CHRODIS+

IMPLEMENTING GOOD PRACTICES FOR CHRONIC DISEASES

GUIDELINE ON IMPLEMENTATION STRATEGY

Module II: Implementation phase and impact assessment

Ane Fullaondo, Jon Txarramendieta and Esteban de Manuel (Kronikgune)

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Table of content

Acknowledgement

In order to support partners during the complex process of implementing practices, a dedicated implementation strategy has been developed. The strategy provides a series of methods and techniques to enhance the adoption and sustainability of practices and the use of tools developed in JA CHRODIS that can be applied in different settings and contexts.

The opinion and perspective of future users has been extensively collected and taken into consideration to ensure that the final strategy meets their particular needs, interests and expectations. This version of the "Implementation Strategy: Implementation phase" document is the result of a productive collaborative work between authors and JA CHRODIS PLUS partners. Therefore we acknowledge all contributors for their support and effort, especially Rokas Navickas, Antonio Sarria and Mirca Barbolini as main reviewers.

1. Introduction

This document complements the Module I of the JA CHRODIS PLUS Guidelines on Implementation strategy. It aims to serve as a guideline for the implementation sites to facilitate the uptake in routine practice of good practices, policies and tools and assess their impact. It includes a series of methods and techniques, concrete procedures and recommendations to enhance the adoption and sustainability of practices and tools with demonstrated success. Everything will be collected and summarized in the SQUIRE 2.0. report., that will also include **the recommendations for future implementation of practices and tools.**

The document is structured as follows:

Section 2 shortly introduces the distinct phases of the whole implementation strategy and the documents produced describing the insights of each phase.

Section 3 describes the methodology for the implementation of the practices and tools, in particular the PDSA cycles. The approach to follow by implementation sites is detailed and the two different scenarios are well defined: sites that only perform one PDSA cycle and sites that will carry out more than one PDSA cycle. The use of the adapted SQUIRE 2.0 reporting tool is explained as well.

Section 4 is focused on the impact assessment of the practices and tools implemented depicting the steps to follow and how to report on SQUIRE 2.0.

Section 5, and final section, explains how to **analyze the factors that might have influenced (positively or negatively) the whole process using the Consolidated Framework for Implementation Research (CFIR). Similar to the other sections, the results of this analysis will be included in a specific item within the SQUIRE 2.0.**

The annexes include the different templates that will be used during the whole process, including Information on the how to organize the meetings (objectives, material needed) with the LIWG needed to carry it out.

2. Implementation strategy. Phases

In JA CHRODIS PLUS, a three-step implementation strategy has been defined that will be followed by all implementation sites. It has been designed to be appropriate from the scientific point of view, applicable considering data availability and feasible according to project´s timeline and resources.

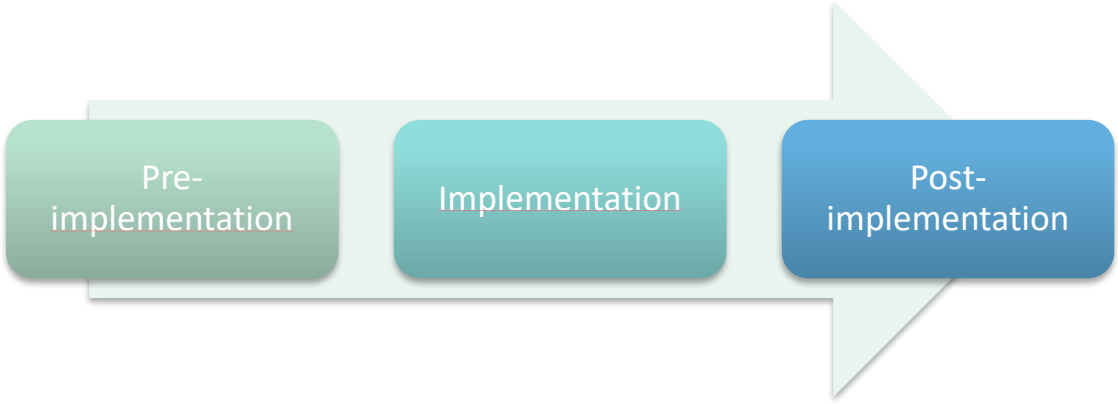


Figure 1: Implementation strategy phases

The implementation strategy is composed of two main documents:

1. Module I: guideline for the Pre-Implementation phase
2. Module II: guideline for the Implementation phase and the Post-implementation phase (assessment)

This document is focused only on techniques of the Implementation phase and impact assessment (Module II).

3. Implementation phase: PDSA cycles

The objective of this phase is to specify and describe the steps in the process of transferring practices and tools into real practice. Pilot Action Plans elaborated during the pre-implementation phase will be followed.

The implementation phase runs between months 14 and 30 of the project, from November 2018 to February 2020.

This phase consists of the following actions:

1. Execution of the implementation.
2. Data collection.
3. Monitoring of the implementation.

The use of the techniques included in the implementation phase will provide information to feed the adapted SQUIRE template which is the reporting framework used in JA CHRODIS PLUS.

3.1 Introduction to PDSA cycles

In comparison to more traditional healthcare research, the Plan-Do-Study-Act (PDSA) cycle presents a pragmatic scientific method for testing changes in complex systems. The four stages mirror the scientific experimental method of formulating a hypothesis, collecting data to test this hypothesis, analyzing and interpreting the results and making inferences to iterate the hypothesis (1,2,3).

The pragmatic principles of PDSA cycles promote the use of an iterative approach to test interventions. This enables rapid assessment and provides flexibility to adapt the intervention according to feedback to ensure fit-for-purpose solutions are developed.

The PDSA cycle promotes prediction of the outcome of a test and subsequent measurement over time (quantitative or/and qualitative) to assess the impact of an intervention on the process or outcomes of interest. In recognition of working in complex settings with inherent variability, measurement of data over time helps understand natural variation in a system, increase awareness of other factors influencing processes or outcomes, and understand the impact of an intervention (1,2,3).

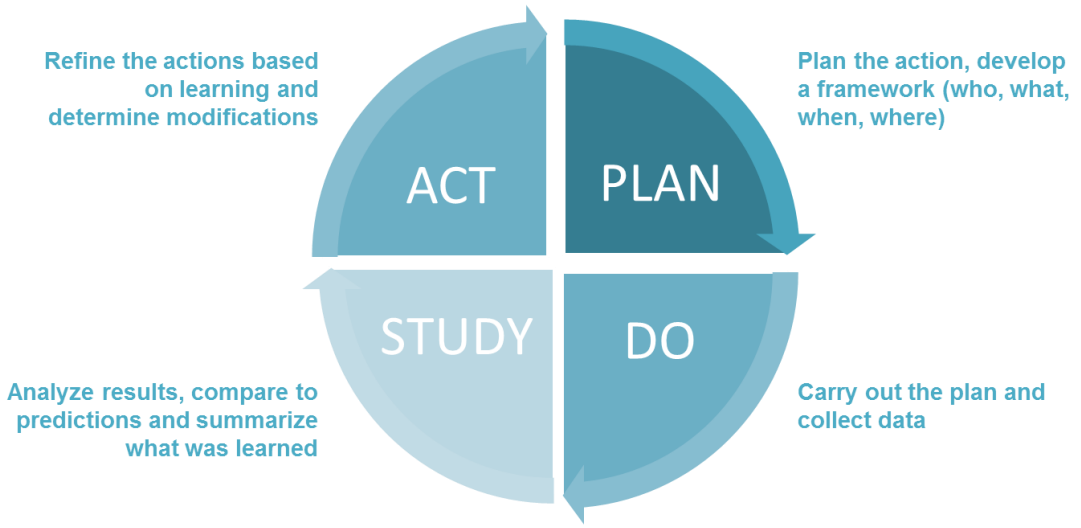
As with any scientific approach, documentation of each stage of the PDSA cycle is important to support technical robustness, quality, team reflection and learning and to ensure knowledge is captured to support organizational development and transferability to other settings (1,2,3).

