

Ecumenical Pharmaceutical Network

Guidelines

for

Effective and Efficient

Pharmaceutical Services

EPN

Ecumenical Pharmaceutical Network
Réseau Pharmaceutique Œcuménique



Just and compassionate quality pharmaceutical services for all

*Providing effective and efficient pharmaceutical services
in the context of a health facility
means that the services provided by the pharmacy
are comprehensive, add value to the care of each patient and are provided
in a way that the resources (human, financial, infrastructure)
invested in providing the service generate maximum returns
(best possible prices for medicines, optimal counselling, minimal expiries).*

EPN welcomes any feedback in order to improve the guidelines and make them relevant to as many health service providers in the developing world as possible. Please send comments, suggestions and feedback to:

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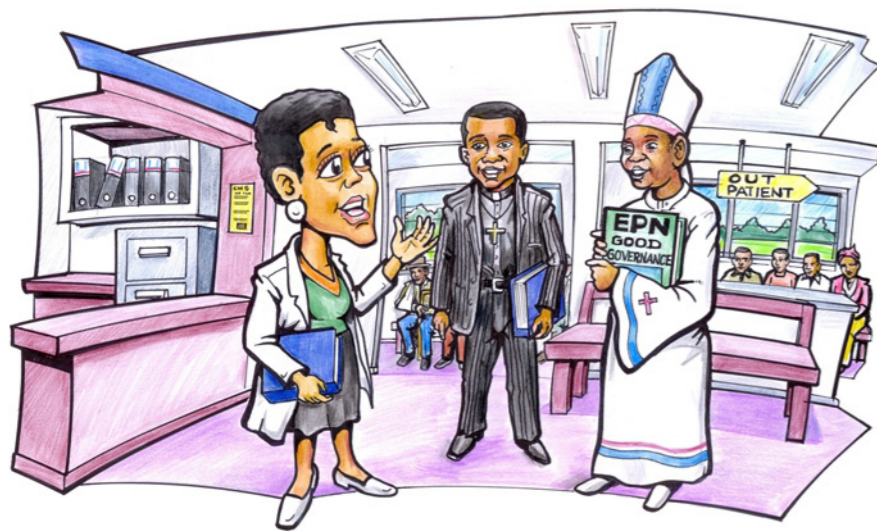
INTRODUCTION

The pharmaceutical unit is a key component of a health service delivery system. It is responsible for ensuring that good quality medicines, vaccines, biologicals and other medical products are available and affordable; and supports their use in prevention or alleviation of human suffering. However if the unit is not well managed it can compromise the efficiency, effectiveness and quality of health service delivery. Good pharmaceutical management is essential to maximize outcomes for patients and all who interact with health systems. Given the lack of qualified pharmaceutical personnel in the church health sector in Africa and the absence of standards of practice for pharmaceutical services, EPN decided to invest in providing guidance in this area. The process of developing these guidelines started in 2004 and various modifications of the guidelines have been undertaken over the years. The version presented here is a version for field testing after which further refinements will be done to ensure that the guidelines have practical application for the building of strong and sustainable pharmaceutical systems.

PURPOSE OF THE GUIDELINES

The EPN guidelines are intended to support health facility managers, pharmaceutical personnel and all those involved in pharmaceutical service delivery with a tool to guide them on the areas they need to pay particular attention to if they wish to provide a high level of service. EPN has defined 25 such areas of emphasis which are discussed below. For each guideline, its aim is briefly described, a few examples given on what can be done to ensure compliance and in some cases indicators that can assist managers and pharmacy staff to measure how compliant they are with the guideline. The guidelines are not intended to replace any local or national legislation or regulations but simply to provide guidance for service delivery where none exists or to supplement whatever other tools, guidelines and standards may be available. The guidelines are presented under the six building blocks of health systems as defined by WHO.





Good governance

Get the facility owners to know and understand their roles and implement principles of good governance

Aim: To ensure that the health facility is run in a proper and transparent manner that returns value to all the stakeholders (owners, staff, patients, public and the government).

