Pharmalink

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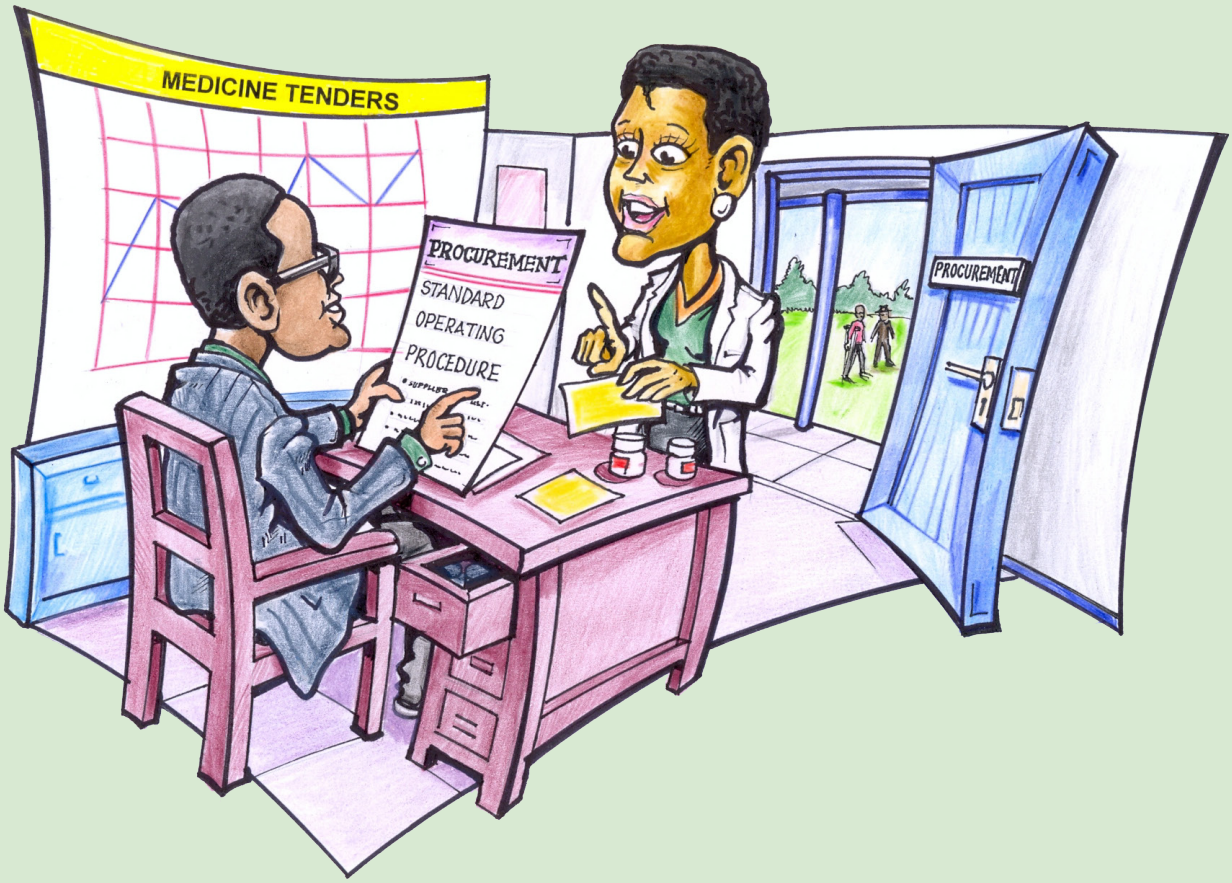
Implementing Standard Operating Procedures, Guidelines and Standards



Strategies for quality services

About Ecumenical Pharmaceutical Network (EPN)

Ecumenical Pharmaceutical Network (EPN) is an independent, not-for-profit, Christian organization whose mission is to support churches and church health systems provide and promote just and compassionate quality pharmaceutical services for all. In addition, the work of EPN is aimed at working towards services that allow no discrimination and guarantee equal access to all.

About the cover image

The image depicts health professionals discussing a standard operating procedure for procurement. The image was used in the EPN Guidelines for effective and efficient pharmaceutical services.

In this issue

Editorial Committee

Dr Andreas Wiegand, Elisabeth Goffin

Translation, layout and design

Elisabeth Goffin

Letters to the editor

Inquiries or comments about this edition of Pharmalink should be directed to:

communications@epnetwork.org.

