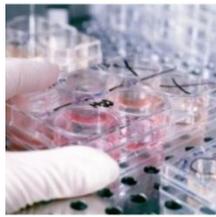




HIV Rapid Test Quality Assurance: System Implementation Requirements to Ensure Accurate Testing

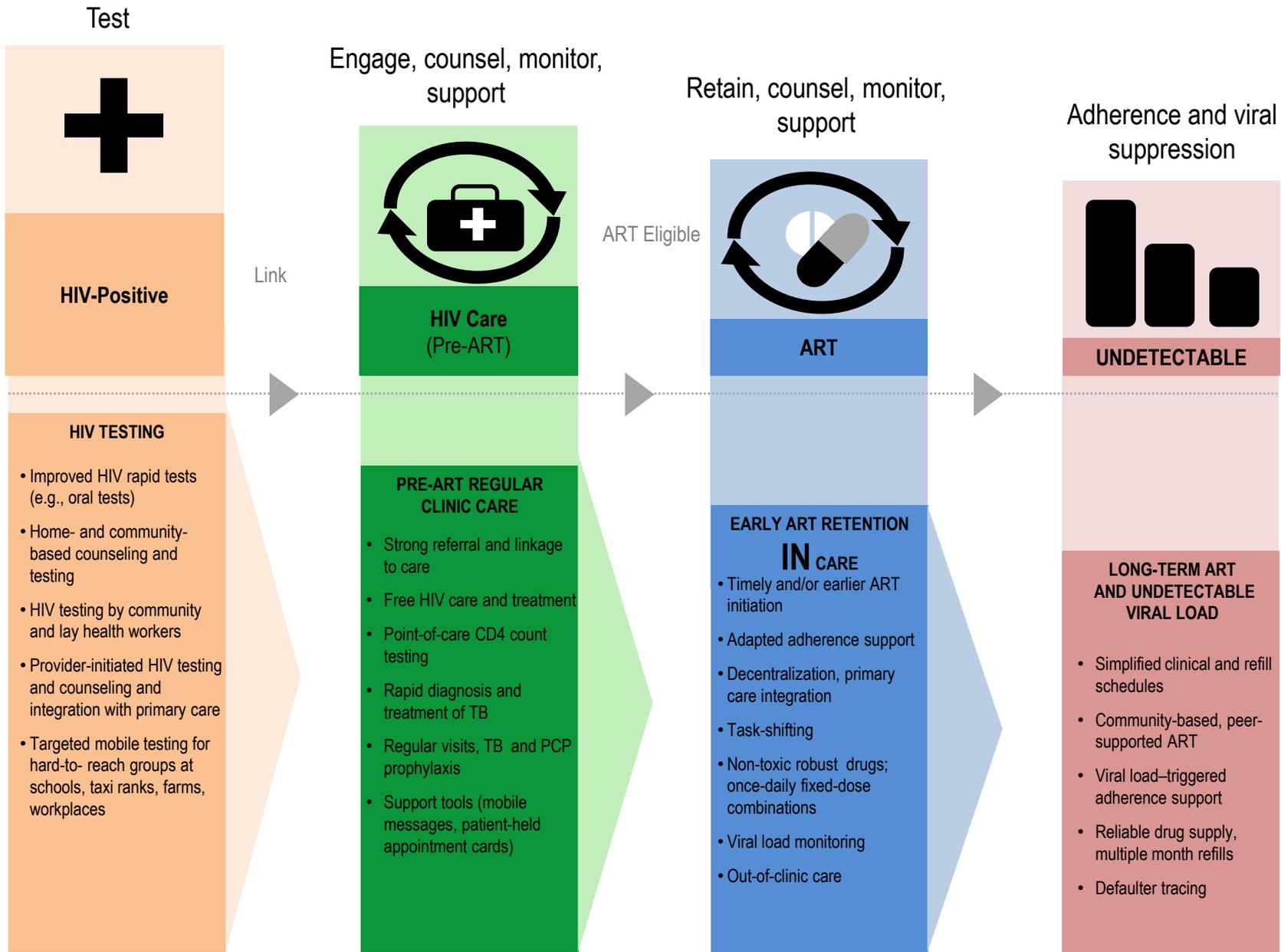
Adrian J Puren

*2nd Serial NDOH/PEPFAR Dissemination Workshop - Draft
Reaching 90-90-90 Part I: Best Practices and Innovations in
HCT and Linkage Innovations 30 November 2015*



