

Implementation Guide and Toolkit for National Clinical Guidelines







NATIONAL CLINICAL EFFECTIVENESS COMMITTEE The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee of stakeholders, including patient representatives, that was established to oversee a National Framework for Clinical Effectiveness. Its Terms of Reference are:

- 1. Provide strategic leadership for the national clinical effectiveness agenda.
- 2. Contribute to national patient safety and quality improvement agendas.
- 3. Publish standards for clinical practice guidance.
- 4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
- 5. Prioritise and quality assure National Clinical Guidelines and National Clinical Audit.
- 6. Commission National Clinical Guidelines and National Clinical Audit.
- 7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
- 8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
- 9. Establish sub-committees for NCEC workstreams.
- 10. Publish an Annual Report.

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Development of the Guide

The development of this Implementation Guide was informed by Implementation Science literature and resources and consultation and interactions with the Clinical Effectiveness Unit in the Department of Health and members of Guideline Development Groups.

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Permissions

Permission has been granted by the National Implementation Research Network (NIRN) for adaptation of their Hexagon Tool in this Guide. Permission has also been obtained to include Proctor et al.'s (2010) Taxonomy of Outcomes [28] and images from the IHI Framework for Leadership for Improvement and the Behaviour Change Wheel.

How to use this Guide

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

Who is this guide for?

The purpose of this Implementation Guide is primarily to support those involved in the development and implementation of National Clinical Guidelines, for planning implementation activities. Throughout this guide we refer to 'guidelines' as the intervention for implementation. However, it will also be of interest to those involved in the development and implementation of other evidence-based interventions, such as clinical practice guidance; policies, procedures, protocols and guidelines (PPPGs), and audit recommendations.



Throughout this Guide, we refer to 'Guideline Groups'. This refers to both the initial Guideline Development Group and the post-publication implementation team(s). There will be some overlap between the initial Guideline Development Group and the implementation team(s). The implementation team is generally a national team, but additional local teams can also be established as required. The implementation team(s) take the guideline forward through the implementation stages, in partnership with the wider health service organisation.

When will it be used?

This Implementation Guide provides the theory, steps and tools for each stage of implementation. Whilst it is recommended that the Implementation Guide be used from the outset in guideline development, existing Guideline Development Groups will also find the various tools useful, regardless of what stage of development they are at.

What needs to be included in the guideline?

NCEC Guidelines already include a plan for implementation. New Guideline Development Groups will be expected to include the following implementation components in their submission for Quality Assurance and in the final published guideline:

- Logic model (one page)
- Implementation plan (actions, timeframe, persons responsible, expected outcomes)

Templates and worked examples for these are included in this guide.

This Implementation Guide provides readers with:

- ✓ Context for the importance of Implementation Science in successfully implementing clinical guidelines
- ✓ An outline of Implementation Science theory and an introduction to key concepts
- ✓ Key elements common to implementation frameworks
- A package of information, tools and resources to facilitate discussions, thinking, and planning for implementation at various stages of the guideline development and implementation process.

This Guide builds on information delivered by the Centre for Effective Services for the National Clinical Effectiveness Committee (NCEC) in the Department of Health at a two-day Introductory Training in Implementation Science and a series of three additional workshops on specific implementation topics delivered to healthcare practitioners, healthcare staff and other stakeholders. However, it is designed in such a way that it can be read and used by stakeholders who were not at these events or who have a broader scope.

Clinical Guidelines are

'systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service users' decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system' [1].

The first section of this Guide is intended as a source of evidence for why implementation of clinical guidelines is an important and useful topic. Following that, there is a brief overview of the main theories and concepts put forward in Implementation Science. This will serve as a useful introduction for those who are new to Implementation Science, or as a refresher for those who are familiar with the discipline and/or who have attended relevant training sessions and workshops. References are provided with hyperlinks at the end of this Guide, where available, and there is also a list of further resources, for those who would like to read further.

The remaining sections provide information, tools and resources for the most relevant and important implementation considerations throughout guideline development and implementation. Implementation stages are discussed in some detail in this Guide, and it is especially helpful to identify which stage a guideline/project is at in the implementation process. Implementation planning is also discussed in detail in this Guide and a template for creating an implementation plan is included in Tool 4.

However, it is important to note that *"implementing research evidence is not just a matter of following procedural steps"* [2, p.4]. Accordingly, this Guide <u>is not</u> a step-by-step guide or checklist for implementing clinical guidelines. Rather, it provides a package of information, tools and resources to help guide discussions, thinking and planning around implementation. It will be up to Guideline Development Groups, implementation teams and other relevant stakeholders to identify implementation activities, given the context in which they are implementing and the nature of what is being implemented. Naturally, these will vary on a case-by-case basis, and we believe that this Guide will become increasingly useful as people gain experience and knowledge of both the theory of Implementation Science and the practice of implementing in the real world.

Implementation of Clinical Guidelines

In Ireland, clinical guidelines that meet specific prioritisation and quality-assurance criteria set forth by the NCEC are endorsed by the Minister for Health and are titled *'NCEC National Clinical Guidelines'*. This is in line with evidence indicating that the quality assurance and evaluation processes used in developing clinical guidelines internationally has improved since the 1990s [3].

However, there is little international evidence of consistent improvements in the dissemination, implementation and clinical use of clinical guidelines. For example, studies have shown that up to 50% of patients can fail to receive clinical interventions in accordance with the best clinical evidence and latest clinical guidelines [4, 5].

Implementation involves the carrying out of specific planned, intentional activities undertaken with the aim of making evidence-informed policies and practices work better for people. It can be thought of as the 'how' as well as the 'what'.

Guidelines have often been found to contain a

large volume of clinical information, and have been described variously as 'cumbersome' [6] and 'unmanageable' [7]. This has left those using the guidelines "frustrated with the vast number of guidelines and uncertain about how to implement them" [8, p.1]. Even when clinicians are aware of and in agreement with clinical guidelines, adoption and adherence can be low, and clinicians indicate a desire for more guidance and support to implement them [9].

Not only is this a sub-optimal return on considerable investment of public money [10], it also indicates a significant loss in potential health gains for patients and populations [5]. In Ireland, this is a driving factor behind the production of this Guide and the increasing focus on implementation of clinical guidelines.

There is an opportunity for guideline developers and stakeholders to do more to translate clinical guidelines into usable materials for practitioners with little time and resources. "*Merely circulating guidelines or other documents to health professionals has only a small effect on practice*" [3, p.276] – health professionals also require dissemination and implementation activities, tools and resources that will help to maximise usage of guidelines [10]. Guidelines should be presented in a manner that is clear, precise and usable, for example in summary documents, 'Plain English' versions, or point-of care checklists and forms [11].

The importance of dedicating time and resources to implementation of clinical guidelines is being increasingly recognised, and the NCEC has included consideration of implementation issues as part of prioritisation and quality assurance processes for National Clinical Guidelines.

Prioritisation occurs at the beginning of the guideline development process. Key aspects of implementation which are assessed by the NCEC during the guideline prioritisation stage include [12, p.12]:

- What is the feasibility of implementation of the clinical guideline?
- What are the facilitators to the guideline application?
- Are there any significant barriers to implementation of the clinical guideline?
- What is the resource impact for implementation of the clinical guideline?
- How acceptable will the clinical guideline be to relevant stakeholders (consumers and clinicians)?

- Did the Guideline Development Group include individuals from all the relevant professional groups, methodological experts and intended users, for example healthcare professionals, hospital managers etc.?
- Is there a degree of urgency for implementation of the clinical guideline?
- What is the likelihood of the clinical guideline implementation strategy being successful?
- How accessible will the clinical guideline be?

Key aspects of implementation which are assessed during the NCEC quality assurance process form part of the 'Applicability' domain of the Appraisal of Guidelines for Research and Evaluation (AGREE II) tool [13], namely:

- The guideline describes facilitators and barriers to its application
- The guideline provides advice and/or tools on how the recommendations can be put into practice
- The potential resource implications of applying the recommendations have been considered
- The guideline presents monitoring and/or auditing criteria.

This guide and the tools are available on the **Department of Health NCEC website**: <u>http://health.gov.ie/national-patient-safety-office/ncec/</u>

Other resources relating to National Clinical Guidelines, National Clinical Audit and Clinical Practice Guidance are also available on the **Department of Health NCEC website** linked above. This includes resources on guideline prioritisation and quality assurance processes, such as the:

- Preliminary Prioritisation Process for National Clinical Guidelines
- National Quality Assurance Criteria for Clinical Guidelines
- Guideline Developers Manual.

Training materials, including videos and e-learning are available on the Department of Health **National Patient Safety Office Learning Zone:** <u>https://health.gov.ie/national-patient-safety-office/ncec/resources-and-learning/</u>

Welcome to the NPSO Learning Zone



Introduction to Implementation Science



Introduction to Implementation Science

What is Implementation Science?

Implementation focuses on operationalising a plan – it is about 'How' something will be carried out, as well as 'What' will be carried out [14]. It is both an art and a science, harnessing knowledge from academic research and practice wisdom, with the aim of successfully incorporating interventions into typical service settings, in order to improve outcomes for service users (children, adults, families, communities and society) [15].



Implementation is conceptually distinct from diffusion and dissemination. Diffusion is a passive process, described as 'letting it happen', meaning the intervention follows an unpredictable, unprogrammed, emergent and self-organising path. Dissemination is a more active, negotiated and influenced means of delivering an intervention ('helping it happen'). Implementation is the most active form of delivering interventions – it involves 'making it happen', through scientific, orderly, planned and managed activities [16].

Interventions are any evidence-informed policy, practice, service or programme being implemented, be it a change to an existing policy, practice, service or programme, or a new intervention.

In this Guide, we use intervention to refer to specific recommendations contained within National Clinical Guidelines, Clinical Practice Guidance (PPPGs) and National Clinical Audit.

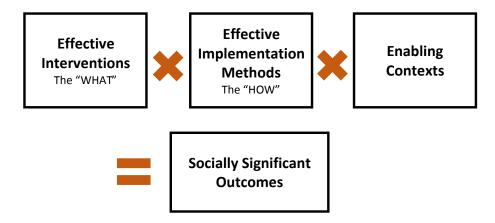
Implementation Science is the formal study of methods and factors that influence how successfully specific interventions are incorporated into service settings, leading to improved outcomes.

Implementation Science is linked to and builds on a number of related disciplines including Improvement Science, Quality Improvement, Project Management, Change Management, Knowledge Translation and Organisational Development.

It is worth noting what Implementation Science is not:

- A magic formula Implementation Science is not the answer to all Implementation problems and will not guarantee the success of clinical guidelines. There are a myriad of factors affecting implementation success, and sometimes it may not be possible or feasible to address them all.
- ✗ A mystical and inaccessible language − while some Implementation Science literature can contain jargon, it builds on 'common sense' and knowledge from a range of related disciplines.
- A way of proving an evidence-based intervention Implementation Science will not prove whether an intervention is effective or not and using Implementation Science will not turn a bad intervention into a good one.

As a field of study, Implementation Science has grown in popularity over the last decade, and there is now a considerable body of research from a wide range of sectors indicating some of the most important factors in determining whether implementation will be successful or not. Implementation is a not a challenge unique to the health sector. Rather, it is a universal phenomenon, and lessons in Implementation Science have been obtained from fields as disparate as education and training; manufacturing and engineering; agriculture and forestry; business and information technology; and more.



Having an effective intervention is just one part (albeit an important one) of getting to positive outcomes. Implementation Science helps us to identify the effective implementation methods and enabling contexts that form the remaining parts of the equation and improve the likelihood of reaching the intended outcomes [15].

Implementation Frameworks

Implementation frameworks provide a conceptual model of implementation, serving to describe specific steps in the planning and execution of implementation, and highlighting potential pitfalls.

The past decade has seen an increase in the number of frameworks appearing in Implementation Science research. In 2012, the count was at more than 60 frameworks [17]; in 2017, it was 100 or more [18]. These frameworks differ in terms of assumptions, aims, context (policy, practice, etc.), and sectors (public health, child welfare, etc.).

The terms *theory, model* and *framework* are often used interchangeably.

For a detailed description of these terms, with particular relevance to Implementation Science, see Nilsen, 2015 [19]

 Websites such as the 'Dissemination & Implementation Models in Health Research & Practice' are now being created to help researchers, policymakers and practitioners determine which framework, or elements of a particular framework, will be most relevant for their implementation problem.

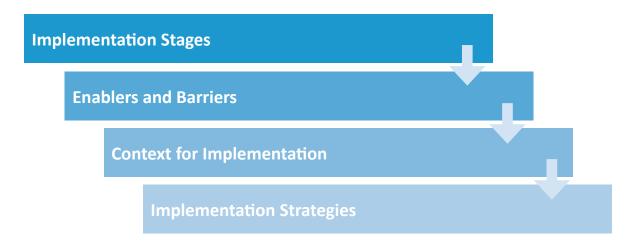
To access this website, click here: <u>http://www.dissemination-implementation.org/</u>

• For those interested in reading further, the **Centre for Effective Services has created a short document summarising several implementation frameworks** with links for further reading.

To access the Summary of Implementation Science Frameworks, click <u>here</u> or see Appendix A.

While Implementation Science is producing growing evidence of generalisable lessons for more effective implementation, the evidence for any individual implementation framework is limited. There is also significant overlap among many of the frameworks. As a result, there is a growing emphasis on combining and improving existing frameworks, and on using the most relevant elements of any one or more frameworks given a specific context.

The remainder of this section will focus on some of the core elements of Implementation Science. These core elements are:



Implementation Stages

Implementation frameworks almost unanimously conceptualise the implementation of any intervention as passing through a given number of stages. The number of stages varies between frameworks (usually 3-5), as does the names provided for each of the stages.

Key messages from Implementation Stages:

- You *cannot skip any stage* of implementation. Each stage requires stakeholders' time and attention.
- Implementation takes time; estimates vary from 2-4 years to 7-10 years, depending on scale and complexity. Rushing through stages or working a particularly large number of hours in a short time does not adequately compensate for this need.
- The stages are *not linear*. Many of the activities overlap, and you may need to re-visit or bring forward tasks from other stages as necessary.
- There are a *range of tools* available to help Guideline Groups navigate each stage. These are signposted throughout the remainder of this Guide.

The four-stage model below is one way to visualise the implementation process of clinical guidelines:

	Stage 1: Exploring & Preparing						
Here the needs of stakeholders are assessed, the reason/rationale for developing the guideline is clarified, and the scope of the guideline is determined.							
 Defining key clin Assessing the fit Specifying outcome 	0	nmendations					
		Stage 2: Planning & Resourcing					
 Stage 4: Full Implementation The guideline is fully operational and integrated, used consistently, and supported by structures and resources. Key activities at this stage include: Evaluating implementation outcomes, service outcomes and client outcomes Engaging in continuous improvement cycles to enhance quality 	4. Full 2. Planning Implementation & Resourcing	 Here the foundation is laid for effective implementation. <i>Key activities</i> at this stage include: Assessing implementation readiness Assessing enablers and barriers for implementation Developing an implementation plan Establishing implementation team(s) and infrastructure for implementation Developing leadership for implementation Designing monitoring, evaluation and feedback systems Determining and delivering staff training, capacity building and support requirements 					

Stage 3: Implementing & Operationalising

Here the guideline is implemented for the first time.

Key activities at this stage include:

- Maintaining ongoing communication, explaining why the guideline is necessary and securing continued buy-in
- Providing ongoing professional development opportunities and support for staff implementing guidelines
- Ongoing monitoring of implementation outcomes, service outcomes and client outcomes
- Using data and feedback mechanisms to inform ongoing improvements
- Adapting implementation plans for local settings, where appropriate

Assessing Implementation Stage

It is very useful for Guideline Groups to assess what stage of implementation their guideline is at. This allows groups to get a sense of how far along the implementation process they are, and consider the most appropriate activities for them, given their stage. Strictly speaking, this assessment could occur at any stage of guideline development and implementation, but is particularly useful in stages 1 and 2, for the purposes of planning and resourcing.

The **Implementation Stages – Key Activities Tool** outlines the four stages of implementation and provides examples of key activities at each stage. It also provides a template for stakeholders to analyse their own progress on the key activities suggested, as well as any additional actions they identify specifically for their intervention(s).

