Review Article

Data-driven laboratory stewardship: an implementation science perspective

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Abstract: When we hear the phrase 'data-driven laboratory stewardship', we often think of this as referring to using data on test use (e.g., test volumes or costs) to highlight opportunities for improvement. While these data are undoubtedly essential, there are many other potential data sources that can inform laboratory stewardship initiatives. Such data sources can be identified by drawing on key lessons from the rapidly developing field of implementation science (the scientific study of methods to facilitate the uptake of best practices into routine, everyday healthcare). Here, we introduce this field and outline some of its key lessons about relevant data to support (I) developing an understanding of the factors influencing over- or under-use of tests and enablers of change/barriers impeding change; and (II) selection of improvement strategies that are most suited to disrupting current patterns of test use and capitalizing on enablers of change/breaking down barriers impeding change. We also provide suggestions for how laboratory stewardship teams can put these lessons into practice as part of stewardship initiative development, and tools that can support these activities. The key lessons are couched within an over-arching framework that can be used to guide the development, implementation, and evaluation of laboratory stewardship initiatives as part of continuous improvement activities embedded within a learning health system.

Keywords: Laboratory stewardship; implementation science; behaviour change; quality improvement

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Introduction

Background

Evidence indicates substantial inappropriate and inefficient use of resources in Pathology and Laboratory Medicine. For example, a synthesis of 42 studies including over 1.6 million test results found that 16–25% of laboratory tests ordered are not clinically indicated, while 34–56% of tests that are clinically indicated are not ordered (1). Over-use can lead to negative effects for patients, including avoidable phlebotomies, pain, delays in appropriate tests, inaccurate diagnosis due to false-positive results, and a cascade of secondary and potentially more invasive testing with increasing likelihood of over diagnosis and 'slippery slope'

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inappropriate treatments that may have adverse side-effects (2-5). Over-use also represents wasted healthcare resources which could have been better used, and increasingly, the negative impacts of over-use on the environment are being recognized (6-8). Under-use can lead to delays in accurate diagnosis and treatment, with delays potentially worsening the patients' condition. Therefore, there is an urgent need to improve quality and more effectively manage scarce resources by reducing low-value testing and increasing high-value testing. Activities focused on improving the appropriateness of Pathology and Laboratory Medicine resource use are advocated as a key component of the quality improvement work conducted by clinical laboratories (9,10). Such activities have been labelled as 'laboratory stewardship', to emphasize a focus on value, i.e., "the quality of the service provided relative to its cost" (10).

Rationale and knowledge gap

Evaluations of laboratory stewardship initiatives show highly variable results. A systematic review of 119 interventions deployed across primary and secondary healthcare settings found that interventions that include an educational component achieved the highest median relative reduction in test volume at 34% (11). Additionally, interventions involving audit and feedback (providing physicians with a summary of their performance compared to their own previous performance or their peers) or system-based interventions involving one-time, permanent changes to test ordering processes both reduced volumes by 22% on average, with the latter advocated as generally requiring fewer resources to implement and more promising for achieving sustainable change (11). Two included studies achieved a 99% reduction in test use, one which changed laboratory policy such that urine microscopy was done only if specifically requested by the physician (12), and another providing education (distributing guidelines) and feedback (flagging tests orders not in line with guidelines) on ordering lactate dehydrogenase (LD)-isozymes (13). However, many effects were much smaller, and some interventions had opposite than intended effects, resulting in increased test use. Whilst conclusions from this review are limited due to heterogeneity between interventions deployed and issues with study quality, the wide variation in effectiveness indicates that more work needs to be done to fully understand how to maximize the effectiveness of laboratory stewardship interventions. This is further supported by a systematic review of 83 studies which identified modifications to existing computerized physician order entry (CPOE) systems, reflex testing, and multifaceted initiatives as 'best practice' approaches (based on the number of studies, study quality ratings, and effect size ratings) (14). No recommendations were made for other initiative types—clinical decision support, education, audit & feedback, test review, and utilization teams—due to insufficient evidence. However, all initiative types worked some of the time, and again the review identified a limited number of good-quality studies. This review also noted that initiatives were not associated with adverse impacts on patient-related outcomes (such as length of stay, morbidity, and mortality).

Whilst many issues may contribute to variations in initiative effectiveness, core issues are likely to be (I) numerous factors drive overuse of testing; (II) the strength of influence of these factors will vary between settings and for different types of tests; and (III) specific initiative types will vary in the extent to which they can adequately address specific influencing factors. An overview of the literature on factors influencing inappropriate testing indicates that influencing factors include intrapersonal issues (such as knowledge, fear of litigation, and cognitive biases); interpersonal issues (such as medical culture, pressure from patients); and issues related to the environment or context (such as protocols, time constraints, and ease of access) (15). It is clear that strategies such as education or system-based interventions would each be better at addressing some of these factors, and likely inadequate for addressing others. This wide range of influencing factors add further challenges to the selection of an appropriate change strategy.

Implementation science approaches can help overcome these challenges. During the emergence of the evidence-based medicine movement in the 1990s when it was argued that practice should be based on current best evidence, it was also acknowledged that effecting practice change is challenging and active efforts would need to be made to encourage the spread and uptake of evidence (16). Implementation science is the scientific study of strategies to facilitate the uptake of best practices into routine, everyday healthcare (17). Implementation strategies can include dissemination of clinical practice guidelines, educational meetings/outreach visits, audit and feedback, reminders, changing physical structure/equipment, local champions who support implementation, and changing incentive/disincentive structures (18,19). Implementation scientists use a range of methodologies, including qualitative methods to investigate barriers to change, randomized controlled trials (RCTs) to investigate the effectiveness of specific implementation