What we talk about when we talk about QA of HIV RT

- **The First 90 and Rapid Test Performance: False positives a problem?**
- **The Guides: Do's and Don'ts: Are we aligned to WHO Guidance?**
- **From Guides to Practice: Implementing the RTQII Plan**
- **Assessment of Tools: The spider's web**
- **Closing the Circle: Not quite but a step in the right direction**



Sources: Top: adapted from: ML McNairy and W. El-Sadr. "The HIV care continuum: no partial credit given," AIDS (2012), 26: 1735-1738. Bottom: Médecins sans Frontières/Doctors without Borders and UNAIDS (2012). "Speed scale-up strategies, tools and policies to get the best HIV treatment to more people, sooner," www.msfn.org/content/speed-scale-strategies-tools-and-policies-get-best-hiv-treatment-more-people-sooner, Accessed November 13, 2012

GUIDELINES



CONSOLIDATED GUIDELINES ON
**HIV TESTING
SERVICES**

5Cs: CONSENT, CONFIDENTIALITY, COUNSELLING,
CORRECT RESULTS AND CONNECTION

JULY 2015

HIV TESTING SERVICES

NATIONAL HIV TESTING SERVICES: POLICY AND GUIDELINES

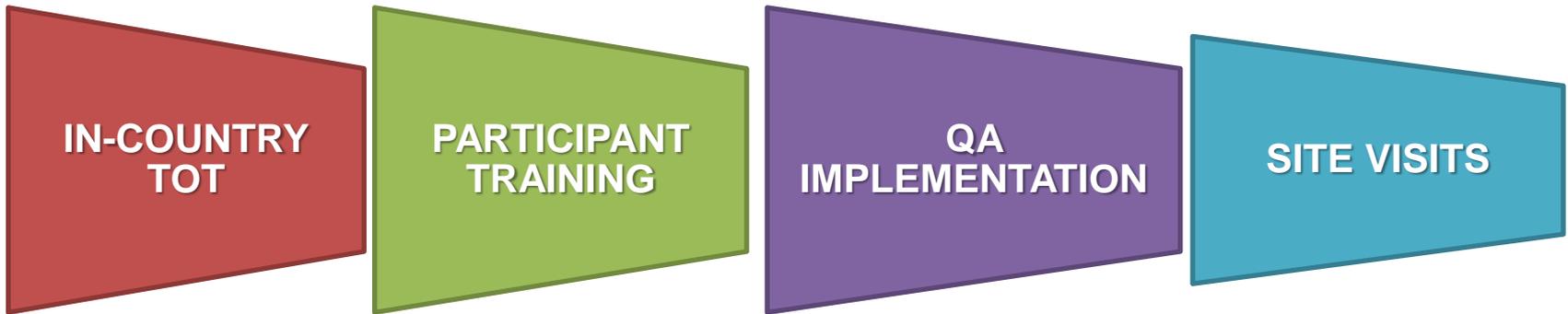
Prepared by the National Department of Health

2015



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



**IN-COUNTRY
TOT**

**PARTICIPANT
TRAINING**

**QA
IMPLEMENTATION**

SITE VISITS

- RTQII Training**
- **Implementing Partners**
- **Provincial RTC**
- **District Trainers**

- Training**
- **District Coordinators**
- **Sub district Coordinators**
- **OPM**
- **Mentors**
- **Lab Advisors**

- PT and IQC**
- **PT Data Management**
- **IQC Data Management**
- **Corrective Actions**

- SPI RT Checklist Quarterly**
- M and E Checklist**
- **Biannually**
- HTC Register**
- **QA data Collection**
- **QA Data Analysis**

Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist

SPI-RT Checklist

Version 2.0

9/14/2014



Purpose of an assessment

- Provides guidance on quality assurance (QA) practices for sites using HIV Rapid Test to diagnose HIV infection.
- Identify areas where improvement is needed
- Develop and implement a work plan to address gaps
- Implement quality assurance elements
- Monitor quality progress
- Maintain continuous quality improvement



Purpose of the Checklist

The SPI-RT checklist will:

- Provide a solid foundation for ensuring the quality of testing
- Specify detailed requirements to conduct an assessment
- Serve as a tool to evaluate a RT site against the requirement for quality improvement
- Act as guidelines for development of policies and procedures



