Guidelines and Recommendations

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Toolkit for emerging technologies in laboratory medicine

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Abstract: An emerging technology (ET) for laboratory medicine can be defined as an analytical method (including biomarkers) or device (software, applications, and algorithms) that by its stage of development, translation into broad routine clinical practice, or geographical adoption and implementation has the potential to add value to clinical diagnostics. Considering the laboratory medicine-specific definition, this document examines eight key tools, encompassing clinical, analytical, operational, and financial aspects, used throughout the life cycle of ET implementation. The tools provide a systematic approach starting with identifying the unmet need or identifying opportunities for improvement (Tool 1), forecasting (Tool 2), technology readiness assessment (Tool 3), health technology assessment (Tool 4), organizational impact map (Tool 5), change management (Tool 6), total pathway to method evaluation checklist (Tool 7), and green procurement (Tool 8). Whilst there are differences in clinical priorities between different settings, the use of this set of tools will help support the overall quality and sustainability of the emerging technology implementation.

Keywords: change management; emerging technology (ies); health technology assessment; laboratory medicine; technology readiness level; unmet clinical need

Introduction

Emerging technologies (ET) and laboratory medicine entered the spotlight in 2019 with coronavirus disease testing (COVID-19). Following the initial report of a cluster of atypical pneumonia-like illnesses in December 2019, the genomic sequence of the then-unknown virus was published as “Wuhan-Hu-1” (MN908947) in Genbank a month later through international collaboration. The genomic sequence allowed rapid development and deployment of in-house (laboratory-developed) molecular tests to detect this rapidly spreading virus and contributed to the global response to this emerging pandemic. One year later several commercial tests became available. The first severe acute respiratory syndrome-coronavirus-2 (SARS-COV-2) molecular diagnostic rapid test for self-testing (Lucira COVID-19 All-In-One Test Kit) was U.S. Food and Drug Administration (FDA)-approved under the Emergency Use Authorization (EUA) scheme on November 11, 2020 [1], and this was followed by the first FDA-approved over-the-counter at-home diagnostic antigen test for SARS-COV-2 (Ellume COVID-19 Home Test) on December 15, 2020 [2]. As of 2023, there are now in the aggregate, hundreds of antigen [3], molecular [4] and antibody tests for SARS-COV-2 [5]. An example of a rapid health technology assessment (HTA) related to serological tests for SARS-COV-2 has been recently published [6]. This rapid pace of SARS-COV-2-related ET introduction into laboratory medicine is unparalleled and demonstrates the importance of international collaboration, clinical needs-driven, laboratory-led test development and deployment, commercial responsiveness, and nimble regulatory frameworks to address a (novel) global threat.

Generally, the clinical laboratory encounters an ET in the later stages of its life cycle. Typically, the first encounter is in the beta-testing phase when a mature ET is evaluated by end users in a clinical laboratory environment to uncover
any last-mile operational or technical issues before a general release. A nuance for ETs is that a technology that would be considered as a developed technology in one area of application, might be considered an ET in laboratory medicine. The application of computers in clinical laboratories is a case in point. Computers were already well-established in many areas of application prior to their entry into the clinical laboratory in the 1960s and 1970s [7]. Likewise, the time of introduction of an ET is dependent on local factors. Global health priorities have recently been ordered by probable timeframe for introduction over the next five, ten and fifteen years [8].

An ET for laboratory medicine can be defined as an analytical method (including biomarkers, software, applications and algorithms) or device that by virtue of its stage of development, translation into broad routine clinical practice, or geographical adoption and implementation has the potential to add value to clinical diagnostics (9). Key attributes include (i) novelty, (ii) relatively fast growth, (iii) coherence, (iv) prominent impact, and (v) uncertainty and ambiguity [10]. Successful ETs have shaped all phases of laboratory medicine from the pre-analytical, to the analytical, to the post-analytical phase, and the process that takes this from the idea through to full implementation is complex.

Considering the laboratory medicine-specific definition, this document examines eight key tools, encompassing clinical, analytical, operational, and financial aspects, used throughout the life cycle of ET implementation (Table 1).