Using PDSA cycles, structured collaborative procedures, pretends to facilitate the implementation and testing interventions and tools in real and system-level.

The steps of the PDSA approach are:

- PLAN: Plan the actions defined in the Pilot Action Plan to test the changes. Detail actors (who), functions and roles (what), timeframe (when) and setting (where).

- DO: Test the action and once is finished, data are collected and any problem or unexpected observation is documented.
- STUDY: The data obtained during the testing step are analyzed. The obtained results are compared to the predictions. Learning is summarized.
- ACT: Based on the lessons learned changes are refined. Modifications are determined. This improved change is then re-implemented in a new PDSA cycle.



3.2 PDSA cycles in JA CHRODIS PLUS

In JA CHRODIS PLUS implementation sites will perform at least one PDSA cycle during the implementation phase. LIWGs will go through the four steps as described below.

PLAN

PLAN phase operationalizes the activities defined in the Change Package of the Pilot Action Plan. It consists of a face-to-face session in which the LIWG members reflect on, discuss, agree and plan in detail how to carry them out. These activities will be implemented locally in the DO step. It is important to note that the procedure to collect the Key Performance Indicators (KPIs) specified in the Action Plan needs to be carefully planned: what type of data is needed, who is the responsible for gathering information, when the data will be collected and which data sources and methods (quantitative and/or qualitative) will be used. e analysis and interpretation of the data will be performed during the STUDY phase.

DO

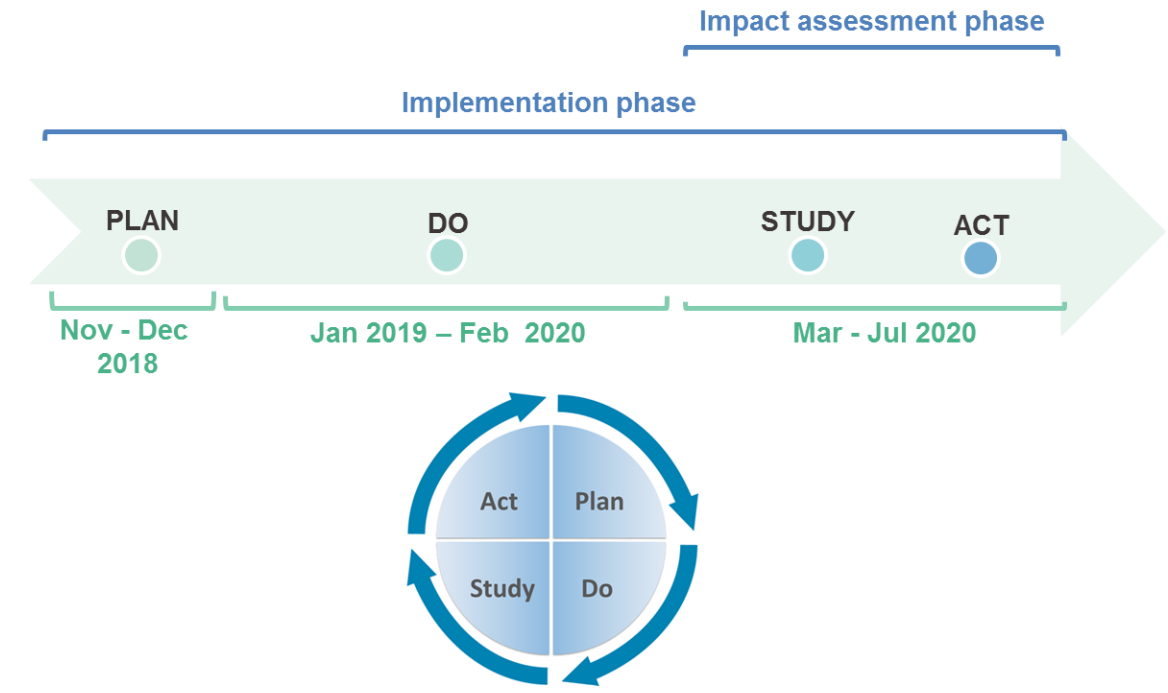
The DO step, which is framed within the action period, implements and tests the activities. Data (KPIs) will be collected and registered to measure the impact during the STUDY step (KPIs). **They are mainly process indicators but health related outcomes might be expected as well.**

