Beyond accuracy: creating a comprehensive evidence base for tuberculosis diagnostic tools

G. Mann,* S. B. Squire,* K. Bissell,† P. Eliseev,‡ E. Du Toit,§ A. Hesseling,§ M. Nicol,¶ A. Detjen,†
A. Kritski#

*Liverpool School of Tropical Medicine, Liverpool, UK; †International Union Against Tuberculosis and Lung Disease,
Paris, France; ‡Arkhangelsk Regional Anti-tuberculosis Dispensary, Arkhangelsk, Russian Federation; §Desmond Tutu
TB Centre, Cape Town, ¶National Health Laboratory Services, Johannesburg, South Africa; #Rede TB, Brasília, Brazil

SUMMARY

The need for a strong and comprehensive evidence base to support decision making with regard to the implementation of new and improved diagnostic tools and approaches has been highlighted by a number of stakeholders; these include members of the New Diagnostics Working Group (NDWG) and the Subgroup for Introducing New Approaches and Tools of the Stop TB Partnership. To compile such evidence in a systematic manner, we have developed an impact assessment framework (IAF) which links evidence on inputs to outcomes.

The IAF comprises five interconnected layers: effectiveness analysis, equity analysis, health systems analysis, scale-up analysis and policy analysis. It can be used by new diagnostics developers and other interested research teams to collect as much policy-relevant data as possible prior to, during and after the demonstration phase of tool development. The evidence collated may be used by international and national policy makers to support adoption, implementation and scale-up decisions. The TREAT TB (Technology, Research, Education and Technical Assistance for TB) initiative uses the IAF in its operational research and field evaluations of new tools and approaches for TB diagnosis. It has also been incorporated into the NDWG's recent publication: 'Pathways to better diagnostics for tuberculosis: a blueprint for the development of TB diagnostics'. This article describes the IAF and the process of improving it and suggests next steps in overcoming the challenges in its implementation.

KEY WORDS: impact; evidence; tuberculosis; policy; diagnostics

*Every TB patient must have access to an effective
diagnosis, treatment and cure.*
—The Global Plan to Stop TB 2006–2015[1]

THE ABOVE PRINCIPLE is key to attaining the vision of the Stop TB Partnership of seeing a tuberculosis (TB) free world by 2050.[1] Access to an 'effective diagnosis' has long been a concern. Smear microscopy is not sufficiently sensitive to detect tuberculosis disease in many cases, and particularly not in children and those who are co-infected with the human immunodeficiency virus. Multi- and extensively drug-resistant TB present new diagnostic and treatment challenges. Thankfully, new diagnostic approaches using existing tools have been recommended and new tools are in the pipeline.[2]

Any new approach or tool must be evaluated before being adopted by national tuberculosis programmes (NTPs); huge sums of money are already spent on TB diagnostics—estimated at more than $1 billion per year globally[3]—and resource-poor countries cannot afford to invest in interventions that are not more cost-effective than those already available. The World Health Organization (WHO) plays a key role in approving and developing guidelines for the use of new tools. The policy making process, described in a recent WHO statement,[4] comprises:

1 identifying the need for a policy change (e.g., the emergence of a new technology);
2 reviewing the evidence (e.g., through commissioning systematic reviews);
3 convening an expert panel to review evidence using the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation, see BMJ 2008[5–9]);
4 assessing draft policies and guidelines (through the Strategic and Technical Advisory Group for TB, STAG-TB); and
5 formulating and disseminating new policies and guidelines.

Recent papers by Pai et al. have noted that systematic reviews, and hence the evidence reviewed in the above policy development process, have concentrated

Correspondence to: Gillian Hazel Mann, Liverpool School of Tropical Medicine–CRESTHA, Pembroke Place Liverpool
L3 5QA, UK. Tel: (+44) 151 705 3139. Fax: (+44) 151 705 3743. e-mail: ghmann@liv.ac.uk

[A version in French of this article is available from the Editorial Office in Paris and from the Union website www.theunion.org]

mainly on test accuracy.[10,11] While such data are necessary, they are not sufficient to assess the contribution new diagnostics can make to the universal access requirements outlined in the Global Plan to Stop TB. A number of stakeholders, the Subgroup for Introducing New Approaches and Tools (INAT) and the New Diagnostics Working Group (NDWG) of the Stop TB Partnership, among others,[11–13] have called for a strong and comprehensive evidence base to support decision making with regard to implementation of new and improved diagnostic tools.