What you can do to ensure compliance:

Hold regular meetings of the board and management of the facility. Have proper human resource policies and procedures in place. Familiarize the board and owners with the services that are provided and the inputs required for good quality of care. Continuously challenge the owners on how to increase access to the poor, without compromising quality of care and the sustainability of the facility and without exploiting the human resources.



Service to the poor

Adopt a pro-poor ethic in the facility

Aim: To ensure that mechanisms are in place for the poor seeking care from the facility not to be simply turned away but attended to in a way that benefits them while protecting the institution.

What you can do to ensure compliance:

Put measures in place to verify the needy cases to ensure that they access the services. In facilities where a social worker is available she/he can be given the responsibility of handling the needy patients and advise accordingly. The health workers should make every effort to promote health insurance schemes (if they exist). Put in place an exemption policy and adhere to it.

Indicators:

- Existence of pricing policies
- Prices compared to other institutions
- Presence of independent (protected) pharmacy budget





Transparency

Have mechanisms for transparency in place

Aim: To carry out pharmaceutical activities in the health facility in a transparent manner as a means to increasing access by all who need the service.

What you can do to ensure compliance:

Ensure that the health workers maintain a high level of professionalism in their daily work. Organize for regular audits by either internal or external auditors to be done. Carry out annual audits. Put a mechanism in place to ensure for annual and strategic planning. Put a policy on monitoring and evaluation in place and implement it. Write and implement staff recruitment policies.

Indicators:

- Audit reports available
- Annual reports available



Awareness

Make Church Leaders aware of key messages on pharmaceutical issues

Aim: To ensure that church leaders are aware of the key services provided by the facility and of the key messages on pharmaceutical issues, such as the need to use medicines properly and to increase access to Antiretroviral Therapies.

What you can do to ensure compliance:

Hold regular meetings with the leaders so as to instil a sense of belonging and to use them to pass on messages to the community on relevant issues, e.g. need for vaccination, availability of medicines for common infections.





Community involvement

Put in place systems for effective community involvement

Aim: To ensure that the community has an interest in the proper running of the health facility and supports its continued existence as a centre for quality care.

What you can do to ensure compliance:

Establish a health unit management board which includes members from the community. The community health workers could be utilized in giving health talks and in creating awareness of the services offered in the health facility to the community. Set up a suggestion box or a complaints centre to facilitate getting feedback from the community. Address the issues raised accordingly.



Representation

Have mechanisms in place to allow for representation of the pharmaceutical function at discussions in the facility and in relevant regional and national level debates

Aim: To ensure that the pharmaceutical issues are taken into account at all levels (regional and national) in relevant debates and that there is someone representing the specific interests of the pharmaceutical function at every relevant level of discussion in the facility.

What you can do to ensure compliance:

Recognize pharmacy professionals as the authority on medicine matters who need to be consulted while planning for the facility. Ensure that the pharmaceutical function interests are represented in all the relevant meetings at the facility, regional and the national level. Include staff from the pharmacy department in relevant meetings. Ensure that all the issues that are to be discussed at a higher level of decision making are forwarded to the representative at that level.

Indicators:

- Evidence of pharmacy function involvement in minutes of meetings
- Evidence of authorization to participate in regional and national level activities





MTCs

Maintain functional medicines and therapeutics committees (MTC) in all hospitals

Aim: To have a multi-disciplinary team that can authoritatively decide on issues of medicine policy, enforce compliance with policies and guidelines on medicines use issues and oversee medicine use practices in the hospital.

