

Xpert MTB/RIF use for TB
diagnosis in TB suspects with no
significant risk of drug resistance
or HIV infection

Results of Group Work

DOTS expansion and enhancement

Objective

- This group deals with the majority of TB suspects and patients
- Most patients needing immediate and more specialized/ additional care are excluded into HIV and DR-TB algorithms
- Primary objective is for early and increased case detection
 - Smear negatives are difficult to diagnose and current algorithm not being practiced
- Global level broad guidance but decisions at country level
 - Promote countries to develop models

Consensus...1

1. Introduction of Xpert should include district level, or sub-district level facilities, preferably, but not limited to, facilities with quality CXR / (public and private)
 - Discussion points for the agreement:
 - Epidemiological situation / individual patient risk factors / level of health system
 - Public health goals versus individual patient care
 - PAL and health system links
 - NTPs and Partners will buy machines – guidance required on where and how to use them given the cost of cartridges

Consensus...2

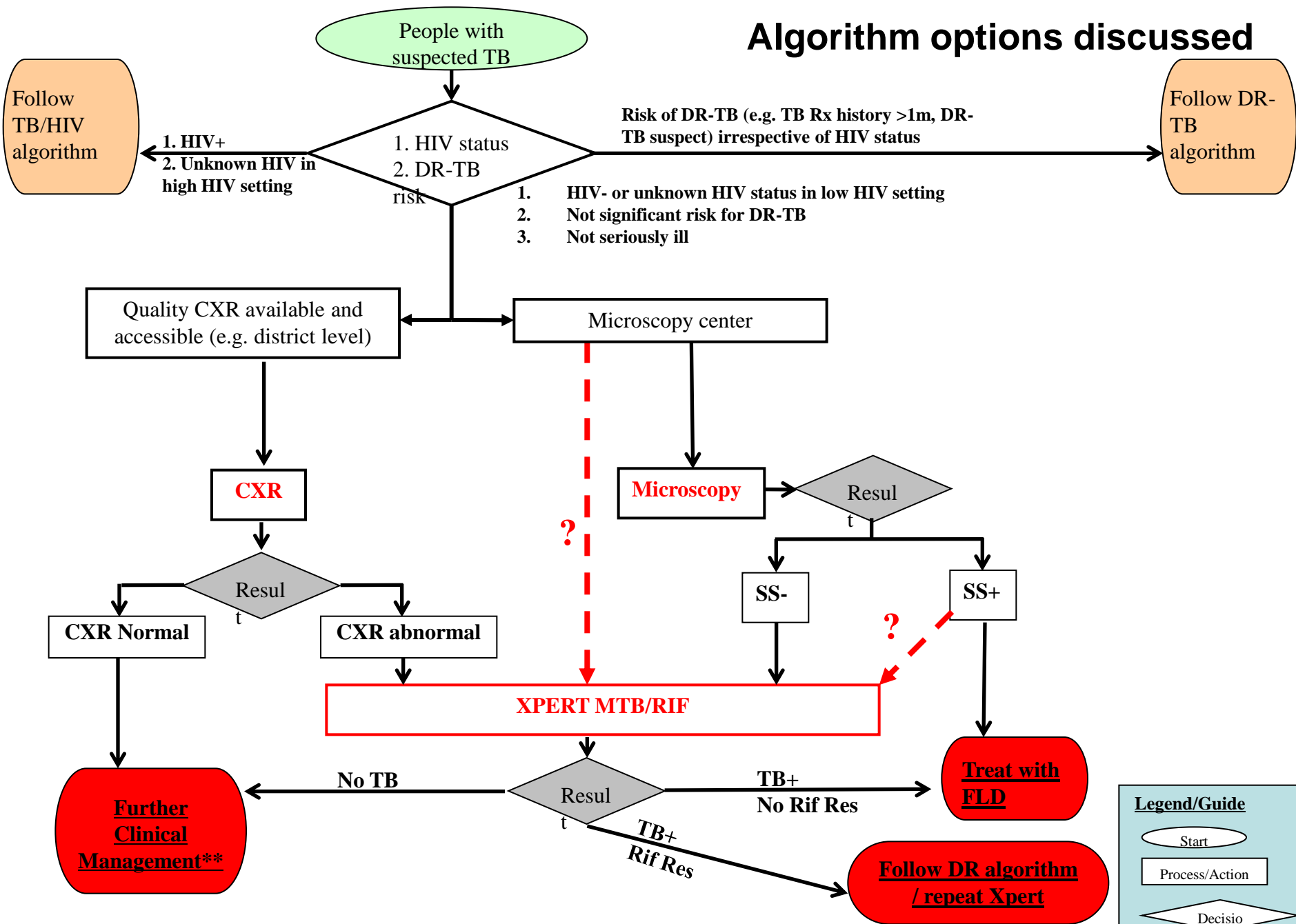
2. For all health facilities develop country level models and test them (public and private)

