Health service perceptions about implementation of a new TB diagnostic in Northern Russia: a qualitative study

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Setting: Many tuberculosis services are implementing new diagnostics to accelerate treatment initiation for multidrug-resistant tuberculosis. Successful implementation and uptake are likely to depend on many factors.

Objective: To describe the perceptions of the Arkhangelsk health services staff in Northern Russia on the process of introducing the line-probe assay and to determine what facilitates the process of uptake into practice.

Design: Process evaluation; semi-structured, in-depth interviews with key informants from civil and penitentiary health services; content analysis.

Results: A good working relationship between the civil and penitentiary sectors and a tradition of positive collaboration between doctors and managers were integral to success. Uptake and adaptation were facilitated by regular discussions between managers and implementers, flexibility in adapting routines and an iterative approach to improving procedures. It is beneficial to allow all types of health care workers affected by the diagnostic to learn about it and contribute to its integration. A multidisciplinary evaluation can detect problems elsewhere in the care pathway. Bringing about change in workplace mindsets and attitudes takes time and management.

Conclusion: People take time to observe the effects of innovations, assess relative advantages and become convinced, sometimes by different types of evidence. Multidisciplinary opportunities for learning, reflecting on care pathways and adaptation should all be a part of introducing new diagnostics.

Multidrug-resistant tuberculosis (MDR-TB) is still a significant burden in the Russian Federation. In the Arkhangelsk region, the incidence of newly diagnosed TB cases was 42.8 per 100 000 population in 2012, of whom 35.4% of new cases and 68.7% of re-treatment cases were MDR-TB.¹ Eighty per cent of all MDR-TB cases were resistant to ethambutol.¹ At the end of 2011, there were 22 cases of extensively drug-resistant tuberculosis (XDR-TB) in the Arkhangelsk region.

The Russian Federation guidelines recommend culture on Löwenstein-Jensen media for diagnosing MDR-TB.² In 2009, however, the TB services in Arkhangelsk began introducing an additional test, the rapid diagnostic line-probe assay (LPA, GenoType® MTBDR_{plus}, Hain Lifescience GmbH, Nehren, Germany), with a view to accelerating treatment initiation for MDR-TB. Although LPA had already been proven to be efficacious, it has been argued that other

factors should be studied to understand its feasibility and acceptability as well as how to facilitate rapid and appropriate uptake of LPA as well as changes in policy and practice.³ The international study, PROVE-IT LPA, was developed to assess the impact of LPA on time to initiation of treatment for MDR-TB in three sites: Cape Town, South Africa,⁴ Arkhangelsk, Russian Federation,⁵ and multiple sites within Brazil. A companion policy transfer analysis conducted in each country aimed to describe perceptions on the process of piloting LPA within the health services and how LPA was being taken up into practice and policy.⁶

Compared with a culture-based algorithm, the implementation of the LPA-based algorithm was associated with a median decrease in time to initiation of MDR-TB treatment of 50–66 days among smear-positive patients and 78 days among smear-negative patients. Several weeks were still needed, however, for treatment initiation in the LPA-based algorithm: 24 days for smear-positive patients and 62 days for smear-negative patients.⁵ In the Russian Federation, doctors and nurses are often perceived to be resistant to changing their ways of working.^{7–9} Furthermore, a lack of coordination between public health services and sectors in the Russian Federation has been identified as a particular challenge.^{10–12} The incomplete uptake of LPA by health service professionals would prevent patients from benefiting from this new technology. This policy transfer analysis aims to understand what facilitated uptake in Arkhangelsk and how to improve processes for the introduction of other new diagnostics for TB and other diseases. This paper reports the results of the qualitative policy transfer study conducted in Arkhangelsk.

METHODS

Between April and November 2010, VK, the principal investigator (PI), a Russian-speaking social scientist and psychiatrist, recruited 15 key informants involved in the diagnosis and treatment of TB at different levels of the health care services and related institutions. They had all been directly or indirectly involved in or affected by the introduction of the LPA diagnostic. Recruitment was conducted by e-mail and/or face-to-face. No informants dropped out after recruitment.

