# Considerations on preventable drug-related morbidity in Primary Care Part II – Strategies to reduce the risk of preventable drug-related morbidity

MARA PEREIRA GUERREIRO\*, JUDITH ANNE CANTRILL\*\*, \*\*\*LUÍS PISCO, \*\*\*\*ANA PAULA MARTINS

#### ABSTRACT

Objective: To review the literature on strategies to reduce the risk of preventable drug-related morbidities in primary care. Methods: We searched nine electronic databases, bibliographies of papers, two authoritative internet sites and used personal contacts to identify literature on strategies to improve the safety and the quality of medicines usage in primary care.

Results: The combined search strategy yielded 96 potentially relevant references. Those which met our inclusion criteria were divided into reviews and original articles; if available the former were used in the present work. References were further grouped into four not mutually exclusive categories, according to the stage of the medication-use process they were directed at: prescribing, dispensing, administration/compliance and monitoring stages. Five main strategies emerged to improve the safety and quality of the medication-use process in primary care: educational strategies for practitioners, educational strategies for patients, behavioural strategies for patients, computerisation and revision of professional roles. These strategies may be applicable to more than one stage of the medication-use process and comprise a large number of possible interventions, such as academic detailing and workshops, the use of memorandums and information technology to support medicine-taking, computerising patient data, employing informatics to support practitioners' decision-making and automated signalling of risk events.

Conclusion: Reducing preventable drug-related morbidities in primary care is likely to require the adoption of multiple strategies at different stages of the medication-use process, targeting simultaneously not only people, but also procedures, and the organisation. The implementation of interventions should ideally be guided by evidence on their value. Educational efforts directed to health care professionals and behavioural strategies to enhance patient compliance have been extensively studied, while the use of informatics and the inclusion of pharmacists in therapeutic management need further research to evaluate their benefit.

Keywords: Morbidity; Primary Care; Safety; Therapy; Quality; Intervention.

\*PharmD, PhD student School of Pharmacy & Pharmaceutical Sciences, University of Manchester, UK \*\*BPharmHon, MSc, FRPharmS Professor of Medicines (Usage, Evaluation and Policy) School of Pharmacy & Pharmaceutical Sciences, University of Manchester, UK \*\*\*MD, President, Institute for Quality in Health Care, Portugal \*\*\*PharmD, MSc, PhD Director of the Professional Area, National Association of Pharmacies (ANF), Portugal

#### Nota do Editor:

O Artigo dos mesmos autores intitulado Considerations on preventable drug-related morbidity in Primary Care Part I – Impact of preventable drug-related morbidity, publicado na Rev Port Clin Geral 2005; 21:269-79 foi classificado por engano na secção Estudos Originais. Na realidade trata-se de um Artigo de Revisão. Pelo erro, da responsabilidade da redacção, pedimos desculpa aos autores e aos leitores.

#### INTRODUCTION

he first article of this series demonstrated that preventable drug--related morbidity (PD-

RM) in primary care remains an under-recognized public health problem<sup>1</sup>. The precise prevalence of PD-RM from drug usage in primary care

is dependent on the definition and methodologies applied, but studies indicate that drug-related morbidities managed in primary care facilities or leading to hospital visit or stay are common, with up to more than half of the cases being avoidable. Data suggest that the prevalence of hospital admissions due to preventable drug-related morbidity is comparable to conditions such as cancer and myocardial infarction in developed countries. Strategies to reduce PDRM have the potential to improve patients' health and quality of life and to enable better use of financial resources, as savings can be obtained from treating patients suffering from avoidable drug-related morbidities and from associated administrative costs (complaints and malpractice litigation).

PDRM and the associated human suffering and economic waste remain unacceptably undiminished but the problem is not new, nor is the discussion of potential solutions, as several policy documents have already addressed it in the context of patient safety and quality in healthcare. Following publication of "To err is human"<sup>2</sup> in 1999, by the North American Institute of Medicine, countries such as the UK3 produced their own analysis. More reports followed<sup>4;5</sup> and recently the "Luxembourg declaration on patient safety" was published under the auspices of the European Union (EU). This document contains top level recommendations for the EU Institutions, National Authorities and health care providers, with the overall aim of establishing a culture of patient safety in health systems. Common to these policy documents is the adoption of more holistic models to improve safety and quality in health, no longer centred on health care providers only. These models take into consideration the complexity of health care (and the medication-use process in particular) by incorporating principles from other disciplines, such as psychology and systems engineering. This shift is illustrated by the words of two patient safety experts<sup>6</sup> "It's becoming clear that providing safe and effective care requires not only expert clinicians, but also well designed care processes and organisational supports".

This paper discusses approaches to improve the safety and quality of the medication-use process in primary care, drawing on the concept of PDRM. We start by briefly discussing key aspects of the theory on human error, to enable a conceptual understanding of the occurrence of adverse events. In the body of the article we present the results of a review on strategies to alleviate PDRM in primary care, focusing on the system level.

#### Human error and system failure

Human error and system failure are described as the causes of PDRM<sup>7</sup>. Errors in the medication-use process are commonly classified by the proximal action contributing to the adverse outcome (e.g. failure to detect a drug interaction). Errors have also been classified in terms of the stage of the process they relate to (e.g. prescribing errors, dispensing errors).