Click here to access the tool on the Centre for Effective Services' website: <u>http://effectiveservices.org/resources/article/implementation-stages-key-activities</u>

Enablers and Barriers

Implementation Science has highlighted a number of factors which increase the probability of any intervention being successfully implemented. The diagram below indicates ten of these most commonly-seen factors and indicates at which stage of implementation they require most attention. These factors are given a variety of names in the literature, including drivers and facilitators, but for simplicity, this Guide will refer to them as **implementation 'enablers'**.

Implementation Enablers	Implementation Enablers Stages of Implementation							
	1. Exploring & Preparing	2. Planning & Resourcing	3. Implementing & Operationalising	4. Full Implementation				
Stakeholder consultation and buy-in								
Leadership								
Resources								
Implementation plan								
Implementation team								
Staff capacity								
Organisational support								
Supportive organisational culture								
Communication								
Monitoring and evaluation								
Data informed improvement cycles								
Implementation Enablers by Stage of Implementation [14]								

Research has also pointed to a number of factors which hinder the implementation process. These are known as **implementation 'barriers'**. These include alignment problems with funding cycles, resistance to change and vested interests. Taking steps to avoid or overcome these barriers, where possible, at an early stage of implementation is very important for successful implementation.

Context for Implementation

Implementation Science indicates the importance of the context in which interventions are implemented and used [19]. Examples of factors that influence context include:

- Providers' perceptions of an intervention
- Patients' needs
- Relationships, networks and communications
- Structural characteristics of the environment
- Local and national policies
- Culture.

Context can be described as 'the set of circumstances or unique factors that surround a particular implementation effort'. This can refer to both the wider, systemic context, as well as the specific setting in which a specific intervention will be implemented [20].



By nature, implementation is inseparable from context. This means that contextual influences explain a lot of the variation in implementation success [19]. For example, if an intervention requires the purchase of new equipment, but the external context means funding is not readily available, the chances of successful implementation are reduced.

As such, it is important to take context into account and design guidelines so that they can leverage favourable contextual factors and overcome unfavourable ones. This can be difficult, as contextual factors are often changeable and transient.

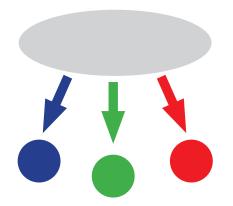
However, context can also be influenced and malleable to change [21]. Implementation enablers such as a sympathetic culture; strong leadership; staff support such as coaching and mentoring; and well-designed feedback and evaluation mechanisms, can all help to influence context in a positive way.

Strategies for Implementation

For some time, there has been evidence that tailored implementation strategies improve implementation success [22]. Implementation Science is now identifying what strategies and activities may be used to target specific enablers and barriers of implementation. These strategies can be either top-down or bottom-up:

Top-Down Implementation Strategies

A linear approach where strategies are led from a central source.

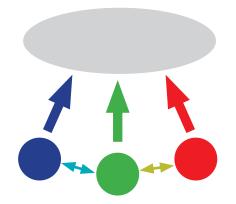


Examples:

- Distribute educational materials
- Conduct ongoing training
- Mandate change

Bottom-Up Implementation Strategies

A decentralised approach where strategies are initiated by stakeholders at community/ local level.



Examples:

- Capture and share local knowledge
- Organise clinician implementation team meetings

The recent Expert Recommendations for Implementing Change (ERIC) project has sought to gather together implementation strategies commonly used by those trying to successfully implement an intervention [23]. This can be used by implementers as a 'menu' of options, whereby they can choose strategies and activities based on what would be most suitable and effective in their specific context.

Click here to access the Expert Recommendations for Implementing Change list of **73 implementation strategies** [23, pp. 8-10].

Unfortunately, there is currently little evidence on how to systematically choose strategies [24], so an element of trial and error should be expected and tolerated.

Stage 1: Exploring and Preparing



Stage 1: Exploring and Preparing

In stage 1 of implementation, the needs of stakeholders are assessed, the reason/rationale for developing the guideline is clarified, and the scope of the guideline is determined. It involves exploring the context in which implementation will take place, and the range of possible actions that will suit this context. For guideline development, this stage typically involves deciding on the range of clinical questions to be included in the guideline, i.e. the scope of the guideline. Specific activities to be carried out in this stage are:

- Stakeholder engagement planning
- Assessing needs and the evidence base
- Assessing the fit, feasibility and implementability of potential recommendations
- Specifying outcomes which the guideline seeks to achieve
- Developing a Theory of Change and Logic Model.

It is worth remembering that while these activities are most suitable during stage 1, they may still be useful for Guideline Groups at other stages of implementation.

The key tools that can be used during this first stage of implementation are:

- Stakeholder engagement tool
- Hexagon tool for assessing the readiness to implement
- Logic model template.

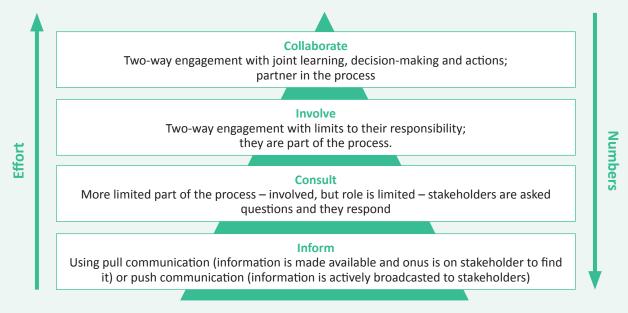
Stakeholder Engagement Planning

In the development, implementation and evaluation of guidelines, the involvement of stakeholders:

- Helps create awareness
- Generates buy-in
- Identifies and acknowledges any resistance
- Aids in the assessment of need, fit, feasibility, capacity and readiness.

Stakeholders are anyone who is affected by or is involved in the development of and delivery of guidelines/projects. They include patients, public, clinicians, managers, professional bodies, unions, educators and policymakers.

The pyramid shown overleaf indicates four potential levels of engagement with stakeholders. Guideline Groups should consider at which level to engage with key stakeholders. The upper levels of the pyramid are more likely to achieve true levels of engagement, whereby stakeholders feel adequately consulted and are willing to buy-in to the intervention. However, the upper levels of the pyramid also have a higher resource requirement in terms of effort and cost.



Levels of Stakeholder Engagement. From Centre for Effective Services, 2017 [25]

It is also important to recognise that, when implementing guidelines, groups of stakeholders may be very diverse, depending on specific local contexts. This means that Guideline Groups may focus on high-level stakeholders, and detailed stakeholder engagement planning may be more effective at a local level.

The **Stakeholder Engagement Tool**, developed by the Centre for Effective Services, helps those implementing a policy or programme to plan for and manage the process of engaging with key stakeholders. It sets out tasks and questions for stakeholder identification, analysis and mapping. It also provides a template and checklist to help develop a stakeholder engagement plan.

Click here to access the Stakeholder Engagement Tool on the Centre for Effective Services website: <u>http://effectiveservices.org/resources/article/stakeholder-engagement-tool</u>

Public Involvement

The NCEC has published a Framework and Toolkit for Public Involvement in Clinical Effectiveness Processes in 2018, which is available on the NCEC website: <u>http://health.gov.ie/national-patient-safety-office/ncec/public-involvement-framework/</u>. The term 'public' includes a wide range and variety of individuals, as well as groups and/or organisations. These include people who use, or have used health care services, carers and family members, parents, organisations who represent patients, patient support groups, charities that represent specific health conditions, individuals with an interest in a topic, and members of the general public [26].

The public are partners in the use of clinical guidelines. Their involvement at all stages of the planning and development process is integral to the feasibility, needs assessment and sustainability of the intervention. Public involvement in clinical effectiveness processes strengthens public participation in healthcare decision-making and brings public knowledge and experience to these processes.

The NCEC Framework and Toolkit for Public Involvement in Clinical Effectiveness Processes outlines the practices that may be undertaken to involve the public in clinical effectiveness processes and includes the NCEC values for public involvement, which apply to engagement with all stakeholders:

- Dignity and respect
- Support
- Transparency and openness
- Learning and responsiveness
- Inclusivity, fairness and diversity
- Sustainability
- Collaboration and partnership.

Needs Assessment

Prior to guideline development and implementation, a needs assessment should be carried out to identify the gap between what is currently in place and what is desirable to have in place, in addition to any variation in practice. These gaps should be assessed at multiple levels (patient, provider, organisation, system). Needs should also be assessed from the perspective of the stakeholders (both individuals and organisations) who will be directly involved in implementation.

Framework for Public Involvement in Clinical Effectiveness Processes	
inclusivity Public transparency dignity sustainapility dignity fairnessinvolvement	I
collaboration ing support spartnership	
DCU SAn Roin Skine States Office Safety Office Construction	

A **Needs assessment** clarifies the extent to which needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritised by an organisation or group of people.

"Clearly, improving the health and wellbeing of patients is the mission of all healthcare entities, and many calls have gone out for organisations to be more patient centred... Consideration of patients' needs and resources must be integral to any implementation that seeks to improve patient outcomes" [20, p.7].

The basic questions to be answered by a needs assessment are [27]:

- What are the gaps?
- What is causing them?
- What can we do to fix it?

A needs assessment should come very early in the guideline development and implementation process, and it is sometimes considered a pre-implementation activity or a necessary first step.

The Hexagon Tool is a planning tool used to conduct a needs assessment and evaluate implementation readiness for interventions during the initial stages of implementation. It helps guideline developers and implementers to broadly consider six factors that help to determine levels of need and indicate where initial implementation efforts would be most impactful. The six factors are: *Need; Fit; Resource Availability; Evidence; Intervention Readiness; and Capacity to Implement.*

The Hexagon Tool is also a very useful way for Guideline Groups to begin considering outcomes and can be considered as an introductory exercise in developing a logic model.

To access the Hexagon Tool, click <u>here</u> or see Tool 1.

Identifying Outcomes

Implementation outcomes are changes resulting from deliberate and purposive actions to implement new treatments, practices, and services. They are distinct from service outcomes and patient/client outcomes, and they serve three main purposes:

- a) They are indicators of implementation success
- b) They highlight implementation processes
- c) They can serve as intermediate outcomes for desired service or client outcomes which may follow (because an intervention is unlikely to be effective unless implemented well).

Outcomes are intended or unintended changes that occur as a result of implementing interventions. These changes can occur at the level of individuals, groups, organisations or population, and can occur in the short-, medium- or longterm.

The diagram below presents a taxonomy of implementation outcomes, service outcomes and client outcomes. This is followed by further details on implementation outcomes.

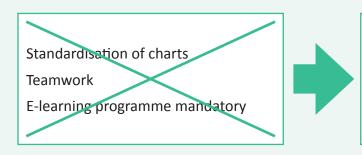
Implementation	Servi		Client
Outcomes	Outco		Outcomes
Acceptability Adoption Appropriateness Costs Feasibility Fidelity Penetration Sustainability	Efficie Safe Effective Equi Patient-cent Timeli	ty eness ty teredness	Satisfaction Function Symptomatology

Taxonomy of Outcomes. From Proctor et al., 2010 [28]

Implementation Outcome	Description	Other terms	
Acceptability	The perception among stakeholders that an intervention is agreeable, palatable or satisfactory.	Content; comfort; credibility	
Adoption	The initial decision to employ an intervention.	Uptake; utilisation; intention to try	
Appropriateness	The perceived fit, relevance or compatibility of an intervention.	Perceived fit; compatibility; suitability; practicability	
Feasibility	The extent to which an intervention may be carried out within a given setting.	Actual fit; suitability for everyday use; practicability	
Fidelity	The degree to which an intervention was delivered as described.	Delivered as intended; adherence; integrity; quality of delivery	
Cost	The cost impact of the implementation activities; both due to the cost of delivering an intervention, and the complexity of the implementation.	Cost-effectiveness; cost- benefit; marginal cost	
Penetration	The integration of an intervention into a service setting and its sub-systems.	Institutionalisation; spread; service access	
Sustainability	The extent to which an intervention is institutionalised within a service's ongoing operations.	Maintenance; continuation; durability; incorporation; integration	

Tips for identifying desired outcomes:

- A range of outcomes relating to implementation, service delivery and clients should be considered.
- Identify which outcomes are achievable in the short-term, and which are more medium- or long-term outcomes.
- For clinical guidelines, well thought-out and articulated outcomes are usefully included in a logic model, forming one of the first steps in a logic model's development. Before going straight to the logic model, the *Hexagon Tool* (Tool 1) helps to start thinking about desired outcomes.
- Frame and label outcomes in the correct language. They should indicate a change from a current position, rather than just an activity, output or decision. The diagram overleaf provides some examples of incorrectly labelled outcomes and how they can be more appropriately framed.

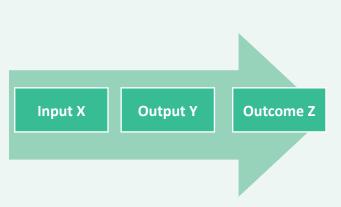


Charts are standardised nationally. Enhanced teamwork across healthcare teams. E-learning programme incorporated

into mandatory training requirements.

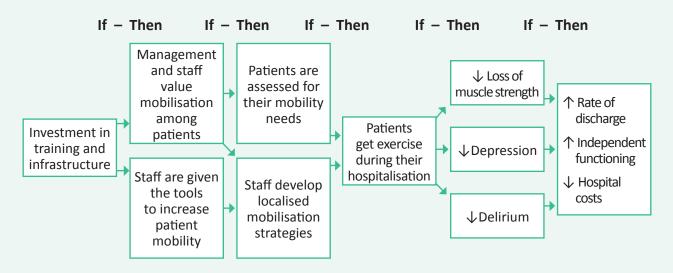
Developing a Logic Model

The potential usefulness of guidelines should be determined with reference to a clearly articulated description of how they will bring about a change. A **Theory of Change** makes this explicit, by indicating why providing input X should lead to a change in outcome Z, by way of output Y. This theory should be evidencebased, and trace how the inputs, outputs and outcomes are conceptually and practically linked.



The overall Theory of Change can be simply broken down into a series of 'if-then' relationships, whereby each step/relationship should be informed by existing evidence about how needs arise and how change is achieved in previous steps/relationships.

An example of a Theory of Change for the Mobilisation of Vulnerable Adults, Ontario (MOVE-ON) [29] study is provided below. This clearly details a number of steps and expected relationships, whereby investment in training and infrastructure can eventually lead to improved outcomes for clients and services.



Theory of Change for the Mobilisation of Vulnerable Elders, Ontario (MOVE-ON) study (created by CES based on [29])

The series of 'if - then' relationships and outcomes that express the programme's theory of change form the underlying basis of a **Logic Model**. The logic model further describes and elaborates on the Theory of Change, allowing stakeholders to systematically work through connections between the essential components of guidelines, usually on a single page.

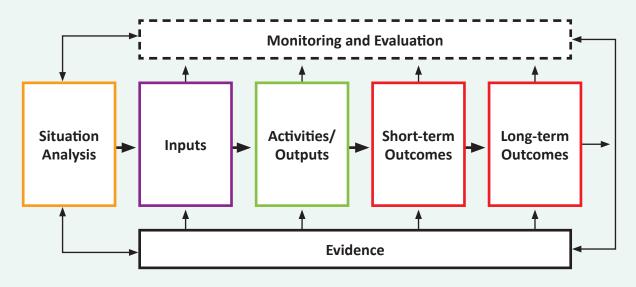
Guidelines designed using a logic model can help to achieve desired results by encouraging a focus on outcomes from the start, making the connections explicit and ensuring that there is evidence to support the connections.

It is important to remember that using a logic model does not take away from the need for flexibility or responsiveness. A logic model is a statement of intent and develops through a live and iterative process rather than a one-off event. This means it can adapt to unexpected events, take advantage of emerging opportunities, and be creative in meeting challenges.

Benefits of using a Logic Model:

- Provides coherence across complex tasks
- Helps differentiate between 'what we do' (outputs) and 'results/changes' (outcomes)
- Keeps focus on shared goals
- Improves evaluation and what variables get measured

However, too many changes, especially if these are reactive, can undermine the value of the logic model. Therefore, a logic model, particularly if very complex, is best seen as a high-level statement which requires a separate, and more detailed, implementation plan (to be developed in stage 2).



