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Methodological Handbooks & Toolkit for Clinical Practice Guidelines and Clinical Decision Support Tools for Rare or Low prevalence and Complex Diseases

Handbook #12: Implementation and Evaluation of the Uptake of CPGs and CDSTs for Rare or Low prevalence and Complex diseases

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This handbook includes a detailed explanation of the process for implementing and evaluating the uptake of CPGs or CDSTs, including:

- ✓ Selection of the CPG or CDST to implement
- ✓ Planning the implementation
- ✓ Analysis of the context
- ✓ Design of the intervention
- ✓ Design of the implementation roadmap
- ✓ Continuous improvement

Purpose:

To provide guidance to systematically plan, perform and evaluate the implementation of CPGs or CDSTs.

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ABBREVIATIONS

AETSA	Andalusian Health Technology Assessment Department
CDSTs	Clinical Decision Support Tools
CER	Comparative Effectiveness Research
CPGs	Clinical Practice Guidelines
CPMS	Clinical Patient Management System
EC	European Commission
ERN	European Reference Network
EU	European Union
FPS	Fundación Pública Andaluza Progreso y Salud
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IACS	Aragon Health Sciences Institute
NCEC	National Clinical Effectiveness Committee
NICE	National Institute for Health and Care Excellence
PDSA	Plan-Do-Study-Act
RNAO	Registered Nurses' Association of Ontario
SPO	Structure-Process-Outcome

01.

BACKGROUND

There are a number of challenges surrounding the development of CPG and CDST for rare diseases. One of the most relevant barriers is the lack of high-quality evidence, in which the foremost methodological frameworks like GRADE rely on [1].

Therefore, there is a need for specific methodological approaches that can provide reliable and useful Clinical Practice Guidelines (CPGs) and Clinical Decision Support Tools (CDST) for rare diseases. The project also aims to provide a common methodology, in order to harmonise the elaboration process of CDST and CPGs.

It is worth noting that within the scope of this handbook, “rare diseases” is the term used to refer to rare diseases as well as low prevalence complex diseases.

02.

AIM OF THIS DOCUMENT

The dissemination and communication of CPGs and CDSTs alone has proven to be insufficient to facilitate the uptake and use of CPG and CDSTs in healthcare. This is mainly due to the fact that there is a gap between the CPG or a CDST and the specific needs and availability of resources at the places where they can be used [2, 3].

Figure 1. Dissemination, communication and implementation

Adapted from NCEC Implementation Guide and Toolkit for National Clinical Guidelines.

In order to cover this gap, it is essential to articulate knowledge transferability processes that can be applied systematically to different healthcare contexts when putting into practice CPGs or CDSTs[2].

This handbook aims at providing a set of steps that can be applied systematically when moving into practice the CPGs and CDSTs for rare disease in the ERN's healthcare settings.

03.

METHOD

A previous exhaustive analysis of the state of the art on methodologies for implementation of CPGs and CDSTs for rare diseases was developed. The documents located in the systematic search in databases and the manual search in relevant organizations' and projects' websites were taken into account in the definition of the implementation process of CPGs and CDSTs for rare diseases.

In order to cover the gaps where no evidence specific for rare diseases was found, this handbook has used well-founded methodologies for the implementation of CPGs and CDSTs for common diseases, considering the particularities that may apply to rare diseases and the ERNs.

04.

SCOPE

The implementation process followed in this handbook is presented as a general process where the steps are suitable for the CPGs, Clinical Consensus Statements, Diagnostic, Monitoring and Therapeutic Pathways, Evidence-based Protocols, Do's and Don't's Factsheets for Diseases and Quality Measures.

4.1 | Sustainability

Sustainability of the intervention implemented is the ultimate goal behind the implementation. An intervention is considered sustainable when not only have the process and outcome changed, but the thinking and attitudes behind them are fundamentally altered and the surrounding systems transformed as well. In other words, the intervention has become an integrated or mainstream way of working rather than something 'added on' [4].

In order to make sustainable interventions possible, it is important to go beyond planning and deploying sensible interventions to working on securing other key elements to facilitate change and viability within healthcare settings [5]. These elements can be summarised in the following:

- ✓ Relevance and expected impact of the need addressed by the intervention
- ✓ Leadership embedded in the setting where the implementation takes place
- ✓ Stakeholder engagement throughout the implementation and beyond
- ✓ Consistent assessment framework and feedback system that can nurture the continuous improvement of the intervention.

These elements are addressed throughout the implementation process proposed in this handbook.

05.

COMPOSITION OF THE IMPLEMENTATION WORKING GROUP

The working group is a multidisciplinary group responsible for leading the implementation and overviewing the completion of all the phases of the implementation process presented herein, including securing the continuity of the continuous improvement cycles around the interventions.

5.1 | Roles and Competencies

Although each implementation process is singular and dynamic, there are certain roles that should be considered when constituting the working group [6]:

Implementation leader: The main responsible for the accomplishment of the implementation process, usually a management profile. She or he should have enough decision-making capacity as to actuate changes at the different care levels involved and leadership capacities.

Methodological Coordinator: She or he leads and oversees the development of the implementation process according to the methodology and coordinates the implementation teams, which are constituted in phase four of this process. More information on the implementation teams can be found in section 6.4 Design of the Interventions.

Specialists: They bring to the working group specific knowledge and expertise needed for the implementation in the following areas:

- ✓ Management of the setting where the implementation takes place. This will help ensure access and understanding of the structures of the organisation and their functioning, including the information systems available (Electronic Healthcare Record and other databases), e.g. managers, data analysts.
- ✓ Practice related to the different care areas and levels, e.g. healthcare professionals, social workers from primary care and acute care.

Methodologist: This profile is needed in order to address the different needs for information collection and analysis at each phase of the process. They can have knowledge on the identification of barriers and facilitators, on the design and operationalisation of activities required for the implementation, such as training activities, or on the assessment of interventions, among others.

Users and/or patients' representative: They are essential in order to ensure a comprehensive perspective is adopted throughout the implementation and relevant objectives are established.

The members of the working group should gather altogether extensive knowledge of the context and the condition that the implementation will be addressing. They should also gather decision-making authority or have direct access to decision-making authority, so that decisions can be made in a timely manner and be able to identify and understand comprehensively the requirements of the implementation and design the specific interventions according to the resources available, barriers and facilitators [3]. Furthermore, including opinion leaders in the implementation working group can ease the implementation process [7, 8]. All members of the ERNs should be represented in the pathway DG, to ensure representativeness of the care context for which the pathway is being developed.

The working group may need to incorporate new profiles along the implementation process, especially after the planning phase, where the scope of the implementation is defined.

Potential conflict of interests within the members of the prioritisation panel should be carefully identified and duly addressed, following the indications established by our partner FPS.

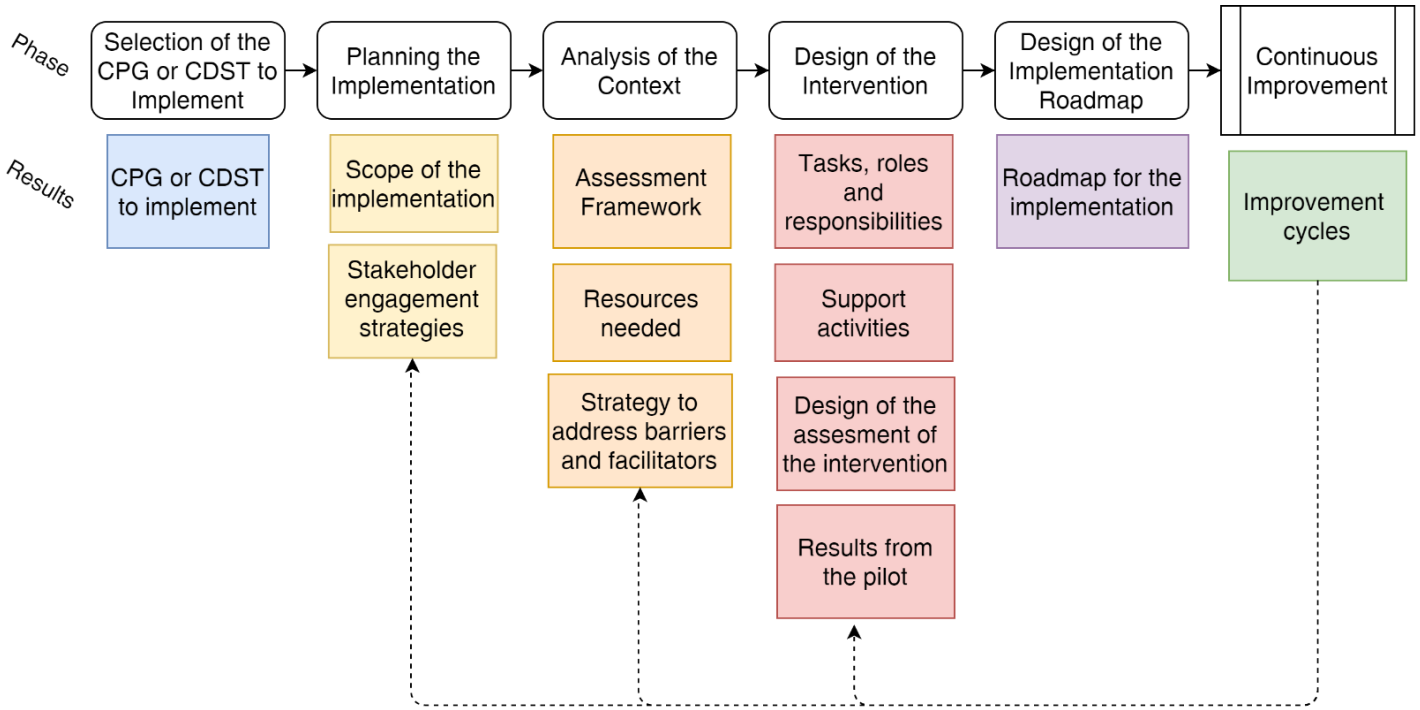
It is important that the working group meets regularly and has fluent communication while the implementation process is being deployed. If some or all of the members being located in different countries or regions, adequate solutions for communication, virtual meetings and file sharing should be prepared and ready to use from the beginning of the process.

06.

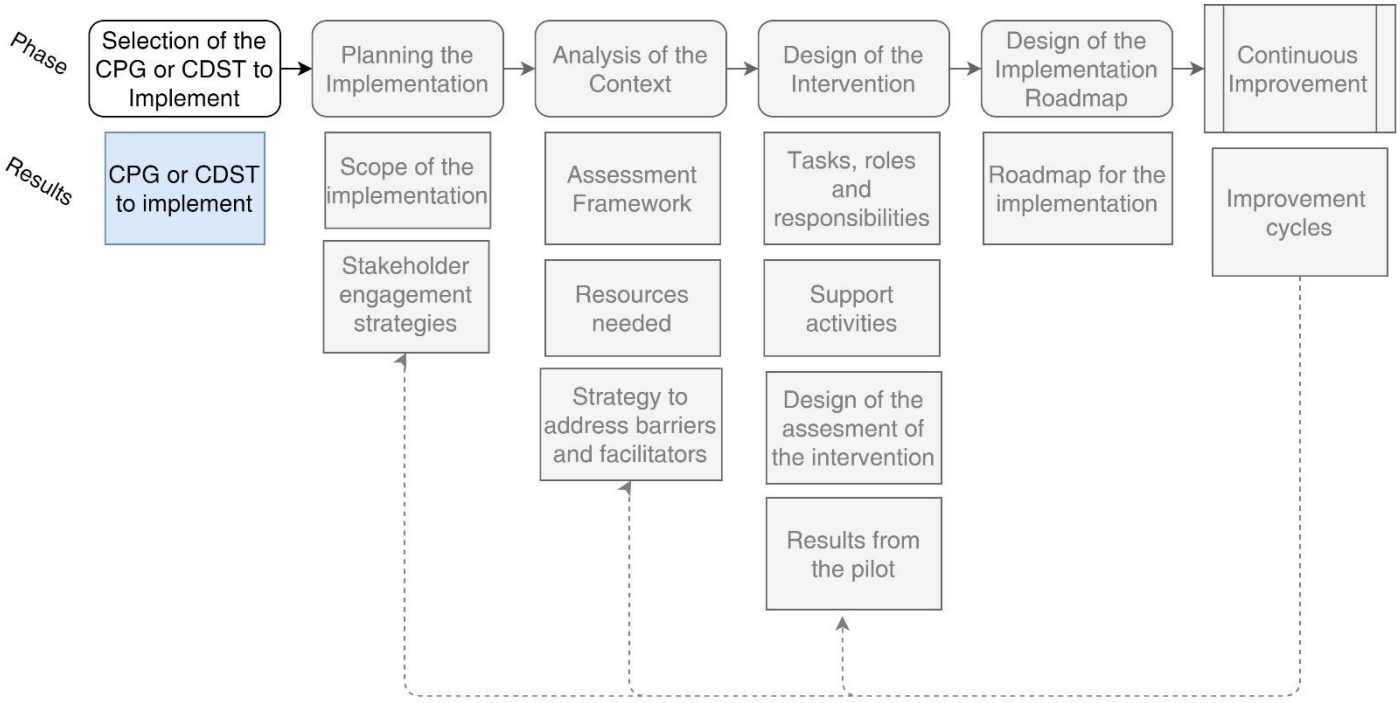
IMPLEMENTATION PROCESS

Herein are depicted and explained the main phases that should be contemplated when implementing a CPG or a CDST for rare diseases. Nonetheless, it is worth noting that the implementation of a CPG or a CDST is a singular process that should consider local particularities and specific needs of the target patients. This is even more important under the circumstances of the ERNs, where multiple care contexts come into play. In this sense, the implementation should be also regarded as a flexible and dynamic process, capable to adapt to changing circumstances through continuous improvement mechanisms (Figure 2).

