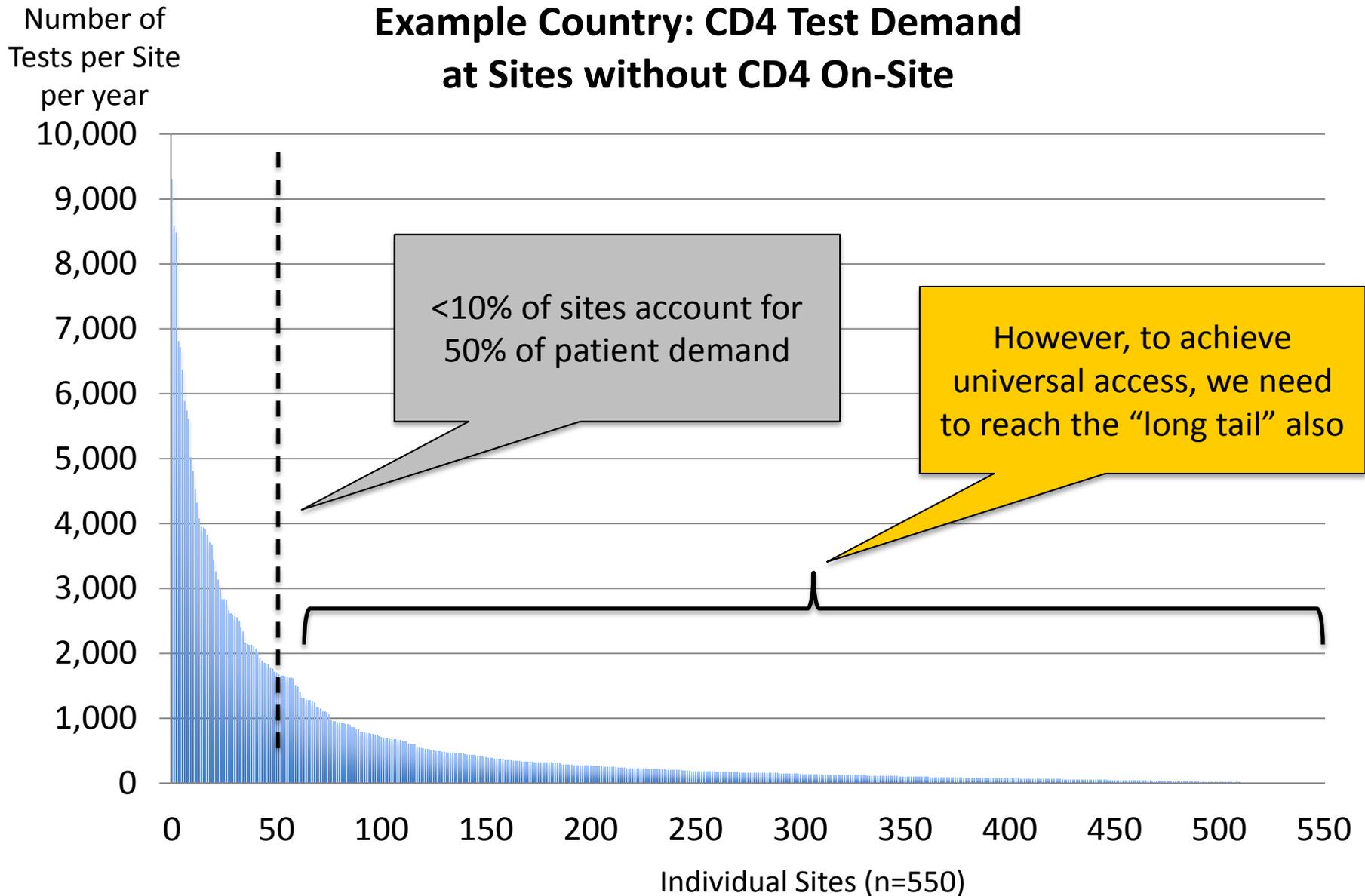


Experience in Implementation of POC CD4 Testing

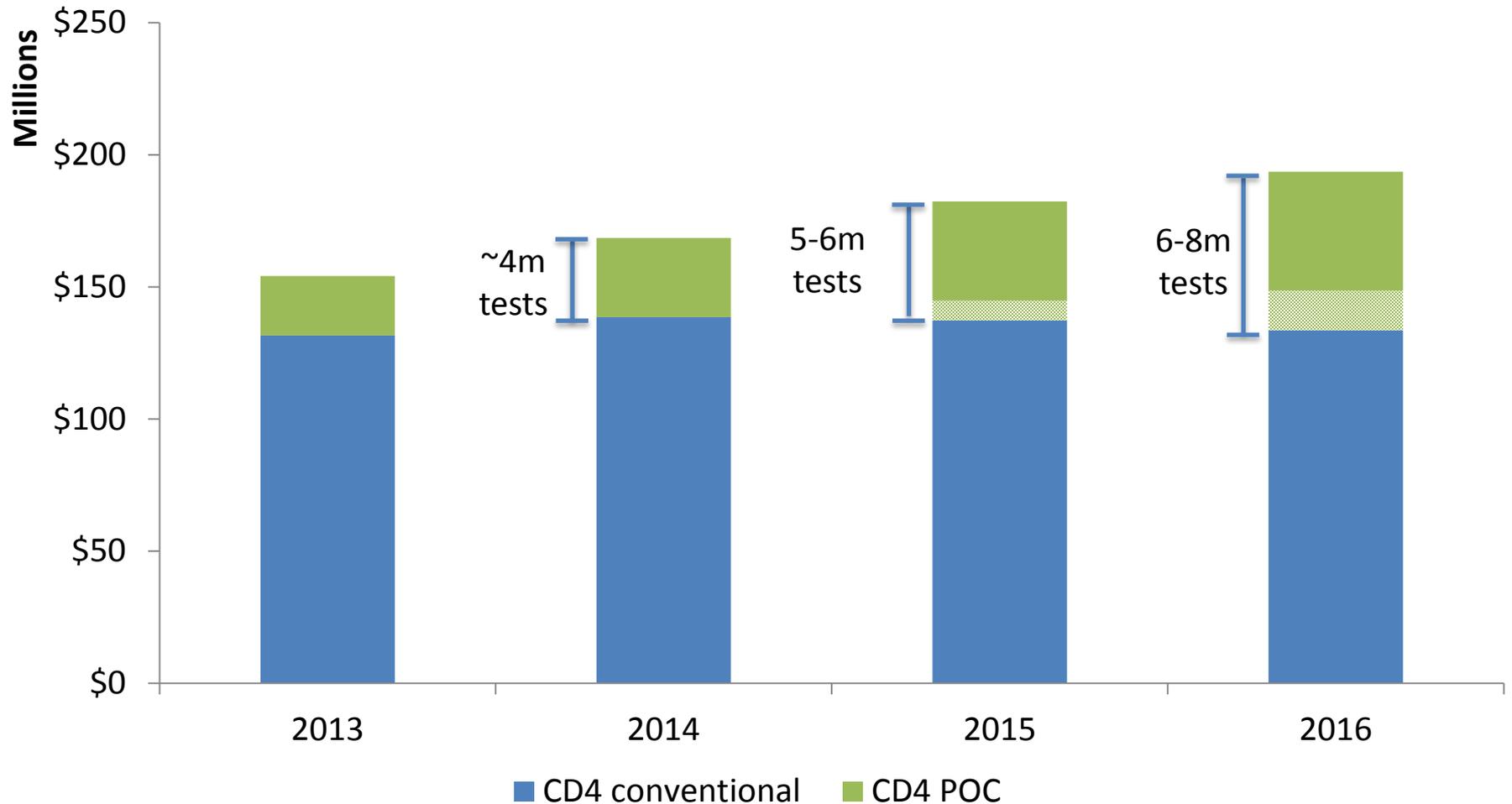
Implementing HIV and TB Diagnostics in Resource-Limited Settings
September 22, 2014



A significant number of health care facilities lack on-site HIV diagnostic testing



The POC segment of the CD4 market is expected to grow to \$45m to \$60m dollar market by 2016



