



Ministry of Health & Population



Developing a List of Tracer Medicines for the Nepal Health Sector Programme-2



Literature Review and Recommendations

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The content of this paper and any misinterpretations remain the responsibility of the author.

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LIST OF ABBREVIATIONS AND ACRONYMS

DH	District Hospital
DOHS	Department of Health Services
EHCS	Essential Health Care Services
GAAP	Governance and Accountability Action Plan
HAI	Health Action International
HP	Health Post
LMD	Logistics Management Division
LMIS	Logistics Management Information System
MOHP	Ministry of Health and Population
MSH	Medicines Sciences for Health
NHSP-2	Nepal Health Sector Programme-2
NHSSP	Nepal Health Sector Support Programme
PHCC	Primary Health Care Centre
PHCRD	Primary Health Care Revitalisation Division
SARA	Service Availability and Readiness Assessment
SEARO	South East Asia Regional Office
SHP	Sub Health Post
STS	Service Tracking Survey
WHO	World Health Organization

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SUMMARY

One of the three main objectives of the 2010 - 2015 Nepal Health Sector Programme-2 is improving health systems to achieve universal coverage of essential health care services, including free provision of 40 'general' essential medicines and additional programme specific medicines. Availability and access to quality assured essential medicines is an important element of health system performance, and availability of medicines at health facilities is one of the indicators for monitoring implementation of the Programme.

In order to make data collection and analysis manageable it is international good practice to use tracer medicines representing priority treatment choices for the most common morbidities and needed for preventive health services. The purpose of this report is to summarise existing approaches for identification of appropriate tracer medicines and the use of tracer medicines lists and related indicators; suggest criteria and a tracer medicines list adapted to the context of Nepal; and provide recommendations on other important aspects related to quality of medicines use and management in the context of health systems strengthening that can be assessed through routine monitoring systems and/or health facility surveys.

Two main aspects are identified that together provide information on whether a health system achieves sustained availability of medicines at health facilities: availability of non-expired tracer medicines at the day of survey (or reporting), and stock-out periods of tracer medicines. Examples for common indicators are given.

An overview of criteria and processes for establishing national lists of tracer medicines with references to internationally accepted methodologies, and examples for resulting global, regional and national lists are provided. Internationally standardized methodologies using tracer medicine lists for assessing national pharmaceutical sector performance and medicines availability and prices are summarised, and their use in the context of health systems strengthening is documented. Examples for how other countries measure availability of medicines in the context of national strategic health plans, using health facility surveys and routine monitoring systems, are presented.

Taking into account medicines availability indicators and tracer lists in use in Nepal a tracer medicines list of 20 items was drafted, drawing from the 40 general essential medicines and additional programme specific medicines. Key criteria for selection included consideration of outpatient morbidity, priority treatment options, inclusion in the National List of Essential Medicines, and representation of paediatric dosage forms. From a health system perspective, monitoring availability and stock-out of the selected tracer medicines will allow judgement on the impact of performance of the public pharmaceutical supply management system on readiness to deliver free health care services to the Nepali population.

Recommendations

1. Two medicines availability Indicators are recommended for the NHSP-2:
 - average percentage availability of tracer medicines at district health facilities
 - percentage of health facilities with stock-out of tracer items during the period under review (stock-out being defined as stock-out of one or more tracer items for at least seven consecutive days)

Extent of stock-out could further be assessed by reporting on the number of tracer medicines out of stock (sub-aggregates in ranges).

2. LMIS and health facility surveys should use the same tracer item lists (this should be easily achieved, as information on all essential medicines is being routinely collected through the LMIS)

3. Use quarterly LMIS reports for routine monitoring of the first indicator and validate information during annual health facility surveys. Collect information for the second indicator during annual health facility surveys, and consider feasibility to include monitoring of stock-outs of tracer items in district routine supervision.
4. Maintain questions on quality of pharmaceutical management at health facilities in the STS tools, considering the specific comments provided separately.
5. Conduct studies on medicines use (prescribing and patient care) separately, because they are time consuming and require specific training of enumerators.
6. Include assessment of the pharmaceutical transport system at district level in annual health facility surveys so that existing constraints are made visible and can be addressed systematically.

1 BACKGROUND

The Nepali Ministry of Health and Population (MOHP) is currently implementing the second phase of the Nepal Health Sector Programme (NHSP-2) running from 2010 to 2015. The overall goal of NHSP-2 is to improve the health and nutritional status of the Nepali population, especially for the poor and excluded. Three specific objectives have been formulated that will support achieving the goal, including improving health systems to achieve universal coverage of essential health care services. One important element of health systems performance is availability and access to quality assured essential medicines, and the NHSP-2 results framework includes levels of stock-out of tracer medicines as an outcome indicator under the health system improvement objective.

The NHSP-2 focusses on provision of Essential Health Care Services (EHCS) to be provided for free to all citizens at sub-district level. This includes a list of 40 essential medicines (some of them in multiple dosage forms): 25 for sub health posts, 35 for health posts and primary health care centres, and 40 for district hospitals.

While the stock status of essential medicines and commodities has been monitored during NHSP-1 and information is included in the annual reports of the MOHP Department of Health Services (DOHS) an officially endorsed list of tracer medicines for measuring this indicator under NHSP-2 is not yet available.

