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Process evaluation of the scale-up of integrated diabetes and hypertension care in Belgium, Cambodia, and Slovenia (the SCUBY project): A study protocol

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Abstract

Introduction: Integrated care interventions for type 2 diabetes (T2D) and hypertension (HT) are effective, yet challenges exist with regard to their implementation and scale-up. The ‘Scale-Up diaBetes and hYpertension care’ (SCUBY) project aims to facilitate the scale-up of integrated care for T2D and HT through the co-creation and implementation of contextualised scale-up roadmaps in Belgium, Cambodia, and Slovenia. We hereby describe the plan for the process and scale-up evaluation of the SCUBY project. The specific goals of the process and scale-up evaluation are to (i) analyse how, and to what extent, the roadmap has been implemented, (ii) assess how the differing contexts can influence the implementation process of the scale-up strategies, and (iii) assess the progress of the scale-up.

Methods and analysis: A comprehensive framework was developed to include process, scale-up, and impact evaluation embedded in implementation science theory. Key implementation outcomes include acceptability, feasibility, relevance, adaptation, adoption, and cost of roadmap activities. A diverse range of predominantly qualitative tools—including a policy dialogue reporting form, a stakeholder follow-up interview and survey, project diaries, and policy mapping—were developed to assess how stakeholders perceive the scale-up implementation process and adaptations to the roadmap. The role of context is considered relevant, and barriers and facilitators to scale-up will be continuously assessed.

Ethics and dissemination: Ethical approval has been obtained from The Institutional Review Board (Ref. 1323/19) at Institute of Tropical Medicine (Antwerp, Belgium). The SCUBY project presents a comprehensive framework to guide the process and scale-up evaluation of complex interventions in different health systems. We describe how implementation outcomes, mechanisms of impact, and scale-up outcomes can be a basis to monitor adaptations through a co-creation process and to guide other scale-up interventions making use of knowledge translation and co-creation activities.

Strengths and limitations of this study

- We developed a comprehensive framework strongly embedded in implementation science theory to guide and evaluate the scale-up of integrated diabetes and hypertension care via policy dialogues and scale-up roadmaps in three different contexts.
- We describe how implementation outcomes and mechanisms of impact can be a basis for monitoring adaptations to the roadmap throughout the scale-up process.
- A diverse range of data collection tools to track the policy dialogue and contextualised roadmap process are described. Limitations are that these are predominantly qualitative data collection tools and that due to the COVID-19 pandemic, data collection may be delayed. This could lead to recall bias of stakeholders in interviews on the process of stakeholder collaboration in policy dialogues.

Key words

Process evaluation, (qualitative) mixed methods, evaluation framework, scale-up, complex intervention, co-creation/policy dialogue

Introduction

To address the rising burden of chronic diseases across the world, global commitments have been made towards an integrated care approach offering multidisciplinary, non-episodic, and patient-centred care.¹⁻⁵ Integrated care leads to better care coordination and (cost) efficiency, and improves the quality of care and patient outcomes by linking services along the continuum of care.^{3 6 7} However, the scale-up of integrated care is challenging because chronic diseases pose a wicked problem⁸⁻¹² requiring multi-stakeholder action and intersectoral coordination at individual healthcare practice, organisational, and political/system levels.^{13 14}

Moreover, little is known on how to scale up complex, adaptive, and strongly contextualised interventions.¹⁴⁻¹⁶ Blueprint approaches to scaling-up health care interventions commonly described in the literature and global health initiatives are linear process models and do not fit the dynamic, emergent, and adaptive scale-up process of complex health interventions.¹⁷ Complexity is not just a property of wicked problems, but also of the intervention and the context (or system) into which the intervention takes place.¹⁸ A complex intervention can be perceived as a process of changing complex systems,¹⁹ involving multi-component, multi-stakeholder, and multi-level efforts that are tailored to the contexts in which they are delivered.^{14 20}

The 'SCale-Up diaBetes and hYpertension care' (SCUBY) project aims to provide evidence on the scaling-up of an integrated care package (ICP) for type 2 diabetes (T2D) and hypertension (HT) in dissimilar types of health systems through the development and evaluation of roadmap strategies that can be adapted for use in different contexts.²¹ In general, the ICP comprises of: (a) early detection and diagnosis, (b) treatment in primary care services, (c) health education, (d) self-management support to patients and caregivers, and (e) collaboration between caregivers.²¹⁻²⁴

SCUBY is a quasi-experimental multiple case study, in which each country (Belgium, Cambodia, and Slovenia) is a case of the ICP scale-up for T2D and HT. The selection of the three cases was based upon their health system characteristics and current focus on scale-up strategies. Scale-up is multi-dimensional and requires various efforts to: (1) increase population coverage, (2) integrate or institutionalise ICP into health system services, and (3) expand the intervention package, i.e., diversifying the ICP with additional components.^{21 25} Appendix 1 provides details on this three-dimensional framework.^{21 25} The scale-up activities are specifically targeted towards improving primary (low-level) care, in all three countries. Each country focuses on a different scale-up dimension and adopts a suitable scale-up strategy that is in line with contextual needs. In Belgium, where multiple projects have been developed in several areas (current horizontal strategy), the roadmap will focus on how the ICP can be made routine practice in the Belgium health system, and which financial, policy, and regulatory reforms can support this transition (*integration*). In Cambodia, where the vertical (i.e., institutional; top-down) strategy is established, the roadmap mainly focuses on adopting a horizontal strategy to increase population *coverage* of the ICP for T2D and HT care, more specifically, increasing the number of health facilities at the primary care level providing T2D and HT care. In Slovenia, the aim of the roadmap is to strengthen diversification (*expanding* the ICP) through enhancing the involvement of patients and informal caregivers in health care. This will be achieved by down-stepping care from health care professionals at the primary care level to patients and informal caregivers. The main focus is therefore on patient empowerment and self-management of T2D and HT.

The SCUBY interventions for scale-up involve the development of evidence-based roadmaps and policy dialogues.²¹ These two methodologies—roadmaps and policy dialogues—are very much intertwined and considered to be key elements for successful stakeholder-supported scale-up.¹⁷ The first versions of the roadmaps in each country were developed based upon the findings of the formative phase and initial policy dialogues with stakeholders in each country. Subsequently, a feasible and relevant evaluation protocol was developed, in accordance with evaluations of complex interventions, which have a flexible, adaptable design.²⁶ The protocol also describes the framework to guide the overall evaluation of the scale-up intervention in the SCUBY project.