The editor also welcomes author's initiatives for future editions.

Dislaimer

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Editorial

"I have not failed. I've just found 10,000 ways that won't work," Thomas Alva Edison. Whether you work in a hospital, a drug supply organization or production unit, you have tools, materials, and last but not least colleagues, customers, people to interact with. To get things right is always a challenge. How do we design our processes, how do we organise ourselves? Who is responsible for what?

Get started! Joint Medical Store, Uganda, shares experiences regarding the implementation of an SOP programme under the quality management system, which culminated into acquisition of ISO certification in 2011. The article provides insight into the steps taken in the process of developing SOPs, which may be of interest to organizations who find themselves at the base of this mountain.

Our eyes are very important for recognising our surroundings. They are also very sensitive if we expose them to dust or spills and eyedrops if contaminated. Read the second article and "see" how the Kabgayi Eye Unit, a Rwandan manufacturer of eye drops has improved the quality of eye drops manufactured in its department through SOPs.

From the other side of the ocean, i+solutions, Netherlands, shares its insight on how well structured processes and quality policies have a direct effect on patient care. They emphasise the need to not only look at the processes but also the people and products involved. An example to learn from is their ISO 9001-2008 certification.

The article by a Diocesan health coordinator in Uganda pinpoints another important aspect: tools for quality management can be very relevant but staff training and staff involvement are crucial, especially in the case of high staff turnover.

Finally, we learn of the leaps and bounds in progress made by Gertrude's Children's Hospital since 2008, when they started developing guidelines and policies for extemporaneous compounding. The quality of extemporaneous preparations has since greatly improved, assuring patients of the safety and potency of their products.

It is up to us to organise ourselves and our processes to improve quality. It will not just happen. The tasks to implement quality management systems appear huge and sometimes overwhelming. The examples in this edition of Pharmalink give proof that the efforts are worth to be taken.

Andreas Wiegand

The success of SOPs at JMS

Emmanuel Higenyi

A Standard Operating Procedure (SOP) is a step by step guide having the force of a directive, outlining the sequence of steps required to accomplish an activity and clearly indicating the start and finish points. Where necessary, SOPs may indicate persons responsible for specific tasks, requisite resources and references. Much as this definition appears rather straightforward, there is usually confusion regarding the difference between SOPs and related management tools such as policies, rules, guidelines, protocols and job aids or written instructions. The International Conference on Harmonisation[1] (ICH) defines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function".

> To realize business excellence, Joint Medical store started implementing the quality management system five years ago, a process that culminated into acquisition of ISO (International Organization for standardization) certification in 2011.

A policy is a plan or course of action made by an institution or body, intended to influence and determine decisions, actions related issues or a guiding principle or course of action adopted toward an objective or objectives. A protocol is a code of correct conduct; a rule on how an activity should be performed (in written or unwritten form). A rule is a prescribed guide for conduct or action. It may be defined as a principle set up by an authority that prescribes or directs an action. A rule differs from a SOP in that it neither refers to a process nor prescribes steps for carrying out an action. A regulation is a rule or order prescribed by an authority to regulate conduct. A guideline is a statement by which to determine a course of action. This is closely related to a SOP but does not prescribe steps. A job aid or work instruction describes step by step what you should do to perform a procedure or task. These usually work hand in hand with SOPs.

Benefits of SOPs

When developed and implemented successfully, SOPs have a number of compelling benefits such as:

- Minimising process variability (person-to-person) thus promoting process consistency
- Minimising result variability thus promoting result consistency and reproducibility
- Sustained return on investment due to reduced process errors
- Performing continual quality improvement
- Facilitating training for new employees
- Investigating discrepancies in results

Although SOPs are widely acknowledged and highly regarded as important business tools, in real practice, the implementation of a SOP programme is daunted with several challenges that limit realization of the maximum benefit endowed in these tools. There is diversity among organizations and institutions regarding experiences with development and use of SOPs. Differences in organizational culture, type of industry and employee mindset may be responsible for a large part of the diversity.

The JMS experience with SOPs

Joint Medical Store (JMS) is a supply chain organization in Uganda whose prime engagement is procurement, warehousing and distribution of

medicines and other supplies used in delivery of health care. This core responsibility is blended with provision of technical assistance to healthcare institutions and service providers.