STUDY

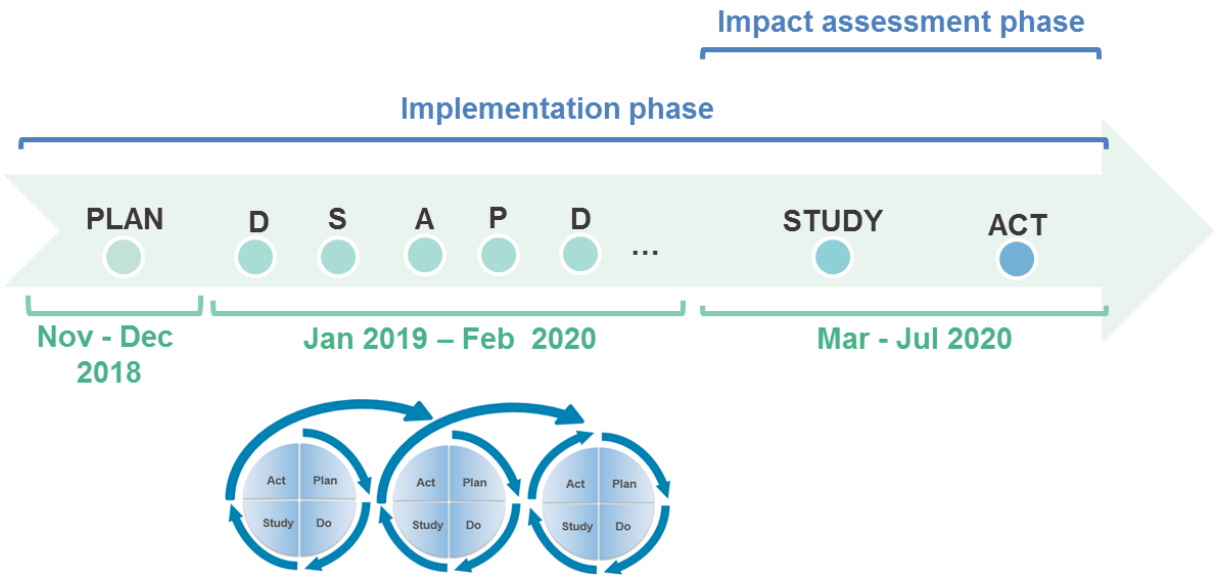
The STUDY step analyzes and interprets the results. It consists of at least one face-to-face session of the LIWG. Key Performance Indicators defined in the Action Plan will be assessed. The collection of quantitative data will depend on local needs and possibilities (data registries and sources, data exploitation resources). Qualitative analysis based on focus groups or semi-structured interviews can be done as well. The discussion of the results can also involve local and national institutions, not only to have a clearer understanding but to support sustainability too.

The assessment of the results will be done at mid-term and at the end of the implementation phase. If sites only perform one PDSA cycle, the STUDY phase will be merged with the final impact assessment phase described in section 4. If sites carry out more than one PDSA cycle, only the STUDY step of the last cycle will be merged with the final impact assessment (see figure below).

OPTION A: one PDSA cycle



OPTION B: more than one PDSA cycle



In any case, the periodicity will vary from site to site depending on the number of PDSA cycles planned and the duration of DO phase(s). Yet meetings in a three-month basis are recommended.

