

# Over the Counter Medicines in Childhood: Issues and Concerns. A Narrative Review of the Literature

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## Abstract

*This narrative review of the literature describes the extent and nature of use of over the counter medicines by parents for their children. Associated potential benefits such as improved access to medicines and reduced workload for over-stretched general practitioners are highlighted, possible risks such as adverse drug reactions, inappropriate drug selection and use and delayed diagnosis of serious conditions are discussed. Factors influencing health advice seeking behaviour and the use of over the counter medicines are explored. Much of the available literature is dated and areas where future research is needed are identified in the light of rapidly evolving changes in the NHS in the UK.*

*The role of the pharmacist is discussed, and it is suggested that this role could be expanded, and opportunities grasped by the pharmacy profession to maximise benefit gained by, and minimise risks to children in the use of over the counter medicines.*

**Key words:** Child – Non-prescription drug – Over the counter medicine – Self medication – Self care – Minor illness

## Introduction

This paper aims to provide a narrative overview of the literature regarding the use of over the counter (OTC) medicines by parents and carers to treat minor illnesses in their children. It explores the available literature discussing the extent and nature of OTC medicine use, potential benefits and problems associated with this use and factors influencing it. The role of the community pharmacist is examined and areas for further research identified.

## Method

MEDLINE (1966 to present day) and EMBASE (1980 to present day) databases were searched

using the search terms 'over the counter medicines', 'children', 'non-prescription drugs', 'minor ailments', 'storage' and combinations of these terms. The Royal Pharmaceutical Society of Great Britain website was also searched for relevant information. Further useful publications were identified from the reference lists of the papers used.

## The Extent and Nature of Use of OTC Medicines

Consumer uptake of OTC medicines is high, and has been for many years. In 1960, 70% of children under 10 years of age on a British housing estate had been given medicines in the 4 weeks prior to study, 21% on a doctor's prescription, the rest

bought OTC<sup>1</sup>. In 1988, 45% of drugs taken by children in the UK were non-prescription<sup>2</sup>. The Association of the British Pharmaceutical Industry estimated the OTC medicine market to be worth £1.24 billion in 1995; 10% of the total UK pharmaceutical market<sup>3</sup>.

The situation is not unique to the UK. Research from the USA showed that from 1967-1975, 79% of children had received some type of medication by the age of 2 years<sup>4</sup>. A later study showed that 70% of 3 year olds recently suffering from an illness episode received a non-prescription medication<sup>5</sup>. By 1997, also in the US 88% of children had received at least one OTC medicine in the two months prior to study<sup>6</sup>. Dated literature suggests a wide range of products have been used, with 32% of mothers using 7 or more medicines for their child in an average year<sup>7</sup>. Up to date information shows that retail sales of OTC medicines in the US in 2000 were over \$19.1 billion, with 77% of Americans taking an OTC product to treat common, everyday ailments<sup>8</sup>.

Coughs, colds and sore throat are the second most frequently suffered minor illness in the UK, and account for 25% of illness in children. Remedies to treat these conditions make up the largest category of OTC medicines. They were estimated to have a combined retail sales value of £215 million in 1994, and made up 17% of the OTC medicine market with more than 100 different preparations being available to treat coughs<sup>9</sup>. Analgesics are amongst the highest used OTC medicines given to children<sup>5,10</sup>. US data shows that more than \$3.5 billion was spent on cough and cold remedies, closely followed by \$3.1 billion on pain remedies in the year 2000<sup>11</sup>. Unfortunately specific data for children is not available amongst this information.

## **Potential Benefits of OTC Medicine Use in Children**

### *Improved access to medicines*

Children attending day nursery may be more prone to infection. Upper respiratory tract infections occur on average 4 times annually in children under 3 years cared for at home<sup>12</sup>. This figure increases to 6-7 times annually in children who attend day nursery. Of those infants in day care, 67% spend more than 60 days unwell with a respiratory illness before their first birthday. The paradox here is obvious. Parents of this group of children need access to drug and health information at times convenient to their personal lives but are likely to have less time available. The community pharmacist with increasing hours of opening, no necessity to make an appointment

and their expertise and ability to supply advice and OTC medicines fill a vital role here.

