Unlicensed medicines guidance health and social care essay

Statements were found in a total of 3 (18%) policies that prescribers always hold liability for the use of unlicensed and off-label medicines. In the remaining policies, 2 (12%) stated that liability for the use of unlicensed and off-label medicines depended on the level of risk of the drug and 7 (41%) accepted that the trust would take full liability for these medicines as long as the guidance had been followed. The remaining policies had no information relating to liability.

4. 2. 7 Informing Patients

The principles detailed within policies for informing patients varied significantly between hospitals. The majority of policies ensured that patients were always made aware when they had been prescribed an unlicensed or off-label medicine; however the number of policies which ensured informed consent was always obtained was much lower. A total of 7 policies stated that the requirement to obtain informed consent was dependent on the level of risk of the medicine, for example informed consent was recommended for medicines which had been previously withdrawn due to toxicity or those with little evidence to support their use. Of these 7 policies, 2 specifically stated that informed consent was required for unlicensed and off-label medicines classified as high risk only. A patient agreement form had been developed in 1 of these policies which was required to be completed before initiating treatment with an unlicensed medicine. Conversely, 4 policies stated that no additional action beyond that taken for licensed medicines was necessary to obtain informed consent. Additionally, 1 policy stated that when seeking consent it may not be necessary to draw attention to the license status of the off-label medicine when current practice supports its use.

N = Total number of policies

(Percentage of unlicensed and off-label medicine policies)

Patient is always made aware if they have been prescribed an unlicensed or off-label medicine

N= 11 (65%)Limited information: 2 (12%)

Patient is made aware if they have been prescribed an unlicensed or off-label medicine dependent on the level of risk the medicine carries

N= 3 (18%)Limited information: 2 (12%)

Prescriber uses their judgement as to whether to inform patients or not

N= 0Limited information: 2 (12%)

Informed consent for use of unlicensed and off-label medicines is always obtained

N= 4 (24%)Limited information: 2 (12%)

Informed consent for use of use of unlicensed and off-label medicines is good practice only

N= 1 (6%)Limited information: 1(6%)

Informed consent for use of unlicensed and off-label medicines must be documented

N= 5 (29%)

Implications of unlicensed and off-label medicines must be communicated to patients

N= 11 (65%)Limited information: 3 (18%)

Pharmacy staff confirm patients awareness of unlicensed and off-label medicines

N= 4 (24%)

Pharmacy staff provide advice about unlicensed and off-label medicines

N= 6 (35%)

Standardised information leaflets are given to patients about unlicensed and off-label medicines

N= 11 (65%)Table 4. 2. 7: Table to show the number of policies containing checklist statements surrounding informing patients. The majority of policies stated that standardised patient information leaflets should be used; however within 2 policies these leaflets were only required for medicines classified as high risk only. Within another 2 polices the guidance stated that traditional patient information leaflets listing the licensed indications of the medicine should be given to patients, and the difference explained to avoid misunderstanding.

Part 5. Discussion

5. 1 Key Findings

5. 1. 1 Questionnaire Findings

A lower percentage of policies were implemented for off-label medicines (40%) than for unlicensed medicines (90%), and interestingly 1 hospital had neither policies for unlicensed nor off-label medicines implemented. It is difficult to establish in detail exactly how these medicines are managed by hospitals without either policy implemented as few additional comments

were made by these hospitals. Just 3 hospitals conducted audits for unlicensed medicines, 1 of these also audited off-label medicines, all of which were conducted within the last 12 months which indicates these audits are fairly regular. Continuous monitoring was followed by 4 hospitals however it is unknown exactly what this involved. Interestingly answers within the Informal Procedures section indicated a low involvement of the trusts' management groups within these settings. This could possibly indicate that the responsibility for managing unlicensed and off-label medicines lies with the responsibility of the prescriber, as the analysis of 3 policies in other UK hospitals, also indicated.