Interviewees included directors and managers of clinical and laboratory services in the civil and penitentiary facilities and the staff involved in implementing the diagnostic process and managing patients, the laboratory technicians, and doctors and nurses who

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KEY WORDS

tuberculosis; qualitative research; diagnostics; uptake; Russian Federation

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FIGURE A model for the analysis of policy transfer.⁷ Reprinted with permission of the International Union Against Tuberculosis and Lung Disease.

work at the central hospital and district-level facilities. Three of the informants were known to the PI from a previous qualitative study involving patients with TB. The three sectors involved in TB control in Arkhangelsk were represented: 1) civil health service, 2) penitentiary health service and 3) academic institutions. The civil and penitentiary services are involved in diagnosing, treating and preventing TB, and collaborate, acknowledging the fact that high-risk populations may move between their services. The academic sector is involved in leading research and informing policy decisions related to TB. Some informants belong to both the civil health service and the academic sector.

Purposive selection was used to achieve a comprehensive understanding of the attitudes and experiences of the informants of the implementation of LPA and the processes by which it had been introduced into the health services in Arkhangelsk region. Selection criteria included level of experience and role regarding LPA implementation as well as willingness to participate. Sampling continued until the thematic categories were saturated.

A heuristic framework for the analysis of health policy transfer was used to develop this qualitative descriptive study (Figure).¹³ Semi-structured, in-depth interviewing with a topic guide was undertaken.¹⁴ The topic guide was developed from the framework and included questions grouped into eight blocks: 1) definitions and perceptions about LPA and its implementation, 2) knowledge and learning about LPA, 3) persuasion and acceptance of LPA, 4)

decision making, 5) communication, 6) the future of LPA, 7) implications for the health care system, and 8) evaluation of the LPA implementation process.

Questions were piloted in Russian in the health service context, then further adapted for the different informants according to their profession and role in the introduction of LPA. Probing was used to explore any relevant issues about which the interviewee had particular insights or experience. Interviews were approximately 1 hour long, conducted in Russian at the workplace of the interviewees, with no one else present. Interviews were recorded with consent, and then transcribed verbatim.¹⁵ Interviewees were not reimbursed for participating.

A process evaluation was also undertaken, consisting of a written questionnaire completed periodically during the study by several groups of health services personnel. This served to triangulate data, capture changes over time and encourage staff to engage in their own analysis of the processes involved in LPA implementation and policy change.

Content analysis was conducted simultaneously with data collection.¹⁵ Coding categories were generated initially from the framework, using the basic components of the model as a starting point for category identification, then from the data in an iterative manner, emerging from participants' accounts of their experiences. Preliminary data analyses allowed the interview guide and coding to be revised iteratively. Analysis focused on generat-

ing categories describing LPA implementation in the Arkhangelsk region. Qualitative data analysis software Open Code 3.4 was used to organise and code the interviews.¹⁶

Coding was performed in Russian by the PI and the codes were then translated into English. The coding and results were discussed with the non-Russian-speaking qualitative researcher (KB), who works for an organisation focused on TB and lung disease. The PI does not work in the management of TB, which helped to minimise potential bias and ensure that data collection and analysis could allow new knowledge to emerge. Categories and themes were organised to provide theoretical coherence regarding the participants' experiences of LPA piloting, implementation and uptake, barriers and facilitating factors, and suggestions for the future of LPA expansion and the piloting of other diagnostics or treatment algorithms. During the analysis, special attention was paid to ideas that might be different from the evolving code list. We used extreme case sampling to achieve rich data for comparison. Memos written during and after data collection as well as during data analysis were used to sort and summarise major findings, and also helped to stimulate thoughts about any additional data requirements. We used member checking to ensure our interpretations respected the participants' opinions. To protect their identity, neither the type nor the workplace of the informant is indicated in the quotations used to illustrate the findings.

Ethics approval was obtained from the ethics committee of Northern State Medical University, Arkhangelsk, Russia, and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France.

RESULTS

Partnership between civil, penitentiary and academic sectors

Within the services dealing with TB in the Russian Federation, it is apparently commonly known that many patients move back and forth between the community and the prisons and that doctors generally lose contact with patients when they are incarcerated. Such patients constitute a large proportion of the cases reported as lost to follow-up each year.¹⁷ In the Arkhangelsk region, however, an atypical organisational arrangement appears to be addressing the challenge of following up patients. An official partnership exists between the civil and penitentiary systems for the management of TB, with the university as an academic partner taking a leading role in research. The civil system includes services provided by the hospital and the university. Many informants described this arrangement as an integral part of the LPA implementation and its success. They referred to the formal agreement between them and a long tradition of positive collaboration between doctors and managers. Several informants also explained that Arkhangelsk has long been considered a good place for trying out new approaches in TB control. For them, LPA was another example of Arkhangelsk being a good testing ground for innovations:

Our patients [in prison] are the same people they see in the civil sector. We work like two communicating vessels. We cannot exist without each other. We know that we will only be able to solve our problems by collaborating.

