Is it justified to let medicines fly without a black box?

A new indicator for assessing good pharmacy practice

Medicine pricing policies in Vietnam

Pharmacist managed anticoagulation clinic in Kenya

Drug and poison information in Pakistan

Medicines dispensing patterns at community pharmacies in Tamilnadu
Southern Med Review
An International Journal to Promote Medicine Use and Access Research

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Context: In developing countries where health systems and health policy are constantly evolving, there is a great need to publish informative research. However, there are few avenues to do so due to, also inexperienced or untrained researchers, topics out of the scope of current mainstream journals and limited funding are some of the other challenges.

Aims and Objectives: Southern Med Review provides a platform for researchers to disseminate commentary and empirical research findings, with a view to improve the rational use of and access to essential medicines.

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Editorial

Community pharmacy practice in high and low income countries: Commonalities, differences and the tension of being “retailer” versus “primary health care provider”

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High income countries (The developed world)

In the ‘high income countries, there has been steady pressure from both health policy-makers1-4 and professional pharmacy associations5-7 for pharmacy to take a greater role in the provision of services surrounding medicines use and to work more closely with other primary care providers such as nurses and doctors in the general practice setting. In this context, community pharmacy is expected to provide support for patients to improve adherence to prescription medicines, to help doctors rationalize their prescribing, through access to the doctor’s clinical notes and vice versa. Pharmacists are deemed to be well positioned to deliver public health programmes such as weight management for chronic diseases like diabetes, swine and bird flu outbreaks, reducing illicit drug and alcohol use, alcohol consumption and so forth. Minor ailment programmes are expected to engage community pharmacists in more clinical activities whilst relieving general practice doctors and nurses from the burden of disease which can be supported by other primary care provider organisations like community pharmacy.

All of these changes, whether from policy-makers or the profession itself will require pharmacy organisations to ‘step up to the mark’ and engage with other health professionals as well as funders and planners of primary health care services. Further, there is a need for health-policy-makers and funders and planners as well other health care professionals to be supportive of the approach the pharmacy needs to take when delivering extended services in the future8. This movement to include patient centred clinical care as part of the pharmacy organisations’ role is deemed “re-professionalisation”9. This approach requires community pharmacy to continue functioning as a source and medicines supplier whilst extending some of its other roles. In the developed world this process is well regulated10. There is legislation, protocols, rules and service contracts regarding the provision of pharmaceutical services. Along with this, there is the requirement to undertake comprehensive post-registration continuing professional development. Despite this highly regulated environment, the tensions between being primarily a retailer and a primary care provider remain. Taking New Zealand as an example of a country in the developed world, these tensions remain a central issue in the community pharmacy sector. Pharmacists seem generally interested in adopting these new roles but the pace at which they have been adopted and implemented has often been slower than expected. Experience suggests that there are significant barriers to changing and adopting a future vision which involves: alignment with health policy (integration into primary care team) and the implementation of extended services which are patient centered. Two of the identified barriers relate to the tension between retailer and care provider. The first is the way pharmacists view themselves and their activities, the way they think and act, as well as the lack of a primary care practice model moving forward. Moving pharmacists from retailers to health care providers may be more difficult than is realized by the profession and policy-makers. The second is pharmacists’ relationship with funder stakeholders and the lack of remuneration for development and implementation of extended patient centered services11. There are small levels of remuneration for the provision of some services over and above basic medicines sourcing, dispensing and distribution but this varies on a regional basis. The nationally set dispensing fee does not support wide spread implementation and integration of these services; nor does the small pockets of regionally controlled money ring fenced by District Health Boards (DHBs). Therefore, it is the retailing side of the pharmacy business that subsidises these extended services, by those pharmacy owners who chose to adopt them. The activities we are talking about include the sale of general and over the counter (OTC) medicines for minor ailments, companion sales of products in those patients on medicines for chronic diseases (e.g. sale of co-enzyme Q10 for patients on statin lipid-lowering medication) and the provision of complimentary medicines.
The low income countries (The developing world)

In many ways the context in which pharmacies provide services and the activities they undertake in the developing world is different from that previously outlined. What is common however is the tension between being a ‘retailer’ and being an effective organization providing primary healthcare. In this issue of SMR Basak and Sathyararayana report interesting findings from the region of Tamil Nadu in India. Looking from the perspective of the developed world, there are several striking aspects to this paper which highlight the opposing positions of retailer and health care provider. Firstly, medicines that are available only on prescription in the developed world are available over the counter. This has two potential effects; that of increased supplier induced demand with pharmacies being “drug sellers” and the demand driven by customers who opt to self medicate by obtaining prescription medicines based on their own knowledge and beliefs. This is highlighted by Hussain et al in their paper in this issue of SMR which reports the medicine seeking behavior of people in various cities of Pakistan.

The second striking aspect reported in this paper is the lack of pharmacist attendance within pharmacy premises. It would be fair to suggest that as with pharmacy assistants in the developed world, “drug sellers” in countries like India are less qualified than their pharmacist counter-parts. However, the difference is that in the “low income countries” this scenario is coupled with the fact that prescription medicines are freely available OTC. As a result, medication is reduced to a commodity item, just like any other “retail item” and is reinforced by patients’ beliefs and values about medicines as an available commodity.

Same broad issues; different contexts

Although we highlight that the “retailer” – “health care provider” paradox is common to both contexts, the drivers and barriers to the dominant retailer behaviour are clearly different. In the developed world the “business” of community pharmacy is, to a large extent, subsidizing any professional services provided (if they happen at all!!) and so the more patient centered the “business” of community pharmacy is with respect to medicine use, the less profitable it will be for the same sales levels. Further, the retailer culture of community pharmacy is solidly ingrained and the shift to a true primary health care provider organization may be a difficult one for many pharmacies.

In the developing world the retailer – health care provider tension is underpinned by a lack of regulation at the policy, legislation and provider levels. Trap et al highlights the similar issues in the current version of the SMR highlighting that staff are often insufficiently trained, inappropriate sales practice is common, drug regulation is often not enforced, and how medicines are stocked is not in line with good storage practices. Linked to all of these issues is the central aim in community pharmacy of keeping the patient safe whilst helping to improve primary care health outcomes. The Guest Editorial by Prof Leufkens in this issue of SMR highlights the need for regulation of drug safety management to ensure good pharmacy practice.

In a nutshell, for the developed world, the challenge lies with pharmacists moving towards the expectations of policy-makers under a fully remunerated system which does not rely on retail sales subsidizing professional activities. For the developing world, the challenge lies with increased government regulation, and to substitute the less qualified staff with fully trained pharmacists.

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References

Is it justified to let medicines fly without a black box?

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On July 21 2010 the Australian scientist David Warren who invented the flight data recorder, since then coined the ‘black box’, died at the age of 85. Warren designed the first flight data recorder in 1956, triggered by the complicated investigation of the mysterious crash in 1953 of the first jet airliner, the Comet. He felt strongly committed to airline safety given that his own father was killed in a plane crash in 1934. The concept of the ‘black box’ has had a major impact on safety analysis in the aviation world with the opportunity to learn from previous mistakes. Not only technically speaking, but also in terms of a creating a safety culture of bringing the best technology, management and learning systems in place to guarantee that airplanes are able to transport hundreds of thousands of travelers daily all over the world, in a relatively very safe fashion. The individual harm per mileage ratio is extremely low.

Recording, monitoring and understanding events over time at a given exposure is also a key requirement in drug safety. It starts of course with measuring, ascertaining and quantifying, the exposure itself. Here the link between aviation and pharmaceuticals is not new, in fact it is well recognised. A few years ago Urquhart used the term ‘pharmionics’, bringing together pharmaceutical and avionics, to address and to study what patients do with prescription drugs, particularly when under-dosing, delayed refills or missed doses affect negatively the efficacy, safety or both of these\(^1\). Given reliable data on drug exposure, and there is increasing awareness that drug exposure is not a dichotomous variable, the subsequent question is how the variance in drug exposure influences variance in drug response, both from an intended (efficacy, effectiveness) and an adverse (safety, costs) perspective. Moreover, drugs do not only have pharmacological effects but also many cultural and public health correlates and this warrants consideration\(^2\).

Allowing medicinal products to enter clinical practice and the pharmaceutical market place is always a decision under conditions of pertinent uncertainties. Ascertaining the right moment is a topic of a lively debate\(^3\). Whatever the outcome of this debate, and the cut-off point chosen for a minimum justifiable level of evidence for a valid benefit-risk decision, a new drug is always ‘unfinished’. As such there is a need for continual fine-tuning through a drugs life cycle, both in the clinical practice arena, as well as and in a regulatory sense. Fine-tuning means having access to reliable data on who is using the drug, under which conditions, co-morbidities, dosing, co-use of traditional medicines, response rates and so on.

Sad to say, despite the surge in record linkage databases, patient registries, and other medical record systems in many European and North American countries, most medicines still ‘fly without appropriate recording of their fate’ through medical practice leaving health care professionals, policy makers and regulators in the dark when it comes to adequate data on medicines’ usage and what it brings to patients and society at large. In effect there is no pharmaceutical black box! In many African countries cohort event systems are developed to evaluate the safety of new anti-malarial drugs\(^4\). This is good news, but a recent survey of pharmacovigilance activities in 55 low- and middle-income countries showed that only in a limited number of countries’ sentinel sites or active surveillance systems were in place to monitor the use and safety of new and existing medicines, i.e. in vulnerable populations, such as children, women of childbearing age, or the elderly\(^5\).

The pharmaceutical field can learn a lot from the aviation sector, but has yet to take up both this challenge and the potential opportunities. Given the high positive impact of medicines on public health and the potential for significant safety issues for society in general, it remains problematic that medicines continue to ‘fly without a black box’. This is not a question of lack of technology. This is mainly due to a lack of political will and a systems approach to therapeutics bringing the right knowledge, economic incentives and technology in place for the benefit of today’s and future patients.

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References

A new indicator based tool for assessing and reporting on good pharmacy practice

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Abstract

Objective: To develop an indicator-based tool for systematic assessment and reporting of good pharmacy practice (GPP).

Method: The tool comprises of a) a set of indicators, b) an indicator and survey manual, c) a data collection sheet, and d) Microsoft Excel based data collection and analysis tool. We developed a set of 34 pharmacy practice (PP) indicators using an iterative process to test their functionality in various pharmacy practice settings in Ethiopia, Uganda and Zimbabwe. Data were collected on the basis of direct observations, record reviews, interviews and simulated clients in surveyed facilities by trained survey teams.

Results: The indicator-based survey assessed five components of pharmacy practice: system, storage, services, dispensing and rational drug use. The manual and a data collection sheet were introduced in the training of surveyors and used as a reference to ensure clear understanding of indicator definitions and a uniform method of sampling and scoring. An Excel-based tool was developed for systematic data sampling and analysis. The survey results are presented in numbers and visualised in histograms and spidographs showing an assessed score against an ‘ideal’ GPP score. This indicator based tool proved to be simple and easy to use when assessing the various features of GPP.

Conclusions: The new GPP indicator-based assessment tool proved to be an easily applicable tool for uniform assessments of pharmacy practices and identification of problem areas. It allows for both intra- and inter-country comparison and for self-assessment. However, the indicators need to be further developed to test their applicability in developed countries. Moreover, research is needed to develop and validate additional indicators, especially those measuring ‘patient care’ including ‘patient/customer satisfaction’, and ‘self medication’ and to refine the existing indicators. It will also be important to define core (‘obligatory’) and complementary indicators.

Keywords: dispensing quality, dispensing practice, pharmacy practices, indicators, medicine management

Introduction

To improve the rational use of and access to essential medicines and provide proper patient care, it is crucial for medicines to be prescribed, managed, dispensed and used properly. The primary sources of medicines for people in developing countries are often a combination of dispensing doctors, pharmacy departments of hospitals, pharmacies, drug or chemist shops, and drug sellers (peddlers). Initial steps have been taken to assess Pharmacy Practices (PP) in public and private pharmacies, but systematic studies on the PP of these facilities are scarce. Findings indicate that in these settings staff are often insufficiently trained, inappropriate sales practice is common, drug regulation is often
A new indicator based tool for assessing and reporting on good pharmacy practice

not enforced, and how medicines are stocked is not in line with good storage practices. Studies from South Africa conducted in the mid-1990s provided a grim picture of dispensing doctors’ pharmacy practices with respect to storage conditions for medicines and the presence of expired drugs. Competition, profit margins and related financial incentives for dispensing medicines may conflict with public health goals and result in poor quality of pharmacy services, and thus poor patient care outcomes.

In 1991, the International Pharmaceutical Federation (FIP) together with the Swedish National Corporation of Pharmacies sponsored a conference that took place in Sweden. The output was the Stockholm Letter, which launched the first step in the development of international standards for pharmacy services, labelled Good Pharmacy Practice (GPP). The GPP elements were further refined and adopted by the World Health Organization (WHO). However, in many countries, there is no information as to what pharmacists, dispensing doctors, chemists and drug sellers should do and how they should perform with regards to GPP, although the WHO has taken steps to outline the role of the pharmacist at an international level.

In this context, the development of PP indicators is important for reliably assessing the components of GPP, including quality of care. Hence, there is a need to develop, adopt and enforce minimum standards for GPP as well as the means to assess PP in both private and public sectors. It is important to mention that the indicators have already been developed in the areas of “measuring medicine use”, “medicines management and quality of services in both public and private settings”. Despite the above efforts, a comprehensive set of international indicators for the assessment of GPP is still lacking.