To realize business excellence, Joint Medical Store started implementing the quality management system five years ago, a process that culminated into acquisition of ISO (International Organization for Standardization)[2] certification in 2011. The process was very challenging with many learning points but each milestone was a major achievement.

The first step was to carry out a comprehensive business review with a view of mapping the business processes. In this exercise, non value adding activities were identified and eliminated while the value adding activities were realigned. This step, much as it may appear simple, was one of the most challenging when initiating a quality management system (QMS). This is because for the QMS to be successful, it should be founded on processes that provide value to all stakeholders, including customers. To facilitate QMS implementation, a document management system was established to guide creation, review and filing of documents including standard operating procedures.

The second step was to review and validate the existing SOPs for specific processes. The SOPs were checked for relevance to the new process map. This step was quite interesting because initially the SOPs were developed on a predominantly function-based organizational structure. The real challenge here was moving beyond organization silos (departments or units operating in isolation without regard of what happens in other departments or units) to develop SOPs that cut across departments and functions. Without doing this, there might have been separate but overlapping procedures giving different steps for shared processes. The other challenge was to do with what level in the structure was to take the lead in reviewing and validating specific SOPs. To surmount this challenge, JMS decided that section heads should take the lead in consultation with their juniors and thereafter forward the completed SOP for review by departmental heads and office managers. This was important to create ownership and increase uptake. An additional challenge was to decide on which activities required work instructions instead of SOPs. It was resolved that individual tasks and subtasks be guided by work instructions while SOPs were reserved for activities. This required careful identification of what qualified to be a task/subtask and what qualified to be an activity. Completed SOPs were then compiled into procedure manuals based on functional units.

The third step was commissioning of the SOPs and other documents such as the quality manual, guidelines and policies. This involved formal approval of the SOPs, assigning them controlled status and intensive training on their use to perform different activities. A formal training programme was adopted for the entire organization with close supervision, monitoring and evaluation.

The fourth step was the implementation phase where the procedures were actively used to perform different processes. This was the consolidation phase of the quality management system. The phase was supported by regular internal process audits to check for compliance or deviation. Deviations were properly investigated using the root cause analysis technique and where a procedure was noted to be a constraint, it was amended through a change management system.

The quality management system facilitated harmonization of business processes thus making it easier to implement SOPs. Currently, JMS has 94 SOPs in use. As a result of effective SOP implementation, it is now possible for JMS to effectively carry out logistics activities such as inventory control, physical inventory, product recall and consignment verification at receipt and dispatch. It is also now easier to conduct internal process audits and plan for quality improvement.

About the Author

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Example of a Standard Operating Procedure at JMS

JOINT MEDICAL STORE	
Document Type: Procedure	
Department: Quality Assurance and training	**Creation Date: 01.07.2010**
Title-Code: QUALITY INSPECTION OF INCOMING GOODS-JMS/QA/07	**Revision No.:01**
Prepared by: **Checked by:**	**Approved by:**
Issue No: 02	**Effective Date: 08.09.2010**
Distribution:	**1.As per distribution list**

- **Purpose**

To provide guidance during the quality inspection of incoming goods to ensure receipt of goods meeting JMS Product Specifications

- **Scope**

Covers all activities related to inspection of incoming goods for quality with an overall aim of ensuring efficient receipt goods that always meet JMS specifications

- **Definitions**

Not applicable

- **Responsibility**

HQA

e) Procedure

No	Procedure	Action Owner
1	**Goods other than Equipment**	
1.1	Receive the Local Purchase Order, GRN and all Certificates of Analysis (where applicable) from HRR/RO.	QAO
1.2	Verify that supplier is pre-qualified and products match with the LPO	QAO
1.3	Randomly sample each batch/lot of incoming product as follows: <10 boxes per batch sample 1 items 10<20 boxes per batch sample 2 items 20<boxes per batch sample 3 items	QAO
1.4	Assess the sampled products for quality using parameters on the Quality checklist JMS/QA/07/OF/02.	QAO
1.5	Verify that sampled items match with the respective JMS Specifications.	QAO
1.6	Change status of the item in the Warehouse Management [illegible] that it [illegible]	QAO

Implementation of Standard Operating Procedures in Kabgayi Eye Unit: local manufacturing of eye drops

Jean Paul Umuhire

The Kabgayi Eye Unit is a department of ophthalmology of Kabgayi Hospital situated in southern province of Rwanda, at 60 km of the capital Kigali. This unit was started in 2003 with the sole objective to make locally produced, good quality eye drops available for the Rwandan population. The unit utilizes simple and appropriate technology in manufacturing the pharmaceutical product.