Error in health care is stigmatised by the commonly held belief that only careless and poorly motivated people commit errors. Perhaps as a consequence, the traditional approach to error in health is blaming the immediate person "at fault". This person approach has a number of limitations<sup>8</sup>. Firstly, it overlooks important features of human error: everyone can err and error occurs in repeated patterns, i.e. the same set

of circumstances is likely to produce the same error, irrespective of the person involved. Secondly, blaming and shaming impairs a reporting culture, which is fundamental to turn unsafe practice into learning opportunities, by analysing in detail what happened. The system approach has been considered a valuable alternative to enhance patient safety and the quality of care. This approach is based on the assumption that humans are fallible and cannot always choose between safe and unsafe practice. Factors associated with the commission of errors, such as inattention and forgetting, are almost impossible to predict and control; errors can therefore occur with the best people and in the best organisations. The systems approach deals with these failures by targeting "the person, the team, the task, the workplace and the institution as a whole"<sup>8</sup>, and not simply by trying to make individuals less fallible. Redesigning a system to make it less error-prone and to absorb errors when these occur it is not to say responsibility should be transferred from the individual to a somewhat vague entity; rather it means looking beyond the individual to improve the system and preventing the same error from happening again. Central to the systems approach is the creation of system defences.

Reason proposed the "Swiss cheese model" to explain the occurrence of system accidents<sup>8</sup>. This analogy compares defensive layers of the system to slices of Swiss cheese, each having holes, which represent safety failures. The presence of holes in one slice does not usually predict an adverse outcome, since the other slices work as safeguards. However, the holes in the layers may line up temporarily, creating an opportunity for an accident. Figure 1 shows how the Swiss cheese model can be employed to explain a PDRM event (for more details on the case see table I). The accident trajectory could have been intercepted by the pharmacist, via the provision of adequate written information, or by the patient, had she been active in seeking information about her medicine (e.g. asking the physician, contacting the pharmacist or reading the package insert). Ultimately, the physician could have prevented the accident, by detecting and correcting nonadherence in the scheduled visit. In this example all the safety barriers failed, causing harm to the patient. Reason's theoretical model is extremely useful to illustrate how the various stages of the medication-use process (prescribing, dispensing, administration and monitoring) and involved parties play a role in the occurrence of PDRM.

System analysis of adverse drug events has been studied in the hospital setting<sup>9</sup> and has been suggested as a valuable method for redesigning the system in primary care<sup>10</sup>. Starting with a PDRM event this approach works backwards, to identify problems directly contributing to the event (proximal causes), and the underlying system failure, i.e. the roots of proximal causes which ultimately lead to the event. However, this is essentially an hypothesis generating exercise<sup>11</sup>, and therefore should not guide the implementation of complex unstudied changes in the system, which might create new failures.

Table I shows an example of systems analysis for a PDRM event, adapted from a case report. Errors and proximal causes may be linked to several system failures; we simplified our system for the sake of clarity.

Error has been defined as the "failure of planned actions to achieve their desired goal"<sup>12</sup>. Lapses or slips are errors of execution, associated with memory and attentional break-down<sup>12</sup>. Mistakes are errors of intention, involving the execution of an inadequate plan<sup>12</sup>. The purpose of distinguishing slips and lapses from

② Pharmacist dispenses the diuretic without providing ④ Physician does not check Accident adequate information adherence to drug therapy trajectory 1 Patient is prescribed a diuretic with unspecific directions ③ Patient takes the divretic in for use the evening. She doesn't check the package insert and stops Patient iniury using the drug due to discomfort (poor disease (getting up frequently during control requiring the night to urinate) hospitalisation)

Figure 1. Swiss cheese model to explain a preventable drug-related morbidity event.

mistakes is twofold<sup>13</sup>. Firstly, factors associated with their occurrence differ. Slips and lapses happen in the presence of competing sensory or emotional distractions, fatigue and stress; mistakes frequently mirror lack of experience or insufficient training. Secondly, the appropriate strategies to deal with these error types are different. Reducing the risk of slips and lapses requires redesigning strategies, such as using checklists, decreasing fatigue, standardising key devices and eliminating distractions (e.g. phones) where possible. Reducing the risk of mistakes involves generally more training or supervision. The classical response within health care is to consider all errors as mistakes, implementing remedial education and/or extending supervision.



For the purpose of this review we assumed the premise that increasing the safety and quality of the medication-use process leads to a reduction of PDRM, understood as avoidable adverse outcomes of drug therapy (injury or harm as a result of ineffectiveness or non treatment). Therefore we considered all studies examining strategies to improve the safety and quality of drug usage in primary care, with restriction to English, Portuguese, French and Spanish languages. We did not exclude literature outside clinical outcomes research, in recognition that other types of evidence have the potential to improve patient safety<sup>14</sup>, particularly when a systems approach is taken, and that it is appropriate to implement "practical, low-risk but understudied interventions that seem likely to work"11.