The basic outline of a logic model is shown above. It should be completed by Guideline Groups in the following sequence of steps:

- **1. Situation Analysis**: Consider the context and what the opportunities, problems and needs in relation to the guideline are. The information contained in this box can draw heavily on the needs assessment. Answering the following questions will help to describe the current situation:
 - Why is the guideline needed?
 - What is the situation and issue(s)?
 - What are the needs of population and target groups?
 - What are the strengths and weaknesses of current provision?
 - Where are the gaps?

- What do we need to improve?
- What are the socio-economic influences?
- 2. Outcomes: As described above, those responsible for development and implementation of guidelines should ask what specific changes are desired in the short-, medium- and long-term. These can include changes in knowledge, behaviour, practice, decision-making, policies, social action, condition, status etc. Long-term outcomes are the desired end-result, and short-term outcomes may or may not be cumulative steps or contributions to the long-term outcomes.
- **3. Outputs/Activities**: These are key areas of work that will help to achieve the desired outcomes. They include specific targets (e.g., numbers of people trained or qualified, resources, reports, new processes and structures), as well as clear statements about:
 - What will be done? (types of activities)
 - Who will be reached? (clients, providers, beneficiaries, other agencies)
 - Where it will happen?
 - When and how often how it will happen?
 - How it will happen?

It is useful to be as clear as possible about your thinking regarding the choice of activities and *include specific targets for numbers to be reached and frequency of activities,* where possible.

- 4. Inputs: This involves being clear about what resources are needed to carry out the activities/ outputs identified. As such, inputs essentially enable outputs. Examples of resources that can be employed include staff, equipment, buildings, technology, information systems, and support structures. The limited nature of resources means it is important to try to leverage or re-organise existing resources as much as possible and include any additional costs in the guideline's Budget Impact Analysis and economic evaluation. If costs are considered unrealistic or not cost effective, then the activities/outputs section may have to be revisited and revised accordingly.
- **5. Monitoring and Evaluation:** This involves assessing the extent to which an intervention is working towards the outcomes stated. In the logic model, it is important to consider how information will be collected, interpreted and reported. It is also important to consider targets, metrics, and Key Performance Indicators (KPIs), as well as baselines and benchmarks, which can provide signs of progress.

More than other sections of the logic model, the monitoring and evaluation section should be high-level, with specific concerns about data and methodology dealt with in detail during planning for Monitoring and Evaluation, which is covered in more detail in later sections of this Guide.

- **6.** Evidence: This should underpin all aspects of the logic model and involves taking data and evidence from research, audit, experience, policy, consultation, and ongoing monitoring and evaluation processes to:
 - Inform understanding of problems

- Identify desired outcomes, and how they may be effectively achieved
- Devising ways of monitoring and evaluating progress.

It is important to consider multiple forms of evidence here, including peer-reviewed research, independent reports, case studies, grey literature, audit data and practice wisdom. Information contained in the logic model can be underpinned by any of these forms of evidence, if the evidence is of high quality.

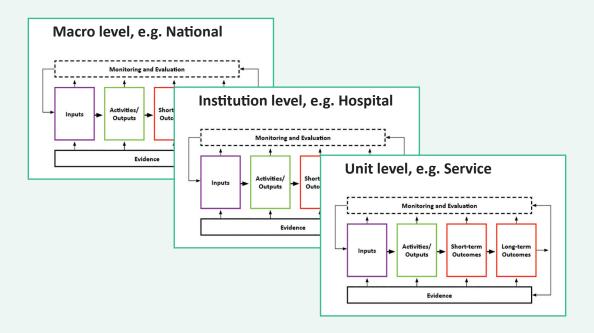
Tips for developing a logic model:

- While a logic model should be read from left to right once completed, it is mostly **developed from right to left**, beginning with outcomes (after completing the situation analysis) and working back through activities/outputs and inputs.
- Though it is often difficult to be precise, **being as concrete as possible**, in terms of figures and targets listed, is better for planning, implementation, accountability and evaluation purposes.
- **Outcomes inserted into a logic model can be clearly grouped** by whether they are related to <u>implementation outcomes</u>, <u>service outcomes</u> or <u>client outcomes</u>.
- List any anticipated inputs and discuss any issues arising. If you are intending to work in partnership, for example, what would you need to consider in terms of planning or implementation?
- Work already done on the Hexagon Tool and outcomes can form the basis for development of a logic model.

To access a **blank version of the Logic Model Tool**, which Guideline Groups can edit and fill in for their own guidelines, *click <u>here</u> or see Tool 2*.

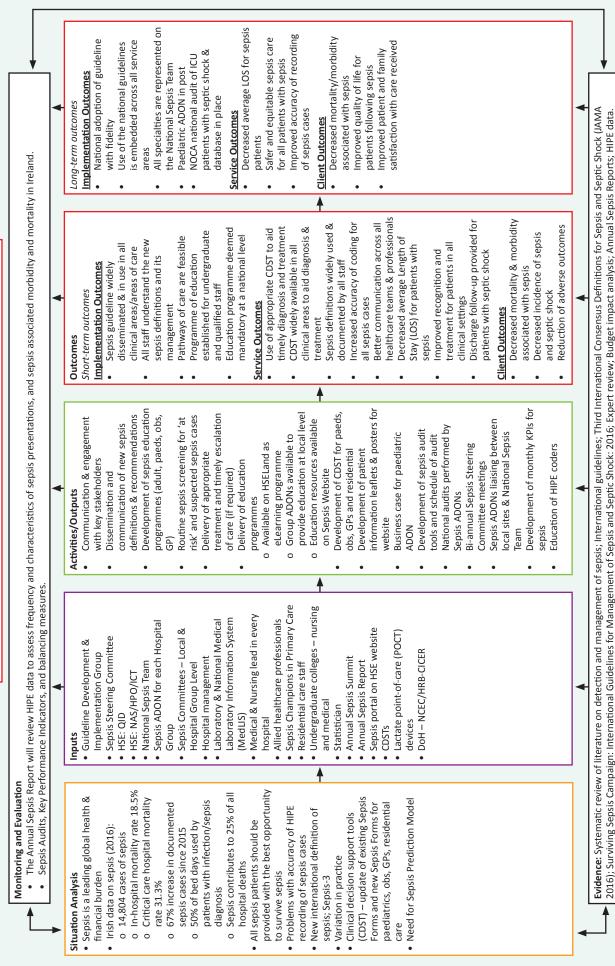
When an intervention is particularly complex, it may be useful for Guideline Groups to create a series of logic models. This may help to break down the overall logic model into a more manageable, clear, concise and relevant way for those responsible for implementing specific recommendations or working in specific contexts. Logic models can be broken down in the following ways:

- 1. Multiple logic models, with each pertaining to a different element of the intervention. This may be particularly helpful in the case of clinical guidelines, which often contain a multitude of different recommendations that are not always easy to group together.
- **2.** Nested Logic Models, with each being applicable at different levels of service delivery (e.g. national, hospital, service). This may help to increase clarity at each level, as well as allowing guideline groups to tailor and adapt the level of detail included in each logic model.



The following page contains a **worked example** of a logic model, created by the Guideline Development Group responsible for the update of the *National Clinical Guideline No. 6: Sepsis Management in 2018.*

Logic Model for National Clinical Guideline – Sepsis Management



Stage 2: Planning and Resourcing



Stage 2: Planning and Resourcing

In stage 2 of implementation, the foundation is laid for effective implementation. This stage involves planning for implementation in more detail, anticipating potential implementation issues, costing the implementation plan and submitting the Budget Impact Assessment as part of the annual service planning process. Specific activities to be carried out in this stage are:

- Assessing implementation readiness
- Assessing enablers and barriers
- Implementation planning
- Expanding the initial Guideline Development Group to include implementation team(s) and develop infrastructure for implementation
- Developing leadership for implementation
- Monitoring and evaluation planning
- Training and capacity building
- Sustainability planning.

It is worth remembering that while these activities are most suitable during stage 2, they may still be useful for Guideline Groups at other stages of implementation.

The key tools that should be used during this second stage of implementation are:

- Implementation enablers and barriers assessment tool (Tool 3)
- Implementation plan template (Tool 4)
- Monitoring and evaluation of implementing National Clinical Guidelines Planning Tool (Tool 5).

Assessing Implementation Readiness

Evidence shows that attempts to implement new interventions often fail because those leading the implementation fail to establish sufficient readiness for the change [30].

Implementation Readiness refers to the extent to which organisations and individuals are both '*willing*' to, and '*capable*' of, implementing any specific intervention [32].

Implementation readiness in healthcare settings is dependent on a number of key factors: [20, 31, 32]

- *Psychological and behavioural readiness* in individuals, teams and organisations staff should be individually and collectively primed, motivated, and technically capable of executing change.
- *General organisational/structural capacity* to successfully implement *any* innovation existing staff, ICT infrastructure, human resources and procedures etc.
- Organisational/structural *capacity that is intervention-specific* specific training, resources and policies etc.
- Leadership engagement leaders can create readiness by consulting all stakeholders in the decision-making process, by giving clear direction on the change, and by acknowledging and validating any concerns.
- Securing *access to resources* needed to implement guidelines the implementation plan must be costed, and a Budget Impact Assessment carried out, to be submitted through the service planning process.

Assessing and understanding implementation readiness can help identify barriers and facilitators to change and inform implementation planning. However, readiness at one stage of implementation does not ensure readiness for the next. This means that assessing readiness is an ongoing and iterative process, that should consider new challenges and address them as they arise [32]. This requires feedback and input from stakeholders at local levels to get an accurate picture of changing contexts and circumstances.

Resources and strategies to help assess and build implementation readiness:

- The Hexagon Tool is useful for assessing needs and readiness, and implementation planning: Click here or see Tool 1
- Normalization Process Theory (NPT):
 - o Toolkit for thinking through potential implementation problems: <u>http://www.normalizationprocess.org/npt-toolkit/</u>
 - o Murray et al. (2010) paper, titled 'Normalisation Process Theory: A framework for developing, evaluating and implementing complex interventions', which outlines four components of readiness, and a list of questions for implementers that are relevant to each component:

http://www.lenus.ie/hse/handle/10147/142753

- The Checklist to Assess Organizational Readiness (CARI) created by Barwick (2011) addresses eight different factors relating to readiness in organisations: <u>http://www.effectiveservices.org/resources/article/checklist-to-assess-organisation-readiness</u>
- Other resources and measures for assessing implementation readiness are available and listed on the California Evidence-Based Clearinghouse website: <u>http://www.cebc4cw.org/implementing-programs/tools/measures/</u>

Assessing Enablers and Barriers

Implementation Ena	ablers
Stakeholder consultation and buy-in	Involving clinicians, the public, patients, administrators and policymakers, among others, as early as possible and throughout the development and implementation process has several benefits: it helps create awareness; it generates continued buy-in; it identifies and acknowledges any resistance; and it aids in the assessment of need, fit, feasibility, capacity and readiness. The NCEC Public Involvement Framework [26] includes tools to assist involving the public in clinical effectiveness processes.
Leadership	Having at least one champion improves the likelihood of implementation success [22]. Champions are early adopters of change, providing vision and support to individual staff and the organisation as a whole.
Resources	It is important to have an accurate calculation (as part of a Budget Impact Analysis) of the costs and cost effectiveness of designing, implementing and delivering a guideline. Once cost has been determined, securing appropriate resources, where necessary, through the service planning process is required for successful implementation. Tools to assist with Budget Impact Assessment and Economic Evaluation are available on the NCEC website: <u>http://health.gov.ie/national-patient-safety-office/ncec/</u> <u>resources-and-learning/ncec-processes-and-templates/</u>
Implementation teams	Implementation teams oversee and attend to moving guidelines through the stages of implementation. These teams make use of active strategies to drive successful implementation and should be made up of members from a range of disciplinary backgrounds with specific expertise in relevant interventions or in implementing change. There may be significant overlap in membership between the original Guideline Development Group and the Implementation Team(s). In addition to a national implementation team, further implementation teams may also be established to drive implementation in specific settings.
Implementation plan	Allowing time for planning how guidelines will be implemented is crucial in ensuring successful outcomes. By involving multiple stakeholders in planning at an early stage of the implementation process, potential hurdles can be more easily anticipated and overcome. It also increases accountability among relevant stakeholders. An implementation plan includes the specific actions to implement the guideline recommendations, details of who is responsible, timelines for delivery and outcome measurements.
Staff capacity	Those who are responsible for the implementation of a specific intervention must have the capacity to deliver it. Therefore, developing and keeping this capacity is pivotal in ensuring desired outcomes are achieved. Staff capacity can be attained through: carefully allocating staff; delivering quality training; and providing ongoing support, such as coaching and mentoring.

Implementation Enablers						
Organisational support	Supportive organisational structures, systems, policies and procedures that align with and support guidelines are important for successful implementation. Examples include: procedures for internal governance and decision-making; and human resources to manage resistance to change.					
Supportive organisational culture	Organisational culture includes the norms, values and beliefs that exist and govern behaviour within an organisation. It is necessary to create a supportive culture so that specific interventions can successfully become embedded in the organisation through: champions communicating a strong vision for change; supporting positive role models; and ongoing training and support.					
Communication	Ongoing and open communication with and between staff is crucial in successful implementation for several reasons: it helps motivate staff and overcome resistance; provides a mechanism for feedback and dealing with concerns; and helps to build trust and morale.					
Monitoring and evaluation	Collecting and interpreting information about implementation and other key outcomes is essential in determining whether guidelines are being successfully implemented. This information helps to inform future actions and increase efficiency.					
Learning from experience	The use of data and information to improve both specific interventions and the guideline implementation process is vital for implementation success. Doing this effectively helps to identify 'quick wins', build credibility and support, and enables continuous improvement cycles.					

Implementation Barriers						
External environment	The external environment can reduce implementation success if existing structures are not in line with guidelines. For example, short policy and funding cycles may interfere with the implementation process by making it more difficult to secure long-term engagement and buy-in.					
Resistance to change	Resistance to change from those delivering specific interventions can undermine implementation efforts and reduce the probability of success. Resistance is commonly generated if: stakeholders feel they have not been consulted; changes are implemented before stakeholders are ready; implementation is perceived as occurring through coercion or control from leadership; the organisational culture is not aligned with the guideline; or appropriate governance structures to support guideline implementation are not put in place.					
Vested interests	Vested interests of staff, managers, lobby groups, and other professional bodies may interfere with the implementation process if they are incongruent with the guidelines. This can occur through stakeholders blocking the implementation process or altering it in a new, less productive direction.					

Implementation Enablers and Barriers: Assessment Tool

The Centre for Effective Services has created a bespoke tool for stakeholders involved in designing and implementing clinical guidelines and other policies, procedures, protocols and guidelines (PPPGs), to assess enablers and barriers. This tool is based on the Consolidated Framework for Implementation Research and the Behaviour Change Wheel. The tool generates consideration of structural and psychological enablers and barriers to implementation in a health context.

To access the tool, click <u>here</u> or see Tool 3.

Implementation Planning

Allowing adequate and appropriate time for planning how clinical guidelines will be implemented is a crucial implementation enabler. Devising an implementation plan enables those driving the change to map out the implementation process and provide a course of action for any challenges. Research shows that implementation is likely to be more successful if this planning is done concurrently with the development of guidelines, rather than after they have been developed [9].

The following steps help to prepare the implementation plan and should be retained by those developing/implementing guidelines:

- Assessment of implementation readiness
- Development of a one-page logic model, including situation analysis, inputs, activities/outputs and outcomes
- Assessment of enablers and barriers
- Identification of specific behaviour change or change in current practice required (i.e. who needs to do what differently in order for this recommendation to be implemented?)
- Clearly documenting baseline/current status and any assumptions being made
- Including any additional resources required in the Budget Impact Assessment.

A comprehensive Implementation Plan should [8]:

- ✓ Detail the implementation objectives
- ✓ Outline tasks and activities necessary for implementation
- ✓ Identify **who is responsible** for the delivery of activities
- ✓ Outline time-frames and milestones
- ✓ Consider **risks** and strategies to manage these risks
- ✓ Identify **monitoring and reporting** processes.

It is important that implementation planning should include public involvement and engagement with multiple stakeholders to secure buy-in and ensure that the plan considers multiple viewpoints. The plan should also remain live throughout the implementation process and be revisited and revised regularly throughout all implementation stages.