Figure 2. Implementation process



6.1 | Selection of the CPG or CDST to Implement



There are two types of CPG or CDST that can be considered for implementation:

1. New CPG or CDST that have been developed following any of the Elaboration Handbooks (Handbook #4 to #11).
2. Existing CPG or CDST that it has been retrieved and appraised following the Handbook #2: Appraisal of existing CPGs and CDSTs for rare diseases and adopted or adapted following the Handbook #3: Adaptation of CPGs and CDSTs.

The main criterion for selecting a CPG or CDST to implement is that it covers the need that has been identified by the ERN. Nonetheless, there are other issues that should be also taken into account:

- ✓ Relevant information regarding implementation already gathered during the development of the CPG or CDST. This includes the considerations for implementation and other information regarding the feasibility, acceptability of applicability regarded in the CPG or CDST [9].
- ✓ If the CPG or CDST has been adapted or adopted, the information related to the acceptability and applicability of the CPG or CDST gathered during the adoption or adaptation (see Handbook #3: Adaptation of CPGs and CDSTs).

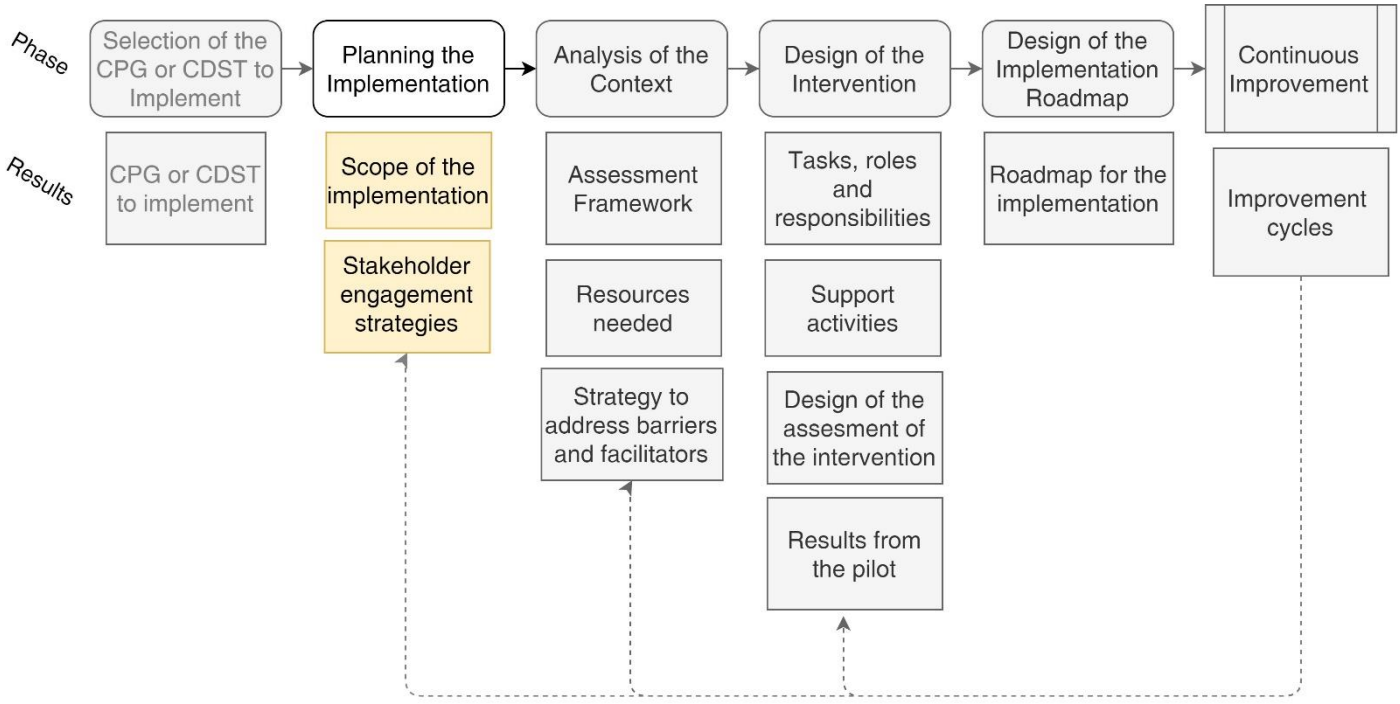
It is worth noting that these issues will be looked into in detail during the implementation process. Nonetheless, taking into account the information related to the implementation that has already been pointed at during the development, adoption or adaptation, can help the user to approach the implementation in a more efficient way (e.g. by having some barriers already identified) or save time and other resources, by rejecting a GPC or CDST whose implementation is not viable in the context(s) that the ERN is considering.

Results of this phase

CPG or CDST to implement

The recommendation(s) from a CPG, Clinical Consensus Statement, a Diagnostic, Monitoring and Therapeutic Pathways, an Evidence-based Protocols, Do's and Don't's Factsheets for Diseases or a set of Quality Measures to be implemented is identified and has been reviewed by the implementation working group.

6.2 | Planning the Implementation



Once the CPG or CDST to implement has been selected, the planning of the implementation begins. The first step of this phase is the constitution of the implementation working group. After this, the scope of the implementation will be defined and the identification and engagement of the stakeholders will start.

6.2.1 | Definition of the scope of the implementation

The definition of the scope provides a more accurate sense of what the actual context and setting for the implementation will be. It is worth noticing that it is likely that the CPG or CDST to be implemented provides some information on the scope, which should be regarded carefully and respected in order to guarantee that the implementation is done according to the evidence on which

the CPG or CDST is based.

At this point, the working group should review the relevant information regarding implementation already identified the development of the document, such as the considerations for implementation of the CPGs, or, if the CDST or CPG has been adopted or adapted, the information related to acceptability and applicability gathered during the adoption or adaptation.

The aspects that should be addressed in order to define the scope are the following:

Identification of the target patients included in the intervention: The implementation working group defines the inclusion and exclusion criteria for the target population so as to ensure it is consistent with the current practice and purpose of the implementation.

Definition of the care areas and levels involved: Which care areas (e.g. paediatrics, social care, cardiology) and care levels (e.g. primary care, hospital care, social care) and the professional profiles that will be involved in the interventions. These professionals will constitute the implementation teams, which will work co-ordinately in the interventions and are defined during phase four of the implementation process.

The level of involvement will not be the same for all the profiles. Some professionals will be required to act proactively, when certain activities of the interventions are led from or performed at their care level, e.g. a certain surgical procedure or a follow-up consultation, and others will act reactively, when their participation in certain activities of the interventions are subject to being activated by others, e.g., consultancy.

Geographical areas involved: Where the CPG and CDST will be implemented. These areas may be located in different regions or countries.

6.2.2 / Stakeholder engagement

A stakeholder is an individual, group and/or organization with a vested interest in the decision to implement a CPG or CDST [10]. Stakeholders include all those individuals or groups who will be directly or indirectly affected by the implementation, or who can directly or indirectly have an impact on the implementation[6]. They can be patients, users, healthcare professionals, managers, social care professionals, educators or policymakers.

Involving stakeholders at early stages of the process is crucial because it [3]:

- ✓ Helps create awareness
- ✓ Generates buy-in
- ✓ Identifies and acknowledges any resistance at an early stage
- ✓ Aids in the analysis of the context

6.2.2.1 | Stakeholder Analysis

Through this analysis, the working group can identify and generate information about stakeholders in order understand their behaviour, plans, relationships and interests. This knowledge can help the implementation working group to determine the support, resources and influences that the stakeholder can bring, to bear and determine how best to engage them [6]].

Some considerations regarding the identification and engagement of stakeholders [6]:

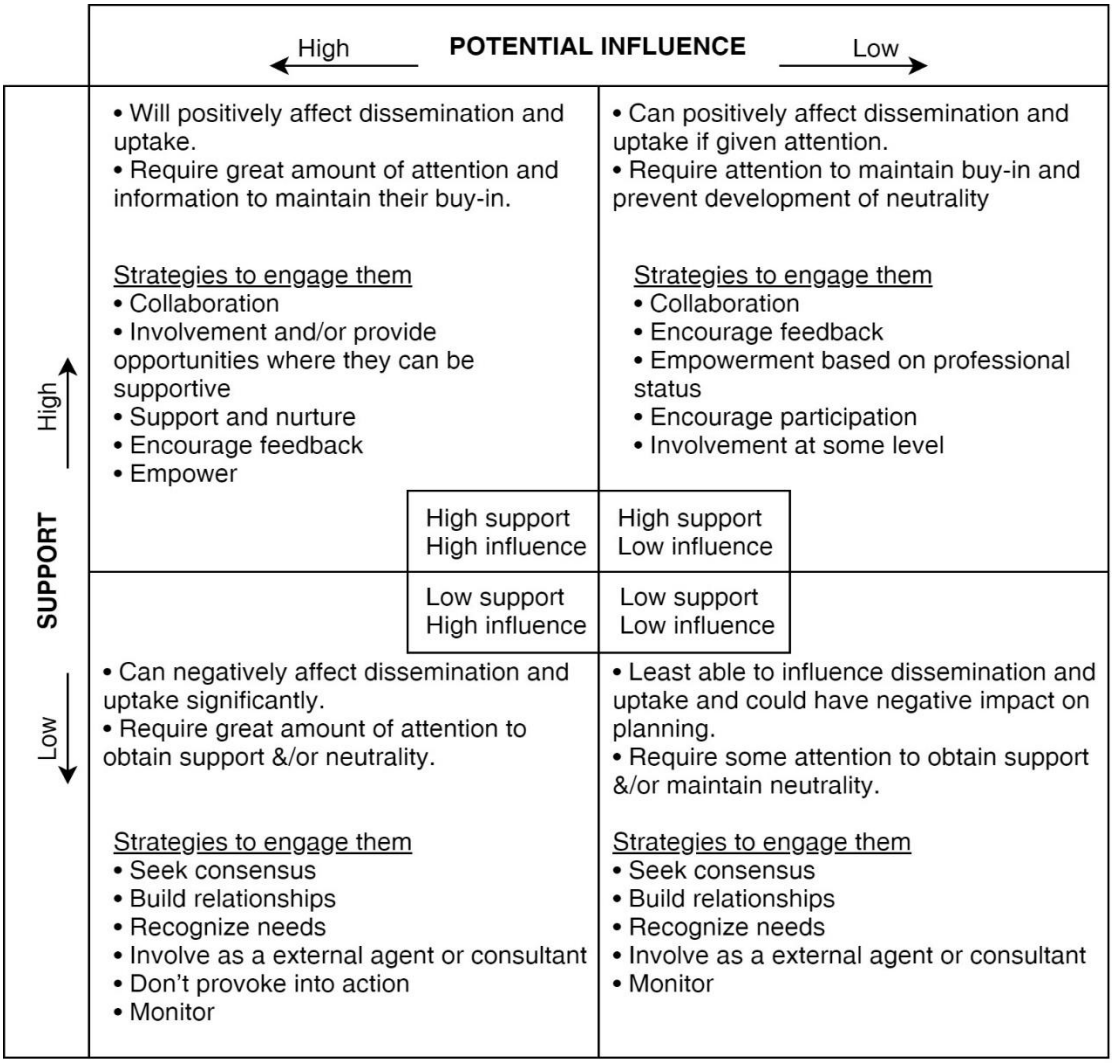
- ✓ Having a clear idea of the components of the implementation and being familiar with the related

issues can help in identifying an initial list of stakeholders. This initial list can help the working group to identify more stakeholders, through a snowball technique.

