

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

Nicole L Rendell ^{Corresp., 1}, Solongo Bekhbat ², Gantungalag Ganbaatar ¹, Munkhjargal Dorjravdan ¹, Madhukar Pai ³, Claudia C Dobler ^{4,5}

¹ National Tuberculosis Program Mongolia, Ulaanbaatar, Mongolia

² Mongolian Anti-Tuberculosis Association, Ulaanbaatar, Mongolia

³ McGill International TB Centre, McGill University, Quebec, Canada

⁴ Woolcock Institute of Medical Research, University of Sydney, New South Wales, Australia

⁵ South Western Sydney Clinical School, University of New South Wales, New South Wales, Australia

Corresponding Author: Nicole L Rendell

Email address: nicole.rendell@gmail.com

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.

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

3

4 Nicole Rendell¹, Solongo Bekhbat², Gantungalag Ganbaatar¹, Munkhjargal Dorjravdan¹,

5 Madhukar Pai³, Claudia C Dobler^{4,5}

6

7 ¹National Tuberculosis Program Mongolia, Ulaanbaatar, Mongolia

8 ²Mongolian Anti-Tuberculosis Association, Ulaanbaatar, Mongolia

9 ³ McGill International TB Centre, McGill University, Quebec, Canada

10 ⁴ Woolcock Institute of Medical Research, University of Sydney, New South Wales,

11 Australia

12 ⁵South Western Sydney Clinical School, University of New South Wales, New South

13 Wales, Australia

14

15 **Corresponding Author:** Nicole Rendell - nicole.rendell@gmail.com

16

17

18

19 **Abstract**

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

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

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

39 **Conclusion:** Our study identified a number of barriers and enablers to implementation of Xpert
40 MTB/RIF in the Mongolian National Tuberculosis Program. Lessons learned from this study can

- 41 help to facilitate implementation of Xpert MTB/RIF in other Mongolian locations as well as
- 42 other low-and middle-income countries.

43 Introduction

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

49

50 Mongolia, a country with a TB burden of 428 incident cases per 100,000 population in 2015
51 (95% confidence interval 220–703)³, has been a relatively late adopter of the Xpert MTB/RIF
52 assay. In Mongolia, the rate of concomitant HIV and TB is low at 0.34 incident cases per 100,000
53 population (95% CI: 0.26-0.44), but the country has a relatively high burden of multi-drug
54 resistant (MDR) and rifampicin resistant (RR) TB cases representing 2.2% (95% CI: 1.1–3.3) of
55 new cases and 33% (95% CI: 29–38) of previously treated cases.³ Resistance against all first-line
56 drugs tested is approximately 60% among sputum smear–positive patients in whom standard
57 first-line TB treatment failed, suggesting successful transmission (versus new mutation) of these
58 highly resistant strains in the community.⁴ At the time of the first introduction of MTB/RIF in
59 Mongolia at the end of 2013, other countries had already analysed their experiences with
60 implementation of Xpert MTB/RIF.⁵ It was, however, not until 2014 that the WHO published a
61 ‘How-To’ Xpert MTB/RIF implementation manual.⁶ It is therefore of interest to explore the
62 specific challenges with Xpert MTB/RIF implementation in Mongolia.

63

64 The National Tuberculosis Reference Laboratory (NTRL) in Ulaanbaatar was the first laboratory
65 in Mongolia to implement Xpert MTB/RIF testing in November 2013. By the end of 2014, there
66 were three GeneXpert machines being used in Mongolia – at the NTRL in Ulaanbaatar, the
67 Hospital of Darkhan-uul, in the northern Darkhan-uul province, near the Russian border, (since
68 June 2014) and the Regional Diagnostic and Treatment Center of Dornod, in Dornod province,
69 Mongolia’s easternmost province, bordering Russia and China (since March 2014). The funding
70 for these machines was supplied by the Global Fund through a series of projects. In 2013, 310
71 patient samples were tested using Xpert MTB/RIF. This had increased to 3,289 in 2014, 3,802 in
72 2015 and 3,991 in 2016 (Table 1).

73

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

80

81 In recent years a number of studies have assessed the performance of the Xpert MTB/RIF assay,
82 specifically, the accuracy and cost effectiveness of Xpert MTB/RIF have been well
83 documented.⁷⁻¹² Only few research studies, however, have investigated implementation issues
84 from an organisational perspective,^{5,13-17} two of which included qualitative tools designed
85 specifically for the study to gather information on user experiences and challenges related to

86 Xpert MTB/RIF implementation.^{5,16} Some of the identified challenges associated with Xpert
87 MTB/RIF implementation in low-and middle income countries include lack of standardised
88 guidance, piecemeal implementation of training, quality assurance, planning processes and
89 equipment servicing and maintenance, issues with continuous power supply and difficulties
90 recording and reporting test results using new technology.^{5,16,17}

91

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

95

96 **Methods**

97 **Study design, setting and participants**

98 We conducted semi-structured interviews with laboratory staff and TB physicians using an
99 inductive-deductive approach. This approach was chosen because we had knowledge about
100 possible barriers and enablers to GeneXpert implementation from studies in other settings,^{5,13-}
101 ¹⁵ while we knew little about contextual factors impacting on Xpert MTB/RIF implementation in
102 Mongolia. We developed semi-structured interview guides (see Appendix A) to collect a wide
103 range of information on participants' experiences and views related to Xpert MTB/RIF use and
104 implementation in Mongolia's NTP. The interview guide was designed based on a literature
105 review of barriers and enablers of Xpert MTB/RIF implementation. These implementation
106 factors were organised into major themes that formed the structure of the interview guide for

107 laboratory staff – guidelines and organisational structures; equipment; training; communication
108 systems; and diagnostic algorithms, case finding for Xpert MTB/RIF, clinical management. A
109 separate interview guide was designed specifically for TB physicians and focused on clinical
110 issues. Open questions were added to the interview guide to explore possible themes that had
111 not been identified from the literature. Two of the researchers (GG and MD) conducted the
112 interviews. Both interviewers were trained in the study protocol and interview technique.