The aim of this study is to describe a new indicator based tool for systematic assessments and reporting of good pharmacy practices.

Methodology

Indicator development

“Good Pharmacy Practice (GPP)” includes assessment of quality of care and that the medicines are available and accessible and are of safe, effective and good quality and are used correctly. Based on indicators measuring rational medicine use, national medicines policy indicators, quality of care indicators developed as part of the Pharm Value Project and indicators used in regular pharmaceutical sector surveys undertaken in Zimbabwe between 1992 and 2004, a set of 34 structural, process and outcome indicators were identified covering five essential components (system, storage, services, dispensing and use) (Table 1).

The chosen GPP indicators assess standard requirements for pharmacy practices which are in line with most countries official licensing requirements. However, requirements and practice implementation vary between countries. These indicators were further developed and refined through application to dispensing doctors and assessing GPP in initially Zimbabwe, Ethiopia and finally Uganda.

The 34 indicators were grouped into the five areas:

1. Five system indicators to assess the availability and use of a prescribing recording system, degree of computerization, and implementation of stock management and re-order system.
2. Seven storage indicators to assess presence of pests, cleanliness of the dispensing and storage area, pharmacy hygiene, storage conditions, system and practices.
3. Six service indicators to assess prescription load, opening hours, staff availability and qualifications, availability of services, and tests and health promotion activities.
4. Eight dispensing indicators to assess information available to dispenser, product range, dispensing time, packaging material, dispensing equipment, dispensing procedure and contact with prescribers.
5. Eight rational use indicators to assess information available to patients, patient care, labelling, rational prescribing, dispensing of ‘Pharmacist initiated medicines’, dispensing of antibiotics without prescription and generic substitution.

Development of a standard manual

Recognizing the importance of having a standard manual based on the experiences of the WHO medicine use and pricing indicator studies, a Pharmacy Practice indicator manual was developed and revised to ensure reliability, reproducibility and uniformity in assessments. The survey manual and Excel based data analysis tool are available on the internet at www.birnatrap.dk and can be downloaded at no charge. The PP manual defines each indicator including assessment area, indicator type, objectives, definition, verification, score calculation and data collection source. An initial PP manual was developed and piloted as part of a study assessing GPP in Initially Zimbabwe, Ethiopia and Uganda using focus group-discussion. The wording of the indicators changed based on the inputs from the surveyors from the three countries. During this iterative process the final manual was developed, however, the assessment area of the individual indicators remained unchanged. Table 2 shows an example of one of the indicators as described in the manual.
A new indicator based tool for assessing and reporting on good pharmacy practice

### Table 1. Indicators and components included in the pharmacy practice assessment tool and scores from private sector facilities in the three test-countries

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A new indicator based tool for assessing and reporting on good pharmacy practice

Data collection

Data collection was undertaken by trained data collectors. A team of eight health professionals with pharmaceutical backgrounds and one with a medical background undertook data collection in Ethiopia, two pharmacists in Uganda and in Zimbabwe four teams each of four, pharmacist, pharmacy technician and nurses. The PP manual was used in the training of the surveyors, providing them with a detailed explanation of the indicators and the data collection sheet. Depending on the surveyors’ experience in data collection, one to three days of training were provided prior to the data collection exercise. A data collection sheet was developed based on the survey manual. Training was given in the use of the data collection sheet followed by testing and role play in simulated practice settings. Special training was given on the three indicators that are based on simulated clients (mystery shoppers/surrogate patients), where the surveyors act as patients and enter the pharmacy for a specific consultation e.g. asking for an antibiotic without a prescription. The simulated clients had to visit the pharmacies with a specific consultation allowing for the assessment. The data collection sheet was developed in English and filled in by the surveyors on location. Patient exit interviews were, in some cases, conducted in the local language. Translation was enabled by the use of regional data collectors.

The data collection tool consisted of a manual, a data collection sheet and an Excel spreadsheet for data entry and analysis. The manual data collection sheet ensured independent data collection on site, of all data required, and allows for planning and optimal utilization of the time available to the survey team at each facility. The sheet contained data collection space for all 34 indicators, in the form of: structured randomized selection, 32 private and 39 public sector facilities in both Ethiopia and Zimbabwe but because of lack of resources, it was only conducted in private sector facilities in Uganda. At this stage, no validation of the tool was carried out, as the focus was more on reproducibility and surveyor-independence of the developed indicator based tool was carried out, as the focus was more on the “process development”.

The WHO drug use indicator study recommended a minimum sample of 20, while Global Alliance of Vaccine and Immunisation (GAVI) recommends a sample of 24 facilities within four districts; these methods were taken into account. Applying structured randomized selection, 32 private and 39 public facilities in Ethiopia, 27 private and 33 public in Zimbabwe and 33 private in Uganda, respectively, were selected from a list of eligible pharmacies provided by the drug regulatory authorities. All facilities in all three countries agreed to participate.

<table>
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<tr>
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<td>1</td>
<td>0.59</td>
<td>0.86</td>
<td>0.74</td>
</tr>
<tr>
<td>E3</td>
<td>1</td>
<td>0.08</td>
<td>0.30</td>
<td>0.80</td>
</tr>
<tr>
<td>E4</td>
<td>1</td>
<td>0.48</td>
<td>0.07</td>
<td>0.33</td>
</tr>
<tr>
<td>E5</td>
<td>1</td>
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</tr>
<tr>
<td>E6</td>
<td>1</td>
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<td>0.09</td>
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<tr>
<td>E7</td>
<td>1</td>
<td>0.00</td>
<td>0.00</td>
<td>0.81</td>
</tr>
<tr>
<td>E8</td>
<td>1</td>
<td>na</td>
<td>na</td>
<td>0.17</td>
</tr>
<tr>
<td>Total score</td>
<td>34</td>
<td>15</td>
<td>14</td>
<td>20</td>
</tr>
<tr>
<td>EAS (Final Assessment Score); % actual score vis-a-vis possible score</td>
<td>100.0%</td>
<td>46.1%</td>
<td>43.6%</td>
<td>60.1%</td>
</tr>
</tbody>
</table>
Table 2. Indicator description from the manual of indicator based assessment and analysis tool for Good Pharmacy Practice

<table>
<thead>
<tr>
<th>C4. Services offered</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment area:</td>
<td>Service quality/Services</td>
</tr>
<tr>
<td>Type:</td>
<td>Structure</td>
</tr>
<tr>
<td>Objective:</td>
<td>To ascertain the availability of services at the dispensing site:</td>
</tr>
<tr>
<td></td>
<td>1. Privacy in dispensing</td>
</tr>
<tr>
<td></td>
<td>2. Sitting facility</td>
</tr>
<tr>
<td></td>
<td>3. Weighing scale</td>
</tr>
<tr>
<td></td>
<td>4. Drinking water</td>
</tr>
<tr>
<td>Definition:</td>
<td>To verify if the services 1-4 are available for the customers</td>
</tr>
<tr>
<td>Verification</td>
<td>a) Check if privacy(^1) can be achieved in dispensing so that it is possible to talk and dispense medicines without other customers/clients listening to the conversation (Yes=1/No=0): _____</td>
</tr>
<tr>
<td></td>
<td>b) Check if there are chairs or benches for the customers to use, (Yes=1/No=0): _____</td>
</tr>
<tr>
<td></td>
<td>c) Check if a weighing scale is available to the clients, (Yes=1/No=0): _____</td>
</tr>
<tr>
<td></td>
<td>d) Check if drinking water (to take tablets) is available to the customers, (Yes=1/No=0): _____</td>
</tr>
<tr>
<td></td>
<td>e) Check if facilities to wash hands is available to the customers, (Yes=1/No=0): _____</td>
</tr>
<tr>
<td></td>
<td>f) Check if soap is available to the customers, (Yes=1/No=0): _____</td>
</tr>
<tr>
<td></td>
<td>g) Check if toilet is available to the customers, (Yes=1/No=0): _____</td>
</tr>
<tr>
<td></td>
<td>h) Check if toilet-paper is available to the customers, (Yes=1/No=0): _____</td>
</tr>
<tr>
<td>Calculation:</td>
<td>Overall score : sum of all Yes (1) divided by 8. Max score is 1.</td>
</tr>
<tr>
<td>Data source:</td>
<td>Dispensary site</td>
</tr>
</tbody>
</table>

\(^1\) Privacy might be achieved by carrying out dispensing in a separate room with only the patient and the dispenser or by having other patients kept away from the dispensing area by at least 2 meter.

Results

To facilitate uniformity and reproducibility of data analysis, information from the data collection sheet was entered centrally by the survey team leader into the Excel-based data collection and analysis tool. When calculating the GPP score, the maximum score of “one” is given for 32 of the indicators if these indicators are responded to correctly. Indicator A1 and A4 are composed of three respectively two sub-indicators (see Table 1), each assessing different aspects of the same indicator. Sub–indicator scores are weighted and allocated related to importers and essentiality given a total sum-score of one. The Excel-based assessment tool depicts the findings in the form of a histogram and a spidograph of all five components calculated for each facility, as well as a mean for all assessed facilities in a jurisdiction/country (Figures 1 and 2).

The histogram in figure 1 depicts component scores as the actual score, compared to the possible maximum score, but comparison is also made taking into consideration indicators that are non-applicable (na) or with missing data (na). Completion rates for data collected per facility or per country were calculated as the difference between “possible” and “possible max” score. Using the data in the histogram, completion rates of Ethiopia were calculated to as 84% (percentages of “possible score” of 28.48 (sum of the five components) divided by “maximum possible score” of 34). Moreover, the histogram is useful for prioritizing possible actions related to a component. The histogram prioritization should always be followed by further assessment of the facility scores for the individual indicators forming the basis for specific interventions.

The spidograph in figure 2 is designed such that all five areas are given equal weight with up to five as maximum score, independent on the number of questions contributing to the assessment. The questions within each of the 5 assessment areas have different weight, for example the “System” area is assessed by 5 questions and “Dispensing” area by 8 questions. In the case of 5 questions, each question has the weight of one (5/5=1) whereas if there are 8 questions, each question is given a lower weight (5/8=0.63).

The spidograph visualizes the strengths and weaknesses of pharmacy practice for each visited facility and for the whole sample of visited facilities depicted in one (mean) spidograph. Contrary to the histogram, the spidograph depicts each component with equal weight (maximum 5), independent of number of measuring point (indicators) and taking into consideration missing data. The spidograph thereby provides a simplistic visual overview of pharmacy practice performance (shaded area) and allows for prioritisation of interventions.

A ‘Final PP- Assessment Score’ (FAS) was also calculated. This score was based on the score of all 34 indicators as a percentage of the actual score relative to the possible score (Table 1).

As the aim of this article is to describe a new indicator based tool for assessment and reporting on GPP, the data from pilot testing are not being presented in this paper in full. Test data is used to illustrate the possibilities of using the tool, i.e. depicting survey results and for illustration of the ability for comparison (Table 1 & 2).
A new indicator based tool for assessing and reporting on good pharmacy practice

Discussion

Descriptive indicator studies have been used for many different purposes. The initial pharmacy practice (PP) indicator studies in Zimbabwe provided information to identify and prioritize problem areas and to assess the effects of interventions\(^1\)\(^{,}\)\(^2\)\(^{,}\)\(^6\). The PP indicator studies have also been undertaken to increase awareness of the problem of inappropriate pharmacy practices by dispensing doctors\(^6\). Moreover, the PP indicator based assessment can also serve to describe the status of GPP implementation, provide a base line for future interventions and form the basis for development of pharmaceutical master plans aimed at improving GPP in private and public sector pharmacies.

This is the first time a standard method has been developed to assess and report on PP status and implementation of policies and regulations. We have developed a PP indicator-based assessment tool encompassing four elements: a) a set of 34 indicators, b) a manual, c) a data collection sheet and d) an Excel based data collection and analysis tool. On the basis of the experience gained from testing the tool in different settings in the three test countries (Ethiopia, Uganda, Zimbabwe) we found that this PP assessment tool provides a simple and comprehensive evaluation of PP status. The PP assessment provides a quantitative indication of PP status and quality of pharmacy services that can facilitate comparison of results over time and place and motivate those who are monitoring the performance. The assessment tool provides information on which components and indicators need most attention. By repeating the assessment, it is possible to quantify the impact of an intervention and make comparisons between “intervention facilities” and “control facilities”\(^1\)\(^,\)\(^2\)\(^7\).

Indicator selection and the manual

Compared to other PP assessment studies\(^2\)\(^–\)\(^4\), we have developed a comprehensive and detailed tool. Three of the indicators assessing rational use involve simulated clients (SCs), surrogate
A new indicator based tool for assessing and reporting on good pharmacy practice

Critical reflection on tool development and testing

For many of the indicators, the ideal situation is obvious and is easily responded to by a ‘Yes’ or a ‘No’. However, for some of the indicators a professional background is required to undertake the necessary assessment and scoring. A background understanding of GPP by the surveyors, preferably a pharmacist or pharmacy technician, is an advantage. However, if a pharmacists or pharmacy assistants is not available then surveyors can be trained. We believe that the introductory training is mandatory in ensuring uniform interpretation, but validation studies are needed to investigate this tool’s reproducibility both with regard to repeated assessment of the same facility and “inter surveyor” fluctuations.