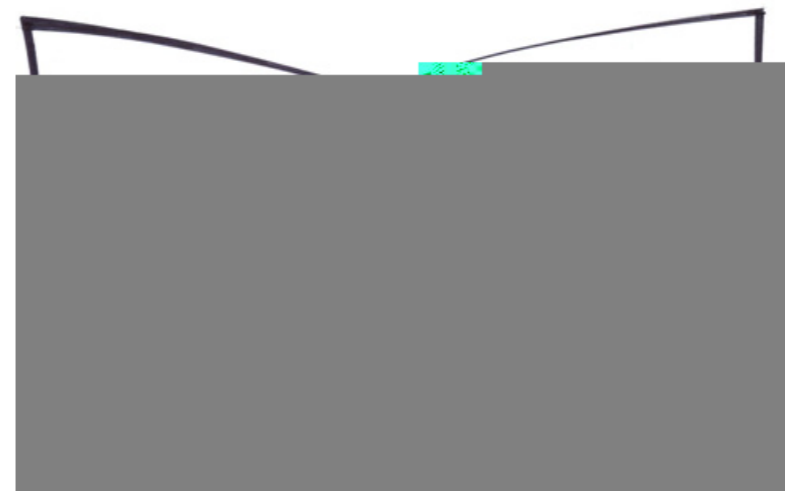
What you can do to ensure compliance:

Ensure that the committee comprises: medical officer in charge (or designate, ordinarily the chairperson); pharmacist in charge (or designate, ordinarily the secretary); a representative clinician from each major specialty including surgery, obstetrics & gynaecology, internal medicine and paediatrics; nursing officer in charge (or designate); hospital administrator, a representative of the laboratory staff and a member of the hospital records department. Other relevant persons may be invited to discuss issues requiring their particular expertise. The functions of the MTC include: advisory committee on all issues pertaining to medicines use, development of medicines use policies, evaluating and selecting medicines for the hospital formulary, developing hospital treatment protocols and guidelines, assessing medicine use to identify problems, conducting effective interventions to improve medicine use, managing adverse reactions to medicines, managing medication use errors, information dissemination, coordination of the medicines management cycle.

Indicators:

- Membership defined
- Terms of Reference in place
- Minutes available

Where the Ministry of Health in a country has issued guidelines on the composition and functioning of MTCs, these should be followed



Work assessments

Regularly assess the work of the pharmaceutical unit

Aim: To ensure that the services provided by the pharmacy meet the defined standards.

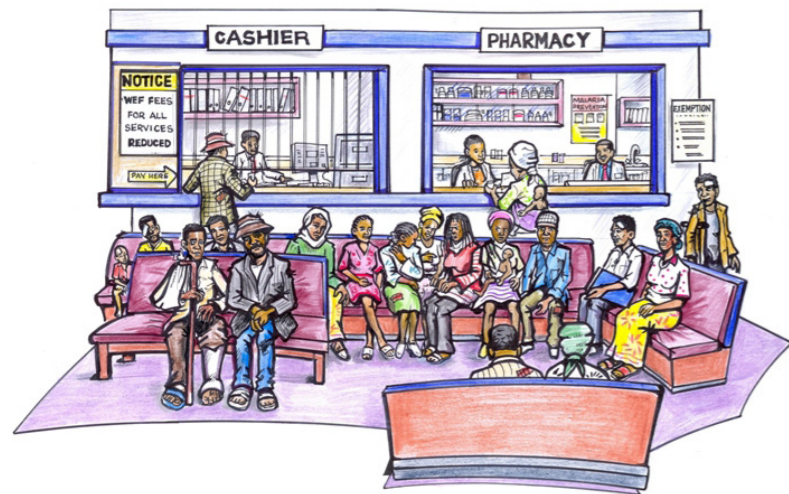
What you can do to ensure compliance:

The facility management team can do their supervision biweekly or monthly as part of the facility supervision. The district management team should supervise the lower facilities once quarterly and give feedback. Health support teams at the provincial and the national level can be requested by the facility to assess it once in a while. Allow regulating authorities (funding agencies or other appropriate organizations) that the facility could be affiliated to, to visit and assess the facility.

If the facility does not employ a pharmacist, identify a pharmacist from another institution or from government who can undertake periodic support supervisory visits and provide the facility management with information on how the pharmacy is performing.

