Implementation of the Xpert MTB/RIF assay for tuberculosis in Mongolia: a qualitative exploration of barriers and enablers

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Objective: The aim of our study was to identify barriers and enablers to implementation of the Xpert MTB/RIF test within Mongolia's National Tuberculosis Program.

Methods: Twenty-four semi-structured interviews were conducted between June and September 2015 with laboratory staff and tuberculosis physicians in Mongolia's capital Ulaanbaatar and regional towns where Xpert MTB/RIF testing had been implemented. Interviews were recorded, transcribed, translated and analysed thematically using NVIVO qualitative analysis software.

Results: Eight laboratory staff (five from the National Tuberculosis Reference Laboratory in Ulaanbaatar and three from provincial laboratories) and sixteen tuberculosis physicians (five from the Mongolian National Center for Communicable Diseases in Ulaanbaatar, four from district tuberculosis clinics in Ulaanbaatar and seven from provincial tuberculosis clinics) were interviewed. Major barriers to Xpert MTB/RIF implementation identified were: lack of awareness of program guidelines; inadequate staffing arrangements; problems with cartridge supply management; lack of local repair options for the Xpert machines; lack of regular formal training; paper based system; delayed treatment initiation due to consensus meeting and poor sample quality. Enablers to Xpert MTB/RIF implementation included availability of guidelines in the local language; provision of extra laboratory staff, shift working arrangements and additional modules; capacity for troubleshooting internally; access to experts; opportunities for peer learning; common understanding of diagnostic algorithms and decentralised testing.

Conclusion: Our study identified a number of barriers and enablers to implementation of Xpert MTB/RIF in the Mongolian National Tuberculosis Program. Lessons learned from this study can help to facilitate implementation of Xpert MTB/RIF in other Mongolian locations as well as other low-and middle-income countries.

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Introduction

In December 2010, the World Health Organization (WHO) formally endorsed use of Xpert MTB/RIF as a new diagnostic tool for active tuberculosis (TB) disease.[1] Since then, use of Xpert MTB/RIF has increased dramatically. Between 2010 and 2015, under concessional pricing arrangements, 4,672 GeneXpert machines had been procured in 122 of the 145 eligible countries, including Mongolia.[2]

Mongolia, a country with a TB burden of 428 incident cases per 100,000 population in 2015 (95% confidence interval 220–703)[3], has been a relatively late adopter of the Xpert MTB/RIF assay. At the time of the first introduction of MTB/RIF in Mongolia at the end of 2013, other countries had already analysed their experiences with implementation of Xpert MTB/RIF.[4] It was, however, not until 2014 that the WHO published a 'How-To' Xpert MTB/RIF implementation manual.[5] It is therefore of interest to explore the specific challenges with Xpert MTB/RIF in Mongolia.

The National Tuberculosis Reference Laboratory (NTRL) in Ulaanbaatar was the first laboratory in Mongolia to implement Xpert MTB/RIF testing in November 2013. By the end of 2014, there were three GeneXpert machines being used in Mongolia – at the NTRL in Ulaanbaatar, the Hospital of Darkhan-uul, in the northern Darkhan-uul province, near the Russian border, (since June 2014) and the Regional Diagnostic and Treatment Center of Dornod, in Dornod province, Mongolia's easternmost province, bordering Russia and China (since March 2014). The funding for these machines was supplied by the Global Fund through a series of projects. In 2013, 310

patient samples were tested using Xpert MTB/RIF. This had increased to 3,289 in 2014, 3,802 in 2015 and 3,991 in 2016 (Table 1).

Diagnostic tools such as Xpert MTB/RIF must be considered in the context of their organisational environment to understand the value of their technical benefits in real terms. Such benefits include the relatively short time frame to determine a result (2 hours) and ease of use compared to other diagnostic methods. Understanding the operational issues associated with implementation of the Xpert MTB/RIF test ensures these technical benefits can be maximised.