In order to comply with the good manufacturing procedure (GMP) requirements as specified in international standards, some difficulties have been observed. Some eye drops produced did not meet the quality requirements.

The analysis of the products by an external quality control laboratory showed that a high number of batches did not meet the quality requirements (see table). The analysis of eye drops produced was consisting in organoleptic analysis, physical-chemical analysis for some products and control of microbiologic contamination by the external laboratory LABOPHAR (Laboratoire Pharmaceutique au Rwanda).

Year	Batches failed (%)
2004	15
2005	6
2006	4
2007	11
2008	13
2009	8
2010	5
2011	2

As the unit strives for the availability of eye drops, the demand was increasingly noticed and therefore several strategies have been adopted in order to put on the market drugs of good quality.

The situation has been a concern of the unit as many problems were still occurring. The evaluation and reduction of possible causes of the contamination have been done during the last six years, and for all steps of manufacturing eye drops in the unit. The plausible causes established were inappropriate level of apparatus and equipments cleaning, personnel not being well trained and not experienced, the absence of written standard operating procedures for the eye drops manufacturing process, the cross contamination between products during manufacturing, etc.

After analyzing the major factors that may exacerbate the problem, the lack of validated or improved standard operation procedures of cleaning occupied the first place. The pharmacist in charge has taken up this concern in order to improve the service rendered to population by Kabgayi Eye Unit.

1. Main goal of the specialist called for situation analysis

After analyzing the situation, the first work for the specialist was the writing of Standard Operating Procedures detailing the cleaning process of the filtration unit (see page 6-7) used in local manufacturing of eye drops.

Sterilization after cleaning glassware

2. Cleaning in pharmaceutical manufacturing process

During the pharmaceutical manufacturing process, contamination and cross-contamination usually come from the environment, the materials used, the process and the operators. When the same equipment is used for processing different products or the same, the next product can be contaminated by other pharmaceutical products (residue), by cleaning agents, or by microorganisms. To avoid this disaster, adequate cleaning procedures are essential. Scientifically, the procedure must be validated using analytical techniques but this option will not be presented in this article.

> By implementing the Standard Operating Procedure, the Unit thinks to meet the requirements of GMP and hopes to gain more benefits in services rendered to the population.

As shown in the Standard Operating Procedure on the next page, the different steps of cleaning the filtration unit used in Kabgayi Eye Unit have been documented and put into a Standard Operating Procedure with the only reason to improve the cleaning, in order to meet the requirements of good manufacturing process of pharmaceutical products. This SOP was put into practice in December 2012. Other SOPs developed in the same period cover issues such as batch documentation and identification, cleaning of premises, collection of distilled water, handling of returned drug product, and in-process control (filtration).

3. Evolution of the situation after implementing the procedure

The Standard Operating Procedure proposed has permitted a positive evolution of the situation as long as it has been validated. The percentage of failing batches has been reduced. Another observation has been that different steps of cleaning previously not well done have been documented and done properly; through the SOPs put in place, personnel now give considerable attention to any steps. The personnel have been trained and the SOPs are taken as tools for the company's success.

By implementing the Standard Operating Procedure, the Unit thinks to meet the requirements of GMP and hopes to gain more benefits in services rendered to the population.

About the Author

Pharmacist Jean Paul Umuhire (B.Pharm; M.Pharm QC&QA) is Chief pharmacist at Kabgayi Hospital, which belongs to the network of Bufmar, Rwanda, a member of EPN.
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Example of an SOP: Cleaning of glassware: filtration unit

KABGAYI EYE UNIT / CLEANING DEPARTMENT/ SOUTHERN PROVINCE

Standard Operating Procedure (SOP)		
Title: *CLEANING OF GLASSWARE:FILTRATION UNIT*		
SOP N° :	**KEU-QA004-V01**	Apparatus N°: NA
Date of Issue :	**25/08/2012**	**First edition**
Replace SOP N° :	**NA**	Revision date:

control manager

1. OBJECTIVE.

This document describes the procedure for cleaning the filtration unit.

2. SCOPE

This procedure is applicable for all glassware used in production especially for the filtration unit.
Example of glassware: Filtration unit SCHOTT DURAN 250 ml, Serial n°: 24-720-50-01.