The evaluation of the SCUBY intervention constitutes the third phase of the project and includes four (process, scale-up, cost, and impact) evaluations with separate research questions.²¹ This protocol comprises the first two evaluations only: the process and scale-up evaluation of the SCUBY intervention. This will increase the understanding of the process of implementing roadmaps to scale-up integrated care and to improve health outcomes, and how this is influenced by different contexts. The specific research questions we aim to address are: (i) how has the country-specific roadmap been implemented and to what extent? (ii) how can the differing contexts influence the implementation process of the scale-up strategies? and (iii) what progress has been made on each of the three axes of scale-up?

Box 1 provides key definitions and their application to the SCUBY project.

Concept	Definition	Application in the SCUBY project
Roadmap	An action plan delineating the targets, planning, and progression of scale-up strategies, identifying actors, actions, and timelines based upon priorities in place and time. ²¹	Scale-up Intervention In SCUBY, a scale-up roadmap constitutes an overall scale-up strategy and aim; roadmap actions or activities; a problem statement, rationale and objectives/aim(s) for each roadmap action, a timeline to plan roadmap activities within a time frame; and a description of the evidence base and key partners/stakeholders involved in the scale-up (the coordination mechanism per roadmap action).
Policy dialogue	An essential component of the policy and decision-making process, where it is intended to contribute to informing, developing, or implementing a policy change following a round of evidence-based discussions, workshops, and consultations on a particular subject. It is seen as an integrated part of the policy-making process and can be conducted at any level of the health system where a problem is perceived and a decision, policy, plan, or action needs to be made. ²⁷	Implementation strategy (to guide the roadmap development to implementation) In SCUBY, policy dialogues are used as an approach in the policy-making process to engage with key stakeholders and to develop the countries' scale-up roadmaps. They will comprise structured formal events, one-to-one interactions with key stakeholders, workshops, consultations, and joining ongoing dialogues within the context. ²⁷
Context	Complex adaptive systems that form the dynamic environment(s) in which implementation processes are situated; ²⁸ a set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded. As such, context is not a backdrop for implementation, but interacts, influences, modifies, and facilitates or constrains the intervention and its implementation. Context is usually considered in relation to an intervention, with which it actively interacts. It is an overarching concept, comprising not	Mediator The context in SCUBY is assessed at micro, meso, and macro levels. Since scale-up is targeting the country level, the process evaluation focusses on the macro-level context, specifically the barriers and facilitators to scale-up. We look at the World Health Organization (WHO) health system building blocks ^{30 31} and broader political, economic, social, technological, environmental, and legal factors.

	only a physical location but also roles, interactions, and relationships at multiple levels. ²⁹	
Scale-up	The efforts to increase the impact of health interventions so as to benefit more people and to foster policy and programme development on a sustainable basis. ³²	Study aim/goal Scale-up efforts in SCUBY can include various efforts to make progress on any of the three axes. Examples of efforts are: increasing coverage of existing interventions, strengthening or expanding the existing ICP package, and changing financing or monitoring systems.

The SCUBY intervention: a scale-up roadmap

The SCUBY intervention is an adaptable, evidence-based roadmap for scale-up. This roadmap comprises an action plan with steps and strategies towards a set goal—the scale-up of an ICP to improve access to affordable quality care for T2D and HT. It thus includes both processes and actions by which the ICP is brought to scale. The roadmaps can consist of a mix of scale-up strategies. The term “scale-up roadmap” is derived from the WHO/ExpandNet framework, which also provides classifications according to the degree of the intention of scale-up, formal planning, and locus of initiative:^{32 33} (a) top-down strategies whereby the central level decides to implement the innovation and institutionalises it through planning, policy changes, or legal action; (b) horizontal strategies to expand geographically or population-based; and (c) diversification strategies referring to adding new elements to an existing intervention. Thus, three major strategic scale-up options are available for roadmaps: a, b, c, or a combination of the aforementioned. The three implementing countries in the SCUBY project follow this categorisation in focus and approach: a vertical, government steered top-down (type a) strategy in Cambodia, a horizontal strategy (type b) in Belgium, and a diversification scale-up strategy (type c) in Slovenia. In addition, countries may deviate from the dominant strategy to include other strategies to maintain progress.

Context in this multi-country study is key, as it interacts with the intervention and the implementation strategy, as well as the (implementation and scale-up) outcomes,²⁶ as shown in Figure 1. Contextual factors include barriers and facilitators to scale-up. Each context will influence the development and implementation process of the roadmap differently due to the large cultural, socio-political, and economic differences between the implementation countries, and vice versa, in each country under study, the roadmap development and implementation process will have a different impact on the context.

Figure 1. The interaction between context and the roadmap development and implementation process.

The main implementation strategy: policy dialogues

Within the SCUBY project, policy dialogues play a crucial role in the implementation of the scale-up roadmaps. Policy dialogues have been introduced by the WHO as a tool to support organisational and/or systemic changes in health and health care.²⁷ Concepts linked to policy dialogue are co-creation,³⁴⁻³⁷ co-production,³⁷⁻⁴⁰ deliberative methods and processes,⁴¹ social and community participation,^{42 43} and collaborative governance.^{44 45}

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3 The policy dialogue is the strategy that all implementing countries have in common. This illustrates
4 the necessity of high-level policy engagement and multi-stakeholder collaboration. The policy
5 dialogue can therefore be viewed as SCUBY's main implementation strategy for the development and
6 implementation of the roadmaps in each country. Because of this ongoing engagement with
7 stakeholders in policy dialogues, the roadmap (intervention) can continue to be adapted and amended
8 over time.
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11 The roadmap development and implementation process in figure 1 represents the "co-creative",
12 emergent process towards scale-up, with multiple feedback loops from the policy dialogues to the
13 roadmap. In addition to scientific and local evidence, the policy dialogues are literally feeding into the
14 roadmap development and implementation; the policy dialogues provide a means to increase
15 stakeholder (and community) support and subsequently contribute to roadmap implementation and
16 thus the scale-up of integrated care for T2D and HT.
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19 **An overarching framework for evaluation**