In recent years a number of studies have assessed the performance of the Xpert MTB/RIF assay, specifically, the accuracy and cost effectiveness of Xpert MTB/RIF have been well documented.[6-11] Only few research studies, however, have investigated implementation issues from an organisational perspective,[4,12-16] two of which included qualitative tools designed specifically for the study to gather information on user experiences and challenges related to Xpert MTB/RIF implementation.[4,15] Some of the identified challenges associated with Xpert MTB/RIF implementation in low-and middle income countries include lack of standardised guidance, piecemeal implementation of training, quality assurance, planning processes and equipment servicing and maintenance, issues with continuous power supply and difficulties recording and reporting test results using new technology.[4,15,16]

The aim of our study was to identify and understand system and context specific factors within Mongolia's National Tuberculosis Program (NTP) that are barriers or enablers to implementing the Xpert MTB/RIF test from the perspective of NTP staff.

Methods

Study design, setting and participants

We conducted semi-structured interviews with laboratory staff and TB physicians using an inductive-deductive approach. This approach was chosen because we had knowledge about possible barriers and enablers to GeneXpert implementation from studies in other settings,[4,12-14] while we knew little about contextual factors impacting on Xpert MTB/RIF implementation in Mongolia. We developed semi-structured interview guides (see Appendix A) to collect a wide range of information on participants' experiences and views related to Xpert MTB/RIF use and implementation in Mongolia's NTP. The interview guide was designed based on a literature review of barriers and enablers of Xpert MTB/RIF implementation. These implementation factors were organised into major themes that formed the structure of the interview guide for laboratory staff – guidelines and organisational structures; equipment; training; communication systems; and diagnostic algorithms, case finding for Xpert MTB/RIF, clinical management. A separate interview guide was designed specifically for TB physicians and focused on clinical issues. Open questions were added to the interview guide to explore possible themes that had not been identified from the literature. Two of the researchers (GG and MD) conducted the interviews. Both interviewers were trained in the study protocol and interview technique.

Participants included laboratory staff (doctors, technicians and administrative officers) who were using the Xpert MTB/RIF diagnostic test and TB physicians who were working either at the Mongolian National Center for Communicable Diseases (NCCD) or in any of the district TB clinics in Mongolia's capital Ulaanbaatar, or in the provinces of Darkhan-Uul or Dornod.

Potential participants were approached by one of the researchers (GG or MD) and interviewed once informed consent was obtained. Because there were only few laboratory staff who were using the Xpert MTB/RIF diagnostic test, all of them were invited to participate in the study. Interviews with TB physicians were continued until saturation of data was apparent, that is until no new themes emerged.[17] All interviews were conducted between July and September 2015.

Participants in Ulaanbaatar were interviewed in person where possible, or alternatively over the phone, and participants based outside of Ulaanbaatar were interviewed over the phone. The interviews were conducted and transcribed in Mongolian. The transcripts were then translated into English by one of the researchers (SB). The English transcripts were verified by another bi-lingual member of the research team (MD) to ensure the English version was clear and the participants' views were adequately represented.

Analysis

In order to determine whether participants would interpret interview questions as intended and whether the order of questions may influence responses, we conducted three pretesting

interviews (with two laboratory staff and one TB physician). Pretesting highlighted questions that were poorly understood by respondents. It also showed that some questions were perceived by respondents to be duplicate questions. We edited the interview guides accordingly by reordering, rewording or deleting questions. In addition, pretesting showed that explanatory information provided by the interviewer varied considerably between interviews. In response to this observation, a written introduction explaining the purpose and benefit of the study was added to the interview instrument for the interviewers to read aloud before the interview commenced. This ensured consistent explanatory information was given to all participants prior to the commencement of the interview. The revised interview guides were used for all future interviews. The pretest interviews were not included in the final analysis.

The first (NR) and last author (CCD) independently reviewed transcripts from the first five interviews to identify key themes and subthemes (ie, patterns within the narrative data), then developed a coding scheme through discussion and consensus. This framework was systematically applied to code themes in subsequent interview transcripts. We reviewed the framework after an additional ten interviews, updating it to reflect newly revealed themes and subthemes that were not apparent in earlier interviews. Coding was completed using the software package QSR NVivo version 10 (QSR International Pty Ltd, Doncaster, Victoria, Australia). The English version of each interview transcript was imported into NVivo and then systematically reviewed and coded for common themes and subthemes.