The NDWG has published 'Pathways to better diagnostics for tuberculosis: a blueprint for the development of TB diagnostics',[2] which outlines the required phases from needs assessment through test development to assessment of epidemiological impact, and all stages in between (Figure). The Stop TB Partnership's Retooling Taskforce, a precursor to INAT, stipulated the need for evidence that captures not only the benefits of new tools but also the risks and health systems implications associated with them.[14] This range of evidence is encapsulated in the Organisation for Economic Cooperation and Development definition of 'impact' subscribed to by multi- and bilateral donors who have signed the Paris Declaration on Aid Effectiveness (2005), which states that impact consists of:

> [The] positive and negative long-term effects on identifiable population groups produced by a development intervention, directly or indirectly, intended or unintended. These effects can be economic, socio-cultural, institutional, environmental, technological or of other types.[15]

Thus, measuring the impact of a diagnostic tool or approach involves assessing its positive and negative effects on different stakeholders (patients, health systems, laboratories, etc).

This entails summarising evidence not only about the test's accuracy, but also its effectiveness in field conditions in terms of diagnosing patients with various TB presentations, especially for the most infectious, and ensuring that they start appropriate treatment, its affordability, ease of implementation and potential for scale-up (for the health system) and accessibility (especially to poor and vulnerable TB suspects). Articulating and communicating this overall impact succinctly and with sufficient evidence is essential. It is required for national policy makers to make rational decisions about which new diagnostic tests and approaches to adopt, when and how to implement them, how to manage and finance them and how to ensure sustainable access and appropriate use.[14]

To compile such evidence in a systematic manner, we have developed an impact assessment framework (IAF) that links evidence on inputs to outcomes. This framework has been included in the NWDG's blueprint and has been adopted by the TREAT TB (Technology, Research, Education and Technical Assistance for TB) initiative for use in its operational research and field evaluations of new tools and approaches that are at late stages of development or have recently achieved international approval for use in TB diagnosis and treatment.

The present study describes the IAF, provides examples of how it can be used and suggests means of overcoming the remaining challenges in its implementation.

THE IMPACT ASSESSMENT FRAMEWORK

The IAF has been developed by a multidisciplinary team at the Liverpool School of Tropical Medicine and collaborators, including clinicians, laboratory specialists, health economists, social scientists and health systems analysts. It is based on a range of prior research activities in different countries that supported different elements of the evidence base.[16–25] These elements have been combined to provide an overarching
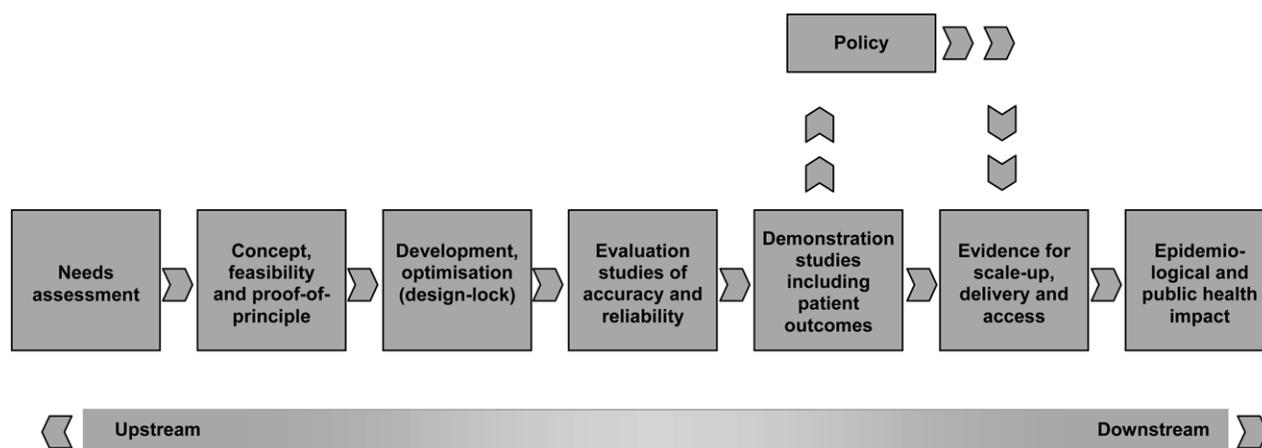