- ✓ Including a variety of care professionals involved or affected by the intervention (e.g. nurses, physicians, social care workers).
- ✓ Other key stakeholders to consider are management professionals and other care professionals.
- ✓ Certain stakeholders may be more involved or critical at specific times during the implementation process. For example, senior management are important in the initial stage to set the scope that are consistent with organisational strategy, front-line employees must be involved where there are changes which directly affect their work, i.e. where they may know best where, what and how to change [11].

The analysis and engagement of the stakeholder should be done in the planning phase of the implementation process, but it can also be revisited throughout the implementation process and after full implementation has been achieved. The analysis should focus on determining their level of engagement and support concerning the implementation. Based on the results of this analysis, the engagement strategies can be placed. In Figure 3, a framework to classify stakeholders according to their influence and potential support is proposed, as well as the actions that could be useful to engage them (adopted from Registered Nurses' Association of Ontario (RNAO) Toolkit [6]):

Figure 3. Strategies to Engage Stakeholders



Results of this phase

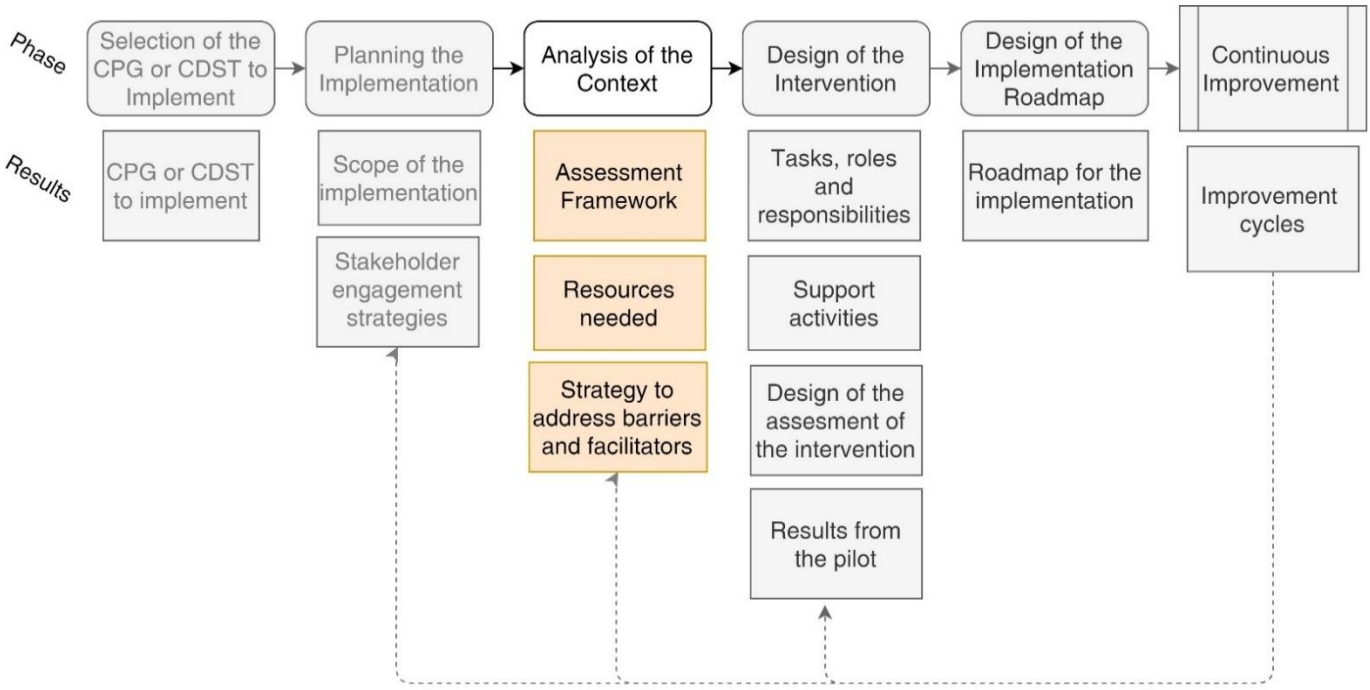
Scope of the implementation

The extent of the implementation including the target patients, the profile of the professionals and the care levels involved in the interventions, and the geographical area covered have been stablished.

Stakeholder engagement strategies

The stakeholders of the implementation are identified, classified according to their potential influence in the development of the implementation and their support and strategies to engage them.

6.3 | Analysis of the Context



It is important to review the local environment considering structures, people, systems, internal and external influences. Given that the context of the ERN has been previously analysed in the elaboration of CPG or CDST, that may be a starting point on the assessment of the current situation and determine what resources are necessary for the implementation activity. Knowing this, subsequently, barriers and facilitators to take the implementation forward should be identified and tackled.

6.3.1 | Baseline assessment in relation to the CPG or CDST

The baseline assessment constitutes a gap analysis comparing the current situation with that recommended in the CPG or CDST that is going to be implemented. That is, explicitly identify those resources currently available to carry out the implementation and those that will need to be allocated, how the processes are developed and identify those actions to carry out (what are the available resources vs. what resources are needed, how practice is being done vs. how practice should be done, etc.). The baseline assessment is, therefore, an analytical framework within which to develop the implementation. If this is not established, subsequent monitoring, evaluation and changes resulting from the implementation may lack reliability.

There are two key aspects to consider when conducting a baseline assessment:

1. **It should be carried out early in the implementation process**. In this way, it is possible to explicitly observe and quantify the resources required, and project the organisational change implications.

2. **It should be pragmatic and based on an assessment framework.** This framework must be robust enough, that is, that gives to implementation working group a useful way

to conceptualise what they want to measure and adequately covers every domain of concern, to be maintained throughout the following phases of the implementation activity.

The National Institute for Health and Care Excellence provides templates and tools that can assist the implementation working group in developing the baseline assessment [11].

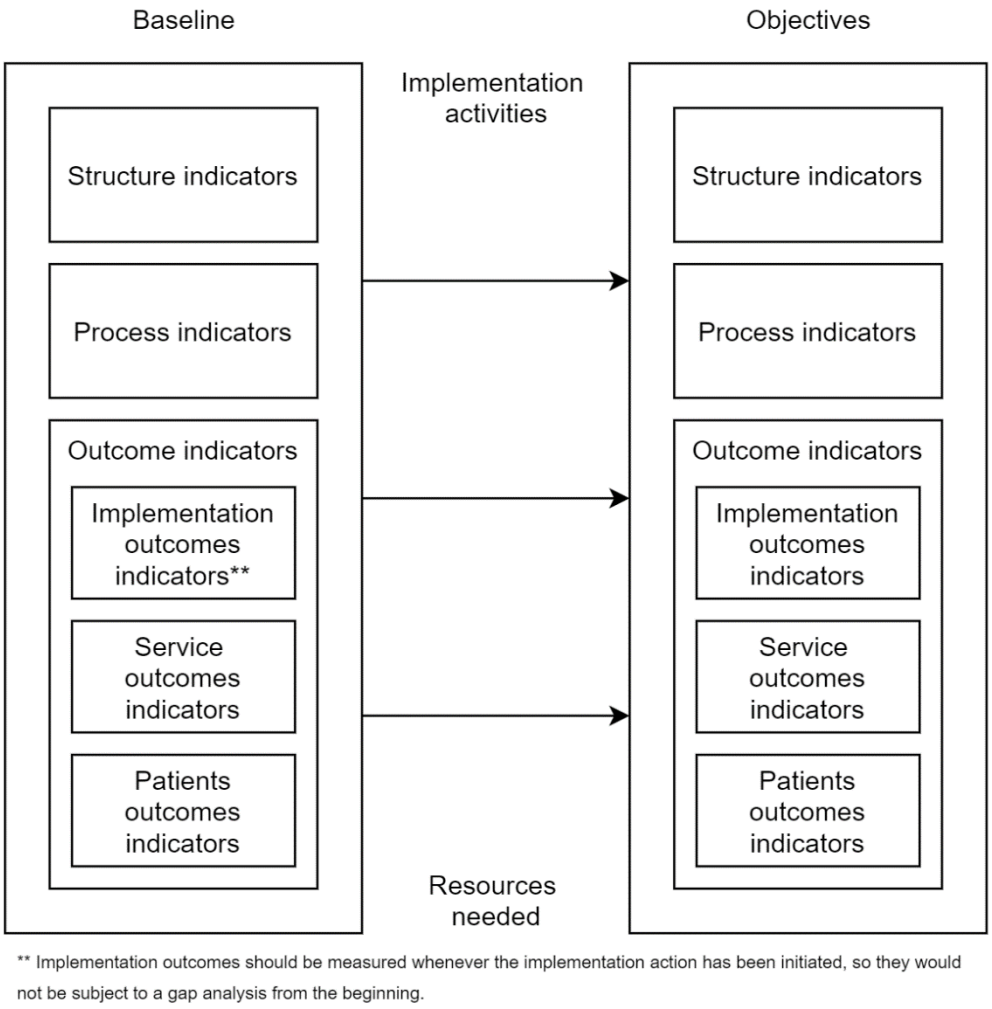
6.3.1.1 | Design of the Assessment Framework

As indicated previously, in order to complete the evaluation framework, the implementation working group need to describe the implementation context using a pragmatic method that will be used initially within the baseline assessment phase and will be the basis for the implementation planning, monitoring and subsequent full deployment.

In the present handbook we suggest an approach that can accommodate the complexity of the multiple dimensions of an implementation initiative but is simple to operate. The Donabedian model of Structure, Process and Outcome (SPO) provides an evaluation framework that supports systematic enquiry into health services [12, 13].

Figure 4 provides an outline of the assessment framework for the baseline assessment and the next steps throughout the implementation, as well as the interactions between the components and indicators.