In a 1996 study based in the UK, the most common source of OTC medicines for minor paediatric illnesses was the community pharmacy. However, 19% of carers used another retail outlet, mainly supermarkets<sup>13</sup>. Self-selection without advice from a pharmacist is likely to increase with more medicines becoming reclassified and available in outlets other than a pharmacy. Whilst the widespread availability of medicines is convenient for carers and is to be welcomed, there is the potential for less appropriate therapies to be purchased and inappropriately used. The impact of this developing situation warrants future surveillance.

### *Reduced numbers of visits to general practitioners*

The availability of increasing numbers of OTC medicines may reduce the frequency with which patients visit their general practitioner and possibly reduce healthcare costs<sup>14</sup>. Calculation of such cost savings would be interesting. It would need to include savings on the doctors time, yet compensate for patients eventually presenting despite having used OTC medicines initially; costs of the consequences of sub-optimal or inappropriate therapy compared to supervised care; and the savings due to potential reductions in numbers of prescriptions written for medicines which carers buy OTC.

73% of American people would prefer to treat themselves rather than visit their doctor. 77% report using an OTC medicine in the past 6 months, almost twice the number consulting a physician in the same time scale<sup>15</sup>. Information specific to children's illnesses is not available in this survey and it would be useful to know if the same attitude applies.

The opinions of GPs themselves on such developments would also be useful to explore. A 1980s study showed only moderate approval by doctors, of mother's management of their child with OTC drugs<sup>7,16</sup>. It would be interesting to know if attitudes have changed with the increasing pressures on GPs and increasing emphasis on encouraging families to self-care at home.

## **Potential Adverse Consequences of OTC Medicine Use in Children**

### *Adverse effects*

OTC medicines are thought by many to be weak, safe, innocuous and even as 'not real

medicines<sup>17,18</sup>. This complacency is a potentially dangerous misconception as commonly used OTC medicines have been associated with problems.

Paracetamol and ibuprofen in OTC doses have been reported to cause adverse drug reactions (ADRs). Children under 4 years old were seen to experience the highest rate of ADRs (22% and 18% respectively)<sup>19</sup>. None were serious, mainly being gastrointestinal problems such as dyspepsia, nausea and vomiting. Ibuprofen is increasing in popularity as an OTC medicine for children. This must be viewed with some caution as it has been implicated in rare cases of renal failure in children following short-term use as an analgesic<sup>20</sup>. This risk is probably low in general. However, in children who are dehydrated or have underlying renal disease the risks are higher<sup>14</sup>. When the medicine is bought OTC, the responsibility for recognising such conditions has been suggested to be transferred to the carer<sup>14</sup>. Appropriate counselling in the pharmacy, however, and close adherence to guidelines for counter prescribing<sup>21</sup> should minimise the risk and maximise benefit gained.

The high use of cough and cold remedies persists despite trials suggesting little if any benefit. Many of these preparations have a potential for a wide range of side effects such as sleepiness, hallucinations, psychosis and respiratory arrest<sup>5,18,22,23</sup>. Some cough and cold preparations contain sub-therapeutic concentrations of their active constituents, many are elixirs containing a significant alcohol content<sup>9,18</sup>. The extensive use of such preparations in children should not be encouraged.

Promethazine elixir has been sold OTC in the UK for many years to treat allergic conditions, nausea and vomiting and for sedation for adults and children. It has been reported to cause agitation, hallucinations, seizures and possibly life threatening events such as apnoeas and Sudden Infant Death Syndrome especially in infants<sup>24</sup>. Again the pharmacist has a vital role to play if such drugs are to be used safely and appropriately when sold OTC.