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21 Figure 2 presents a comprehensive framework to guide the evaluation of the roadmap
22 implementation. This framework has been developed to support the process, scale-up, and impact
23 evaluation of the SCUBY intervention. It is useful to gain insight into how the key steps of the roadmap
24 development and implementation process can be linked to outcomes and what effective
25 measurement tools are used to capture the roadmap implementation and scale-up process.
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31 *Figure 2. An overall framework for process, scale-up, and impact evaluation. Note: Key informant interviews in*
32 *SCUBY include interviews with stakeholders from resource and implementing organisations³² and with SCUBY*
33 *research team members in the different implementing countries.*
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35 This framework was adapted from the Medical Research Council (MRC) guidance framework for
36 process evaluations,²⁶ emphasising the relevance of context, and its interaction with not only the
37 intervention, but also the implementation process, the underlying mechanisms of impact, and early,
38 midterm implementation outcomes and scale-up outcomes. As an overarching framework, it brings
39 together the complex intervention and implementation strategy, presenting it as a process of
40 incremental and cyclical change and adaptation, whilst linking this process to key indicators, tools, and
41 types of evaluation.
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44 The framework distinguishes three types of evaluation: process, scale-up, and impact evaluation.
45 Context evaluation can be seen as a sub-part of the process evaluation, whereas context has a major
46 influence on the development and implementation process of the complex intervention. The
47 outcomes and measurement tools in this framework are further described in the methods section of
48 this protocol.
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51 **Methods and analysis**

52 **Study population and design**

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54 The SCUBY study is a quasi-experimental multiple case study, in which each country is a case. The
55 process and scale-up evaluation in this protocol use a mixed method design, the process evaluation
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3 being qualitative and the scale-up evaluation mostly quantitative.⁴⁶ The study population for the
4 process evaluation are the stakeholders involved in the policy dialogues and the roadmap
5 development and implementation process. The WHO/ExpandNet framework³² derives two main
6 categories: resource and implementing (user) organisations.^{47 48} Another meaningful classification for
7 stakeholder categorisation comes from Campos and Reich.⁴⁹ These authors distinguish stakeholder
8 groups that are likely to influence implementation: interest groups, bureaucrats (civil servants from
9 public administration), financial decision-makers, political leaders, beneficiaries, and external actors.⁴⁹
10 In the SCUBY project, we distinguish one additional (seventh) group: scientific actors. The study
11 population for the scale-up evaluation are the target population (e.g. healthcare providers; patients)
12 living in the areas in which scale-up activities were performed.
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16 **Implementation process and scale-up outcomes**

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18 This project focuses on the implementation process and scale-up (or progression) outcomes. Their
19 definitions, as well as their theoretical basis, application to the SCUBY project, and corresponding
20 assessment methods and tools are described in Table 1.
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23 Specific outcomes will be used depending on the stage of the project: early, mid, and late.⁵⁰
24 Acceptability, feasibility, and relevance are key implementation outcomes of roadmaps in the early
25 stage, while adaptation, adoption, and cost of roadmap activities will become more relevant from an
26 early to mid-stage as displayed in the middle row in Figure 2. In each of these stages (early, mid, and
27 late), the role of context will remain relevant, and barriers and facilitators to scale-up will be
28 continuously assessed. Relevant attributes of the context and intervention used in implementation
29 science are elasticity (of the context) and plasticity (of the intervention). Elasticity is linked to
30 institutional fit and change in context brought about by the intervention (and implementation)
31 process, while plasticity is related to the concept of adaptation.⁵¹ Measurement of the implementation
32 outcomes is guided by multiple evaluation frames, including RE-AIM (reach, effectiveness, adoption,
33 implementation, maintenance),⁵² the MRC implementation fidelity,²⁶ and the NASSS (non-adoption,
34 abandonment, scale-up, spread, sustainability) framework.^{15 53}
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39 The mechanisms for impact refer to the effects or (causal) pathways of a specific intervention and
40 answer the question “how does the delivered intervention produce change?” The assessment of
41 mechanisms of impact focuses on the policy dialogue which is the major implementation strategy for
42 the roadmap. Potential mechanisms for impact were identified through literature review on the
43 success factors of policy dialogues⁵⁴⁻⁵⁷ and related to: (1) environment, (2) content, (3) participants.⁵⁸
44 The mechanisms of impact specific to policy dialogues are presented in Table 2.
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48 Next to implementation outcomes, scale-up outcomes (“late stage” box of the conceptual model
49 displayed in Figure 2) will be tracked. We distinguish three scale-up outcomes: (1) Coverage, (2)
50 Integration, and (3) expansion. In the literature some overlapping concepts are used.⁵⁰ In
51 implementation literature, the concept of reach is often used interchangeably with coverage.
52 Similarly, maintenance, sustainability, and institutionalisation are used to assess integration.⁵⁰
53 Expansion as a third dimension—in SCUBY specifically used to indicate an extra element added in the
54 ICP—is similar to the WHO’s use of diversification in their ExpandNet strategy for scale-up.³² The scale-
55 up outcomes will be measured both quantitatively and qualitatively. Expansion will be measured
56 through the ICP grid on ICP implementation in a particular area/organisation before the start of scale-
57 up and at the end of the project. This way, we can assess whether ICP coverage along its five
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3 components has expanded over four years (2019 vs. 2022). To complement the ICP grid, interviews
4 with implementors will be conducted, especially if a specific programme-intervention (e.g. training or
5 new health education programme for patients) or new policy gets implemented. Coverage will be
6 measured quantitatively, using a population survey or Electronic Health Records. If time and resources
7 allow, multiple time series data can be used to track ICP coverage. The axis integration will be assessed
8 through health facility stakeholder interviews, and review of policy documents and grey literature.
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11 In the final stage, health outcomes are analysed to assess the impact of the roadmap implementation
12 on the health care delivery process as depicted in Figure 2. Hence, patient and clinical data are
13 collected. The impact evaluation will measure the difference in the Cascade of Care (CoC) (proportion
14 of patients tested, diagnosed, in care, or in treatment for T2D and HT) before and after the scale-up
15 of the ICP. Details of the CoC analysis and the sources of data are introduced in the main SCUBY
16 protocol.²¹
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Table 1. Roadmap implementation and scale-up outcomes and measurement