5. 1. 2 Unlicensed Medicines Guidance

A key finding was that unlicensed medicines were managed in very similar ways within the more comprehensive hospital policies. The more detailed policies applied to all healthcare professionals who may encounter these medicines within a hospital setting, and clearly outlined their responsibilities. The overlap between policies was very common, but was found in particular with 2 policies identified from the literature search. Another policy also referenced 8 NHS trust hospital policies as information sources; 4 of which were identified in this literature search, which may account for some similarity found. The main differences between these overlapping policies were the responsibilities and which healthcare professionals they applied to. For example, 7 hospitals had assigned a designated pharmacist who had overall responsibility for unlicensed and off-label medicines, whereas hospitals without a designated pharmacist generally shared this responsibility across all pharmacy staff. The principles listed under the GMC

guidance for doctors for managing unlicensed and off-label medicines was directly copied into 5 policies, and reworded in the majority. The reproducibility of these unlicensed medicine policies highlights a possibility for integration of guidelines. An interesting finding was that within 2 policies for unlicensed medicines and 1 for off-label medicines, the guidance principally focused on informing patients and on the transfer of prescribing into primary care. Within these 3 policies there was very little information on how these medicines are managed within the hospital; they contained some generic principles for prescribers only.

5. 1. 3 Off-label Medicines Guidance

Another key finding was the lower number of policies found for off-label compared to unlicensed medicines; just 4 off-label medicine policies were found for North West hospitals compared to 9 for unlicensed medicines, and 8 policies out of a total of 13 identified in the literature search were for off-label medicines. Comments made in the questionnaire highlighted the difficulty that exists when managing off-label medicines which could be reflected by the lower number of policies for these medicines. Several policies stated that pharmacists should ensure the prescriber is aware that a medicine is being used off-label, when such uses can be inferred from the prescription. However no systems were implemented in policies which make pharmacy staff aware of a medicine being used off-label; this highlights the difficulty that exists in identifying off-label medicines. Off-label medicine request forms were not included within the analysis checklist, but were in fact developed within 5 hospitals. However it is unknown how frequently these off-label request forms are used in practice; 2 policies restricted their

use for high risk off-label medicines only and 1 policy accepted their use was not always feasible, for example within paediatrics. Nevertheless, these may have been developed as an attempt to help monitor off-label medicine usage within these hospitals. Interestingly, comments made within the questionnaire suggested that off-label medicine usage was relatively common within the sector of mental health compared to the low frequency of unlicensed medicines. Consequently, all 4 hospitals identified as being within this sector had an off-label medicine policy implemented. The higher frequency of medicines used off-label within this sector may explain why these hospitals do not routinely audit, but continuously monitor these medicines instead. Within 1 of these mental health hospitals, their unlicensed medicines policy was much more detailed compared to their policy for off-label medicines. This is interesting as the respondent commented in the questionnaire that off-label medicines were relatively common in practice yet unlicensed medicines were quite rare, and sometimes non-existent. Prescribers themselves were required to assess whether an off-label medicine fell into 1 of 2 risk categories, which subsequently affected which action needed to be followed. The guidance itself stated this categorisation was a " grey area". After assigning a risk category, the guidance itself was quite limited; for example prescribers were required to follow any " authoritative guidance available" for medicines classified within a level 1 risk category. The regulation of medicines used off-label within this setting had virtually no involvement from the DTC, but was largely the prescriber’s responsibility. It is possible that the high level of medicines used off-label in this hospital meant it was not feasible for these

medicines to be managed in the same thorough way as unlicensed medicines.

5. 1. 4 Quality

The majority of policies contained comprehensive information for the procurement of unlicensed medicines; detailing which hospital staff should purchase these medicines, who should be informed of the purchase, which suppliers to use, how to assess their quality as well as how to assess specifications from new suppliers. These policies also detailed the record requirements and outlined that these records should legally be kept for 5 years. The pharmacy department was stated as having responsibility for procurement within 69% of policies. Interestingly, only 31% of policies stated that the pharmacy maintains a list of approved suppliers of unlicensed medicines. Several policies mentioned " NHS approved" sellers of unlicensed medicines; it is therefore possible that approved suppliers are listed within hospital pharmacy Stand Operating Procedures (SOPs) but not detailed within these policies. No policies detailed the guidance that should be followed for the extemporaneous preparation of unlicensed medicines i. e. products manufactured under Section 10 of the Medicines Act, 1968. However it was outlined in 38% of policies that the pharmacist who prepared (or ordered) the unlicensed medicine was legally considered to be the manufacturer. This area of unlicensed medicines was stated as being specifically excluded from several policies; although 1 policy stated their hospital pharmacy’s SOP should be followed. It is unknown whether SOPs implemented in hospital pharmacies are developed around the same specific

guidance, such as the " Handbook of Extemporaneous Preparations" as previously discussed, and whether it is standardised between NHS trusts(6).