Figure 4. Assessment Framework



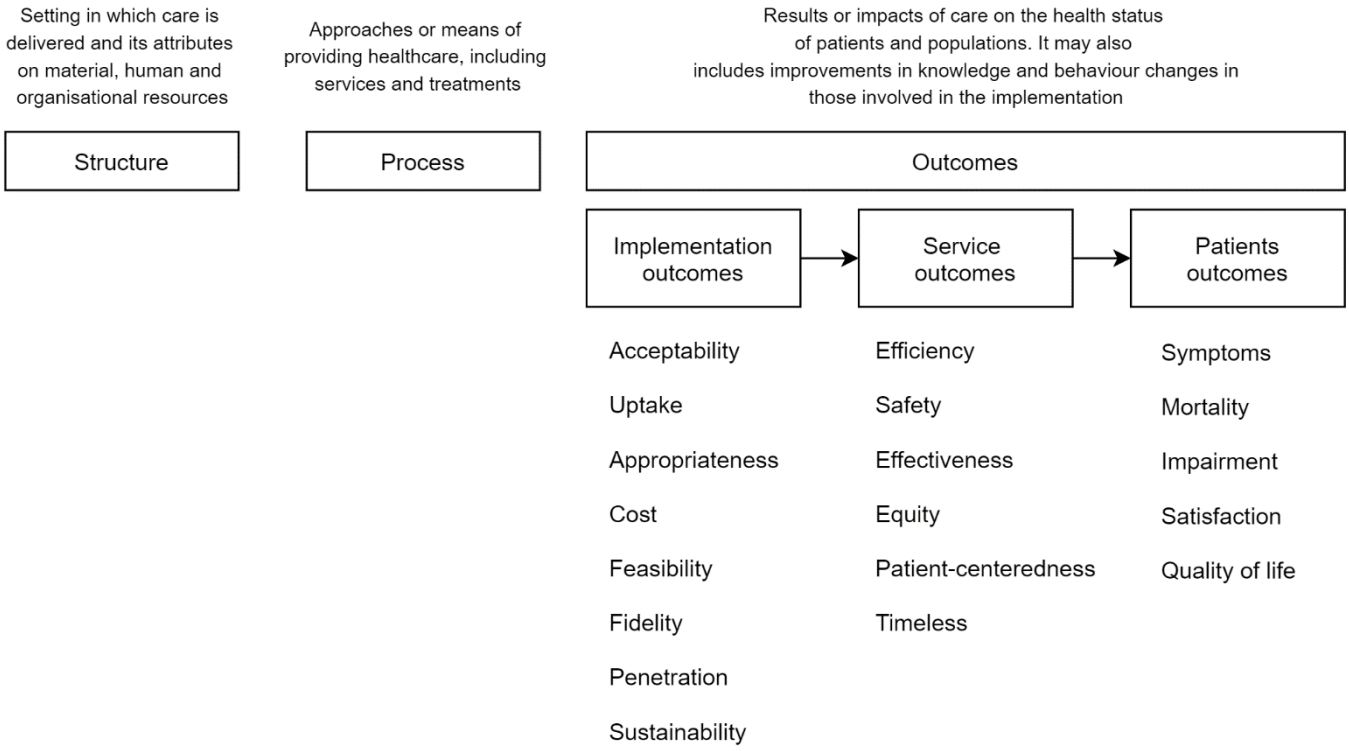
This model, traditionally used for evaluating quality of care, is consistent with the implementation in the sense that the improvement of health care quality is the expected result of evidence-based practice [14]. Donabedian divides the healthcare into three components (structure, process and outcomes), a construct whereby each component is influenced by the previous, making the components interdependent [15-17]. Within the framework describes the three components as follows:

- ✓ Structure: Refers to the setting in which care is delivered and its attributes on material resources, human resources, and organisational structure. For example, how many healthcare professionals trained in a proper technique are available? Is the necessary health technology available within the implementation setting? Is the setting equipped with the means to develop training materials on the CPG or CDST? Can the information systems collect the information to monitor the implementation activity?
- ✓ Process: Refers to the approaches or means of providing health care, which includes the services and treatments the patients receive. Examples of process indicators are the number of meetings required with the teams that are to pilot the change, number of professionals who need to participate in the meetings, number of professionals enrolled in training activities, etc.

- ✓ Outcome: Refers to the result or impact of care on the health status of patients and populations. It may also involve improvements in patient's knowledge & behaviour and degree of patient satisfaction.
    - *Implementation outcomes* correspond specifically to the activities carried out to implement the CPG or CDST. There are eight implementation outcomes (acceptability, uptake, appropriateness, cost, feasibility, fidelity penetration and sustainability), the definition of each of them is detailed in Annex I. They should be measured whenever the implementation action has been initiated as they are directly related to it. A more detailed description on the types of implementation outcomes and how to evaluate them is provided in the assessment of implementation section.
    - *Service outcomes* can be derived from the six healthcare quality improvement aims that determine that healthcare should be safe, effective, patient-centred, timely, efficient, and equitable. In this case, indicators can be developed to address each of these levels, so that the impact of implementation can be described on the different dimensions of the health system. An example of a service outcome indicator related to the safety domain would be the ratio of nosocomial infections over a period for a target population.
    - *Patient outcomes* aim to describe the health status of patients. Usually, they seem to represent the "gold standard" in measuring the effect of an intervention (patient satisfaction, mortality, impairment, mobility, and others related to global quality of life such as the consideration of personal image, doing usual activities, etc.). One of the important issues of patient outcomes is their comparability, especially in the case of rare diseases. Risk-adjustment methods are mathematical models that correct for differing characteristics within a population, such as patient health status. For example, the number of readmissions after 30 days after a concrete surgical intervention.

The diagram below presents the taxonomy of implementation outcomes, service outcomes and patient outcomes. This is followed by further details (Figure 5):

Figure 5. Implementation context components to consider within the Baseline Assessment



Handbook #10: Methodology for the elaboration of Quality Measures for rare diseases provides more detailed information on the characteristics and steps in the development of measures, which will be useful for implementation.

6.3.1.2 | Key characteristics of the measures

Indicators that are developed within the baseline assessment must meet a series of quality characteristics, these are elements that must be taken into account when preparing measures that can be used, both in the initial context analysis and in the future evaluation of implementation actions. This is applicable for all types of indicators, whether to describe the structure, processes or outcomes. A brief list of recommendations is provided below [15]:

- ✓ Measures or indicators should be standardised, which means that, if there are multiple organisations or services involved in the implementation, information is due to collect and report the same kind of data in the same way.
- ✓ If appropriate, the data collected should be adjusted for external factors to obtain accurate measurements that reflect the situation, isolating it from interfering components; such factors include age, education, gender, income, and health status of a CPG or CDST target population. That is, measures which make possible to compare those phenomena that are comparable.
- ✓ Data should be available for the whole setting or organisation that is being analysed for the implementation.

- ✓ Data that populates indicators should be available in time when it is most needed by the implementation group and stakeholders.
- ✓ The indicators measured should address those elements that are of concern or may have an impact for developing the implementation activities.
- ✓ The measures should be adequately tested to ensure that they consistently and accurately reflect the organisation or setting information needed for the analysis.
- ✓ It would be desirable that the organisation have experience with colleting and reporting these measures, so that the working group can be confident that the measure reflects actual performance and not shortcomings in information systems.
- ✓ The measures should not be scheduled to be removed from a measurement data set before the implementation activity is completed, even if it is data or averages that are only taken at the beginning of the implementation process
- ✓ The measures collected by these indicators should be evaluated as either higher or lower than others or whether they are close or no from a target value, in contrast to just being descriptive. For example, a complication rate is an evaluable measure because it is known that a lower rate is always better; in contrast, the number of a concrete procedures in a month, without having threshold or objective values is not evaluable because it do not necessarily indicates whether a higher rate or a lower rate is desirable.
- ✓ The measures should be able to reveal significant differences among implementation context before the implementation and after.

6.3.1.3 | Data sources and methods for data collection

There are several types of data collection platforms that can be useful to obtain information to populate the baseline assessment indicators, each one is developed with specific objectives and has its own advantages and disadvantages. They are reviewed below with reference to their particular use [18, 19]. The different existing data sources are described in detail in the Handbook #10: Methodology for the elaboration of Quality Measures for rare diseases.

6.3.2 | Define the resources needed

Ideally, the decision of whether and how to implement a CPG or CDST should take into consideration estimates of the costs and benefits of the dissemination and implementation strategy, and the costs and benefits of the resulting changes in patient care [20].

Implementation working group can use a framework to guide their decisions about how best to use the limited resources. The steps to follow when planning resources for an implementation activity are to identify the use of resources, to measure or quantify them and to value or assign a monetary cost [21].

6.3.2.1 | Identification of relevant resources

This phase consists of identifying those types of resources that should be included in the implementation plan, trying to obtain a comprehensive list, regardless of their magnitude and subsequent degree of difficulty in measuring.

The baseline assessment provides detailed information on the resources available within the implementation setting. This is of great interest when defining the specific actions to implement

the CPG or CDST. In this way, Donabedian SPO model helps to identify and classify the nature of the resources needed [12].

Thus, structure and process indicators are useful to determine the need for structure (including material, human resources, systems to collect information on the implementation process, financing or means to incorporate new elements or health technologies required by the evidence-based practice to be implemented, etc.) and actions (training, dissemination of educational materials, feedback and audit, reminders, etc.) within the implementation activity. As an example, the implementation working group should identify whether trained professionals are available in the setting to develop the practice according to the CPG or CDST.

The nature of the resources must be taken into account to assess whether they need to be purchased or different distribution of existing resources is required. In other words, the opportunity cost must be considered, since by allocating resources for the implementation objective, other activities would not be done. For example, when a professional attends a training, he/she will not be doing his/her usual practice.

6.3.2.2 | Quantification of resources identified

Once the structure resources have been identified, the next step is to estimate the amount that could be required for conducting the implementation actions. In order to fulfil this, resources identified in the previous step must be expressed in natural units. For example, number of health professionals who are due to participate in training or number of units of a required health technology.

The indicators raised from the baseline assessment may provide an idea of the units/times for each resource needed. This value will be determined by the difference between the current level of existing resources and the objective value that is desirable to develop the implementation plan. For example, implementation working group should stablish the number of professionals that must attend specific training in order to adjust their practice to the CPG or CDST.

6.3.2.3 | Valuation of the required resources

Those resources that were previously identified and quantified must be attributed a monetary cost, multiplying the cost of the resource by the number of units/times it is expected to be used. In general, the unit costs are usually listed within official publications, public prices or analytical accounting data.

In order to quantify and value these resources, if conducted within the CPG or CDST, cost analysis or economic evaluations may serve as valid estimate of the specific resources required and their valuation in monetary units. In general, if the intention to implement a CPG or CDST is established from the beginning of its development, the final recommendations or actions should be accompanied by useful information to plan its implementation from an economic/financial point of view [22]. An example of this may be the training costs associated with the use of a new health technology, which are often included in economic evaluations.

6.3.3 | Identification of Barriers and Facilitators

Barriers and facilitators can be defined as those factors that can hinder or ease, totally or partially, the implementation of the CPG or CDST [23].

The identification and understanding of the existing facilitators can help the implementation working group to enhance them, thus strengthening the implementation process, and the

identification and understanding of the existing barriers can help the implementation working group to design strategies to timely tackle them. It is important to consider that some barriers can be significant enough to make implementation not viable. For this reason, a thorough analysis of the potential barriers and facilitators should be put in place at this early stage.

6.3.3.1 | Methods for identifying and analysing barriers and facilitators

As mentioned at the beginning of this handbook, some barriers and facilitators may have been already identified during the development, adoption or adaptation of the CPG or the CDST. Although this information should be certainly reviewed and taken into account as a possible starting point for this analysis, the working group should approach the identification of barriers and facilitators in a systematic way and being aware of the fact that it requires a thorough analysis of the context in which the implementation will take place.

Conducting a survey to identify barriers and facilitators or to analyse them can be an efficient technique, but it may have to be complemented with other research techniques or it may not be the most suitable one. There are alternatives to the survey, such as different individual and groups techniques. A list with some of the most frequently used can be found in Annex II: Research techniques to explore the context.

In some cases, it could be useful to use a combination of different techniques, e.g. a survey to explore a broad subject and a focus group to delve into specific issues identified in the survey [23].

The selection of the most suitable technique or techniques requires specialised knowledge and expertise and its complexity may vary depending on the CPG or CDST that will be implemented (i.e., implementing a complete CPG may entail more interventions and potentially involve more care levels and professionals than the implementation of a recommendation). The resources needed should also be taken into account (e.g. for conducting the research or analysing the data). The working group should carefully explore each option and consult a methodologist outside the group if necessary.

6.3.3.2 | Considerations regarding the identification of barriers and facilitators

Framework of analysis: If the subject of the implementation is a set of recommendations (more than one) from a CPG or a CDST, the analysis of the barriers and facilitators related to the recommendations should be addressed separately, unless the implementation working group identifies there are enough common elements that justify addressing them together, i.e., tackling the analysis of barriers and facilitators in a single process.

Prioritisation: The areas or activities related to the implementation where more considerable need for improvement has been observed in the baseline assessment should be prioritised to be analysed in search for barriers and facilitators.