150 **Ethics**

151 The study was approved by the Scientific Council of the Mongolian NCCD.

152

153 Results

154 We contacted 24 NTP staff (8 laboratory staff and 16 TB physicians), all of whom agreed to be
155 interviewed (ie, a 100% response rate). Five laboratory staff members were located at the NTRL
156 in Ulaanbaatar and 3 in provincial laboratories. Of the 16 TB physicians, 5 worked at the NCCD,
157 4 worked in any of the district TB clinics in Ulaanbaatar and 7 worked in the provinces of
158 Darkhan-Uul or Dornod.

159

160 Participants identified a range of barriers and enablers associated with implementation of Xpert
161 MTB/RIF testing in Mongolia based on their experiences. These are summarised in Table 2, and
162 described below according to the following themes: 1) guidelines and organisational structures,
163 2) equipment, 3) training, 4) communication systems, 5) diagnostic algorithms, case finding for
164 Xpert MTB/RIF and clinical management. Laboratory staff participants were interviewed using
165 guiding questions for each theme. For TB physicians, the guiding questions focussed on the last
166 theme, diagnostic algorithms, case finding for Xpert MTB/RIF and clinical management.

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Guidelines and organisational structures

Barriers

Poor awareness of program guidelines: Around half of all participants stated that they were not aware of any written guidelines to support the use of Xpert MTB/RIF *(authors' comment: the Mongolian NTP issued guidelines for all NTP staff, which included information on the use of Xpert MTB/RIF in December 2014).* Instead, many participants referred to training arrangements when asked about NTP guidelines. One participant thought that the English manual for the operation of the Xpert machine was equivalent to the NTP guidelines available to staff. The guidelines did not appear to be clear enough about which samples (type of body fluid/tissue) could be used for testing with Xpert MTB/RIF, in particular if testing of samples other than sputum, e.g. pleural and cerebrospinal fluid, was allowed. This resulted in inconsistent practices regarding Xpert MTB/RIF testing of non-sputum samples (*authors'comment: According to the Mongolian NTP guidelines 2014 the following specimens can be used for Xpert MTB/RIF testing: sputum, urine, stool, pleural fluid, ascites, gastric lavage, and surgical tissue samples*). One laboratory participant suggested that patients are being inappropriately referred for Xpert MTB/RIF testing (inconsistent with guideline recommendations, summarised in Table 3), which was potentially driving excess demand.

Inadequate staffing arrangements: Participants identified that their workload had increased in response to the introduction of the Xpert MTB/RIF testing into their laboratories, and inadequate staffing was mentioned as a problem by staff of the NTRL in Ulaanbaatar.

192 ***Enablers***

193 ***Clear guidelines in local language:*** Participants, who were aware of the NTP guidelines, found
194 the guidelines useful for working with Xpert MTB/RIF and they understood how to apply the
195 guidelines in practice.

196 ***Extra staff, shift working arrangements, increase of Xpert MTB/RIF modules:*** Staff of the
197 regional laboratories felt that while there was an initial increase in their workload, their staffing
198 arrangements and laboratories were able to accommodate the change. Staff of the NTRL in
199 Ulaanbaatar suggested a range of options to improve their ability to meet the demand. These
200 included additional staff, a staff member allocated only to Xpert MTB/RIF, shift arrangements,
201 installing more GeneXpert machines or a new GeneXpert machine with a greater number of
202 modules (in order to perform more tests at the same time).

203

204 Equipment

205 ***Barriers***

206 ***Poor supply chain management of cartridges (stock-outs):*** Since implementation of Xpert
207 MTB/RIF testing, the only time the test had been unavailable for about a month was due to a
208 cartridge supply issue that affected all the laboratories that offered Xpert MTB/RIF testing.
209 Other than this occasion, cartridge supply appeared to be well managed.

210 ***Absence of local repair options:*** Mongolia's harsh climate and low population density generally
211 did not appear to have affected transportation of cartridge supplies or equipment. Although,
212 one of the modules in one of the regional machines had broken on arrival and there were
213 difficulties arranging its repair. The lack of expertise to repair GeneXpert machines in the

provinces was identified as a problem. This was in contrast to other laboratory equipment, which could be repaired by the available engineers.