The Nepal Health Sector Support Programme (NHSSP) that supports implementation of the NHSP-2 has contracted a consultant to assist the MOHP in the process of finalising a list of tracer medicines that are suitable for tracking progress of implementation of the NHSP-2.

This tracer list would ideally be integrated in the existing Logistics Management Information System (LMIS) and also be used by health facility surveys (Service Tracking Surveys) for validation of LMIS data, and for collecting additional information not available through the LMIS on quality of medicine management and use.

The assignment consisted of two stages:

1. Conduct a desk review and prepare a briefing paper on
 - indicators used for tracking timely availability of medicines
 - the selection of tracer medicines for data collection (to consider methodologies and criteria used by comparable health systems and international bodies)
 - how data collection is being integrated in routine monitoring systems or specific surveys
 - how tracer medicines can be used to inform about health system functioning
 - how quality of pharmaceutical services can be measured in health facility surveys; and provide recommendations for the development of the MOHP tracer list, specific medicines indicators, and how to integrate these in routine monitoring systems.
2. Provide technical support to the MOHP to finalise the tracer medicines list and to analyse medicines related information obtained through the recent Service Tracking Survey (STS).

2 INTRODUCTION

Essential medicines are a key input for health service delivery and 'medical products, vaccines and technologies' have been identified as one of the six building blocks of the WHO Health Systems Framework (WHO 2007-a). Indicators measuring availability, affordability and use of essential medicines have been widely used internationally and by countries for some time, and common definitions are available.

National Health Strategic Plans usually include indicators on availability of essential medicines at service provider level in their monitoring and results frameworks. However, pharmaceutical logistics management information systems are rarely computerised down to primary care level, and information on stock levels and stock outs of the complete set of essential medicines and related supplies at individual health facilities is not routinely available at regional or national level. In order to keep data collection and data analysis manageable information is then collected for a smaller number of representative items (tracer medicines, medicines basket). Tracer medicines can be used for routine reporting systems (e.g. the Health Management Information System) and in periodic or specific surveys. Recently community based reporting has been piloted using mobile devices for alerting about stock-outs¹.

3 USING TRACER MEDICINES

Tracer medicines are used to generate quantitative information on the performance or desired outcomes of the pharmaceutical sector. The two main areas where tracer lists are used are medicines availability and medicines prices (as an indication for affordability).

For availability measurements tracer lists are established to facilitate data collection while at the same time ensuring that information will be relevant, i.e. focussing on priority diseases and their related treatment. For price information, the use of uniform tracer lists ensures that any comparison and aggregate analysis will be on the same basis, comparing like with like. The focus of this section is on measuring medicines availability.

To establish availability of medicines at service level two data items are usually collected: physical availability of unexpired tracer items on the day of survey; and the time tracer items were out of stock during a defined period. The first data item needs survey personnel to actually visit the health facility; information for the second data item can be collected either through routine reporting systems or through retrospective record review during a survey or supervisory visit.

Physical availability of tracer medicines on day of survey

For each tracer medicine it is checked whether it is available in the health facility store (or pharmacy outlet if private sector is included). Only non-expired products qualify for a 'YES' answer. Availability of tracer medicines is calculated as percentage for each facility visited and later aggregated as average or median percentage availability in all health facilities visited. Depending on the sample size information can also be aggregated per facility type:

- Average (median) % availability of non-expired tracer medicines at health facilities on day of survey
(national aggregate and subsets for type of health facility)

Aggregated information could further be presented as median availability of each of the tracer medicines across all health facilities or per level of care or sector.

While this indicator provides a general idea of access to medicines (and readiness to provide essential health services) and can highlight problems, this is restricted to the day of visit of the survey team. Availability might be established as 100%, but only because the health facility received new supplies just a short while before the visit took place (or vice versa).

This indicator is useful if inventory records showing availability over a period of time are either not available (e.g. private sector medicines outlets) or not providing reliable information (e.g. not being maintained at public sector health facilities). In addition, because data collection is easy, and because this is the main instance where evidence for availability is being established by external

¹¹ See e.g. <http://stopstockouts.org/>

assessors, information on tracer medicines availability on the day of visit should always be included in health facility surveys.

Time tracer items are out of stock

For each tracer item, the number of days out of stock during a defined period under review (e.g. previous 12 months) is determined from inventory records. Different indicators can be established using this information, for example

- Percentage of tracer items continuously available (national aggregate and subsets for type of health facility)
- Average percentage of time tracer items were out of stock at health facilities (national aggregate and subsets for type of health facility)
- Percentage of health facilities experiencing stock-outs of tracer medicines during the period under review

A threshold can be established for the maximum acceptable time medicines can be out of stock and information be collected from inventory records accordingly. For example, in Burundi monthly supervisory visits determine the percentage of tracer items that were out of stock for more than 3 days during the previous month (Ministère de la Santé Burundi 2010).

These indicators provide a measure for how effective the medicines supply and distribution system is in maintaining a constant supply. From a health system perspective sustainable access to essential medicines is being assessed.

4 DEVELOPING A LIST OF TRACER MEDICINES

The initial step is to define the purpose of data collection including what should be measured and monitored (e.g. health sector performance, pharmaceutical supply chain performance, vertical programme performance); what is the definition of the indicator(s); what are the preconditions that selected tracer medicines will be representative and provide accurate and reliable information on the sector or programme.

