Research Article

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

not enforced, and how medicines are stocked is not in line with good storage practices[1-4]. 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[5-7]. Competition, profit margins and related financial incentives for dispensing medicines may conflict with public health goals and result in poor quality of pharmacy services[8,9], 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[10], 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[11] and adopted by the World Health Organization (WHO)[12,13]. 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[14,15].

In this context, the development of PP indicators is important for reliably assessing the components of GPP, including quality of care[16]. 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"[17], "medicine prices"[18], as well as to gauge the level of implementation of national medicine policies[12]. The development of these indicators has increased knowledge and awareness of medicine prices and use, as evidenced by the increased number of indicator-based surveys undertaken globally. A small number of studies have previously used a limited number of indicators to assess specific topics around pharmacy practice[3, 8, 19]. In Zimbabwe a comprehensive set of indicators was developed and used for time-series studies to assess storage practice, medicines management and quality of services in both public and private settings[1]. 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[8]. Based on indicators measuring rational medicine use[17], national medicines policy indicators[12], quality of care indicators developed as part of the Pharm Value Project[20] and indicators used in regular pharmaceutical sector surveys undertaken in Zimbabwe between 1992 and 2004[1,21], 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[8] and assessing GPP in initially Zimbabwe, Ethiopia[22] and finally Uganda[23].

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[17,18], 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 of dispensing and non dispensing doctors in Zimbabwe[8]. This PP manual was further developed to assess GPP in private and public pharmacy settings. Moreover, an iterative process was applied to ensure uniformity in interpretation and assessment based on inputs from surveyors in 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[1,8,21-23]. 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.