Enabler

Capacity for troubleshooting internally: Other temporary problems with the GeneXpert machine have occurred without major interruption to the workflow because local staff were able to remedy them easily. For example, one laboratory participant mentioned that the laboratory had bought an uninterruptable power supply in response to manage issues with the power supply.

Training

Barrier

Inconsistent formal training options: The training that laboratory staff had received on the operation of Xpert MTB/RIF varied widely. Some laboratory staff participated in formal training courses, others learned on the job through instruction by trained colleagues or superiors. Two members of laboratory staff based in Ulaanbaatar participated in an online training course organised by the supplier of the GeneXpert machines. Components of different trainings included operation and maintenance of GeneXpert, but also information on indications for GeneXpert use in Mongolia.

When asked about the value of the training received, most laboratory staff felt that it was sufficient to meet their job requirements. While staff in Ulaanbaatar were satisfied that the training they had received equipped them to use Xpert MTB/RIF testing, regional laboratory staff were keen to receive further training.

There were also differences in the training opportunities provided for other TB diagnostic methods, primarily smear testing. Laboratory staff were aware of scheduled annual trainings for smear testing, but were unsure about any future and/or regular ongoing training opportunities for Xpert MTB/RIF testing.

Enablers

Access to experts: Access to external experts to support implementation of Xpert MTB/RIF differed for staff based in regional clinics and those based in Ulaanbaatar. Regional laboratory staff received guidance from NTRL staff, who received guidance directly from international experts.

Peer learning: All staff recognised the value of learning from their peers.

Communication systems

Barrier

Paper based system: Results of the Xpert MTB/RIF test were communicated to TB clinics using paper forms that were delivered using one or more of the following options: 1) patients collected the paper form directly from the laboratory and took it to the doctor at the TB clinic, 2) doctors were contacted over the phone and informed about the results ahead of receiving the paper form, and 3) doctors and/or nurses collected the results on paper directly from the laboratory. Paper reports were associated with delays of 2 days on average to receive the results following a request being sent to the laboratory. A few TB physicians suggested the delay was longer, up to a week, and one TB physician even suggested that the delay between

257 requesting Xpert MTB/RIF testing to receiving the result was up to 2 weeks. Urgent requests
258 were prioritised.
259

260 Diagnostic algorithms, case finding for Xpert MTB/RIF and clinical management

261 ***Barriers***

262 ***Treatment initiation in MDR-TB delayed until after consensus meeting***: Treatment for drug
263 sensitive cases (who tested positive for TB on GeneXpert, but negative for rifampicin resistance)
264 was usually started immediately after physicians received the results. TB physicians described
265 that the delay to initiating treatment for presumptive MDR-TB (following a positive result for
266 rifampicin resistance), as well as the specifics of the MDR-TB treatment regimen depended on
267 the timing of the weekly MDR-TB meeting (held at the central NTP office in Ulaanbaatar, to
268 discuss each case of MDR-TB in Mongolia and decide on the best approach for the patient's
269 treatment). Some participants reported that there was no delay in commencing treatment
270 following a positive test for rifampicin resistance. Others reported that it took 1 to 2 weeks to
271 initiate treatment because the treatment could not commence until the treatment plan had
272 been agreed upon at the MDR-TB meeting.
273 ***Poor sample quality:*** 'Error results' from Xpert MTB/RIF testing (i.e., notification of an error is
274 displayed in the Check Status screen of the GeneXpert machine) were reported to occur
275 occasionally. In these instances, the test was always redone and some participants reported
276 that error results triggered machine maintenance as well. The quality of the sample (e.g. when
277 patients did not collect sputum correctly) was reported as the most common reason for error
278 results experienced by participants when using Xpert MTB/RIF testing.