Outcomes	Definition	Theoretical basis	Application to SCUBY	Assessment methods and tools
<i>Roadmap implementation outcomes</i>				
Acceptability	The perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory. ⁵⁰	Cf. social validity ⁵⁹	Acceptable: (resource and implementation) stakeholders have mostly consensus, or at least majority on way to go.	Surveys; Key informants' interviews
Feasibility	The extent to which a new treatment, innovation, strategy, or programme can be successfully used or carried out within a given agency or setting. ⁶⁰	Cf. compatibility ⁶¹	Feasibility signifies it is possible to reach the set goals specified within the roadmap.	Surveys; Key informants' interviews
Relevance	The perceived fit, appropriateness, or compatibility of the innovation or evidence-based practice (roadmap) for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem. ⁵⁰	Cf. appropriateness, perceived fit ⁵⁰	Fit and relevance of the proposed framework, strategies, and actions to government policy agenda and stakeholder perception/interest.	Surveys; Key informants' interviews
Adoption	The intention, initial decision, or action to try or employ an innovation or evidence-based practice. ⁵⁰ Can be expressed as the absolute number, proportion, and representativeness of settings (contexts) and intervention agents (implementers) that are willing to initiate a programme (policy or intervention).	RE-AIM; ⁵² NASSS framework, Cf. non-adoption/abandonment ^{15 53}	Uptake of the proposed roadmap (element).	Policy dialogue reporting form; Surveys; Key informants' interviews
Adaptation	The extent to which a policy or intervention is changed, the opposite of delivered as intended by its developers and in line with the programme model. It refers to the customisation and ongoing adaptation of the care package or programme model; ¹⁵ in this study, the adaptation of (preliminary and non-final versions of) the roadmap. Also linked to the concept of plasticity—"the extent to which interventions and their components are malleable and can be moulded to fit their contexts". ⁵¹	MRC implementation fidelity; ²⁶ Plasticity ⁵¹		Policy dialogue reporting form; Surveys; Key informants' interviews; Document reviews
Elasticity of the context	Elasticity can be defined as "the extent to which contexts can be stretched or compressed in ways that make space for intervention components and allow them to fit". ⁶²	Elasticity ⁵¹	Changes in the context that allow an acceleration or slow-down of roadmap strategies. Example 1: COVID-19 (slow-down because of other priorities, accelerator because of increased digitalisation efforts). Example 2: government change.	Follow-up stakeholder interviews (question on B&F); Policy mapping on timeline (keep eye on policy developments and implications)

<i>Scale-up outcomes</i>				
Coverage (horizontal scale)	The extent to which the target group is reached, in absolute and relative count. ⁶³	RE-AIM, ⁵² Cf. Reach	Target population reached; number of people actually covered by the intervention. Example: People who have access to GPs/practices with improved ICP/ACIC score in Belgium. Number of HCs (population covered by HCs) implementing newly modified PEN package in Cambodia. Target group members reached with m-health and peer support intervention in Slovenia.	EHRs; Population survey; Health report/data; Health facility assessment
Integration	<u>Integration</u> into health system and services (based upon Meessen et al. (2017), inspired by the universal coverage framework. ⁶⁴	RE-AIM, ⁵² Cf. maintenance Cf. penetration, institutionalisation, sustainability ⁵⁰	The extent to which complex systems (structure and processes) allow (maintain and institutionalise) ICP implementation. Example 1: Through laws, regulation, financing. The level of institutionalisation of the recommendations in the roadmap. Example 2: In Belgium, health financing reforms and legal reform facilitating nurses in primary care. Example 3: In Cambodia, functioning NCD clinics and community-based peer support are linked to HC-PEN. Example 4: In Slovenia, integration of telemedicine and peer support for chronic patients' management to primary care.	Key informants' interviews; Document reviews; Health facility assessment/ICP grid, EHRs
Expansion	Expanding the intervention programme (the ICP package to cover other elements). Similar to diversification as a type of scaling up in ExpandNet, also called functional scaling up or grafting, consists of testing and adding a new innovation to one that is in the process of being scaled up, hence, exploring the possibility of pilot testing an added component to the innovation. ³²	Cf. diversification ³²	Additional components in ICP; addition of comorbidities to package. Example: In Belgium, addition of nurses to GP practice; in Cambodia, newly modified PEN package; in Slovenia, addition of m-health and peer support to ICP.	Pre-post ICP implementation evaluation via ICP grid appraisal of practices; Key informants' interviews

Abbreviations: NCD: Non-communicable disease, ICP: Integrated Care Package, ACIC: Assessment of chronic illness care, GP: General Practitioner, PEN: package of essential noncommunicable, HC: Health center, EHR: Electronic Health Records, WHO: World Health Organization, B&F: barriers and facilitators.

Note: tools can be found in the Web annexes.

Table 2. Mechanisms of impact specific to policy dialogues

Policy dialogue indicators	Clarification or definition	Relating question
<i>'Theme – Environment':</i>		
Location	The location the policy dialogue takes place.	Was the room/location suitable?
Moderation/ Facilitation	How well the dialogue was moderated; this is key to having meaningful and comprehensive discussions.	How was the moderation? Who was moderating? Why was this person selected?
Technical/material conditions	Such as PowerPoint presentation, video, paper/report/information package provided, catering (lunch/snacks/reception).	How were technical/material conditions?
<i>'Theme – Content':</i>		
High-priority issue	An issue of (local, regional,) national, and international concern.	Was it a high-priority issue (for dialogue participants)?
Clear meeting objectives	This goes hand in hand with a clear vision of what outcomes and results would be expected.	Were clear meeting objectives set?
Information shared	A pre-circulated information package, including the agenda, evidence summaries, a list of policy directions to be discussed, related background information, and an evaluation form.	Which information was shared with participants (in advance, during, and after policy dialogue)?
Evidence used	Synthesis of high-quality research evidence used to identify needs and educate participants: policy dialogue discussions and participants need to be based on effective stakeholder and context analyses, part of which is evidence-based background information.	Was evidence used/presented in the meeting?
Agreement on outcomes and action plan	List of possible and tangible actions or steps.	Was agreement reached on outcomes and action plan?
Rules of engagement	The format of the meeting and rules of engagement (giving a clear overview of purpose, participants, design, method, and materials).	Was there a formal or informal format? What was the set-up or rules?
Preparation of content	The materials created for the policy dialogue and the management of the event of the meeting overall.	Was the policy dialogue well-prepared?
Follow-up	The continuation of the policy dialogue, in terms of ongoing communication of next steps and engagement, to keep the momentum alive and renew or regenerate the projects' or programme's goals. ¹⁴	Was there proper follow-up (on next actions, next meeting, evidence/information shared)?
<i>'Theme – Participants':</i>		
Representation	The stakeholder groups represented or excluded. A mix of participants and stakeholders representing all perspectives and interests: representation of decision-makers, researchers, and those affected by the issue under discussion (user/patients groups, formal and informal caregivers).	Which stakeholder groups were represented? Which were excluded?
Participation	Social participation requires all stakeholders in the participatory process to be able to adequately and fully exercise their roles. In order to do so, all stakeholders should be, as far as possible, on an equal footing with each other in terms of ability to have influence on the	Was there equal participation of stakeholders during the discussion? Who participated more? Who participated less?