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

		INDICATOR	Score Max	Ethiopia n=32	Uganda n=33	Zimbabwe n=27
System	A1	1. Is a prescription book/computerized system available for recording prescription data? Y=0.5, N=0	0.5	0.03	0.36	0.48
		2. Does the system provide for recording date, patient, prescriber and drug names? Y=each score:0.1, N=0	0.4	0.03	0.29	na
		3.Are old prescriptions kept? Y=0.1, N=0	0.1	0.05	0.01	0.10
	A2	Percentage of correctly filled dispensary entries: >75% = 1, < 75% = 0	1	0.06	0.95	0.92
	A3	1. Is the pharmacy computerised? N=na to A3. If yes, answer A3.2.	na	86% na	82% na	15% na
		2. Is the computerized system used for a) stock management b) FEFO (first expire first out) c) labelling d)patient information e)recording prescriptions f)patient medication profiles. Sum of yes (1) to a-f divided by 6	1	0.03	0.33	0.69
	A4	1. Does the pharmacy have a formalized stock management system based on stock cards or a computerized inventory system? Y (if either system in use)= 0.5, N=0 management system	0.5	0.28	0.03	0.37
		2.Does the pharmacy use a stock management system for monitoring stock levels, e.g. stock cards? Y=0.5, N=0	0.5	0.20	0.00	0.31
	A5	Is a stock management system in place for calculating/controlling reorder levels, known from records, stock cards or similar? Y=1, N=0	1	0.34	0.12	0.37
Storage	B1	Are there or have there been signs of pests? Y=0, N=1	1	1.00	1.00	0.96
	B2	Is the dispensing area a)very clean and tidy b) acceptably clean and tidy?, Is the storage area c) very clean and tidy d) acceptably clean and tidy? Sum of a to d: a,c: 0.5; b,d:0.3, N=0	1	0.84	0.82	0.79
	B3	Is there a)a toilet b)are the toilet facilities acceptable, hygienic and functioning? c) toilet paper d) hand washing facilities e) soap. Sum of yes (1) to a-e divided by 5	1	0.66	0.38	na
	B4	a) Are medicines protected from direct sunlight b)is the temperature monitored c) is temperature regulated d) is there any cold storage e) are only medicines stored in refrigerator f) are vaccines stored in centre of refrigerator g) is the temperature recorded h) is the roof appropriate with no leakage i) is the storage space sufficient and adequate. Sum of a-i yes (1) divided by 9 minus NA's.	1	0.71	0.45	0.68
	B5	a) Are medicines stored on shelves b) are medicine stored systematically c) are the shelves labelled d) does the storage cupboard have a lock e)does the storage room have a lock? Sum of yes (1) to a-e divided by 5	1	0.88	0.45	0.64
	B6	a) Are open bottles dated b) are there lids on opened containers c) no storage on floor d) record for expired drugs e) expired drugs stored separately f) procedure for disposing of expired medicines. Sum of yes (1) to a-f divided by 6	1	0.55	0.59	0.43
	B7	Adherence to FEFO? Y=1, N=0	1	0.56	0.97	0.78
Services	C1	Average number of prescriptions filled per day - no score	na	na	na	na
		Total number of opening hours per week -0.25 if open > 4 hrs per weekday, 0.5 if open > 8 hrs per weekday, 0.25 if open on Saturday, 0.25 if open on Sunday	1	0.89	0.93	0.75
	C2	Qualifications and working hours of pharmacy staff - 0.7 for full-time pharmacist(s), 0.2 for part-time pharmacist(s), and 0.3 for trained assistants such as pharmacy technicians or nurses; if neither =0	1	0.43	0.52	0.66
	C3	How much time (in hours) does the pharmacist spend in the pharmacy on average on a daily basis? Y(> 80% of opening hours of pharmacy) = 1, N(< 80% of opening time)=0	1	0.59	0.09	0.75
	C4	Patient accessibility to a) privacy b) seating c) scale d) drinking water e) hand-washing facilities f) soap g) toilet h) toilet paper? Sum of yes (1) to a-h divided by 8	1	0.68	0.29	0.93
	C5	Availability of testing for a) cholesterol b) blood pressure (monitoring) c) pregnancy d) glucose level e)asthma peak-flow meter f) prescription glasses? Sum of yes (1) to a-f divided by 6	1	0.05	0.02	0.26
	C6	Health promotion/public health activities engaged in during the past year? a)smoking b)obesity c)HIV/AIDS/TB d)family planning e)diabetes f)school education g)other? If >2 =1,if 1=0.5, if 0=0	1	0.06	0.00	0.04
Dispensing	D1	Availability of information sources a) drug catalogues e.g. MIMS b)(national) drug formulary c) EDL (essential drug list) d) internet access e) handbook? Sum of yes (1) to a-e divided by 5	1	0.19	0.34	0.61
	D2	Total number of items in stock (different brands, strengths and formulations): a)<100, b)100-200, c)201-500, d)501-1000, e) >1000: a)=0; b)=0.25; c)= 0.5; d)= 0.75; e) =1	1	0.41	0.61	0.60
	D3	Total number of brands or different generic cotrimoxazole tablets available containing the active ingredient cotrimoxazole in the form of tablets or capsules. No. of available products: >4 = 1; 3=0.5; 2=0.25; 1=0	1	0.91	0.33	0.31
	D4	Average dispensing time for six patients: < 30sec: 0; 30-60 sec: 0.5; >60 sec: 1	1	0.25	0.24	0.17
	D5	Packaging material used a) new bottles b) dispensing envelope c) old bottles only used after washing d) containers from manufacturers e) patient do not bring own containers/bottles f)only appropriate containers. Sum of yes (1) to a-f divided by 6	1	0.83	0.96	0.97
	D6	Dispensing equipment: a)a spatula b)non-filled (empty) labels c)tablet counting tray or similar d)tablets not counted by bare hands e)graduated measuring flask. Sum of yes (1) to a-e divided by 6	1	0.63	0.52	0.96
	D7	Counter checked before dispensing? Yes=1, N=0	1	0.41	0.00	0.63
	D8	a)Record or file for recording contacts to prescribers b) last entry < 3 month. Sum of yes(1) to a-b divided by 2	1	0.02	0.00	0.00

		INDICATOR	Score Max	Ethiopia n=32	Uganda n=33	Zimbabwe n=27
Rational drug Use	E1	Information sources: a) patient leaflets b) computer printouts c) access to computers d) medicine handbooks. Sum of yes(1) to a-d divided by 4	1	0.05	0.01	0.59
	E2	Of 10 patient interviews: a) No discrepancy between prescribed and dispensed and knowledge about patients knowledgeable about b) dose c) frequency d) duration e) treatment cause f) if other information is provided. Sum for all 10 observations of yes (1) for a-f divided by total no. of (1+0)*100: >90%=1; 89-75%=0.75; 74-50%=0.5; 49-30%=0.25; <30%=0	1	0.59	0.86	0.74
	E3	Out of 10 medicine labelling : % of medicines correctly labelled: a) name b) strength c) quantity d) date e) dose f) patient name g) facility name. Sum for all 10 observations of sum of yes (1) for a-g divided by total no. of (1+0)*100: >90%=1, 89-75%=0.75, 74-50%=0.5, 49-30%=0.25, <30%=0	1	0.08	0.30	0.80
	E4	a) Average number of medicines prescribed per encounter b) generic prescribing. a)<2:0.5, >2:0 plus b)<85%:0.5, <85%:0	1	0.48	0.07	0.33
	E5	Of 20 prescriptions: % appropriate dosage (sum of 1/sum of (1+0))*100: 100%=1, <100%=0	1	1.00	1.00	1.00
	E6	Was the pharmacist involved in dispensing medicines initiated by the pharmacist? Y=1, N=0	1	na	0.09	0.23
	E7	Would the pharmacy sell antibiotic tablets/capsules without a prescription? Y=0, N=1	1	0.00	0.00	0.81
	E8	a) is generic substitution practiced? b)is it explained? a) y=0.8,N=0 and b)yes=0.2, N=0	1	na	na	0.17
		Total score	34	15	14	20
		FAS (Final Assessment Score): % actual score vis-a-vis possible score	100.0%	46.1%	43.6%	60.1%