4.1 Criteria for inclusion

There is broad consensus on the general criteria to apply for establishment of a list of tracer medicines (e.g. WHO 1993; MSH 1995; Brudon, Reinhorn, Reich 1999; MSH 2011; WHO 2007-b; WHO/HAI 2008). These are based on public health considerations. Potential tracer medicines should

- address the priority health needs of the population/burden of disease (be most important therapeutically and included in the applicable standard treatment guidelines);
- be included in the National Essential Medicines List or formulary;
- be the most widely used amongst alternatives (availability is expected to be 100% and medicines not commonly used should be excluded);
- be adequate for the target level of care (mostly specified as outpatient treatment at primary care level).

Any items considered problematic or being of specific interest but known not to be widely available should not be included in the tracer list because this affects validity of the indicator value. If required, these medicines can be monitored separately using the same data collection process.

The WHO/HAI methodology for measuring availability and prices of medicines (WHO/HAI 2008) includes additional criteria that countries might want to apply for establishing their country specific supplementary list of tracer items:

- because information is being collected in private and public sector establishments items do not necessarily need to be included in the National Essential Medicines list;
- if of special interest a limited number of hospital-only items can be included;
- products for which information is being collected need to be approved for marketing in the country.

Further considerations are suggested in ‘Rapid Pharmaceutical Management Assessment’ published by Management Sciences for Health (MSH 1995):

- include a few medicines not on the National Essential Medicines list, if it is known that these are widely used (e.g. if essential medicines list is not being implemented or has not been updated for a long time);
- allow for a range of dosage forms including paediatric formulations (especially if child health is a focus of the national health programme).

The specific purpose for which the tracer list will be used needs to be considered, too. For example, different lists will result if the aim is to generate uniform information that can be compared between countries; if information to be generated should describe the situation of the whole pharmaceutical market or the public sector only; if availability is measured at specific levels of the supply and health care delivery system within a country; or if focus is on medicines availability for specific disease priorities or patient groups.

The literature emphasizes that tracer lists need to be adapted to local circumstances. For that reason medicine availability and price surveys that do intend to also generate internationally and regionally comparable information include three sets of tracer medicines: a global core list applicable to any country; a regional core list (available for six regions) considering regional burden of disease and use of tracer medicines in the region; and a national supplementary list to address a specific country context.

4.2 Number of medicines on a tracer list

Deciding on how many items to include in a basket of tracer medicines will be a compromise between reliability of information to be generated and the effort to collect the required data.

Recommendations in the standard literature are coherent, suggesting that lists containing 10 to 20 items are usually adequate. The WHO Level II standard methodology requires identification of 15 tracer medicines for measuring medicines availability and prices at health facility level. During a workshop in 2006 experts discussed whether this number should be increased to 30 but concluded that 15 were adequate (WHO 2006).

Although requiring data collection for 50 tracer medicines the WHO/HAI methodology for measuring medicines availability and prices somehow keeps in line with these recommendations, as it uses three different tracer item lists with 14 (global list), 16 (regional list), and 20 (country list) items respectively.

These numbers apply to surveys that seek information on general essential medicines. If the intention is to do sub-analyses for specific medicine categories (e.g. antibiotics, family planning supplies) then the number of tracer items can be larger.

In line with what has been presented in this section, the WHO Level II methodology recommends the following steps to arrive at a tracer medicine list of 15 items:

1. List the top 15—20 morbidities for adults and children.
2. Remove from that list conditions that would not be treated as general outpatient cases at primary health care services.
3. For each remaining morbidity, assign the most important medicine that corresponds to the applicable Standard Treatment Guidelines. Be sure to include medicines for both adults and children.
4. The resulting list will probably be longer than 15 medicines, prioritize and reduce the list of key medicines to reflect the principles listed above.
5. Revisit the list and ensure that important medicines used for the alleviation of common symptoms and important preventive medicines have not been excluded. If they have, make appropriate substitutions in order to have a list of 15 medicines.

(WHO 2007-b)

4.3 Examples for tracer medicines used internationally and at country level

The global and South East Asia regional core lists used for WHO/HAI medicine price and availability surveys are reproduced in Table 1. Examples for supplementary country tracer medicines are included for India and Indonesia for surveys done in 2004 and 2005 respectively (Patel, Thawani, Gharpure 2005; Ministry of Health Indonesia 2005), and information is provided which of these tracer medicines are part of the 40 essential medicines that are being provided for free in the context of the Essential Health Care Services (EHCS) programme in Nepal.

Table 1: WHO/HAI Global, regional and country tracer medicines lists

Tracer Medicine	Global Core List	SEARO Core List	Suppl. List India	Suppl. List Indonesia	Nepal EHCS List
Amitriptyline 25mg cap/tab	√				
Amlodipine 5mg cap/tab		√			
Amoxicillin 500mg cap/tab	√				√
Amoxicillin suspension 125mg/5ml		√			*
Atenolol 50mg cap/tab	√				√
Atorvastatin 10mg cap/tab		√			
Azithromycin 500mg tab/cap				√	
Beclometasone inhaler 250mcg/dose		√			
Benzathine Penicillin Inj 12 lac			√		
Candesartan 8mg tab/cap				√	
Captopril 25mg cap/tab	√				
Ceftriaxone injection 1g/vial	√				
Celecoxib 200mg tab/cap				√	
Chloroquine 250 mg tab			√		
Ciprofloxacin 500mg cap/tab	√				√
Clotriazole 1% cream		√			
Co-trimoxazole suspension 40+200mg/ml	√				*
Diazepam 5mg tab/cap	√				
Diclofenac 50mg cap/tab	√				

