Introduction

It is estimated that £110 million of prescription medicines are returned unused to community pharmacies in England each year.[1] Under current regulations, medicines that are returned unused to pharmacies in the United Kingdom (UK) cannot be supplied (or redistributed) to other patients.[2] As such, they are treated as waste and subsequently destroyed.[2] It is also known that some unused medicines that are not returned to pharmacies are disposed of via waste water systems, with pharmaceutical chemicals having been detected in aquatic environments in the UK as well as elsewhere.[3] There is, therefore, considerable interest in decreasing medicines wastage, not only because of the economic burden it places on health systems and societies, but also due to the environmental issues associated with the disposal of unused medicines.[1,4,5]

Not all prescription medicines wastage is preventable or the result of poor prescribing practice.[1] A proportion of waste is considered to be unavoidable, arising from medicines being discontinued by a prescriber after failing to achieve the desired therapeutic effect, adverse effects leading to discontinuation or patient death.[1,6,7,8] As it is inevitable that a proportion of prescribed medicines will be returned to pharmacies unused, it is, perhaps, unsurprising that there has been much discussion concerning the redistribution of returned medicines.[8-13]

At present, medicines which have left the pharmacy (or hospital) and are subsequently returned are not redistributed within the UK due to the commonly cited barriers of tampering and storage.[14] It is believed that the quality and safety of returned medicines cannot be guaranteed as there is the potential for these medicines to be tampered with or stored in inappropriate conditions.[14] Similar barriers towards the redistribution of medicines seem to be perceived internationally as only a small number of reports of operational redistribution schemes are to be found in the literature.[15-18]

Several authors have argued that the use of 'newer' packaging technologies, such as tamper evident seals and temperature sensitive smart labels, could act as solutions to the commonly cited barriers to redistribution (tampering and storage).[8,9,10] Additionally, a survey of healthcare professionals (HCPs) in the North East of England found that the majority of pharmacist respondents (61.6%, n=95) would be happy for their patients to receive a redistributed medicine in certain circumstances.[12] Although much has been written around medicines redistribution, the majority of articles are non-peer reviewed opinions, with little research published on this topic. Given the potential financial and environmental benefits of redistributing medicines, the aim of the present study was to investigate whether or not consensus could be achieved between pharmacists on the barriers and potential solutions they perceive towards the redistribution of medicines in the UK.

Methods

Study Design

A modified Delphi design was used to address the aim of the study. The classical Delphi design was modified in two ways: 1) qualitative interviews replaced the typical first round questionnaire comprised of open ended questions and 2) questionnaires were distributed to participants via email in preference to postal dissemination.

Study Setting and participants

The study was conducted within the geographical boundaries of one Health Board (HB) in the South East of Wales between June and November 2014. The HB Research and Development Department deemed that NHS research ethics approval was not required. Legislative powers for health and health services are devolved to the National Assembly for Wales and the Welsh Government by the UK Parliament. Since 2007 all patients registered with a Welsh General Practitioner (GP) who have prescriptions dispensed from Welsh pharmacies receive prescription medicines free of charge.

Pharmacists working within the HB who were involved in the 'day to day use of medicines (prescribing, supply, administration and monitoring)' were eligible to participate in the study.

Overview of Delphi

The Delphi technique, a consensus method with iterative rounds of questionnaires, was employed as it can be used to define levels of agreement in areas which are prone to debate.[19] It was pre-determined that there would be two rounds of questionnaires to reduce respondent fatigue and to satisfy the research time-frame. A similar two-round Delphi design was recently adopted in another study.[20]

A pharmacist only expert panel was selected as it was considered unlikely that enough medical and nursing professionals would be recruited to form a heterogeneous panel of sufficient size. This conclusion was reached after an appraisal of the response rate to the invitation for interview from these professional groups and acknowledged the previously reported poor response rates of general practitioners to survey research.[21]

While no single sample size is advocated for Delphi studies, sample sizes of 10 to 15 are considered sufficient for homogenous panels such as the panel in this study.[19] It was therefore decided that a panel size of between 10 and 20 would be used for this study.