5. 1. 4 Informing Patients

This study was particularly interested in whether patients or carers are informed when they have been prescribed an unlicensed or off-label medicine. The majority of policies (65%) state that patients should always be made aware when they have been prescribed an unlicensed or off-label medicine, and the implications of such medicines should be communicated to patients. Only 24% of policies state that pharmacy staff confirm patient's awareness if they have been prescribed such medicines; the responsibility for informing patients in the majority of policies therefore lies with the prescriber, as additional questionnaire comments also suggested. Standard leaflets were developed by 65% of policies to help patients understand the implications of their treatment with an unlicensed or off-label medicine. Systems were described in just 25% of policies to alert pharmacy staff that an unlicensed medicine was being prescribed, and no such systems were described for alerting pharmacy staff of a medicine being used off-label. Additional comments were made by 4 North West hospital pharmacists stating that unless a member of the pharmacy department is part of the multidisciplinary team, then the off-label use of a medicine largely goes unnoticed. If pharmacy staff are unaware of an unlicensed or off-label medicine being prescribed, this could raise the question of whether pharmacy staff are dispensing these leaflets to patients. Furthermore, poor awareness of pharmacy staff may also affect patients' understanding within the 35% of hospitals without leaflets developed. The generic patent

information leaflet (PIL) which is dispensed with an off-label medicine will not reflect the patient’s treatment accurately, and if pharmacy staff are unaware that a medicine is being used off-label then this difference may not be explained to patients. Therefore this could raise safety issues if patients do not take their medicine as intended. A total of 11 policies had developed standard leaflets to help patients understand about their unlicensed or off-label medicine; 9 leaflets were found within an appendix to these policies. Leaflets were developed to explain both unlicensed and off-label medicines within 4 policies, and leaflets for just unlicensed medicines were developed in 5 hospitals, 1 of which also had a parent or carer version for use within paediatrics. The leaflets had similarities; 4 leaflets lacked much information but stated that the patient’s doctor has chosen to prescribe an unlicensed medicine, who to direct any further questions to, and information for obtaining further supplies. The other 5 leaflets were much more comprehensive, containing a broad overview of unlicensed medicines in a way that was easy to understand; 4 followed almost identical formats and the 5th followed a very similar question and answer layout. There is no legal requirement to obtain informed consent of patients when prescribing an unlicensed or off-label medicine(7). This may reflect why a lower percentage of policies (24%) required that informed consent was obtained, compared to the 65% which required patients to be made aware they have been prescribed an unlicensed or off-label medicine. The GMC guidance states that patients should be given sufficient information about their medicine to make an informed decision, however in some circumstances it may not be necessary to draw attention to the licence status of the medicine for example, when a realistic alternative treatment does not exist(7).

5. 2 Implications of the Study

5. 2. 1 Strengths

The major strength arises from the novelty of this study; no previous studies have been identified which have explored how unlicensed and off-label medicines are managed in UK hospitals. Studies of this type, which explore how these medicines are managed in individual hospital settings, could aid the implementation of national guidelines. Another strength of this study was the design of the data collection tool that was developed, which fulfilled the aims of the study. The self-completion questionnaire was simple to distribute and allowed key information to be collected about the management of unlicensed and off-label medicines. The request for policies to be returned meant it was quicker and easier for respondents to complete the questionnaire too. These factors may have contributed to this questionnaire achieving a response rate of 77%. Finally, this study required hospital pharmacists to reflect on their trust's current management of unlicensed and off-label medicines which consequently, may have influenced existing practice. Two respondents commented in the questionnaire that they believed audits of unlicensed medicines should be conducted within their trusts, and the same comment was made by another respondent for off-label medicines. Similarly, another hospital pharmacist commented that they were considering conducting an audit for unlicensed medicines, once their trust's policy was ratified. This study discusses several major implications arising from these medicines and also highlights various procedures that hospitals follow regarding their management. These procedures may be considered by other hospitals when their current policies are next reviewed.