Tracer Medicine	Global Core List	SEARO Core List	Suppl. List India	Suppl. List Indonesia	Nepal EHCS List
Diethylcarbamazine citrate 50mg cap/tab		√			
Doxycycline 100mg cap/tab		√			
Enalapril 5mg cap/tab		√			
Erythromycin 250mg tab/cap				√	
Esomeprazole 20mg tab/cap				√	
Fluconazole 150mg tab/cap				√	
Fluoxetine 20mg cap/tab		√			
Ganciclovir 500mg injection				√	
Gentamycin 0.3% eye drops		√			
Glibenclamide 5mg cap/tab	√				
Gliclazide 80mg cap/tab		√			
Ibuprofen 400mg cap/tab		√			
Lisinopril 20mg tab/cap				√	
Metformin 500mg cap/tab		√			
Metronidazole 400mg cap/tab		√			√
Ofloxacin 200mg tab/cap				√	
Olanzapine 5mg tab/cap				√	
Omeprazole 20mg cap/tab	√				
Paracetamol 120mg/5ml suspension	√				√
Paracetamol 500mg tab			√		√
Phenobarbitone 30mg tab			√		
Rifampicin 300mg cap			√		
Risperidone 3mg tab/cap				√	
Salbutamol inhaler 100mcg/dose	√				
Simvastatin 20mg cap/tab	√				
Stavudine 40mg tab/cap				√	

*: the NEPAL EHCS list contains dispersible tablets instead

In the context of monitoring availability of medicines for tracking progress with implementation of the NHSP-2, tracer medicines used by countries for assessing medicines availability using the WHO Level II health facility survey methodology might be more relevant (country specific tracer lists are used). Level II survey reports are not easily found on the internet, and in those that were identified information on the national tracer medicine list is not always included. Four reports could be traced that provide this information (Ministry of Health Tanzania 2002, Batangan DB, Juban N 2009, FMOH Nigeria 2010-a, PAHO/MOH St Lucia 2011). Table 2 provides information on the tracer medicines used in these surveys and shows commonalities with the medicines provided under the Nepal EHCS programme.

Table 2: Examples for tracer medicines used in WHO Level II surveys

Tracer Medicine	Tanzania 2002	Philippines 2009	Nigeria 2010	St Lucia 2011	Nepal EHCS List
Albendazole tab			√		√
Amitriptyline 25mg tab/cap				√	
Amoxicillin 250mg cap/tab	√				√
Amoxicillin 500mg cap/tab		√		√	√
Artesunate amodiaquine tab			√		
Artesunate lumefantrine tab			√		
Aspirin 300mg tab	√				√
Atenolol 50mg tab/cap				√	√
Benzoic acid comp. ointment	√		√		√
Benzyl Penicillin injection			√		
Captopril 25mg tab/cap		√		√	
Cefalexin 500mg tab		√			
Ceftriaxone 1g vial				√	
Chloramphenicol eye ointment			√		√
Chlorpheniramine 4mg tab	√				√
Ciprofloxacin 500mg cap/tab		√		√	√
Clotrimazole cream			√		
Co-trimoxazole 400/80mg tab	√			√	√
Co-trimoxazole 800/160mg tab		√			√
Co-trimoxazole syrup			√	√	*
Diazepam 5mg cap/tab				√	
Diflofenac 50mg cap/tab				√	
Ferrous salt + Folic acid tab			√		√
Ferrous salts 200mg tab	√				
Folic acid 5mg tab	√				
Glibenclamide 5mg cap/tab		√		√	
Isoniazid 50mg tab				√	
Mebendazole 100mg tab	√		√		
Mefenamic Acid 500mg cap/tab		√			
Metformin 500mg tab		√			
Metoprolol 50mg tab		√			
Metronidazole 400mg tab			√		√
Omeprazole 20mg cap/tab				√	
Oral rehydration salts (ORS)	√		√		√
Paracetamol 120mg/5ml syrup			√	√	√
Paracetamol 500mg tab	√	√			√

Tracer Medicine	Tanzania 2002	Philippines 2009	Nigeria 2010	St Lucia 2011	Nepal EHCS List
Povidone iodine solution	√		√		√
Procaine penicillin 4MU injection	√				
Quinine 600mg/2ml injection	√				
Salbutamol 0.1mg/dose inhaler				√	
Simvastatin 20mg cap/tab		√		√	
Sulfadoxine/pyrimethamine 500/25mg tab	√		√		
Tetracycline 1% eye ointment	√				
Vitamin A 100 IU cap				√	

*: the NEPAL EHCS list contains dispersible tablets instead

Commonality of tracer medicines between countries is relatively low. This shows that the year of survey (changes in morbidity and/or preferred treatment options) and country contexts matter. A more comprehensive comparison of different tracer medicines lists that also include therapeutic categories has been done and has been available in a separate spread sheet file.

5 INTEGRATION OF TRACER MEDICINES IN FACILITY SURVEYS AND ROUTINE MONITORING SYSTEMS

At global level availability of essential medicines is monitored under Millennium Development Goal 8, Target 8.E: *“In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries”*. *“Proportion of population with access to affordable essential drugs on a sustainable basis”* is monitored under indicator 8.13. One component of this indicator is medicines availability, and the percentage of facilities where a tracer medicine was found on the day of data collection is being reported on. Aggregate values are established from existing country surveys that used the WHO/HAI methodology to measure medicine availability and prices. (UN 2011)

Internationally standardized methodologies are available for country **health facility surveys** that include measuring availability of essential medicines. Standardisation facilitates comparability of results between countries or regions.

