently, CYP have little involvement in their own consultations and adult-CYP communication can be dominated by misleading over- or under-estimation of a CYP’s ability. For example, research suggests that some CYP with diabetes can do their own blood tests and injections from the age of 4, whereas other older CYP may want their parents to speak for them in a consultation. A recent review of triadic communication (CYP-parent-practitioner) in primary care suggests that pre-adolescent CYP may take part during information gathering but are unlikely to participate in the treatment planning and discussion part of the consultation. Less than 10 percent of involvement was commonly reported. Adult carers interrupted “doctor-CYP” talk when the adults had not had their concerns expressed early in the consultation. The lack of involvement of CYP may be due partly to the practitioner’s unwillingness to challenge parental authority, or due to the culturally subordinate role of the CYP to both adults. The resultant adult-led agenda has serious limitations when trying to understand the health perceptions and behaviours of CYP. However, even when prompted, CYP may not present the problem themselves, suggesting that increased communication between parents and CYP prior to the consultation should be encouraged, so that parents can act as advocates when necessary.

It is not easy to assess the quality of the clinical consultation, although some consensus work has been carried out with paediatricians to attempt to identify key components. Unsurprisingly, key factors appear to centre on practitioner, parent and patient characteristics, the situation, task outcomes and final outcomes, including adherence to recommended courses of action. An assessment of 352 paediatrician-parent-CYP interactions suggests that the poorest aspect of the consultation was giving time to discuss the family’s agenda.

Increasing the involvement of the patient in the consultation has been attempted successfully in adults. A recent systematic review identified 33 randomised trials of interventions to help patients ask questions and gather
Meta-analyses showed that the interventions resulted in small but statistically significant increases in question-asking and patients’ satisfaction, a large but not statistically significant decrease in anxiety before consultations, and small but not statistically significant effects on anxiety after consultations and length of consultations. The effects of the interventions on patients’ knowledge were unclear owing to methodological difficulties. This review found only one paediatric study, relating to bicycle safety. The review did not assess the impact of the pre-consultation questions on actions taken by the patient or by the prescriber.

5.3.5 Implications for TABS intervention design

We concluded that the TABS intervention should engender open discussion between parents, CYP and prescribers to identify key modifiable barriers to adherence, and remove barriers to adherence where possible. We proposed the use of a pre-consultation tool as a mechanism to encourage disclosure of real reasons for non-adherence from the CYP, rather than those assumed by the parent of practitioner, to allow an appropriate intervention to be tailored to the reason for non-adherence. This would be driven by the results of the systematic review of interventions. We know that this approach can be effective in adults, but there is little evidence in CYP.

It should incorporate both a pre-consultation tool as a prompt that facilitates discussion of medicines taking between parent and CYP to develop the “proactive patient” (in this case the patient being the parent-CYP dyad) prior to the consultation. To support the “prepared practitioner”, the intervention should include information about real reasons for non-adherence and a consultation framework that enhances the parents’ and CYP’s input into the discussion with the practitioner about medicines and encourages honest disclosure of medicines taking behaviour.

5.3.6 Pre-consultation tools in CYP

We looked for pre-consultation tools that had been developed for use in CYP but were not able to locate any that were focused on medicines in these age groups. We also investigated a wide range of media through which to deliver the tool:

- Paper survey (such as GAPS)
- Person (talking to telephone helpline or onsite before consultation)
- Interactive IT (touchscreen on-site/website/digital TV from home).

Due to its flexibility in development and revision, we selected a paper survey for this stage of the research, although the medium could be developed further in a future study.
5.3.7 Supporting the practitioner, improving triadic communication and the consultation environment

We looked for models of supporting practitioners in improving triadic communication. An intervention to train GPs in triadic communication was developed by Mary Eminson. This intervention involved a whole day of training, which we did not feel appropriate here, but we felt that the use of video simulated interviews upon which to base discussions of consultation skills would be transferable.

There are many documents and publications that intend to inform or support practitioners in communication with CYP, with adolescents in particular, and competencies in communication with CYP are part of general practitioner and paediatrician training. There are also many documents that suggest ways to improve the general environment of a clinic or surgery to make it more appealing to CYP and how to ensure other members of the team are also able to support medicines-taking. We sought to build on these resources and reinforce their message with practitioners, rather than introduce a new training schedule.

We proposed to support practitioners by providing a briefing on actual reasons for non-adherence in CYP derived from our work, and to facilitate a more patient-centred consultation, with the following suggestions taken from consultation of the material referred to above and NICE guidance on adherence:

1. Use language that is readily understood.
2. Present information in such a way to take account of the patient’s beliefs.
3. Check understanding of any information that has been given, such as asking direct questions to check understanding.
4. Normalise non-adherent behaviour such that parent and CYP do not feel the need to conceal such behaviour.
5. Ensure that both the CYP’s and the parent’s views are elicited and concerns are discussed and given sufficient weight.
6. Ensure the environment in which the consultation takes place is “CYP-friendly”.

These consultations should not need to increase significantly the work burden of the practitioner. A recent study carried out in adults in Nottinghamshire and Leicestershire found that the use of a patient agenda and GP education increased the number of problems found during a consultation, increasing satisfaction, and increasing the consultation length by 1.9 minutes.

An algorithm could be used for assisting the practitioner in directing CYP and parent to appropriate resources.
Potential contents of a resource pack

The action plan for enhancing adherence will depend upon key modifiable barriers identified, remembering that non-adherence may be intentional or non-intentional. The main themes for supporting adherence are likely to be:
1. Motivational strategies.
2. Written information.
3. Internet use, websites.
4. Self-management plans.
5. Memory aids (mobile phone, email, written plans).
7. Referral to e.g. asthma nurse for inhaler training.
8. Telephone/web-based support from practitioner.
9. Peer support groups.

An action plan should be decided upon during the consultation, and the actions reviewed at the next consultation. One-off interventions are not likely to be as effective as sustained interventions in improving adherence in this population.218

5.3.8 Feedback on intervention from parents, CYP, practitioners

A pilot TABS tool consisting of the sections above was developed and presented to parents, CYP and practitioners for evaluation via the interviews and focus groups reported in Chapter 4, and through a stakeholder workshop funded by Ask About Medicines Week (AAMW).

CYP’s views about the proposed TABS tool

Of the 18 children interviewed, 12 felt that that the TABS tool would be useful to them, two felt that it might be useful and four did not comment on its usefulness. Six children gave examples of how the tool could be useful

“It would give me the chance to ask questions.” (YP08)

“.. This helps my health and this is probably what I’d raise.” (YP01)

“Because it’s relevant to me, at school.” (YP11)

“(Helps) the doctors know what to talk about.” (YP05)

“You, if they like helped you learn more about your medicines.” (YP09)

“Well I think it might make a difference because it’s better to fill out a form than just being asked all these questions, so I know.” (YP04)

Seven children made additional positive comments about the TABS.

“Like how the questions are asked and like I know how to take my medicines.” (YP02)
“They’re easy to understand.” (YP15)

“I think it’s quite easy really. Like you know what you are doing...

..and also it’s not too many floppy leaflets or anything. I think it’s quite good really because I mean you don’t want too much information.” (YP01)

“Like how the questions are asked and like I know how to take my medicines.” (YP02)

“It’s easy to understand.” (YP06)

“It doesn’t take too long to fill out.” (YP09)

“It’s something to do (in the clinic).” (YP07)

Six children said they would like to receive the tool by post but more (8/18) wanted to use the tool in the clinic setting. Furthermore these children were more likely to qualify their choice “And then it’s kind of fresh in your mind” (YP09); “(I’d) pick it up at the clinic, because I’d probably forget” (YP11). Two children didn’t mind when they received the tool.

Parents’ views about the proposed TABS tool

The majority of parents (19/25) felt the TABS tool would be useful for them and/or their CYP. One parent (P01) thought it “absolutely brilliant” and commented that it would encourage the CYP to ask questions. This was echoed by another parent (P02) who felt that it would be useful “because you don’t think to discuss things with the child”. Another parent (P09) felt that she often forgot to raise things in consultations and that “…it would immediately make me think. I’d always have something to prompt me”.

Three parents specifically commented on its simplicity. “It’s not too much, It’s quite simple and it might just trigger you to think oh yeah..”(P025)

Four parents felt it would useful for other families or would have been useful for them in the past. Two parents were more equivocal about the use of the tool, one feeling that they already had a lot of information (P16) and another feeling only “that they might want to use it.” (P17)

The majority of parents felt the TABS tool would be useful for them and/or their CYP as it would encourage the CYP to ask questions, stimulate discussion with the CYP, remind the parent to raise things in consultations and that it was simple to use. It may be more useful earlier on in the course of the illness.

Practitioners’ views
A snapshot of the feedback we obtained from the 19 practitioners involved in focus groups and the four practitioners present at the AAMW day is illustrated below.

“We prefer a prompt sheet that you could look through and the possible actions related to each of them. More and more we are being asked to show evidence of action so maybe a tick box at the end to show what actions we have taken as a record in the notes i.e. given leaflets or website address etc.

For the resource pack we prefer tables with phone numbers or websites and useful lists of contacts. I like the last sheet where I can add my own phone numbers for people who may be able to help.

I think there is a difference between useful places for me to know about to find info and useful places for the families or children that I could hand out.”

(Community paediatrician)

“It may be helpful to know that we have a section at the beginning on the scope or the problem, then how to communicate with families and children. In here you can put empathise etc without sounding patronising.

Then potential obstacles e.g. taste, availability etc then how proceed i.e.

1. listen
2. seek an explanation
3. record the issues
4. collate any collateral info e.g. on social service register etc
5. action

1. Patients not aware that a drug is unlicensed and not given any info about the medication etc.
2. Patients told about general side effects but not aware that there may be long term problems that we have no data on yet.
3. With regards to knowledge, patients are confused re frequency and dose of medication. What is written on the box is not what they are told and no-one has written it down, esp if medication needs to be modified e.g. asthma preventative medication vs reliever.
4. Problems with taking medication in relation to timing and access at school. Has required conversations with parents re when to give it but also with schools.
5. No info for extended family or other carers
6. No acknowledgement about people who speak different languages or even those that cannot read.

7. Not been shown how to make up medicines. Paperwork is confusing. e.g. Gaviscon, make it up but you cannot get it through the bottle.

8. Few children are given leaflets or written info on who to take their medication when leaving the clinic. Same for families.

9. Different people prescribing different things. very confusing for everyone

10. We mention palatability but sometimes it is that older children cannot take tablets and are prescribed them i.e. not tailored to their needs or that tablets are too large” (Paediatric nurse specialist)

“Consultation Pack. It is currently too long and extremely busy

I think it would look good as a leaflet style with main points on – as per NICE recommendation leaflet, as all the wording loses its direction.

Or would it be better in the form of an algorithm and supporting evidence (so it can be easily looked through and it guides you appropriately, but you have access to further information if needed) I think the information included is very important and relevant but it’s too much.

I think the overall pitch is ok – it’s assisting people to improve practice for the benefit of the patient with possible fewer problems for clinicians in the future (perhaps that could be made clearer in the professional workshops, I think if not there is a little danger that professionals will argue they do it already!!)” (Paediatric nurse specialist)

These views supported the overall utility of the tool, presentation method, flexibility around when the tools could be presented to the parent and CYP (at home, or at the clinic), the use of a prompt sheet for practitioners, the use of a resource sheet for practitioners, and the need to shorten the consultation pack for practitioners.

### 5.4 Intervention design

The resultant TABS intervention consisted of a pre-consultation tool for the parents and CYP to complete and use as a basis for discussion around medicines with the clinician. The clinician had received a briefing session around barriers to medicines taking in CYP and how to engage CYP in consultations. During the initial consultation an action plan was to be developed which would form the basis of future follow-up consultations (see Figure 7).
5.4.1 Stage 0 Practitioner briefing

Each practitioner or group of practitioners carrying out the TABS intervention was invited to a short (30 to 45 minute) briefing/training session. All briefings took place at the practitioners’ workplace and included not only the medical practitioners but any specialist nursing staff and administrative staff (for example, GP Practice Managers and clinic or GP practice receptionists).

Practitioner consultation support package

The learning objectives of the training sessions included:
- Main modifiable and non-modifiable causes of non-adherence in CYP.
- The role of pre-consultation tools in increasing patient participation.
- How to improve communication with CYP during the consultation.
- Ways to improve adherence to medicines in CYP.
- The application of the TABS intervention.

The briefing comprised:
- A 20 minute interactive and didactic session covering adherence in children using a PowerPoint presentation.
- Film of problematic consultation with a young person (Jason 1) followed by reflection of how to improve the consultation (HEAR DVD extract).²¹⁹
- Film of effective consultation with a young person (Jason 3) followed by reflection of how this was an improved consultation (HEAR DVD Extract).²¹⁹
- Introduction to the TABS intervention.
  - TABS pre-consultation tool (see Appendix 7.13)
  - Conduct of consultation
Organising the overall implementation and outcomes of the Tabitha Study:

- TABS checklist
  - Summary, debrief and evaluation.

Learning materials were provided and the package included:
- PowerPoint presentation
- Information for practitioners
- TABS pre-consultation tools for parents and different aged CYP (see Appendix 7.13)
- TABS consultation reference guide (see Appendix 7.14)
- TABS checklist (see Appendices 7.15 and 7.16)
- HEAR DVD extracts (Jason 1 and Jason 3 consultations)

Clinicians were provided with a two-sided laminated prompt sheet for use during the consultation and to enable them to respond to issues raised (e.g. sign posting to additional information or resources). (see Appendix 7.14)

Side one of the prompt listed fourteen key challenges to adherence and a corresponding list of possible actions and resources to address the issues raised. The identified challenges and responses were based on evidence from Chapters 2 and 3. The second side provided a five-step checklist for the consultation process.

5.4.2 Stage 1. Pre-consultation tool
The pre-consultation tool consisted of a parent version and child version for completion prior to consultation with their usual health care provider (hospital consultant, community paediatrician, specialist nurse, GP or pharmacist.) (see Appendix 7.13)

The tool was sent to parents and CYP one to two weeks before their appointment and additional copies were available at the time of the consultation.

The parent version aimed to elicit responses concerning:
- Beliefs about benefits of prescribed medicines.
- Beliefs about barriers to using medicines as prescribed.
- Cues to action in terms of medicines taking (this could include routine, CYP symptoms).
- Child’s understanding of medicines (prompt parent to record child’s understanding).
- CYP’s feelings about medicines (prompt parent to explore CYP’s feelings using the tool).
- Support for medicines-taking, for example, at school.

The CYP version of the pre-consultation tool was developed to elicit responses on the following:
- Structured questions relating to feelings of control and self-efficacy.
- Beliefs about benefits of medicines.
- Beliefs about barriers to taking medicines.
- Cues to taking medicines (routine, symptoms etc).
- Perceived support with medicines-taking.
• Space to write down question they would like to ask about their medicines.

5.4.3 Stage 2. Initial consultation
The parent and CYP were encouraged by the researcher to take the completed pre-consultation tool into the consultation with the practitioner. The practitioner was provided with a copy of the “practitioner prompt” for reference during the consultation (see Appendix 7.14).

5.4.4 Stage 3. Action plan
Clinicians were instructed to develop an action plan with the patients to be recorded on the consultation record checklist (see Appendix 7.16).

5.4.5 Stage 4. Follow up consultation
The follow up consultation was intended to examine whether points on the action plan had been addressed, and whether new actions needed to be taken. This was not carried out as part of this study, due to time constraints in following up parent-CYP dyads.

5.5 Case study design
We piloted the TABS package in purposively selected case studies, to allow us to make preliminary assessments of efficacy (impact on attitudes, behaviour, clinical outcomes), acceptability, patient-centredness and sustainability in three transitional age bands and four key disease groups. The conditions chosen are conditions where there is evidence supporting use of medicines above other treatment options and over doing nothing, and high levels of adherence are essential to ensure efficacy.

We aimed to recruit 48 case studies in the East Midlands in England, covering the following characteristics:
• Key disease groups: asthma; CHD; epilepsy and diabetes.
• Transitional age bands (5 to 7 years; 10 to 12 years; 15 to 17 years).
• A range of ethnic and socio-economic backgrounds within the Nottingham and Leicester conurbations.
• A range of clinical settings, including primary care; secondary care; community paediatrics and community pharmacies.

The case studies involved:
• An introduction to the TABS package by the research team to service providers and practitioners (TABS Stage 0).
• An introduction to the pre-consultation tool by the research team to patients and their families.
• A pre-consultation tool completed by parents and CYP before their scheduled consultation (TABS Stage 1).
• Observation of the consultation, with digital recording alongside contemporaneous note-taking (TABS Stage 2 and 3).
• Collection of baseline data (on disease specific indicators and recent NHS contact) from health care provider or medical notes.
• Separate telephone or face to face interviews lasting approximately 30 minutes each, with the parent and CYP and, one-week post consultation to assess short term response to the intervention.
• Separate face-to-face interviews or telephone interviews with parent and CYP two months post consultation, to assess a longer term response to the intervention.

At this stage of intervention design we did not require control groups. We intended to generate a range of experiences to inform intervention design, to be evaluated in a future proof of concept study, following MRC complex intervention design guidelines.\textsuperscript{64,220}

The expected duration of participation was for a single consultation, with follow up at one week and two months. Participants were, therefore, involved in the study for up to a maximum of three months.

### 5.6 Data collection during the case studies

A successful intervention needs to have the following characteristics:

- Acceptable to all stakeholders (children, parents, health care providers)
- Feasible within the current and future service delivery environment
- Generalisable and replicable across a range of age groups, indications and care settings
- Able to demonstrate sustainable improvements in care delivered, behaviour change, and clinical outcomes
- Affordable within current and future funding provision

Specific domains of acceptability and feasibility assessed were:

**User acceptability:**

- Do the children, parents and health care providers see a value to the package?
- Do children, parents and health care providers feel more satisfied with, or clear about, their roles in the child’s care?
- Satisfaction with the process (all)
- Assessment of the quality of the service by the parent or child
• Perceptions of the impact of the service on providers
• Usefulness of pre-consultation tool and post-consultation information (all)
• Recall of important points in consultation from their perspective (all)
• Perceived impact upon medicine-related activities (child & parent)

Implementation issues:
• Roll-out times
• Resources, support and training required
• Learning curves for all stakeholders and assessment of need for “run-in” period
• What are the threats to successful implementation?

Process issues:
• Do parents and children fill out the pre-consultation questionnaire?
• Do parents and children and health care professionals use the response package?
• Does the use of the response package lead to changes in management or behaviour?
• Is the response package flexible/appropriate/pragmatic/integratable into service provision?
• Consistency and replicability of the delivery of the intervention

The ability of the intervention to address previously encountered problems affecting adherence and promote behaviour change was examined within each case study by collecting data at both baseline and at two follow-up points (1 week and 2 months after the consultation). An evaluative framework assessing clinical outcomes and resource consumption was also developed:

Clinical and patient-centred outcomes collected at baseline and follow up:
• Disease specific indicators
• Self-reported adherence to medicines
• Child health status and locus of control; perceived self-efficacy
Resource use parameters collected at baseline and follow-up:

- Length of initial and subsequent consultations
- NHS contact (primary and secondary care)
- Medicines consumption

5.6.1 Baseline data collection

Parents (guardians or legal representatives) and CYP were asked to provide demographic information prior to the initial consultation. The following data were also collected:

- Demographics: age, ethnicity, parent education, time since diagnosis, co-morbidities, health care outcomes and NHS contact.
- Completion of shortened CHQ-PF28.221
- Completion of internal locus of control items scale (CLoC) (adapted version of the Children’s Asthma Locus of Control scale).222 223
- Self-reported adherence: Medication Adherence Self-Report Inventory (MASRI).224
- Medicines self-efficacy derived from standard questions using self-ratings of confidence in ability to take medicines as prescribed in various circumstances (e.g. if wanting to play with friends).225

We also collected specific baseline data from a range of sources for the CYP by the health care provider:

- Disease specific indicators
  - Asthma
    - Last recorded FEV₁ (asthma)
    - Oral steroid use in the last month
    - Number of exacerbations in the last month
  - Congenital heart disease
    - Most recent blood pressure
    - Most recent serum cholesterol
    - Most recent INR
  - Diabetes
    - Last recorded HbA₁c
    - Number of hypoglycaemic events in the last month
  - Epilepsy
    - Number of absence seizures in the last month
    - Number of petit mal seizures in the last month
    - Number of grand mal seizures in the last month
- NHS contact within the last 3 months (appointments with the health professional, outpatient appointments, hospital admissions).

Contemporaneous notes of the consultation were made by the researcher including audio recording. Finally, feedback from the parent, CYP and
practitioner was obtained following the consultation (see Appendices 7.17 and 7.18)

5.6.2 Follow-up data collection at 1 week and 2 months

The following data were collected from CYP and their parents / carers at one week and two months:
- Repeat measures of baseline
  - CHQ-PF28 (two months only) (Appendix 7.19)
  - Medicines self-efficacy,
  - CLoC (CYP aged 10 and older)
  - MASRI
- Health care outcomes
- NHS contact
- Satisfaction with the process
- Usefulness of pre-consultation tool and post-consultation information
- Perceived impact upon medicine-related activities.

A telephone interview with parent and eligible CYP was conducted at one week. The data collected included medicines management since the observation, use of the pre-consultation tool, remembrance of agreed key action points, changes in medication, current medication, NHS contact, non-medical costs, reported adherence, self-efficacy, provision of medicines and recall of the consultation and the use and usefulness of the pre-consultation tool. The CYP was asked, in addition, to complete a questionnaire determining locus of control. The date for the second follow up interview was arranged.

A further interview was scheduled at two months and completed, if possible, in the participant’s home. A reminder letter was sent to the participants to confirm the date and time of the appointment and included a second copy of the Child Health Questionnaire-PF28 for completion before the appointment. The interview followed a similar pattern to the first follow up and data were collected on the usefulness of the pre-consultation survey, recollection of the key action points and any change in medicines management as a result of the consultation. Parents were asked about their attitudes towards young people taking increased responsibility for their medication, their CYP’s transition to adult services and any help or support that could be offered by health professionals. Parents’ feelings about future challenges for their CYP as they grew up were discussed. They were also asked about any changes or improvements to the pre-consultation tool. Data were collected on changes in medication and current medication, clinical and patient-centred outcomes, NHS contact and non-medical costs, patient-reported adherence, and self-efficacy. Parents were asked about the time taken to supply their CYP’s medicines and asked to describe any problems in obtaining the medicines. Finally, parents were asked to review their impression of the consultation and the pre-consultation tool,
any further important points from the consultation and whether there had been any change in medicine-related activity. CYP asked the same set of questions and for further information relating to locus of control.  

5.7 The consultation observation

The consultation was observed, audio recorded, where the practitioner-parent-CYP agreed, and notes taken by the researchers.

The information recorded the context of the consultation including the setting and provider of consultation, and the CYP-friendly nature of environment. The consultation was assessed using the Paediatric Consultation Assessment Tool (PCAT) (see Appendices 7.20 and 7.21). The researchers were trained in the use of the Paediatric Consultation Assessment Tool (PCAT) to evaluate the quality of the clinical consultation. They assessed the level of consensus by evaluating recorded interviews from the HEAR DVD and by two joint observations of “live” consultations.

5.7.1 Context

The observations were undertaken in a variety of clinical settings and providers: secondary care outpatient clinics, GP surgeries, CYP’s community services and in a community pharmacy.

5.7.2 Process

The researchers identified themselves to the clinic/surgery reception staff and explained about the TABS study. They informed the staff of the names of the patients, asked that the staff indicate when the patients arrived and explained that the parents-CYP had been asked to attend clinic 30 minutes before their appointment time. The researchers also identified themselves to the relevant nursing staff in the clinic and, if necessary, explained the TABS project and the observation process. All of the reception and nursing staff across all of the study sites were helpful and supportive.

The researchers also checked the name of the practitioner that was booked to see the parent/CYP, introduced themselves to the practitioner before the consultation and took written consent. If the practitioner had not been briefed about the TABS project, the researcher explained the purpose of the study and, if the practitioner were willing to participate, gained consent.

Clinic staff were asked to provide a private area where the pre-consultation interviews could take place. If this were not possible, then the interviews had to take place in the reception or waiting areas. Researchers checked with the participants that they were comfortable with this arrangement.

After the parent/CYP were booked into clinic and identified by the clinic staff, they were approached by one of the researchers who introduced
herself and her colleague(s) and thanked the parent/CYP for taking part in the study. At least two researchers were usually available for the observation and, if acceptable to parent and CYP, one researcher dealt with the parent, the other with the CYP. The researchers confirmed that the parent and CYP had received all of the TABS pre-consultation paperwork and checked that both had understood the information leaflet, the extent of their participation in the study and their right to withdraw from the study. Written consent was taken from the parent and from young people aged 16 and over. Assent was gained from CYP below the age of 16. The CYP were given a £5 or £10 voucher from a high street store (5 to 7 year old CYP or CYP aged 10 and above respectively) for participating in the study and were asked to sign a receipt.

The researcher dealing with the parent checked that the Child Health Questionnaire (CHQ-PF28) and the parent pre-consultation tool had been completed. The researcher asked whether the parent had any questions or concerns about the completion of the forms and, if required, offered clarification on completion of the paperwork. If the parent had not completed the CHQ-PF28 or the pre-consultation tool, the researcher provided another copy and was available to guide the parent through the form.

Parents and CYP were then asked to complete the pre-consultation paperwork. The researchers discussed the questionnaires with the parent and CYP and completed the forms. The parent was asked for baseline demographic data and information about the CYP’s medicines, NHS contact, non-NHS care, adherence, self-efficacy and supply of medicines. CYP aged 10 and over were asked about their medicines, the “locus of control”, adherence, self-efficacy and supply of medicines.

Following the completion of the pre-consultation paperwork, the researcher(s) waited with the parent-CYP until they were called to see the clinician and the researcher accompanied the parent and CYP into the consulting room. Where possible, the researcher sat behind the parent and CYP in an attempt to be unobtrusive. The audio recorder was placed on any available surface out of sight of the participants. One young person requested that the researcher did not use the audio recorder. Audio recordings of the consultation were used as an aide memoire when writing the individual case studies and were subsequently deleted.

The researcher completed the observation data collection form as the consultation progressed and made contemporaneous notes while referring to the laminated PCAT marking key.

Notes were also taken in addition to the PCAT, throughout the consultation, on the style and content of the interaction between the practitioner-parent-CYP triad. The researcher recorded whether the consultation was provider-centred, CYP-centred or parent-centred and the focus of decision-making. The notes were documented in a series of case study reports.
Parent, CYP and clinicians were asked for feedback immediately following the consultation. The researcher remained in the room for a post-consultation debrief with the clinician, completing the clinician consultation record and checklist recording eight components of the consultation concerning adherence, barriers to adherence, eliciting the views of the young person, action points, follow-up consultation, consideration of separate consultations for adolescents and completion of the patient record. Practitioners were also asked to list two to three agreed action points.

The second researcher undertook the short interview/debriefing with the parent and CYP. The questions asked their overall opinion of the consultation; whether they used the pre-consultation tool or the practitioner prompt; whether this had been useful or any reasons for not using it.

Finally, and when possible, the researcher arranged a time for the one week follow up telephone interview.

**Participant follow up**

Follow up interviews with participants (parent and CYP aged 10 or over) were planned for one week by telephone and at two months at the participant’s home. Where possible, parent and CYP were interviewed separately. The follow-up interviews were scheduled to last approximately 30 minutes using a semi-structured questionnaire.

### 5.8 Case study reports

Brief case study reports were written for all observations and follow up interviews. These reports are available on request from the authors. The format is summarised below:

- Date of observation, follow up 1 and follow up 2
- Index condition, sex, age, location
- Health care provider
- Background information about parent/CYP dyad
- Check whether the pre-consultation tool was sent and completed before the observation
- Issues with pre-consultation tools
- Other relevant contextual information
- Consultation process
- Use of the pre-consultation tool
- Discussions about medicines
- Action plan
• Post consultation follow up with parent and CYP dyad
• Post consultation follow up with practitioner
• One week follow up
• Two month follow up
• Overall recall of the use and usefulness of the pre-consultation tool.

5.9 Identification and recruitment of clinical sites and practitioners

We planned to recruit practitioners from regions of the East Midlands (Nottingham, Nottinghamshire, Leicester, Leicestershire County and Rutland) that fall within the area covered by the Primary Care Research Network East Midlands and South Yorkshire (PCRN-EMSY). Practitioners were chosen to represent a range of clinical settings including primary care, secondary care, community services and community pharmacy. This study was adopted by the Medicines for Children Research Network (MCRN) and co-adopted by PCRN-EMSY. With the assistance of these two networks, we recruited practitioners from eleven clinical settings: five hospital outpatient clinics, one community child health service clinic, one community pharmacy, and four general practices. We were, however, able to recruit patients from only three of the general practices.

Staff involved in providing care for CYP at each test site were invited to attend a site-based briefing session to introduce the TABS package. Briefings were delivered to nine practitioner groups (including GP practice managers and other administrative staff) and six individuals. As a result of communication “difficulties”, eight further briefings to individual practitioners had to be undertaken immediately before the clinic observation.

Clinicians were also asked to provide information for a support package and resource pack. The aim was to include a list of resources appropriate to the specific setting within which the clinician operated and to enable them to respond to issues raised (for example, sign posting to additional information or resources). We did not receive any input to the support package or resource packs from any of the practitioners.

5.10 Process of patient identification, recruitment, enrolment and informed consent

We adopted strategies for recruitment identified by the PROSPER (Planning Recruitment Options: Strategies for Primary Care Research) web based
resource, developed by the NIHR Research Design Service for the East Midlands. Practitioners were invited to identify potential parent-CYP dyads that fitted the study inclusion criteria. It was recognised that that more motivated parent-CYP dyads would agree to participate in the study and accepted that recruitment bias could not be totally eliminated. People from ethnic minorities and lower socio-economic groups are generally under-represented in research studies therefore we adopted various means of increasing representation from these groups.

We aimed to achieve breadth within our desired recruitment parameters. We anticipated that our mix of recruitment settings, including community pharmacies and community child health services, would provide a broad mix of participants. We also requested that practitioners identify CYP in whom they suspect poorer adherence (e.g. repeated non-attendance at clinic; lower numbers of prescriptions than expected for duration and the proportion of bronchodilator to inhaled steroid prescriptions in asthma).

5.10.1 Identification of participants and invitations to participate

Eligibility

CYP were eligible for inclusion in the study if they fell into the following categories: in the age ranges of 5 to 7, 10 to 12 and 15 to 17 with asthma, CHD, diabetes or epilepsy. Because of the nature of some of the conditions, notably heart disease and epilepsy, CYP were drawn from a catchment area that extended beyond the identified geographical boundaries. These CYP, however, were under the care of clinicians within the geographical area and were considered eligible for inclusion in the study population.

Practitioners were provided with appropriate eligibility criteria to help select CYP and families. Eligibility criteria consisted of being within the study age groups; the CYP having one of the four index conditions and being on at least one regular daily medication for their condition. Eligible participants should also have been able to give full written informed consent (assent for those under 16) and be able to understand the written material within the TABS package.

Exclusion criteria

Originally excluded from the study were those parents from whom we were unable to gain written informed consent / assent and those parents who were unable to read the written material provided.
5.10.2 Recruitment strategies

Different recruitment strategies were adopted for the different clinical settings. In secondary care, patients falling within the criteria and whose appointment fell within the study time frame were identified from the clinic lists by the local research support staff, consultants’ secretaries and research nurses. Researchers were informed of the number of CYP falling into the study age groups and invitation “packs” were prepared and delivered to the hospital-based support staff for distribution. The invitation packs contained five different documents (clinician invitation letter, TABS invitation letter with a code identifying the site and practitioner, response form, parent information leaflet and age-specific CYP information leaflet (See Appendix 7.22) plus a FREEPOST envelope. A pro-forma invitation letter was adapted and personalised by the clinician for each participating site and included in the invitation pack. The packs were addressed and mailed out by the hospital-based staff.

Research support staff at one secondary care site were somewhat indiscriminate in their use of the invitation packs for two of the consultants and sent them out to every patient on their list whether conforming to the inclusion criteria or not. This resulted in a number of telephone calls to the researchers from confused parents of ineligible CYP seeking clarification. Secondly, the invitation letters had been coded to help identify the clinical site and practitioner but the packs had not been sent to the appropriate CYP and, again, there was a level of misunderstanding that required explanation. For example, one CYP (L40) received an invitation letter with a code that suggested he attended a clinic with a consultant paediatric neurologist; the parent responded to the researchers identifying his index condition as CHD and the CYP was subsequently, and coincidentally, recruited into the study at another clinical site under a different consultant.

In the primary care setting it was not possible to identify patients from a specific clinic list and practice staff searched the practice database to find all CYP who fulfilled the criteria. Invitation packs were prepared by the research team and delivered to the surgery where the personalised invitation letter was included and the packs mailed out.

In community pharmacy, the pharmacist identified patients from his lists who had not recently presented for a medicines use review (MUR). The pharmacist then contacted them using the invitation packs and personalised letter.

5.10.3 Response to researchers

Participants replied directly to the researchers using the response form included in the invitation pack. Researchers responded to the participants by letter, thanking them for their willingness to take part, confirming their appointment, requesting that they attend the clinic 30 minutes before the
appointment time and enclosing the appropriate paperwork for completion before the observation. Any other contact with the participants and the arrangements for the observation depended on the clinic setting.

Patients attending hospital outpatient clinics received a letter from the researchers confirming the appointment time requesting that parent arrived 30 minutes before the appointment and included a copy of the parent pre-consultation tool, the CHQ PF-28 and, if appropriate, the CYP pre-consultation tool, for completion before their clinic attendance. The practitioner was informed that the patient was recruited into the study.

Arrangements for a clinic observation were more complicated in primary care. Patients who replied that they would like to be included in the study were initially contacted by the researchers to establish whether or not they had an existing appointment with the GP. If an appointment had already been arranged, it was planned to use the appointment for the TABS study. For all of the participants, however, an additional appointment had to be made with the GP by the patients themselves who subsequently informed the researchers. The participants were sent the pre-consultation paperwork and arranged to meet them 30 minutes before the consultation. The GP was informed.

The community pharmacist had agreed to contact patients from his lists and request an MUR. Thirty invitation packs were supplied for distribution by him with the covering letter. The pharmacist had anticipated at least ten participants but replies were received from only two parent/CYP dyads. The pharmacist had approached three “likely” candidates directly and appears to have obtained their agreement to participate before sending them the invitation pack. The researchers contacted the participants, arranged an appointment time and informed the pharmacist. Again, the researchers then sent the pre-consultation paperwork to the participants and arranged to meet them 30 minutes before the consultation.

The observations undertaken in hospital clinics (including community health) and in primary care and community pharmacy differed in that consultations in hospital were of existing appointments whereas those in GP practices and community pharmacy had to be specially arranged for the study, often by the patient themselves.

The data collection forms themselves were adapted in content and format after the initial observations to be more manageable between the (usually) two researchers responsible for different aspects of the data collection process. The forms were also colour coded to assist identification: yellow paper was used for the CYP forms, blue for the parent documents, green for clinician documents and white for the researcher forms.

We agreed to adapt the design of the TABS invitation letter, information sheets, consent forms and voucher receipts to include the logo and address of one hospital Trust.
5.10.4 Informed consent

The informed consent process was undertaken at the time of the routine consultation with their practitioner, along with minimal demographic information, including ethnic background; family make-up and roles and contact details where participants indicate that they would like to receive copies of the study findings. Parents completed the informed consent process for themselves and their CYP under the age of 16 (See Appendix 7.25). Young people over 16 completed the informed consent process. CYP under 16 completed the informed assent process. (See Appendix 7.24). Participants were asked to consent / assent for the use of a digital recorder at the observed consultation.

5.10.5 Data analysis

Descriptive statistics of parameters collected at all stages of the study are reported. Additional feedback on the intervention from participants is also presented, as are researcher observations. Five vignettes have been prepared from the case study reports to illustrate the key players, context and content of the interactions between the TABS researchers and the parent-CYP-provider triad. These are presented in the discussion section of this chapter.

5.11 Results

5.11.1 Practitioner recruitment

All but two of the practitioners approached agreed to participate in the TABS study. One clinician based in secondary care who agreed to take part in the study subsequently withdrew as s/he felt that the intervention was too disruptive to clinics. The nurse specialist for these clinics agreed to continue in the study and two further observations were completed.

In total, 24 clinicians were recruited into the study across primary care (3), secondary care (19), community paediatric services (1) and community pharmacy (1) (see Table 9).
### Table 9. Practitioners recruited by clinical site and NHS organisation

<table>
<thead>
<tr>
<th></th>
<th>Nottingham City PCT</th>
<th>Nottinghamshire County PCT</th>
<th>Leicester City PCT</th>
<th>Leicestershire County and Rutland PCT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary care</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Secondary care</td>
<td>13</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td>Community paediatric services</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Community Pharmacy</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>24</td>
</tr>
</tbody>
</table>

**Number of invitation packs distributed and associated parent-CYP dyad recruitment**

A total of 736 invitation packs were prepared and delivered to the hospital, practice and pharmacy based staff for distribution (see Table 10). Twenty seven packs were returned to the researchers unused and it is unlikely that all of the invitation packs prepared were sent out to patients. A denominator of 709 has been used to calculate response and recruitment rates.
Table 10. Number of invitation packs sent and response rate by clinic site

<table>
<thead>
<tr>
<th>Clinic site</th>
<th>Number of packs sent</th>
<th>Parent-CYP responses</th>
<th>Recruitment to Phase 2^a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary care: diabetes clinic (N)</td>
<td>161</td>
<td>19</td>
<td>10</td>
</tr>
<tr>
<td>Secondary care: CHD clinic 2 (N)</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Secondary care: Respiratory (N)</td>
<td>39</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Secondary care: Neurology/epilepsy (N)</td>
<td>42</td>
<td>8</td>
<td>9^a</td>
</tr>
<tr>
<td>Secondary care: CHD clinic 1 (L)</td>
<td>52</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>Secondary care: Neurology/epilepsy (L)</td>
<td>83</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Secondary care Diabetes (L)</td>
<td>34</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>GP practice 1 (NVS)</td>
<td>63</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>GP practice 2 (NHH)</td>
<td>25</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>GP Practice 3 (LHT)</td>
<td>88</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>GP Practice 4 (LBE)</td>
<td>73</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Community paediatric clinic 1 (N)</td>
<td>7</td>
<td>0</td>
<td>1^a</td>
</tr>
<tr>
<td>Community paediatric clinic 2 (L)</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Community paediatric clinic 3 (L)</td>
<td>30</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Community Pharmacy (L)</td>
<td>3^b</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>709</strong></td>
<td><strong>68</strong></td>
<td><strong>40^a</strong></td>
</tr>
<tr>
<td><strong>Recruited in clinic</strong></td>
<td></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td><strong>Total including patients recruited in clinic</strong></td>
<td></td>
<td></td>
<td><strong>75 (10.6%)</strong></td>
</tr>
</tbody>
</table>

^a Number includes patients recruited in clinic

^b 30 packs sent, 27 returned by practitioner

Sixty-eight written responses were received, from which 33 participants were recruited. A further eight potential participants were approached in clinic and seven agreed to take part bringing the total number of patients responding to the invitation to participate in TABS to 75, a response rate of
rate of 10.6 percent. Of the 75 respondents, 40 were recruited into the study: a recruitment rate of 5.6 percent.

Twenty-eight of the responders were excluded from participation in the study. The largest single group (13) was ineligible because of a clinic appointment beyond the anticipated recruitment period. Other reasons included no planned appointments (7); cancellation of appointments by the hospital (2); shared clinical care in a geographical site outside the study area (3); replies received after the appointment date (2). The remaining respondents, a father-son, could not be recruited into the study because the doctor refused to take part despite both having been consented and completing the pre-consultation interviews immediately before their clinic consultation.

Table 11. Summary of recruitment of parent-CYP dyads by clinical condition and age group

<table>
<thead>
<tr>
<th>Clinical condition</th>
<th>5 to 7</th>
<th>10 to 12</th>
<th>15 to 17</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>Congenital heart disease</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2</td>
<td>6</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>11</strong></td>
<td><strong>16</strong></td>
<td><strong>13</strong></td>
<td><strong>40</strong></td>
</tr>
</tbody>
</table>

The largest group of CYP recruited were CYP with asthma (14). Eleven CYP were included with diabetes, 11 with epilepsy and 4 with congenital heart disease (see Table 11). The largest group of CYP were observed in secondary care (29), eight in primary care, only two in community pharmacy and one in community paediatric services. (See Table 12).

Table 12. Summary of recruitment of parent-CYP dyads by clinical care setting and age group

<table>
<thead>
<tr>
<th>Setting</th>
<th>5 to 7</th>
<th>10 to 12</th>
<th>15 to 17</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary care</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Secondary care</td>
<td>8</td>
<td>12</td>
<td>9</td>
<td>29</td>
</tr>
<tr>
<td>Community paediatric services</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Community pharmacy</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>11</strong></td>
<td><strong>16</strong></td>
<td><strong>13</strong></td>
<td><strong>40</strong></td>
</tr>
</tbody>
</table>
5.11.2 Challenges to recruitment targets /changes in recruitment strategy

Recruitment proved erratic. Initially responses were received only from parents-CYP with diabetes being seen in secondary care and, in primary care, from patients with asthma. We reviewed the recruitment strategy and altered the recruitment process. Three changes were proposed to increase response rates. Firstly, the mail shot to eligible patients in primary care was to be repeated and an amended practice invitation letter was drafted and approved by the local REC. This was agreed in principle but not pursued in practice as the response rates from primary care had been minimal and the clinicians were reluctant to undertake additional observations.

Secondly, participating practitioners would be asked to telephone eligible patients and invite them to participate. This proposal was not approved by the REC.

The third proposal was agreed by the local REC as a “substantial amendment”. The researchers would approach potential respondents, who had been sent the invitation pack but who had not replied, when they attended for their outpatient clinic appointment. This was approved by the REC and the three hospitals involved in the study. Two of the PCTs did not, however, accept the new strategy and proposed an alternative which was not subsequently adopted by the research team as too cumbersome and time consuming to implement.

Where the new strategy was accepted, the research team was provided with the list of eligible patients and attended the clinics. Clinic reception staff were told which patients were expected; they informed the research team when the patient arrived and the researchers spoke with the parent and CYP, introducing themselves and asking if they remembered receiving the invitation pack. If they had received the pack, the researcher explained the purpose of the study and asked if they would be willing to take part. Eight people were approached, one declined, and a further seven participants were recruited. (see Figure 10)

Advice was also received from participating clinicians who suggested colleagues and five additional clinicians were contacted of whom three were subsequently recruited into the study, including a community pharmacist.
The timescale for clinic observations was extended to the end of September 2010. We originally planned to re-recruit if we lost participants at follow-up, to ensure that we completed 48 case studies, but this did not prove feasible within the timescale and the initial difficulties we experienced in recruiting to the study.

5.11.3 Participant follow up (see Figure 11)

Participants were followed up at one week by telephone (Follow up 1; n=39) and with a home visit (36 participants) or telephone call (one parent/CYP) at two months (Follow up 2; n=37). In total, three participants were lost to follow up. All of the CYP “lost to follow up” were CYP aged five to seven.

One participant could not be contacted by telephone, despite repeated attempts, for the one week or two month interviews. A second participant partially completed the two month interview and refused to continue because she “… had answered all the questions already…” A third participant could not be contacted to arrange the two month follow up.
**Figure 11. CONSORT summary of parent-CYP dyad flow through study**

<table>
<thead>
<tr>
<th>Practitioners (number of dyads)</th>
<th>Age bands (number of CYP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPs n = 8</td>
<td>Aged 5 to 7 n = 11</td>
</tr>
<tr>
<td>Hospital consultants n = 29</td>
<td>Aged 10 to 12 n = 16</td>
</tr>
<tr>
<td>Community paediatricians n = 1</td>
<td>Aged 15 to 17 n = 13</td>
</tr>
<tr>
<td>Pharmacists n = 2</td>
<td>N = 40</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Index conditions (number of CYP)</th>
<th>Location (number of dyads)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma n = 14</td>
<td>Nottingham n = 24</td>
</tr>
<tr>
<td>Congenital heart disease n = 4</td>
<td>Nottinghamshire n = 2</td>
</tr>
<tr>
<td>Diabetes n = 11</td>
<td>Leicester n = 8</td>
</tr>
<tr>
<td>Epilepsy n = 11</td>
<td>Leics County and Rutland n = 6</td>
</tr>
<tr>
<td>N = 40</td>
<td>N = 40</td>
</tr>
</tbody>
</table>

Selected for case study, baseline data collected and consultation observed (N=40)

Engaged at 1st follow up (consultation +1 week) (n=39)

Did not engage at 1st follow up (n=1)

Engaged at 2nd follow up (consultation + 2 months + 1 week) (n=37)

Did not engage at 2nd follow up (n=2)

Completed and analysed (n=37 plus one partial FU2 completed)
5.12 Sample descriptive data

5.12.1 Participant characteristics

Equal numbers of boys (20) and girls (20) were recruited into the study. The mean age of the CYP at recruitment was 11.6 with a median age at diagnosis of 6 years (see Table 13).