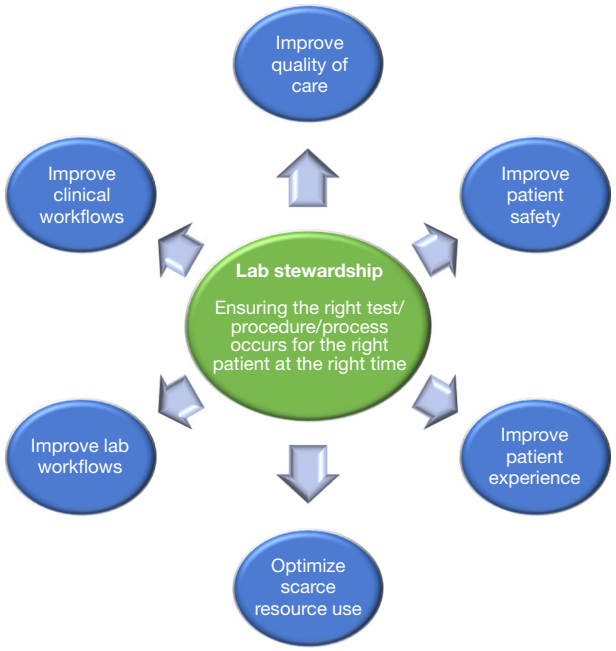


Figure 1 Laboratory stewardship: working definition and possible outcomes.

strategies, and systematic reviews to synthesize evidence about strategy effectiveness. Behaviour change-informed implementation science approaches conceptualize efforts to close a gap between best evidence and current practice as supporting people in the healthcare system to change their behaviour (20). Ordering laboratory tests is something that healthcare professionals physically do as part of their role: i.e., a behaviour. The purpose of laboratory stewardship efforts can therefore be conceptualized as supporting healthcare professionals—as well as others in the healthcare system where necessary (for example, laboratory team members or clinical/hospital leaders)—in changing their behaviour. Correspondingly, initiatives (such as education, audit & feedback, and system-based interventions) can be conceptualized as behaviour change strategies. Framing laboratory stewardship as a behaviour change endeavour facilitates stewardship teams in drawing on more than 50 years of research on predicting and influencing behaviour in the psychological and behavioural sciences.

Objective

In this article, we build upon our experiences of developing a laboratory stewardship program within a network of hospital-based clinical laboratories [the Eastern Ontario Regional Laboratory Association (EORLA)]. We outline how behaviour change-informed implementation science approaches can be applied to laboratory stewardship problems to enable teams to consider new forms of data concerning (I) the factors influencing over- or under-use of tests and enablers of change/barriers impeding change; and (II) behaviour change strategies that are most suited to disrupting current patterns of test use and capitalizing on enablers of change/breaking down barriers impeding change. This is embedded within an over-arching approach to guide the design, implementation, and evaluation of laboratory stewardship initiatives.

An implementation science-informed approach to laboratory stewardship

Laboratory stewardship definition and project approach

We formed a multi-hospital laboratory stewardship committee to help guide our stewardship work. Individuals in various roles relevant to stewardship issues were invited to join the committee. As such, the committee includes those in the following roles: Laboratory Director, Laboratory Manager, Division Head, Physician, Patient Advisor, Quality Improvement Specialist, Implementation Scientist, and Hospital Senior Management Representative. Our committee defines stewardship activities as those which help ensure that the right test/procedure/process occurs for the right patient at the right time. Stewardship initiatives supported by our committee should target one or more of the (interlinked) outcomes specified in *Figure 1*. Within this framing, financial perspectives can be incorporated (e.g., as part of optimizing scarce resource use) but should not be the sole or main reason for an initiative, and should not run contrary to quality of care or patient safety. We established an approach, informed by the implementation science literature (21-24), to help guide laboratory stewardship projects after a specific laboratory target is selected (*Figure 2*). This also includes implementation science/behaviour change tools that can be used to support project activities at specific stages, which are further described below. The first step focuses on establishing the project scope. For this step, we identify the key metrics to be measured at baseline and follow-up to evaluate initiative effectiveness and develop a plan for analyzing these metrics. Key metrics can include test volumes, test costs, blood volumes, blood transfusions, and patient safety outcomes such as hospital length of stay, readmission, morbidity, and mortality. Targets for

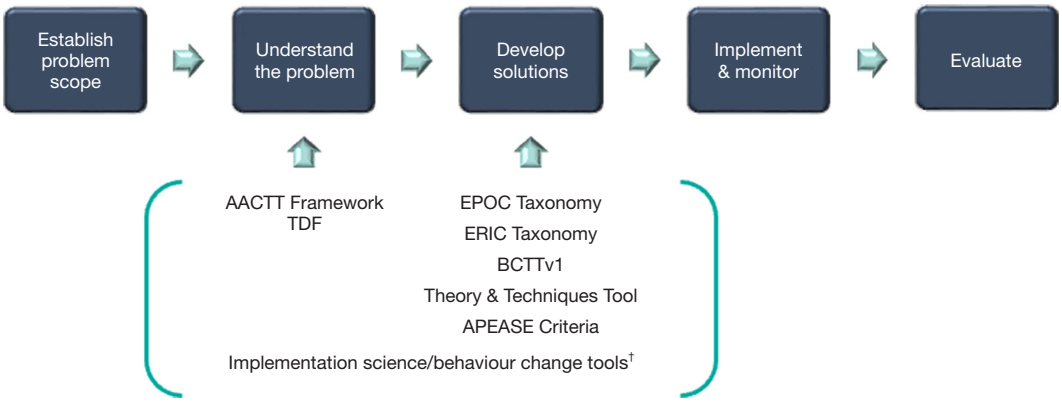


Figure 2 Laboratory stewardship project approach. Informed by implementation science literature and associated tools (18,19,21-29). †, tools list is not exhaustive: tools mentioned are those that are discussed herein. AACTT, Action, Actor, Context, Target, Time; TDF, Theoretical Domains Framework; EPOC, Effective Practice and Organization of Care; ERIC, Expert Recommendations for Implementing Change; BCTTv1, Behaviour Change Techniques Taxonomy Version 1; APEASE, Acceptability, Practicability, Effectiveness, Affordability, Side effects, Equity.

improvement should be clinically meaningful and realistic. Some sites may end their project participation after baseline analyses are conducted (for example, if they decide that the project is not high-priority based on the findings for their specific site). The next step involves understanding the problem. This requires activities to establish the enablers of improved test use and any barriers to practice change. Based on this information, the third step involves developing solutions, i.e., selecting change strategies/implementation interventions that address these enablers/barriers. The fourth step involves implementing and monitoring those solutions (for example, by assessing fidelity i.e., the extent to which the intervention is deployed as intended). The final step focuses on evaluation, wherein the pre-planned outcomes are analyzed to determine the impact of the solutions implemented. This article focuses primarily on understanding laboratory stewardship problems and developing solutions (steps 2 and 3). A mock case in which a stewardship project team follows these steps is provided in Appendix 1.