For few indicators, the correct answer or ‘pass’ values are not that obvious. An example of this is dispensing and counselling time. The score system was selected based on an estimate of the time required for appropriate dispensing. We have assumed that it takes time to dispense medicines appropriately including provision of information. A dispensing time of more than 60 seconds gives the maximum score of 1. Between 30 and 59 seconds gives 0.5 and less than 30 seconds score 0. There is a need to further define how the indicators should be surveyed or verified in the future.

Conclusion

Internationally applicable PP indicators are critical to improve good pharmacy practice in both the public and private sectors. The pharmacy practice tool discussed in this paper provides easy, reliable way to improve the use of medicines. The data needed for the indicators are easily collected from direct observations, records, interviews and simulated clients. However, the indicators need to be further tested to evaluate their applicability in developed countries and in other settings. Research is also needed to develop and validate additional indicators, especially those measuring self-medication and patient care. It will also be important to define core (‘obligatory’) indicators and additional indicators. The use of the tool is expected to improve GPP, which will lead to improved quality of services, management, dispensing and rational use of medicines.

Acknowledgement

We would like to thank Nina Grøntved for her assistance with data collection in Uganda, and the European Commission for funding the studies in Zimbabwe.

Conflict of interest

We have not identified any conflicts of interest.

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Policy Analysis

Medicine pricing policies: Lessons from Vietnam

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Abstract

Objectives: The objective of this paper is to provide an analysis of the medicine pricing policies in Vietnam. These policies are reflected in legislation and associated governmental administrative instruments.

Methods: All the legislation and sub-legislation such as laws, ordinances, decrees, and circulars relating to medicine pricing policies in the period of health reform from 1989 to March 2008 and the policy context were examined using a documentary analysis. The analysis was constructed around the three components of the policy cycle: policy formulation, implementation and accountability.

Results: The Vietnamese Government has sought to limit inappropriate increases in medicine prices through legislation designed to ensure public access to essential medicines. The principal legislative mechanism has been one of transparent declaration and publication of medicine prices. The most progressive regulation has been Joint Circular No.11/2007/TTLT-BYT-BTC-BCT, which controls the wholesale mark-ups in the medicine supply chain through the declaration of a reasonable wholesale price to the Ministry of Health. These marked legislative changes have yet to reach their full potential because some administrative prerequisite elements have yet to be implemented.

Conclusions: Analysis of the regulatory reforms demonstrates that Vietnam medicine pricing regulations have become increasingly sophisticated. While appropriate legislation is pivotal to control medicine prices, it is an insufficient mechanism alone to achieve the level of change required. Enforcement of legislation at the administrative level is also of critical importance, as is ongoing monitoring of legislative effects including the socio-economic factors affecting prices. More work is needed to ensure reasonable prices of medicines in Vietnam.

Keywords: Vietnam, medicine pricing policy, access to medicines, policy cycle, policy implementation

Introduction

Almost all developed countries have exercised some form of medicine price control1. Those measures include direct price controls (maximum fixed prices, negotiated prices, international price comparisons and price cuts or freezes) and indirect approaches (profit regulation or reference or index pricing)2. The United States (US) is the only major developed country that does not regulate medicine prices as a matter of policy3. However, in the US, Health Maintenance Organizations (HMOs) negotiate the prices of medicines purchased1. While often lacking any form of health insurance, developing countries usually have less regulated pharmaceutical markets4. Prior to 1989, the health care system was heavily subsidized in Vietnam. All health care services and medicines were supplied free of charge5. A strict medicine price control strategy was in place5. Medicines, from central and local sources, were sold only via the public sector with one uniform price set by Government throughout the country5, 6. On 5 November 1987, joint Circular 28-TTLT of the State Price Committee and the Ministry of Health was issued. This provided a measure of flexibility in medicine pricing by permitting local sources to have a different designated price level within a price bracket set by the Ministry of Health. In 1989, Vietnam made important heath sector reforms. The provision of free medicines dispensed through the public...
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health care system was replaced by a system of direct payment by patients\(^9\). Former restraints on the production and sale of pharmaceuticals were liberalized and private medical and pharmacy practices legalized\(^9\). With the shift to free market pricing for medicines without government control, medicine prices became unaffordable for most people. Adjusted for Purchasing Power Parity in 2005, the prices to patients in the public sector were 46.58 and 11.41 times the international reference price for innovator brands and lowest-priced generic equivalents, respectively\(^11\). To remedy this problem, the Vietnamese Government introduced legislation to stabilize medicine prices.

Recognizing the inadequacy of pharmaceutical regulations introduced since 1954, the Vietnam Ministry of Health commenced drafting the first Pharmaceutical Law in 1997 which was finally enacted on 14 June 2005, after almost a decade of consultation, discussion, drafting and development. The new law provided a comprehensive legislative framework for all aspects of the pharmaceutical sector, including specific medicine pricing provisions. Subsequently, additional legislation and regulations on medicine pricing followed.

Notwithstanding the significance of these legislative measures, medicine prices in Vietnam kept growing\(^12\). Prices to patients for some medicines were up to ten times their imported prices, an example being paracetamol intravenous imported by Danang Pharmaceutical and Medical Equipment Joint Stock Company (9.28 times)\(^13\). Low compliance of medicine pricing regulations was also reported when some medicines were sold at prices of up to 300% more than those declared by their registrants at the Vietnam Drug Administration. In other cases, a hedge price of 200% more than the actual imported or selling prices was declared or published\(^12\). An understanding of how and on what basis the pricing provisions were developed is necessary prior to formulating effective solutions. This paper analyses the strengths and weaknesses of the legislation which determines medicine pricing policy in Vietnam, and its impact on prices. Feasible options are recommended to maintain medicine prices at reasonable levels, including implementation features.

Methodology

A systematic documentary analysis was undertaken in consultation with Vietnam Ministry of Health officials from April to July 2008. Relevant regulatory documents in the Vietnamese language (or English language where available) were obtained and analyzed. All legislation and sub-legislation from January 1989 to March 2008, namely laws, ordinances, decrees, and circulars, regarding medicine prices and policy context were included. Technical reports of implementation of these regulatory documents were also examined. The main sources of these documents were the Drug Price Management Division of the Drug Administration of Vietnam, the Inspectorate of Vietnam Ministry of Health, the website of the Ministry of Justice of Vietnam: http://vbqpl.moj.gov.vn/law/vi/index.html (later replaced by the current website: http://vbqpl.moj.gov.vn/Pages/vbpq.aspx), and a commercial website: http://legal.khaitri.vn. Web-based searches on Vietnamese language documents as they related to key topics such as giá thuốc (drug price), chính sách giá thuốc (drug pricing policy), quản lý giá thuốc (drug price control) were conducted. The initial list of identified documents was expanded by checking cross-references stated in the legal basis section of each regulatory document. Consultations with officials in the Drug Price Management Division of the Drug Administration of Vietnam were undertaken, in order for them to suggest other documents and reports that were not available on the web prior to finalizing the list of documents for analysis.

An analytical framework was developed for the three components of the policy cycle: formulation, implementation and accountability\(^4\). Policies and legislation related to medicine pricing were analyzed for the extent to which they were appropriately developed and sufficiently implemented to control medicine prices. Also investigated was the degree of government accountability in this process. Based on the policy cycle framework, a structured set of questions adapted from Rist (1994) was developed to facilitate analysis (see Appendix 1).

Individual regulatory documents were analyzed by the first author (ATN) using the questions developed. Technical and inspection reports of implementation of these documents were used to assist in answering these questions. Where documentary data were not available to answer a question, consultations with Vietnamese medicine pricing authorities were conducted. Answers attained were compared across different policy documents to assess the regulatory reforms.

Results

Vietnam only accepts legislative and sub-legislative regulatory documents, not case law, as legal manifestation. The former comprises the Vietnam Constitution, Laws or Law Sets, and Resolutions of the National Assembly. The latter includes Ordinances, Resolutions of the Standing Committee of the National Assembly; Decrees of the Government (often issued to elaborate laws/ordinances); and Ministerial Circulars (to guide implementation of Decrees)\(^9\).

An extensive discussion of all legal instruments and policies introduced by the Vietnamese Government post 1989 to stabilize unaffordable medicine prices goes beyond the scope of this paper. Instead, the analysis focuses on the most pertinent current medicine pricing provisions regulated by Pharmaceutical Law No 34/2005/QH11, elaborated in Government Decree 79/2006/ND-CP; and the implementation Joint Circular 11/2007/TTTL-BYT-BTC-BCT. Also investigated were past pricing provisions, outlined in Joint Circular 08/2003/TTTL-BYT-BTC and in Government Decree 120/2004/ND-CP, which formed the basis of current medicine pricing policies.
**Context of medicine pricing regulations in Vietnam**

In 2003, the Vietnamese Government requested that the Ministry of Health in cooperation with the Ministry of Finance issue a joint Circular guiding price management for essential medicines, to stabilize medicine prices at a reasonable level\(^\text{16}\). Consequently, Joint Circular 08/2003/TTLT-BYT-BTC (Circular 08) was issued and came into force on 21 August 2003, expiring on 16 October 2007.

Circular 08 had limited success: medicine prices kept increasing. In response, the Government urged the Ministry of Finance in collaboration with the Ministry of Health to submit a Decree on the management of medicine prices to the Government for approval\(^\text{17}\). Accordingly, Government Decree No 120/2004/ND-CP (Decree 120) on the management of prices of preventive and curative medicines for human use was promulgated. The Decree came into effect from 4 June 2004 to 7 September 2006. This Decree was the first legal instrument issued by the Vietnamese Government specifically designed to manage medicine prices.

Decree 120 was replaced by Decree 79/2006/ND-CP (Decree 79), enacted 9 August 2006. This regulated in detail, implementation of a number of Articles of Pharmaceutical Law No 34/2005/QH11, including elaborating Article 5 of the law on “State management of medicine prices”. A year later, Joint Circular No 11/2007/TTLT-BYT-BTC-BCT (Circular 11), the result of cooperation among the Ministry of Health, the Ministry of Finance, and the Ministry of Industry and Trade, was promulgated to guide implementation of Government Decree 79 on State management of medicine prices. Circular 11 came into force on 16 October 2007 and replaced Circular 08. Circular 11 together with Decree 79, which was effected on 7 September 2006, comprise the current medicine pricing policy in Vietnam.

**The mechanism of medicine pricing policies**

The regulatory framework for medicine pricing is based on a modified free market pricing structure. Pharmaceutical Law No 34/2005/QH11 states that medicine suppliers and distributors are free to set prices of their products based on market forces, subject to stabilization by the State. Declaration and publication of price information aimed at improving transparency has been one of Vietnam’s main mechanisms for stabilizing pharmaceutical prices.

**The reasonableness of declared prices and published prices**

Circular 08 did not regulate the reasonableness of the declared prices and published prices. After it came into effect on 21 August 2003, the prices of a number of medicines increased sharply. For example, one box of 10 dissolvable tablets vitamin C 1g had a price of VN Dong\(^*\) 19,000 to 20,000 in July 2003. It was sold with a price of VN Dong 22,000 to 23,000 in September 2003, while the published price was VN Dong 25,000/box\(^*\). Pricing instruments other than Circular 08 used one or more tools such as selected international comparisons and imposition of maximum distribution margins to ensure reasonable declared prices.

**International comparison system**

Decree 120, Decree 79, and Circular 11 all used a comparative pricing system. This system attempted to ensure that the prices of medicines in Vietnam were reasonable in relation to comparable countries. There are, however, differences in the use of the comparative pricing system across pricing instruments, based on the type of prices for comparison, the standard of comparison, and the selection of countries for comparison.

None of the Vietnamese regulations explicitly and clearly defined the type of prices for international comparisons (i.e. ex-factory price or wholesale price or retail price, before or after taxes). By requiring manufacturers not to set a price in Vietnam higher than that of the medicines of the same category sold in comparator countries, Decree 120 implicitly referred to ex-factory price for comparison. It did not indicate if the price was before or after taxes were applied. Decree 79 stated that declared prices could not be higher than corresponding prices for medicines of the same categories sold in comparator countries, implying a range of prices for comparison. Circular 11 used as a benchmark the average cost, insurance, and freight (CIF) price of the medicine that the foreign producer had sold to other comparable regional countries, but did not specify what type of prices declared in Vietnam should be used for comparison.

Decree 120 and Decree 79 used the highest price standard and category base for international comparisons. They required the price of a medicine sold in Vietnam “not to be higher than” prices of medicines of “the same categories” sold in comparable countries. In contrast, Circular 11 used the average price standard and a medicine-to-medicine comparison base. It stated that the declared price of a medicine imported into Vietnam was not to be higher than the “average CIF price” of “this medicine” sold in comparator countries.

Decree 120 specified comparator countries as those having similar medical and commercial conditions as Vietnam. It did not, however, nominate the comparator countries or specify selection criteria. It was not until Decree 79 that specific criteria were nominated, with statistical indices similar to those of Vietnam (see Article 10(4)): (i) per-capita gross domestic product (GDP) per year; (ii) per-capita GDP at purchasing power parity (PPP) per year; and (iii) networks of providing services for preventive medicine, medical examination and treatment, functional rehabilitation and health improvement, and medicine supply. In 2008, two years after Decree 79 came into force, the Ministry of Health proposed a list of comparator countries: Thailand, Malaysia, Indonesia, The Philippines and Cambodia. This feature, however, has yet to be implemented. Similarly, Circular 11 required the Government to decide and announce the list of comparators annually, but no list of comparator countries has yet been established.