- Consider:
 - Local context of flow patterns for patient, specimen and result
 - Balance between decentralization, local needs, hardware feasibility
 - Prioritization is a country level decision
 - Consider SS- suspects, abnormal CXR
 - Amongst SS- decide which risk groups require Xpert on a priority
 - Do not exclude pediatric, private sector, etc.

Consensus....3

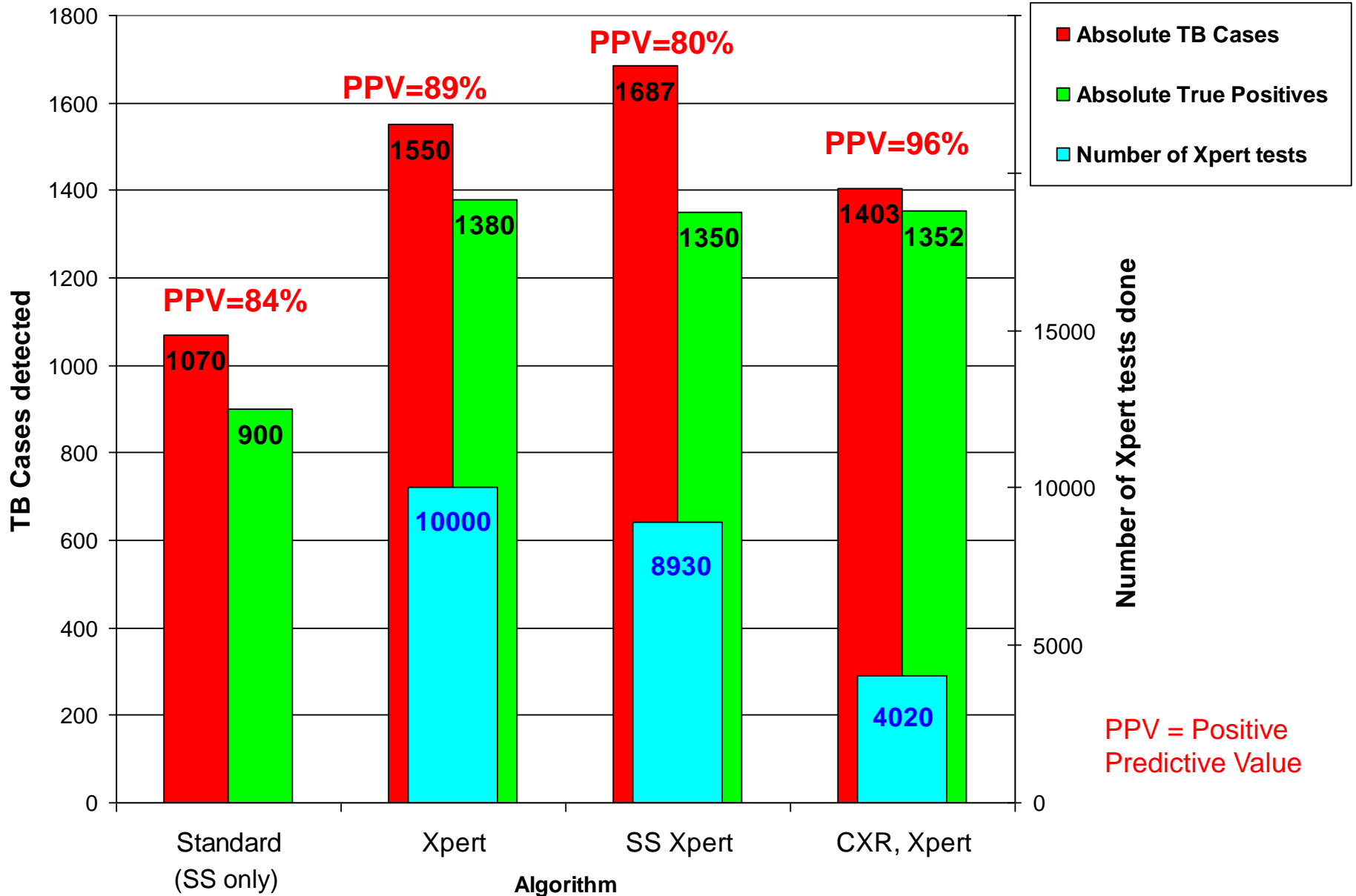
3. Diagnostic algorithms

Algorithm options discussed

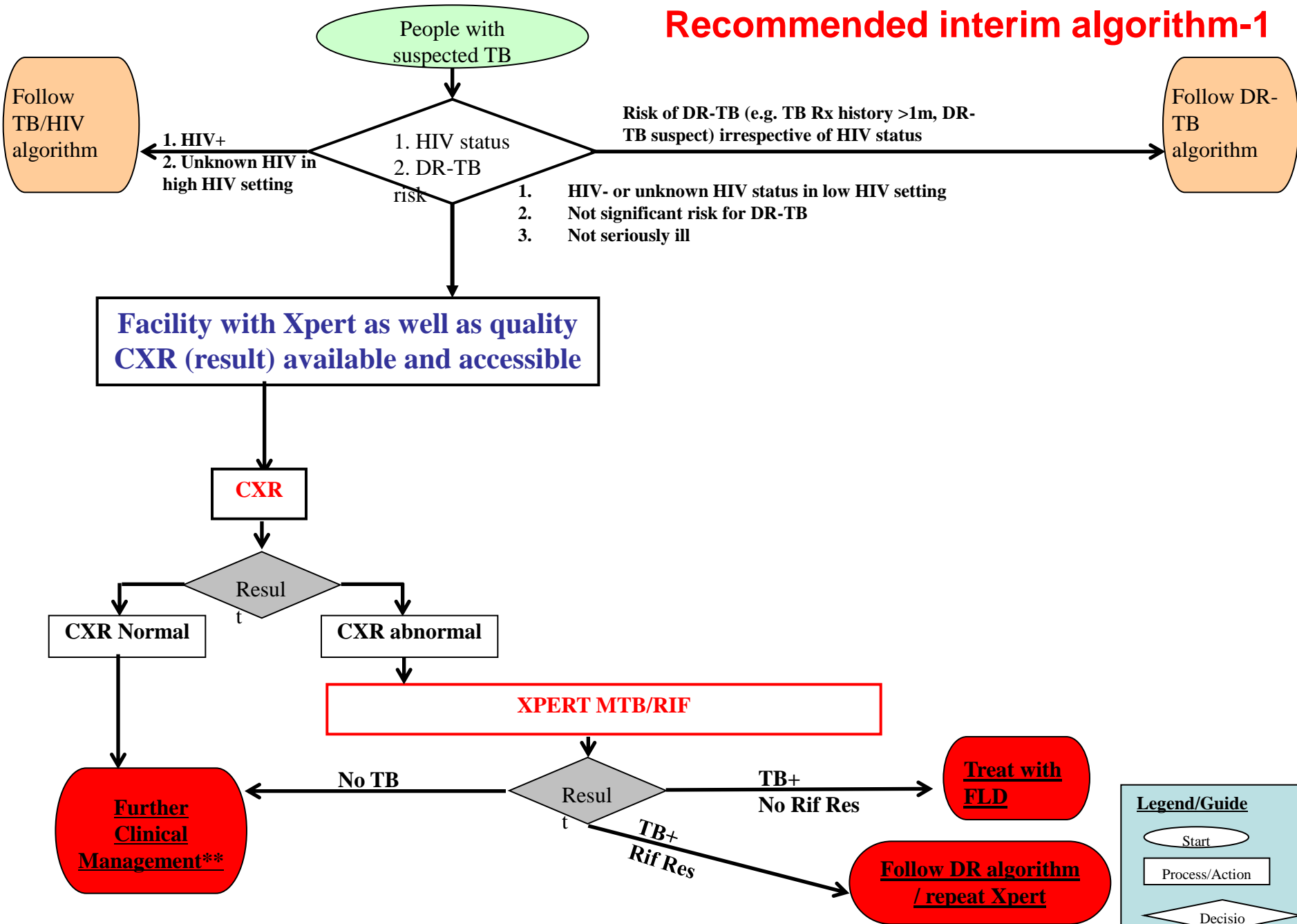


**TB diagnosis can not be totally ruled out, particularly for the TB suspects who have normal CXR and did not undergo any bacteriological examination. For this specific category of patients, a sputum smear examination may be needed.