We collaborate closely with the TB services. This type of partnership is extremely rare. We have got a good technical system and materials and a progressive professor.

The collaboration with the department of phthisiopulmonology at the university has allowed us to achieve such good results and to use this method [LPA] in our institution.

Initial support and uptake

Key informants spoke positively about how the LPA project came about. Support appeared to be more active and enthusiastic from those who had a specific active role to play in the new test, such as the laboratory staff who had to change their procedures and who saw things improve. Support was also discernible, although somewhat more passive, from those whose procedures had not changed and who would not necessarily have seen any differences in timelines or procedures for their patients. Doctors in out-patient clinics, for example, would not actually see any reduction in diagnostic delay, since all patients with suspected MDR-TB are interned at the Tuberculosis Dispensary during diagnostic procedures and treatment.

Most informants spoke of 'total support' for the project from others; staff felt the heads of institutions and managers had been supportive and vice versa. Descriptions of support included commitment at the outset for the concept of testing LPA as well as supportive attitudes and procedures during the process of implementation.

Researcher: Over the last while, were there people who supported these ideas [about implementing LPA]? Did anyone resist them?

Informant: Everyone agreed. The prison system, the civil sector, the anti-tuberculosis dispensary ... all the doctors were for it, and as for the patients, everyone wants to know which mycobacterium is in his or her body, since the treatments are totally different.

The work in the dispensary was adjusted and we were all glad to be doing something new. We had been a long way away from using molecular methods, and then we found out more about them. Applying them became a real possibility. We were very glad about this and started planning.

Initially, however, not everyone reacted as positively as the project organisers would have hoped. Some scepticism and concerns arose early on due to initial technical problems as well as people not understanding or trusting the changes implicit in the new technology. Some were concerned about the speed at which test results were available and whether the results were reliable.

While we were all getting accustomed to the process, not everything went right, not everything arrived on time... this led to some negativity from doctors. They were worried when they heard that the answer would be available in 2–3 days...

First we tested it to see if the results were correct or not. We had to do that.

Resolution of these initial technical problems and discussion between the professionals, in particular explanation of the differences between the new and old methods, were among the factors that overcame scepticism in the early stages.

When we presented the method, it didn't happen in a single step. We had to show it and explain it several times. It was understandable that everybody wanted to wait for their own results. The first step in the implementation and organisation took too long. But it was a case of getting the technical aspects sorted out.

The level of motivation apparently increased as the project advanced. Some informants attributed this to people adjusting their

attitudes and behaviour as they began to understand more about the method and to observe how the LPA project was already starting to improve the whole series of procedures for diagnosis and patient management.

Every step [in the process] was treated as important. There were no unimportant events...Now everything works as one unified system.

Before [at the beginning of the project] it was steps, now it's a system.

Before, doctors would work in any part of the lab. Now there is a division of labour, tasks are more specialised.

Yes, many people have changed their minds; and more will change. This is not the end. Things will develop further when the methods become cheaper.

For the LPA project, it seems that some health professionals were initially sceptical, but that their concerns disappeared during the implementation phase, possibly once they had observed the results and begun to trust the new method. Several said that it took about half a year for people to adapt to the new algorithm. Many spoke of people needing to adapt what can be described as their mentality, mind-set or attitudes.

...It is the same way people react to anything that is new. They were used to waiting several months for results; there was a proven method and they trusted it. Then along comes a new method... would they just rush ahead and trust it? ... No, there was a space of about half a year before they really trusted the new method.

They saw they were getting exactly the same results, so they said, 'Let's go!'

The concept of needing a critical mass of people to support a change also arose.

It is very hard to change something when only two or three people want to change. If 200 or 250 people of sound mind out of 300 want to do it, then everything will work okay.

Some informants said that in a relatively short time, the new intervention had become an essential part of people's routines. Some believed that it would now be impossible to provide proper treatment without LPA.

Well, last month we ran out of reagent for the new method. It was a scandal, because now doctors do not know how to manage patients without testing drug resistance. One patient asked 'When will we start my treatment? And what about my diagnosis?!' The doctor had to see the patient every day and did not know what to say, because there were no results. So, now we don't know how to survive without this method!