Figure   Pathway for the development of tuberculosis diagnostics, from needs assessment to delivery [reproduced from reference 2 with permission from the World Health Organization].

framework (the IAF) to indicate how sufficient information for policy decisions could be collected in a systematic manner for all new diagnostic tools and approaches. The sufficiency of information has been considered in line with the international targets of the Global Plan to Stop TB and the Millennium Development Goals (MDGs).[26] The IAF, with references relating to different types of evidence, is shown in Table 1.

The IAF comprises five interconnected layers:

1 Layer 1: Effectiveness analysis
2 Layer 2: Equity analysis
3 Layer 3: Health systems analysis
4 Layer 4: Scale-up analysis
5 Layer 5: Policy analysis

Table 1 The impact assessment framework

Layer of assessment	Kinds of question(s) being addressed	References to studies addressing these questions
Layer 1 Effectiveness analysis	How well does the new tool work in terms of accuracy?	16
	How many additional cases will be identified who would otherwise not have been identified?	20
	How many additional cases will actually start (and complete) treatment as a result of using the new tool?	21
Layer 2 Equity analysis	Who benefits from the new tool (ambulant vs. hospitalised, poor/less poor, men/women, adults/children)?	27
	Why do these benefits accrue (level health system in which new diagnostic is deployed, change in time to issue of results, change in patient costs)?	22
Layer 3 Health system analysis	What are the human resource implications of introducing the new tool (training, number and cadre of staff)?	19
	What are the infrastructure implications (equipment, laboratory layout, safety installations)?	23
	What are the procurement implications (reagents, consumables, documentation)?	28
	What are the implications for quality assurance (internal and external)?	17
Layer 4 Scale-up analysis	What are the projected impacts of going to scale with the new tool? 1 Cost savings to patients in relation to income 2 Cost savings to health providers/ the health system 3 Effects on transmission of improved infection control as a result of the new tool	18
Layer 5 Policy analysis	What other similar technologies are available or likely to become available?	29
	How do similar existing or emerging technologies compare in their projected performance within each of the layers above?	25

Layer 1: Effectiveness analysis

This layer requires evidence about the accuracy (sensitivity and specificity) of new tools and approaches, but also flags the need to go further than this and build evidence on effectiveness. Data on sensitivity and specificity are universally provided by developers of new diagnostics, and their positive and negative predictive values have been suggested by GRADE as proxies for patient-important outcomes in the assessments of new tools. However, estimations of the number of patients who might start and complete appropriate treatment are typically calculated by extrapolating these parameters, rather than relying on evidence from field trials to provide estimates of actual numbers. All too often, diagnostic evaluations assess new tests solely in terms of their diagnostic potential (accuracy), which may not always translate into appropriate clinical or public health management decisions for patients within the context of health services (effectiveness).

Layer 2: Equity analysis

This layer examines who benefits from the new intervention. The Global Plan to Stop TB highlights the need to 'prioritise the needs of the poor and vulnerable', recognising that the greatest burden of TB is found among poor people, who also face the greatest barriers in access to care.[22] Typically, however, the systematic measurement of equity in health and health interventions is either absent or sporadic. Although the first MDG is expressed in terms of an equitable outcome, the health and other goals that are intended to contribute to this make no specific reference to equity or distributional issues.[30]

Layer 3: Health systems analysis

This layer examines the health systems requirements of a new intervention, for example human resources, infrastructure, operating procedures, quality assurance, procurement and maintenance.

These data are sometimes collected during the demonstration studies (Figure)—studies in optimised operational settings—of new diagnostics, but not in all cases. Even where they are collected, the improvement to operations necessarily provided through the demonstration study may mask issues that become apparent in implementation ('real world') studies. This layer provides crucial data for assessing the feasibility of implementation and for identifying where key constraints, or bottlenecks, in the system may occur.