#### *Drug interactions*

Interactions of OTC medicines with prescribed medicines is another potential risk which parents are unlikely to be aware of unless they judiciously read patient information leaflets provided<sup>25</sup>. Potential relevant interactions for paediatric patients include the use of ibuprofen in patients taking ciclosporin (increased nephrotoxicity) or methotrexate (increased toxicity). While the number of paediatric patients taking these drugs

is low, other examples apply to much higher numbers of patients. These include paracetamol being taken by patients already taking other paracetamol containing products. 66% of parents could state the brand name of a paracetamol syrup product they used regularly, but only 8% knew the generic name for the drug<sup>6</sup>. This lack of understanding creates a risk for carers to give doses of the same drug using different branded products. A further example is the potential use of sedative antihistamines purchased OTC, in children taking other CNS depressant drugs such as anti-convulsant agents.

It has been suggested that the burden of preventing drug interactions rests with the patient or carer when using OTC medicines<sup>14</sup>. They must read the information leaflet and identify interacting medicines that their child is taking. However, it is essential for, and indeed the responsibility of, the pharmacist to be aware of prescribed drugs when recommending an OTC medicine, and for the doctor to be aware of OTC medicines, which may be being administered, when prescribing for a child. It is also their responsibility to ensure that families are aware of these issues.

#### *Doses administered*

In an assessment of parent's practical skills of drug administration, only 30% were able to accurately calculate and measure a dose for their child on a weight basis<sup>6</sup>. Calculating a dose when using OTC medicines is not normally a problem as the dose is usually stated in terms of 5ml spoonfuls based on age ranges. However, this study does highlight the lack of understanding of the majority of the public regarding units of measurement and the use of different measuring devices available to them. It emphasises the need for directions to be simple and easy to understand if errors are to be avoided.

#### *Accidental ingestion*

In the UK in 1987 the average number of medicines stored in 97% of houses with a child under 5 years of age was estimated to be 10, with 8% of such households storing more than 20 different medicines<sup>26</sup>. Other dated studies have reported similar figures<sup>7,27</sup>. Packaging changes and the introduction of child resistant containers (CRCs) have substantially reduced the incidence of unintentional ingestions, especially serious overdose<sup>26,28</sup>. However, it must be remembered that while CRCs are a deterrent to children ingesting medicines, small children can quickly learn to open them and they are not the ultimate answer. In 1998 it was estimated that up to 8,500

UK children under the age of 5 were admitted to accident and emergency departments with suspected poisoning by medicines<sup>29</sup>. A telephone survey of 2,042 people in 1997 found that 8 out of 10 adults living with young children do not lock medicines safely away, but instead commonly store them in unlocked drawers and cupboards, on open shelves and in handbags<sup>29</sup>. These reports suggest a need for investigation into parental awareness of the dangers of drugs themselves, and education into their safe use and storage.

#### *Dental caries*

Taste is an important factor in influencing purchasing trends particularly where children are involved. Medicines in acceptable liquid formulations are essential when treating children in order to facilitate administration and optimise compliance. Sugar, flavourings and colourings are likely to improve the chances of patient compliance. Consequently, 45% of total liquid sales are sugar-based and the dental health of patients taking these is of growing concern<sup>30,31</sup>. Sugar in medicines is just as harmful to teeth as that in sweets<sup>32,33</sup>. Liquid oral preparations contain on average 55% sugar to make them palatable and disguise the taste of the drugs they contain<sup>34</sup>.

Parents seem to have diverse opinions regarding sugar in medicines. Parents of children with chronic conditions seem more likely to actively seek sugar-free OTC medicines as some have already experienced dental problems in their children subsequent to long-term ingestion of sugar-containing medicines<sup>33,34</sup>. Many parents however feel that the amount of sugar ingested in medicines is insignificant in relation to the benefit to be gained from the child taking the medicine<sup>33</sup>. Evidence now suggests that this is a misconception, but a lack of information in this area encourages cariogenic behaviour in carers.

Pharmacists are in a position to contribute to education of carers on this issue. However, only 2 of the 14 most popular named OTC paediatric

medicines stocked by over 90% of pharmacists studied in the north-west of England were sugar free<sup>35</sup>. These pharmacists recommended sugar-containing medicines more frequently than sugar-free for 7 out of 12 common paediatric illnesses.