Absolute Increases in bacteriologically identified Case Detection Asuming 15% C+ in Population of 10,000 TB Suspects



Recommended interim algorithm-1

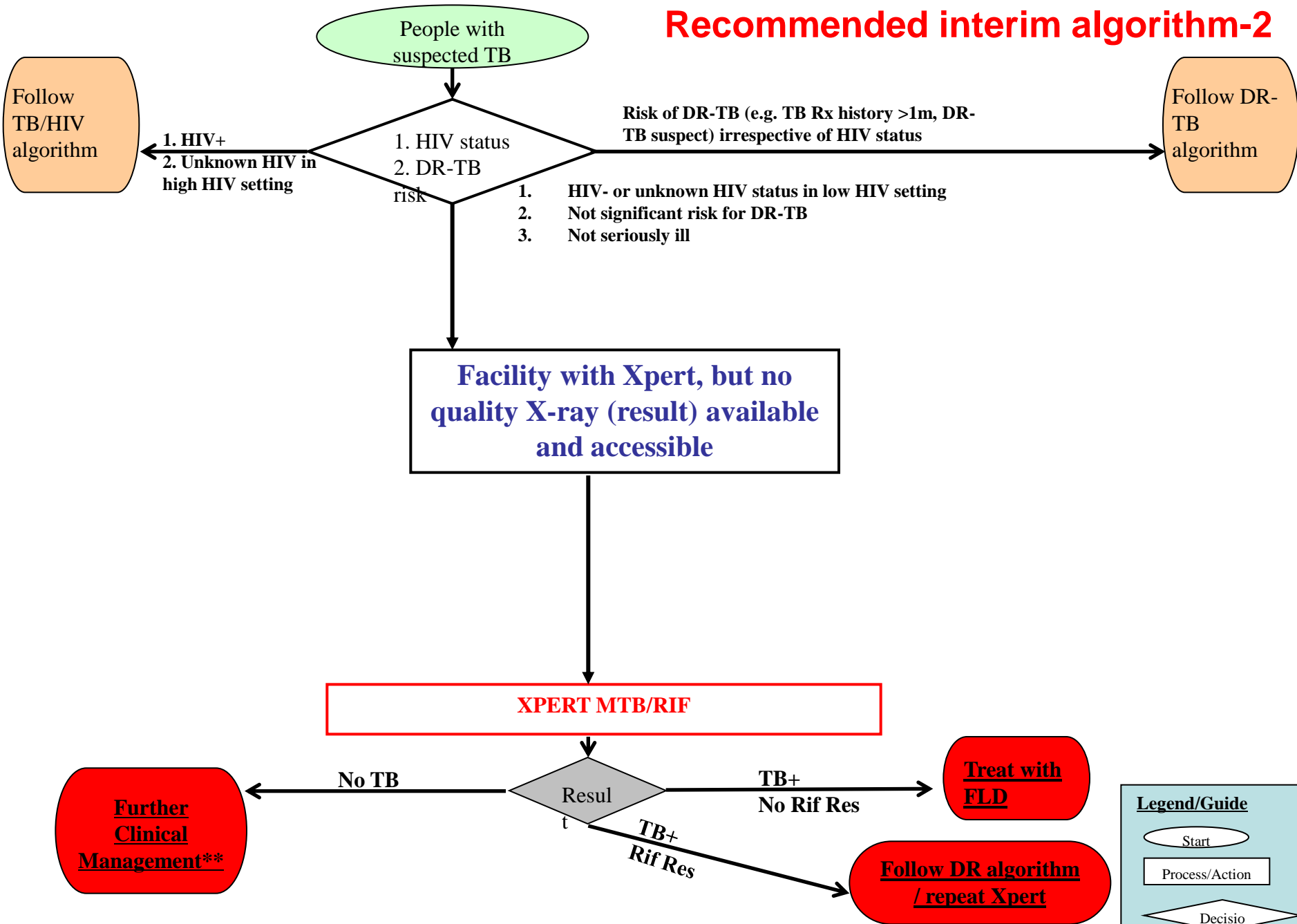


Legend/Guide

- Start
- Process/Action
- Decision
- Endpoint

**TB diagnosis can not be totally ruled out, particularly for the TB suspects who have normal CXR and did not undergo any bacteriological examination. For this specific category of patients, a sputum smear examination may be needed.

