

**INFORMATION PRESCRIPTIONS PILOT PROPOSAL APPLICATION FORM**

**Proposed pilot site**  
 Evelina Children’s Hospital, Guys and St Thomas NHS Foundation Trust. London.  
 Evelina Children’s hospital is the first new children’s hospital to be built in London for over 100 years serving the local community and taking referrals from the wider population in the South East of England and beyond.

**Contact information: Job title, name, address, telephone number and e-mail**  
 Steve Tomlin, Consultant Pharmacist- Children’s Services, Pharmacy Department, Evelina Children’s Hospital, Guys and St Thomas’ NHS Foundation Trust, London. SE1 7EH.  
 Tel: 0207 188 9202  
[Stephen.Tomlin@gstt.nhs.uk](mailto:Stephen.Tomlin@gstt.nhs.uk)

**Please outline proposals for introducing information prescriptions and areas that you are proposing to cover (see section 7 of criteria document)**

**Background**  
 Little written information for children, their parents or carers about medicines in children exists. The information that does exist is often developed in-house with no standardisation or quality assurance. Legislation requires patient information leaflets with every dispensed medicine, but these seldom relate to medicine use in children.  
 Many medicines used in children are used outside of a product licence (this is particularly true in secondary care and the rationale behind the production of the British National Formulary for Children distributed by the Department of Health). This means that children and their carers often receive inappropriate information, no information or even dangerous information about medication that they are to take. Many old and current projects have looked at producing appropriate information (mainly local examples), but there has never been a robust way to centrally co-ordinate that information and ensure that the most up to date and consistent advice is available to this vulnerable section of our population. This project is designed to start changing this situation and reviews a service that could be used on a national basis

**Aim**  
 To pilot a pharmacist led information prescription process for parents and carers of children with long term conditions attending Evelina Children’s Hospital (ECH) with a review of how the process could be adopted by community pharmacy services.

**Setting**  
Secondary care: Parents and carers of children will be included when the child is an in-patient and as an out-patient at ECH for the conditions included in the pilot.  
Primary care: In parallel a scoping exercise to identify what would be required in primary care to operate a pharmacy led model leading to a small scale demonstration in community pharmacy practice. Boots the Chemist , Tescos and Co-operative chains will each identify a participating pharmacy to

run a study involving parents and carers of children when they present a prescription for their child's medicines for the conditions included in the study.

### **Develop content**

Content will be identified through a process of literature review to identify key requirements for information to support use of medicines in children. This will be followed by a scoping of existing information available from various resources including other paediatric hospitals, voluntary organisations, web based resources, pharmacy organisations, Royal College of Paediatrics and Child Health, pharmaceutical industry. Through the NHS Direct (NHSD) Health Information and Library Service and the Knowledge Centre at Guys and St Thomas NHS Foundation Trust information about local support groups and networks will be identified. The planned pilots for NHS Health Direct commissioned by the DH and managed by NHS Direct will contribute any additional information to support social care needs where appropriate.

### **Establish directories of content**

The aim within the pilot is to develop a core set of information for each condition with a directory of medicine specific material that can be selected at the time of each consultation with the pharmacist.

To support the prescription, directories of content will be established with specific focus on children for:

- Information about the condition and its treatment including non-drug treatments.
- Support groups and self-help organisations
- Information available for the child to access directly
- Medicines information including the unlicensed and off label-use of the products available to treat the conditions included in the pilot

Information related to Benefits and social care support will be addressed outside the scope of the pilot once it is completed. However, if any specific need is identified for individual parent/carer this will be met where possible.

### **Generate a template**

A proforma set of information will be tested with a small number of carers/parents using a semi-structured questionnaire, to get feedback on suitable material for each condition. A prescription "form" will be devised electronically and used to write the prescription using a combination of checklists and options for patient specific information needs. A coding system will be devised to identify the prescription for that particular parent/carer in both primary care and secondary care settings. It is anticipated that the prescription will be sent electronically by email to NHS Direct and can be returned in the same way with the option for the form itself to be made available in hard copy as required. Patient demographics will not be sent routinely to NHS Direct unless specifically requested by the parent/carer to enable hard copy postage of

information directly to a specified address

### **Process for quality assurance of content**

The EQIP process of evaluating the quality of information, developed by Becky Moulton, Health Information and Language Manager, Great Ormond St (GOS) Hospital, will be used to assess the quality of information used in the project. This process is identified by the Patient Information Forum (PiF) for information to support children and their parents/carers.

<http://www.pifonline.org.uk/?o=1476>. Advice will be sought from the Knowledge Centre at Guys and St Thomas' NHS Foundation Trust to support the process. Wherever appropriate nationally recognised information sources be used, e.g. NHS Direct website, Health Information and Library services, Prodigy information PILs (Patient.uk resource) and Miniguides, Royal College of Paediatrics and Child Health medicine information leaflets, Contact a Family website <http://www.cafamily.org.uk/>.