A pragmatic approach was taken

# TABLE I

### AN EXAMPLE OF A PREVENTABLE DRUG-RELATED MORBIDITY (ADAPTED FROM56) AND ITS ROOTS TO SYSTEM FAILURE

Event (adverse events are shadowed)	Proximal cause*	System failure
<ul> <li>MS is a 73 year-old Caucasian female with high blood pressure and congestive heart failure (HF) who is prescribed furosemide 40 mg, with directions to take one tablet daily;</li> <li>The prescription is filled via mail-order pharmacy and labelled as in the prescription;</li> <li>MS starts taking furosemide at bedtime and has to get up three to five times per night to urinate, so she stops taking the drug after three doses;</li> </ul>	<ul> <li>Inattention or forgetfulness (physician and pharmacist)</li> <li>Insufficient patient education</li> <li>Deficient follow-up between medical appointments (e.g. telephone calls by a pharmacist or a nurse)</li> </ul>	<ul> <li>Lack of a computerised software at the prescribing and dispensing stages with default information on directions</li> <li>Inadequate provider-patient communication</li> <li>Inadequate organisation of resources</li> </ul>
<ul> <li>In a scheduled visit MS's physician finds her HF had worsened and prescribes digoxin 0.25 (one tablet daily) without inquiring about adherence;</li> <li>The prescription is filled via mail-order pharmacy and labelled as in the prescription;</li> </ul>	<ul> <li>Inattention or forgetfulness (physician)</li> <li>Violation (patient)</li> </ul>	<ul> <li>Inadequate organisation of resources (e.g. heavy workload)</li> <li>Lack of motivational support</li> </ul>
MS is hospitalised with acute pulmonary oedemo	a and heart failure	
<ul> <li>MS fills an hospital issued prescription for captopril 25 (1 tablet twice a day) in a pharmacy, as well a prescription dated 2 months prior to hospital admission with potassium chloride 10 mEq (two tablets twice a day);</li> <li>The pharmacist does not spot a relevant interaction nor checks the prescription date;</li> <li>MS does not refill furosemide and digoxin;</li> </ul>	<ul> <li>Lack of drug knowledge (pharmacist)</li> <li>Inattention or forgetfulness (pharmacist)</li> <li>Lack of information about the patient at the time of dispensing</li> <li>Insufficient patient education</li> </ul>	<ul> <li>Lack of a computerised software with alerts for interactions and adherence based on refills</li> <li>Inadequate organisation (e.g. interruptions)</li> <li>Inadequate training of staff on drug therapy and how it should be used and monitored</li> <li>Inadequate provider-patient communication</li> </ul>
Three weeks later MS suffers a second hospitali	sation caused by hyperkalaemia	
<ul> <li>MS is discharged to a nursing home with indication to continue all medications brought from home, including potassium chloride;</li> <li>Once in the nursing home MS starts taking all medicines – a consultant pharmacist takes her medication history, assesses the drug regimen and orders laboratory tests, which showed high levels of potassium, creatinine and digoxin;</li> <li>The pharmacist makes a recommendation to stop the potassium supplement and halve both digoxin and captopril doses, but no action is taken by the attending physician.</li> </ul>	<ul> <li>Lack of drug knowledge (hospital physician)</li> <li>Faulty communication between health care professionals</li> <li>Lack of drug knowledge (nursing home physician)</li> </ul>	<ul> <li>Inadequate inter-professional communication (e.g. procedure in place to ensure priority issues are discussed)</li> <li>Inadequate training of staff on drug therapy and how it should be used and monitored</li> </ul>
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to identify relevant literature:

• Electronic database search, as described elsewhere<sup>1</sup>.

• Internet search, by accessing the "Patient Safety Network" website (http://www.webmm.ahrq.org), maintained by the North-American Agency for Health Care Research and Quality, and "Safer Health Care" website (http://www.saferhealthcare.org.uk/ihi), run by the British National Patient Safety Agency, the BMJ publishing group and the US--based Institute for health care improvement.

• Bibliography scans in retrieved papers.

• Contacting researchers.

#### RESULTS

Electronic database search and scanning the reference list of retrieved papers yielded the majority of the references. Personal contacts resulted in four references: a manuscript due to be submitted, part of a Cochrane review protocol<sup>15</sup>, a published systematic review on compliance<sup>16</sup>, a manuscript due to be submitted on cross-cultural validation of instruments and a conference abstract<sup>17</sup>. Internet searching allowed the identification of a considerable number of references, but many did not fall under our inclusion criteria. Examples of excluded articles are references on safety culture and critical incidents reporting systems; although these aspects are critical and link with PDRM management at a macro level it is not possible to cover them in the present work due to space limitations. Readers with interest in these areas can refer to other sources<sup>18-20</sup> for detailed information. Another common reason to reject articles was their focus on the hospital setting.

As anticipated, uncovered references offered different levels of evidence, ranging from practices accepted in other industries to systematic reviews of experimental studies in health care. Reviews were used where available. References were further classified in one of the four following categories, according to the stage of the medication-use process they were directed at: prescribing, dispensing, administration/compliance and monitoring/follow-up stages, although a degree of overlapping existed.

# Strategies to reduce PDRM in primary care

A considerable amount of literature has been published on strategies directed at prescribing, probably mirroring the belief that prescribing errors are the most prevalent form of medication errors. However, research findings show that errors associated with PDRM also occur often at the stages of monitoring and patient adherence<sup>10;21;22</sup>; it is sensible for prevention strategies to target these three stages of the medicationuse process. On this basis, and given limited space, we do not allude to strategies aimed at the dispensing stage. Furthermore, an effort should be made to focus at patients taking drugs most often associated with morbidity in primary care (see Box 1).

Figure 2 shows suggested interventions to reduce PDRM linked to the stage of medication-use in primary care. We summarily discuss these interventions below.