	participation-based discussions. ⁶⁵	
Collaboration	The process of two or more people or organisations working together to complete a task or achieve a goal.	How was the collaboration between stakeholders?
Consensus	General agreement on something (by most participants). Five steps in the consensus-building process are: convening, clarifying responsibilities, deliberating, deciding, and implementing agreements.	Was consensus reached between stakeholders on a certain issue?
Trust	Firm belief in the reliability (or ability) of someone, relational	Was there trust between stakeholders?
Mutual respect	Mutual respect is defined as a proper regard for the dignity of a person or position; due regard for each other's feelings, wishes, or rights.	Was there mutual respect?
Willingness to implement	Gore et al. distinguish three types of commitment, ⁶⁶ namely: expressive commitment, institutional commitment, and budgetary commitment. " <i>Expressed commitment</i> refers to verbal declarations of support for an issue by high-level, influential political leaders. <i>Institutional commitment</i> comprises the adoption of specific policies and organisational infrastructure in support of an issue. Finally, <i>budgetary commitment</i> consists of earmarked allocations of resources towards a specific issue relative to a particular benchmark. The <i>combination</i> of the three dimensions signals that a state has an explicit intention or policy platform to address this health area."	Was there willingness to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? Type of political commitment? (Expressive/financial/institutional (i.e. policy))? How has COVID-19 influenced political will towards NCD care?
Leadership	The willingness to initiate, convoke, or lead an action for or against the health reform policy. ⁶⁷	Which stakeholder displayed the most leadership?
Urgency	The degree to which stakeholder claims call for immediate attention. ⁶⁸	Which stakeholder displayed the most urgency?
Legitimacy	A generalised perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions. ⁶⁸	Which stakeholder displayed the most legitimacy?
Ownership	Act, right, or degree of ownership (possession) and responsibility (taken by the resource/implementing organisation, community, and/or beneficiaries) towards any programs or activities	Which stakeholder had most ownership over the issue?

Abbreviations: NCD: non-communicable diseases

Data sources and collection tools

Key data collection tools developed for the process evaluation include:

1. The policy dialogue reporting form
2. The policy dialogue survey
3. The researcher interview guide
4. The follow-up stakeholder interview guide
5. Project diaries
6. Policy mapping: document review to generate a policy timeline
7. ICP grid for implementation assessment

Most of these are used to collect data on the policy dialogue and roadmap process, as well as on context. Tools were defined based on both the indicators (as displayed in tables 1 and 2) to be included and the activities entailed in the roadmap. Some tools, in particular, the policy dialogue reporting form

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3 and the survey are based on instruments developed by CHRODIS+.⁵⁵ All methods and tools will be
4 adapted to the specific needs and context of the countries' scale-up strategies.
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6 The policy dialogue reporting form (tool 1 in appendix 2) serves as a self-report to be filled in by the
7 research team to evaluate the policy dialogue, the roadmap progress, and contextual barriers.⁵⁵ Aside
8 from a section with general questions concerning the policy dialogue, a section is foreseen for the
9 rapporteur to write the minutes of the meeting, preferably during (and/or immediately after) the
10 policy dialogue.
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13 The policy dialogue survey (tool 2 in appendix 3) is to be completed by participants at the end of each
14 policy dialogue (that is organised by SCUBY).⁵⁵ A survey link is generated through the REDCap®
15 database^{69 70} and can be made accessible to participants online using mobile telephones. A paper
16 version can be an option if country teams prefer this and if this better fits the circumstances
17 (depending on the location). Items are related to the relevance and feasibility of discussed (roadmap)
18 actions and strategies (implementation outcomes) and to barriers and facilitators for the
19 implementation and scale-up of discussed strategies (context).
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23 Qualitative, in-depth follow-up researcher interviews (tool 3 in appendix 4) with the country teams will
24 be planned regarding the reporting forms to elaborate on items related to the roadmap and policy
25 dialogue (in line with the implementation outcomes and mechanisms). Additional qualitative
26 explanatory follow-up stakeholder interviews (tool 4 in appendix 5) will be undertaken to further
27 explore perceptions of policy dialogue and roadmap processes and contextual factors in depth.
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30 The aim of the project diary (tool 5 in appendix 6) is to display key research activities undertaken for
31 roadmap development and implementation. The policy mapping (tool 6 in appendix 7) will help track
32 key policy developments and evolutions in the field of integrated care. Furthermore, as a tool, it can
33 be used to guide or contextualise the purpose of the (next) policy dialogue meeting. Both the project
34 diary (tool 5) and the policy document mapping (tool 6)—which will generate a policy timeline on
35 integrated care—assess how the context influences SCUBY's activities and vice versa. The policy
36 mapping will inform the stakeholder interview (tool 3) and vice versa, especially in relation to the
37 existing policy and political barriers and facilitators that stakeholder participants might wish to further
38 comment on. Also, other policies and political events or activities (e.g. elections) might be tracked if
39 they impact integrated chronic care policy, such as COVID-19 restrictions or new regulations for the
40 care and control of the chronically ill in COVID-19 times (e.g. different modes of delivery, changed
41 duration, materials or location, increased use of IT tools and online consultations, etc.).
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46 The ICP grid at the healthcare practices (tool 7) which was used as part of context analysis in year 1,²¹
47 will be used again to evaluate expansion of the ICP grid, so that it can serve as a before-after evaluation
48 in those areas where it was used before.²¹
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50 **Data management and analysis**