279 ***Enablers***

280 ***Common understanding of indications for Xpert MTB/RIF testing****:* Both laboratory staff and TB
281 physicians were aware of the approved indications for Xpert MTB/RIF use in Mongolia (Table 3),
282 including testing in patients with possible MDR-TB (patients with TB relapse, positive sputum
283 smear result at the 3rd and 5th month of treatment and screening of MDR-TB close contacts), as
284 well as testing for confirmation of TB (smear negative cases with abnormal chest x-ray and very
285 ill patients with uncertain diagnosis).
286 There was variation in the details of each participant's response regarding indications for
287 GeneXpert use, but broadly the indications as outlined above were consistent among
288 participants and consistent with Mongolian guidelines (see table 3).
289 ***Testing availability in provincial centres (decentralised):*** Participants from the provinces
290 pointed out that while Xpert MTB/RIF testing is available in regional areas of Mongolia, samples
291 need to be sent to the central reference laboratory in Ulaanbaatar for further drug
292 susceptibility testing from culture. They did, however, still value access to Xpert MTB/RIF
293 testing, because it meant that a rapid diagnosis of drug resistant TB was possible in the regional
294 areas when previously, it could only be done in Ulaanbaatar.
295 Most physicians had not experienced difficulties starting their patients on MDR-TB treatment
296 following a diagnosis of rifampicin resistance. However, those that did reported that the reason
297 they could not commence treatment was because of patient related factors rather than
298 program related issues.
299
300

Suggestions for future Xpert MTB/RIF implementation and scale up

All study participants viewed the new diagnostic technology positively and appreciated the time saving benefits unique to the Xpert MTB/RIF test. When asked about what future changes they would like to see to implementation of Xpert MTB/RIF testing in Mongolia, participants highlighted the need for change in the following three areas:

- Increase in the number of available sites for Xpert MTB/RIF testing (upscaling to more districts of Ulaanbaatar and more provinces in Mongolia)
- Use of Xpert MTB/RIF to test for drug resistance on all smear positive patients before starting treatment
- Increase in the number of machines at existing sites.

Discussion

This study highlighted a range of potential factors within the Mongolian NTP that served as a barrier or enabler to the implementation of Xpert MTB/RIF testing. While all study participants appreciated the benefits of the new diagnostic technology, potential barriers discussed included lack of awareness of program guidelines; inadequate staffing arrangements; problems with cartridge supply management; lack of local repair options for the Xpert machines; lack of regular formal training; paper based system; delayed treatment initiation due to consensus meeting and poor sample quality. Enablers included availability of guidelines in the local language; provision of extra laboratory staff, shift working arrangements and additional modules; capacity for troubleshooting internally; access to experts; opportunities for peer

322 learning; common understanding of diagnostic algorithms and decentralised testing. Lessons
323 learned from this study can inform the implementation and upscaling of GeneXpert in other
324 settings in Mongolia and in other low-and middle income countries.
325
326 Policies and guidelines as well as training opportunities provided by an organisation facilitate
327 the uptake of any new technology.[5] In our study, those that knew about the NTP's guidelines for
328 the use of GeneXpert found them to be invaluable. However, only around half of study
329 participants were aware of any guidelines relating to GeneXpert use and relied on random
330 opportunities for training and/or visits from national and international experts to advise them
331 on the use of Xpert MTB/RIF. Adherence to program guidelines, which should incorporate Xpert
332 MTB/RIF testing into the national diagnostic strategy and algorithms,[5] is important for
333 sustainable implementation of Xpert MTB/RIF in a local context. Diagnostic algorithms and
334 other policies outlined in program guidelines are essential to realise and maximise the potential
335 of new technologies in practice.[18-20]
336
337 Only staff from NTRL, but not from the regional laboratories, had concerns about their capacity
338 to meet the demand for Xpert MTB/RIF testing. This is most likely because the regular requests
339 for the population that the NTRL laboratory covered went above their pre-existing surge
340 capacity. In contrast, the regional laboratories only felt under pressure initially, while they were
341 still learning how to use the technology. A feasibility study conducted in India also found that in
342 a decentralised setting, there were minimal infrastructure modifications and human resource
343 concerns following the implementation of Xpert MTB/RIF testing.[14] The lower population

density in settings covered by existing laboratories in the decentralised and regional areas, potentially allowed the introduction of new diagnostic technology using the pre-existing surge capacity of the laboratory workforce.