5. 2. 2 Limitations

In order to fulfil the objectives of this study, this data collection tool relied heavily on respondents returning copies of hospital policies with the questionnaire. The statement requesting that respondents attach copies of their policies was repeated several times within the questionnaire. Questionnaires were also distributed via email after acknowledging that online copies of policies could easily be attached to emails. Therefore, the major limitation of this study was the low number of policies returned, as only 40% of respondents also attached copies of their policies. Similarly, some of the policies returned with the questionnaire made reference to separate policies, such as their hospital's guidelines for informed consent. Had these additional policies also been returned, they would have provided a better insight into different management procedures followed within the hospital. Limitations also arise from the time constraints which were imposed on this study. A cut-off date was set for questionnaires to be returned by, which subsequently affected how many questionnaires were included in the study. Time constraints meant that exploring other UK regions and using alternative data collection tools such as interviews with pharmacists, were not feasible. Finally, the search strategy itself which relied on the internet as a source for hospital policies gave rise to a limitation, as policies may have been revised since being published online. The earliest policy identified from the literature search was written in 2008, and it is possible that the content of these updated policies has changed slightly since their review date.

5. 3 Recommendations for Practice

5. 3. 1 Integration of Hospital Policies

The majority of polices contained comprehensible and similar approaches for managing unlicensed and off-label medicines, however there is still no centralised approach between hospital trusts for managing these medicines. The majority of policies follow a similar management structure; whereby the DTC, or equivalent, has constructed a list of commonly used unlicensed medicines which bear some degree of safety and quality assurance, making them suitable for initiation by prescribers within the hospital. The broader policies also have similar approaches implemented for the management of medicines used off-label. The majority of policies have adopted a classification system for medicines contained on these lists, with varying restrictions and requirements for medicines within each category. Prescribers wishing to use an unlicensed or off-label medicine not contained on this list, must submit standardised request forms for consideration by the DTC. A thorough risk assessment is then conducted to assess the safety, efficacy and quality of such medicines, during which prescribers must await approval prior to initiating treatment. However the risk assessment process that many hospitals conduct are not currently standardised between NHS trusts(9). This leads to the recommendation that following review of hospital guidelines elsewhere in the UK, integration would be beneficial in order to produce national guidelines to guide NHS healthcare practitioners. This study highlights there is a role for NICE in taking a lead on this work, for the establishment of a standardised approach across the UK. Although NICE has occasionally recommended the off-label use of medicines within their clinical

guidelines, this does not constitute formal guidance(15). National guidance would mean hospitals with less comprehensive guidelines would also benefit, such as the 3 previously mentioned policies which contained very little information for managing unlicensed and off-label medicines.

5. 3. 2. Informing Patients

Standard leaflets were described in 65% of policies to help patients understand the implications of their treatment; it would be beneficial if all hospitals developed these leaflets for both unlicensed and off-label medicines. The more comprehensive leaflets were used within 5 hospitals and followed an almost identical format; these could be used as templates to formulate leaflets in other hospitals. Dispensing generic PILs to patients will not reflect the patient's treatment accurately, which may lead to non-adherence and potential patient harm. Using standard leaflets whenever possible will help patients be adequately informed about their medicine, as outlined within the relevant GMC guidance(7). Section 5. 3. 4 discusses how to overcome the poor awareness amongst pharmacy staff of medicines used off-label. This is important to help ensure that pharmacy staff are indeed dispensing these leaflets to patients, when prescribed such medicines. The majority of policies (65%) require that patients are made aware when they have been prescribed an unlicensed or off-label medicine. This study acknowledges that within the 35% of hospitals without this requirement detailed within policies, prescribers may in fact be informing patients. However due to the risks associated with these medicines it is recommended that all hospitals develop protocols within their policies for informing patients, as a matter of good practice.

5. 3. 3. Audits for Unlicensed and Off-label Medicines

Within North West hospitals, just 3 audited unlicensed medicines and just 1 audited off-label medicines. Comments were made in the questionnaire by 2 respondents, stating they believed audits for unlicensed medicines should be conducted within their hospital, and 1 respondent made the same comment for off-label medicines. The hospital with guidance currently under development commented that audits for unlicensed medicines may be conducted after ratification of their policy. The recommendation is that clinical audits should be enforced by these respondents and indeed be considered by those hospitals which did not audit these medicines, if feasible within these settings. Auditing these medicines would help to assess adherence to guidelines, address any safety issues and help with the long term monitoring of two risky classes of medicines. Audits may also help to implement changes within these settings to improve the awareness of pharmacy staff and achieve patients' awareness and understanding.