#### PRESCRIBING STAGE

The conventional approach to make prescribing safer is targeting physicians<sup>\*</sup>. It has been demonstrated that an active intervention is required; the distribution of educational

#### BOX I

#### DRUG CLASSES FREQUENTLY IMPLICATED IN PREVENTABLE DRUG-RELATED HOSPITAL ADMISSIONS (ADAPTED FROM<sup>22,55</sup>)

- Cardiovascular (including diuretics, cardiac glycosides and beta-blockers)
- NSAIDs and analgesics
- Psychotropics
- Antibiotics
- Antiplatelets
- Antiepileptics
- Hypoglycaemics

materials and mass mailings alone has very limited results23. Educational outreach shows promise in changing prescribing behaviour<sup>24</sup>. This intervention, also known as academic detailing, is an educational visit by a trained person to a health care professional in his or her setting; it is commonly used for marketing purposes by pharmaceutical companies. Group education produces variable effects; interactive workshops have been shown to be effective in improving professional practice while lectures alone are unlikely to produce any change<sup>25</sup>. Providing physicians with data on their performance (audit and feedback) has a small to moderate effect in improving practice; better results seem to be achieved when baseline compliance with recommended practice was low<sup>26</sup>. Audit and feedback is many times multimodal, comprising interventions such as provision of information together with educational meetings; however the current evidence does not support the use of multifaceted interventions as being more effective<sup>26</sup>. The effectiveness of interventions such as participatory guideline development is less well investigated, but using local consensus processes seems to be im-



Figura 2. Interventions to reduce PDRM linked to the stages in the medication-use process in primary care.

portant<sup>23</sup>.

An increasingly popular approach to make prescribing safer is employing computerisation to store and manage patients' data (e.g. co-morbidities, renal and hepatic function and past history of side effects) and drug information (data on doses, cautions, contra-indications, sideeffects and interactions). More than 90% of British general practices regularly use clinical computer systems, opposed to only about 5% of US ambulatory care providers<sup>27</sup>. Computerisation enables timely access to critical data for the prescriber to decide on the risks and benefits of drug therapy. However, to maximize safety a critical feature of software packages is the generation of pro-active warnings when users attempt to do an action likely to be hazardous, such as prescribing a

contra-indicated drug, or fail to take action needed to prevent harm, such as ordering blood tests prior to the commencement of certain drugs<sup>28</sup>. Other important safety features in GPs computer systems are avoiding spurious alerts, making it difficult to override critical alerts, having audit trails of such overrides and the possibility to run safety reports<sup>28</sup>. The four main computing systems available in the UK have incorporated many of these features, although failures were detected in generating clinically relevant alerts<sup>29</sup>.

A systematic review has been published on the impact of computers on primary care consultations<sup>30</sup>. Not surprisingly there was a relatively small amount of literature on the impact of computerisation on patient outcomes, with contradictory results. The effect of computers on

practitioners' performance is better studied, but the few papers looking at prescribing examined mainly cost issues<sup>30</sup>. A recent randomised controlled trial set out to determine the impact of computerisation on the quality of prescribing found a reduction in the initiation rate of potentially inappropriate medication, but a modest decrease in the discontinuation of such prescriptions<sup>31</sup>. Furthermore, the positive impact of information systems was found to decline over time in a North-American setting<sup>32</sup>. In fact, although most GPs have positive views on the use of computer systems<sup>30</sup> a number of barriers to their effective use have been identified<sup>30;32</sup>, such as confidentiality, impact on the doctor-patient relationship, cost issues, time-related aspects (e.g. being too busy, slow computers, too many reminders, lack of time to document a justification), providers' views on the applicability of the reminder and limited knowledge on how to use the software. Training is definitely an issue to be addressed, as another study showed that only a minority of the surveyed GPs had received instructions on the system safety features<sup>27</sup>.

Quality indicators may be a useful tool in improving prescribing, either in a computerised form<sup>33</sup> or as aids to medication reviews. Quality indicators are commonly designated by the medication-use stage they refer (e.g. prescribing indicators). Prescribing indicators have been used in British primary care for more than two decades<sup>34</sup> as medication performance tools, although some prescribing indicators are cost-based and do not assess quality. Preventable drug-related morbidity (PDRM) indicators can also be useful to improve the medication-use process in primary care. This tool surpasses conventional quality indicators by com-

bining in the same instrument process and outcome (see table II for examples). PDRM indicators predict worsening in patients' health status as a result of suboptimal management of drug-therapy; their development dates back to 199935 in the US, following a comprehensive literature review combined with expert opinion. Work in this area was pursued by others in the US36, UK37-40 and Canada<sup>41;42</sup>, aiming not only at developing and validating indicators but also at testing their use. There is on-going work in Denmark and Portugal; the latter, part of a doctoral programme of the first author, yielded a valid version of 36 PDRM indicators for Portuguese primary care.

We chose to discuss repeat prescribing separately, as the bulk of drugs prescribed in general practice are issued on a repeat prescribing basis<sup>43</sup>. Several approaches have been advocated to minimise the risk of PDRM associated with this practice<sup>10;44</sup>. These include creating explicit lists of drugs that should not be issued on repeat prescription, available to staff handling requests, and consulting patients' records to check dosage and dosage instructions. Another suggested procedure is employing software packages linked with medical records to issue prescriptions; these enable an array of safety checks without increasing workload excessively: printing dosing instructions automatically, blocking repeats after a certain number of requests, generating review letters and flagging up patients that are potentially under or overusing their medication. Computer systems in British general practice have shown deficiencies in managing repeat prescribing<sup>29</sup>.