The Royal College of Paediatrics and Child Health Research lead, Dr Linda Haines, will be consulted about the quality of the information used, alongside the Neonatal and Paediatric Pharmacists Group through Steve Tomlin (Chair). Both organisations are key stakeholders for producing the BNF for Children.

The template and directories of content for the prescription will be developed by a project group including:

- ECH medical specialist
- ECH clinical pharmacist
- Knowledge information specialist, Guys and St Thomas NHS Foundation Trust
- NHSD health information manager
- NHSD IT project lead
- Pilot project manager

The project Advisory Board will be consulted as part of the template development process and to seek advice on content. (See section re governance arrangements)

### **Process for issuing the information prescription for the secondary care setting**

(See annex 1- flow diagram)

A paediatric pharmacist as part of their usual practice checks the medicines prescribed for the children on a daily basis as in-patients. At some point after diagnosis and/or change of treatment and again at discharge the pharmacist will undertake a review with the parent/carer of the child to agree the content of their information prescription. Pharmacists will also review information prescription needs for parents/carers who attend out-patients with their children identified either at time of consultation with clinician in the out-patients department or when collecting medicines from the pharmacy.

It is anticipated that up to 100 patients/carers/parents may be recruited within the timescale of the project

The prescription will be generated using a template core set of

information sources and sign-posting resources about the condition and supporting networks. The pharmacist will personalise the prescription adding the medicine information prescription details and send the prescription electronically to NHS Direct. At the time of the consultation the parent/carer will be asked how they would like to receive the information: email, hard copy post, through personal contact (e.g. GP, Evelina Children's hospital staff, local pharmacist), via Healthspace. Messaging services will be offered such as text or telephone to inform parent/carer the information is ready for collection.

NHS Direct Health Information services will dispense/issue the information and send the information to the requested destination for collection. A copy of the prescription will be included in the patient's electronic care record at ECH and the parent/carer will receive a copy of the original prescription in their chosen format. At discharge a copy will also go the patient's GP.

### **Community Pharmacy setting**

A small scale feasibility pilot in community pharmacy will test the process in primary care. Three to four community pharmacies will be identified by partner organisations: Boots the Chemist, Tesco, Cooperative stores to provide a range of small and large scale settings. When parents/carers attend a pharmacy at one of the participating pharmacies to collect medicines included in the directory of medicines used to treat their child for the conditions identified in the pilot, they will be asked if they wish to participate in the project. It is anticipated that up to 10 patients/parents/carers will be identified per pharmacy during the timescale of the pilot. Once consent is given, the pharmacist will conduct a consultation and agree the prescription using the same model as the ECH setting. The prescription will be sent to NHS Direct either via email or fax dependent on the existing arrangements the pharmacy has for information transfer. The information will be collected by the parent/carer according to their chosen method including in person upon return to the pharmacy.

### **Long term condition and care needs**

The pilot will focus on information prescriptions for the parents and/or carers of children to support the use of medicines in the treatment of long term conditions in childhood. Information is more often only available about the treatment of adults and the package leaflet with the medicines usually only describes medicine use in adults. This can lead to misleading information about administration, side effects and how the parent/carer supports the child to adhere to the medication treatment. The conditions identified for the pilot are:

- Epilepsy
- Other neurological disorders
- Renal transplant
- Cardiac problems
- Asthma
- Medicines will be included that are un-licensed medicinal products, or medicines used off-licence

The conditions have been selected particularly due to their prevalence in the settings and in the case of renal transplant and cardiac problems the difficulty in accessing information outside of the care setting to support care in primary care. (See Annex 2 for supporting literature review)

**Inclusiveness: Support available for access to the information prescription**

For children in care homes (social services), full evaluation of medicines information needs in this setting could be assessed in a subsequent phase of this project. It is likely the *process* of needs assessment and *provision of information* will be similar to that developed in the main part of this pilot. However children living in a care home will be included in the sample surveyed if they have one of the conditions specified

To ensure information is available in accessible formats language translation will be offered as appropriate through Guys and St Thomas NHS Foundation Trust and existing services will be used to support the project, e .g. XPIL <http://xpil.medicines.org.uk/>

XPIL is a service available free of charge to provide pharmaceutical manufactures' package leaflets for those with sight difficulties. The service offers Braille, audio and large font text. Where possible learning difficulty information needs will be met for individuals dependent on the available resources.

The information needs of the children involved in the project will be examined as part of the project scoping to identify a potential child specific information prescription template for medicines information. The needs of children assessed by parent/carer and pharmacy staff will also be included where possible and the information will be made available at the time.