Becoming convinced about LPA and convincing others

The majority of the informants stressed that the first step in the process of introducing a new intervention should always be informing and convincing people. Some described how people are the real power that will either build or destroy a project. One informant clarified that convinced people are the basis for creating a stable system, since they will then remain with the project even through hard times. Ensuring that people with managerial as well as operational roles had knowledge about the intervention and the opportunity to learn about it during the implementation period, alongside others in their workplace, appeared to be factors

that had a positive influence on uptake and motivation. The most positive experience took place when 'knowledge' included understanding about the technical and operational elements of the diagnostic as well as the expectations for what it should help the health services to achieve.

We need to inform people that time is reduced [with LPA], that LPA is just as good as other methods, we get reliable results. We can motivate people this way.

We need to teach people. We need qualified staff. Bacteriological tests are very expensive, so we need to plan for these expenses.

We can apply any new methods, but people can sabotage them unconsciously because of their attitude. We need to inform and to teach people. Misunderstandings are the main obstacle in such a project!

Learning stimulates change. You escape from ordinary routines where everything goes along in the same old way...and you sit there like a dummy with nothing challenging you to achieve things.

Informants described the following reasons for becoming convinced about the new intervention: seeing a reduced time to diagnosis; observing the reliability of the test and its concordance with other diagnostic methods; seeing how it could help improve patient adherence to treatment; and being able to distinguish mycobacteriosis from tuberculosis.

I left work early on Friday. [After I left] a patient was brought in from a district with fever. He had had TB about seven years ago, or maybe four years ago. Anyway, he had not been examined for a very long time. He had no medical documents with him. They were able to get a sputum sample, but couldn't do an X-ray because it was too late [in the day]. The patient's condition was good and the doctor let him leave. But on Monday I got the test results and it was smear-positive. This is an example of how fast it goes now. Before, it took many days.

It is testing mycobacteria with solid and liquid media. We see 100% of matching results; this is the criteria of success [of LPA].

We can test a patient fast, work out the treatment and make the patient safe. Move from contagious to non-contagious. So I consider that the project is successful.

One patient was treated here two years ago. Yesterday he had tests done. Today he called me and asked, 'What are my results?' Before, was he interested in his results? No!

Although all the informants identified the main difference between the old and the new diagnostic methods as obtaining results faster and thus being able to start treatment a few days after the first meeting with the patient, the doctors from the laboratory also described the change in terms of how it improved the whole chain of care and their ability to manage and communicate with patients.

I like this method. It is very modern. It is much easier to converse with patients. Within two weeks you see results and can prescribe treatment for sensitive TB or resistant TB. It is easy. Before, patients used to accumulate in the department, and you couldn't discharge them...

It is fundamentally different. The work became more dynamic. In one week we know what we are dealing with [for the diagnosis].

Communication and decision making

Some informants in high-level, decision-making positions mentioned learning about LPA at conferences, through communication with the company that produces LPA and through exchanges of experience with other countries and between other regions in the Federation. Managers and doctors from the laboratory described this type of communication as an important part of the project that improved their skills and helped them to work out how to implement and adapt the method to their context.

Our advantage is that we can share our experience and benefit from the experience of others. This is very important.

Some doctors had very different responses when asked about the level of communication they had had about LPA. They declared that they were not involved in communication about the project; they simply performed their duties. These informants were mostly clinic-level doctors who work with test results and do not work directly with the laboratory or managers.

There is a small service market. I didn't communicate with anyone in particular.

I don't work with the method...

Some Norwegians came... I had no communication with them.

Decisions about project implementation were reported to have been made by the leaders of the various institutions involved: the university, TB dispensary, regional penitentiary system and regional Ministry of Health. Some informants believed that consultative decision-making and good working relationships between the key people in these institutions contributed significantly to the success of LPA implementation.

[Decisions were made] together at all levels... not separately... between university, leadership in the Ministry of Health, leadership of medical service of our region, leadership of civil anti-tuberculosis system...

As with communication in the section above, most clinic-level doctors said that they did not participate in decision-making and simply performed their duties. They appeared not to expect to be involved in the decision-making.

...Ordinary doctors and heads of departments in the dispensary were not involved. A particular circle of people dealt with it.

Nobody informed us; we just got on with the work.

Adapting during implementation

During the implementation of the new LPA procedure, informants mentioned a number of elements that were adapted. Some were procedural processes related to the LPA method itself. Some of the tasks in the laboratory, for example, are organised differently now, and communication between TB doctors and the laboratory revolves around the rapidly available results, whereas doctors used to have to wait many days, often weeks, for results. Other elements involve broader systems issues that existed before LPA but were now being raised, seemingly because of all the discussions around the LPA project. Several informants mentioned how it would be important throughout the Arkhangelsk services to improve information and education for patients about diagnosis and treatment as well as the organisation of the TB services. Some suggested that without improving components such as sputum collection, case detection and adherence to treatment, the

success of any new diagnostic method would be somewhat irrelevant. Some proposed making treatment compulsory for patients, on the basis that any gains from applying new methods to reduce delay would be in vain if health services continue to lose patients to follow-up.