**Tool 1. Unmet need**

Before an ET is considered for clinical laboratory application, there should be careful assessment of whether it is the appropriate solution to address an unmet need [11]. The assessment should start with clinical considerations and include their interactions and relationships with analytical, operational, and financial aspects of the clinical laboratory testing. For an ET replacing an existing laboratory procedure for the same biomarker, e.g., by implementing automation, a greater emphasis may be placed on the analytical, operational, and financial evaluations.

To begin, the laboratory should first identify the unmet clinical need. The Test Evaluation Working Group of the European Federation of Clinical Chemistry Laboratory Medicine (TE-WG EFLM) has produced a helpful evaluation framework for biomarkers that can be adapted for ET and can be applied as Tool 1 [11, 12].

**Discussion**

Central to assessing the unmet clinical needs is the role of the ET in the clinical pathway and may include questions related to the health condition/clinical management problem, target patient, current clinical practice, limitations of current practice and the prespecified desired outcomes. This may entail literature review and stakeholder engagement. Once a clinical unmet need is identified, the hypothesis can be tested by evaluating whether the current practice can be optimized to solve the problem, determining if the ET will be clinically and financially effective, and understanding potential barriers to implementation. Relevant barriers to implementation may include ethical, cultural, infrastructure, technical support, and workforce issues. These are explored further in Tool 2 forecasting methods.

To validate the intended use of the ET, it is important to consider how it may alter and improve current practice, the expected outcomes and how these outcomes compared to the prespecified desired outcome. Suitable clinical studies should be conducted to provide objective evidence such as clinical performance and clinical effectiveness to support the adoption of the ET. Finally, the factors driving the feasibility of the ET should be assessed, including commercial, economical, technical, and organizational viability.

Once it is determined that the ET adds clinical diagnostic value for improved patient care [9] and is mature for clinical deployment (e.g., as assessed by technology readiness – Tool 3), the laboratory should define the desired performance given its intended clinical use [13]. For ET that are testing methods, areas where analytical performance may be specified include method evaluation, quality control and periodic performance verification such as lot-to-lot, calibration, linearity, and between-instrument correlation. The analytical performance specification may be based on clinical outcomes, biological variation, or state-of-the-art [13]. It may be also necessary to consider performance specifications for

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**Table 1:** Summary of the eight key tools that support implementation of emerging technologies into laboratory medicine.

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<thead>
<tr>
<th>No.</th>
<th>Tool</th>
<th>Main reference/s for resource</th>
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<td>Organizational impact map</td>
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<td>6</td>
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<td>Total pathway to method evaluation checklist</td>
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<td>8</td>
<td>Green procurement</td>
<td>[66–69]</td>
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pre- and post-analytical processes to ensure the total testing process meets the clinical need – Tool 7.

Following analytical specification, the ET should be integrated into the laboratory and clinical operational workflows. Laboratory staff training, competency evaluation, infrastructure, technical support, and logistics are essential to ensure smooth transition into routine operations. Likewise, the integration of the ET into routine clinical care requires appropriate education and communication with the relevant clinical stakeholder. Suitable laboratory comments may be employed in the pre-analytical (test selection or test ordering) and post-analytical (test interpretation) phases to improve its clinical utility and effectiveness.

Broader consideration of the impact (disruption) of the ET on the healthcare system should also be managed to optimize the potential. For example, a novel early diagnostic procedure should be accompanied by an early referral and clinical management process to allow timely intervention. The converse may be true where novel therapeutic options should motivate development of novel therapeutic or response monitoring procedures.

The financial effectiveness of an ET should ideally be assessed from a healthcare system perspective (e.g., using health technology assessment (HTA) – Tool 4) instead of narrowly focusing on the operational costs within the laboratory. This is because ET is often novel and hence may not have reached mass adoption for economies of scale to reduce the unit cost relative to precedent/existing technology. Yet, the improved performance of the ET may produce significant benefits upstream or downstream of the clinical pathway and improve patient outcome or reduce associated costs. Tools 5 and 6 respectively provide the organizational impact map and change management tools and Tools 7 and 8 respectively provide a laboratory implementation checklist and green procurement tools to support the effective and appropriate ET implementation.

