EPN Access to essential medicines guidelines

Indicators for the guidelines were used to develop the baseline tool for the access to essential medicines project. The guidelines are as follows.

1. Compliance with best practices for drug storage and management.
2. Compliance with rational use of medicines guidelines.
3. Functioning medical supply system.
4. Functioning Drug and Treatment Committees (DTC) in hospitals.
5. All 'owners' with maximum understanding of roles, best practice, and management information, understanding of revolving fund concept and implementation of methods of increasing access for the poorest.
6. Implementation of standard operating procedures for procurement.
7. Improvement in access to medicines for an institution passed on to patients.
8. Quality assurance policy in place and implemented.
9. Pricing policies in place and operationalized.
10. Government subsidies extended.
11. Pro-poor ethic in evidence.
12. Tax exemptions available to CHSs.
13. Transparency mechanisms in place in support of 'Health for All'.
14. Effective community involvement system in place.
15. Cross-institutional information sharing, including provision of information to national drugs policy and national health management information systems.
16. Compliance with drug donations guidelines.
17. Mechanism in place to allow for representation at regional and national levels in relevant debates.
18. At least one pharmaceutically trained person per institution.
19. Access to key pharmaceutical information.
20. Regular assessment of pharmaceutical unit work.
21. Church leaders' awareness of key messages.
22. Pharmaceutical function represented at all levels of discussion.
23. Disaster preparedness procedures in place (e.g., earthquake, flood, influx of refugees, conflict).

It is understood that levels of compliance of many of the guidelines above might vary depending on whether the service was a hospital, clinic, health post, etc. It is also understood that the guidelines do not address issues beyond the control of CHSs, such as foreign exchange rates, storage outside the CHS system, patient poverty, number of pharmaceutical staff (e.g., pharmacists available), and patient information from other sources (e.g., advertising). Nor do the guidelines address issues that are beyond the remit of EPN to help CHSs, such as access to transport, construction of stores, the CHS system in its entirety, the expansion of the CHSs to serve larger populations, and the health service of a country in general. These areas are recognized as being important but are nonetheless beyond the remit of this particular project.

1.1 Guideline creation process

Step 1: Each EPN country focal point was asked to identify the strengths and weaknesses of the CHSs in their country. From the combined responses, a list of common factors was drawn up.

Step 2: A specialist working group then examined these factors in detail against the following criteria:

- What factors affect the cost of pharmaceuticals to the CHS?
  - Factors external to the CHS
  - Factors internal to the CHS.
- What factors affect the cost of pharmaceuticals to patients?
- Which of the resulting factors can EPN and CHSs address?
- What are the initial indicators for these guidelines?

Step 3: The results of the working group were presented to a larger meeting of 16 drug supply organizations and EPN Board members, who together agreed to add a number of guidelines, prioritized their importance, and addressed the search for indicators for each of the guidelines.

Step 4: The appropriateness to these guidelines and indicators was tested in Malawi. The result was that the number of guidelines was reduced to 24.

1.2 The guideline approach

Fundamental to this approach are three factors:

1. The initial baseline study for each country that reveals the current level of compliance on each of the specific guidelines and provides an impact assessment tool.
2. The development of country-specific plans, owned by EPN members, to increase compliance in a specific country.
3. The transfer of knowledge to members in other countries to increase their capacity to carry out such work.

The impact of individual guidelines is cumulative and there is no specific prioritization within them. However, for access to be maximized, it is believed that all the specifics detailed by the guidelines need to be in place.

Each country will have its own pattern of compliance and the importance of interventions will depend on country specifics. It is believed that, as countries are at different levels of compliance, the priority for intervention to increase compliance should reflect local circumstances and not an external priority list. Thus, in any particular country, a small intervention may 'top up' a particular guideline activity and therefore may be prioritized over a large intervention targeting another recommended guideline from start-up to compliance. For example:

- If 70% of hospitals with over 50 beds have working DTC committees then an intervention targeted on those 30% without committees may be prioritized over work to support the implementation of local community involvement in 100% of hospitals with more than 50 beds.
- A particular country could decide that work to get tax exemptions extended to CHSs would have a greater immediate impact than training hospital 'owners'.

The key to developing country-specific plans is the results from the baseline survey. These results will provide information for decision-making, as well as allow impact evaluation and monitoring.

1.3 Guideline indicators

Below are listed the full set of indicators available for use in the baseline study. In the actual tool design, a reduced list of indicators has been used.

