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Supply of unlicensed medicines to children: exploring carers’ experiences

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<td>Manuscript ID</td>
<td>bmjpo-2017-000051</td>
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<tr>
<td>Article Type</td>
<td>Original article</td>
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<tr>
<td>Date Submitted by the Author</td>
<td>25-Apr-2017</td>
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<td>Husain, Nicola; King's College London, Institute of Pharmaceutical Science; Evelina London Children's Hospital, Pharmacy Department; Davies, John; King's College London, Institute of Pharmaceutical Science; Tomlin, Steve; Guys St Thomas@NHS Foundation trust, PHARMACY</td>
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Title of the article: Supply of unlicensed medicines to children: exploring carers’ experiences

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ABSTRACT

Objectives: To explore the experiences of parents and carers relating to the supply of unlicensed medicines for their child after discharge from hospital.

Methods: Semi-structured interviews were conducted with parents and carers of children who were newly-prescribed an unlicensed medicine. Interviews were conducted at least four weeks after the child’s discharge from hospital. Qualitative thematic analysis of the data was carried out.

Results: Problems were frequently encountered by parents when attempting to obtain further supplies of their child’s unlicensed medicine. Problems included GPs refusing to prescribe the medicine, GPs prescribing a dose or formulation that differed to what had been prescribed previously, pharmacists who were unable to source a suitable medicine, medicines that were not labelled with administration instructions and delays in obtaining the medicine. Action or intervention by the parent was often required to overcome the problems faced. The necessity of these actions or interventions, and the implication of not succeeding, frequently caused parents anxiety, frustration and dissatisfaction.

Conclusions: Strategies for improving the process of medicine supply during the transition between secondary and primary care are necessary and must involve greater communication amongst healthcare professionals and carers. GPs and community pharmacists should have access to greater support and guidance to facilitate the safe prescribing and supply of unlicensed medicines. Parents and carers should be informed about the process to ensure understanding, create empowerment and to build relationships between them and the professionals responsible for the care of their child.
INTRODUCTION

The use of ‘off-label’ and ‘unlicensed’ medicines is common within paediatric care.[1] Paediatric use of unlicensed and off-label medicines is associated with a greater incidence of medication errors, adverse drug reactions and unplanned hospital admissions when compared to licensed medicines.[2,3,4] The increased risk of such occurrences may result from a lack of prescribing guidance for unlicensed medicines, lack of product standardization and from dosage form manipulation.[5,6]

Treatment with unlicensed or off-label medicines is typically initiated within secondary care, with responsibility for ongoing supply adopted by the child’s general practitioner (GP) and community pharmacist. This arrangement allows the child’s parent or carer to obtain medicines close to home. However, previous studies have shown that taking responsibility for the use of these medicines is a source of concern for GPs and community pharmacists, many of whom admit to a poor understanding of the licensing process and the implications of supplying unlicensed or off-label medicines to children.[7,8,9,10] Furthermore, a study in 2006 found that 33% of carers experienced problems when attempting to obtain unlicensed and off-label medicines for their child after being discharged from a specialist paediatric hospital.[11]

Whilst it has been shown that some carers experiences difficulties when attempting to obtain unlicensed medicines for their child, limited studies have described their experiences during this process. This qualitative study was therefore designed to explore the experiences of parents and carers relating to the supply of unlicensed medicines for their child after discharge from hospital.

METHODS

Participant selection and recruitment

Prescriptions for newly-prescribed unlicensed medicines, for which prescribing was expected to be continued by the child’s GP, were identified by pharmacy staff at the Evelina London Children’s Hospital (ELCH). Participants (parents and carers) were recruited purposively using a sampling matrix that accounted
for the age of the child, their in-/out-patient status and the clinical speciality of the indication for the unlicensed medicine.

Data collection
Telephone interviews with participants were conducted approximately four weeks after their child’s discharge from hospital. A topic guide was designed, piloted and refined with input from specialist paediatric pharmacists (see Figure 1). A qualitative, semi-structured format was used to allow participants to describe their own experiences and to permit the disclosure of thoughts and ideas that were not anticipated by the researcher. Interviews were audio recorded and transcribed verbatim.

| How participants sought to obtain further supplies of the medicine |
| Issues/problems encountered and how they were overcome |
| Views on the participants’ experiences of the medicine supply process |
| Views of how the medicine supply process could be improved |
| Any other comments or views on the subject |

Figure 1: Topic guide for semi-structured interviews

Qualitative data analysis
Text blocks from the transcripts were open-coded into categories and sub-categories using an inductive thematic analysis approach. Categories and sub-categories were iteratively refined until a robust analytical framework was developed. The finalised framework was re-applied digitally to all transcripts using NVivo version 10 qualitative data analysis software (QSR International Pty Ltd, 2012). The coded data was reviewed and interpreted in the context of individual interviews and the complete data set. Commonalities and themes were identified and explored.

Ethical approval
Ethical approval was granted by the North-West National Research Ethics Service Committee on 29 April 2014 (reference 14/NW/0243).
RESULTS

Twenty-three parents consented to take part. Of these, eight were not interviewed for the following reasons: medicine was discontinued (4); participant was not contactable (3); hospital discharge was delayed beyond the period of data collection (1). The characteristics of the children of the 15 participants interviewed are shown in Table 1.

Table 1: Child characteristics

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Child’s age</th>
<th>Prescription type</th>
<th>Clinical speciality of newly-prescribed medicine(s)</th>
<th>Newly-prescribed medicine(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>2 m</td>
<td>Ward discharge</td>
<td>Metabolic</td>
<td>Clonidine liquid, glycine sachets, omeprazole liquid, levetiracetam liquid, levcarnitine liquid</td>
</tr>
<tr>
<td>P2</td>
<td>2 y</td>
<td>Outpatient</td>
<td>Dermatology</td>
<td>Beclometasone dipropionate 0.0025% ointment</td>
</tr>
<tr>
<td>P3</td>
<td>3 y</td>
<td>Ward discharge</td>
<td>Cardiology</td>
<td>Spironolactone liquid, furosemide liquid</td>
</tr>
<tr>
<td>P4</td>
<td>12 y</td>
<td>Outpatient</td>
<td>Endocrinology</td>
<td>Colecalciferol liquid</td>
</tr>
<tr>
<td>P5</td>
<td>4 y</td>
<td>Outpatient</td>
<td>Renal</td>
<td>Tacrolimus liquid</td>
</tr>
<tr>
<td>P6</td>
<td>2 w</td>
<td>Ward discharge</td>
<td>Metabolic</td>
<td>Sodium benzoate liquid, levetiracetam liquid, levcarnitine liquid</td>
</tr>
<tr>
<td>P7</td>
<td>6 y</td>
<td>Ward discharge</td>
<td>Cardiology</td>
<td>Spironolactone liquid, lisinopril liquid</td>
</tr>
<tr>
<td>P8</td>
<td>7 m</td>
<td>Ward discharge</td>
<td>Neurology</td>
<td>Melatonin liquid, omeprazole liquid, carbamazepine liquid, sodium valproate liquid, vigabatrin sachets, midazolam buccal solution, clobazam liquid</td>
</tr>
<tr>
<td>P9</td>
<td>11 y</td>
<td>Outpatient</td>
<td>Endocrinology</td>
<td>Colecalciferol liquid</td>
</tr>
<tr>
<td>P10</td>
<td>6 m</td>
<td>Outpatient</td>
<td>Dermatology and renal</td>
<td>Beclometasone dipropionate 0.0025% ointment, sodium chloride oral solution</td>
</tr>
<tr>
<td>P11</td>
<td>15 y</td>
<td>Outpatient</td>
<td>Endocrinology</td>
<td>Colecalciferol liquid</td>
</tr>
<tr>
<td>P12</td>
<td>5 y</td>
<td>Ward discharge</td>
<td>Cardiology and neurology</td>
<td>Spironolactone liquid, clonidine liquid, glycopyrrolate tablets, hyprosmellose eye drops, furosemide liquid, omeprazole dispersible tablets, ethosuximide liquid</td>
</tr>
<tr>
<td>P13</td>
<td>2 y</td>
<td>Outpatient</td>
<td>Dermatology</td>
<td>Beclometasone dipropionate 0.0025% ointment</td>
</tr>
<tr>
<td>P14</td>
<td>1 y</td>
<td>Ward discharge</td>
<td>Cardiology</td>
<td>Lisinopril liquid, propranolol liquid, furosemide liquid</td>
</tr>
<tr>
<td>P15</td>
<td>11 y</td>
<td>Ward discharge</td>
<td>Neurology</td>
<td>Clonidine liquid</td>
</tr>
</tbody>
</table>