Data-driven approaches to understanding the problem

While it is tempting to immediately begin selecting and executing 'common-sense' interventions to facilitate practice change once a problem is identified, this approach may results in the selection of strategies that are not best placed to solve the problem (for example, deploying an educational solution when the key driver of test use is structural/organizational, rather than a lack of knowledge). Just as the most appropriate diagnostic tests cannot be ordered until details about patient symptoms have been gathered, the most appropriate implementation intervention cannot be selected until information has been gathered about the factors causing the stewardship problem and potentially impeding change. So, it is important to focus initially on understanding the problem and the contributing factors. To solve healthcare quality problems using a behaviour change-informed approach, the first step involves clearly outlining the behaviour(s) that need to be changed. This amounts to answering the question, '*Who needs to do what, differently?*' (21). Multiple behaviours conducted by individuals and by teams may play a role in the chain of events leading to the stewardship issue occurring. Knowing this information up-front helps with selecting behaviours for change that are central to bringing about the desired outcomes (25). For example, resident physicians are often responsible for inputting test orders, but their behaviour may not be the only target for change. Residents describe worrying about being perceived as incompetent for asking too many questions about test ordering, have concerns about criticism from senior colleagues at ward rounds, and want to avoid being 'caught out' when a test requested by their attending was not ordered, all of which contribute to test over-use (30). In this case, an initiative targeted solely at residents may not have maximal impact: considering the significant social pressures in this context, it may also be beneficial to target their attendings and senior colleagues. This demonstrates the

Table 1 Suggested activities for developing a list of behaviour(s) involved in the relevant test ordering process

Activities for developing a list of behaviour(s)
• Review local procedures and processes of care (e.g., medical directives)
• Review clinical guideline recommendations and relevant literature regarding appropriate behaviours/evidence-practice gaps (either brief or in-depth)
• Gather site audit data and compare this with guidelines/evidence
• Have discussions with key stakeholders in different professional roles to help identify important behaviours, embedded within existing meetings if time and resources are limited
• Conduct observations of care processes, taking notes on who does what
• Have informal conversations with those involved in care processes (or conduct more formal, research-based interviews or focus groups), asking them to describe what they do (and potentially what those in other roles do) as it relates to the stewardship problem

value of considering the multiple actors that may be involved and their behaviours at the outset of initiative planning.

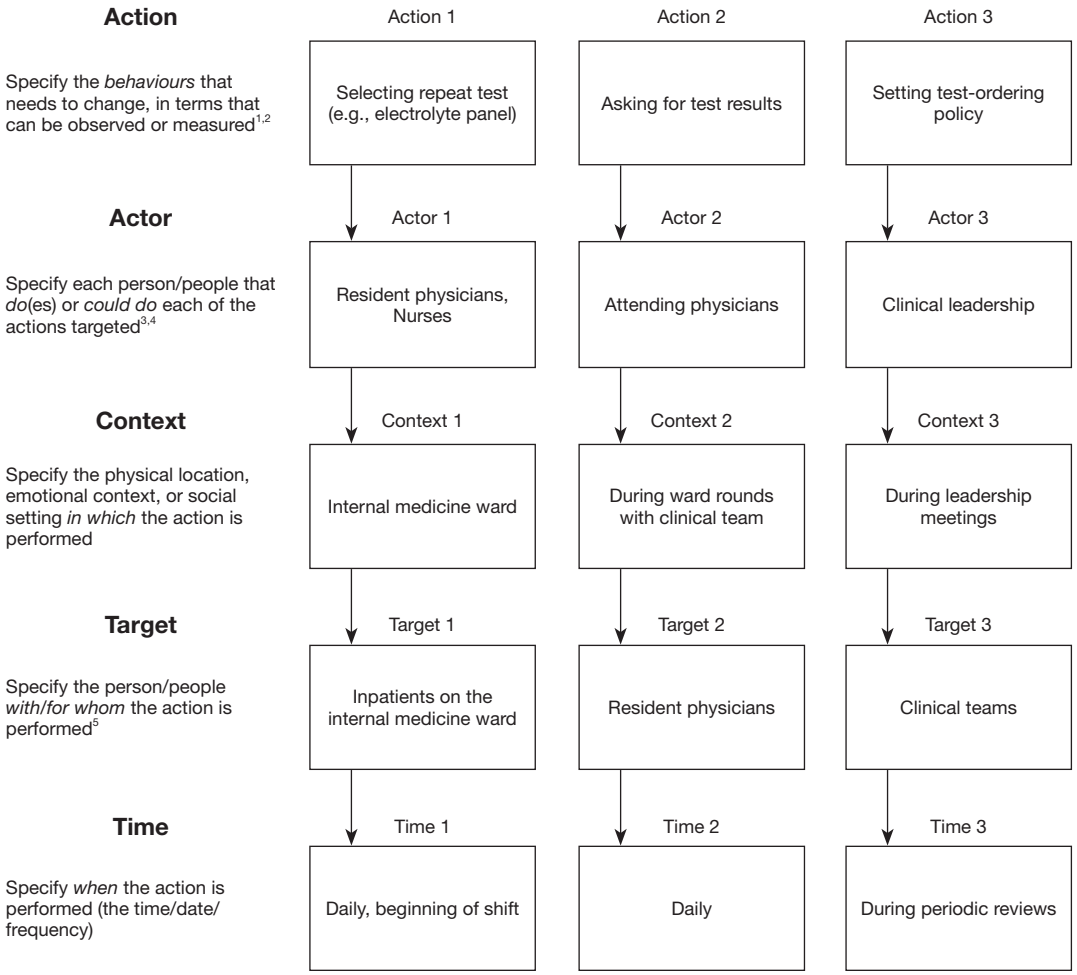
Identifying relevant behaviour(s) for change involves (I) developing a list of the behaviour(s) involved in the care process to be improved; and then (II) selecting one or more to target with a change initiative (25). Activities that stewardship groups can conduct to help develop a list of behaviour(s) involved in the relevant testing-ordering process are outlined in *Table 1*. The suggested activities vary in terms of resource-intensiveness, as well as relative depth or comprehensiveness of assessment. For example, discussions at existing meetings are less resource-intensive than formal one-on-one interviews or observations of care processes, but may provide a less fulsome picture of the contributing behaviours. However, positive impacts can still be achieved with limited resources.