51 Primary and secondary quantitative data collected from the implementation sites will be collated into
52 the main study REDCap® database via validated electronic survey forms. Anonymised data will be
53 transferred over the internet using secured data communication protocols for analyses. Qualitative
54 data will be stored as transcripts in country-specific databases as pseudonymised data. The transcripts
55 will be stored in formats that are exportable to NVivo software (NVivo qualitative data analysis
56 software; QSR International Pty Ltd.) for analysis.
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3 For the implementation outcomes, thematic analyses will be conducted based on the reporting forms,
4 interviews, and surveys. As such, evidence from different tools on policy dialogue (success factors),
5 roadmap (progress on adoption and implementation), and context (barriers and facilitators to scale-
6 up) will be triangulated, taking into account the various perspectives of implementors, other
7 stakeholders, and the SCUBY researchers. Themes will be deduced both from existing literature and
8 theory surrounding policy dialogues and roadmaps and grounded in the data. Many of the developed
9 tools have clear topics, relating either to underlying policy dialogue mechanisms or to roadmap
10 implementation outcomes. A theorising approach will be used to explore how context, actors,
11 roadmap activities, outcomes (cf. framework) are connected.⁷¹

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15 The dynamic policy and political processes (events, actions, and activities) unfolding over time in
16 context will be explored using processual analysis.^{72 73} Policy document review, desk research, and
17 input from interview participants on an initial policy mapping will be triangulated and further refined
18 to enable tracking the emergence of integrated care policies from a historical perspective, resulting in
19 a more detailed chronic care policy timeline. A minor part of the analysis will consist of a retrospective
20 stakeholder analysis on the sole attribute of the position of stakeholders on the roadmap development
21 and implementation.

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25 For the analysis of the scale-up dimensions, findings from different measurement tools will be
26 triangulated. For expansion, interviews with implementors and the ICP grid will be analysed again at
27 the end of the project to give an estimate on how ICP implementation has improved or deteriorated
28 across its five components, in comparison to the previous ICP implementation assessment of 2019.

30 **Patient and public involvement**

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32 Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans
33 of our research. The individual countries are likely to have community and patient involvement (e.g. in
34 the policy dialogues), depending on the specifics of each scale-up roadmap, and hence, their
35 involvement is beyond the scope of this current protocol.

39 **Discussion**

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42 This paper outlines the protocol for the evaluation of the process and scale-up of an integrated care
43 package for type 2 diabetes and hypertension, with the roadmap being the scale-up intervention and
44 policy dialogues as the main development and implementation strategy for the roadmaps.

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47 Scale-up is a complex intervention. In the SCUBY scale-up, multiple components and stakeholders
48 interact, producing emergent effects which are different from the effects of the individual elements
49 and actors within a socio-ecological system.^{26 74} The interventions can change over time because of
50 contextualisation and adaptation. Willis et al. highlight the importance of renewing and regenerating
51 complex interventions.¹⁴ Recent implementation studies have therefore stressed the relevance of
52 documenting modifications to evidence-based practices.⁷⁵⁻⁷⁷ The SCUBY scale-up intervention indeed
53 emphasises and documents the (continuous) adaptation as a result of a co-creative process.

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57 When planned early in the project, process evaluations are not only useful to understand
58 implementation, but can also feed back into the process and thereby strengthen implementation in
59 the project itself.

Strengths and limitations

A key strength of this evaluation protocol is the comprehensive framework to guide the evaluation and how it can serve as a guide for other scale-up interventions following knowledge translation and co-creation principles. It follows the MRC guidance framework,²⁶ emphasising the relationships between implementation, mechanisms of impact, and context. In a complex co-creative scale-up process such as in the SCUBY project, multiple indicators need to be assessed in order to identify which mechanisms lead to success. Willis et al. emphasise how process evaluations of scale-up interventions, in particular, need to support documentation of the success at key moments and at different time points, such as increased stakeholder awareness and commitment.¹⁴ Another strength is that the comprehensive and theoretical framework has been translated into relatively simple process evaluation tools that can be easily used and adopted by various SCUBY team members across multiple countries. This is crucial for cross-country learning. It also facilitates the use and adoption of tools for other scale-up projects.

The SCUBY study uses a quasi-experimental study design to evaluate the implementation of an evidence-based roadmap for the scale-up of integrated care for T2D and HT. The research team thus has limited control over many factors of the scale-up intervention. It would be difficult to verify all of the assumptions needed to establish causality between the scale-up of ICP and improvement in health outcomes.

The research team has limited control over the geographical areas in which the scale-up strategies will be rolled out, which implies adaptive planning for data collection. The availability of administrative data to evaluate the coverage of the scale-up is also dependent on the capacity and collaboration with government partners. The co-creation process of the scale-up intervention and subsequent strong relationships with relevant partners helps to mitigate part of this risk.

Evidence, stakeholders, and roadmap actions have a different role in each context, and have their own timelines and priorities. Specifically, country teams have differing capacities and priorities, and measuring the ICP expansion makes sense for countries that have focused their efforts on a diversification scale-up strategy (e.g. Slovenia). An overall challenge in this research will be, on the one hand, to collect sufficient data at various time points (dependent to some extent on the frequency of the policy dialogues in each country), and on the other hand, to analyse all collected data in an effective manner.

An added value is that the research team will also use empirical findings to refine theory on scale-up, to uncover how and why the adoption and implementation of the roadmaps through policy dialogues lead to scale-up of integrated care and improved health. This way, a theorising approach applied in the implementation and scale-up phase will advance the knowledge of mechanisms of implementation and specifically of scale-up science.⁷¹

Conclusion

The SCUBY project involves complex interventions in different healthcare systems, requiring multiple feedback loops to support adaptation, attention to local context, and the engagement of key actors such as resource and implementing organisations. Such complex interventions need an evaluation of multiple elements such as implementation processes, mechanisms, intermediate outcomes, and impact. This protocol offers a theory-based framework and methods to support scale-up research. It

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3 could be used in different healthcare systems for context-tailored processes and scale-up
4 interventions.
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8 **Ethics and dissemination**

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10 The Institutional Review Board (Ref. 1323/19) at Institute of Tropical Medicine (Nationalestraat 155,
11 2000 Antwerp, Belgium) approved this study on 1st July 2021. Findings will be reported to (1)
12 national, regional and local governments to inform policy; (2) funding bodies (European Commission)
13 and networks, such as the Global Alliance of Chronic Diseases (GACD), in line with their 2019 Scale Up
14 Call; (3) presented at local, national and international conferences; and (4) disseminated by peer-
15 review publications.
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19 **Declarations**