**Cost of providing the information prescriptions**

Cost of delivery will depend on the format chosen by the parent/carer. The use of text messaging is relatively cheap compare to the face to face delivery of hard copy information. The staff time involved to generate and dispense an information prescription will be monitored. An evaluation of delivery costs will be built into the pilot for both the secondary care and primary care models. Wherever possible existing services will be used and additional running costs will be identified.

The pilot will identify the potential set up and running costs for an information prescription service beyond the pilot and for wider roll out across secondary and primary care settings.

**Impact**

The information prescription service is provided on the assumption information provided to support patients and carers supports healthy outcomes. The measure of satisfaction with the information and the service will be an essential measure of impact.

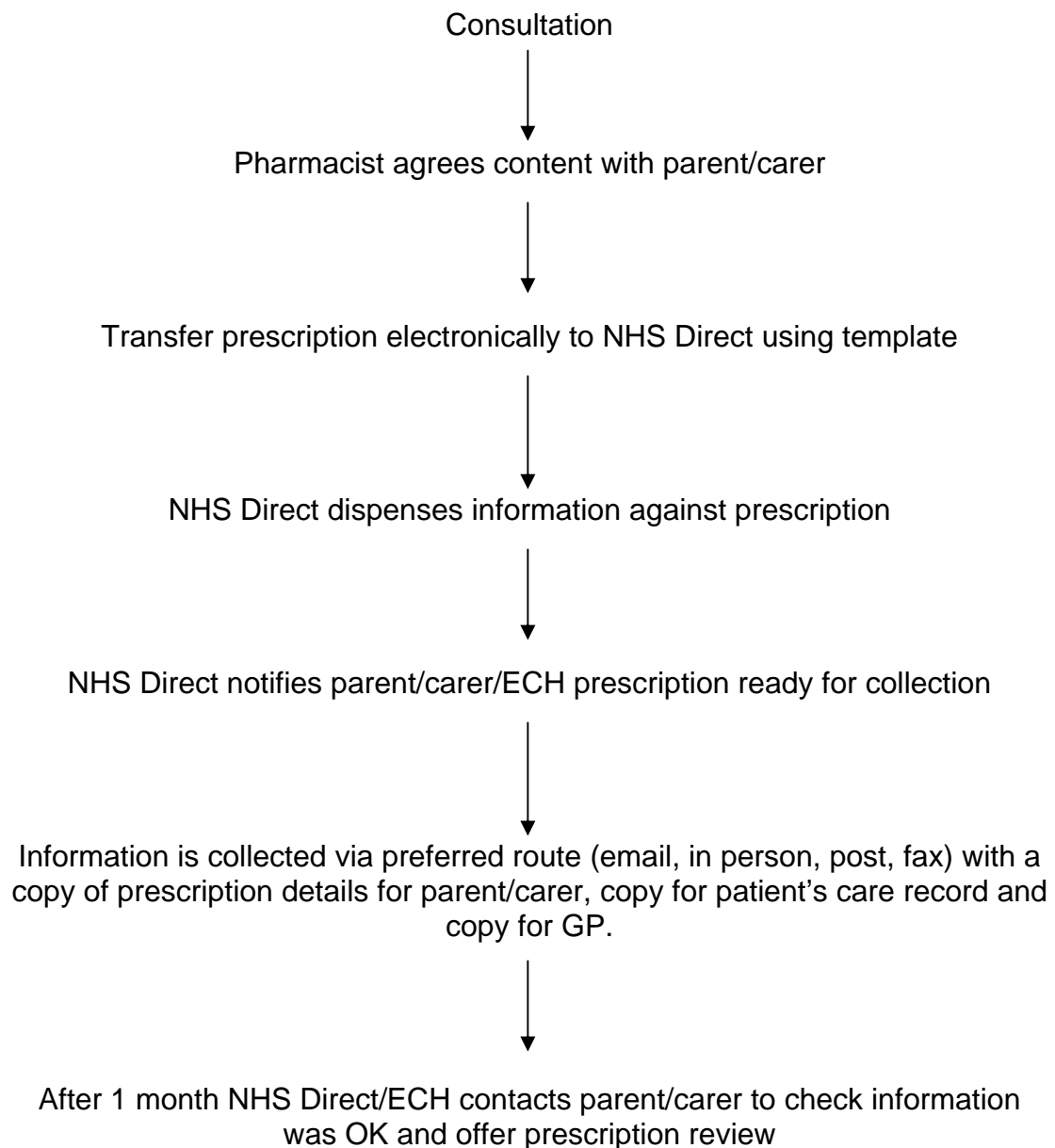
	<p><b>Impact on recipients</b></p> <p>The impact on parents/carers will be a focus of the pilot. A sample of 60-100 patients (and patients/carers) will be surveyed to assess the impact of information prescriptions. This will include assessing parent/carer's satisfaction with information provided, whether they have read the information, whether they have accessed the additional sources provided e.g. websites, support groups. We aim to include a sample of school teachers and school nurses in this survey.</p> <p><b>Impact on health professionals</b></p> <p>We plan to assess whether health professionals particularly pharmacists in secondary and primary health care access information prescriptions recorded in patients' notes, whether they find them useful, and how they could be used as a routine part of patient care planning and to support the supply of medicines to patients/carers/parents.</p> <p>The evaluation of information prescriptions in the community pharmacy setting will particularly focus on the professional impact, including time to assess information needs and send information prescriptions, time to address later questions and resources used to implement the process within a community pharmacy including ICT needs. A postal questionnaire to all NHS community pharmacy contractors in England will be undertaken through the services of an independent pharmacist consultant specialising in patient information, Mark Duman. Mark is the current chair of the Patient Information Forum, PiF (<a href="http://www.pifonline.org.uk">www.pifonline.org.uk</a>)</p> <p><b>Generalisability of processes developed in pilot</b></p> <p>The process developed in the pilot to provide medicines information for unlicensed medicines in children, is likely to be suitable for roll-out to unlicensed medicine use in all patient groups. This would address the current problem where provision of an information sheet to patients is a legal requirement for all medicines dispensed. For unlicensed medicines there is often no information leaflet or it is not in English language. It would also reduce variability and standardise the unlicensed medicine information provided nationally.</p>
<p>Please give an overview of the project governance arrangements. Include clear identification of project management arrangements.</p>	<p>Steve Tomlin, Consultant Pharmacist- Children Services, ECH – Information Prescription Project Director with overall responsibility for project delivery.</p> <p>Project manager to be appointed- Accountable to Anne Joshua, NHSD National Pharmaceutical Advisor for the project work (managed by the NHSD Health Information service)</p> <p>Project group will be established (see above) to act as an operational team to support the delivery of the project. Project plan will be reviewed by project group and time lines agreed with ST and AJ with key milestones to be achieved along- side any problem areas for resolution at regular project meetings. A representative of the Project group will be</p>