#### **ADMINISTRATION STAGE**

Administration of medicines in pri-

TABLE II		
EXAMPLES OF PDRM INDICATORS (UK VERSION) <sup>37,38</sup>		
	EXAMPLE	
Prescribing indicators	Outcome: Acute urinary retention.	
	<b>Process of care:</b> Use of an anticholinergic agent in a patient with a PMH or current diagnosis of benign prostatic hypertrophy.	
	Outcome: A second MI.	
Failure to prescribe	Process of care: In the absence of any contraindication, failing to	
indicators	prescribe aspirin in a patient with a past medical history of a myocardial	
	infarction (MI).	
Monitoring indicators	<b>Outcome:</b> Hyperkalaemia (potassium level $\geq$ 5.5 mmol / litre).	
	Process of care: Use of an angiotensin converting enzyme (ACE) inhibitor	
	without monitoring the potassium level before starting therapy, within six	
	weeks of commencement and at least annually thereatter.	
Dispensing indicators	Outcome: Hospital admission due to an acute exacerbation of asthma or	
	COAD.	
	Process of care: Dispensing and issuing a prescription, by a pharmacist,	
	for beta-blocker eye drops to a patient with a known history of asthma or	
	COAD without advising them to contact their GP in the event of any	
	deterioration of their respiratory symptoms.	

mary care has often been described in terms of patients' compliance or adherence. Although these terms are sometimes used interchangeably it is accepted they have different meanings. The concept of adherence is associated with a shift towards patient empowerment, generally by providing information on drug-therapy. It has also been pointed out that this concept represents a move from a model centred on individual characteristics of the patient to a wider social context<sup>45</sup>. The widely documented insufficient levels of compliance<sup>16</sup> may cause preventable drug-related morbidities as a result of lack of effectiveness or non treatment. Strategies to improve compliance have been extensively investigated and recently a systematic review of 30 reviews was published<sup>16</sup>. It is acknowledged that simple and highly effective solutions to poor compliance do not exist, nor is there a "one-size-fits-all" approach to improving medicine-taking; interventions should be tailored to individual patients based on likely causes of non-compliance.

Interventions to enhance compliance may be grouped into two categories: educational and behavioural<sup>16</sup>. Educational interventions aim to increase knowledge about the medication and/or the disease; they consist of the provision of information to patients either in a group or individually. The purpose of behavioural interventions is to incorporate drug-therapy into the patient's routine. Classic illustrations of behavioural interventions are enhancing communication and counselling, simplifying the dosing schedules, using memorandums and involving patients in their treatment via self-monitoring. Many of the interventions employ information technology to support medicine-taking, such as automated reminders. Perhaps a less well-known example of a behavioural intervention is rewarding improvements in compliance or clinical outcomes by means of, for instance, monetary incentives. Educational interventions are the most commonly applied but alone show little effectiveness; behavioural interventions have proven to be useful but further research is needed into the relative effectiveness of different strategies<sup>16</sup>.

The concept of compliance is based on the assumption that only health care professionals have expertise in drug-therapy; thus patients should do as they are told by health care professionals to ensure the best use of medicines. This paternalistic approach has been challenged and a new model based on partnership<sup>46</sup>, the concordance model, has been proposed for the process of prescribing and medicine-taking. Central to the concordance model is the focus on the consultation, rather than a patient behaviour47. There are non-concordant consultations but it is not possible to have non-concordant patients. In a concordant consultation the patient and the health care professional participate as partners in a discussion on drug-therapy, in recognition that the patient also possess expertise on his or her illness and response to treatment<sup>47</sup>. Full benefits of drug-therapy (and consequently a lesser chance of PDRM) are expected to be achieved by taking into account the patient's beliefs, concerns and preferences. Detailed information on concordance can be found elsewhere<sup>46</sup>.

More than a difference in terminology, concordance is about a change in the prevailing attitudes of health care professionals. There is evidence suggesting that health care

professionals generally perceive patients as knowing more and wanting to know less than they actually do<sup>48</sup>. Similarly, research suggests that health care professionals are unable to predict in a precise way the patients' preferred role in decision-making47, but often assume patients do not want to be involved. This demonstrates the utility of instruments to assess patients' desires in these domains. The "extent for information desire" (EID) scale was initially developed in the UK to measure chronic patients desire for information; a valid Portuguese version will be available soon<sup>17</sup>. The application of such a tool, if feasible, may help to optimise this stage of the medication-use process.

#### MONITORING STAGE

Monitoring involves following-up the patient both to identify and prevent morbidity associated with drug--therapy and to evaluate progress against therapeutic objectives. The importance of monitoring to reduce PDRM is acknowledged by GPs<sup>49</sup>; however the prevalence of avoidable drug-related hospitalisations caused by monitoring problems suggests a system-wide improvement is needed.

The involvement of pharmacists to improve monitoring of drug-therapy, independently or liaising with medical practitioners, is thought to be a valuable strategy. Community--based pharmacists can play multiple roles. They have been used to follow-up patients' drug therapy in scheduled visits in-between medical appointments and to review patients' on long-term medication. Systematic reviews on this topic<sup>50;51</sup> concluded that there is some evidence supporting pharmacist involvement in therapeutic management in primary care, but few of the large number of published studies are methodologically sound. Other roles for community pharmacists include the management of repeat prescriptions, which has been shown in one randomised controlled intervention study to enable the identification of clinical problems, such as adverse drug reactions<sup>52</sup>.