An implementation plan must be included in published NCEC guidelines. The template provides an example of a tool that can be used for implementation planning, prompting Guideline Groups to lay out the implementation tasks (*in the form of specific actions*); which guideline recommendation(s) these tasks refer to; which group/unit/organisation has lead responsibility for the task; an indicative

timeframe for completion; and some detail on expected outcomes and how they will be verified or measured. It can also include implementation enablers and barriers, some of which will be common to multiple recommendations.

Guideline recommendation	nmendation enablers/ intervention/task responsibility for		Timeframe for completion			Expected outcome and		
or number(s)	barriers/gaps	to implement recommendation	delivery of the action	Year 1	Year 2	Year 3	verification	
			<u> </u>				<u> </u>	

Implementation Planning Tools

• The above template is contained in an **Implementation Planning Tool (Tool 4)**. Completed NCEC guidelines must include an implementation plan. The tool also helps stakeholders to consider implementation team processes; dissemination and communication strategies; and development of specific implementation tools and resources.

To access the Implementation Planning Tool, click <u>here</u> or see Tool 4

- The following pages contain a **worked example** of an implementation plan completed by the Ovarian Cancer Guideline Development Group.
- <u>Click here to access a Gagliardi et al. (2015) paper</u> 'Developing a checklist for Guideline Implementation Planning' which contains a **useful checklist to help stakeholders consider different aspects of implementation planning** for clinical guidelines [9, pp. 5-6].

Expected outcome and verification		Outcome: All women with suspected ovarian cancer will have timely access to transvaginal ultrasound, carried out by experienced personnel.	Transvaginal ultrasound will provide greater sensitivity for diagnosing ovarian cancer.	Verification: Completed assessment of equipment and waiting times.	Verification: Equipment in place. Access to diagnostics.	Verification: Completed workforce assessment.	Verification : Staff in place. Training provided/staff training records.
-	2 Year 3						×
Timeframe for completion	1 Year 2				×		
Timet	Year 1	×				×	
Lead responsibility for delivery of the action		HSE Clinical Programme for Radiology			NCCP & Hospital Groups	HSE Clinical Programme for Radiology	NCCP & Hospital Groups & HSE Clinical Programme for Radiology
Action/intervention/task to implement recommendation		 Assess the availability of ultrasound equipment, including sterilisation equipment. 	tests.		 Secure resources/funding* for Equipment: Additional ultrasound equipment + replacement/ maintenance. (This action will be based on the results of the equipment assessment) 	Assess the current number of personnel with specialist training in sonography.	 Secure resources/funding* for Training: Specialist training of radiology staff. Staffing: Personnel with specialist training in sonography. (This action will be based on the results of the workforce assessment).
Implementation enablers/ barriers/gaps		Enabler: National Cancer Strategy Recommendation #14 (Capital Plan).	Barrier: Access to transvaginal			Enabler: National Cancer Strategy, Recommendation #10, 16 & 50	(radiology training, consultant staffing, workforce planning). Barrier: Limited availability of appropriately trained staff.
Guideline recommendation or number(s)	Guideline recommendation or number(s) In patients with suspected ovarian carcinoma, a combination of transvaginal ultrasound should be performed and interpreted using the IOTA simple rules in conjunction with clinical assessment.						

Implementation Plan – Ovarian Cancer Guideline

*Funding requirements included in Budget Impact Assessment, for submission in the HSE financial estimates/service planning process.

Guideline recommendation or number(s)	lmplementation enablers/ barriers/gaps	Action/intervention/task to implement recommendation	Lead responsibility for delivery of the action	Timeframe for completion	me for iion	Expected outcome and verification
				Year 1	Year 2 Year 3	
Recommendation #2 CT thorax, abdomen and pelvis with oral	Enabler: National Cancer Strategy Recommendation #14 (Canital Dlan)	 Assess the access to CT. Assess the waiting times for CT. 	HSE Clinical Programme for Radiology	×		Outcome: All patients with ovarian cancer will have timely access to CT.
contrast is contrast is recommended for the stacing of overian	(Capital Flatt). Barrier: Acress to Computerised					All patients with a high suspicion of relapse of ovarian cancer will have timely access to CT.
cancer. cancer. Recommendation #4 For patients with	Tomography (CT).					Verification: Completed assessment of CT equipment and waiting times.
a high suspicion of relapse of ovarian cancer either clinically or biochemically, CT thorax, abdomen and pelvis is recommended as the first line imaging test.		Secure resources/funding* for • Equipment: Additional CTs. This action will be based on the results of the equipment assessment.	NCCP & Hospital Groups & HSE Clinical Programme for Radiology		×	Verification : Equipment in place. Access to diagnostics.
Recommendation #3 If the CT is indeterminate, patients should be discussed at a	Enabler: National Cancer Strategy Recommendation #13 multidisciplinary team meeting.	Preparation of a Standard Operating Procedure (SOP) for ovarian cancer multidisciplinary team meeting.	NCCP & Hospital Groups	×		Outcome: Patients diagnosed with ovarian cancer will have their case formally discussed at a multidisciplinary team meeting.
multidisciplinary team meeting.	Barrier: Availability of imaging for discussion at multidisciplinary team meeting.					Verification: KPI 12 Cancer Strategy: Ensure that patients have their case discussed at a multidisciplinary team meeting.
	2					SOP is developed and available.

*Funding requirements included in Budget Impact Assessment, for submission in the HSE financial estimates/service planning process. For full implementation plan, see published guideline.

Governance and Implementation Team

disciplines and the chairs of each Cancer Guideline Group. The group meets quarterly to assess progress, provide oversight and leadership to guideline groups, address any queries and to Governance: Governance of the guideline is provided by a multidisciplinary Steering Group chaired by the Director of the NCCP. Membership includes representatives from all relevant ensure the guideline development and implementation process uses an evidence-based approach. The Surgical Gynaecology Oncology Clinical Leads group was established in 2012 to ensure that the seven centres designated for Surgical Gynaecology Oncology build on robust local clinical governance arrangements, to operate as a cohesive national clinical network for clinical audit, sharing of good practice and problem solving.

Implementation Team: A Steering/Implementation committee has been set up by the NCCP and the HSE to guide the implementation of this Guideline. The Steering/Implementation Group includes all relevant stakeholders including – pathologists, radiologists, gynaecology oncologists, palliative care, hospital managers, nursing, ICT, informatics, laboratory scientists, patients and a representative from the NCCP. Implementation will be supported by the organisations that are represented on the Guideline Group, which include the Faculty of Radiologists, Royal College of Surgeons in Ireland, The Faculty of Pathologists Royal College of Physicians Ireland, National Lead Clinician for Hereditary Cancer and Patient Advocate Groups.

Dissemination and communication plan

Radiology/Pathology/Palliative Care, RCSI, Faculty of Surgery/Radiology/Pathology, HSE Patient Forum, Irish Cancer Society, Cancer Care West etc.). The guideline will also be available via The Guideline will be circulated and disseminated through the professional networks who participated in developing and reviewing this guideline (HSE Clinical Programmes in Surgery/ the NCEC and NCCP websites. A dissemination strategy has been prepared and the Guideline will be officially launched and circulated to all relevant faculties and colleges for dissemination to their members. The NCCP will co-ordinate with HSE Communications to distribute, share and disseminate through the media (HSE Broadcast, Health Matters, and Twitter). The implementation of the Guideline will also be supported by communication, training and education.

Implementation tools: The following implementation tools are available on the NCCP website at https://www.hse-ie/eng/services/list/5/cancer/nccp/

- GP Referral guideline and referral form:
- o Ovarian cancer GP Referral Guideline for symptomatic women
 - o Ovarian cancer GP Referral form for symptomatic women
- Booklet NCCP (2018) Sexual wellbeing after breast or pelvic cancer treatments a guide for women
 - Algorithms for clinicians available in the guideline:
- o Staging algorithm for patients with suspected ovarian cancer
- o Staging algorithm for patients with suspected recurrence of ovarian cancer
- Clinician guidance document Health Service Executive Guidance for decontamination of semi-critical ultrasound probes; semi-invasive and non-invasive ultrasound probes (https:// www.hse.ie/eng/about/who/gid/nationalsafetyprogrammes/decontamination/ultrasound-probe-decontamination-guidance-feb-17.pdf •
 - HSE policy to guide staff National Consent Policy 2017 https://www.hse.ie/eng/about/who/gid/other-quality-improvement-programmes/consent/ •
 - Patient information on cancer genetics <u>https://www.cancergenetics.ie/</u>
 - Training and resources in Evidence based Practice

Establishing Implementation Teams

Implementation teams are groups of stakeholders that oversee and attend to moving guidelines through the stages of implementation. They are established to *make it happen*, i.e. actively use strategies and supports to facilitate implementation.

Implementation teams are typically made up of 3-12 people, and the composition of the group is extremely important. It is possible to repurpose existing Guideline Development Groups when forming a post-publication implementation team, but the following points should be considered:



- *Diversity* does the team have an appropriate balance of perspectives, training and expertise, experience, relationships and priorities?
- Decision-making authority the implementation team should contain members who have their own decision-making authority or have direct access to decision-making authority, so that decisions can be made in a timely manner
- *Knowledge* the implementation team should contain members who have expert knowledge of specific interventions contained within guidelines, data use, implementation, and systems change.

It is important that there is some degree of overlap in membership between Guideline Development Groups and implementation teams, as implementation needs to be considered throughout all stages of guideline development. It is recommended that there is an 'Implementation Lead' on the Guideline Development Group from the beginning, to ensure that guideline recommendations are implementable and to coordinate the development of the implementation plan.

It is worth noting that one implementation team may not be sufficient to implement guidelines at a national level. In this case, it might be appropriate to establish an infrastructure of **linked implementation teams** to encourage greater integration and coherence in large systems. Teams can operate at different levels (e.g. national, hospital group, individual hospital, community) or teams can work to implement different recommendations contained in clinical guidelines.

Key implementation team functions:

- Move guidelines through the stages of implementation
- Ensure fidelity to interventions contained within guidelines
- ✓ Identify **barriers** and find solutions where needed
- ✓ Identify **enablers** and leverage them if possible
- Ensure Budget Impact Assessment is submitted to the service planning process



- ✓ Put implementation infrastructure in place
- ✓ Engage with stakeholders and communities
- ✓ Build cross-sector collaboration to ensure service partners are aligned with new ways of working
- ✓ Work with other teams to monitor progress
- ✓ Use data to make decisions and support implementation capacity
- ✓ Ensure **decisions** are purposeful and planned

Developing Leadership for Implementation

There is broad consensus on the importance of leadership for effective implementation. This is due to the potential for leadership to inspire and motivate staff to adopt and sustain the attitudes and behavioural changes necessary for effective implementation [33].

Research linking leadership and the quality of healthcare indicates a need for a collective network of leaders, including practitioners at all levels, distributed throughout the healthcare systems [34] and public involvement. This may require distribution and decentralisation of leadership power to wherever expertise, capability and motivation sit in the system.

Creating an organisational culture where leaders flourish has benefits for both staff and the leaders themselves:

- If leaders and implementers create positive, supportive environments for all practitioners, those practitioners then create caring, supportive environments for patients
- Where there is a culture of collective leadership, practitioners are likely to intervene to solve problems, to ensure quality of care and to promote responsible, safe innovation.

The following table provides examples of different leadership activities which can support implementation [35]:

Relations-oriented behaviours	Change-oriented behaviours	Task-oriented behaviours
 Communicate with practitioners about clinical issues Recognise efforts to change Provide reminders Encourage and support collaboration with specialists and inter- professionals Support change visibly and symbolically 	 Demonstrate commitment to change Reinforce vision and goals of change Understand difficulties with change Advocate for change internally and externally Advocate for additional resources or reorganisation of existing resources internally and externally 	 Conduct regular leadership meetings Clarify roles and responsibilities Monitor performance and outcomes Modify care-plans and documentation Procure resources, education, training and policies to reflect change

While individual members of Guideline Groups may not be in high-level leadership positions themselves, they can seek to influence those who are, and be champions for the guidelines themselves.

Monitoring and Evaluation Planning

National Clinical Guidelines endorsed by the Minister for Health are mandated for implementation in the Irish health system. Accordingly, the NCEC guideline development process requires monitoring and audit criteria, including Key Performance Indicators (KPIs), to be included in each guideline.

- *Monitoring* is the routine and systematic collection of information against a plan. It makes use of existing data and information about inputs, outputs and outcomes, or about outside factors affecting the organisation or project, to inform improvement.
- *Evaluation* is a planned investigation of a project, programme, or policy used to answer specific questions, often related to design, implementation, and results (cause and effect).
- *Clinical or Healthcare Audit* is a process to improve patient care and outcomes involving a documented, structured and systematic review and evaluation, against clinical standards, or clinical guidelines, and, where necessary, actions to improve clinical care.

Clinical audit is part of the clinical governance agenda and is intended to provide the evidence for assuring the quality of clinical care and helping to bring about improvements where necessary.

Clinical audit is a cyclical process, recognised as having the following elements:

- a commitment to quality improvement and learning
- measurement measuring a specific element of clinical practice
- comparison comparing results with an accepted benchmark, these are national or international standards, or clinical guidelines
- evaluation and action reflecting the outcome of audit and where indicated, changing practice accordingly (sometimes referred to as 'closing the loop').

Information and tools to help guideline developers think about monitoring and audit criteria are available from:

- The National Clinical Effectiveness Committee guideline development manual
 <u>http://health.gov.ie/national-patient-safety-office/ncec/resources-and-learning/ncec-processes-and-templates/</u>
- The National Clinical Effectiveness Committee website <u>http://health.gov.ie/national-patient-safety-office/ncec/</u>
- The HSE Quality Improvement Division website https://www.hse.ie/eng/about/who/qid/ measurementquality/clinical-audit/

For implementation to be measured accurately, all three of the above mechanisms may be used with different levels of emphasis, depending on the context. There is no single measurement type that comprehensively measures all elements of implementation, and a hybrid methodology may be required. Currently, implementation of NCEC National Clinical Guidelines is monitored through the HSE Performance Assurance Reports, compliance with the National Standards for Safer Better Healthcare and alignment with the clinical indemnity scheme [36].

The purpose of this section is not to focus on methodologies or KPIs for monitoring, evaluation and audit. Instead, the remainder of this section will focus on planning for monitoring and evaluation, particularly when considering **how to monitor whether the guideline has been successfully implemented.** Accordingly, the table overleaf provides a series of prompts and questions that guideline groups can use to guide planning for monitoring, evaluation and audit.

Planning for Monitoring and Evaluation	– Prompts and Questions
 What is the purpose(s) of our evaluation? Why do we want to do it? 	 Is it about effectiveness, efficiency, economy, relevance, implementation, process and/or impact? Is it about population change or performance accountability?
2. What is the evaluation question(s)? What will we monitor and evaluate?	 What is the theory of change underpinning the guidelines or specific interventions to be evaluated? From the logic model for the guideline, what will be prioritised for monitoring and evaluation?
3. Who will use the learning from the evaluation? How can we involve them from the start?	 What indicators will we use to address different audiences? What methods will we use in the evaluation to involve key stakeholders?
4. What resources and expertise do we have for our evaluation? What resources do we have/will we need, including outside support?	 What is the budget for the evaluation? What are our experiences of evaluation? What are our skills and what are the gaps that need to be filled?
5. What is our plan for operationalising the evaluation (tasks, responsibilities, timescales etc.)? How will we do it? When will we do it?	 Who will manage and coordinate the evaluation? How long will it take? Do we have a schedule of activities?
6. What are the main challenges? Who will do it, and do they have the right skills?	 What staff will be involved and what training is required? How will we secure active participation, engagement, motivation?
7. What is our plan to disseminate and use our learning from the evaluation? What will we do with the information we get?	 Who will write up the findings and help with interpretation? What other strategies are needed to disseminate and share learning with different stakeholders? How will the findings be used to inform quality improvements?

Monitoring and Evaluation of Implementation: Planning Tool

The Centre for Effective Services has created a bespoke tool to help Guideline Groups to think about and **plan for monitoring and evaluation of the implementation process**. This tool should be used at an early stage of guideline development to ensure that monitoring and evaluation are embedded into the implementation process.

To access the Monitoring and Evaluation of Implementation Planning Tool, click <u>here</u> or see Tool 5.