Indicator:

- Reports on the evaluation



Pricing policy

Put in place and operationalise pricing policies

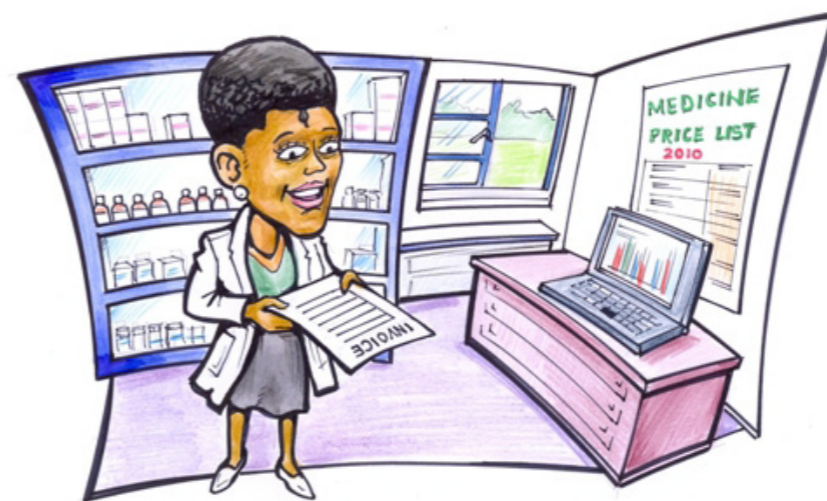
Aim: To ensure that the pricing of medicines is consistently and accurately done and meets the needs of the health facility to, among others, ensure continuous availability of affordable quality medicines while facilitating access by the community.

What you can do to ensure compliance:

- Provide written pricing policies and procedures.
- Issue a medicines price list regularly which is freely available to all prescribers, pharmacy staff and others who may need it.
- Consider all costs when determining the price of medicines: the purchase cost, transport costs, the storage costs, the human resource cost, among others.
- Regularly review medicines prices to ensure that they are at a level that meets the need of the facility.
- Calculate and monitor revenue generated from the sale of medicines.

Indicators:

- Written pricing policy (formula and accounting process, and accounting for windfalls)
- Price list
- Evidence of implementation of the pricing policy



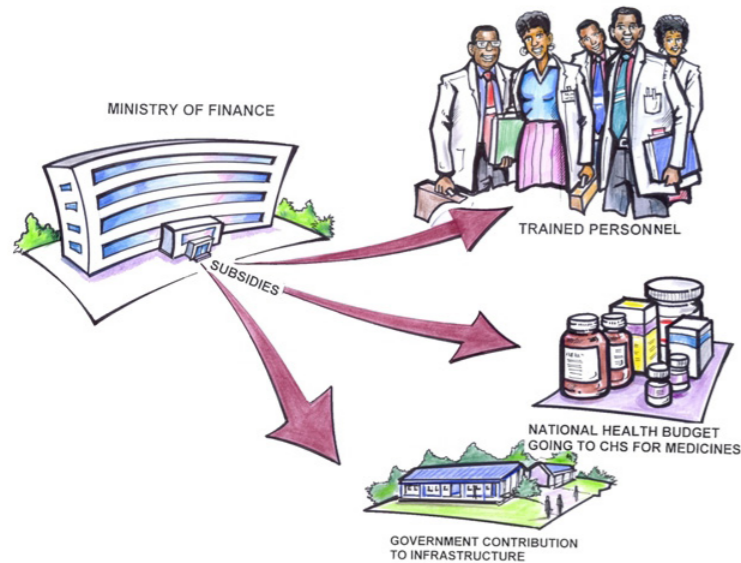
Pricing policy

Put measures in place to transfer improvements in access to medicines to patients

Aim: To ensure that the benefits obtained by the facility such as free, subsidized and lower priced medicines are passed on to the patient.