20 **Authors' contributions**

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22 The first (MM) and final (DB) authors were responsible for the conceptualisation and writing of the
23 manuscript. EW, JVO, and KGG reviewed different versions throughout the drafting process. MM, DB,
24 EW, JVO, KKG, GMK, ZKK, SrC, SaC, VB, KD, NS, CZ, APS, WVD, PI and RR were involved in the
25 development of the data collection tools. All authors contributed to the final draft of the manuscript,
26 have read the manuscript and approved it for submission.
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37 **Competing interests**

38 The authors declare that they have no competing interests
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List of Abbreviations

ACIC	Assessment of chronic illness care
B&F	Barriers and facilitators
CoC	Cascade of Care
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HC	Health centre
HT	Hypertension
ICP	Integrated care package
IT	Information technology
KII	Key informant interview
MRC	Medical Research Council
NASS (framework)	Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability
NCD	Non-communicable disease
NGO	Non-Governmental Organisation
PDRF	Policy Dialogue Reporting Form
PDS	Policy Dialogue Survey
PEN	Package of essential noncommunicable
RE-AIM (framework)	Reach, Effectiveness, Adoption, Implementation, Maintenance
SCUBY	Scale-Up diabetes and hypertension care
T2D	Type 2 diabetes
WHO	World Health Organisation

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For peer review only

interacts with intervention, implementation strategy and outcome

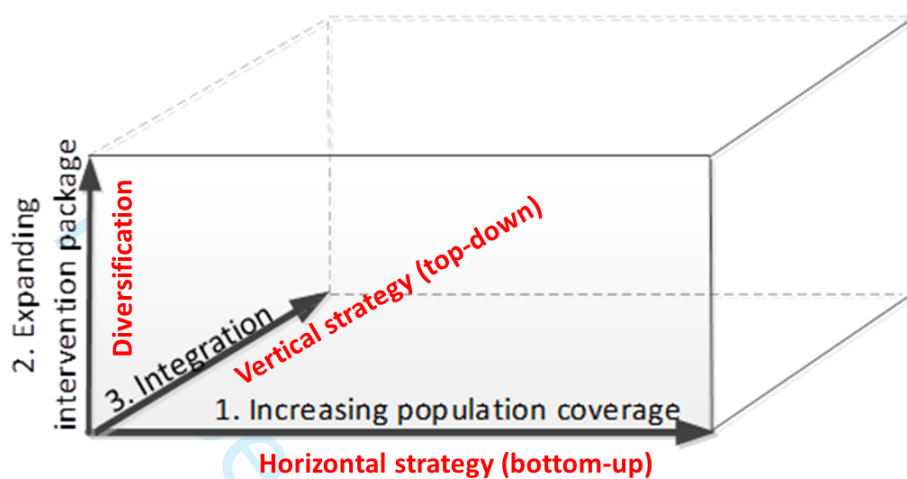


Roadmap development and implementation process



Appendix 1: Three-dimensional scale-up framework

Comprehensive scale-up

Types of strategy

Adapted from: van Olmen J, Menon S, Poplas Susic A, et al. Scale-up integrated care for diabetes and hypertension in Cambodia, Slovenia and Belgium (SCUBY): a study design for a quasi-experimental multiple case study. *Global health action* 2020;13(1):1824382

Appendix 2: Policy Dialogue Reporting Form (tool 1)

SCUBY Policy Dialogue Reporting Form

Policy Dialogue:

Country:

Date:

Completed by: [SCUBY team member(s)]

This sheet is used for **policy dialogue monitoring**. This document is based on the CHRODIS+ Policy Dialogue Reporting Form.

Please **also report more informal stakeholder meetings**, as we have adopted a very broad definition of policy dialogue. These reporting forms will help us keep track of the whole process.

Note: The first policy dialogue description table only needs to be **fully completed for a larger (multi-stakeholder!) dialogue** or when **SCUBY** is the organiser of the policy dialogue. Hence, for a meeting with one stakeholder group, e.g. a few policy makers, some questions do not need to be completed (as indicated in the table below).

INDEX

1. Policy Dialogue Description
2. Minutes of the Policy Dialogue
3. Action plan
4. Attachments:
 - Agenda/pre-circulated question list
 - List of documents

POLICY DIALOGUE description

General questions on Policy Dialogue	Complete fields underneath (when applicable; otherwise N/A)
1. "Title" or topic: What was the title or topic of the Policy Dialogue? [please write title between "... " to differentiate]	
2. Number of the Policy Dialogue	
3. Date: What date was the policy dialogue held on?	
4. Location: In what location did the policy dialogue take place?	
5. Main objective:	
6. Specific objectives: [please number them or use bullets]	
7. Number of participants:	
8. Members roles: Who was the <ul style="list-style-type: none"> • Organiser/coordinating team: • Moderator(s): • Keynote speaker(s): • Rapporteur(s)*: • Other Participants: <p>* mention if officially appointed in a meeting, otherwise N/A.</p>	<ul style="list-style-type: none"> • ... • ... • ... • ... • ...
9. Duration: (...h...min)	
10. Conclusions: (They should be aligned with the objectives)	

Questions about the Roadmap	Complete fields underneath (when applicable; otherwise N/A)
<p>1. Roadmap adaptation/plasticity: Has the roadmap (or a certain activity) been adapted based on the discussion(s) with stakeholders? Name all roadmap adaptations, briefly indicate how this (these) adaptation(s) came about or why it is (they are) appropriate.</p>	<p>Yes/no/N-A What/which? Why?</p>
<p>2. Context/elasticity: Please summarise (contextual) barriers to action plan/in roadmap</p>	
<p>Questions about the Policy Dialogue</p> <p>! : All questions need to be completed for big* policy dialogues (otherwise only questions 4–5 and 8, see green boxes)</p> <p>* when SCUBY is the organiser, or when it is a multi-stakeholder dialogue</p>	<p>Complete fields underneath (when applicable; otherwise N/A)</p>
<p><i>Please briefly comment on following items within ‘Theme – Environment’:</i></p>	
<p>1. Suitability of room/location: Was the room/location suitable? Why (not)?</p>	<p>Yes/no Why?</p>
<p>2. Moderation/facilitation: How was the moderation? Who was moderating? Why was this person selected?</p>	<p>Very poor/poor/neutral/good/very good (or N/A) Why?</p>
<p>3. Technical (material) conditions:</p>	<p>Which:</p>
<p><i>Please briefly comment on following items within ‘Theme – Content’:</i></p>	
<p>4. Information shared with participants in advance:</p>	<p>Yes/no Which:</p>
<p>5. Was evidence used/presented in the meeting? If so, what kind and what evidence specifically?</p>	<p>Yes/no? Qualitative/quantitative? Specify what:</p>
<p><i>Please briefly comment on following items within ‘Theme – Participants’:</i></p>	
<p>6. Representation: Which stakeholder groups were represented? Which were excluded?</p>	
<p>7. Participation:</p>	<p>Equal/unequal Who more?</p>