Tool 2. Forecasting

Several different methods are used to forecast the emergence of new technologies and predict their likely impact. These include horizon scanning, patent applications, scientific literature, the internet, external quality assurance programs and social media. Whilst to forecast, prepare and plan for change a combination of approaches are needed. Horizon scanning provides a structured approach to detect impending change to identify threats and opportunities, facilitate operational preparedness, and design future strategies. A freely available horizon scanning step-by-step guide was produced in 2022 and can be applied as Tool 2 [14].

Discussion

Horizon scanning

Some horizon scanning methods for identifying an ET in laboratory medicine include:

Anonymous (expert/stakeholder) contributors

In this horizon scanning method, contributors (a “diverse group of experts and stakeholders, including users, balanced by discipline, geographical distribution and gender”) provide issues that would shape the future. The issues are then scored and ranked to provide a shortlist and this was further refined and reranked to produce a list of identified topics. This technique was used by the World Health Organization to identify 15 new and emerging technologies and scientific advances that may have a significant impact on global health over the next two decades [8]. Issues identified were divided into three distinct five year time frames for expected implementation:

- <5-year time frame – Pandemic preparedness and prevention; Vaccine distribution; Machine learning for antibiotic discovery; Apps for disease screening; Coordinated biobanking; Addressing misinformation and disinformation; and using real-world evidence.
- 5–10-year time frame – Biosensor-based point-of-care diagnostic methods; Artificial intelligence (AI)-assisted clinical reasoning support systems Pull-through drug development; Genetically engineered phage therapy; Digital health and surveillance.
- >10 or more year time frame – Telemedicine; Microbiome-based therapies; Migrant health.

Primary, secondary and tertiary information sources

This in-depth horizon scanning for ETs starts with gathering information from various primary sources (e.g., manufacturers, research institutes, start-ups, innovators), and secondary and tertiary information sources (e.g., other horizon scanning organizations). Gathered data is categorized, prioritized, and shortlisted following a structure funnel approach under the supervision of a Core Governing Body and a Technology Advisory Committee. For example, a study to develop a fit-for-purpose horizon scanning methodology for the Asia-Pacific region analyzed information from >350 health technology companies across the Asia-Pacific region derived nine major ET categories (Wearables, Augmented, Mixed and Virtual Reality, Smart Device, Implants, Medical robotics, TeleHealth, Bio-fabrication, AI/Deep Learning, Information portal) based on a variety of factors (e.g., route to market, delivery channel and the function served by the technology) [15].
Patent applications

This has been an obvious place to look in an attempt to scan the horizon for an ET [16]. Candidates identified by this method may or may not lead to future change. In addition, a patent application, whilst having future potential does not show current trends. Therefore, it is not always a useful place to identify or quantify an ET.

Scientific literature

Another obvious method is to use keyword searches of the scientific literature (e.g., PubMed, Google Scholar). Evidence of an increase in search “hits” over time can help define if a candidate technology or a specific application of a technology is increasing, for example the more than doubling of the number of publications (PubMed) year on year beginning in 1987 was indicative of the ultimate importance of the polymerase chain reaction (PCR) as an ET. Likewise, the post-1971 rapid growth in the number of publications on enzyme-immunoassay were, in retrospect, an accurate indication of the ultimate success of this ET. Similarly, Nuclear Magnetic Resonance was first introduced in 1947 with citations continuing to rise to 54,000 in 2021, however in this case it has not been truly translated into the diagnostic clinical laboratory [17, 18].

The internet

Not all ETs will result in increases in the peer-reviewed literature because it may be considered a tool in an application. Take as an example the introduction of acoustic liquid handler technology which can be used for miniaturized tipless transfer of PCR primers and many other applications. Whilst PCR has demonstrated an increase in the scientific literature and a multitude of examples exist of its application in the clinical diagnostic laboratory, the comparative citations for acoustic liquid handlers is low from a dedicated scientific literature perspective (i.e., the first use of acoustic liquid handler was in 2008 and the count of citations peaked at 15 in 2015). However, the internet general search produces more than ten thousand hits on Google and highlight dedicated interests on the topic [19].

External quality assurance (EQA)

More specifically focused on laboratory medicine is the use of external quality assurance program data, e.g., hemostasis testing [20], and testosterone measurement principles [17]. Likewise demand for an EQA program can demonstrate a change, such as for dihydrotestosterone [21]. However, there are limitations for analytes that have not gained the momentum for inclusion in an EQA scheme such as 21-deoxy cortisol [22].