What you can do to ensure compliance:

Avail medicines to the community at a cost affordable to them and competitive in price compared to other institutions. Establish flexible pricing structures to allow benefits obtained to be quickly passed on to the patient. In case there are any exemptions for patients, they should be well documented and all relevant staff informed.



Subsidies

Solicit and advocate to obtain Government subsidies

Aim: To encourage/promote support from the government for the provision of quality pharmaceutical services by church health facilities as a means to increasing access to care by the poor.

What you can do to ensure compliance:

The government should provide staff, supply essential medicines to the facility or provide other appropriate forms of support to the health facility. The facility staff should also be included in training and refresher courses that the government provides. Other services that the government can provide are contribution to infrastructure development e.g. construction of the medicines store.

Indicators:

- % qualified pharmaceutical personnel paid for (subsidized) by Government
- % by value of medicines provided by Government



Taxation

Obtain relevant tax exemptions

Aim: To ensure that health facility is aware of and benefits from all relevant tax exemptions and looks out for opportunities to apply for benefit from tax waivers.

What you can do to ensure compliance:

Make a documentation of the current government tax policy, including all exemptions, available in the institution. Ensure that the facility has the capacity to apply for tax exemptions. Ask the facility's auditors and relevant officials at the district or in the Ministry of Health to advise on which possible exemptions may be available.

Indicators:

- Knowledge of exemption policy
- Number of exemptions awarded



Availability of medicines

Put systems in place to support continuous availability of quality and affordable medicines

Aim: To ensure that mechanisms are in place to ensure that supplies of medicines are adequate to meet the facility needs while at the same time not too excessive so as to cause losses due to unnecessary storage and handling costs and expiry.

What you can do to ensure compliance:

A good balance of stocks is required to ensure that stock-outs are minimized but at the same time there are no losses due to wastage and subsequent expiry. It is also important to remember that over stocking costs money which could be availed for other uses. Key to ensuring that the right balance is maintained is good regular quantification of requirements and monitoring of stock levels. Provide sufficient storage areas so that the quantity of stock required that meets the needs of the facility can be held.



Quality Assurance

Develop and implement quality assurance policies

Aim: To ensure that the pharmaceutical products supplied and services provided are of high quality.

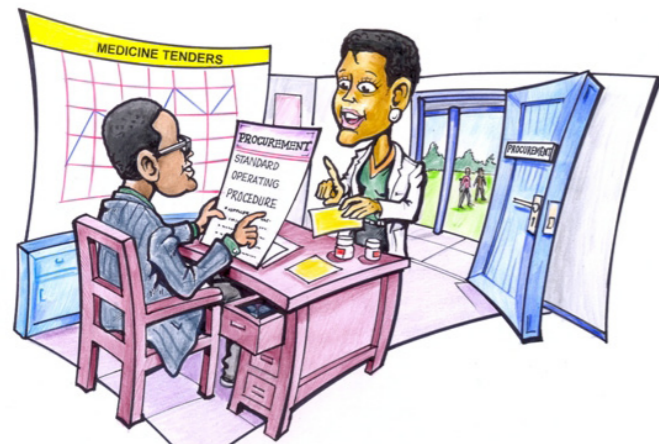
What you can do to ensure compliance:

- Put in place Standard Operating Procedures for all the key activities undertaken by the pharmacy staff
- Consult the Ministry of Health to advise or provide any information on quality standards for pharmacies in health facilities. Adopt or adapt this for use in your facility.
- Register all medicines purchased for use in the country with the national medicines regulating authority and buy all medicines from reputable suppliers.
- Consult the medicines regulatory authorities for any concerns on quality of medicines.
- Put in place systems for feedback from the patients about the quality of service either through suggestions boxes and formal or informal exit interviews

Indicators:

- Written Standard Operating Procedures for key pharmacy activities
- Existence of a Quality assurance policy
- Evidence of measures taken to guarantee quality of medicines





SOPs

Put in place Standard Operating Procedures for procurement

Aim: To ensure that procurement of medicines is standardized and transparent and supports provision of continuous availability of quality medicines at the lowest possible price.