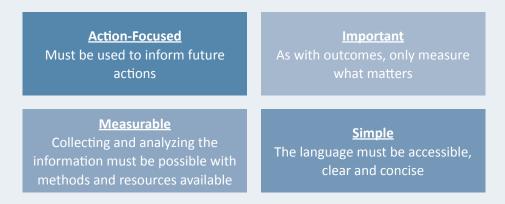
Involving relevant stakeholders is a crucial part of the monitoring and evaluation process – they should be consulted with at all stages of developing and implementing clinical guidelines. This is to ensure that specific responsibilities of all those involved can be clarified and agreed before

monitoring and evaluation commences, and that the added burden of collecting and recording data is feasible and manageable. To determine which stakeholders should be involved in the monitoring and evaluation of clinical guidelines, it is important to establish [37]:

- 1. Who is involved in the delivery of the care or service?
- 2. Who is in receipt of, uses or benefits from the care or service?
- 3. Who has the authority to support implementation of any identified changes?

Indicators

It is also important to consider what indicators can be feasibly and accurately used to monitor and evaluate implementation outcomes. To ensure that efforts to collect data are streamlined and that the data is relevant, these indicators should be *action-focused, important, measurable and simple.*



A number of Quality and Patient Safety Performance Indicators that measure implementation and the impact of National Clinical Guidelines already exist and are specified in the HSE Service Plan: <u>https://www.hse.ie/eng/services/publications/serviceplans/national-service-plan-2018.pdf.</u>

When deciding how to monitor and evaluate implementation of clinical guidelines, existing indicators and data collection mechanisms should be used where available. Other useful types of data collection methods may also already be in place, such as patient satisfaction/patient experience surveys, evaluation, quality indicators, audit and research.

The **HSE Measurement for Improvement Team** combines expertise in quality improvement, statistical analysis and qualitative research with clinical experience. The team provides a number of useful *tools and resources* on their website, as well as *training and advice* on how to analyse and present information gathered from monitoring and evaluation processes.

To access the tools, resources, training and advice, see the HSE Measurement for Improvement Team website: <u>https://www.hse.ie/eng/about/who/qid/measurementquality/</u> measurementimprovement/measurement-for-improvement-team.html

Additional information and tools for clinical audit are available in the following documents:

- A Practical Guide to Clinical Audit (HSE) https://www.hse.ie/eng/about/who/qid/ measurementquality/clinical-audit/
- Improvement Knowledge and Skills Guide (HSE)
 https://www.hse.ie/eng/about/who/qid/improvement-knowledge-and-skillsguide/

Training and Capacity Building

One of the most important factors in building leadership in an organisation or setting is building and maintaining staff capacity. One aspect of this; coaching and mentoring – is covered in detail in stage 3. There are also several other key mechanisms to build staff capacity for implementation [22]:

- Assignment/recruitment of staff
- Training

When planning for implementation, Guideline Groups should seek to highlight the staff training and capacity-building needs that are associated with the guideline. While not necessarily expected to design these procedures and processes, it is important that these groups consider how they may be developed. Again, internally available resources should be leveraged, where possible, and any additional resources required should be included in the guideline's Budget Impact Analysis.

Assignment/recruitment of staff

Staff who will be involved in implementing clinical guidelines should have the appropriate skills and knowledge to do so, or the ability to learn these. Effective assignment/recruitment of staff requires specifying what the required skills and abilities for the specific intervention are; the development of methods for identifying these skills and abilities in practitioners; and criteria for selecting practitioners with those skills and abilities. These aspects should be included in job descriptions, staff induction and continuous professional development.

Training

Staff should be facilitated to develop their knowledge, experience and skills of specific interventions through effective and timely training. Training programmes should provide knowledge related to the theory and underlying principles and values of the intervention; introduce the key components of practices; and provide opportunities to practice new skills and receive feedback in a safe, supportive environment. The content and format of training may vary depending on the intervention and should be developed with the needs of staff and patients in mind.

Sustainability Planning

Guidelines aimed at improving healthcare need to be sustained improved outcomes for to be maintained. Essentially, sustainability means that one year or longer after implementation, at a minimum, the situation has not reverted to the old way of working, or old level of performance.

The United Kingdom's National Health Service defines **sustainability** as achieved when 'not only have the process and outcome changed, but the thinking and attitudes behind them are fundamentally altered and the systems surrounding them are transformed as well. In other words, the change has become an integrated or mainstream way of working rather than something "added on" [38, p.6].

For interventions contained within guidelines to be sustainable, they should be able to withstand challenges and variation, evolve alongside other changes and continue to improve over time. There is a tension between needing to maintain 'fidelity' to a specific intervention and needing to evolve in a changing healthcare context. Changes to implementation plans may need to be made so that an intervention can continue to be used in practice and maintain the benefits for patients and communities.

To maximise the potential for sustainability, sustainability planning should commence near the beginning of the guideline development and implementation process. However, it is useful at all stages of implementation, and sustainability plans should be revisited at several different points so that sustainability can be monitored over time. Through continuously assessing and identifying potential barriers to sustainability, strategies can be put in place to anticipate and address potential implementation problems.

The following table outlines some key questions to consider in relation to different elements of sustainability [38, 39]:

Key elements of Sustainability	Questions
Planning for sustainability	 Is sustainability planning an active component of all stages of implementation? Can existing services integrate a specified intervention?
Credibility of the evidence	 Are benefits to service users, staff and organisations visible? Is there evidence that this type of change has been achieved elsewhere?
Seeking commitment and support	 What leaders/managers support the implementation of guidelines? Are the guidelines congruent with other policy objectives/contexts at the time/future?
Engagement and partnerships	 Is there evidence that appropriate and influential stakeholders, including the public, are accepting/supportive of guidelines?
Programme champions	 Are there local 'champions' to promote the value of guidelines and is interest likely to be ongoing?
Fit with organisation	Are guidelines contributing to the overall organisational aims?Is 'fit' assessed in an ongoing manner?
Building capacity – organisational and community	 Are staff involved in the implementation of guidelines? Is there a capacity-building infrastructure to ensure the skills necessary to continue implementation will exist/remain?
Infrastructure for sustainability	 Have crucial elements of guidelines been embedded into policies and procedures? Are new requirements built into job descriptions?
Adaptability	 Do structures and policies allow some flexibility and evolution, as required, to maintain and improve outcomes?
Evaluation	 Are outcomes measured to determine continued benefit? Is evidence used to develop and improve guidelines? Are there feedback mechanisms in place to communicate results and initiate action?
Funding	 Is funding available to support implementation to a level that effects are maintained (or increased)? What existing resources can be leveraged or reorganised to support implementation?
Policy/economic environment	• What changes are occurring in the policy and economic environment that may have an impact on guideline implementation?

Sustainability Planning Tool

The United Kingdom's National Health Service has produced a Sustainability: Model and Guide, which acts as a diagnostic tool to help plan for sustainability and monitor progress over time, and as a guide offering practical advice on how to maximise success at sustaining change.

It identifies a range of factors that influence sustainability, including:

- Credibility of the benefits of an intervention
- Effectiveness of the system to monitor progress and measure change
- Staff involvement and training to sustain the process
- Senior and clinical leadership engagement and support
- Alignment with organisational strategic aims and culture.



Guideline Groups are not necessarily expected to design these systems and processes. Instead, they should aim to signal the importance of these factors, identify needs, cost the implementation process, and influence high-level decision-makers where possible. This point may be particularly relevant for stakeholders and implementers at a more local level.

Click here to access the NHS Sustainability Model and Guide: <u>https://improvement.nhs.uk/</u><u>resources/Sustainability-model-and-guide/</u>

Stage 3: Implementing and Operationalising



Stage 3: Implementing and Operationalising

In stage 3 of implementation, guidelines are implemented in clinical and healthcare settings for the first time. Essentially, guidelines are put into practice by practitioners and organisational supports and functions begin to operate to help implementation. Guidelines will be signed off at this point, however, stakeholders can continue to be influential in their implementation through highlighting needs, taking up membership of implementation teams, and acting as champions for the guidelines.

Specific activities to be carried out in this stage are:

- Maintaining communication with stakeholders and securing continued buy-in
- Providing professional development opportunities and support, such as coaching and mentoring
- Ongoing monitoring of implementation outcomes, service outcomes and client outcomes
- Using data and feedback mechanisms to inform ongoing improvements
- Adapting implementation plans for local settings where appropriate.

It is worth remembering that while the activities highlighted are most suitable during stage 3, they may still be useful for Guideline Groups at other stages of implementation.

Maintaining Communication

Ongoing communication between implementation teams, practitioners, champions, public representatives, and all other relevant stakeholders is an important enabler of implementation for several reasons:

- Communicating a vision for change helps to motivate staff and overcome resistance to change
- Communication provides an important mechanism for obtaining feedback
- Open communication helps to build trust and teamwork between various stakeholders, teams and organisations responsible for implementation.

Both formal and informal communication are important, with networking and 'water cooler' conversations having as much potential to change individual behaviour as formal broadcasts. The following strategies relating to communication can all contribute to more effective implementation [20]:

- ✓ Assimilating new staff and making them feel welcome
- ✓ Fostering peer collaboration and open feedback and review across hierarchical levels
- ✓ Clear communication of guidelines' purpose and goals
- ✓ Use of champions to encourage cohesion between staff and positive informal communication about guidelines.

Coaching and Mentoring

Evidence suggests that training alone is insufficient to change the skills of professionals. A meta-analysis of research in education showed that with training alone, only 5-10% used the new practice; this increased to 80-90% when supplemented with coaching [40]. Accordingly, coaching and mentoring are increasingly being used as a method of supporting and building capacity among professionals.

Coaching is a formal, typically short-term, arrangement between a coach and an individual focused on developing work-related skills or behaviours.

Mentoring is a formal or informal arrangement, which typically involves an ongoing relationship of support for significant transitions in knowledge, thinking and skills [42].

Building quick and accurate use of new skills and behaviours in the real world is challenging. Coaching and mentoring offer additional benefits to traditional training approaches and provide opportunities for staff to receive support and assistance in the development of skills aligned with specific interventions. Benefits include [41, 42]:

- Helping staff to adjust to and implement change
- Decreasing frustration by focusing on helping staff meet performance goals and reducing burnout
- Motivating and helping staff to build fluency and accuracy with effective skills
- Providing time to problem-solve, rehearse, and get feedback about how to use practices
- Strengthen staff capacity to integrate new practices and to learn from experience
- Ensuring implementation fidelity
- Increasing self-confidence and enhancing professional networks.

Coaching and Mentoring Tools and Resources

• For an evidence review produced by Centre for Effective Services on what works in coaching and mentoring, click here:

http://effectiveservices.org/resources/article/coaching-and-mentoring-an-accessevidence-report

- For a one-page infographic produced by the Centre for Effective Services that highlights the differences between coaching and mentoring, click here: http://effectiveservices.org/resources/article/coaching-and-mentoring-table
- The NCEC website has resources and advice for Guideline Groups, including videos from stakeholders who have experience of the guideline development process: <u>http://health.gov.ie/national-patient-safety-office/ncec/</u>

Networks

Networks seek to deepen knowledge and expertise of their members and the group as a whole by interacting with each other on an ongoing basis. Networks among groupings of individuals, organisations and/or agencies can take many forms and serve different purposes. Two such examples include:

- *Knowledge Networks* These lead to accumulation, augmentation and exchange of tacit knowledge and improved skills required for implementing specific interventions
- *Communities of Practice* These aim to solve specific problems by forming self-selected, informal groups linked by shared experience, passions or goals.

Ongoing Monitoring of Outcomes

Based on the planning for monitoring and evaluation conducted during stage 2, implementation teams should look to engage in ongoing monitoring of implementation outcomes, service outcomes and client outcomes.

At this point, Guideline Groups are likely to have identified outcomes, KPIs and audit measures as part of guideline development. Using this information and revisiting documents developed during stages 1 and 2, (such as the logic model, implementation plan, enablers and barriers assessment, and the monitoring and evaluation plan) implementation teams can therefore seek out and obtain any emerging information about these outcomes.

Benefits of ongoing monitoring of outcomes:

- Increase accountability
- Identify and deliver 'early wins'
- Learn about activities and results
- Promote reflection
- Identify strengths and weaknesses
- Ultimately, inform future actions and improve practice

At this stage of implementation, monitoring is formative in nature – it provides an indication of whether guidelines are functioning and being implemented as planned, an indication of what is working well or not well, and how changes can be made to inform improvement.

It is also important to get an early sense of any changes in service outcomes and client outcomes – if the changes are positive, these can be used to generate increased buy-in and support from patients, public, healthcare staff, management and policy-makers.

Resources to support ongoing monitoring of outcomes

• A guidebook produced by the National Resource Centre in the US for 'Strengthening Nonprofits: A Capacity Builder's Library' aims to help stakeholders **understand the concepts, uses and limitations of measuring outcomes**. While this resource is not designed specifically for healthcare settings, it provides useful information for stakeholders involved in monitoring guidelines.

To access 'Strengthening Non-profits: A Capacity Builder's Library', click here: <u>http://www.</u> <u>strengtheningnonprofits.org/resources/guidebooks/MeasuringOutcomes.pdf</u>

Data-Based Decision Making

Guideline Groups should use processes for collecting and analysing different types of data to guide decisions towards improvement of clinical guideline processes and outcomes on an ongoing basis. This data can come from multiple sources, including both standard audit procedures and specific efforts to monitor and evaluate implementation of clinical guidelines.

Data-Based Decision Making: using processes for collecting and analysing different types of data to guide decisions towards improvement of processes and outcomes on an ongoing basis.

Some questions related to implementation that this data can provide answers to include:

- Are the projected outcomes laid out in the implementation plan being met?
- Are the indicators highlighted in the implementation plan providing useful information?
- Are guidelines being implemented with fidelity?
- Have any risks emerged?

For meaningful decisions and actions to arise out of this monitoring process:

- ✓ Data relating to guidelines must be collected
- ✓ Data must be measured, analysed and reported accurately
- ✓ Appropriate reporting and review mechanisms must be in place to determine whether desired outcomes are being achieved
- ✓ Decisions for action must be clearly informed and linked to the data and other evidence.

Data should also be used to support effective feedback loops across multiple system levels. "Without effective feedback loops within and across levels of an organizational system, effective innovations are often changed to fit the existing systems, as opposed to existing systems changing to support effective innovations" [43, p.8]. Continuous quality improvement relies on gathering and assessing feedback and communication between various stakeholders in the implementation process. This helps to connect policy to practice and promote reflection that can lead to barriers being identified and addressed on a continuous basis. Therefore, systems should be put in place that ensure stakeholder experiences are being fed back to guideline groups and decision-makers and play a role in their data-based decision-making processes. It would also be helpful for guideline groups to consider if, and how, this feedback could be usefully shared throughout the Irish healthcare system and beyond.

Adapting Implementation Plans for Local Settings

Implementation requires management of many interacting elements in the internal and external environments. This means that all implementation plans contain a degree of tension between maintaining fidelity to an intervention's design and needing to consider and adapt implementation plans to local context and conditions. In reality, due to natural variation in real world contexts, it is almost impossible to apply an implementation plan with 100% fidelity.

The Dynamic Sustainability Framework [45] challenges the notion that interventions can be designed and tested in a single form that will be applicable across all healthcare settings and populations over time. It argues that the characteristics of settings in which interventions are being delivered are constantly evolving, including human and capital resources, information systems, organisational culture, climate and structure, and processes for training and supervision of staff. The success of sustaining an intervention is therefore dependent on its ongoing fit within a setting.

Ongoing adaptation of implementation plans with a primary focus on fit between guidelines and practice settings may therefore be required. This will then lead to ongoing improvement in healthcare service delivery and outcomes. Dynamic sustainability can therefore be thought of as the process of managing and supporting the evolution of guidelines over time within a changing context.

Researchers have argued that there are two separate categories of implementation activities [20]: **Core components** – these are essential and indispensable elements of the implementation plan, which cannot be changed without undermining effectiveness. All core components must be delivered with total fidelity.

Adaptable periphery – these are elements of the implementation plan which may be tailored to local settings. Guideline groups may be able to make evidence-based decisions on how best to adapt elements of their implementation plan to the context, without undermining the integrity of the intervention.

Evidence-based healthcare/Evidence-based Practice (EBP) is comprised of three factors: best available evidence, clinical expertise and patient values. Accordingly, specific clinical recommendations may not be appropriate in all cases and it may be necessary to deviate from the guideline. In these individual cases, the healthcare practitioner records this decision in the patient's chart.