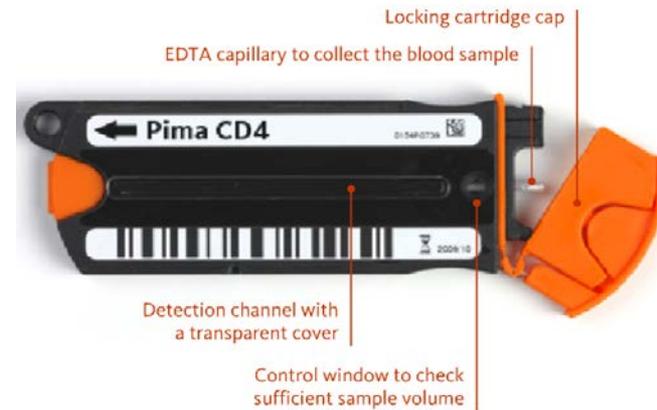
Source: POC figures for 2013 and 2014 based on data from country teams.

Excludes money spent to expand install base of instruments

Assumes per test cost of \$7.50 for both conventional and POC

laboratory based testing volumes based on CD4 testing coverage data from high HIV-burden CHAI countries

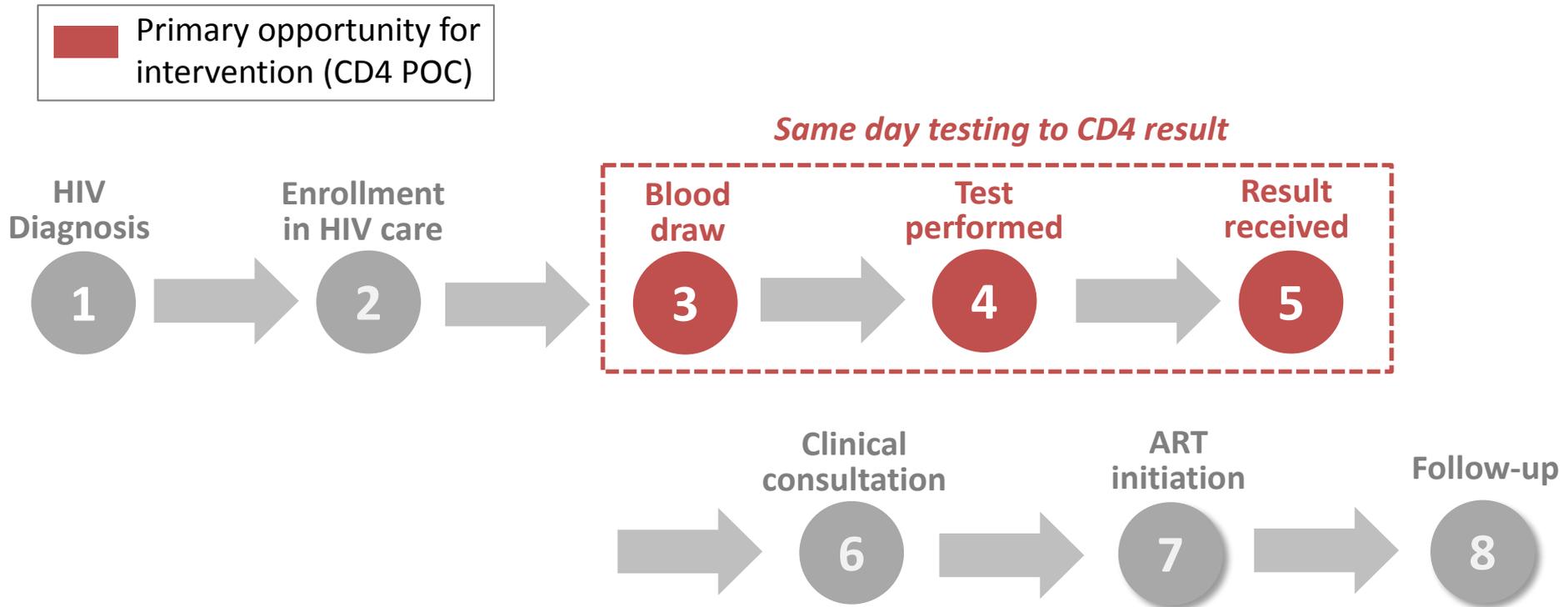
Alere PIMA™ CD4 Analyzer



- Finger-prick or venous blood
- Dried reagents – no refrigeration required
- Reagents in sealed disposable cartridge
- No manual sample processing
- Output – CD4 absolute count only
- Power Source – A/C with rechargeable battery
- Run time – 20 minutes/test
- Throughput – 20 tests/day