Recommended interim algorithm-2

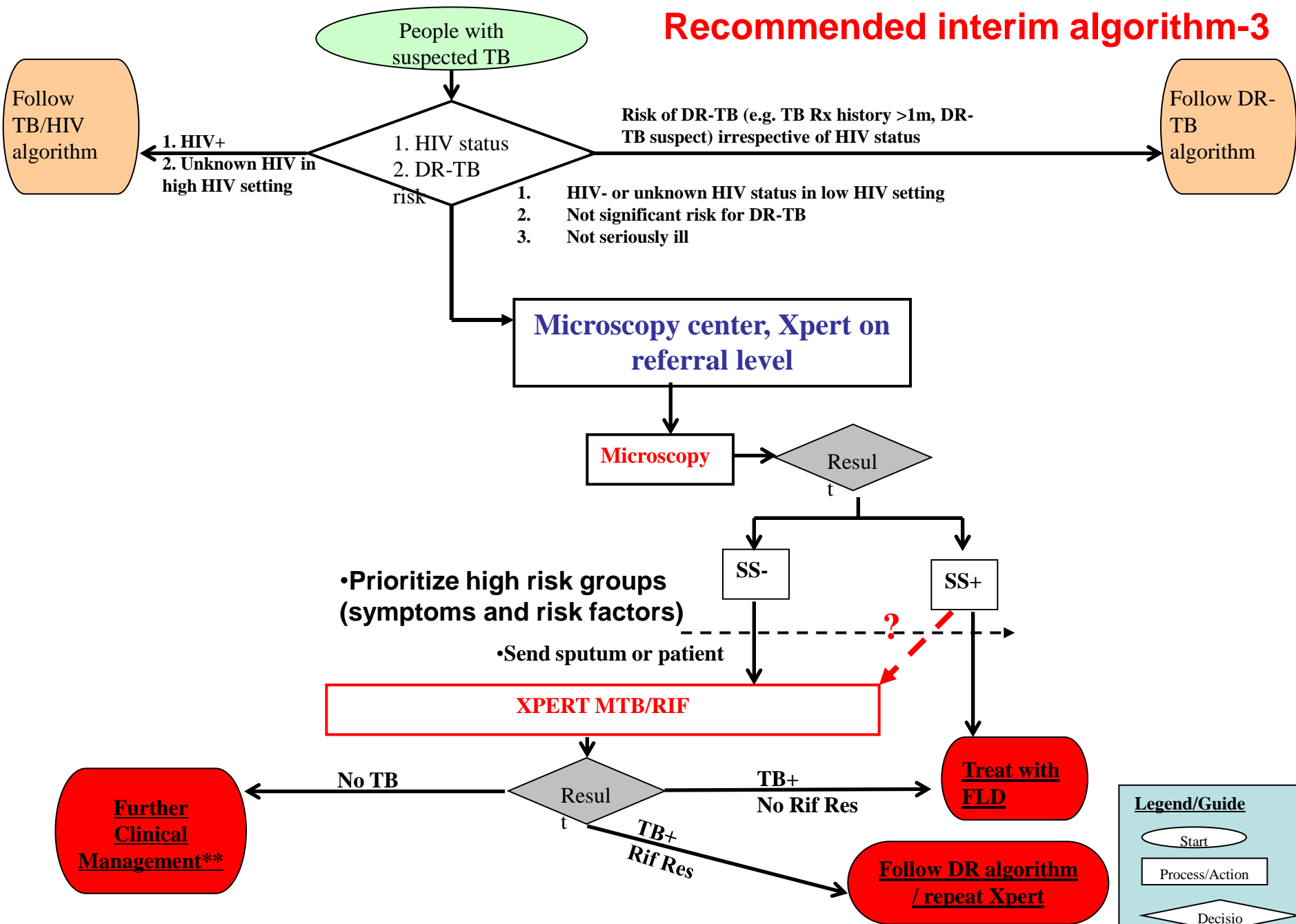


Legend/Guide

- Start
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**TB diagnosis can not be totally ruled out, particularly for the TB suspects who have normal CXR and did not undergo any bacteriological examination. For this specific category of patients, a sputum smear examination may be needed.