	<p>identified to attend the DH pilot evaluation group.</p> <p>An Advisory Board for the project will draw on the resources and expertise of the Medicines information Project, MIP (set up initially by the DH Medicines Partnership Programme to lead a patient focussed medicine information project linked to NHS Direct website and available as independent Medicine Guides.(<a href="http://www.medicines.org.uk">www.medicines.org.uk</a>)- MIP representatives are from Medicines and Healthcare products Regulatory Agency (MHRA), Long Term Medical Conditions Alliance (LMCA), National Pharmaceutical Association (NPA), Royal Pharmaceutical Society of Great Britain (RPSGB), Royal College of Nursing (RCN), Royal College of General Practitioners (RCGP), Datapharm Ltd., Medicines information experts, Association of the British Pharmaceutical Industry (ABPI), Company Chemists Association (CCA), Epilepsy Action , Proprietary Association of Great Britain (PAGB), Ask About Medicines Week Campaign (AAMW). Further details about the MIP Board can be accessed at: <a href="http://medguides.medicines.org.uk/mip.aspx#7">http://medguides.medicines.org.uk/mip.aspx#7</a></p> <p>The Advisory Board members will act as a resource to provide advice and network to support the project development and evaluation. It is anticipated the Board will meet no more than once to review the project plan and advise on content. The current Chair of the Board represents the LMCA. The Chair rotates between the LMCA, RPSGB, AAMW and MHRA.</p>
<p>Please indicate proposals for providing data to the national evaluation organisation (including ethical clearance)</p>	<p>Ethical clearance will be sought by ECH through the Guy's and St Thomas' NHS Foundation Trust and by NHSD for the particular part of the service they provide. Parents and carers will be asked for consent for the details of their information prescriptions to be available to the DH evaluation team</p> <p>The following data will be made available for the national evaluation:</p> <ul style="list-style-type: none"> <li>• Demographics of patients involved (excluding names).</li> <li>• Details of carers, e.g. parent or carer, care home, school.</li> <li>• Processes used to issue prescription including preferences for format, staff time involved, costs.</li> <li>• Details of prescriptions issued</li> <li>• Feedback from professionals involved</li> <li>• Feedback from carers/parents</li> <li>• Feedback from children involved, e.g. individual , focus group.</li> <li>• Report of scoping exercise of community pharmacy</li> </ul> <p>Further data requirements will be met where possible as identified by DH.</p> <p>Where possible electronic communication of data will be undertaken.</p>
<p>Please provide a description of your proposals to:</p> <p>Work with stakeholders and partners</p>	<p><b>Work with stakeholders and partners</b></p> <p><b>Partners:</b> ECH, NHS Direct, community pharmacy organisations (Tesco's, Coop, Boots the Chemist) There will be potential for collaboration with other pilots based in community pharmacy services to share processes and directories of content.</p> <p><b>Stakeholders:</b> MIP Advisory Board, and PiF, Royal College of</p>