5. 3. 4. Off-Label Medicines Management

As previously discussed, a lower number of policies addressed the management of off-label medicines compared to unlicensed medicines, despite risks being associated with both classes of medicines. No policies described systems implemented to make pharmacy staff aware of a medicine being used off-label. It was also highlighted in the questionnaire by 4 respondents that unless a pharmacy member was part of the multidisciplinary team, then such off-label medicines largely go unnoticed. The first recommendation is for the development of approaches to overcome this. One approach is for prescribers to endorse prescriptions to alert

pharmacy staff of an off-label medicine, as 2 policies described for unlicensed medicines. Alternatively, alerts could be entered into computer systems for those off-label medicines which are routinely used in certain hospitals, as 2 policies described for unlicensed medicines. These alerts could state the most common off-label uses of that medicine within that hospital, which might improve the awareness of pharmacy staff. The second recommendation is for a national approach to be developed in the UK to regulate off-label medicines. As previously mentioned, the off-label medicines policy within 1 hospital relied on the prescriber assigning a risk category for the medicine which consequently determined how the medicine was managed. Although the risk assessment processes between NHS trusts are similar, they are not standardised. Regulation has been demonstrated to some extent elsewhere; France has recently introduced a new legislation to aid the national regulation of these medicines(19). This new concept was heavily influenced by a single off-label drug, whose use over 33 years was linked to an estimated 500-2000 deaths(20). This framework which was introduced in 2012, involves awarding " Temporary Recommendations for Use" also referred to as a TRUs, to particular off-label medicines for a maximum period of 3 years(19). A TRU allows pharmaceutical manufacturers to extend the indications listed under the current marketing authorisation of a drug(19). A TRU is granted alongside strict conditions; patients must be continually monitored, and safety and efficacy data must be collected(19). This new regulatory approach aims to formalise the risk-assessment process conducted for off-label drugs, gain improved national control for off-label prescribing and potentially develop new indications for drugs(19).

Information reflecting the long term effectiveness of this approach is not

available, as this new framework is still very recent. If shown to be successful, the UK may benefit from adopting a similar regulatory approach.

5. 4 Future Research

This study had a particular interest in patients' awareness and understanding of unlicensed and off-label medicines, when prescribed such treatments. This study focused on the guidance contained within hospital policies surrounding informing patients. Further research into this area could explore whether this guidance is being followed in hospitals, for example with the use of audits to assess whether patients are indeed being adequately informed. The questionnaire used within this study contained a section about informal procedures followed within hospitals. A more in-depth qualitative study, for example interviews with Chief Pharmacists, would be useful to establish any informal procedures which may be unique to hospitals, and which may not have been commented on within the questionnaire nor included within their hospital guidelines. Finally, further research would help to establish exactly how the transfer of prescribing is managed for unlicensed and off-label medicines, which are initiated in hospitals and continued into primary care. Specifically, it could be determined whether GPs are indeed informed when a patient of theirs has been initiated on such treatments, the course of action followed should GPs refuse to continue prescribing these treatments, and any other issues arising from the transfer of care. Just one study was identified in the literature search which examined the problems for patients when obtaining further supplies of unlicensed medicine upon discharge(12). It would be interesting

to establish whether the PILs given to patients contain sufficient information about availability to overcome this problem.

Appendices

Appendix 1.

Table A: Identification of Issues Surrounding Use of Off-label and Unlicensed Medicines

Study

Reference

Aim

Setting

Perspective

Summary of Results

National study of extemporaneous preparations in English paediatric hospital pharmacies

Yeung. VW, Tuleu. CLC, Wong, ICK. 2004 (11)To identify the types of extemporaneously prepared medicines, their frequency and method of production. To compare this to the number of preparations available from specials manufacturersSeven English paediatric hospitals(Alder Hey Hospital in Liverpool, Birmingham, Royal Alexandria Hospital in Brighton, Derby, Great Ormond Street Hospital in London, Manchester, Sheffield)Hospital pharmacistsA national survey surrounding extemporaneous formulations was developed and distributed. Over the 1 year study period, 3729 preparations were recorded. Extemporaneously produced products constituted a high proportion of the workload (58%). Over a quarter of preparations were

unlicensed and 52% were available from specials. Reasons for not using specials included short expiry dates, cost, wastage and lack of instant availability. Quality was known to be compromised due to the method of cutting and grinding tablets, inconsistent procedures, varying ingredient qualities and therefore unknown bioavailability.