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

117

118 Potential participants were approached by one of the researchers (GG or MD) and interviewed
119 once informed consent was obtained. Because there were only few laboratory staff who were
120 using the Xpert MTB/RIF diagnostic test, all of them were invited to participate in the study.
121 Interviews with TB physicians were continued until saturation of data was apparent, that is until
122 no new themes emerged.¹⁸ All interviews were conducted between July and September 2015.

123

124 Participants in Ulaanbaatar were interviewed in person where possible, or alternatively over
125 the phone, and participants based outside of Ulaanbaatar were interviewed over the phone.
126 The interviews were conducted and transcribed in Mongolian. The transcripts were then
127 translated into English by one of the researchers (SB). The English transcripts were verified by

128 another bi-lingual member of the research team (MD) to ensure the English version was clear
129 and the participants' views were adequately represented.

130

131 **Analysis**

132 In order to determine whether participants would interpret interview questions as intended
133 and whether the order of questions may influence responses, we conducted three pretesting
134 interviews (with two laboratory staff and one TB physician). Pretesting highlighted questions
135 that were poorly understood by respondents. It also showed that some questions were
136 perceived by respondents to be duplicate questions. We edited the interview guides
137 accordingly by reordering, rewording or deleting questions. In addition, pretesting showed that
138 explanatory information provided by the interviewer varied considerably between interviews.
139 In response to this observation, a written introduction explaining the purpose and benefit of
140 the study was added to the interview instrument for the interviewers to read aloud before the
141 interview commenced. This ensured consistent explanatory information was given to all
142 participants prior to the commencement of the interview. The revised interview guides were
143 used for all future interviews. The pretest interviews were not included in the final analysis.

144

145 The first (NR) and last author (CCD) independently reviewed transcripts from the first five
146 interviews to identify key themes and subthemes (ie, patterns within the narrative data), then
147 developed a coding scheme through discussion and consensus. This framework was
148 systematically applied to code themes in subsequent interview transcripts. We reviewed the
149 framework after an additional ten interviews, updating it to reflect newly revealed themes and

150 subthemes that were not apparent in earlier interviews. Coding was completed using the
151 software package QSR NVivo version 10 (QSR International Pty Ltd, Doncaster, Victoria,
152 Australia). The English version of each interview transcript was imported into NVivo and then
153 systematically reviewed and coded for common themes and subthemes.
154 The study results are reported in accordance with the Consolidated Criteria for Reporting
155 Qualitative Research (COREQ) checklist.¹⁹

156

157 **Ethics**

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

159

160 **Results**

161 We contacted 24 NTP staff (8 laboratory staff and 16 TB physicians), all of whom agreed to be
162 interviewed (ie, a 100% response rate). Five laboratory staff members were located at the NTRL
163 in Ulaanbaatar and 3 in provincial laboratories. Of the 16 TB physicians, 5 worked at the NCCD,
164 4 worked in any of the district TB clinics in Ulaanbaatar and 7 worked in the provinces of
165 Darkhan-Uul or Dornod.

166

167 Participants identified a range of barriers and enablers associated with implementation of Xpert
168 MTB/RIF testing in Mongolia based on their experiences. These are summarised in Table 2, and
169 described below according to the following themes: 1) guidelines and organisational structures,

170 2) equipment, 3) training, 4) communication systems, 5) diagnostic algorithms, case finding for
171 Xpert MTB/RIF and clinical management. Laboratory staff participants were interviewed using
172 guiding questions for each theme. For TB physicians, the guiding questions focussed on the last
173 theme, diagnostic algorithms, case finding for Xpert MTB/RIF and clinical management.

174

175 **Guidelines and organisational structures**

176 ***Barriers***

177 ***Poor awareness of program guidelines:*** Around half of all participants stated that they were
178 not aware of any written guidelines to support the use of Xpert MTB/RIF (*authors' comment:*
179 *the Mongolian NTP issued guidelines for all NTP staff, which included information on the use of*
180 *Xpert MTB/RIF in December 2014*). Instead, many participants referred to training
181 arrangements when asked about NTP guidelines. One participant thought that the English
182 manual for the operation of the Xpert machine was equivalent to the NTP guidelines available
183 to staff. The guidelines did not appear to be clear enough about which samples (type of body
184 fluid/tissue) could be used for testing with Xpert MTB/RIF, in particular if testing of samples
185 other than sputum, e.g. pleural and cerebrospinal fluid, was allowed. This resulted in
186 inconsistent practices regarding Xpert MTB/RIF testing of non-sputum samples
187 (*authors'comment: According to the Mongolian NTP guidelines 2014 the following specimens*
188 *can be used for Xpert MTB/RIF testing: sputum, urine, stool, pleural fluid, ascites, gastric lavage,*
189 *and surgical tissue samples, although the protocol for collecting and transporting specimens*
190 *collected for testing was not included in the guidelines at the time of the study*). One laboratory
191 participant suggested that patients are being inappropriately referred for Xpert MTB/RIF testing

192 (inconsistent with guideline recommendations, summarised in Table 3), which was potentially
193 driving excess demand.