POC CD4 accelerates and eases treatment initiation for those who need it

Continuum of Care Pre-Initiation and Opportunities for Impact



POC CD4 combines a number of steps required pre-ART initiation making it less burdensome for patients

POC CD4 is highly effective at cutting LTFU and reducing time to initiation

Malawi¹

- **LTFU:** Increase of PMTCT initiation during pregnancy from 51 to 78%
- **Time to CD4 result:** time from CD4 blood draw to result reduced from 11 to 0 days

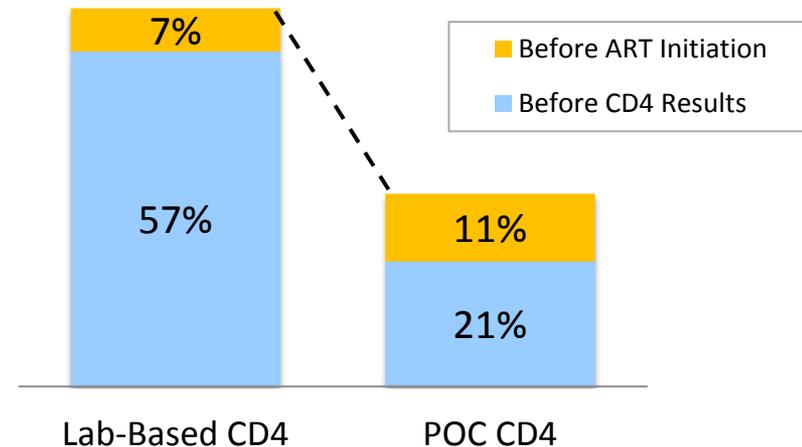
Uganda²

- **Time to initiation:** 48 days earlier ART initiation

Mozambique³

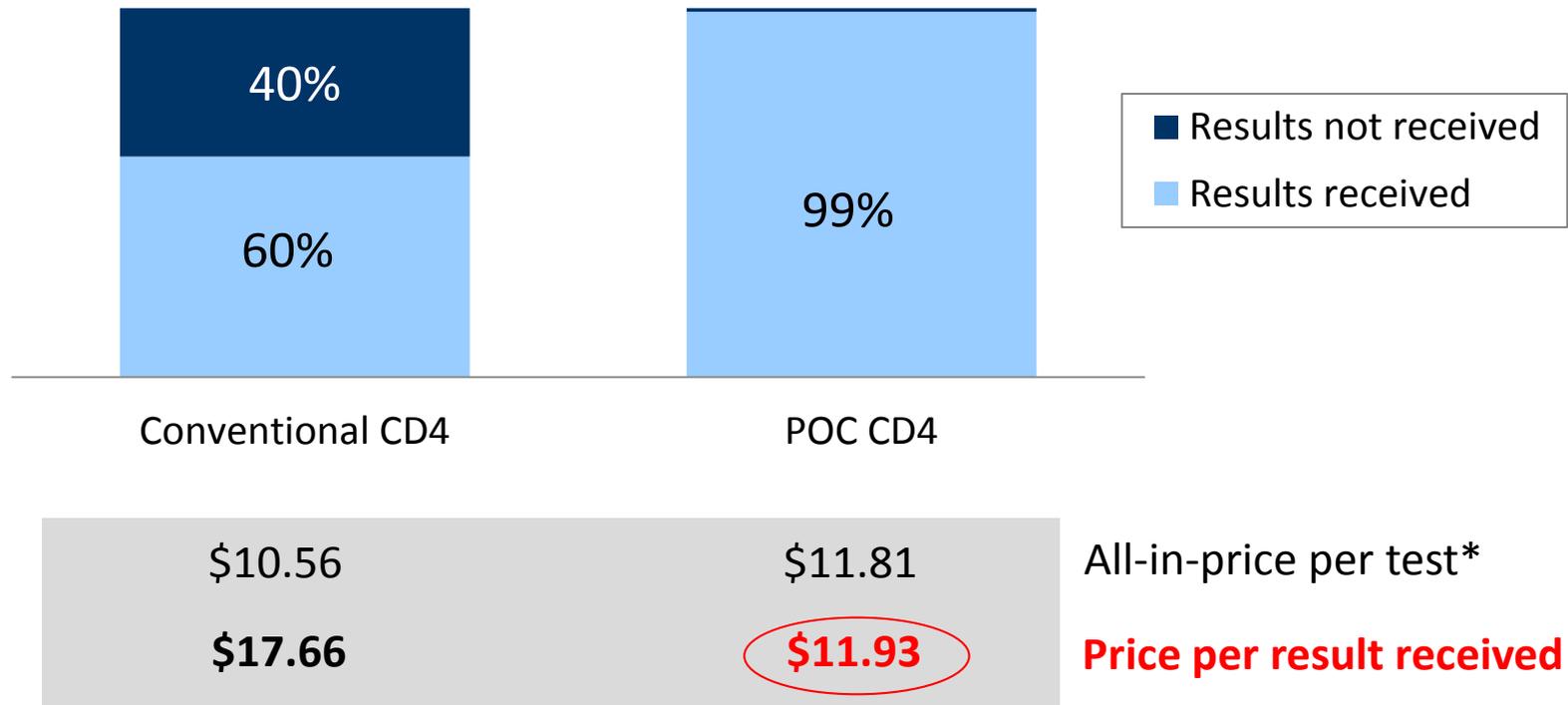
- **LTFU:** 50% increase in retention from diagnosis to ART initiation
- **ART Initiation:** 85% increase in ART initiation
- **Time to initiation:** Time between enrollment and ART initiation reduced by 28 days