<p>Develop a system for delivering information prescriptions in your area</p>	<p>Paediatrics and Child Health, Paediatric hospitals involved in medicine information provision, UK clinical Pharmacist Association (UKCPA), Neonatal and Paediatric Pharmacist group</p> <p>In particular work with stakeholders will examine the long term implications for a wider role out in community pharmacy and secondary care. The Pharmaceutical Services Negotiating Committee (PSNC) will be consulted to identify community pharmacy contractor issues.</p> <p><b>Development of a delivery system.</b> (See previous sections above describing process of delivery.)</p> <p>The following key steps will be included when developing a delivery system:</p> <ul style="list-style-type: none"> <li>• Review of information systems that can be used in ECH to produce the demographics for the prescription and copy of prescription for the patient care record.</li> <li>• Review of the existing NHSD Online Enquiry service to support the information prescription delivery with an identified call centre to support.</li> <li>• Existing information systems evaluated within NHSD for supporting delivery including CAS decision support software for long term conditions with particular reference to the primary care setting for supporting asthma.</li> <li>• Synergies with the requirements for paediatric prescribing systems for the provision of information. Work stream led by Dr Roderick MacFaul, Connecting for Health National Action Team on Children's prescribing. Specification currently undergoing consultation with stakeholders. (Steve Tomlin and Anne Joshua – members of advisory group)</li> </ul>
<p>Identify the content for information prescriptions</p>	<p><b>Content</b> (See previous sections above describing content development and quality assurance.)</p> <p>Project group to identify content of core information as part of template following review of existing information sources and formats hard copy and web based material, e.g. Contact a Family <a href="http://www.cafamily.org.uk/index.html">http://www.cafamily.org.uk/index.html</a> Well Child <a href="http://www.wellchild.org.uk/">http://www.wellchild.org.uk/</a> YourChildshealth <a href="http://www.yourchildshealth.nhs.uk/">http://www.yourchildshealth.nhs.uk/</a> NHS Direct website material and health information and library service, Medicine information specific resources produced by Royal College of Paediatrics and Child Health, Paediatric hospital resources (usually only available through local contacts), Great Ormond St Hospital website <a href="http://www.ich.ucl.ac.uk/">http://www.ich.ucl.ac.uk/</a> Medicine Guides <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> National Library of Medicines <a href="http://www.nelm.nhs.uk/home/default.aspx">http://www.nelm.nhs.uk/home/default.aspx</a> Patient.UK <a href="http://www.patient.co.uk/">http://www.patient.co.uk/</a></p>
<p>When do you anticipate that work will start?</p>	<p>February 07- project group established and ethical approval sought March/April 07- develop process and content</p>

	May 07- commence recruitment pending ethical approval
<b>Signatures:</b>          Chief Executive	

**Annex 1: Process for issuing an Information Prescription to support parents and carers with information about medicines treatment for managing long term conditions in childhood.**



**Annex 2: Literature review of Information needs of children, parents and carers. Internal report for Information about Children's Medicine Stakeholder group, Medicines Partnership. 2005**

**Evidence of the need for better information about medicines for children**

---

**Key Messages**

There is a clear need for better information about medicines for children

- Demonstrated through research
- Expressed by children, adolescents and their parents

The sort of information that children and parents need is more than an information leaflet

- Something which enables them to engage in a discussion with a health professional

Better information can also help health professionals to explain the complex factors involved in prescribing for children in a manageable time frame

**1 Background**

Research reveals widespread unlicensed and off label use of drugs in prescribing for children.

- 11% in General practice<sup>i</sup>
- 36% in general paediatric wards<sup>ii</sup>
- 70% in intensive paediatric wards<sup>iii</sup>
- 90% in intensive neonatal wards<sup>iv</sup>

This is not as a result of 'bad practice' on the part of doctors but as a result of necessity<sup>v</sup> 13. Due to the costs of running clinical trials for a potentially small paediatric market and the ethical issues with testing drugs on children, pharmaceutical companies often do not get their drugs licensed for use in children, even when there is a potential or existing application.

Since approximately 65% of children receive a prescription over a year<sup>1</sup>, this means that this year around 7% of children and adolescents in the UK are taking a medicine that has not been licensed for use in paediatrics. In these situations, clinicians are making prescribing decisions on the basis of a 'body of responsible opinion'<sup>11</sup>, rather than on the basis of evidence from clinical trials.