Child’s age: m = months, y = years; newly-prescribed medicine(s): non-italic = unlicensed; italic = off-label usage

The finalised analytical framework contained three categories and 21 sub-categories, which are shown in Table 2.

Table 2: Categories and sub-categories

<table>
<thead>
<tr>
<th>Category</th>
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<th>Problems and concerns</th>
<th>Actions and strategies</th>
<th>Views and perceptions</th>
</tr>
</thead>
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<tr>
<td>GP unwilling to prescribe, or other prescribing issue</td>
<td>Additional interaction with GP surgery staff</td>
<td>Perceptions of GP surgery and pharmacy staff</td>
</tr>
<tr>
<td>Communication difficulties with GP surgery staff</td>
<td>Additional interaction with pharmacy staff</td>
<td>Perceptions and understanding of the medicine supply process</td>
</tr>
<tr>
<td>Wrong product, formulation or strength prescribed</td>
<td>Requested assistance from other healthcare professional</td>
<td>Views on how the medicine supply process should be delivered or improved</td>
</tr>
<tr>
<td>Insufficient quantity prescribed</td>
<td>Requested larger quantity to be prescribed</td>
<td></td>
</tr>
<tr>
<td>Communication difficulties with pharmacy staff</td>
<td>Asked pharmacy staff to keep medicine as stock</td>
<td></td>
</tr>
<tr>
<td>Delay in obtaining medicine from pharmacy</td>
<td>Used one regular pharmacy</td>
<td></td>
</tr>
<tr>
<td>Medicine not labelled with directions</td>
<td>Used multiple pharmacies</td>
<td></td>
</tr>
<tr>
<td>Lack of information about the medicine</td>
<td>Obtained medicine from local or specialist hospital</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Planning and organising the process</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sought information about the medicine</td>
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### Problems and concerns

The first step to obtaining further supplies for all participants was making contact with GP surgery staff. In most cases, communication with surgery staff was reported as good, although some difficulties were faced:

> P7: “What we’ve found - and we found it again this time - when he has his meds changed, the first time we had to get the prescription written up, it’s really frustrating and becomes a bit of a pain if it is not written up right…

> **So like this time…his prescription got written up but his GP didn’t put it on repeat… Trying to explain to the receptionist…and they say ‘well, the GP has not put it on repeat’, and you say ‘he’s just come out of hospital’… again, it’s sometimes like you are having to battle...”

Most participants reported that a consultation with the GP had not been required. This was generally acceptable to participants, although one (P6), whose child had been in hospital since birth, believed a medical review would have provided reassurance:

> P6: “We haven’t seen the GP yet, they didn’t want to see us… So the GP’s never seen [my son]… But then we’ve got our 6-weekly check next week, so that’s where our confidence, I think, will get a bit better.”
A number of participants reported that their child’s GP was unwilling to prescribe the new unlicensed medicine. Perceived reasons for this were ‘cost’ (colecalciferol liquid; beclometasone dipropionate 0.0025% ointment) and that the GP was ‘not allowed’ to prescribe it (clonidine liquid; chloral hydrate liquid). In three cases, supplies from the hospital had been exhausted and parents had been unable to obtain a new supply.

A frequent complaint concerned the quantity of medicine that the GP would prescribe. Concerns about receiving small quantities focussed on the frequency with which prescriptions would need to be obtained to replenish supplies, a desire to keep additional supplies at home in case of loss or spillage and to provide supplies to parents who lived separately but shared childcare responsibilities.

All participants were aware that the unlicensed medicine was unlikely to be immediately available at local pharmacy. However, participants expressed dissatisfaction at the time it took for the medicine to be procured, especially when they were not informed by the pharmacy staff about the anticipated waiting time. The time needed to procure unlicensed medicines was a worry for participants:

P12: “What happens if I drop the bottle, for instance? I’m absolutely terrified I won’t be able to get any more quick enough.”

For several participants, it transpired after receiving the medicine that the formulation or strength prescribed by the GP differed to the product prescribed at ELCH. Some reported receiving a liquid medicine that was a different strength to that issued at the hospital; all reported that the change had not been communicated to them although most had identified that the resulting dosage volume needed to change. In addition to the discrepancies identified by participants, one prescribing error was identified by the interviewer: a change in formulation made by the GP (from liquid to capsules) resulted in a 10-fold dose decrease of colecalciferol. Several participants reported that the new medicine was not labelled with administration instructions.
Actions and strategies

Participants reported a variety of strategies for overcoming the issues they had encountered. Several participants who faced problems obtaining a prescription enlisted the help of other healthcare professionals - including health visitors, community nurses, hospital nurse specialists and other GPs - to liaise with the child’s GP on their behalf. The perception expressed was that another healthcare professional would have more influence over the GP:

P2: “This morning I contacted my health visitor - because they seem to be very good at passing on messages and making people do what they are supposed to do - so at some point today she’s trying to get the doctor to do the prescription.”

In response to the time delay between requesting a prescription and obtaining the medicine, nearly all participants believed that planning and organisation were critical to ensure continuity of supply. This was particularly evident for participants who had prior experience of obtaining unlicensed medicines.

P7: “We’ve been through this now for six years - we know what’s going to happen and we pre-empt things. Luckily, when we get his prescriptions - due to things like delays or having to get medicines ordered or anything like that - we always do it with at least a week’s worth of medicines still to go.”