We need to teach patients how to collect phlegm instead of saliva, otherwise all the new methods will be useless!

We have to explain the method to patients, so that we can improve adherence to treatment.

If a patient goes back to the countryside, who manages them there? There is not really any organised service there that can make sure they finish their treatment. A molecular lab is useless if that service is not working!

There is a problem with the transportation of materials to our lab, not with diagnosis! That can delay it [diagnosis] for half a month or a whole month! So, not 100% get susceptibility testing.

Several informants spoke about how important it was to improve the overall system for managing patients. Some remarked on how important it had been to have a team of specialists (health service managers from each institution, clinical doctors, laboratory professionals) from all levels of the services to implement the new diagnostic method, as this had allowed discussion about how strategies for diagnosis and management could be adapted and improved. One informant described how doctors involved in the work had 'changed the system through their daily activities'. In a sense, they achieved some systems changes due to the one 'link' (LPA) in the 'chain' changing, and by having to adapt the rest accordingly.

Our system of diagnostics and treatment has developed like a logical chain of successive events. But now we are changing some links in the chain. This has led to changes in other links in the chain. Let's see: before LPA, doctors saw patients then had a 1-2 month wait for the results. Now they don't! Doctors have to run and think quickly. It is an amazing process!

The future of LPA

All informants viewed the continuation of LPA as very likely and very positive.

It has definitely been successful; this method will be used for a very long time in medical practice.

The project will be successful, it is successful already.

Informants were asked what, if anything, needed to be done to consolidate and expand LPA implementation. Several suggested ways in which to improve technology and health service organisation.

We need to reduce the time spent transporting materials to the lab; cut it right down to the minimum.

We need to think about each step so we can make the method fit as well as possible into everyday routine.

Everything will work fine if all aspects of how the method is to be used in daily practice are organised coherently. And if people are motivated.

Because we needed a common understanding among us all, including those at management level, to implement the LPA project.

When considering broader expansion, to other regions of the Russian Federation, for example, the obstacles to address included a lack of financial support, insufficient communication and the challenge of changing people's opinions and ways of working.

If there were enough funds, our neighbours [in other regions] would already have started adopting this technology. But you need at least two million rubles [EUR 27 202] for lab equipment.

Many health care professionals don't know about the method yet. Respiratory physicians know about it, but not the [general practitioners, GPs]....They haven't been informed.

People have to change their mind-set. Many institutions were used to waiting 2–3 months for results. So nobody was in a hurry.

The activities required to facilitate expansion included the dissemination of information and results, stimulating high-level interest, advocating for financial support and promoting policy change.

It would be very interesting for people to learn about the method. We haven't approached other institutions yet, but [we know] they are interested.

It is quite an opportunity for us to be able to use this technology. We are getting good quality information and it can be shared with others.

We need to be aware of the need for this method in places where not only has it not been used yet, but where it has not even been discussed, because of financial or other reasons.

It is expensive doing all these different tests [instead of just doing LPA] ... that may be the only way we can argue the case [for LPA].

Changing TB policy and training programmes to include LPA would be key, and international guidelines would help.

It would be very important to have recommendations from the WHO [World Health Organization] [on LPA]. That said, even the WHO seems a long way away to some politicians. They think that everything in Russia is special, that they know better. There are some organisations in the country, for example, the Ministry of Health, that can say, 'That method does exist, but it is not suitable for us'. They can make a decision just like that without any explanation.

Several informants pointed out that there are currently no official documents concerning the use of molecular methods for the diagnosis of TB and that this is complicating the expansion and development of LPA in the Russian Federation. Current guidelines state that it is compulsory to use solid or liquid culture as diagnostic tools. While LPA may be used in addition to culture, it is not permissible to use LPA alone. Anyone who stops using culture could be disciplined.

We cannot move away from the gold standard without receiving an order from above...

We need recommendations from the WHO...

...There is the Order relating to TB diagnosis and management ... it is very hard to make any decision [to stop using some of the culture methods], because that could be seen to be going against the Order...We have a lot of methods, and we keep on providing all the old methods because of the Order...But we really should be stopping some of the methods.