LTFU in Mozambique using POC CD4 vs. Lab-based tests



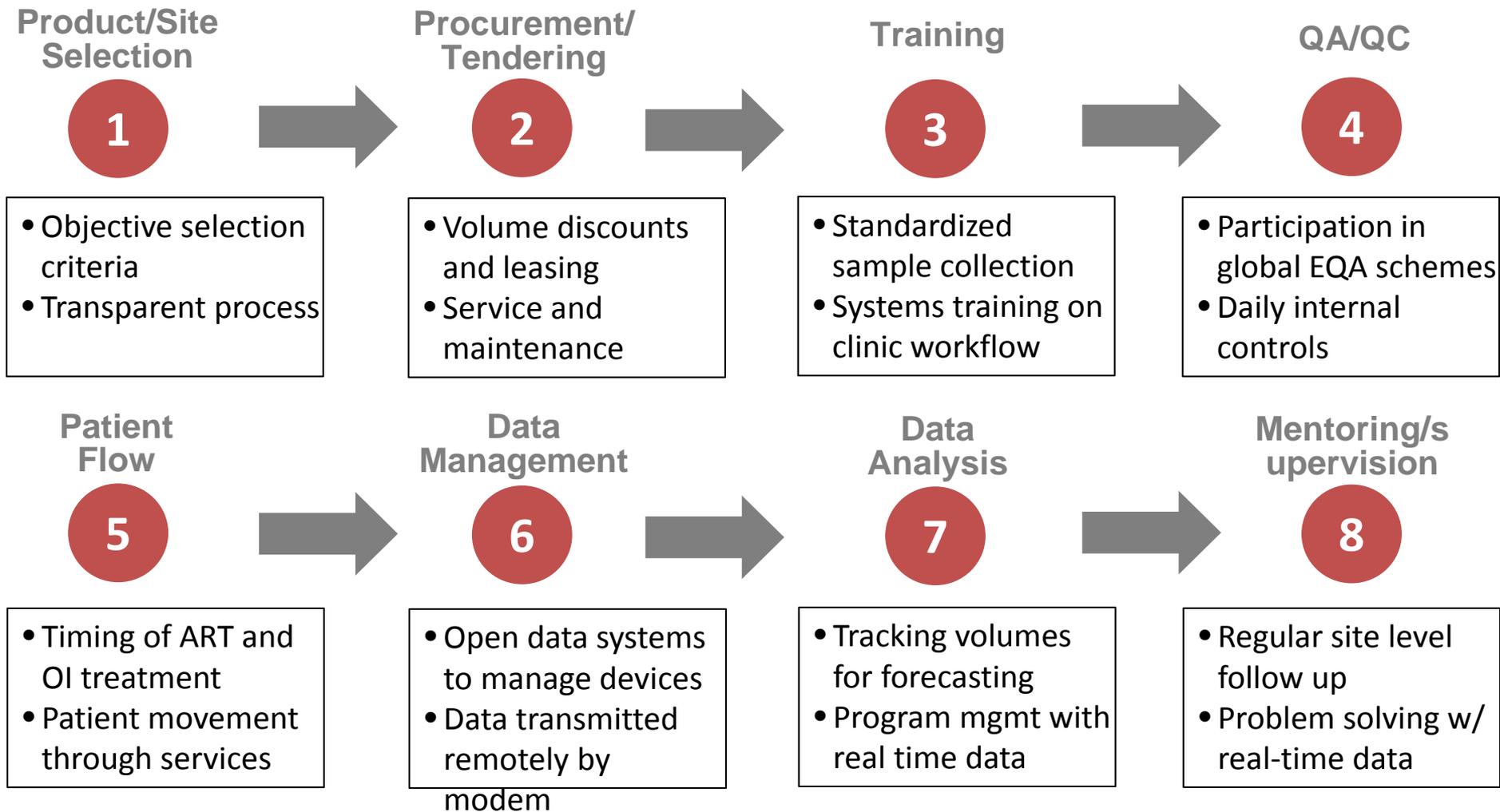
POC saves significant costs through more efficient service delivery