2. **Compliance with best practices for drug storage and management.**
   - Presence of checklist for good storage conditions
   - Percentage of stock outs
   - % of expired medicines (in relation to average inventory value)
   - Service level (% fulfilment of requested demands)
   - Presence and use of bin or stock cards
   - Regular calculation of minimum and maximum stock
   - Presence of annual audit/inventory reports of drug store
   - Presence of SOPs (procurement, receiving, issuing)
   - Regular monitoring reports.
3. **Compliance with rational use of medicines guidelines.**
   - Prescribing levels
   - Dispensing practices
   - Standard operating procedures
   - Existence of rational use of medicines activities.
4. **Functioning medical supply system.**
   - Structures—warehouse and stores
   - EDL stocked
   - Meets CHS needs for supply, cost, and delivery
   - Low levels of wastage
   - Availability of stock records
   - Availability of standard operating procedures and evidence of implementation
   - Procedure manuals or guidance for personnel and financial activities.
5. **Functioning Drug and Therapeutic Committees (DTCs) in hospitals.**
   - Membership defined
   - ToR in place
   - Regular meeting
   - Date of last meeting
   - Drug list adapted to needs
   - Standard treatment guidelines in evidence
6. **All 'owners' with maximum understanding of roles, best practice, and management information.**
   - Revolving drug fund concept: Understanding of concept and implementation of methods of increasing access for the poorest
   - Rational use of medicines concept
   - Essential medicines concept
   - Management of HIV/AIDS–related demands

- Awareness of health and drug production in country
- Costing mechanisms for pharmaceutical services
- Sustainability of CHS concepts
- Strategic planning.

7. **Implementation of standard operating procedures for procurement.**
   - Availability of SOP procurement document
   - Self-assessment results of SOP audit.
8. **Improvement in access to medicines for an institution, passed on to patients.**
   - Affordable prices
   - Prices compared to other institutions
   - Independent pharmacy budget
   - List of exemptions.
9. **Quality assurance policy in place and implemented.**
   - Structure in place to ensure compliance to registration standards
   - Frequency of regulatory authority visits
   - Written standard operating procedures
   - Access to and usage of a quality control laboratory
   - Compliance with national regulatory authority standards (or an appropriate alternative, such as WHO).
10. **Pricing policies in place and operationalized.**
    - Documented pricing policy (formula and accounting process, and accounting for windfalls)
    - Price list
    - Implementation evidence.
11. **Government subsidies extended.**
    - % trained personnel (pharmaceutical)
    - % salaries paid by government
    - % national health budget that goes to CHSs for medicines (subsidized medicines received)
    - Government contribution to infrastructure development.
12. **Pro-poor ethic in evidence.**
    - Exemption policy
    - Promotion of insurance schemes
    - Differential pricing
    - Advocacy activities
    - Provision/subsidies for the poor.
13. **Tax exemptions available to CHSs.**
    - Documentation of existing taxes (current government tax policy)
    - List of current exemptions
    - Documentation (application letters, acceptances and rejections).

14. **Transparency mechanisms in place in support of 'Health for All'.**
    - Audited reports available
    - Annual reports available
    - Collective planning (annual, strategic) mechanism in place
    - Policy on monitoring and evaluation written and implemented
    - Organogram (professional profile)
    - Staff recruitment policies written and implemented.
15. **Effective community involvement system in place.**
    - Evidence of system
    - Evidence of topics raised and actions resulting from the system
    - Awareness levels of the local community of system.
16. **Cross-institutional information sharing.**
    - Evidence of information collected
    - Evidence of information passed to other institutions, the government system's national drugs policy, national health management information systems, and within hierarchies.
17. **Compliance with drug donations guidelines.**
    - Availability of guidelines within facility
    - Language used on donated drugs
18. **Mechanism in place to allow for representation at regional and national levels in relevant debates.**
    - Evidence of mechanism
19. **At least one pharmaceutically-trained person per institution.**
    - Quantification of drug needs
    - Drugstore management
    - Quality assurance
    - Rational use of medicines
    - Unit costing
    - Record and data management
    - Appropriate financial management.
20. **Access to key pharmaceutical information.**
    - Available in the pharmacy area:
        - Essential Drugs List
        - National (or WHO) formulary
        - Standard treatment guidelines
        - New and obsolete drugs list
        - Registered drugs list
        - Local production manuals.
    - Available in the facility:
        - National drugs policy
        - DTC/PTC guidelines

- WHO essential medicines publications
- International medicines pricing indicators
- Rational use of medicines information
- Reports from CHSs on pharmaceuticals
- Managing drug supply manuals.

21. Regular assessment of pharmaceutical unit work.

- Annual reports of unit evaluation.

22. Church leaders' awareness of key messages.

- Comparison to baseline in three selected areas appropriate to the local environment.

23. Pharmaceutical function represented at all levels of discussion.

- Minuted discussions at various levels
- Interview results.

24. Disaster preparedness procedures in place (e.g., for earthquake, flood, influx of refugees, conflict).

- Evidence of preparedness.