Methods used to evaluate test site operations



Review the
RT site
records



Observe
the RT site
operations



Ask open-
ended
questions



Follow
client
specimen
or result
through
the testing
process

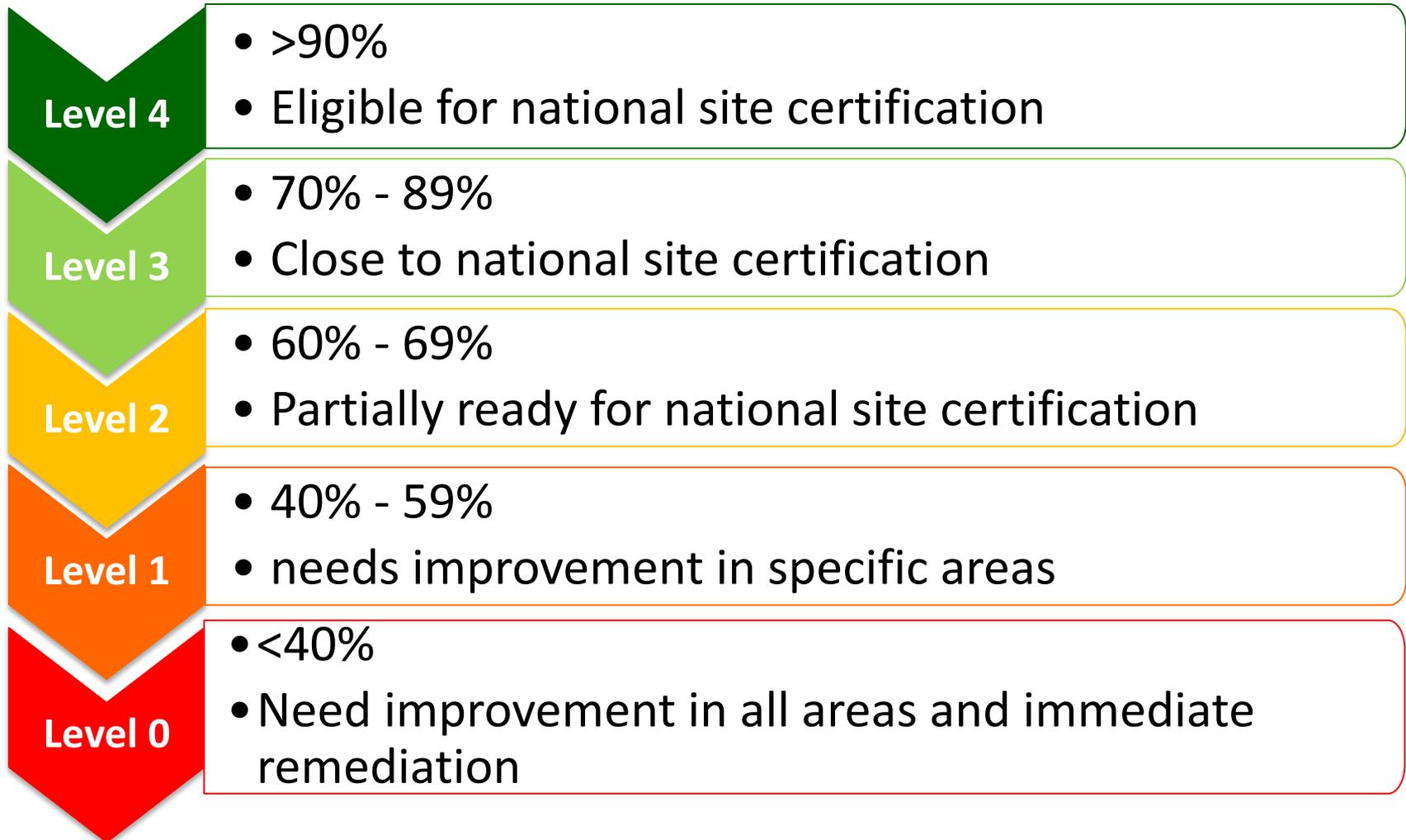
Organization of the SPI RT checklist

Assessment Score Sheet

Section	Section Name	Total Points
Section 1	Personnel Training and Certification	11
Section 2	Physical Facility	5
Section 3	Safety	9
Section 4	Pre-Testing Phase	12
Section 5	Testing Phase	9
Section 6	Post-Testing Phase	4
Section 7	Document and Record	7
Section 8	External Quality assessment	13
TOTAL SCORE		70