Recommended interim algorithm-3



Legend/Guide

- Start (Green oval)
- Process/Action (White rectangle)
- Decision (Grey diamond)
- Endpoint (Red rounded rectangle)

**TB diagnosis can not be totally ruled out, particularly for the TB suspects who have normal CXR and did not undergo any bacteriological examination. For this specific category of patients, a sputum smear examination may be needed.

Footnotes to algorithms

- Algorithm is for adults
- Seriously ill patients are not included
 - Likely to be a very small proportion – will require quick and appropriate clinical management, including referral for hospitalization.
- Process of diagnosis to be completed on a single day

Opportunities

- For reemphasising policy
 - On front loaded microscopy; HIV testing for TB suspects; PAL
- Health system related
 - Investing on CXR
 - Use of Xpert for other diseases
 - Human resource benefit from Xpert
 - Engaging private sector
- CXR
 - QA, new X-ray technology, automated reading technology
 - Collecting evidence on CXR containing algorithm as a whole
- Strengthening specimen referral system
- Improving quality assurance of smear microscopy
- Improving availability of drugs for additional patients
- Electronic notification, data storage, inventory

Unresolved issues

- Diagnostic algorithm for pediatric TB
- Case definitions and treatment outcome definitions
- Treatment monitoring tool
 - Need to preserve smear in monitoring of TB treatment
- Scaling up availability of quality Xray – Health system issue
- Xpert in low burden setting / active case finding
 - Role of screening tests, or repeat Xpert to increase PPV
- Regulatory issues related to Xpert

Operational research questions

- Reassess the definition of TB suspect
- Proportion of TB suspects with CXR already available & quality of CXRs
- Cost and CE of different algorithms and definitions of TB suspect
- Impact of the whole algorithm in different settings and risk groups
 - Additional yield, sensitivity, specificity and predictive values
 - Impact on treatment and patient management
 - Impact on access to care by different socio-economic groups
- Performance of Xpert in remote and peripheral settings
- Performance of Xpert in pediatric TB suspects
- Use and results of screening tests in the FIND demonstration studies
- Impact of automated, electronic notification from Xpert machines for improving patient care and engaging all care providers using Xpert

- In addition, basic minimum data to be collected within programmatic M&E
- OR questions should not impede scaling up

Private sector and Xpert

- PPM subgroup to work on this and form a global task force
- In addition, include in the discussion with the manufacturer:
 - Creating inventory of Xpert machines supplied to private sector
 - Use the incentive of negotiated pricing of cartridges/machines for linking private providers to NTP

Key next steps

- Finalize algorithm and guidance
- Announce WHO policy
- Disseminate policy and guidance to countries and donors
- Provide technical assistance

Thanks

CXR considerations

- CXR is a good screening test, not a diagnostic test
- In many settings a large proportion of TB suspects already have a CXR done
 - Because of clinical practice for management of patients with respiratory symptoms, both in public hospitals and private sector
- Benefits of using CXR to screen TB suspects prior to Xpert:
 - increases pre-test probability and therefore PPV for Xpert;
 - reduces the number of Xpert test (cost) by screening out TB suspects with normal CXRs

Assumptions and principles

Beyond the current algorithm for improved early case detection

- Intensified early case detection of **all TB cases** is essential for TB control
- **Delays and patient costs** need to be substantially decreased
- Beyond finding the appropriate place of Xpert in the current algorithms, we also need to **re-consider the whole algorithm**, including potentially changed role of microscopy and X-ray for screening, diagnosis and case categorization.
- X-ray is already widely used. It is a poor tool for diagnosis of TB, but a good TB screening tool, if used correctly.
- There are other new tools in the pipeline that may be more relevant in low MDR settings

Principles in the ISTC and patient charter

- "To prove a diagnosis of tuberculosis, every effort must be made to identify the causative agent of the disease." (ISTC-2)
- "All persons with chest radiographic abnormalities should have sputum specimens submitted for TB laboratory examination." (ISTC-4)
- The diagnosis of TB should be provided free of cost to the patient (Patient Charter), this includes the cost of microscopy, CXR, Xpert MTB/RIF and culture.
- Prompt notification of all definite TB cases, including those diagnosed by Xpert, should be done by all care providers (ISTC-17)