Participants commented that the need to plan and organise prescriptions and medicine supplies caused them “worry” and “stress”. Several participants kept ‘spare’ supplies in case of loss or spillage, although the short shelf life of some medicines limited the effectiveness of this approach. Another strategy to safeguard against running out of medicines involved asking the GP to prescribe a greater quantity on each occasion. Other participants asked their pharmacy to stock the unlicensed medicine so that it would be readily available when they presented a prescription; however the responses received were variable:

P12: “[The pharmacist] said ‘we don’t order it for anybody else, so we don’t ever keep any as stock, but what I will do is... I’ll order a spare, so we will always have one in the pharmacy’. Which was lovely.”
P6: “[The pharmacist] said no, because it costs...I think they said £50 a bottle. They wouldn’t keep any in stock, which is obviously a concern.”

Five participants had contacted ELCH or their local hospital to request supplies of the unlicensed medicine after failing to obtain it locally. Others reported needing to visit several pharmacies before finding one able to supply the medicine. The possibility of not obtaining the medicine in time caused participants to experience “panic” and “frustration” and to feel “afraid”.

Views and perceptions

A common view expressed by participants was that the hospital consultant was the singular ‘prescriber’ of the medicine and the GP’s role in the supply process was to furnish the participant with a prescription to enable them to obtain further supplies from a pharmacy. One participant (P6) thought that the GP was “…just signing stuff…without really knowing what he’s signing”. They believed that the GP “…is trumped by the consultants”. Another participant described their understanding of the process:

P1: “It’s prescribed at the Evelina, but we need to go to the GP to get a prescription... It must come from the surgery but it doesn’t really come from them, it comes from [Dr at ELCH], so it is a bit confusing.”

Participants who expressed views about their interaction with pharmacy staff focussed mostly on communication. Some expressed frustration when questioned by pharmacy staff:

P7: “When...they start asking the same questions again it gets a bit frustrating. But it’s one of those things, I’d rather be questioned than not questioned to ensure that there are people looking out for [my son]’s safety.”

Others believed that greater interaction would have provided reassurance:
P6: “[They said] nothing – they just handed them over. I think it’s just that interaction… I just went up and picked them up, there was no ‘are you happy with them?’ They just gave me the bag. It was as if you went and bought some Anadin from behind the counter.”

DISCUSSION

Summary of findings

This study demonstrates that the current approach to supplying unlicensed medicines to children has a number of major failings relating to both the prescribing and dispensing stages. Participants encountered GPs who were either unwilling to prescribe for their child, or prescribed a dose, formulation or strength of medicine that differed to what had been issued previously. Participants faced long waiting times for medicines to be procured and received minimal limited information from pharmacy staff. Many participants expressed dissatisfaction with their experience; the primary cause of this was the uncertainty of knowing whether a continued supply of the medicine was assured and therefore whether their child would receive the medicine. These experiences challenged the relationships between participants and their child’s healthcare professionals.

Clinical implications for the child

Within this study, three children missed doses as a result of prescribing or dispensing issues. Several others would have missed doses had the parent not secured emergency supplies from ELCH or a local hospital. Participants also reported that changes were made to the medicine’s strength or formulation. Whilst a change in product does not necessarily compromise care, unlicensed medicines are not subject to the same regulations as licensed medicines and so bioavailability - and therefore clinical effect - may vary between products. Changes to a product’s formulation or strength and omitted dosing instructions can also result in inadvertent administration errors unless such changes are explicitly explained to the parent.

Implications for the carer
Participants expected their child’s GP to prescribe, and their local pharmacy to dispense, the medicine initiated by ELCH. The participants’ expectations are logical and understandable but may not be realistic within the current medicine supply system: it cannot be presumed that a GP will agree to continue a medicine recommended by another physician and pharmacists may lack the clinical or pharmaceutical expertise to source or dispense unlicensed medicines.

Many participants expressed feelings of frustration, stress and anxiety from their experiences of negotiating the transition of medicine supply between hospital and primary care. For many, a successful outcome depended on perseverance and organisation. Some went to great lengths to ensure doses were not omitted: making an emergency trip to hospital to collect a medicine, for example.

**Recommendations for practice**

There is an increasing focus in the UK on improving medicines safety and in optimising the way patients use medicines.[12] Unlicensed and off-label medicines are associated with a greater safety risk than medicines that are used within the constraints of their marketing authorisation. Improving the process of supplying unlicensed and off-label medicines to children is therefore an important area of focus.

Some issues identified in this study may be prevented through improvements in communication between hospital healthcare professionals and those within primary care. Earlier dialogue would ensure GPs have the necessary information to prescribe and monitor the patient safely, or if they feel unable to assume the prescribing role, to inform the child’s consultant prior to the child’s discharge from secondary care. Furthermore, greater contact between hospital and community pharmacists may help those in community to source suitable products and prevent dispensing or labelling issues. GPs and community pharmacists who are unable or unwilling to assume responsibility should have a duty to assist the parent to liaise with hospital staff to facilitate supply from an alternative source.
For parents and carers to be satisfied and engaged with the process of medicine supply, it is vital that they are informed about the process and understand the roles of GPs and community pharmacists. Throughout the transition from hospital to primary care, staff should ensure that parental expectations concerning waiting times and quantity of supply are realistic and should highlight the common problems associated with unlicensed medicines, such as the implication of strength changes of liquid medicines.

CONCLUSIONS

This study highlights the nature and severity of problems that parents and carers encountered when attempting to obtain unlicensed medicines for their child following discharge from hospital. Strategies for improving this process are necessary: greater dialogue between healthcare professionals is required and greater support should be provided to GPs and community pharmacists to facilitate safe supply of unlicensed medicines within primary care. Parents and carers should be engaged throughout the transition process to ensure they understand the roles of the healthcare professionals involved and what to expect when the child’s care is transferred from hospital to community.

Acknowledgements

The Authors wish to thank the participants for sharing their experiences.

Competing interests

The Authors declare that they have no conflicts of interest to disclose.

Funding

This research received no specific grant or funding.

Sponsor

This research was co-sponsored by King’s College London and Guy’s and St Thomas’ NHS Foundation Trust.
What is already known on this topic

‘Off-label’ and ‘unlicensed’ medicines use is associated with medication risk. GPs and community pharmacists often admit to a poor understanding of licensing regulations and the implications of supplying unlicensed or off-label medicines to children.

What this study adds

Parents and carers experience problems when attempting to obtain unlicensed medicines for their child following discharge from hospital. Problems can occur at the prescribing and dispensing stage and are a source of concern and anxiety for parents and carers.
REFERENCES


How participants sought to obtain further supplies of the medicine

Issues/problems encountered and how they were overcome

Views on the participants' experiences of the medicine supply process

Views of how the medicine supply process could be improved

Any other comments or views on the subject
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ABSTRACT

Objectives: To explore the experiences of parents and carers relating to the supply of unlicensed medicines for their child after discharge from hospital.