Item Generation

Statements for the first round Delphi questionnaire were generated from qualitative interviews which sought the views of healthcare professionals on the barriers and potential solutions they perceived towards the redistribution of medicines. Interviews were conducted with 14 pharmacists (5 hospital, 4 community, 5 primary care), 7 nurses (3 hospital, 4 based in GP practices) and 6 doctors (4 GPs, 2 hospital). Interview participants were recruited by an email which was sent out to all nurses (n=536) and doctors (n=170) employed by the medical directorate, all hospital (n=70) and primary care pharmacists (n=11) and all GP practices (n=46) and community pharmacies (n=77) in the HB. This self selecting sampling method was adopted as a request for lists of nurses, doctors and pharmacists employed by the HB, to enable a purposive sampling strategy, was denied. All those responding positively to the initial invite to interview were subsequently interviewed. The interview schedule was developed from the existing redistribution literature and was piloted on a hospital pharmacist, a community pharmacist, a hospital nurse and a GP. Interviews were recorded and then transcribed verbatim using Microsoft Word 2013®. Individual statements for the questionnaire were formulated for each potential barrier and solution identified from the interview transcripts which were relevant to the background scenario presented to panellists (see bellow). Where possible, statements were composed of less than 25 words using simple vocabulary.[22]

Round 1

Thirty seven statements were generated for the first round questionnaire, with 26 statements (Table 1) categorised as barrier statements and 11 as solution statements (Table 2). Barrier statements were further sub-categorised into four sections according to the type of barrier they related to, as detailed in Table 1. Statements were rated on an ordinal scale, from 1 to 7 (where 1 equated to strongly agree, 4, neither agree or disagree, through to 7, which equated to strongly disagree) based on whether respondents felt that the issue described represented a barrier or solution to the redistribution of medicines.[23]

The expert panel comprised pharmacists with daily involvement in the prescribing, supply or monitoring of medicines. The panel was recruited via an email invitation forwarded by the Personal Assistant to the Head of Medicines Management to all hospital (n=70) and primary care pharmacists (n=11) employed within the HB and by the Lead Pharmacist for Community and Primary Care Pharmacy to all community pharmacies (n=77) in the Health Board. The email contained an attachment which provided potential panellists with information about the study and the first round questionnaire (also as an attachment). Panellists were also given the option of completing a paper based version of the questionnaire. Where panellists opted to complete a paper based version, the questionnaire was posted with a stamped addressed envelope included for completed questionnaires. Questionnaires for both rounds were distributed to the panel with a 2-week deadline for responses. The first round questionnaire was piloted by four hospital pharmacists independent of the expert panel with ambiguities identified resolved prior to distribution. Based on feedback from the qualitative interviews, a single redistribution scenario was presented to the panel to increase validity of the results and limit the size of the questionnaire. The panellists were asked to consider the following background scenario when rating the statements in the questionnaire: "The supply of prescription only tablets and capsules which have previously been returned in their original blister packs (i.e. complete strips) and original outer packaging by other patients." In both rounds, space was provided below each statement for participants to justify their response or make comments about the issue described. In the first round only, space was provided at the end of each section for participants to suggest barriers or solutions which were not included in the questionnaire.

Completion and return of study questionnaires was taken as implied consent as it considered that fully informed consent for questionnaire based studies can only be achieved once participants have had a chance to assess study materials.[24]

[Insert Table 1 here]

[Insert Table 2 here]

Round 2

Five additional statements were formulated and added to the second round survey following suggestions from participants and analysis of comments made in round 1. One statement was categorised as a barrier and was sub-categorised as relating to safety. Three solution statements were also added for round two. The second round questionnaire was piloted on three hospital pharmacists independent of the expert panel. Minor amendments based on the feedback received from the pilot were made to the questionnaire prior to dissemination.

In the second round questionnaire panellists were presented with their own personal score for each statement and the median score of the panel for each statement. Additionally, anonymised comments made by panellists about individual statements in the previous round were also included as feedback. Panellists were asked to consider the feedback provided by other panel members and the median panel score from the previous round and were offered the opportunity to re-score each statement. Panellists were also advised that they did not have to re-score statements if they did not wish to.