Instrument description:

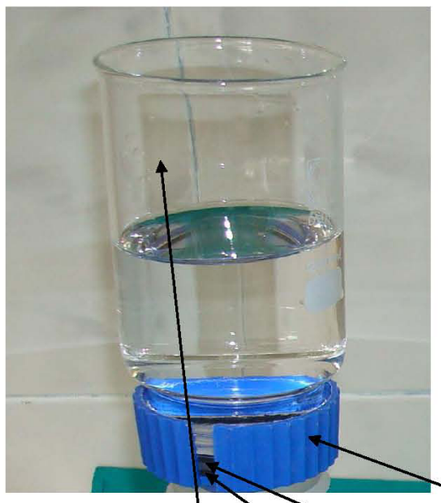

Figure 1. : Filtration unit

Components: Filter head, viton sealing ring, sintered glass/filter disc, funnel of polypropylene

KABGAYI EYE UNIT / CLEANING DEPARTMENT/ SOUTHERN PROVINCE

Standard Operating Procedure (SOP)		
Title: *CLEANING OF GLASSWARE:FILTRATION UNIT*		
SOP N° :	**KEU-QA004-V01**	Apparatus N°: NA
Date of Issue :	**25/08/2012**	**First edition**
Replace SOP N° :	**NA**	Revision date:

Put into operation: 12/2012

Main responsible technician: Chief lab technician

Document storage location: QA/QC manager office (soft & hard copies), head of cleaners (hard copy), production manager (hard copy), Direction of the unit (soft & hard copies).

3. RESPONSIBILITY.

The chief lab technician in collaboration with the head of cleaners shall ensure that the cleaning of filtration unit has been operated in accordance with this Standard Operating Procedure.

4. STEP BY STEP PROCEDURE.

4.1. Wear safety equipment (glasses, hand gloves, blouses, shoes);
4.2. Enter in production room and separate equipments used according to their types;
4.3. Keep all equipments to be cleaned in a well closed container;
4.4. Correct the different containers for an Cleaning Out of Place (COP);
4.5. Number the different containers to use from 1 to 3;
4.6. Before taking any action start completing the cleaning control form described on point 5;
4.7. Disassemble the equipment and drench all parts of filtration unit in container full of hot distilled water;
4.8. Mark the starting time of drenching on cleaning control form;
4.9. After 30 minutes ,write down on the cleaning control form the drenching end time ;
4.10. Remove the wet parts one by one and place them in container numbered 2 full of distilled water;
4.11. Using a proper brush, scrub each parts one by one;
4.12. After scrubbing ,place the scrubbed parts in container numbered 3 full of hot distilled water;
4.13. Change water of the container numbered 3 after finishing scrubbing all equipments;
4.14. Soak the all parts again in hot distilled water in the same container for 15 minutes;
4.15. Write down the starting as well as ending time on cleaning control form;
4.16. After 15 minutes rinse the finished material with run distilled water;
4.17. Let dry all parts in a drier adjusted at 100°C for 30 minutes;
4.18. Switch off the drier and allow to cool for 20 minutes;
4.19. Remove all dried parts;
4.20. Place the dried parts in reserved container ;
4.21. Label the container with the following information: date of cleaning and holding time (not more than one week).

N.B: Before using any equipment, if cleaning holding time exceed one week, proceed as Indicated from stapes 4.8.

Total Quality: processes, people, products

Drs. Davey Groothoff

In order to realize total quality for your patients, you need to secure the whole supply chain: your processes, your relations (e.g. vendors), your people and your products.

i+solutions is an international organization specialized in pharmaceutical supply chain management, capacity building, training and consultancy services. As pharmaceutical procurement partner in the Partnership for Supply Chain Management, we implement the Supply Chain Management System (SCMS) funded by the US Government/PEPFAR program and the Voluntary Pooled Procurement program (VPP) for the Global Fund. Last year we procured for almost 300 million USD of pharmaceuticals, contributing to the treatment of more than 2 million HIV/AIDS patients and 15 million patients suffering from Malaria.

The ISO 9000 family of standards is related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to the product. The standards are published by ISO, the International Organization for Standardization[1], and available through National standards bodies[2]. ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles on which the family of standards is based (Wikipedia): Customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factural approach to decision making, mutually beneficial supplier relationships.