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Conclusions: Strategies for improving the process of medicine supply during the transition between secondary and primary care are necessary and must involve greater communication amongst healthcare professionals and carers. GPs and community pharmacists should have access to greater support and guidance to facilitate the safe prescribing and supply of unlicensed medicines. Parents and carers should be informed about the process to ensure understanding, create empowerment and to build relationships between them and the professionals responsible for the care of their child.
INTRODUCTION

Within paediatric care medicines are commonly prescribed outside the terms of the medicine’s marketing authorisation (termed ‘off-label’). Furthermore, the use of medicines without marketing authorisation (termed ‘unlicensed’) is often necessitated.[1] Paediatric use of unlicensed and off-label medicines is associated with a greater incidence of medication errors, adverse drug reactions and unplanned hospital admissions when compared to licensed medicines.[2,3,4] The increased risk of such occurrences may result from a lack of prescribing guidance for unlicensed medicines, lack of product standardization and from dosage form manipulation.[5,6]

Treatment with unlicensed or off-label medicines is typically initiated within secondary care, with responsibility for ongoing supply adopted by the child’s general practitioner (GP) and community pharmacist. This arrangement allows the child’s parent or carer to obtain medicines close to home. However, previous studies have shown that taking responsibility for the use of these medicines is a source of concern for GPs and community pharmacists, many of whom admit to a poor understanding of the licensing process and the implications of supplying unlicensed or off-label medicines to children.[7,8,9,10] Furthermore, a study in 2006 found that 33% of carers experienced problems when attempting to obtain unlicensed and off-label medicines for their child after being discharged from a specialist paediatric hospital.[11]

Whilst it has been shown that some carers experiences difficulties when attempting to obtain unlicensed medicines for their child, limited studies have described their experiences during this process. This qualitative study was therefore designed to explore the experiences of parents and carers relating to the supply of unlicensed medicines for their child after discharge from hospital.

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Participant selection and recruitment
Prescriptions for newly-prescribed unlicensed medicines, for which prescribing was expected to be continued by the child’s GP, were identified by pharmacy staff at the Evelina London Children’s Hospital (ELCH). Participants (parents and carers) were recruited purposively using a sampling matrix that accounted for the age of the child, their in-/out-patient status and the clinical speciality of the indication for the unlicensed medicine. Written consent was obtained prior to the child’s discharge from hospital.

**Data collection**

Telephone interviews with participants were conducted approximately four weeks after their child’s discharge from hospital. A topic guide was designed, piloted and refined with input from specialist paediatric pharmacists (see Figure 1). A qualitative, semi-structured format was used to allow participants to describe their own experiences and to permit the disclosure of thoughts and ideas that were not anticipated by the researcher. Interviews were audio recorded and transcribed verbatim.

![Figure 1: Topic guide for semi-structured interviews](image-url)

**Qualitative data analysis**

Text blocks from the transcripts were open-coded into categories and sub-categories using an inductive thematic analysis approach. Categories and sub-categories were iteratively refined until a robust analytical framework was developed. The finalised framework was re-applied digitally to all transcripts using NVivo version 10 qualitative data analysis software (QSR International Pty Ltd, 2012). The coded data was reviewed and interpreted in the context of individual interviews and the complete data set. Commonalities and themes were identified and explored.

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Ethical approval was granted by the North-West National Research Ethics Service Committee on 29 April 2014 (reference 14/NW/0243).
RESULTS

Twenty-three parents consented to take part. Of these, eight were not interviewed for the following reasons: medicine was discontinued (4); participant was not contactable (3); hospital discharge was delayed beyond the period of data collection (1). The characteristics of the children of the 15 participants interviewed are shown in Table 1. Their age ranged from two weeks to 15 years (median age 3 years).

Unlicensed medicines were prescribed for seven children in the outpatient setting and for eight children who were discharged from inpatient wards. Unlicensed medicines were prescribed for the following clinical specialities: cardiology (4 patients), dermatology (3 patients), endocrinology (3 patients), neurology (3 patients) metabolic (2 patients), and renal (2 patients). The unlicensed medicines prescribed were: beclometasone dipropionate 0.0025% ointment, clonidine liquid, colecalciferol liquid and spironolactone liquid (3 patients each); lisinopril liquid and omeprazole liquid (2 patients each) and glycine sachets, glycopyrrolate tablets, melatonin liquid, midazolam buccal solution, sodium benzoate liquid, sodium chloride oral solution and tacrolimus liquid (1 patient each).

Table 1: Child characteristics

<table>
<thead>
<tr>
<th>Participant ID</th>
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<th>Prescription type</th>
<th>Clinical speciality of newly-prescribed medicine(s)</th>
<th>Newly-prescribed medicine(s)</th>
</tr>
</thead>
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<tr>
<td>P1</td>
<td>2 m</td>
<td>Ward discharge</td>
<td>Metabolic</td>
<td>Clonidine liquid, glycine sachets, omeprazole liquid, levetiracetam liquid, levocarnitine liquid</td>
</tr>
<tr>
<td>P2</td>
<td>2 y</td>
<td>Outpatient</td>
<td>Dermatology</td>
<td>Beclometasone dipropionate 0.0025% ointment</td>
</tr>
<tr>
<td>P3</td>
<td>3 y</td>
<td>Ward discharge</td>
<td>Cardiology</td>
<td>Spironolactone liquid, furosemide liquid</td>
</tr>
<tr>
<td>P4</td>
<td>12 y</td>
<td>Outpatient</td>
<td>Endocrinology</td>
<td>Colecalciferol liquid</td>
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<tr>
<td>P5</td>
<td>4 y</td>
<td>Outpatient</td>
<td>Renal</td>
<td>Tacrolimus liquid</td>
</tr>
<tr>
<td>P6</td>
<td>2 w</td>
<td>Ward discharge</td>
<td>Metabolic</td>
<td>Sodium benzoate liquid, levetiracetam liquid, levocarnitine liquid</td>
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<tr>
<td>P7</td>
<td>6 y</td>
<td>Ward discharge</td>
<td>Cardiology</td>
<td>Spironolactone liquid, lisinopril liquid</td>
</tr>
<tr>
<td>P8</td>
<td>7 m</td>
<td>Ward discharge</td>
<td>Neurology</td>
<td>Melatonin liquid, omeprazole liquid, midazolam buccal solution, carbamazepine liquid, clozapam liquid, sodium valproate liquid, vigabatrin sachets</td>
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<tr>
<td>P9</td>
<td>11 y</td>
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<td>Endocrinology</td>
<td>Colecalciferol liquid</td>
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<tr>
<td>P10</td>
<td>6 m</td>
<td>Outpatient</td>
<td>Dermatology and renal</td>
<td>Beclometasone dipropionate 0.0025% ointment, sodium chloride oral solution</td>
</tr>
<tr>
<td>P11</td>
<td>15 y</td>
<td>Outpatient</td>
<td>Endocrinology</td>
<td>Colecalciferol liquid</td>
</tr>
<tr>
<td>P12</td>
<td>5 y</td>
<td>Ward discharge</td>
<td>Cardiology and neurology</td>
<td>Spironolactone liquid, clonidine liquid, glycopyrrolate tablets, furosemide liquid, ethosuximide liquid</td>
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<td>P13</td>
<td>2 y</td>
<td>Outpatient</td>
<td>Dermatology</td>
<td>Beclometasone dipropionate 0.0025% ointment</td>
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<td>P14</td>
<td>1 y</td>
<td>Ward discharge</td>
<td>Cardiology</td>
<td>Lisinopril liquid, propranolol liquid, furosemide liquid</td>
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<tr>
<td>P15</td>
<td>11 y</td>
<td>Ward discharge</td>
<td>Neurology</td>
<td>Clonidine liquid</td>
</tr>
</tbody>
</table>
The finalised analytical framework contained three categories and 21 sub-categories, which are shown in Table 2.