ACT

In the ACT step the activities implemented are adjusted or even reformulated based on the findings of the STUDY step. The LIWG is responsible for discussing and agreeing the next steps. The decisions made during this phase are the starting point of the next PDSA cycle. If implementation sites perform only one PDSA cycle, ACT phase will define actions that go beyond the timeframe of the JA CHRODIS PLUS.

In Annex I, templates to report each phase of the PDSA cycle are included to ensure systematic and rigorous reporting of the process. These templates aim to be operational tools to gather in a structured manner the work done during the different steps of the PDSA cycles.

4. Impact assessment

The impact assessment evaluates the implementation results in order to provide evidence on key outcomes. The selected Key Performance Indicators need to be completed aligned to these outcomes so the evidence generated is relevant to real settings (4).

The impact assessment phase runs between months 31 and 35 of the project, from March 2020 to July 2020.

As explained before, when just one PDSA cycle, impact assessment merges with the STUDY step. When more than one PDSA, it merges with the last STUDY step of the last cycle. Both health-related outcomes on the target population and process measures reflecting achievement of expected outcomes will be analyzed.

The instruments to investigate the outcomes can include methods of both statistical analysis field and qualitative studies. The selection of the analysis techniques (already included in the Pilot Action Plan) depends on the intervention implemented. During this phase LIWGs will analyze, interpret and discuss the results.

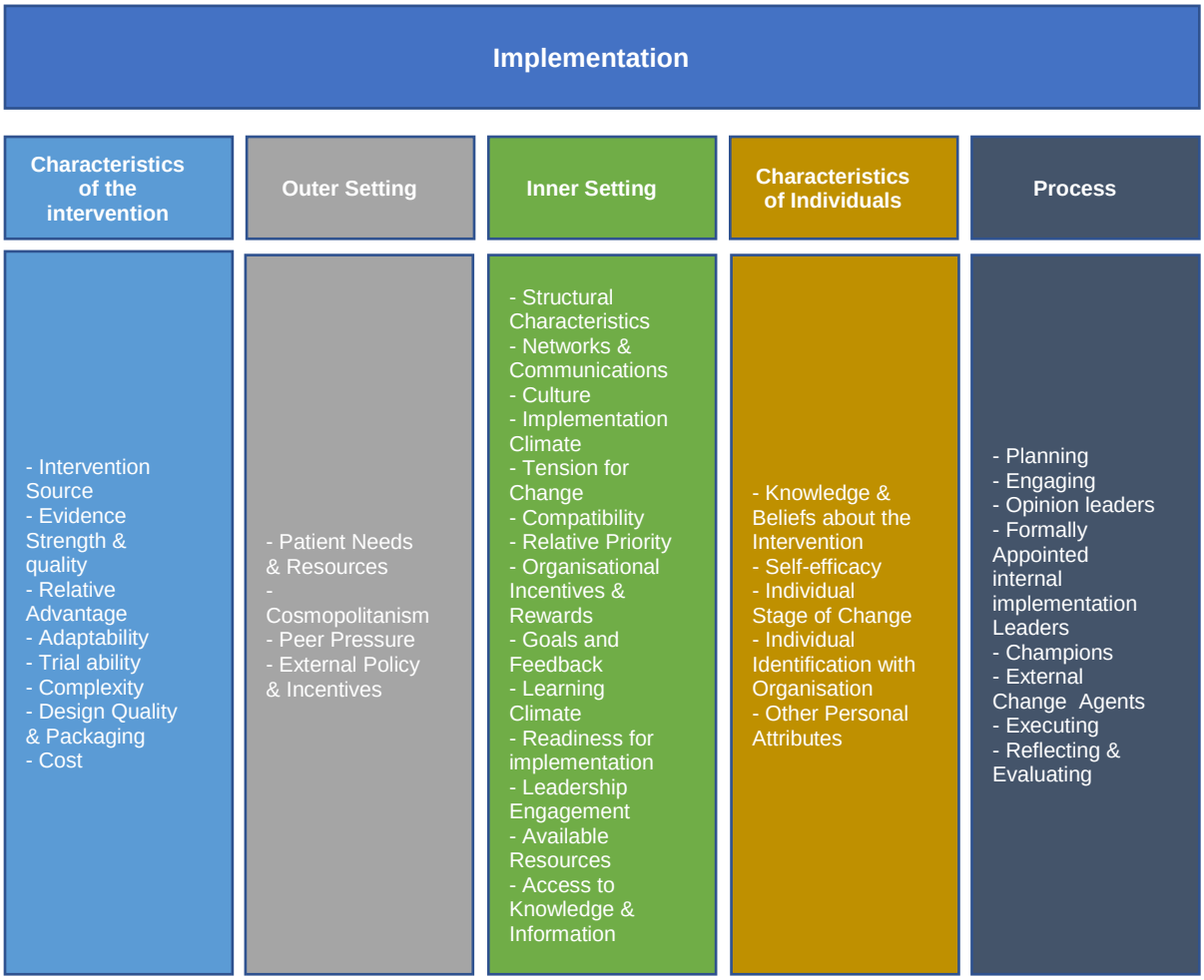
The information collated in this phase will feed specific items of the adapted SQUIRE template (see Annex II) which is the reporting framework used in JA CHRODIS PLUS.