There is now widespread acceptance that this situation is not acceptable

- More research is needed into paediatric application of drugs
- Health professionals need better information available to them in order to make prescribing decisions
- Child patients and parents need better information than that contained in existing Patient Information Leaflets, which merely state that, the medicine is unlicensed for use in children.

## **2 Importance of children and parents being involved in decisions about treatment has been widely recognised**

Non-compliance is an issue with children just as it is in adults. A report by the US National Council on Patient Information and Education estimated children's compliance to medication regimens to be 54%<sup>vi</sup>. Other studies have reported compliance rates in children to range from 25-82%<sup>vii</sup>. A review of non-compliance in children and adolescents concluded that compliance is lower in children than in adults, particularly in adolescents as they approach independence<sup>viii</sup>.

Research has shown that concern about side effects weighed up against perception of benefits is the biggest predictor of compliance<sup>ix</sup>. In paediatric medicine this could be a case of children themselves deciding not to comply, or because their parents make a decision on their behalf not to administer medicine due to concerns they have.

It is therefore important to address child and parent beliefs about medicines and involve child patients and their carers in decisions about treatment.

This is reflected in several core policy statements:

- Children and young people have the fundamental right to be informed in all matters that affect them and have their views taken into account.  
*Article 12, 13 & 17 United Nations Convention on the Rights of the Child*
- Part of standard 10 requires that: "In all settings, professionals enable parents, young people and, where appropriate, children to be active partners in the decisions about the medicines prescribed for them."  
*National Service Framework for Children, Young People and Maternity Services: Medicines.*
- "Health professionals must respect the right of child patients and their parents to participate in decisions on the health of the child, and seek to ensure that those decisions are properly informed. In normal paediatric practice no additional steps, beyond those taken when prescribing licensed medicines, are required to obtain the consent of patients and parents/carers for the use of unlicensed medicines"  
*Royal College of Paediatricians and Child Health<sup>x</sup>*

## **3 Children and patients need information to engage in shared decision making**

Children and parents need to understand the basis on which the doctor is recommending a particular medicine and how it compares with other options in order to engage in shared decision making. However, communicating this information can be challenging since the justification of the health professional's decision to prescribe may be more complex in the case of off-label use of children's medicines. Until a product has been given regulatory approval for a particular patient group, it is technically an experimental entity. The prescriber must weigh up the risk of withholding a potentially beneficial product against the risk of treating a patient in what is essentially an uncontrolled clinical trial. It can be frustrating and bewildering for parents who share a strong sense of responsibility to make the 'right' decision for the

child, but who cannot understand the reasoning behind many of the doctor's choices.

Sharing information about risks and benefits can be difficult because decisions are based on a "body of responsible opinion", not evidence based research<sup>xi</sup>. Health professionals may be concerned about whether patients and their parents can understand the implications of risks in using unlicensed medicine<sup>xii</sup>. Since children of different ages have varying abilities to think about the consequences of action and the future, this has obvious implications for delivering information about side effects and risk communication.

However, the National Service Framework for Children<sup>xiii</sup> highlights the importance of information provision in enabling children and parents to make decisions about medicines. Standard 10 sets the target that:

- "Children, young people, their parents or carers, and health care professionals in all settings make decisions about medicines based on sound information about risk and benefit".
- "Clear, understandable and up-to-date information is required, in a variety of media, formats and languages including an honest assessment of the risks and benefits of medicines, side effects and long-term effects".

#### **4 Regulation focuses on Patient Information Leaflets (PILs) to meet the information need**

Regulation is commonly seen as key to addressing the issues around prescribing medicine for children. However, to date it has tended to focus on the information needs of health professionals. Where information for children and parents is brought in, it is in the context of improving PIL's.

##### **4.1 *Emphasis on information needs of health professionals***

It is important that health professionals have the best information available in order to make decisions about prescribing for children. But it is important to recognise that it is the child and their parent who actually make the decision whether to take the medicine. In the case of children's medicine this is often forgotten. Recently commenting on the new Department of Health strategy, Lord Warner commented that:

"Health professionals need the latest information so that **they can make the right choices about the medicines and treatments for their younger patients**, and that is why the new British National Formulary for Children is so important".