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 technicians 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 at the start of data collection in order not to be recognized as surveyors. Data collection including simulated clients requires ethics review and approval. In the case of Ethiopia, Zimbabwe and Uganda ethical review was obtained from the Ministry of Health and the National Drug Regulatory Authorities.

Selection of interviewers and randomised selection of records was part of the training adhering to the recommendation provided by the WHO for investigating medicines use in health facilities[17]. To facilitate data collection and ensure freedom to independently assess the pharmacy site, the Ministry of Health or in the case of Ethiopia the Drug Regulatory Authority provided each data collection team with an acknowledgement letter requesting the pharmacy to support the survey team. Approval was obtained in private sector by pharmacy owner or manager and in public sector by the District Health Officer/ Ministry of Health. Data were collected within a two to three-week period covering two to three facilities per day. The survey applied both retrospective and prospective data collection using direct observations, records review, interviews and simulated clients. The number of items, prescriptions or patients assessed for individual indicators is set with a view to estimate the minimum required 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 and unstructured information. To test the tool, data were collected both in private and 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 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[24] recommended a minimum stratified sample of 20, while Global Alliance of Vaccine and Immunisation (GAVI) recommends a sample of 24 facilities within four districts[25]-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 2. Indicator description from the manual of indicator based assessment and analysis tool for Good Pharmacy Practice

C4. Services offered	
Assessment area:	Service quality/Services
Type:	Structure
Objective:	To ascertain the availability of services at the dispensing site: 1. Privacy in dispensing 2. Sitting facility 3. Weighing scale 4. Drinking water
Definition:	To verify if the services 1-4 are available for the customers
Verification	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): ____ b) Check if there are chairs or benches for the customers to use, (Yes=1/No=0): ____ c) Check if a weighing scale is available to the clients, (Yes=1/No=0): ____ d) Check if drinking water (to take tablets) is available to the customers, (Yes=1/No=0): ____ e) Check if facilities to wash hands is available to the customers, (Yes=1/No=0): ____ f) Check if soap is available to the customers, (Yes=1/No=0): ____ g) Check if toilet is available to the customers, (Yes=1/No=0): ____ h) Check if toilet-paper is available to the customers, (Yes=1/No=0): ____
Calculation:	Overall score : sum of all Yes (1) divided by 8. Max score is 1.
Data source:	Dispensary site

[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).

Figure 1. Histograms depicting pharmacy practices assessment scores of the five components (by country)