5. General assessment of the whole process: Consolidated Framework for Implementation Research (CFIR)

The Consolidated Framework for Implementation Research (CFIR) will be used to analyze the factors related to distinct levels of care provision (patient, care provision groups, health organization or policy) that might have hindered or facilitated the implementation process. Using CFIR will allow LIWGs not only to learn a specific methodology that helps identifying relevant factors affecting the implementation but also to increase success rate in future implementation experiences. The results of this analysis will be included in a specific item within the SQUIRE 2.0.

The CFIR provides a menu of constructs that have been associated with effective implementation. The CFIR is easily customized to diverse settings and scenarios. It comprises five major domains (the

intervention, inner and outer setting, the individuals involved, and the process by which implementation is accomplished) and each of them includes several constructs. These domains interact in rich and complex ways to influence implementation effectiveness (5-9).



The CFIR provides researchers with a framework in which they can select the most relevant constructs in the particular field of their study and use them to analyze and better understand the implementation process and improve further deployment of the practices and tools.

The description of the CFIR constructs by domain is included in Annex III.

In JA CHRODIS PLUS LIWGs will meet to review and reflect on the potential variables that, in their opinion, could have had impact on the implementation process. Group members will not only highlight and analyze the factors (constructs) that have acted as barriers or facilitators during the

whole process but also define a battery of recommendations based on learning for future deployment of practices and tools.

The analysis and the recommendations for future implementation of practices and tools will be reported in the adapted SQUIRE 2.0 (section 13).

Information on the how to organize the meetings (objectives, material needed) with the LIWG is included in the Annex 4.

Annex I. PDSA Templates

QUESTIONS FOR ALL MEETINGS	DESCRIPTION
Stage (Plan/Study)	
Date of the meeting	
Number and profile of the participants in the meeting	
Organizations involved	

1. PLAN

All implementation sites will complete the templates below irrespective of the number of PDSA cycles implemented.

ACTIVITIES

Each of the actions of the Change Package included in the Pilot Action Plan has to be operationalized and planned in detail. The following table will be filled in for each of the actions.

QUESTIONS	DESCRIPTION
What activity are we implementing?	*Specific action of the Change Package*
When are we implementing? How long will the activity take to implement?	*Dates and number of months*
Where are we implementing? ***Setting***	
What resources will the implementation need?	*Human resources, infrastructure…*
What do we expect to happen? ***Objectives of the activities***	

DATA

QUESTIONS	DESCRIPTION
What data do we need to collect?	
Who will collect the data?	
When will the data be collected?	
How will the data be collected? ***Explain data sources and***	

quantitative and qualitative methods	

2. DO

All implementation sites will complete the templates below irrespective of the number of PDSA cycles implemented.