- In collaboration with partners WHO developed a comprehensive set of indicators to assess and monitor countries’ pharmaceutical sectors. Outcome indicators, including three indicators measuring medicines availability, are being generated through ‘Level II’ health facility surveys. Lists of 15 tracer medicines for data collection for these indicators are being established at country level based on the criteria reported in Section 4.1. These surveys are not conducted regularly. (WHO 2007-b)
- The WHO/HAI methodology on assessing medicine availability and price also uses a standard methodology for health facility and provider surveys. There is only one indicator for medicines availability. To date over 80 surveys have been completed or are under way.²
- A methodology recently developed by WHO and The Global Fund provides a tool for countries to generate pharmaceutical sector country profiles based on existing information. Availability of essential medicines is one of the indicators, and the value for this indicator is preferably to be sourced from previous WHO/HAI surveys on medicine availability and price.

² See: <http://www.haiweb.org/medicineprices/> (accessed 23-04-2012)

Alternatively information generated through other surveys can be provided.³ A pharmaceutical country profile for Nepal, where this methodology was applied, has been produced in 2011 (MOHP 2011). Availability of medicines is not reported because a medicine availability and price survey has not yet been conducted in the country.

There seems to be a general trend to accept the WHO/HAI methodology including the global core tracer item list as international standard. For example, the general **service readiness indicators** suggested for Service Availability and Readiness Assessments (SARA) in the context of **health systems strengthening** include one indicator for availability of essential medicines using the WHO/HAI global core tracer item list. The same instrument includes additional tracer medicines to measure specific service readiness (e.g. family planning, ante-natal care or child health services). Information is collected through health facility surveys. (WHO 2011) The Indicator Handbook for monitoring the Health System Building Blocks published by WHO recommends that countries add a few medicines reflecting the specific country context to those of the global core list for monitoring the Medical Products building block. In addition, programme specific medicines are included for monitoring of the Health Service Delivery building block (WHO 2010).

The same approach is suggested in a publication by the International Health Partnership⁺ and WHO on **monitoring national health strategies**. Availability of 14 tracer medicines is suggested as one of the core indicators for service readiness. (IHP⁺ and WHO 2011)

In Nepal implementation of the free health care policy had been monitored previously through quarterly health facility surveys that included medicine availability indicators (percentage of health facilities experiencing stock outs of essential drugs for more than one week, disaggregated by type of facility and number of items that were out of stock). The use of a tracer medicine list is not documented. (RTI International 2009)

Similar to the NHSP-2, monitoring frameworks for national health strategic plans tend to include indicators on medicines availability. For example,

- Nigeria: Health facilities experiencing stock-outs of key health commodities within the last one month.
The indicator is included in Priority Area 2: Health service delivery. Information to be sourced from quarterly monitoring reports (supervisory visits) generated by State Ministries of Health and from annual health facility surveys. The list of key health commodities is not specified. (FMOH Nigeria 2010-b)
- Zambia: Percentage of health facilities without any stock-outs of tracer supplies in a month.
A clear description on how data is being generated and what the tracer supplies are is not provided. The results framework – aligned with the WHO health systems framework building blocks - includes additional indicators for the ‘medical products’ building block: storage facility standards, value of expired medicines, staff trained in rational use of medicine, and functional drug therapeutics committees. (MOH Zambia 2011)

Countries also routinely generate health facility level information on medicines availability **using specific pharmaceutical (logistics) information management systems** with aggregation at national level. Indicators measuring medicines availability are included in these systems. For example:

- Burundi: Monthly reporting by district health facilities on the percentage of tracer medicines available at the end of the month, and on percentage of tracer medicines with a stock out duration of more than three days. The tracer list contains 16 medicines and information is initially being collected during monthly supervisory visits by the district health office. Once

³ See: http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index2.html (accessed 23-04-2012)

capacity has been built health facilities will be responsible for generating the respective reports themselves (Ministère de la Santé Burundi 2010)

- Namibia: The pharmaceutical management information system provides quarterly health facility reports generated at district level. Availability is measured as percentage of key items without stock-out in any health facility, and percentage of health facilities without stock out of key items. Key items include 11 general essential medicines plus all EPI vaccines, medicines of the emergency trolleys, and all TB medicines. Availability of anti-retrovirals is measured separately. The system started at district hospitals and is being rolled out to include primary health care facilities. (Phulu B, Sumbi V, Lates J 2011)
- Zambia: Availability of 20 tracer medicines and related pharmaceutical supplies is monitored quarterly. Two different tracer lists for hospitals and health centres are used. Availability is reported as % availability of tracer items on the day of visit, and % availability in the last 3 months (calculated as number of days available during the last 90 days/90 x 100)⁴.

6 ASSESSING QUALITY OF PHARMACEUTICAL MANAGEMENT AND SERVICE PROVISION

Quality can be assessed in relation to management of pharmaceutical supplies and in relation to medicines use by prescribers and patients (rational use of medicines). Tracer medicine lists are not used for this purpose.

