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Abstract

Study objectives: The aim of this study was to develop quality criteria for further development and use in the Medicines Management (MM) process in European hospitals.

Methods: Criteria for MM were developed in three steps using a modified two-stage Delphi-technique. In the first step a literature search was performed and 300 topics were listed. These topics were grouped into three dimensions, eight main and 23 sub areas, rephrased and a questionnaire including 114 criteria that could be perceived as important today and in the near future was prepared. In steps 2 and 3 a panel of experts independently, based on questionnaires, evaluated the importance between the dimensions, areas, and criteria on a four-level Likert-scale. In the second questionnaire the panel had access to the group results from the first questionnaire. Total importance and the three domains of patient safety, environment, and cost-effectiveness were evaluated.

Results: Nine of 11 experts completed the two questionnaires. The three dimensions of patient use, healthcare handling, and strategic MM work, were well balanced and the importance ratings between them were 35, 39, and 26%, respectively. No criteria had a full mean importance of 4 but 31 criteria scored between 3.6 and 3.9. The patient safety domain importance scores were generally very high and the environmental domain low. Five criteria were considered to be of very big importance among all experts in the patient safety domain and none in the other two domains.

Conclusion: This study provides important information on criteria for the further development of standards and indicators for a quality system in hospital settings, High Performance Medicines Management (HPMM).

Keywords

Criteria, hospital, Medicines Management, quality system, Sweden

Introduction

Medications are normally products shown to have positive effects on morbidity, mortality or economy in clinical trials. In standard care, errors and problems in the use of medications are common. This leads to avoidable adverse drug events and reactions, morbidity, mortality and costs [1-3]. In Sweden there is a focus on improving medication use and a national strategy is developing based on a pre-study stating that 3,000 Swedish residents die each year due to drug-related injuries and that 6–16% of hospital admissions are drug related at an annual cost of Euros 0.6-2.3 billion [4]. There is also information from hundreds of international organisations showing that incomplete communication of medical information is responsible for up to 50% of medication errors in hospitals and up to 20% of drug injuries [5].

Quality assurance is probably the key for improvement and has been defined as 'all activities to create, protect and improve quality in healthcare' [6]. According to Keele University, Staffordshire, UK, 'Medicines Management seeks to maximise health gain through the optimum use of medicines' [7]. It encompasses all aspects of medicines use, from the prescribing of medicines through the ways in which medicines are taken or not taken by patients. According to the National Health Services, Medicines Management (MM) comprises clinical benefit, cost-effectiveness, and also the safe and secure handling of drugs [8].

Several organisations and authorities have published various types of help for improving MM with a focus on patient safety. There are examples from the Institute for Healthcare Improvement (IHI), Institute for Safe Medication Practice (ISMP), European Union Network for Patient Safety (EUNetPaS), and the European Medicines Agency (EMA). The National Health Service in the UK and the American Society of Health-System Pharmacists have developed self-assessment tools [8-9]. The International Pharmaceutical Federation (FIP) has developed international consensus statements reflecting the pharmacy profession's preferred vision of practice in the hospital setting [10] and a draft of Joint FIP/WHO Guidelines on good pharmacy practice [11]. The Health Systems Pharmacy Executive Alliance has developed a tool for self evaluation of MM-practice, High Performance Pharmacy (HPP) [12]. In all of these documents and support there is a very strong focus on the pharmacist or pharmacy responsibility. Also the method used for preparing statements and criteria, i.e. whether a consensus method or importance rating was used or not, as well as the country-specific aspects (mostly US-based) limit the use in Sweden, Scandinavia and in most European countries.

The Delphi-technique is a consensus method based on technological forecasting developed in the 1950s. It has been used widely including in the fields of healthcare and education [13-15], for health technology assessment [16], for the international

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classification of patient safety [17], and as indicators for safe medication use [18]. The method can be adapted to various situations and the foundation is based on statements from a panel of experts within the area to explore [14]. The experts do not meet each other during the course of the study and are completely anonymous to each other to avoid bias of the results based on status and dominance.