\(^*\) Vietnam currency
Maximum distribution margins

Maximum distribution margins to ensure the reasonableness of wholesale and retail prices were only explicitly used in Decree 120. Decree 120 allowed wholesalers and retailers a separate maximum margin for their services. The Ministry of Finance was required to regulate these maximum mark-ups. However, up until Decree 120 expired on 7th September 2006, there was no implementation Circular to guide this provision. As a result, no specific wholesale or retail margin was set or regulated.

As such, a number of preconditions intended to ensure the reasonableness of medicine prices declared in Vietnam have either not been regulated or not administratively enforced. This, together with the shortage of personnel and resources for assessing the reasonableness of declared prices of all medicines marketed in Vietnam, has meant that most of the information on medicine prices declared by pharmaceutical companies has not been analyzed or validated. Not unexpectedly, this situation has been exploited by pharmaceutical companies to an unacceptable degree, as shown by discrepancies in declared and actual medicine prices outlined in the following example.

The CIF price of medicine X in the Vietnam custom declaration for import commodity was US $4.5/box of 100 capsules. However, the registrant (Company A) declared with the Drug Administration of Vietnam a false CIF price of VN Dong 540,000/box (US $ 34.4), 764% higher than the actual CIF price (Table 1). Without validation from the Drug Administration, this inflated, false CIF price enabled the company to declare a reasonable-looking retail price of VN Dong 700,000/box (approximately 30% higher than the false CIF price1 and still lower than the price in India, which is also unchecked). After being imported from Company A, this medicine went through several rounds of “buying and re-selling” and the final price to hospitals and clinics was VN Dong 650,000/box, still below the declared price of VN Dong 700,000/box but 920% higher than the real CIF price.

Declaration and publication provisions

Relationship between the declared price and published price or selling price

Circular 08 and Decree 120 did not regulate the relationship between the declared and the published prices, or between the declared and the selling prices, while Decree 79 regulated it insufficiently. In contrast, Circular 11 required medicine producers or importers to declare the final wholesale price of medicines for the entire wholesale chain. Wholesalers were not permitted to sell medicines at prices higher than those declared. Nevertheless, the relationship between the declared and the retail prices was not regulated.

Responsibility for publishing retail prices on the package of medicines

Other pricing regulations required retailers to publish retail prices on medicine packages. Circular 08 also required the pharmaceutical manufacturers and importers to do this. However, this provision was opposed by a number of manufacturers and importers when implemented on 1 October 2003. Consequently, the Ministry of Health first delayed the deadline for implementation of this provision to 1 November 2003 (Official dispatch No 9080/YT-QLD of 22 September 2003), then postponed it further to 1 January 2004 (Official dispatch No 9251/YT-QLD of 29 September 2003).

Re-declaration

Neither Circular 08 nor Decree 120 regulated how established medicines could receive a re-declared price in future years. In contrast, Decree 79 and Circular 11 required changes to be made to the system of setting declared prices. Producers or importers wanting to sell their medicines at prices higher than those originally declared were required to make a re-declaration with an explanation prior to applying new prices. Table 2 summarizes characteristics of the declaration and publication mechanism used in the pricing regulations of interest.

Other pricing provisions

Except for Circular 08, all pricing instruments prescribed additional price controls for two targeted medicine groups. The first group included medicines directly ordered and purchased by the State, not using a tender. The prices of these medicines were determined directly by the Minister of Finance. The second group comprised medicines purchased by hospitals and other health care institutions that were paid for by the State budget and health insurance. The prices of these medicines were controlled by a tendering process, first regulated in Joint Circular No 20/2005/TTLT-BYT-BTC of 27 July 2005 and subsequently by Joint Circular No 10/2007/TTLT-BYT-BTC of 10 August 2007. The successful tender prices were not allowed to be higher than the latest maximum price as announced by the Ministry of Health every six months. However, the Ministry of Health has yet to find a way of determining this maximum price. Accordingly, no price-cap or price ceiling has yet been implemented.

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1 An unwritten rule that Vietnam medicine pricing authorities used in appraising the pharmaceutical registration dossier of pharmaceutical companies before granting a market license (locally called a visa number) is that if the difference between declared selling price and declared CIF price of a medicine is more than 30% of the CIF price, the registrant of the medicine will be requested to explain how they set declared selling price, and the medicine is likely not to get its visa number if the registrant fails to provide a rationale for that.
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Table 2. Summary of preconditions of declaration and publication mechanism used in Vietnam pricing regulations

<table>
<thead>
<tr>
<th></th>
<th>The reasonableness of declared prices</th>
<th>Declaration and publication provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>International comparison standard</td>
<td>Wholesale/retail mark-ups</td>
</tr>
<tr>
<td><strong>Circular 08 (2003)</strong></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Decree 120 (2004)</strong></td>
<td>Highest price</td>
<td>Category base</td>
</tr>
<tr>
<td><strong>Decree 79 (2006)</strong></td>
<td>Highest price</td>
<td>Category base</td>
</tr>
<tr>
<td><strong>Circular 11 (2007)</strong></td>
<td>Average price</td>
<td>Medicine-to-medicine base</td>
</tr>
</tbody>
</table>

Discussion

Vietnam’s legislation and associated instruments were intended to ensure transparency of medicine prices along the supply chain, through the mechanism of price declaration and publication of price information. These initiatives have been less successful than expected because they did not address all the preconditions necessary for the laws to operate effectively in practice. These included the need for reasonableness of declared prices and the relationship between declared, published and selling prices. Additionally, some provisions of the regulations were not monitored or enforced.

The reasonableness of declared prices and published prices

Circular 08 contained a major flaw. It did not require the declared prices and published prices to be reasonable. Thus, pharmaceutical suppliers declared and published medicine prices as high as the market would bear, resulting in a sharp increase in the price of many medicines. In response, the Ministry of Health was forced to proclaim that Circular 08 was not for management of medicine prices, but only for implementation of price declaration and publication. In retrospect, Circular No 08 might be considered of limited benefit in controlling escalating medicine prices.

Although Decree 120, 79 and Circular 11 did require reasonableness of declared prices, the tools for assessing reasonableness were either not complete, or inadequate. Firstly, the type of prices for international comparison was not specified. The final consumer price of a medicine is generally composed of four parts: an ex-factory price paid to the manufacturer; a wholesaler’s margin paid to the wholesaler; a retailer’s margin paid to pharmacies; and whatever taxes are imposed on medicines. The price varies along the supply chain. A valid comparison is only achieved when prices are compared at similar levels of the supply chain. Without specification of price type, comparisons used in Vietnam became less effective.

Practical consideration was not given to the inclusion of the whole price range for comparison regulated in Decree 79. The comparison with “corresponding price” resulted in a number of comparisons between a range of prices from import price to wholesale price to retail price, or additional taxes. This caused intractable difficulties in the collection of comparative price data as a benchmark for enforcement.

Circular 11 should have clearly indicated that the price at the same level (the CIF price) declared in Vietnam be the comparator. When implemented, the effect was that the system could only ensure the reasonableness of the CIF price, (i.e. the price at ex-manufacturer/importer level). Although medicine prices were controlled at wholesale level through declaration of the final wholesale price for the entire chain, criteria for assessing the reasonableness of the declared price were not clear-cut, causing further compliance difficulties for suppliers.

Secondly, consideration should have been given to the level of the comparison base and standard. The use of category base comparisons posed methodological dilemmas of category definition. Comparisons can be applied to different levels of medicine groups such as those that have identical bioactive ingredients, a group of analogue medicines (i.e. chemically slightly different but related medicines with comparable or identical indications), or a group of all medicines used to treat a particular condition. Using a medicine-to-medicine comparison, specifying the same active ingredients, strength and dosage form, as regulated in Circular 11 avoids this methodological problem.

Using the highest price comparison standard proved problematic. A strict interpretation of the comparison "not
Medicine pricing policies: Lessons from Vietnam

higher than" implies that the price in Vietnam could be as high as the highest price among the comparator countries. Using this approach, the Vietnamese Government unwittingly created an opportunity for pharmaceutical suppliers to set the highest price for each medicine, resulting in higher average prices in Vietnam than in the comparator countries. Using the average price standard as in Circular 11 overcomes this problem. However, if the comparators include one or more countries with unreasonably high prices, the outliers will result in a higher average price. Choosing a broader list of comparators and taking the average price in the three lowest-priced countries among those referenced, as modeled by Columbia or the Slovak Republic, may be a solution. Alternatively, the median price standard can be used to reduce the influence of outliers.

Finally, because no list of comparators was established in Vietnam, external reference pricing could not be employed. Although the current criteria for selection are specific, it seems difficult to find another country with entire networks of health care and drug supply similar to Vietnam, as regulated in Decree 79. More flexible criteria for medical condition are needed. Selecting countries with some form of price control to ensure prices in the calculation are not unreasonably high, or where reliable medicine price information is available could also be considered.

Declaration and publication provisions

Prior to marketing in Vietnam, a medicine must be registered with the Ministry of Health with a declared price nominated by the registrant company. The Ministry issues an approval license, usually valid for five years after which the product must be re-registered. However, in accepting the declared price, Circular 08 and Decree 120 did not take into account the life-span of the approval license. It failed to provide for the re-declaration of prices in response to changed economic circumstances, such as adjustments for inflation over the life of the license. Thus registrants were implicitly encouraged to declare the highest possible price to leave room for future cost fluctuations.

Overcoming shortcomings of previous pricing regulations, Decree 79 and Circular 11 required producers or importers to declare increases in prices with an explanation prior to applying new prices. This important clause provided a legal framework for monitoring increases in medicine prices as well as ensuring they remain realistic throughout the license period. The clause also permits suppliers to change their prices after the declaration, thus releasing the pressure of having a fixed price for the entire five-year approval cycle.

This provision however, is only effective if the declared prices are reasonable. The motive remains for suppliers to ‘hedge’ their prices to leave room for future increases. This is problematic because it counters the effect of price declarations. The suppliers can take advantage of this feature to charge customers higher prices based on the hedge price declared to the Government. The authorities also cannot monitor increases in medicine prices if the increased prices are still below the hedge declared prices. Medicine prices can decrease naturally (e.g. when a medicine goes off patent) affording an opportunity which would be lost by reliance on this declaration and publication mechanism. Thus, over-regulation in a functioning market may be counterproductive, keeping prices artificially high.

All pricing regulations have stipulated that drug suppliers cannot sell their products at a price higher than those published. This has enabled the published price to be a ceiling to control actual selling price. The success of this mechanism has depended therefore on the assurance of the reasonableness of the published price. The reasonableness of prices however could not be assessed since the provision of maximum retail margin was not implemented (Decree 120), nor was there any provision of maximum retail margin regulated (Decree 79 and Circular 11). There was also no provision to regulate the relationship between the published and declared retail prices. As a result, pharmacies often published hedge retail prices that were much higher than actual selling prices, sometimes 200% more than the selling prices.

Recommendations

While external price benchmarking is most widely used to limit medicine prices, different countries select different baskets of comparators based on their own goals. As Vietnam aims to control prices, criteria to select comparator countries may include: (1) commercial conditions: per-capita GDP both in real term and at purchasing power parities; (2) medical conditions: coverage of public health insurance; relative importance of domestic medicine production and import; per-capita medicine spending (as a share of total health care spending and as a share of GDP); (3) system for controlling medicine prices and; (4) availability of price information international cooperation to develop price information linkages would be beneficial. This would enable Vietnam to obtain reliable data to ensure integrity in price reporting.

The Drug Administration of Vietnam should also regularly analyze medicine price trends, including declared prices and those paid by public healthcare facilities. This will assist in future policy development and facilitate monitoring the integrity of reported medicine prices and effectiveness of pricing regulating measures. Nevertheless, a methodology to assess the effect of pricing policy on medicine prices is required, and the development of a drug-pricing bureau with research capacity would be advisable.

Current pricing instruments do not prevent fluctuations below declared prices. Stricter direct limits on price increases are needed. Given Vietnam’s heavy dependence on the international pharmaceutical market, a complete freeze on medicine price increases, although not uncommon in many European countries, is impractical at this stage. Limits on the frequency of price increases in Vietnam may be a policy option. Specific limits on permissible medicine price increases such as limits to
increases in the Consumer Price Index may provide a better basis for an assessment of reasonable medicine price increases when medicine prices are renewed. Other provisions of the Pharmaceutical Law such as measures to promote generic medicines and the domestic pharmaceutical industry may also be desirable to complement the medicine pricing policy, entailing in some cases new legislation. However, regulation alone may not guarantee access. Pushing prices too low without taking into consideration socio-economic factors may force pharmaceutical firms to withdraw products from sale to prevent loss, thus reducing the availability of medicines.

Conclusions
Analysis of the regulatory reforms demonstrates that substantial improvements have been made in medicine price control within Vietnam. While appropriate legislation is pivotal to control medicine prices, it is insufficient alone to achieve the required changes. Also critical is the enforcement of legislation and ongoing monitoring, including socio-economic factors affecting prices. More work is still needed to ensure reasonable medicines prices in Vietnam.