Guideline Groups may work with healthcare professionals and other relevant stakeholders in local settings to help define which elements of an implementation plan may be appropriate to adapt for local settings. Clinical judgement in any such decisions must be clearly documented.



Stage 4: Full Implementation



Stage 4: Full Implementation

In stage 4 of implementation, guidelines are fully operational and integrated, used consistently, and embedded in structures. This means that skills and activities are sustained throughout the health system, policies and procedures are fully in place to support changes, and outcomes are ready to be evaluated. The majority of the specific implementation tasks will be completed at this point, meaning that the important tasks for stakeholders will be to show that guidelines are working and to look at how processes and outcomes can be continuously improved.

Specific activities for implementing clinical guidelines at this stage include:

- Evaluating implementation outcomes, service outcomes and client outcomes
- Engaging in continuous improvement cycles to produce more efficient and effective guidelines

Evaluation

Upon reaching full implementation, guidelines should be fully operational and integrated into routine practice, i.e. the standard way in which services carry out their work. This means that all implementation outcomes, service outcomes and client outcomes are ready to be evaluated. This differs from ongoing monitoring as it is largely summative in nature, providing evidence of whether guidelines are having the desired impact on outcomes.

Appropriate reporting and review mechanisms, such as KPIs and audit, should have been planned at earlier stages of implementation, and, at this point, must be fully in place to determine whether desired outcomes are being met. Having accurate data to demonstrate whether the guideline is being implemented and intended outcomes are being produced is of paramount importance.

Client outcomes, service outcomes and implementation outcomes should all be evaluated. Some service-focused stakeholders may show most interest in whether guidelines are achieving the results they anticipate and desire. However, it is critical that time and resources are dedicated to gathering and analysing data on all aspects of the implementation process in order to make the necessary adjustments to meet local, contextual conditions and in order to understand how the quality of implementation affects outcomes [43].

Returning to the Monitoring and Evaluation of Implementation Planning Tool (Tool 5) to review implementation outcomes may be useful at this point. This tool was created by the Centre for Effective Services to help Guideline Groups to think about and plan for monitoring and evaluation of the implementation process. While this tool should initially be used at an early stage of guideline development to ensure that monitoring and evaluation are embedded into the implementation process, it is beneficial to return to the tool when evaluating implementation at later stages of implementation.

To access the Monitoring and Evaluation of Implementation: Planning Tool, click <u>here</u> or see <i>Tool 5.

 The HSE Website provides information, tools and resources that encourage the accurate collection, analysis and reporting of monitoring, evaluation and clinical audit data: <u>https://www.hse.ie/eng/about/who/qid/measurementquality/</u>

Continuous Improvement Cycles

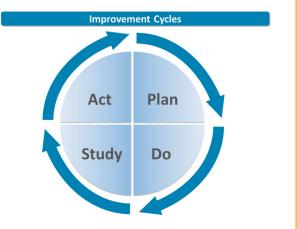
Reflecting on emerging evidence on outcomes and implementation provides opportunities to learn from experience and inform future implementation. If guidelines are not being implemented as intended or are being used as intended but not producing desired outcomes, improvement cycles can be used to support continued improvement and change. This will have the benefit of:

- ✓ Enabling Guideline Groups to engage both themselves and leadership in using data to support implementation capacity, fidelity, and patient outcomes.
- Ensuring decisions are data-based, purposeful and planned, rather than opportunistic and reactionary.

Continuous Improvement Cycles

A commonly used method is the Plan-Do-Study-Act Cycle (PDSA), which has four phases:

- Plan: use data to identify barriers and challenges and specify the plan to address them, as well as measures to monitor progress
- **2. Do**: carry out the plan to address challenges
- **3. Study**: use measures identified during the planning phase to assess and track progress
- **4.** Act: make changes to the next iteration of the plan to improve implementation.



To access the HSE 'Model for Improvement: Guidance Note on Key Concepts', which contains useful information on using the PDSA method, click here: <u>https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/pressureulcerszero/model-for-improvement-guidance-document.pdf</u>

The HSE has also published '*Improving our Services - A users guide to managing change in the Health Service Executive*'. <u>https://www.hse.ie/eng/staff/resources/hrstrategiesreports/improving-our-services,-a-guide-to-managing-change-in-the-the-hse---oct-2008.pdf</u>

It is important to recognise that by undertaking continuous improvement cycles, Guideline Groups and other stakeholders will not be able to solve all challenges. Implementation is a lengthy process that should not be rushed, and continued support is needed from leadership, management, or other key partners in the health system to address barriers to implementation. Ongoing communication, therefore, continues to be necessary at this stage of implementation, so that management and policy makers are equipped with the information and confidence needed to change the system so that desired outcomes can be achieved.

Implementation Research: In 2018, the Centre for Implementation and Improvement Science in Kings College London published the *Implementation Science Research Development (ImpRes) Tool*. This tool provides a step-by-step approach to designing implementation research. ImpRes encourages research teams to design robust implementation research by clearly articulating the implementation aims that the research seeks to address, understanding the activities associated with each implementation stage, and selecting an appropriate study design. http://www.kingsimprovementscience.org/ImpRes

Glossary



Glossary

Note: Many of the terms included in this glossary have been adapted from the National Implementation Research Network (NIRN) online glossary: <u>https://nirn.fpg.unc.edu/learn-implementation/glossary</u>.

Adaptable Periphery: elements of an implementation plan which may be tailored to local settings without undermining the integrity of the intervention itself.

Barriers: factors which hinder the implementation process and reduce the probability of successful implementation.

Capacity: the ability or power to do, understand or absorb something. This can apply to an individual, a team, an organisation or a whole system.

Clinical/healthcare Audit: a process to improve patient care and outcomes involving a documented, structured and systematic review and evaluation, against clinical standards, or clinical guidelines, and, where necessary, actions to improve clinical care.

Clinical Guidelines: systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service users' decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system.

Coaching: a formal, typically short-term, arrangement between a coach and an individual focused on developing work-related skills or behaviours.

Community: a group of people living in a particular area or having characteristics in common (e.g., city, neighborhood, organisation, service agency, business, professional association); the larger socio-political-cultural context in which an implementation programme is intended to operate.

Consultation: the action or process of formally discussing something with a stakeholder – generally asking the stakeholder a relevant question and receiving an answer to that question.

Context: the set of circumstances or unique factors that surround a particular implementation effort. This can refer to both the wider, systemic context, as well as the specific setting in which a specific intervention will be implemented.

Continuous Improvement Cycles: ongoing use of emerging data and evidence on outcomes and implementation of guidelines, and using that information to learn from experience, inform future implementation and improve outcomes. Progress is, therefore, achieved in an incremental manner over time.

Core Components: essential and indispensable elements of implementation, which cannot be changed without undermining the intervention. All core components must be delivered with total fidelity.

Data-Based Decision Making: using processes for collecting and analysing different types of data to guide decisions towards improvement processes and outcomes on an ongoing basis.

Diffusion: the process by which an innovation is communicated through certain channels over time among the members of a social system. The spread of ideas is generally a passive process, following an unpredictable, unprogrammed, emergent and self-organising path.

Dissemination: an active, negotiated and influenced means of distributing information about guidelines.

Enablers: factors which increase the probability of successful implementation.

Evaluation: a planned investigation of a project, programme, or policy used to answer specific questions, often related to design, implementation, and results (cause and effect).

Evidence-Based Interventions: practices, programmes, policies, strategies or other activities that have been empirically shown through research and evaluation processes to improve outcomes to some degree.

Fidelity: delivering an evidence-based intervention exactly as set out and intended by those who developed it.

Framework: a structure, overview, outline, system or plan consisting of various descriptive categories, e.g. concepts, constructs or variables, and the relations between them that are presumed to account for a phenomenon. Frameworks do not provide explanations; they only describe empirical phenomena by fitting them into a set of categories.

Implementation: the carrying out of specific planned, intentional activities undertaken with the aim of making evidence-informed policies and practices work better for people. It can be thought of as the 'how' as well as the 'what'.

Implementation Plan: a list of key activities, responsibilities, assumptions, resource requirements, risks and other information required to achieve the desired outcomes from guidelines.

Implementation Readiness: the extent to which organisations and individuals are both 'willing' to, and 'capable' of, implementing any specific intervention.

Implementation Science: the formal study of methods and factors that influence how successfully specific interventions are incorporated into service settings, leading to improved outcomes.

Implementation Team: a group of stakeholders that oversees and attends to moving guidelines through the stages of implementation. They actively use strategies and supports to facilitate implementation.

Intervention: any evidence-informed policy, practice, service or programme being implemented, be it a change to an *existing* policy, practice, service or programme, or a *new* intervention.

Leadership: the action of leading a group of people, or the ability to do this. This does not just apply to leading a whole organisation or system – leadership can take multiple forms and can occur at any level of an organisation or system.

Logic Model: a graphical depiction of an intervention's Theory of Change, describing connections between the intervention's context, inputs, outputs, and outcomes. It also provides some

information on evidence underpinning the intervention and the monitoring and evaluation processes attached to it.

Mentoring: a formal or informal arrangement which typically involves an ongoing relationship of support for significant transitions in knowledge, thinking and skills.

Model: a deliberate simplification of a phenomenon or a specific aspect of a phenomenon. Models are intended to be descriptive and need not be completely accurate representations of reality to have value.

Monitoring: the routine and systematic collection of information against a plan. It makes use of existing data and information about inputs, outputs, outcomes, or about outside factors affecting the organisation or project, to inform improvement.

Needs Assessment: a process which clarifies the extent to which needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritised by an organisation or group of people.

Outcomes: intended or unintended changes that occur as a result of implementing interventions. These changes can occur at the level of individuals, groups, organisations or population, and can occur in the short-, medium- or long-term.

Organisational Culture: the norms, values and beliefs that exist and govern behaviour within an organisation.

Resources: a stock or supply of money, materials, staff, and other assets that can be drawn on by a person or organisation in order to effectively implement guidelines.

Stakeholders: anyone who is affected by or is involved in the development and delivery of guidelines, including patients, public, clinicians, managers, professional bodies, unions, educators, and policy-makers.

Sustainability: guidelines can be considered to be sustainable when not only have the process and outcome changed, but the thinking and attitudes behind them are fundamentally altered and the systems surrounding them are transformed as well. In other words, the intervention has become an integrated or mainstream way of working rather than something 'added on'.

Theory: a set of analytical principles or statements designed to structure our observation, understanding and explanation of the world. A 'good theory' provides a clear explanation of how and why specific relationships lead to specific events.

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Additional Implementation Websites and Resources



Additional Implementation Websites and Resources

Centre for Effective Services implementation resources <u>http://www.effectiveservices.org/resources/tag/implementation</u>

Dissemination and implementation models in health research and practice – interactive website <u>http://www.dissemination-implementation.org/</u>

European Implementation Collaborative (EIC) implementation resources <u>http://www.implementation.eu/resources</u>

Guidelines International Network (GIN) <u>http://www.g-i-n.net/home</u>

Kings College London – Centre for Implementation Science https://www.kcl.ac.uk/ioppn/depts/hspr/research/cis/index.aspx

National Implementation Research Network (NIRN) (US) resource hub <u>http://implementation.fpg.unc.edu/</u>

National Patient Safety Office Learning Zone (including videos and slides from the Centre for Effective Services' 2-Day Introduction to Implementation Science Training) <u>https://health.gov.ie/national-patient-safety-office/ncec/resources-and-learning/</u>

Scottish Intercollegiate Guidelines Network (SIGN) http://www.sign.ac.uk/

Trinity College Dublin Postgraduate Certificate in Implementation Science <u>https://www.tcd.ie/medicine/public_health_primary_care/postgraduate/cis/index.php</u>

University College London, Centre for Behaviour Change <u>http://www.ucl.ac.uk/behaviour-change</u>

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Appendix A – Summary of Implementation Science Frameworks

- Tool 1. The Hexagon Tool
- Tool 2. Logic Model
- **Tool 3. Implementation Enablers and Barriers: Assessment Tool**
- **Tool 4. Implementation Planning Tool**

Tool 5. Monitoring and Evaluating Implementation: Planning Tool

Copies of the individual tools are also available to download from the NCEC website https://health.gov.ie/national-patient-safety-office/ncec/

Appendix A – Summary of Implementation Science Frameworks

1. Active Implementation Framework

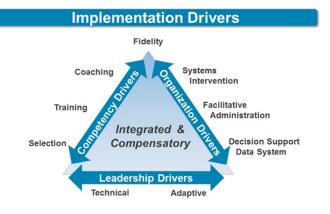
Description

Associated with the National Implementation Research Network (NIRN) in the US, the Active Implementation Framework emerged from a synthesis of the implementation literature.¹

Key Features

Framed around four 'key ingredients' for active implementation:

- 1. It takes time stages of implementation
- 2. It takes a village implementation teams
- 3. It takes support competency, organisational and leadership supports
- 4. It takes communication feedback loops



Link

Active Implementation Hub: http://implementation.fpg.unc.edu/

2. Consolidated Framework for Implementation Research (CFIR)

Description

This framework combines common elements from multiple implementation theories, offering consistent terminology. It places an emphasis on adapting interventions to fit the setting where they will be implemented, and continuous improvement of implementation throughout the process.²

Key Features

Five major domains:

- 1. Intervention characteristics
- 2. Outer setting
- 3. Inner setting
- 4. Individual characteristics of the implementers
- 5. The process of implementation

Each is broken down into component parts, enabling detailed analysis.

Link

http://www.cfirguide.org/

3. Promoting Action on Implementation Research in Health (PARiHS)

Description

This framework is designed to aid in implementing research into practice. It focuses on organisational change, rather than individual change, noting that organisations with transformational leaders, elements of learning organisations, and evaluation mechanisms have the most success.³

Key Features

Three factors determine research use:

- Robust Evidence research; clinical experience; patient preferences; local information
- Receptive Context culture; leadership; evaluation
- Facilitation of Change respect; credibility; empathy; clarity; flexible; consistent

All three are equally important, meaning that the context in which evidence is being used, and the way it is introduced, has as much to do with implementation as the quality of the evidence.

Link

Summary of the framework: http://www.nccmt.ca/resources/search/85

4. RE-AIM (Reach Effectiveness Adoption Implementation Maintenance)

Description

This is a comprehensive framework designed for evaluation of public health, health promotion and community-based interventions. It allows for policy, environmental and individual level components to be evaluated with measures suited to their setting, goals and purpose.

Key Features

The framework is made of five major elements for evaluating implementation:

- Reach
- Effectiveness
- Adoption
- Implementation
- Maintenance

Link

http://re-aim.org/

5. Normalisation Process Theory

Description

This theory and its associated tools primarily target researchers who are designing complex interventions. Rather than focusing on the process for implementation, as many other frameworks do, it aims to ensure that there is good potential for implementation due to the design of the intervention. The tools encourage the creation of interventions which are capable of widespread implementation and can easily be normalised into routine practice.⁴

Key Features

There is a dynamic relationship between four major elements:

- Coherence meaning and sense-making by participants
- Cognitive Participation commitment and engagement by participants
- Collective Action the work participants do to make the intervention function

Sources of behaviour

Intervention functions

Policy categories

• Reflexive Monitoring – participants appraise the intervention

Link

Tools available at: <u>http://www.normalizationprocess.org/</u>

6. COM-B

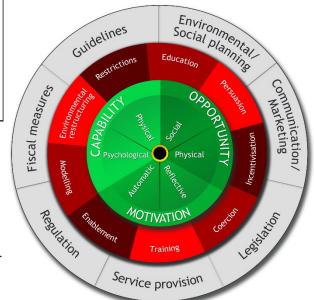
Description

A model of behaviour change used to identify what is needed to attain the desired behaviour at individual, practitioner or organisational level.