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

197 ***Enablers***

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

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

208

209 **Equipment**

210 ***Barriers***

211 ***Poor supply chain management of cartridges (stock-outs):*** Since implementation of Xpert
212 MTB/RIF testing, the only time the test had been unavailable for about a month was due to a
213 cartridge supply issue that affected all the laboratories that offered Xpert MTB/RIF testing.

214 Other than this occasion, cartridge supply appeared to be well managed (sufficient number of
215 cartridges available to meet demand without cartridge expiration issues due to oversupply).

216 **Absence of local repair options:** Mongolia's harsh climate and low population density generally
217 did not appear to have affected transportation of cartridge supplies or equipment. Although,
218 one of the modules in one of the regional machines had broken on arrival and there were
219 difficulties arranging its repair. The lack of expertise to repair GeneXpert machines in the
220 provinces was identified as a problem. This was in contrast to other laboratory equipment,
221 which could be repaired by the available engineers.

222 **Enabler**

223 **Capacity for troubleshooting internally:** Other temporary problems with the GeneXpert
224 machine have occurred without major interruption to the workflow because local staff were
225 able to remedy them easily. For example, one laboratory participant mentioned that the
226 laboratory had bought an uninterruptable power supply to manage issues with the power
227 supply. Another laboratory participant mentioned the need for more basic office equipment to
228 cater for the introduction of the new equipment.

229

230 **Training**

231 **Barrier**

232 **Inconsistent formal training options:** The training that laboratory staff had received on the
233 operation of Xpert MTB/RIF varied widely. Some laboratory staff participated in formal training
234 courses, others learned on the job through instruction by trained colleagues or superiors. Two
235 members of laboratory staff based in Ulaanbaatar participated in an online training course

236 organised by the supplier of the GeneXpert machines. Components of different trainings
237 included operation and maintenance of GeneXpert, but also information on indications for
238 GeneXpert use in Mongolia.

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

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

247 ***Enablers***

248 ***Access to experts:*** Access to external technical experts to support implementation of Xpert
249 MTB/RIF differed for staff based in regional clinics and those based in Ulaanbaatar. Regional
250 laboratory staff received guidance from NTRL staff, who received guidance directly from
251 international experts on operations and troubleshooting of the machines.

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

253

254 **Communication systems**

255 ***Barrier***

256 ***Paper based system:*** Results of the Xpert MTB/RIF test were communicated to TB clinics using
257 paper forms that were delivered using one or more of the following options: 1) patients

258 collected the paper form directly from the laboratory and took it to the doctor at the TB clinic,
259 2) doctors were contacted over the phone and informed about the results ahead of receiving
260 the paper form, and 3) doctors and/or nurses collected the results on paper directly from the
261 laboratory. Paper reports were associated with delays of 2 days on average to receive the
262 results following a request being sent to the laboratory. A few TB physicians suggested the
263 delay was longer, up to a week, and one TB physician even suggested that the delay between
264 requesting Xpert MTB/RIF testing to receiving the result was up to 2 weeks. Urgent requests
265 were prioritised.

266 Administrative reports were generated weekly on a computer, based on the information on the
267 paper forms that was manually input into a computer file. Despite having regular administrative
268 reporting of the results to facilitate a quality control mechanism, participants did not value the
269 reporting system in this way. It is unclear based on the interview data how the information
270 contained in the reports could be used to prompt action to improve processes.

271

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

273 ***Barriers***

274 ***Treatment initiation in MDR-TB delayed until after consensus meeting:*** Treatment for drug
275 sensitive cases (who tested positive for TB on GeneXpert, but negative for rifampicin resistance)
276 was usually started immediately after physicians received the results. TB physicians described
277 that the delay to initiating treatment for presumptive MDR-TB (following a positive result for
278 rifampicin resistance), as well as the specifics of the MDR-TB treatment regimen depended on
279 the timing of the weekly MDR-TB meeting (held at the central NTP office in Ulaanbaatar, to

280 discuss each case of MDR-TB in Mongolia and decide on the best approach for the patient's
281 treatment). Some participants reported that there was no delay in commencing treatment
282 following a positive test for rifampicin resistance. Others reported that it took 1 to 2 weeks to
283 initiate treatment because the treatment could not commence until the treatment plan had
284 been agreed upon at the MDR-TB meeting.

285 **Poor sample quality:** 'Error results' from Xpert MTB/RIF testing (i.e., notification of an error is
286 displayed in the Check Status screen of the GeneXpert machine) were reported to occur
287 occasionally. In these instances, the test was always redone and some participants reported
288 that error results triggered machine maintenance as well. The quality of the sample (e.g. when
289 patients did not collect sputum correctly) was reported as the most common reason for error
290 results experienced by participants when using Xpert MTB/RIF testing. Some laboratory staff
291 participants also reported seeking additional training and/or assistance to minimise error
292 results.