The aim of this study was to develop criteria that could be used in a quality system for the hospital MM process—High Performance Medicines Management (HPMM). The criteria focuses on quality in the Swedish, Scandinavian, and the European perspective and should be possible to use for benchmarking development within and between hospitals based on the impact on patient safety, economic, and environment benefits domains.

Methods

Development of criteria

Criteria for MM were developed in three steps using a modified two-stage Delphi-technique. In the first step a literature search was performed; the text words health, quality, medication/medicine/drug, management, and Delphi/consensus were combined and a total of 10 interesting publications were identified. A similar search on google.com and on international patient safety organisation homepages was performed. We also used our network for additional documentation. Based on this information, we listed and grouped (in MS Excel) all relevant information from all relevant sources [1-12, 18] and organisations (IHI, ISMP, EUNetPaS, EMA) that could be used as criteria. The list included more than 300 different topics. We further regrouped, analysed and rephrased the possible criteria based on content analysis [19] and relevance to hospital care (including quality after discharge) and the aim of our investigation. The criteria should be perceived as important today and in the near future. To avoid specific focus on the pharmacy, as discussed above, a specific responsible professional or department was specified, i.e. pharmacist, physician, drug and therapeutics committee, in the criteria only if there were legal aspects or specific evidences. A total list of 114 possible criteria was identified, each with references and evidence for inclusion as a criterion. The criteria were finally grouped into three dimensions, eight main and 23 sub areas as shown in Table 1. Our network of experts within each domain were also consulted.

In the second step, the criteria from step 1 were formulated as a questionnaire where an expert panel could evaluate the importance between the three dimensions and also between the 2–3 main areas within each dimension (summing up to eight main areas in total). For each level they had 100 points to allocate. They also had to evaluate each of the 114 MM criteria on a four-level Likert-scale (1–4: no, limited, big, very big importance). The panel was instructed to evaluate each criteria based on the total importance for patient safety, environment, and cost-effectiveness. The panel had the opportunity to add new criteria and also to comment on the proposed ones. Before sending out material to the panel, the questionnaire was also pilot tested for readability and compliance to instructions by two experienced pharmacists.

The expert panel opinions were collected and analysed. A second questionnaire was developed (step 3) including the added criteria from the expert panel and where the experts also had access to the group results from the first questionnaire presented as percentage response on each score for each criterion. In the third step, the expert panel could evaluate the MM criteria again, first

Table 1: Hierarchical grouping of criteria

Dimension	Main area	Sub area
1. Patient medication use	Use and follow-up	Admission
		Medication review
		Patient satisfaction and influence
	Patient support	Reconciliation from hospital settings
		Education and information
2. Healthcare medication handling	Supply	Storage
		Secured availability
		Ordering, delivery and control
		Waste, complaints and withdrawals
		Manufacturing
	Prescription and documentation	Prescription and documentation in hospital settings
		Prescription support
	Preparation and dispensing	Preparation
		Dispensing
3. Overall strategic work with medicines management	Reporting, follow-up, and development	Reporting system (for events)
		Management (continuous)
		Research and development
	Human Resources	Staff management
		Education and training
	Governance and direction	Overall govern and direction
		Chief Pharmacist
		Finance
		Procurement

based on the total importance and then separately based on the importance for the domains patient safety, cost-effectiveness, and environment.

Experts and implementation of the study

In the first step we informally involved ten domain-specific experts (patient safety, environmental and economy) from our network (mostly pharmacists). Some were asked to comment on all criteria and some were asked direct questions. Sixteen new experts with more general competencies were asked to participate in the formal expert panel and eleven accepted. All communication and information was by email individually to each member of the panel and the responses were sent back to a research assistant responsible for decoding the identity of the respondent, according to the Delphi methodology [14].