Association between licence status and medication errors

Conroy. S. 2011 (4)To determine the relationship between medication errors and licence status. Paediatric ward and neonatal intensive care unit, Children’s hospital (Derbyshire Children’s Hospital)Health care professionals in paediatricsThis study relied on hospital staff to detect and report medication errors. Over the 2 year study period, all 158 reports were analysed. Errors causing moderate harm were significantly more likely to be related to unlicensed and off label drugs than licensed drugs. Unlicensed drugs used in paediatrics and neonates were significantly more likely to be related with errors than licensed drugs. Prescribing errors including incorrect doses, dispensing errors including labelling and packaging mistakes and administration errors involving lateness of doses were acknowledged as being the main causes.

Adverse drug reactions to unlicensed and off-label drugs on paediatric wards: a prospective study

Turner. S, Nunn. AJ, Fielding. K, Choonara. I. 1999(10)To determine the frequency of adverse drug reactions (ADRs) to unlicensed and off-label drugs. Children’s Hospital (Alder Hey Children’s Hospital, Liverpool)Health care professionals in paediatricsThe clinical research pharmacist collected data on all patients and the medicines they had been prescribed. Over a 13

week study period of 5 paediatric wards, 4455 prescriptions were administered to patients and 35% were either unlicensed or off-label. A significant relationship was found between ADR risk and unlicensed or off-label medicine use; ADRs were associated with 3. 9% of licensed drugs and 6% of unlicensed or off-label drugs. Children on high numbers of drugs are more prone to suffering an ADR, as are critically ill children with changes in their metabolism.

Supply problems of unlicensed and off-label medicines after discharge

Wong. IC, Basra. N, Yeung. VW, Cope. J.(12)To determine the availability of unlicensed and off-label medicines for patients and carers post-dischargeCommunity, post-dischargeCommunity pharmacists and patientsPatient discharge forms were reviewed over the 3 month study period; 5976 medicines were dispensed for 338 paediatric patients, 12% were unlicensed or off-label medicines. 72 carers of patients experienced difficult in obtaining medicines, 26 of these reported GPs who refused to supply the treatment, 19 whose local pharmacy did not stock the treatment and 19 whose pharmacy was unable to supply the right formulation. Pharmacies found difficulty locating manufacturers, experienced manufacturers who were unable to produce the appropriate formulation, or were themselves reluctant to keep stocks of specials due to their short expiry dates. This study acknowledges treatment disruptions can be harmful and even life-threatening.

Healthcare professionals' understanding of children's medicines

Venables. W, Marriott. J, Stirling. H. 2012 (21)To determine paediatric healthcare professionals level of understanding of the licence status of medicines they are prescribing or administeringHospital (University of Birmingham, University Hospital Coventry and Warwickshire)Physicians, nurses and pharmacistsWritten questionnaires asked for the following definitions: off-licence, off-label, specials, NICE approved and marketing authorisation. 32 questionnaires were completed; 12 from paediatric consultants, 9 from paediatric trainee doctors, 4 from senior paediatric nurses and 7 from pharmacists. 40% of answers were defined correctly, 17. 5% were partially correct and 42. 5% were incorrect or unknown. This study acknowledges healthcare professionals may be unaware of potential implications of these medicines including supply problems, variations in formulation pharmacokinetics or cost.

Healthcare professional experiences and attitudes on unlicensed/off-label paediatric prescribing and paediatric clinical trials

Mukattash. T, Hawwa. A. F, Trew. K, McElnay. J. C. 2011 (14)To determine the knowledge and views of a variety of healthcare professionals concerning unlicensed and off-label medicines in childrenHospital and communityGPs, community pharmacists, paediatric consultants and paediatric nursesWritten questionnaires were developed and 563 were completed; 59. 8% from GPs, 32. 8% from community pharmacists. 72% of consultant paediatricians and 43. 3% of paediatric nurses replied. 51. 7% of respondents learnt about unlicensed and off label medicines from their working practices rather than

training. 23. 8% of respondents admit having experienced treatment failure and 11. 2% an adverse drug reaction when using unlicensed or off-label medicines in children.

Adverse drug reactions in a paediatric intensive care unit

Gill. A. M, Leach. H. J, Hughes. J, Barker. C, Nunn. A. J, Choonara. I.(22)To determine the frequency and severity of adverse drug reactions in critically ill infants and childrenChildren's Hospital (Alder Hey Children's Hospital, Liverpool)Health care professionals in paediatricsThe clinical research pharmacists reviewed all reports during the 28 month study period. Hospital staff were urged to report adverse drug reactions using a scheme developed in the hospital. 86 adverse drug reactions were recorded in 899 patients. 76 adverse drugs reactions were included in the study; 35 drugs were involved and 25 of these were drugs used outside of their product licence and 1 was an unlicensed drug. Critically ill patients are monitored more extensively so this study acknowledges that results may not be applicable to all paediatrics settings.