The AACTT framework (26) can be used to specify behaviours in a systematic way, as demonstrated in *Figure 3*. Using this framework, behaviours are specified in terms of: the relevant "Action" (a discrete observable behaviour); "Actor" (the individual or group of individuals who perform (or should/could perform) the action; "Context" (the physical setting in which the actor performs (or should/could perform) the action; "Target" (the individual or group of individuals for/with whom the actor performs the action; and "Time" (the time period and duration that the actor performs the action in the context with/for the target).

Having specified the behaviour, the next step is to identify what needs to change in the person and/or the environment in order to achieve the desired change in behaviour. Suggestions of activities for identifying enablers of change and/or barriers impeding change are outlined in *Table 2*. Again, these activities vary in terms of resource-intensiveness and relative depth or comprehensiveness of assessment.

Lists of barriers/enablers can be assembled from the various sources outlined in *Table 2*. It can often be difficult to organize the information in a systematic and consistent way. Fortunately, the task of organizing barriers and enablers is facilitated with theory and evidence-based tools that list factors influencing care processes, such as the Theoretical Domains Framework (TDF) (27,31,32). It comprises a set of domains representing modifiable individual, socio-cultural, and environmental factors that can influence behaviour in healthcare contexts (33). The domains can be used to (I) inform targeted questions to ask your stakeholders/actors about barriers and enablers; (II) guide observations or documentation/literature reviews; and/or (III) map any of the information you gather to help identify key influences. *Table 3* outlines the 14 domains, with some example barriers relevant to laboratory testing. Choosing Wisely Canada's 'Using Blood Wisely' initiative provides an example of using the TDF to structure questions to identify key barriers to change (34). More detailed guidance on using the TDF is available elsewhere (27).

Regardless of the approach taken to identifying barriers/enablers, it is typically not possible or feasible to address them all in one initiative. They will likely have to be prioritized. It may be helpful to discuss prioritization within the project team and wider stakeholders as appropriate. Questions to consider which may help with prioritization include (35,36): (I) which barriers/enablers were most commonly reported/identified? (II) Where are there conflicting views (e.g., conflicting comments about which professional groups are responsible for the test ordering)? (III) Which factors seem to be (or are reported as) most strongly enabling change or preventing change? (IV) Which



[1], actions can be either a behaviour of the key actor of interest or an ancillary behaviour that supports another actor and action.
[2], add arrows between behaviours when one supports another.
[3], actors can be anyone at any organizational level (e.g., healthcare professional, patient, member of the public, teacher, family member, middle manager, leader).
[4], actors can be different members of a team/group that work together in the same context and time or could be linked organizationally so that e.g., behaviour of a leader provides necessary capacity for a healthcare professional's behaviour.
[5], for healthcare providers, the target might often be a patient, but could be colleague. For leaders, middle managers, the target would often be the healthcare provider.

Figure 3 Example behaviours involved in unnecessary routine testing of hospital inpatients, mapped to the AACTT framework. AACTT framework published by Presseau *et al.*, 2019 (26). AACTT, Action, Actor, Context, Target, Time.

barriers/enablers could potentially be grouped together and targeted with a similar type of change strategy? (V) Which barriers/enablers are easiest or most feasible to address in the current context?

Data-driven approaches to developing solutions

Whilst there has been substantial research into the effectiveness of different implementation strategies, none work all of the time. Taking time to think through and select the strategies which are best placed to capitalize on identified enablers of change and/or break down barriers to change will increase chances of success and help to minimize the waste of resources (time, energy, effort) that can occur using trial-and-error approaches which may not lead to change. Indeed, Rubinstein and colleagues noted in their review of laboratory test utilization initiatives that "*A comprehensive LTU approach should evaluate the merit of planned test utilization practice interventions … prior to implementation*" (14). Selection of strategies can be informed by a range of existing theory-

Table 2 Suggested activities for identifying enablers of change and/or barriers impeding change

Activities for identifying barriers/enablers
• Gather key stakeholders' thoughts and experiences regarding factors influencing the behaviours to be changed (e.g., at existing meetings)
• Have informal conversations (or conduct formal, research-based interviews, focus groups, or questionnaires) with a few of those who will be targeted by the intervention (i.e., your 'actors') about what drives what they do, and what would need to change for them to change their behaviour—create a safe environment for people to open up
• Conduct structured observations of care processes, taking notes on factors observed to influence behaviour
• Review relevant local documents which may provide some insights into factors influencing behaviour (e.g., medical directives)
• Review relevant literature on known barriers to change for the specific stewardship problem, and consider applicability to your particular context (either brief or in-depth)