We have made substantial savings for our donors/recipients. Other important activities are training and capacity development in procurement and supply management and the development of projects that address bottlenecks in supply chains. We currently have a programme on procurement, distribution and social marketing of female condoms in countries like Nigeria, Cameroon and Mozambique. Another programme is a comprehensive health commodity and training programme in Rwanda, Burundi and DRC, together with Cordaid and Swiss TPH.

ISO 9001-2008

ISO (International Organization for Standardization)[1] 9001-2008 focuses primarily on processes, relations and people. i+solutions is ISO 9001-2008 certified since 2010. This certification covers our procurement and supply delivery services as well as capacity building, implementation and technical support on project design for low and middle income countries. Important building blocks are: describing all processes/activities, responsibilities and competences, working with kpi's (key performance indicators), setting norms/goals, appointing process-owners (e.g. handler of complaints), internal and (independent) external audits, training procedures, etc. The key objective is to organize and realize a continuous improvement in the way of thinking and doing in your organization. Not bureaucratic, but active, basic, down to earth, keeping it simple and workable. Let's say like in school: getting your organization and people from grade C to B to A and possibly A+. In ISO this is called learning loops. We have to document lessons learned and convert them in action points to become better all the time.

An i+solutions training on quality aspects

Quality Assurance

Quality Assurance (QA) focuses more on the products (medicines, reproductive health) in the whole supply chain including the necessary process controls and competences. In line with i+solutions' vision of universal access to high quality, affordable medicines and health products, the QA policy has been formulated to articulate the commitment of i+solutions for operating a quality system for the procurement, supply chain management of all pharmaceutical and medical products. The implementation of this policy is supported by i+solutions Pharmaceutical QA standard operating procedures (SOPs) which contain detailed written instructions on performance of each function.

i+solutions considers Quality Assurance of all pharmaceutical and medical products supplied to its clients as its primary responsibility. i+solutions commits to comply with the standards and regulations specified by the European Union (Guidelines 2013/C 68/01 and 2001/83/EC), The Netherlands' Government (Inspectie voor de Gezondheidszorg, IZG) and the recipient country's National Regulatory Authority and the Donor's Quality Assurance Policies.

i+solutions Pharmaceutical Quality Assurance Standard Operating Procedures (SOPs) are continuously updated to be aligned with the latest quality standards and referential norms set by WHO, in particular the WHO Model Quality

Assurance System for Procurement Agencies (WHO MQAS).

Our QA policy covers all activities in the entire supply chain to ensure that all commodities procured or supplied by i+solutions meet specified requirements and standards including: product specification; compliance with national regulation; pre- and post-shipment quality control; storage and distribution; and inventory management.

Total quality in a broader perspective

Quality policies normally are focused on the products and the supply chain, the manufacturing and delivering of the goods. As professionals in the field, we should be aware there are all kinds of influencing factors that could be a barrier to realize an excellent quality care result for the patient. Let's think of:

- Health market dynamics: for example, till recently there was only one prequalified manufacturer for female condoms. This formed a barrier to the possibility to select and choose, and increased costs.
- Health information: for example clinical, logistical, financial information. Operational and management information plays a major role in effective quality for the patient.
- Health financing: for example, without health insurance, sick patients may not go to the doctor, in which case they possibly can not have access to your excellent quality care system.
- Human resources: for example, it could happen that a medical professional describes the wrong medicine, or too much or too little. Therefore effective training in e.g. treatment guidelines is an important factor to realize real quality care for the patient.
- Health care technology: for example, with the help of E-learning, more medical professionals can be reached in the coming years. And mobile phones already play an important role in preventing stock-outs in some remote areas. It makes your quality care system even more effective in the field.
- Health individuals/communities: for example, there could be all kinds of human barriers for making your quality care for people effective. Think of lack of knowledge on sexually transmitted infections or cultural restraints to use of medicine. This requires promotion and explanation in the field of the what-why-when-where of the use of medicine. Only if individuals and communities are really convinced, can quality care reach the patient.

High quality services delivery for your patients needs to be embedded in a broader perspective on health to ensure total quality of care to the patient.

In summary, high quality services delivery for your patients needs to be embedded in a broader perspective on health (ISO 9001-2008, QA, other health quality influencers) to ensure total quality of care to the patient.