Results Received Using Conventional vs. POC CD4



Globally, countries could purchase an additional 5.3 million POC tests with the amount of wastage resulting from conventional tests

Implementation: A number of processes required for new products



For effective POC testing, product agnostic systems are needed

Implementation guidelines: Driven by country's overall plan

Malawi

- Task force formed by MOH in February 2012 to draft strategy
- Strategy was for CD4, EID, VL, chemistry, hematology, opportunistic infections such as TB, etc.
- Strategy defines POC, provides guidelines and criteria for selecting products and sites for deployment, and encourages “competition in the marketplace”

Includes a roadmap for product-agnostic systems for training, quality assurance, supply chain and distribution, service and maintenance, data management, and M&E

- Strategy approved in June 2012.

GOVERNMENT OF MALAWI

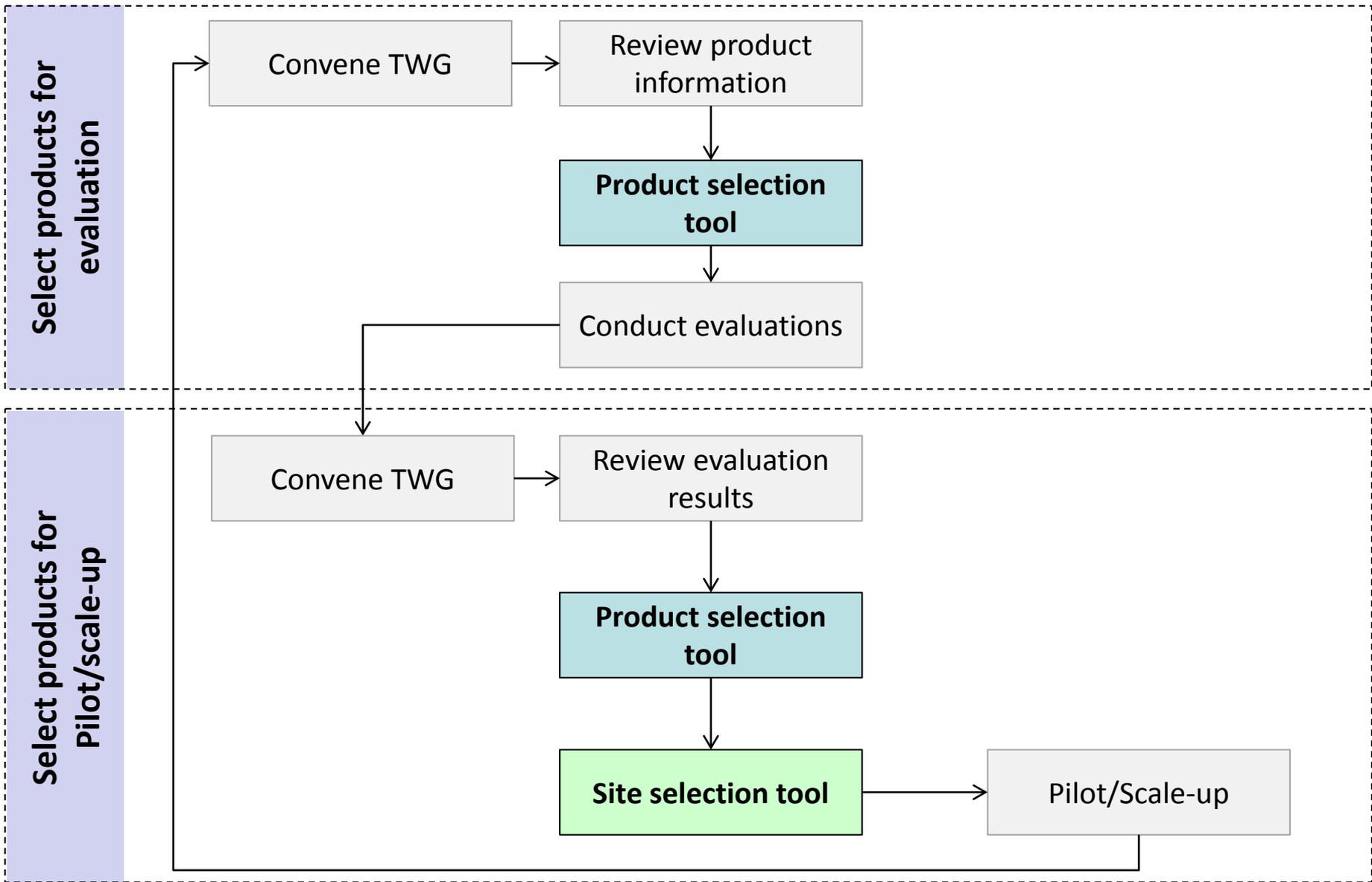