Table 3 Example barriers to change mapped to the TDF

Example barriers to change	Relevant TDF domain label & description
Clinicians are not aware of updated evidence base which demonstrates that the test is low-value	Knowledge: existing procedural knowledge, knowledge about guidelines, knowledge about evidence
Clinicians have not been trained in discussing harms and downstream impacts of over-testing with patients	Skills: competence in and abilities to perform the relevant procedural techniques
Clinicians have a strong sense of medical obligation to do all they can for the patient, which includes ordering this test	Social/professional role and identity: extent to which the practice is something the individual thinks they are supposed to do as part of their role; boundaries between professional groups
Clinicians are less confident in their ability to identify deteriorating patients without ordering the test	Beliefs about capabilities: individuals' perceptions about their competence and confidence/self-efficacy
Clinicians are not hopeful that an initiative to modify testing patterns will be effective	Optimism: the outlook that things will happen for the best or that desired goals will be attained
Clinicians believe that the risks of not ordering the test outweigh the benefits	Beliefs about consequences: perceptions about positive and negative outcomes
Clinicians missed something in a patient once, now order the test indiscriminately	Reinforcement: the impact of previous experiences
Clinicians do not have strong intentions to reduce their ordering of the test	Intentions: a conscious decision to act in a certain way
Reducing testing is not a high-priority goal compared to other patient care goals	Goals: mental representations of end states that an individual wants to achieve (priorities, importance)
Clinicians order the tests habitually/as part of the clinical routine	Memory, attention and decision processes: ability to retain information, focus selectively and choose between two or more alternatives; extent of forgetting; impact of routines and habits
It is logistically very easy to order the test or add it to a previous order	Environmental context and resources: influence of any circumstance of the situation or environment (e.g., organizational, physical, financial)
Clinicians order the tests they know a senior supervising colleague will ask for the results of	Social influences: interpersonal processes; external influence from others; views of other professions, patients, families
Clinicians feel overwhelmed, ordering the test streamlines care processes	Emotion: influence of feelings, moods, affect (positive or negative)
Clinicians do not self-monitor their test ordering patterns or use any strategies to help reduce their testing	Behavioural regulation: strategies that individuals use to self-monitor/ manage/change their practice

Domain labels and descriptions published by Cane *et al.*, 2012 (32). TDF, Theoretical Domains Framework.

and evidence-informed resources, including (I) taxonomies of implementation strategies; (II) evidence synthesis for specific implementation strategies; and/or (III) tools which support mapping of identified barriers/enablers to strategies best placed to address them (37). These resources can be used to inform project team discussions that form the basis of solution development.

Taxonomies

Taxonomies are formal classification systems. In recent years, implementation and behavioural scientists have focused on developing taxonomies which list and describe different types of change strategies and provide examples of how they can be used. These can provide novel ideas and support consideration of a broader range of potentially helpful strategies. They also provide a shared language for describing strategies that can improve clarity and support future replications or scale and spread of successful strategies (e.g., to different departments/sites). Two commonly used taxonomies in healthcare change work are: the Cochrane Effective Practice and Organization of Care (EPOC) taxonomy (18) and the Expert Recommendations for Implementing Change (ERIC) taxonomy (19). The Behaviour Change Techniques Taxonomy Version 1 (BCTTv1) (28), whilst operating at a different level of specificity than the EPOC and ERIC taxonomies, is also often used. The BCTTv1 is currently being updated and transformed into an ontology (a classification system that includes relationships between entities) (38). The taxonomies can be used together: generally speaking, the EPOC and ERIC taxonomies contain high-level strategies that are defined more broadly (e.g., continuing education meetings/workshops), whilst the BCTTv1 lists behaviour change techniques (BCTs) that can be embedded within those broader strategies (e.g., instruction on how to perform the behaviour; information about health consequences; demonstration of the behaviour; information about others' approval; behavioural practice/rehearsal; goal setting; and/or problem solving). However, some ERIC strategies are more granular than BCTs (39). It can be helpful to read over these taxonomies and discuss potentially useful strategies as part of the solution development process.

Evidence syntheses

There are many published evaluations of implementation strategies. Much of this evidence has also been synthesised, to draw broader conclusions about the effectiveness of different types of strategies. These syntheses can also be helpful for informing your strategy selection. Due to the sheer number of evidence syntheses produced and their varying quality, it can be helpful to initially consider the syntheses produced by Cochrane, a global independent network focused on producing high-quality, relevant, up-to-date systematic reviews to inform health decision making (40). The Cochrane Library contains systematic reviews of strategies designed to improve healthcare systems and healthcare practice (41), and can be searched for reviews on specific strategies. Some reviews also identify contextual factors that can enhance the effectiveness of specific implementation strategies. For example, audit & feedback is most effective when the feedback is relayed by a supervisor or colleagues, is provided more than once, is delivered in both verbal and written formats, and when it includes both explicit targets and an action plan (42). Reviews of different types of strategies specifically evaluated in a laboratory stewardship context can also be consulted (11,14). Considering these multiple sources of evidence may help strengthen the rationale for selecting specific approaches: for example, giving feedback repeatedly is also suggested to improve effectiveness of audit & feedback for laboratory test ordering outcomes specifically (14). Where a laboratory stewardship project team has a shortlist of a few different types of potential implementation strategies, consulting the evidence base can help with deciding which ones to take forward, and with designing the selected strategies in such a way to maximize their effectiveness.

Mapping tools

Tools exist which can help with mapping identified enablers of change and/or barriers to change to the specific strategies which are best placed to address them (25,29,43,44). Here we introduce the Theory and Techniques Tool (43), because it specifically links to the framework introduced in the previous section on identifying barriers/enablers (i.e., the TDF) and one of the taxonomies introduced above (BCTTv1). This tool was developed based on a synthesis of results from a literature review and an expert consensus study (29). It comprises a matrix of 74 BCTs and 26 mechanisms of action (which include the 14 TDF domains). The matrix includes green colour-coding to identify techniques which may be more likely to help overcome specific barriers. As an illustrative example, *Table 4* outlines example barriers related to over-use of laboratory testing, how they map to TDF domains, potentially helpful BCTs identified from the Theory and Techniques Tool, and an example of how to use the BCT.