Further suggested strategies to improve monitoring include improving practitioners' education and putting organisational changes in place, to allow physicians to devote more time to medication reviews<sup>10</sup>.

An issue that deserves separate discussion is laboratory monitoring for drugs, which is frequently impaired by the lack of clear evidence on how often tests should be performed; even when recommendations are available the system is deficient in ensuring patients are monitored appropriately<sup>33</sup>. Suggested approaches to overcome this problem include the development of practice protocols for blood test monitoring of drugs such as diuretics, lithium, statins, digoxin, ACE inhibitors, thyroid agents and anticonvulsants, the implementation of recall mechanisms linked to repeat prescribing systems, and the empowerment of patients, by giving information on tests needed and how these can be requested<sup>33</sup>. Computer generation of clinical reminders based on automated recognition of patient data may also be of help53. For instance, a warning "Potassium due now" may be displayed in the record of a patient on a potassium-wasting diuretic. Valid monitoring indicators (Table 2) can be an additional tool in laboratory testing.

# Limitations of the Literature Review Methodology

One of the strong points of our re-

## Revisões

view is the wide perspective we have taken, by looking at literature presenting strategies to reduce the risk of avoidable morbidity from drug usage in all the critical stages of the medication-use process in primary care. However, our review has a number of limitations. Firstly, the systematic search we conducted had the main purpose of characterising the impact of PDRM and the search vocabulary was defined accordingly; articles on strategies to improve the safety and quality of the medication--use process were a "by-product" of this search. An electronic search with terms more sensitive to the present review would certainly yield more references, making our work potentially more comprehensive. Secondly, internet searching is hardly reproducible, even when explicit criteria are employed. A number of flaws have been associated with unsystematic reviews<sup>54</sup>, namely bias in identifying and selecting studies, which may compromise the accuracy of conclusions. However, it is important to note we did not attempt to conclude on the relative merit of different interventions. Lastly, we did not rate the methodological quality of references, as we deliberately did not restrict the search to studies measuring clinical outcomes.

We do not claim this review to be definitive; rather we aimed at presenting a state-of-the-art on this topic to inform debate.

#### CONCLUSION

The experience of other industries and the theory on human error indicate that reducing preventable drug--related morbidities requires the adoption of *multiple* strategies at different stages of the medication-use process, targeting simultaneously not only people, but also procedures, situations and the organisation. Given the traditional attitude towards safety in health care it is not surprising that most strategies illustrated in this work are still directed at people. Some, such as educational efforts directed to health care professionals and behavioural strategies to enhance patient compliance, have been extensively studied, with important implications for practice. In contrast others, such as the use of informatics and the inclusion of pharmacists in therapeutic management, need to be developed to allow a better understanding of their value. Interventions with proven value in other industries should not be dismissed, but it is necessary to assess the impact of their implementation in health care, especially in the case of complex interventions. Moreover, research is needed on criteria to allocate resources in clinical practice where information on the economics of interventions is not available. Evaluation of the interventions should be coupled with investigations on the beliefs and values of people concerning safety issues within an organisation, the socalled safety culture, in order to make improvements in preventable drug-related morbidities in primary care sustainable.

"For every complex problem there is always a simple solution. And it is wrong" H.L. Mencken (1880-1956)

#### **REFERENCE LIST**

1. Guerreiro MP, Cantrill JA, Pisco L, Martins AP. Considerations on preventable drug-related morbidity in primary care - Part I: Impact of preventable drug-related morbidity. Rev Port Clin Ger 2005; 21: 269-79. 2. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington DC: National Academy of Sciences; 1999.

3. Department of Health. An organisation with a memory. London: The Stationery Office; 2000.

4. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington DC: National Academy of Sciences; 2003.

5. Department of Health. Building a safer NHS for patients - implementing an organisation with a memory. London: The Stationery Office; 2001.

6. Elwyn G, Corrigan JM. The patient safety story. BMJ 2005 Aug 6; 331 (7512): 302-4.

7. Hepler CD, Segal R. Preventing medication errors and improving drug therapy outcomes. Boca Raton: CRC Press; 2003.

(8). Reason J. Human error: models and management. BMJ 2000 Mar 18; 320 (7237): 768-70.

9. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA 1995 Jul 5; 274 (1): 35-43.

10. Avery AJ, Sheikh A, Hurwitz B, Smeaton L, Chen YF, Howard R, et al. Safer medicines management in primary care. Br J Gen Pract 2002 Oct; 52 Suppl: S17--S22.

11. Shojania KG, Duncan BW, McDonald KM, Wachter RM. Safe but sound: patient safety meets evidence-based medicine. JAMA 2002 Jul 24-31; 288 (4): 508--13.

12. Reason JT. Understanding adverse events: the human factor. In: Vincent C, editor. Clinical risk management - enhancing patient safety. London: BMJ books, 2001. p. 9-30.

13. Glossary. www.webmm.ahrq.org/glossary. Accessed on 02-07-2005.

14. Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. JAMA 2002 Jul 24-31; 288 (4): 501--7.

15. Smeaton L., Sheikh A, Avery A., Royal S., Hurwitz B, Dewey M. Interventions for reducing preventable drug-related hospital admissions or preventable drugrelated morbidity in primary care. Cochrane Database Syst Rev (protocol) 2002; Issue 4.

16. Bugalho A, Carneiro AV. Norma de Orientação Clínica: Intervenções para aumentar a adesão terapêutica em patologias crónicas [Portuguese: Clinical Guideline: interventions to enhance compliance in chronic conditions]. Lisboa: Centro de Estudos de Medicina Baseada na Evidência da Faculdade de Medicina de Lisboa; 2004.