What you can do to ensure compliance:

Procurement is an important part of the medicines management cycle which involves the actual purchase of medicines from the supplier and delivery to the facility. The procurement process is critical because it is vulnerable and yet represents a significant proportion of health facility expenditure.

- Develop Standard Operating Procedures to guide the procurement process and make these available and easily accessible. The SOPs should provide guidance on needs assessment, supplier selection, comparison of terms and conditions of different sources, awarding of orders to the suppliers, preparation of purchase orders, receiving suppliers, payment and evaluation of the process.
- Protect funds for purchase of medicines so as to ensure that medicines are always available and the facility is not disadvantaged by buying small quantities at high prices.
- Do regular audits to ensure the procedures are adhered to.

Indicators:

- Availability of written procurement SOPs/procurement manual/ procurement procedure
- Results of procurement audits

An SOP for physical examination of medicines on receipt to ensure quality compliance would include instructions such as

1. Check that the medicine container is well labelled with the generic name, the batch number and the expiry date
2. Check for discolorations, damages, breakages, unusual smell or other unusual appearance
3. Report any anomalies to the head of the health facility and the local medicines regulating authorities or a district pharmacist



What you can do to ensure compliance:

Establish systems to ensure that donations match the expressed need of the facility and the donor respects the wishes and authority of the facility. Accept only quality medicines usable by the facility within their remaining shelf life.

Provide religious leaders, politicians and others who solicit for donations on behalf of the facility with the health facilities policy on donations or the WHO interagency guidelines on drug donations.

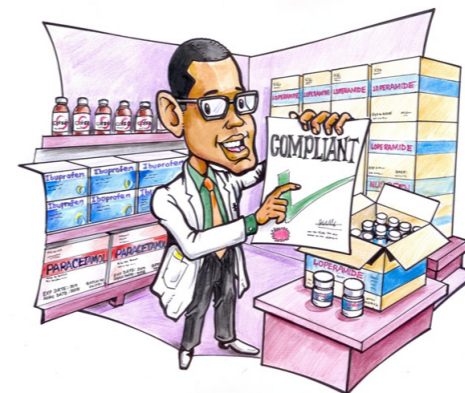
Indicators:

- Availability of medicine donation guidelines within facility
- Level of compliance of donated medicines with the guidelines

Medicine donations

Comply with medicine donation guidelines

Aim: To ensure that any pharmaceutical product donated to a health facility is of good quality and matches an expressed need.



What you can do to ensure compliance:

- Arrange medicines according to the first expiry first out system to ensure that no items expire before use.
- Put in place systems to ensure that products that cannot be used by their expiry date are passed on to other facilities that may be able to use them.
- Ensure that all the storage areas do not go beyond the expected temperature and are kept clean. Store each product according to the recommended storage conditions.
- Have a stock management system in place, computerized or manual. Up to date stock records aid in monitoring stocks and minimize stock losses due to pilferage and expiry. In addition to maintenance of good records, periodic stock counts should be carried out to cross check the records with the physical stock.
- Develop SOPs for various processes such as procurement, receiving and issuing of commodities and ensure that they are followed.

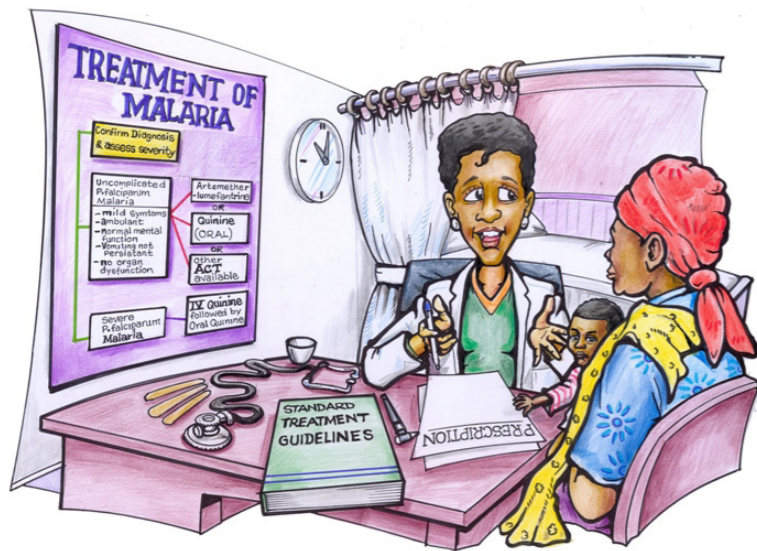
Indicators:

- % of expired medicines (in relation to average inventory value)
- % of fulfilment of requested demands (Service level)
- Presence and use of bin or stock cards
- Availability of written SOPs on various processes such as procurement, receiving and issuing

Medicine management

Comply with best practices for medicines storage and management

Aim: To ensure that the facility adopts and complies with recommended storage conditions and stock management procedures that guarantee that every pharmaceutical product maintains its integrity until it is used.



Medicine use

Implement interventions to promote rational use of medicines

Aim: To ensure that patients receive medication appropriate to their clinical conditions in doses that meet their own individual requirements for an adequate period of time at the lowest cost to them and the community.

What you can do to ensure compliance:

The use of national essential medicines, institutional formularies and standard treatment guidelines supports prescribers to make correct diagnoses and prescribe the correct medicine in line with what is available in the country. Good dispensing of medicines includes proper medication use counselling, adherence counselling and proper labelling. Educate the community served by the facility on proper medication use.

Indicators:

- Existence of rational use of medicines activities in the facility
- Compliance with WHO prescribing and dispensing indicators



Home-based care

Empower home-based care teams in rational medicine use

Aim: To ensure that home-based care teams are well informed on rational medicine use so as to support appropriate medicine use in the home.

What you can do to ensure compliance:

Include rational use of medicine in training programmes for home-based care teams. HBC teams should be able to reinforce the messages given during medication use counselling and to support adherence monitoring.

Indicator:

- Training sessions on rational use of medicines for HBCT



Availability of information

Key pharmaceutical information available within the institutions

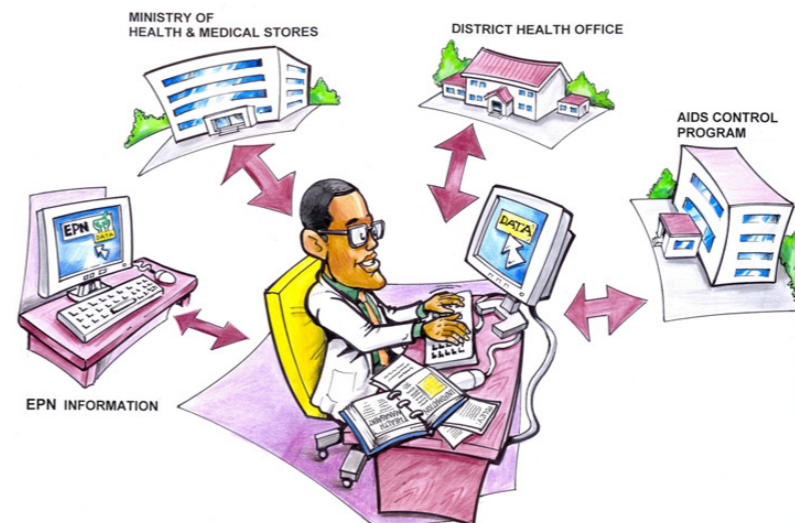
Aim: To ensure that those providing pharmaceutical services have access to technical information to enable them to comply with current best practice and deliver quality services.

What you can do to ensure compliance:

Access to current and credible information is important for any professional. Make some essential publications available at the pharmacy area, such as: national standard treatment guidelines, national essential medicine list, facility formulary, recent British National Formulary, WHO formulary, new and obsolete medicines list, facility medicines list. If possible, facilitate the pharmacy unit with a computer and access to the internet.