Social media and commissioned reports

Popular media is good at highlighting emerging technologies and spreading awareness [23]. Horizon scanning reports are also available from specialized market research companies and these may include specific predictions for market size and growth (e.g., [24–27]).

A scan of the horizon using any of the above methods may reveal candidate ETs. Once identified, there is an interest in predicting the likely impact of the ET on the current practice and future of laboratory medicine, e.g., broad adoption, displacement of an established technology. Such predictions may not only relate to future, but also replacement of current technologies e.g., through automation of some manual processes or use of improved technology. Many of these predictions focus on the scale and scope of the impact of an ET (e.g., AI, robotics). As with all predictions, some have proven to be accurate, whilst others have proved to be inaccurate, especially when attempting to predict far into an uncertain future [28, 29].

In the short term, an unexpected and rapidly developing public health threat, such as the COVID-19 pandemic can accelerate the adoption or exploitation of an ET, as has been the case for ETs (e.g., Loop-mediated isothermal amplification) used in point-of-care tests for SARS-COV-2. The pandemic has also been a driver for an expansion in pharmacy-based testing and at-home self-testing [30].

A recent set of predictions for 2022 published in 2021 identifies AI and machine learning (ML) as playing an “increasing role in the laboratory environment” [31]. This view of AI/ML as an ET is supported by the growing number of patents and large body of scientific literature relating to the clinical applications of AI, and the growing number of AI/ML-enabled medical devices authorized by the FDA since 1997 (e.g., 138 approvals in 2020) [32].

Tool 3: Technology readiness level (TRL)

The idea that technology needs to go through stages of development was first conceived by NASA in 1974 [33]. This initial seven-step scale was later updated to a nine-step technology readiness levels (TRL) in the 1990s and has been applied broadly [34]. This tool has been implemented, with some adaptation, in many industries and is applicable for consideration of emerging technologies in laboratory medicine [34, 35]. An applicable example of the nine levels applied is provided in Figure 1 [35].
Discussion

For laboratory medicine, the starting point for an ET is an idea, perhaps motivated by a clinical diagnostic problem or an unmet clinical need [11], that is sufficiently compelling to be developed further. Further development may lead to an invention disclosure and patent application, then through various development stages (captured in the successive TRLs) including demonstration of proof of principle, and preliminary testing, and finally the technology matures and emerges into routine clinical laboratory medicine practice [34, 35]. The latter stages of development involve formal regulatory approval such as the FDA 510(k) clearance or FDA PMA approval in the US and the CE/IVDR approval in the European Union.

As noted in the introduction, in a public health crisis, emergency approval (e.g., FDA EUA) for an ET may be granted to expediently make available tools that can help address the threats. This brings with it a level of risk in moving through the TRLs with minimal due diligence and consideration of the benefit needs to significantly outweigh the potential harm of rapid progression.

Tool 4. Health technology assessment (HTA)

An HTA is the systematic evaluation of an ET to understand its properties, effects, and their potential impact. “The main purpose of HTA is to inform a policy decision making in health care, and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system” [36]. Hence, these assessments are often performed by academic and government organizations and involve a multidisciplinary team that looks at practicality of implementation, social and ethical effects, and economical valuation. Such assessments are also necessary as part of determining priorities for implementation as part of the local context [9].

Excellent resources for HTA are available from the WHO [36, 37] Danish National Board of Health [38], and the National Institute of Health and Care Excellence (NICE) UK [39, 40]. With the view to harmonization, there is an international body formed to support HTA agencies. A toolkit for the adaptation of HTA to a local context has been developed [41].

Discussion

In many developed countries, a HTA is increasingly used to inform decisions about which health technologies can be implemented, and inform the funding mechanism for the technologies [42]. For example, in Australia, as part of these reviews the guiding principles provide a framework for assessment, and “should be: sustainable; transparent; accountable and independent; consultative and reflective of Australian community values; administratively efficient; flexible and fit for purpose; and informed by robust and relevant evidence” [42]. Such assessments can be applied to device and biomarker analysis [43]. Deciding what needs translation into clinical practice depends on answering the

The need to perform local HTA for the adoption of ET is important because of regional differences and specific considerations can also include local unmet needs in clinical care; infrastructure e.g., water quality, electricity supply, health care process and systems. Current technologies available and options for support; healthcare models (e.g., public vs. private); socioeconomic circumstances; and the ability to implement and sustain a new technology [44]. As noted earlier, HTA strategies are currently implemented by many countries and there are some differences between these strategies. It is important to consider the HTA mechanisms as the health system becomes matures (Figure 2) [37].