Supervision guidelines at district level often include checklists for assessing **quality of medicines management** at health facilities. These usually have sections on cleanliness, storage practices, protection of stocks from light and water, temperature monitoring, or practice of the “First Expiry – First Out” principle. In addition, quality of record keeping might be checked. This will be based on a random sample of stock records, because use of a tracer list for this purpose provides a negative incentive to health workers to only attend to the records of the tracer items. An additional quality indicator for medicines management is the value of expired drugs during the period under review. Examples for data collection forms are included in the WHO Level II survey methodology and the MSH Rapid Pharmaceutical Management Assessment (WHO 2007-b, MSH 1995).

For assessing **quality of medicine use** a standard methodology is available that has been applied in many countries for many years (WHO 1993). In Nepal, planned and ad-hoc surveys also used this methodology. A recent country visit draft report provides a summary of these surveys conducted in Nepal from 2000 onwards (Holloway K 2011). The methodology requires the assessment of dispensing time, quality of labelling, and patient knowledge prospectively (30 outpatient encounters). Information on prescribing behaviour can be assessed either retrospectively (if records are available) or prospectively for 30 patient encounters.

Usually medicine use surveys are not integrated into larger health facility surveys but conducted on their own. The reason is, that they are quite time consuming. There are some countries, however, that use specific medicine use indicators for routine monitoring and reporting (self-reporting by health facilities).

⁴ Personal communication from Deputy Director Pharmaceuticals, MOH Zambia (May 2012)

7 MONITORING AVAILABILITY OF ESSENTIAL MEDICINES IN NEPAL

This section includes findings from the field visit and the resulting recommendations for a tracer medicines list suitable for monitoring medicines availability in the context of the public health sector in Nepal.

7.1 Indicators and tracer lists currently in use

Indicators for monitoring availability of essential medicines are being used in the public health sector of Nepal for different purposes. A summary of those that were identified during the mission is provided in Table 3 below.

Table 3: Medicines availability indicators used in Nepal

Indicator	Used for	Value	Data collection
% district facilities with no stock-outs > 1 month per year	NHSP-2 Outcome indicator (Obj. 3 – HSS)	To be determined	Annual health facility survey
% district facilities with stock-outs > 1 week	NHSP-2 2009 baseline	76.7	Quarterly health facility surveys monitoring implementation of free health care policy (December 2009)
% of health facilities with tracer drug stock outs	NHSP-2 GAAP indicator	To be determined	Joint Annual Review
Average % of tracer medicines out of stock in health facilities (4 quarter average)	DOHS Annual Report	24.4 (2009/10)	LMIS (captures any stock out occurring at quarterly reporting date)
% HP/SHP with stock-out >1week/quarter	Free health care quarterly monitoring 2009	85.4% (3 rd quarter)	Health facility survey (use of tracer medicines not clear)
% PHCC/DH with stock-out > 1 week/quarter	Free health care policy quarterly monitoring 2009	76.5% (3 rd quarter)	Health Facility survey (use of tracer medicines not clear)

Tracer medicine lists and lists of key commodities that are monitored routinely are used at different levels of the health care system. A summary is provided in Table 4 below.

Table 4: Tracer and key commodity lists used in Nepal

Type	Use & Comment
7 key commodities	Monitoring of stock situation at district level (in the context of the Nepal Family Health Programme II)
12 key family planning, child health & nutrition commodities	Monthly stock level reporting through HMIS (not clear what this information is used for)
16 Essential medicines & family planning commodities	Calculation of availability indicator for DOHS annual report; availability indicator is disaggregated for family planning, Maternal & Child Health and Essential medicines availability showing evolution over time
19 Essential medicines & family planning commodities	Revised tracer list used by Logistics Management Division for DOHS report?
11 Essential medicines; plus family planning, Maternal & Child Health and Malaria medicines & commodities and vaccines	Logistics Management Division national quarterly pipeline review meetings

For easy comparison the specific tracer items and key commodities included in the lists above have been listed in a spread sheet which has been made available separately. Commonality between the lists is relatively high.

7.2 Criteria and process for developing a tracer medicines list for monitoring outcomes of the NSHP-2

A draft tracer medicines list for use in future STS has been developed applying the general criteria outlined in Section 4 and specific criteria taking into account the country context, i.e.

- ✓ Consider existing tracer and key commodity lists
- ✓ Ensure inclusion of medicines for NHSP-2 priority interventions & prevention
- ✓ Consider burden of disease (outpatient morbidity)
- ✓ Consider treatment protocols (general Standard Treatment Guidelines from 1999 are under revision and own judgement had to be used to identify first line treatment options for main morbidities)
- ✓ Inclusion in the National List of Essential Medicines (GON 2011-b)
- ✓ Inclusion of paediatric dosage forms
- ✓ Draw from EHCS free medicines list and additional programme items supposed to be available at all levels at all times
- ✓ Have list of 20 items, out of which at least 15 available up to Sub Health Post level

To arrive at a draft list of 20 tracer items a spread sheet was designed listing all ‘free medicines’ with their different dosage forms plus additional essential medicines that are being provided through specific NSHP-2 priority programmes. For the latter only those medicines that are supposed to be available at all times in all health facilities were included (e.g. anti-malaria medicines or anti-retroviral products were excluded). The originally listed medicines were assessed by linking their use to the top out-patient morbidities, priority programmes and existing tracer and key commodity lists. Advice from the Logistics Management Division (LMD) was sought to ensure that in case of alternatives that most used item was selected.