Table 4 Example barriers to change mapped to potentially helpful change strategies

Barrier to change	TDF domain	Potentially helpful BCT	Example of how to use the BCT
My colleagues are doing this testing, and so I do the same as them	Social influences	6.2. Social comparison	Provide audit & feedback reports which compare physicians' ordering practices with their top-performing colleagues
Our clinical leaders have not raised any issues with levels of testing	Social influences	6.3. Information about others' approval	Have clinical leaders advocate for and champion the appropriate practice, and have all initiative communications signed by them
I order these tests habitually/as part of the clinical routine	Memory, attention and decision processes	7.1. Prompts/cues	Add a best practice alert in the CPOE which prompts physicians to reconsider orders for specific tests in specific patient groups
I don't consciously order these tests: they are ordered automatically as part of an order set and I can't de-select them	Environmental context and resources	12.1. Restructuring the physical environment	Remove the test from the order set

Domain labels published by Cane *et al.*, 2012 (32); BCT labels published by Michie *et al.*, 2013 (28). TDF, Theoretical Domains Framework; BCT, behaviour change technique; CPOE, computerized physician order entry.

Table 5 The APEASE criteria for selecting between multiple intervention options

APEASE criteria	Description
Acceptability	How acceptable is it to all key stakeholders?
Practicability	Can it be implemented as designed within the intended context, material and human resources?
Effectiveness	How effective and cost-effective is it in achieving desired objectives in the target population?
Affordability	How far can it be afforded when delivered at the scale intended?
Side effects	How far does it lead to unintended adverse or beneficial outcomes?
Equity	How far does it increase or decrease differences between advantaged and disadvantaged sectors of society?

APEASE criteria published by Michie *et al.*, 2014 (25). APEASE, Acceptability, Practicability, Effectiveness, Affordability, Side effects, Equity.

Choosing between intervention strategies

There are often multiple possible techniques or strategies that can be used to address a barrier/enabler, and multiple ways in which those techniques and strategies can be put to use. In addition, specific laboratory stewardship strategies are more or less feasible to implement in specific contexts depending on aspects such as organizational structures or budgetary considerations (14). The APEASE criteria (Acceptability, Practicability, Effectiveness, Affordability, Side effects, Equity) (25) can be used to help select between multiple options (*Table 5*). Potential options can be rated against each of these criteria to help with decisions about which to take forward. This can be done with stakeholders using formal ranking/consensus processes such as the Delphi technique, which involves multiple rounds of rating and feedback (45). APEASE can also be integrated into an iterative process whereby initiative teams work out what can be done given potential delivery mechanisms and contexts: for example, the criteria can be used to frame stakeholder discussion about different options.

Distinguishing the 'what' from the 'how' of implementation strategies

A key part of intervention development is deciding exactly how selected strategies will look in the specific context in which they will be deployed. For example, if the aim is to target identified gaps in knowledge, what specific content should be developed to address those gaps, who will deliver it, and when, where, and how will it be delivered? Alternatively, if a prompt will be added to the CPOE, how should it be phrased, and how can it be designed to minimize additional cognitive load (i.e., be appropriately attention-grabbing and facilitate quick decision making without overloading the clinician with too

much information)? The results of the barriers/enablers assessment should help with this, since this will have supported the laboratory stewardship project team with identifying very specific issues relevant to the target group that can inform exactly how to put the selected strategies into use. When designing the initiative, it is important to distinguish the 'what' and the 'how' of change strategies (37). The 'what' is the content that is anticipated to lead to change, and the 'how' is the mode of delivery of that content. It is advisable to start with the 'what', and then consider the best way to package this content. For example, if specific knowledge gaps are identified in the target clinical group during the barriers assessment, content which specifically targets these can be developed (i.e., the 'what'), which could be delivered via an educational session, or physical educational materials, or embedded within best practice alerts or an audit and feedback report (i.e., the 'how'). Or, if a specific issue with the ordering process in the CPOE is identified, there may be multiple ways in which the CPOE environment can be changed to target that issue. There are no hard-and-fast rules for working up intervention content, and it is typically a somewhat iterative process involving input from key stakeholders who will impact or be impacted by the change.

Evaluation of interventions

While this article primarily focuses on understanding laboratory stewardship problems and developing solutions (steps 2 and 3 in the laboratory stewardship approach introduced previously), a brief discussion of evaluation methods is warranted. Approaches used in implementation science have much to offer the field of laboratory stewardship in this regard. Laboratory stewardship interventions are typically complex and multifaceted and deployed in real-world environments as opposed to tightly-controlled experimental contexts, which can make evaluation challenging. For example, although RCTs are considered the gold standard evaluation methodology (46), they are not always feasible in quality improvement contexts given the resource and logistical constraints. Where RCTs are used, recently published guidance on designing and undertaking randomized trials of implementation interventions should be informative (47). Where an RCT is not feasible, an interrupted time series (ITS) design serves as a robust, quasi-experimental approach to evaluation (48). With an ITS approach, repeated observations of a particular outcome are collected over time (for example, monthly volumes of electrolyte panels ordered per inpatient day) and divided into two segments: one before the interruption (i.e., the time point at which the intervention was deployed), and one after (49). A segmented regression analysis can then be applied to the data to determine the immediate and longer-term impact of the intervention. ITS models are more robust than other quasi-experimental methods (e.g., before-and-after studies), as they focus on calculation of intervention effects over-and-above any secular trends (i.e., changes in outcomes that would have happened had there been no intervention) (50).

Whilst RCTs and ITS designs focus on establishing whether an intervention works, process evaluation approaches can be used to help understand how or why an intervention works (or does not work). Process evaluations can focus on understanding aspects of the implementation process (e.g., fidelity—to what extent was the intervention deployed as intended?), mechanisms of action (e.g., does an intervention designed to operate via knowledge actually increase knowledge?), and/or the context in which the initiative is deployed (e.g., why does intervention effectiveness vary depending on different ways that clinical teams work together across different wards?) (47,51). A range of methodologies can be used to fulfill process evaluation aims, including surveys, observations, interviews, and documentation analysis (51). Broader guidance is also available for developing and evaluating complex interventions (52). Taken together, the systematic and robust evaluation approaches used in implementation science can be easily transferred to laboratory stewardship contexts and used to provide a more fulsome understanding of stewardship intervention effectiveness.