**Tool 5. Organizational impact map (OIM)**

Assessing the organizational aspects and consequences before implementing an ET in laboratory medicine is crucial for ensuring successful adoption and implementation of the technology [45, 46]. This involves evaluating how the technology will fit into the existing organizational structure and processes, and how it will impact the workflow, job roles, and responsibilities of different stakeholders. An organizational impact map tool has been developed under the HTA to support the process [46].

**Discussion**

One of the main reasons for assessing organizational aspects is to identify potential challenges and barriers that may arise from the implementation of the technology. For example, introducing a new technology may require changes to existing workflows and processes, which can be disruptive and may lead to resistance from staff. Similarly, the introduction of new technology may require additional training for staff, which can be time-consuming and costly. Furthermore, assessing the organizational aspects of ET can help to identify opportunities for optimization and improvement. For example, the introduction of new technology may allow for more efficient and streamlined processes, reducing errors and improving patient outcomes. By understanding the existing organizational structure and processes, it becomes easier to identify areas for improvement and to develop strategies that can maximize the benefits of the technology.

*Figure 2: Emerging technology Tool 4: Health technology assessments, “extending the mandates of HTA mechanisms as the health system becomes stronger” [37].*
Assessing the consequences of ET on the organizational level is also important for ensuring long-term sustainability and scalability of the technology. This involves evaluating the financial, operational, and strategic implications of the technology, and identifying ways to maximize its value and impact. For example, it may be necessary to consider the costs of maintenance and upgrades, as well as the potential for integration with other existing technologies and systems. On the other hand, the introduction of ET may displace/replace certain job functions and it is important for organisations to redesign and reassign staff responsibility to minimise the impact and optimise deployment of human resources.

Finally, it can help to increase stakeholders' engagement and buy-in. By involving different stakeholders, such as laboratory technicians, physicians, patients and management, in the assessment process, it becomes easier to understand their needs and concerns, and to develop strategies that can address these.

Tool 6. Change management (CM)

“Change is the law of life. And those who look only to the past or present are certain to miss the future.” ~ John F. Kennedy [47]. The leading drivers for change in laboratory medicine are new insights and understanding of clinical, analytical and operational aspects of the specialty, advancement in technology, innovation in workflow and processes and economic demands. Successful capitalisation of these drivers requires management and the term “change management” is an overarching term that applies to the collection of theories and processes to successfully implement change.

The change or implementation management tool is a collective of tools to undertake the change process and support staff expectations. Whilst the social science aspects of change management theory dates back to the early part of the 20th Century, it is the collective innovative concepts of individuals and teams such as the diffusion of innovation curve by Everett Rogers [48, 49], the change curve described by Elisabeth Kubler-Ross [50], the Professional plus Science (Prosci) model by Jeff Hiatt [51], the plan do check/study act cycle by Edwards Deming [52], and the associated Toyota Production Systems [53, 54] that together underpin the change management Tool 6.

Discussion

Change management is an essential component of ET implementation as it causes disruption and this precipitates the need to understand and manage it. Fundamentally, for the ET to be successfully and sustainably introduced into routine practice, it needs to be complimented by existing available technologies and support. For example, a total laboratory automation cannot be introduced into a laboratory that has poor information technology infrastructure or lack of competent technical support to troubleshoot any issues that may arise during clinical use.