QUESTIONS	DESCRIPTION
What was actually implemented? *Any deviation from the planned actions*	
What happened?	
Problems? Unexpected findings?	

3. STUDY

This template will be completed only by LIWGs that are performing more than one PDSA cycle. The information collected here will help them to redefine the actions to implement in the following PDSA cycles.

QUESTIONS	DESCRIPTION
Description of measured results	
Comparison to the predictions	
What was learned?	
Unintended consequences, surprises, successes and failures?	

Below some guidelines that might help collecting information on process supporting sustainability.

Institutional: describe if, as effect of the activities, there was a further involvement of key institutions at the sub national and national level and the related effects in terms of strategies, policies regarding the project's objectives and expected results;

Stakeholder's involvement: describe the involvement of beneficiaries, institutions and actors important for the development and continuation of the activities beyond the implementation;

Intersectoral collaboration: if relevant, describe the involvement of relevant sectors (health, social, community, others);

Allocation of Resources: describe if, as effect of the project activities, funding and resources were allocated to continue the activities beyond the implementation;

Organizational changes: describe if, as effect of the activities, decisions of changes in the design and delivery of services were taken;

Multiplier effect: describe the changes in terms of replication and extension of good practices, Model and tools.

4. ACT (Steps for future Improvements)

This template will be completed only by LIWGs that are performing more than one PDSA cycle. The information collected here will help them to redefine the actions to implement in the following PDSA cycles.

QUESTIONS	DESCRIPTION
What modifications should we make before the next cycle (if planned)?	
Proposed activities for the future?	
Will the approach tested be abandoned/substantially modified?	

Annex II. Adapted SQUIRE 2.0

The sections in grey have been completed in the Pre-implementation phase. Only non-coloured sections need to be filled in at this stage.

Introduction	*Why did you start?*
1. Problem Description	• Nature and significance of the local problem *"Problem/challenge" of the scope definition template*
2. Available knowledge	• Summary of what is currently known about the problem, including relevant previous studies
3. Rationale	• Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work
4. Specific aims	• Purpose of the project and of this report *"General purpose of the intervention" of the scope definition template* *"Objectives" of the collaborative methodology*
Methods	***What did you do?***
5. Context	• Contextual elements considered important at the outset of introducing the intervention(s) *Main output of the Situation Analysis. SWOT analysis*
6. Intervention(s)	• Description of the intervention(s) in sufficient detail that others could reproduce it *"Target population" of the scope definition* *Areas of improvement and Change package of the Collaborative methodology* • Specifics of the team involved in the work *Description of the LIWG participants (number, profiles, roles)*
7. Study of the Intervention(s)	• Approach chosen for assessing the impact of the intervention(s) (quantitative or qualitative analysis) • Approach used to establish whether the observed outcomes were due to the intervention(s)
8. Measures	• Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their

	operational definitions, and their validity and reliability *Key Performance Indicator of the Collaborative methodology*
9. Chronogram	Expected timing of the activities of the Change package, scheduling the start and end month
10. Analysis	• Qualitative and quantitative methods used to draw inferences from the data • Methods for understanding variation within the data, including the effects of time as a variable *PLAN template: How will the data be collected? Explain data sources and quantitative and qualitative methods*
11. Ethical considerations	• Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest
12. Results	• Intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project *DO template: What was actually implemented? Any deviation from the planned actions.* *If more than one PDSA cycle, please report the information taking into consideration all cycles.* • Details of the process measures and outcome *STUDY template (only in case that more than one PDSA cycle is implemented) and Impact assessment: final outcome analysis* • Observed associations between outcomes, interventions, and relevant contextual elements • Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). *STUDY template (only in case that more than one PDSA cycle is implemented) and Impact assessment: final outcome analysis* • Details about missing data *Impact assessment: final outcome analysis*
13. Implementation process	• Facilitators and barriers of the implementation process • Set of recommendations for future implementation *Input from the analysis of the implementation process using Consolidated*