Levels of analysis: The analysis should be consistent with the levels included in the baseline analysis and generally consider the following types of factors:

- ✓ Evidence-related factors: related to the evidence that supports the recommendation or CDST.
- ✓ Target Audience-related factors: related to the stakeholders and other individuals involved directly or indirectly in the implementation.
- ✓ Resource-related factors: related to the resources needed for the implementation, including

human, financial and other.

- ✓ Organization –related factors: other factors related to the setting where the implementation will take place, including leadership or other innovation projects, strategies or policies that may be related to the interventions proposed in the implementation in some way.

If different contexts of care are involved (e.g. different regions or countries), the levels of analysis and possible strategies deployed should be considered at each setting

Follow-up: It is advisable to monitor the development of the barriers and facilitators identified at this phase during the implementation and continue with the analysis at other points of the implementation, e.g., after the piloting (see Pilot section) and full deployment [24, 25].

6.3.3.3 | Potential strategies

The strategies to foster the facilitators and tackle the barriers identified should be specific and tailored to the context and the intervention. Nonetheless, there are some potential strategies that can guide the implementation working group in devising and customizing the solutions to the particularities of the implementation context. These strategies can be consulted in Annex III. Potential Strategies to Maximise Facilitators and Minimise Barriers, adapted from Registered Nurses' Association of Ontario (2012) [6].

Results of this phase

Assessment Framework

A pragmatic method that will be used initially within the baseline assessment phase and will be the basis for the implementation monitoring and subsequent full deployment, including structure, process and outcome indicators.

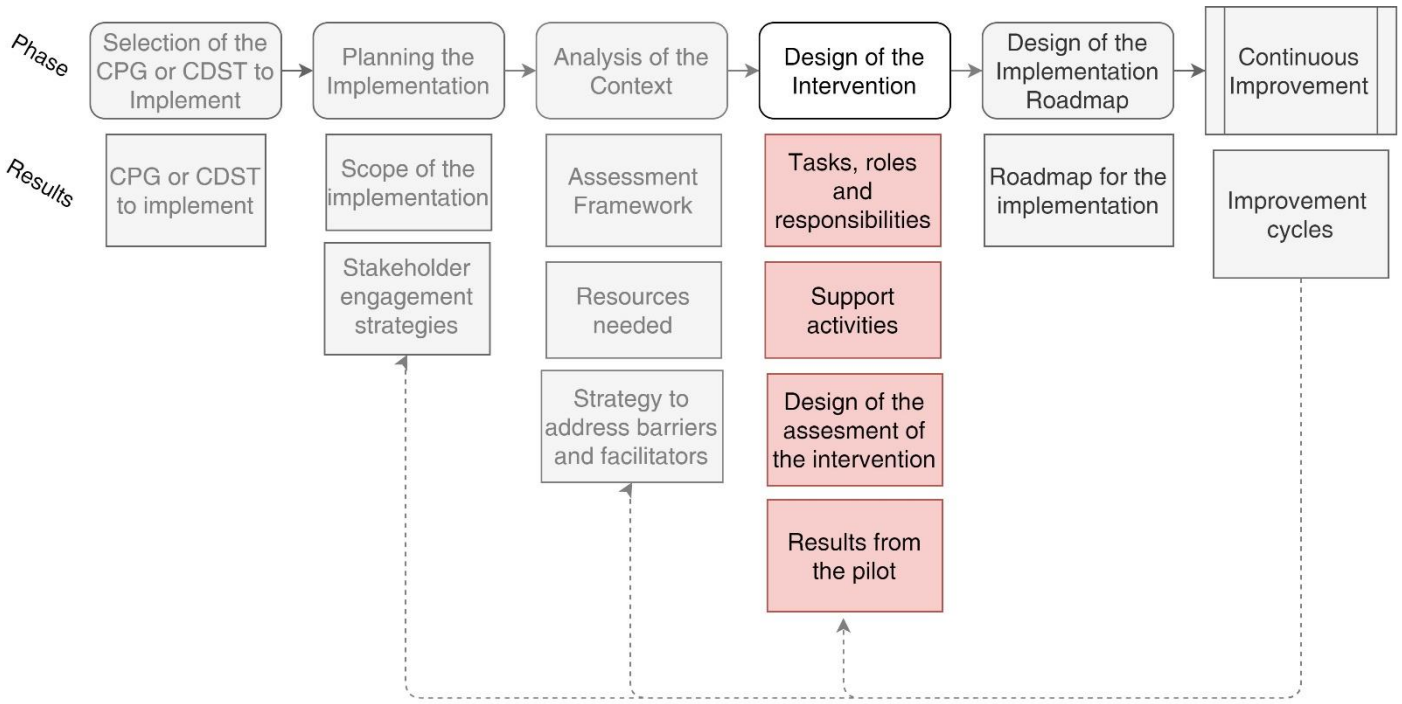
Resources needed

The structure (including material, human resources, systems to collect information on the implementation process, financing or means to incorporate new elements or health technologies required by the evidence-based practice to be implemented, etc.) and actions (training, dissemination of educational materials, feedback and audit, reminders, etc.) required for the implementation are identified and quantified.

Strategy to address barriers and facilitators

The factors that could hinder (barriers) or ease (facilitators) are identified, analysed and strategies to tackle the existing barriers and foster facilitators are in place.

6.4 | Design of the Interventions



In order to design the specific interventions that will be implemented in the selected care setting, the implementation working group has to define certain aspects related to the operationalisation of the implementation, i.e., the milestones, tasks, roles and responsibilities, the support activities and the assessment strategy.

6.4.1 | Tasks, roles and responsibilities of the interventions

The tasks required to implement the interventions are detailed by the implementation working group, including the sequence of actions, the main responsible for the task and the other roles involved.

At this point, the professionals that will be involved in the interventions are organised into teams called implementation teams. As explained in the definition of the scope section, the implementation teams are groups of professionals that act co-ordinately to deliver intervention. The roles and responsibilities should be clearly defined within the team. It should be taken into account that the roles are defined with regards to the implementation can be different from the profile or position of the professional filling that role. The configuration of the teams that take part in the implementation is linked to the interventions and type of CPG or CDST that is going to be implemented (e.g. depending on the care levels involved).

6.4.1.1 | Opinion leaders and physician champions

At this point, the implementation working group should consider including local opinion leaders and champions, if they have not already been included. Opinion leaders can help the implementation working group to meet with the key staff at each organization and act as 'early adopters' [7, 8].

Champions are likely to be more driven by the improvement to which the new CPG or CDST will lead, thus being eager to promote adherence to it [26].

6.4.2 / Support Activities

The support activities will be deployed together with the implementation in order to make them possible and foster the sustainability of the intervention. They can help overcome some of the barriers identified during the analysis of the context as well as cover the gaps identified during the baseline analysis.

Training activities to cover the training needs identified during the analysis of the context. Many barriers to implementation are related to the knowledge, skills and abilities of the potential user of the CPG or CDST [9]. Training activities can be aimed at providing knowledge on a specific technique, skill or process. These activities should be interactive [27, 28] and e-learning should be considered when possible and deemed relevant by the implementation working group [29]. Possible options for training activities are educational meetings and educational outreach visits [30], audit and feedback [31-34], workshops and small-group interactive sessions [35, 36].

Dissemination and communication activities to ensure all stakeholders, participants and other care professionals of the healthcare setting where the implementation takes place are informed of the implementation. These types of activities have been identified as central for the success of the implementation [30, 33, 37].

The communication activities should start early in the design of the interventions and should communicate on a regular basis on the development of the implementation and on the next steps of the implementation. Furthermore, it is recommended that information on the recommendation or CDST that is being implemented, as well as on the evidence that supports it, is provided.

An internal communication plan should be deployed in order to keep the professionals involved directly in the implementation informed of the development and any deviations from initial plan. This plan should include effective means of communication like email and periodic follow-up informative sessions.

6.4.3 / Design of the Assessment for the Implementation

Again, the use of the Donabedian SPO model is suggested given that it allows us to use different evaluation methods for each component (structure, processes and outcomes). The National Institute for Health and Care Excellence provides templates and tools that can assist the implementation working group when assessing the implementation actions [38].

6.4.3.1 | Structure evaluation

First of all, the evaluation of the implementation process will revisit those indicators that were measured as part of the baseline assessment and determine if the implementation process has reached the objectives related to the provision of materials, trained staff and other structural resources. These structural elements are important in the first steps of the implementation, when the processes and results have not yet been launched, these indicators allow us to keep track of progress.

6.4.3.2 | Process evaluation

Process evaluations can provide valuable insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised. Process

evaluations aim to provide the more detailed understanding needed to inform practice. They examine the processes through which a group of interventions and actions within the implementation generate outcomes. There are three essential dimensions which that can be observed when evaluating a process [39]:

- ✓ Fidelity: Was the implementation activity going as intended? For example, all the coordination meetings foreseen in the implementation plan are taking place; all the training activities are being carried out, all the foreseen data are being collected from the information systems.
- ✓ Reach: Did the implementation activity reach its target population? For example, those professionals or staff profiles that should adapt their practice according to the intervention are properly informed of the actions to be taken.
- ✓ Dose. Has participation in implementation activities been of the expected intensity? For example, healthcare professionals that attend totally/partially to training sessions provided.

To conduct process evaluations on how well CPG or CDST is implemented, data collected in the baseline assessment will be useful to observe how the processes develop and what elements have changed with the implementation.

In order to proceed with process evaluation, the following points should be considered [39-41]:

- ✓ Consider data monitoring at multiple time points to capture changes to the intervention over time.
- ✓ It may be possible to analyse information using both qualitative and quantitative methods:
  - Use quantitative methods to quantify key process variables and allow testing of pre-hypothesised mechanisms of impact.
  - Use qualitative methods to capture emerging changes in implementation, experiences when carrying out the activities and unanticipated or complex causal pathways to generate new theory.
  - It is also possible to collect information through direct observation during the evaluation of the process. These new data can be incorporated in subsequent phases of the implementation process (continuous improvement). It may be important to collect such data while the implementation activity is taking place, rather than at the end when recall will be less accurate.
  - Try to avoid that participants change their behaviour because they are being observed.

6.4.3.3 | Outcome evaluation

Implementation outcomes evaluation

Implementation outcomes give us a description on the implementation action success and may serve as indicators on the necessary preconditions for attaining subsequent changes in patient or service outcomes. This reasoning assumes that an intervention or treatment will not be effective if it is not implemented well. Additionally, the working group should asses and explain whether there are interrelationships between implementation outcomes in order to develop a coherent strategy for its measurement. For example, if an intervention is costly will likely have a slower uptake [42].

The implementation outcomes and their proper ways of measurement are listed in

Table 1 [3, 42]:

Table 1. Implementation outcomes

Implementation outcomes[¥]	When it is important to measure	Methodologies for measurement
Acceptability	Early for adoption, ongoing for penetration, late for sustainability, Ratings of acceptability may be different when taken, for example, pre-implementation and later throughout various stages of implementation	Surveys, qualitative or semi-structured interviews, administrative data
Uptake	Early to mid	Administrative data, observation, qualitative or semi-structured interviews, surveys
Appropriateness	Early (prior to adoption)	Administrative data, observation, qualitative or semi-structured interviews, surveys
Cost (incremental or implementation cost)	Early for adoption and feasibility, mid for penetration and late for sustainability	Survey, Administrative data
Feasibility	Early (during implementation adoption)	Survey, Administrative data
Fidelity	Early to mid	Observation, checklist, self-report
Penetration	Mid to late	Case audit, checklist
Sustainability	Late	Case audit, semi-structured interviews, questionnaires, checklists

[¥]Definitions provided in Annex I

Service outcomes evaluation

Service outcomes are those results or impacts of the implementation activity that have a specific relationship with any of the six aims for healthcare, mentioned in previous sections of this handbook.

Usually, the vast majority of measures address effectiveness and safety, a smaller number examine timeliness and patient-centeredness, and very few assess the efficiency or equity of care. There are different strategies to evaluate service outcomes, according to the measure or indicator that is being evaluated. For example, quantitative or qualitative methodologies, surveys, etc. The use of systematically collected data sources is recommended as the most efficient way to obtain information on the evolution of indicators related to every domain.