In the Russian Federation, it is usual for people to wait for orders from the top. It is very unusual for Russian specialist doctors to introduce something new themselves, as in the case with LPA, although some examples regarding treatment for the human immunodeficiency virus/acquired immune-deficiency syndrome (HIV/AIDS) have been reported.¹⁸ Some informants described the project as an initiative that would surely end up changing the gold standard from the bottom upwards. They clarified that such a policy change would be a very rare occurrence.

We are moving toward a change in the gold standard, moving away from the current gold standard. That will mean working in line with international guidelines; that is, stopping solid media. Our current Order was created back in 1998.

If we adopt the new method, everybody will need to know about it: from the GPs to the dispensary doctors who take patients through to the end of their treatment.

We need to teach staff. Bacteriological methods are very expensive; we have to plan the financial resources.

For several key informants, LPA has in fact become much more than a new method for diagnosing TB. The project itself, including the way it has been run as a collaborative research project, with regular discussions and dissemination of progress, seems to have generated much innovative thinking. Some people are now thinking about how to develop the method further, asking questions such as 'How can we use this method for other infections?' or 'Is it necessary to use LPA for all patients or only for those with confirmed smears?' Some are also considering its use in connection with GeneXpert® (Cepheid, Sunnyvale, CA, USA) in the admissions room. New bacterial mutations were also mentioned as new horizons for development.

DISCUSSION

This qualitative study interviewed key stakeholders involved in the provision of diagnostics and care for patients with TB in Arkhangelsk and captured their perceptions about the process of introducing and evaluating a new diagnostic, LPA. The findings allow us to draw a number of important lessons, which should help to improve processes for piloting and introducing future diagnostic innovations into the TB care pathway (Table). These lessons are likely to be relevant for other parts of the Russian Federation and may also generate useful reflection for TB programmes in other countries.

First, a good working relationship between sectors, here the civil and penitentiary sectors, as well as a long tradition of positive collaboration between doctors and managers, emerged as being integral to the successful evaluation and uptake of the method. Both sectors had already pragmatically acknowledged the need to collaborate on the provision of patient care. This existing relationship seemed to facilitate the collaboration, extending to a willingness to share operational data in the context of the PROVE-IT study that set out to evaluate the introduction of LPA. The Arkhangelsk model of partnership warrants further evaluation, as other regions of the Russian Federation are confronted with high burdens of TB, including MDR-TB and XDR-TB, among high-risk populations and within prisons.

Second, the rational and efficient adaptation of the innovation to its context was facilitated by the regular discussions between managers and implementers about what further changes might be necessary in the procedures and systems. Adaptation seems to

TABLE Lessons learnt about the process of introducing and facilitating the uptake of a new TB diagnostic in Northern Russia

Number	Lesson
1	Establish or maintain good working relations between all sectors involved in managing TB patients, especially high-risk populations
2	Acknowledge that civil and penitentiary services need to collaborate in management of TB in the interests of public health and patients
3	Develop a partnership between sectors for conducting operational research to inform decisions about introducing new diagnostics. Consider academic sector leadership of such research
4	Determine what other elements of the TB care pathway may be contributing to diagnostic delay and start addressing these. (Uptake may be jeopardised if people think the innovation, however good, will be less effective due to problems with other aspects of care)
5	Conduct qualitative research to capture patient perspectives about what causes diagnostic delay.
6	Inform all health care workers involved in the care pathway (including laboratory staff, doctors, nurses) about changes in: <ul style="list-style-type: none"> • diagnostic timelines, e.g., receipt of results, contacting patients • presentation and interpretation of results • recording and reporting procedures • information and key messages for patients
7	Manage the change by organising regular opportunities for health care workers to: <ul style="list-style-type: none"> • reflect on how the whole patient pathway is being affected by the change • communicate to managers about any problems and/or further adaptations to procedures that might be required
8	Facilitate uptake by using programme data and/or operational research to help health care workers form an opinion about the new diagnostic. People tend to judge by: <ul style="list-style-type: none"> • comparing existing methods with new methods • observing how the procedures they are involved in change • observing how operational and/or patient outcomes change
9	Be aware that it can take time for people to become convinced about a new procedure. Plan for monitoring of uptake and/or further operational research to assess and report outcomes

TB = tuberculosis.

have been enhanced by having a well-qualified and experienced team that understood how much flexibility was needed to adapt procedures and was willing to work iteratively through the chain of events in the laboratories affected by the introduction of the new diagnostic.