#### *Other issues*

Inaccurate self-diagnosis, delayed or sub-optimal treatment of serious conditions, wasting money on inappropriate medicines and diminishing the role of physicians in supervising care have also been suggested as other potential areas of concern in the use of OTC medicines<sup>14</sup>. The impact of these issues on paediatric patient care warrant further investigation, but once more it is suggested that adequate input from the community pharmacist could minimise concern.

### **Influences on the Use of OTC Medicines**

Self-care of children's illnesses is the first line for many families. A British survey showed that 67% of parents would use a home remedy, an OTC medicine, a prescription medicine already in the house or alternatively instigate no treatment for a minor illness in their child<sup>36</sup>. A British survey of 350 mothers in 1994 found that 76% would approach a pharmacist for medication before consulting their GP<sup>37</sup>. There may be a number of factors that influence OTC medicine purchasing and self-management of illness (Table 1).

#### *Family size*

There is conflict in the literature regarding the effects of family size on this behaviour and a lack of up to date information. A US study found no correlation between the number of medicines kept and the number of children in a family<sup>7</sup>. In the UK in the 1960s however, children in larger families tended to be given less OTC medicines than children in families with just one or two children<sup>1</sup>.

**Table 1. Factors influencing the use of OTC medicines in children**

<b>Factor</b>	<b>Effect</b>
Family size	Large families possibly receive fewer OTC medicines
Socio-economic status	Poorer families possibly receive fewer OTC medicines
Parental use of OTC	Probable direct relationship
Perceptions of vulnerability to illness	Probable direct relationship
Age	Probable direct relationship
Advertising	Probable direct relationship
Cost	Unclear



### *Socio-economic status*

In the 1980s American mothers of high socio-economic status (SES) were found to possess more OTC medicines for their children than mothers of low SES<sup>7,16,38</sup>. Middle class mothers who kept numerous non-prescription drugs valued the autonomy this afforded them when managing their child's illness. More recent work from the US suggests that women who gave OTC medicines to their children tended to be white, 21 years of age or older, were more highly educated, had a greater household income and were married<sup>5</sup>. Early studies in the UK also suggested a similar trend in relation to the father's profession<sup>1</sup>. More recent research in the UK, however, suggests no effect of either income or education<sup>37</sup>.

Different categories of OTC medicines may be kept and used by families of different socio-economic groups. An example is the possession and use of laxative agents, which was reported in the 1960s and 1980s to be more common in lower socio-economic groups, while the opposite was true for dermatological anti-infective agents<sup>1,16</sup>.

### *Carer's use of medicines*

Early work in the UK had noticed that mothers who took medicines themselves tended to administer more to their children compared to mothers less inclined to take medicines<sup>1</sup>. Similarly, Esmay et al suggested that children of high OTC medicine users tended to follow suit and themselves became high users of OTC medicines<sup>4</sup>.

### *Perception of vulnerability to illness*

Mothers thinking their children were susceptible to illness and with a belief in the efficacy of OTC medicines were more likely to keep and use them in higher numbers and more regularly<sup>16,38</sup>.

### *Age*

Mothers engaging in higher levels of OTC medicine use have been noted to be older, suggesting mothers with prior experience and increased confidence in treating their children's symptoms may be more likely to keep and use these medicines<sup>7</sup>. Younger parents (under 24 years of age) may be less likely to consult a pharmacist in preference to their GP, with only 63% of this group visiting the pharmacist first compared to 76% of older mothers<sup>37</sup>. The child's age may also influence this, mothers with older children may be more likely to keep and use non-prescription medication. Older children are also more likely to self-medicate with or without the knowledge of their parents<sup>39</sup>.

### *Advertising*

Advertising has a major impact on the purchasing of OTC medicines, especially newly deregulated ones<sup>40</sup>. The placebo effect of cough and cold remedies, reinforced by manufacturers advertising may be significant<sup>4,9</sup>.