Processes are in place to develop a new EU regulation on children's medicine, although unfortunately the initiative is unlikely to be finished before 2006. One of the overall objectives is to encourage transparency of information on products and treatments currently used in children. There is a proposal to collect pan-European information on existing uses of medicines as well as clinical trials and proposed trials. This will help health professionals, but this information also needs to be appropriately passed on to child patients and parents to inform their own risk-benefit judgement

##### **4.2 *Strategies that exist for addressing patient information need focus on PIL***

The joint MHRA/DH strategy on medicines for children was issued in July 2004. One of the three areas it tackles is paediatric information for healthcare

professionals and patients/carers. For health professionals, the strategy focuses on producing the BNF for children. For patients the strategy focuses on PILs. It states:

“The Patient Information Leaflet (PIL) is frequently either not written in a child-friendly manner or may be confusing to the patient/carer if the use is off label. An exercise is currently underway within the MHRA to improve the readability of PILs. It will also address the improvement of paediatric specific information”<sup>xiv</sup>

Another initiative focussing on PILs is the CSM Paediatric Medicines Working Group. Its objectives are

- To advise [the licensing authority] on how the information provided in the summaries of product characteristics and patient information leaflets may be improved.
- To advise on templates for paediatric advice/information to be used in the summary of product characteristics

## **5 Patient Information Leaflets alone are not the answer**

There is undoubtedly a lot that can be done to improve the existing PILs for drugs that are prescribed off-license and off-label to children. However, evidence suggests that PILs alone are not the most effective medium through which to communicate the information about benefits and risks that children and parents need.

For example, a survey by the National Consumer Council revealed that only 12% to 27% of adults read information leaflets about medicines.<sup>xv</sup> The same study showed that adults across all socio-economic groups are more likely to look at the internet than read a medicine leaflet.

With children and adolescents this is even more so. One US study reported that more than 70% of 15-17 year olds say they have used the internet to look up health information<sup>xvi</sup>. Children are also receiving daily messages about medicines from television, radio, magazines and their parents<sup>24</sup>. A leaflet by itself won't change behaviour and studies have shown the value of educating both children and their parents by using patient-centred communication.<sup>xvii</sup>

Research more generally into whether PILs address patients' information needs has shown them to be too narrow, too negative and too late. They only cover one drug, are legally obliged to list all side effects without any relative comparison of risk and are only accessible once a prescribing decision has taken place<sup>xviii</sup>.

## **6 There is a need for better information about medicines for children**

There is no doubt that existing information about children's medicines do not meet the need of either children or their parents. For example, 95% of parents approached in a recent prospective study identified the need for more information, designed for parents.<sup>xix</sup>

Even in an improved format, it is clear that Patient Information Leaflets are not going to address this gap.

It is also important to realise that information in isolation is not the answer. The relationship with and communication style of the health professional plays a huge role. In the same prospective study of parents who wanted more information, 92% said that information given did not affect their decision to give the medicines to their children – their trust of the doctor did<sup>19</sup>.

And it is just as important to address children's information needs as it is their parents'. All too often, decisions about medicine are seen as the responsibility of the parent and health professional, with no need to communicate to the child. Children's social status is still commonly perceived as being lower or inferior to adults and their ability to understand information and express opinions is underrated<sup>xx</sup> <sup>xxi</sup>. As an example, in a study where paediatricians and adolescents were asked to evaluate a range of drug information leaflets, paediatricians were not good judges of which leaflets would appeal. They leant towards leaflets with comic strip illustrations and those that had been written in a 'cool' or witty style. In contrast, adolescents preferred leaflets with high quality factual information combined with clear illustrations<sup>xxii</sup>. Existing studies across 4 countries show that children have considerable autonomy in medicine taking and that they are currently ill informed and want more information about medicines<sup>24</sup>. However a recent paper reported that Adolescents feel exclude from discussions about medicines, particularly where side effects are concerned <sup>25</sup>. There is evidence that attitudes towards and presumptions held by health professionals about childhood and adolescence need to be challenged and addressed <sup>xxiii</sup>. The new Children's NSF is a welcome step forward in doing so.

When considering delivery of information, it is also important to recognise that communicating information to children requires a flexible approach:

*"They are not small adults; Their views about health and illness vary with their level of cognitive development and the complexity of children's thinking increases with age. This should determine how we present information to children"*  
*Professor Padel, FIP 2002* <sup>xxiv</sup>

Children may also have fundamentally different information needs to parents, in addition to requiring that content be delivered in a flexible format. In one study, a need for information relating to coping with the consequences and impact of a chronic condition on day-to-day life (e.g. how to manage with school, coping with peers) was identified<sup>xxv</sup>. Other information needs that children and adolescents find difficult to raise directly with health professionals and parents were also highlighted:

- Lifestyle questions e.g. drinking alcohol, or areas where the young person might not want to hear about restrictions.
- Sensitive/personal information needs e.g. worrying questions about future health.
- Questions which might reveal poor compliance or engaging in activities that are 'forbidden' or 'discouraged'.

- Questions where there might be potentially negative consequences e.g. revealing worsening symptoms, which might result in hospitalisation.