Table 13. Gender and age of CYP in case studies

<table>
<thead>
<tr>
<th>Parameter</th>
<th>All</th>
<th>Asthma</th>
<th>CHD</th>
<th>Diabetes</th>
<th>Epilepsy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td>n=40</td>
<td>n=14</td>
<td>n=4</td>
<td>n=11</td>
<td>n=11</td>
</tr>
<tr>
<td>Male</td>
<td>20</td>
<td>8</td>
<td>2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>20</td>
<td>6</td>
<td>2</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age (SD) (range)</td>
<td>11.6</td>
<td>10.9</td>
<td>12.3</td>
<td>11.7</td>
<td>12.0</td>
</tr>
<tr>
<td>Median 12.0</td>
<td></td>
<td>(5-17)</td>
<td>(5-17)</td>
<td>(7-15)</td>
<td>(7-17)</td>
</tr>
<tr>
<td>Median age at diagnosis (SD) (range)</td>
<td>6.0</td>
<td>3.0</td>
<td>3.0</td>
<td>10.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Mean = 5.9</td>
<td></td>
<td>(0-16)</td>
<td>(0-7)</td>
<td>(1-14)</td>
<td>(0-15)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 to 7</td>
<td>11</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10 to 12</td>
<td>16</td>
<td>5</td>
<td>1</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>15 to 17</td>
<td>13</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

There was slight variation in numbers recruited into each age group: the largest number of CYP were recruited into the 10 to 12 age group (16), the smallest number were included in the 5 to 7 age group (11). Fourteen CYP were recruited with asthma, four with congenital heart disease, 11 CYP with diabetes and 11 with epilepsy.

Participants were asked at baseline and at follow up to describe any other conditions (in addition to the index condition) experienced by the CYP. Less than half (18) of the CYP had no co-morbidity. The most frequently mentioned conditions were hay fever (9) and “allergies” (4) (See Table 14). Nine CYP had two or more conditions in addition their index condition. Thirteen CYP presented with one additional medical condition, four CYP with two and five with three (see Table 15).
Table 14. Co-morbidity (range of conditions) reported by participants

<table>
<thead>
<tr>
<th>Conditions</th>
<th>All</th>
<th>Asthma</th>
<th>CHD</th>
<th>Diabetes</th>
<th>Epilepsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=40</td>
<td>n=14</td>
<td>n=4</td>
<td>n=11</td>
<td>n=11</td>
<td></td>
</tr>
<tr>
<td>Number of CYP with co-morbidities</td>
<td>22</td>
<td>11</td>
<td>3</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Allergies other than hay fever</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asthma</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Eczema</td>
<td>6</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hay fever</td>
<td>9</td>
<td>8</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Autism</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Other(^b)</td>
<td>13</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>8</td>
</tr>
</tbody>
</table>

\(^a\)Total exceeds 40 as there were CYP with more than one co-morbidity

\(^b\)Each of the following reported once: cavernomas (multiple); cerebral palsy; challenging behaviour; communication difficulties; Duchenne muscular dystrophy; global developmental delay; learning difficulties; metabolic disorder; mitochondrial disorder; nerve damage to leg (resulting from surgery for heart condition); Osgood-Schlatter disease; partially sighted; seizure.

Table 15. Number of co-morbidities

<table>
<thead>
<tr>
<th>No. co-morbidities</th>
<th>All</th>
<th>Asthma</th>
<th>CHD</th>
<th>Diabetes</th>
<th>Epilepsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>No co-morbidity</td>
<td>18</td>
<td>3</td>
<td>1</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>One condition</td>
<td>13</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Two conditions</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Three conditions</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Total CYP</td>
<td>40</td>
<td>14</td>
<td>4</td>
<td>11</td>
<td>11</td>
</tr>
</tbody>
</table>

CYP with asthma (11 of 14) and CHD (3 of 4) appeared more likely to experience co-morbidity than the CYP with the two other conditions. A statistically significant association was noted between CYP with asthma and the presence of co-morbidities compared with the “non-asthma” group (\(\chi^2 = 3.481; df=1; p \text{ value } [1 \text{ tail}] p = 0.014\)) Ten CYP shared their index condition (asthma) with other family members; five fathers, three mothers and one uncle. In one family, this included father, mother and all four siblings. Data were missing for seven participants: these had all been

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recruited on an *ad hoc* basis in clinic. The majority of main care givers were the mother (26), 10 participants reported that both parents shared responsibility and the father was classed as the main carer in only one case. Data were not available for three participants.

Data on self-reported ethnicity showed the majority of participants were White British (32). (see Table 16)

**Table 16. Reported Ethnicity of Participants (See Appendix 7.26 for ethnicity reporting categories)**

<table>
<thead>
<tr>
<th>Ethnic category</th>
<th>All</th>
<th>Asthma</th>
<th>CHD</th>
<th>Diabetes</th>
<th>Epilepsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1 White British</td>
<td>32</td>
<td>11</td>
<td>3</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>B1 White and Black Caribbean</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>B3 White and Asian</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>B4 Any Other Mixed Background</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>C1 Indian</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>14</strong></td>
<td><strong>4</strong></td>
<td><strong>11</strong></td>
<td><strong>11</strong></td>
</tr>
</tbody>
</table>

Participants were asked their highest educational achievement level and current or last occupation (see Table 17).

**Table 17. Main care giver education**

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>No formal qualifications</td>
<td>2</td>
</tr>
<tr>
<td>GCSE/O-Level/CSE</td>
<td>14</td>
</tr>
<tr>
<td>A-Level/NVQ L3</td>
<td>10</td>
</tr>
<tr>
<td>Graduate/BTEC/Bachelors/Diploma</td>
<td>10</td>
</tr>
<tr>
<td>Post-graduate/PhD</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
</tr>
</tbody>
</table>

The occupation of the main care giver was also recorded but in insufficient detail to map to the ONS classification of occupational categories. The range of occupations given by the parents varied between “None” or “Full time carer” to “Managing Director” and “Dentist”. (see Appendix 7.27)
The three main occupational groups represented among the parents were teaching (11), administrative and managerial (9), and retail/shop work (6). Other categories included health (5), “Other” (4), no current occupation (5) including two participants described themselves as home-maker or full-time carer, and factory worker (1). Data were missing for one participant.

The educational level of the participants who were involved in teaching or education, ranged from a teaching assistant (GCE/GCSE/CSE) to three teachers with postgraduate/PhD qualifications. Participants working in administrative or managerial posts held qualifications between GCE/GCSE/CSE and Graduate/BTEC/Bachelors/Diploma. The qualifications of people working in the health sector varied between GCE/GCSE/CSE and postgraduate/PhD.

Postcode data were collected for all participants. The postcodes were recoded into the English Indices of Multiple Deprivation (IMD) 2007 scores and rank by Dr Jean Robinson, Head of Information, NHS Nottingham City.

<table>
<thead>
<tr>
<th>Region</th>
<th>N</th>
<th>Range</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>East Midlands</td>
<td>2732</td>
<td>77.64</td>
<td>0.73</td>
<td>78.37</td>
<td>20.01</td>
<td>14.44</td>
</tr>
<tr>
<td>England</td>
<td>32482</td>
<td>85.09</td>
<td>0.37</td>
<td>85.46</td>
<td>21.67</td>
<td>15.71</td>
</tr>
<tr>
<td>TABS participants</td>
<td>40</td>
<td>47.66</td>
<td>0.73</td>
<td>48.39</td>
<td>14.62</td>
<td>10.78</td>
</tr>
</tbody>
</table>

IMD scores and ranks relate to a geographical area, rather than individual, measures of deprivation, so we cannot say with certainty that these scores reflect the level of deprivation of the individual participants.

The range of IMD scores obtained (see Table 18) suggests that participants came from a wide cross section of society, from among the least to the most deprived in the East Midlands, and in England. The least deprived IMD Score/Rank of IMD was 0.73/32475; the most deprived 48.39/2612. The corresponding IMD scores and ranks for England are 0.37/32482 (least deprived) and 85.46/1 (most deprived). The IMD scores suggest that the TABS study population lived in areas that were “less deprived” in relation to both England and the East Midlands.

**Practice characteristics for participants and practitioners**

Participants were recruited in four care settings, predominantly secondary care, including children’s community services (n=28). Ten participants were recruited in primary care, and two in community pharmacy. CYP with asthma were seen in a variety of settings, albeit that the majority were observed in primary care. Ten CYP attended GP surgeries, two were seen by
the community pharmacist and two in a children’s outpatient department. The CYP we recruited with diabetes (n=11) were seen exclusively in a hospital setting as were CYP with CHD (n=4).

The majority of practitioners were recruited from secondary care including CYP’s community health services (n=20), three from primary care and one from community pharmacy. The 19 practitioners in secondary care saw CYP from all groups whereas primary care practitioners saw CYP with asthma only (n=5).

The “child-friendliness” nature of the environment differed both between and within the different settings. Outpatient clinics in the three secondary care settings varied. One clinic (Clinic A) was bright and cheerful with open areas and views to the outside, wide corridors, plenty of toys and activities for CYP of different ages, posters and reading materials. Alternatively, another clinic in a different hospital setting (Clinic B) formerly an adult clinic, had a small reception area provided with games, toys and a computer but this led on to a series of relatively narrow corridors where parents and CYP were asked to wait before seeing the practitioner. The windowless corridors were brightened with posters and toys were available but the width of the corridors appeared to restrict any play activity and there was constant through-traffic as staff and patients moved between the waiting room and consulting rooms. One CYP, aged 11, described his feelings about the clinic:

“... when you are younger you have all the games ... B is not as good as ( ) ... lot more to do while you are waiting ... not so scary white walls ...” (N17)

Another CYP’s outpatient clinic in the same hospital (Clinic C) had a larger waiting area furnished with toys, games and activities but, again, parents and CYP had to wait on internal corridors before seeing the doctor or nurse. There was a small annex to Clinic C which contained further games and toys, and was brightened with two large specially commissioned wall paintings. The scope and quality of the reading material was varied and, somewhat bizarrely, included copies of Saga magazine and Arthritis Today. Both of these clinics had allocated a separate room for teenagers but this did not seem to be used. The two other CYP’s outpatient clinics (Clinic D and Clinic E) were spacious and welcoming and furnished with toys, games and appropriate reading material. In both of these clinics, parents and CYP remained in the reception area before being called in to see the doctor.

Two of the three GP surgeries (F, G, H) had provided a small play area for CYP in the waiting room and supplied a few toys and books.

Clinic I was held in one-storey building set apart from the main campus of the hospital. The entrance corridors leading to the main waiting area were bright and cheerful with large windows looking out onto grassed areas. There was a door from the waiting area onto an outdoor play area which provided a picnic bench and a variety of larger toys.
The consultation in community pharmacy (J) was held in a very small, private, room off the main area of the shop. The size of the room was just adequate for two people containing two chairs, a small table and a filing cabinet. Unfortunately, the observed consultation included four adults. There had been no attempt, and no space, to make the room “child-” or “adolescent-friendly”.

Reception staff in all of the clinics appeared friendly and welcoming, addressing the CYP as well as the parents as they arrived.

5.13 Acceptability and feasibility

5.13.1 Use and usefulness of the pre-consultation tool and the practitioner prompt

Assessing the use and usefulness of the pre-consultation tool and practitioner prompt required combining researcher observations and parent/CYP/practitioner report. Parents and CYP (aged 10 and above, N=27) were asked for feedback on their use of the TABS pre-consultation tool immediately after the consultation and at the one-week and two-month follow up interviews. Questions on the helpfulness of the pre-consultation tool in the consultation were asked only of parents and CYP >10 years at one week and two month follow up interviews. Two CYP in this age group lacked capability. Number of CYP aged 10 or above with capability = 27. Practitioners were also asked for feedback on their use of the practitioner prompt and/or pre-consultation tool.

Practitioners, parents and CYP and were asked if they had used the pre-consultation tool, its usefulness or their reasons for not using it. Parents and CYP were asked at the beginning of the follow up interviews whether the pre-consultation tool had helped improve the consultation. The follow up interviews concluded with repeating the questions asked at the observation about the use and usefulness of the pre-consultation tool.

Table 19 provides details of the use and usefulness of the pre-consultation tool and the practitioner prompt observed and reported during the 40 case studies. 31/40 parents and 20/40 CYP completed the pre-consultation form before coming to the appointment and 9/40 parents and 5/40 CYP filled it out at the clinic/practice. 15/40 CYP did not fill in the tool, sometimes this was due to inability, but other reasons were not clear, other than that parents had completed the form alone. All parent-CYP dyads took the pre-consultation tool into the consultation and 8/40 handed it to the practitioner.

The CYP found the pre-consultation tool useful in 17/27 consultations. The parent found the pre-consultation tool useful in 21/40 consultations. The
practitioner found the pre-consultation tool or practitioner prompt useful in 14/40 consultations. The number of consultations where the pre-consultation tool was used either by the parent or the CYP was 26/40. In 12/40 consultations, CYP and parent used the tool. Each member of the triad used the tool in 8/40 consultations.

The number of consultations where the pre-consultation tool or the practitioner prompt was used by any member of the triad was 29/40. In the eleven consultations where the tools were not used at all, the cases were a mix of primary (2) and secondary (9) care, asthma (3), CHD (1), diabetes (3) and epilepsy (4). In these eleven consultations, the pre-consultation tool was never given to the practitioner. There was no dominant reason for not using the tool. Filling in the tool beforehand, or at the clinic did not appear to affect use in the consultation, although most parents and CYPs had filled in the form before coming to their appointment. Some parents and CYPs reported that they knew what they needed to ask anyway, suggesting that the tool would be more useful earlier in the disease.
## Table 19. Table CYP, Parents’ and Practitioners’ Use of Tools

<table>
<thead>
<tr>
<th>UPN</th>
<th>condition</th>
<th>sex</th>
<th>age</th>
<th>setting</th>
<th>P-c tool completed by parent</th>
<th>P-c tool completed by child</th>
<th>P-c tool brought to appointment</th>
<th>Use of P-c tool reported</th>
<th>Use of P-c tool reported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>before or at appointment</td>
<td>before or at appointment</td>
<td>by parent by child given to clinician</td>
<td>by child</td>
<td>by parent</td>
</tr>
<tr>
<td>N15</td>
<td>Asthma</td>
<td>M</td>
<td>5</td>
<td>2ndry care</td>
<td>before</td>
<td>not completed</td>
<td>no no No</td>
<td>No</td>
<td>no</td>
</tr>
<tr>
<td>L22</td>
<td>Asthma</td>
<td>M</td>
<td>6</td>
<td>1ry care</td>
<td>before</td>
<td>before</td>
<td>yes Yes No</td>
<td>not used</td>
<td>not used</td>
</tr>
<tr>
<td>N25</td>
<td>Asthma</td>
<td>M</td>
<td>5</td>
<td>2ndry care</td>
<td>before</td>
<td>not completed</td>
<td>yes no No</td>
<td>CYP did not use</td>
<td>Nurse did not use</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L14</td>
<td>Asthma</td>
<td>F</td>
<td>7</td>
<td>1ry care</td>
<td>at clinic</td>
<td>not completed</td>
<td>yes no yes</td>
<td>couldn’t remember</td>
<td>Dad was particularly pleased and said that the consultation was better than usual</td>
</tr>
<tr>
<td>UPN</td>
<td>condition</td>
<td>sex</td>
<td>age</td>
<td>setting</td>
<td>P-c tool completed by</td>
<td>P-c tool completed by</td>
<td>P-c tool brought to</td>
<td>Use of P-c tool reported</td>
<td></td>
</tr>
<tr>
<td>-----</td>
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<td>-----</td>
<td>---------</td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>parent before or at appointment</td>
<td>child before or at appointment</td>
<td>appointment by parent given to child</td>
<td>by child by parent by practitioner</td>
<td></td>
</tr>
<tr>
<td>N27</td>
<td>Asthma</td>
<td>M</td>
<td>7</td>
<td>2ndry care</td>
<td>before</td>
<td>not completed</td>
<td>yes</td>
<td>no</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N23</td>
<td>Asthma</td>
<td>M</td>
<td>10</td>
<td>1ry care</td>
<td>before</td>
<td>before</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>L11</td>
<td>Asthma</td>
<td>M</td>
<td>11</td>
<td>1ry care</td>
<td>before</td>
<td>before</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UPN</td>
<td>condition</td>
<td>sex</td>
<td>age</td>
<td>setting</td>
<td>P-c tool completed by parent before or at appointment</td>
<td>P-c tool completed by child before or at appointment</td>
<td>P-c tool brought to appointment by parent</td>
<td>P-c tool brought to appointment by child</td>
<td>given to clinician</td>
</tr>
<tr>
<td>-----</td>
<td>-----------</td>
<td>-----</td>
<td>-----</td>
<td>---------</td>
<td>-----------------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>------------------------------------------</td>
<td>------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>N17</td>
<td>Asthma</td>
<td>M</td>
<td>11</td>
<td>2ndry care</td>
<td>before</td>
<td>before</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>P-c tool completed by child before or at appointment</td>
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<td>Use of P-c tool reported by child by parent by practitioner</td>
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<td>before by parent by child before</td>
<td>yes yes</td>
<td>No</td>
<td>P thought the P-c tool had helped &quot;a bit&quot;, she had not used the P-c tool as she knew what she wanted to go over with the pharmacist.</td>
<td>Mother did not use or refer to the P-c tool</td>
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<td>16</td>
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<td>yes yes</td>
<td>ye s</td>
<td>The P-c tool enabled mother and son to discuss issues before arrival.</td>
<td>Mother felt that the P-c tool had helped them to focus their minds before the consultation although she had been thinking about her son taking more responsibility for his medication.</td>
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<td>no</td>
<td>She had not used the P-c tool as she&quot; ... I know about my medicine ... I know how to take them.&quot;</td>
<td>Mother did not use the P-c tool as she had assumed that the patient would use it.</td>
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<td>no</td>
<td>P-c tool &quot;gave me an idea of what it was going to be about.&quot;</td>
<td>Did not use P-c tool as already had an idea of what she wanted to ask, but P-c tool helpful - helped you to focus on it, think about it beforehand.</td>
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Project 08/1704/212
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<td>helped CYP focus on questions about medicines</td>
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<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>CYP not able to engage in consultation</td>
<td>Mother did not use or refer to the P-c tool as she knew what she wanted to ask and what she wanted from the consultation, and CYP was agitated, but thought it would be useful</td>
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<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>CYP did not use (unable)</td>
<td>Mother had not used the P-c tool as &quot;we just talked about it anyway&quot; but also said that it had been useful &quot;jotting things down helps – forget things at least one&quot;, but having dyslexia have to hold everything in my head ... can't hold anything I've read in my head ... can remember what we discussed on the sheet&quot;</td>
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</table>

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Project 08/1704/212
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<th>P-c tool completed by child before or at appointment</th>
<th>P-c tool brought to appointment</th>
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<td>CYP did not use</td>
<td>Did not use P-c tool as had own method which involves lists and spider diagram, P-c tool may &quot;... have helped when in the preliminary stages, quite seasoned to it now and you know what you want to ask but you do forget.&quot;</td>
<td>Did not use prompt or P-c tool – didn’t remember.</td>
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<td>Epilepsy</td>
<td>F</td>
<td>10</td>
<td>2ndry care</td>
<td>before</td>
<td>not completed</td>
<td>yes no no</td>
<td>Had found the P-c tool useful/helpful &quot;Yes ... had a lot of information I didn’t know ... helped talk to the doctor”, &quot;yes, helped me explain it a bit more”. Remembered action points</td>
<td>Did not use P-c tool – knew what was going to ask. &quot;It would have been good if it was the first consultation because you have so many things you want to ask.”</td>
<td>Did not use P-c tool</td>
<td></td>
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<td>Epilepsy</td>
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<td>2ndry care</td>
<td>before</td>
<td>not completed</td>
<td>yes no no</td>
<td>CYP did not use (unable)</td>
<td>Did not use P-c tool, already had questions in mind therefore did not need to use.</td>
<td>Doctor did not refer to P-c tool or prompt; P-c tool &quot;not apparent” and “not given it”.</td>
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<td>12</td>
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<td>before</td>
<td>yes yes no</td>
<td>CYP did not use as was too upset but P-c tool had been helpful</td>
<td>&quot;I was so churned up (I) didn’t think about it”.</td>
<td>Doctor and nurse did not use due to stressful nature of consultation</td>
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<td>age</td>
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<td>Use of P-c tool reported by parent</td>
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<td>2ndry care</td>
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<td>no</td>
<td>no</td>
<td>P-c tool useful, &quot;...the actual questions helped, getting the information, being spoken to...the actual sheet helped me.&quot;</td>
<td>P-c tool useful. Can't remember the key action points. Consultation didn't really help.</td>
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<td>Didn't use the P-c tool – didn't take it into the room. P-c tool was helpful in thinking about how to take your medicines. Did not use P-c tool – didn't need to, knew everything</td>
<td>Did not use P-c tool (but) having reviewed that, probably more pertinent for people who have just started on medication</td>
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<td>yes</td>
<td>yes</td>
<td>Did not use the P-c tool but did fill it in, didn't use as nothing really to ask.</td>
<td>Didn't use P-c tool, didn't feel the need to</td>
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</tbody>
</table>

UPN: Unique person identifier

P-c tool: preconsultation tool

1ry: Primary

2ndry: Secondary
Feedback from practitioners, parents and CYP following the consultation

Fourteen of the 24 practitioners said they had used the pre-consultation tool or practitioner prompt during the consultation. Of these, ten had found it useful at the time and an additional practitioner, who had not thought the pre-consultation tool useful said that it could be helpful under different circumstances:

"No, I know it anyway but it (is) useful for some people ... if a new person ... (I) have own proforma ..." (N25)

Twelve parents said they had used the pre-consultation tool in the consultation and 15 that it had been useful. One parent, who had not “used” the pre-consultation tool said s/he had found it useful and that it would also be useful for other people.

Nine CYP had used the pre-consultation tool during the consultation and seven had found it useful.

Feedback from parents and CYP at the one week follow up interview and two month interview

Parents’ recall at the one week and two month follow up interviews suggested an increase in the use and, to a lesser extent, the usefulness of the pre-consultation tool. The most marked change in response was the potential usefulness of the pre-consultation tool for other people or at a different stage in the disease process (for example, newly or recently diagnosed). Only one parent had mentioned the possible usefulness of the tool in this context immediately after the consultation but this increased to eight at the first follow up interview and further to 13 parents at the two month follow up.

The reaction of CYP to the use and usefulness of the pre-consultation tool fluctuated; fewer CYP (6) said they had used the pre-consultation tool at the first follow up than in the feedback following the consultation (9). Twelve CYP reported using the tool, however, at the two month follow up. Responses from the CYP were more consistent for the usefulness of the tool; twelve had, apparently, found it useful when interviewed at one week and two months. One CYP, at the two month follow up also commented that it could be helpful for other people.

Explicit use of the pre-consultation tool in the consultation and reported use.

The researchers attempted to judge the “use” of the pre-consultation tool during the consultation process. We recorded “use” in a broad sense wherever the parent, CYP or practitioner referred to the tool even if this did
not include actively referring to the piece of paper during the consultation itself.

Some parents (and CYP) were uncertain about the purpose of the pre-consultation tool despite this being explained to them in the contact with the researchers before the consultation took place.

The use of the pre-consultation tool ranged from being utilised throughout the consultation (e.g. N10); not used or referred to at all, or acting as a “prompt” for discussion about medicines before, or during, the consultation. For example, one father said that he had not used the pre-consultation tool during the consultation but that

“the fact that (I) was holding it reminded (me) to ask the question.” (N03)

In one instance, a mother turned to the researcher during the consultation and asked what she should do with the tool (N06). The researcher responded to the mother could use them or not, as she wished. The mother then passed the forms to the practitioner who read through them and immediately focussed the discussion on the questions raised by the CYP.

Other parents and CYP were familiar with the consultation process and confident in keeping their own notes in preparation for the meeting with the practitioner. They said that they felt the pre-consultation tool was of less benefit to them but it might be useful for other people. One mother, who had found it useful, but had not realised that it was something to use with the practitioner, said

“... you are plunged into this world of gobbledegook, you don’t understand what you have been told, only later do you know what you need to ask ... it would be most helpful for people entering this new world ...” (L18)

Predictability and familiarity with the consultation process, however, may also lead to a level of cynicism and weariness about the purpose of completing the pre-consultation tool:

"Did Dr (X) look at it? Well, then... if he doesn’t look at it there’s no point.” (CYP aged 11: N17)

**Agreement between parents and practitioners on the usefulness of the pre-consultation tool.**

We tested the level of agreement in the usefulness of the pre-consultation tool between the parent and the practitioner at baseline using Cohen’s κ. The value based on the primary 40 observations was κ = 0.500. When the two additional “nurse” observations were included (N15n and N17n), there was a slight increase to κ = 0.511. Using the Landis and Koch criteria, this suggests a moderate level of agreement, above that expected by chance, between parent and practitioner on the usefulness of the tool.
**Use, and adaptation of, the practitioner prompt.**

We obtained consent from a range of settings to carry out the intervention. Once we had obtained consent, we arranged for all interested practitioners to attend a briefing, where they had the purpose of the prompt explained to them and were asked to use it in the study consultation(s). We also carried out one-to-one briefings with practitioners who could not attend the practice/clinic briefing. In practice, there was a mismatch of practitioners. The practitioners who attended the briefings were often not the practitioners who carried out the consultation with the recruited parent-dyad. This was either due to the CYP being cared long term for by a different practitioner (and we had no control over which CYP was recruited within a practice) or where a different practitioner happened to be seeing that CYP that day. Therefore, we had many situations where the practitioner needed to be briefed immediately before a consultation, and may not have been as motivated to take part in the study.

One practitioner adapted the prompt and incorporated it into the set of questions s/he routinely used, others preferred to use their own prompt list. The reasons for not using the prompt ranged from not having been given it by the researchers, forgetting about it or being "... caught up in the consultation ..." (N26) or confidence in their usual style of consultation "... (I) "already knew it in my mind ...” (L21).

Ten practitioners overall, had found the tool or prompt “useful” and four of these were primary care practitioners. Both of the practitioners who thought the prompt/pre-consultation tool would be useful for other people or for people at a different stage in the consultation process were in primary care.

**Confusion over the use of the pre-consultation tool**

Other reasons for not using the pre-consultation tool or the practitioner prompt centred on the perceived "locus of control" within the consultation process itself. Parents and CYP said they had not used the pre-consultation tool because the "doctor had not mentioned it". Some practitioners did not use the prompt or refer to the pre-consultation tool, leaving the responsibility for using the tool to the parent or CYP.

### 5.13.2 Scope and quality of the consultation

Information on the scope and quality of the consultation between the practitioner, parent and CYP was recorded during the observation using the PCAT Marking Key. The PCAT measured a range of behaviours grouped into two main categories, Content Skills and Process Skills, eight sub-categories and 22 assessment components. Each of the criteria were “marked” on a scale of 1 (very poor) to 7 (very good) with a summary score for both
parent and CYP for each of the components, and for overall performance (see Table 20).

The first category, Content Skills, included four measures which were excluded from our assessment as they covered elements which required clinical knowledge to judge. The excluded measures were “Gathers relevant information”, “Undertakes pertinent examination”, “Generates appropriate diagnosis” and “Formulates relevant management plan”.

Data were collected from observing 42 consultations with 40 parents/CYP dyads: we recorded information from two “double” consultations for two participants with a nurse specialist in addition to the consultation with the medical practitioner.

**Table 20. Mean scores (range) of the Paediatric Consultation Assessment Tool (PCAT) (content skills not included)**

<table>
<thead>
<tr>
<th>Process Skills</th>
<th>All</th>
<th>Primary care</th>
<th>Secondary care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=42</td>
<td>n=10</td>
<td>n=32</td>
</tr>
<tr>
<td></td>
<td>(Scores 1=worst to 7=best)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Child/young person</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building the relationship</td>
<td>5.54 (1-7)</td>
<td>6.78 (6-7)</td>
<td>5.19 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Initiating the session</td>
<td>4.93 (1-7)</td>
<td>6.00 (4-7)</td>
<td>4.59 (1-7)</td>
</tr>
<tr>
<td>n=42</td>
<td>(n=10)</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Gathering information</td>
<td>5.26 (1-7)</td>
<td>6.30 (5 to 7)</td>
<td>4.94 (1-7)</td>
</tr>
<tr>
<td>n=42</td>
<td>n=10</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Physical Examination</td>
<td>5.48 (1-7)</td>
<td>5.86 (5 to 7)</td>
<td>5.35 (1-7)</td>
</tr>
<tr>
<td>n=27</td>
<td>n=7</td>
<td>n=20</td>
<td></td>
</tr>
<tr>
<td>Explanation and planning</td>
<td>5.53 (1-7)</td>
<td>6.56 (5 to 7)</td>
<td>5.23 (1-7)</td>
</tr>
<tr>
<td>n=40</td>
<td>n=9</td>
<td>n=31</td>
<td></td>
</tr>
<tr>
<td>Closure</td>
<td>5.22 (1-7)</td>
<td>6.33 (5 to 7)</td>
<td>4.91 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td><strong>Parent</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building the relationship</td>
<td>5.93 (1-7)</td>
<td>6.67 (5 to 7)</td>
<td>5.72 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Initiating the session</td>
<td>5.17 (2-7)</td>
<td>6.10 (5 to 7)</td>
<td>4.88 (2-7)</td>
</tr>
<tr>
<td>n=42</td>
<td>n=10</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Gathering information</td>
<td>5.76 (1-7)</td>
<td>6.50 (5 to 7)</td>
<td>5.53 (1-7)</td>
</tr>
<tr>
<td>n=42</td>
<td>n=10</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Explanation and Planning</td>
<td>5.98 (1-7)</td>
<td>6.33 (5 to 7)</td>
<td>5.88 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Closure</td>
<td>5.85 (1-7)</td>
<td>6.33 (5 to 7)</td>
<td>5.72 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td><strong>Structuring the interview</strong></td>
<td>5.39 (1-7)</td>
<td>6.00 (3-7)</td>
<td>5.22 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td><strong>Overall performance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child/young person (n=38)</td>
<td>5.24 (1-7)</td>
<td>6.44 (5 to 7)</td>
<td>4.91 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
<tr>
<td>Parents (n=38)</td>
<td>5.66 (1-7)</td>
<td>6.11 (5 to 7)</td>
<td>5.53 (1-7)</td>
</tr>
<tr>
<td>n=41</td>
<td>n=9</td>
<td>n=32</td>
<td></td>
</tr>
</tbody>
</table>

For PCAT statistical analysis, see Howells et al. (2010), p4.

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Project 08/1704/212
Results showed a slight difference in scores between primary and secondary care (Figure 12). Primary care practitioners’ skills were rated higher for both parent and CYP aspects of the consultations. The communication between the primary care practitioners and the CYP was scored highest at 6.78 (building the relationship). In contrast, the lowest mean score, 4.59 (initiating the session) was recorded for the consultation between secondary care practitioners and CYP (n=31). There was greater variation in the scores from the secondary care practitioners (range: 1 to 7) than primary care (range 5 to 7). The number of observations (10) in primary care is, however, too small to support any meaningful comparison with secondary care.

The data suggest that parents received a slightly better quality of consultation than the CYP with the practitioners’ mean overall scores being higher for the CYP in only four of the observations. The practitioner-CYP scores were lower than practitioner–parent scores for nine consultations. The parent and CYP score were equally good, or bad, in 11 consultations, ten of these achieving a mark of 6.00 or above.

The greatest disparity within a practitioner-parent and practitioner-CYP consultation occurred in secondary care. Practitioner U, scored 2.5 for the quality of consultation with the CYP and 6.0 with the parent.
Figure 12. Mean overall Paediatric Consultation Assessment Tool (PCAT) score for parent and CYP by provider type (n=24)

Practitioner (A to X) and provider type: Primary or secondary care

Pr  Primary care
Sec  Secondary care
Clinicians were asked to complete a checklist following the consultation with parent and CYP, the results are summarised in Table 21.

### Table 21. Clinician consultation record and checklist

<table>
<thead>
<tr>
<th>Checklist item</th>
<th>Possible responses</th>
<th>All (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you made an assessment of adherence from prescription refills and patient’s condition?</td>
<td>Yes 28 No 11</td>
<td></td>
</tr>
<tr>
<td>Did you obtain the parent’s and child/young person’s assessment of adherence?</td>
<td>Yes 25 No 5</td>
<td></td>
</tr>
<tr>
<td>Did you obtain the key barriers to adherence raised by parent and child/young person?</td>
<td>Yes 29 No 11</td>
<td></td>
</tr>
<tr>
<td>Did you ensure that the child/young person’s and the parent’s views were elicited and concerns are discussed and given sufficient weight?</td>
<td>Yes 33 No 7</td>
<td></td>
</tr>
<tr>
<td>Have you agreed on 2-3 action points?</td>
<td>Yes 31 No 9</td>
<td></td>
</tr>
<tr>
<td>Have you scheduled a follow-up consultation?</td>
<td>Yes 29 No 11</td>
<td></td>
</tr>
<tr>
<td>Have you completed the patient record for this consultation?</td>
<td>Yes 33 No 7</td>
<td></td>
</tr>
<tr>
<td><strong>Adolescent participants (n=13)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the patient is an adolescent have you considered having consultations away from the parent?</td>
<td>Yes 6 No 7</td>
<td></td>
</tr>
</tbody>
</table>

The practitioner was asked to consider having a separate consultation, away from the parent(s), with adolescent patients. Practitioners reported that they had made this consideration in 16 of the observations (n=40). There were, however, only 13 consultations with adolescent patients and practitioners had addressed the idea of a separate consultation in only half (6) of the observations. In practice, this resulted in only one separate consultation; the CYP was seen at the beginning of the consultation and the parent later invited to join.
5.14  Clinical and patient-centred outcomes

5.14.1  Disease specific parameters

Information on disease specific parameters was collected at baseline and at the two month follow up from parents and, where feasible, from the practitioner.

Among CYP with asthma (n=14), at baseline, only one parent reported oral steroid use and that as “very little”. At the second follow up, two parents reported one instance; and one parent reported daily oral steroid use in the previous two months (“... every day ... brown one ...”). There were no recorded exacerbations at baseline but at follow up four parents reported one at follow up, one parent reported four, and another parent daily instances.

The latest recorded blood pressure was obtained at baseline for three of the four CYP with CHD but only for one CYP at the second follow up. At baseline, reported blood pressure was 101/56, 99/61 and 110/68 for the three CYP for whom data were available. None of the parents were able to provide information at the second follow up apart from one who said the BP “... was fine ...”. The data on serum cholesterol levels was equally elusive and comments from three parents ranged from “pass” to “fine, normal” and “no idea”. Data on INR levels were available for two CYP at baseline, 3.4 and 1.1, but only for one CYP at follow up. The INR level for the CYP who recorded 3.4 at baseline had fallen slightly to 3.1 at the two month follow up.

Information was more easily available for CYP with diabetes. Ten of the eleven parents were able to report the latest HbA$_{1c}$ levels which ranged from 5.5 to 12.5 (mean 8.7). Information was available for nine CYP at the two month follow up; eight of the reported levels ranged from 4.8 to 10.1. The HbA$_{1c}$ for one CYP was 26: the school rang the mother during the course of the follow up interview with the reading, expressed their concern and asked the mother to collect the CYP. The mean number of hypoglycaemic events in the previous two months at baseline was 4.6 (range 0-25) but had increased at follow up to a mean of 9.7 (range 0-50). At baseline, parents of six CYP reported no events however only three parents recorded no events at follow up. At the high end of the range, the CYP who had suffered 25 hypoglycaemic events at baseline was recorded as having 50 events during the two months prior to the follow up interview.

Information was also collected from parents of CYP with epilepsy. Five CYP at baseline and two at follow up had experienced absence seizures. Generalised tonic-clonic seizures had affected three CYP in the month before the observation and one CYP in the two months before the follow up.
interview. One CYP at baseline and two at follow up had experienced a focal seizure. One CYP had experienced a simple partial seizure in the two months before follow up (none at baseline) and one CYP at baseline and at follow up had been affected by a complex partial seizure. We were unable to classify the type of seizure experienced by two CYP (N35 and N37) at baseline.

5.14.2 Medicines adherence

Analysis of baseline data for the whole group revealed high levels of self-reported adherence to medication as rated by CYP (mean 85.3%) and parents (mean 88.6%). There were strong correlations between parents and CYP’s ratings of percentage adherence at baseline ($r_s=0.76$, $n=29$, $p<0.001$) and at follow-up ($r_s=0.62$, $n=27$, $p=0.001$).

5.14.3 Self-efficacy

Self-efficacy in relation to the CYP’s medicines taking was also high with a mean of 3.5/4 for parent ratings and 3.8/4 for CYP ratings.

5.14.4 Locus of control

Mean locus of control scores were 7/10 with higher scores indicating a stronger sense of personal control of medicines taking.

5.14.5 Generic child health status

Scrutiny of CHQ scores showed that the sample of CYP had low levels of physical and psycho-social wellbeing. The mean score for the physiological summary scale was 43.7 (SD 16.2), with 15 CYP (37.5%) scoring below more than 1 SD below US norms suggesting poor physical health. The mean score for the psycho-social summary was 44.8 (15.1) with 16 (40%) scoring more than 1 SD below US norms (there are no UK norms at time of printing). Overall there was no significant change in any of the variables with exception of locus of control where the child’s sense of control had improved.
5.15 Resource use

5.15.1 Medicines and medical devices

Asthma

CYP were prescribed between two and 11 medicines (see Table 22 for details). One CYP in the 10 to 12 year age group was reported to be taking two different short acting beta-2 agonists, the reason for, or accuracy of, this is unclear.

Table 22. Medicines and CYP with asthma

<table>
<thead>
<tr>
<th>Number of CYP in each age group</th>
<th>Short acting beta-2 agonist + regular standard dose inhaled corticosteroid (Step 2 BTS asthma guideline)</th>
<th>Short acting beta-2 agonist + regular standard dose inhaled corticosteroid + long acting beta-2 agonist + leukotriene receptor antagonist (Step 3 BTS asthma guideline)</th>
<th>Other medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 to 7</td>
<td>2</td>
<td>3</td>
<td>Emollient (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Corticosteroid cream (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antihistamine (2)</td>
</tr>
<tr>
<td>10 to 12</td>
<td>3 +1 (not taking)</td>
<td>1</td>
<td>Emollient (2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Corticosteroid cream (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antihistamine (3)</td>
</tr>
<tr>
<td>15 to 17</td>
<td>4</td>
<td></td>
<td>Emollient (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Corticosteroid cream (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Antihistamine (2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Adrenaline Epipen®</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Beclometasone nasal spray (1)</td>
</tr>
</tbody>
</table>

In four patients the researcher identified medicines that the CYP was documented in the notes or by the doctor as being prescribed, but in three cases neither the CYP nor parent mentioned them. In one case the CYP but not the parent mentioned the medicine in question. In three cases the CYP mentioned medicines not identified by the researcher or the parent. In one case the parent reported the CYP being prescribed a different brand of combination inhaler to that reported by the researcher, the reason for, or
accuracy of, this is unclear. Five parents and CYP referred to their beta-2 agonist inhaler as the ‘blue’ inhaler and their corticosteroid as the ‘brown’ one – they were not sure of the drug names. Doses and strengths of inhalers were often missing from the reports from the CYP and their parents. One CYP was using a beclometasone inhaler on an ‘as required’ basis rather than regularly.

**Congenital heart disease**

One CYP was in the 5 to 7 years age group and took five medicines, one in the 10 to 12 years age group and took two medicines, and two in the 15 to 17 years age group were taking two and eight medicines daily. One 15 to 17 year old was unsure of their medicines. The other 15 to 17 year old stated different doses of several of their drugs compared to their parent, confirmed by the researcher from their observations (see Table 23).

<table>
<thead>
<tr>
<th>Number of CYP in each age group</th>
<th>Oral anticoagulants</th>
<th>ACE inhibitor</th>
<th>Diuretic</th>
<th>Beta blocker</th>
<th>Digoxin</th>
<th>Other medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 to 7</td>
<td>1 (warfarin)</td>
<td>1 (lisinopril)</td>
<td>1 (furosemide)</td>
<td>1 (carvedilol)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>10 to 12</td>
<td>1 (warfarin)</td>
<td>1 (enalapril)</td>
<td>0</td>
<td>1 (carvedilol)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>15 to 17</td>
<td>0</td>
<td>2 (lisinopril, perindopril)</td>
<td>1 (furosemide)</td>
<td>1 (carvedilol)</td>
<td>0</td>
<td>short acting beta-2 agonist + inhaled corticosteroid + long acting beta-2 agonist + LTRA (1); antihistamine (1); proton pump inhibitor (1); antibiotic (1)</td>
</tr>
</tbody>
</table>

**Diabetes**
The CYP were taking two or three medicines (see Table 24). Most parents and CYP seemed very knowledgeable of their medicine regimen being able to name the insulin by brand and the dose regimen. Three CYP knew that they had ‘insulin’ four times daily but did not refer to the fact this comprised NovoRapid® three times daily and glargine insulin at night.

Table 24. Medicines in CYP with diabetes

<table>
<thead>
<tr>
<th>Number of CYP in each age group</th>
<th>Short acting subcutaneous insulin</th>
<th>Intermediate subcutaneous insulin</th>
<th>Long acting subcutaneous insulin</th>
<th>Other medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 to 7</td>
<td>2 Novorapid®</td>
<td>1 (Insulatard®)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 (NovoMix®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 to 12</td>
<td>4 Novorapid®</td>
<td>2 (Humalog®)</td>
<td>6 (glargine)</td>
<td>1 (ibuprofen);</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 carbamazepine</td>
</tr>
<tr>
<td>15 to 17</td>
<td>3 Novorapid®</td>
<td>0</td>
<td>3 (glargine)</td>
<td>0</td>
</tr>
</tbody>
</table>

Epilepsy

The CYP took one to seven medicines (see Table 25). Most parents were very knowledgeable about their CYP’s medicines including drug and dose. Many of the CYP were unable to describe their medicines however.

Table 25. Medicines and CYP with epilepsy

<table>
<thead>
<tr>
<th>Number of CYP in each age group</th>
<th>Carbamazepine</th>
<th>Clobazam</th>
<th>Ethosuximide</th>
<th>Gabapentin</th>
<th>Lamotrigine</th>
<th>Levetiracetam</th>
<th>Sodium valproate</th>
<th>Topiramate</th>
<th>Other meds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The most inconsistent information when comparing that from CYP, parent and researcher observational data was present in the CYP with asthma where a number of inconsistencies were highlighted as stated above. It is unclear how important these discrepancies are from a clinical point of view. In diabetic CYP both parent and CYP generally seemed very knowledgeable. In the CYP with epilepsy group the parents again generally seemed very knowledgeable whereas the majority of the CYP could not discuss their medicines with us, maybe due to their age or the effects of their condition.

One CYP was fitted with a vagal nerve stimulation (VNS) implant.

**Daily frequency of medication (Baseline)**

Data were collected on the daily frequency of long term medications taken by the CYP. Baseline data are presented in Table 26.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>All</th>
<th>Asthma</th>
<th>CHD</th>
<th>Diabetes</th>
<th>Epilepsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once a day</td>
<td>25</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Twice a day</td>
<td>38</td>
<td>16</td>
<td>7</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Three times a day</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Four times a day</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>When needed</td>
<td>25</td>
<td>17</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Not known</td>
<td>13</td>
<td>5</td>
<td>0</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>111</td>
<td>44</td>
<td>15</td>
<td>25</td>
<td>27</td>
</tr>
</tbody>
</table>
5.15.2 NHS contact (Baseline, FU1, FU2)

We recorded the level of NHS contact, for all conditions including index condition and any other condition, from parents and CYP aged ten and above with the capability to respond. The data are presented in Table 27 below. NHS contact is summarised for each type of contact by the number of CYP participants and by the total number of attendances.

NHS contact included:
- Length of initial consultation
- Admissions to hospital
- A and E attendances (but not admitted to hospital)
- Outpatient attendances
- Seen by GP in the GP surgery
- Seen by the Practice Nurse in the GP surgery
- Seen by the GP at home

Participants were asked about contact in the previous three months at baseline (parent only), in the previous week at one week follow up (parent and CYP), and in the previous two months at the two month follow up (parent and CYP), summarised in Table 27.

Initial consultation

The total length of the consultation time was estimated from data available from 29 audio recordings of the consultations. The mean length of the consultation was 22 minutes (SD 9.19, median 20, range 9 to 52 minutes).

Other NHS contact
### Table 27. NHS Contact reported by CYP and parents (index condition plus any other condition)

<table>
<thead>
<tr>
<th>NHS Contact related to index condition plus any other condition</th>
<th>Baseline Parent</th>
<th>FU1 Parent</th>
<th>FU1 CYP</th>
<th>FU2 Parent</th>
<th>FU2 CYP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In the last 3 months</td>
<td>In the last week</td>
<td>In the last 2 months</td>
<td>In the last 2 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n=40)</td>
<td>(n=39)</td>
<td>(n=27)*</td>
<td>(n=37)</td>
<td>(n=27)*</td>
</tr>
<tr>
<td>How many times has your son or daughter been admitted to hospital ... ?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>32</td>
<td>35</td>
<td>25</td>
<td>33</td>
<td>23</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total contact (participants)</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total contact (attendances)</td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Missing*</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>How many times has your son or daughter been seen in A&amp;E but not admitted to a ward ... ?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>36</td>
<td>35</td>
<td>25</td>
<td>30</td>
<td>19</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total contact (participants)</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Total contact (attendances)</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Missing*</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>How many times has your son or daughter been seen in outpatients appointments ... ?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>25</td>
<td>33</td>
<td>23</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>1</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>NHS Contact related to index condition plus any other condition</td>
<td>Baseline Parent</td>
<td>FU1 Parent</td>
<td>FU1 CYP</td>
<td>FU2 Parent</td>
<td>FU2 CYP</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>----------------</td>
<td>-----------</td>
<td>--------</td>
<td>-----------</td>
<td>--------</td>
</tr>
<tr>
<td>Total contact (participants)</td>
<td>13</td>
<td>2</td>
<td>2</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Total contact (attendances)</td>
<td>19</td>
<td>2</td>
<td>2</td>
<td>27</td>
<td>7</td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

How many times has your son or daughter been seen by the GP in your G.P surgery ... ?