Issues with the infrastructure supporting Xpert MTB/RIF testing were observed by many laboratory staff and focused on the one month where cartridge supply was an issue, and to a lesser extent, access to repairs. In our study the demand for cartridges was met without expiration issues due to high turnover of cartridges, except for one month when the cartridge supply was exhausted. No Xpert MTB/RIF testing could be undertaken during this month. Previous studies investigating Xpert MTB/RIF implementation have highlighted the importance of program levers to assist in the management of cartridge supply.[4,13] They have suggested measures such as staggered cartridge shipments and design of diagnostic algorithms that combine Xpert with other methods to increase yield.[4,13] A Brazilian study assessing the pilot implementation of Xpert MTB/RIF calculated that 10% of Xpert MTB/RIF equipment needed replacement during the nine month pilot study, yet spare parts were not immediately available.[13] Although our study did not quantify faulty equipment, a similar experience of limited access to repairs was observed by laboratory staff. The authors of the Brazilian study suggested that both cartridge supply and maintenance should be negotiated with manufacturers.[13]

Communication of Xpert MTB/RIF results occurred through different methods that were paper based and reliant on the accuracy of the contact information written on the Xpert MTB/RIF

366 request form. Interestingly, no participant would have preferred computer based record
367 keeping or an online system, although administrative reports were generated weekly on a
368 computer, based on the information in the paper forms. A study undertaken in two Brazilian
369 cities found that the implementation of concomitant IT technology to support Xpert MTB/RIF
370 integration into organisational workflows, led to delays in physicians receiving laboratory
371 results.[15] In that study, difficulties with the online system were thought to be a result of poor
372 knowledge on how to use the equipment and networks effectively, low availability of online
373 systems and available systems not interacting with each other leading to repeated input of
374 data.[15] Given the limited availability and uptake of electronic databases and online systems
375 within Mongolia's NTP, it is reasonable to assume that Mongolian NTP staff may have concerns
376 about upscaling IT technology that echo the experience outlined in the Brazilian study.[15]
377 However, IT solutions enable more efficient record keeping internally and capacity for
378 connectivity externally to pool surveillance data that can benefit TB control efforts within the
379 region.[21]
380
381 Several studies have highlighted issues with sample quantity and quality for GeneXpert
382 testing.[4,13,14] Our findings are consistent with these studies – participants suggested the most
383 common reason for experiencing an error message was related to the sample's quantity and/or
384 quality. Participants reported conflicting information on the type of specimen that could be
385 used for Xpert MTB/RIF testing, indicating the need for better education and training in this
386 area.
387

388 The rapid testing feature of Xpert MTB/RIF (results available in 2 hours) means that the
389 technology is poised for point of care (POC) testing. Our study supports the findings of studies
390 on POC testing that found that simply having the rapid test technology available does not
391 guarantee a natural fit into the program environment to enable POC testing.[12, 22-24] Detailed
392 recommendations on how to facilitate integration of GeneXpert with clinical care have been
393 made.[25] Two of these recommendations, standardised training and establishment of automated
394 processes for prescriptions,[25] would address important barriers identified in our study.
395
396 In our study, processes that followed a diagnosis of MDR-TB contributed to time delays until
397 treatment initiation despite the rapid availability of Xpert MTB/RIF results. An Indian study on a
398 POC testing program found that diagnostic delays, such as those observed in our study,
399 undermined the full potential of rapid tests.[26] However, two trials suggest that the benefit of
400 prompt treatment initiation gained using Xpert MTB/RIF may not translate into improved
401 patient outcomes. One randomised controlled trial found that nurses in African primary care
402 clinics had the capacity to accurately administer Xpert MTB/RIF at the clinic, which resulted in
403 more patients starting same-day treatment, more culture-positive patients starting therapy and
404 a shorter time to treatment initiation compared to the use of sputum smear microscopy.[27]
405 However, the trial also found that these benefits did not translate into lower tuberculosis
406 related morbidity. The other trial, a South African cluster-randomised trial, found that there
407 was no reduction in mortality at six months when using Xpert MTB/RIF compared to smear
408 microscopy.[28] In Mongolia, Xpert MTB/RIF is currently not implemented as a POC test, as the
409 laboratories performing the testing are not directly integrated with the TB clinics. Improving

integration of GeneXpert with clinical care by addressing some of the issues outlined above could potentially increase the value of GenXpert testing.