Data management and analysis

As in previous Delphi studies, the interquartile range (IQR) was employed to describe the degree of agreement between the panel, with an IQR of 1 or less selected *a priori* to represent consensus.[25] There is an absence of clear guidance on which measure of consensus should be used for the Delphi Technique, with the reporting of the rationale for the selection of this criteria limited in published studies; the use of the IQR to determine consensus is, however, considered to be robust.[26,27]

The quantitative data from the Delphi rounds were analysed using Microsoft Excel®. The ordinal nature of the data dictated that the median be used to describe the response of the panel.

Results

Of the 158 pharmacists invited to participate in the study, 18 indicated that they were willing to participate in the Delphi study. Seventeen of the 18 (94%) pharmacists invited to participate in the Delphi completed round one. All seventeen pharmacists who completed round one completed round two. A breakdown of panellists by main sector of practice is given in Table 3. Fourteen participants completed the questionnaire electronically, responding by email (with the completed questionnaire as an attachment), with the remainder (n=3) electing to complete a paper based version of the questionnaire. Nine members of the Delphi panel had also participated in the qualitative interviews in the study (3 community pharmacists, 1 hospital pharmacist and all 5 primary care pharmacists).

[Insert Table 3 here]

Statements achieving consensus

Consensus was achieved for 7 barrier statements (27%) following the second round (Table 1). Two statements from the 'Safety' sub-category, 3 from 'Quality' and 2 from the 'Scheme' category reached consensus. No statements from the 'Patients' sub-category achieved consensus. The highest level of agreement was achieved for statement B25 (100 %). The IQR for all statements (apart from B13, which remained the same between rounds) decreased between rounds indicating a move towards agreement between the panel. Statement B27 was the only statement which was added following the first round to achieve consensus. Consensus was achieved for 7 solution statements (50%) following the second round (Table 2). All panel members (17/17) agreed with statements: S11, S1, S7 and S10. The IQR for all statements (apart from S11 and S7 which remained the same between rounds) decreased between rounds. None of solution statements added following the first round achieved consensus.

Discussion

This Delphi study found agreement between pharmacists on potential barriers and solutions they perceive towards the redistribution of medicines in solid dosage forms. Consensus was reached that the appearance and smell of the packaging that some medicines are returned in, the absence of individual liability protection for pharmacists redistributing medicines and guidance from the professional regulator on redistribution and the inappropriate storage of medicines in direct sunlight were barriers to the redistribution of medicines. Tamper evident seals, smart labels capable of reliably identifying returned medicines that have been exposed to temperatures above that recommended for storage, more information on how temperatures affect the stability of individual medicines and extensive public engagement and education were identified as potential solutions. From these findings, key criteria which would need to be met for pharmacists to potentially redistribute medicines in solid dosage forms have been suggested (Table 4).

[Insert Table 4 here]

There are several limitations to the current study which should be noted. The restriction of the study to one Health Board in Wales limits the degree to which the findings can be generalised to other pharmacists practicing in the UK. Only conducting two rounds of the Delphi study can also be viewed as a limitation of the study, particularly given the high response rate in the second round. It is possible that further rounds of Delphi may have led to consensus being reached on more statements. The inclusion of interview participants in the Delphi panel may also be viewed as a limitation. A panel composed of participants with no prior involvement in the study may have provided the opportunity for other barriers and solutions to be identified, or, if no further barriers or solutions were identified, an indication that the barriers and solutions identified in the interviews may be representative of the views of the profession. The inclusion of interview participants in the expert panel of Delphi studies modified in a similar way to the present study, has, however, been recommend as a strategy to increase panellist retention between rounds.[26]

The inclusion of pharmacists working in the hospital sector can be viewed as a strength of the study (as the three main patient facing branches of the profession have been represented) and a limitation. Medicines management practices, such as the storage of medicines in bedside lockers on hospital wards, may have influenced the views of the hospital pharmacist members of the panel and this should be considered when interpreting the results of the study. Also, as only a single redistribution scenario was presented to panellists, the current study does not contribute to the identification of specific medicines which may be suitable for redistribution. Whilst this issue has been explored elsewhere, further consideration of this issue is needed, in light of the findings of this study.[30]

