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

DOTS expansion and enhancement

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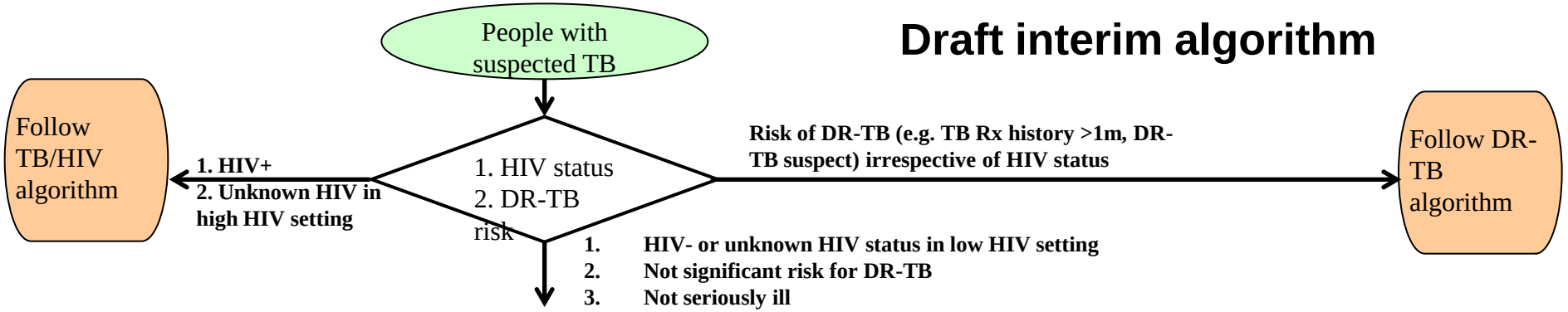
Assumptions and principles

- 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.
- "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.