<table>
<thead>
<tr>
<th>How many times</th>
<th>Baseline Parent</th>
<th>FU1 Parent</th>
<th>FU1 CYP</th>
<th>FU2 Parent</th>
<th>FU2 CYP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>19</td>
<td>32</td>
<td>23</td>
<td>25</td>
<td>19</td>
</tr>
<tr>
<td>1</td>
<td>13</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total contact (participants)</td>
<td>20</td>
<td>3</td>
<td>2</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Total contact (attendances)</td>
<td>30</td>
<td>3</td>
<td>2</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

How many times has your son or daughter been seen by the practice nurse in your G.P surgery ... ?

<table>
<thead>
<tr>
<th>How many times</th>
<th>Baseline Parent</th>
<th>FU1 Parent</th>
<th>FU1 CYP</th>
<th>FU2 Parent</th>
<th>FU2 CYP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>34</td>
<td>35</td>
<td>25</td>
<td>31</td>
<td>21</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total contact (participants)</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total contact (attendances)</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

How many times has your son or daughter been seen at home by your GP ... ?

<table>
<thead>
<tr>
<th>How many times</th>
<th>Baseline Parent</th>
<th>FU1 Parent</th>
<th>FU1 CYP</th>
<th>FU2 Parent</th>
<th>FU2 CYP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>39</td>
<td>35</td>
<td>25</td>
<td>32</td>
<td>24</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total contact (participants)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
NHS Contact related to index condition plus any other condition

<table>
<thead>
<tr>
<th></th>
<th>Baseline Parent</th>
<th>FU1 Parent</th>
<th>FU1 CYP</th>
<th>FU2 Parent</th>
<th>FU2 CYP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total contact</strong></td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>(attendances)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>All contact</td>
<td></td>
<td>31</td>
<td>5</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0</td>
</tr>
<tr>
<td>&gt;4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total contact</strong></td>
<td></td>
<td>74</td>
<td>5</td>
<td>4</td>
<td>41&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>(participants)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total contact</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(attendances)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Number of CYP interviewed aged ten or above and with capability.

<sup>b</sup>Calculated as 12 attendances. Parent (N29) reported 12-15 outpatient attendances across a variety of providers (including Birmingham, Nottingham, London, Liverpool, Chester, Oxford) for a range of assessments relating to CYP's condition.

The greatest level of contact occurred with the GP and in outpatient departments.

**Baseline**

Twenty parents reported contact with the GP on 30 occasions within the previous three months. Other contact with primary care was less frequent with five CYP having contact with the practice nurse on six occasions and no reports of home visits by the GP.

Hospital outpatient attendances were recorded for 13 participants on 19 appointments. Admissions to hospital were reported for 7 CYP on 11 occasions. Attendance at A&E departments was rare with 3 CYP attending on 8 occasions.

**Follow-up one (one week)**

Contact with the NHS was reported infrequently at one week follow up. Three parents reported that the CYP had been seen by the GP at the GP's
surgery; two parents reported that their CYP had attended an outpatient appointment.

**Follow-up two (two months)**

Contact with the GP at the GP surgery had been made by eight CYP on 11 occasions. Two CYP had had one appointment by the practice nurse and no one had received a home visit from the GP. Contact with secondary care services again centred on outpatient appointments, 11 CYP attending on 27 occasions. Six CYP attended A&E.

**Discrepancies in reporting between parent and CYP**

There were a number of discrepancies between parents and CYP in the reporting of NHS contact that were included in the follow up interviews. The differences in reporting were most marked at the two month follow up. Two CYP reported an admission to hospital where the parent had recorded none. Six CYP said they had attended A&E but this was reported by only one parent. CYP reported a higher level of contact with the practice nurse (4 CYP, 4 attendances) than their parent (2 CYP, 2 attendances).

**Pharmacy**

Most parents (36) were able to identify the pharmacist that they used to supply the medicines for their CYP. Parents were also asked at observation, follow up 1 and follow up 2 for the number of visits they had made to a pharmacist in the previous four weeks, previous week and in the previous two months, respectively. (see Table 28)

**Table 28. Visits to pharmacy reported by parent**

<table>
<thead>
<tr>
<th>Number of visits</th>
<th>Baseline (n=40)</th>
<th>FU 1 (n=39)</th>
<th>FU 2 (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visited a pharmacy in previous 4 weeks</td>
<td>Visited pharmacy in previous week</td>
<td>Visited a pharmacy in the previous 2 months</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>17</td>
<td>30</td>
<td>14</td>
</tr>
<tr>
<td>1 to 2</td>
<td>18</td>
<td>9</td>
<td>16</td>
</tr>
<tr>
<td>3 to 4</td>
<td>2</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>More than 4</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Range</td>
<td>0-7</td>
<td>0-2</td>
<td>0-5</td>
</tr>
</tbody>
</table>
5.16 Exploratory investigation of the effect of use of the pre-consultation tool

We explored whether use of the pre-consultation tool had any effect within our case studies. As the study was not powered, or designed to carry out this comparison, this is a very exploratory post-hoc analysis to provide any insights possible regarding future intervention design and aspects of study design such as sample size. Of 40 parent-CYP dyads, the 14 who were observed by the researchers to have actively used the pre-consultation tool during the consultation form the p-c tool group described below. Many more parents and CYPs reported using the tool, or its usefulness, but for this exploratory work, we used the “objective” assessment of use from the researchers’ observations.

CYP in the p-c tool group were compared to those not using the tool. Parents in the p-c tool group were more likely to have degree level education (Fisher exact probability = 0.044) and there was a trend for CYP who used the tool to be older (Fisher exact probability = 0.061) but there were no other detectable differences between groups in terms of demographic characteristics (see Table 29).

Table 29. Demographic characteristics of those who did and did not use the p-c tool

<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>Used p-c tool (n=14)</th>
<th>No use of p-c tool (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 to 7</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>10 to 12</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>15 to 17</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td>Condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Congenital Heart Disease</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Diabetes</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td>Main caregiver</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
There were no differences between the groups at baseline in terms of adherence (parent and CYP reported), self-efficacy for medicines taking (parent or CYP reported), locus of control in relation to medicine taking or CHQ scores (Table 30).

Table 30. PCAT, Parent-reported adherence, self-efficacy and CHQ at baseline and two month follow-up for whole cohort

<table>
<thead>
<tr>
<th>Mean parameter (SD)</th>
<th>Used p-c tool (n=14)</th>
<th>No use of p-c tool (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total PCAT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent score</td>
<td>5.88 (0.74)</td>
<td>5.59 (1.52)</td>
</tr>
<tr>
<td>CYP score</td>
<td>5.94 (0.74)</td>
<td>5.56 (1.56)</td>
</tr>
<tr>
<td></td>
<td>5.29 (1.55)</td>
<td>5.37 (1.80)</td>
</tr>
<tr>
<td><strong>Estimated adherence (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>88.3 (20.5)</td>
<td>88.7 (23.5)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>97.3 (3.9)</td>
<td>89.8 (22.3)</td>
</tr>
<tr>
<td><strong>Self-efficacy for medicine taking</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.5 (1.2)</td>
<td>3.5 (3.1)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>3.8 (0.4)</td>
<td>3.6 (0.9)</td>
</tr>
<tr>
<td><strong>CHQ Physiological summary scores</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>48.6 (6.1)</td>
<td>41.1 (19.3)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>44.8 (13.2)</td>
<td>39.0 (19.0)</td>
</tr>
<tr>
<td><strong>CHQ Psycho-social summary scores</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>42.6 (15.7)</td>
<td>46.0 (15.0)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>52.3 (8.8)</td>
<td>47.5 (14.2)</td>
</tr>
</tbody>
</table>

* 1 missing value  b 2 missing values * P<0.05

In order to look at change over time, scores at baseline were compared to scores at 2 month follow-up for each group separately using Wilcoxon tests. There were no significant changes in outcome scores for the non- p-c tool
group but in the p-c tool group there was a significant improvement in psycho-social well-being over time (Z=-2.76, p=0.006). Although the scores for the total PCAT were higher than in the group that used the pre-consultation score this difference was not significance. It did however seem that the lowest scores were more likely to be in the group who had not used the pre-consultation tool. None of the group that used the pre-consultation tool had PCAT aggregate scores below 4 compared to 5 (19%) in the other group. As only one CYP in the p-c tool group was in the 5 to 7 year old group and as CYP in this younger age group did not complete self report measures, analyses were repeated excluding the 5 to 7 year old age group (Table 31).

Table 31. Parent-reported adherence, self-efficacy and CHQ at baseline and two month follow-up (excluding CYP aged 5 to 7)

<table>
<thead>
<tr>
<th>Mean parameter (SD)</th>
<th>Used p-c tool (n=13)</th>
<th>No use of p-c tool (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CYP’s adherence (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>79.6 (33.4)</td>
<td>89.7 (13.7) a</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>91.3 (11.7) a</td>
<td>85.1 (26.8) b</td>
</tr>
<tr>
<td><strong>CYP’s self-efficacy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.6 (0.8)</td>
<td>3.9 (0.3) a</td>
</tr>
<tr>
<td>1 month follow-up</td>
<td>3.7 (0.6)</td>
<td>3.93 (0.3) b</td>
</tr>
<tr>
<td><strong>LOC in relation to medicine taking</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>7.2 (1.7)</td>
<td>6.8 (1.9) a</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>8.0 (2.0)*</td>
<td>7.5 (1.6) b</td>
</tr>
<tr>
<td><strong>Parent’s reporting of CYP adherence (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>87.6 (21.2)</td>
<td>89.4 (21.2)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>97.3 (3.9) a</td>
<td>91.9 (19.9)</td>
</tr>
<tr>
<td><strong>Parent’s reporting of CYP self efficacy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.5 (1.2)</td>
<td>3.6 (1.1)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>3.8 (0.4)</td>
<td>3.6 (1.0)</td>
</tr>
<tr>
<td><strong>CHQ Physiological summary scores</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>49.4 (5.5)</td>
<td>42.1 (18.3)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>44.8 (13.2)</td>
<td>41.0 (18.4) a</td>
</tr>
<tr>
<td><strong>CHQ Psycho-social summary scores</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>44.8 (13.2)</td>
<td>49.62 (14.97)</td>
</tr>
<tr>
<td>Two month follow-up</td>
<td>52.3 (8.8) a **</td>
<td>49.4 (13.5) a</td>
</tr>
</tbody>
</table>
Selecting out for the older CYP in the p-c tool group (age>9), in the p-c tool group, psycho-social summary scores had significantly improved between baseline and two month follow-up ($Z=-2.76$, $p=0.006$) and CYP rated themselves as being more in control of their own health at follow-up compared to baseline ($Z=-2.233$, $p=0.026$). There also appears to have been improvements in ratings of adherence but these failed to reach significance. There were no significant changes in outcomes in the older CYP who had not used the tool.

This very exploratory analysis suggests that parents with higher educational levels, and older CYP may be more likely to use the tool, and this should be taken account of in future intervention design. This very exploratory analysis suggests that parents with higher educational levels, and older CYP may be more likely to use the tool which may suggest that some families may need more support for their use of the tool. Subgroup analysis within the context of a randomised controlled trial may help to explore these issues further. Even in this small, heterogeneous sample with high self-reported adherence, some trends towards improved adherence, psychosocial health and self-rated control of health can be noted.

5.17 Discussion (including illustrative case study vignettes)

5.17.1 User acceptability and feasibility

Fourteen out of 24 practitioners used the tool, 10 found it useful in that consultation. 12/27 CYP used the tool in the consultation, 10 finding it helpful, a further 12 who didn’t use it in the consultation thought it was useful. 17/39 parents used the tool in the consultation, 13 finding it helpful, a further 17 who didn’t use it in the consultation thought it was useful. Thirteen parents thought it would be useful for other patients at different stages of the disease.

Of the 40 parent-CYP dyads, 14 were observed by the researcher to have actively used the pre-consultation tool during the consultation.

A subset of both parents and CYP appeared to find the pre-consultation tool useful and acceptable. They appeared to use it to develop an agenda for discussion about medicines with the practitioner. This approach has been explored more fully in adult patients. We applied this method to the parent-CYP dyad to facilitate increased involvement of both members in the parent-CYP-practitioner triad, and then evaluated the interaction, on a
triadic basis. This approach has not been used very often before. Parent-practitioner interactions have been assessed. Most studies have ignored the implications of a CYP's presence in medical encounters, research methodologies used are usually based on dyads. As Tates et al (2001) suggest “because the interactional dynamics of a triad differ fundamentally from those of a dyad, triadic analyses are a prerequisite for a full account of the communication between practitioner, parent and child.” Use of a triadic method of assessment, such as the PCAT used in this study, is the only way that the limited involvement of the CYP can be characterised and thus adjusted.

Despite extensive piloting and consultation with parents and CYP, feedback from one of the parents approached in clinic said they had thought that the invitation pack was junk mail and another that the paperwork for the study looked too complicated. Feedback after the consultation suggested that some of the parents and CYP were uncertain how to use the pre-consultation tool despite this being explained in the pre-consultation interview. Some thought it was a survey “testing” their use and knowledge of the medicines or a checklist to remind them how to administer their CYP’s medication.

5.17.2 Scope and quality of the consultation

Although there was a wide range of PCAT scores in this sample the overall mean aggregate of 5.69 was rather higher than the mean of 4.78 from 188 consultations with paediatricians. In the Howells study, however, 19 paediatricians were assessed an average of 10 times each which may have resulted in more naturalistic assessments. Parents and CYP expressed varying levels of satisfaction with the consultation, and our evaluations suggested that some consultations demonstrated room for improvement, across primary and secondary care. Research suggests that the quality of the consultation can affect patient satisfaction, adherence to recommended treatments and health outcomes.

We cannot conclude whether the quality of the consultation was affected by use of the pre-consultation tool or practitioner prompt. The observed non-statistical advantage in the group which used the tool is consistent with the prediction that empowering the CYP to participate more fully in the consultation will improve the quality of the consultation. The mean scores of different aspects of the consultation were high, but with variability in the scores of individual practitioners. Parents and CYP aspects were either scored very similarly within an individual consultation, or the CYP aspect scored the poorer, suggesting that consultations were often targeted at the parent.
5.17.3 Implementation issues

It was difficult to co-ordinate the researcher, parent-CYP dyad and practitioner all being in the same place at the same time. Different arrangements were necessary for different clinical settings.

Many of the practitioners did not attend the training session, only attended for part of it, or did not engage with the topic. In one instance, a doctor turned off the replay of the video as he found it “irritating”. It was not possible to assess either baseline knowledge or learning from the session. None of the clinics or practices briefed provided any information for the resource packs. Individual practitioners had varied interest in the intervention, providing briefing or training had very variable success, and there was variable, or no, use of the TABS tools by the practitioner in individual consultation. There is no educationalist on the team. RAE has been teaching adherence to undergraduate and postgraduate pharmacists for 11 years; DC is involved in developing training materials for the RCGP and other members of the research team (AA, WW, AS, CG, SC) are employed in Medical or Pharmacy Schools and are closely involved in undergraduate, postgraduate and work-based training. We also worked very closely with medical educationalists to develop the intervention (see section 5.3.7). Future work in this area would require educational research input.

Communication within clinical teams was sometimes problematic. On several occasions a “briefing” had to be undertaken with a practitioner immediately before the patient’s appointment as the patient had not been allocated to any of the practitioners who attended the training sessions. Clinics and GP practices were informed that the TABS researchers would be attending their clinics to observe the consultation with a particular patient but this information was not usually disseminated to other members of the care team or administrative and reception staff.

Self-reported awareness and monitoring of adherence issues by practitioners in this study is likely to reflect an overestimate of the adherence that occurs in standard practice. There is also dissonance between self-reported practitioner behaviour and both the perceptions of parents and CYP in phase 1 of the study and in published research about adherence. Practitioner training might be enhanced by emphasising the benefits of using pre-consultation checklists (to facilitate the inclusion of CYP concerns) on subsequent psychosocial status, even in the absence of a direct effect on adherence. The use of audit tools that provide direct patient feedback to practitioners may provide them with greater insight into their actual behaviour than conventional training methods. The experiences of variable practitioner engagement in this study are not unusual. A recent review of clinician training programmes found little effect on communication behaviour. Studies with the most adequate designs reported the fewest
positive training effects. In our study, most practitioners had undergone communications training and felt they did not need training. We know that most categories of health professional undergo communications training, although some research suggests that this is a very small proportion of training, individual practitioners’ engagement can be variable, and increasing experience does not automatically improve communication skills. However, we designed our briefing session with communication skills kept in the background, with the subject of CYP’s medicines-taking brought to the fore, as recommended by other researchers.

We were careful to make the briefing context-bound, and held the sessions in the practitioners’ place of work. Due to the brevity of the sessions, we were not able to incorporate case studies for discussion. We know that live media is more effective than print and multimedia is more effective than single media interventions, and used this in our sessions, with variable effect. We also know that paediatricians and general practitioners prefer supporting evidence in the form of randomised controlled trials and expert consensus, presented as algorithms or flow charts/flow diagrams on plastic sheets, pocket cards or handheld electronic devices and we used these sources and some of these media.

In other work, we, and others, have found that an effective alternative to practitioner training is to employ a relevant health care professional within the practice for a significant period of time to allow relationships to form, and sustained contact and discussion around specific patients, and strategies that focus on, and are designed for, the specific patient mix and culture of that specific practice, rather than a didactic generic approach.

5.17.4 Development of the evaluation framework

The ability of the intervention to address previously encountered problems affecting adherence and promote behaviour change was examined within each case study by collecting data at both baseline and at two follow-up points (1 week and 2 months after the consultation). An evaluative framework assessing clinical outcomes and resource consumption was also developed. Generally, we were able to collect the data we needed. In terms of evaluation, all the measures used performed well and appeared to be discriminatory. Obtaining measures of clinical control of the disease from parents or CYP was not always successful, so in future, this measure should be sourced from clinical notes, to allow assessment of the effectiveness of the intervention.
It was difficult to obtain consensus from practitioners about which clinical outcomes were recorded routinely and a useful measure of disease control or adherence. For example, in asthma, night-time awakenings in a week requiring rescue therapy may be a more useful measure than FEV$_1$, a measure often used in research, but not routinely used in practice, especially in young children.

The sample contained dyads from minority ethnic groups and low socioeconomic groups, although these were under-represented. Analysis of baseline data for the whole group revealed high levels of self-reported medicines adherence and self-efficacy and a strong sense of personal control of medicines-taking, but poor physical and psycho-social wellbeing. As expected and in line with previous research, our group of CYP with chronic health conditions had poorer health-related quality of life, as measured by the CHQ-PF28 physical summary scores of life, compared to CYP without a chronic health condition. For the physical summary score CYP our mean of 43 is comparable to that of 45 in a UK sample of CYP with juvenile rheumatoid arthritis and below both US norms and the mean of 55.5 found in a UK normal population. The mean psycho-social summary score of 42.7 was also markedly below US norms and the mean of 51.6 found in a UK sample of healthy CYP.

We were able to collect data for a range of resource use parameters including length of initial and subsequent consultations, NHS contact (primary and secondary care) and medicines consumption. There appeared to be a higher incidence of NHS contact, as reported by CYP, compared with parents. This discrepancy may be due to poor recall, or may be due to social desirability bias, where parents feel that NHS contact is a sign of their poor management of their child’s condition. There were also differences in medicines use (names and doses) reported by CYP and parents, which needed to be clarified with practitioners or by examining actual medicines containers.

5.17.5 Exploratory investigation of the effects of the TABS intervention

At two month follow-up, there was a significant improvement in psycho-social well-being over time in the group that used the pre-consultation tool ($p=0.006$) and CYP rated themselves as being more in control of their own health at follow-up compared to baseline ($p=0.026$). There were improvements in adherence but these failed to reach significance.
There was a non-significant decline in physical wellbeing over time but the in the group of CYP who had used the pre-consultation tool, CHQ-PF28 psycho-social summary scores had increased by an average of nearly 10 points. This difference is statistically significant (p=0.007) and also clinically significant since a mean change of five points is considered meaningful difference. There was no change in psycho-social wellbeing in the non- p-c tool group and although one cannot infer any causation from these findings it is notable that the baseline psycho-social summary scores between the groups were very similar suggesting that CYP in the p-c tool group were not more advantaged in terms of mental health at baseline. Furthermore there was no overall improvement in mental wellbeing.

Interestingly, the mean improvement in sense of control at one month follow-up in a randomised trial of an educational intervention for children with asthma was 0.8 in the intervention group, comparable to the present study. The control group in that study showed a very small decrease in self-ratings of control at follow-up suggesting that the scale is sensitive to change. There is some evidence, therefore, that the pre-consultation tool increased the CYP’s sense of control over medicines-taking. Improved mental health and sense of personal control over illness are important since a more positive self-concept and internal locus of control have been shown to be associated with better adherence in CYP with asthma. A related concept, self-efficacy, has also been shown to be associated with better adherence but self-efficacy did not improve in this study which may reflect a ceiling effect in the brief 2 item scale.

Increases in both CYP and parent ratings of percentage adherence were observed in the group that used the pre-consultation tool but these differences were not significant, possibly due to the small sample sizes. The change was particularly notable in the CYP ratings where adherence had increased in the p-c tool group but declined in the non p-c tool group. Evidence suggests that for CYP in the 10 to 11 age range percentages are an effective way of conveying risk, lending validity to these findings.

We must not over-interpret the improvements found with the TABS pre-consultation tool. The parents and CYP who chose to use the pre-consultation tool may well have been highly motivated and destined to succeed, with or without the tool.

5.17.6 Limitations of the study

We worked with ten clinical sites, who sent out 736 information packs to recruit parent-CYP dyads to Phase 2. Of these, we recruited 40 parent-CYP dyads. There were difficulties around identifying parent-CYP dyads and knowing if the packs had been sent out. We had no control over the selection of patients, by the clinical sites, due to R&D restrictions, although we did ask for patients with poor adherence (see section 5.10). We agree
that this has reduced the potential utility of the intervention. Some clinical sites sent out invitation packs to people who did not fit the inclusion criteria, and we had no control over this process, due to R&D restrictions. This contributed to the increased length of time taken to recruit, reduced relevance of potential patients to the intervention, and the ultimate reduction in numbers recruited to the study.

We requested that clinical sites selected patients that they suspected were not adhering to medicines, but we had no control over this. We feel the high rate of reported adherence was caused by lack of appropriate selection of patients by clinical sites; participation in the study selecting dyads who are already more interested in their medicines and may be more adherent; social desirability bias leading to unwillingness to admit to non-adherence by patients, parents and practitioners. From our experience, it takes skill to present non-adherence as a “norm” in medicines use behavior, such that CYP and parents feel they can disclose real behaviour. We have reviewed the literature on adherence and the adherence levels reported here are much higher than in non-intervention studies.

The study was not designed to test differences or the effectiveness of the TABS intervention. Due to the time constraints of the study we were not able to schedule or attend a follow-up consultation, so the longer term usefulness of the intervention could not be studied.

5.17.7 Future development of the TABS Tool

We had no control over which patients were recruited to the study, leading to a sample of CYP with high levels of adherence. This has substantially reduced the ability to demonstrate the utility of this intervention.

Despite this, our study suggests that the parent/CYP pre-consultation tool was quite successful and acceptable, whereas the practitioner briefing and prompts were not always so successful.

Future versions of the pre-consultation tool could be designed more simply, and take into account the social context of the user, for example, delivering it via mobile phone technology. It could also become more integrated in care pathways, such as incorporating the CYP responses and any resultant action plan into the GP PMR.\(^{239}\)

One improvement might be to target the pre-consultation tool to parent-CYP dyads with specific triggers:\(^{2}\)

- Early in the lifetime of the illness as suggested by our research.
- Initiating treatment for newly prescribed medication.\(^{241}\)
• Where sub-optimal adherence is suspected by the practitioner, or reported by the parent-CYP dyad, although it is not clear that this improves effectiveness from our literature reviews.

We did not provide feedback to the practitioners on the quality of their interaction with the parent-CYP dyad, which, in a future study, may prove more effective as a vehicle for behaviour change, than a brief training intervention alone.251

Future versions of the TABS intervention may be more effectively delivered by a nurse or a pharmacist, the latter may be feasible given that 90 percent of our parent-CYP dyads had a named regular community pharmacist, and made regular visits to their pharmacy. The case study data we have generated could provide future educational vignettes for use with practitioners.

From this early work, we would recommend that a future version of this intervention has the following characteristics:

• Ensure all members of triad understand the purpose of the tool,
• Encourage parents and CYP to complete tool beforehand,
• Make sure practitioner has had a briefing about the intervention,
• Ensure that the CYP or parent hands pre-consultation tool to practitioner at the beginning of the consultation,
• Do not exclude the parents of older CYP from discussions,
• Do not exclude younger CYP from discussions.

We also suggest that the tool is targeted at CYP starting a new medicine for a chronic condition, or where poor adherence is suspected by practitioners (or parents).

5.17.8 Illustrative case study vignettes

The case study vignettes in this section have been selected to illustrate each disease group, age group, setting and sex.

Case study 01 (15 year-old young man with diabetes, seen in secondary care)

This young man attended clinic with his father. He has only been diagnosed with diabetes for approximately 8 months and has only visited the clinic a couple of times. The pre-consultation tool and CHQ-PF28 were completed by the parent and child before arrival at the clinic. These were brought along for the appointment by both the young man and his father.
During the consultation, many issues were explored. The consultant asked about units of insulin used and how units may change when drinking alcohol. S/he also spoke about having low blood glucose readings in the evening, before bed and how the dose should alter and what dose this related to. S/he also spoke about the young man moving to a transition clinic and told him that at his next appointment he would be asked if he would like to go into the consultation by himself and explained why.

The father was asked if he had any questions/issues, and he raised problems with supply from the pharmacy. The consultant offered no advice/reply to this, and just acknowledged his concern. The PCt was not used during the course of the consultation.

Two month follow-up: It became apparent at this point that the young man’s parents are separated and that although the father regularly attends clinic with him and engages in his health care, he does not live at the family home. The mother had not been present at the clinic appointment, but was assured that it had gone well as her son had not reported adversely. The mother did not know the names of the insulin that her son was using.

The patient reported that there had been no changes to the medication regimen since the clinic appointment; no contact with NHS and just one visit to the local pharmacy. Mother reported that there had been a medicines use review with the GP since the last hospital appointment (this was not part of the young man’s recall.)

Although the p-c tool had not been used overtly during the clinic consultation, the young man reported that he had asked the clinician a couple of questions that were a direct result of having received the p-c tool prior to the clinic appointment.

**Case study 15 (5 year-old boy with asthma, seen in secondary care)**

Father and son attended for clinic at the requested time. Before the consultation, the father claimed that although the boy had been prescribed Symbicort, the “health visitor” should have been to the house to demonstrate its use, but “had not bothered to turn up,” therefore the child had not used the medication. The TABS forms had been completed at home, but not brought to appointment as a sibling was unwell, creating disruption at home.

Two secondary care professionals were observed (P1 and P2), who shared the boy’s care. Neither referred to the practitioner prompt: P1 did not think of using it and was under time pressure. P2 didn’t use the pre-consultation tool as s/he was “engrossed” in the consultation.

Discussion with P1 around medicines was focussed on the child, with P1 referring to the father for clarification or where information (given or received) was most appropriate for the parent. In contrast, the consultation process with P2 focussed almost solely on the parent; the child was virtually ignored - even during an examination. The style of the interaction was abrupt, argumentative and confrontational, with both participants becoming somewhat loud during the discussion. P2 challenged the father about the use of the inhaler, and the father’s smoking. The father responded with the difficulties of getting hold of anyone in the clinic. P1 joined the consultation and although the “tone” mellowed, P2 was still abrupt with the father. Concern was expressed about the child’s use of the inhaler and it was finally agreed that the father would arrange a time for someone from clinic to visit them at home.
During the encounter, the child played alone quietly with the toys in the corner of the consulting room.

Two month follow-up: Follow up visit with the father, who was very angry with the quality of care his son was receiving from P2, and disagreed with P2 about the medication his son should be taking, refusing to give him the azithromycin prescribed. He felt that information given about his son’s medication was too vague and needed more structure.

The father had not found the pre-consultation tool useful, but thought that it might be helpful for someone who was new to the illness.

**Case study 20 (17 year-old young woman with asthma, seen in primary care)**

The young woman and her mother attended the appointment together. Both went into the consultation. The young woman did most of the talking, and the doctor spoke to her. The mother spoke at points to prompt the young woman about things she had said at home that were relevant, or that she had wanted to ask. During the consultation the young woman spoke about her asthma, the contraceptive pill which she was taking, and a problem which she was experiencing with her ear/hearing. The doctor asked about when the young woman used her inhalers/pill, and how she should be using/taking them. The pre-consultation tool was not used. The doctor had assumed that the patient would use it.

Two month follow-up: The young woman has recently left school and started work. She had just arrived home when the interview took place. She felt that the pre-consultation tool had not helped with the consultation, later saying: “At my age, you don’t need a list - you already know what to ask”. She thought that children should start taking more responsibility at about 13 or 14; she has been visiting the GP on her own for the last 3 or 4 years. The major challenges she faced with her medication was forgetting: “[I] recently started work and I’m too busy to take my medication”. She felt her asthma was getting worse, despite later reporting her adherence as 99 percent.

The mother said that she had not used the pre-consultation tool, and that the consultation had made no difference to her daughter’s management of her medication. She has left the responsibility to the daughter, although she does have to remind her to get the prescriptions. Both mother and daughter were vague about the medication that the young woman was taking.

**Case study 29 (7 year-old female with epilepsies, seen in community care)**

The girl, her mother, and her mother’s partner attended the clinic. This young girl also has cerebral palsy, vision difficulties, and challenging behaviour. The mother and partner both said that they were dyslexic, and experienced some difficulty in completing the paperwork and had assistance to do so. The consultation took place in a large consulting room, with a number of toys, paper and crayons for the children. Throughout the consultation, the young girl played with the toys and spent time drawing. She interacted with the doctor (and researcher) as well as her parents.
The consultant established a rapport with the girl from the beginning of the consultation and spent some time talking to her, playing with her, being supportive, giving her encouraging feedback: cheering and clapping when the girl was able to catch or throw a ball, identify and name colours, and point to and name different parts of a doll. Discussion centred mainly on the patient’s change in behaviour since a recent brain operation, and on the reduction in seizures from 5 to 20 a day to none since the surgery. They agreed to a “washout” of melatonin for one week, and to reintroduce if necessary. The mother had not used the pre-consultation tool as “we just talked about it anyway”, but also said that it had been useful: “jotting things down helps”. The consultant forgot to use pre-consultation tool or prompt.

Two month follow-up: The mother said that her daughter had started taking responsibility for her medicines at age 3: “Then the epilepsy got worse and we had to force feed her.” She felt that professionals could help children with their medication. She also felt that they could make medicines taste better “make them with no taste or chocolate – what kid doesn’t like chocolate?” The mother also mentioned that “they never teach you how to give them (medicines), different ways ...”. The mother explained that she and her partner sometimes had to “pin down” her daughter to get her to take her medicines: it is not easy for M to get C to take her medicines but she is confident that she can do so. There have been no problems in getting hold of the medicines from the pharmacy. There has been no change in her daughter’s medication since the observation, but the mother will discuss giving her daughter diazepam, to calm her down at her next consultation with the consultant. She was also planning to wean her daughter off rufinamide, and informed the consultant of her intention.

She gave a qualified “yes” to using the pre-consultation tool but said “I do it my way” and that, for her, it was easier to have had it read out to her but it did help. She explained that she cannot read and write “so it depends on someone reading it to you”.

Case study 40 (15 year-old male with CHD, seen in secondary care)

The patient attended clinic with his mother. The young man uses an electric wheelchair. The mother had difficulty in completing the CHQ. YP is confined to a wheelchair, and M felt that a number of the questions were not applicable. The young man has Duchenne muscular dystrophy. His heart condition was identified while taking part in a study at another hospital.

The practitioner did not introduce themselves, or the medical student also present. The young man and his mother were not asked if they agreed to presence of medical student. The practitioner seemed weary, and the consultation was mostly a series of closed questions. The practitioner concentrated on the young man, during the consultation even when his mother answered.

The practitioner suggested an increase in the patient’s medication and the young man became adamant that he did not want to increase the medicine: “Can’t have any more ... wouldn’t be a good idea”. The practitioner and his mother tried to persuade him, but did not explore the reasons for his refusal. The practitioner explained that the young man was on a small dose for his size. They eventually agreed to “leave things as they are” and review in six months, or compromise and increase the evening dose only.
Two month follow-up: The young man refused to take part in the interview; the mother had tried asking him on several occasions, and was very apologetic. The mother appeared quite weary throughout the meeting.

The mother didn’t use the pre-consultation tool as she knew what questions she was going to say. For her, the consultation “...is about the same thing every time...” She could not remember any action points agreed, but said that the dosage of her son’s medication had increased: the dosage he had been on “was not sufficient to help his condition”.

The mother didn’t know what age young people should take more responsibility for their medication - “when they are capable” - and could not think of any way in which healthcare professionals could help children and young people to take responsibility “… depends on the child ... if they are responsible enough ... but they always need their parents to remind them.”. She thought YP would be moving to adult services at 18 and did not see any challenges ahead for him when he left school.

6 Conclusions and recommendations for future actions

CYP with long-term illnesses face a range of challenges presented by the illness, their medicines and the family, social, cultural and healthcare context within which they function. This occurs against a background of developmental changes, and within the complex dynamics of a constantly evolving relationship with parents/caregivers.
Reasons for the CYP’s non-adherence are usually subsumed by the parents’ and practitioner’s agenda. The effectiveness of the practitioner in supporting the parent and CYP needs to be improved, particularly in more accurately and sensitively assessing the level of responsibility for medicines taking taken by parent or CYP, making more effort to involve the CYP. Parents were often very distressed by their CYP’s illness, and generally were very closely involved in management, irrespective of age. Practitioners need to acknowledge that parents generally care deeply about their CYP’s health, so should not be too hasty in excluding the parent from management discussions, without assessing the individual situation.

We have proposed an intervention that, with further development, may improve CYP’s involvement in discussions and decisions about medicines-taking, and this could lead to improved medicines-taking and associated health benefits.

The strength of this study was that we were able to investigate the behaviour of the TABS tool in a range of clinical settings, being used by different practitioners, disease areas, disease severity and age groups.

6.1.1 Reflections on the approach of this study

This study used a range of methods, and a range of overlapping literature to address the study objectives.

The advantage of this approach is that the different sources informed the objectives differently. For example, the use of published evidence in combination with focus group and interview data provided a much richer view of reasons for non-adherence in children and young people, and an increased relevance for the local context, given that most evidence was not based in the UK. The disadvantage of this approach is the large amount of data available, the extent to which evidence from different sources can be synthesised, and the subjective nature of interpreting data of this type. The resultant interpretation was reliant upon the perspectives, experience and expertise of the research team. The interpretation of these data was validated with a range of stakeholders, and an Expert Advisory Panel. Involvement of stakeholders throughout this project has enabled us to ensure that the research is relevant and accessible.

Examination of the published evidence combined with primary data to determine barriers and facilitators for medicines-taking in Phase 1 provided an essential basis for intervention design, approaches for practitioner briefings, and content for intervention paperwork.
We planned an innovative, evidence-based approach to managing medicines in CYP with chronic illness, by investigating the role of the triad of parent, CYP and practitioner. This meant that we had to observe and evaluate the TABS-based intervention, which introduced a level of complexity to the research process, and artificiality to the intervention process. However, this was a successful approach and we would repeat this method in future work.

6.1.2 Reflections on the impact of R&D approval processes

Implementing the primary research in two phases was intended to allow the interviews and focus groups to inform intervention design, before testing it in Phase 2. This was partially successful. Unfortunately, we were delayed significantly by two sets of transitional NHS R&D process changes, such that our researchers were taken away from field work in order to complete the approval processes.

Due to the significant delays and uncertainties in the approval processes, other than NHS ethical approval, we started Phase 1 five months late. The period for running these groups now overlapped with Christmas 2008, when NHS clinics are busy and running on limited numbers of staff. This means we were unable to recruit over the period, and we required a further month to complete the groups. This meant that this phase was completed six months behind schedule.

We experienced further external delays in project approval for Phase 2 of the study. The delay occurred because we had been informed during the ethical approval process for Phase 1 that we would not require a separate application for Phase 2, but that it would go through as an amendment. This advice was subsequently altered and we had to submit a full new application for Phase 2. The delays we experienced as part of Phase 1 R&D approval occurred because of the lack of organization, resource, clarity or consistency of the process between the four PCTs and hospital Trusts. We were advised that this was caused by a lack of a standardized system in place, and that once the CSP system was running, we would not experience this same labour intensive activity. However, when we applied for R&D approval from the same organizations for Phase 2, the CSP system, although in place, was clearly undergoing serious set-up problems. We had to negotiate with different individuals from those involved in Phase 1, and a different set of rules and requirements from Phase 1. Therefore, we experienced further lack of organization, resource, clarity or consistency of the process between the four PCTs and hospital Trusts.
This necessarily reduced the time spent working with clinical sites to ensure appropriate recruitment of patients, appropriate briefing of practitioners, and removed our ability to schedule a follow-up consultation. Furthermore, we had no control over which patients were recruited to the study, leading to a sample of CYP with high levels of adherence. This has substantially reduced the ability to demonstrate the utility of this intervention.

This study has failed to deliver as we would have wished, mostly due to the Pythonesque experience the TABS team, a group of people highly experienced in running NHS-based research, had with a chaotic, disorganised and changing R&D system, such that we spent a lot more time on process, rather than research. This was frustrating, demoralising and led to a substantive waste of public money due to extensions required, waste of our intellectual input, and a waste of the support of the substantial numbers of stakeholders. We would urge policymakers to reflect on the fatally negative effect NHS research governance has had on this study, and possibly others.

6.2 Implications for future research

6.2.1 Evidence syntheses

There are key gaps and limitations in the evidence around facilitators and barriers to medicines-taking in CYP. Apart from variations in quality of studies, there was uneven distribution of the numbers of studies examining each theme, from over 50 examining social context (impact of family structure, friends, peer groups, media) to five looking at educational context. Most of the research is from the USA, so application to the UK context may be variable, and studies in asthma dominate, meaning that there is less evidence for other key illnesses. There are some studies in diabetes and epilepsy, but only three in heart disease. It is not clear how research carried out in one disease type can be applied to other diseases.

Synthesis of the data is complicated by different countries of origin, study designs, use of different and overlapping age ranges, use of different measurements and estimates of adherence and other parameters such as knowledge and socio-economic status. This was compounded by the general lack of use of validated measures of adherence. Self-report or parent-report were the most common measures used, which generally overestimate adherence.

Most studies examined parent report of factors rather than CYP report, consequently, it is not often known what is important to CYP. Where both parents’ and CYP’s views or behaviour were examined, there is a suggestion that these are likely to differ.
Few studies examined the association between multiple factors and adherence behaviour. Therefore it is difficult to assess the relative importance of individual factors. For example, very few of the studies, other than the 44 studies that specifically examined age, controlled for effect of age. Where multiple regression techniques were used, studies tended to measure a subset of factors, rather than the full spectrum of possible factors.

### 6.2.2 Further development of TABS tool

Parents and CYP generally welcomed and completed the pre-consultation tool across all settings, age groups and disease types in the study. Future versions of the pre-consultation tool could be designed more simply, and take into account the social context of the user, for example, delivering it via mobile phone technology.

It could also become more integrated in care pathways, such as incorporating the CYP responses and any resultant action plan into the GP PMR. Future versions of the TABS intervention may be more effectively delivered by a nurse or a pharmacist.

In terms of evaluation, all the measures used performed well and appeared to be discriminatory. Obtaining measures of clinical control of the disease from parents or CYP was not always successful, so in future, this measure should be sourced from clinical notes, to allow assessment of the effectiveness of the intervention.

One improvement might be to target the pre-consultation tool to parent-CYP dyads with specific triggers:

- Early in the lifetime of the illness as suggested by our research.
- Initiating treatment for newly prescribed medication.
- Where sub-optimal adherence is suspected by the practitioner, or reported by the parent-CYP dyad, although it is not clear that this improves effectiveness from our literature reviews.

From this early work, we would recommend that a future version of this intervention has the following characteristics:

- Ensure all members of triad understand the purpose of the tool,
- Encourage parents and CYP to complete tool beforehand,
- Make sure practitioner has engaged with the concepts, feels ownership over the process and has had a briefing about the intervention,
• Ensure that the CYP or parent hands PCT to practitioner at the beginning of the consultation,
• Do not exclude the parents of older CYP from discussions,
• Do not exclude younger CYP from discussions.

Any future version of the TABS intervention needs to better address the challenges of practitioner engagement and education, but from our experience in this study, ways need to be found to enable practitioners to better support medicines use in this age group. We encountered initial enthusiasm by practitioners, and acceptance that medicines use was suboptimal. This was succeeded by lack of engagement in the practice situation. This may illustrate the complexities in introducing a new tool into practice that needs new ways of working, and is trying to change the power dynamic between CYP, parents and practitioners. The lack of engagement by practitioners in this study appeared to result in parents becoming resigned to not being listened to. However, where the tool was used during the consultation, there was evidence of behaviour change, which is encouraging for any future work.

Further work is needed to assess an optimal method of delivery of the TABS intervention.

To target the intervention more effectively, future studies should target parents and CYP either earlier in the disease course, when the parent, CYP or practitioner may be more willing to engage, and once the disease is established, the tool may be used to maintain adherence.

Key research needs in this subject are:

1. Better understanding of CYP-parent-practitioner interactions and their influence on adherence;

2. Better appreciation of the needs of CYP as they age and develop, keeping a regular dialogue with age-appropriate updates on medicines;

3. Methods for effective practitioner engagement and education;

4. Simpler design and CYP-centred delivery of the TABS pre-consultation tool, and integration in care pathways, such as incorporating the CYP responses and any resultant action plan into the GP PMR, and targeting CYP earlier in the disease;

5. Future NICE guidance should include advice relating to CYP
6. Research governance procedures should be examined such that study design of ethically appropriate studies is not compromised unnecessarily, with associated waste of public sector research resources.

6.2.3 Implications for policymakers

The good health of CYP is crucial to maintaining economic and social stability. They are the parents and carers of the near future: an increasingly scarce and valuable resource in the context of an ageing, increasingly dependent wider population.

The body of work in this report encompasses literature reviews, interviews, focus groups, intervention development and feasibility testing. Reasons for non-adherence in CYP have been well-researched, but this evidence is not used to inform practice or policy. The evidence from this study is that non-adherence to medicines is significant in CYP with chronic illness, and likely to have long term health and economic impact as the individual moves into adulthood. Increased emphasis on tackling this situation is required in future policy around paediatric, adolescent and transitional health services. Despite the small sample and heterogeneous nature of the participants in our intervention feasibility study, it is clear that most issues around adherence in this age group cut across disease type, medicines prescribed, clinical setting and type of practitioner involved. There also needs to be an assessment of whether current health professional training and competency frameworks prepare the practitioner appropriately for supporting this population.

Given the emphasis on evidence-based medicine, clinical guidelines and prescribing quality assessment in today’s health care environment, the engagement of the patient, at whatever age, is essential for these initiatives to be effective. Previous initiatives have been intermittent, optimistic, not patient-centred, short-lived and poorly evaluated. Given that recently proposed reforms aim to ensure an increased patient focus in the NHS, policy makers need to consider whether health policy arising out of current NHS reforms makes any real, focused, pragmatic, evidence-based or patient-centred effort to improve medicines-taking. Future NICE guidance on adherence should include advice for CYP.

6.2.4 Implications for practitioners

Practitioners from all professions who talk about medicines need to take account of the complexity of the situation when dealing with the parent-CYP dyad. There is a perception on the part of some practitioners that they are dealing with medicines issues, but this is not evident in published literature, or from our primary work. Flexibility to deal with different reasons for non-
adherence, increased efforts to empower the CYP to voice their agenda and promote honest disclosure of medicines-taking behaviour, and sensitivity to the level of parental involvement wanted within a specific family are essential if practitioners are going to improve their ability to enhance medicines-taking in this population.

Specific recommendations for practitioners are:

- Be aware of the importance of the CYP-parent-practitioner interaction for parents and CYP;
- Be aware of the challenges associated with eliciting honest disclosure of medicines-taking behaviour from both CYP and parents;
- Be aware of the needs of CYP as they age and develop, keeping a regular dialogue with age-appropriate updates on medicines;
- Do not exclude the parents of older CYP from discussions;
- Do not exclude younger CYP from discussions.