The suggested draft list consists of 20 essential and programme medicines including one vaccine. Nineteen of the 20 tracer medicines are supposed to be available up to Sub-Health Post level (see Annex 1).

From a **health systems perspective** monitoring availability and stock-out of the selected tracer medicines will allow judgement on the impact of performance of the public pharmaceutical supply management system on readiness to deliver free health care services to the Nepali population (contribution to the health service delivery building block). It also provides information for one of the two core indicators suggested by WHO for assessing performance of the health system’s ‘medical products’ building block (WHO 2010). The tracer item list has not been designed to allow assessment of service readiness of specific priority programmes. For this purpose specific tracer medicines would need to be identified.⁵

There are no examples for how tracer items can be used to measure other aspects of health systems functioning. With regard to the specific issue of functioning of the cold chain, enumerators could record whether the vaccine vial monitors for a random sample of vaccines indicate breakages of the cold chain.

⁵ The data collection form used in the recent STS includes in Section 1 data items on the availability of specific medicines required for priority services.

7.3 Recommendations: Availability Indicators

The Nepal MOHP has committed to providing EHCS including specific essential medicines for free to the population at district level (with some restrictions at district hospital level). To fulfil this commitment essential medicines need to be available at health facilities in adequate quantities at all times. There are two main measurements that together provide information on whether this is being achieved, i.e.

- ⇒ Availability of tracer medicines at day of reporting (surveys or LMIS report), and
- ⇒ Stock-out situation of tracer medicines during the period of review

1. Availability of tracer medicines

Percentage availability of (non-expired) tracer medicines will be established for each individual health facility, and reported as national aggregate and sub-sets for level of care i.e.

- ⇒ **average percentage availability of tracer medicines at district health facilities** (district hospitals, primary health care centres, health posts, sub health posts)

For example, 'on average 64% of tracer medicines were available on the day of data collection/reporting at district health facilities in Nepal'.

2. Stock out of tracer medicines

Keeping in line with previous health sector surveys in Nepal and international practice it is recommended to define stock-out as a period of seven consecutive days (1 week). The period of one month suggested in the NHSP-2 appears too long to ensure sustained access by the population. Results can be reported in different ways (by tracer items, by facilities). For the purpose of NHSP-2 monitoring the focus on health facilities appears appropriate, i.e.

- ⇒ **percentage of health facilities with stock-out of tracer items** during the period under review

where stock-out is defined as stock-out of one or more tracer item for at least seven consecutive days.

If additional information on the extent of stock out is required, the collected information can further be analysed by the number of the tracer items that were out of stock in each health facility. For this it is recommended to establish ranges, e.g. 1-5, 6-10, 11-15, >15 as has been done previously (RTI International 2009). For example

- ⇒ percentage of health posts with stock out of 6-10 tracer medicines during the period under review

where stock-out is defined as stock-out for at least seven consecutive days.

7.4 Recommendations: Monitoring availability using routine reporting systems

The LMIS captures and reports stock-outs of tracer medicines occurring at health facilities at the quarterly reporting date (Indicator: average % of tracer items out of stock at health facilities). The current stock-out indicator can easily be converted to report on average % availability of tracer items at health facilities - in line with the availability indicator suggested above.

The LMIS is well established with reporting rates consistently over 90% (GON 2011-a). Data entry is done at central level and reports are available at best 2 months after receipt of health facility forms.

Annual health facility surveys could be used to triangulate results from self-reporting by health facilities through the LMIS system where data audits are not done systematically. For this it is recommended that the LMIS adopts the tracer medicine list that will be used for monitoring of NHSP-2 through STSs.

None of the existing routine monitoring systems is set up to capture stock out periods of essential medicines. This information needs therefore to be collected during health facility surveys using retrospective record review. For making information available more frequently it is recommended to consider including monitoring of stock-out periods of tracer medicines in the integrated district supervision system.

8 ASSESSING OTHER ASPECTS OF MEDICINES MANAGEMENT AND USE IN NEPAL

The recently conducted STS included useful aspects of **quality of pharmaceutical management** (storage practices, expiry of medicines) and procurement practices (central versus local procurement). Specific comments on these areas have been provided separately.

The LMIS quarterly health facility report forms provide for recording quantities of **expired medicines** removed from stock during the reporting period. Assessing whether this information is provided, being analysed and/or acted upon was beyond the scope of this study.

Integrating aspects of **quality of medicines use** in health facility surveys seems difficult due to the time required for data collection at each health facility (see Section 6). The Primary Health Care Revitalisation Division (PHCRD) at the DOHS is responsible for assessing and supporting rational use of medicines and is engaging in related activities (e.g. self-monitoring followed by peer group discussions of prescribers at Ilaka and district level in selected districts). PHCRD would probably be best placed to conduct national medicine use surveys. The International Network for Rational Use of Drugs (INRUD) has a strong chapter in Nepal where technical support would be available.

Information from recent health facility surveys and the LMIS indicate that availability of essential medicines at health facilities is inadequate. Interviews with officials from PHCRD and LMD and a recent survey of the public pharmaceutical procurement and supply system (Stoermer et al 2009) suggest that this is not related to budget constraints. Both, LMD and PHCRD seem to have responsibilities for **monitoring the supply chain** and availability of essential medicines at health facilities. It is not known whether this is being done routinely and an overall study identifying existing challenges and bottlenecks in the procurement and supply system (including functionality of the district level pull system) might be warranted⁶.