This study uses the qualitative method of documentary analysis based on a framework of the key elements of the policy cycle. The study has provided substantial in-depth understanding of the contextual framework of medicine pricing laws and policies in Vietnam, identifying where additional improvements can be made to stabilize medicine prices. Moreover, given the paucity of rigorous quantitative studies evaluating pharmaceutical pricing policies, this study has demonstrated an alternative approach to examining medicine pricing policies. Based on this study, the approach is likely to be more applicable to developing countries which often lack a reliable and systemic data source on medicine prices; a precondition for rigorous quantitative assessment of pricing policies and their impact.

Contributors
All authors contributed to the paper’s conception and design. ATN undertook the analysis and interpretation of the data. ATN drafted the paper with contribution from RK, AM, QMC, and GB. All authors participated in critical revision and have approved the final version for submission.

Acknowledgements
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References
Appendix 1: Medicine pricing policy in Vietnam: Document analysis framework


1. General information:
   1.1. What is the document title and issuer?
   1.2. What is the date of issuance?
   1.3. What is the type of the document?
   1.4. What is the scope and subjects of application of the document?

2. Policy formulation: Addressing this component will assess if past and current pricing policy has been appropriately developed.
   2.1. What is known about the policy problem or condition at hand?
      2.1.1. Are there clear definitions of the problem or conditions for the pricing policy to address?
      2.1.2. What are they?
      2.1.3. How well can they be measured?
   2.2. What is known about previous initiatives in response to controlling medicine prices?
      2.2.1. What regulations have been previously initiated?
      2.2.2. How long did they last?
      2.2.3. Who developed them?
      2.2.4. In what context were they developed?
      2.2.5. How successful were they?
      2.2.6. How receptive were the stakeholders to these regulations?
      2.2.7. How did the stakeholders react to the regulations?
      2.2.8. What outcomes were resulted because of the regulations, both anticipated and unanticipated?
   2.3. What is known about the previous efforts and their impacts that would help policy makers choose among alternatives?
      2.3.1. What was the time period for measurable outcomes or impacts to appear?
      2.3.2. How did the policy makers in those circumstances hold on to the public support and keep the coalition intact long enough for the results to emerge?
   2.4. What is known about the chosen alternative (the current policy of interest)?
      2.4.1. What are the measures policy makers choose to address the problem or condition?
      2.4.2. What are their strengths and weaknesses?

3. Policy implementation: Addressing this component will determine if the pricing policy of interest was efficiently implemented to control medicine prices.
   3.1. What is known about the implementation process?
      3.1.1. What is the degree to which the policy is reaching the intended audience?
      3.1.2. What are the aspects of the policy that are or are not operational?
      3.1.3. Is there the institutional capacity to respond effectively to the enforcement of the policy?
   3.2. How has the problem changed over time and has the implementation of policy changed with it?
      3.2.1. Has the problem improved, worsened or remained static?
      3.2.2. Do the aims of the policy still match the assumptions and previous understandings of the problem?
      3.2.3. Are there subsequent complementary changes within policies related to the current problem?
   3.3. How and what do institutions or agencies respond to the problem?
      3.3.1. Do the policy makers, policy implementation staff have the same understanding of the problem?
      3.3.2. What has been the transformation of the relevant institutions’ or agencies’ understandings that have taken place when the policy is actually being implemented?

4. Policy accountability: Addressing this component will determine if there has been accountability in relation to the pricing policy of interest.
   4.1. Were the objectives met?
      4.1.1. What were the anticipated and unanticipated outcomes in relation to controlling medicine prices?
      4.1.2. Were changes in the understanding of medicine pricing practice due specifically to the policy?
      4.1.3. What social changes, if any, resulted from the policy?
      4.1.4. What were the strengths and weaknesses of the organizational structure that was used to implement the policy?
   4.2. What changes occurred within the medicine price problem?
      4.2.1. Has the policy changed with the more current circumstances?
   4.3. How accountable was the organization in the implementation of the policy?
      4.3.1. Was the policy appropriately managed or supervised?
      4.3.2. Was data regarding drug pricing practice used in decision making?
Research Article

Implementation of a pharmacist managed anticoagulation clinic in Eldoret, Kenya

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Abstract

Objectives: This investigation characterizes the demographic characteristics of the patients attending a pharmacist managed anticoagulation clinic in the resource-constrained setting of western Kenya and outlines the challenges of delivering an anticoagulation monitoring service in this setting

Methods: Through the collaboration of Purdue University College of Pharmacy faculty and local Kenyan pharmacists, a contextualized anticoagulation clinic care model has been developed which incorporates community health workers, pharmacy technologists, and physicians to deliver protocol-based care. Through the collection of data on standardized encounter forms, the initial demographic characteristics of this population are described.

Results: The unique mix of indications for anticoagulant therapy of the 83 patients enrolled thus far can be seen as 9.6% have artificial heart valves, 18.0% have rheumatic heart disease induced valvular changes, and 59.0% have deep vein thrombosis or pulmonary embolism. Several setting specific challenges have been identified including the potential for drug interactions with warfarin due to concomitant therapies for disease states such as tuberculosis and Human Immunodeficiency Virus (HIV).

Conclusions: With the increased awareness of the growing burden of diseases requiring anticoagulation therapy in sub-Saharan Africa, there is an emerging need for anticoagulation infrastructure in the context of provision of health care in western Kenya.

Keywords: Kenya, pharmacist, anticoagulation clinic

Introduction

The United States Agency for International Development-Academic Model Providing Access to Healthcare (USAID-AMPATH) has been providing healthcare in rural western Kenya since 1989. Initially, the USAID-AMPATH model focused on providing care for the public health crisis encompassing human immunodeficiency virus (HIV) USAID-AMPATH has recently broadened its scope and now provides healthcare to over 108,000 patients living with HIV in Western Kenya. However, USAID-AMPATH has recently broadened its scope of practice to address all areas of healthcare, with a growing emphasis on developing infrastructure for primary care and chronic disease management. With this expanded focus on chronic disease management, there is a growing need for a shift in the role of pharmacists in resource-constrained settings from the dispensing role to a more clinical, patient focused role to address the healthcare workforce shortage. It is within this imperative need that the Purdue University College of Pharmacy (PUCOP), in conjunction with USAID-AMPATH, Moi Teaching and Referral Hospital (MTRH), and Moi University School of Medicine in Eldoret, Kenya has developed a model for providing anticoagulation services.

It is estimated that there are approximately 200,000 new cases of rheumatic heart disease (RHD) in Kenya each year. This high incidence of RHD is thought to be a result of poverty and associated poor living conditions in resource-constrained settings. Due to this high incidence of RHD-induced valvular dysfunction, the need for anticoagulation and appropriate monitoring is significant. In a previous analysis at MTRH, 43% of outpatient cardiology clinic patients were candidates for oral anticoagulation therapy with 93% of outpatients receiving suboptimal therapy based on evidence based guidelines. Furthermore, a subsequent review of MTRH inpatients showed that 4% were candidates for anticoagulation with 70% receiving suboptimal therapy.
Anecdotally, patients who required anticoagulation were often not started on warfarin because of the absence of an effective anticoagulation monitoring service and the logistical challenges associated with the monitoring of warfarin therapy. The few patients who were placed on warfarin were followed up by physicians in the medical and cardiology outpatient clinics with little success due to the timely and costly nature of laboratory monitoring of International Normalized Ratio (INR). Because of these limitations, patients on warfarin would seldom get their INRs checked on a regular basis. Moreover, there was inadequate laboratory infrastructure in order to provide timely and reliable INRs as most results would not appear in the patient’s medical record until several days after the test was completed. Because of the large need for increased access and improved quality of anticoagulation care, pharmacists have developed an inpatient/outpatient anticoagulation monitoring service (AMS) appropriate to the context of this rural resource constrained setting at MTRH. This program provides comprehensive protocol based INR monitoring services for patients requiring vitamin K antagonist (VKA) therapy based on the most current American College of Chest Physician Guidelines. This analysis will discuss many of the findings from the implementation of this service to help inform providers of the many unique demographic characteristics which must be considered when establishing similar services in sub-Saharan Africa.

Methodology

Patients are enrolled into the AMS through referral by healthcare providers from all areas of the hospital with a specific emphasis on the public inpatient and outpatient setting. Prior to receipt of care, patients are evaluated for any contraindications to warfarin therapy, such as pregnancy or prior history of bleeding. Because of the documented teratogenic potential of warfarin therapy, female patients of child bearing age are required to present a negative pregnancy test prior to the provision of VKA therapy from the AMS. Due to the high burden of RHD in this setting and the need for comprehensive cardiovascular care, the anticoagulation clinic has established a convenient referral system for the cardiology specialty clinic such that the anticoagulation clinic is situated adjacent to cardiology specialists for immediate referral. Pharmacists also provide clinical pharmacy services in the public hospital’s inpatient wards and assume responsibility for the management of all aspects of anticoagulation both during the inpatient stay and subsequent to discharge. Due to the work intensive nature of this program within different areas of the hospital, pharmacists have attempted to develop a care model designed to provide high quality services while minimizing cost. Within this model, pharmacists have tried to overcome limitations in availability of health care worker resources by working with all available levels of providers, including recent high school graduates from the community and pharmacy technologists. These individuals perform many of the time intensive aspects of the clinic including completion of initial assessment forms capturing demographic information, filling pill boxes with warfarin, doing finger-sticks for point of care INR tests, and providing phone based patient follow-up. The pharmacist’s role in the clinic is mainly to interpret INR results and adjust warfarin doses in addition to counseling patients on adherence, dietary vitamin K intake, drug interactions and monitoring of adverse effects such as bleeding. Moreover, the pharmacist provides an overall supervisory role for all clinic activities to ensure patients receive optimal anticoagulation care. Pharmacy staff have developed collaborative relationships with physicians within the cardiology clinic to facilitate immediate referral for any patients suffering from potential complications of VKA therapy or their underlying disease processes. All patient care visits are recorded on standardized encounter forms which were developed and customized for management of patients in this setting by the program staff. The approach has helped ensure all essential aspects of care are addressed and documented utilizing validated scales wherever possible. Descriptive statistics were used to describe the preliminary findings of demographic characteristics of the population utilizing the anticoagulation clinic.

Results

Since the clinic’s inception in December 2008 and data analysis in November 2009, the number of patients utilizing this service has steadily increased to a total of 83 patients. The unique demographic characteristics of this patient population require considerable attention as they help illustrate many of the understudied differences and challenges inherent in managing patients from resource-constrained settings in sub-Saharan Africa (Table 1).

With the anticoagulation clinic’s direct involvement in both the outpatient cardiology clinic and inpatient wards, the majority of patients enrolled in the clinic require anticoagulation as a result of RHD-induced valvular changes (18.1%) or because of deep vein thrombosis (DVT)/pulmonary embolism (PE) (59.0%).

Table 1 illustrates the unique mix of underlying diseases, such as tuberculosis and HIV, which have a disproportionately higher prevalence in resource-constrained settings. The prominence of HIV as a thrombotic risk factor in this population is clearly apparent as 28.6% of the patients enrolled with DVT/PE also have HIV.

The limited ability of patients to afford the costs of this care is evident as none of the patients possess outpatient insurance and more than one-third report that they are not able to afford the costs of any additional tests or medications. While 28.9% have inpatient insurance, this insurance does not provide any coverage for outpatient services. The limited availability of access to AMS in this region is also illustrated by the many hours patients travel to attend clinic. Almost 40.0% of the population requires more than 1 hour travel to the clinic with 7.2% traveling greater than 4 hours.
Table 1. Demographic Characteristics of the Population Utilizing Anticoagulation Services at Moi Teaching and Referral Hospital

<table>
<thead>
<tr>
<th>Parameters</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients ever enrolled</td>
<td>83</td>
</tr>
<tr>
<td>Active patients</td>
<td>66 (79.5)</td>
</tr>
<tr>
<td>Female patients</td>
<td>67 (80.7)</td>
</tr>
<tr>
<td>Kenyan patients</td>
<td>83 (100)</td>
</tr>
</tbody>
</table>

**Indications for anticoagulation**
- Rheumatic Heart Disease induced valvular dysfunction: 15 (18.1)
- Deep Vein Thrombosis / Pulmonary Embolism: 49 (59.0)
- High Risk Atrial Fibrillation without Rheumatic Heart Disease: 6 (7.2)
- Artificial Valve: 8 (9.6)
- Dilated Cardiomyopathy: 2 (2.4)
- Left Atrial/Right Ventricular Thrombus: 2 (2.4)
- Recurrent Stroke: 1 (1.2)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with care giver availability</td>
<td>57 (68.7)</td>
</tr>
<tr>
<td>Patients with a history of tuberculosis</td>
<td>15 (18.1)</td>
</tr>
<tr>
<td>Patients currently on treatment for tuberculosis</td>
<td>8 (9.6)</td>
</tr>
<tr>
<td>Patients aware of HIV status</td>
<td>73 (88.0)</td>
</tr>
<tr>
<td>Patients who are HIV positive</td>
<td>20 (24.1)</td>
</tr>
<tr>
<td>Patients who are on antiretrovirals</td>
<td>12 (14.5)</td>
</tr>
<tr>
<td>Patients who smoke or use tobacco products</td>
<td>0</td>
</tr>
<tr>
<td>Patients who consume alcohol</td>
<td>0</td>
</tr>
</tbody>
</table>

**Distance from clinic**
- Less than 30 minutes: 25 (30.1)
- Between 30-60 minutes: 26 (31.3)
- Between 1-2 hours: 20 (24.1)
- Between 2-3 hours: 4 (4.8)
- Between 3-4 hours: 2 (2.4)
- Greater than 4 hours: 6 (7.2)

**Mode of transportation**
- Public Bus (matatu): 83 (100)
- Walk: 0
- Bicycle: 0

**Insurance Status**
- Patients with inpatient health insurance: 24 (28.9)
- Patients with outpatient health insurance: 0
- Patients without any health insurance: 59 (71.1)

**Self reported ability to pay**
- Patients who can’t pay for or afford any tests or medication: 29 (34.9)
- Can afford up to 500 Ksh (~$7 USD) a month: 23 (27.7)
- Can afford up to 1000 Ksh (~$14 USD) a month: 16 (19.3)
- Can afford up to 1500 (~$21 USD) a month: 3 (3.6)
- Can afford up to 2000 (~$28 USD) a month: 4 (4.8)
- Patients who can pay for or afford any test or medication: 8 (9.6)

Despite these obstacles, patients are very well positioned to address their healthcare needs as there is a high availability of caretakers and no participation in high-risk behaviors such as smoking and alcohol consumption. The utilization of caretakers in assisting with the provision of care has become an essential component of each visit as more than two-thirds of the population have readily available caretaker support.