### 6.2.5 Implications for service users

Service users in this context are both parents/caregivers and CYP. It is clear from this study that service users have a complex set of relationships with each other, their medicines and their practitioners. It is also clear that, in many cases, CYP are not contributing to the discussion and decision-making processes around medicines that they themselves are taking. This does not appear to be confined to one disease, age group or practice setting. Parents of older CYP (adolescents) appear to be requesting more involvement in managing their CYP’s medicines, they felt marginalised or excluded by practitioners who were keen to move quickly to transfer responsibility to the CYP. The relative rights and responsibilities of parent and CYP with regards to medicines-taking is relatively under-researched, and not explored within a practice context. CYP and their parents need to be supported to discuss medicines more openly with one another, and be supported in presenting their issues to their practitioner.
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7 Appendices

7.1 Search methods for identification of explanatory studies (EMBASE, MEDLINE and PsycINFO)

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7.2 Summary of evidence around factors affecting adherence to medicines in children and young people

Person factors
1. Severity and duration of illness
2. Forgetting
3. Self-efficacy, roles, empowerment, rights and responsibilities
4. Psychological functioning of child and parent, including presence of depression
5. Transitional concerns and impact of age
6. Use and sources of information, incl parental knowledge
7. Impact of educational levels

Regimen factors
8. Side effects
9. Complexity of regimen
10. Ability to use medicines
11. Palatability of regimen
12. Access to medicines, including off-label use

Context factors
13. Beliefs and expectations, experiences and concerns about disease and medicines (child and parent), incl stigma
14. Social context (impact of family structure, friends, peer groups, media)
15. Financial context (impact of socio-economic status)
16. Cultural context (impact of racial/ethnic or cultural background)
17. Educational context (impact of school)
Relationship factors

18. Parent-child dyad interaction and communication
19. Provider-child dyad and parent-child-provider triad
20. Child and parent interaction with the health system in community, primary and hospital care from initial contact to medicines supply, and over time
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<tr>
<td>Severity and duration of illness</td>
<td>20 studies. ADHD (3)(^1)-(^3), asthma (3)(^4)-(^6), bipolar disorder (2)(^7)-(^8), diabetes (3)(^9)-(^11), epilepsies (2)(^12)-(^13), HIV (2)(^14)-(^15), juvenile idiopathic arthritis (2)(^16)-(^17), and renal transplant (2)(^18)-(^19),(^20). Studies were from the USA (10), Finland (4), Canada (2), Iran (1), Taiwan (1), UK (1), Uganda (1). All studies quantitative, a minority using multivariate regression techniques to identify an independent effect. Most used non-validated methods to measure adherence.</td>
<td>Severity: ★ ★ ★</td>
<td>Effect of different age groups</td>
<td>Asthma: 3 studies CHD: none Diabetes: 3 studies Epilepsies: 2 studies 7 studies looked at adolescents and young people (13-22) 5 studies looked at the whole age range (2-21), and 8 studies did not quote an age range. No study examined explanatory factors by age.</td>
</tr>
<tr>
<td>Forgetting</td>
<td>21 studies. acute lymphoblastic anaemia (1)(^21), ADHD (2)(^22)-(^23), asthma (7)(^24)-(^30), diabetes (1)(^31), HIV (4)(^32)-(^35), malaria (1)(^36), spina bifida (1)(^37), hepatic (1)(^38), and renal transplant (3)(^19),(^20),(^39). Studies were from the USA (11), Australia (1), Brazil (1), Canada (1), China (1), Ivory Coast (1),</td>
<td>Child’s report: ★ ★</td>
<td>Effect of different age groups (one study found link)</td>
<td>Asthma: 7 studies CHD: none Diabetes: 1 study Epilepsies: none 1 study looked at children under 3, 1 study had an age range of: .5 to 7, 4-9, 5-12,</td>
</tr>
</tbody>
</table>
Netherlands (1), Poland (1), Taiwan (1), Uganda (1), UK (1). Six studies were qualitative and 15 were quantitative, three of these using multivariate regression techniques. Most used non-validated methods to measure adherence.

| Self-efficacy, roles, empowerment | 18 studies | † self efficacy†
Adolescents: † self efficacy†
Parent reporting of children’s self-efficacy ⇩
Parent’s reporting of own self-efficacy ⇩ | Few good quality studies
Strength of associations not clear | 8-9, 4 studies looked at adolescents, 9 studies looked at the whole age range (2-21), and 2 studies did not quote an age range. Two studies reported that forgetting was more common in adolescents than in younger children. No other studies examined explanatory factors by age.

Asthma (4),\textsuperscript{40-43} diabetes (6),\textsuperscript{10;44-48} epilepsy (1),\textsuperscript{12} heart lung transplant (1),\textsuperscript{49} HIV (2),\textsuperscript{50;51} JIA (2),\textsuperscript{52;53} renal failure (1)\textsuperscript{54} and TB (1).\textsuperscript{55}

Eleven studies were from the US. Other studies came from Hong Kong (1), Netherlands (1), Finland (4) and UK (1). All studies were quantitative and the majority (9)
used multivariate statistics. Thirteen studies were less than 10 years old.

Risky behaviour: 11 studies asthma (2), heart transplant (1), HIV (1), TB (1), diabetes (4), epilepsy (1) and a range of chronic conditions (1). Four studies were conducted in the USA, 6 in Finland and 1 in the UK. All were quantitative and only 2 used multivariate statistics

Most used non-validated methods to measure adherence

| Psychological functioning of child and parent, including | Six studies: diabetes (2), epilepsy (1), HIV (2), oppositional disorder (1), renal transplant (1), sickle cell | Presence of anger in child  
|---|---|---|---|---|

<table>
<thead>
<tr>
<th> </th>
<th>Drinking alcohol ?</th>
<th>Smoking ?</th>
<th>Poor eating attitudes ( \diamond )</th>
<th>Lack of exercise ?</th>
<th>Earlier age at first marijuana use ?</th>
<th>Sexual activity( \Rightarrow )</th>
</tr>
</thead>
</table>

11-19 (1); 12-24 (1); 16-24 (1); adolescents (3) No study examined explanatory factors by age Asthma: 2 CHD: 1 (heart transplant) Diabetes: 4 Epilepsies: 1 These behaviours may be a proxy for adolescence, and non-adherence may also be mediated by adolescence. However, all studies were carried out in adolescent populations.

| &nbsp; | Asthma: none CHD: none Diabetes: 1 |

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| presence of depression | anaemia (1).[^62]  
All papers were less than 10 years old and from USA  
All were quantitative, 4 of which stated use of multivariate regression techniques. | Depression ? | association s not clear | Epilepsies: 1  
Age ranges: 0-21 (1); 4-13 (1); 8-19 (1); 12-18 (1); 13-18 (1); 16-24 (1) |
|---|---|---|---|
| Transitional concerns and impact of age | 44 studies.  
ADHD (5),[^1-3;22;23] asthma (7),[^41;63-68] cancer (1),[^69] cystic fibrosis (2),[^70;71] diabetes (5),[^11;56;72-74] epilepsies (2),[^13;75] hepatic transplant (1),[^76] HIV (9),[^14;33;59;77-82] heart transplant (2),[^83;84] JIA (1),[^16] leukaemia (1),[^85] psychiatric disorders (1),[^86] renal transplant (3),[^20;87;88] sickle cell anaemia (1),[^89] TB (1),[^90] and bipolar disorder (2).[^7;8]  
Studies were from the USA (31), Canada (2), Taiwan (2), Australia (1), Brazil (1), France (1), Iran (1), Italy (1), Ivory Coast (1), The Netherlands (1), South Africa (1), Thailand (1).  
33 of the 44 papers were less than | Increased age: ♦ ♦ (?)  
 NotImplemented: ♦ ♦ optimism: ♦ ♦ sense of normalcy: ♦ | Strength of association s not clear  
Effect of transition between different age groups | Asthma: 7  
CHD: 2 (Tx)  
Diabetes: 5  
Epilepsies: 2  
1 study looked at children 0-12, 0-17 (2), 0-18, 0-25, 1-11, 1-13, 1-19, 2-12 (2), 2-18, 2-21, 3-18, 5-16, 5-17, 5-18, 5-20, 6-12 (2), 6-13, 6-17, 6-21, 7-14, 7-17, 7-22, 8-13, 8-16, 8-17, 8-18, 8-22, 9-16 (2), 9-19, 10-17, 10-19 (2), 12-18, 12-19, 12-20, 13-18, 15-31, 16-23, 16-32. 5 studies looked at |
Most studies were from the USA, so relevance to UK behaviour is not clear. Three studies were qualitative, three used mixed methods, and 38 were quantitative, ten of these stating use of multivariate regression techniques.

Most used non-validated methods to measure adherence.

<table>
<thead>
<tr>
<th>Use and sources of information, incl knowledge</th>
<th>Strength of associations not clear</th>
<th>Effect of different age groups</th>
<th>Sources of information</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 studies. ADHD (3), asthma (9), cancer (1), congenital heart disease (1), cystic fibrosis (1), diabetes (1), epilepsies (3), HIV (3), malaria (1), renal transplant (3), UTI, multi-condition (1).</td>
<td></td>
<td>Asthma: 9</td>
<td></td>
</tr>
<tr>
<td>Studies were from the USA (12), Hong Kong (2), UK (2), Australia (1), Brazil (1), Canada (1), China (1), France (1), Ireland (1), South Africa (1), Taiwan (1), Zambia (1).</td>
<td></td>
<td>Diabetes: 1</td>
<td></td>
</tr>
<tr>
<td>18 of the 25 papers were less than 10 years old.</td>
<td></td>
<td>Epilepsies: 3</td>
<td></td>
</tr>
<tr>
<td>1 study looked at children 0-5, 0-12 (2), 0-15, 0-21, 1-11, 2-16, 2-21, 3-13, 3-17, 4-21, 5-10, 5-13, 5-20, 6-12, 7 + 12, 7-14, 7-16, 8-13, 8-18, 9-16, 9-19, 11-18, 12-18. 4 studies looked at children 0-12, 17 studies looked</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Most studies were from the USA, so relevance to UK behaviour is not clear. Three studies were qualitative, one used mixed methods, and 21 were quantitative, nine of which stated use of multivariate regression techniques.

Most used non-validated methods to measure adherence.

## Impact of educational levels

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Impact</th>
<th>At Adolescents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low child educational level</td>
<td>Very poor evidence</td>
<td>at adolescents (ages anywhere between 13 and 19), 5 studies looked at the whole age range for the TABS study (5-17), 1 study no age range</td>
</tr>
<tr>
<td>Low parent educational level</td>
<td>Effect of different age groups</td>
<td></td>
</tr>
<tr>
<td>School environment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 11 studies

- ALL (1), asthma (4), epilepsy (1), HIV (1), acute otitis media (1), renal transplantation (1), ADHD (1)

These papers were taken from Brazil (1), Israel (1), USA (5), Taiwan (1), China (1), South Africa (1), Australia (1)

All studies were quantitative, six of these using multivariate regression techniques. Only one of the studies was 10 years old or more, so the evidence base is relatively current.

Most used non-validated methods to measure adherence.

### Educational Levels

- Asthma: 4
- CHD: none
- Diabetes: none
- Epilepsies: 1

### Age Ranges

- Asthma: 18 months to 7 years (1); 2-16 (3); 3-18 (1); 5-13 (1); 5-16 (1); under 18 years (1); under 15 (1); not stated (1)
## Side effects

| 17 studies | ADHD (2), asthma (8), bipolar disorder (1), depression (1), HIV (3), malaria (2), neurogenic bladder (1), psychoactive substance abuse disorder (1), social phobia (1), TB (1), hepatic transplant (1) and renal transplant (2). Studies were from the USA (13), Canada (2), UK (2), Australia (1), China (1), Germany (1), Malaysia (1), Netherlands (1), Papua New Guinea (1), Uganda (1). Most studies were from the USA, so relevance to UK behaviour is not clear. Six studies were qualitative and 18 were quantitative, three of these using multivariate regression techniques. Most used non-validated methods to measure adherence. |
| Experience: ⬤ ⬤ | Parents’ anticipation/fear: ⬤ |
| Children’s anticipation/fear of side effects | Effect of different age groups |
| Asthma: 8 studies | CHD: none |
| Diabetes: none | Epilepsies: none |
| 1 study looked at children under 3, 1 4-9, 1 5-12, 1 7-14, 6 studies looked at adolescents, 5 studies looked at the whole age range (2-21), and 2 studies did not quote an age range. No study examined explanatory factors by age |

## Complexity of regimen

| 32 studies | ADHD (3); asthma (3); cystic fibrosis (1); diabetes | ✧Number of medicines: ✧ (HIV sometimes) | Conflicting evidence about effect of |
| Asthma: 3 | CHD: 1 (heart transplant) |
| 1 study looked at children under 3, 1 4-9, 1 5-12, 1 7-14, 6 studies looked at adolescents, 5 studies looked at the whole age range (2-21), and 2 studies did not quote an age range. No study examined explanatory factors by age |
(2)\textsuperscript{120;121}, epilepsy (2)\textsuperscript{13;122}, growth disorders (1)\textsuperscript{123}, HIV (13)\textsuperscript{32;34;35;59;77;79;81;111;124-128}, RSV prophylaxis (1)\textsuperscript{129}, sickle cell anaemia (1)\textsuperscript{62}; transplant (5).\textsuperscript{19;20;49;130;131}

Studies were from the USA (18), UK (4), Canada (2), Taiwan (2), Italy (2), Finland (1), Iran (1), Spain (1), South Africa (1).

Most studies were from the USA, so relevance to UK behaviour is not clear. Most were quantitative (20), seven of these using multivariate or logistic regression techniques. Eight studies were qualitative, three had a mixed methodology and one was the development of an adherence scale. Only three studies were 10 years old or more, so the evidence base is relatively current.

Most used non-validated methods to measure adherence.

<table>
<thead>
<tr>
<th>Ability to use medicines</th>
<th>Ten studies: asthma (5)\textsuperscript{29;98;132-134}, CF (1)\textsuperscript{135};</th>
<th>⤵ instruction from practitioner ⤵</th>
<th>Asthma: 5</th>
<th>CHD: 0</th>
</tr>
</thead>
</table>

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Project 08/1704/212
fieber (3)\textsuperscript{136-138} and growth disorders (1).\textsuperscript{139}

Studies were from USA (4), Taiwan (1), Canada (1), Spain (1), Netherlands (1), Israel (1) and India (1).

Nine studies were quantitative, of these two included multivariate analysis, one study was qualitative. Only three of the ten studies were ten years older or more so the evidence base is relatively current. Adherence was assessed using assessment of administration technique in 6 studies, one involving a mock scenario. Three used self reporting by carer/patient using questionnaires or interviews.

<table>
<thead>
<tr>
<th>Palatability and acceptability of regimen</th>
<th>19 studies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>asthma (5)\textsuperscript{24;29;94;140;141}, general (1)\textsuperscript{142}, growth disorders (1)\textsuperscript{123}, HIV (6)\textsuperscript{34;35;77;81;125;126}, malaria (2)\textsuperscript{36;113}, and transplant (4).\textsuperscript{38;49;130;131}</td>
<td></td>
</tr>
<tr>
<td>Studies were from USA (10), Italy</td>
<td></td>
</tr>
</tbody>
</table>

\begin{itemize}
  \item regular follow up & assessment of technique for drug delivery devices by practitioner \textsuperscript{\dag}
  \item ability of child to use device themselves \textsuperscript{\dag}
  \item choice of device \textsuperscript{\dag}
\end{itemize}

| Diabetes: 0 |
| Epilepsies: 0 |

Age ranges were all children: 5-16yr; 8-13yr; 1-14yr; under 5yr; 4-18yr.
The oldest study was 9 years old therefore the database is relatively up to date. Fifteen studies were quantitative and of these only one used multivariate analysis. Three studies were qualitative and one used a mixed methodology. Adherence was measured mainly by carer/patient report in questionnaires or interviews (14). Pharmacy refill data was used in four studies, pharmacokinetic data in two and physician rating in two. An electronic monitoring device, GP prescribing records, clinic appointment attendance and examination of medicines were all used in one study each. Some studies used a combination of methods.

| Access to 5 studies: asthma (1)²⁴; HIV | ▲ cost ▼ | Effect of Asthma: 1 |

Most studies involved children in the ranges 1.4-14.9yr; 18month-7yr; 7yr or 12yr; 3-18yr. Parents were studied in one paper looking at palatability of oral corticosteroid preparations.
<table>
<thead>
<tr>
<th>Medicines, including off-label use</th>
<th>(3)(^{33,34,124}); malaria (1)(^{113})</th>
<th>Availability of medicines (\uparrow)</th>
<th>Unlicensed and off label prescribing on access and adherence</th>
<th>CHD: none</th>
<th>Diabetes: none</th>
<th>Epilepsies: none</th>
</tr>
</thead>
<tbody>
<tr>
<td>No studies of issues around unlicensed and off label prescribing causing problems with access to medicines were found.</td>
<td>length of prescription (\downarrow)</td>
<td>The one study involving asthmatic patients included children 18months to 7years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Studies were from West Africa (1), USA (1), Australia (1), Canada (1) and Papua New Guinea (1) therefore applicability to the UK setting is likely to be low. Four studies were quantitative with one including multivariate analysis and one was qualitative. The oldest study was five years old therefore all were relatively recently published. Adherence was measured using carer/patient report in interviews/questionnaires in four studies, pharmacy refill data and an electronic monitoring device in one study each (one study used a combination of methods).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Beliefs and expectations, experiences and concerns about</th>
<th>28 studies: ADHD (1)(^{143}); A&amp;E discharges (1)(^{144}); asthma (8)(^{4,145-151}); atopic dermatitis (1)(^{152}); diabetes</th>
<th>Parental beliefs about necessity: (\downarrow) (\downarrow)</th>
<th>Children’s beliefs</th>
<th>Asthma: 10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Effect of</td>
<td></td>
<td>CHD: 1 (Heart Tx)</td>
</tr>
</tbody>
</table>

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### Disease and Medicines (Child and Parent), incl stigma

<table>
<thead>
<tr>
<th>Disease/Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>10;48</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>2;12;153</td>
</tr>
<tr>
<td>HIV</td>
<td>5;34;149;154-156</td>
</tr>
<tr>
<td>Inflammatory bowel disease</td>
<td>1;49</td>
</tr>
<tr>
<td>JIA</td>
<td>2;16;52</td>
</tr>
<tr>
<td>Sickle cell anaemia</td>
<td>4;157-160</td>
</tr>
<tr>
<td>General illness study</td>
<td>1</td>
</tr>
</tbody>
</table>

Studies were from: USA (14), Finland (4), Canada (3), UK (2), Saudi Arabia (1), Puerto Rico (2), International 8 countries (1) and Belgium (1). Twenty-eight studies were quantitative, 13 of these using multivariate regression techniques. Only 8 of the studies were 10 years old.

### Social Context (Impact of Family Structure, Friends, Peer Groups, Media)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>2;23</td>
</tr>
<tr>
<td>Asthma</td>
<td>11;26;41;42;63;64;66;67;96;99;106;162</td>
</tr>
<tr>
<td>Cancer</td>
<td>1;69</td>
</tr>
<tr>
<td>Cystic fibrosis</td>
<td>2;71;163</td>
</tr>
<tr>
<td>Diabetes</td>
<td>10;11;56;73;74;99;120;164-167</td>
</tr>
<tr>
<td>Epilepsies</td>
<td>3;58;75;99</td>
</tr>
<tr>
<td>HIV</td>
<td>10;59;78-80;82;111;112;155;168;169</td>
</tr>
<tr>
<td>Solid organ transplant</td>
<td>1;19</td>
</tr>
<tr>
<td>Renal transplant</td>
<td>5;54;88;130;170;171</td>
</tr>
<tr>
<td>Heart transplant</td>
<td>2;172;173</td>
</tr>
<tr>
<td>Other family member</td>
<td>1;174</td>
</tr>
</tbody>
</table>

51 studies.

### Child's Beliefs about Necessity

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>2;23</td>
</tr>
<tr>
<td>Asthma</td>
<td>11</td>
</tr>
<tr>
<td>Cancer</td>
<td>1</td>
</tr>
<tr>
<td>Cystic fibrosis</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes</td>
<td>10</td>
</tr>
<tr>
<td>Epilepsies</td>
<td>3</td>
</tr>
<tr>
<td>HIV</td>
<td>10</td>
</tr>
<tr>
<td>Solid organ transplant</td>
<td>1</td>
</tr>
<tr>
<td>Renal transplant</td>
<td>5</td>
</tr>
<tr>
<td>Heart transplant</td>
<td>2</td>
</tr>
</tbody>
</table>

**Effect of stigmata**

- Age ranges: 0.5-5 (1); 0-7* (2); 11 months to 12 years (1); 11-17 (2); 11-18 (1); 13-17 (3); 13-18 (1); 2-12 (2); 3-17 (1); 5-12 (2); 6-10 (1); all ages (8); not stated (4)

No study examined explanatory factors by age.

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inflammatory bowel disease (1), leukaemia (1), psychiatric disorders (1)\textsuperscript{66} general (1), TB (1).\textsuperscript{55}

Studies were from the USA (37), Canada (3), Finland (2), Thailand (2), UK (2), Brazil (1), France (1), Germany (1), Israel (1), Taiwan (1)

39 of the 51 papers were less than 10 years old.

Most studies were from the USA, so relevance to UK behaviour is not clear. Ten studies were qualitative, three used mixed methods, and 38 were quantitative, seventeen of which stated use of multivariate regression techniques.

Most used non-validated methods to measure adherence

<table>
<thead>
<tr>
<th>Financial context (impact of socio-economic status)</th>
<th>12 studies</th>
<th>Lower socio-economic status: □□ □□</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD (1),\textsuperscript{2} ALL (1);\textsuperscript{21} asthma (2)\textsuperscript{24;30}; cancer (1)\textsuperscript{177}; diabetes (1)\textsuperscript{178}; HIV (1),\textsuperscript{179} epilepsy (1)\textsuperscript{75}; JIA (1)\textsuperscript{17}; psychiatric disorders</td>
<td>17, 1-13, 1-19, 2-12, 2-17, 3-14, 3-18, 5-10, 5-12, 5-13, 5-18 (2), 5-23, 6-12 (2), 6-16, 6-17, 6-21, 7-14, 7-15, 7-16, 7-17, 7-20, 7-22, 8-13, 8-16, 8-18, 9-16 (2), 9-18, 9-19, 10-17, 10-19 (2), 11-17, 11-18 (2), 11-19, 11-21, 12-18, 12-21, 13-17 (3), 13-18, 16-23, 16-24, 17-25. 3 studies looked at children 0-12, 43 studies looked at adolescents (ages anywhere between 13 and 19), 2 studies looked at the whole age range for the TABS study (5-17), 1 study no age range</td>
<td></td>
</tr>
<tr>
<td>17, 1-13, 1-19, 2-12, 2-17, 3-14, 3-18, 5-10, 5-12, 5-13, 5-18 (2), 5-23, 6-12 (2), 6-16, 6-17, 6-21, 7-14, 7-15, 7-16, 7-17, 7-20, 7-22, 8-13, 8-16, 8-18, 9-16 (2), 9-18, 9-19, 10-17, 10-19 (2), 11-17, 11-18 (2), 11-19, 11-21, 12-18, 12-21, 13-17 (3), 13-18, 16-23, 16-24, 17-25. 3 studies looked at children 0-12, 43 studies looked at adolescents (ages anywhere between 13 and 19), 2 studies looked at the whole age range for the TABS study (5-17), 1 study no age range</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Financial context (impact of socio-economic status)**
- ADHD (1),\textsuperscript{2} ALL (1);\textsuperscript{21} asthma (2)\textsuperscript{24;30}; cancer (1)\textsuperscript{177}; diabetes (1)\textsuperscript{178}; HIV (1),\textsuperscript{179} epilepsy (1)\textsuperscript{75}; JIA (1)\textsuperscript{17}; psychiatric disorders
- Lower socio-economic status: □□ □□
- Very poor evidence
- Effect of different age groups
- Asthma: 2
- CHD: none
- Diabetes: 1
- Epilepsies: 1

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(1) renal transplantation (1),
sickle cell anaemia (1). Stu-
dies were from China (1), South
Africa (1) Brazil (1), USA (7),
Canada (1), Australia (1).
All studies were quantitative, two of
these using multivariate regression
techniques. Only five of the studies
were 10 years old or more, so the
evidence base is relatively current.
Most used non-validated methods
to measure adherence.

<table>
<thead>
<tr>
<th>Cultural context (impact of racial/ethnic or cultural background)</th>
<th>Ethnicity:</th>
<th>Very poor evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 studies</td>
<td>Minority status:</td>
<td>Effect of different age groups</td>
</tr>
<tr>
<td>74;176;182; TB (1)</td>
<td></td>
<td>Effect of specific ethnic features</td>
</tr>
<tr>
<td>All studies from the USA.</td>
<td></td>
<td>Effect of language barriers</td>
</tr>
<tr>
<td>All papers were less than 10 years old</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All quantitative studies, nine using multivariate regression techniques</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to identify an independent effect. Most used non-validated methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to measure adherence.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Educational</th>
<th>No clear indicators</th>
<th>No evidence on</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 studies</td>
<td>Asthma: 3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age ranges:</th>
<th>Asthma: 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3-16.7 (1); 2.5-20.9 (1); 3-10 (1); 6-12 (1); 13-21 (1); aged under 18 (2); under 17 (1); under 15 (1); not stated (1); 0.3 to 24.2 yrs (1)</td>
<td></td>
</tr>
<tr>
<td>CHD: none</td>
<td></td>
</tr>
<tr>
<td>Diabetes: 3</td>
<td></td>
</tr>
<tr>
<td>Epilepsies: none</td>
<td></td>
</tr>
<tr>
<td>age range: 0-16 (2); 1-11 (1); 2-16 (1); 3-17 (2); 9-18 (1); 11-19 (1); 12-21 (1); under 18 years (2)</td>
<td></td>
</tr>
</tbody>
</table>
| context (effect of school) | ADHD (1), asthma (3), diabetes (2) and HIV (1). Only one of the studies was from the UK, two from the USA and one from Italy. Two studies were quantitative, none of these using multivariate regression techniques. None of the studies were 10 years old or more, so the evidence base is relatively current. Most used non-validated methods to measure adherence. | association of school to adherence | CHD: none  
Diabetes: 2  
Epilepsies: none  
Age ranges: 1-17 (1); 8-15 (1); 8-18 (1); 13-14 (1) |
|---|---|---|---|
| Parent-child dyad interaction and communication | 19 studies  
ADHD (1), asthma (4), cancer (1), cystic fibrosis (4), depression (1), diabetes (3), HIV (2), JIA (1), renal transplant (4), TB (1). Studies were from the USA (13), Canada (1), Finland (2), Israel (1), Taiwan (1), UK (1). Most studies were from the USA, so relevance to UK behaviour is not clear. Sixteen studies were quantitative, nine of | Parental supervision  
Authoritative and warm parenting  
Conflicts | Asthma: 1  
CHD: none  
Diabetes: 3  
Epilepsies: none  
Age ranges: 3-10 (1); 3-11 (1); 6-17 (1); 8-17 (2); 8-18 (1); 9-16 (1); 10-17 (1); adolescents (5); not stated (1); all ages (1); under 12 (1) |
these using multivariate regression techniques. Only 5 of the studies were 10 years old or more, so the evidence base is relatively current. Most used non-validated methods to measure adherence.

| Provider-child dyad, Parent-child-provider triad | Eight studies | Increased child satisfaction ↑  
Lack of concern shown by HCP ↓  
Effect of different age groups  |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>HIV (1), diabetes (2), epilepsy (1), asthma (2), cystic fibrosis (1) and mixed diagnoses (1).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most studies conducted in Finland (5), with one study from Taiwan, US and UK. Of the 5 quantitative studies only one used multivariate statistics. Only two of the studies were 10 years old or more, so the evidence base is relatively current. Most used non-validated methods to measure adherence.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| child and parent interaction with the health system in community, primary and hospital care | 5 studies | Poor relationship with HCP ↓  
Very poor evidence  
Effect of different age groups  |
<table>
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<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD (1), asthma (2), general adolescent medicine (1), renal transplant (1).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>These studies were based in the</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Asthma: 3  
CHD: none  
Diabetes: 3  
Epilepsies: 2  
Age ranges: 8-13 (1); 13-17 (4); 13-18 (1); 16-14 (1); under 12 (1)
from initial contact to medicines supply, and over time

| Evidence that factor increases adherence significantly |
| Evidence that factor increases adherence very significantly |
| Evidence that factor decreases adherence significantly |
| Evidence that factor decreases adherence very significantly |
| Evidence that factor has little or no effect on adherence |
| Conflicting evidence about the effect of the factor on adherence |
| No evidence about the effect of the factor on adherence |

USA (4) and Germany (1).

Three studies were quantitative, two of these using multivariate regression techniques. Only two of the studies were 10 years old or more, so the evidence base is relatively current. Most used non-validated methods to measure adherence.

3 studies covered all age ranges, 1 adolescents, 1 7-12
Reference List


Marhefka SL, Farley JJ, Rodrigue JR, Sandrik LL, Sleasman JW, Tepper VJ. Clinical assessment of medication adherence among HIV-infected children:


(40) van Es SM, Kaptein AA, Bezemer PD, Nagelkerke AF, Colland VT, Bouter LM. Predicting adherence to prophylactic medication in adolescents with asthma: an application of the ASE-model. Patient Education & Counseling 2002; 47(2):165 to 71.


(56) Moreland EC, Tovar A, Zuehlke JB, Butler DA, Milaszewski K, Laffel LMB. The impact of physiological, therapeutic and psycho-social variables on


(67) Buford TA. Transfer of responsibility for asthma self-management from parents to their school-age children 2002.


(76) Annunziato RA, Emre S, Shneider B, Barton C, Dugan CA, Shemesh E. Adherence and medical outcomes in pediatric liver transplant recipients who transition to adult services.[see comment]. Pediatric Transplantation 2007; 11(6):608-14.


(98) Chen SH, Yin TJ, Huang JL. An exploration of the skills needed for inhalation therapy in schoolchildren with asthma in Taiwan. Annals of Allergy, Asthma, & Immunology 2002; 89(3):311-5.


(124) Veinot TC, Flicker SE, Skinner HA, McClelland A, Saulnier P, Read SE et al. "Supposed to make you better but it doesn't really": HIV-positive youths'


(159) Elliott V, Morgan S, Day S, Mollerup LS, Wang W. Parental health beliefs and compliance with prophylactic penicillin administration in children with


(168) Callery P. Families with parents and children living with HIV described strategies to meet 3 common goals for normalization... commentary on Rehm RS, Franck LS. Long-term goals and normalization strategies of children and families affected by HIV/AIDS. ANS 2000 Sep;23:69-82. Evidence-Based Nursing 2001; 4(3):92.


Wright K. Examining racial and ethnic disparities and predictors of medication use among California's African-American, Latino, and White


(195) Zorc JJ, Scarfone RJ, Li Y. Predictors of primary care follow-up after a pediatric emergency visit for asthma. Journal of Asthma 2005; 42(7):571-6.


7.3 Search strategy for Medline/Embase/Psychinfo for intervention studies review

<table>
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<tr>
<th>#</th>
<th>Searches</th>
<th>Results</th>
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### 7.4 Details of intervention studies included in review

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<thead>
<tr>
<th>Author, Year, Country, Disease</th>
<th>Intervention being tested</th>
<th>Study Design</th>
<th>Patient group</th>
<th>Results*</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Anderson, B. J. et al. 1989.134 USA Type 1 diabetes mellitus | Comparing the effects of peer-group intervention on metabolic control of adolescents With Type 1 diabetes mellitus. Adolescents and their peers attended self monitoring of blood glucose (SMBG) education sessions in addition to standard care. Emphasis in the intervention group was on adolescents learning to use data from SMBG to make regimen adjustments. | RCT group design, outpatient study | Inclusion criteria:  
- 11 to 14 years with IDDM  
- Seen at the paediatric diabetes clinic at the University of Michigan Hospitals in 1983-1984  
- Had been diagnosed for at least 1 year  
- Agreed to attend clinic every 3-4 months (3hr each visit) for the 18 months duration of the study.  
Authors did not discuss exclusion criteria  
Sex: % Female  
Arm 1 53.3 | Main outcomes are glycaemic control and exercise. Adherence inferred indirectly by authors from metabolic control measured from glycosylated haemoglobin (HbA1c) levels. Exibited stable or improved metabolic control:  
Arm 1 = over 76%  
Arm 2 = 50%  
At follow-up: >1% increase in HbA1c over baseline values, indicating a deterioration in | Stratified random sampling was used  
Concealment method is not addressed.  
Selection bias: families could not be blinded if they needed to commit to being available for test intervention sessions.  
More people used SMBG to adjust insulin dose, but did not reach significance, therefore no difference reported |
<table>
<thead>
<tr>
<th>Author, Year, Country, Disease</th>
<th>Intervention being tested</th>
<th>Study Design</th>
<th>Patient group</th>
<th>Results*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Arm 1: intervention group</td>
<td>stratified random sampling was used. No further details on randomisation</td>
<td>Arm 2 53.3</td>
<td>metabolic control</td>
<td>JADAD score: 3</td>
</tr>
<tr>
<td></td>
<td>Arm 2: control group (standard care)</td>
<td>Blinding: not reported</td>
<td>Ethnicity: Not reported</td>
<td>HbA1c was lower in the intervention group (p=0.04) so significant difference in outcome.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Power calculation: sample size was based on the number of eligible families from the specific clinic. No further details of sample size calculation</td>
<td></td>
<td>Arm 1 = 23% exhibited &gt;1% deterioration in control drugs (mean 11.04 SD 2.28%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>Arm 2 = 50% deteriorated in control drugs. (mean 10.10% SD 2.00%) indicating a significantly lower value in arm 1 (p=0.04)</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>% of adolescents used SMBG information when they exercised</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Arm 1 = 60.0</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>Arm 2 = 33.3 ((\chi^2=4.29, p=0.04))</td>
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</tr>
<tr>
<td>Author, Year, Country, Disease</td>
<td>Intervention being tested</td>
<td>Study Design</td>
<td>Patient group</td>
<td>Results*</td>
<td>Comments</td>
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</table>
| Anderson, B. J. et al. 1999. USA | An office-based intervention to maintain parent-adolescent teamwork in diabetes management. | RCT | Inclusion criteria:  
• Pre- and young Adolescents. Aged 10–15 years  
• With Type 1 diabetes >1 year  
• Glycaemic control (HbA1c from 6.6 to 10.4%)  
• No documented serious medical or psychiatric condition in the patient or their parents  
• Residence in New England or New York,  
• At least one outpatient medical visit in the previous year,  
• Ability to go to Joslin for medical visits 3–4 times over the next calendar year.  
Authors did not discuss exclusion criteria | Parent involvement in diabetes management, diabetes-related family conflict, and glycaemic control were measured in this study. HbA1c was used as a clinical indicator of adherence to insulin and blood glucose duelling regimen. Adherence results not reported Parent involvement in insulin administration Arm 1 = no major deterioration (0%)  
CG = 16% major deterioration in the combined comparison (p<0.03). Deterioration in parent involvement with blood | **Baseline number of participants for Arm 3 n=24, however the number of participants at 12 month follow up for Arm 3 n=27 In the results ‘comparison group = Arm 2 and Arm 3 combined’ as no differences found between them. Reported results 12 months after end of intervention, some sustained effect. JADAD score: 2 |
<table>
<thead>
<tr>
<th>Author, Year, Country, Disease</th>
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<th>Patient group</th>
<th>Results*</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Ansah, E. K. et al. | Comparing the use of Pseudo-randomised CT Inclusion criteria: Adherence was defined in Over a six week period. | in each group.*** | Sex: % Male***
Arm 1  50
Arm 2  50
Arm 3  52
Ethnicity: Not reported | glucose monitoring
Arm 1 = no families showed major deterioration.
CG = 11% deterioration in the comparison group (p<0.07).
On both the Diabetes Family Conflict Scale and the Diabetes Family Behaviour Checklist, Arm 1 families reported significantly less conflict at 12 months.
Analysis of HbA1c over the 12- to 24-month follow-up period
Arm 1 = (68%) improved their HbA1c
CG = (47%) improved their HbA1c (p<0.07). |
<table>
<thead>
<tr>
<th>Author, Year, Country, Disease</th>
<th>Intervention being tested</th>
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<th>Patient group</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2001. Ghana, Malaria</td>
<td>pre-packed chloroquine tablets vs. chloroquine syrup to improve adherence to malaria treatment for children over a 6-week period.</td>
<td>Total patients: n=301 recruited, n=299 involved in the study.</td>
<td>• Patients aged 0-5 years</td>
<td>relation to dosage, frequency of daily administration and duration of treatment. A patient was said to have adhered if the caregiver exactly followed the prescriber's instructions.</td>
<td>children aged 0-5 years diagnosed with malaria at the clinic, received either pre-packed tablets or syrup</td>
</tr>
<tr>
<td></td>
<td>Arm 1: Tablets group, Arm 2: Syrup group</td>
<td>Arm 1: n=155, Arm 2: n=146</td>
<td>• Diagnosed with malaria</td>
<td>80% (n = 115) of the caregivers who received syrup used different kinds of spoons to measure the dose: some had teaspoons, others used dessert or tablespoons. Four caregivers used two different devices to administer the chloroquine syrup to the same child. The remaining 20%. (n = 29) used a small cup, and one person used the cover of a bottle to measure the dose. Measuring devices varied in volume from 1 to about 9 ml.</td>
<td>JADAD score: 1</td>
</tr>
<tr>
<td></td>
<td>Arm 2: from the 146, n=2 were excluded due to admission to hospital</td>
<td>Follow up period: 4 days from treatment to interview. Unclear duration from treatment to the focus groups held. Recruitment rate: not reported.</td>
<td>Exclusion criteria: • Patients admitted with complicated malaria • Patients diagnosed with other co-morbidities</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Sex: Not reported</td>
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<td></td>
<td>Ethnicity: The people are mainly of Fanti ethnic origin with some migrant (mainly government) workers from other parts of the country. No further details reported.</td>
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<tr>
<td>Author, Year, Country, Disease</td>
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<td>Study Design</td>
<td>Patient group</td>
<td>Results*</td>
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<tr>
<td>Baum et al. 1986&lt;sup&gt;154&lt;/sup&gt;</td>
<td>To evaluate whether self-management skills taught to children with asthma taking</td>
<td>RCT group design, outpatient study</td>
<td>Inclusion criteria: not reported&lt;br&gt;Total patients n=20 (16 at follow up)&lt;br&gt;Ages 6-16</td>
<td>Main outcomes are asthma attacks&lt;br&gt;Adherence: measured by theophylline levels, pill</td>
<td>Caregiver adhered with the prescribed treatment&lt;br&gt;Arm 1 = 91% (141) of the 155&lt;br&gt;Arm 2 = 42% (61) of the 144 (v² = 78.3; p&lt; 0.001).&lt;br&gt;No randomisation or blinding reported, highly susceptible to bias.&lt;br&gt;Very small study so unlikely</td>
</tr>
<tr>
<td>Author, Year, Country, Disease</td>
<td>Intervention being tested</td>
<td>Study Design</td>
<td>Patient group</td>
<td>Results*</td>
<td>Comments</td>
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</tbody>
</table>
| USA Asthma                    | theophylline and their parents would improve medication compliance  
Group 1: training in self-monitoring  
Group 2: self-monitoring, educational and positive reinforcement components | Arm: n=8  
Arm: n=8  
Follow up period: 3 weeks  
Recruitment rate: not reported  
Randomisation method: not reported  
Blinding: not blinded  
Power calculation: not carried out | Authors did not discuss exclusion criteria  
Sex: % Female  
Group 1 25%  
Group 2 25%  
Ethnicity: not reported | counts by parents, self-monitoring  
Results  
Adherence self report (child)  
Group 1 50%  
Group 2 83%  
Outcomes: not reported by intervention group | to find any statistically significant differences.  
JADAD score: 1 |
After a baseline period of 2 months the patients were randomised to one of two study groups.  
Intervention: a slide show explaining the RCT  
n=45 initially recruited  
22 not included in study  
n=13 – Can’t take tablets  
n=7 – parental refusal to follow-up | Inclusion criteria:  
• Ages not stated; mean age 37 months (range 9-84 months)  
• Homozygous SCD  
• Receiving prophylactic penicillin twice a day  
• Regularly attending the sickle cell clinic  
No comment on exclusion criteria  
Sex: Not reported | Outcome measures include knowledge (results not reported), compliance and hospital admissions.  
Compliance was monitored using the Medication Event Monitoring System (MEMS).  
Compliance during the 2 month baseline assessment was (mean ± s.d.; range) | No randomisation or blinding reported, highly susceptible to bias.  
Very small study so unlikely to find any statistically significant differences.  
JADAD score: 2 |
<table>
<thead>
<tr>
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<th>Comments</th>
</tr>
</thead>
</table>
|                                | pathogenesis of SCD and its complications. Weekly phone calls for 8 weeks and a calendar to be used as a diary to document compliance. | n= 1 – MEMS broke  
n= 1 – was not called by the researcher  
Arm 1: n=13  
Arm 2: n=10  
After baseline  
Arm 1: n=7  
Arm 2: n=6  
(n=3 lost to follow-up at 2 months n=7 lost to follow-up at 4 months)  
Follow up period: 6 months  
Recruitment rate: 45 were initially recruited and 23 were included in the study  
Randomisation method: not reported | Ethnicity: Not reported | Arm 1: 66.0%±32.5 (1.3-98.2 range) (n=13)  
Arm 2: 69.3%±25.4 (19.9-96.5 range) (n=10) (p=0.79). During the next 2 months, compliance in  
Arm 1 (n=11) was 79.0%±31.4 (11.0-100.0 range)  
Arm 2 (n=9) was 66.0%±20.2 (42.2-96.8 range) (p=0.297). The final two month monitoring period compliance  
Arm 1 = 82.0%±34.7 (3.8-100.0 range) (n=7)  
Arm 2 = 65.8%±25.3 (25.0-98.2 range) (n=6) (p=0.366). | Patients admitted to hospital |
<table>
<thead>
<tr>
<th>Author, Year, Country, Disease</th>
<th>Intervention being tested</th>
<th>Study Design</th>
<th>Patient group</th>
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</thead>
</table>
| Berrien et al 2004 | Home-based nursing intervention to improve adherence to antiretroviral therapy in children with HIV, through improvement of knowledge and understanding of HIV disease and medicines and to resolve or modify barriers to adherence | RCT, outpatient study | Inclusion criteria: not reported | Arm 1: n=3  
Arm 2: n=3 | Main outcomes: pre and post CD4 and viral load  
Adherence: measured by self-report, medication refill history  
Also inferred adherence from pre and post CD4 and viral load  
Results  
medication refill history  
Arm 1 2.7  
Arm 2 1.7 (p=0.002)  
Adherence self report (child):NS  
Outcomes: JADAD score: 3 |

| | | | | Arm 1: n=20  
Arm 1: n=17 | |
| | | | | Follow up period: 6-11 months  
Recruitment rate: 67%  
Randomisation method: Small Table of Random Digit Method  
Blinding: not blinded  
Power calculation: not carried out | |
| | | | | Inclusion criteria: not reported  
Ages 1.5-20  
Authors did not discuss exclusion criteria  
Sex: % Female  
Arm 1 55%  
Arm 2 45%  
Ethnicity:  
Hispanic 50, 64%  
African American 35,29% | |

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</tr>
</thead>
</table>
| Bonner et al 2002 USA Asthma  | Intensive three-month educational intervention (family education and physician intervention, three workshops, telephone support, allergy testing) based on a readiness model delivered by a family coordinator in urban Latino and African American children with asthma | RCT | Caucasian 15.7% | pre and post CD4 and viral load: NS | Main outcomes:  
Symptom persistence:  
Adherence: measured by family reported adherence  
Results:  
Adherence family report  
Arm 1: 3.14  
Arm 2: 2.14  
P<0.001  
Outcomes:  
Arm 1: 5.46  
Arm 2: 6.78 |

| | Arm 1 intervention | Arm 2 usual medical care | Total patients n=119 families interviewed at baseline and 100 at three-month follow-up  
Arm: n=56  
Arm: n=63  
Recruitment rate: 28%  
Follow up period: 3 months  
Randomisation method: not reported  
Blinding: not blinded  
Power calculation: not carried out | Inclusion criteria: not reported  
Ages 4.2-19.1 years  
Authors did not discuss exclusion criteria  
Sex: % Female  
Arm 1: 42.9%  
Arm 2: 55.6%  
Ethnicity:  
Latino 71.75%  
African American 23.22% | JADAD score: 1 |

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<tbody>
<tr>
<td>Butz, A. M. et al. 2005. 136</td>
<td>Comparing the effects of a symptom/nebuliser education intervention (SNEI) intervention with a standard asthma education intervention (SAE).</td>
<td>RCT</td>
<td>Other 5.3%</td>
<td>P&lt;0.01</td>
<td>JADAD score:2</td>
</tr>
<tr>
<td>USA Asthma</td>
<td>SNEI was delivered by 6 home visits (by one of four community health nurses) over a 6-month period. Parents taught asthma symptoms and use of a peak flow meter (PFM) in children over 5 years of age, so as to make accurate treatment decisions. SAE intervention was delivered during three home visits designed to</td>
<td>Total patients n=210 Arm 1: n=105 Arm 2: n=105</td>
<td>Inclusion criteria: Diagnosis of mild, moderate, or severe persistent asthma, based on national guidelines Use of a nebuliser Child/parent families with child aged 2-8 years</td>
<td>Outcomes defined as a decrease in frequency of asthma symptoms and decrease in number of ED visits. Adherence to correct inhaler technique assessed in this study.</td>
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<td>Follow-up period: Unclear Recruitment rate: Families enrolled, preintervention n=221 Families completed the study n=210 Postintervention n=192. No further information</td>
<td></td>
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<td>Two asthma management skills that were not different between pre-intervention and post-intervention were (a) checking their child’s medications for expiration dates</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sex: % Male Arm 1 62.9 Arm 2 67.6 Ethnicity: nArm 1 Arm 2 African American 97 90</td>
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<tr>
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<td>Patient group</td>
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<td>assist families in establishing regular primary care and understanding basic asthma management principles.</td>
<td>Randomisation method: based on even or odd digits from a random digit list.</td>
<td>Other 3 10</td>
<td>(b) cleaning the nebuliser medicine cup and mouthpiece after each use.</td>
<td></td>
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<tr>
<td></td>
<td>Arm 1: SAE</td>
<td>Blinding: not reported</td>
<td>Arm 1 2</td>
<td>Arm 1 n=75 (80.6%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arm 2: SNEI</td>
<td>Power calculation: not reported</td>
<td>Arm 2 4</td>
<td>Arm 2 n=77 (85.6%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Per-protocol analysis</td>
<td>Baseline asthma severity: n=</td>
<td>Mild intermittent 2 4</td>
<td>(no statistical test reported)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Mild persistent 62 69</td>
<td>Moderate persistent 27</td>
<td></td>
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<td></td>
<td></td>
<td>Severe persistent 14 14</td>
<td></td>
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<td></td>
<td>Overall, symptom identification and self-management skills significantly improved from pre-intervention to post-intervention for all variables.</td>
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<td></td>
<td>No difference in adherence to correct nebuliser technique, or increased use of prophylactic medicines</td>
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<td>More children in the post-SNEI group reported that they would treat cough</td>
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<tbody>
<tr>
<td>Butz, A. M. et al. 2006.128 USA Asthma</td>
<td>A randomised controlled trial conducted to evaluate the effectiveness of: Arm 1: basic or standard asthma education (CON) vs. Arm 2: home-based educational intervention (INT) Education focused on symptom frequency, appropriate nebuliser and asthma medication use, and ED visits and hospitalisations. Parents of children in the INT group received 6 x 1 hour home visits. All home</td>
<td>RCT</td>
<td>Inclusion criteria: Aged 2 to 9 years With persistent asthma Daytime asthma symptom frequency at least 2 or more times a week within the past 30 days Night time asthma symptom frequency at least 2 or more times a month for the past 30 days Use of a nebuliser to administer asthma medication within the past 30 days</td>
<td>Pharmacy records were obtained from all pharmacies used by each child. Pharmacies were contacted for complete lists of all medications dispensed for each child. Outcomes included estimates of mean differences in asthma symptom frequency, number of ED visits and hospitalisations and appropriate quick relief, controller medication, and nebuliser practice over 12 months. Adherence to correct home nebuliser technique assessed in this study</td>
<td>The lack of difference between intervention and 'control' groups may be due to lack of effectiveness of the intervention or due to lack of significant difference in the intervention used in each group. i.e. the control group was also subject to an intervention, albeit less intensive Child health outcome and nebuliser practice measures were collected by face-to-face and telephone questionnaire interviews conducted with the parent or caregiver at baseline and at the 12-month follow-up. Data collection, pharmacy</td>
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<tr>
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<td>education visits were delivered by 3 community health nurses with paediatric asthma training and were supervised monthly by a paediatric nurse asthma specialist. Parents of children randomised into the control group received basic asthma education comparable to asthma education received during non-urgent care visits</td>
<td>these, 221 consented and were enrolled and randomised. Randomisation method: not reported Blinding: not reported Power calculation: not reported Per-protocol analysis</td>
<td>Resident of Baltimore 1 or more ED visits for asthma within the past 12 months or hospitalisation for asthma in the past 12 months Authors did not discuss exclusion criteria, however reasons for exclusions from the final analysis were reported; Low or no nebuliser use in the prior 30 days and to children newly diagnosed as having asthma. Incomplete pharmacy record data</td>
<td>Severity remained stable at follow-up. Children in Arm 1 were more likely than those in Arm 2 to have had 1 or more hospitalisations and/or 1 or more ED visits for asthma during the past 6 months (p&lt;.05 for both). The mean number of non-urgent care visits over the past 6 months decreased from 3 to 2 from baseline to follow-up, with no differences by group. No difference in adherence to correct nebuliser technique, or increased use of prophylactic records, and electronic monitoring of home nebuliser use. JADAD score: 2</td>
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<td>Sex: n</td>
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<td></td>
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<td>Male</td>
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<td></td>
<td></td>
<td></td>
<td>Arm 1</td>
<td>70</td>
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<td>Arm 2</td>
<td>75</td>
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<td>Ethnicity: n=</td>
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<td>Arm 1</td>
<td>103</td>
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<td>Arm 2</td>
<td>94</td>
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<td></td>
<td>African American</td>
<td>16</td>
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<td>White or other</td>
<td>8</td>
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<td></td>
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<td>Baseline asthma severity: n=</td>
<td></td>
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<td></td>
<td></td>
<td>Arm 1</td>
<td>5</td>
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<td></td>
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<td></td>
<td>Arm 2</td>
<td>5</td>
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<td></td>
<td></td>
<td></td>
<td>Mild intermittent</td>
<td>65</td>
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<td></td>
<td></td>
<td></td>
<td>Mild persistent</td>
<td>69</td>
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<td></td>
<td>Moderate persistent</td>
<td>27</td>
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<td></td>
<td></td>
<td></td>
<td>Severe persistent</td>
<td>14</td>
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<td>17</td>
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</table>

All participants were from low income families defined as living in medicines.