More broadly, funding arrangements and health system functioning have also been identified in the literature to have an important role in the implementation of new diagnostic technologies.[29] However, these concepts were outside the scope of this study because we focused on the experiences of operational staff.

A limitation of our study was that interview questions and answers had to be translated from English into Mongolian and from Mongolian into English respectively, possibly resulting in loss or misinterpretation of information. To reduce these risks, we pretested the interview guides and adjusted them based on participant feedback, and the English interview transcripts were verified by a second bi-lingual member of the research team to ensure the English version was clear and the participants' views were adequately represented.

In summary, this study identified a number of barriers and enablers of Xpert MTB/RIF implementation in Mongolia that extended beyond purchasing the equipment and installing it locally. The program environment is important for the successful implementation of Xpert MTB/RIF. Our study found that factors affecting implementation centred around awareness of program guidelines, cartridge supply management, local repair options for GeneXpert technology, regular formal training, communication systems and processes for sample collection. Upscaling of Xpert MTB/RIF testing facilities in Mongolia and other low-and middle

income countries will lead to implementation of Xpert MTB/RIF in new settings in future, and we believe that the lessons learned from our study can help to facilitate this process.

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Supporting Information

S1 File. Appendix A – Interview Guides

537 **Table 1. Number of patient specimens tested using Xpert MTB/RIF, by laboratory, in**

538 **Mongolia, 2013-2014**

Laboratory location	Commencement	Number of patient specimens tested			
		2013	2014	2015	2016
Ulaanbaatar	November 2013	310	3,022	3,493	3,588
Dornod	March 2014	—	130	114	162
Darkhan-uul	June 2014	—	137	195	241

539

540 **Table 2. Barriers and enablers of Xpert MTB/RIF implementation, 2015**

Barriers	Enablers
Framework, guidelines and organisational structures	
Poor awareness of program guidelines	Clear guidelines in local language
Inadequate staffing arrangements	Extra staff in NTRL
	Shift working arrangements
	Increase in the number of modules
Equipment	
Poor supply chain management of cartridges (stock-outs)	Capacity for troubleshooting internally
Absence of local repair options	
Training	
Inconsistent formal training options	Access to experts
	Peer learning
Communication Systems	
Paper based system	
Diagnostic algorithms, case finding for Xpert MTB/RIF and clinical management	
Treatment initiation in MDR-TB delayed until after consensus meeting	Common understanding of indications for Xpert MTB/RIF testing (diagnostic algorithms)
	Testing availability in provincial centres (decentralised)
Poor sample quality	

542 **Table 3. Summary of indications for clinicians to prescribe the Xpert MTB/RIF test, Mongolian**

543 **National Tuberculosis Program Guidelines, December 2014**

Indication	Additional detail
All smear negative pulmonary TB cases	
Patient with presumed pulmonary TB diagnosed with HIV/AIDS	
Patients with presumed MDR-TB	• Smear positive at the 2nd (3rd) and 5th month of TB treatment with category I and II • Smear positive after interruption of TB treatment category I and II • Relapse (after TB treatment category I and II) • Indefinite previous treatment regimen or smear negative • Smear positive after being smear negative during treatment initiation • Identification of TB case from contact investigation of a DR-TB case.
Patients with presumed XDR-TB	• Used category II drugs for 2 or more months • Culture positive at the 3rd month of MDR-TB treatment • Not converted to negative at the end of intensive treatment phase of MDR-TB • Smear positive again by bacteriological analysis after conversion to negative during continuous treatment phase of MDR-TB • MDR-TB case defined to be resistance to fluoroquinolone group or second line injectable TB drugs • Close contacts of XDR-TB case.
All smear positive new cases aged 15-34 years old (this guideline is yet to be implemented)	

544 Note: These indications are a summary adapted from treatment algorithms and other guidance outlined within the

545 Mongolian National Tuberculosis Program Guidelines