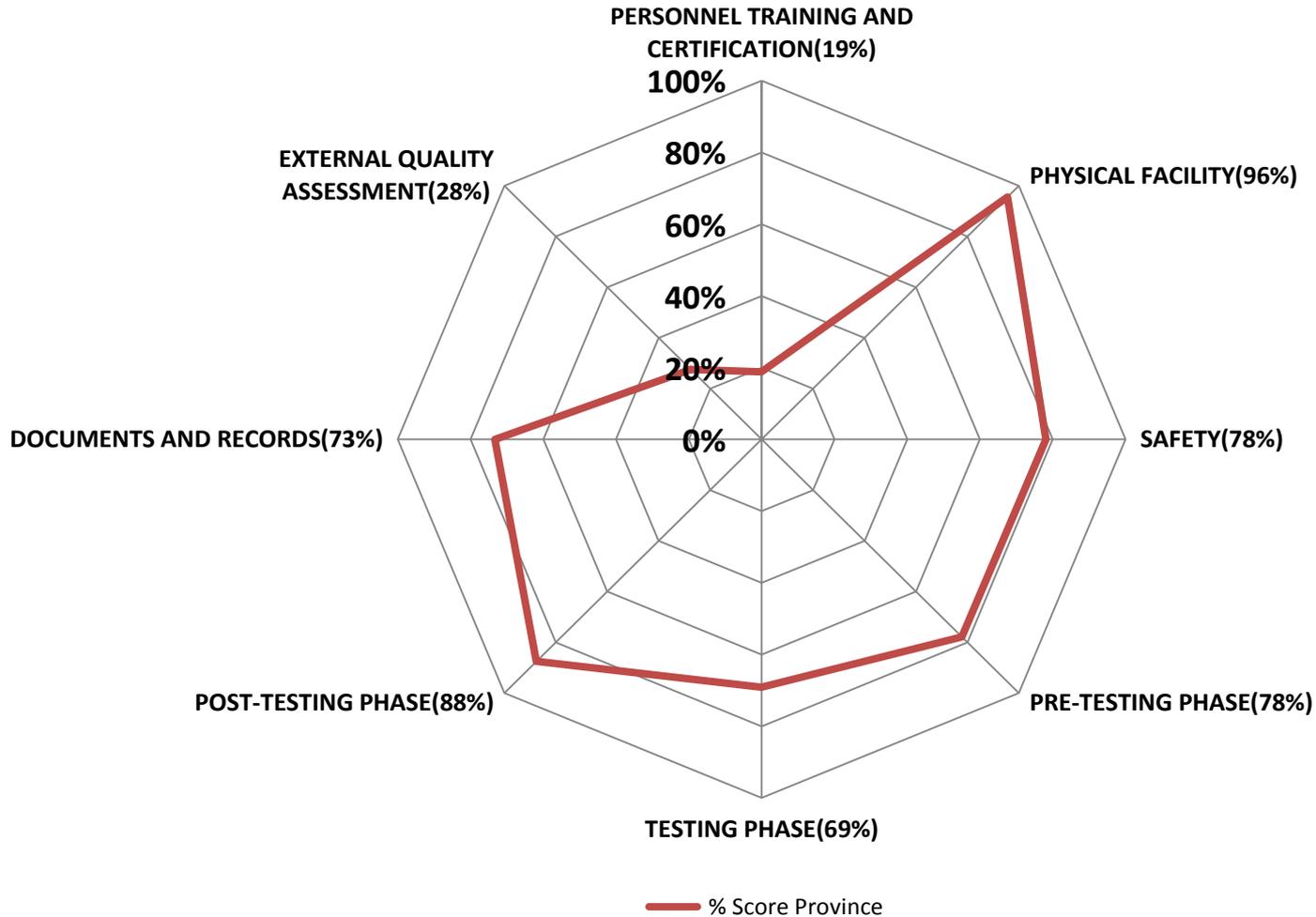
Five pre-certification levels for testing sites



Eastern Cape: Site Data

District	Number of sites	SPI RT Level 1	SPI RT Level 2	Average % Score per District
Amatole	13	4	9	64%
Alfred Nzo	13	5	8	60%
NMMM	14	10	4	60%
Sarah Baartman	10	2	8	64%
Chris Hani	13	2	11	65%
Joe Gcabi	13	4	9	52%
OR Tambo	11	6	5	60%
TOTAL	87			

% Score: Provincial (n= 87)