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Relevance of tools for quality management in Kampala Diocesan Health Units - Uganda

Regina Bakitte N.M

The diocesan health units (DHU[1]) in Uganda are headed by in charges at clinical officer level for Health Centre 111s and enrolled nurses for Health Centre 11s.
The Ministry of Health (MOH), Uganda Catholic Medical Bureau (UCMB), Joint Medical Store (JMS) and other partners have developed manuals, procedures and guidelines used in management of health services at facility level. These include a standard operating procedure manual developed by JMS, Uganda Clinical guidelines by MOH, and a patient safety manual developed by UCMB in partnership with the MOH plus other health unit management committee tools.
For monitoring purposes, the health coordinator designs or uses already existing tools to monitor proper service delivery and management of health services at health facilities in Kampala Archdiocese.

In January 2013, Diocesan Health Coordinator Regina Bakitte carried out a survey in 15 DHUs, with the purpose to look into ordering, procurement and distribution processes. The initiation of this survey came as a result of integrated support supervision visits with the district teams, recommendations from in charge review meetings and experience sharing in meetings attended such as the EPN workshop on developing Monitoring & Evaluation tools in April 2012 in Nairobi, Kenya.

Guidelines and SOPs

The survey showed that 90% of the units had the approved 2010 Uganda Clinical Guidelines and were making use of them in diagnosis of disease.

With regard to Standard Operating Procedures (SOPs), JMS last trained in charges 5 years ago. At the time of the survey, only 10% of those

Community members lining up for free HIV counselling and testing on World Health Day in April 2013 held at Muzinda Katereke Health Centre 11 in Nabbingo Parish

health in charges were still in place, the rest had left. This made it impossible for most of the health units to design SOPs on procurement i.e. minimum and maximum stock levels, stock management (update of stock cards, consumption), designing dispensing logs, storage (FIFO[2]), etc.

On guidelines for treatment of disease, 80% of the health units had received IEC[3] material from the Ministry of Health and the district and these were found at visible places in the facility. The materials covered issues such as integrated management of childhood illnesses (IMCI[4]), antenatal care (ANC), HIV counselling and testing (HCT), bites, among others.

Quality of services

On quality of services, it was noted that 80% of the health units had placenta pits, proper garbage disposal, waste management through sorting, support supervision from the district, 58% qualified medical staff, but aging equipment and tools. The registers for outpatient department (OPD), inpatient (IP), ANC, HIV/AIDS, were in place and in use. Only 10% of the health units had patient committees but they were still not sensitized on their roles. Only 1 unit had a medicines and therapeutics committee in place.

In conclusion, designing tools is one aspect but ensuring that staff have the training, the tools are understood, implemented and evaluated is very important for access, efficiency and quality of services in the network.

About the Author

Regina Bakitte N.M is the Diocesan Health Coordinator at Kampala Archdiocese- Uganda. The Kampala Archdiocesan Health department is one of the dioceses under the UCMB network, a member of EPN.
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Standards-based Pharmacy Practice at Gertrude's Children's Hospital - Enhanced Extemporaneous Compounding

Jaguga Pambo C. D

Gertrude's Children's Hospital has over the years recognized the need to adopt in its practice evidence-based, peer-reviewed components of best practice in the delivery of healthcare to patients. This has been driven by the need to consistently offer patients high quality of care, at an affordable cost. As a result, the pharmacy department in the hospital has embraced in its practice, systems to ensure continuous improvement in the delivery of pharmaceutical care by regularly benchmarking practice standards with best practices, identifying gaps, establishing improvement priorities and working to close the targeted gaps. The processes, structures and resources that must be in place for the provision of safe and high quality care are given utmost priority and the hospital's management has been very supportive to this end.

> We can now, with certainty, assure patients of the quality of our extemporaneously prepared formulations.

The department has policies, guidelines and standard operating procedures (SOPs) that direct the practice of pharmacy at the main hospital and all its satellites. These guide all the phases of medication management and use in the hospital. These phases include selection, procurement, storing, ordering/prescribing, distributing, preparing, dispensing, administering and monitoring of medication therapies. The standards are revised once a year with provision for clinical staff to recommend amendments before the review date. Such recommendations are raised through the hospital's quality management software known as Q-pulse and addressed to the Chief Pharmacist. Depending on the scope of the proposed amendment, it can either be reviewed by a team of pharmacy personnel or tabled as an agenda for discussion by the Medicines and Therapeutics Committee. Once evidence-based consensus is generated, the document is amended, the version number altered, re-uploaded onto Q-pulse and circulated to staff.