Patient outcomes evaluation

Patient outcomes evaluation measures implementation effects in the CPG or CDST target population by assessing the progress in the outcomes or outcome objectives that the program aims to achieve. Comparative Effectiveness Research (CER) could be considered as a useful strategy for evaluating an intervention that has been implemented in practice within a context.

CER compares the benefits and/or harms of health interventions in real-world settings in which care is provided to patients under routine clinical practice conditions. CER aims to improve health outcomes through the generation of evidence about which interventions are most effective for which patients under which conditions. CER can include pragmatic trials or observational studies (e.g., cohort, case–control and cross-sectional) [43, 44].

Specific information on study designs and their characteristics is included in the Annex IV.

6.4.4 / Pilot

The pilot is a small-scale version or trial run, done in preparation for the major study [45]. Ideally, it should be done in a small area within the geographical area previously defined, representative enough of the rest of the area for the purposes of the pilot. If there are different regional or national care context involved in the implementation, the intervention may be piloted in different small areas.

The reasons for piloting the intervention are numerous. It helps identify the weaknesses of the intervention, i.e., where it could fail, the points at which adherence to the intervention are not followed or the inappropriateness of certain procedures or tools because of their lack of usability, for example. It can also help refine the data entry and registration. In addition to this, the results and conclusions derived from the pilot, although preliminary and limited to the time span of the pilot, can contribute to support the intervention and maintain or increase buy-in from the stakeholders [46].

It is worth noting that piloting the intervention requires additional resources, mainly devoted to measuring the development of the pilot and to the testing of certain procedures or methods that may not be included in the final intervention, that should be considered during the definition of resources needed.

6.4.4.1 | Considerations for the pilot

When planning the pilot there are certain aspects that should be considered:

Time

The time dedicated to the pilot may vary depending on the intervention(s) complexity and may be subject to the availability of resources for the pilot and the urge to fully deploy the implementation.

The time needed to draw conclusions and make the necessary adjustments to the implementation should be added up to this time.

Assessment

Although the findings with regards to the uptake of the implementation and to the improvement of the quality of care intended that can be gathered in the assessment of the pilot may offer some information on the performance and results of the interventions, they should be treated with caution because of the limitations to the representativeness of these results that the small numbers and time span of the pilot pose [46].

This should not be regarded as an issue, because, as explained above, the pilot has specific objectives that do not completely coincide with those of the implementation. Therefore, the assessment will not be exactly the same. Together with the assessment of the interventions, previously explained, other issues should be explored during the pilot:

- ✓ Adequacy of means: Whether the means available for the intervention, e.g., the equipment, place, data entry tools, are actually usable and useful and the reasons for that motivate possible issues.
- ✓ Adherence to the intervention: Whether all the steps are completed in time and form and the reasons for possible deviations, such as acceptability of the intervention or complexity.
- ✓ Strong points and weaknesses of the intervention and the reasons behind them.

In other words, there are differences between the pilot and evaluation of implementation objectives. For example, in the pilot, more attention is paid to analyse whether the implementation plan is being carried out as planned (the structure and processes components are especially relevant, since they are expected to be triggers for outcomes). In the other hand, within the evaluation, structure and processes are observed, but attention is also paid to the effects that the plan produces among the implementation subjects or stakeholders (implementation outcomes), healthcare system or setting (service outcomes) and patients.

It should be considered that the results of the pilot may be related, to a certain extent, to the barriers and facilitators identified during the analysis of the context or to new barriers and facilitators that had gone unnoticed.

Qualitative group techniques and surveys, or a combination of both, are more suitable for exploring these issues during the pilot. In Annex II. Research techniques to explore the context can be found more information on the techniques available and resources to use them.

Results of this phase

Tasks, roles and responsibilities

The tasks of the interventions are detailed, including the sequence of actions, the main responsible for the task and the other roles involved. Professionals are organised in implementation teams.

Support activities

Training, dissemination, communication activities and other support activities needed for the implementation are designed and arranged.

Design of the assessment of the intervention

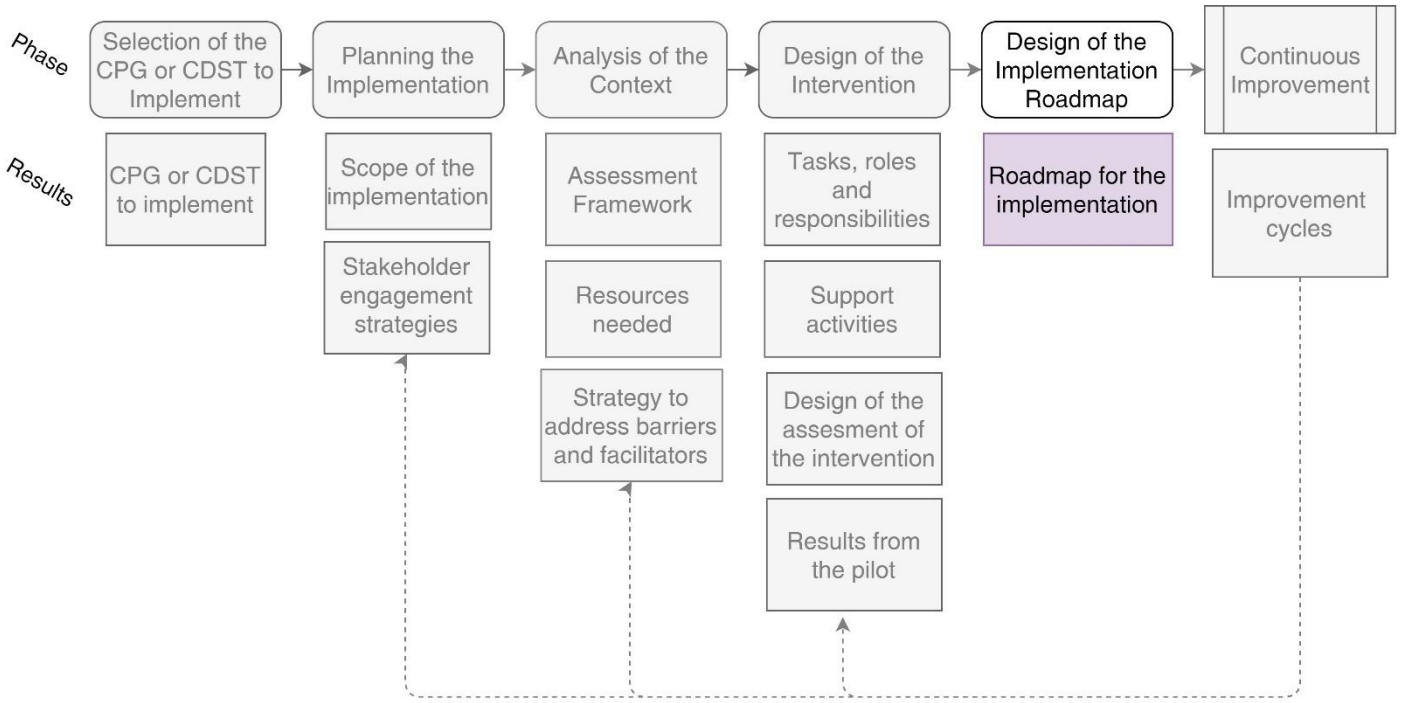
The assessment strategy to capture the effects of the implementation activities on the different stakeholders involved and their attitudes and impact on the healthcare system, and patients is designed.

Results from the pilot

The results from the small-scale test run of the implementation (pilot) are gathered and analysed to ascertain whether the resources are adequate, the adherence to the intervention and the strong points and weaknesses of it.

07.

DEVELOPMENT OF THE IMPLEMENTATION ROADMAP



The implementation roadmap is the document in which the rationale of the implementation, its objectives and the means to achieve it are clearly explained and depicted. It gathers the information developed throughout the whole implementation process in a clear way and presents it sequentially. It is the main reference document for the implementation working group to monitor the deployment of the implementation, as well as for the implementation teams to follow-up on it.

The use of a roadmap brings several benefits [3]:

- ✓ Provides coherence across complex tasks
- ✓ Helps distinguish between the outputs of the implementation (what is done) and the outcomes (the changes/ results that come out).
- ✓ Helps to keep focus on common goals within the teams.

7.1 | Components of the Implementation Roadmap

The implementation roadmap should include the following sections:

Background

- ✓ What motivates the change? What justifies the need for implementing these interventions?
- ✓ How is this need currently being addressed? What gaps are there? What needs to be improved?

Objectives

- ✓ What is the objective of the implementation? What outcomes have to be achieved?
- ✓ What specific changes are desired in the short-, medium- and long-term?

Activities (Outputs)

- ✓ What will be done to achieve the objectives? (types of activities)
- ✓ Who will be the target patients?
- ✓ Where will it be done?
- ✓ When and how often how will it be done?

It is desirable to include specific targets for numbers to be reached and frequency of activities, where possible.

The activities include the activities that make up the intervention(s), the support activities for the implementation and the assessment activities.

Resources (Inputs)

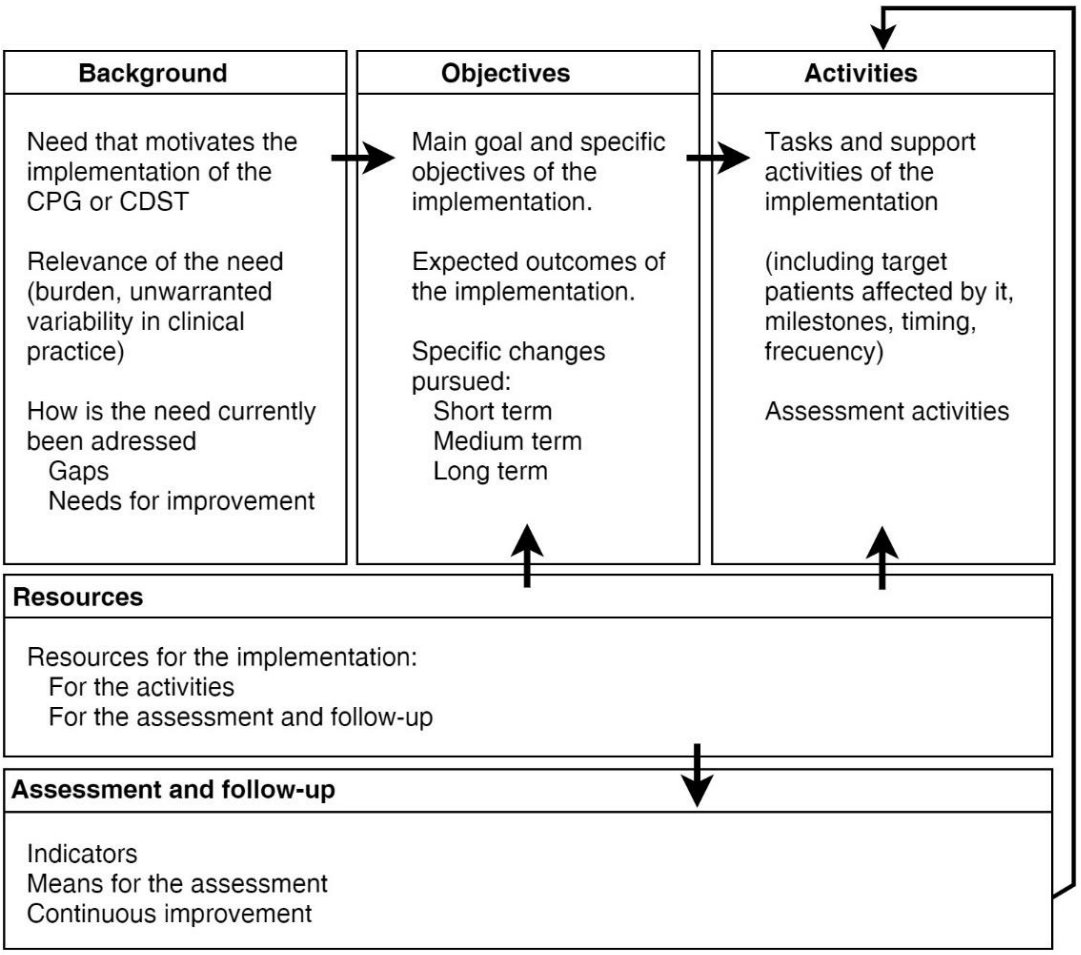
- ✓ What resources will be provided to perform the activities and the assessment and follow-up?