All comparisons between groups and by severity were non significant (p range, 0.13 to 0.94).
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</thead>
<tbody>
<tr>
<td>Camus, D. et al. 2004.</td>
<td>The trial was designed to assess the frequency of adverse events in non-immune paediatric travellers receiving either Arm 1: Atovaquone-proguanil or Arm 2: Chloroquine-proguanil.</td>
<td>RCT</td>
<td>households with parents reporting at least a high school level of education and annual incomes of less than $20000</td>
<td>The frequency of adverse events, treatment-limiting adverse events and clinical outcome of the 2 prophylactic regimens were assessed.</td>
<td>Inclusion criteria ages differ to those included in the trial (2-17 years). A total of 232 subjects were enrolled in the study, with the majority (79%) recruited from the centres in France. 223 were eligible but only 221 patients are accounted for in the study. Noncompliance was defined for the pretravel period as receipt of no doses, and during the travel and posttravel periods, it was</td>
</tr>
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<td>Recruitment rate: 232 subjects were enrolled, 223 were eligible subjects. Randomisation method: not reported. Blinding: not reported. Power calculation: The study was not powered to statistically compare safety between the 2 treatment regimens because many more subjects would have been required than could be reasonably expected to enroll in the trial. Intention-to-treat analysis. Where prophylaxis with chloroquine-proguanil would be inappropriate. A history of active malarial infection within 12 months of screening. Travel to an area where malaria is endemic within 60 days of screening.</td>
<td>where prophylaxis with chloroquine-proguanil would be inappropriate. A history of active malarial infection within 12 months of screening. Travel to an area where malaria is endemic within 60 days of screening.</td>
<td>Sex: n Male Arm 1 62 Arm 2 65 Ethnicity: n= Arm 1 Arm 2 Asian, 4 3 Black, 8 10 White, 88 82</td>
<td>defined as more doses missed than taken. For the atovaquone-proguanil group, subjects who missed ≥2 consecutive doses were also considered to be noncompliant. On the basis of observed trends, proportion of subjects who took ≥80% of prescribed doses in the post-travel period. Arm 1 = 90% Arm 2 = 95% and during travel. Arm 1 = 98% Arm 2 = 99% and 100% Recipients that took ≥80% of prescribed doses in the post-travel period. Arm 1 = 97%</td>
<td></td>
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<tr>
<td>Chan, D. S. et al. 2007&lt;sup&gt;139&lt;/sup&gt; USA Asthma</td>
<td>Pilot study comparing the effects of internet based education with traditional office based education. Paediatric patients with persistent asthma were provided with home computers and Internet access and monitored</td>
<td>RCT</td>
<td>Other 10 16</td>
<td>Arm 2 = 87% and 93% group. (no statistical test reported) No serious adverse events or deaths occurred in this study. Patients that reported adverse events between the start of travel and 7 days after returning Arm 1 = 35% Arm 2 = 37%</td>
<td>There is lack of clarity about the aim of this paper, which seems to have two interventions - one controlled and the other not. Small numbers and dissimilar groups mean that this should really just be interpreted as a pilot study. There is lack of information</td>
</tr>
</tbody>
</table>

Total patients n=10 Arm 1: n=5 Arm 2: n=5 Recruited from paediatric asthma clinic. Follow up period: up to 6 moths

Inclusion criteria:
- Children aged 6-17
- With persistent asthma.
- All patients were taking inhaled corticosteroids for long-term asthma control
- All used a spacer with MDI or a DPI

Outcomes assessed included measurements of patients’ adherence to treatment and disease control.

Diagnostic or treatment adherence was assessed by examining selected aspects of therapeutic and
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<td>biweekly over the Internet. All patients were seen in the paediatric clinic at 0, 2, 6, 12, and 24 weeks.</td>
<td>Recruitment rate: not reported</td>
<td>Authors did not discuss exclusion criteria</td>
<td>diagnostic monitoring. Diagnostic adherence – The rate of symptom diary adherence decreased significantly in period 2 %</td>
<td>about the controlled intervention (educational website)</td>
</tr>
<tr>
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<td>Arm 1: Internet based education 'virtual group'</td>
<td>Randomisation method: randomised with a random numbers table to one of 2 study groups</td>
<td>Blinding: not reported</td>
<td>Sex: n Male Arm 1 1 Arm 2 4</td>
<td>JADAD score: 2</td>
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<tr>
<td></td>
<td>Arm 2: Office-based traditional education 'office' group. Office group had scheduled office visits, the virtual group received all education online (via an educational website - for which no details are given - at 2/52, 6/52, 3/12, and 6/12 after enrolment). Parent’s input data (peak flow readings daily symptom diagnostic monitoring. Therapeutic adherence was reflected in the submission of 193 videos of inhaler use during the first 90 day study period and 128 for days 91–180 (240 videos were expected in each period). The adherence rate for inhaler video submission in</td>
<td>Power calculation: was a pilot feasibility study, a power analysis was not conducted</td>
<td>Ethnicity: Not reported</td>
<td>Baseline asthma severity: n= Arm 1 Arm 2 Mild persistent 1 3 Moderate persistent 4 2</td>
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<td>m 1 Arm 2 Period 1 18.7 65.1 Period 2 6.7 19.6 (p&lt;0.01)</td>
<td>Peak flow values significantly increased for both groups p=0.05</td>
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</tbody>
</table>

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<td>diaries) office group recorded data on hard copy diaries. Questionnaire was used at enrolment and 6 months.</td>
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</table>

<p>| | Study Design | Patient group | Results* | Comments |
| | | | the first 90 days | |
| | | | Arm 1 = 70% | |
| | | | Arm 2 = 91% | |
| | | | Overall adherence rates in the second study period to submission of videos of inhaler use | |
| | | | Arm 1 = 54% | |
| | | | Arm 2 = 52% | |
| | | | No differences in outcome measures at 180 days between Arm 1 and Arm 2. | |
| | | | Overall there was significant difference in inhaler technique between periods 1 and 2 (87.3% in period 1 and 94.3% in period 2) p&lt;0.05. Adherence to submission of videos decreased between period 1 and 2 p=0.01. | |</p>
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<td>Christiansen, S.C. et al. 1997</td>
<td>Evaluation of the impact of school-based asthma education programme for Inner-city children. 5 (20 minute) session school-based asthma education programme, led by a school nurse practitioner, focussing on information; identification of signs; medications; use of peak flow meters; action plans and emergency plans.</td>
<td>RCT</td>
<td>Inclusion criteria: 4th grade student volunteers at 4 San Diego schools  Aged 9-12 years  Only those with current asthma-related symptoms</td>
<td>Outcomes include asthma knowledge, use of peak flow meter, Inhaler technique. Parent questionnaire used for identification, additional study data came directly from students. Results were analyzed by comparing baseline with post-education scores. Improvement in mean scores for: asthma knowledge in Arm 1 was from 9.9 to 13.7 (n=34, SEM = 0.44) significant p≤.00001 peak flow techniques from 3.9 to 6.4 (n=34, SEM = 0.33) inhaler technique from 2.3 to 4.3 (n=32, SEM = 0.26) All changes in this</td>
<td>Adherence to correct inhaler technique assessed in this study  Reported that drop out occurred only where student relocated out of the school district. (2 from Arm 1) Intervention varied between subjects in terms of input and duration. JADAD score: 1</td>
</tr>
<tr>
<td>USA</td>
<td>Asthma</td>
<td>Total patients n=49</td>
<td>Arm 1: n=34  Arm 2: n=15</td>
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<td>Follow up period: duration varied considerably between different subjects. The mean ± SEM total duration of monthly follow-up data was 402 ± 43 days in Arm 1 and 404 ± 31 days in Arm 2</td>
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<td>Recruitment rate: not reported</td>
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<td>Randomisation method: not reported</td>
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<td>Blinding: not reported</td>
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<td>Baseline asthma severity: At entry to the study, the 27 subjects in the education program and 15 control subjects completing the prospective monthly follow-up did not differ either in wheezing frequency scores (1.22 ± 0.22)</td>
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<td><strong>Iron deficiency anaemia (IDA)</strong></td>
<td>The purpose of this study was to compare the efficacy of various doses and treatment methods on haemoglobin (Hb) concentration after 8 weeks of treatment in anaemic children</td>
<td>Cluster RCT</td>
<td>0.08 vs 1.27 ± 0.12) or overall assessment of asthma severity (1.52 ± 0.20 vs 1.60 ± 0.19).</td>
<td>group were highly significant (p≤.00001) None of the changes in the control group reached statistical significance</td>
<td>Symptom scores at 180 days for arm 1 vs. arm 2 were significant p=0.0188</td>
</tr>
<tr>
<td><strong>Christofides, A. et al. 2006.</strong></td>
<td>Five interventions: Arm 1: Sprinkles 12.5 mg Fe day⁻¹ Arm 2: n= 26 Arm 2: n= 28 Arm 3: n= 27 Arm 4: n= 27 Arm 5: n= 25 Follow up period: 8 weeks</td>
<td>Total patients n=133</td>
<td>Inclusion criteria: • Aged 6–18 months • Axillary temperature less than or equal to 37.5°C • No history of iron supplementation within 2 weeks prior to the day of recruitment • Willingness to stay within the study area for at least 2 months • Ingesting a semi solid weaning food • Hb concentrations 70–99 g L⁻¹</td>
<td>The primary outcome was Hb concentration at 8 weeks from baseline. Secondary outcomes included IDA and serum ferritin concentrations at the end of 8 weeks; and adherence, ease of use and side effects during the 8-week study period Mean change in Hb was 1.4 g L⁻¹ (SD=1.8) (p=0.0001). Change in Hb concentrations from baseline to 8 weeks was significant in all groups</td>
<td>JADAD score: 3</td>
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<tr>
<td>Author, Year, Country, Disease</td>
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<td>Arm 2: Sprinkles 20 mg Fe day(^{-1})</td>
<td>Recruitment rate: 284 children from 265 housing compounds were assessed for eligibility, and out of them, 133 children (127 housing compounds) entered the study</td>
<td>• Hb concentrations &lt;70g L(^{-1})</td>
<td>(p=0.0001–0.0007), with no differences across groups. Geometric means of serum ferritin varied from 18.6 to 44.0μg L(^{-1}) at baseline. At week 8, these means were in the interval of 48.0–78.3 μg L(^{-1}), with no group differences. Prevalence of iron deficiency anaemia decreased significantly from baseline to 8 weeks in all groups with the exception of the iron drops group, with no group differences.</td>
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<td>Arm 3: Sprinkles 30 mg Fe day(^{-1})</td>
<td>Randomisation method: Housing compounds (clusters containing no more than four participants) were randomly assigned to one of the five intervention groups using a random digit generator</td>
<td>Sex: n</td>
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<td>Arm 4: Ferric Pyrophosphate sprinkles 20 mg Fe day(^{-1})</td>
<td>Blinding: not reported</td>
<td>Arm 1 10</td>
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<td>Arm 5: Iron drops (liquid ferrous sulphate) 15mg day(^{-1})</td>
<td>Power calculation: Sample size was calculated using Bonferroni’s correction for multiple comparisons with an alpha error of 0.05, beta error of 0.20 (80% power). Based on these assumptions, at least 17 infants were required per group to detect a 10gL(^{-1}) increase.</td>
<td>Arm 2 17</td>
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<td></td>
<td></td>
<td>Ethnicity: Not reported</td>
<td>Arm 3 15</td>
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<td>Arm 4 16</td>
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<td></td>
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<td></td>
<td>Arm 5 10</td>
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<tr>
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<tr>
<td></td>
<td></td>
<td>difference in Hb concentration at the 8-week follow-up.</td>
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<td>Adherence was Mean % (SD)</td>
<td>Adherence in arm 5 was significantly lower compared with Sprinkles groups (p=0.001).</td>
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<td>Arm 1 = 85 (8)</td>
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<td>Arm 2 = 84 (9)</td>
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<td>Arm 3 = 84 (12)</td>
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<td></td>
<td></td>
<td>Arm 4 = 83 (8)</td>
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<td>Arm 5 = 69 (7)</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>Arm 1 = 95 (8)</td>
<td>Ease of use Mean % (SD)</td>
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<td></td>
<td>Arm 2 = 99 (3)</td>
<td>(p=0.001)</td>
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<td>Arm 3 = 98 (6)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Arm 4 = 99 (3)</td>
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<td></td>
<td>Arm 5 = 82 (22)</td>
<td>(p=0.001)</td>
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<tbody>
<tr>
<td>Daley, B. J, 1992.</td>
<td>Comparing the effect of a sponsorship intervention on outcomes Type 1 diabetes mellitus in adolescents.</td>
<td>RCT</td>
<td>Inclusion criteria: 12-16 years of age</td>
<td>Adherence is measured using glycosylated haemoglobin (HbA1c). Using a self-esteem scale, self-esteem was measured. Comparisons of changes in responses to the Self-Perception Profile for adolescents from pre to post intervention showed that there were significant increases in self-esteem with regard to social acceptance and romantic appeal in the intervention group. (mean difference 0.19, p&lt;0.05) No significant difference in mean levels of glycosylated haemoglobin between the two groups (values not reported).</td>
<td>Selection criteria poorly reported</td>
</tr>
<tr>
<td>USA</td>
<td>Each of the intervention group adolescents was paired with an adult who also had Type 1 diabetes. Adults received two training sessions from a social worker and were supported over a 10 month period at group sessions held at 6 week intervals. Adolescent and adult met twice a month.</td>
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<tr>
<td>Type 1 diabetes mellitus</td>
<td>Total patients n=54</td>
<td>Numbers allocated to intervention and control groups not reported.</td>
<td>Sex: n male 21</td>
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<td></td>
<td>Follow up period: 10 months</td>
<td></td>
<td>Ethnicity: % Hispanic 33 African American 11 Other 56</td>
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<tr>
<td></td>
<td>Recruitment rate: not reported</td>
<td>Recruitment method: not reported</td>
<td></td>
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<td></td>
<td>Blinding: not reported</td>
<td>Power calculation: not reported</td>
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<tbody>
<tr>
<td>Downs, J. A. et al. 2006.</td>
<td>Comparing the benefits of an education program on the self-management of aerosol and airway clearance techniques (ACT) for children with cystic fibrosis. An intense 10 week, 10 chapters, pen and paper education programme were completed by the child and the caregiver together at home. Each of the 10 chapters taking approximately 20 minutes to complete and providing child-friendly information and behavioural exercises.</td>
<td>Multi-centre RCT</td>
<td>adolescents were approached or how they were recruited. This is also the same for the adult sponsors.</td>
<td>Adherence to aerosol and ACT regimens and caregiver self-management behaviours, were recorded on a one-week diary card developed for this study. Other outcome measures include responsiveness of ACT performance when the child was unwell, child knowledge of ACT, child feelings about regular performance of aerosol and ACT treatment regimens, and caregiver self-efficacy to manage aerosol and ACT treatment regimens. Arm 1 increased their % of JADAD score: 2</td>
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<tr>
<td>Australia</td>
<td>Cystic fibrosis</td>
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<td>'Airways'</td>
<td>provided information, developed practical assessment, treatment and decision-making skills, and provided strategies to overcome barriers to treatment. Arm 1: intervention group Arm 2: control group</td>
<td>Randomised permuted blocks, followed by stratification by age: 6-8; 9-11. Blinding: not reported</td>
<td>Ethnicity: Not reported</td>
<td>prescribed aerosol medications taken between pre- and post-intervention significantly more than the control group (p &lt; 0.001) and maintained this increase at the 12-month follow-up (p &lt; 0.001). (mean + SD) Arm 1 Pre-test 66.3 ± 24.2 Post-test 100.6 ± 24.4 6month FU 98.5 ± 22.6 12month FU 91.7 ± 15.8 Arm 2 Pre-test 77.2 ± 28.3 Post-test 70.9 ± 26.8 6month FU 77.5 ± 28.9 12month FU 74.2 ± 24.3 (p&lt;0.001)</td>
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<td>Ellis, D. A. et al. 2005.¹⁴¹</td>
<td>Comparing the use of Arm 1: multisystemic therapy (MST) with Arm 2: normal care to improve regimen adherence among adolescents with Type 1 diabetes in chronic poor metabolic control</td>
<td>RCT, with a repeated measure design</td>
<td>Inclusion criteria: Diagnosed with Type 1 diabetes for at least 1 year Average HbA1c 8% during the year before study entry Aged 10 – 17 years</td>
<td>There was no change in the percentage of prescribed ACT performed, although when the child was unwell, caregivers in Arm 1 were more responsive and increased the frequency and or duration of ACT Mean difference in scores for responsiveness were Arm 1: 0.28 ± 0.35 Arm 2: -0.04 ± 0.34 (p=0.028)</td>
<td>Significantly more males were randomly assigned to MST. 7% of families dropped out of the study before completing follow up data collection and 6% did not</td>
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<tr>
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<td>MST consisted of intensive home based psychotherapy, delivered by therapists plus standard medical care</td>
<td>Follow up period: 24 months. The study was ongoing and the paper reports at 7 month follow-up. Recruitment rate: 70% recruitment into a home-based intervention. Randomisation method: Randomisation to treatment was completed immediately after baseline data collection by the project statistician. To ensure equivalence across treatment condition, randomisation was stratified by level of A1C at the baseline visit. Blinding: All records that were ambiguous were reviewed and coded by a paediatric endocrinologist who was blind to the participant’s</td>
<td>Sufficient mastery of English to communicate with therapists and complete study measures Exclusion criteria: Moderate/severe mental retardation or psychosis. Sex: n Male Arm 1 38 Arm 2 24 Ethnicity: Arm 1 African American, 44 White, 13 Other 7</td>
<td>visits. Insulin adherence: No significant treatment X time interaction was found for [F(1,125) = 1.90, p=0.171] Adolescents in arm 1 significantly increased their frequency of blood glucose testing from baseline to 7-month follow-up compared with arm 2, for whom no change was evident</td>
<td>complete data collection within the specified window (87% completion rate). JADAD score: 1</td>
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<td>Farber, H. J &amp; Oliveria, L. 2004.</td>
<td>Arm 1: In the intervention group, the adult accompanying the child received (a single-session) basic asthma education (shown a video; goals fears and concerns discussed);</td>
<td>RCT</td>
<td>7</td>
<td>Arm 2  23.8  23.8 (p=0.847). Arm 1 had a significantly reduced number of admissions, whereas the number of admissions increased in arm 2 Baseline 7month FU Arm 1  0.44  0.13 Arm 2  0.43  0.54 (p=0.014).</td>
<td>Asthma severity scores were similar at baseline for both arms – both arms had scores suggesting moderate to severe asthma. Most of these subjects were under treated; only 25% reported use of inhaled anti-</td>
</tr>
</tbody>
</table>

**Study Design**

- randomisation status
- Power calculation: Power calculations were based on outcomes from our preliminary studies regarding the effect of the MST intervention on metabolic control. The trial was powered to detect a 1.10% difference in A1C between the two groups using a two tailed α of 0.01 and power=0.80, with a total of 120 subjects (60 per group).
- Intention-to-treat analysis
- And per-protocol analysis

**Patient group**

- Inclusion criteria:
  - Aged between 2 and 18 years
  - Has State of Louisiana Medicaid insurance
  - Has a telephone at home
  - Has a history of asthma

**Results**

- Arm 1: n = 28
- Total patients n=56

**Outcome measures include:**

- Medical care utilisation and asthma severity score.
- Adherence measured by levels of dispensing of asthma controller medication
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Intervention being tested</td>
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<tr>
<td>describe normal lungs; describe what happens to lungs in an asthma episode; describe the role of preventive vs. symptom relieving medication), a written asthma management plan (principles of an asthma management plan illustrated; write out asthma management plan) and a prescription for both quick-relief and long-term control medications (discuss asthma triggers; reinforce asthma management behaviour; teach inhaler/holding chamber device technique) as part of the emergency department visit.</td>
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<td>Author, Year, Country, Disease</td>
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<tr>
<td>Garrett, J. et al. 1994. 174</td>
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<td>Asthma New Zealand.</td>
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<td>Guendelman, S. et al. 2002.</td>
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<td>Author, Year, Country, Disease</td>
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<tr>
<td>Asthma</td>
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<td>Exclusion criteria:</td>
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<tr>
<td>Sex: n</td>
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<td>Arm 1</td>
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<td>Arm 2</td>
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<tr>
<td>Ethnicity: Arm 1</td>
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<tr>
<td>African American</td>
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<tr>
<td>White</td>
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<td>Persistent asthma</td>
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<td>Percentage:</td>
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<td>Seldom or never</td>
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<td>Most of the time</td>
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<td>All of the time</td>
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<tr>
<td>Missing data</td>
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<tr>
<td>n (%)</td>
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<td>Author, Year, Country, Disease</td>
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<tr>
<td>Hederos et al 2005 updated in 2009 180 183 Sweden</td>
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</table>
| Asthma                        | Arm 1: group session with education and a written treatment plan  
Arm 2: education and a written treatment plan | Arm 2: n=28  
Follow up period: 18 months (85%)  
Recruitment rate: not reported  
Randomisation method: not reported  
Blinding: not blinded  
Power calculation: not carried out | Authors did not discuss exclusion criteria  
Sex: % Female  
Arm 1: 41%  
Arm 2: 39%  
Ethnicity: not reported | Adherence: measured by patient diaries and weighing MDIs  
Results  
Poor adherence  
Arm 1: 8%  
Arm 2: 30% P=0.015  
Outcomes:  
No differences reported |
| Holzheimer, L. et al. 1998. | Comparing effects of age-sensitive educational materials:  
Arm 1: Video tape alone  
Arm 2: Book alone  
Arm 3: Combined book and video tape  
Arm 4: Control group – | Controlled experimental study - evaluation of impact of educational resources, compliance and health status  
Total patients n=80  
Arm 1: n=20  
Arm 2: n=20  
Arm 3: n=20 | Inclusion criteria:  
- Aged 2-5 years  
- Has been diagnosed with asthma by a medical practitioner  
- Requires daily asthma medication.  
Authors did not discuss exclusion criteria. Only enrolled children who | Throughout the 4 months of the study, parents were asked to maintain a daily diary record of their child's non-compliance with medication, experience of asthma symptoms and need for medical care (phone calls and/or consultations with a medical practitioner for care)  
Groups analysed as per protocol (4 groups: 3 experimental and 1 control) but children who stopped using daily medication for more than 14 days were excluded from compliance comparison (varied between 8 and 4 out of 20) – i.e. did not analyse on |
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| were shown unrelated video and given unrelated book of similar length and level. | Arm 4: n=20  
follow-up period: 4 months.  
Recruitment rate: not reported  
Randomisation method: not reported  
Blinding: The researchers were blind to the group membership of each child  
Power calculation: not reported  
Per-protocol analysis | ceased taking daily medication for more than 14 days were excluded from data analysis relevant to compliance and health  
Sex: Not reported  
Ethnicity: Not reported  
Baseline asthma severity: Not reported | asthma).  
Mean improvement scores (in knowledge) - video and book vs. control p=0.001; video only p= 0.049; book vs. control p=0.032; video and book vs. video, p=0.036;  
The only statistically significant difference (p<0.05) found was between groups one and four with regard to the number of medical consultations for asthma.  
Mean non-compliant days  
Arm 1 n=9.75  
Arm 2 n=7.62  
Arm 3 n=9.08  
Arm 4 n=14.89  
Not statistically significant  
Mean days without wheeze | intention-to-treat basis.  
Children in the experimental groups experienced, on average, less non-compliant days, less days with wheezes or coughs and sought medical advice less often than children in Arm 4. Stats showed No significant differences  
JADAD score: 1
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<tbody>
<tr>
<td>Hovell, M. F. et al. 2003 USA</td>
<td>Patients in Arm 1: the usual medical care received care group were from community clinics and were given 300 mg of INH (1 tablet) per day. At physicians’ discretion, adolescents were placed on 6 or more months of INH therapy; adolescents returned to the clinic monthly for evaluations and new prescriptions, or they were provided 3 months of medication</td>
<td>RCT</td>
<td>Inclusion criteria: Positive screen via mantoux skin tests and chest x-rays for LTBI. Latinos aged 12 to 19 years both sexes Had no medical contra indications Spoke English/Spanish, and planned to remain in the San Diego Tijuana area for 12 months</td>
<td>Adherence was measured via interviews and validated with urine assays. Coaching resulted in significant increases in adherence compared with self esteem and usual care groups.</td>
<td>JADAD score: 1</td>
</tr>
<tr>
<td></td>
<td>Arm 1: n=96</td>
<td>Total patients n=286</td>
<td>Arm 1: n=96</td>
<td>Arm 1 n=37.31</td>
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<tr>
<td></td>
<td>Arm 2: n=92</td>
<td>Arm 2 n=40.15</td>
<td>Arm 2</td>
<td>Arm 2 n=51.47</td>
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<tr>
<td></td>
<td>Arm 3: n=98</td>
<td>Arm 3 n=29.10</td>
<td>Arm 3</td>
<td>Arm 3 n=51.47</td>
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<td>Follow up period: 6 months</td>
<td>Follow up period: 6 months</td>
<td>Arm 4</td>
<td>Follow up period: 6 months</td>
<td>Arm 4 n=51.47</td>
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<tr>
<td></td>
<td>Recruitment rate: 2698</td>
<td>Recruitment rate: 2698</td>
<td>Not statistically significant</td>
<td>Not statistically significant</td>
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<td>and returned when they needed a prescription refill or had experienced symptoms or side effects. Comparing the impact of Arm 2: adherence coaching and Arm 3: self esteem counselling (attention control) on increasing Latino adolescents' adherence to treatment for latent tuberculosis infection (LTBI).</td>
<td>adolescents screened, 486 (18%) exhibited induration reactions of at least 10 mm; of these, 413 were eligible. Randomisation method: Analysis of variance (ANOVA) was used to test for group differences in baseline characteristics to confirm random assignment and to assess differences in cumulative mean adherence to INH treatment by group.</td>
<td>Patient non – consent, Pregnancy, Learning disabilities, An atypical isoniazid regimen in Mexico</td>
<td>Sex: n Male&lt;br&gt;Arm 1 51&lt;br&gt;Arm 2 50&lt;br&gt;Arm 3 58</td>
<td>group main effect for both 9- and 6-month analyses. For both time periods, the coaching condition had the highest cumulative mean number of tablets consumed, and pair wise comparisons using the Tukey honestly significant difference test indicated that members of the adherence coaching group took significantly (p&lt;.05) more tablets than members of the arm 1 and arm3 respectively.</td>
<td>Blinding: Investigators, staff, and treating physicians were blind to outcome data. Bilingual interviewers were blind to condition of the patients. Self-esteem counsellors were blind to adherence coaching procedures, and vice versa.</td>
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<td>Howe, C. J. et al 2005.</td>
<td>Two intervention groups and one control. Arm 1: Control (standard care) Arm 2: Education (ED) - One-time session by the study coordinator that aimed to provide families with basic diabetes management skills plus standard care Arm 3: Education and telephone case management group (ED &amp; TCM) – TCM consisted of standardised telephone calls which reviewed blood sugars, safety</td>
<td>RCT Total patients n = 89 Total completed study: Arm 1: n = 28 Arm 2: n = 21 Arm 3: n = 26 The group allocation for the remaining fourteen patients (not included in the study analysis) is not reported. Follow up period: 6 months Recruitment rate: Of those approached, less than half of these subjects followed up with the enrollment process (paperwork returned) or with</td>
<td>Inclusion criteria: • Aged 1 to 16 years • Patients had two consecutive (HbA1c) results of 8.5% or higher • Had been diagnosed with Type 1 diabetes for at least 1 year.</td>
<td>HbA1c is the primary outcome measure. Diabetes knowledge (KNOW), improved adherence (ADH), and better parent–child teamwork (TEAM) were the secondary outcomes. There were no significant differences among groups in mean HbA1c change at 3 or 6 months from baseline (Group X Time interaction), F(4, 71) = 0.12, p = 0.97, and no overall group differences, F(2, 72) = 0.65, p = 0.52</td>
<td>No discussion of age sensitivity of intervention or outcome measures despite the fact that ages’ ranged from 2.8 to 16.9 years. JADAD score: 3</td>
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<td>issues, problem solving skills, diet and meal planning, and changing insulin dose, as well as parenting and behaviour management skills with parents as needed.</td>
<td>The initial study intervention (education session). No further details on recruitment rate</td>
<td>per-protocol analysis</td>
<td>African: 12 6 14 American:</td>
<td>ADH is an 11-item clinician checklist used to evaluate child/family behaviours related to diabetes safety and control. ADH scores are reported as a percentage of positive adherence ('yes' on the adherence evaluation). Not statistically significant</td>
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<td>The study coordinator followed a standardised telephone protocol. Telephone calls were typically 5 to 15 minutes</td>
<td>Randomisation method: A randomisation schedule was produced using Statistical Analysis System (SAS) program with subjects blocked by race, age group, sex, and family structure (single vs. two parents). Within each block, subjects were randomly assigned to one of the three treatment groups. Blinding: not reported Power calculation: Calculations were based on an effect size of 8% improvement in HbA1c. Calculations estimated a total of 135 subjects - 45 per group. Assuming overall type 1 error of .05 and power of 85%</td>
<td></td>
<td>for ADH scores, the results indicated that the Group X Time interaction was statistically significant, F(2, 69) = 68.8, p=.0006. Post hoc analysis indicated that ADH in the arm 2 and arm 3 had improved by 24% over a 6-month period compared with 2% improvement for subjects in arm 1 (t = 3.9, p=.0002). Statistically significant</td>
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| Hughes, D. M. et al 1991 \(^\text{161}\) | Comparing the effect of a home and ambulatory | RCT | Inclusion criteria:  
  - Age 6-16 years with Compliance inferred from theophylline levels.  | The only significant effect was seen in adherence between arm 3 compared to arm 2 and arm 1, p=0.0006; post hoc analysis p=0.0002. Baseline adherence (M ±SD)  
  Arm 1 = 51.2 ± 25.1  
  Arm 2 = 49.8 ± 7.5  
  Arm 3 = 48.3 ± 19.7  
  p=0.91  
  Adherence at 6 months  
  Arm 1 = 49.2 ± 28.0  
  Arm 2 = 54.1 ± 23.9  
  Arm 3 = 72.3 ± 19.7  
  TEAM scores also improved p= 0.002; post hoc analysis p=0.0003. | JADAD score: 1 |

\(^\text{161}\) Project 08/1704/212
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<td>Canada, Asthma</td>
<td>programme for asthmatic children on medication adherence and patient outcomes</td>
<td>Total patients n=95 arm 1: n=47 arm 2: n=48 follow up period: 2 years n=89 (93%) completed study</td>
<td>diagnosis of asthma during previous 5 years • Residence in locality • Absence of other major medical conditions • No previous treatment by the authors.</td>
<td>Theophylline measures were done at the start of the study and at each assessment visit. Aerosol technique was assessed by study nurse. There were no significant differences in theophylline levels. More than half the subjects in each arm had serum theophylline levels below the lower limit of the therapeutic range (55 to 110 μmol/L) (10 to 20 mg/dL) at each assessment visit (data not available). Absenteeism (mean number of days) Arm 1 10.7 Arm 2 16.0 significant improvements in arm 1 compared to arm 2 (p=0.04)</td>
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<td>Canada, Asthma</td>
<td>Arm 1: Intervention group received 3 month clinic visits, education and home visits by specially trained research nurse. Arm 2: Control group received usual care from family physician</td>
<td>recruitment rate: n=2220 names retrieved; exclusions by age; and additional exclusions as per protocol and if the child moved away. From n=149, n=95 approved - remainder not approved, unable to contact or ineligible. Randomisation method: a process of restricted randomisation based on age (6 through 10 years, 11 through 16 years) and number of previous hospitalisations (one, more than one) during the previous 5 years was carried out. Subjects were alternately assigned to arm 1 or arm 2.</td>
<td>Sex: n Male arm 1 23 arm 2 37</td>
<td>Ethnicity: Not reported Baseline asthma severity: Not reported</td>
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<td>assigned to study or control groups, with the initial assignment for each pair determined by a coin toss.</td>
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<td>Good inhaler technique (%)</td>
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<td>Blinding: Technicians carrying out the pulmonary function tests were “blind” to the subsequent randomisation</td>
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<td>Pre-12 month study follow-up</td>
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<td></td>
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<td>Power calculation: not reported</td>
<td></td>
<td>Arm 1 33.3 93.5</td>
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<td>Arm 2 46.7 62.1 (p=0.008)</td>
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<td>number of days admitted subject admitted to hospital study follow-up year year</td>
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<td>Arm 1 3.67 5.83</td>
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<td>Arm 2 11.1 5.33 (p=0.02)</td>
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<td>Number of hospital admissions at:</td>
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Good inhaler technique (%)
Pre- 12 month study follow-up
Arm 1 33.3 93.5
Arm 2 46.7 62.1 (p=0.008)

Number of days admitted subject admitted to hospital study follow-up year year
Arm 1 3.67 5.83
Arm 2 11.1 5.33 (p=0.02)
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<td>Iqbal, S. et al 2004.\textsuperscript{165}</td>
<td>The aim of the present study was to compare the performance of the trial.</td>
<td>Open, randomised, crossover trial.</td>
<td>Inclusion criteria: - 11–36 months - Asthmatic children on</td>
<td>study follow-up year year Arm 1 20 8 Arm 2 25 7 (p =0.02) After 1 year, child taken responsibility for management Arm 1 72.1 Arm 2 33.1 (p=0.006) Improvement in small airways obstruction 50% and 25% vital capacity p=0.0001, (p=0.001 disappeared after 12 months)</td>
<td>Very short term study and very small samples</td>
</tr>
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<td><strong>UK</strong></td>
<td>new HaloLite Paediatric Nebuliser (HPN) with that of a pressurised metered dose inhaler and valved holding chamber (pMDI VHC, Aerochamber) with an integral datalogger (DL) when used with face masks by children under age 3 years.</td>
<td>Total patients n= 14 n=2 were withdrawn, one because of a prolonged admission for a bronchiolitic illness shortly after entering the study, and one because of total non adherence to treatment after the first 4-week period. No reason was given by authors for the lack of adherence.</td>
<td>regular treatment with inhaled corticosteroids • Presently using either a pMDI VHC with facemask or a jet nebuliser with facemask for aerosolised drug delivery Authors did not discuss exclusion criteria Sex: (n after withdrawals) Male 11 Ethnicity: Not reported Baseline asthma severity: Not reported</td>
<td>parent and patient acceptability, adherence to treatment regimen, effective use of device (device compliance), and true adherence. Adherence to treatment regimen was calculated as total number of treatments started/prescribed number of treatmentsx100. All patients had a twice-daily treatment regimen, but there was no specification as to timing of treatment. True adherence was measured using The HPN. It is programmed to monitor adherence to the prescribed treatment regimen and compliance to instructions regarding the use of the device. The median delivered dose</td>
<td>The shape, size, and weight of the HaloLite Paediatric Nebuliser were generally less acceptable than the shape, size, and weight of the pMDI VHC with datalogger. These results indicate that reproducible quantities of drug can be delivered to very young children using AADTM technology such as that incorporated into the HPN. Drug delivery with the pMDI VHC was more variable, but parents preferred this device. JADAD score: 2</td>
</tr>
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<td><strong>UK</strong> Asthma</td>
<td>Children received, in random order, budesonide inhalation suspension delivered with the HPN for 2 weeks, and 2 weeks of budesonide pMDI delivered through a VHC with a built-in integral datalogger.</td>
<td>Follow up period: 4 weeks Recruitment rate: not reported Randomisation method: not reported Blinding: not reported Power calculation: not</td>
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<tr>
<td>Kamps et al 2008 USA</td>
<td>A targeted educational and behavioural intervention to improve adherence to ICS in children with asthma</td>
<td>RCT group design, outpatient study</td>
<td>Inclusion criteria: nonadherent patients Ages 7-12 Authors did not discuss exclusion criteria Sex: 33% Female Ethnicity:</td>
<td>Adherence: measured by Electronic monitor (MDILog) Main outcomes Pulmonary spirometry outcomes Adherence: measured by Electronic monitor (MDILog) Results Adherence self report</td>
<td>Very small study No randomisation or blinding reported, highly susceptible to bias. Data analysed using pooled time series analysis (PTSA)</td>
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Note: No Stats reported

The median device compliance was 30% and 51% and the median true adherence was 23% and 36%, respectively.