Extemporaneous compounding

Pharmacy practitioners have always been faced with the challenge of modifying oral dose formulations intended for adult use into suitable forms for paediatric use[1]. Due to the absence of ready-made products, it is common to prepare oral liquids from tablets, capsules or powdered medicine dispersed or dissolved in suitable bases. This in many cases is done without evidence-based protocols and Gertrude's Children's Hospital was not an exception approximately eight years ago. One area in which the enacting of standards has led to consistent quality of pharmaceu-

A pharmacy staff compounding an extemporaneous preparation

tical care in the department is with extemporaneous compounding of such formulations. Prior to the introduction of guidelines and standard compounding formulae, tablets were crushed or capsules opened and contents dissolved in distilled water or multivitamin syrups without regard to their physico-chemical properties, compatibility and bioavailability properties. There was no reliable information on stability and storage conditions for the preparations made. It was not possible, with certainty, to assure patients of the potency of the compounded preparations. Documentation was scanty and medication labels were not of a standard format.

The department defined its desired performance standards in line with best practices and noted the gaps. Consequently, in 2008, guidelines were developed, appropriate resources acquired and sensitization sessions for pharmacy staff held. The developed guidelines outlined the required documentation for each preparation made, labeling details and standards, instructions to be given to patients during dispensing, appropriate protective apparel and handling of deviations from the formulae among others. Compounding formulae for different formulations were collated from several peer-reviewed references and compiled to form an extemporaneous formulary.

Each compounding formula has the following information; formula number, name of product, ingredients and quantities, procedure for compounding, shelf life, desirable storage conditions, correct packaging and other relevant instructions for the appropriate use of the medicine.

The standard operating procedure requires that at a minimum the following steps are carried out for each compounded formulation: cleaning of the compounding area and equipment, washing of hands, putting on protective apparel (dust coats, apron or gloves), identification and assembling of all relevant materials and equipment, performance of the necessary calculations to establish the amount of each ingredient needed and independent verification of the same, compounding according to laid down procedure, assessing patient weight variation, adequacy of mixing, clarity, odour, colour, consistency of preparation and pH as appropriate, documentation of the compounding process in the extemporaneous preparation form - this record can be used to address any questions that may arise at a later date, final verification and provision of patient counselling.

The development and implementation of these guidelines has led not only to the consistency in the manner in which extemporaneous preparations are made, but also to better quality products with evidence-based medication use information. We can now, with certainty, assure patients of the quality of our extemporaneously prepared formulations, adding up to over 600 formulations per year. Plans are underway to forward some of the formulations we prepare to the national quality control laboratory for analysis of quality.

About the Author

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References

ARTICLE: The success of ***SOPs at JMS*** (p. 1-3)
1. http://www.ich.org/
2. http://www.iso.org/

ARTICLE: ***Total Quality: processes, people, products*** (p. 8-10)
1. http://www.iso.org/
2. http://en.wikipedia.org/wiki/Standards_organization#National_standards_bodies

ARTICLE: ***Relevance of tools for quality management in Kampala Diocesan Health Units - Uganda*** (p. 11-12)
1. These are lower level health units in the 19 dioceses, coordinated by the respective diocesan health coordinators.
2. FIFO – First In, First Out
3. IEC - Information, Education and Communication
4. These are services at consultation such as weighing, immunization, nutritional information, prevention of diarrhoea.

ARTICLE: ***Standards-based Pharmacy Practice at Gertrude's Children's Hospital - Enhanced Extemporaneous Compounding*** (p. 13-14)
1. Extemporaneous formulations of oral liquids, A guide, http://www.pharminfotech.co.nz / manual / Formulation / extemprep.pdf. Accessed: 14th August 2013.

Resources on compounding of children's medicines

Pharmacy Compounding Manual

The Alberta Health Services - Calgary (AHS) published the latest edition of their Pharmacy Compounding Manual on the internet: PHARMACY COMPOUNDING MANUAL , September, 2013.
It offers a well written introduction with many state of the art aspects to assure the quality of the compounding process and the resulting products.

http://www.sbgh.mb.ca/dop/files/calgaryCompManual.pdf

Compounding recipes

The Hospital for Sick Children (SickKids), which is a health-care, teaching and research centre affiliated with the University of Toronto offers a lot of data on their website. The alphabetic list allows you to click on a link of a certain medicine in order to access the compounding recipe.

http://www.sickkids.ca/Pharmacy/Compounding-Service/

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