Assessment and follow-up

- ✓ This includes the specific indicators that will be used to monitor the achievement of the objectives.

The Implementation Roadmap can be a detailed document, but it should include a summarized version. The scheme showed in Figure 5 can be used as a reference to build the summarized version.

Figure 6. Implementation Roadmap



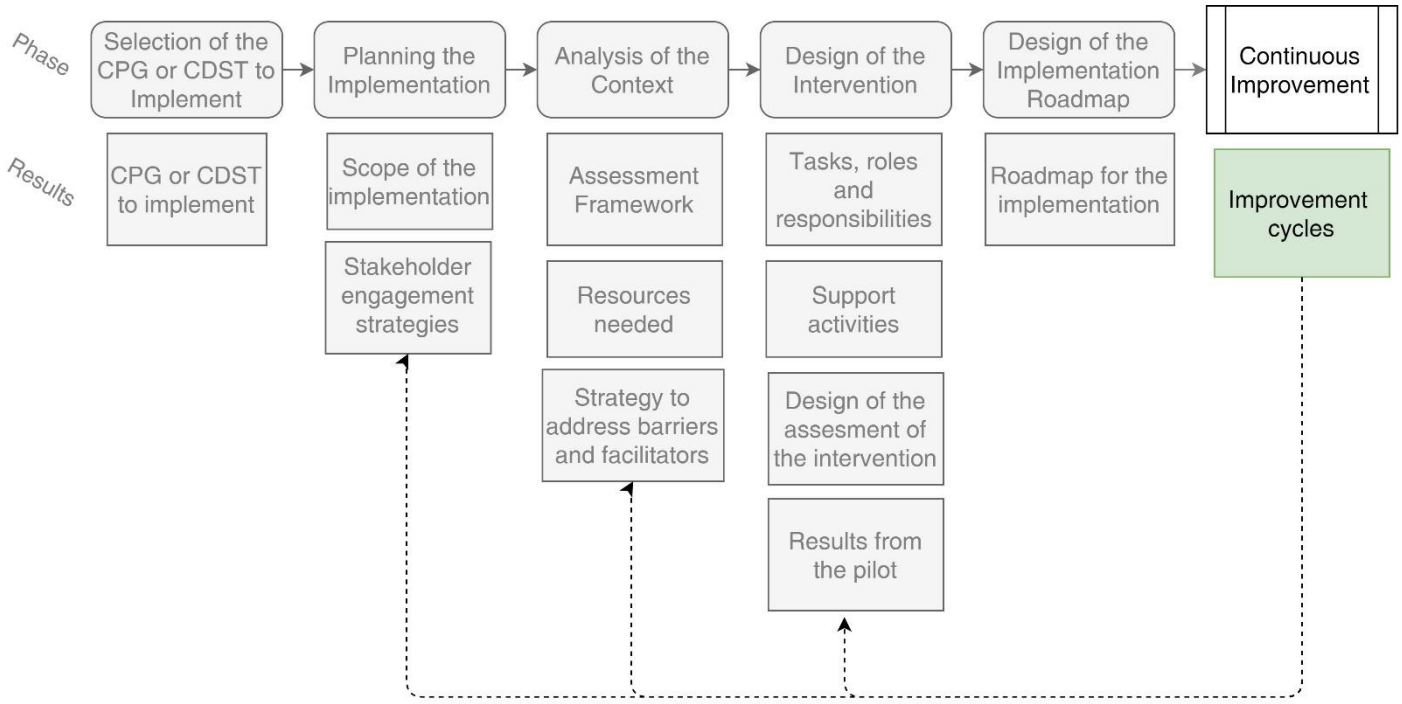
Results of this phase

Roadmap for the implementation

The main reference to monitor the advance of the evaluation, including the background, objectives (outcomes), activities (outputs) of the implementation as well as the resources in place and the assessment and follow-up mechanisms for the implementation.

08.

DESIGN OF THE CONTINUOUS IMPROVEMENT MECHANISM



Once the implementation has reached the whole area defined during the planning, full implementation has been reached. Since the implementation of a CPG or CDST is an iterative process, subject to frequent corrections and the identification of new activities to incorporate to the main strategy, a continuous improvement mechanism, including improvement cycles should be followed.

8.1 | Continuous Improvement theory

When planning any CPG or CDST implementation, it is essential to know what the goals are to achieve, how to measure changes produced in the long term and to be explicit about how the change will be tested. If a CPG or CDST is not being implemented as intended or is being implemented as intended but not producing desired outcomes, improvement cycles can be used to support continued

improvement until the whole change is implemented. A commonly used method is the Plan-Do-Study-Act (PDSA) cycle, a model that consists of a logical sequence of four repetitive steps for continuous improvement, specific activities and recommendations regarding every step are included below [14, 47-49]:

- ✓ Plan –the change to be tested or implemented
    - Define the objective, questions and predictions
    - Plan to answer the questions "Who?, What?, Where?, When?"
    - Plan data collection to answer these questions

      Defining both ultimate goals as well as incremental objectives that can be used to gauge short-term progress.
- ✓ Do – carry out the test or change
    - Carry out the plan
    - Collect the data
    - Begin analysis of the data

      It helps to think on this stage as a number of "mini-cycles" within the larger improvement cycle, in the sense that the working group is likely to go through multiple iterations of testing and refining before the specific changes add up to a real implementation of new practice.
- ✓ Study – based on the measurable outcomes agreed before starting out, collect data before and after the change and reflect on the impact of the implementation and what was learned.
    - Complete the analysis of the data
    - Compare data to predictions
    - Summarise what was learned

      Small-scale tests of the implementation activity allow for incremental modifications of implementation activities to fix problems.
- ✓ Act – plan the next change cycle or full implementation.
    - Plan the next cycle
    - Decide whether the change will be implemented

      It is important not to let the work go on too long without ongoing measurement in order to be sure that progress is being made towards achieving goals.

Overall, evaluations undertaken in this framework should be sufficiently flexible in terms of design and measurements and allow refinements, as required, to appropriately address the aims of the implementation activities.

In some cases, simultaneous cycles may occur when the changes are more complex, involving several departments. It is important to identify any interactions between simultaneous cycles.

8.2 | Revisit/ iterate on the Interventions: How to apply improvement cycles to a long-term implementation strategy

Substantial changes in the organisation cannot be implemented by a single change but by a whole series of changes. Such way of testing gets a dimension of repeated cyclical process, where each completed cycle represents the beginning of the next one. In this way the test turns into a life-long learning, because the organisation acquires new knowledge that can be applied, verified and

expanded in each subsequent cycle [47].

The final stage of the PDSA cycle involves adopting the intervention and evaluating it against the long term goals of the CPG or CDST implementation project. The PDSA framework includes three key questions to answer when a new cycle is beginning. This may help us to check how the implementation is taking place.

8.2.1 / Identifying possible deviations

1. What are we trying to accomplish?

Implementation working group need to set clear and focused goals with measurable targets. These goals require clinical leadership and should focus on conditions that cause concern, as well as on patients and professionals. It is advisable to assess whether these objectives are remaining in force and whether the activities that are being carried out lead to the achievement of those objectives.

8.2.2 / Determine whether to conduct a new set of analysis or using new indicators

2. How will we know if the change is an improvement? What measures of success will we use?

In order to answer this question, you will need to measure outcomes. This should affect the measures and demonstrate over time whether the change has led to sustainable improvement. Measures in this model are tools for learning and demonstrating improvement, not only for assessment. In every complete cycle measures and indicators should be reviewed to assess whether they are valid and meet the reporting objectives.

8.2.3 / Sustain and spread the improvements over time

3. What changes can we make that will result in improvement?

A change does not necessarily lead to improvement, but every improvement requires sustained changes. For these reasons it is suggested that changes be carefully selected, tested and refined. Ongoing communication continues to be necessary at this stage of implementation, so that management and policy makers are equipped with the information and confidence needed to keep applying those changes within the system so that desired outcomes can be achieved [3].

Results of this phase

Improvement cycles

The mechanism to ensure the intervention will be regularly revisited to ensure it stays current and meaningful with regards to the need that motivated the implementation in the first place.

09.

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10. ANNEXES

ANNEX 10.1 | Implementation outcomes definitions

Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory. Acceptability may be measured from the perspective of various stakeholders, such as administrators, professionals or patients. For example, patient's acceptance to an invasive diagnostic test.

Uptake is defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice. Uptake could be measured from the perspective of provider or organisation. For example, nursing professional's uptake to a new protocol for inserting peripheral intravenous catheters.

Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given setting or patient; and/or perceived fit of the innovation to address an issue or problem. For example, a treatment might be considered a good fit for treating a given condition but its features (for example, rigid protocol) may render it unacceptable to the provider.

Cost (incremental or implementation cost) is defined as the cost impact of an implementation action and depends upon the costs of the intervention to be implemented, the actions carried out and the participants involved. For example, implementing processes that do not require ongoing supervision or consultation, such as computerised medical record systems, may carry lower costs than implementing new psychosocial treatments.

Feasibility is defined as the extent to which a new evidence-based recommendation can be successfully used or carried out within a given setting. For example, an intervention may be appropriate for a setting, but may not be feasible due to resource or training requirements.

Fidelity is defined as the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers. Fidelity has been measured more often than the other implementation outcomes, typically by comparing the original evidence-based intervention and the implemented intervention. Measurement could be done in terms adherence, quality of delivery, program component differentiation, exposure to the intervention, and participant responsiveness or involvement.

Penetration is defined as the integration of a practice within a service setting and its subsystems. A way of measurement could be in terms of the number of settings who deliver a given service or intervention, divided by the total number of settings trained in or expected to deliver the service.

Sustainability is defined as the extent to which a newly implemented treatment is maintained or

institutionalized within a service setting's ongoing, stable operations. Penetration and sustainability may be related conceptually and empirically, in that higher penetration may contribute to long-term sustainability.

ANNEX 10.2 | Research techniques to explore the context

Herein are introduced different research techniques that can be used to explore the context of the implementation. Within the scope of this handbook, these techniques can be especially useful for identifying and analysing barriers and facilitators and for analysing the results of the pilot. The purpose of this annex is to provide information on the main features of these techniques in order to inform the implementation working group on the most suitable technique. However, in order to put any of these techniques into practice, professionals with experience on the subject should be consulted and involved.

Delphi

Consensus technique in which a group of experts anonymously answer a questionnaire and subsequently receive feedback in the form of a statistical representation of the "group response," after which the process repeats itself. It reduces the range of responses and helps the group to arrive at something closer to expert consensus.

It requires more time than other consensus techniques, although it does not require face-to-face meetings between the experts.

For example, it can be used to refine a set of barriers and facilitators, as well as to prioritise them according to their relevance. Besides, new barriers and facilitators can be identified.

Nominal Group Technique (NGT)

Structured technique that gathers contributions from all the members of the group and aims at the prioritisation of issues, problems or solutions, by reaching agreement on their relative importance. It combines the importance ratings of individual group members into the final weighted priorities of the group.

It requires less time than the Delphi and fosters the interaction between participants, which can be a source of information in itself.

For example, it can be used to identify and prioritise strengths and weaknesses of the intervention after the pilot, and find potential solutions to them.

Group discussion

Group technique that aims at exploring values, cultural representations, references, motivational aspects, etc. that prevail in a certain group through the identification of a common speech, which comprises the interactions and psychological relations within the group.

It has to be done face-to face and the analysis of the information may require more time than in other techniques. If done properly, it can provide a myriad of relevant aspects related to the perspective of the group subject to the technique.

For example, it can be used to identify potential barriers related to the work culture or potential motivational factors that can act as facilitators concerning a specific professional group that will be involved in the implementation

Focus Group

Similar to the group discussion technique in most aspects, except for the fact that the focus group aims at delving into the individual speech of the participants.

Interview

Individual techniques. There are different types of interviews:

Structured interview: Based on a pre-defined set of questions. They have to be asked in the same way and order to all participants.