of budesonide was 36 mg (range, 31–45 mg; for the HPN and 53 mg (range, 17–85 mg) for the pMDI VHC. The median adherence was 68% (range, 11–96%) with the HPN and 71% (range, 11–100%) with the pMDI VHC. The median device compliance was 30% and 51% and the median true adherence was 23% and 36%, respectively.
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<td>Asthma</td>
<td>behavioural intervention, home based</td>
<td>Recruitment rate: 22.4% Randomisation method: not clear, stratification carried out by age Blinding: not blinded Power calculation: not carried out</td>
<td>African American: 3 Hispanic American: 4 European American: 8</td>
<td>16.38% improvement in intervention group (PTSA results) Outcomes: Pulmonary outcomes improved in Arm 2. Specific results not clear.</td>
<td>JADAD score: 1</td>
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<tr>
<td>Lawson, M. L. et al 2005. 162 Canada Type 1 diabetes mellitus</td>
<td>Comparing the effect of: Arm 1: Regular standardised (educational) intervention via weekly telephone contact initiated by a Diabetes Nurse Educator (DNE) Arm 2: Usual care to assist with diabetes management.</td>
<td>Single blind, 6 months RCT, parallel design. Total patients n=49 Total in the study: n=46 Arm 1: n=23 Arm 2: n=23 Follow up period: 6 months and 6 months post hoc study follow-up Recruitment rate: not reported</td>
<td>Inclusion criteria: • Adolescents ages 13-17 • With Type 1 diabetes, for at least 1 year, • Receiving insulin x 2 / 3 daily • Poor metabolic control (HbA1c &gt; 8.5% over previous 6 months.) Exclusion criteria: Adolescents with other chronic conditions (with the exception of hypothyroidism or asthma</td>
<td>Compliance with blood glucose testing measured by logbook records, downloaded meter results, and the Compliance with Diabetes Management Scale (CDMS) questionnaire. Higher scores correlate with better metabolic control. Compliance with the telephone contact was recorded by the DNEs No significant effects at 6 month follow up. No significant difference in</td>
<td>JADAD score: 3</td>
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<td>Randomisation method: The research assistant randomised participants to standard diabetes management or to the telephone intervention plus standard care, with a pharmacy department computer-generated sequence using randomly permuted blocks of four, coded in sequentially numbered opaque sealed envelopes. Blinding: DNEs and subjects were aware of their treatment assignment. Investigators, treating physicians other diabetes team members and data management personnel were masked to the treatment assignment (97% successful). Power calculation: calculated based upon the primary requiring oral glucocorticosteroids less than twice per year) Sex: % Male Arm 1 61 Arm 2 52 Ethnicity: Not reported</td>
<td>self-reported compliance to insulin regimen according to Likert scale (p=0.29). However, at 6 months post hoc follow up, HbA1c levels decreased (1% compared to baseline) in 6/21 of the study groups and 0/18 of control group; while HbA1c increased in 4/21 study group compared to 8/18 control group (p=0.015)</td>
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| LeBaron, S. et al 1985. USA | Comparing the effects of Arm 1: an intensive education and Arm 2: standard care to improve compliance with cromolyn sodium | RCT | Inclusion criteria:  
- 6 - 17 years of age  
- Mild to moderate asthma.  
- Receiving theophylline and/or beta-adrenergic agents and cromolyn  
Exclusion criteria: On corticosteroids or immunotherapy at the initiation of the study. | Outcome measure was patient knowledge of cromolyn, compliance, subjective and objective assessments of medical status and patient symptoms. Parents were asked to self-rate their compliance. At the beginning of study visits 2 through 5. Each patient was asked to describe and rate | All families were of low middle income or greater. Self report compliance  
0 = noncompliant,  
10 = excellent |  
JADAD score: 1  
<p>| | In the intervention group, the education program was administered in three | | | |  |
| | outcome measure (HbA1c) using an estimated standard deviation of 0.9%, and 90% power to demonstrate a 1% decrease in HbA1c at 6 months, at a significance level of p=0.05 (two-tailed). Twenty-three subjects per group allowed for a 20% rate of dropouts and losses to follow-up. Intention-to-treat and per-protocol analysis | | | |  |</p>
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<td>sessions by a nurse educator to patients and their parents. It consisted of demonstrations on the use of cromolyn and discussions about how, why and when use of cromolyn and how to anticipate problems with its use. Arm 1: Intervention: Education group Arm 2: Control: Non-education group</td>
<td>referred to the study, n=12 were unable to participate Randomisation method: not reported Blinding: not reported Power calculation: not reported</td>
<td>Sex: n Male 23 Ethnicity: n Black 1 Mexican-American 4 Anglo 26 Baseline asthma severity: Not reported</td>
<td>the degree of compliance with each of his/her medications during the previous months using a 10 point Likert scale. Spot urine samples were obtained for assay of cromolyn sodium levels, cromolyn concentration was assayed by high pressure liquid chromatography. The mean compliance ratings increased significantly in Arm 1 Arm 1: Visit 2 Visit 5 6.21 8.64 (p&lt;0.04). Arm 2: Visit 2 Visit 5 9.00 8.43 In Arm 1, multiple range tests showed that self ratings at the end of the</td>
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<td>Lewis, C. E. et al 1984, USA</td>
<td>A.C.T. (Asthma Care Training) educational intervention for children and parents. Arm 1: Control group received 4 ½ hours of lecture presentations on asthma and its management (6-12 families or 12-25 people) Arm 2: Experimental group classes were limited to 5–7 children and their parents per group – 5 interactive sessions of 1-hour at weekly intervals - one</td>
<td>RCT</td>
<td>Inclusion criteria: • Aged 7 to 12 • 'Severe' asthma - medication required at least 25% of the days of the month • Able to speak English Authors did not discuss exclusion criteria</td>
<td>Knowledge, beliefs, skills and compliance behaviour were study outcomes. Differences between control and experimental group tested using ANCOVA Knowledge: no difference between groups; shift in beliefs about severity in experimental groups p=0.001; reductions in use of emergency room p=0.01. Compliance behaviour: 88% of both arm 1 and arm 2 parents and children indicated that medication was accessible to the child on pre-test. This increased slightly on post-test. When</td>
<td>Sample was made up of members of Southern California Permanente medical group - health management organisation (HMO). All were under the care of paediatric allergists with the standard of healthcare prior to the study judged to be high. JADAD score: 3</td>
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| **Lozano, P. et al. 2004**<sup>148</sup> USA Asthma | 2 intervention arms and usual care  
Arm 1: Peer leader education intervention consisted of training 1 physician per practice in asthma guidelines and peer teaching methods.  
Arm 2: Planned care | Cluster RCT over a 2 year period  
Total patients n=638  
Arm 1: n= 226  
Arm 2: n= 213  
Arm 3: n=199  
Follow up period: 2 years | Inclusion criteria  
- Aged 3 to 17 years  
- With mild to moderate persistent asthma  
- Enrolled in primary care practices affiliated with managed care organizations (MCOs).  
Exclusion criteria | Outcome measures: annualised asthma Symptom days, asthma-specific functional health status (Children’s Health Survey for Asthma), and frequency of brief oral steroid courses (bursts).  
Adherence measures by | Imbalance in types of medicines being used at baseline  
Overall participant rate was estimated to be 27%. A total of 554 subjects (87% of those enrolled) was available at the end of the study and analysed for |
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| Planned care combined the peer leader program with nurse-mediated organisational change through planned visits with assessments, care planning, and self-management support, in collaboration with physicians. Arm 3: Usual care. Practices randomised to this arm received a copy of the EPR2 and a tool kit of patient education materials 1 year into the study. Analyses compared each intervention with usual care. The peer leader education coordinator documented peer leader recruitment. | Planned care combined the peer leader program with nurse-mediated organisational change through planned visits with assessments, care planning, and self-management support, in collaboration with physicians. Arm 3: Usual care. Practices randomised to this arm received a copy of the EPR2 and a tool kit of patient education materials 1 year into the study. Analyses compared each intervention with usual care. The peer leader education coordinator documented peer leader recruitment. | Recruitment rate: 7052 children met the Automated Data Criteria. 5286 were contacted for phone screening, 3041 agreed to be screened, 1000 children were eligible, 42 clinic’s were randomised and 638 children were enrolled. The overall participation rate was estimated to be 27%. | - Children with ‘serious’ co-morbid condition
- Children with severe asthma
| Sex: % | Male | Arm 1 | 57 |
| Arm 2 | 62 |
| Arm 3 | 60 |
| Ethnicity: % | Arm 1 (Arm2) [Arm 3] | Black/African American; | 22 (18) [13] |
| White; | 58 (69) [70] |
| Hispanic; | 6 (4) [6] |
| Others; | 14 (9) [11] |
| Baseline asthma severity: | | | | Arm 1 – 36.5 |
| Arm 1 vs. Arm 3: 6.5 fewer symptom days per year (95% CI −16.9 to 3.6), NS, and 36% (95% CI, 11% to 54%) lower oral steroid burst rate per year | Three hundred fifty (55%) were taking controller medication. Mean±SD annualised asthma symptom days was 107.4 ±122 days. | Eighty-two of the 84 subjects who dropped out contributed at least 1 periodic telephone survey to the outcome data. JADAD score: 1 | % controller adherence (parent report)

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</table>
| **McCrindle, B. W. et al. 1997.**<sup>163</sup> Canada | Acceptability and compliance with two forms of cholestyramine in the treatment of hypercholesterolaemia in children. | Randomised crossover trial of 8 weeks on each formulation, with 6 week washout period. Total patients n=40 Phase 1: | Inclusion criteria:  
- From 2 paediatric lipid disorder clinics  
- aged 10-18 years  
- At least 1 parent having heterozygous familial hypercholesterolemia | Questionnaire regarding ease of use and compliance after 4 and 8 weeks of medication use. Unused medication returned and counted. Compliance defined as % of expected | Pilot study  
40 patients enrolled; including 2 siblings from 6 families and 3 siblings from 1 family.  
ADAD score: 2 |

Reports of asthma-related activities through telephone contacts attempted every 1 to 2 months.  
Proportion of days with symptoms, using a 2-sided test based on a logit transformation of proportions.  
Not reported  

Arm 2 – 46.7  
Arm 3 – 37.2  

In multivariate models adjusting for regular controller use at baseline, planned care subjects had a greater frequency of parental report of regular controller use during the follow-up period compared with usual care subjects (rate ratio, 1.05 [95% CI, 1.00 to 1.09]). No effect of the peer leader intervention on controller use was detected.
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<tbody>
<tr>
<td>Hypercholesterolemia</td>
<td></td>
<td></td>
<td>type IIA or IIB</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Fasting serum LDL level 3.4 mmol/L or more while on American Heart Association step 2 diet</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• No contraindications with cholestyramine</td>
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<td></td>
<td></td>
<td></td>
<td>Authors did not discuss exclusion criteria</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Sex: n Male</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Arm 1 12</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Arm 2 11</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ethnicity: Not reported</td>
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</tbody>
</table>

**Study Design**

- Arm 1: pill group n=19
- Arm 2: powder group n=21
- Phase 2: (post crossover)
- Arm 1: pill group n=18
- Arm 2: powder group n=20
- 38 patients (95%) completed study
- Follow-up period: 28 weeks, including 6 week washout period.
- Recruitment rate: No patients declined.
- Randomisation method: Patients were randomly assigned in pairs with a table of random numbers
- Blinding: not reported
- Power calculation: not powered, pragmatic sample from 2 clinics.

**Results**

- medication amount actually taken during the study period.
- Of 40 children enrolled, 38 completed both medication periods with a median age of 13 years (range 10 to 18).
- 82% preferred pills 16% powder and 2% neither form. Mean compliance was greater for pills (61%) than powder (50%)
- Compliance in pills over powder p =0.01; mean reductions for LDL in pills p=0.006 and powder p=0.0001
<table>
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<tbody>
<tr>
<td><strong>Mitchell, E. A. et al. 1986.</strong></td>
<td>Comparing the effect of an additional education programme with standard care for children and their families with asthma from two ethnic groups. Intervention was delivered by community child health nurses in the children's homes. Intervention group was visited monthly by a nurse for six months.</td>
<td>RCT stratified by ethnic group</td>
<td>Inclusion criteria: Patients discharged from paediatric medical wards of a single hospital over a 1 yr period April 1983-April 1984.</td>
<td>Outcome variables were readmissions, missed schooling, and parental reports of the medical management of their child's asthma and their perception of their own and their child's management skills. A check on drug compliance (inspection of the contents of bottles of medicine to ensure drugs do not run out) and correct use of aerosols. European children in arm 1 were taking significantly more drugs for the treatment of asthma six months after the index admission to hospital than those in arm 2. p=0.001. They were taking more theophylline (56.6% v 37.0%). p=0.012 and inhaled steroids (34.9% v 21.0%) p=</td>
<td>It is not clear whether the control group received any form of contact with the research nurses. It is assumed that controls continued with normal care. The paper does not give the numbers of children &lt;2 &amp; out of catchment patients excluded. European children were significantly socio-economically advantaged compared to Polynesian children. From the results, it is difficult to conclude whether children's care necessarily improved. There was no baseline assessment of the outcomes of interest before the intervention was delivered.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Asthma</td>
<td>Total patients n=368 Because there were considerable differences in the medical management of their asthma, patients were divided into two ethnic groups, (1) Polynesians, which included Maoris and Polynesian Pacific Islanders, (2) Europeans, By ethnic grouping: European children n=200 Arm 1: n=94 Arm 2: n=106 Polynesian children n=168 Arm 1: n=84 Arm 2: n=84 Follow-up period: 6 months</td>
<td>Patients aged 2 to 14 years</td>
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<td></td>
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<td>Exclusion criteria: Patients whose home was outside the hospital catchment area</td>
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<td></td>
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<td></td>
<td>Patients who had previous life - threatening attacks. Non European / Polynesian ethnic groups.</td>
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<td></td>
<td></td>
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<td>Male:Female ratio European 1.4:1</td>
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<tr>
<td></td>
<td></td>
<td>Recruitment rate: all patients</td>
<td>Polynesian 1:6:1</td>
<td>No difference for parental reports of improvement, missed schooling and in severe attacks of asthma, of not responding to the usual treatment at home.</td>
<td>No details given about patients who were not enrolled.</td>
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<td></td>
<td></td>
<td>Randomisation method: not reported</td>
<td>Ethnicity: n</td>
<td></td>
<td>JADAD score: 1</td>
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<tr>
<td></td>
<td></td>
<td>Blinding: not reported</td>
<td>European 200</td>
<td></td>
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<td></td>
<td></td>
<td>Power calculation: not reported</td>
<td>Polynesian 168</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Baseline asthma severity:</td>
<td>Not reported</td>
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<td>European children use of hospital service for primary care: %</td>
<td>Arm 1: 34</td>
<td>More admissions in the European intervention group in 6 months after the index admission p = 0.067. 6-18 months after the index admission, more patients were re-admitted from the intervention group than the</td>
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<td>Arm 2: 11</td>
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<td>p =0.043.</td>
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<td>Morisky et al 2001 USA Tuberculosis</td>
<td>Behavioural and educational intervention to improve adherence in adolescents with latent tuberculosis. Four group design to assess the independent and combined effects of peer counselling and a participant-parent contingency contract intervention Arm 1 Peer counselling Arm 2 contingency</td>
<td>RCT group design, outpatient study Total patients n=794 Arm 1: n=199 Arm 2: n=204 Arm 3: n=196 Arm 4: n=195 Recruitment rate: 79% Treatment completion rate: 79.8% Randomisation method: not reported Inclusion criteria: not reported Ages 11-19</td>
<td>Adherence: measured by treatment completion Results Arm 1: 80.3% Arm 2: 76.4% Arm 3: 84.8% Arm 4: 77.8% NS</td>
<td>control groups p=0.008 and the number of re-admissions was also greater p=0.003. Polynesian children - no differences between the control and intervention groups 6-18 months after the index admission.</td>
<td>JADAD score: 0</td>
</tr>
<tr>
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</table>
| Murphy, K. R. et al. 2003. | contracting Arm 3 combination Arm 4 usual care | Blinding: not blinded Power calculation: not carried out | Inclusion criteria:  
- Aged 2 to 6 years  
- Mild to moderate persistent asthma  
- Asthma symptoms > twice weekly within 6 months of entry to the study  
- Night time asthma symptoms more than twice monthly  
- At least 1 asthma exacerbation requiring steroids within 6 months of enrolment  
- At least 2 such exacerbations within 9 months of enrolment and daily use of at least 1 long-term controller asthma medication within 3 months of the study | Primary outcomes were caregiver burden; satisfaction and compliance. Adherence was secondary outcome. Caregiver satisfaction, treatment convenience, ease of use, and compliance were assessed at baseline and weeks 8, 28, and 52 with a 4-item compliance/Caregiver Satisfaction Questionnaire (CCSQ), which was developed specifically for the study. Mean scores for caregiver satisfaction, convenience, ease of use, and compliance, based on the CCSQ, were significantly ($p \leq 0.001$) | Sample size was based on primary outcome measures. No sample size calculation was made for adherence and quality of life outcomes. The apparent improvement in adherence in the Arm 1 could be attributed to a simpler dosing regimen or greater clinical effectiveness |}

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</table>
|                               | n=3 disease deterioration  
n=1 adverse event  
n=20 for other reasons (withdrawal; non-compliance; randomisation error; relocated.)  
n=10 lost to follow-up.  
Follow-up period: 52 weeks  
Recruitment rate: not reported  
Randomisation method: Patients were randomised 1:1, not other detail reported.  
Blinding: not reported  
Power calculation: not reported | Exclusion criteria:  
- Intermittent or long-term steroid treatment within 15 days or 12 weeks of enrolment respectively.  
- Premature birth  
- History of severe or unstable asthma with ventilator assistance  
- Hospitalised for airway obstruction within 30 days of study enrolment,  
- URTI and infectious sequelae or LRTI within 14 days of study enrolment  
- Concomitant lung disease or other significant medical conditions.  
Sex: n Male  
Arm 1 104 | greater for those caregivers and children in arm 1 than those in arm 2  
Caregivers who were completely or very satisfied  
Arm 1 = 90.7%  
Arm 2 = 53.4%  
p ≤ 0.001 | The compliance question (of the CCSQ), assessed how often patients took their asthma medication in the past 2 weeks, are based on a 5-point scale from 1 (daily) to 5 (not at all).  
Compliance with daily |
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</table>
| Ng D. K. K. et al. 2006.176    | Comparing the effect of a structured intensive asthma education program with a standard | Prospective randomised single blind study | Inclusion criteria:  
- Children 2 – 15 years  
- Admitted with an acute asthma attack | Visits per patient to ED, unscheduled GP visits, number of symptoms, days of school absences, episodes | JADAD score: 2 |

| | | | Arm 2 | 110 |
| | | | Ethnicity: | Arm 1 | Arm 2 |
| | | | Black | 139 | 131 |
| | | | White | 19 | 25 |
| | | | Asian | 3 | 4 |
| | | | Other | 7 | 7 |
| | | Mean ±SD asthma severity: | Arm 1 | 1.3±0.5 | 1.3±0.6 |
| | | | Night time | 1.3±0.5 | 1.3±0.6 |
| | | | Daytime | 1.4±0.5 | 1.4±0.5 |

| | | | Arm 1 = 76% | Arm 2 = 57% |
| | | | p ≤ 0.001 | | No subgroup analysis |

medication regimens were reported for % children.
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</table>
| China Asthma                   | education program for hospitalised asthmatic children.  
|                                | two asthma education programs:  
|                                | Arm 1: Standard (program A), three parts to the program, requiring a total of 1 hour of nursing time.  
|                                | i) An Asthma Nurse acted upon referral 1 – 2 days after admission.  
|                                | ii) A two-page written information sheet. An asthma diary was also given to parents for recording the child's asthma symptoms, relief medication used, school absence, emergency department visits and unscheduled visits to | Total patients n=100  
|                                | Arm 1: n=45  
|                                | Arm 2: n=55  
|                                | Baseline assessment of asthma severity showed no difference between two groups  
|                                | Follow-up period: 3 months  
|                                | Recruitment rate: not reported  
|                                | Randomisation method: randomised using a computer generated random number table  
|                                | Blinding: not reported  
|                                | Power calculation: assuming 50% of children are re-admitted within 3 months, 45 children are required in each arm to detect a difference of 30% to give a type1 error of verified by paediatrician  
|                                | Exclusion criteria:  
|                                | • Children with a severe asthmatic attack that needed intensive care  
|                                | • Non-Chinese speaking children/parents  
|                                | Sex: n  
|                                | Arm 1 31  
|                                | Arm 2 43  
|                                | Ethnicity: Not reported  
|                                | Baseline asthma severity: n=Arm 1 Arm 2  
|                                | Mild intermittent  
|                                | 24 30  
|                                | Mild and moderately  
|                                | of asthma attacks, compliance to medication prescribed, were assessed.  
|                                | There was no significant difference in the asthma severity between the two groups (p = 0.90). There was a significant reduction in the number of visits to the Accident and Emergency department, (p = 0.01) and the number of hospitalisations (p = 0.01) in arm 2.  
|                                | A nominal scale was used for compliance with medication.  
|                                | Medication compliance  
|                                | Arm 1 = 69%  
<p>|                                | Arm 2 = 85% (p=0.029) A higher percentage reported better compliance in Arm 2 |</p>
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<td>General practitioners.</td>
<td>(iii) A 30 min teaching and discussion. Arm 2: Intensive (program B) 6 part program, requiring a total of 2 hours of nursing time. i) An Asthma Nurse contacted patients/parents within 24 hours of admission. ii) An attractive booklet with the same information and action plan as in Program A was given but modified with cartoon figures in order to increase patients’ and parents’ interest and understanding. An asthma diary was also provided.</td>
<td>0.05 and type II error of 0.2.</td>
<td>Persistent 21 25</td>
<td></td>
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<tr>
<td>Patterson, E. E. et al. 2005</td>
<td>The impact of asthma clubs on quality of life in Cluster RCT</td>
<td>Inclusion criteria: • Children aged 7 to 11</td>
<td>Outcomes of interest were QOL: activity limitation;</td>
<td>Because of nature of intervention, it was not</td>
<td></td>
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<tr>
<td>Northern Ireland Asthma</td>
<td>primary school children: the School Care and Asthma Management Project (SCAMP)</td>
<td>The intervention included weekly school based asthma clubs for 8 weeks in which a structured educational program was delivered (training pack, asthma awareness to caregivers, and asthma action plans)</td>
<td>years with asthma whose parents had notified school</td>
<td>symptoms and emotional function compared between immediate group and delayed group; Inhaler technique compared between groups at week 16. No significant differences in QOL. Inhaler technique at week 16 was markedly better in Arm 1 Arm 1 = 56% Arm 2 = 15% (p&lt;0.001) Inhaler technique improved. Weighted difference (95% CI) Correct: 29 to 54 Correct and partially correct: 24 to 73 (p&lt;0.001)</td>
<td>possible to conceal the groups to which participants were allocated. Nurses performing inhaler technique assessment were not blinded to the intervention or groups of allocation: this could have contributed to observer bias. No adjustment for potential effect of cluster sampling on study results JADAD score: 2</td>
</tr>
<tr>
<td></td>
<td>Arm 1: Immediate group Arm 2: delayed group</td>
<td>Total patients n=173 n=Consent received from 176 children Arm 1: n = 84 Arm 2: n= 92 Follow-up period: 15 weeks Recruitment rate: within the 22 schools randomised, 176 children were eligible and consented. 128 were attended preliminary assessments Randomisation method: schools were matched in pairs on socio-economic characteristics, size, and date of entry. In each pair, the toss of a coin was used to randomise schools to either immediate or delayed</td>
<td>Children attending at one of the 22 schools identified in South and East Belfast, whose parents had notified the school of their diagnosis. Exclusion criteria: Children needing immediate medical attention (e.g. FEV1&lt;80%, severe breathlessness)</td>
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<tr>
<td></td>
<td></td>
<td>Sex: n Male Arm 1 37 Arm 2 53 Ethnicity: Not reported</td>
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<tr>
<td>Rapoff, M. A. et al. 2002. 150 USA Juvenile rheumatoid arthritis (JRA)</td>
<td>This trial evaluated a clinic-based, nurse-administered educational and behavioural intervention to prevent the anticipated drop in adherence to non-steroidal medications among newly diagnosed patients with juvenile rheumatoid arthritis</td>
<td>RCT Repeated-measures Design</td>
<td>Inclusion Criteria: Between 2 and 16 years old Diagnosed within the past year with JRA according to established standards Had been on a stable NSAID regimen for at least 1 month. Authors did not discuss</td>
<td>Primary outcome is adherence. There were significant group and Group X Time effects for adherence (assessed with an electronic monitor over a 13-month period) favouring arm 1. In contrast, the arms did not differ significantly in disease activity or functional limitations. One-tailed $\alpha = 0.05$ was used</td>
<td>JADAD score: 3</td>
</tr>
</tbody>
</table>

intervention.

Blinding: not reported

Power calculation: To have 90% power to detect a statistically significant ($p<0.05$; two tailed) difference of 1 unit in mean change between groups over the first 15 weeks would require 36 children per group in a trial of conventional design.
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<tr>
<td>Arm 1: Experimental group participants received an intervention that included educational and behavioural strategies for enhancing adherence. Special attention was placed on arranging environmental contingencies to prompt and reinforce adherence. Participants and their parents viewed a 10-min audiovisual program and received a booklet, both of which described adherence-enhancement strategies. The study nurse reviewed and rehearsed these strategies with participants and their parents and answered</td>
<td>n=7 taken off medications n=7 incomplete data n=6 and withdrew from the study 34 completed the study Arm 1: n = 19 Arm 2: n = 15 Follow-up period: 52 weeks</td>
<td>exclusion criteria Sex: n Male Arm 1 4 Arm 2 7</td>
<td>to test the predicted group difference in post-intervention adherence. For the 52-week post-intervention follow-up, arm 1 showed significantly better overall mean adherence Arm 1 = 77.7% Arm 2 = 56.9% (p= 0.02)</td>
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<td>Recruitment rate: Recruitment occurred over 42 months. Parents of 90 prospective participants were sent recruitment letters. Thirty-six (40%) of these declined. Randomisation method: Participants were stratified by age (2–6 years, 7–11 years, 12–16 years) and JRA</td>
<td>Ethnicity: Arm 1 Arm 2 Caucasian 14 18 Other 1 1</td>
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<td>Arm 2: Control group participants received a general educational intervention in which they and their parents viewed a 13-min audiovisual program that reviewed the types of JRA, signs and symptoms, and medical treatments. The nurse then answered questions and distributed Arthritis Foundation pamphlets about the medications’ purposes, benefits, and potential side effects and how to minimise side effects. The nurse did not review adherence-enhancing strategies.</td>
<td>subtype (polyarticular, pauciarticular, or systemic-onset) and randomised within strata to arm 1 or arm 2</td>
<td>Blinding: not reported</td>
<td>Power calculation: Post hoc power analysis showed that 5.0% difference would require 1,190 participants per group to achieve 80% one-tailed power at α= .05</td>
<td>Per protocol analysis</td>
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</tbody>
</table>
| **Salisbury, C. et al. 2002.** | A programme of asthma care, delivered by nurse-led clinics in four secondary schools, was examined. Pupils at these schools were individually randomised to receive an invitation for a review of their asthma, at school (school clinic group) or in general practice (practice care group). Due to the possible contaminating effect of the clinic on those pupils not invited to it, a parallel observational comparison was conducted between pupils in the practice care group of the randomised trial and pupils in two control schools (observational RCT). | Total patients n= 455  
n=2 Not randomised in error  
n=3 Mis-allocated  
Arm 1: n=157  
Arm 2: n=151  
Arm 3: n=142  
Follow-up period: 6 months  
Recruitment rate: 790 pupils identified with asthma were approached to take part in the study. Consent was obtained from 455 pupils (57.6%).  
Randomisation method: Block randomisation, stratified by school, was used to allocate pupils in the four trial schools. | Inclusion Criteria:  
- Adolescents with asthma were identified based on a brief screening questionnaire administered at school to all pupils in years seven to 11, cross-referenced with computerised prescribing records from local general practices.  
- Those pupils that answered positively to at least one of the screening questions and also had been prescribed treatment for asthma in the previous two years were eligible for inclusion. | Primary outcome measures were attendance for asthma review, symptom control, and quality of life. Secondary outcomes were knowledge, attitudes (based on a quiz), inhaler technique, use of steroids, school absence and peak flow rate.  
The proportion of patients who had a review consultation for asthma (%)  
Arm 1: 90.8  
Arm 2: 51.0  
Arm 3: 58.1 (p<0.001)  
The median quality of life score was  
Arm 1: 6.2 (5.5 - 6.7)  
Arm 2: 6.1 (5.5 - 6.7)  
Arm 3: 6.2 (5.2 - 6.5)  
(p=0.63).  
The median (IQR) symptom score was | JADAD score: 3 |
<table>
<thead>
<tr>
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</tr>
</thead>
</table>
|                               | comparison; control school group). Adolescents were contacted at school for an appointment and a reminder card was also sent. The care provided was similar to that offered in general practice, but the discussion was specifically targeted at the needs and interests of adolescents. | to receive invitations to the school asthma clinic, or to continue normal care. Pupils at the two control schools all continued normal care. Randomisation was carried out independently of the clinical team involved in providing care, by statisticians at North Bristol NHS Trust using a computer random number generator. | Sex: n Male  
Arm 1: 80  
Arm 2: 70  
Arm 3: 81  
Ethnicity: Not reported  
Baseline asthma severity: Median symptom score — Steen (IQR)  
Arm 1: 17 (14 - 22)  
Arm 2: 17 (14 - 21)  
Arm 3: 18 (14.5 - 22)  
(p=0.42). | The mean (SD) knowledge of asthma scores  
Arm 1: 2.64 (0.66)  
Arm 2: 2.26 (0.76)  
Arm 3: 2.39 (0.69)  
(p=0.001). | The median score (IQR) for attitude towards asthma  
Arm 1: 5.0 (4.6 - 5.2)  
Arm 2: 4.8 (4.4 - 5.2)  
Arm 3: 4.8 (4.4 - 5.2)  
(p=0.007).  
Both these favoured the intervention patients. |
|                               | Arm 1: School clinic  
Arm 2: Practice care  
Arm 3: Control school | Power calculation: this was based on a published study in which the outcomes were an improvement from 40 to 60% in the proportion of adolescents receiving an asthma review, and an improvement of half a standard deviation in the quality of life measure. Ninety- | | Inhaler technique scores (IQR) were significantly better in Arm 1 than in Arm 2  
Arm 1: 4 (3 - 5)  
Arm 2: 3 (2 - 4)  
Arm 3: 3 (2 - 4) | |

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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>seven adolescents in the intervention arm and 63 in the control arm were needed in order to have 80% power to detect such differences at a 5% level of significance.</td>
<td></td>
<td>(p=0.007) differences in scores varied significantly between schools (p=0.04)</td>
<td>There were no statistically significant differences in the use of steroids days off school with asthma, and peak flow measurements.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of steroids according to pupil. Number (%), taking steroids everyday Arm 1: 35 (31.8) Arm 2: 38 (29.5) Arm 3: 40 (35.1)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Days off school with asthma, Number (%) having at least one day off Arm 1: 34 (30.6) Arm 2: 42 (32.6) Arm 3: 35 (30.2)</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>The mean (SD) peak flow measures Arm 1: 434.8 (65.0)</td>
</tr>
<tr>
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<tr>
<td>Sanmarti LS et al 1993 Spain</td>
<td>A controlled clinical trial to evaluate the efficacy of three alternative health education strategies to improve compliance with anti-TB prophylaxis in tuberculin/Mantoux positive children</td>
<td>RCT group design, outpatient study</td>
<td>Inclusion criteria: tuberculin/Mantoux positive children</td>
<td>Arm 2: 427.0 (65.4) Arm 3: 441.2 (71.9)</td>
<td>The effectiveness analysis showed that the clinical outcomes were not significantly different across the groups. Improvements associated with the school clinic were observed only for some process measures.</td>
</tr>
<tr>
<td></td>
<td>Arm 1: information leaflet given to parents</td>
<td>Total patients (at follow up) n=318 (264)</td>
<td>Ages and sex not reported</td>
<td>Arm 1: n=77 (50) Arm 2: n= 80 (75) Arm 3: n= 79 (75) Arm 4: n= 82 (64)</td>
<td></td>
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<tr>
<td></td>
<td>Arm 2: Arm 1 plus telephone call from</td>
<td>Follow up period: 12 months</td>
<td>Authors excluded children with active TB</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Recruitment rate: not reported</td>
<td>Ethnicity: not reported</td>
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</tbody>
</table>

Main outcomes
Adherence: measured by urine isoniazid

Results
Adherence
Arm 1 56%
Arm 2 85%
Arm 3 90%
Arm 4 75%

JADAD score: 1
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Shope J. 1980 USA Epilepsy</td>
<td>Mothers of children taking phenytoin or phenobarbital for paediatric seizures underwent an educational intervention in the form of a mothers’ group discussion led by a clinical social worker</td>
<td>RCT group design, outpatient study</td>
<td>Inclusion criteria: mothers of children taking phenytoin or phenobarbital for paediatric seizures where the serum level was low for at least one medicine</td>
<td>All three intervention groups were more effective than the control group (p&lt;0.001 for Arms 2 and 3, p&lt;0.025 for Arm 4)</td>
<td>Children in the control group were older than those in the intervention group. (p=0.01) Used per protocol analysis instead of intention to treat analysis. JADAD score: 0</td>
</tr>
<tr>
<td></td>
<td>Arm 1: usual care</td>
<td>Arm 1: n= 39</td>
<td>Ages 1-15 years (mean: 9)</td>
<td>Adherence scores</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arm 2: educational intervention</td>
<td></td>
<td></td>
<td>Arm 1: 2.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arm 3: Arm 1 plus home visit by nurse and urine isoniazid compliance test every 3 months</td>
<td>Randomisation method: not reported</td>
<td></td>
<td>Arm 2: 2.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arm 4: Arm 1 plus clinic visit with clinician and urine isoniazid compliance test every 3 months</td>
<td>Blinding: not blinded</td>
<td></td>
<td>P=0.02</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Power calculation carried out</td>
<td></td>
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<th>Comments</th>
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<tr>
<td>Smith, N. A. et al. 1986.</td>
<td>Impact of educational and behavioural interventions delivered by physicians on adherence of children with asthma. Written information: Leaflets with drug</td>
<td>Pseudo RCT</td>
<td>Inclusion Criteria: Aged 1 to 16 years old Children with chronic asthma Continuous medication for asthma Spoke English or an</td>
<td>Compliance (%) = Number of doses taken per week/number of doses per week x 100. Compliance (mean ± SEM) Arm 1 = 78.0 ± 2.1%; n=93 Arm 2 = 54.5 ± 2.9%; n=103</td>
<td>No outcomes reported, just adherence JADAD score: 3</td>
</tr>
<tr>
<td>Australia Asthma</td>
<td>Arm 2: two mothers’ group discussion led by a clinical social worker held on consecutive weeks</td>
<td>Arm 2: n= 28</td>
<td>Authors did not discuss exclusion criteria Sex: 50% Female Ethnicity: 67% black</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow up period: 20 weeks Only 14 of the intervention group attended the sessions. Recruitment rate: four refused to be in the study Randomisation method: not reported Blinding: not blinded Power calculation: not carried out</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Total patients n=217 Arm 1: n=102 Arm 2: n=115 Follow-up period: not explicit. Patients are interviewed up to 3 times</td>
<td></td>
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<th>Results*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>information and rationale of asthma medication</strong></td>
<td><strong>Study Design</strong></td>
<td>Recruitment rate: not reported</td>
<td>interpreter was available</td>
<td>differed significantly</td>
<td><strong>Arm 1</strong> had a better knowledge of asthma and of the medications, and was more satisfied with the physician and with the regimen than the control group. better knowledge correlated to better compliance.</td>
</tr>
<tr>
<td>Behavioural strategies:</td>
<td></td>
<td>Randomisation method: at each clinic the physicians were assigned at random to see either control patients or intervention patients. Thus each clinic session a physician would see either all intervention or all control patients according to the allocation of random numbers. No other details</td>
<td>Authors did not discuss inclusion or exclusion criteria any further</td>
<td></td>
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<tr>
<td>Tailoring medication to patients child’s daily routine, increased supervision, stressing and reinforcing</td>
<td></td>
<td>Blinding: not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control group patients received no intervention</td>
<td></td>
<td>Power calculation: not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arm 1: intervention group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arm 2: control group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tinkelman DG et al 1980</strong></td>
<td><strong>Intervention to evaluate compliance to two different formulations of theophylline at either six or twelve hourly intervals</strong></td>
<td><strong>RCT crossover group design, outpatient study</strong></td>
<td><strong>Inclusion criteria: children with asthma and exercise-induced bronchospasm</strong></td>
<td><strong>Main outcomes</strong></td>
<td><strong>Doses were tailored to response, so it is not clear that the differences in theophylline levels are only caused by differences in adherence.</strong></td>
</tr>
<tr>
<td>USA</td>
<td></td>
<td>Total patients n=20</td>
<td>Ages 11-18</td>
<td>Adherence: measured by theophylline level, tablet count</td>
<td>Pulmonary function</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm: n=20</td>
<td>Authors did not discuss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author, Year, Country, Disease</td>
<td>Intervention being tested</td>
<td>Study Design</td>
<td>Patient group</td>
<td>Results*</td>
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</tbody>
</table>
| Asthma                        | Arm 1: short acting theophylline requiring 6 hourly administration  
Arm 2: sustained release theophylline requiring 6 hourly administration | Follow up period: 6 weeks  
Recruitment rate: not reported  
Randomisation method: not reported  
Blinding: not blinded  
Power calculation: not carried out | exclusion criteria  
Sex: 60% Female  
Ethnicity: not reported | Results  
Adherence: returned unused medication  
Arm 1 6.66%  
Arm 2 3.40%  
P=0.015 | JADAD score: 0 |
| Turgeon. J. P. et al. 1996. Canada Asthma | Arm 1: In the experimental group, patients received an interactive teaching session from the asthma clinic nurse that lasted around 15 minutes. Instruction was given using picture diagrams provided with inhalation devices. This was followed by interactive teaching consisting of immediate correction in inhalation technique | RCT  
Total patients n=96  
Arm 1: n=47  
Arm 2: n=49  
Follow up period: 6 months  
Recruitment rate: not reported  
Randomisation method: a computer generated list of random numbers – stratified by age. | Inclusion criteria:  
• Children 1 – 18 years  
• Starting aerosol therapy for the first time  
• All patients seen in the clinic on scheduled appointment only  
• Sources of referrals are the emergency room and/or the inpatient wards for follow up, as well as referrals from private physicians and parents coming on their own | Morbidity was assessed at baseline and six month follow up. Adherence was measured by inhalation technique. Inhalation technique and parental perceptions of treatment were also calculated at one, three and six month visits.  
There was no statistical difference between morbidity between arms at six month visit.  
At one month visit, parents of | JADAD score: 2 |
<table>
<thead>
<tr>
<th>Author, Year, Country, Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention being tested</td>
</tr>
<tr>
<td>displayed by the parent/child.</td>
</tr>
<tr>
<td>Arm 2: Patients in the control group only received only instruction by picture diagrams (didactic teaching) given by another nurse who had no contact with the experimental group.</td>
</tr>
<tr>
<td>All patients received two teaching sessions, at the initial and one-month follow-up visits.</td>
</tr>
<tr>
<td>Inhalation devices used were metered-dose inhalers with aerochamber, a nebulizer or a ventahaler and dry powders with diskhaler or turbohaler.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Design</th>
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</thead>
<tbody>
<tr>
<td>Blinding: patients were evaluated by a research assistant who was blind to the teaching assignment group at the initial visit and at the one, three and six month follow up visits.</td>
</tr>
<tr>
<td>Power calculation: sample size was calculated to detect an upgrade from 50% to 75%. A one-sided type I error of 0.05 and a one-sided type II error of 0.2, resulted in a sample size of 45 children per group.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Patient group</th>
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<tbody>
<tr>
<td>for a second opinion</td>
</tr>
<tr>
<td>Exclusion criteria:</td>
</tr>
<tr>
<td>• Aged below 1 year or above 18 years</td>
</tr>
<tr>
<td>• Previous teaching session of technique of aerosol administration</td>
</tr>
<tr>
<td>• Language other than French or English</td>
</tr>
<tr>
<td>• If another family member suffered from asthma and was using inhalers</td>
</tr>
<tr>
<td>Sex: n Male</td>
</tr>
<tr>
<td>Arm 1 29</td>
</tr>
<tr>
<td>Arm 2 28</td>
</tr>
<tr>
<td>Ethnicity: Not reported</td>
</tr>
<tr>
<td>Baseline asthma severity: n (%) Arm 1 Arm 2</td>
</tr>
<tr>
<td>Mild 27 (57) 27 (55)</td>
</tr>
<tr>
<td>Moderate 15 (32) 17 (35)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results*</th>
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</thead>
<tbody>
<tr>
<td>the interactive teaching group achieved better mean inhalation technique score (p=0.04)</td>
</tr>
<tr>
<td>At one month visit, parents in arm 1 expressed more satisfaction with teaching approach than in arm 2 (χ² = 10.05, p=0.02). They also seemed to find it easier to remember to give the medication. Although the difference between both arms did not reach statistical significance (χ² = 8.5, p=0.07). There were no significant differences between arms at the three month and six month visits.</td>
</tr>
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<table>
<thead>
<tr>
<th>Comments</th>
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<th>Patient group</th>
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</tr>
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<tbody>
<tr>
<td>Van Es, S. M. et al. 2001.173</td>
<td>An intervention programme using the ASE-model aimed at enhancing adherence in adolescents with asthma</td>
<td>RCT</td>
<td>Severe 5 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>The intervention programme was based on the ASE (attitude-social influence self-efficacy) model, aimed at enhancing adherence to asthma medication and proximal values of the adapted ASE model.</td>
<td></td>
<td>5 (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>Patients were randomly allocated to either</td>
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<tr>
<td></td>
<td>Arm 1: Usual care by a paediatrician (control group) or</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Arm 2: The intervention programme</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Inclusion criteria:</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Asthma diagnosed by a physician</td>
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<tr>
<td></td>
<td>• Treatment prescribed by a paediatrician with daily inhalation of prophylactic asthma medication during a preceding period of at least two months</td>
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<td></td>
<td>• Aged between 11 to 18 years of age</td>
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<td></td>
<td>• Attending secondary school</td>
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<tr>
<td></td>
<td>• The ability to fill in a questionnaire in Dutch</td>
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<tr>
<td></td>
<td>Authors did not discuss exclusion criteria</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Sex: n</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Arm 1 31</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arm 2 27</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Ethnicity: Arm 1 Arm 2</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Adherence was assessed using self administered questionnaires. Assessed by asking participants to score their adherence on a 10 point scale.</td>
<td></td>
<td>Mean (SD) adherence</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arm 1 = 7.7(2.0)</td>
<td></td>
<td>Arm 2 = 6.7(2.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=0.05</td>
<td></td>
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<tr>
<td></td>
<td>Other outcomes not statistically significant as well. No impact of program on social influences, attitude, and self efficacy.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>There seems to have been no substantial effect from the intervention programme</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>JADAD score: 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Author, Year, Country, Disease</td>
<td>Intervention being tested (experimental group).</td>
<td>Study Design</td>
<td>Patient group</td>
<td>Results*</td>
<td>Comments</td>
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<td>--------------------------------</td>
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<tr>
<td>Volovitz, B. et al. 2000.178</td>
<td>This trial investigated the preference, satisfaction, and adherence of parents and children with either montelukast chewable tablets or inhaled cromolyn aerosol in children with asthma after 4 weeks of therapy. Parent and child preference for montelukast versus cromolyn and satisfaction with each treatment were assessed with l-question preference and multi-centre, randomised, open-label, crossover trial.</td>
<td>Blinding: not reported&lt;br&gt;Power calculation: not reported</td>
<td>Caucasian 39&lt;br&gt;Non Caucasian 17</td>
<td>JADAD score: 2</td>
<td>The primary end point of the trial was parent preference for either montelukast or cromolyn. Of 254 parents included in the analysis, 249 parents (98%) expressed a preference; of these, significantly more preferred oral montelukast over inhaled cromolyn (219 [88%] vs. 30 [120%], p&lt;0.001). Significantly more children expressed a preference for montelukast over cromolyn (201 [80%] vs. 50 [20%], p&lt;0.001).</td>
</tr>
</tbody>
</table>

Inclusion criteria:  
- Children aged 6 - 11 years  
- History of persistent asthma  
- Forced expiratory volume in 1 second (FEV,) values between 60% and 85% of the predicted value (twice during run-in) together with 12% improvement in FEV, after beta-agonist administration  
- Symptoms requiring beta-agonist therapy on at least 7 of 14 days before randomisation.  
- Non-smokers  

Follow-up period: 12 weeks. 4 weeks with each treatment |

Total patients n=266  
n=254 included in the primary efficacy analysis  
n=12 children excluded,  
n=9 did not start period IV,  
n=2 discontinued before day 7 of period IV,  
n=1 was missing primary end-point data at the end of period IV. |

Baseline asthma severity: Not reported |
<table>
<thead>
<tr>
<th>Author, Year, Country, Disease</th>
<th>Intervention being tested</th>
<th>Study Design</th>
<th>Patient group</th>
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<td></td>
<td>question satisfaction questionnaires. A 2 week washout period separated the treatment periods.</td>
<td>with a 2 week washout period</td>
<td>• In good health except for asthma. Girls who had begun menses were required to have a negative urine pregnancy test at visit 1. Exclusion criteria: If they had had emergency treatment for asthma within 1 month of the first visit, Hospitalisation for asthma within 3 months, Unresolved upper respiratory tract infection within 3 weeks An active sinus infection. Excluded asthma medications included inhaled or oral</td>
<td>Parents and children both expressed significantly greater satisfaction with montelukast than with cromolyn across all questions in the questionnaires (p&lt;0.001). Adherence with study medications and beta-agonist use was assessed by means of diary cards. Two hundred fourteen children (84%) were highly adherent (&gt;95% of days) to montelukast therapy, whereas 122 children (48%) were adherent to cromolyn therapy (p&lt;0.001).</td>
<td></td>
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<th>Author, Year, Country, Disease</th>
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<th>Patient group</th>
<th>Results*</th>
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<td></td>
<td>corticosteroids, theophylline, nedocromil, long-acting or oral beta-agonists, anticholinergics, or long-acting antihistamines within 2 weeks of the pre-study visit Cromolyn within 1 month, or previous use of montelukast. Sex: n Male 170 Ethnicity: % White: 70 Asian: 6 Other races: 24%</td>
<td>Daily beta-agonist use was significantly lower during montelukast therapy than during cromolyn therapy (p=0.001). Both therapies were generally well tolerated.</td>
<td>Baseline asthma severity:</td>
<td></td>
<td></td>
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<td>Author, Year, Country, Disease</td>
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<tr>
<td>Wysocki, T. et al. 2001. 151</td>
<td>Behaviour therapy interventions for families of adolescents with diabetes. A complex intervention aimed at a variety of factors including adherence. Arm 1: Behavioural–Family Systems Therapy (BFST)-10 sessions consisting of 4 therapy components: problem solving training, communication skills training, cognitive restructuring and functional and structural family therapy, plus $100 monetary incentive for attending all 10 intervention sessions.</td>
<td>RCT</td>
<td>Inclusion criteria: Adolescents 12-17 years Type 1 diabetes, disorder in adolescents or parents during the previous six months. Each parent or step-parent residing with the patient was required. Exclusion criteria: Children with major chronic diseases Incarcerated children Children in foster care or needing psychiatric care, with mental retardation, diagnosis of psychosis, major depression, or substance abuse</td>
<td>Outcomes assessed using validated self-care inventory for 3, 6 and 12 months treatment. Outcomes were adolescent and parent relationship and diabetes specific psychological adjustment and 24 hour recall of treatment adherence The 14-item Self-Care Inventory (SCI), which was validated by Greco et al., was used to measure diabetes treatment adherence during the preceding 3 months. Higher scores indicate better treatment adherence. Persistence of significant between-group differences favouring BFST at 6 and 12</td>
<td>JADAD score: 2</td>
</tr>
<tr>
<td>USA Type 1 diabetes mellitus 12 month follow up data of study initially reported in Wysocki, T. et al. 2000 252</td>
<td>Follow-up period: 12 months Lost to follow up: Arm 1 n=3 Arm 2 n=4 Arm 3 n=4 Recruitment rate: Initially, 380 families were informed of the study. No other information given. Randomisation method: a research assistant randomly assigned each family to one of the three conditions.</td>
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<td></td>
<td>Outcomes**</td>
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<td>Author, Year, Country, Disease</td>
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<td>Study Design</td>
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</table>
| Zorc, J. J. et al. 2003. 152   | Scheduled follow up after a paediatric emergency department | RCT | Inclusion criteria:  
  - Aged 2-18 years  
  - Discharged after | Primary care provider (PCP) visits; asthma related morbidity and daily use of | Convenience sample |

Arm 3: Current therapy (CT) - received usual care

Arm 2: Education and support group (ES) - families attended 10 group diabetes education and social support meetings (45 minute educational presentation by diabetes professional + 45 minute interaction among the families), plus $100 monetary incentive for attending all 10 intervention sessions.