(A) The diffusion of innovation (DOI) theory curve was developed by Everett Rogers in the 1960s. This curve divides people into five adopter groups: (1) the innovators (2.5 %), early adopters (13.5 %), early majority (34 %), late majority (34 %) and laggards (16 %). Whilst the percentages in this Bell-shaped-like curve may be approximate, their use provides a perspective of how the momentum for adoption can be supported or its progress hindered. This diffusion concept is often used to look at market share and acceptance of an ET. It can equally be applied to organisational change and team culture. In particular, the chasm between the early adopters and the early majority can represent the momentum to support a change initiative, and can be pivotal to the overall successful implementation of an ET. Likewise, this 16 % of the laggards is loosely related to the Pareto principle or 80/20 rule or law of the vital few, where 80 % of consequences come from 20 % of causes. Therefore, conversely if 20 % of a team (i.e., 1 in 5 people) have significant resistance to the change, then complete change will be difficult. This social science concept of innovation adoption (and the following change management curve) provide perspectives on ET adoption and the power and importance of communication and emotional intelligence [48, 49]. Examples of DOI theory have been applied broadly to public health initiatives [55–57].

(B) The change curve was originally proposed by the psychiatrist Dr Elisabeth Kubler-Ross in relation to the change in emotions of terminally ill patients [50]. In the extrapolation of this original concept for laboratory medicine, the change is the loss of the current normal practice because of implementation of for example, a new test, process, or informatics. As such, the curve is useful to understand staff and team motivation and competence as an organisation looks at a new process. For staff/teams/organisations not used to change, i.e., less agile, the move from the current “norm” can cause the initial emotion of shock followed by feelings of denial, frustration and depression (often referred to as the trough of disillusionment) as staff look back and let go. This is particularly true if the staff identifies the change as a loss. With a successful change, the process
of looking forward occurs, the new reality is tested, the change is accepted, and over time staff/teams feel ownership of the new process and it becomes the “new norm”. It is important to note that members of an organisation can take varying amounts of time to move through the curve and take ownership of the change. Therefore, change management needs to empathise with multifaceted emotions, and the formation of habits and hence feeling comfortable with the new process will vary in time [58]. Understanding this change curve and where people may sit on this curve will help to navigate through challenges and to communicate and support change appropriately. Thus applying the concepts of the change curve and translating these into emotional intelligence can significantly help negate the negative emotions generated with the introduction of an ET.

(C) The Professional plus Science (Prosci) model comprises seven best practices in change management identified that encompass: (1) “mobilize active and visible executive sponsorship”; (2) “apply a structured change management approach”; (3) “communicate frequently and openly”; (4) “engage with front-line employees”; (5) “dedicate change management resources”; (6) “engage and integrate with project management”; and (7) “engage with and support middle managers” [51]. Active and visible sponsorship of the change by organizational management is a key leader of success [51]. Ultimately success is demonstrated by projects that meet objectives, finish on time, in budget, and where forecasted return on investment is realized (Figure 3).

(D) Plan Do Check/Study Act (i.e., Deming’s PDCA cycle) and associated management tools led a generational change in project management [52]. This is particularly true of the influence of Deming’s management practices on the quality of products generated in post-war Japan. The techniques were employed by many organizations and acknowledged for the contribution to their success. The implementation of any change or project management traditionally focused on “planning” and then “doing” the change and then no further action is taken. In the PDCA cycle there are the important data driven processes of checking or studying the change, often using root cause analysis, and then acting on any non-conformities. This process can be used for both small and large changes. Whatever the size of the change, the study and acting on poorer than anticipated quality indicators to implement follow-up improvements is well known to laboratory medicine professionals who seek accreditation to ISO15189:2022. Element 8.6.1 states “the laboratory shall evaluate the effectiveness of the actions taken”, “laboratory management shall ensure that the laboratory participates in continual improvement” and “communicate to personnel its improvement plans and related goals” [59].

Toyota Motor Corporation advanced using Deming’s management practices focusing on quality and the customer which lead them to be the number one car manufacturer in the world [53, 54]. Whilst Toyota manufactures cars, laboratory medicine manufactures results, and our main customer is the patient and their medical support teams. In addition, in both scenarios the quality of the manufactured...
goods underpins safety and the tools developed by Toyota equally work in the medical laboratory environment. As an example, the Kaizen model for continuous improvement focuses decisions on the customer (e.g., patient) and therefore change in practice will more readily be based on addressing clinical need [60]. The adage, *if you can’t quality it you can’t change it*, pertains to Toyota’s visualization of status and change management data in tools such as Kanban boards, Leadtime diagrams, and GANTT charts. The Toyota production systems now incorporate hundreds of tools underpinned by the evolution of concepts of continuous improvement, lean, agile, quality and customer focus [53, 54, 61]. Some or all these tools can be used to support and communicate data-driven change in laboratory medicine.