Semi-structured interview: Based on a pre-defined set of questions that are used as a guide, enabling the interviewer to formulate them in different ways or orders and allowing her or him to add new questions in order to deepen into relevant topics identified during the interview.

In-depth interview: Based on a guide make up of open questions and issues previously identified. The interview is completely open to the information that the interviewee shares with the interviewer, who will try to identify relevant topics and delve into them, building the appropriate questions based on the information provided by the interviewee.

ANNEX 10.3 | Potential Strategies to Maximise Facilitators and Minimise Barriers

Barrier/ Facilitator	Potential Strategies
Evidence-related	
Awareness of where and how to access the main CPG or CDST	Make CPG of CDST recommendations or summary readily available at point of care (e.g., attach to patient charts, display around unit).
Level of understanding and how to implement it in practice	Provide real-world examples, relevant to the setting. Tailor education to needs of end users.
Quality of the evidence	Provide information that demonstrates the CPG or CDST was based on the highest level of evidence possible. Provide examples that demonstrate how CPG or CDST implementation improved outcomes in other settings. Provide the staff with the opportunity to discuss any disagreement they may have with the CPG or CDST and try to achieve consensus. Pilot test the innovation with a target audience in a small area prior to implementation.
Compatibility with what is already known, believed and done	Provide examples as to how the new CPG or CDST is consistent with what is already done, known and believed for that setting. Involve those who will be using the CPG or CDST in the implementation process.
Target audience-related	
Attitudes and beliefs towards research use in practice	Encourage attendance at conferences and in-services; highlight positive experiences with CPG or CDST use. Draw on past successes, provide encouragement and incentives.
Level of knowledge and skill	Provide education/training where knowledge and skill necessary to implement the changes recommended in the CPG or CDST are assessed to be deficient.
Time to read and implement CPG or CDST	Provide health-care providers with dedicated/protected time to read the CPG or CDST. Schedule information sessions about the CPG or CDST at various times.
Belief that CPG or CDST will make a difference	Demonstrate the disparity between current practice and new CPG or CDST.
Degree of consensus between / within professions	Allow for interprofessional discussions. Interprofessional participation and awareness.
Opportunities to exchange information	Educational opportunities (e.g., in-services, on line learning, conferences).
Ability of team to work together	Draw on history of collaboration. Team building activities.
Resources-related	
Presence of adequate staff	Ensure that there are extra staff available to provide relief during education sessions and other implementation-related activities.
Availability of financial resources necessary to implement the CGP or CDST	Examine all sources of possible funding: foundations, fundraising, professional organizations, government, etc.
Ensure that the target audience have enough time to engage in implementation efforts	Be aware of competing demands and projects. Ensure that there is time available to participate in all stages of the implementation. Build a realistic timeline to bring about change and plan accordingly.
Access to required equipment and supplies	Ensure availability of • Computers/ electronics resources if required

	• Equipment and supplies
Adequacy of physical facilities for implementation	Ensure physical space is conducive to learning.
Organization-related factors	
Fit with existing policies and procedures	Assess fit between new CPG or CDST and existing policies and procedures.
Presence of effective change agents/opinion leaders	Ask staff to identify natural leaders. Engage change agents/opinion leaders in the CPG or CDST implementation process.
Manageable workload	Consider complexity of patients.
Concurrent projects	Examine what other changes are occurring simultaneously in the organization and unit. Too many changes at once can overwhelm a team.
Concurrent with organizational priorities	Examine corporate priorities and strategic goals to see if the new CPG or CDST is reflected in them. Engage stakeholders early in the CPG or CDST implementation process.
Speed at which administrative/ organizational process works	Know whose approval is required. Plan far enough ahead to allow time for lengthy administrative/organization decisions, approval and change.

ANNEX 10.4 | Experimental and non-experimental designs

More detailed information on the characteristics and basic classification of research designs is presented below (Figure 7), in this way the implementation working groups can consider those designs that best fits the characteristics of its target population, its implementation activity and the outcomes they need to assess [50]:

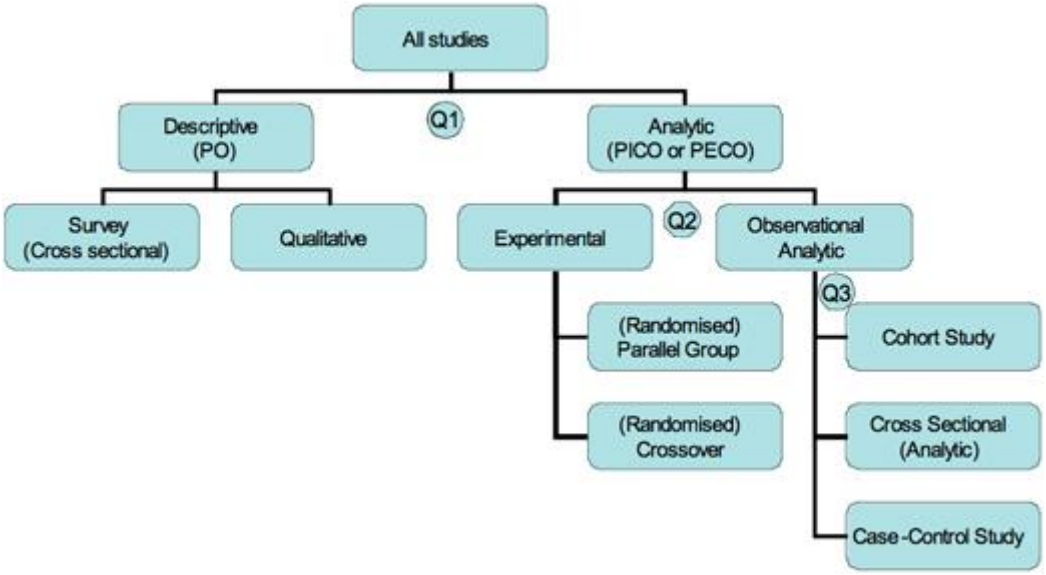

Figure 7. Classification for experimental and non-experimental research designs

IV.1. Analytic or non-analytic studies (Q1)

Non-analytic or descriptive studies do not try to quantify relationship between an action and its consequences but tries to provide a picture of what is happening in a population (e.g. prevalence, incidence, or experience of a group). Types of descriptive studies are case reports, case-series, qualitative studies and surveys studies, which tend to measure the size or importance of a problem.

Analytic studies attempt to quantify the relationship between two factors, that is, the effect of an intervention or exposure on an outcome. To quantify the effect, it is necessary to know the rate of outcomes in a control group as well as the intervention or exposed group. Whether the researcher actively changes a factor or imposes uses an intervention determines whether the study is considered to be observational (passive involvement of researcher), or experimental (active involvement of researcher).

IV.2. Experimental or non-experimental studies (Q2)

Experimental studies are those in which the researcher manipulates the exposure, allocating subjects to the intervention or exposure group. Experimental studies, or also called randomised controlled trials (RCT) have the potential to control for most of the biases that can occur in scientific studies.

Advantages:

- unbiased distribution of confounders
- randomisation facilitates statistical analysis

Disadvantages:

- expensive: time and money
- ethically problematic at times

IV.2.1. Experimental designs for evaluating implementation interventions

Experimental designs attempt to link any measured differences in health outcomes with the implementation activity. This approach is the more effective method for assessing causality. There are different ways of designing randomized trials that ensure the evaluation and correct attribution of effects of implementation activities [39, 51].

- *Individually randomised trials:* Individuals are randomly allocated to receive either an experimental intervention or an alternative such as standard treatment, a placebo, or remaining on a waiting list. In the case of an implementation activity, it would consist of randomising patients between one implementation strategy or another (or none). Such trials are sometimes dismissed as inapplicable to evaluating implementation, but there are many variants, and often solutions can be found to address the issues associated with randomisation.
    - *Cluster randomised trials* are one solution to the problem of contamination of the control group, leading to biased estimates of effect size, in trials of population level interventions. Groups such as different organisation or settings are randomly allocated to the experimental or control intervention.
    - *Stepped wedge* designs may be used to overcome practical or ethical objections to experimentally evaluating an intervention for which there is some evidence of effectiveness or which cannot be made available to the whole population at once. It allows a trial to be conducted without delaying roll-out of the intervention. Eventually, the whole population receives the intervention, but with randomisation built into the phasing of implementation.

- *Pragmatic clinical trials* are designed to test interventions in the full spectrum of everyday clinical settings in order to maximise applicability and generalizability. The research question under investigation is *whether an intervention actually works in real life.* The intervention is evaluated against other ones (established or not) of the same or different class, in routine practice settings. Pragmatic trials measure a wide spectrum of outcomes, mostly patient-centered, whereas explanatory trials focus on measurable symptoms or markers (clinical or biological).

- *Preference trials and randomised consent designs*: Practical or ethical obstacles to randomisation can sometimes be overcome by using non-standard designs. When there is a preference for patients receive a specific intervention, basing allocation on patients' preferences may be appropriate.

- *N-of-1 designs*: Conventional trials aim to estimate the average effect of an intervention in a population. N of 1 trials, in which individuals undergo interventions with the order or scheduling decided at random, can be used to assess between and within person change and to investigate theoretically predicted mediators of that change. N-of-1 trials can be functional for assessing rare disease patient outcomes, this may be an appropriate design when several of the following criteria coexist [Price 2002]:
    - There are significant doubts about treatment or intervention real-world effectiveness
    - Potential important benefits/harms exist
    - CPG or CDST considers using expensive drug treatment

- The disease is chronic and stable, or frequently recurring, so that modes but clinically important effects can be detected
- Relevant outcomes need to be measured
- Patient likely to comply through a sufficiently prolonged trial
- The implementation working groups has or has access to experts on clinical trials designs

IV.2.1.1. Choosing between randomised and non-randomised designs

However, often the use of an experimental design is not feasible. Below are some criteria that can help to select which type of design may be the most appropriate [39].

- *Size and timing of effects:* Randomisation may be unnecessary if the effects of the implementation are so large or immediate that confounding or underlying trends are unlikely to explain differences in outcomes before and after exposure. It may be inappropriate if the changes are very small or take a long time to appear. In these circumstances a non-randomised design may be the only feasible option, in which case firm conclusions about the impact of the intervention may be unattainable
- *Likelihood of selection bias:* Randomisation is needed if exposure to the implementation activity is likely to be associated with other factors that may influence outcomes. Post-hoc adjustment is a second-best solution; its effectiveness is limited by errors in the measurement of the confounding variables and the difficulty of dealing with unknown or unmeasured confounders.
- *Feasibility and acceptability of experimentation:* Randomisation may be if the main decisions about the steps in which the implementation will take place have already been made, as is often the case with policy changes and interventions whose effect on health is secondary to their main purpose.
- *Cost:* If an experimental study is feasible and would provide more reliable information than an observational study but would also cost more, the additional cost should be weighed against the value of having better information.

IV.3. Analytic non-experimental (also known as observational studies) (Q3)

Are those in which the researcher simply measures the exposure or interventions of the groups. Analytical observational studies include case-control studies, cohort studies and some population (cross-sectional) studies. These studies all include matched groups of subjects and assess of associations between intervention/activity or exposure and outcomes. Observational studies investigate and record exposures (such as implementation activities) and observe outcomes (such as implementation/service/patient outcomes) as they occur [50].

Advantages:

- ethically safe
- can establish timing and directionality of events
- eligibility criteria and outcome assessments can be standardised
- administratively easier and cheaper than RCT
- in the case of evaluating patient outcomes is a feasible method for rare diseases or those with long lag between exposure and outcome (case-control studies)

Disadvantages:

- exposure may be linked to a hidden confounder
- potential bias: recall, selection
- for rare disease, large sample sizes or long follow-up necessary to observe patient outcomes (cohort studies)

There are two types of observational studies (Q3):
Cohort studies refers to those where data are obtained from groups who have been exposed, or not exposed, to the activity or factor of interest (using information from databases). No allocation of exposure is made by the researchers. It is useful to study the which factors can trigger a certain outcome.
Case-control studies are those in which patients with a certain outcome or disease and an appropriate group of controls without the outcome or disease are selected and then information is obtained on whether the subjects have been exposed to the factor under investigation.

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