Layer 4: Scale-up analysis

This layer projects and models the full economic costs as well as the clinical and epidemiological effects of going from demonstration or implementation studies to full scale (national or regional) with a new intervention. Health system, patient and societal

perspectives are all important here. Modelling techniques can provide information concerning the epidemiological benefits of scaling up and, when combined with patient costs from Layer 2, total additional costs or savings for patients. At the same time mathematical systems analysis techniques can outline the potential constraints to and resources required for scale-up. When combined with cost analyses from Layer 3, these can give an indication of total resources required as well as identify and quantify likely resource gaps.

Layer 5: Policy analysis

This layer critically appraises the new intervention studied in Layers 1–4 against other interventions that are available or may become available for uptake in the short to medium term. An important part of this layer is a scoping of the risk that a given new diagnostic test may be supplanted by newer technology within a short period of time. It requires a rapid assessment of data on other pipeline diagnostics from the previous four layers and a review of whether changes made for one diagnostic may provide a better platform for the next technology or, alternatively, whether the new technology is 'disruptive',[31] or 'market transformational',[32] both terms used to describe a technology that could radically alter the way in which TB diagnosis is achieved.

USING THE IAF

The IAF can be used by diagnostics research teams during the 'demonstration' and 'evidence for scale-up, delivery and access' phases of development shown in the Figure. The latter may take the form of field evaluation, or implementation, studies in non-optimised settings, or of other operational research activities. The framework can also be used by international policy makers during the policy development process to systematically assess a broader range of evidence, and by national policy makers to support adoption, implementation and scale-up decisions.

The IAF has already been used for the development of protocols for a multi-country research programme to study the implementation of line-probe assays (LPAs), which were recommended by WHO STAG-TB in 2008.[33] Representatives from three countries (Russia, Brazil and South Africa), all clinicians or laboratory specialists, with other members of the TREAT TB core group, discussed the priority research questions they would like to answer with regard to the use of LPAs, and mapped these questions to each layer of the IAF. All the questions raised mapped to one layer of the framework, and all layers were addressed; the resulting framework is shown in Table 2. Each of these teams now has a different protocol for collecting the evidence, due to the stage at which their NTPs are with regard to rolling out LPA. Nevertheless, each will provide data against the same set of

Table 2 Use of the IAF for designing LPA field studies

Layer of assessment	Kinds of questions being addressed: questions and issues raised by multi-country research teams
Layer 1 Effectiveness analysis	How many additional cases will be identified who would otherwise not have been identified? How many additional cases will actually start treatment/achieve cure/avoid death as a result of using LPAs? What will be the effect on tuberculosis transmission? How will LPA affect the timeliness in results influencing a clinical or treatment decision?
Layer 2 Equity analysis	Who is benefiting from LPA implementation and why? Is the test sufficiently accurate for all patients? What are the risks to patients/others? What costs will patients face? How acceptable is the test to patients? Are there inequalities in access to LPA?
Layer 3 Health system analysis	What is the effectiveness and/or efficiency from a health system perspective? What effect will LPA have on how cases are managed in the health system? What quality assurance mechanisms need to be in place? What information systems need to be in place? What are the human resource requirements in the health system? What are the laboratory issues (including infrastructure, e.g., utilities, space; personnel, e.g., numbers and skills; monitoring system for laboratory)? How will the challenge of mixed infections be addressed? What are the safety issues? How will the results be interpreted and standardised?
Layer 4 Scale-up analysis	What are the obstacles to the rollout? What are the human resource and training requirements for full national scale-up?
Layer 5 Policy analysis	How does LPA compare with conventional 'old' methods vs. other new methods that may be available in the short to medium term? How does LPA interface with other existing and new diagnostics that will be recommended and implemented in the future (e.g., GeneXpert)?[34] Should routine drug susceptibility testing be completely dropped and replaced by LPA?

IAF = impact assessment framework; LPA = line-probe assay.

outcome indicators, facilitating comparisons across different epidemiological settings.

The central methodology that we advocate to feed robust evidence into Layers 1–3 is the prospective randomised controlled trial (RCT). This design permits comparison between the existing technology and approach (control) and the new (intervention), as follows:

For Layer 1, a comparison of effects on 1) numbers of patients achieving important outcomes (including diagnosis, start of treatment and treatment completion), and 2) time to achieving these outcomes.