Randomisation was stratified by the adolescent’s sex and by the treatment centre, so that each centre enrolled a similar number of boys and girls into the three groups

Blinding: not reported

Power calculation: not reported

Sex: n
  - males 51

Racial composition: %
  - Caucasian 79
  - African-American 20
  - Hispanic 1

Blinding: not reported

Power calculation: not reported

Month follow-up for the Extreme Beliefs, the Overt Conflict/Skill Deficits.

Analyses of change in SCI scores revealed a significant group by time interaction effect [F (2,104) = 3.80, p<0.05] such that there were no significant between group differences at posttreatment, but the BFST group showed improved treatment adherence at 6- and 12-month follow-up, whereas the CT and ES groups showed deteriorated adherence.

Actual adherence rates not reported, so assessment of real change in adherence is not possible.
<table>
<thead>
<tr>
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<th>Comments</th>
</tr>
</thead>
</table>
| USA Asthma                    | visit for asthma: a randomised trial. | Arm 1: n=142  
Arm 2: n=144  
(6 subsequently excluded 3 - previous study enrolment; 2 non-urban residence; 1 diagnosis changed from asthma; Further 2 withdrew)  
Follow-up period: 4 weeks post ED discharge, sub-group followed for 1 year (via primary care records)  
Recruitment rate: 1305 screened, 592 eligible, 186 not approached. Of those approached, 286 (70%) consented.  
Randomisation method: After obtaining written informed consent, study staff assigned patients to intervention or control groups using a series of treatment for acute asthma in an urban children's hospital  
- Residing within Philadelphia city limits  
- History of asthma confirmed by medical  
Exclusion criteria:  
History of coronary heart disease  
Non – urban home  
Non – English speaking  
Previous study enrolment  
Sex: n  
Arm 1 Arm 2  
Male 93 80  
Ethnicity: Arm 1 Arm 2  
Black 132 129  
Other 7 10  
Subjects saw a PCP within 4 weeks of the initial ED visit were more likely to report using a controller medication 4 weeks after the ED visit than those who did not make a follow-up visit (OR 1.46, p = 0.01).  
23% of subjects saw a PCP for follow up within recommended 5 days - rate significantly greater amongst intervention subjects than control (p = 0.03). Rate of PCP follow up within 4 weeks for subjects with verification significantly greater amongst | JADAD score: 3 |
<table>
<thead>
<tr>
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<th>Comments</th>
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</thead>
</table>
|                               |                           | numbered, opaque envelopes that had been pre-randomised in blocks of 8.  
Blinding: Telephone interviewers unaware of patient assignment, otherwise, no further concealment  
Power calculation: Estimated predicted follow up rate among controls of 50%. Assuming 10% loss to follow up and setting (a2) = 0.05, 280 subjects needed to provide power of 90% to detect a 20% increase in the follow up rate. | Baseline asthma severity: Not reported | intervention subjects than controls (p=0.002) Median time to next PCP visit was significantly less for intervention groups that control p=0.004 and 2 survival curves significantly different by log-rank analysis p=0.01 | Study groups did not differ in return ED visits, missed school or work, or the percentage reporting daily use of a controller medication, so no sig difference in outcome |
### 7.5 Stakeholders involved in TABS

<table>
<thead>
<tr>
<th>Clinical and service delivery stakeholders</th>
<th>CONTACTS AND ADDRESSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCGP Adolescent Task Group</td>
<td>Lionel Jacobson</td>
</tr>
<tr>
<td>RCPCH research division</td>
<td>Prof Terence Stephenson, William Vanthoff, Jill Turner</td>
</tr>
<tr>
<td>Neonatal and paediatric pharmacists group</td>
<td>Ms Sharon Conroy</td>
</tr>
<tr>
<td></td>
<td>(Rowena McArtney)</td>
</tr>
<tr>
<td>Children’s services, Nottinghamshire County PCT</td>
<td>Gary Stokes</td>
</tr>
<tr>
<td>Leicester PCT Research Alliance</td>
<td>Sue Palmer-Hill, Research Management and Governance Lead</td>
</tr>
<tr>
<td>Community trust director, Leicester</td>
<td>Dr Adrian Brooke, chair Leicester medicines management group</td>
</tr>
<tr>
<td>Clinical director for children’s health, Leicester and Nottingham</td>
<td>Dr David Luyt</td>
</tr>
<tr>
<td></td>
<td>Prof David Walker (Professor of Paediatric Oncology)</td>
</tr>
<tr>
<td>Nottinghamshire County Teaching PCT R&amp;D lead</td>
<td>Amanda Sullivan, Director of Nursing and Integrated Governance</td>
</tr>
<tr>
<td>Nottingham PCT County Trust,</td>
<td>Rachel Illingworth</td>
</tr>
<tr>
<td></td>
<td>Head of Research and Development</td>
</tr>
<tr>
<td>School liaison</td>
<td>Maureen Burnett, Consultant community paediatrician, Leicester, lead for educational medicine</td>
</tr>
<tr>
<td>AYPH</td>
<td>Prof Fiona Brooks</td>
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</table>

<table>
<thead>
<tr>
<th>Disease specific group stakeholders</th>
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<tbody>
<tr>
<td>Heart Link</td>
<td>Geoff Smart –</td>
</tr>
<tr>
<td></td>
<td>Mary McCann</td>
</tr>
<tr>
<td></td>
<td>Sharon Bowcott</td>
</tr>
</tbody>
</table>
| **MAARA**                     | Edward Staiger (chairman)  
|                              | MAARA, PO BOX 1057 Leics, LE2 3G |
| **Leicester children’s diabetes group (Branch of Diabetes UK)** | Jill Stanley (Leicester parents group) Chair  
|                              | James Greening |
| **Asthma UK**                | Leanne Male, Assistant Director, Research Asthma UK, Summit House, 70 Wilson Street, London, EC2A 2DB |
| **British Epilepsy Association** | Margaret Rawnsley New Anstey House, Gate Way Drive, Yeadon, Leeds, LS19 7XY. |
| **Parent and/carer and child/young people groups stakeholders** | Paul and Sue Harrison |
| **Parent/carer council**     | Jenny Preston  
|                              | MCRN Consumer Liaison Officer  
|                              | Medicines for Children Research Network Coordinating Centre, University of Liverpool, Institute of Child Health, Alder Hey Children’s Hospital, Eaton Road, Liverpool, L12 2AP |
| **Contact A family**         | Sasha Henriques  
|                              | Contact a Family, 209-211 City Road, LONDON EC1V 1JN |
| **Expert Patients Programme Community Interest Company** | Catherine Wilson, Trainer  
|                              | Expert Patients Programme Community Interest Company  
|                              | 32-36 Loman St, Southwark, London SE1 0EE T |
7.6 Initial stakeholder input to Phase 1 interview and focus group schedules

Prior to the roll out of focus groups and interviews, patient, family, and health care provider stakeholders were surveyed for their views on a range of issues around medicines taking in children. The responses are listed below, and were used to inform the focus group and interview schedules.

A) What are the main worries for your child around taking medicines?

I worry about the long term effects of the amount of medication Chloe takes on a regular basis and has taken for many years.

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Side effects (esp. cosmetic e.g. weight gain, feeling spaced out) and associated impact on school, friendships, bullying
Taking it in school – other people’s attitudes, including teachers (esp. around injecting)
Medications don’t seem to work/do much good
Doctors don’t explain properly/don’t know much about their condition/don’t speak English
Feeling different to peers
Frustrated/angry that we have to rely on medication
Not able to make spontaneous plans (e.g. sleep overs) because you need to have medication with you
Parents being overprotective or nagging about your medication

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

What are the main concerns around medicine taking in your patient population?

Clinical perspective----Tablets difficult to swallow or split to get to reduced dose. So need to be liquids or break open and mask in food or drinks.
No one likes injections complexity or administration. If multiple drugs volume to take at a go.

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Size of tablet/capsule, liquid formulation availability, administration in school, safety.
1. parents saying children wont take their medicine
2. children being ‘nagged’ to take their medicine when the benefits are unclear

Non compliance particularly in the adolescent group.

1 (a) What are the adverse effects associated with long term use of short and long acting bronchodilators; inhaled and oral steroids; and combination and additive therapies in adults? (N.B this includes children aged 12 years old and over)
1 (b) What are the adverse effects associated with long term use of short and long acting bronchodilators; inhaled and oral steroids; and combination and additive therapies in children?

2. What is the most effective way of managing asthma with other health problems?
3. What are the key components of successful ‘Self Management’ for a person with asthma?
4. What is the most effective strategy to educate people with asthma and health professionals about managing the adverse effects of drug therapies?
5. What is the most effective way of managing asthma triggers?
6. What is the role of complementary therapies in asthma management?
7. What are the benefits of breathing exercises as a form of physical therapy for asthma?
8. What type of patient (children and adults) and health professional education is most effective in gaining asthma control?
9. What is the most effective way to manage consultations and asthma control in adolescence and young people?
10. Psychological interventions for adults with asthma?

What are the main concerns around medicine taking for the children/adolescents voiced by parents or children?

Psychotropic medicines - Is it really necessary? worry about side effects, worry about addiction. Adverse publicity eg Ritalin.

Remembering to take, taste of medicines (Palatability), getting medicine into small children (babies and toddlers), size of tablets, fitting in with school, supply in community.

Lack of understanding what the medicine does.

Unsure of safety profile and side effects and what those side effects mean.

Timing of doses.

What if vomit/dose missed.

Tablet burden.
Liquid volume.
Food restrictions.
Feeling in control.

B) What are the main barriers for your patient population around medicine taking?

From Education (schools) perspective— non-prescription ie over the counter products.

Injections especially on horizon for Diabetes with blood testing to monitor/dosage adjust of insulin and multiplicity of doses. Rectal preps eg diazepam and worse still paraldehyde with addition of mixing. Multiple administrations. Post effect of giving

Schools refusing to administer medication during school day

Reluctant to take medicines, don’t want to be seen as dependent on medicines.

School, supply problems, not wanting to take tablets at all/be different from peers (adolescents).

Different information from different professionals

Taste
Confusion when doses of medicines change or strengths change.

Devices.
The fight to administer to small children.

Language.
Cultural.

Personal privacy (HIV).

1. lack of explanation re why it is needed
2. not suitable in work/school time
3. some are illiterate

For injections needle phobia ,young children chaotic family environments, for the adolescent deliberate omission

- Anxiety regarding side-effects (especially steroids), dependence and over-dosage
- Awkwardness of taking medication via a large volume spacer
• Denial of having asthma or of the severity of the illness, especially in children and young adults
• Inconvenience of treatment
• Forgetfulness, laziness and/or carelessness
• Struggle with the authority
• Unwillingness to adapt lifestyle
• Treatment too complex or too time-consuming
• Inadequate training in inhaler technique
• Lack of understanding about the need for long-term preventative treatment
• Cultural pressures
• Chaotic home environment

C) What can make it difficult for your child to take their medicines?

Chloe went through a denial for her inhalers but Asthma was never medically explained to her.

Might not want to or refuse to take meds because of side effects. Having a complicated medicine regimen. Simply forgetting to take it!

What are the main barriers for your profession/organisation in medicine taking in children/young people?

Not once or bd preps. Needed to minimise need of medicines in schools and EY settings. Not self administrable. Need to be where ever possible even for young and learning or physically or sensory disabled.

Range of medication available which is suitable for gastrostomy fed children

1. not sticking to medication regimen
2. not knowing when to take their “PRN”

Often outside licensed indications and/or age range hence inappropriate PILS with medicines. Suitable paediatric formulation not always available.

Continuity of supply, GP prescribing of unlicensed meds.

Discontinuation of product lines and also shortages

Lack of good information for parents and especially for children.

MHRA.

PILS – inappropriate / lack of

Lack of PILs for unlicensed medicines.
Unlicensed drugs.
Accessibility to full range of meds after leaving hospital.
Cost.
Lack of PILs for “Specials”

D) How do you think children/young people, can be helped in their medicines taking?
I think that once they get to an age of understanding they should have simplified knowledge of what they take and why they take it.

Honest discussions and genuine partnership working between doctor and patient about what THEY want and what they don’t want. Knowledge of side effects and what the alternatives are (if any). Many young people express a desire to have time with the doctor away from their parents so they can discuss things e.g. medication/conditions impact on relationships/alcohol that they feel unable to do with their parents there. Specialists who have in depth knowledge of the condition and its treatment (this is brought up particularly with ref to mental health conditions e.g. OCD. Doctors who really listen and don’t patronise. Strategies to remember e.g. alarms on phones. Making teachers more informed about certain medications so young people feel more comfortable/able to take them in school without embarrassment/questioning. Web-sites/chat rooms/ workshops about being a young person with a condition.

Psychological support, care plans, observed therapy in some case of insulin omission

Better education of patients and parents
Provision of adequate health and treatment information that meets their needs
Simplifying treatment plans eg reduction of doses through combination/long acting therapies
Improved communication between doctors, nurses and patients – better training for healthcare professionals
Implementation of innovative techniques eg telemonitoring of patients

Maturity, stable and supportive family, care information in clinic. Blister packs for the days from pharmacy

Published research (and our experience) indicates that the following are successful:
Informational interventions to educate and motivate patients eg face-to-face (eg inhaler demonstrations), written (eg booklets, website), oral, audiovisual, telephone, interactive
Behavioural interventions designed to influence behaviour through shaping, reminding or rewarding desired behaviour, including reinforcement eg calendars, skills building by healthcare professionals
- Family and social interventions – social support strategies provided by family or another group eg family counselling, group sessions
- Better adherence of healthcare professionals to asthma management guidelines and recommendations
- A combination of the above

What are the things that help your patient population with medicine taking?
Soluble, palatable tablets/capsules.
Daily or bd preps.
Carry self ie portable and self administer.

Good information about benefit of medication, clinic attendance, good rapport, listening to child/YP, adjusting dose or formulation in response to child/YP views.

1. explanation of why/when to take
2. reminder from professionals
3. support from pharmacies

Reassurance from health professionals.
Individualised medicine charts compliance to take home, lots of practice on ward with self med schemes, easy access to liaison nurse/pharmacist for queries, occasionally dosette boxes.

Good professional interaction / information
Quality products with long shelf life, easy dosing regimen.
Good primary/secondary care communication.
Continuity of supply.
Information – age appropriate.
charts, medidose boxes, etc.
Appropriate formulations.
Reducing frequency and tablet burden.
Combination preparations.
Medication review.

What helps your child take medicines?
Chloe takes paracetamol and ibuprofen on a regular basis, this is for her Arthritis, she takes it because she knows it dulls the pain to help her get through the sports she does. I have also decorated Chloe’s spacer with stickers to make it look more fun and encourage her to take it.

F) Is there anything about your child’s medicines that you’d want to know more about?

I would like to know the long term effects of her medication. She has had asthma since the age of 10 months old and been on both relievers and preventatives since then. She has also taken ibuprofen and paracetamol at least 3 times a week for the past 2 years.

G) Are you aware of any documents, reports, projects or initiatives that have helped medicines taking in children/adolescents?

LOCAL guidance adaption of Managing Medicines in Schools and EY settings (DfES/DoH)

Sweet talk motivational messaging via SMS

From talking to colleagues within the charity, we are not currently familiar with any specific activities Asthma UK has done to help with this but a lot of the work that <<stakeholder name>> does tries to indirectly influence this through its information materials, children and young people’s section of the website, activity holidays for children and young people etc. With regards to other activities that may have helped, as with anything like this, unless it is done in a controlled research setting so that the influence of the intervention on medicines taking can be independently evaluated, it is difficult to attribute any improvement to a single intervention or series of interventions specifically. A literature review could help answer this and establish other activities that have been shown to have helped.

H) What areas around medicine taking do you think need more research/discussion?

Diabetes—insulin—blood sampling/dose adjustment/dose administration needs to be ‘seamless /automated’ process irrespective of age.

Child input into design of inhaler technology, choice of flavourings (could flavour be added by pharmacist?), why is nausea so common with medicine taking?

1. compliance/concordance
2. overt benefits of Rx – does not taking cause as much harm as assumed?

In Child Mental Health there is a need for more suitable information about drugs used in treatment of disorders other than ADHD.
Incentives/psychology for non-compliant teenagers.

What is the link between information and compliance and concordance?

What initiatives would allow for interaction early on in life to improve concordance across the years?

Formulations.

Transition from parental to self control of medication.

Age appropriate information.

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Deliberate omission for reasons of weight loss, the psycho-social impact on non adherence, effect of family discord

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<<stakeholder name>> is currently undertaking a project looking specifically at the links between concerns about the side effects of steroids and medication adherence in asthma. However I think overall that this whole area needs more investment and attention in asthma; researchers in the field also echo this

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Attempting to improve adherence/compliance/concordance with medication is embedded in all of the work that <<stakeholder name>> does, both in the information materials it produces and the practices it promotes in the healthcare setting, as good asthma control through effective treatment is crucial to prevent asthma exacerbations, hospital admissions and in some cases even death.

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7.7 TABS Expert Advisory Panel

The expert advisory panel (EAP) comprised experts in clinical paediatric and adolescent health (Dr Jonathan Klein (Chair)), paediatric medicines and pharmacology (Prof Imti Choonara), health behaviour (Bryony Beresford), service implementation, and study design and evaluation to ratify and inform the study. The EAP met five times via teleconference during the project with the PI, senior researcher and RMG members. The chair also attended an RMG meeting. The EAP provided input at all stages of the TABS study. Meeting notes are available on request.

Members and affiliation:

- Jonathan Klein (chair), Director of the American Academy of Pediatrics, University of Rochester, School of Medicine and Dentistry;
- Steve Tomlin, Consultant Pharmacist – Children’s Services, Evelina Children’s Hospital, Guy’s & St. Thomas’ NHS Foundation Trust;
- Imti Choonara Professor in Child Health, Academic Division of Child Health (University of Nottingham) The Medical School Derbyshire Children’s Hospital;
- Bryony Beresford, Research Director, Children and Families Team, Social Policy Research Unit, University of York.
7.8 Information sheet for interviewees under 18

This is an invitation to take part in a project that we think may be important, but whether you decide to take part or not is YOUR CHOICE. One of the doctors or nurses looking after you has talked to you about the project and, with your agreement, given us your name so we could get in touch.

Before you decide if you want to take part in the project, it is important for you to understand why the research is being done and what your participation will involve. Please read the following information carefully. Discuss the study with your family, friends or others if you wish. If you have any questions just get in touch with us. Our phone number and email address is over the page.

1 … So what’s the project?

We are studying the services offered by the….., which is trying to provide more information, care and support for adults and children who are very sick. We want to find out how you feel about the services, what you like about them and what you don’t like about them and how they compare to other services that you have used in the past.

2 … Who are we?

We are researchers from Nottingham University. We are working to make sure that young people get a say in planning services designed for them. The person who would like to speak with young people is our researcher, Jacky Williams and her details are over the page.

3 … What will happen if I take part?

A researcher will come and speak to you about the services that you use and how you feel about them. This will take about an hour and, if you like, one of your parents can stay with you the whole time. If you agree, we would like to tape-record what you say to make sure that we have an accurate record of what you said and don’t forget anything. You don’t have to say anything that you don’t want to. If you don’t want to speak to us, we won’t mind. You don’t even need to give a reason.

4 … Who will know what I say?

We usually make tape recordings, but we use false names so just the people there at the time know it’s you talking. The only people who listen to the tape afterwards are members of the research team. They will type up what you have said into a document, but because you have chosen a false name, no one will know it’s you talking.

The only time we might want to talk to someone else about what you say is if something said in the group makes us think you or someone else is in danger of...
being hurt. We would always want to talk to you about this directly before discussing it with anyone else.

5 ... What will happen to the information I give?

We will use what you say to tell people who plan health services about young people’s views. We will be writing a report for people who run services. We will also be setting up a website for the project so you will be able to see what other young people have said. We will use false names in the report and on the website so no one will be able to link what has been said to you.

Any information that you give within the project will kept in a locked cabinet with the false name you choose on it. This information will be kept for 5 years and after this time it will all be destroyed.

Just so you know, the University indemnity insurance cover provides no fault compensation. So, if you have a complaint please contact the Insurance Clerk at University of Nottingham.

6 ... What if I change my mind?

If, in the middle of talking to us, you decide you don’t want to take part after all, that’s fine, just tell us. And if we ask you a question which you don’t want to answer, that’s also fine – just tell us and we’ll go on to a different question. You don’t have to give a reason, unless you want to.

7 ... What if I have any concerns?

If you have concerns or other questions about this project or the way it has been carried out, you can contact the researcher, Jacky Williams (details below), or you can contact the complaints department at [site name].

8 ... Want to know more?

It’s up to you whether you take part, so if you have any questions or worries just get in touch and ask.

Jacky Williams, Research Fellow. Mobile Tel. XXXXXXXXXXX
Email: jacky.williams@nottingham.ac.uk
7.9 Health professional focus group schedule

12.30pm Procedure: On arrival, the researchers will complete the informed consent process, any expenses forms as required and invite participants to help themselves to lunch and a drink.

Over lunch appropriate web clips will be shown on lap top computers.

The facilitator and observers will ask participants to write down single words or phrases on cards that will be provided, to reflect their key concerns relating to medicine-taking for children and young people and the barriers they perceive to children and young people taking their medicines as they were prescribed.

**Question 1 “What sort of things do you think stop the children and young people with chronic conditions (that you care for) from taking their medicines in the way that it said on their prescription?”**

The cards will be handed back to the observers who will sort them, to identify themes and duplicates. Themes will be listed by the observers.

Participants will also be asked to write their first name (or a chosen name) on a card, which they will bring to the table with them.

**Introductions / ice breaker**

12.50pm Participants will sit around the table and the recording equipment will be switched on.

The facilitator will explain the ground rules for the group (e.g. confidentiality and use of recording equipment) and invite participants to introduce themselves by the name they have chosen to be known as for the purposes of this group and explain their role in relation to medicine taking in children.

- **12.55pm Barriers to medicine-taking**

We asked you “What sort of things you think stop the children and young people with chronic conditions (that you care for) from taking their medicines in the way that it said on their prescription?” These are the issues or barriers that you have identified and you may think of more as we progress.

The cards with the various barriers on will be placed on the table and participants will be asked to consider which (2 or 3) they think are the most important for 5 to 7 year olds; 10 to 12 year olds and 15 to 17 year olds with chronic conditions such as asthma, diabetes, epilepsies and congenital heart disease and why and which are least important barriers to adherence or good medicine management and why.

Whilst undertaking this process, participants will be encouraged to explain why they think specific issues are important / not important and if there are any other barriers or concerns they would like to add.

*Observers will create list of barriers by age (in columns) which will be shown to the participants at this stage.*
Observers will be invited to comment at the end of the discussion.

1.20 pm  **Ways to improve medicine-taking – solutions**

**Question 2.** What sorts of things do you think could help children and young people with chronic conditions such as asthma, diabetes, epilepsies and congenital heart disease (and their parents) to take their medicines as they were prescribed?

Round table discussion

**Prompts:**
- **Talking through their problems** – if so, what kind of problems? Is this the parent or the child?
- **How do you get the children and young people to talk?**
- **Information resources** – if so, which?
- **Do you use reward structures of any kind?**
- **Providing alternative formulations** (Interviewer notes e.g. liquids, sprinkles, soluble tablets, opening capsules, advice on disguising in food, cutting tablets, creams, choice of inhaler devices, etc)
- **Providing appropriate containers/labelling for medicine use in school**
- **Other resources (e.g. diaries, Dosette boxes)** - if so, which?
- **When would you refer a child, if ever, due to concerns about medicines use, and to whom?**
- **What kind of training (if any) have you had for this role?**
- **What sort of support is there for you to help medicines use, in your local NHS structure?**
- **What about children that represent challenging cases?**

1.40pm **Question 3.** How do you think children and young people can be helped to take responsibility for their own medicines as they get older?

**Prompt:** When should this happen?

What about the different stages of transition e.g. starting school, changing schools, leaving school, etc

What about children with challenging situations, such as those in care, or young mothers?

 ➢  **Developing a pre-consultation tool**

Research team will suggest different ways of presenting a pre-consultation tool e.g. tick-box questionnaire, computer program, / IT system or a person to sit with children or young people and invite comments.

1.50pm **Question 4.** What resources and / or further training (if any) do you think should be available to enhance the way health care providers / professionals such as GPs, nurses, pharmacists talk to children and young people, and their parents, about their medicines?

 ➢  **Further discussion**  - Observers may wish to come in here

1.55pm **Question 5.** Is there anything else that you would like to say about children, young people, their parents, and medicine-taking?
7.10 Face-to-face interview schedule – parents

The interviewer will introduce herself, explain the purpose of the study; the use of the tape recorder and take informed consent.

1. Can you tell me what condition(s) (name of child) has and what medicine(s) he / she takes?

2. How do you see your role in helping (name of child) to take his / her medicines?

3. Are there any particular difficulties in managing (name of child’s) medications or any special arrangements that have to be made?

4. What sort of things do you think might prevent (name of child) from taking his /her medicines in the way that it said on their prescription?

5. How would you deal with this?

6. Do you and (name of child) ever discuss their medicines?

7. What sort of things do you talk about?

8. Do you ever have any disagreements with (name of child) about anything to do with taking medicines?

9. Do you or (name of child) ever discuss their medicines with the doctors, nurses or pharmacists that you see?

10. What sort of things do you talk about?

11. What sorts of things have helped you to help your son/daughter to take their medicines?

Prompts:
   o Talking to someone – if so, who?
   o Things you’ve read / seen – if so, where?
   o Formulations e.g. liquids, sprinkles, soluble tablets, opening capsules, disguising in food, cutting tablets, creams, choice of inhaler devices, etc
Pharmacist providing appropriate containers/labelling for medicine use in school

12. Who looks after the medicines for *(name of child)*?

13. Has this changed as *(name of child)* has got older?

14. Do you think this will change in the future?

15. At what point do you think children and young people should take responsibility for their own medication?

16. How could health professionals (like consultants, GPs, nurses and pharmacists) help children and young people to take responsibility for their own medicines as they get older?

17. When do you think that *(name of child)* should move to adult services?

18. Is that move likely to cause any difficulties? If so, what sort of difficulties?

19. Do you foresee any particular challenges ahead as *(name of child) – use examples appropriate to current situation* starts school, changes school, or leaves school?

- **Developing a pre-consultation tool**
  
The researcher will show the parents ideas for a pre-consultation tool generated from group sessions and the critical evidence synthesis

20. Would these ideas help you and *(name of child)* to improve the way that you talk to their medicine provider (doctor, nurse or pharmacist) about their medicines?

21. Is there anything else that we would need to add or change to help you and your child?

22. Is there anything else that you would like to say about children, young people and medicine-taking?
7.11  Ask About Medicines Week funded stakeholder workshop

Ask About Medicines Week was an initiative started in 2003 (the campaign ended in 2009, but materials continue to be available from www.askaboutmedicines.org), which sought to increase patient knowledge about medicine-taking. One strategy used in this multi-strand campaign was raising awareness of 5 questions that every patient should ask before taking a medicine:

- WHAT does this medicine do?
- WHY is it important that I take this medicine? Are there any other treatment options?
- WHEN and how should I take it?
- HOW long should I take it for?
- WHAT should I be aware of when taking this medicine? (e.g. possible risks, side effects, taking medicines with certain foods/drinks/activities, what to do if I don’t feel well while I am taking it, how to store it safely etc)
- WHERE can I go for more information?

‘Ask About Medicines Week’ took place every autumn from 2003 to 2008. In 2003, one of our team had placed a survey within the ‘Teenage Health Freak’ website to explore visitors’ (aged 11 and over) perceptions of their need to ask these questions (Gray et al, 2004). Interest in side-effects was notable, and a slight gender difference for those saying that they thought all the AAMW questions were important to ask (46% of girls vs. 28% of boys). In 2007/8, the theme was ‘AAMW as we grow up’, including school-based lesson packs on the theme. AAMW offered annual awards to projects that supported initiatives in this field. The TABS project was successful in securing one of these grants.

Reference:
TABS Workshop Programme East Midlands Conference Centre,
17th February 2009

10am: Registration Coffee / juice will be available Gallery room 1
10.15am – 10.45am Introductions - Gallery room 2
10.45 am – 11am Introduction to DigiTV system
11.00am -11.15am Coffee break in Gallery room 1
11.15am – 12.30pm – Group work
   Group 1. Children and young people (Gallery Room 1)
   Group 2. Health care professionals (Gallery room 2)
   Group 3. Parents and representatives of organisations (Gallery rm 3)
12.30pm – 1.15pm Lunch in Gallery room 1
   Arrangements made for vegetarian and gluten free options.
1.15 pm – 1.45 pm Feedback from morning sessions Gallery room 2
1.45 pm – 3pm TABS virtual families
   Yellow family (Gallery room 1); Blue family (Gallery room 2); Green family (Gallery room 3)
3pm – 3.15pm –Closing session Gallery room 2
7.12 Code book for scoring parent interviews

PARENTS’ NEED TO MAINTAIN CONTROL AND SUPERVISION OF MEDICATION

Describes how parents achieve adherence by monitoring medicine taking. It includes the parent’s perception that the child needs to be supervised or that they need to supervise for parent’s own peace of mind. Also describes importance of retaining control and monitoring the regimen, being involved and parents’ response to attempts by health professionals to reduce parental control of medicine taking.

1.1 Label: Supervision of medicines as part of parental responsibility

Definition: Describes how parents accept control for the child’s medication as part of parental duty and an integral part of parenting.

Look for: The parent gives an example of he or she manages child as part of parental role. It can include references to the child not being ready to take on responsibility or it not being appropriate for the child to take responsibility because of the child’s age. Also includes the parent no wanting give up this aspect of the parental role or implicit acceptance that managing medicines is a parental duty.

Example:

"I would say that I would probably continue to manage it, I don't know till she's fifteen, sixteen, probably even older. I just can't imagine her going round to the doctors, at the moment I just can't imagine her being old enough to go round to the doctors on her own and getting her own prescriptions, because I can't imagine her being fourteen, fifteen. So at the moment it feels like it will always be me”.

Exclusions: Where it is clear that the parent is taking responsibility just because the child is not capable of managing medicines.

1.2 Label: Supervision seen as safety netting

Description: Parental supervision resulting from the parent’s perception that the child can’t be relied on to manage the medication rather than a need to be in control per se – a form of safety netting.

Look for: The parent indentifying the need to protect the child and/or to maintain optimum management. It can include the need to remind children.
Example

“Yeah, so we don't, I don't do it for her any more, she does it herself, but I make sure she does it”.

Exclusions: When management is seen as the parent’s responsibility.

1.3 Label: Perceived pressure from health professionals to let child take responsibility and reduce parental role in managing medication

Description: Theme captures how difficult parents find it to be excluded from discussions with health professionals. They often explained this in terms of the child wanting them to be there or the need to be fully informed. Some parents recognised the need for the child to be independent and sometime there was a discrepancy between parents’ views with one parent more willing to allow the child to have more responsibility.

Look for: The parent clearly perceives that the health professional is trying to give more control to the child or is trying to take some control parent. There may be a sense that the parent knows that this is desirable but still has an element of concern or reluctance. It also includes the parent taking the child’s perspective and identifying the child’s reluctance to take responsibility.

Example:

“I think the hospital are pushing for J to take more responsibility, if J wants to do that we haven't got a problem but I think it's when.....when he's ready”

Exclusions: When the pressure for child to be independent is coming from the parent or where there is no reference to a health professional.

THEME 2: CHILD DEVELOPING RESPONSIBILITY FOR MEDICINE TAKING

Parents’ perceptions of the implications of the child’s developmental stage for adherence.

2.1 Label: Parental recognition that the child’s contribution to medicine is developing or changing over time
Description: This can be either way- children becoming more and less responsible. Children developing expertise as they get older. The need to take into account developmental stage when giving a child responsibility. Recognition that children will be able to do more to manage their medication as they get older.

Look for: The parent makes reference to the child’s changing contribution to managing medicines as a function of age or understanding. It can also include the perception that the child is competent beyond their years or a sense that self-management has deteriorated.

Example

“Yeah, I suppose as she gets to be a teenager it will be down to her recognising the signs during the day won’t it?”

Exclusions: Statements which refer to change in management but which exclude any reference to the child’s age or stage of development.

2.2 Label: Parental role in developing the child’s autonomy

Description: Parent identifies developmentally appropriate independence or evidence of developing expertise or shared care with parents. Parental acknowledgement of child’s autonomy or skill. Includes examples of where parent negotiates or shares care with child

Look for: Perception of change in level of child’s contribution.

Example

"T is a lot more experienced, he knows what he's doing and quite often we'll sit there and we'll see his bloods and I'll say 4 and he'll sort of say "Do you think I should have 5, because it's a bit higher than," or whatever, or he'll say "Shall I have 3 because I'm going out and I was only whatever before my dinner and I'm going out on my bike," so he is actually quite responsible and quite often we'll tweak it one way or the other under T's input"

Exclusion

Where there is no acknowledgment of the child’s contribution or potential contribution to medicines taking.
2.3 Label: **Perception that child should take more responsibility**

Description: Parent describes attempts to get child to take more responsibility or acknowledges the need for the child to be more independent.

Look for: The parent gives example of the child not taking enough responsibility for their age or identifies an expectation that the child should be more independent or will be more independent.

Example

"I view it as a fact he's now 11 and he should be thinking I should be doing this and I should do it but that doesn't happen. Maybe it does with other children I don't know".

Excludes: Parent describes actual change in child’s self-management.

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**THEME 3: PARENTS’ PERCEPTION OF AVAILABLE SUPPORT**

3.1 Label: **Support for medicine taking within the family**

Description: Captures division of responsibility within the family and the extent to which it falls on one parent or is shared. Also includes feelings about the level of involvement of other family members.

What to look for: The parent referring to the contribution or lack of contribution of other family member. This could be practical eg holding or emotional eg discussion. Also look for examples of parents wanting more support from other family members or lack of support from family. Generally a recognition that sharing the responsibility is important.

*Example:*

I don't know, there was a couple of times when I've said to her "Have you took your medicine?" and she says yeah and then my husband has gone to stock her box back up for her and said "Well she's missed that day,"

Exclusions: No reference to other family member
3.2 Label: **School as an importance source of support**

Description: Describes the way school can support the child’s medicine taking, the perceived importance of such support and the extent of cooperation between school and parent.

What to look for: Evidence that parents perceive the school to be important in maintaining adherence and perceptions that school isn’t meeting expectations. Look for specific examples of support through school, for example dealing with stigma, adapting physical environment, changing school routines for the child and learning about child’s treatment. Also includes support from classmates and example schools failing to meet needs of children.

Example

“The school nurse has been trained on how to use it (nebuliser), so basically if he's not feeling well, puts his hand up in class, goes and sees the school nurse and takes it”

Exclusions: No mention of school

3.3 Label 3: **Health professionals lack of interest and concern for medicine taking**

Description: Parents perceive health professionals as unconcerned about adherence or do not expect health professions to be interested. Includes lack of information, poor communication hindering parents’ understanding or control of regimen.

What to look for: Emotional support for child rather than practical support for medicine taking. Lack of involvement of specific health professionals eg GPs. Health Professionals failing to take concerns about medicines seriously.

*Example:*

“Interviewer: Okay, did the hospital advise you get one of those (tablet dispenser)?

Parent: No.

Interviewer: Do they know you use one of those?”
Parent: I don’t know”

Exclusions: No mention of health professional, comment not related to medicine taking.

3.4 Label: Parents perceptions that medication taking was supported and facilitated by health services and pharmacists

Description: This included a few examples of shared decision making and perceptions that pharmacists were a useful source of information.

What to look for: Examples of support specifically for medicines taking. Evidence of cooperation between HP and parent and/or child to improve adherence. Provision of appropriate information.

“..he’s (child) had so many different combinations that we’ve played around with, to see which one is having the best effect. So yeah, they’ve explained to us, we’ve worked with them, trial and error, we’ve gone back and said hang on this ain’t working, that’s not working and it’s evolved over time”

Exclusion: no mention of health professional or not related to medicine taking.

THEME 4: BARRIERS AND FACILITATORS FOR MEDICINE TAKING.

This theme describes factors which the parents explicitly identify as impinging on the child’s medicine taking

4.1 Label: Role of stigma

Description: Parents acknowledge that stigma might interfere with medicine taking.

What to look for: An acknowledgement by the parent that stigma associated with the condition or the treatment could interfere with medicine taking

Example
“The only thing that worries me is whether they'll be embarrassed to have the Ventolin inhaler when they're out”

Exclusion: Comments refer to stigmatising effects of illness generally

4.2 Label: **Problems with regimen**

*Description: Describes aspects of the medication or delivery of the medication that helps, hinders or potentially hinders adherence, including difficulties with supply*

*What to look for: Examples of where the characteristics of the medication (e.g., method of administration, timing, complexity) impact or potentially impact on adherence.*

“Sometimes there's one tablet that sometimes, I'm trying to think, it might be an antibiotic, and he finds that sometimes that can explode before it's gone down, so it leaves a horrible like powder, as you can imagine. But apart from that I think it's okay”

*Exclusions: No reference to aspect of medicine delivery.*

4.3 Label: **Strategies to overcome barriers to adherence**

Describes ways parents encourage children and overcome difficulties with adherence, including use of routine.

*What to look for: Parents reporting ways that they have found of improving adherence or preventing non-adherence. These could include specific cues including charts and dispensers. Also attempts to identify and anticipate barriers. Examples of problem solving in relation to medicine taking.*

Example: “I don't think he has to take them with food, but it's just easier, it's just a set pattern we've got into”.

*Exclusions: Comment not directed to medicine taking.*

4.4 Label: **Child forgetfulness as a barrier to medicine taking**

*Description: Parents identify how children forget medications and the particular circumstances associated with forgetting, for example time of day.*
What to look for: Any reference to child forgetting medication or the parent having to remind child.

Example

“The only thing would be is if as I say at the night time, or if he's away at his friends, if he stays over with one of his friends which is they've always been wanting to do that this summer, is unless we remember to tell him to take it with him he doesn't”

Exclusions: Failure to take medication attributed to other factors such as taste or developmental stage.

4.5 Label: Side effects of medication

Description: Theme describes parental concerns about medicines, perception that child is worried about side effects or parents’ belief that the medicine causes side effects.

What to look for: Identification of a known side effect, acknowledgement that treatment might have side effect attribution of behaviour or problem to the child’s medication. Parental perception that child is worried.

“I do sometimes have conversations around my concern, E is quite, she's very slim, very skinny and she's quite, in comparison to her peer group, she's quite small and I have read things in papers, where or magazines where it says that you know, continued use of steroids can stunt growth. And obviously the Serevent has got steroids in it”

Exclusion: Difficulty not explicitly or implicitly linked to drug.

THEME 5: PERCEIVED NECESSITY OF MEDICATION AS A DRIVER FOR ADHERENCE

Parent perceives that medication is important or believes that the child needs to believe medication necessary. Perception that child adheres because they feel it is important. This was a very strong theme in relation to medicine taking.

5.1 Label Parents motivation to ensure adherence driven by perceived necessity of the medication.
Description: Theme captures how adherence is affected or potentially affected by the need for the medication. It includes issues about difficulty assessing need for medication when condition well controlled or balancing need with unwanted effects of medication

What to look for: Reference to the importance of medication, concern about whether the medication is needed, a perception that without the medication the child would be very ill, that the medicine is important.

Example:
"..we always make sure, we’re very, very hot on it, because I don’t want anything you know, anything to happen".

Exclusion: No implicit or explicit reference to adherence

5.2 Label: Parents stressing the necessity of the medication to encourage adherence.

Description: Captures how parents use or would like to use the perceived necessity of the medication to drive the child’s adherence. Reflects also the need to balance the consequences of non-adherence with the need to avoid disturbing the child.

What to look for: Parent identifying the benefit of the medication or the negative consequences of the medication as an inducement to adherence. Parent stating the importance of the medication or a sense that the child has to have it.

"That's the only thing because she has to, I mean we just say to her ‘Look you know if you don't take it, I know it's horrid, but if you don't, well if you don't take it you're going to be poorly and you need to probably have to go back into hospital’ 

Exclusions: Necessity identified as influencing parent’s motivation but not translated into a strategy to improve child’s motivation.

5.3 Label: Perception that child’s adherence is driven by an understanding of the importance of the medication.
Description: This highlights how strongly parents feel that children’s adherence is driven by their understanding of the importance of the medication for their health and the negative impact of their failure to understand the potential consequences of non-adherence.

What to look for: Example that child’s adherence is dependent in some way on the child appreciating that the medicine is important or that the consequences of non-adherence will be negative.

“It can't be an issue, she has to have it, it's as simple as that, it's a no brainer, she doesn't take the medicine, doesn't take steroids, she goes downhill and she can't cope, she gets through it like that”.

Exclusions: No mention of child’s own perception of necessity or use of necessity as a personal motivator.

5.4 Label: Child’s acceptance of condition

Description: Describes how the child’s level of acceptance of the condition influences willingness to take medication.

What to look for: Adherence linked to the child’s feelings about the condition and acceptance of long term medication. Child challenging medicine taking rather than accepting that it has to be done.

Example

“No, no I think she just knows that that's life and that's what she's got to do. She’s never questioned it really, no I don't think so”.

Exclusions: Acceptance not linked to medicine taking only to condition itself.
### 7.13 Pre-consultation tool - child

**TABS – Talking about Medicines**

**Questions for a child or young person**

These are some things that other people have said about medicines. Please put a circle around or colour in the answer that fits closest to how you feel. There are no right or wrong answers and this is not a test.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>I’m not sure</th>
<th>Not always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I know how to take my medicine(s).</td>
<td>✓</td>
<td>?</td>
<td>X</td>
</tr>
<tr>
<td>My medicine(s) help to keep me well.</td>
<td>✓</td>
<td>?</td>
<td>X</td>
</tr>
<tr>
<td>I remember to take my medicine(s).</td>
<td>✓</td>
<td>?</td>
<td>X</td>
</tr>
<tr>
<td>I am happy to take my medicine(s).</td>
<td>✓</td>
<td>?</td>
<td>X</td>
</tr>
<tr>
<td>My medicine(s) tastes alright.</td>
<td>✓</td>
<td>? I don’t have to taste my medicine(s)</td>
<td>X</td>
</tr>
<tr>
<td>I can take my medicine(s) at school.</td>
<td>✓</td>
<td>? I don’t need to take my medicine(s) at school</td>
<td>X</td>
</tr>
<tr>
<td>I need to take my medicine(s).</td>
<td>✓</td>
<td>? I’m not sure</td>
<td>X</td>
</tr>
<tr>
<td>I think my medicine(s) causes side-effects (other problems).</td>
<td>✓</td>
<td>? I’m not sure</td>
<td>X</td>
</tr>
<tr>
<td>It is easy to take my medicine(s).</td>
<td>✓</td>
<td>? I’m not sure</td>
<td>X</td>
</tr>
</tbody>
</table>
My family understand about me and my medicines.

<table>
<thead>
<tr>
<th>?</th>
<th>No</th>
<th>Yes, some of the time</th>
<th>Yes, most of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Don’t know</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

My friends understand about me and my medicines.

<table>
<thead>
<tr>
<th>?</th>
<th>No</th>
<th>Yes, some of the time</th>
<th>Yes, most of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Don’t know</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please turn over

Have you got any questions about your medicines that you would like to ask your doctor, nurse or pharmacist? Here are some questions that other people ask. You can use these, or write your own questions in the box below.

WHAT does this medicine do?

WHY is it important that I take this medicine? Is there anything else that I could take instead?

WHEN and how should I take this medicine?

HOW long should I take this medicine for?

WHAT sort of things do I need to know about taking this medicine?

WHERE can I go for more information?
If there is anything else important about you and your medicines you would like to say or ask, please write it in the box below.

I would like to tell you that ..........

Thank you for answering these questions.
### Pre-consultation tool - parent

**TABS – Talking about Medicines**

**Questions for a Parent / Carer**

What do you think about your son or daughter’s medicines? The medicines that your son or daughter takes can change their, and your, life. These are some comments that other people have made. Please tell us how you feel and how your life is affected as well. Please circle the best answer for you for each statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>Not Sure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taking their medicines helps to keep my child well.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taking their medicine prevents my child’s condition getting worse.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side-effects (or problems) from their medicine bother my child.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I think that my child’s medicine gets forgotten.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is hard for my child to take their medicines at school.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taking the medicine is difficult to remember every day.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting my child’s medicine from the pharmacy is a problem.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My child finds it difficult to take their medicines.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My child understands their medicines.</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Project 08/1704/212
Do you have any other questions about your son or daughter’s medicines that you would like to ask your doctor, nurse or pharmacist? Here are some questions that other people have asked. You can use these, or write your own questions in the box below.

**WHAT** does this medicine do?

**WHY** is it important that I take this medicine? Is there anything else that I could take instead?

**WHEN** and how should I take this medicine?

**HOW** long should I take this medicine for?

**WHAT sort of things do I need to know about** taking this medicine?

**WHERE** can I go for more information?

If there is anything else important about your child’s medicines you would like to say or ask, please write it in the box below.