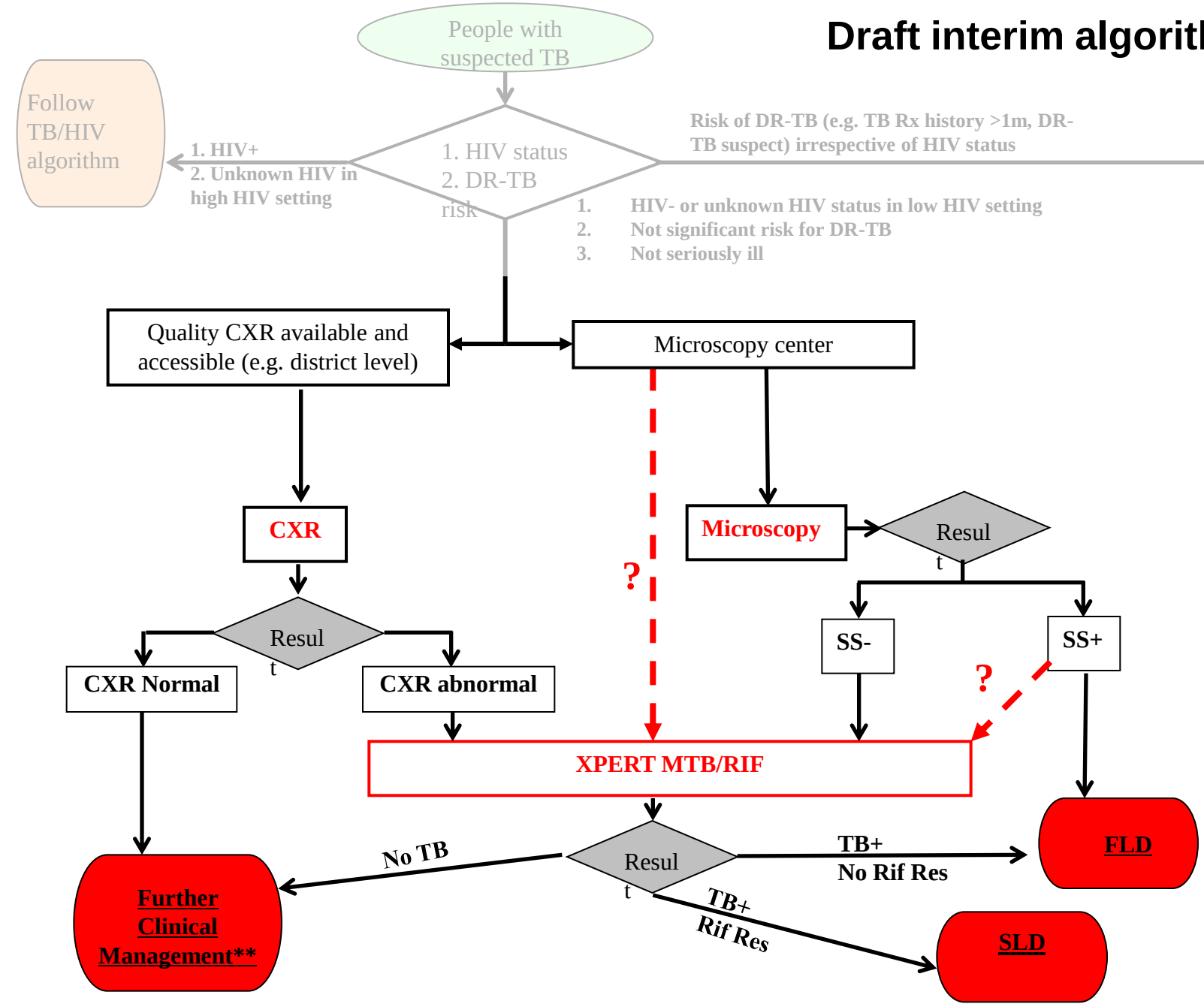
Draft interim algorithm



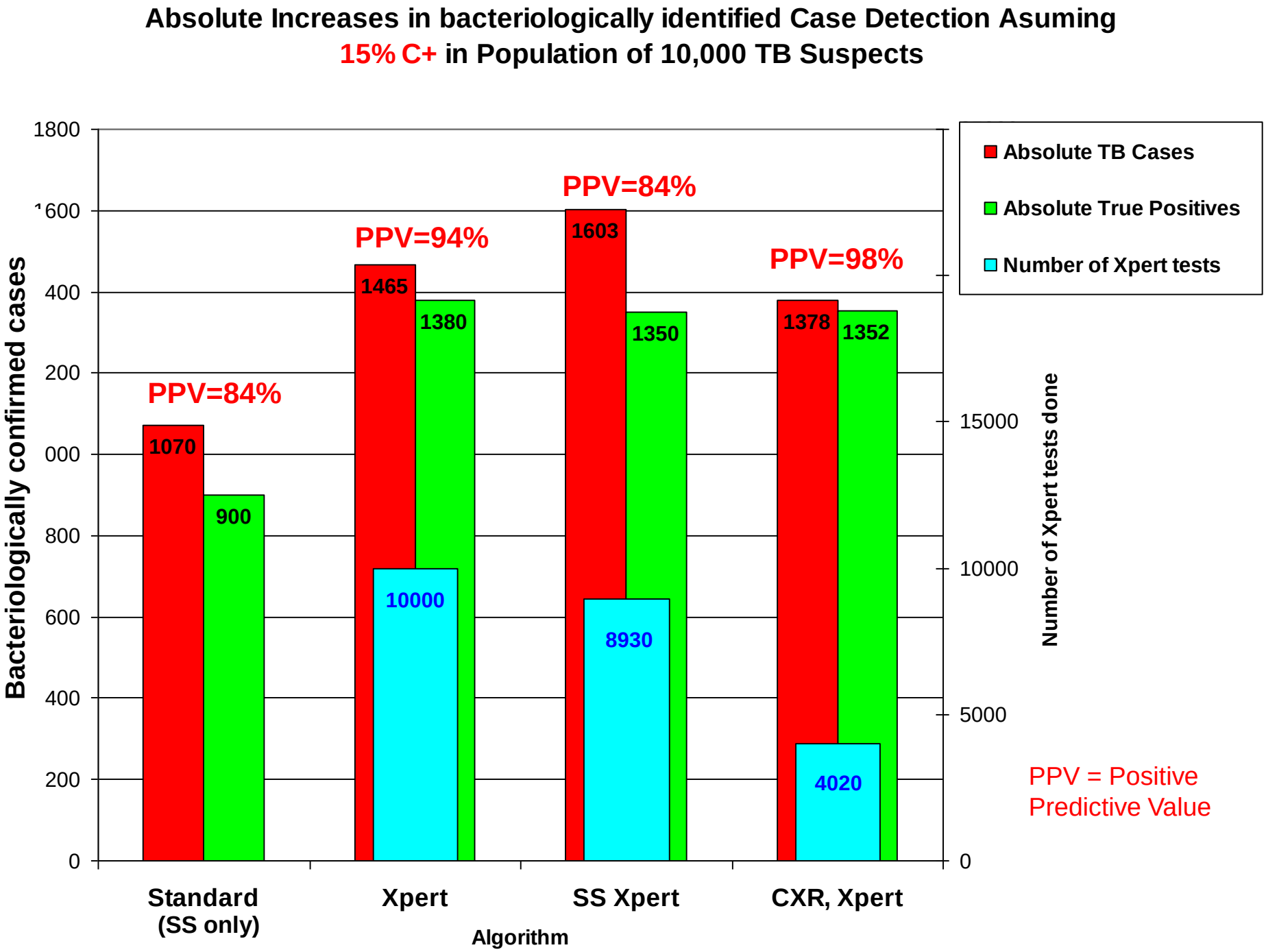
?

- Not enough resources to do Xpert for all suspects
- Use Xpert in high risk groups only?
- Add screening step before confirmation with Xpert?

Draft interim algorithm



**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
Absolute TB Cases
Absolute True Positives
Number of Xpert tests
Bacteriologically confirmed cases
Number of Xpert tests done
1800
1600
400
200
000
800
600
400
200
0
15000
10000
5000
0
PPV=84%
1070
900
PPV=94%
1465
1380
10000
PPV=84%
1603
1350
8930
PPV=98%
1378
1352
4020
Standard
(SS only)
Xpert
SS Xpert
CXR, Xpert
Algorithm
PPV = Positive
Predictive Value

Discussion points

- In what epidemiological situation, and for what target groups (other than people at risk of HIV or MDR) is it relevant and high priority to use Xpert?
- Ethical issues around MDR diagnosis. Consider other available and emerging tests that may be more appropriate when low MDR prevalance and/or no PMDT?
- What are the implications for use of smear and X-ray when Xpert is introduced?
- Where is the appropriate place of Xpert in the health system and what are the financial and logistic challenges and what are the capacity strengthening needs for Xpert, X-ray, smear microscopy, R&R, etc?
- What are the health systems strengthening implications, pros and cons of different algorithms?
- Strategy for Xpert use in the private sector:
  - Maintain global inventory of the sale of Xpert machines outside public sector TB programmes
  - Need to notify TB and manage TB according to Standards
  - NTPs to seek information on Xpert buyers in the country and proactively engage them
  - Offer Xpert at subsidized costs to NTP affiliated private providers offering free TB care?
- Should a generic operational research protocol be prepared and promoted in all settings implementing Xpert? What are the priority research questions?

Low TB prevalance in suspects, active case finding, etc: Absolute Increases in bacteriologically identified Case Detection Asuming 5% C+ in Population of 10,000 TB Suspects