Results

The study was performed from May to July 2011. The first questionnaire was sent to eleven experts, one withdrew due to time constraints, one did not respond, and nine completed both questionnaires. Among the experts one was a physician and the rest were pharmacists, all with great experience in the use and handling of medicines at hospitals in the middle and south of Sweden and including participation in Pharmacy and Therapeutics Committees. Four were employed at a hospital pharmacy, four by a County Council and one by a National authority. In total for both questionnaires there was one missing value for the six criteria. After the first questionnaire the panel suggested one new criterion which was included in the second questionnaire.

Scoring of dimensions and main areas

The final score of the importance of dimensions and main areas are presented in Table 2. The experts agreed on the importance to a great extent, especially in the main area and within the healthcare handling dimension where the variance was very low. According to the experts almost all dimensions and main areas were important, but 'Human resources' was rated as having lower importance.

Scoring of sub areas

In the second questionnaire the panel scored the importance of all 114 criteria based on total benefit and also for each of the three domains. As shown in Table 3, almost all sub areas in the total benefit evaluation of importance had a mean score above 3.0 and the domain patient safety scored very high for most of the sub areas, whereas environmental impact scored low except for 'waste, complaints and withdrawals' and 'manufacturing'.

Scoring of criteria

The experts in the panel changed their total mean group score for the criteria between the two questionnaires from 3.180 mean score in questionnaire 1 to 3.147 mean score in questionnaire 2 resulting in a mean decrease of 0.3%. They increased their scoring in 34% (39/114) of criteria and decreased it in 48% 55/114). The most dramatic decrease was observed in the criteria, 'Procurement helps to minimise the risk of supply shortages from the supplier and to minimise the use of drugs outside the pharmaceutical insurance and pharmaceuticals that are not produced in a manner that supports sustainable development' (0.44 mean score decrease from 3.33 to 2.89). The most dramatic increase was observed in the criteria, 'There are regular follow-ups concerning which drugs and how much is discarded in the unit and the results of these reported back to the chief pharmacist' (0.44 mean score increase from 2.00 to 2.44).

No criteria had a full mean importance of 4, but 31 criteria scored between 3.6 and 3.9. These criteria are presented in Table 4 for each dimension. The patient safety domain importance scores were very high in general and the environmental domain was low. Six criteria were considered to be of very big importance among all experts in the patient safety domain (* in Table 4) and none in the other two domains.

Discussion

Our study, using a modified two-stage Delphi method gave important information for further development of a quality system for HPMM in hospitals.

The preparation of possible criteria for HPMM were based on literature reviews and supported by input from our network. This gave a very good background to the first questionnaire and few changes were needed for the second one. Especially, the patient safety domain was evaluated with very high importance scores but also the other domains were important although most criteria in the environmental domain scored lower than the rest. Our grouping in three dimensions was well balanced

Table 2: Mean importance in per cent between and within dimensions and main areas from questionnaire 1

Dimension	Importance % (SD)	Main area	Importance % (SD)
1. Patient medication use	34.8 (13.2)	Use and follow-up	54.4 (8.8)
		Patient support	45.6 (8.8)
2. Healthcare medication handling	39.2 (16.2)	Supply	30.6 (7.3)
		Prescription and documentation	36.7 (4.3)
		Preparation and dispensing	32.8 (4.4)
3. Overall strategic work with medicines management	25.9 (12.3)	Reporting, follow-up, and development	43.8 (11.4)
		Human resources	25.9 (11.0)
		Governance and direction	30.3 (9.2)

SD: standard deviation.

Table 3: Mean importance based on total benefit and for each domain for all sub areas from questionnaire 2