Indicator:

- Availability in the pharmacy area of National Essential Medicines List, standard treatment guidelines and a reputable formulary



Sharing

Health institutions share information with all relevant agencies

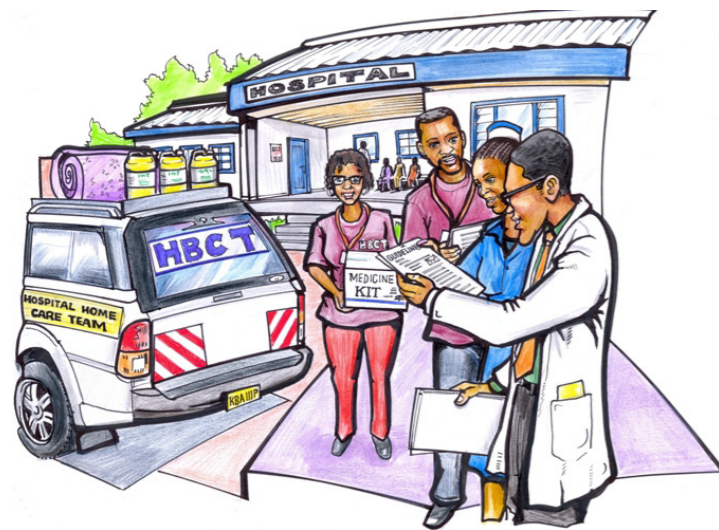
Aim: To ensure that the health facility is able to generate and provide the information required at district or national level for proper functioning of the health system as a whole.

What you can do to ensure compliance:

Have systems in place to ensure that all the relevant reports whether monthly, quarterly or annual are submitted on time to the right agency. Make sure the health facility is able to receive feedback from these agencies and act on it.

Indicators:

- Evidence of information collected
- Evidence of information passed to other institutions



Qualified staff

Have at least one pharmaceutically trained person available in each institution

Aim: To ensure that each facility is able to provide good quality and professional pharmaceutical services.

What you can do to ensure compliance:

Ensure that the personnel dealing with the pharmaceutical function has training in the following areas: medicines management, quantification of drug needs, quality assurance, rational use of medicines, unit costing, record and data management, appropriate financial management and local production (compounding of medicines at the facility level). Define pharmacy functions clearly, document expected results and organize regular supervision to ensure compliance.

Indicator:

- Number of staff with at least three months formal training in pharmacy



ART

Provide Antiretroviral Therapy (Health centres and hospitals)

Aim: To ensure that antiretroviral therapy and related services are brought as close to the patients as possible.

Provision of Antiretroviral Therapy should be in line with national guidelines on appropriate facilities and acceptable regimens

What you can do to ensure compliance:

Ensure that health workers have the relevant training on ART and the facility meets the national requirements for ART centres. Make regular updates on the most current treatment guidelines available. Put in place a system to ensure the constant availability of medicines to minimize stock-outs. To ensure proper monitoring of adherence, formulate a system to trace the defaulters almost immediately.

Indicator:

- Type of ART service available



Disasters

Have disaster preparedness procedures in place

Aim: To make sure that the pharmacy unit is well equipped to support the health facility to handle any form of disaster that they may be faced with.

What you can do to ensure compliance:

Make the pharmacy accessible day and night in the event that bulk supplies are needed to deal with an emergency. Have pharmacy staff represented on the disaster preparedness committee. Lay out well documented procedures on how to respond to any type of disaster in the facility. Make a checklist of the vital commodities required for any type of disaster available and stock the commodities, e.g. adequate diclofenac and morphine injection should be available in readiness for road traffic accident victims if the facility is close to a highway or major road.

“Your concern with treating the people should be greater than your concern for collecting fees, for the latter can only be obtained by healed persons; whereas he who seeks revenue without healing destroys the country and the people.”

Anonymous

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