293 ***Enablers***

294 ***Common understanding of indications for Xpert MTB/RIF testing:*** Both laboratory staff and TB
295 physicians were aware of the approved indications for Xpert MTB/RIF use in Mongolia (Table 3),
296 including testing in patients with possible MDR-TB (patients with TB relapse, positive sputum
297 smear result at the 3rd and 5th month of treatment and screening of MDR-TB close contacts), as
298 well as testing for confirmation of TB (smear negative cases with abnormal chest x-ray and very
299 ill patients with uncertain diagnosis).

300 There was variation in the details of each participant's response regarding indications for
301 GeneXpert use, but broadly the indications as outlined above were consistent among
302 participants and consistent with Mongolian guidelines (see table 3).

303 ***Testing availability in provincial centres (decentralised):*** Participants from the provinces
304 pointed out that while Xpert MTB/RIF testing is available in regional areas of Mongolia, samples
305 need to be sent to the central reference laboratory in Ulaanbaatar for further drug
306 susceptibility testing from culture. They did, however, still value access to Xpert MTB/RIF
307 testing, because it meant that a rapid diagnosis of drug resistant TB was possible in the regional
308 areas when previously, it could only be done in Ulaanbaatar.

309 Most physicians had not experienced difficulties starting their patients on MDR-TB treatment
310 following a diagnosis of rifampicin resistance. However, those that did reported that the reason
311 they could not commence treatment was because of patient related factors rather than
312 program related issues.

313

314 **Suggestions for future Xpert MTB/RIF implementation and scale up**

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

- 319 • Increase in the number of available sites for Xpert MTB/RIF testing (upscaling to more
320 districts of Ulaanbaatar and more provinces in Mongolia)

- 321 • Use of Xpert MTB/RIF to test for drug resistance on all smear positive patients before
322 starting treatment
- 323 • Increase in the number of machines at existing sites.
- 324

325 **Discussion**

326 This study highlighted a range of potential factors within the Mongolian NTP that served as a
327 barrier or enabler to the implementation of Xpert MTB/RIF testing. Since the implementation of
328 Xpert MTB/RIF testing in Mongolia, according to NTP data, the number of notified cases
329 detected in Ulaanbaatar, Darkhan and Dornod has increased from 2,783 cases in 2012 to 3,029
330 cases in 2015. While all study participants appreciated the benefits of the new diagnostic
331 technology and were supportive of its implementation, all participants were able to identify
332 areas where integration into the existing program could be improved. Potential barriers
333 included lack of awareness of program guidelines; inadequate staffing arrangements; problems
334 with cartridge supply management; lack of local repair options for the Xpert machines; lack of
335 regular formal training; paper based system; delayed treatment initiation due to consensus
336 meeting and poor sample quality. Enablers included availability of guidelines in the local
337 language; provision of extra laboratory staff, shift working arrangements and additional
338 modules; capacity for troubleshooting internally; access to experts; opportunities for peer
339 learning; common understanding of diagnostic algorithms and decentralised testing. Lessons
340 learned from this study can inform the implementation and upscaling of GeneXpert in other
341 settings in Mongolia and in other low-and middle income countries.

342

343 Policies and guidelines as well as training opportunities provided by an organisation facilitate
344 the uptake of any new technology.⁶ In our study, those that knew about the NTP's guidelines for
345 the use of GeneXpert found them to be invaluable. However, only around half of study
346 participants were aware of any guidelines relating to GeneXpert use and relied on random
347 opportunities for training and/or visits from national and international experts to advise them
348 on the use of Xpert MTB/RIF. Adherence to program guidelines, which should incorporate Xpert
349 MTB/RIF testing into the national diagnostic strategy and algorithms,⁶ is important for
350 sustainable implementation of Xpert MTB/RIF in a local context. Diagnostic algorithms and
351 other policies outlined in program guidelines are essential to realise and maximise the potential
352 of new technologies in practice.²⁰⁻²²

353

354 Only staff from NTRL, but not from the regional laboratories, had concerns about their capacity
355 to meet the demand for Xpert MTB/RIF testing. This is most likely because the regular requests
356 for the population that the NTRL laboratory covered went above their pre-existing surge
357 capacity. In contrast, the regional laboratories only felt under pressure initially, while they were
358 still learning how to use the technology. A feasibility study conducted in India also found that in
359 a decentralised setting, there were minimal infrastructure modifications and human resource
360 concerns following the implementation of Xpert MTB/RIF testing.¹⁵ The lower population
361 density in settings covered by existing laboratories in the decentralised and regional areas,
362 potentially allowed the introduction of new diagnostic technology using the pre-existing surge
363 capacity of the laboratory workforce.