Third, a new diagnostic can require changes in many parts of the chain of care in addition to the laboratory, such as the timelines for getting results and contacting patients, the recording and reporting procedures and the explanations to patients. It is thus important to communicate not only with staff working in the laboratory, but also with the managers, clinicians, nurses and others involved in the care pathway, and to provide them with opportunities to learn about the innovation and the new procedures as well as to offer feedback about any further adaptations required.

This multidisciplinary approach, focused on evaluation and adaptation, may also be a way to allow implementers and managers to detect new problems in the TB care pathway in the Russian Federation or to reflect on how to address already acknowledged challenges^{19–20} that might ordinarily constrain the impact of the innovation. As the results demonstrated, some informants perceived that LPA already was, or should be, able to solve an identified problem, such as reducing delays in diagnosis. Some informants were concerned that other elements throughout the entire care pathway needed to be improved if LPA was to fulfil its potential.

Fourth, to become convinced and to decide to fully adopt an innovation, it seems that most people need some time either to compare it with the old methods, based on their own observations about how procedures or operational outcomes change, or to have their attention drawn to data or other observable results. Support for the innovation was widespread, although it was particularly strong from those most closely involved and most able to see its advantages relative to existing diagnostic procedures. These findings correspond to the features of observability and relative advantage, and have been described by numerous au-

thors.^{21,22} Data also confirm that different people and professions may be convinced by different types of evidence,^{23,24} and that stakeholder attitudes can facilitate or constrain the implementation of innovation.¹⁸ In piloting or introducing a diagnostic innovation, we should thus acknowledge that it will take time for people to change their attitudes and that we need to provide all professionals involved in the care process with access to the type of evidence that they will value.

These first four lessons seem to indicate that opportunities for learning, reflecting on the whole care pathway and adapting, should be built into the process of introducing a diagnostic innovation as part of what has been described as the ‘managing the change process’.²⁵ Operational research that is accompanied by a qualitative component, such as a process evaluation or qualitative interviewing,¹³ might be a good way to help achieve this. When conducted in parallel with an impact assessment,³ these methodologies provide a valuable complement to the type of new diagnostics feasibility studies that have a more quantitative and technical mandate and scope.²⁶

A final lesson is that the uptake of a diagnostic innovation can only go so far without policy change. For LPA to be adopted elsewhere in the country, people spoke of needing to attract the interest of high-level policy makers, advocate for greater financial support for LPA and promote policy change. It would seem that the first phases of piloting or introducing a diagnostic innovation should be accompanied by operational research designed to produce the type of data that will allow policy makers to determine whether expansion of the innovation to other places would be feasible and advisable, and if so, how to accomplish expansion. This lesson was explored further in the second phase of the data collection, and will be reported in a separate paper.

One limitation of the study might be that the patient perspective of the introduction of LPA was not included. Our study design, however, necessarily focused on understanding health service perceptions about the process. We knew that a separate qualitative study conducted in Arkhangelsk specifically aimed to

describe the experiences and opinions of patients and doctors on the reasons for diagnostic delay. As that study was able to be more comprehensive in capturing patient perspectives on the diagnostic experience,²⁷ we did not include patient informants in the current study. It is, however, useful to compare findings. The diagnostic delay study found that patients in the Arkhangelsk region had delayed TB diagnoses because they avoided going to the health services, did not look after their health and used self-treatment. Only the realisation that death was a probable outcome was a sufficient motivator for them to seek medical help. Delays arose because patients had limited willingness to contact the health system, and the health system had limited resources to reach them. Health system delay was influenced by factors such as organisational problems, and lack of knowledge and experience of medical personnel. Our study of health service perceptions about the process of LPA implementation has shown that LPA has probably helped to improve some of the issues mentioned by patients (although patients are not aware of the changes in the internal health service processes). Our study suggests that the improvements may be due not only to reorganisation of the laboratory procedures but also to the improvements in communication between specialists, as well as between specialists and patients.

There may also have been some recall bias, given that the interviews were conducted after the LPA had been introduced. The interviews, however, were held only 1 year after the beginning of the implementation. Moreover, as it was part of the study design to benefit from the reflections of the informants on the process, some time needed to elapse before the interviews could be conducted. Comparison and triangulation were useful means of analysing the data.

The study had a number of strengths. As the literature contains few qualitative studies about innovation uptake and the operations of regional TB health services in the Russian Federation, these findings contribute to filling a recognised gap. This study had access to the key individuals involved in the research. The informants represented the different levels and sectors involved in activities related to LPA, including the penitentiary sector, which is reportedly usually hard to access. Broad participation allowed a wide range of perspectives to be captured and analysed.