To the best of our knowledge, this is the first study to identify consensus on the key criteria which must be met for medicines' redistribution of solid dosage forms within the UK to be potentially accepted by pharmacists. This study also represents one of the first empirical studies into medicines redistribution to have been published in a peer reviewed publication. As has been observed in other studies which have sought the views of pharmacists and other healthcare professionals on medicines redistribution, panellists in the present study were principally concerned with ensuring the quality and safety of the medicines in solid dosage forms to be redistributed. The majority of barriers towards the redistribution identified in the study have been reported or commented on previously.[1,8,9,10,11,12,14,16] However, it is of

note that barriers such as individual pharmacist liability and the need for guidance from the professional regulator of pharmacists on redistribution have not previously been reported in the context of medicines redistribution in the UK. Concerns about individual liability and the need for guidance from the professional regulator have, however, been raised by pharmacists on a number of occasions when discussing other new developments or hypothetical scenarios.[28,29]

A finding of, perhaps, more interest was that consensus was reached between pharmacists on potential solutions to some of the commonly cited barriers towards redistribution such as tampering and the potential for medicines to be stored inappropriately. Whilst agreement was not reached that tampering posed a barrier to redistribution, panellists were in agreement that tamper-evident seals would need to be used as 'a solution' as part of a redistribution scheme. This is not the first mention of tamper evident seals as a potential solution to concerns about tampering.[8,9,10,30] Indeed, respondents to a questionnaire distributed by Casey to ten doctors and pharmacists indicated that the use of tamper–evident packaging would be essential to any medicines redistribution scheme.[30]

Consensus was not reached on the commonly cited barrier that medicines may have been stored outside the manufacturer's recommendations once they have left the pharmacy. However, in agreement with findings and comment from elsewhere, the panel did reach a consensus that packaging technologies, such as irreversible temperature sensitive stickers, which can indicate if a medicine has been stored at temperatures exceeding that recommended by the medicines manufacturer must be used as part of a redistribution scheme.[8,9,10,30]

While a consensus was not reached on any of the barrier statements concerning potential negative public views on redistribution, it is evident that this was a concern of panellist as a consensus was reached that public engagement and educational would need to be an essential component of any hypothetical redistribution scheme. As yet, little work has been undertaken to understand patient views on the redistribution of medicines. Research into the views of patients on redistribution is therefore essential, particularly if educational or awareness campaigns are to be designed to address potential negative views or concerns about medicines redistribution that may be held by the public.

The findings of the present study should serve as a stimulus for more work and discussion in the wider healthcare community on this issue. The next phase of research in this area should investigate whether it is possible for consensus to be achieved on the barriers and solutions to redistribution between other healthcare professionals who are involved in the use of medicines. We have laid the foundation for this work by conducting qualitative interviews with nurses and doctors working in both primary and secondary care. The views of experts in medicines regulation and the wider fields of pharmaceutics, health technology appraisal and, potentially, from the third sector must also be gathered if policy change in this area is to become a reality. Perhaps most importantly, however, is that work is undertaken to ascertain whether the newer packaging technologies, identified as solutions in the present study, can be validated in practice settings to verify the safety and quality of returned medicines.

Conclusions

This study suggests that pharmacists would potentially redistribute medicines in solid dosage forms (tablets and capsules) if certain criteria, principally relating to the quality and safety of medicines to be redistributed, were met. For this issue to be taken forward, it is essential

that the public views on the redistribution of medicines are sought. Also, for redistribution to be accepted, particularly amongst pharmacists, the use of newer packaging technologies which are able to identify medicines that have been tampered with or stored incorrectly must be included as part of any scheme. For redistribution to become a reality, evidence that newer packaging technologies can reliably indicate if returned medicines are of an appropriate quality and safe to be redistributed when used in practice settings is needed.

Declarations

There are no conflicts of interest to declare. The project was undertaken by DM as part of an MSc in Clinical Pharmacy at Cardiff University. Course fees were provided by the Medicines Management Directorate of Cwm Taf University Health Board.

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Table 1: 'Barrier' statements with median (Med) scores, IQRs and percentage agreement ($_a$), disagreement ($_d$) or neither agreement or disagreement ($_-$). Consensus statements in bold.