364

365 Issues with the infrastructure supporting Xpert MTB/RIF testing were observed by many
366 laboratory staff and focused on the one month where cartridge supply was an issue, and to a
367 lesser extent, access to repairs. In our study the demand for cartridges was met without
368 expiration issues due to high turnover of cartridges, except for one month when the cartridge
369 supply was exhausted. No Xpert MTB/RIF testing could be undertaken during this month.
370 Previous studies investigating Xpert MTB/RIF implementation have highlighted the importance
371 of program levers to assist in the management of cartridge supply.^{5,14} They have suggested
372 measures such as staggered cartridge shipments and design of diagnostic algorithms that
373 combine Xpert with other methods to increase yield.^{5,14} A Brazilian study assessing the pilot
374 implementation of Xpert MTB/RIF calculated that 10% of Xpert MTB/RIF equipment needed
375 replacement during the eight month pilot study, yet spare parts were not immediately
376 available.¹⁴ Although our study did not quantify faulty equipment, a similar experience of
377 limited access to repairs was observed by laboratory staff. The authors of the Brazilian study
378 suggested that both cartridge supply and maintenance should be negotiated with
379 manufacturers.¹⁴
380
381 Communication of Xpert MTB/RIF results occurred through different methods that were paper
382 based and reliant on the accuracy of the contact information written on the Xpert MTB/RIF
383 request form. Interestingly, no participant would have preferred computer based record
384 keeping or an online system, even though administrative reports were generated weekly on a
385 computer, based on the information in the paper forms, manually input into the computer files.
386 Regular reporting in this way is inefficient and did not appear to facilitate a quality control

387 mechanism that would be of value to the participants. A study undertaken in two Brazilian
388 cities found that the implementation of concomitant IT technology to support Xpert MTB/RIF
389 integration into organisational workflows, led to delays in physicians receiving laboratory
390 results.¹⁶ In that study, difficulties with the online system were thought to be a result of poor
391 knowledge on how to use the equipment and networks effectively, low availability of online
392 systems and available systems not interacting with each other leading to repeated input of
393 data.¹⁶ Given the limited availability and uptake of electronic databases and online systems
394 within Mongolia's NTP, it is reasonable to assume that Mongolian NTP staff may have concerns
395 about upscaling IT technology that echo the experience outlined in the Brazilian study.¹⁶
396 However, IT solutions enable more efficient record keeping internally and capacity for
397 connectivity externally to pool surveillance data that can benefit TB control efforts within the
398 region.²³

399

400 Several studies have highlighted issues with sample quantity and quality for GeneXpert
401 testing.^{5,14,15} Our findings are consistent with these studies – participants suggested the most
402 common reason for experiencing an error message was related to the sample's quantity and/or
403 quality. Specimen transportation systems are in place at the three levels of the health system –
404 community, district/provincial and central. All health care workers with responsibility for
405 collecting specimens receive training on the collection and effective transportation of
406 specimens. When collecting specimens, patients are provided with verbal and written
407 instructions. Participants also reported conflicting information on the type of specimen that

408 could be used for Xpert MTB/RIF testing, indicating the need for better education and training
409 in this area.

410

411 The rapid testing feature of Xpert MTB/RIF (results available in 2 hours) means that the
412 technology is poised for point of care (POC) testing. Our study supports the findings of studies
413 on POC testing that found that simply having the rapid test technology available does not
414 guarantee a natural fit into the program environment to enable POC testing.^{13, 24-26} Detailed
415 recommendations on how to facilitate integration of GeneXpert with clinical care have been
416 made.²⁷ Two of these recommendations, standardised training and establishment of automated
417 processes for prescriptions,²⁷ would address important barriers identified in our study.

418

419 In our study, processes that followed a diagnosis of MDR-TB contributed to time delays until
420 treatment initiation despite the rapid availability of Xpert MTB/RIF results. An Indian study on a
421 POC testing program found that diagnostic delays, such as those observed in our study,
422 undermined the full potential of rapid tests.²⁸ However, two trials suggest that the benefit of
423 prompt treatment initiation gained using Xpert MTB/RIF may not translate into improved
424 patient outcomes. One randomised controlled trial found that nurses in African primary care
425 clinics had the capacity to accurately administer Xpert MTB/RIF at the clinic, which resulted in
426 more patients starting same-day treatment, more culture-positive patients starting therapy and
427 a shorter time to treatment initiation compared to the use of sputum smear microscopy.²⁹
428 However, the trial also found that these benefits did not translate into lower tuberculosis
429 related morbidity.²⁹ The other trial, a South African cluster-randomised trial, found that there

430 was no reduction in mortality at six months when using Xpert MTB/RIF compared to smear
431 microscopy.³⁰ In Mongolia, Xpert MTB/RIF is currently not implemented as a POC test, as the
432 laboratories performing the testing are not directly integrated with the TB clinics. Improving
433 integration of GeneXpert with clinical care by addressing some of the issues outlined above
434 could potentially increase the value of GeneXpert testing.

435

436 More broadly, funding arrangements and health system functioning have also been identified in
437 the literature to have an important role in the implementation of new diagnostic
438 technologies.³¹ However, these concepts were outside the scope of this study because we
439 focused on the experiences of operational staff.

440

441 A limitation of our study was that interview questions and answers had to be translated from
442 English into Mongolian and from Mongolian into English respectively, possibly resulting in loss
443 or misinterpretation of information. To reduce these risks, we pretested the interview guides
444 and adjusted them based on participant feedback, and the English interview transcripts were
445 verified by a second bi-lingual member of the research team to ensure the English version was
446 clear and the participants' views were adequately represented. The interviews were semi-
447 structured with open-ended questions, which allowed respondents to explore the mentioned
448 topics as they saw fit. Adding more structured interview questions to explore some issues in
449 more detail (e.g. sample collection, distance and subsequent travel time of samples, transport
450 conditions particularly during winter and waste disposal system for cartridges) might have been
451 useful.