For Layer 2, a comparison of effects on different patient sub-groups (e.g., poor vs. less poor, adults vs. children). Equity may be assessed based on outcome indicators among different groups, in terms of morbidity or mortality measures, or process indicators such

as health service use.[30] Analysis of socio-economic status may use asset-based measures to define different socio-economic groups.[35] Demographic and health surveys and more recent TB prevalence surveys are increasingly using these methods.[36,37]

For Layer 3, a comparison of the health system inputs is required. Data for this may be gained through economic analyses of standard vs. new diagnostic interventions, focusing on the health system and not just the tool, and through interviews with health systems personnel.

Data for these comparisons can be obtained across all study participants in both intervention and control arms, or through nested sub-studies on more limited numbers. For example, in-depth qualitative and quantitative research on patient costs incurred during a diagnostic process (either control or intervention) is time consuming, and data are thus only collected for a subgroup of study participants. Data from Layers 1–3 can then be fed into the modelling and other methodologies required in Layers 4 and 5.

We recognise that the type of randomised trial employed will depend on the stage of diagnostic development to which the IAF is being applied. During demonstration studies (which may be conducted prior to STAG-TB approval), an explanatory RCT with well-controlled study conditions and data collection instruments is appropriate. During subsequent implementation or operational research, a pragmatic RCT (PRCT) approach using existing health system data will be more suitable (for a fuller description of the difference between explanatory and pragmatic RCTs see Zwarenstein et al.[38]) There are concerns that RCT designs deny some patients (those in the control arm) the assumed benefits of a new technology —especially in the implementation research of STAG-approved technologies. Such ethical concerns need to be addressed, for example by ensuring that the PRCT includes a scale-up plan, such as through a step wedged approach in which all sites access the technology, but in a phased manner, to allow for comparisons between those with and those without the technology.

NEXT STEPS AND OVERCOMING CHALLENGES TO USING THE IMPACT ASSESSMENT FRAMEWORK

The framework will continue to be revised as experience in using it for research design and implementation continues. It will have value for other diagnostics tools and also for drugs and vaccines. The research methodologies for addressing each of the different layers are under constant development. As the multidisciplinary research teams needed to implement these methodologies are currently uncommon in many countries, capacity building involving training, mentoring and partnership between service delivery programmes, academic organisations and patient organisations will be required. The increased focus on patient-centred outcomes in particular will provide opportunities for patient representatives and organisations to become more engaged in the research process. If patient groups are empowered to collect and analyse relevant data—particularly in Layer 2—it will give them a greater voice in policy decision-making at the national and international levels.

When it was originally developed, the IAF was envisaged as being applicable to single new tests. However, as we move further into implementation research it is clear that it will also need to be applied to packages of tests, or combinations of existing and novel tests, along with all the additional inputs required to introduce such packages and combinations in different algorithms; this challenge is currently being addressed under the TREAT TB initiative.

The questions in the different layers of the IAF do not all necessarily carry equal weight in any given circumstance. For example, a new test for detecting drug resistance that is best suited for deployment in a central reference laboratory may be more important in monitoring drug resistance patterns than in directly improving patient access. The questions about which patient group or type of patient benefits (Layer 2) may then assume lesser importance, whereas these may be key research questions in a diagnostic approach or test that is aimed at 'point of care'.

We also recognise that while the IAF provides a body of evidence for policy makers, evidence alone is often not the only driver of policy change; process, context and sometimes subjective factors, for example expert or political opinion, can also play a substantial role. These factors need clearer and more systematic documentation and analysis in the process of implementation research. This is the subject of a forthcoming study by Bissell et al.

There are concerns that accumulating a comprehensive evidence base such as the one we advocate here will take too long and be too costly; rather than promoting the rational uptake of new technologies, it will instead impede the introduction of much needed innovations. Such concerns are valid, but they must be balanced against the dangers of the premature introduction of tools into unprepared and under-resourced health systems, often as a result of lobbying or forceful marketing. To counter both sides of this argument, research and implementation partners need to come together and collaborate on an unprecedented scale, and with a renewed sense of urgency. By directly addressing the concerns of policy makers through the research process, the adoption and implementation of new tools should be achieved more rapidly, sustainably and with beneficial effects for affected populations.