Table 2: Categories and sub-categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Sub-category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problems and concerns</td>
<td>GP unwilling to prescribe, or other prescribing issue</td>
</tr>
<tr>
<td></td>
<td>Communication difficulties with GP surgery staff</td>
</tr>
<tr>
<td></td>
<td>Wrong product, formulation or strength prescribed</td>
</tr>
<tr>
<td></td>
<td>Insufficient quantity prescribed</td>
</tr>
<tr>
<td></td>
<td>Communication difficulties with pharmacy staff</td>
</tr>
<tr>
<td></td>
<td>Delay in obtaining medicine from pharmacy</td>
</tr>
<tr>
<td></td>
<td>Medicine not labelled with directions</td>
</tr>
<tr>
<td></td>
<td>Lack of information about the medicine</td>
</tr>
<tr>
<td>Actions and strategies</td>
<td>Additional interaction with GP surgery staff</td>
</tr>
<tr>
<td></td>
<td>Additional interaction with pharmacy staff</td>
</tr>
<tr>
<td></td>
<td>Requested assistance from other healthcare professional</td>
</tr>
<tr>
<td></td>
<td>Requested larger quantity to be prescribed</td>
</tr>
<tr>
<td></td>
<td>Asked pharmacy staff to keep medicine as stock</td>
</tr>
<tr>
<td></td>
<td>Used one regular pharmacy</td>
</tr>
<tr>
<td></td>
<td>Used multiple pharmacies</td>
</tr>
<tr>
<td></td>
<td>Obtained medicine from local or specialist hospital</td>
</tr>
<tr>
<td></td>
<td>Planning and organising the process</td>
</tr>
<tr>
<td></td>
<td>Sought information about the medicine</td>
</tr>
<tr>
<td>Views and perceptions</td>
<td>Perceptions of GP surgery and pharmacy staff</td>
</tr>
<tr>
<td></td>
<td>Perceptions and understanding of the medicine supply process</td>
</tr>
<tr>
<td></td>
<td>Views on how the medicine supply process should be delivered or improved</td>
</tr>
</tbody>
</table>

Problems and concerns

The first step to obtaining further supplies for all participants was making contact with GP surgery staff. In most cases, communication with surgery staff was reported as good, although some difficulties were faced:

P7: “What we’ve found - and we found it again this time - when he has his meds changed, the first time we had to get the prescription written up, it’s really frustrating and becomes a bit of a pain if it is not written up right…

So like this time…his prescription got written up but his GP didn’t put it on repeat… Trying to explain to the receptionist…and they say ‘well, the GP has not put it on repeat’, and you say ‘he’s just come out of hospital’… again, it’s sometimes like you are having to battle...”
Most participants reported that a consultation with the GP had not been required. This was generally acceptable to participants, although one (P6), whose child had been in hospital since birth, believed a medical review would have provided reassurance:

P6: “We haven’t seen the GP yet, they didn’t want to see us... So the GP’s never seen [my son]... But then we’ve got our 6-weekly check next week, so that’s where our confidence, I think, will get a bit better.”

A number of participants reported that their child’s GP was unwilling to prescribe the new unlicensed medicine. Perceived reasons for this were ‘cost’ (colecalciferol liquid; beclometasone dipropionate 0.0025% ointment) and that the GP was ‘not allowed’ to prescribe it (clonidine liquid; chloral hydrate liquid). In three cases, supplies from the hospital had been exhausted and parents had been unable to obtain a new supply.

A frequent complaint concerned the quantity of medicine that the GP would prescribe. Concerns about receiving small quantities focussed on the frequency with which prescriptions would need to be obtained to replenish supplies, a desire to keep additional supplies at home in case of loss or spillage and to provide supplies to parents who lived separately but shared childcare responsibilities.

All participants were aware that the unlicensed medicine was unlikely to be immediately available at local pharmacy. However, participants expressed dissatisfaction at the time it took for the medicine to be procured, especially when they were not informed by the pharmacy staff about the anticipated waiting time. The time needed to procure unlicensed medicines was a worry for participants:

P12: “What happens if I drop the bottle, for instance? I’m absolutely terrified I won’t be able to get any more quick enough.”

For several participants, it transpired after receiving the medicine that the formulation or strength prescribed by the GP differed to the product prescribed at ELCH. Some reported receiving a liquid medicine that was a different strength to that issued at the hospital; all reported that the change had not been
communicated to them although most had identified that the resulting dosage volume needed to change.

In addition to the discrepancies identified by participants, one prescribing error was identified by the interviewer: a change in formulation made by the GP (from liquid to capsules) resulted in a 10-fold dose decrease of colecalciferol. Several participants reported that the new medicine was not labelled with administration instructions.

**Actions and strategies**

Participants reported a variety of strategies for overcoming the issues they had encountered. Several participants who faced problems obtaining a prescription enlisted the help of other healthcare professionals - including health visitors (community public health nurses or midwives), community nurses, hospital nurse specialists and other GPs - to liaise with the child’s GP on their behalf. The perception expressed was that another healthcare professional would have more influence over the GP:

*P2: “This morning I contacted my health visitor – because they seem to be very good at passing on messages and making people do what they are supposed to do - so at some point today she’s trying to get the doctor to do the prescription.”*

In response to the time delay between requesting a prescription and obtaining the medicine, nearly all participants believed that planning and organisation were critical to ensure continuity of supply. This was particularly evident for participants who had prior experience of obtaining unlicensed medicines.

*P7: “We’ve been through this now for six years - we know what’s going to happen and we pre-empt things. Luckily, when we get his prescriptions - due to things like delays or having to get medicines ordered or anything like that - we always do it with at least a week’s worth of medicines still to go.”*

Participants commented that the need to plan and organise prescriptions and medicine supplies caused them “worry” and “stress”. Several participants kept ‘spare’ supplies in case of loss or spillage, although the short shelf life of some medicines limited the effectiveness of this approach. Another strategy to safeguard
against running out of medicines involved asking the GP to prescribe a greater quantity on each occasion.

Other participants asked their pharmacy to stock the unlicensed medicine so that it would be readily available when they presented a prescription; however the responses received were variable:

P12: “[The pharmacist] said ‘we don’t order it for anybody else, so we don’t ever keep any as stock, but what I will do is… I’ll order a spare, so we will always have one in the pharmacy’. Which was lovely.”

P6: “[The pharmacist] said no, because it costs…I think they said £50 a bottle. They wouldn’t keep any in stock, which is obviously a concern.”

Five participants had contacted ELCH or their local hospital to request supplies of the unlicensed medicine after failing to obtain it locally. Others reported needing to visit several pharmacies before finding one able to supply the medicine. The possibility of not obtaining the medicine in time caused participants to experience “panic” and “frustration” and to feel “afraid”.