Whilst there are limitations of these behavioral change theories, including that they were not specifically developed for laboratory medicine, a pragmatic review and collective use of the emotive (items A to C) and logical (item D) components of the change management provide an effective tool to support ET implementation. The data-driven visual processes to manage ET implementation within laboratory medicine offer the current best practice in the logical components of change management. Active and visual sponsorship with emotional intelligence are the primary drivers for individuals and teams to take ownership of the change. In using these change management tools teams can implement ET with appropriate empathy and organization.

**Tool 7. Total pathway to method evaluation checklist (MEC)**

The decision to implement a new test, method, process involves consideration of multiple components. Evaluation of methods is an integral part of the total quality system in laboratory medicine. In the case of an ET, it is likely to be the first encounter between the novel technology and the laboratory. The ability to implement an ET will be dependent on the capacity and capabilities of the laboratory and therefore a systematic evaluation of fitness for purpose is required. Here we have adapted a recently developed table to create a checklist that encompasses the total pathway for implementation of a new method/process into the laboratory [62]. This checklist consists of 44 items that are divided into pre-development, development and post-development and is available for download in Supplemental Table 1.

**Discussion**

The development and post-development of the checklist are usually subject to regulatory and accreditation requirements to document their clinical fitness for purpose by the performing laboratory [59, 63].

There is an increased emphasis on the appropriate rollout of ET for laboratory medicine to improve service delivery for patient care. For an ET that is novel with no existing comparator, e.g., a novel biomarker or a new class of analytical method, the clinical effectiveness (e.g., clinical sensitivity, clinical specificity) for the stated clinical utility (e.g., screening, diagnosis, monitoring, prognostication) needs to be demonstrated in appropriately designed clinical studies [64]. The components of the method validation will depend on the type of technology (e.g., biomarker, measurement procedure, algorithms), the clinical utility and relevant regulatory requirements [12]. However, this can be challenging when the laboratory professionals are considered removed from the clinical pathway or technology development, which impedes the laboratory involvement in activities in technology readiness [34]. For a novel ET, a thorough characterisation of the analytical performance is required and to validate its performance, i.e., method validation [65].

There is a potential gap between mobile health device suppliers and laboratories in relation to the requirement to perform method evaluations. Regulatory marking by, for example, the FDA is considered sufficient by manufacturers for the distribution of mobile health devices. However, for laboratories to add these mobile health applications to their testing panel requires in house method evaluation in order to meet accreditation/regulatory requirements. Mobile phone based applications for health testing provide additional challenges when the tests are assigned to a patient’s mobile phone number and the data is controlled by the application owner rather than the laboratory. Laboratory professionals have a responsibility as experts for professional oversight, hence the role should support the quality and transparency of mobile applications through engagement, development of guidance documents and education.

**Tool 8: Green procurement**

Sustainability refers to the ability of a technology to meet the needs of the present without compromising the ability of future generations to meet their own needs. Evaluating the sustainability of emerging technologies can help to ensure that laboratory practices are environmentally responsible,
ally and socially beneficial. The overarching document is the international standard for environmental management [66]. Green laboratories in itself is an emerging area and the EFLM guideline for green labs is freely available and a checklist and other resources are planned for future implementation to provide practical guidance on evaluating the sustainability of ET for laboratory medicine [67].

A twelve-point assessment of analytical greenness (AGREEEnness) has been proposed by the American Chemical Society and consists of: 1. Sample treatment; 2. Sample amount; 3. Device positioning; 4. Sample preparation stages; 5. Automation miniaturization; 6. Derivatization; 7. Waste; 8. Analysis throughput; 9. Energy consumption; 10. Source of reagents; 11. Toxicity; and 12. Operator's safety. With each step a score is given, and the twelve scores are individually assessed and also overall assessed, with the higher the value indicating a greener method. This AGREE checklist and associated software is freely available for download [68].