Key Features

This model posits that behaviour occurs as an interaction between three conditions:

- **Capability** Psychological or physical ability to enact behaviour
- Motivation Reflective and automatic mechanisms that activate or inhibit behaviour
- **Opportunity** Physical and social environment that enables the behaviour



The Behaviour Change Wheel⁵ shows how these conditions may be affected by certain interventions, and how policy decisions may impact on these interventions. This allows you to:

- Identify behaviours that need to change
- Understand these behaviours
- Consider a range of effective strategies

Link

http://www.behaviourchangewheel.com/

7. IHI Framework for Leadership for Improvement

Description

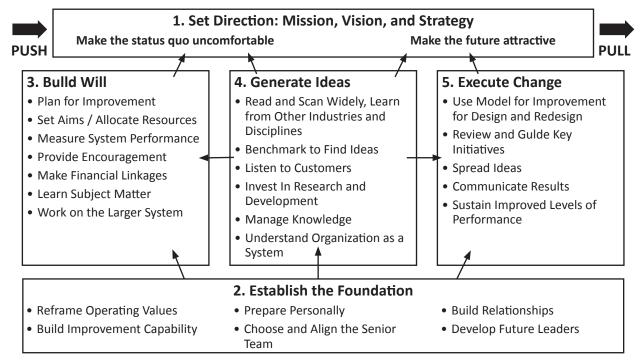
Developed by the Institute for Healthcare Improvement (IHI), this framework organises leadership processes that focus the organisation and senior leaders on improvement⁶.

Key Features

Primary uses:

- Provides an organising structure to understand how the activities of healthcare leaders contributes to transformation and improvement
- Assessment and improvement of organisations
- Guide the design of leadership development programmes

IHI Framework for Leadership for Improvement

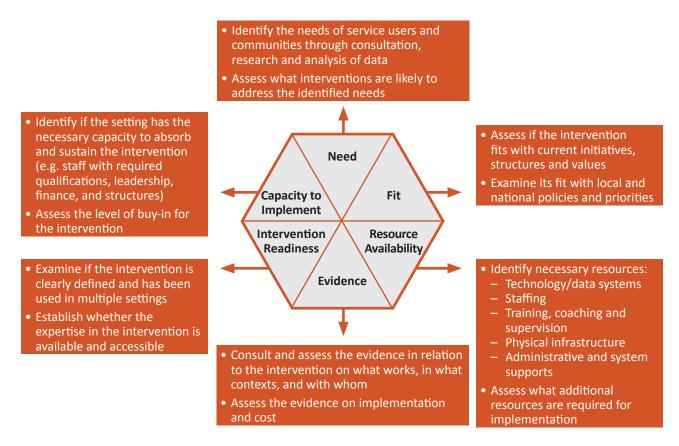


Link http://www.ihi.org/resources/Pages/Tools/IHIFrameworkforLeadershipforImprovement.aspx

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Tool 1 – The Hexagon Tool



Intervention:

The Hexagon Tool can be used as a planning tool to evaluate potential evidence-based guideline recommendations during the **Exploration Stage** of implementation.

Please rate the following aspects of implementation readiness in accordance with your guideline (tick the appropriate box):

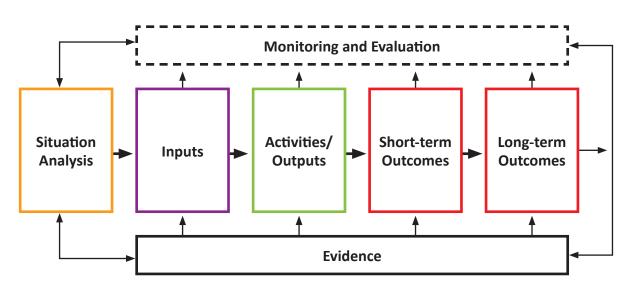
	High	Med	Low
Need			
Fit			
Resource Availability			
Evidence			
Intervention Readiness			
Capacity to Implement			

Adapted from the National Implementation Research Network (NIRN) Hexagon Tool by the Centre for Effective Services, with permission from NIRN. Original version available at: <u>https://implementation.fpg.unc.edu/sites/implementation.fpg.unc.edu/files/resources/NIRN-HexagonDiscussionandAnalysisTool2018_FINAL.pdf</u>





Tool 2 – Logic Model



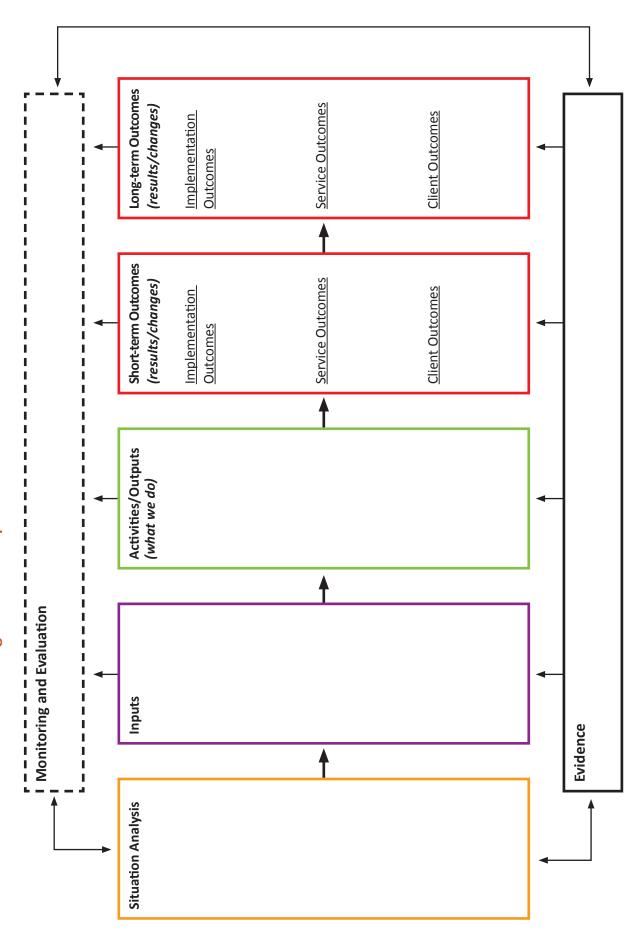
The basic outline of a logic model is shown above and a blank, editable version is provided on the following page. It should be completed by Guideline Groups in the following sequence of steps:

- 1. Situation Analysis
- 2. Short-Term and Long-Term Outcomes
- 3. Activities/Outputs
- 4. Inputs
- 5. Monitoring and Evaluation
- 6. Evidence underpinning all aspects of the Logic Model

Guidance for completing each specific section of the logic model is provided in the text of the Implementation Guide. The following tips and hints should also help Guideline Groups to fill in a logic model for their guideline:

- While a logic model should be read from left to right once completed, it is mostly **developed from right to left**, beginning with outcomes (after completing the situation analysis) and working back through activities/outputs and inputs.
- Though it is often difficult to be precise, **being as concrete as possible**, in terms of figures and targets listed, is better for planning, implementation, accountability and evaluation purposes.
- **Outcomes inserted into a logic model can be clearly grouped** by whether they are related to <u>implementation outcomes</u>, <u>service outcomes</u> or <u>client outcomes</u>.
- List any anticipated inputs and discuss any issues arising. If you are intending to work in partnership, for example, what would you need to consider in terms of planning or implementation?
- Work already done on the Hexagon Tool and outcomes can form the basis for development of a logic model.





Tool 3 – Implementation Enablers and Barriers: Assessment Tool

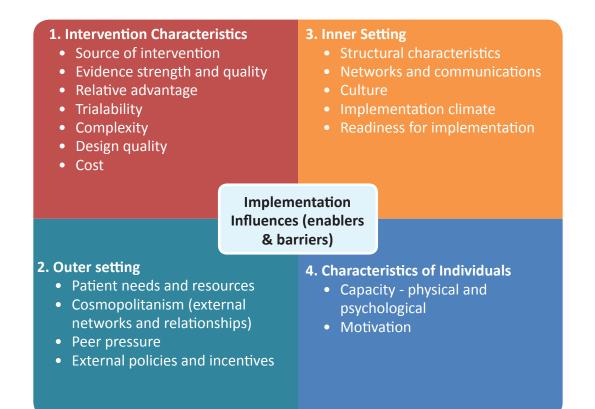
Introduction to the Implementation Enablers and Barriers Assessment Tool

A wide range of factors influence whether implementation is successful. Assessing and understanding these factors can help to identify barriers and facilitators to change and inform implementation planning. This assessment tool provides an overview of key factors that influence implementation and assists people in assessing these. It also helps with identifying opportunities to strengthen implementation.

The factors influencing implementation are organised around the four areas presented in the graphic:

This tool builds on two theoretical frameworks:

- The **Consolidated Framework for Implementation Research** (CFIR) (Damschroder *et al.*, 2009)^[1] and
- The Behaviour Change Wheel (Michie et al., 2011)^[2].





EFFECTI

COMMITTEE

This tool can be completed for **individual recommendations** within National Clinical Guidelines, or for a **guideline/project as a whole**. It can also be used to assess enablers and barriers at **various levels**, such as at a national level or in a particular healthcare setting.

In completing this tool, you should focus on factors that are **most relevant and salient** to your guideline and its stage of implementation. For example, you may wish to focus on factors that will be most fruitful to address. We recommend that you choose between five to seven factors to assess and at least one factor from each of the four areas. Use the table below to select the factors you are focusing on by ticking (\checkmark) in the relevant boxes

FAC	TORS INFLUENCING IMPLEMENTATION	Tick (√)
1. I	ntervention characteristics	
a)	Intervention source	
b)	Evidence strength and quality	
c)	Relative advantage	
d)	Trialability	
e)	Complexity	
f)	Design quality	
g)	Cost	
2. 0	Outer setting	
a)	Patient needs and resources	
b)	Cosmopolitanism (networks and relationships)	
c)	Peer pressure	
d)	External policies and incentives	
3. I	nner Setting	
a)	Structural characteristics	
b)	Networks and communications	
c)	Culture	
d)	Implementation climate	
e)	Readiness for Implementation	
4. 0	haracteristics of Individuals	
a)	Capacity - physical and psychological	
b)	Motivation	

1. INTERVENTION CHARACTERISTICS

An intervention is defined as any *change* to policy or practice. It could refer to a National Clinical Guideline and/or individual recommendations within them. A range of intervention attributes can influence the success of implementation.

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The perceived legitimacy and credibility of the source (e.g. academic college, HSE clinical programme or advocacy group) of the intervention,

including whether the intervention is developed externally or internally.	nally or internally.	including whether the intervention is developed externally or internally.
If this is an existing intervention, who developed it; who is the sponsor; who is responsible for	To what extent is the intervention considered to	What are the next steps for strengthening this? (If unsure, what additional information do you need?)
update and implementation?	be appropriate? (tick response)	
	 High 	
	Medium	
	Low	

B) EVIDENCE STRENGTH AND QUALITY The quality and validity of the evidence indicating that the intervention will have the desired outcomes.	it the intervention will have th	e desired outcomes.
What supporting evidence shows the intervention will work?	How do stakeholders perceive the strength of the evidence base for the intervention? (<i>tick response</i>) High Medium Low 	What are the next steps for strengthening this? (If unsure, what additional information do you need?)
C) RELATIVE ADVANTAGE The advantage of implementing the intervention versus an alternative solution.	us an alternative solution.	
What advantages does the intervention have compared to alternatives?	To what extent is the intervention considered to be better than current and/or alternative practices? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (If unsure, what additional information do you need?)

D) TRIALABILITY The ability to test the intervention on a small scale in a setting, and to be able to reverse course (undo implementation) if warranted.	a setting, and to be able to rev	erse course (undo implementation) if warranted.
Has the intervention been piloted or are there plans to pilot the intervention prior to full-scale implementation?	To what extent is it possible to trial/pilot the intervention prior to full- scale implementation? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If unsure, what additional information do you need?</i>)
E) COMPLEXITY The complexity of the intervention, reflected by dur required to implement.	ation, scope, radicalness, disr	E) COMPLEXITY The complexity of the intervention, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
How complicated is the intervention?	What is the level of change required to implement the intervention and replace existing practices? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If unsure, what additional information do you need?</i>)

F) DESIGN QUALITY AND PACKAGING Quality of the materials and supports available to hel	p implement and use the intervention.	vention.
What resources, tools and supports are available to help implement and use the intervention?	How do you rate the quality of the resources developed to support implementation of the intervention? (tick response) I High Medium Low	What are the next steps for strengthening this? (<i>If unsure, what additional information do you need?</i>)
G) COST Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.	plementing the intervention in	icluding investment, supply, and opportunity costs.
What categories of costs will be incurred in implementing the intervention? (e.g. staffing, equipment, IT)	What level of costs will be incurred in implementing the intervention? (<i>tick response</i>) High Medium Low 	What are the next steps for strengthening this? (If unsure, what additional information do you need?)

2. OUTER SETTING The wider economic, political, social and cultural context influences implementation.	ntext influences implementati	ion.
A) PATIENT/CLIENT NEEDS AND RESOURCES The extent to which patient needs, as well as barriers	and facilitators to meet those	and facilitators to meet those needs, are accurately known and prioritised.
How were the needs and preferences of patients/ clients considered when deciding to implement the intervention?	To what extent will the intervention meet the needs and preferences of patients? (tick response) Image: High Medium Low	What are the next steps for strengthening this? (<i>If</i> unsure, what additional information do you need?)
B) COSMOPOLITANISM (EXTERNAL NETWORKS AND <i>The quality and extent of relationships and networks</i>	RELATIONSHIPS) with other external organisations (social capital).	ons (social capital).
What kind of information exchange/networking do staff have with others outside their setting?	What is the level of information exchange/ networking staff have with others outside of their setting/organisation? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If</i> unsure, what additional information do you need?)

External policies and incentives that spread interventions, including government policy and regulations, external mandates, recommendations Competitive pressure to implement an intervention, mainly from other professionals/services/organisations who have already implemented What are the next steps for strengthening this? (lfWhat are the next steps for strengthening this? (// unsure, what additional information do you need?) unsure, what additional information do you need?) incentives supporting the To what extent are other implementation of the services/professionals external policies and To what extent are implementing the (tick response) (tick response) intervention? intervention? and guidelines, collaboratives, and public or benchmark reporting. Medium Medium High High Low Low the intervention. This can aid adoption of interventions. Are other services/professionals implementing the guidelines which could impede or conflict with Are there external policies, regulations or **D) EXTERNAL POLICIES AND INCENTIVES** implementation of the intervention? intervention or similar practices? **C) PEER PRESSURE**

Implementation Guide and Toolkit for National Clinical Guidelines

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NNER S	organi

3. INNER SETTING The organisational structure, culture and climate play an important role in successful implementation.	ıy an important role in success	sful implementation.
A) STRUCTURAL CHARACTERISTICS The age and size of the organisation, level of staff turnover, geographic spread, physical layout etc.	nover, geographic spread, phys	sical layout etc.
What kind of infrastructure changes are needed to accommodate the intervention (e.g. changes to policies, information and record systems)?	To what extent is the level of infrastructure required to implement the intervention in place? (tick response) High Medium Low	What are the next steps for strengthening this? (<i>If</i> unsure, what additional information do you need?)
B) NETWORKS AND COMMUNICATIONS The nature and quality of social networks, and formal and informal communications within an organisation.	l and informal communications	s within an organisation.
How do staff find out about new initiatives, accomplishments, best practice etc.?	How do you rate the quality of communication in the organisation? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If</i> unsure, what additional information do you need?)

C) CULTURE Norms, values, and basic assumptions of an organisation.	tion.	
How do you think the organisation's culture will affect the implementation of the intervention?	To what extent are new ideas embraced and used to make improvements? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If</i> unsure, what additional information do you need?)
D) IMPLEMENTATION CLIMATE The absorptive capacity for change, shared receptivity of involved ind will be rewarded, supported, and expected within their organisation.	ı of involved individuals to an in ir organisation.	D) IMPLEMENTATION CLIMATE The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organisation.
How well does the intervention fit with existing work processes and practices?	To what extent is the organisation receptive to implementing the intervention? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If</i> unsure, what additional information do you need?)