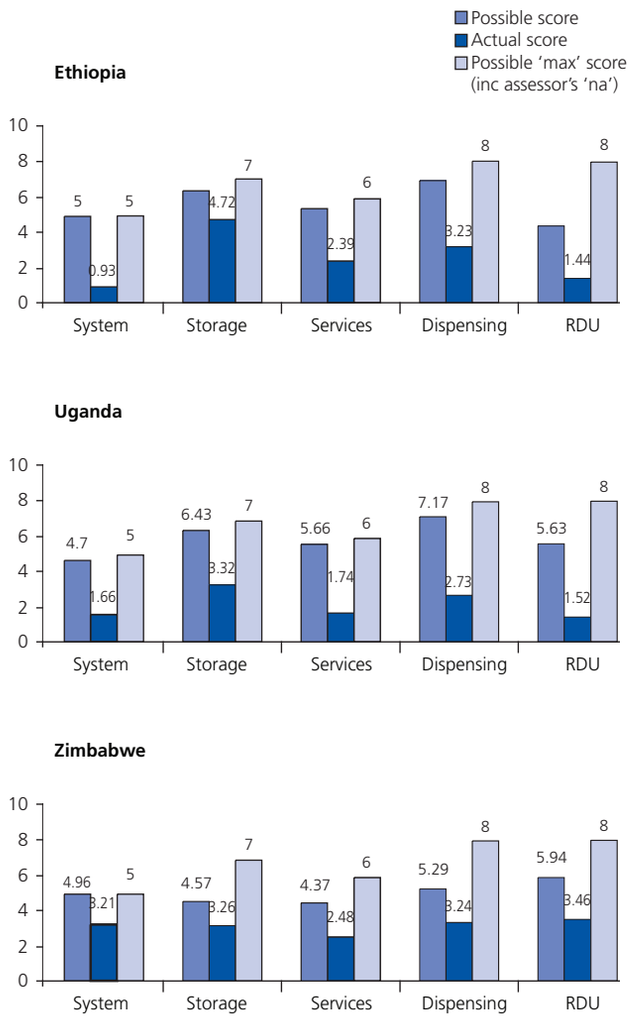
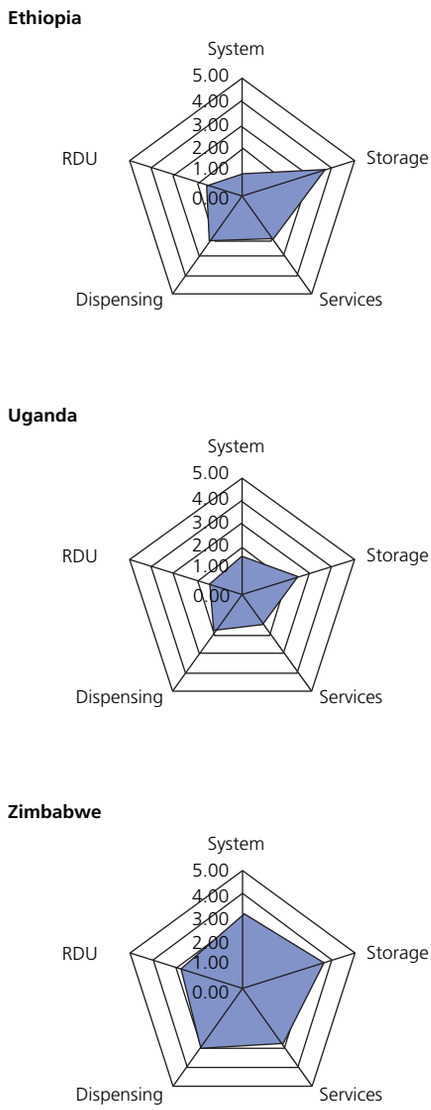


Figure 2. Spidograph depicting Pharmacy Practices assessment scores of the five components (by country)



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[1,21,26]. The PP indicator studies have also been undertaken to increase awareness of the problem of inappropriate pharmacy practices by dispensing doctors[8]. 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, 27].

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

patient or 'mystery shoppers'. One SC assesses appropriate dispensing and consultation with respect to 'pharmacist initiated medicines', one SC assesses the possibility of obtaining 'prescription only medicines', and one SC explores 'generic substitution' practices. These three assessments are similar to those assessed in previous studies using mystery shoppers[28]. Aspects of pharmacist-initiated dispensing of medicines have been assessed in New Zealand[29], and the obtainability of prescription only medicines, e.g. antibiotics and steroids without prescription, has been assessed in Vietnam as part of an educational intervention study[9, 19].

The WHO indicators assess prescribing practices, e.g. average number of medicines prescribed per prescription or generic prescribing. These indicators are primarily connected to the prescribers' practices and it could be argued not to include these indicators when assessing pharmacy practice. However, we found it important to assess Rational drug use (RDU), as prescribing practices can be influenced by the dispenser. Hence, the dispenser should act as a quality assurance or safeguard for the patient in ensuring rational prescribing. The PP assessment indicators were grouped into five components. Another study has grouped a set of check-list questions into seven sub-systems: registration (country specific requirement) (I), physical environment (II), order in pharmacy (III), storage of drugs (IV), and maintenance of cold chain (V), documentation (VI) and dispensing (VII)[4]. The six general sub-systems are easily included in our five components. The majority of the questions included in sub groups II, III, IV and V are questions included in the storage component. Sub groups VI and VII are comparable to our component on dispensing and rational drug use. However, while the sub-groups are comparable to our components, there are differences between the selected questions and our indicators. Our five components cover all main parts of the Good Pharmacy Practice concept and thereby ensure an overall PP assessment[8].

Only two of the RDU indicators (E6 and E7) are measuring 'self medication'. The indicators are descriptive and do not try to quantify a problem, but rather aim to detect if a practice takes place or not – either /or – and the method does not attempt to measure occurrence frequency. This was undertaken to make data collection feasible within a few hours at each facility. An example is the indicators assessing generic substitution or dispensing of prescription only medicines without a prescription, where only one interaction is assessed per facility.

The indicators still have to be separated into core and complementary indicators based on further country experience. This will be important in order to facilitate both universal and national application.

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[24,30]. 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.

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Conflict of interest

We have not identified any conflicts of interest.

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