452 In summary, this study identified a number of barriers and enablers of Xpert MTB/RIF
453 implementation in Mongolia that extended beyond purchasing the equipment and installing it
454 locally. The program environment is important for the successful implementation of Xpert
455 MTB/RIF. Our study found that factors affecting implementation centred around awareness of
456 program guidelines, cartridge supply management, local repair options for GeneXpert
457 technology, regular formal training, communication systems and processes for sample
458 collection. Upscaling of Xpert MTB/RIF testing facilities in Mongolia and other low-and middle
459 income countries will lead to implementation of Xpert MTB/RIF in new settings in future, and
460 we believe that the lessons learned from our study can help to facilitate this process.

461

462 **Acknowledgements**

463 This work was supported (in-kind) by the NTP of Mongolia. We thank Dr Buyankhishig
464 Burneebaatar for her assistance during the ethics approval process and sourcing background
465 information.

466 **References**

467

- 468 1. World Health Organization. WHO endorses new rapid tuberculosis test [Internet].
469 Geneva (Switzerland): World Health Organization; media release 8 December 2010
470 [cited 17 November 2016]. Available from
471 http://www.who.int/mediacentre/news/releases/2010/tb_test_20101208/en/
- 472 2. World Health Organization. Global Tuberculosis Report 2016 [Internet]. Geneva
473 (Switzerland): World Health Organization; 2016 [cited 17 November 2016]. Available
474 from [http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-](http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1)
475 [eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1)
- 476 3. World Health Organization. Mongolia – Tuberculosis profile [Internet]. Geneva
477 (Switzerland): World Health Organization [cited 3 January 2017]. Available
478 https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/P
479 [ROD/EXT/TBCountryProfile&ISO2=mn&outtype=pdf](https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/P)
- 480 4. Dobler CC, Korver S, Batbayar O, Nyamdulam B, Oyuntsetseg S, Tsolmon B,
481 Surmaajav B, Bayarjargal B, Marais BJ. Multidrug-Resistant Tuberculosis in Patients
482 for Whom First-Line Treatment Failed, Mongolia, 2010-2011. *Emerg Infect Dis.* 2015;
483 21(8): 1451-1454 [cited 21 May 2017]. Available from
484 <https://www.ncbi.nlm.nih.gov/pubmed/26196504>
- 485 5. Creswell J, Codlin AJ, Andre E, Micek MA, Bedru A, Carter EJ, Yadav R, Mosneaga A,
486 Rai R, Banu S, Brouwer M, Blok L, Sahu S and Ditiu L. Results from early

- 487 programmatic implementation of Xpert MTB/RIF testing in nine countries. BMC
488 Infect Dis. 2014; 14(2): p. 2. doi 10.1186/1471-2334-14-2
- 489 6. World Health Organization. Xpert MTB/RIF Implementation Manual: Technical and
490 Operational 'How-To'; Practical Considerations [Internet]. Geneva (Switzerland):
491 World Health Organization; 2014 [cited 5 December 2016]. Available from:
492 <https://www.ncbi.nlm.nih.gov/books/NBK254329/>
- 493 7. World Health Organization. Xpert MTB/RIF assay for the diagnosis of pulmonary and
494 extrapulmonary TB in adults and children – Policy Update [Internet]. Geneva
495 (Switzerland): World Health Organization; 2013 [cited 17 November 2016]. Available
496 from http://apps.who.int/iris/bitstream/10665/112472/1/9789241506335_eng.pdf
- 497 8. Armand S, Vanhuls P, Delcroix G, Courcol R, Lemaître N. Comparison of the Xpert
498 MTB/RIF test with an IS6110-TaqMan real-time PCR assay for direct detection of
499 Mycobacterium tuberculosis in respiratory and nonrespiratory specimens. J Clin
500 Microbiol. 2011; 49(5): 1772-6. doi 10.1128/JCM.02157-10
- 501 9. Nhu NT, Ha DTM, Anh ND, Thu DD, Duong TN, Quang ND, Lan NT, Quyet TV, Tuyen
502 NT, Ha VT, Giang DC, Dung NH, Wolbers M, Farrar J, Caws M. Evaluation of Xpert
503 MTB/RIF and MODS assay for the diagnosis of pediatric tuberculosis. BMC Infect Dis.
504 2013; 13: 31. doi 10.1186/1471-2334-13-31
- 505 10. Huh HJ, Jeong B, Jeon K, Koh WJ, Ki CS, Lee NY. Performance evaluation of the Xpert
506 MTB/RIF assay according to its clinical application. BMC Infect Dis. 2014; 14: 589. doi
507 10.1186/s12879-014-0589-x