4. CHARACTERISTICS OF INDIVIDUALS The characteristics of individuals, including their capa	icity and motivation, influence c	4. CHARACTERISTICS OF INDIVIDUALS The characteristics of individuals, including their capacity and motivation, influence changes in behaviour required to implement interventions.
A) CAPACITY – PHYSICAL AND PSYCHOLOGICAL The physical and psychological capacity of individuals	s to deliver the intervention, incl	A) CAPACITY – PHYSICAL AND PSYCHOLOGICAL The physical and psychological capacity of individuals to deliver the intervention, including physical strength, knowledge, skills and stamina.
Who (i.e. what groups) are needed to deliver the intervention?	To what extent do individuals have the capacity (physical and psychological) to enact the changes required? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If</i> unsure, what additional information do you need?)
B) MOTIVATION Brain processes that energise and direct behaviour, including knowledge, beliefs, and confidence.	ncluding knowledge, beliefs, and	l confidence.
How do individuals feel about implementing the intervention?	To what extent are staff motivated to enact the changes required? (<i>tick response</i>) High Medium Low	What are the next steps for strengthening this? (<i>If unsure, what additional information do you need?</i>)

Guidance and Definitions for Implementation Enablers and Barriers Assessment Tool

1. Intervention Chara The characteristics of a	cteristics the intervention being implemented.
Intervention source	Legitimacy and credibility of the intervention source
Evidence strength and quality	Quality and validity of the evidence indicating that the intervention will achieve desired outcomes
Relative advantage	Intervention has more advantage than another alternative
Trialability	Ability to test the intervention on a small scale in the organisation and to be able to reverse course (undo implementation) if warranted
Complexity	Difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, number of steps required to implement
Design quality and packaging	Excellence in how the intervention is bundled, presented and assembled, including what online supports are available
Cost	Costs of the intervention itself and costs associated with implementing the intervention, including investment, supply and opportunity costs
2. Outer Setting The economic, politica	l, social and cultural context within which an organisation resides.
Patient needs and resources	Extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritised
Cosmopolitanism	The quality and extent of relationships and networks with other external organisations (social capital)
Peer pressure	Competitive pressure to implement an intervention, mainly from outside professionals/services/organisations who have already implemented the intervention
External policies and incentives	External strategies to spread interventions, including policy and regulations, external mandates, recommendations and guidelines, collaboratives, public or benchmarking reporting
3. Inner Setting Structural, political an	d cultural context through which an implementation process will proceed
Structural characteristics	Social architecture, age, maturity, size, staff turnover of an organisation
Networks and communications	Nature and quality of social networks, and formal and informal communications within an organisation (e.g. teamwork)
Culture	Norms, values and basic assumptions of an organisation

Implementation climate	Tension [perceived need] for change Compatibility – innovation fit with existing systems Relative priority within the organisation Organisational incentives and rewards Goals communicated, and feedback taken Learning climate of trying new methods, reflecting, learning
Readiness for implementation	Leadership engagement Available resources for implementation Access to information and knowledge about how to implement the intervention
4. Characteristics of In Knowledge, beliefs and process. May also refe	skills that individuals need in order to carry out the implementation
Knowledge and beliefs about the intervention	Individual beliefs that the intervention will be successful in their setting, given existing evidence and plans
Self-efficacy	Individual belief in their own, and their colleagues', ability to implement the innovation
Individual stage of change	The phase an individual is in, according to Rogers'/Prochaska's Stages of Change, they progress towards skilled, enthusiastic and sustained use of the intervention
Individual identification with organisation	How individuals perceive the organisation, their relationship with it and the degree of commitment to the organisation
Other personal attributes	Including tolerance of ambiguity, intellectual ability, motivation, values, competence, and learning style

References

- [1] Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*, 4(1), pp. 50-64. Available from: <u>https://doi.org/10.1186/1748-5908-4-50</u>
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Tool 4 – Implementation Planning Tool

Implementation is a key requirement for Guideline Groups and completed published guidelines must include an implementation plan. Groups should fill out the template provided on the following page, listing specific actions that are required for implementation, and linking them to: guideline recommendations (a number of recommendations can be grouped together, where appropriate); who is ultimately responsible for leading the action; the expected timeframe for completion; and the measure/indicator that will be used to verify that the recommendation has been fully implemented. These are described in greater detail below.

Explanatory notes for implementation plan

- **Guideline recommendation/number:** This refers to the specific guideline recommendation(s) which the action/intervention aims to achieve. One action may address several recommendations, e.g. training programme or additional staff. Ensure all guideline recommendations are included in the implementation plan.
- **Barriers and enablers:** Identify the barriers and enablers for implementing this recommendation. Completing the 'Implementation Enablers and Barriers: Assessment Tool' in Tool 3 will help you to complete this section. Note that some barriers and enablers will be common to multiple recommendations. Consider capability, opportunity and motivation, which influence behaviour.
- Action/intervention/task to implement recommendation: This is the specific high-level action, intervention or task which is needed to implement the guideline recommendation(s). Determine the actions, interventions or tasks that are effective and best suited to address the identified needs and barriers. The actions, interventions or tasks should specify the change required to current practice, i.e. who needs to do what differently for this recommendation to be implemented effectively.
- Lead responsibility for delivery of the action/intervention/task: Many actions, interventions or tasks are carried out by multidisciplinary teams and multiple stakeholders. This column should be used to specify the lead group/unit/organisation responsible for implementing the action/intervention/task. Ensuring that these stakeholders are on your Guideline Group from the beginning will help to ensure that the guideline recommendations are implementable.
- **Timeframe for completion:** Specify the timeframe you expect for full implementation of this action, intervention or task within the three years following publication. For additional detail, the quarter (Q1, Q2, Q3, or Q4) can also be added. It is useful to spread these out over the 3 years. Some interventions may be dependent on additional funding and can be denoted as such. The guideline is updated after 3 years, with a new implementation plan.
- **Expected outcome and verification:** Specify the expected outcome and how you will verify or measure it, i.e. how will you know when the recommendation has been fully implemented? How will you know if the expected outcome has been achieved? Use existing data/measurement sources where available.
- Allowing adequate and appropriate time for planning how clinical guidelines will be implemented is a crucial implementation enabler, enabling those who are driving the change to map out the implementation process and provide a course of action to address any potential challenges.



Implementation Plan (for inclusion in the published guideline)

			1	1	[]
Expected outcome and	Verincation				
for n	Year 3				
Timeframe for completion	Year 2				
Tim CO	Year 1				
Lead responsibility for	action				
Action/intervention/task to implement recommendation					
Implementation barriers/	enablers/gaps				
Guideline recommendation	or number(s)				

Implementation of the overall guideline

While the implementation plan is specific to the individual recommendations in the guideline, some actions will assist with guideline implementation as a whole. These include establishing an implementation team; developing a dissemination and communication plan and developing specific implementation tools and resources. In the boxes below, please give a high-level description of how these actions will be ncorporated into the implementation of your guideline:

Implementation team: Describe the structure and governance of your implementation team, outline process for risk identification and management, list your implementation team members and specify meeting frequency. Outline planned training and capacity building for team members. Dissemination and communication plan: Describe your communications strategy and dissemination plan for distributing, sharing, promoting and applying guideline recommendations e.g. reporting schedule, publications/articles, presentations, awareness-raising activities, media, knowledge transfer, collaboration and networking.

Implementation tools: List the supporting tools and resources developed to support this guideline/project and where these tools can be accessed, e.g. materials on website, patient information leaflets, training linked to CPD, e-learning, podcasts, study days, research, checklists, audit tools, monitoring and reporting processes, seminars, conference, patient pathways, toolkits, algorithms, teaching aids, presentations.

Tool 5 – Monitoring and Evaluating Implementation: Planning Tool

Introduction

This tool has been produced by the Centre for Effective Services, based on Proctor et al.'s (2011) taxonomy of implementation outcomes and the Reach Efficacy Adoption Implementation Maintenance (RE-AIM) framework (Glasgow, Vogt & Boles, 1999). It has been produced to help those involved in developing and implementing National Clinical Guidelines to plan for the monitoring and evaluation of implementation of their guideline.

It relates specifically to the eight implementation outcome areas relevant to the implementation of National Clinical Guidelines that are listed below. For each outcome area, the levels of analysis are listed, some questions regarding monitoring and evaluation, and potential data collection methods are listed. It is important to remember that many of the outcomes below are interrelated. Further, some of these outcomes are more relevant for early stages of implementation (e.g. appropriateness) and others are more relevant for later stages of implementation (e.g. sustainability).

These implementation outcome areas are separate from service outcomes (e.g. efficiency, safety, effectiveness, equity, patient-centredness, timeliness) and client outcomes (e.g. satisfaction, function, symptomatology). They are also separate from service and process measures required in NCEC published guidelines. Implementation outcomes relate specifically to implementation of an intervention and are key areas for consideration in the implementation process.

This tool can be used by Guideline Groups to consider important factors in implementation of their guideline, and to create action plans for how to monitor and evaluate these factors. This will then inform the actual collection, collation, analysis and reporting of data on implementation.



Implementation Outcomes





i.	 Acceptability The perception amo experience 	<mark>Acceptability</mark> The perception among stakeholders that an intervention is agreeable, palatable or satisfactory, and leads to an improved general service experience	nproved general service
	<u>Level of Analysis</u>	Monitoring and Evaluation Questions	Potential Methods
• •	Individual Patient/ Service user Individual Provider	 What level of knowledge do providers have about the content and complexity of the intervention? What are providers' attitudes toward the intervention? Do providers rate the evidence for the intervention as strong? From the patient/service user's perspective, does the intervention improve how patients/service users experience a service? 	Survey Interviews Administrative Data
Ar sh	ction Planning (What nould be informed by	Action Planning (What actions do the Guideline Group and other stakeholders need to take to help accurately assess acceptability? Actions should be informed by level of analysis, answers to the questions posed above and potential methods for data collection):	s acceptability? Actions on):

2. Appropriateness/Feasibility The extent to which the inter	Appropriateness/Feasibility The extent to which the intervention is compatible, relevant and implementable within a given context or setting	
<u>Level of Analysis</u>	Monitoring and Evaluation Questions	Potential Methods
 Individual Patient/ Service User Individual Provider Organisation/ Setting 	 Does the organisation have the resources, staff and equipment to implement the intervention? Do staff have the time, skills, training and ability to implement the intervention? Is there any aspect of the intervention that could make it inappropriate for providers or the target population? (e.g. due to culture, religion, beliefs, values etc.) 	 Survey Interviews Focus Groups
Action Planning (Wh feasibility? Actions sh	Action Planning (What actions do the Guideline Group and other stakeholders need to take to help accurately assess appropriateness/ feasibility? Actions should be informed by level of analysis, answers to the questions posed above and potential methods for data collection):	assess appropriateness/ nods for data collection):
		_

 Adoption The initial decisions 	Adoption The initial decisions by providers to utilise the intervention in the first place, and then where it is implemented and who is implementing it	d who is implementing it
<u>Level of Analysis</u>	Monitoring and Evaluation Questions	Potential Methods
 Organisation/ Setting Individual Provider 	 Who is the target group and in what settings are they being targeted? Who can help gather information about this? Who will deliver the intervention, and do they have the skills and time? How will you know if staff used the intervention? 	 Survey Observation Interviews Focus Groups Administrative Data
Action Planning: (W ^t should be informed b ^r	Action Planning: (What actions do the Guideline Group and other stakeholders need to take to help accurately assess adoption? Actions should be informed by level of analysis, answers to the questions posed above and potential methods for data collection):	/ assess adoption? Actions ection):

 Level of Analysis Individual What are What are What cost and burde Analysis? How will y 	Level of Analysis Monitoring and Evaluation Questions Potential Methods • Individual • What are the key elements of the intervention that must be delivered to be successful? • Observation • Provider • What costs and resources associated with adapting the intervention (including time and burden, not just money) need to be considered and included in the Budget Impact Analysis? • Checklists • How will you assess delivery of the intervention? • Focus Groups • Focus Groups • How will you assess delivery of the intervention? • Self-Report • Self-Report	Potential Methods Observation Checklists Content Analyses Focus Groups Self-Report fidelity? Actions should
 Individual What ar What co What co What co and bur Analysis How will 	are the key elements of the intervention that must be delivered to be successful? costs and resources associated with adapting the intervention (including time urden, not just money) need to be considered and included in the Budget Impact sis? will you assess delivery of the intervention? do the Guideline Group and other stakeholders need to take to help accurately assess answers to the questions posed above and potential methods for data collection):	 Observation Checklists Content Analyses Focus Groups Self-Report fidelity? Actions should
A -Hand Notice (M/hat actions do	do the Guideline Group and other stakeholders need to take to help accurately assess answers to the questions posed above and potential methods for data collection):	fidelity? Actions should
Action Flaming (what actions up be informed by level of analysis, ar		

5. Penetration/Reach The degree to which	Penetration/Reach The degree to which the intervention is integrated into a service setting, including whether it effectively reached the target population	che target population
<u>Level of Analysis</u>	is Monitoring and Evaluation Questions	Potential Methods
 Individual Patient/ Service User Population 	 Who is the target group? Define the intended beneficiaries/target population(s), and what sectors of that target population you intend to reach. How and where will you reach them? How confident are you that you will be able to do this? How will you know if those who are using the intervention are representative of the intended beneficiaries/target population(s)? (this can be based on stakeholder analysis activities) How will you use to attract underserved populations and focus on health inequities? 	 Survey Case Studies Interviews Administrative Data
Action Planning (W [†] Actions should be inf	Action Planning (What actions do the Guideline Group and other stakeholders need to take to help accurately assess penetration/reach? Actions should be informed by level of analysis, answers to the questions posed above and potential methods for data collection):	 assess penetration/reach? ata collection):

6. Implementation Effectiveness The degree to which pre-define	l mplementation Effectiveness The degree to which pre-defined outcomes are achieved as a result of implementing the intervention	
<u>Level of Analysis</u>	Monitoring and Evaluation Questions	Potential Methods
 Individual Patient/ Service User Patient/ Service User Population Organisation/ Setting 	Individual • What are the most important outcomes you expect to see? • Survey Patient/Service • How will you define success in achieving these outcomes? • Gase Studies Patient/Service • How will you utefine success in achieving these outcomes? • Interviews Barent/Service • How will you utefine success in achieving these outcomes? • Case Studies User • Now will you measure these changes? • Administrative bata User Population • Who will the outcomes matter to? • Administrative bata • Mow will you are the biggest threats to seeing the outcomes you want? • Administrative bata • What are the biggest threats to seeing the outcomes might there be? • Administrative bata Action should be informed by level of analysis, answers to the questions posed above and potential methods for data collection): • Steps Action should be informed by level of analysis, answers to the questions posed above and potential methods for data collection): • Interviews	 Survey Case Studies Interviews Focus Groups Administrative Data y assess implementation ential methods for data

7. Implementation Cost The resources and fur	Implementation Cost The resources and funding required to implement the intervention, and the net cost impact of implementing and delivering the intervention	elivering the intervention
<u>Level of Analysis</u>	Monitoring and Evaluation Questions	Potential Methods
 Individual Patient/ Service User Organisation/ setting 	 How much will it cost to deliver each recommendation? How will the costs vary across different settings? What is the cost effectiveness of the proposed intervention? Are there any cost savings anticipated with this intervention? What are the timescales for the service planning/funding cycles (to ensure timely submission of your budget impact assessment to the service planning process)? 	 Administrative data HIPE data HTA HTA Resources on conducting Budget Impact Assessment and economic evaluation available on the NCEC website)
Actions should be infi	Actions should be informed by level of analysis, answers to the questions posed above and potential methods for data collection): Actions should be informed by level of analysis, answers to the questions posed above and potential methods for data collection):	ess implementation cost? a collection):

8. Maintenance/Sustainability The extent to which the inter	Maintenance/sustainability The extent to which the intervention will be renewed and institutionalised into the organisation/setting's ongoing operations	oerations
Level of Analysis	Monitoring and Evaluation Questions	Potential Methods
 Organisation/ setting 	 What will happen over the long-term? Consider for both individual beneficiaries and settings. 	SurveyCase Studies
	 Can organizations sustain the initiative over time? Is there an initiastructure of staff and resources in place? How likely is your initiative to produce lacting offects for individual patients and providers? 	 Record and Policy Reviews
	 How will you be able to follow your initiative for an extended period of time? 	 Interviews
	 How will you continue to track success; changes made over time; and provide ongoing feedback? 	
	How will you get the word out about your intervention and lessons learned?	
Action Planning (W sustainability? Actio collection):	Action Planning (What actions do the Guideline Group and other stakeholders need to take to help accurately assess maintenance/ sustainability? Actions should be informed by level of analysis, answers to the questions posed above and potential methods for data collection):	accurately assess maintenance/ and potential methods for data
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The following articles are examples of how the RE-AIM framework and Proctor's taxonomy of implementation outcomes have been used and adapted to monitor and evaluate implementation of interventions in the health sector:

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