Section	Statement	1st RND			2nd RND		
Barriers (n=27)		Med	IQR	%	Med	IQR	%
Safety (n=5)							
B1	Returned medicines may have been deliberately tampered with (adulterated) and therefore should not be redistributed	5	3	53_d	5	2	65_d
B2	Returned medicines may have been inadvertently tampered with (blister pack placed in incorrect outer box) and therefore should not be redistributed	4	3.5	41_-	4	2	47_d
B3	**Some of the seals currently used on the outer packaging of medicines are not robustly tamper proof**	**2**	**3**	**71_a**	**2**	**1**	**94_a**
B4	The packaging of medicines may become contaminated (e.g. by disease causing microbes) while in a patient's possession and therefore should not be redistributed	4	2.5	47_a	4	2	47_b
B5	Returned medicines should not be redistributed as it will provide another point of access for counterfeit medicines to enter the supply chain	4	2.5	47_d	5	2.5	59_d
B27	**Medicines previously supplied to patients in unsealed packaging should not be redistributed**	**-**	**-**	**-**	**2**	**1**	**82_a**
Quality (n=8)							
B6	Returned medicines may have been stored above the recommended temperature and therefore should not be redistributed	2	3	71_a	2	3	71_a
B7	Medicines returned in complete blister packs in their original outer packaging may have been stored in a moist environment (e.g. humid bathroom) and should, therefore, not be redistributed	3	3.5	53_a	4	3.5	47_a
B8	**Medicines returned in complete blister packs in their original outer packaging may have been stored in direct sunlight and should, therefore, not be redistributed**	**3**	**2**	**59_a**	**3**	**1**	**59_a**
B9	Medicines returned one month after being collected should not be redistributed	2	4.5	59_a	3	4.5	53_a
B10	Medicines returned one week after being collected should not be redistributed	5	3	53_d	6	2	71_d
B11	Medicines returned one day after being collected should not be redistributed	6	2.5	77_d	6	1.5	82_d
B12	**Returned medicines with damaged or stained packaging should not be redistributed**	**1**	**1.5**	**88_a**	**1**	**1**	**82_a**
B13	**Returned medicines which have a strong unpleasant smell (e.g. of cigarette smoke) should not be redistributed**	**1**	**0.5**	**94_a**	**1**	**0.5**	**94_a**
Patients (n=4)							
B14	Medicines should not be redistributed as patients will not accept medicines that have been returned by another patient	4	3	47_d	5	2	53_d
B15	Medicines should not be redistributed as some patients may think that a medicine is less likely to be effective if it has been returned by another patient	5	2.5	65_d	4	3	41_d
B16	Medicines should not be redistributed as patients may move their prescriptions to pharmacies they perceive as not or rarely supplying redistributed medicines	4	3	47_d	4	3	41_d
B17	Medicines should not be redistributed as such medicines may negatively affect patients adherence to their medication	5	2.5	59_d	5	1.5	59_d
Scheme (n=10)							
B18	Medicines should not be redistributed as there would be too much opportunity for fraud to be committed by those involved in the redistribution scheme	5	2.5	59_d	5	1.5	59_d
B19	Medicines should not be redistributed as it would not be possible to ascertain which patients had received medicines which needed to be recalled for safety reasons	5	2.5	71_d	5	2	71_d
B20	Medicines should not be redistributed as the costs incurred by administering such a scheme would outweigh any cost savings made	5	1.5	53_d	5	1.5	53_d
B21	**Medicines should not be redistributed if individual pharmacists will be held liable for patients experiencing adverse events thought to be caused by medicines which have been correctly* redistributed**	**2**	**3**	**71_a**	**2**	**1**	**88_a**
B22	Medicines should not be distributed as too few medicines are returned in a condition likely to be acceptable for redistribution to make any scheme cost effective	5	2	53_a	5	2	65_a
B23	Medicines should not be redistributed if no payment is to be made to pharmacies for the assessment of returned medicines for redistribution	3	4	59_a	3	4	59_a
B24	Medicines should not be redistributed as the likely burden of paperwork for the scheme will make participation not cost effective for community pharmacies	4	1.5	41_-	4	1.5	47_-
B25	**Medicines should not be redistributed until official guidance on redistributing medicines is published by the General Pharmaceutical Council**	**1**	**1**	**100_a**	**1**	**0.5**	**100_a**
B26	Pharmacists should not be expected to redistributed medicines that were not issued from the pharmacy in which they work	2	3	71a	2	2	82_a

***Correctly in this instance means in a manner consistent with approved official protocols or procedures**

Table 2: Solution statements with median (Med) scores, IQRs and percentage agreement ($_a$), disagreement ($_d$) or neither agreement or disagreement ($_-$). Consensus statements in bold.