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RÉSUMÉ

La nécessité d'une base de preuves solide et complète pour servir à la prise de décisions en ce qui concerne la mise en œuvre d'outils de diagnostic et d'approches nouvelles et améliorées a été soulignée par un certain nombre de responsables ; parmi ceux-ci, des membres du groupe de travail sur les nouveaux outils diagnostiques New Diagnostics Working Group (NDWG) et du sous-groupe pour l'introduction d'approches et d'outils nouveaux (Subgroup for Introducing New Approaches and Tools) du Partenariat Stop TB. Afin de rassembler ces évidences de manière systématique, nous avons élaboré un réseau d'évaluation d'impacts (IAF) qui fait le lien entre apports et résultats finaux.

L'IAF comporte cinq couches interconnectées : analyse d'efficience, analyse d'équité, analyse des systèmes de santé, analyse de l'extension et analyse de la politique. Il peut être utilisé par ceux qui élaborent de nouvelles techniques de diagnostic et par d'autres équipes de recherche intéressées à rassembler autant de données possibles en rapport avec la politique à suivre avant, pendant et après la phase de démonstration de l'élaboration de l'outil. Les évidences rassemblées peuvent être utilisées par les décideurs politiques internationaux et nationaux pour soutenir des décisions d'adoption, de mise en œuvre et d'extension. L'initiative TREAT TB (Technologie, Recherche, Education et Assistance Technique) utilise l'IAF dans sa recherche opérationnelle et dans ses évaluations sur terrain des nouveaux outils et des nouvelles approches du diagnostic de la tuberculose ; l'IAF a été incorporé dans la publication récente du NDWG : « Pathways to better diagnostics for tuberculosis: a blueprint for the development of TB diagnostics ». Cet article décrit l'IAF et les processus employés pour son amélioration et suggère les étapes ultérieures pour surmonter les défis que comporte sa mise en œuvre.

RESUMEN

Varios interesados directos, entre ellos el Grupo de Trabajo sobre Nuevos Diagnósticos (NDWG) y el subgrupo de introducción de nuevos enfoques e instrumentos de la Alianza Alto a la Tuberculosis, han destacado la necesidad de contar con una base de datos científicos sólida y exhaustiva, a fin de respaldar la toma de decisiones relacionadas con la introducción de nuevos enfoques e instrumentos perfeccionados de diagnóstico. Con el objeto de recoger estos datos de manera sistemática, se ha diseñado un marco de evaluación del impacto (IAF), que vincula los datos aportados con los resultados obtenidos.

El marco de evaluación del impacto comporta cinco estratos interconectados: el análisis de eficacia, el análisis de equidad, el análisis de los sistemas de salud, el análisis de la ampliación de escala y el análisis de las políticas. Este marco pueden usarlo los creadores de nuevos métodos diagnósticos y otros grupos científicos interesados, durante el desarrollo de un nuevo instrumento con el fin de recoger la máxima cantidad de datos pertinentes a las políticas, antes de la fase de demostración, durante la misma o después de ella. Los datos científicos recogidos pueden ser útiles a los encargados de definir las políticas a escala nacional o internacional, a fin de respaldar las decisiones de adopción, ejecución o ampliación de escala. En la iniciativa TREAT TB (Tecnología, Investigación, Educación y Asistencia Técnica para la Tuberculosis) se aplica el IAF en las evaluaciones de la investigación operativa y de terreno de los nuevos instrumentos y estrategias utilizados en el diagnóstico de la tuberculosis. También se ha incorporado en la publicación reciente del NDWG: 'Pathways to better diagnostics for tuberculosis: a blueprint for the development of TB diagnostics' (Estrategias encaminadas a mejorar los métodos diagnósticos de la tuberculosis: un plan de acción para el desarrollo de medios diagnósticos). En el presente artículo se describe el IAF y los mecanismos que permiten mejorarlo y se sugieren nuevos pasos que contribuyan a superar las dificultades que plantea su ejecución.