MINISTRY OF HEALTH

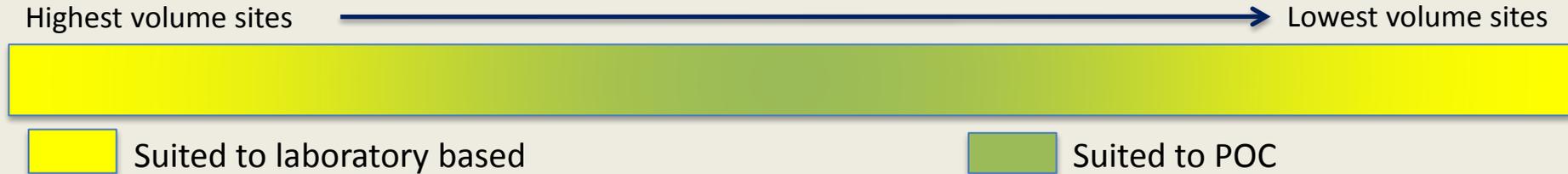
Point-of-Care Implementation
Guidelines
Directing Scale-up of Point-of-Care Testing for
HIV-related Diagnostics in Malawi

June 2012

Selection tools can play an important role but the overall process is important for sound and transparent decision making



There is a sweet spot for sites where laboratory based and POC testing make economic sense based on throughput, cost and complexity



Actual share of the market will depend on:

1. Country preference

Leverage current laboratory based platforms?

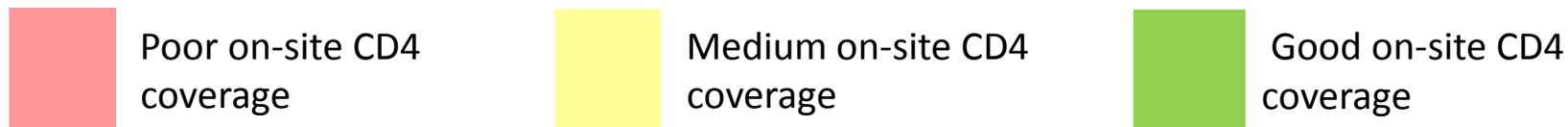
2. Price points for device/reagents

Cost of POC test vs laboratory based + sample transport

3. Throughput of POC/near-POC

of machines required to meet patient need vs. burden on health workers

Site-level data can be used to identify gaps in testing coverage and target opportunities to use POC to maximize linkage to treatment