17. Costa F, Duggan C, Bates I. Validation of the "extent of information desired" (EID) into Portuguese, a pilot study [Conference abstract A27]. Pharm World Sci 2004; 26 (2): A27.

18. Fragata J, Martins L. O Erro em Medicina - perspectivas do indivíduo, da organização e da sociedade [Portuguese: Error in Medicine: perspectives of the individual, the organisation and the society]. Coimbra: Almedina; 2004.

19. Clarke SG. Safety culture: under--specified and overrated? Int J Manage Rev 2000 Mar; 2 (1): 65-90.

20. Hale AR. Culture's confusions. Saf Sci 2000 Feb; 34 (1-3): 1-14.

21. Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger AC, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA 2003 Mar 15; 289 (9): 1107-16.

22. Howard RL, Avery AJ, Howard PD, Partridge M. Investigation into the reasons for preventable drug related admissions to a medical admissions unit: observational study. Qual Safe Health Care 2003 Aug; 12 (4): 280-5.

23. Pearson SA, Ross-Degnan D, Payson A, Soumerai SB. Changing medication use in managed care: a critical review of the available evidence. Am J Manag Care 2003 Nov; 9 (11): 715-31.

24. Thomson O'Brien MA, Oxman AD, Davis DA, Haynes RB, Freemantle N, Harvey EL. Educational outreach visits: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 1997; Issue 4.

25. Thomson O'Brien MA, Freemantle N, Oxman AD, Wolf F, Davis DA, Herrin J. Continuing education meetings and work-shops: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 2001; Issue 1.

26. Jamtvedt G, Young JM, Kristoffersen DT, Thomson O'Brien MA, Oxman AD. Audit and feedback: effects on professional

practice and health care outcomes. Cochrane Database Syst Rev 2003; Issue 3.

27. Morris CJ, Savelyich BS, Avery AJ, Cantrill JA, Sheikh A. Patient safety features of clinical computer systems: questionnaire survey of GP views. Qual Saf Health Care 2005 Jun; 14 (3): 164--8.

28. Avery AJ, Savelyich BS, Sheikh A, Cantrill JA, Morris CJ, Fernando B, et al. Identifying and establishing consensus on the most important safety features of GP computer systems: e-Delphi study. Inform Prim Care 2005; 13 (1): 3--11.

29. Fernando B, Savelyich BS, Avery AJ, Sheikh A, Bainbridge M, Horsfield P, et al. Prescribing safety features of general practice computer systems: evaluation using simulated test cases. BMJ 2004 May 15; 328 (7449): 1171-2.

30. Mitchell E, Sullivan F. A descriptive feast but an evaluative famine: systematic review of published articles on primary care computing during 1980-97. BMJ 2001 Feb 3; 322 (7281): 279-82.

31. Tamblyn R, Huang A, Perreault R, Jacques A, Roy D, Hanley J, et al. The medical office of the 21st century (MOXXI): effectiveness of computerized decision-making support in reducing inappropriate prescribing in primary care. CMAJ 2003 Sep 16; 169 (6): 549-56.

32. Patterson ES, Doebelling BN, Fung CH, Millitelo L, Anders S, Asch SM. Identifying barriers to the effective use of clinical reminders: bootstrapping multiple methods. J Biomed Inform 2005 Jun; 38 (3): 189-99.

33. Avery A. Appropriate prescribing in general practice: development of the indicators. Qual Health Care 1998 Sep; 7 (3): 123.

34. Ashworth M, Golding S, Majeed A. Prescribing indicators and their use by primary care groups to influence prescribing. J Clin Pharm Ther 2002 Jun; 27 (3): 197--204.

35. MacKinnon NJ. Risk assessment of preventable drug-related morbidity in older persons [dissertation]. Gainesville: University of Florida; 1999.

36. Faris R. Explicit definitions to identify preventable drug-related morbidity in an elderly population and their use as an indicator of quality in the medication use system [dissertation]. Gainesville: Florida; 2001.

37. Morris CJ, Cantrill JA, Hepler CD,

Noyce PR. Preventing drug-related morbidity - determining valid indicators. Int J Qual Health Care 2002 Jun; 14 (3):183-98.

38. Morris CJ, Cantrill JA. Preventing drug-related morbidity - The development of quality indicators. J Clin Pharm Therap 2003 Aug; 28 (4): 295-305.

39. Morris CJ, Cantrill CA, Bate JR. How the use of preventable drug-related morbidity indicators can improve medicines management in primary care. The Pharmaceutical Journal 2003 Nov 15; 271 (7275):682-6.

40. Morris CJ, Rodgers S, Hammersley VS, Avery AJ, Cantrill JA. Indicators for preventable drug related morbidity: application in primary care. Qual Saf Health Care 2004 Jun; 13 (3): 181-5.

41. Flanagan PS, MacKinnon NJ, Bowles SK, Kirkland SA. Validation of four clinical indicators of preventable drug-related morbidity. Ann Pharmacother 2004 Jan; 38 (1): 20-4.

42. Robertson HA, MacKinnon NJ. Development of a list of consensus-approved clinical indicators of preventable drug-related morbidity in older adults. Clinical Therap 2002 Oct; 24 (10): 1595--613.

