Estimation of RDT needs, product selection procurement and supply management

Estimation of needs for RDTs

In order to quantify requirements for the public sector:

1. Define target area, number of health facilities and level of care where RDTs will be deployed (hospitals, health centres, dispensaries, health units, health posts, and community providers);
2. Consider if the number of health facilities will be increasing or decreasing in timeframe of the quantification (e.g. health sector development plan);
3. Provide estimates of expected variations in attendance of health facilities after introduction of the new malaria treatment policy, pricing of medicines and access to new diagnostic services.
4. Take into account the number of unexpired RDTs already in the system (in storage and deployed)

a1

Initial estimation of needs for RDTs

5. Public sector unconfirmed malaria-like fever for target area =

$$\frac{\text{(no. of reported malaria cases* – no. of blood examinations for malaria)}}{\text{proportion of complete \& timely reports** of malaria cases received}}$$

* In areas where the proportion of confirmed malaria cases is low, the number of reported malaria cases is close to the number of suspected malaria cases recorded as malaria. If the proportion of confirmed malaria cases is high, use instead the number of suspected malaria cases.

** Example: if 80% of reports from the target area are received with complete malaria data within the established timeframe, then the above number should be divided by 0.80

Estimation of needs for RDTs

5. The overall requirements should be adjusted to the RDT deployment plan, reflecting changes of coverage over time.

- Example 1: if peripheral health posts are initially not included, the RDT requirement should be increased by the number of cases to be seen at health posts at which health workers can be trained within the time period for RDT deployment.
- Example 2: if RDTs will be introduced as part of new programme for home-based management of malaria, the requirements should be calculated on the basis of expected number of suspected malaria cases that will be tested by the community health workers enrolled and trained in the programme.
  (e.g. 1 year requirement: 200 CHW x 10 febrile patients x 200 days)

To convert estimated needs in orders…

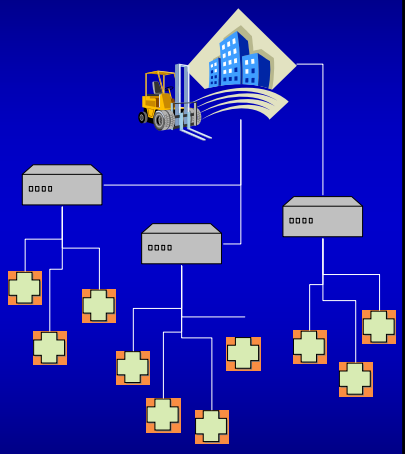
1. Estimate the requirements to fill the supply pipeline, based on number of supply points at each level, their frequency of requisition and delivery, the amount of safety stock at each level, in line with the overall plan of distribution of the RDTs;
2. Consider the impact of lead time, including the procurement process, to place an order, production time, time for shipment, custom clearance, and arrival in the central warehouse;
3. Adjust the amounts on the basis of damage, spoilage, expiration and theft (at least 10% for losses) - allow loss in quantifying vital items;
4. The order quantity needs then to be adjusted according to pack sizes (e.g. multiples of 25, 30 or 50 treatment units) as well as to minimal order size;
5. Estimating total procurement costs, using prices from local suppliers and international procurement agencies, adding freight and insurance costs;
6. Adjust estimated budget according to anticipated international devaluation and devaluation of local currency, and possible rising shipping costs;
7. Reduce the estimated quantities to conform with budget as necessary.

The public drug supply distribution system

…has several layers of stores, generally:

- one (or more) primary stores receives orders, and serves a whole country or a region/province
- intermediate stores (often within regional or district hospitals)
- health facility stores

- The physical size of stores at each level is determined by the demand for items they have to distribute and by the supply frequency. The stock levels within the supply system and the number of supply points at each level constitute the supply pipeline. The number of levels, the frequency of requisition and delivery, and the amount of safety stock at each level will influence the amount of RDTs needed to fill the supply pipeline.



How to calculate safety stocks

- Since it is impossible to estimate the requirements with complete accuracy and to be certain about the supplier's performance, a certain amount of RDTs in stock (inventory) is needed to absorb fluctuations in supply and demand and to reduce the risks of stock-outs. Since high stock levels increases inventory costs (personnel, storage, as well as risk of spoilage, expiry and theft), most public supply systems need to calculate the minimum "safety stock" to protect against stock-outs.
- The safety stock should be calculated multiplying the adjusted average monthly consumption by the expected lead time, according to the formula:

Safety Stock (SS) = Ca x LT

where: Ca = average consumption, adjusted for stockouts
LT = lead time (from order to delivery in warehouse)

same unit of measure, often in months

Consumption from stock record card

- The stock record form allows to calculate the consumption over a certain period, according to:

Consumption = opening stock + RDTs received - closing stock

- In this example the consumption for the period from 15/9/2005 to 14/11/2005 has been of 120+400-305= 215 unit forms (i.e. boxes containing 30 RDTs each)