Market Segmentation by facility level and pre-ART patient population

Criteria	Provincial Hospitals	District Hospitals	Health Centers	TOTAL
>20 Patients per Day	10%	9%	13%	32%
10-20 Patients per Day	2%	10%	11%	23%
5-10 Patients per Day	<1%	6%	10%	16%
0-5 Patients per Day	<1%	6%	23%	29%
TOTAL	12%	31%	57%	100%

Site Selection: Countries map all sites by key criteria and select sites most appropriate for POC diagnostics deployment based on country priorities

Mozambique: Key criteria used to select sites most appropriate for POC diagnostics deployment

Key criteria

- Availability of onsite CD4
- Patient volumes at each site
- Distance from a regional lab
- ART coverage rate
- CD4 coverage rate
- HIV prevalence
- Road quality

Country Priorities

Prioritizing **more remote** within each province



Kenya: Mapping sites by district to prioritize for POC diagnostics deployment based on key criteria

Potential key criteria

- Patient volumes
- Access to labs
- Others

Remote data monitoring through connectivity can help ensure quality POC CD4 testing and rapid responses

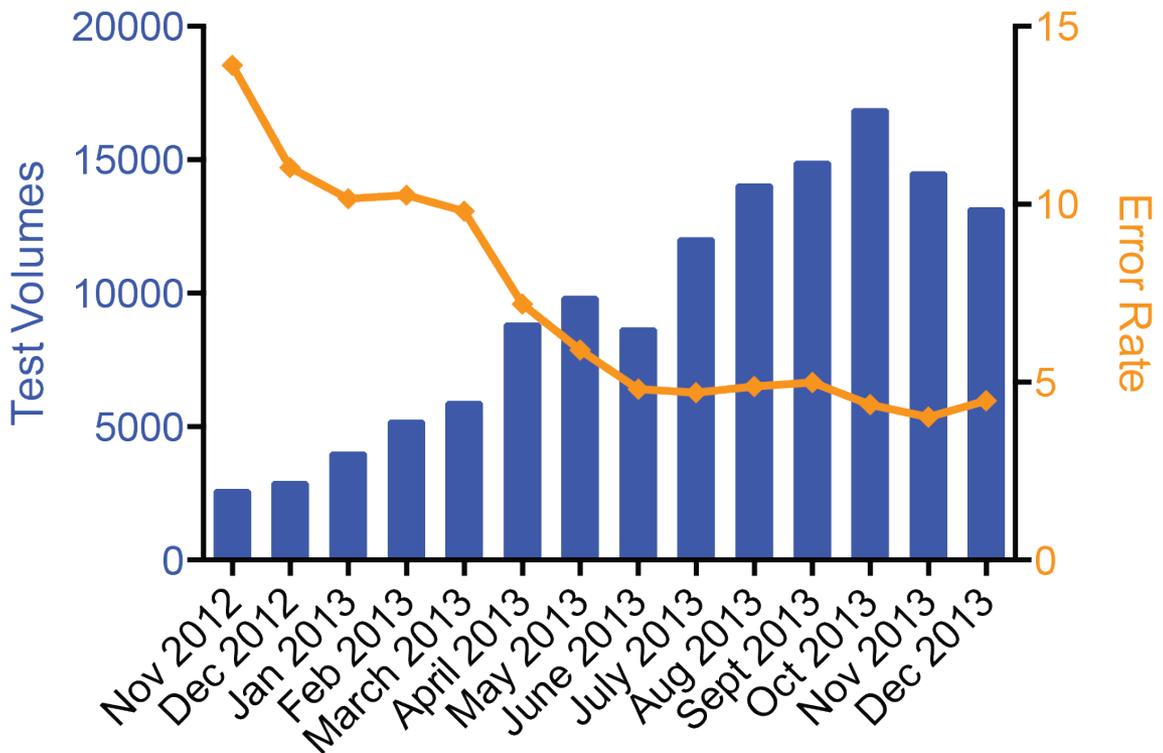
In Mozambique, over 140 devices have been deployed with modems across all 11 provinces

Data transmitted to central database include:

- Number of tests performed
- Error codes encountered
- Internal QA results

Which allow for:

- Re-training when necessary
- Remote troubleshooting
- Stock management
- Device management



Though EQA results remained consistently low throughout the same period, connectivity triggered remote monitoring and helped reduce error rates.

Thank you