- 508 11. Menzies NA, Cohen T, Lin H, Murray M, Salomon JA. Population health impact and
509 cost-effectiveness of tuberculosis diagnosis with Xpert MTB/RIF: a dynamic
510 simulation and economic evaluation. *PLoS Med.* 2012; 9(11): e1001347. doi
511 10.1371/journal.pmed.1001347
- 512 12. Vassall A, van Kampen S, Sohn H, Michael JS, John KR, den Boon S, Davis JL,
513 Whitelaw A, Nicol MP, Gler MT, Khaliqov A, Zamudio C, Perkins MD, Boehme CC,
514 Cobelens F. Rapid diagnosis of tuberculosis with the Xpert MTB/RIF assay in high
515 burden countries: a cost-effectiveness analysis. *PLoS Med.* 2011; 8(11): e1001120.
516 doi:10.1371/journal.pmed.1001120
- 517 13. Engel N, Davids M, Blankvoort N, Pai NP, Dheda K, Pai M. Compounding diagnostic
518 delays: a qualitative study of point-of-care testing in South Africa. *Trop Med Int*
519 *Health.* 2015; 20(4): 493-500. doi 10.1111/tmi.12450
- 520 14. Durovni B, Saraceni V, Cordeiro-Santos M, Cavalcante S, Soares E, Lourenço C,
521 Menezes A, van den Hof S, Cobelens F, Trajman A. Operational lessons drawn from
522 pilot implementation of Xpert MTB/Rif in Brazil. *Bull World Health Organ.* 2014;
523 92(8): 613-7. doi <http://dx.doi.org/10.2471/BLT.13.131409>
- 524 15. Raizada N, Sachdeva KS, Sreenivas A, Vadera B, Gupta RS, Parmar M, Kulsange S,
525 Babre A, Thakur R, Gray C, Ramachandran R, Alavadi U, Ghedia M, Vollepore B,
526 Dewan P, Boehme C, Paramsivan CN. Feasibility of decentralised deployment of
527 Xpert MTB/RIF test at lower level of health system in India. *PLoS One.* 2014; 9(2):
528 e89301. doi 10.1371/journal.pone.0089301

- 529 16. de Camargo Jr KR, Guedes CR, Caetano R, Menezes A, Trajman A. The adoption of a
530 new diagnostic technology for tuberculosis in two Brazilian cities from the
531 perspective of patients and healthcare workers: a qualitative study. *BMC Health Serv*
532 *Res.* 2015; 15: 275. doi 10.1186/s12913-015-0941-x
- 533 17. Albert H, Nathavitharana RR, Isaacs C, Pai M, Denkinger CM, Boehme CC.
534 Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons
535 have we learnt and how can we do better? *Eur Respir J.* 2016; 48: 516–525. doi
536 10.1183/13993003.00543-2016
- 537 18. Patton MQ. *Qualitative evaluation and research methods.* Newbury Park (CA): Sage
538 Publications Inc; 1990.
- 539 19. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research
540 (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care.*
541 2007; 19(6):349-57 [cited 21 May 2017]. Available from
542 <https://www.ncbi.nlm.nih.gov/pubmed/17872937>
- 543 20. McNerney R, Cunningham J, Hepple P, Zumla A. New tuberculosis diagnostics and
544 rollout. *Int J Infect Dis.* 2015; 32: 81–86. doi: 10.1016/j.ijid.2015.01.012
- 545 21. Kirwan DE, Cárdenas MK, Gilman RH. Implementation of New TB Diagnostic Tests: Is
546 It Too Soon for a Global Roll-Out of Xpert MTB/RIF? *Am J Trop Med Hyg.* 2012; 87(2):
547 197-201. doi:10.4269/ajlmh.2012.12-OI07
- 548 22. Giang DC, Duong TN, Ha DTM, Nhan HT, Wolbers M, Nhu NT, Heemskerk D, Quang
549 ND, Phuong DT, Hang PT, Loc TH, Lan NT, Dung NH, Farrar J, Caws M. Prospective

- 550 evaluation of GeneXpert for the diagnosis of HIV- negative pediatric TB cases. BMC
551 Infect Dis. 2015; 15:70. doi 10.1186/s12879-015-0814-2
- 552 23. Andre E, Isaacs C, Affolabi D, Alagna R, Brockmann D, de Jong BC, Cambau E,
553 Churchyard G, Cohen T, Delmee M, Delvenne JC, Farhat M, Habib A, Holme P,
554 Keshavjee S, Khan A, Lightfoot P, Moore D, Moreno Y, Mundade Y, Pai M, Patel S,
555 Nyaruhirira AU, Rocha LE, Takle J, Trébuq A, Creswell J, Boehme C. Connectivity of
556 diagnostic technologies: improving surveillance and accelerating tuberculosis
557 elimination. *Int J Tuberc Lung Dis.* 2016; 20(8): 999–1003. doi 10.5588/ijtld.16.0015
- 558 24. Cowan J, Michel C, Manhiça I, Monivo C, Saize D, Creswell J, Gloyd S, Micek M.
559 Implementing rapid testing for tuberculosis in Mozambique. *Bull World Health*
560 *Organ.* 2015; 93: 125–130. doi 10.2471/BLT.14.138560
- 561 25. Pai NP, Vadnais C, Denkinger C, Engel N, Pai M. Point-of-Care Testing for Infectious
562 Diseases: Diversity, Complexity, and Barriers in Low- And Middle-Income Countries.
563 *PLoS Med.* 2012; 9(9): e1001306. Doi 10.1371/journal.pmed.1001306
- 564 26. Clouse K, Page-Shipp L, Dansey H, Moatlhodi B, Scott L, Bassett J, Stevens W, Sanne
565 I, Van Rie A. Implementation of Xpert MTB/RIF for routine point-of-care diagnosis of
566 tuberculosis at the primary care level. *S Afr Med J.* 2012; 102(10): 805. doi
567 10.7196/SAMJ.5851
- 568 27. Dominique JK, Ortiz-Osorno AA, Fitzgibbon J, Gnanashanmugam D, Gilpin C, Tucker
569 T, Peel S, Peter T, Kim P, Smith S. Implementation of HIV and Tuberculosis
570 Diagnostics: The Importance of Context. *Clin Infect Dis.* 2015; 61(S3): S119–25. doi
571 10.1093/cid/civ552