Extemporaneous (magistral) preparation of oral medicines for children in European hospitals

Brion. F, Nunn. A. J, Rieutord. A. (13)To determine the methods of extemporaneous formulation of oral medicines in European children's hospitals. To establish if these medicines are available as licensed products in other countries. Children's Hospital (Alder Hey Children's Hospital, Liverpool and Robert Debré Hospital, Paris)Paediatric hospital pharmacistsWritten questionnaires were distributed and 21 hospital pharmacists from 16 European countries were completed. 75% of the top 20

oral liquids, 75% of the top 20 capsules and 30% of the top 20 powders were available as licensed preparations in other European countries, USA or Australia. This study suggests manufacturers should make licensed preparations available to other countries. However only 1 or 2 questionnaires were retuned for each country which is insufficient to extrapolate these conclusions to the whole country.

Appendix 1.

Table B: Identification of hospital policies (studies)

Study

Reference

Aim

Setting

Perspective

Assessment for need of guideline

Recommendations

Unlicensed medicines: risk and reward

Houston. J, Tolan. J, Kean. D, Drain. M, Kerr. A, Brady. A. 2010(17)To develop a risk assessment procedure to manage unlicensed products for use within the hospital. Hospital (Belfast City Hospital)Consultants and pharmacy services managementA risk assessment of all 139 unlicensed medicines used within the hospital was conducted; 57. 6% were low risk, 7. 9% minor risk, 20. 1% as moderate and 14. 4% major risk. 65. 5% of unlicensed medicines in the hospital were classed as low or minor risk, and did not

require records for supply. A new policy resulted in a standardised scheme for categorising unlicensed medicines. This scheme resulted in reduced administration work in the dispensary by 75% and removal of 109 unlicensed medicines not currently used within the hospital. Alerts were added to the pharmacy computers to notify pharmacy staff of the category of the medicine and its risks. Consequently, low risk medicines were made available as ward stock. All new unlicensed medicines will be classified using this new classification scheme.

Adherence to prescribing unlicensed medicines policy: a clinical audit

Hyung. J. W, Safiee. A, Hitch. G. 2012 (16)To determine from the audit whether prescribers in the hospital are adhering to the Trust's Prescribing Unlicensed Medicines Policy requirements. Hospital (Moorfields Eye Hospital NHS Foundation Trust, London)PrescribersAfter a review of 337 prescriptions; 79. 2% were for unlicensed eye drops, 17. 5% were for equivalent licensed alternatives. The Trust's policy states an unlicensed medicine should be prescribed only if an equivalent licensed does not exist; therefore this requirement was not met. 20% of prescribers noted their wish to use an unlicensed medicine on both prescriptions and patient medical records. The Trust's policy states the use of an unlicensed medicine should be discussed with the patient and noted in their medical records; therefore this requirement was not met. Actions have been made to notify prescribers in particular of the legal problems of unlicensed medicines, the importance of informed consent and role of the pharmacist when dispensing unlicensed medicines. Presentations surrounding clinical governance and medical

induction days have been conducted for prescribers. The Trust’s Prescribing Unlicensed Medicines Policy has been revised and made available to prescribers. This includes a list of equivalent licensed medicines that are available. The outcome of these changes will be determined in a subsequent re-audit.

Developing a database to manage use of unlicensed medicines[1]

Townsend. P. (18)To manage administrative requirements necessary to dispense unlicensed medicinesChildren’s Hospital (Birmingham Children’s Hospital)Pharmacy staff440 different lines of unlicensed medicines were used in the hospital. Information was taken from product monographs which had been prepared by pharmacy stuff over the years, inputted into the database, linked to a product image and checked by the hospital formulary pharmacist. Patient details are also inputted, however due to the high frequency of unlicensed medicine usage at this hospital, these details are only recorded for high risk medicines. Information about incoming unlicensed medicines, such as expiry dates and batch numbers can be stored, which complies with the Trust’s Unlicensed Medicines Policy which states this information must be kept for 5 years. If a medicine’s licence status changes, this is updated on the system. The database is a fully functional reference source. In the future, there is an option to make this database available to other hospitals.