Sub area	Total benefit Mean (SD)	Domain benefit		
		Patient safety Mean (SD)	Cost-effectiveness Mean (SD)	Environment Mean (SD)
Admission	3.6 (0.61)	3.8 (0.40)	2.7 (0.60)	1.6 (0.50)
Medication review	3.3 (0.70)	3.2 (0.72)	2.9 (0.88)	1.8 (0.68)
Patient satisfaction and influence	2.6 (0.61)	2.6 (0.73)	1.9 (0.93)	1.3 (0.45)
Reconciliation from hospital settings	3.6 (0.63)	3.7 (0.46)	3.3 (0.62)	1.8 (0.87)
Education and information	3.2 (0.60)	3.2 (0.66)	2.5 (0.72)	1.7 (0,95)
Storage	3.3 (0.64)	3.3 (0.63)	3.0 (0.90)	2,4 (0.91)
Secured availability	3.7 (0.48)	3.8 (0.44)	3.3 (0.72)	2.0 (0.90)
Ordering, delivery and control	3.1 (0.53)	2.9 (0.62)	2.9 (0.89)	2.2 (0.92)
Waste pharmaceuticals, complaints and cancellations	3.1 (0.64)	2.5 (0.98)	2.7 (0.82)	2.7 (1.12)
Manufacturing	3.8 (0.43)	3.8 (0.40)	3.3 (0.60)	2.9 (1.00)
Prescription and documentation in hospital settings	3.4 (0.54)	3.6 (0.53)	2.9 (0.95)	1.6 (0.77)
Prescription support	3.2 (0.67)	3.2 (0.75)	2.8 (0.78)	1.8 (1.02)
Preparation	3.0 (0.80)	3.0 (0.97)	2.6 (0.76)	2.3 (1.04)
Dispensing	3.2 (0.71)	3.3 (0.74)	2.6 (1.01)	1.6 (0.77)
Reporting system (for events)	3.1 (0.67)	3.0 (1.09)	2.4 (1.01)	1.8 (0.92)
Management (continuous)	2.9 (0.72)	2.8 (0.87)	2.7 (0.86)	2.0 (0.80)
Research and development	3.1 (0.36)	3.1 (0.41)	2.9 (0.65)	2.3 (0.81)
Personnel management	2.7 (0.83)	2.5 (0.90)	2.5 (0.88)	1.5 (0.74)
Education and training	3.1 (0.63)	3.1 (0.68)	2.9 (0.77)	1.8 (0.88)
Governance and direction	3.0 (0.91)	2.7 (0.93)	2.5 (0.88)	1.8 (0.99)
Chief Pharmacist	2.9 (0.92)	2.6 (0.84)	2.7 (0.82)	2.2 (1.01)
Finance	3.0 (0.87)	2.6 (0.90)	3.1 (0.81)	2.0 (0.90)
Procurement	3.2 (0.86)	3.1 (0.50)	3.1 (0.63)	2.2 (1.03)

Calculated as the mean of all separate criteria scores in the sub area. The importance was evaluated from 1–4: no, limited, big, very big importance. SD: standard deviation.

with importance ratings from 26–39%. This evaluation of the importance between dimensions and also between main areas was performed to be used as weighting factors for summary scoring of indicators in a quality system. The scoring separately of patient safety, environment, and economy was performed in order to evaluate quality indicators in those domains separately in a quality system.

Our plan is to develop a self-assessment tool similar to those produced by other organisations [8, 9, 12]. To our knowledge, published scientific studies are not available for the development of those tools. Also we believe that it is very important that MM-tools are not restricted to quality aspects in hospital pharmacies and that they are not too much focused on the pharmacist's responsibility as is the case in most other documents. We believe that the scientific background and the more broad hospital- and healthcare perspective is needed for greater interest in improving MM in hospitals, at least in Sweden, Scandinavia, and in most European countries.

There are some limitations in our study. The number of experts is low but above the minimum number of seven as stated by Mullen [14]. Below this number, the internal validity decreases quickly and with an increased number it increases slowly. The criteria were developed based on a European perspective. However, since all experts came from Sweden, the final scoring of importance is only valid in similar healthcare systems such as the Scandinavian countries. All experts were pharmacists except one. We asked four physicians to participate but only two accepted and one completed the questionnaire. We believe that this is a limitation but in other investigations and assessments [1-12] we have not found any evidences that

Table 4: Mean total importance for criteria with a score above 3.5 in questionnaire 2