Strengths and limitations

This article presents current evidence and approaches from implementation science which can be embedded into laboratory stewardship programs to support rigorous development and evaluation of stewardship initiatives. We have focused on behaviour change-informed approaches, which conceptualize efforts to close a gap between best evidence and current practice in a healthcare setting as involving at least one person at some level in the healthcare system doing something—i.e., behaving—differently. It should be noted that there are other theories, models, frameworks, and approaches developed or applied within implementation science not addressed here which may provide different perspectives on quality improvement

problems and be informative for this work (53,54).

Discussion

Laboratory stewardship has become an important focus in healthcare. Stewardship consists of identifying areas of over or under use and involves multidisciplinary strategies for implementing interventions that have far ranging implications for patient care, healthcare finances, as well as environmental and health human resource sustainability. Effective laboratory stewardship relies on data-driven methodologies, which are fundamental in the field of implementation science. Implementation science uses evidence-based methods to promote the systematic uptake of research findings and best practices into routine healthcare and public health, with the overall aim of improving quality and effectiveness (17). Implementation science is rooted in using data to (I) understand factors contributing to evidence-practice gaps; (II) identify behaviors that need to be changed; (III) recognize the enablers of change and barriers to change; and (IV) select the appropriate intervention strategies. Thus, implementation science is by nature data-driven and highly relevant to laboratory stewardship, offering many evidence-based tools and approaches to design, guide, and facilitate effective interventions, as described in this article.

In the context of an appropriately resourced and supported stewardship structure, the initial step is to develop in-depth understanding of the problematic behaviour(s). This understanding is achieved by outlining the behaviour(s) that need to be changed, and answering the question, '*Who needs to do what, differently?*' (21). Different strategies can be used to identify the relevant behaviours, such as reviewing clinical guidelines, local laboratory utilization audits, direct observations of ordering practices and processes, and discussions with key stakeholders. This information can then be organized using the AACTT framework, which systematically categorizes behaviours in terms of Action, Actor, Context, Target, and Time (26).

Upon identifying the target behaviour, the next step involves understanding what needs to change in the person or environment to achieve the desired behaviour. This can include gathering key stakeholders' thoughts and experiences, conducting structured observations, reviewing relevant procedures, and considering literature on known barriers to change. To assist in organizing the identified barriers and enablers, stewardship programs can use tools such as the TDF. The TDF is a comprehensive framework designed to identify and understand the psychological and environmental factors that influence behaviour (27,31,32). The TDF consists of 14 domains, each representing a key aspect of behaviour, such as knowledge, skills, emotions, beliefs about capabilities, and environmental context and resources. By using such frameworks, stewardship leaders can systematically identify barriers to behaviour change, thereby aiding the design of intervention strategies.

When selecting intervention strategies, it is important to consider various theoretical and evidence-informed resources, including taxonomies of implementation strategies, evidence syntheses, and mapping tools. Taxonomies like the Cochrane EPOC, ERIC, and BCTTv1 can provide a range of potential strategies (18,19,28). Evidence syntheses, particularly those conducted by Cochrane, can provide valuable insights into the effectiveness of various strategies, while mapping tools such as the Theory and Techniques Tool can link identified barriers/enablers to strategies best placed to address them (41,43). To choose among multiple options, the APEASE criteria (Acceptability, Practicability, Effectiveness, Affordability, Side effects, Equity) can be used, involving formal ranking/consensus processes or stakeholder discussions framed using these criteria (25). Ultimately, any intervention requires a holistic and collaborative approach with consideration of site-specific issues and limitations, but the outcomes are more likely to be achieved with adoption of known, evidence-based strategies for behaviour change.

The final step in developing interventions involves deciding how the chosen strategies will be implemented in a specific context. This involves distinguishing between the 'what' and the 'how' of change strategies, wherein the 'what' is the content that leads to change, and the 'how' is the mode of delivery of that content. The design process should be iterative, involving key stakeholders who will impact or be impacted by the change.

Whilst the examples provided in this article focus primarily on supporting change in the behaviours of clinicians involved in the test ordering process, it is important to reiterate that the multiple actors that are involved in the testing process more broadly should be identified and their potential role in the initiative considered at the outset of initiative planning. This may include hospital administrators, clinical biochemists, hematologists, microbiologists, laboratory managers, laboratory technologists, and patients. In some instances, these actors may themselves be targets for intervention. In others, they could play a key role in intervention delivery, or

could serve on the project team responsible for developing and evaluating the initiative.

While implementation science has to date not been widely used in laboratory stewardship initiatives, there is widespread use and advocacy for quality improvement methodology (55,56). Quality improvement methods, which tend to focus on processes and systems, can be highly useful for helping to close a specific local gap in quality, such as under- or over-use of tests. Quality improvement projects may be augmented with integration of implementation science approaches for specific purposes, including to (I) determine barriers to change using existing literature and locally-gathered data; (II) design an intervention and develop the associated theory of change using evidence-supported theories and associated change techniques; and (III) support the spread of successful projects elsewhere by facilitating fulsome description of all of these elements of the initiative (57). From an evaluation and statistical perspective, integration of ITS analyses offers an opportunity to strengthen the analyses approaches typically used in quality improvement projects (58).

Conclusions

In summary, to effectively implement laboratory stewardship interventions, it is crucial to understand the underlying problem, identify the behavioural changes needed, acknowledge the barriers to these changes, and employ practical, evidence-based intervention strategies. Systematic intervention development in this manner should then be followed by rigorous intervention evaluation. All of these aspects, from problem definition, intervention design, implementation delivery, and evaluation can be well-informed by implementation science principles and driven by associated data.