CONCLUSIONS

This study has demonstrated that there are ways to facilitate the uptake of a diagnostic innovation. Health services need to have a process that enables the workplace and all others involved to learn, communicate and adapt attitudes and procedures to incorporate the diagnostic innovation so that it can achieve maximum benefits for patient care. Mixed-method operational research seems a good approach for creating an atmosphere of learning and for generating data and knowledge that will convince implementers to take up the innovation and to help them to adapt it rationally and efficiently to their context. This knowledge may help to improve the processes of piloting and implementing future new diagnostics in Arkhangelsk and other parts of the Russian Federation, and may generate useful reflection in the TB programmes of other countries.

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Contexte : De nombreux services de tuberculose mettent en œuvre de nouveaux diagnostics afin d'accélérer la mise en route du traitement de la TB multirésistante. Cependant, le succès de leur mise en œuvre et de leur adoption est susceptible de dépendre de nombreux facteurs.

Objectif : Décrire les perceptions des services de santé d'Arkhangelsk dans le Nord de la Russie à propos du processus d'introduction des tests par sonde en ligne et déterminer ce qui facilite leur adoption en pratique.

Schéma : Evaluation du processus ; entretiens semi-structurés approfondis avec des informateurs clés des services de santé civils et pénitentiaires ; analyse du contenu.

Résultats : De bonnes relations de travail entre les secteurs civil et pénitentiaire et une tradition de collaboration positive entre les médecins et les gestionnaires ont été partie intégrante du succès. L'adoption et l'adaptation ont été facilitées par des discussions

régulières entre les gestionnaires et les responsables de la mise en œuvre, la souplesse de l'adaptation des pratiques de routine et une volonté permanente d'améliorer des procédures. Permettre au personnel de santé de tous les niveaux concernés par le diagnostic d'en apprendre plus à son sujet et de contribuer à son intégration est bénéfique. Une évaluation multidisciplinaire peut contribuer à détecter des problèmes ailleurs dans le parcours de soins. Amener un changement des mentalités et des attitudes sur les lieux de travail demande du temps et une bonne gestion.

Conclusion : Il faut du temps aux gens pour observer les effets des innovations, pour évaluer leurs avantages relatifs et être convaincus, quelquefois par différents types de preuves. L'introduction de nouvelles méthodes de diagnostic devrait s'accompagner d'occasions multidisciplinaires d'apprentissage, de réflexion sur les parcours de soins et d'adaptation.

Marco de referencia: Muchos servicios de tuberculosis están introduciendo nuevos métodos diagnósticos con el propósito de acelerar el comienzo del tratamiento de la tuberculosis multirresistente. Sin embargo, la introducción adecuada y la aceptación de los métodos dependerán de diversos factores.

Objetivo: Describir las percepciones sobre el proceso de introducción de la hibridación con sondas en tiras en los servicios de salud de Arkhangelsk en el norte de Rusia y determinar los factores que pueden facilitar su adopción en la práctica.

Método: En la evaluación del proceso se utilizaron entrevistas exhaustivas a informantes claves de los servicios de salud del sector civil y penitenciario y se llevó a cabo un análisis de contenido.

Resultados: La buena relación laboral entre el sector civil y penitenciario y una tradición de colaboración positiva entre el personal médico y administrativo fueron aspectos fundamentales en el éxito. Los factores que facilitaron la aceptación de las pruebas y su

adaptación fueron los siguientes: una comunicación periódica entre los administradores y los encargados de la implementación, la flexibilidad para adaptar los procedimientos rutinarios y una estrategia iterativa destinada a mejorar los procedimientos. El hecho de procurar que todas las categorías de personal que intervienen en el diagnóstico aprendan sobre el método y contribuyan a su integración es un elemento favorable. La evaluación multidisciplinaria puede ayudar a detectar los problemas en otros campos del trayecto asistencial. Modificar las mentalidades y las actitudes en el lugar de trabajo precisa tiempo y organización.

Conclusión: Las personas necesitan tiempo para percibir los efectos de las innovaciones, evaluar las ventajas relativas y convencerse de su utilidad con diferentes tipos de pruebas. Las oportunidades multidisciplinarias de formación, la inclusión de todos los itinerarios asistenciales y la adaptación deben formar parte integrante de la introducción de los nuevos medios diagnósticos.