Dimension	Criteria	Mean (SD)
1. Patient medication use	There are support systems that make it possible to monitor a patient's current prescriptions and picked-up drugs	3.9 (0.33)*
	High-risk patients are captured at enrolment and receive extra attention during hospitalisation	3.9 (0.33)
	The next level of care is informed in a systematic manner, including a Medication Report in Discharge Information	3.9 (0.33)
	The patient has clear prescription information with them upon discharge	3.8 (0.44)
	The patient is informed and has the opportunity to discuss objectives, possible treatment options, benefits and risks of each drug prescription	3.8 (0.44)
	There is systematic collaboration between the physician, the team around the patient (including nurses, pharmacists and paramedical) and the patient for each drug review	3.6 (0.53)
	Any communication must take into account the individual patient's needs, level of education, culture, language, physical and mental ability, and that takes into account the confidentiality and information environment	3.6 (0.53)
2. Healthcare medication handling	Storage of medicines and related products is done in a systematic way	3.9 (0.33)
	There is a continuous effort to reduce the risk of confusion in drug stores	3.9 (0.33)*
	Vital, emergency medicine not normally stocked in all basic supply is still available around the clock for all current units	3.9 (0.44)*
	The availability of drugs for cardiac arrest and anaphylaxis are secured	3.9 (0.50)*
	There is an electronic medical record that includes an electronic prescription list where all treatments are immediate prescribed and shall provide a complete picture of patient treatment	3.9 (0.40)
	Wrong route of administration for critical drug delivery are prevented in a systematic way	3.9 (0.67)*
	Manufacturing of drugs not intended for immediate use are produced at units with MPA approval, or in a hospital pharmacy with extemporaneous manufacturing of drugs for a given time	3.8 (0.53)
	There is a named expert with the right skills for the manufacture of dialysis, radio pharmacy, paediatrics and cytotoxic drugs	3.8 (0.50)
	Prescription opportunity and access to patient medical records are secured in case of computer crash	3.7 (0.87)
	There are electronic systems for prescription signalling risk combinations (interactions), unsuitable drugs to specific patient populations, allergies, and the maximum dose	3.7 (0.35)*
	A standardised and limited range (basic supply) of the unit's most important/common drug based on the needs of the business, science and proven experience is designed	3.6 (0.33)
	The availability of specific drugs at specific events in the community, e.g. natural disasters and epidemics are secured	3.6 (0.50)
	Counterfeit drugs are prevented from entering the system through various security measures	3.6 (0.53)
	There is a clear model for different types of prescription orders, and for documentation in the patient's medical record	3.6 (0.50)
	Selection and monitoring of antibiotics and other antimicrobial therapy follow national or regional care programmes and recommendations or equivalent	3.6 (0.60)
	Administration and documentation of drug doses is done in a systematic way	3.6 (0.78)
	Information of a patient's medication need never be moved by hand/in writing between different systems	3.6 (0.71)
3. Overall strategic work with medicines management	There are support systems that make it possible to monitor all patient's current prescriptions and picked-up drugs	3.9 (0.33)
	High-risk patients are captured at enrolment and receive extra attention during hospitalisation	3.9 (0.33)
	The next level of care is informed in a systematic manner, including a medication report in discharge information	3.9 (0.33)

(*Continued*)

Table 4: (*Continued*)

Dimension	Criteria	Mean (SD)
	The patient has clear prescription information with them upon discharge	3.8 (0.44)
	The patient is informed and has the opportunity to discuss objectives, possible treatment options, benefits and risks of each drug prescription	3.8 (0.44)
	There is systematic collaboration between the physician, the team around the patient (including nurses, pharmacists and paramedical) and the patient for each drug review	3.6 (0.53)
	Any communication must take into account the individual patient's needs, level of education, culture, language, physical and mental ability, and the confidentiality and information environment	3.6 (0.53)

The importance was evaluated from 1–4: no, limited, big, very big importance.
*Indicates a very big importance rating among all experts (mean 4.0) for the patient safety domain. SD: standard deviation.

other professionals except pharmacists have been involved. All criteria were obviously not normally distributed but we chose to present data as mean and standard deviation for easy comparison of data.

Conclusion

This study provides important information on criteria for the further development of standards and indicators for a HPMM quality system in hospital settings.

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