Views and perceptions

A common view expressed by participants was that the hospital consultant was the singular ‘prescriber’ of the medicine and the GP’s role in the supply process was to furnish the participant with a prescription to enable them to obtain further supplies from a pharmacy. One participant (P6) thought that the GP was “...just signing stuff...without really knowing what he’s signing”. They believed that the GP “...is trumped by the consultants”. Another participant described their understanding of the process:

P1: “It’s prescribed at the Evelina, but we need to go to the GP to get a prescription... It must come from the surgery but it doesn’t really come from them, it comes from [Dr at ELCH], so it is a bit confusing.”

Participants who expressed views about their interaction with pharmacy staff focussed mostly on communication. Some expressed frustration when questioned by pharmacy staff:
P7: “When...they start asking the same questions again it gets a bit frustrating. But it's one of those things, I'd rather be questioned than not questioned to ensure that there are people looking out for [my son]'s safety.”

Others believed that greater interaction would have provided reassurance:

P6: “[They said] nothing – they just handed them over. I think it’s just that interaction... I just went up and picked them up, there was no ‘are you happy with them?’ They just gave me the bag. It was as if you went and bought some Anadin from behind the counter.”

DISCUSSION

This study demonstrates that the current approach to supplying unlicensed medicines to children has a number of major failings relating to both the prescribing and dispensing stages. Participants encountered GPs who were either unwilling to prescribe for their child, or prescribed a dose, formulation or strength of medicine that differed to what had been issued previously. Participants faced long waiting times for medicines to be procured and received minimal limited information from pharmacy staff. Many participants expressed dissatisfaction with their experience; the primary cause of this was the uncertainty of knowing whether a continued supply of the medicine was assured and therefore whether their child would receive the medicine. These experiences challenged the relationships between participants and their child’s healthcare professionals.

Some doses were missed as a result of difficulties faced by participants when attempting to obtain their child’s unlicensed medicine. Participants also reported that changes were made to the medicine’s strength or formulation. Whilst a change in product does not necessarily compromise care, unlicensed medicines are not subject to the same regulations as licensed medicines and so bioavailability - and therefore clinical effect - may vary between products. Changes to a product’s formulation or strength and omitted dosing instructions can also result in inadvertent administration errors unless such changes are explicitly explained to the parent.
Participants expected their child’s GP to prescribe, and their local pharmacy to dispense, the medicine initiated by ELCH. The participants’ expectations are logical and understandable but may not be realistic within the current medicine supply system: it cannot be presumed that a GP will agree to continue a medicine recommended by another physician and pharmacists may lack the clinical or pharmaceutical expertise to source or dispense unlicensed medicines. Indeed, some children’s hospitals have elected to provide long-term supplies of unlicensed medicines to patients and are reimbursed by commissioners for delivering this service.[12]

Many participants expressed feelings of frustration, stress and anxiety from their experiences of negotiating the transition of medicine supply between hospital and primary care. For many, a successful outcome depended on perseverance and organisation. Some went to great lengths to ensure doses were not omitted: making an emergency trip to hospital to collect a medicine, for example.

Some issues identified in this study may be prevented through improvements in communication between hospital healthcare professionals and those within primary care. Earlier dialogue would ensure GPs have the necessary information to prescribe and monitor the patient safely, or if they feel unable to assume the prescribing role, to inform the child’s consultant prior to the child’s discharge from secondary care. Furthermore, greater contact between hospital and community pharmacists may help those in community to source suitable products and prevent dispensing or labelling issues. GPs and community pharmacists who are unable or unwilling to assume responsibility should have a duty to assist the parent to liaise with hospital staff to facilitate supply from an alternative source.

For parents and carers to be satisfied and engaged with the process of medicine supply, it is vital that they are informed about the process and understand the roles of GPs and community pharmacists. Throughout the transition from hospital to primary care, staff should ensure that parental expectations concerning waiting times and quantity of supply are realistic and should highlight the common problems associated with unlicensed medicines, such as the implication of strength changes of liquid medicines.
CONCLUSIONS

This study highlights the nature and severity of problems that parents and carers encountered when attempting to obtain unlicensed medicines for their child following discharge from hospital. Strategies for improving this process are necessary: greater dialogue between healthcare professionals is required and greater support should be provided to GPs and community pharmacists to facilitate safe supply of unlicensed medicines within primary care. Parents and carers should be engaged throughout the transition process to ensure they understand the roles of the healthcare professionals involved and what to expect when the child’s care is transferred from hospital to community.

Acknowledgements

The Authors wish to thank the participants for sharing their experiences.

Competing interests

The Authors declare that they have no conflicts of interest to disclose.

Funding

This research received no specific grant or funding.

Sponsor

This research was co-sponsored by King’s College London and Guy’s and St Thomas’ NHS Foundation Trust.

What is already known on this topic

‘Off-label’ and ‘unlicensed’ medicines use is associated with medication risk. GPs and community pharmacists often admit to a poor understanding of licensing regulations and the implications of supplying unlicensed or off-label medicines to children.
What this study adds

Parents and carers experience problems when attempting to obtain unlicensed medicines for their child following discharge from hospital. Problems can occur at the prescribing and dispensing stage and are a source of concern and anxiety for parents and carers.

Contributorship Statement

Nicola Husain

Conception or design of the work
Data collection
Data analysis and interpretation
Drafting the article
Critical revision of the article
Final approval of the version to be published

J Graham Davies

Conception or design of the work
Critical revision of the article
Final approval of the version to be published

Stephen Tomlin

Conception or design of the work
Critical revision of the article
Final approval of the version to be published

REFERENCES


how participants sought to obtain further supplies of the medicine
issues/problems encountered and how they were overcome
Views on the participants' experiences of the medicine supply process
Views of how the medicine supply process could be improved
Any other comments or views on the subject
Supply of unlicensed medicines to children: semi-structured interviews with carers

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TITLE PAGE

Title of the article:
Supply of unlicensed medicines to children: semi-structured interviews with carers

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ABSTRACT

Objectives: To explore the experiences of parents and carers relating to the supply of unlicensed medicines for their child after discharge from hospital.

Methods: Semi-structured interviews were conducted with 15 parents and carers of children who were newly-prescribed an unlicensed medicine. Interviews were conducted at least four weeks after the child’s discharge from hospital. Qualitative thematic analysis of the data was carried out.

Results: Problems were frequently encountered by parents when attempting to obtain further supplies of their child’s unlicensed medicine. Problems included GPs refusing to prescribe the medicine, GPs prescribing a dose or formulation that differed to what had been prescribed previously, pharmacists who were unable to source a suitable medicine, medicines that were not labelled with administration instructions and delays in obtaining the medicine. Action or intervention by the parent was often required to overcome the problems faced. The necessity of these actions or interventions, and the implication of not succeeding, frequently caused parents anxiety, frustration and dissatisfaction.