	Framework for Implementation Research (CFIR)
14. Summary	• Key findings, including relevance to the rationale and specific aims *Impact assessment: final outcome analysis* • Particular strengths of the project
15. Interpretation	• Nature of the association between the intervention(s) and the outcomes • Comparison of results with findings from other publications • Impact of the project on people and systems • Reasons for any differences between observed and anticipated outcomes • Costs and strategic trade-offs, including opportunity costs *Impact assessment: final outcome analysis*
16. Limitations	• Limits to the generalizability of the work • Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis • Efforts made to minimize and adjust for limitations *Impact assessment: final outcome analysis*
17. Conclusions	• Usefulness of the work • Sustainability • Potential for spread to other contexts • Implications for practice and for further study in the field • Suggested next steps
18. Funding	• Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting

Annex III. Description of the CFIR constructs by domain

Construct		Short Description
I. INTERVENTION CHARACTERISTICS		
1	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
2	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
3	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
4	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
5	Trial ability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
6	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
7	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
8	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
9	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
10	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
11	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
12	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
13	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
14	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.

15	Culture	Norms, values, and basic assumptions of a given organization.
16	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 organization.
17	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
18	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
19	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
20	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
21	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
22	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
23	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
24	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
25	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
26	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
27	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
28	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
29	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
30	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
31	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

V. PROCESS		
32	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
33	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
34	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
35	Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
36	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.
37	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
38	Executing	Carrying out or accomplishing the implementation according to plan.
39	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

Annex 4. Organization of the LIWG meetings

All the LIWG members will be invited to participate in the meetings to ensure a wide variety of opinions and interests. The LIWG's Organizer would be responsible for:

- Schedule, coordinate and run the meetings
- Identify and engage appropriate stakeholders
- Prepare the needed documentation
- Propose the agenda and oversee the minutes
- Produce the corresponding reports
- Share the results and reports with the LIWG members
- Monitor the implementation process
- Lead the impact assessment
- Liaise with WP leaders

Meetings with the LIWG will be in-person and each of them is expected to require between 2 to 3 hours. The number of meetings will depend on the PDSA cycles performed by the implementation site,

whereas the number of PDSA cycles will differ from site to site according to their possibilities (magnitude and complexity of the practice or tools to be implemented and project time constraints).

Below the proposal to organize the working sessions:

Meeting: PLAN

- Explain objectives of the session
- Present the implementation phase
- Review the Pilot Action Plan
- Discuss the actions required for the implementation Plan the procedure to collect key performance indicators
- Plan the actions agreed

Material needed:

- Presentation on the implementation phase
- Guidelines on the Implementation Strategy
- Template to collect data
- PC and projector
- White boards
- Markers

Meetings: STUDY and ACT

Note that the number of these meetings will vary depending of the PDSA cycles implemented at the site and the duration of DO phase(s); yet meetings in a three-month basis are recommended to monitor and analyze results.

- Explain objectives of the session
- Briefly present the PDSA cycle (reminder)
- Review the actions implemented
- Analyze the results and findings
- Discuss and agree the actions to further implement

Material needed:

- Guidelines on the Implementation Strategy: STUDY and ACT phase
- Templates to collect data (STUDY)
- Template to plan next PDSA (if any) (ACT)
- PC and projector
- White boards
- Markers

Meeting: analysis of the implementation process

- Explain objectives of the session
- Briefly present the CFIR (rationale, objectives)
- Present the CFIR dimensions and constructs
- Select the constructs that have influenced most the implementation
- Analyze the nature of the influence (positive, negative)
- Discuss and agree on recommendations for future implementation processes

Material needed:

- Guidelines on the Implementation Strategy: analysis of the implementation process
- Templates to collect information (constructs of interest, nature of influence, recommendations
- PC and projector
- White boards
- Markers

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