**Discussion**

Early findings from the pilot of anticoagulation care in this setting reveal many of the unique features and obstacles of managing anticoagulation care in sub-Saharan Africa. Despite almost complete eradication of RHD in resource-rich settings, RHD continues to contribute a large burden of disease in resource-constrained settings in sub-Saharan Africa. The importance of VKAs has been consistently shown within the RHD population as appropriate treatment drastically reduces the risk of complications. In a study by Fleming, a 25% incidence of emboli among 500 untreated patients with RHD was found, while only 5 episodes occurred in 217 patients treated with VKA yielding an incidence of 0.8% per patient-year (RR= 0.32)². Despite the clear benefits of VKA therapy in patients with RHD, very few patients have access to organized anticoagulation management in resource-constrained settings where RHD is most prevalent³. Prior to the availability of this service, the majority of patients, including those who had received mechanical valve replacements, were typically placed on aspirin or received no anticoagulation despite the clear necessity of VKA therapy³. Prior to the implementation of the AMS, several contraindicated practices, such as the routine provision of VKA to pregnant patients despite being Pregnancy Category X were encountered. Through the organized approach described with the AMS, this and many of the other inappropriate practices have been corrected.

The increased risk of DVT in patients with HIV is also illustrated within this population. This is significant, as thousands of patients throughout sub-Saharan Africa are now receiving care for HIV⁴. Previous investigations have revealed an almost fourfold increase in the risk for DVT among HIV-infected populations compared to general populations⁵. As HIV care programs continue to grow and expand throughout sub-Saharan Africa, there must also be a focus on developing the infrastructure for many of the complementary aspects of HIV care, such as anticoagulation monitoring to ensure patients have access to all essential aspects of care. The high prevalence of tuberculosis and HIV within the population requiring anticoagulation also carries several drug management challenges. These include the unpredictable drug interactions associated with rifampin derivatives, non-nucleoside reverse transcriptase inhibitors, and protease inhibitors often requiring dramatic warfarin dosage adjustments⁶. Additional factors complicating the delivery of optimal anticoagulation therapy include the unique vitamin k rich diet of the rural Kenyan population. With the large consumption of kale and traditional vegetables, anticoagulation
Implementation of a pharmacist managed anticoagulation clinic in Eldoret, Kenya

clinics in similar sub-Saharan African settings must also take into consideration the variability in warfarin response due to the higher vitamin K content included within typical diets\textsuperscript{11,12}. To address this source of variation, clinic staff have developed a scoring system to determine the relative changes in vitamin K intake between clinic visits, based on diet change.

As the population relying on this service continues to grow, the investigators intend to research the relationship between HIV and thromboembolism, utility of a vitamin K scoring system, drug interactions, and risk reduction with VKA in RHD in this cohort of patients. To ensure high quality, cost-effective care, the clinic also performs continuous quality improvement initiatives designed to ensure the clinic’s performance meets the established standards for anticoagulation care\textsuperscript{13}.

Conclusion
With the growing awareness of the unique burden of diseases in resource-constrained settings, there is a clear need to expand access to anticoagulation monitoring services to address RHD and HIV-related thromboembolic events. As additional programs in resource-constrained settings consider the implementation of similar anticoagulation clinics, many of the unique features of management in sub-Saharan Africa must be addressed to ensure successful implementation.

Acknowledgement
The clinic would like to thank Bristol Myers Squibb for their initial donation of Coumadin® product for the piloting of this clinic service. Staff would also like to thank Saint Joseph Family Medicine Center (South Bend, IN) for their initial donation of the Coaguchek XS point of care INR testing device to initiate this potentially life-saving service for the many patients in need within our setting. This research was supported in part by a grant to the USAID-AMPATH Partnership from the United States Agency for International Development as part of the President’s Emergency Plan for AIDS Relief (PEPFAR).

Conflicts of interest
The authors of this paper have no conflicts of interest to report.

References
Research Brief

An assessment of telephone calls received by the drug and poison information centre at Aga Khan University Hospital, Karachi, Pakistan

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Citation: Fazal O, Madraswala M, Bangash SS, M, Karim M. An assessment of toxicology telephone calls received by the drug and poison information centre at Aga Khan University Hospital, Karachi, Pakistan. Southern Med Review (2010)3;2:24-26

When this work was conducted ozma fazal was the pharmacist incharge at the Drug & Poison Information Centre, Department of Pharmacy, Aga Khan University Hospital, Karachi, Pakistan.

Abstract

Objectives: The objectives of this study were to assess the toxicology telephone calls received by the Drug and Poison information Centre at Aga Khan University Hospital, Karachi, Pakistan.

Methods: A retrospective analysis was performed of 9 month data from the log sheets at the Drug and Poisoning Information Centre (DPIC) of the Aga Khan University Hospital (AKUH). The data was then categorized according to the various classes of poisoning as referenced in the Toxicology Handbook (Lexi-comp).

Results: The results showed a total of 88 calls received and answered by the Center over a 9 month period between Jan and Sept 2007. The highest numbers of poisoning cases were Drug (Medicine) Poisoning, followed by Chemical and Household poisoning respectively. In the Drug poisoning group, ingestion of sedative drugs like benzodiazepines was the most common type of poisoning, accounting for 21 % of the cases. Among the household poisons, Mortein (active ingredient Allethrin) repellent preparations were at the top followed by Dettol® and household mercury thermometers respectively. Thirty nine calls (44%) were recommended specific antidote treatments whereas forty calls (46%) were advised to administer symptomatic relief options. Nine calls (10%) were found to be ‘not harmful’ and dealt with accordingly.

Conclusions: The Center has been instrumental in identifying the symptoms related to cases presented and thus provides the best available handling in the situation. The centre is providing a state of the art service in terms of poisoning management in an efficient and timely manner.

Key words: Pakistan, Poisoning calls, pharmacy services, The Aga Khan University Hospital

Introduction

Karachi is the capital of the province Sind, and is the most populated city in Pakistan. It is located on the coast of the Arabian Sea in south eastern Pakistan, northwest of the Indus Delta. The city is the financial and commercial centre, as well as the largest port in Pakistan. It is also counted amongst the most populated cities of the world. The Aga Khan University Hospital (AKUH) is a 563 bed private academic medical centre committed to providing the best treatment options for diagnosis of disease. It also has the highest doctor/patient, nurse/patient ratios in the city of Karachi. AKUH is the first hospital in Pakistan and among the first few teaching hospitals in the world to be awarded the prestigious Joint Commission International Accreditation (JCIA) for practicing the highest internationally recognized quality standards in health care.
Similarly, the Hospital also holds ISO 9001:2008 certification for practicing consistent international standards of quality service\(^1\). The department of pharmacy provides state of the art services in terms of a true hospital pharmacy practice in the country. Besides a well structured Pharmacy & Therapeutics committee, it also houses a pool of well trained and competent pharmacists performing clinical as well as other support services\(^6\). The department provides sterile compounding preparations as well as intravenous and cytotoxic admixtures prepared under the supervision of experienced and competent pharmacists. The "point of care pharmacy service" is a clinical service run by clinical pharmacists and has a huge impact on patient care as well as medication management, especially in the intensive care setting\(^6\). A number of abstracts have also been published from the Aga Khan Hospital pharmacy highlighting the role of the clinical pharmacists\(^5\).

**Drug and Poison Information at AKU**

The Drug and Poisoning Information Center (DPIC) of the AKU is the sole service in the city dealing with drug and poison related queries from customers within as well as outside the hospital setting. Since its inception, the Department has dealt with thousands of calls related to drug information as well as toxicology; however the data was not published.

Acute poisoning carries a significant impact with regards morbidity and mortality\(^8\) and poses a serious threat to public health. Anecdotal evidence suggests that organophosphate poisoning seems to be on a rise similar to Jinnah Post Medical Centre (JPMC), which houses the other public sector poison control centre in the country. Organophosphate insecticides have been indicated as the main means of suicide attempts in Pakistan in a study conducted at Karachi in 2000\(^7\). Another such study shows that women used organophosphate insecticides more than men did\(^7\). Pakistan Institute of medical sciences reported a total of 40 snake bites during a one year period, 30 (75\%) of which warranted the use of anti-snake anti-venom\(^9\) whereas studies form endemic areas of Pakistan like those from Thar report a total of 771 cases of snake bite during a one-year period\(^10\). An Observational study on 40 cases performed in Peshawar showed that mammalian bite injuries from dogs and other animals accounted for 10 \% of these cases\(^11\). Data about drug induced poisoning form a tertiary care hospital in Karachi implicates benzodiazepines as the major cause of suicidal poisonings. The fact that they are easily available and do not require a prescription at the chemist shop makes their use even more rampant\(^12\).

In this context drug and poison information at AKUH is playing an important role in the city to provide objective and reliable information regarding these cases. Hence the objectives of this study were to report, document and categorize the Poisoning calls received at the Drug & Poison Information Center of the Aga Khan University Hospital

**Methodology**

A retrospective analysis of the logged calls was performed. Data from poisoning calls were recorded in pre-printed forms (log sheets) which include columns for type of poisoning, symptoms, patient condition as well as any treatment offered at the time of the call. These log sheets were hand filled by the pharmacist in charge for the day. At the end of the day, the log sheets were separated and data transcribed to the computer using Microsoft Excel\(^\text{®}\). These log sheets were then compiled into computerized data bases which were then analyzed on a monthly basis for work load and nature of calls as well as responses given to queries. This process is a part of the quality assurance circle available to the DPIC. The data was then categorized according to the various classes of poisoning as referenced in the Toxicology Handbook (Lexi-Com)\(^13\) as well as other reputed drug information handbooks like Poisoning and Drug Overdose\(^14\). Sources from the internet, including Micromedix\(^\text{®}\), were also utilized.

**Results & Discussions**

The results showed a total of 88 calls received and answered by the center over a 9 month period (Jan-Sept 2007). The highest numbers of poisoning cases were drug (medicines) poisoning, followed by chemical and household poisoning respectively. In the drug poisoning group, alprazolam (a benzodiazepine) was the most common agent of poisoning accounting for 21 \% of the cases (Fig 1). This was followed by pain killers (14\%) and anti-hypertensive medications (11\%). Among the household poisons, Mortein repellent preparations were the greatest number of poisonings followed by Dettol and house hold mercury thermometers respectively (Table 1).

Organophosphate poisoning is common in our society, owing largely to the agricultural background of this region\(^15\). Whether intentional or accidental, an average of three cases were reported per month at the DPIC , sounding bells of alarm for

**Figure 1. Various types of medicines and poisoning calls**

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidepressants</td>
<td>3%</td>
</tr>
<tr>
<td>Antidiabetics</td>
<td>8%</td>
</tr>
<tr>
<td>Antifectives</td>
<td>3%</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>8%</td>
</tr>
<tr>
<td>Cough preparations</td>
<td>8%</td>
</tr>
<tr>
<td>Antipsotics</td>
<td>11%</td>
</tr>
<tr>
<td>Antiprohypertics</td>
<td>14%</td>
</tr>
<tr>
<td>Blood pressure lowering medicines</td>
<td>14%</td>
</tr>
<tr>
<td>Pain killers</td>
<td>14%</td>
</tr>
<tr>
<td>Antihistamines</td>
<td>5%</td>
</tr>
<tr>
<td>Vitamins/ minerals</td>
<td>8%</td>
</tr>
<tr>
<td>Appetite stimulants</td>
<td>3%</td>
</tr>
<tr>
<td>Sedatives</td>
<td>21%</td>
</tr>
</tbody>
</table>

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An assessment of telephone calls received by the drug and poison information centre

Table 1. Types of various toxins

<table>
<thead>
<tr>
<th>Chemical toxins</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organophosphates</td>
<td>25</td>
</tr>
<tr>
<td>Typhoon (turpentine)</td>
<td>5</td>
</tr>
<tr>
<td>Cyanide</td>
<td>5</td>
</tr>
<tr>
<td>Kerosene Oil</td>
<td>25</td>
</tr>
<tr>
<td>Phenol</td>
<td>15</td>
</tr>
<tr>
<td>Silica gel</td>
<td>15</td>
</tr>
<tr>
<td>Rat Poison</td>
<td>20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Household toxins</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortein (Allethrin)</td>
<td>5</td>
</tr>
<tr>
<td>Dettol (chloroxylenol)</td>
<td>4</td>
</tr>
<tr>
<td>Mercury thermometer</td>
<td>3</td>
</tr>
<tr>
<td>Finis repellent liquid (DEET)</td>
<td>2</td>
</tr>
<tr>
<td>Bleach (sodium hypochlorite)</td>
<td>2</td>
</tr>
<tr>
<td>Mospel (N,N-diethyl-m-toluamide)</td>
<td>2</td>
</tr>
<tr>
<td>Phenyl liquid</td>
<td>1</td>
</tr>
<tr>
<td>Naphtalene balls</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biological toxin</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snake Bite</td>
<td>1</td>
</tr>
<tr>
<td>Plant exposure</td>
<td>1</td>
</tr>
<tr>
<td>Lizard Bite</td>
<td>2</td>
</tr>
<tr>
<td>Animal Bites</td>
<td>4</td>
</tr>
</tbody>
</table>

In spite of the shortcomings and limited resources, the centre has been instrumental in responding to poisoning cases in an appropriate manner. It has also been able to identify the symptoms and categorise them as needing symptomatic or antidote treatment. This data also sheds light on specific and rampant poisonings related to organophosphates and prescription medications respectively. Information collected was reported and documented as well as categorised based on type of poison/toxin thus helping to form a computerised data base, which is both easily accessible as well as workable for future analysis.