Conclusions: Strategies for improving the process of medicine supply during the transition between secondary and primary care are necessary and must involve greater communication amongst healthcare professionals and carers. GPs and community pharmacists should have access to greater support and guidance to facilitate the safe prescribing and supply of unlicensed medicines. Parents and carers should be informed about the process to ensure understanding, create empowerment and to build relationships between them and the professionals responsible for the care of their child.
INTRODUCTION

Within paediatric care medicines are commonly prescribed outside the terms of the medicine’s marketing authorisation (termed ‘off-label’). Furthermore, the use of medicines without marketing authorisation (termed ‘unlicensed’) is often necessitated.[1] Paediatric use of unlicensed and off-label medicines is associated with a greater incidence of medication errors, adverse drug reactions and unplanned hospital admissions when compared to licensed medicines.[2,3,4] The increased risk of such occurrences may result from a lack of prescribing guidance for unlicensed medicines, lack of product standardization and from dosage form manipulation.[5,6]

Treatment with unlicensed or off-label medicines is typically initiated within secondary care, with responsibility for ongoing supply adopted by the child’s general practitioner (GP) and community pharmacist. This arrangement allows the child’s parent or carer to obtain medicines close to home. However, previous studies have shown that taking responsibility for the use of these medicines is a source of concern for GPs and community pharmacists, many of whom admit to a poor understanding of the licensing process and the implications of supplying unlicensed or off-label medicines to children.[7,8,9,10] Furthermore, a study in 2006 found that 33% of carers experienced problems when attempting to obtain unlicensed and off-label medicines for their child after being discharged from a specialist paediatric hospital.[11]

Whilst it has been shown that some carers experiences difficulties when attempting to obtain unlicensed medicines for their child, limited studies have described their experiences during this process. This qualitative study was therefore designed to explore the experiences of parents and carers relating to the supply of unlicensed medicines for their child after discharge from hospital.

METHODS

Participant selection and recruitment
Prescriptions for newly-prescribed unlicensed medicines, for which prescribing was expected to be continued by the child’s GP, were identified by pharmacy staff at the Evelina London Children’s Hospital (ELCH). Participants (parents and carers) were recruited purposively using a sampling matrix that accounted for the age of the child, their in-/out-patient status and the clinical speciality of the indication for the unlicensed medicine. Written consent was obtained prior to the child’s discharge from hospital.

Data collection

Telephone interviews with participants were conducted approximately four weeks after their child’s discharge from hospital. A topic guide was designed, piloted and refined with input from specialist paediatric pharmacists (see Figure 1). A qualitative, semi-structured format was used to allow participants to describe their own experiences and to permit the disclosure of thoughts and ideas that were not anticipated by the researcher. Interviews were audio recorded and transcribed verbatim.

Figure 1: Topic guide for semi-structured interviews

Qualitative data analysis

Text blocks from the transcripts were open-coded into categories and sub-categories using an inductive thematic analysis approach. Categories and sub-categories were iteratively refined until a robust analytical framework was developed. The finalised framework was re-applied digitally to all transcripts using NVivo version 10 qualitative data analysis software (QSR International Pty Ltd, 2012). The coded data was reviewed and interpreted in the context of individual interviews and the complete data set. Commonalities and themes were identified and explored.

Ethical approval

Ethical approval was granted by the North-West National Research Ethics Service Committee on 29 April 2014 (reference 14/NW/0243).
RESULTS

Twenty-three parents consented to take part. Of these, eight were not interviewed for the following reasons: medicine was discontinued (4 patients); participant was not contactable (3 patients); hospital discharge was delayed beyond the period of data collection (1 patient). Unlicensed medicines were prescribed for seven children in the outpatient setting and for eight children who were discharged from inpatient wards. Their age ranged from two weeks to 15 years (median age 3 years). Unlicensed medicines were prescribed for the following clinical specialities: cardiology (4 patients), dermatology (3 patients), endocrinology (3 patients), neurology (3 patients) metabolic (2 patients), and renal (2 patients). The unlicensed medicines prescribed were: beclometasone dipropionate 0.0025% ointment, clonidine liquid, colecalciferol liquid and spironolactone liquid (3 patients each); lisinopril liquid and omeprazole liquid (2 patients each) and glycine sachets, glycopyrrolate tablets, melatonin liquid, midazolam buccal solution, sodium benzoate liquid, sodium chloride oral solution and tacrolimus liquid (1 patient each). The unlicensed and off-label medicines that were prescribed are listed in Table 1.

Table 1: Medicines prescribed to the children

<table>
<thead>
<tr>
<th>Unlicensed medicines</th>
<th>Licensed medicines prescribed off-label</th>
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<tbody>
<tr>
<td>Beclometasone dipropionate 0.0025% ointment</td>
<td>Carbamazepine liquid</td>
</tr>
<tr>
<td>Clonidine liquid</td>
<td>Clobazam liquid</td>
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<tr>
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Problems and concerns

The first step to obtaining further supplies for all participants was making contact with GP surgery staff. In most cases, communication with surgery staff was reported as good, although some difficulties were faced:

P7: “What we’ve found - and we found it again this time - when he has his meds changed, the first time we had to get the prescription written up, it’s really frustrating and becomes a bit of a pain if it is not written up right… So like this time…his prescription got written up but his GP didn’t put it on repeat… Trying to explain to the receptionist…they say ‘well, the GP has not put it on repeat’, and you say ‘he’s just come out of hospital’… again, it’s sometimes like you are having to battle…”

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P6: “We haven’t seen the GP yet, they didn’t want to see us... So the GP’s never seen [my son]... But then we’ve got our 6-weekly check next week, so that’s where our confidence, I think, will get a bit better.”
A number of participants reported that their child’s GP was unwilling to prescribe the new unlicensed medicine. Perceived reasons for this were ‘cost’ (colecalciferol liquid; beclometasone dipropionate 0.0025% ointment) and that the GP was ‘not allowed’ to prescribe it (clonidine liquid; chloral hydrate liquid). In three cases, supplies from the hospital had been exhausted and parents had been unable to obtain a new supply.

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All participants were aware that the unlicensed medicine was unlikely to be immediately available at local pharmacy. However, participants expressed dissatisfaction at the time it took for the medicine to be procured, especially when they were not informed by the pharmacy staff about the anticipated waiting time. The time needed to procure unlicensed medicines was a worry for participants:

   P12: “What happens if I drop the bottle, for instance? I’m absolutely terrified I won’t be able to get any more quick enough.”

For several participants, it transpired after receiving the medicine that the formulation or strength prescribed by the GP differed to the product prescribed at ELCH. Some reported receiving a liquid medicine that was a different strength to that issued at the hospital; all reported that the change had not been communicated to them although most had identified that the resulting dosage volume needed to change. In addition to the discrepancies identified by participants, one prescribing error was identified by the interviewer: a change in formulation made by the GP (from liquid to capsules) resulted in a 10-fold dose decrease of colecalciferol. Several participants reported that the new medicine was not labelled with administration instructions.
Actions and strategies

Participants reported a variety of strategies for overcoming the issues they had encountered. Several participants who faced problems obtaining a prescription enlisted the help of other healthcare professionals - including health visitors (community public health nurses or midwives), community nurses, hospital nurse specialists and other GPs - to liaise with the child’s GP on their behalf. The perception expressed was that another healthcare professional would have more influence over the GP:

P2: “This morning I contacted my health visitor - because they seem to be very good at passing on messages and making people do what they are supposed to do - so at some point today she’s trying to get the doctor to do the prescription.”