Common Deficiencies

Training and Certification

- No evidence of training documents on site
- Records of competency not available
- No refresher training available
- No National certification Program in place

Pre-testing

- No SOPs/Job aides in place for tests
- Current national algorithm not used
- Tests kits not labeled

Testing Phase

- Testing procedure not adhered to
- Job aids not available
- Timers available but not working
- QC Logs not reviewed by supervisor

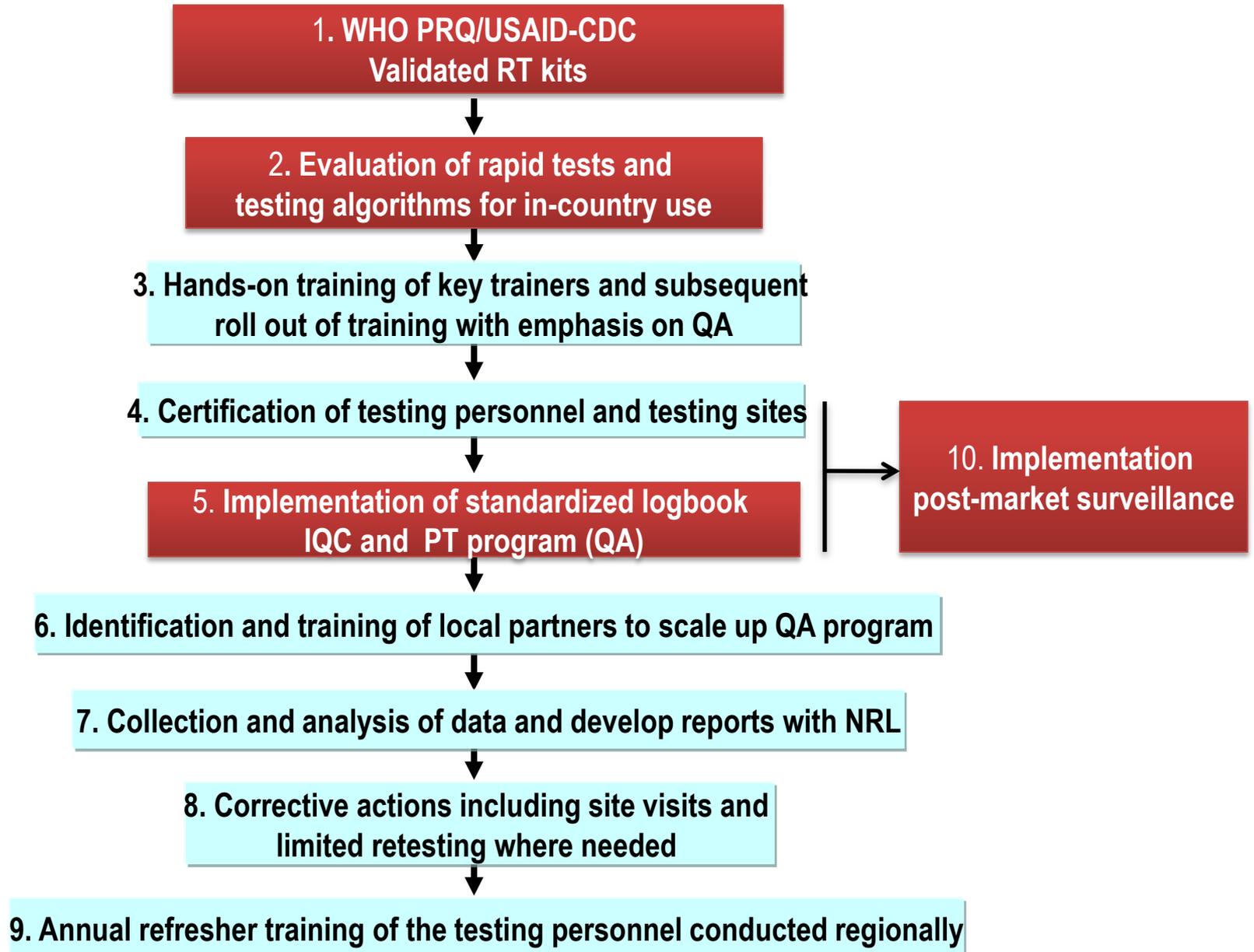
Post-testing phase

- National standardized register not used (PHC Register used)
- No disinfection of testing area

External Quality Assessment

- EQA(PT) not implemented

Multi-Step Approach to QA





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