Conclusion

In spite of the shortcomings and limited resources, the centre has been instrumental in responding to poisoning cases in an appropriate manner. It has also been able to identify the symptoms and categorise them as needing symptomatic or antidote treatment. This data also sheds light on specific and rampant poisonings related to organophosphates and prescription medications respectively. Information collected was reported and documented as well as categorised based on type of poison/toxin thus helping to form a computerised data base, which is both easily accessible as well as workable for future analysis.

Acknowledgment

The author wished to thank Muhammad Hamad, Staff Pharmacist at the Drug and Poison Information Centre, Aga Khan Hospital, Karachi for his help.

References:

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Research Brief

Evaluating medicines dispensing patterns at private community pharmacies in Tamilnadu, India

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Abstract

Objectives: To evaluate patterns of dispensing of medicines from private community pharmacies in Tamilnadu and to identify and analyze problems in medicine supply or dispensing toward its rational use.

Methods: A cross-sectional study was carried out in two towns of Tamilnadu, India between July 10 and October 25, 2009. Medicines dispensed from 24 randomly selected pharmacies, each from a different area of two towns were investigated. Two 2 hour study visits were made. Data were collected by observations and interviews with pharmacists or drug retailers.

Results: A total of 1160 medicines were dispensed; 44.2% on a doctors prescription and the remaining over the counter (26.9% on request by clients themselves and 28.9% on recommendations from pharmacists). Anti-infective agents were the most commonly dispensed (20.6% of all items), followed by medicines acting on the gastrointestinal system (18.2%), vitamins and nutritional supplements (10.9%), analgesics and antipyretics (10.5%). More than three-quarters of the anti-infective agents (n=188; 78.7%) were provided over the counter. The study indicates that 61.2% of prescription-only medicines were dispensed over the counter.

Conclusions: Extensive supply of medicines (both prescription-only and over the counter) from private pharmacies, including those used for serious illnesses, has been observed. The study shows trends toward inappropriate dispensing. Educational and managerial interventions to improve dispensers’ knowledge, professional behavior and attitudes are required to improve the situation.

Keywords: Dispensing patterns, private pharmacy, inappropriate dispensing, self-medication, India

Introduction

Rational use of medicine is defined as when patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at affordable prices. The existence of widespread unregulated supply of medicines has been reported in developing countries and several studies have examined deficiencies in over the counter medicine use. Dispensing medicines in an appropriate manner is a key element to promote rational medicine use hence the dispenser/drug seller should be regularly updated with information and other related skills. Unlike other countries, the current regulations in India do not require pharmacists to periodically update their knowledge and skills. In addition, existing regulations restricting the dispensing or sale of medicines are not strictly implemented and enforced.

In many developing countries including India, private community pharmacies are the main source of medicines. Consumers tend to utilize private pharmacies rather than public facilities. This is due to factors such as ease of access, shorter waiting time, more flexible opening hours, availability of cheaper medicines and availability of credit. However the quality of dispensing provided seems to be inappropriate and is way below than acceptable levels of “Good Pharmacy Practice”. In India, dispensing is undertaken by pharmacists and drug retailers or sellers. Drug sellers or retailers include individuals who are only associated with private pharmacies, but do not have formal training in dispensing medicines and may not have even obtained secondary school education. Hence, the aim of our study was to investigate patterns of dispensing of medicines at private community pharmacies in two selected towns of Tamilnadu state, India and to identify and analyze problems in medicine supply and dispensing.
Methodology

The study was conducted in 24 randomly selected private pharmacies covering all areas of Chidambarm and Villupuram towns of Tamilnadu state (coastal towns of south east coast of Indian peninsula) during July - October, 2009. These two towns were selected based on the logistic feasibility of the study (close proximity to the study centre). An appeal was sent to each owner/manager, of 32 randomly chosen pharmacies scattered in and around Chidambarm and Villupuram towns, explaining the purpose of the study. The sample frame excluded any medicine retail outlets in these two towns selling only homoeopathic or herbal medicines or where a medical doctor was practising. The research was carried out with 24 private pharmacies who agreed to participate (response rate: 75%).

From each outlet, a pharmacist was identified. If a pharmacist was unavailable, the most experienced drug retailer was interviewed, a single respondent thereby being selected for each retail drug outlet. Data were collected mainly by observations and supplemented by interviews with pharmacists or drug sellers by two trained final year Bachelor of Pharmacy students of the Department of Pharmacy, Annamalai University. The interview included questions on prescription types, medicines dispensed, dosage regimens, and number of medicines dispensed. Information on patterns of dispensing medicines were recorded based on observations and confirmed by interview. Information was collected on all medicines dispensed/supplied from each of pharmacy during a 4 hour study period. The study period was divided into two parts: a 2 hour period each in the morning and the afternoon business hours of one working day. In this paper, the term ‘hospital prescription’ is used to include medication orders issued by the physician for patients in a hospital or dispensary maintained or supported by government or local body. The term ‘private prescription’ refers to the broader category of medication orders issued by private general practitioners. Hospital or private prescriptions which were more than 7 days old were categorized as ‘old prescriptions’. The word ‘prescription medicines’ was used to include medicines that can be sold/dispensed with a prescription according to the Schedules H and X of the Drugs and Cosmetics Rules18 1945. Medicines dispensed with or without a prescription were categorized according to therapeutic groups as listed in the Current Index of Medical Specialties (CIMS) India19. The appropriate dosage is the dosage regimen recommended by the British National Formulary (BNF) or CIMS India19. Medicines which may have more than one indication were included in the therapeutic category of most common use. Combination medicines were analyzed by including them in different categories as appropriate. Prescriptions containing radiographic or diagnostic products were excluded from the study. Results of the study were analyzed using Microsoft Excel 2005 spreadsheet.

Results

It was recorded that a total of 1160 medicines were dispensed during the study period. Medicine items were supplied to a total of 696 clients (222 with a prescription and 474 without a prescription). In all, 513 medicines (44.2%) were dispensed with a prescription from a physician and 647 (55.8%) were dispensed without a prescription (Table1). Out of the 647 items dispensed over the counter, 26.9% were dispensed on the request of clients themselves and 28.9% on the recommendation of a pharmacist or drug seller. Furthermore, there were 396 (61.2%) medicines which should have dispensed on a prescription only, however they were dispensed without prescriptions. The average number of medicines dispensed from each of the pharmacies during the observation period was 48.33. This figure varied considerably from pharmacy to pharmacy – ranging from 14 to 96 items.

A total of 222 prescriptions were presented during the study visits of which 182 (82.0%) were private prescriptions and 6.4% were old prescriptions (more than a week old). A further 12.7% of the prescriptions were hospital prescriptions. The average number of medicines per prescription was 2.31 and with a significant proportion of prescriptions (64.0%) having two or more medicines. The average number of medicines purchased without prescription per client was 1.36. Out of the 474 clients who obtained medicines without prescription, 338 (71.3%) obtained one medicine, 107 (22.5%) obtained two medicines and 29 (6.2 %) obtained three or more medicines. On the other hand, out of the 222 clients who obtained their medicines on prescriptions, 80 (36.0%) one medicine, 96 (43.3%) two and 46 (20.7%) three of more medicines.

The details of different medicines dispensed by therapeutic categories are listed in Table 2. Anti-infectives, gastrointestinal medicines and nutritional supplements including vitamins were the most commonly dispensed medicines. The category with the highest number of medicines dispensed (on a prescription) was gastrointestinal medicines (n=112, 21.6%). Approximately

<table>
<thead>
<tr>
<th>Type of dispensing</th>
<th>No. (%)</th>
<th>n (%) (n=1160)</th>
</tr>
</thead>
<tbody>
<tr>
<td>With prescription (n=513)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private prescription</td>
<td>416 (81.1)</td>
<td>513 (44.2)</td>
</tr>
<tr>
<td>Hospital prescriptions</td>
<td>64 (12.5)</td>
<td></td>
</tr>
<tr>
<td>Old prescription Subtotal</td>
<td>33 (6.4)</td>
<td></td>
</tr>
<tr>
<td>Without prescription (n=647)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Request by client Recommended by pharmacist Subtotal</td>
<td>312 (48.2)</td>
<td>647 (55.8)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>335 (51.2)</td>
<td>1160 (100)</td>
</tr>
</tbody>
</table>

* Prescription medicines-321, OTC medicines-192
* Prescription medicines-396, OTC medicines-251
Table 2. Medicines dispensed by therapeutic categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Prescription</th>
<th>Request by a client</th>
<th>Recommended by pharmacist or drug seller (drug seller are the ones with no formal pharmacy qualifications)</th>
<th>Total*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Anti-infectives</td>
<td>51</td>
<td>9.9</td>
<td>86</td>
<td>27.6</td>
</tr>
<tr>
<td>Medicines for GIT</td>
<td>112</td>
<td>21.8</td>
<td>43</td>
<td>13.8</td>
</tr>
<tr>
<td>Vitamins and nutritional supplements</td>
<td>82</td>
<td>16.0</td>
<td>18</td>
<td>5.7</td>
</tr>
<tr>
<td>Analgesics and antipyretics</td>
<td>39</td>
<td>7.6</td>
<td>37</td>
<td>11.9</td>
</tr>
<tr>
<td>Medicines for respiratory systems</td>
<td>60</td>
<td>11.7</td>
<td>26</td>
<td>8.3</td>
</tr>
<tr>
<td>Anti-diabetics</td>
<td>45</td>
<td>8.8</td>
<td>37</td>
<td>11.9</td>
</tr>
<tr>
<td>Medicines for CVS</td>
<td>34</td>
<td>6.6</td>
<td>21</td>
<td>6.7</td>
</tr>
<tr>
<td>Medicines for CNS</td>
<td>16</td>
<td>3.1</td>
<td>10</td>
<td>3.2</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>74</td>
<td>14.5</td>
<td>34</td>
<td>10.9</td>
</tr>
<tr>
<td>Total</td>
<td>513</td>
<td>100</td>
<td>312</td>
<td>100</td>
</tr>
</tbody>
</table>

* Prescription medicines-717 (61.8%), OTC medicines-443 (38.2%)

Note: GIT- Gastrointestinal Tract, CVS-Cardiovascular system, CNS-Central nervous system

63% of the clients received medicines over the counter without a prescription. Anti-infectives were found to be highest number of medicines dispensed to the clients on request (n=86; 27.6%) and upon pharmacists’ or drug sellers recommendations (n=102; 30.4%). The majority of the anti-infectives (n=188; 78.7%) were dispensed over the counter (on request by clients themselves and on recommendations from pharmacists). Table 3 shows the pattern of dispensing of anti-infectives. A total of 239 anti-infectives were dispensed accounting for 20.6% of all medicines. Of these 239 products, 36.0% were recommended by pharmacists, 42.7% were provided on request and only 21.3% were dispensed as prescription medicines.

The majority of the anti-infectives (68.2%) dispensed (regardless by prescription, pharmacist’s recommendation or client’s request) were inappropriate or were having insufficient dosage regimens. Only 13.9% of the anti-infectives dispensed on request by clients were complete courses of these medicines (Table 4). The most of the inappropriate dosages of anti-infective agents supplied were one or two tablets/capsules, one day’s supply or two day’s supply.

Table 3. Anti-infective agents dispensed

<table>
<thead>
<tr>
<th>Class</th>
<th>Prescription</th>
<th>Request by a client</th>
<th>Recommended by pharmacist</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
<td>27</td>
<td>48</td>
<td>52</td>
<td>127</td>
</tr>
<tr>
<td>Antifungals</td>
<td>02</td>
<td>01</td>
<td>01</td>
<td>04</td>
</tr>
<tr>
<td>Anti-amoebics</td>
<td>04</td>
<td>07</td>
<td>05</td>
<td>16</td>
</tr>
<tr>
<td>Anti-filarials</td>
<td>05</td>
<td>02</td>
<td>05</td>
<td>12</td>
</tr>
<tr>
<td>Anthelmintics</td>
<td>02</td>
<td>03</td>
<td>03</td>
<td>08</td>
</tr>
<tr>
<td>Topical anti-infectives</td>
<td>11</td>
<td>25</td>
<td>36</td>
<td>72</td>
</tr>
<tr>
<td>Total (%)</td>
<td>51</td>
<td>(21.3)</td>
<td>86</td>
<td>(36.0)</td>
</tr>
</tbody>
</table>
Other medicines which should not have been dispensed over the counter included medicines for cardiovascular diseases, medicines acting on central nervous system (CNS), anti-diabetics, antispasmodics, oral contraceptives and eye preparations. All categories of the antacids were the most common medicines dispensed on a prescription. Other common medicines dispensed or supplied on prescription included antibiotics, analgesics/antipyretics, and ‘vitamins and minerals’.