43. Harris CM, Dajda R. The scale of repeat prescribing. Br J Gen Pract 1996 Nov; 46 (412): 649-53.

44. McGavock H, Wilson-Davis K, Connolly GP. Repeat prescribing management - a cause for concern? Br J Gen Pract 1999 May; 49 (442): 343-7.

45. Lutfey KE, Wishner WJ. Beyond "compliance" is "adherence": improving the prospect of diabetes care. Diabetes Care 1999 Apr; 22 (4): 635-9.

46. Medicines partnership - from compliance to concordance. www.medicinespartnership.org. Accessed on 26-04-2005.

47. Weiss M, Britten N. What is concordance? Pharm J 2003 Oct 11; 271 (7270): 493.

48. Astrom K, Carlsson J, Bates I, Webb DG, Duggan C, Sanghani P, et al. Desire for information about drugs: a multi-method study in general medicine patients. Pharm World Sci 2000 Aug; 22 (4): 159-64.

49. Flanagan PS, MacKinnon NJ, Hanlon N, Robertson H. Identification of intervention strategies to reduce preventable drug-related morbidity in older adults. Geriatr Today: J Can Geriatr Soc 2002 May; 5 (2): 76-80.

50. Tully MP, Seston EM. The impact of

pharmacists providing a prescription review and a monitoring service in ambulatory care or community practice. Ann Pharmacother 2000 Nov; 34 (11): 1320-31.

51. Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilisation, costs, and patient outcomes (Cochrane Review). Cochrane Database Syst Rev 2000;Issue 2.

52. Bond C, Matheson C, Williams S, Williams P, Donnan P. Repeat prescribing: a role for community pharmacists in controlling and monitoring repeat prescriptions. Br J Gen Pract 2000 Apr; 50 (453): 271-5.

53. Peterson JF, Williams DH, Seger A, Gandhi TK, Bates DW. Drug-lab triggers have potential to prevent adverse drug events in outpatients. J Am Med Inform Assoc 2002; 9 (6 Suppl): S39-S40.

54. Greenhalgh T. How to read a paper. 2nd ed. London: BMJ Books; 2001.

55. Beijer HJ, De Blaey CJ. Hospitalisations caused by adverse drug reactions (ADR): a meta-analysis of observational studies. Pharm World Sci 2002 Apr; 24 (2): 46-54.

56. Cooper JW. Geriatric drug therapy intervention failure and associated costs. Journal of Geriatric Drug Therapy 1997; 11 (4): 65-70.

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Mara Pereira Guerreiro Drug Usage and Pharmacy Practice Group School of Pharmacy & Pharmaceutical Sciences University of Manchester M13 9PL Manchester - UK E-mail: mara.guerreiro@postgrad. manchester.ac.uk Tel: +44 (0)161 2758334 Fax: + 44 (0)161 2752416

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#### CONSIDERAÇÕES SOBRE MORBILIDADE EVITÁVEL RELACIONADA COM MEDICAMENTOS EM CUIDADOS PRIMÁRIOS PARTE II – ESTRATÉGIAS PARA REDUZIR O RISCO DE MORBILIDADE EVITÁVEL RELACIONADA COM MEDICAMENTOS

#### RESUMO

Objectivo: Rever a literatura sobre estratégias para reduzir o risco de morbilidade evitável relacionada com medicamentos em cuidados primários.

Metodologia: Para identificar literatura pesquisou-se em nove bases de dados electrónicas, listas de bibliografia dos artigos obtidos pela pesquisa, dois sítios da Internet e contactou-se investigadores.

Resultados: A pesquisa identificou 96 artigos potencialmente relevantes. As referências que obedeceram aos critérios de inclusão foram divididas em revisões de conjunto e em estudos originais; quando existentes, as primeiras foram utilizadas em detrimento dos segundos. Posteriormente as referências foram classificadas em quatro categorias, não mutuamente exclusivas, de acordo com o estádio do processo de uso do medicamento a que diziam respeito: prescrição, dispensa, administração e monitorização. Identificaram-se cinco estratégias principais para melhorar a segurança e a qualidade do uso do medicamento em cuidados primários: estratégias educacionais dirigidas aos profissionais de saúde (PS) e aos doentes, estratégias comportamentais dirigidas aos doentes, informatização e revisão da função dos PS. Estas estratégias podem ser aplicáveis a mais do que um estádio e incluem um número considerável de intervenções. São exemplos destas intervenções workshops e visitas educacionais a PS, o uso de memorandos e de tecnologias de informação para apoiar a toma de medicamentos pelos doentes, o emprego de meios informáticos para apoiar a tomada de decisão dos PS, o registo informático de dados clínicos e a emissão de alertas automáticos para identificar potenciais factores de risco.

Conclusões: Reduzir a morbilidade evitável relacionada com medicamentos em cuidados primários requer possivelmente a adopção de estratégias múltiplas dirigidas aos vários estádios do processo de uso do medicamento, tendo como alvo os vários componentes do sistema, nomeadamente os indivíduos, os procedimentos e a organização. A implementação de intervenções deve idealmente ser orientada pela evidência do seu benefício. As estratégias educacionais dirigidas aos PS e as intervenções comportamentais para melhorar a adesão à terapêutica foram amplamente estudadas. É necessária mais investigação para avaliar o valor da informatização e da inclusão de farmacêuticos na gestão da terapêutica.

Palavras-chave: Morbilidade; Medicamento; Cuidados Primários; Segurança; Evitabilidade; Intervenção.