In response to the time delay between requesting a prescription and obtaining the medicine, nearly all participants believed that planning and organisation were critical to ensure continuity of supply. This was particularly evident for participants who had prior experience of obtaining unlicensed medicines.

P7: “We've been through this now for six years - we know what's going to happen and we pre-empt things. Luckily, when we get his prescriptions - due to things like delays or having to get medicines ordered or anything like that - we always do it with at least a week’s worth of medicines still to go.”

Participants commented that the need to plan and organise prescriptions and medicine supplies caused them “worry” and “stress”. Several participants kept ‘spare’ supplies in case of loss or spillage, although the short shelf life of some medicines limited the effectiveness of this approach. Another strategy to safeguard against running out of medicines involved asking the GP to prescribe a greater quantity on each occasion. Other participants asked their pharmacy to stock the unlicensed medicine so that it would be readily available when they presented a prescription; however the responses received were variable:

P12: “[The pharmacist] said ‘we don’t order it for anybody else, so we don’t ever keep any as stock, but what I will do is... I’ll order a spare, so we will always have one in the pharmacy’. Which was lovely.”
P6: “[The pharmacist] said no, because it costs...I think they said £50 a bottle. They wouldn’t keep any in stock, which is obviously a concern.”

Five participants had contacted ELCH or their local hospital to request supplies of the unlicensed medicine after failing to obtain it locally. Others reported needing to visit several pharmacies before finding one able to supply the medicine. The possibility of not obtaining the medicine in time caused participants to experience “panic” and “frustration” and to feel “afraid”.

Views and perceptions

A common view expressed by participants was that the hospital consultant was the singular ‘prescriber’ of the medicine and the GP’s role in the supply process was to furnish the participant with a prescription to enable them to obtain further supplies from a pharmacy. One participant (P6) thought that the GP was “...just signing stuff...without really knowing what he’s signing”. They believed that the GP “...is trumped by the consultants”. Another participant described their understanding of the process:

P1: “It’s prescribed at the Evelina, but we need to go to the GP to get a prescription... It must come from the surgery but it doesn’t really come from them, it comes from [Dr at ELCH], so it is a bit confusing.”

Participants who expressed views about their interaction with pharmacy staff focussed mostly on communication. Some expressed frustration when questioned by pharmacy staff:

P7: “When...they start asking the same questions again it gets a bit frustrating. But it’s one of those things, I’d rather be questioned than not questioned to ensure that there are people looking out for [my son]’s safety.”

Others believed that greater interaction would have provided reassurance:
P6: “[They said] nothing – they just handed them over. I think it’s just that interaction... I just went up and picked them up, there was no ‘are you happy with them?’ They just gave me the bag. It was as if you went and bought some Anadin from behind the counter.”

DISCUSSION

This study demonstrates that the current approach to supplying unlicensed medicines to children has a number of major failings relating to both the prescribing and dispensing stages. Participants encountered GPs who were either unwilling to prescribe for their child, or prescribed a dose, formulation or strength of medicine that differed to what had been issued previously. Participants faced long waiting times for medicines to be procured and received minimal limited information from pharmacy staff. Many participants expressed dissatisfaction with their experience; the primary cause of this was the uncertainty of knowing whether a continued supply of the medicine was assured and therefore whether their child would receive the medicine. These experiences challenged the relationships between participants and their child’s healthcare professionals.

Some doses were missed as a result of difficulties faced by participants when attempting to obtain their child’s unlicensed medicine. Participants also reported that changes were made to the medicine’s strength or formulation. Whilst a change in product does not necessarily compromise care, unlicensed medicines are not subject to the same regulations as licensed medicines and so bioavailability - and therefore clinical effect - may vary between products. Changes to a product’s formulation or strength and omitted dosing instructions can also result in inadvertent administration errors unless such changes are explicitly explained to the parent.

Participants expected their child’s GP to prescribe, and their local pharmacy to dispense, the medicine initiated by ELCH. The participants’ expectations are logical and understandable but may not be realistic within the current medicine supply system: it cannot be presumed that a GP will agree to continue a medicine recommended by another physician and pharmacists may lack the clinical or pharmaceutical
expertise to source or dispense unlicensed medicines. Indeed, some children’s hospitals have elected to
provide long-term supplies of unlicensed medicines to patients and are reimbursed by commissioners for
delivering this service.[12]

Many participants expressed feelings of frustration, stress and anxiety from their experiences of
negotiating the transition of medicine supply between hospital and primary care. For many, a successful
outcome depended on perseverance and organisation. Some went to great lengths to ensure doses were
not omitted: making an emergency trip to hospital to collect a medicine, for example.

Some issues identified in this study may be prevented through improvements in communication between
hospital healthcare professionals and those within primary care. Earlier dialogue would ensure GPs have
the necessary information to prescribe and monitor the patient safely, or if they feel unable to assume the
prescribing role, to inform the child’s consultant prior to the child’s discharge from secondary care.
Furthermore, greater contact between hospital and community pharmacists may help those in community
to source suitable products and prevent dispensing or labelling issues. GPs and community pharmacists
who are unable or unwilling to assume responsibility should have a duty to assist the parent to liaise with
hospital staff to facilitate supply from an alternative source.

For parents and carers to be satisfied and engaged with the process of medicine supply, it is vital that they
are informed about the process and understand the roles of GPs and community pharmacists. Throughout
the transition from hospital to primary care, staff should ensure that parental expectations concerning
waiting times and quantity of supply are realistic and should highlight the common problems associated
with unlicensed medicines, such as the implication of strength changes of liquid medicines.

This study highlights the nature and severity of problems that parents and carers encountered when
attempting to obtain unlicensed medicines for their child following discharge from hospital. Strategies for
improving this process are necessary: greater dialogue between healthcare professionals is required and
greater support should be provided to GPs and community pharmacists to facilitate safe supply of unlicensed medicines within primary care. Parents and carers should be engaged throughout the transition process to ensure they understand the roles of the healthcare professionals involved and what to expect when the child’s care is transferred from hospital to community.

Acknowledgements

The Authors wish to thank the participants for sharing their experiences.

Competing interests

The Authors declare that they have no conflicts of interest to disclose.

Funding

This research received no specific grant or funding.

Sponsor

This research was co-sponsored by King’s College London and Guy’s and St Thomas’ NHS Foundation Trust.

What is already known on this topic

‘Off-label’ and ‘unlicensed’ medicines use is associated with medication risk. GPs and community pharmacists often admit to a poor understanding of licensing regulations and the implications of supplying unlicensed or off-label medicines to children.

What this study adds

Parents and carers experience problems when attempting to obtain unlicensed medicines for their child following discharge from hospital. Problems can occur at the prescribing and dispensing stage and are a source of concern and anxiety for parents and carers.
Contributorship Statement

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Conception or design of the work  
Data collection  
Data analysis and interpretation  
Drafting the article  
Critical revision of the article  
Final approval of the version to be published

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Conception or design of the work  
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REFERENCES


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