Discussion

The study highlights that the percentage of medicines in all therapeutic categories dispensed without a prescription or on advice from a pharmacist or drug seller was much higher than dispensed with prescription. High proportions of the anti-infective agents were dispensed without a prescription. Also majority of medicines for cardiovascular diseases and diabetes and medicines for which adverse effects are relatively common (e.g. non-steroidal anti-inflammatory drugs and hypnotics) were dispensed without advice and prescription. All these drugs are prescription medicines in India and these findings are in agreement with those reported in earlier studies. Our study found that on an average one-third of the clients visit private pharmacies for self-medication. It is very common practice for clients to go directly to pharmacies and obtain medicines for their self-limiting symptoms. Self-medication is often a necessary part of health care in India, especially in suburban and rural areas where consumers have limited access and little capacity to pay for modern health care services; however this perhaps shows the need to improve “Good Pharmacy Practice”.

Steroids, third generation antibiotics, narcotic analgesics, antihistamines and sedatives were freely available across the counter without a prescription. This may be because the licensed pharmacist is rarely present in a pharmacy, and a pharmacy assistant or drug seller with any formal qualification in pharmacy works behind the counter. The findings of our study highlight the problems of self-medication and inappropriate dispensing in India. Especially the use of inappropriate anti-infective could lead to antimicrobial resistance which could have major implications for public health.

The majority of the clients with a prescription from a physician received more than one medicine, while a large number of prescriptions were having two or more medicines. Since many products are multi-medicine combinations in India, the actual number of individual medicines obtained was likely to be even higher. A high proportion of the anti-infective agents were dispensed as incomplete dosage regimens and about more than half of the prescription-only medicines were dispensed over the counter. These findings reflect the problems in drug regulation as well as the lack of knowledge and training of pharmacists and drug sellers. The principal limitations of the study are that the total number of pharmacies studied was low and they were located in two suburban, less developed areas. Convenience sampling of the pharmacies may also have created a selection bias of pharmacies.

Conclusions

The study shows that majority of medicines were dispensed or supplied without a prescription and inappropriate dispensing and over the counter dispensing of many drugs including anti-infective products was common. Educational and regulatory interventions are needed which include improving knowledge and professional behavior of pharmacists, pharmacy assistants and drug sellers. The results and discussion presented in this paper provide a baseline for further research in this area.

Acknowledgements and funding

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References

Evaluating medicines dispensing patterns at private community pharmacies in Tamilnadu, India

Letter to the Editor

Exploring health seeking behavior, medicine use and self medication in urban and rural Pakistan


The nature and extent of self-medication varies in different cultural contexts and social and educational influences may be greater than the influence of medical practice\(^1\). In the United States, several studies indicate considerable use of ‘leftovers’, drugs obtained from a family member, a pharmacy, or a source outside of the country. For example, in a Hispanic neighborhood of New York City, it was found that antimicrobial drugs were available without a prescription. In Europe, studies describing self-medication and storage of antimicrobial drugs in Spain, Greece, Russia, and Malta also suggest use of the drugs without consulting a physician\(^2\). The data regarding “health seeking behavior” and “medicines use” is scarce in Pakistan and a study was conducted to evaluate these issues. This letter to editor briefly reports the results of this study.

A randomized, cross-sectional, questionnaire-based, multi-center study of the prevalence of self-medication was performed in 4 large cities in Pakistan. These cities were Rawalpindi, Islamabad, Abbotabad and Peshawar and their adjacent rural areas were also included. The study was conducted between July 2007 and January 2008 and a stratified random sample of 1346 households was selected. Altogether there were 703 (52.2%) households from rural areas and 643 (47.8%) from urban areas. These households were followed up for a period of 10 weeks for the actual practices in the event of a health problem; appraisal of self-medication practices and the prevailing concept of modern medicine in the family. Male and female final-year pharmacy students from the Punjab University, Lahore and Peshawar University, Peshawar were trained and set forth to follow-up these households on a weekly basis and to maintain records of all of the health disorders occurring during that period as well as the action taken by the family members. If medicines were taken either through self-medication or on a prescription then a complete record of the administration and duration was maintained.

The results show that sixty-two percent of the respondents were females and 38.0 % were males. Modern medicines were available in 54.5% of households, other drugs (including traditional and complementary medicines) in 2.5% while 43% households had no drugs. Availability of modern medicines was studied with respect to several factors. Those that were found to be significantly associated were urban/rural location of household and level of household education. The most common drugs available in the households were analgesics including tablets and syrup formulations of paracetamol (29.7%), oral antibiotics (15.2%), vitamins and minerals (9.9%), Non Steroidal Anti-inflammatory Drugs (NSAIDs) (11.2%), cough syrups (12.9%), anti-allergy agents (6.6%), anti-diarrheal (3.4%), Oral Rehydration Salt (ORS) 2.5%) and other drugs (8.7%). The detailed breakdown of modern drugs available at home (Table 1)

The households were followed up to determine the health-seeking behavior of the individuals and during this period 1798 episodes of illnesses were recorded. Across both rural and urban settings the mean episodes of illness were 2.9 per household per two-month period. In the rural areas there were 3.2 episodes, while in the urban areas there were 2.7 episodes of illnesses per household. The ailments that were documented during this period include: acute illnesses of shorter duration and chronic illnesses of much longer duration. Among the short duration

<table>
<thead>
<tr>
<th>Types of drugs</th>
<th>Number of drugs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesics</td>
<td>385</td>
<td>29.7%</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>197</td>
<td>15.2%</td>
</tr>
<tr>
<td>Cough syrup</td>
<td>167</td>
<td>12.9%</td>
</tr>
<tr>
<td>Vitamins &amp; minerals</td>
<td>127</td>
<td>9.8%</td>
</tr>
<tr>
<td>Non Steroidal Anti-inflammatory Drugs NSAIDs</td>
<td>145</td>
<td>11.2%</td>
</tr>
<tr>
<td>Anti-allergies</td>
<td>85</td>
<td>6.6%</td>
</tr>
<tr>
<td>Anti-diarrheal</td>
<td>44</td>
<td>3.4%</td>
</tr>
<tr>
<td>Oral Rehydration salt (ORS)</td>
<td>32</td>
<td>2.5%</td>
</tr>
<tr>
<td>Others</td>
<td>113</td>
<td>8.7%</td>
</tr>
<tr>
<td>Total</td>
<td>1295</td>
<td>100%</td>
</tr>
</tbody>
</table>
exploring health-seeking behavior, medicine use and self-medication in urban and rural pakistan

Table 2. Breakdown of diseases recorded during the study period

<table>
<thead>
<tr>
<th>Diseases</th>
<th>Number of cases</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Illnesses of Short Duration</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever (of all categories)</td>
<td>816</td>
<td>30.5%</td>
</tr>
<tr>
<td>Aches and Pains (all categories)</td>
<td>479</td>
<td>17.9%</td>
</tr>
<tr>
<td>Respiratory Tract Infections</td>
<td>198</td>
<td>7.4%</td>
</tr>
<tr>
<td>Skin and oral ulcers and rashes</td>
<td>177</td>
<td>6.6%</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td>174</td>
<td>6.5%</td>
</tr>
<tr>
<td>Others</td>
<td>364</td>
<td>13.6%</td>
</tr>
<tr>
<td>Acute Total</td>
<td>2191</td>
<td>81.9%</td>
</tr>
<tr>
<td><strong>Illnesses of Long Duration</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>102</td>
<td>3.8%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>178</td>
<td>4.4%</td>
</tr>
<tr>
<td>Cardiovascular diseases</td>
<td>48</td>
<td>1.8%</td>
</tr>
<tr>
<td>Accident &amp; Injuries</td>
<td>32</td>
<td>1.2%</td>
</tr>
<tr>
<td>Anemia</td>
<td>32</td>
<td>1.2%</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>13</td>
<td>0.5%</td>
</tr>
<tr>
<td>Others</td>
<td>139</td>
<td>5.2%</td>
</tr>
<tr>
<td>Chronic Total</td>
<td>484</td>
<td>18.1%</td>
</tr>
<tr>
<td>All Total</td>
<td>2676</td>
<td>100%</td>
</tr>
</tbody>
</table>

illnesses, the most common were: fever (30.5%); upper and lower respiratory tract infections (7.4%) including pneumonia (0.9%); gastroenteritis (6.5%); skin disorders (6.6%), and aches and pains across all therapeutic categories (17.9%). Among the chronic diseases the most common were diabetes mellitus (4.4%), hypertension (3.8%), tuberculosis (0.5%), and cardiovascular problems (1.8%). A breakdown of the diseases recorded during the follow-up period is provided in (Table 2).

Of the 1482 episodes of illnesses that required treatment, 2644 drugs were prescribed and the average number of drugs taken was 1.6. Fifty-one percent of patients received at least one drug, 20.0% two drugs, 15% three drugs and 6% four or more drugs. In 8% of cases the patients were given a traditional medicine or natural home remedy. The most commonly used drugs were antibiotics (20.5%), analgesics (18.0%), vitamins/minerals (8.6%), NSAIDs (6.6%), cough syrups (6.1%) and ORS (4.1%). Other drugs that were used included cardiovascular drugs (3.3%), hematinics (2.9%), antacids (2.9%), tranquilizers (2.1%), anti-diarrheals (2.0%) and steroids (1.6%). There were no rural (73%) urban (74%) differences in the health-seeking behavior with respect to the private sector. When the consultations among private sector providers were separately analyzed, of the 576 such instances 64% were made with qualified General Practitioners (GPs) and 36% with other providers. Urban patients consulted GPs (72.2%) more often than their rural counterparts (60.3%). A similar analysis for public sector providers revealed that of the 209 consultations, 32% were with public sector physicians and the remainder with paramedics. Rural patients consulted a public sector physician much more frequently (40%) as compared to urban patients (13.4%). Self-medication was reported in 7.1% of cases as compared to urban areas at 2.6%. The source from which drugs were obtained was also analyzed. Of all the drugs purchased by rural residents 59% were from private facilities as compared to 74.0% in the case of urban residents. In rural areas the GPs (27.6%), chemist shops (25.4%) and public health facilities (25.2%) were almost equally common sources of drugs, followed by the Lady Health Workers (15.6%). In 6.0% of cases drugs were acquired from other sources i.e. Hakims (traditional healers), homoeopaths or faith healers. Table 3 provides details of the sources of drugs in this study.

In Pakistan, almost every pharmacy sells drugs without a prescription; a phenomenon seen in many developing countries. Drug retail outlets are reported to be the major sources of drugs that are used for self-medication and the availability of drugs in informal sector contribute to the increase in the practice of self-medication. The main limitation of our study was we did not determine whether the leftover antibiotics stored in homes were due to poor patient compliance, where patients did not complete the entire course of antibiotics as prescribed, or whether the leftover medicine was simply due to too large packaging of antibiotics. This detail might be relevant since incomplete courses of antibiotics could themselves possibly contribute to antibiotic resistance.

In the context of Pakistan, there is a scarcity of literature available on the treatment seeking behavior, self-medication or self-care of urban and rural populations and the differences

Table 3. Sources of drug acquisition – urban and rural

<table>
<thead>
<tr>
<th>Source</th>
<th>Rural n (%)</th>
<th>Urban n (%)</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacies (Chemists)</td>
<td>260 (25.4)</td>
<td>232 (44.4)</td>
<td>492 (31.9)</td>
</tr>
<tr>
<td>General Practitioners (GPs)</td>
<td>282 (27.6)</td>
<td>122 (23.4)</td>
<td>404 (26.2)</td>
</tr>
<tr>
<td>Public facility</td>
<td>258 (25.2)</td>
<td>26 (5.0%)</td>
<td>284 (18.4)</td>
</tr>
<tr>
<td>LHW (Lady Health Workers)</td>
<td>160 (15.6)</td>
<td>110 (21.1)</td>
<td>270 (17.4)</td>
</tr>
<tr>
<td>Others</td>
<td>62 (6.1)</td>
<td>32 (6.1)</td>
<td>94 (6.1)</td>
</tr>
<tr>
<td>Total</td>
<td>1022 (100)</td>
<td>522 (100)</td>
<td>1544 (100)</td>
</tr>
</tbody>
</table>
Exploring health-seeking behavior, medicine use and self medication in urban and rural Pakistan

between each. However, some individual research articles, report of National Health Survey of Pakistan and Economic Survey of Pakistan11 have some information on disease patterns, medication and available treatment facilities. This study adds that a large number of people are using medicines in rural and urban areas; there is a need to develop educational interventions which could improve “quality use of medicines” in Pakistan. There is also a need to educate patients regarding the harm associated with the inappropriate use of prescription medicines.

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