*I would like to tell you that ...........

Thank you for your help in completing this survey.
### 7.15 Practitioner prompt

Also consider:
- Directing young person and caregiver to relevant websites and support groups
- Referral to relevant health care or social care service

<table>
<thead>
<tr>
<th>Key challenges to adherence</th>
<th>Possible action and resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Caregiver’s and young person’s knowledge about condition / medicines</td>
<td>• Review treatment and monitoring regimen</td>
</tr>
<tr>
<td>2. Caregiver’s and young person’s beliefs about necessity of medicines</td>
<td>• Give positive feedback on management</td>
</tr>
<tr>
<td>3. Anticipation and experience of side effects</td>
<td>• Empathise with challenges and normalise that people have problems with taking medicines, to encourage honest disclosure</td>
</tr>
<tr>
<td>4. Reduced severity or increased duration of illness</td>
<td>• Use open questions to check young person and caregiver understanding, discuss experiences and fears, and challenge beliefs about:</td>
</tr>
<tr>
<td></td>
<td>• medicines (efficacy and side effects),</td>
</tr>
<tr>
<td></td>
<td>• illness (symptom severity, long term risks)</td>
</tr>
<tr>
<td>5. Forgetting</td>
<td>• Suggest memory aids (eg: mobile phone alerts)</td>
</tr>
<tr>
<td>6. Large numbers of medicines, multiple daily doses, inconvenience, ability to use medicine</td>
<td>• Simplify regimen (eg: SR preparation, different drug with fewer daily doses, choice of inhalers)</td>
</tr>
<tr>
<td></td>
<td>• Involve caregivers in reminding, if appropriate</td>
</tr>
<tr>
<td></td>
<td>• Is forgetting the real reason for non-adherence?</td>
</tr>
<tr>
<td>7. Palatability of regimen</td>
<td>• Explore problems with palatability and access, investigate ways of improving this with the family.</td>
</tr>
<tr>
<td>8. Access to medicines (off-label, unlicensed)</td>
<td>• Encourage family to speak to their community pharmacist, or practitioner to contact directly.</td>
</tr>
<tr>
<td>9. Self-efficacy of young person (their perceived ability to manage their illness and medicines)</td>
<td>• Explore young person’s perceived ability to manage their illness and medicines</td>
</tr>
<tr>
<td></td>
<td>• Help develop coping strategies</td>
</tr>
<tr>
<td></td>
<td>• Consider suggesting peer group support</td>
</tr>
<tr>
<td>10. Young person’s feelings of isolation and optimism about the future</td>
<td>• Explore these feelings and discuss concerns about the future</td>
</tr>
<tr>
<td></td>
<td>• Consider suggesting peer group support</td>
</tr>
<tr>
<td>11. Quality of relationship with parents and siblings, family structure and routines, effect of living in more than one household, more than one carer, effect of peers and friends</td>
<td>• Adherence may be reduced in chaotic, unstructured or dysfunctional families, and they may require more intensive support and talking through coping strategies, possibly as part of a wider case review with social services</td>
</tr>
<tr>
<td></td>
<td>• Consider seeing the young person alone</td>
</tr>
<tr>
<td></td>
<td>• Consider multiple supplies of medicines for children living in more than one household</td>
</tr>
<tr>
<td>12. Lack of parental supervision</td>
<td>• Discuss how parents can help with medicines taking, if appropriate</td>
</tr>
<tr>
<td>13. Young person and caregiver interaction with the health system</td>
<td>• Discuss experiences and problems with negotiating health care and discuss coping strategies. If necessary, intervene directly to assist negotiation, access or relationships.</td>
</tr>
<tr>
<td></td>
<td>• Discuss possible impact of prescription charges</td>
</tr>
<tr>
<td>14. Access to medicines at nursery, or school</td>
<td>• Discuss access to medicines in school</td>
</tr>
<tr>
<td></td>
<td>• Consider what information the school needs</td>
</tr>
<tr>
<td></td>
<td>• Refer to school nurse or form teacher.</td>
</tr>
</tbody>
</table>
7.16 Consultation process checklist

1. Listen to child/young person & parent/carer to find out barriers to taking medicines
2. Discuss barriers to taking medicines, seek explanations and explore possible solutions
3. Use collateral information sources to consider other barriers to medicines taking
4. Match most important barriers to 1-2 key, measurable actions
5. Agree action plan and date for follow-up visit with child/young person and parent/carer

- Refer to preconsultation survey
- Record key barriers and challenges
- Eg social service register
- Refer to checklist overleaf
- Record action plan & date for follow-up visit
## 7.17 TABS – Practitioner consultation record form and checklist

<table>
<thead>
<tr>
<th>Unique Participant Number (Location specific e.g. L or N)</th>
<th>Child / young person’s name</th>
<th>Date of Birth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### CONSULTATION CHECKLIST

<table>
<thead>
<tr>
<th>Consultation Components</th>
<th>Completed By Practitioner</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Have you made an assessment of adherence from prescription refills and patient’s condition?</td>
<td></td>
</tr>
<tr>
<td>☐ Did you obtain the parent’s and child/young person’s assessment of adherence?</td>
<td></td>
</tr>
<tr>
<td>☐ Did you obtain the key barriers to adherence raised by parent and child/young person?</td>
<td></td>
</tr>
<tr>
<td>☐ Did you ensure that the child/young person’s and the parent’s views were elicited and concerns are discussed and given sufficient weight?</td>
<td></td>
</tr>
<tr>
<td>☐ Have you agreed on 2-3 action points?</td>
<td></td>
</tr>
<tr>
<td>☐ Have you scheduled a follow-up consultation?</td>
<td></td>
</tr>
<tr>
<td>☐ If the patient is an adolescent have you considered having consultations away from the parent?</td>
<td></td>
</tr>
<tr>
<td>☐ Have you completed the patient record for this consultation?</td>
<td></td>
</tr>
</tbody>
</table>

### ACTION POINTS

1. ..................................................
2. ..................................................
3. .................................................

Practitioner Notes

Please return the completed form to TABS researchers who will take a copy for their records
### A. CHILD/ YOUNG PERSON / FAMILY DETAILS

*Personal information to be collected from the child, young person or main caregiver, by a member of the research team (this information to be used to populate main DCF)*

<table>
<thead>
<tr>
<th>Name of child/young person</th>
<th>Gender and date of birth</th>
<th>Age group</th>
<th>Ethnicity</th>
<th>Index condition</th>
<th>Age at diagnosis</th>
<th>Co-morbidities</th>
<th>Main caregiver</th>
<th>Main caregiver’s name</th>
<th>Contact details for follow up:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(Mother / Father /Other)</td>
<td>First name:</td>
<td>Home telephone:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Last name:</td>
<td>Mobile telephone:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>E-mail:</td>
</tr>
</tbody>
</table>

*(NB. note if main caregiver or child / young person)*

<table>
<thead>
<tr>
<th>Postcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and location of healthcare provider</td>
</tr>
<tr>
<td>Location:</td>
</tr>
<tr>
<td>Healthcare Provider Code</td>
</tr>
<tr>
<td>Name and address of child or young person’s GP practice (for notification)</td>
</tr>
<tr>
<td>GP address</td>
</tr>
<tr>
<td>Date of observed consultation</td>
</tr>
<tr>
<td>Date of 1 week follow up</td>
</tr>
<tr>
<td>Date for 2 month follow up</td>
</tr>
</tbody>
</table>

*In the interests of patient confidentiality, this personal information will be stored separately from all other TABS study data.*
7.19  Data collection form observation child – young person 10-17

Phase 2 consultation data collection form: Child over 10 or young person under 17

A. CHILD/YOUNG PERSON DETAILS

Data to be pre-populated from response slip and personal information DCF.

<table>
<thead>
<tr>
<th>Place of recruitment</th>
<th>GP practice</th>
<th>Community pharmacist</th>
<th>Hospital clinic</th>
<th>Community paediatrician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender and age of child/young person</td>
<td>Male</td>
<td>Female</td>
<td>Age years</td>
<td>Date of birth</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition/s</td>
<td>Asthma</td>
<td>CHD</td>
<td>Diabetes</td>
<td>Epilepsies</td>
</tr>
<tr>
<td>Age at diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-morbidities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of participant healthcare provider</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Place of observed consultation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date for observed consultation</td>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td></td>
</tr>
</tbody>
</table>

B. BASELINE DATA

Current medication (prescription, over the counter and herbal or homeopathic medicines)

Research team will only ask these questions of child or young person aged 10 or over or parent if child / young person unable to respond.

<table>
<thead>
<tr>
<th>Medication name</th>
<th>Dose</th>
<th>Frequency</th>
<th>Form (e.g. tablet, crushed tablet, injection; turbo-haler etc)</th>
<th>How long have you been taking this medicine?</th>
</tr>
</thead>
</table>

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Project 08/1704/212
### Child locus of control

*This section completed by child/young person or parent?*

<table>
<thead>
<tr>
<th>Child / young person</th>
<th>Parent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please read the statements below and put a circle around the √ if you agree and round the X if you disagree with the statement.

**Practice:**

- People with my illness have to take medicines
  - If you agree with this, put a circle around √
  - If you disagree, put a circle around X

- People never get ill
  - If you agree with this, put a circle around √
  - If you disagree, put a circle around X

<table>
<thead>
<tr>
<th></th>
<th>Yes, I agree</th>
<th>No, I disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. There are many things I can do to keep from getting ill</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>2. People with my illness who never miss taking their medicines are just lucky</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>3. When I am ill, I can do things to get better</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>4. Only a doctor or nurse stops me being ill.</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td>5. I can do many things to help me take my medicines</td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>6. If I miss taking my medicines, it’s just bad luck</td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>7. I can choose how to take my medicines</td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>8. There are things I can do to improve my medicine taking</td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>9. Other people must tell me how to take my medicines</td>
<td>✔</td>
<td>✗</td>
</tr>
<tr>
<td>10. I can do many things to stop me from missing my medicines</td>
<td>✔</td>
<td>✗</td>
</tr>
</tbody>
</table>
**Child and parent-reported adherence**

**Medication Adherence Self Report Inventory (MASRI)**

<table>
<thead>
<tr>
<th>This section completed by child/young person or parent?</th>
<th>Child / young person</th>
<th>Parent</th>
</tr>
</thead>
</table>

We understand that many people on medication find it very difficult to take it regularly and often miss doses. We won’t be surprised if you have missed lots of doses as well. We need to know how many doses you have missed.

1. How many doses of medication did you miss yesterday?

   None  1  2  3  Don’t know

2. How many doses of medication have you missed in the 2 weeks before that?

   0  1  2 or more (roughly how many…?)  All of them  Don't know

3. When was the last time you missed a dose of medication?

   Today  Yesterday  Earlier this week  Last week

   Less than a month ago  More than a month ago

   Never  Don’t know

4. Put a cross on the line below at the point showing your best guess about how much medication you have taken in the last month.

   We would be surprised if this was 100% for most people, e.g. 0% means you have taken no medication; 50% means you have taken half your medication; 100% means you have taken every single dose of medication.

   ![Medication adherence scale](image-url)
# SELF-EFFICACY

## Child/young person

<table>
<thead>
<tr>
<th>Perceived self-efficacy of the child/young person</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>It is easy to take my medicines as they should be taken.</td>
<td>Yes</td>
<td>Maybe</td>
<td>No</td>
</tr>
<tr>
<td>I am confident (sure?) that I can take my medicines as they should be taken.</td>
<td>Yes</td>
<td>Maybe</td>
<td>No</td>
</tr>
</tbody>
</table>

## Time to supply of appropriate medicine

For your last prescription, how long was it from the time you/your child got the prescription from your doctor to the time you actually got the medicine from the pharmacy (chemist)?

## Interruptions in medicines provision

In the last week, can you remember if you/your child has had to go without your/their medicines at all because of problems with obtaining them?

If yes: which medicine, and how long was the delay?

What was the cause of the problem? E.g. GP would not prescribe or the pharmacist did not have in stock?
Were you advised that there might be a delay?
7.20 **Child Health Questionnaire (CHQ-28)**

![Child Health Questionnaire (CHQ-PF28) Form]

**INSTRUCTIONS:** This form asks about your child’s health and well-being. Your responses will be treated confidentially. There are no right or wrong responses. If you are unsure how to respond to a question, give the best response you can. It is important that you fill in each question. Please use blue or black ink.

Correct Marks: ■ × ✔ ✗

**SECTION 1: YOUR CHILD'S GLOBAL HEALTH**

1.1. In general, would you say your child's health is

<table>
<thead>
<tr>
<th></th>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 2: YOUR CHILD'S PHYSICAL ACTIVITIES**

The following questions ask about physical activities your child might do during a day.

2.1. During the past 4 weeks, has your child been limited in any of the following activities due to health problems?

<table>
<thead>
<tr>
<th></th>
<th>Yes, limited a lot</th>
<th>Yes, limited some</th>
<th>Yes, limited a little</th>
<th>No, not limited</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- a. Doing things that take a lot of energy, such as playing soccer, or running?
- b. Doing things that take some energy such as riding a bike?
- c. Bending, lifting or stooping?

**SECTION 3: YOUR CHILD'S EVERYDAY ACTIVITIES**

3.1. During the past 4 weeks, has your child been limited in the AMOUNT of time he/she could spend on schoolwork or activities with friends due to EMOTIONAL difficulties or problems with his/her BEHAVIOUR?

<table>
<thead>
<tr>
<th></th>
<th>Yes, limited a lot</th>
<th>Yes, limited some</th>
<th>Yes, limited a little</th>
<th>No, not limited</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.2. During the past 4 weeks, has your child been limited in the KIND of schoolwork or activities he/she could do with friends due to problems with his/her PHYSICAL health?

<table>
<thead>
<tr>
<th></th>
<th>Yes, limited a lot</th>
<th>Yes, limited some</th>
<th>Yes, limited a little</th>
<th>No, not limited</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION 4: PAIN

4.1. During the past 4 weeks, how often has your child had bodily pain or discomfort?

- None of the time
- Once or twice
- A few times
- Fairly often
- Very often
- Every/Almost every day

SECTION 5: BEHAVIOUR

Below is a list of items that describe children’s behaviour or problems they sometimes have.

5.1. How often during the past 4 weeks did each of the following statements describe your child?

<table>
<thead>
<tr>
<th></th>
<th>Very often</th>
<th>Fairly often</th>
<th>Sometimes</th>
<th>Almost never</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Argued a lot?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Had difficulty concentrating or paying attention?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Lied or cheated?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.2. Compared to other children your child’s age, in general would you say his/her behaviour is:

- Excellent
- Very good
- Good
- Fair
- Poor

SECTION 6: WELL-BEING

The following phrases are about children’s moods.

6.1. During the past 4 weeks, how much of the time do you think your child:

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Felt lonely?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Acted nervous?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Acted bothered or upset?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 7: SELF-ESTEEM

The following ask about your child’s satisfaction with self, school, and others. It may be helpful if you keep in mind how other children your child’s age might feel about these areas.

7.1. During the past 4 weeks, how satisfied do you think your child has felt about:

<table>
<thead>
<tr>
<th></th>
<th>Very satisfied</th>
<th>Somewhat satisfied</th>
<th>Neither satisfied nor dissatisfied</th>
<th>Somewhat dissatisfied</th>
<th>Very dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. His/her school ability?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. His/her friendships?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. His/her life overall?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

healthactchq Two International Place, 16th Floor / Boston, MA 02110 / www.healthactchq.com

Child Health Questionnaire – Parent Form 21 (CHQ-PT21) © 2006 HealthActCHQ, Inc. English (UK and Ireland) All rights reserved.
SECTION 8: YOUR CHILD’S HEALTH
The following statements are about health in general.

8.1. How true or false is the statement for your child?
   a. My child seems to be less healthy than other children I know.
   b. My child has never been seriously ill.
   c. I worry more about my child’s health than other people worry about their children’s health.

8.2. Compared to one year ago, how would you rate your child’s health now:

<table>
<thead>
<tr>
<th>Much better now than 1 year ago</th>
<th>Somewhat better now than 1 year ago</th>
<th>About the same now as 1 year ago</th>
<th>Somewhat worse now than 1 year ago</th>
<th>Much worse now than 1 year ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

SECTION 9: YOU AND YOUR FAMILY

9.1. During the past 4 weeks, how MUCH emotional worry or concern did each of the following cause YOU?
   a. Your child’s physical health
   b. Your child’s emotional well-being or behaviour

<table>
<thead>
<tr>
<th>None at all</th>
<th>A little bit</th>
<th>Some</th>
<th>Quite a lot</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

9.2. During the past 4 weeks, were you LIMITED in the amount of time YOU had for your own needs because of:
   a. Your child’s physical health
   b. Your child’s emotional well-being or behaviour?

<table>
<thead>
<tr>
<th>Yes, limited a lot</th>
<th>Yes, limited some</th>
<th>Yes, limited a little</th>
<th>No, not limited</th>
</tr>
</thead>
<tbody>
<tr>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

9.3. During the past 4 weeks, how often has your child’s health or behaviour:
   a. limited the types of activities you could do as a family?
   b. interrupted various everyday family activities (eating meals, watching tv)?

<table>
<thead>
<tr>
<th>Very often</th>
<th>Fairly often</th>
<th>Sometimes</th>
<th>Almost never</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

9.4. Sometimes families may have difficulty getting along with one another. They do not always agree and they may get angry. In general, how would you rate your family’s ability to get along with one another?

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
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</tr>
</tbody>
</table>
# 7.21 Paediatric Consultation Assessment Tool (PCAT) marking key

## Building the relationship

| Non-verbal skills: eye contact, open posture, avoids writing / reading notes | Minimal eye contact, obstructive posture, excessive reading or writing notes with no explanation | Minimal eye contact, awkward posture, refers to / writes in notes with no explanation | Quite good eye contact and posture, occasionally inappropriate nonverbal behaviour | Very good nonverbal skills ± explains need to use notes |
| Is empathetic and supportive – shows concern, responds to family’s predicament | Ignores patient’s predicament completely; totally unsupportive ± rude | Minimal response to parent/child’s predicament, limited support | Warmth towards family but occasionally poor response to predicament | Much warmth and natural empathy throughout consultation |
| Appropriately engages child from the early stages of consultation | Completely ignores child | Almost completely ignores child or is awkward / inappropriate | Engages child but occasionally inappropriate, insensitive or overpowering | Sensitive tries to engage child, adjusting approach to child’s response |

## Initiating the session

| Introduces self, clarifies role, determines who is present | Does not establish who is present | Minimal information clarified | Most but not all is clarified eg self and role, but not family members | Explains role and identity, sensitively determines who is present |
| Identifies reasons for the consultation – the doctor’s and family’s reasons | Neither explains purpose for consultation nor checks family’s reasons | Limited coverage of own or family’s reasons for consultation | Explains own reasons for consultation; responds poorly to family’s reasons | Explains own reasons for consultations and acknowledges those of family |
| Screens for other problems and negotiates the agenda for the consultation | No check for other problems and no agenda identified | Screens for but ignores other problems | Screens but no agenda set / only doctors needs are discussed | Screens for and responds to other problems, contracts a clear agenda with family |

## Gathering information

<table>
<thead>
<tr>
<th>Listens attentively,</th>
<th>Interrupts all the</th>
<th>Interrupts</th>
<th>Moderate facilitation</th>
<th>Shows interest by</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>facilitating</strong> verbally and nonverbally</td>
<td>time or invalidates family’s story or excessive use of notes</td>
<td>moderately often or poor facilitation or a little too much use of notes</td>
<td>with occasional interruption</td>
<td>verbal and nonverbal facilitation, good use of silence</td>
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<td>---</td>
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</tr>
<tr>
<td><strong>Picks up and responds to verbal and non-verbal cues</strong></td>
<td>No response to obvious verbal nonverbal cues or is rude in response</td>
<td>Minimal response to verbal / non-verbal cues (despite being present)</td>
<td>Picks up and responds to cues but occasionally misses cues</td>
<td>Repeatedly picks up verbal and nonverbal cues, with sensitive response</td>
</tr>
<tr>
<td><strong>Uses appropriate questioning techniques (eg open → closed questions)</strong></td>
<td>Obstructs patient narrative, exclusive use of closed questions</td>
<td>Too little space for narrative or too many closed too early</td>
<td>Appropriate questioning, a few too many closed questions</td>
<td>Natural sequence of questions, sensitive questioning style for all family members</td>
</tr>
<tr>
<td><strong>Explores parent/child’s ideas, concerns, feelings, expectations</strong></td>
<td>Does not explore parent/child’s perspective at all, obstructs discussion</td>
<td>Limited or awkward discussion of parent/child’s perspective</td>
<td>Moderate amount of exploration of parent/child’s perspective</td>
<td>Sensitively explores and values parent/child’s perspective</td>
</tr>
</tbody>
</table>

### Paediatric Consultation Assessment Tool – Marking Key

<table>
<thead>
<tr>
<th><strong>Process Skills</strong></th>
<th>1</th>
<th>3</th>
<th>5</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical examination</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Prepares</strong> for examination eg by attending to privacy, toys</td>
<td>Does not prepare for examination at all</td>
<td>Minimal preparation for examination</td>
<td>Some preparation for examination</td>
<td>Carefully attends to accessories, seating, others in room, etc</td>
</tr>
<tr>
<td><strong>Maintains rapport</strong> with the child throughout the examination</td>
<td>No rapport: is rude or abrupt, or ignores child</td>
<td>Some effort to develop rapport but still awkward</td>
<td>Good rapport but occasional inappropriate behaviour</td>
<td>Sensitively maintains rapport throughout examination process</td>
</tr>
<tr>
<td><strong>Explanation and Planning</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Tailors</strong> amount and type of information for parent/s and child</td>
<td>No attempt at all to adjust information to parent/child’s needs</td>
<td>Determines but does not respond to starting point, little chunking and checking</td>
<td>Some tailoring / chunking of info but could still be better</td>
<td>Checks starting point, tailors information well</td>
</tr>
<tr>
<td><strong>Uses skills which aid recall</strong></td>
<td>Muddled</td>
<td>Disorganised</td>
<td>Organised</td>
<td>Well-organised,</td>
</tr>
<tr>
<td>and understanding</td>
<td>information, lots of jargon, no checking for understanding</td>
<td>information, a little jargon, limited or no checking for understanding</td>
<td>information, a little jargon, some checking for understanding</td>
<td>jargon-free info, repeated checks for understanding ± asks for restate</td>
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<tr>
<td>-------------------</td>
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<td>-------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Incorporates parent/child’s perspective into explanation</td>
<td>Completely ignores or belittles perspective</td>
<td>Limited incorporation of parent/child’s perspective into explanation</td>
<td>Some incorporation of parent/child’s perspective into explanation</td>
<td>Very good incorporation of parent/child’s perspective into explanation</td>
</tr>
<tr>
<td>Involves parent/s and child in decision making</td>
<td>Prescriptive management plan, no consideration of family’s wishes</td>
<td>Describes options but still offers little choice to parent/child</td>
<td>Some involvement of parent/child in decision making</td>
<td>Parent/child fully participant in decision making</td>
</tr>
</tbody>
</table>

**Closure**

<table>
<thead>
<tr>
<th>Establishes and clarifies next steps with parent/s and child</th>
<th>Does not establish or clarify next steps at all</th>
<th>Some plans re next steps made, but no cross-checking with family</th>
<th>Clear plans made re next steps but not fully cross-checked with family</th>
<th>Carefully explains next steps and cross-checks with family if acceptable and understood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Makes contingency plans</td>
<td>No contingency plans or disparages requests for contingencies</td>
<td>Limited or transparently impractical contingency plans</td>
<td>Contingency plans made but not clarified with family</td>
<td>Clear contingency plans clarified with family</td>
</tr>
</tbody>
</table>

**Structuring**

| Uses skills which provide structure (eg summarising and signposting) | Neither of skills used at all, despite opportunity OR chaotic consultation without being patient-centred | Minimal use of summarising and signposting, despite opportunity | Some use of summarising and signposting, could have beneficially used more | Very good (abundant and appropriate) use of summarising and signposting |
## 7.22 Data collection forms observation (researcher) (includes PCAT)

### Observation data collection form: Researcher

#### OBSERVATION AND FOLLOW UP DETAILS

Data to be pre-populated from response slip and personal information DCF. Data to be checked and missing data to be collected from the child, young person or main caregiver, by a member of the research team.

<table>
<thead>
<tr>
<th><strong>Observation data collection form:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of recruitment/observed consultation</strong></td>
<td><strong>Day</strong></td>
</tr>
<tr>
<td><strong>Name and role of participant healthcare provider</strong></td>
<td></td>
</tr>
<tr>
<td><em>(E.g. Dr, Specialist Nurse etc)</em></td>
<td></td>
</tr>
<tr>
<td><strong>Place of recruitment.</strong></td>
<td></td>
</tr>
<tr>
<td><em>(E.g. GP practice, Hospital, Hospital outpatient clinic, Community Paediatrician, Community Pharmacist, Other)</em></td>
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</tr>
<tr>
<td><strong>Location of observed consultation</strong></td>
<td></td>
</tr>
<tr>
<td><em>(E.g. Nottingham, Leicester)</em></td>
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</tr>
<tr>
<td><strong>Date/time for 1 week follow up</strong></td>
<td><strong>Day</strong></td>
</tr>
<tr>
<td><strong>Date/time for 2 month follow up</strong></td>
<td><strong>Day</strong></td>
</tr>
<tr>
<td><strong>Time to complete the documentation before the consultation</strong></td>
<td><strong>Start</strong></td>
</tr>
<tr>
<td><strong>Length of consultation with healthcare provider</strong></td>
<td><strong>Start</strong></td>
</tr>
<tr>
<td><strong>Time taken for hospital / clinic visit</strong></td>
<td><strong>Start</strong></td>
</tr>
</tbody>
</table>

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Project 08/1704/212
### BASELINE DATA

Current medication (prescription, over the counter and herbal or homeopathic medicines)

*Clinician to complete  (research team will check against parent / child response)*

<table>
<thead>
<tr>
<th>Medication name</th>
<th>Dose</th>
<th>Frequency</th>
<th>Form (e.g. tablet, crushed tablet, injection; turbo-haler etc)</th>
<th>How long has the patient been taking this medicine</th>
</tr>
</thead>
<tbody>
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<tr>
<td>Illness category</td>
<td>Indicator 1</td>
<td>Indicator 2</td>
<td>Indicator 3</td>
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<tr>
<td>------------------</td>
<td>-----------------------------------------</td>
<td>--------------------------------------------</td>
<td>------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>Step 1-5 (See below)*</td>
<td>Oral steroid use in the last month:</td>
<td>How many exacerbations in the last month:</td>
<td></td>
</tr>
<tr>
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</tr>
<tr>
<td>Congenital heart disease</td>
<td>Most recent blood pressure</td>
<td>Most recent serum cholesterol</td>
<td>Most recent INR</td>
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</tr>
<tr>
<td>Diabetes</td>
<td>Most recent HbA(_1c)</td>
<td>How many hypoglycaemic events in the last month:</td>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Epilepsy</td>
<td>How many absence seizures in the last month</td>
<td>How many petit mal seizures in the last month</td>
<td>How many grand mal seizures in the last month</td>
<td></td>
</tr>
</tbody>
</table>

**Management of chronic asthma. Child 5-18 years***
Step 1 | Occasional relief bronchodilators
---|---
Step 2 | Regular inhaled preventer therapy
Step 3 | Inhaled corticosteroids + long acting inhaled beta₂ agonist
Step 4 | High-dose inhaled corticosteroids + regular bronchodilators
Step 5 | Regular corticosteroid tablets

* BNF for Children 2009 p170

### PAEDIATRIC CONSULTATION ASSESSMENT TOOL (PCAT)¹

Use one copy per consultation.

**Content skills.** Score the clinician’s diagnostic and management skills.

**Process skills.** Make judgments about the skills the clinician uses to communicate with the child / young person and his/her carers. Use the behaviourally anchored ratings (the Marking Key) to guide you. Fill in the boxes for each individual skills, then use these judgements to guide your overall scores for each section.

Where indicated, and whenever the patient is able to contribute to the conversation, evaluate the skills used with child and parent/s separately.

Use the free text boxes to record what you saw / heard. Record actual phrases if you can.

*(Consultation, Clinician and Observer categories removed – recorded elsewhere.*)

<table>
<thead>
<tr>
<th>Content Skills</th>
<th>1 = very poor, 7 = very good</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gathers relevant essential information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Skills (Refer to marking key)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5 6 7 Comments</td>
</tr>
</tbody>
</table>

### Building the relationship

<table>
<thead>
<tr>
<th>Non-verbal skills: eye contact, open posture, avoids writing/reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is <strong>empathetic</strong> and <strong>supportive</strong> – responds to family’s predicament</td>
</tr>
<tr>
<td>Appropriately <strong>engages</strong> child from the early stages of the consultation</td>
</tr>
</tbody>
</table>

**Building the relationship (parent/s): overall rating 1 2 3 4 5 6 7**

**Building the relationship (child): overall rating 1 2 3 4 5 6 7**

### Initiating the session

<table>
<thead>
<tr>
<th>Introduces self, clarifies role, determines who is present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifies reasons for the consultation – the doctor’s and family’s</td>
</tr>
<tr>
<td>Screens for other problems + negotiates the consultation’s agenda</td>
</tr>
</tbody>
</table>

**Initiating the session (parent/s): overall rating 1 2 3 4 5 6 7**

**Initiating the session (child): overall rating 1 2 3 4 5 6 7**

### Process Skills continued (Refer to marking key)
### Gathering information

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gathers</strong></td>
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<td><strong>Listens</strong></td>
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<td><strong>Listens</strong></td>
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<td><strong>Attentively</strong></td>
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<td><strong>Facilitating</strong></td>
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<td><strong>Verbally</strong></td>
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<td><strong>Non-verbally</strong></td>
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<td><strong>Picks up</strong></td>
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<td><strong>Responds</strong></td>
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<td><strong>Verbal</strong></td>
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<tr>
<td><strong>Non-verbal cues</strong></td>
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<tr>
<td><strong>Appropriate questioning techniques</strong></td>
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<td><strong>Explores</strong></td>
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<td><strong>Parent/child's ideas</strong></td>
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<td><strong>Concerns</strong></td>
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<td><strong>Feelings</strong></td>
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<td><strong>Expectations</strong></td>
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</tbody>
</table>

**Gathering information (parent/s): overall rating 1 2 3 4 5 6 7**

**Gathering information (child): overall rating 1 2 3 4 5 6 7**

### Physical Examination

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Comments</th>
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<tbody>
<tr>
<td><strong>Prepares</strong></td>
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<td><strong>For examination</strong></td>
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<td><strong>Such as</strong></td>
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<tr>
<td><strong>By attending to privacy, toys</strong></td>
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<tr>
<td><strong>Maintains rapport</strong></td>
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<td><strong>With the child</strong></td>
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<tr>
<td><strong>Throughout the examination</strong></td>
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</table>

**Physical Examination: overall rating 1 2 3 4 5 6 7**

### Explanation and Planning

<table>
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<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tailors</strong></td>
<td></td>
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<tr>
<td><strong>Amount and type of information</strong></td>
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</tr>
<tr>
<td><strong>For parent/s and child</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Uses skills which aid recall and understanding</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Incorporates</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Parent/child's perspective</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Into explanation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Involves parent/s and child in</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Decision making</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Explanation and Planning (parent/s): overall rating 1 2 3 4 5 6 7**

**Explanation and planning (child): overall rating 1 2 3 4 5 6 7**

### Closure

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Establishes and clarifies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Next steps with parent/s and child</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Makes contingency plans</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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Project 08/1704/212
### Structuring the interview

<table>
<thead>
<tr>
<th>Uses skills which provide structure (e.g. summarising, signposting)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Structuring the interview: overall rating** 1 2 3 4 5 6 7

<table>
<thead>
<tr>
<th>Overall performance (parent/s) 1 2 3 4 5 6 7</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Overall performance (child) 1 2 3 4 5 6 7</th>
</tr>
</thead>
</table>

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## POST CONSULTATION

### Parent

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall, how did you feel that the consultation went?</td>
<td></td>
</tr>
<tr>
<td>Did you use the pre-consultation tool?</td>
<td></td>
</tr>
<tr>
<td>(Yes) How useful was it?</td>
<td></td>
</tr>
<tr>
<td>(No) Was there any reason for not using it?</td>
<td></td>
</tr>
</tbody>
</table>

### Child / young person

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall, how did you feel that the consultation went?</td>
<td></td>
</tr>
<tr>
<td>Did you use the pre-consultation tool?</td>
<td></td>
</tr>
<tr>
<td>(Yes) How useful was it?</td>
<td></td>
</tr>
<tr>
<td>(No) Was there any reason for not using it?</td>
<td></td>
</tr>
</tbody>
</table>

### Practitioner

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall, how did you feel that the consultation went?</td>
<td></td>
</tr>
<tr>
<td>Did you use the pre-consultation tool?</td>
<td></td>
</tr>
<tr>
<td>(Yes) How useful was it?</td>
<td></td>
</tr>
<tr>
<td>(No) Was there any reason for not using it?</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>

**NOTES**
We would like to invite you to take part in a research project. Before you decide, we want to tell you why it is being done and what we would like you to do. Please read this leaflet and talk to other people about it if you wish. Ask us if anything is not clear or you would like to know anything else. Have a think about whether or not you wish to take part.

Thank you for reading this. 😊

**Why is the project being done?**

You probably know that some young people have to take medicines every day to keep them feeling well. We want you to tell us what is important to you about taking medicines. The aim of this project is to try to help children and young people to be more confident and informed about their medicines so that they can get the best benefit from them.

**Why me?**

Because you take some medicines regularly for one of the following conditions: asthma, congenital heart disease, diabetes or epilepsy.

**Do I have to take part?**

No. It is up to you if you would like to take part or not. If you take part you can keep this paper and you and your parent(s) will be asked to sign a form. If you decide to talk to us you can change your mind at any time without telling us why. If you don’t want to talk to us at all that is fine. None of this will change how your doctors, nurses or pharmacists look after you.
What will happen if I take part?

First we will send a survey to you and your parents to fill in at home. We will come and talk to you about medicine-taking before you have your appointment with your medicine provider (who could be a doctor, a nurse or a pharmacist). Your parents will also talk to us. This will be done somewhere private and will take about 20 minutes. We will then sit in and listen while you talk to your medicine provider and afterwards we will ask you how you think things went. We will also phone or visit you and your parents one week later and two months later - just to see how you are getting on. We will use a digital recorder during the appointment and interviews. The recorded conversations will be typed up, but we will remove names and places so it will not be possible to identify you. We will also need to collect some information about your conditions and medicines from your medical notes. If you agree to this then we will ask your health professional to share the notes with us. We will not make copies and we will not take the notes away.

You will receive a voucher from a High Street store for taking part.

What are the possible good things if I take part?

We hope that the project will help doctors and others to understand what is important to children, young people and their families about taking medicines.

What happens when the project stops?

We will write a report in journals that doctors, nurses and pharmacists read to tell other people about what we have found.

What if I change my mind?

You can leave the project at any time, without giving any reason and without your future care being affected in any way.

Will my taking part in this study be kept private?

We will tell your GP that you are helping us, but not what you say to us. We will use a digital recorder and make some notes while we are with you. We will not use your name in our reports.

What will happen to the results of the project?

The results will be put in journals read by doctors, nurses and pharmacists who work with young people, and we will speak about the study at conferences. If you would like a copy of a short report at the end of the study, please let us know.

Who is doing and paying for the project?
The research is organised by the Division for Social Research in Medicines and Health, University of Nottingham and paid for by the NHS Service Delivery and Organisation (SDO) Programme.

Who has reviewed the study?

A special 'ethics committee' made up of doctors and other people who make sure that you and your family have all the information you need about the project. They also check that the way we are going to do the study is in line with good research practice.

Complaints

If you wish to make any complaints about this study, you should contact the Chief Investigator, Professor Rachel Elliott at the address below.

Contact for Further Information

If you would like to know anything else please contact:

Freepost RRZS-AELX-ZHXU, TABS Study,
School of Pharmacy, Pharmacy School Building,
University Park, Nottingham, NG7 2RD

Tel: 0115 8232282
Email: deborah.watmough@nottingham.ac.uk

THANK YOU FOR READING THIS INFORMATION😊
7.24 **Clinic observation attendance letter**

Division of Social Research in Medicines and Health
School of Pharmacy
University of Nottingham
University Park
Nottingham
NH7 2 RD

Date

Dear ………………………

Re: “Talking About Medicines” TABS study.

Thank you for expressing an interest in the TABS research study. We understand that your appointment with ........ is on ................ at ........

We would like to meet you a short while before this appointment so could you please be at the clinic by ..... on .......

We have enclosed some documents that we would like you and ........ to complete and bring along with you to the appointment.

- The Child Health Questionnaire (CHQ-PF28) to be filled in by the parent or caregiver.
- Brief pre-consultation surveys to be filled in by:
  - Parent / caregiver form on blue
  - Child / young person form on yellow.

If you happen to forget these forms, we will have some spare ones with us when we meet you at the clinic, but it would be very helpful if you could complete them at home and bring them with you.

We would also like to talk to you briefly immediately after your appointment, and again one week afterwards and two months afterwards. This is to find out your views and
experiences about the consultation and ....... medicines. This can be either by telephone or face to face, which ever suits you best.

........ will receive a voucher from a High Street store for participating.

If you have any further questions, please do not hesitate to contact us.

If for any reason you are unable to attend the scheduled clinic appointment, please let us know urgently on 0115 8232282.

Once again, thank you for your interest in the study. We look forward to meeting you.

Yours sincerely,

Deborah E Watmough
Research Associate, TABS Study
Telephone: 0115 8232282
Email: deborah.watmough@nottingham.ac.uk
ASSENT FORM FOR CHILDREN AND YOUNG PEOPLE
(to be completed by child 5 to 7)

Project title: Talking about Medicines (TABS)

Child or /young person to circle all they agree with:

Have you read (or had read to you) an information sheet about this project?  
Yes/No

Has somebody explained this project to you?  
Yes/No

Do you understand what this project is about?  
Yes/No

Have you asked all the questions you want?  
Yes/No

Have your questions been answered in a way you understand?  
Yes/No

Do you understand it’s OK to stop taking part at any time?  
Yes/No

Are you happy for us to use a digital audio recorder?  
Yes / No

Are you happy to take part? 😊  
Yes/No

If any answers are 'no' or you don’t want to take part, don’t sign your name!

Patient Identification Number
If you do want to take part, you can write your name below

Your name ___________________________

Date ___________________________

The person who explained this project to you needs to sign too:

Print Name ___________________________

Sign ___________________________

Date ___________________________

Thank you for your help 😊
7.26 Consent form parent

Title of Study: TABS - Talking about medicines.

Phase 2 Parent / child CONSENT FORM

Chief Investigator: Professor Rachel Elliott, School of Pharmacy, University of Nottingham, NG7 2RD Telephone: 0115 8468596
e-mail: rachel.elliott@nottingham.ac.uk

Please initial each box and print name, sign and date at the end of the page

1. I confirm that I have read and understood the participant information sheet, version 2 dated September 2009 for the above study and I have had the opportunity to ask questions.

2. I understand that my and my child’s participation is voluntary and that we are free to withdraw at any time, without giving any reason, without our medical care or legal rights being affected.

3. I understand that neither I nor my child will be identified in any document relating to this study.

4. I agree to the use of digital audio recording as part of the process.
   I know that only people from the research team will listen to the recordings and they will be kept safely locked away and destroyed at the end of the study.

5. I know that our GP will be told that myself and my child are taking part.

6. I agree to the research team consulting my child’s medical notes, and that they will not make copies nor remove the notes from the health professional.
7. I agree to take part in the above study and give permission for my child to participate.

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Person taking consent</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Name of researcher</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 7.27 Ethnicity categories

<table>
<thead>
<tr>
<th><strong>To which of these ethnic groups do you consider you belong?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>White</strong></td>
</tr>
<tr>
<td>British</td>
</tr>
<tr>
<td>Any other White background</td>
</tr>
<tr>
<td><strong>Mixed</strong></td>
</tr>
<tr>
<td>White and Black Caribbean</td>
</tr>
<tr>
<td>White and Black African</td>
</tr>
<tr>
<td>White and Asian</td>
</tr>
<tr>
<td>Any Other Mixed background</td>
</tr>
<tr>
<td><strong>Asian or Asian British</strong></td>
</tr>
<tr>
<td>Indian</td>
</tr>
<tr>
<td>Pakistani</td>
</tr>
<tr>
<td>Bangladeshi</td>
</tr>
<tr>
<td>Any Other Asian background</td>
</tr>
<tr>
<td><strong>Black or Black British</strong></td>
</tr>
<tr>
<td>Caribbean</td>
</tr>
<tr>
<td>African</td>
</tr>
<tr>
<td>Any Other Black background</td>
</tr>
<tr>
<td><strong>Chinese or other ethnic group</strong></td>
</tr>
<tr>
<td>Chinese</td>
</tr>
<tr>
<td>Any Other</td>
</tr>
</tbody>
</table>

### 7.28 Main care giver occupational education

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Educational level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching/education</strong></td>
<td></td>
</tr>
<tr>
<td>Teacher (secondary)</td>
<td>1 Postgraduate /PhD</td>
</tr>
<tr>
<td>Special needs teacher; LA consultant</td>
<td>1 Postgraduate /PhD</td>
</tr>
<tr>
<td>Primary school teacher</td>
<td>1 Postgraduate /PhD</td>
</tr>
<tr>
<td>Education, learning and support mentor</td>
<td>1 Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Teaching assistant</td>
<td>3 Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Pre-school manager</td>
<td>1 A Level/NVQL3</td>
</tr>
<tr>
<td>Mother - Early years practitioner**</td>
<td>1 A Level/NVQL3</td>
</tr>
<tr>
<td>Midday Manager of Primary School</td>
<td>1 GCE/GCSE/CSE</td>
</tr>
<tr>
<td>Teaching Assistant (Mother)*</td>
<td>1 GCE/GCSE/CSE</td>
</tr>
<tr>
<td><strong>Health</strong></td>
<td></td>
</tr>
<tr>
<td>Dentist (Part time)</td>
<td>1 Postgraduate /PhD</td>
</tr>
<tr>
<td>Midwife</td>
<td>1 Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Staff Nurse</td>
<td>1 Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Student nurse</td>
<td>1 GCE/GCSE/CSE</td>
</tr>
<tr>
<td>Nursery nurse</td>
<td>1 GCE/GCSE/CSE</td>
</tr>
<tr>
<td><strong>Administrative and managerial</strong></td>
<td></td>
</tr>
<tr>
<td>Managing Director</td>
<td>1 Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Parking management, city council</td>
<td>1 Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Medical PA</td>
<td>1 A Level/NVQL3</td>
</tr>
<tr>
<td>Banker</td>
<td>1 A Level/NVQL3</td>
</tr>
<tr>
<td>Office manager</td>
<td>1 A Level/NVQL3</td>
</tr>
<tr>
<td>Temporary Admin Full-Time</td>
<td>1 A Level/NVQL3</td>
</tr>
<tr>
<td>Financial administrator</td>
<td>1 GCE/GCSE/CSE</td>
</tr>
<tr>
<td>Information gatherer for HIPS packages</td>
<td>1</td>
</tr>
<tr>
<td>---------------------------------------</td>
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</tr>
<tr>
<td>Inland revenue</td>
<td>1</td>
</tr>
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</table>

**Retail/marketing/shop workers**

<table>
<thead>
<tr>
<th>Sales adviser</th>
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<th>A Level/NVQL3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retail Manager (Father)*</td>
<td>1</td>
<td>GCE/GCSE/CSE /</td>
</tr>
<tr>
<td>Shop assistant</td>
<td>1</td>
<td>GCE/GCSE/CSE</td>
</tr>
<tr>
<td>Marketing coordinator</td>
<td>1</td>
<td>GCE/GCSE/CSE</td>
</tr>
<tr>
<td>Pharmacy dispenser</td>
<td>1</td>
<td>GCE/GCSE/CSE</td>
</tr>
<tr>
<td>Shop/factory</td>
<td>1</td>
<td>None</td>
</tr>
</tbody>
</table>

**Full time carer / no current occupation**

<table>
<thead>
<tr>
<th>Full timer carer</th>
<th>1</th>
<th>Graduate/BTEC/Bachelors/Diploma</th>
</tr>
</thead>
<tbody>
<tr>
<td>No (tennis coach)</td>
<td>1</td>
<td>Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Home-Maker</td>
<td>1</td>
<td>GCE/GCSE/CSE</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>GCE/GCSE/CSE</td>
</tr>
<tr>
<td>None (bar work, retail)</td>
<td>1</td>
<td>GCE/GCSE/CSE</td>
</tr>
</tbody>
</table>

**Factory work**

| Machinist                            | 1 | None |

**Other**

<table>
<thead>
<tr>
<th>Electrical engineer</th>
<th>1</th>
<th>Graduate/BTEC/Bachelors/Diploma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Engineer</td>
<td>1</td>
<td>Graduate/BTEC/Bachelors/Diploma</td>
</tr>
<tr>
<td>Software developer (father) **</td>
<td>1</td>
<td>A Level/NVQL3</td>
</tr>
<tr>
<td>PCSO</td>
<td>1</td>
<td>A Level/NVQL3</td>
</tr>
</tbody>
</table>

**Note**

1. Data for >40 parents – information included for two joint carers (* and **)
2. Joint carers ** parents of children L13 and L14 included in the TABS study