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Footnote

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Appendix 1: Mock stewardship project

Based on internal data indicating that tests such as complete blood counts and electrolyte panels were frequently repeated when previous test results were in the normal range, the multidisciplinary laboratory stewardship committee at a hospital decided to implement an initiative to reduce repetitive routine testing on hospitalized inpatients. A project team was set up which included an internal medicine physician leader and nurse leader, two laboratory leaders, two patient advisors, a quality improvement practitioner, and a data analyst.

As their first step in planning the initiative, the team attempted to understand who is involved in the testing process and their actions as they relate to test ordering. They observed ward rounds on the internal medicine ward over the course of a week and noted any actions that were taken in relation to ordering of complete blood counts and electrolyte panels, and who did those actions. Over the course of another week, they also had a series of informal conversations with resident physicians, nurses, and attending physicians working on the internal medicine ward, and asked them to describe their role in clinical decision-making pertaining to complete blood counts and electrolyte panels, including selecting these tests/requesting that they be ordered, making the order for the test, requesting the results of the test, interpreting the results of the test, and making further clinical decisions subsequent to the test results. They were also asked what others in different roles on their team do as it relates to this. Using this information, the team mapped out all of the behaviours and the links between them. They then selected one of the behaviours as the one to initially target for the first initiative, keeping the diagram for further reference in the future should they decide to subsequently target other behaviours in future initiatives focused on this topic. The selected target behaviour was then specified in accordance with the AACTT framework, as follows: **resident physicians in the internal medicine ward placing orders for complete blood counts and electrolyte panels for stable inpatients when inputting lab orders at the beginning of the day**.

Once a target behaviour had been selected, the team selected outcomes with which to evaluate the impact of the initiative which corresponded to the target behaviour. The outcomes selected were the number of electrolyte panels ordered per inpatient day; the number of complete blood count tests ordered per inpatient day; the volume of blood drawn per inpatient day; hospital length of stay; and the number of readmissions within 30 days.

Next, the team did some further work to investigate the drivers of this behaviour, and the barriers to and enablers of behaviour change. They did this by having another set of informal conversations with the residents (some of the same individuals they had already spoken to, and some different). The questions guiding the conversation were informed by the TDF, to try and identify what drives selection of those tests, and what would need to change for them to change their behaviour. The residents were asked questions such as:

- **Knowledge:** Do you use any guidelines or local policies when placing orders for complete blood counts and electrolyte panels?
- **Beliefs about capabilities:** How easy or difficult would it be for you to stop placing orders for complete blood counts and electrolyte panels for stable inpatients? What would make it easier?
- **Beliefs about consequences:** What do you think would be the positive impacts of you stopping placing orders for complete blood counts and electrolyte panels for stable inpatients? (for yourself, your patients, your colleagues, your setting?)
- **Beliefs about consequences:** Are there any negative impacts that you think would occur? (for yourself, your patients, your colleagues, your setting?)
- **Environmental context and resources:** Is there anything in your work environment that influences you to place orders for complete blood counts and electrolyte panels for stable inpatients?
- **Social influences:** How might the views or opinions of others affect you placing orders for complete blood counts and electrolyte panels for stable inpatients? (such as colleagues; supervisors; patients; others?)
- **Emotion:** Would you have any worries or concerns about stopping placing orders for complete blood counts and electrolyte panels for stable inpatients?

Based on the participants' responses, a list of barriers to and enablers of change for each TDF domain was generated. The project team then selected priority barriers/enablers to focus on which were relatively often mentioned, could be feasibly addressed with the resources available for the initiative, and which were relatively likely to lead to the desired behaviour

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change if addressed. Three barriers selected were:

- Residents are not aware of the evidence base which demonstrates that this testing is low-value and the resulting negative impacts that this can have on patient safety and patient experience;
- Residents place orders for the tests habitually/as part of the clinical routine;
- Residents place orders for the tests because they expect that a senior supervising colleague will want to see the results at ward rounds.

Next, the team selected strategies to overcome these barriers. They reviewed the ERIC Taxonomy and, through a series of discussions amongst the team and with members of the hospital senior management team, they selected and developed the following strategies:

- Conduct educational meetings: Continuing Professional Development (CPD) sessions were developed to introduce low-value care, provide evidence from the literature supporting reductions in repeat testing, and to specifically highlight the negative impacts of repeat testing on patients. These were targeted at all internal medicine staff types and CPD credits were provided where relevant.
- Remind clinicians: a best practice alert was embedded into the CPOE system used to order tests. So as not to contribute to alert fatigue, the alert only appeared in specific circumstances, i.e., when a complete blood count or electrolyte panel was selected and a normal result was available from the previous day for the patient in question. The alert was designed to remind physicians that the order could be low-value care resulting in negative impacts for the patient and to prompt physicians to consider un-selecting the tests on that basis. The default response option to close the alert was to un-select the test.
- Inform local opinion leaders: present the initiative to members of the hospital senior management team seen as influential to residents and their supervisors (i.e., Chief of Staff, Department Heads) and provide template text about the initiative that they can embed into their written and verbal communications with clinicians to make their support for the initiative explicit.
- Identify and prepare champions: recruit and train attending physician representatives from the Internal Medicine ward to support the initiative by discussing and explicitly supporting the initiative during ward rounds, clarifying that they do not want these tests to be ordered when not clinically needed, signposting to the educational meetings, being available to discuss and resolve any concerns raised, and spreading these messages amongst their attending colleagues.

The strategies were implemented over a 3-month period. An ITS analysis was used to assess the impact of the initiative on the target outcomes. For example: the number of electrolyte panels ordered per inpatient day was extracted from the Hospital Information System for each week for the 26 weeks (i.e., 6 months) before the initiative, and for the 26 weeks after the end of the 3-month implementation period. These data were plotted on a graph and an ITS analysis involving a segmented regression approach was used to assess whether there was an immediate and/or a more gradual impact of the initiative on test volumes.

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