Section	Statement	1st RND			2nd RND		
		Med	IQR	%	Med	IQR	%
Solutions (n=16)							
S1	**Robust tamper evident seals would need to be added to original packaging as part of a medicines redistribution scheme**	**1**	**0.5**	**100$_a$**	**1**	**0**	**100$_a$**
S2	**Additional robust tamper evident seals could be added as part of the dispensing process**	**2**	**2**	**82$_a$**	**2**	**1**	**88$_a$**
S3	Visually inspecting the original packaging of a returned medication which had been unopened (robust seals intact) would identify if the medication had been tampered with	2	2.5	64$_a$	3	2	71$_a$
S4	Wiping the packaging of a returned medicine with an appropriate disinfectant would ensure that any disease causing microbes have been removed from the packaging	4	1.5	35$_-$	4	1.5	41$_-$
S5	Any redistribution of medication scheme would need to be designed to allow identification of patients which had received redistributed medicines to facilitate safety recalls	1	3	76$_a$	2	1.5	82$_a$
S6	**Stickers designed and validated to robustly indicate if a returned medication has been stored above the recommended temperature must be used as part of any redistribution scheme**	**1**	**1**	**94$_a$**	**1**	**0.5**	**94$_a$**
S7	**More information on how temperatures effect the efficacy of specific medicines would help identify medicines which may be appropriate for redistribution**	**1**	**1**	**88$_a$**	**1**	**1**	**100$_a$**
S8	A medication in a sealed original packet returned a few hours after leaving the pharmacy by a patient known to me is likely to be appropriate for redistribution	3	3.5	71$_a$	5	1.5	82$_a$
S9	**A medication in a sealed original packet returned the day after leaving the pharmacy by a patient known to me is likely to be appropriate for redistribution**	**2**	**3**	**71$_a$**	**2**	**1**	**82$_a$**
S10	**If a medication has been correctly assessed by a pharmacist for redistribution, that pharmacist should not be liable for any untoward event caused by the use of that medicine**	**1**	**1.5**	**82$_a$**	**1**	**1**	**100$_a$**
S11	**Any redistribution of medication scheme must be accompanied by extensive public engagement and education**	**1**	**0**	**100$_a$**	**1**	**0**	**100$_a$**
S12	Returned medicines to be redistributed should be transferred to new outer packaging to protect future recipients from disease causing microbes	-	-	-	3	2	65$_a$
S13	Informed consent from individual patients agreeing to accept redistributed medicines should be sought prior to such medicines being supplied	-	-	-	2	3	71$_a$
S14	Stickers designed and validated to robustly indicate if a returned medication has been stored within the moisture limits which the packaging provides protection to the medicine for must be used as part of any redistribution scheme	-	-	-	2	2	88$_a$

Table 3: Characteristics of the pharmacists invited to participate in the Delphi study by main sector of practice

	Pharmacists invited (n=18)	Completed Round 1 (n=17)	Completed round 2 (n=17)
Hospital	7	6	6
Community	6	6	6
Primary care	5	5	5

Table 4: Criteria which must be met for pharmacists to accept the redistribution of medicines in solid dosage forms (tablets and capsules)

1. Protection for pharmacists:	Liability arrangements for individual pharmacists to redistribute Guidance from professional regulator
2. Tamper evident seals:	Only medicines returned with intact robust tamper evident seals should be considered for redistribution
3. 'As new' packaging:	Medicines to be redistributed must be supplied in packaging in a state consistent with the primary dispensing of the medicine
4. Technologies to indicate inappropriate storage:	Packaging technologies which can indicate if a returned medicine has been stored outside of the manufacturer's recommendations must be used
5. Public engagement:	Extensive public engagement on medicines redistribution is needed