Discussion

The valuation of sustainability is essential in the assessment of ET and is becoming a broadly recognized requirement for implementation [66–72]. ET can have a significant impact on the environment, economy, and society, and it is crucial to evaluate their sustainability to ensure that they are developed and implemented in a way that is environmentally and socially responsible. This includes considering the entire life cycle of the technology, including its manufacture, use, and disposal. Laboratories should consider the environmental impact of the technology, including its impact on energy usage, water usage, waste generation, and the use of environmentally harmful materials.

One critical aspect of sustainability evaluation is the assessment of the environmental impact of ET. The environmental impact can be assessed through a life cycle assessment (LCA), which considers the entire life cycle of a technology from the extraction of raw materials to the disposal of waste. LCAs can help to identify potential environmental hotspots and provide insights into ways to reduce the environmental impact of the technology.

Another critical aspect of sustainability is the evaluation of economic and social sustainability. ET should be economically viable and should not have a negative impact on social and cultural values. The evaluation of economic and social sustainability can be achieved by considering the entire value chain of the technology, including its impact on local communities, social and economic factors, and cultural values. Furthermore, evaluation of sustainability is essential in meeting regulatory requirements and standards. For instance, the International Organization for Standardization (ISO) has developed ISO14001, which is a standard for environmental management [66]. Compliance with this standard can help organizations to evaluate and manage the environmental impact of their activities, products, and services, including emerging technologies in laboratory medicine.

Additional considerations when using these ET tools

The assessment of emerging technologies in laboratory medicine is a complex and multifaceted process that requires the involvement of multidisciplinary teams (e.g., laboratory staff, physicians, patients) and thorough evaluation of user needs [73–75]. This multidisciplinary process is a pillar of HTA and several frameworks and models have been developed to guide the assessment of emerging technologies in laboratory medicine, such as the Model for Assessment of Telemedicine Applications (MAST) [76]. The importance of this cannot be overstated, as it is essential for ensuring that the technologies developed are safe, effective, and meet the needs of their intended users.

Embedded in various aspects of the toolkit, but not explicitly detailed is the need to consider socio-economic factors, gender equity, ethical and legal requirements as part of the implementation and assessment strategy. Each of these aspects is briefly discussed below:

- **Socio-cultural factors such as race, ethnicity, religion, and socioeconomic status** can all influence the acceptance and adoption of emerging technologies [77]. For example, some cultures may have different beliefs and attitudes towards technology, which may affect their willingness to use it. The importance of evaluating socio-cultural, ethical, and legal aspects of emerging technologies in laboratory medicine is further highlighted in the MAST framework [76].

- **Gender equity** is another critical aspect to consider in the assessment of ET [78, 79]. Gender biases can exist in the development and implementation of technology, which can result in or accentuate inequalities in access and use. For example, some medical devices and tests may be designed with a bias towards male physiology, which can result in inaccurate results or less effective testing for female patients. Evaluating gender equity can help to identify potential biases and ensure that emerging technologies are designed and implemented in a way that is equitable for all genders. Furthermore, gender equity and socio-cultural factors are closely
intertwined, and evaluating both aspects can lead to a more comprehensive assessment of ET. For instance, cultural beliefs about gender roles may influence the use of certain technologies by women or men. Evaluating both aspects can help to identify and address any potential barriers to access and use for different genders and cultures.

– Ethical considerations is another critical aspect for ET [80]. The evaluation of ethical aspects helps to identify the ethical implications of the technology and ensures that the technology is developed and used in an ethical manner. Evaluating ethical implications can help to ensure that the technology is developed and used in a way that respects ethical principles and to provide the human warrantee at different stages of evaluation [81].

– Legal considerations are also important when assessing ET [82]. The evaluation of legal aspects helps to identify the legal implications of the technology and ensures that it complies with relevant laws and regulations. For instance, the use of electronic health records may raise legal issues such as data protection, privacy, and liability. Evaluating legal implications can help to ensure that the technology is developed and used in a way that complies with relevant laws and regulations.

Conclusions

A systematic approach to the implementation of emerging technologies in laboratory medicine underpins the ability to meet clinical need. The eight key tools identified here usually start with identifying the unmet need (Tool 1) forecasting (Tool 2), technology readiness assessment (Tool 3), HTA (Tool 4), implementation management (Tool 5–7), and green procurement (Tool 8). Whilst there are differences in clinical priorities between community settings, the use of a common harmonized tool kit helps support the overall quality and sustainability of ET implementation.

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