Date	From whom rec./issu.	Qty Rec.	Qty Issu.	Balance	Expiry	Signature
15/9/05	Inventory			120	06/2006	
17/9/05	Clinic a		10			
23/9/05	HC a		30			
25/9/05	Clinic b		10			
26/9/05	Clinic c		10			
1/10/05	Hosp		40			
3/10/05	HP a		5			
3/10/05	CMS	400			07/2007	
5/10/05	Clinic b		10		06/2006	
8/10/05	HC a		30		5 - 06/2006 25 - 07/2007	
12/10/05	Clicnic a		10			
15/10/05	Clinic c		10			
23/10/05	Hosp		40			
29/10/05	HP b		5			
1/11/05	HPa		5			
14/11/05	Inventory			305		

Time and quantity for re-ordering

- WHEN: once the stock has reached a minimal (re-order) level
- AMOUNT: Once the basic inventory has been established, the amount of medicines to order is based on a "pull system", the adjusted average monthly consumption multiplied by the sum of the lead time and procurement period plus the safety stock levels after removing from the latter the stock on order and the stock in inventory. This is expressed as:

Qo = Ca x (LT + PP) + SS - (Si + So) where:

- Qo = Quantity of medicines to re-order in the next procurement period
- Ca = average monthly consumption, adjusted for stockouts
- LT = lead time
- PP = procurement period
- SS = Safety stock
- Si = Stock in inventory (on hand)
- So = Stock on order, but not yet received

Monthly Stock Management Form

Item	Indicate duration of stock out *(tick as appropriate)*			Stock management *(treatment courses)*						Quantity re-ordered
	None	< 1 week	> 1 week	Safety stock	Opening stock *(stock at beginning of the month)*	Closing stock *(balance at the end of the month)*	Monthly consumption	Expected variation	Lead time	
Name of ACT				a	b	c	d	e	f	Qo
1. ACT presentation 1										
2. ACT presentation 2										
3. ACT presentation 3										
4. ACT presentation 4										
5. 2nd Line:.....										
6. Parenteral quinine										
7. Artemisinin suppositories										
8. Sulfadoxine-pyrimethamine										
Add additional medicines or supplies										
9.										
10.										
11.										
Laboratory supplies										
12. Giemsa stain										
13. Malaria slides										
14. RDTs										
15. Lancets										

Useful to assess adequacy of re-orders

Qo = Ca x (LT + PP) + SS - (Si + So) where:

Qo = Quantity of medicines to re-order in the next procurement period
Ca = average monthly consumption, adjusted for stockouts
LT = lead time
PP = procurement period
SS = Safety stock
Si = Stock in inventory (on hand)
So = Stock on order, but not yet received

Qo = (d x f x e) + a - c

Developing malaria RDT shortlist for procurement

Parameter	Decision process	Decision
1. Plasmodium species to detect	Distinguish non-Pf from Pf or mixed? Yes → **Combination test**: HRP2- pLDH; HRP2- aldolase; pLDH Pf -pLDH; pLDH Pf-pLDH Pv; HRP2-pLDH-pLDH Pv No → **Pf-only test**: HRP2; pLDH Pf (may be combined with pan-specific pLDH)	.....
2. Expected areas of use	Store and use in tropical environment without temperature control Yes → **High-stability required**: High stability demonstrated, at specific temperature e.g. ⩾35C No → **Temperature not critical**: Accept lower stability and <35°C specified storage	.....

Developing malaria RDT shortlist for procurement

Parameter	Decision process	Decision
3. Likely clinical scenarios	Likely to use for re-testing soon after treatment / treatment-monitoring Yes → **Target non-persistent antigen**: pLDH-detecting *P.falciparum* No → **Antigen persistence not critical**: HRP2 or pLDH-detecing *P.falciparum*	.....
4. End-user	For use by health workers outside medical laboratories Yes → **Simple format, all-inclusive**: Cassette design, few steps, lancet, swabs etc in package No → **Design less critical**: Include dipsticks; Test-only packaging	.....

Selection of RDTs

- Based on the priority selection criteria (described in the above procurement algorithm or other similar approaches), select, from WHO malaria RDT product testing report*, RDTs that fit the above criteria and have:
  - high detection rate,
  - low false positive rate,
  - low invalid rate.
- In populations with low immunity, high capacity to detect low parasitaemia should be taken into consideration
- Once all of the above have been evaluated, RDT price offers should be evaluated

** Report available at: www.wpro.who.int/sites/rdt/who_rdt_evaluation/*

Good Procurement Practices of RDTs

Request to the manufacturer:

- Temperature-stability data
- Evidence of accuracy / good field trial data
- Evidence of viability of manufacturer
- Evidence of good manufacture QA (ISO131485:2003)
- Product support
- Sample products … to test for ease of use etc.
- Agreement for replacement of failed product
- Appropriate packaging
- Staggered delivery of single orders