This highlights the need for alternative information sources for children and adolescents (e.g. written information, peer support, help lines, the internet) that are accessible, appropriate and acceptable<sup>25</sup>. A review of factors contributing to adolescent non-compliance identified potentially beneficial interventions including personalised written supporting information and peer support groups that provide counselling and information<sup>8</sup>.

## 7 Conclusion

To conclude, there is a clear need for better information about medicines for children, demonstrated through research and expressed by children, adolescents and their parents. The sort of information that children and parents need is more than an information leaflet, but something which enables them to engage in a discussion with a health professional. From the health professional's perspective, better information could be also be used to help them express the complex factors involved in prescribing for children in a manageable time frame.

<sup>i</sup> McIntyre J, Conroy S, Avery A, Corns H, Choonara I. Unlicensed and off label prescribing of drugs in general practice. *Arch Dis Child* 2000;83:498-501.

<sup>ii</sup> Turner S, Longworth A, Nunn AJ, Choonara I. Unlicensed and off label use in paediatric wards: prospective study. *BMJ* 1998;316:343-345

<sup>iii</sup> Turner S, Gill A, Nunn T, Hewitt B, Choonara I. Use of "off label" and unlicensed drugs in paediatric intensive care unit [letter]. *Lancet* 1996;347:549-550.

<sup>iv</sup> Conroy S, McIntyre J, Choonara I. Unlicensed and off label drug use in the neonate. *Arch Dis Child Fetal Neonatal Ed* 1999;80:F142-F144.

<sup>v</sup> Royal College of Paediatrics and Child Health. *Medicines for children*. 1<sup>st</sup> ed. London: RCPCH, 1999.

<sup>vi</sup> National Council on Patient Information and Education (1989). *Children and America's other drug problem: guidelines for improving prescription medication use among children and young adults*.

<sup>vii</sup> Sclar DA, Tartaglione TA, Fine MJ. Overview of issues related to medical compliance with implications for the outpatients management of infectious diseases. *Infectious Agents Dis* 1994; 3:266-273

<sup>viii</sup> Costello I, Wong I Nunn A. A literature review to identify interventions to improve the use of medicines in children. *Child Care Health Dev*. Accepted for publication 16 August 2004.

<sup>ix</sup> Horne R & Weinman J (1999) Patients' beliefs about prescribed medicines & their role in adherence to treatment in chronic illness. *Journal of Psychosomatic Research* 47(6): 555-567

<sup>x</sup> Royal College of Paediatrics and Child Health. The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice. Policy statement produced by the joint RCPCH/NPPG Standing Committee on Medicines. February 2000.

<sup>xi</sup> Bolam v Friern Hospital Management Committee [1957] 2 A11 ER

<sup>xii</sup> Valerie L Isitt. Children's human rights are violated. *BMJ* (letter), Aug 2002; 325: 338.

<sup>xiii</sup> Department of Health. *National Service Framework for Children, Young People and Maternity Services*. London: Stationary Office, 2004.

<sup>xiv</sup> MHRA/DH Strategy on medicines for children. July 2004.

<sup>xv</sup> National Consumer Council. *Health literacy: being able to make the most of health*. 2004.

<sup>xvi</sup> Hansen D, Derry H, Resnick P, Richardson C. Adolescents searching for health information on the internet: an observational study. *Journal of Medical Internet Research* 2003;5(4):e25.

- 
- <sup>xvii</sup> Sleath B, Bush P, Pradel F. Communicating with children about medicines: a pharmacist's perspective. *Am J Health-Syst Pharm.* 2003; 60:604-7
- <sup>xviii</sup> Raynor DK & Britten N. Medicines information leaflets fail concordance test. *British Medical Journal* 2001;322:1541
- <sup>xix</sup> Osbourne JP. Information Needs of Patients and Children for Medicines Prescribed for Epilepsy. July 2004. A short report for the RCPCH research unit.
- <sup>xx</sup> Beresford B. *Personal Accounts: Involving Disabled Children in Research.* London: The Stationary Office, 1997.
- <sup>xxi</sup> McGurk H, Glachan M. Children's conversation with adults. *Children Soc* 1988;2:20-34.
- <sup>xxii</sup> Jones R, Finlay F, Crouch V, Anderson S. Drug information leaflets: Adolescents and professional perspectives. *Child Care Health Dev* 2000;26:41-8.
- <sup>xxiii</sup> House of Commons Health Committee. *The Specific Needs of Children and Young People. Volume 1.* London: Stationary Office, 1997.
- <sup>xxiv</sup> World Congress of Pharmacy and Pharmaceutical Sciences. *Pharm J*; 269 no. 7215: 371.
- <sup>xxv</sup> Beresford B, Sloper P. Chronically Ill Adolescent's Experiences of Communicating With Doctors: A Qualitative Study. *Journal of Adolescent Health* 2003;33:172-179.