Health facility surveys conducted in the context of monitoring of the free health care policy reported on the time it takes for medicine consignments to reach health facilities from the region or districts (RTI International 2009). Due to the lack of a benchmark results are difficult to interpret. However, **transport from district stores to health facilities** seems to be a challenge and monitoring might be considered for future STSs.

8.1 Recommendations: Monitoring capacity of the health system to ensure timely delivery of medicines to health facilities

In the context of STSs focus should be on delivery of pharmaceutical supplies from district stores to health facilities. In line with existing policies and guidelines a few questions can be included that allow identification of common challenges, e.g.

- Availability of (ordering and) delivery schedule
 - If yes, is it being adhered to?

⁶ Holloway mentions in her draft report (Holloway 2011) a recent study: Chhetri MK and Deva JSG. Final Report on Assessment of Drug Management at Selected DHO/DPHOs, PHCs, HPs and SHPs in 10 Districts of Five Regions of Nepal. Submission to WHO Nepal by Poly Clinic and Research Centre, Kathmandu, Nepal, 2010. It might be worthwhile to consult the findings of this study.

- Responsibility for transport
 - District to send
 - Health facility to collect
- Means of transport from district stores to health facility
 - Car, motor cycle, bicycle, on foot
- Constraints
 - District has no budget
 - Health facility has no budget
 - Responsibilities not clear
 - Others

The list of variables should be finalised with input from individuals who are familiar with the reality at district level.

In addition, it is recommended to assess with LMD the stock situation of tracer medicines at district level stores at the time of the survey (for districts using the web-based LMIS online information is supposed to be available at national level). This would allow a judgement whether any stock-out situation at district stores impacts availability of medicines at health facilities.

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ANNEX 1: PROPOSED LIST OF TRACER MEDICINES

	Name	Strength	Form	Category	Programme	Target group
1	Albendazole	400mg	cap/tab	helminthic infection	Nutrition, Family & Child Health	All
2	Aluminium hydroxide + Magnesium hydroxide	250mg	tab	gastro-intestinal	Essential drugs	Adults
3	Amoxicillin	250mg	cap/tab	bacterial infection	Essential drugs	Adults
4	Amoxicillin	125mg	disp tab	bacterial infection	Essential drugs	Children
5	Chloramphenicol	1%	eye applicap	eye infection	Essential Drugs, IMCI	New borns
6	Ciprofloxacin	250mg	Cap/tab	bacterial infection	Essential drugs	
7	Compound solution of Sodium lactate (Ringers' L)		infusion sol.	electrolyte	Essential drugs	Adults
8	DMPA	150mg	injection	family planning	Family Planning	Women
9	Ferrous salt + Folic acid	60+0.4mg	cap/tab	anti-anaemia	Nutrition	Pregnant women, children
10	Gamma benzene hexachloride	1%	Lotion	skin disease	Essential drugs	Adults
11	Gentamycin	80mg/2ml	injection	bacterial infection	Essential drugs	Children
12	Hyoscine butylbromide	10mg	cap/tab	gastro-intestinal	Essential drugs	Adults
13	Metronidazole	200mg	cap/tab	bacterial infection	Essential drugs	Adults
14	Oral Rehydration Solutions (ORS)		powder	gastro-intestinal	CDD	Children
15	Paracetamol	500mg	cap/tab	fever, pain	Essential drugs	Adults
16	Povidone iodine	5%	solution	skin disease	Essential drugs	All
17	Sulfamethoxazole + Trimethoprim	100/20mg	disp tab	bacterial infection	ARI	Children
18	Vitamin A	200,000 IU	cap/tab	vitamin	Nutrition	Children, women
19	Zinc sulphate	20mg	disp tab	gastro-intestinal	CDD	Children
20	Vaccine DPT, HepB, Hip (pentavalent)		vial	prevention	EPI	Children

ANNEX 2: MEETINGS HELD DURING THE COUNTRY VISIT

Name	Position	Organisation
Monday 7 May		
Nancy Gerein	NHSSP International Lead	MOHP
Ajit Pradhan	NHSSP M&E Strategic Advisor	MOHP
Pradeep Poudel	NHSSP M&E Implementation Advisor	DOHS
Laxmi Bilas Acharya	NHSSP Senior Research Associate	MOHP
Suresh Mehata	NHSSP Research Associate	DOHS
David Hepburn	NHSSP Senior Procurement Advisor	DOHS, LMD
Astrid Thygesen	NHSSP Senior Procurement Advisor	DOHS, LMD
Sarad Shrestha	Programme Officer NFHP-2	DOHS, LMD, LMIS
Prem Adhikari	Programme Officer NFHP-2	DOHS, LMD, LMIS
Suresh Tiwari	NHSSP Health Finance Advisor	MOHP
Tuesday 8 May		
Radha Raman Prasad	Director General	Department of Drug Administration
Wednesday 9 May		
Mahendra Prasad Shrestha	Chief Public Health Administrator	Kathmandu District
Dr Maureen Dariang	NHSSP EHCS Advisor	DOHS
Ananda Kumar Shrestha	Director	DOHS, PHCRD
Dr Ganga Shakya	NHSSP MNH Advisor	DOHS
Thursday 10 May		
Heem Shakya (by telephone)	Team Leader Logistics	NFHP II
Friday 11 May		
Krishna Bahadur Chand	Deputy Director	DOHS, LMD