- 572 28. Engel N, Ganesh G, Patil M, Yellappa V, Vadnais C, Pai NP, Pai M. Point-of-care
573 testing in India: missed opportunities to realize the true potential of point-of-care
574 testing programs. *BMC Health Serv Res.* 2015; 15: 550. doi 10.1186/s12913-015-
575 1223-3
- 576 29. Theron G, Zijenah L, Chanda D, Clowes P, Rachow A, Lesosky M, Bara W, Mungofa S,
577 Pai M, Hoelscher M, Dowdy D, Pym A, Mwaba P, Mason P, Peter J, Dheda K; TB-
578 NEAT team. Feasibility, accuracy, and clinical effect of point-of-care Xpert MTB/RIF
579 testing for tuberculosis in primary-care settings in Africa: a multicentre, randomised,
580 controlled trial. *Lancet.* 2014; 383: 424–35. doi 10.1016/S0140-6736(13)62073-5
- 581 30. Churchyard GJ, Stevens WS, Mametja LD, McCarthy KM, Chihota V, Nicol MP,
582 Erasmus LK, Ndjeka NO, Mvusi L, Vassall A, Sinanovic E, Cox HS, Dye C, Grant AD,
583 Fielding KL. Xpert MTB/RIF versus sputum microscopy as the initial diagnostic test
584 for tuberculosis: a cluster-randomised trial embedded in South African roll-out of
585 Xpert MTB/RIF. *Lancet Glob Health.* 2015; 3: e450–57. doi 10.1016/S2214-
586 109X(15)00100-X
- 587 31. Engel N, Wachter K, Pai M, Gallarda J, Boehme C, Celentano I, Weintraub R.
588 Addressing the challenges of diagnostics demand and supply: insights from an online
589 global health discussion platform. *BMJ Global Health.* 2016; 1: e000132.
590 doi:10.1136/bmjgh-2016-000132
- 591 32. Ministry of Health Mongolia. 1st Annex of the Ministerial order of the Ministry of Health
592 (N319) - Manual on the Management of Tuberculosis care and services. 2014; Ulaanbaatar:
593 Ministry of Health Mongolia.

594

595 **Supporting Information**

596 **S1 File. Appendix A – Interview Guides**

597 **Table 1. Number of patient specimens tested using Xpert MTB/RIF, by laboratory, in**
598 **Mongolia, 2013-2014**

Laboratory location	Commencement	Number of patient specimens¹ 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

599

600 ¹ Specimens include all pulmonary and extra-pulmonary specimens

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

Barriers	Enablers
Guidelines and organisational structures	
<ul style="list-style-type: none"> • Poor awareness of program guidelines – staff members were not always aware that guidelines existed and how they could be accessed • Inadequate staffing arrangements – laboratory staff participants indicated an increase in their workload without a change in staffing arrangements to accommodate the increased workload. 	<ul style="list-style-type: none"> • Clear guidelines in local language – in situations where participants were aware of guidelines in Mongolian, they were considered valuable guidance for working with Xpert MTB/RIF • Extra staff in NTRL, shift working arrangements and/or an increase in the number of modules - these arrangements would have assisted staff in meeting the increased demands that resulted from the introduction of Xpert MTB/RIF.
Equipment	
<ul style="list-style-type: none"> • Poor supply chain management of cartridges (stock-outs) – this happened on one occasion and meant Xpert MTB/RIF testing ceased. • Absence of local repair options – difficulties were reported for arranging repairs when required because of limited availability of trained mechanics to repair Genexpert machines in Mongolia. 	<ul style="list-style-type: none"> • Capacity for troubleshooting internally – there were some situations where the participants were able to determine the cause of machine faults and resolve them using a locally sourced solution. This meant little interruption to the work flow.

603

Barriers	Enablers
Training	
<ul style="list-style-type: none"> Inconsistent formal training options – some laboratory staff participated in formal training courses, others learned on the job through instruction by trained colleagues or superiors. 	<ul style="list-style-type: none"> Access to experts – some participants had direct access to visiting international technical experts Peer learning - all staff recognised the value of learning from their colleagues.
Communication Systems	
<ul style="list-style-type: none"> Paper based system – storing patient information on paper forms through the laboratory workflow meant results were communicated inefficiently through a paper based system and administrative reporting required a manual input of information. 	
Diagnostic algorithms, case finding for Xpert MTB/RIF and clinical management	
<ul style="list-style-type: none"> Treatment initiation in MDR-TB delayed until after consensus meeting – some participants reported a delay in initiating MDR-TB treatment because of the procedural requirement to determine the MDR-TB treatment plan at a weekly meeting in Ulaanbaatar. Poor sample quality - this was the most commonly reported error experienced by study participants. 	<ul style="list-style-type: none"> Common understanding of indications for Xpert MTB/RIF testing (diagnostic algorithms) - all participants reported an awareness of the indications for Xpert MTB/RIF use in Mongolia Testing availability in provincial centres (decentralised) – participants in provincial clinics value the accessibility of a tool to diagnose MDR-TB locally.

605 **Table 3. Summary of indications for clinicians to prescribe the Xpert MTB/RIF test, Mongolian**
 606 **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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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)	

607 Note: These indications are a summary adapted from treatment algorithms and other guidance outlined within the
 608 Mongolian National Tuberculosis Program Guidelines³²