### *Cost*

Research into the effects of cost is scant. British mothers in the 1980s demonstrated conflict between anxiety over the expense of OTC drugs and doing what they perceived to be best for their child. Some felt pressured to buy medicines now rather than wait for the GP who would give them a free prescription later<sup>41</sup>. Many were too embarrassed to ask for a medicine that they knew they could buy OTC<sup>10,41</sup>. Conversely, women in the US without health insurance were significantly more likely to give OTC medicines to their children than those with it<sup>5</sup>.

It can be seen that much of this information is old, the availability of medicines OTC has increased and attitudes to healthcare are changing. Research to establish the current impact of these different factors on self care would be very valuable.

## **Role of the Pharmacist**

The role of the pharmacist seems to be incompletely understood by many, varying in the eyes of a group of mothers from being unrecognised to specialist advice providers<sup>10,41</sup>. In between these extremes, the pharmacist was seen to have other roles such as reassurer, differential diagnosis provision, alternative to doctor, stepping stone to doctor and assistant in decision making regarding the child's health as well as being the source of OTC medicines.

Perception of the pharmacist's role is influenced by previous experience and level of contact. Asthmatic patients who had received a high level of pharmaceutical care, including advice and enquiries from the pharmacist as to the benefits or problems they were encountering with their medicines, perceived the pharmacist as able to help them manage their disease and its treatment and prevent health problems<sup>42</sup>. In the same study 20% of patients did not feel able to rate their pharmacists, having had little direct contact with them.

Many patients do not expect to consult a pharmacist when they attend a pharmacy to buy a drug<sup>42</sup>. This may be because the amount and frequency of advice given by community

pharmacies when selling OTC medicines is variable<sup>43</sup> and that the person giving the advice also varies between pharmacies. 55% of all customers were shown to receive no advice regarding medicine purchases, with paediatric medicines being common amongst the requests<sup>43</sup>. Pharmacists were shown to offer advice almost twice as often as counter assistants, however, their involvement in medicine sales was 'opportunistic and unplanned'.

The Royal Pharmaceutical Society of Great Britain Code of Ethics and Standards requires certain procedures to be followed when medicines are being sold. These procedures aim to ensure that OTC medicines purchased are safe, effective and appropriate for the condition to be treated and the intended recipient and that advice on products purchased is provided<sup>44</sup>. Counter prescribing guidance includes detail on recognition and interpreting the condition, determining the goal of treatment, recommending a treatment if appropriate, provision of advice and quality assurance and audit<sup>21</sup>. There are requirements for adequate competencies of staff involved in counter prescribing and for referral to a pharmacist when necessary. Specifically 'procedures must ensure that the particular care needed is provided when supplying products for children...'

Consultations in the shop occur daily, however at the moment the pharmacist has to advise without the benefit of information which would be provided by access to medical records. Information to base decisions on is therefore restricted to that given by the parent<sup>45</sup>. Conversely, although patient records of prescribed drugs are kept by pharmacists, OTC medicine sales for individual patients are rarely recorded. Comprehensive recording of all medicines and availability of this information to GP and pharmacist would assist in prediction and avoidance of drug interactions. Such sharing of information and collaboration between GP and pharmacist may facilitate identification and reporting of ADRs. This would be an important development as reporting of ADRs to OTC medicines is currently sadly lacking<sup>46</sup>.

In the UK, there are likely to be developments in the near future with the pharmaceutical profession's response to the document 'Pharmacy in the Future – Implementing the NHS Plan'<sup>47</sup>. This report aims to redesign services around the needs of the patient including the provision of convenient and timely access to pharmacy services, especially improving out of hours services. It also includes taking on medicines management roles to help patients gain maximum

benefit from their medicines and reduce improper use and the risk of side effects. Other proposals include increasing the range of OTC medicines available, and pharmacist prescribing to further increase the range of products which pharmacists can supply to patients without a doctor's prescription. These measures should help to raise the pharmacists' profile and encourage patients to use them to help get the best from medicines available to them and their families.

The community pharmacist has an essential role to play in the treatment of children with OTC medicines for minor illnesses. Guidelines and professional standards are already in place to maximise benefit and minimise risks involved to children being treated at home and parliamentary aims to optimise public recognition and utilisation of pharmacists are welcome.

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