1 2 3 4 5 6 7	Was participation of stakeholders during the discussion equal? Who participated more? Who participated less?	Who less?
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	8. Will to implement of policy-makers and/or implementers* 1) Was there will to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? 2) Specify type of political commitment (expressive/financial/institutional (i.e. policy)? 3) How has COVID influenced political will towards NCD/integrated care? * Question only relevant if resource or implementing organisation(s) are participating	1) Yes/No/NA Which? Who? Comment why? 2) Expressive/financial/institutional commitment? Why? 3) How, positively? How, negatively?
25 26 27	9. Leadership Which stakeholder displayed most leadership?	Who?
28 29 30 31	10. Ownership Which stakeholder had most ownership over the issue?	Who?

Minutes of the Policy Dialogue

Narrative Minutes:

(Explain the points of discussion).

Attachments to the Policy Dialogue Reporting form

1. Agenda/Schedule

Policy dialogues should last between two and four hours.

Example:

10 mins	Welcome/Tour de Table → Policy Dialogue rules, reporting, and introduction of moderator, rapporteur, and organizer/coordinating team.
15 mins	Keynote Speech (not mandatory)
3–5 mins	Opening Statements of each participant, reflecting the various views and perspectives concerning the defined problem and policy action
60–90 mins	Guided Discussion (including consensus building on actions/next steps)
30 mins	Optional slot on EU level declaration concerning chronic diseases (Consensus Statement)
15 mins	Conclusions

2. List of shared documents and (ppt) presentations used

The research team provides here an overview of the invitation, information package(s), report(s) etc. that were shared with the policy dialogue participants as well as presentations.

Appendix 3: Policy Dialogue Survey (tool 2)

INTRODUCTION:

Thank you for taking the time to provide your valuable feedback relating to the Policy Dialogue you recently attended in the context of the EU-funded SCUBY project (2019–2022), developing and implementing a scale-up roadmap for chronic diseases (specifically for diabetes type 2 and hypertension).

To evaluate the effectiveness and relevance of the Policy Dialogues and consultations with experts, we kindly ask for your assistance in completing this feedback survey. Your insights and comments will help shape and strengthen future Policy Dialogues. The data from this survey will be combined with information from other sources; this information can be used in reports, reports, conferences and publications in professional journals

The survey should take less than **5 minutes to complete**. Responding to the survey signifies your consent. You may opt not to answer or to skip questions; however, we will not be able to remove any information you have already provided should you opt to withdraw your participation thereafter. Your responses to this survey will be kept **confidential**.

SURVEY QUESTIONS:

Please provide us with the following information about yourself:

1. You are: [Drop down menu of **occupations**]

- a policy maker/politician
- a civil servant in public health administration or at the Ministry of Health
- a civil servant in social affairs or at the Ministry of Social Affairs
- a civil servant at health insurance institute or at the Ministry of Finance
- a professional medical association
- an association of social/informal care worker
- a patient organisation
- in academia
- an NGO
- an (international) donor organisation (funder)
- a healthcare worker (nurse, GP, specialist)
- a social worker
- an informal caregiver
- a patient

[listed occupations can be contextualised per country]

2. How would you rate each of the following?

From 1-Poor to 5-Excellent

1. The location of the Policy Dialogue
2. Technical conditions (material, etc.) for the Policy Dialogue

3. Moderation
4. Background information shared in preparation for the Policy Dialogue
5. Sufficiency of evidence provided and discussed in the Policy Dialogue
6. Relevance of the topics covered [high priority issue]
7. Achievement of goals as delineated in the agenda
8. Definition and agreement of outcomes and action plan to move forward

3. What is, in your opinion, the **most relevant topic, strategy or idea covered/shared** during this Policy Dialogue for you and your country and why?
4. Which topic is **your organisation** committed to (one that was mentioned in the Policy Dialogue meeting or not mentioned)?
5. Rate the discussed topics in relation to their **relevance and feasibility** (1=low relevance/feasibility; 10=high relevance/feasibility)

Topics (strategies/roadmap elements) to be completed before/after policy dialogue by the country teams e.g. education; training; telemedicine as part of diabetes self-management; health financing (provider incentives); data monitoring; community involvement; primary care practice (integration) guidelines; etc.

6. What do you see are the **primary enhancing factors (facilitators)** for the implementation and scale-up of discussed proposals/actions/strategies agreed in this Policy Dialogue in your National Policies?
7. What do you see are the **(financial/political/operational) barriers** for the implementation and scale-up of discussed proposals/actions/strategies agreed in this Policy Dialogue in your National Policies?
8. How has **COVID influenced the will to change/adapt/improve** towards better NCD/integrated care? How, positively? How, negatively?
9. In your opinion, what do you think worked well and what **could be improved from this meeting**?
10. Overall, how would you **rate this Policy Dialogue**?
From 1-Very Poor, to 10-Excellent
11. Do you have any further comments or suggestions?

Thank you for taking the time to complete this survey. We truly value the information you have provided. Your responses will contribute to our analysis and help us to improve policy dialogues in the future.

Appendix 4: Researcher Interview Guide (tool 3)

Researcher interview guide

Interview participant(s):

Country:

Date:

Conducted by:

This guide is a complementary tool to the policy dialogue reporting form and aims to explore policy dialogue and roadmap-related indicators in more depth. Following items, based on implementation outcomes will be explored in depth:

- Adoption
- Stakeholders' support
- Implementation and scale-up dimensions
- Adaptation
- Policy dialogue environment-content-participants

Interview questions**A. Questions about the Roadmap****1. Roadmap adoption:**

Is a roadmap activity/action/strategy adopted? Yes/no/N-A? Which?

Does this policy dialogue lead to the roadmap element envisaged?

Make reference to the adopted action points.

Can you elaborate on why/how it got adopted?

2. Stakeholders' support:

Which/how many roadmap elements were discussed?

Who were the key stakeholders that gave feedback/critiqued certain roadmap elements?

Who was in full support of the roadmap element(s)?

Fill in for each discussed (roadmap) element for each key participant from resource and/or implementing organisations:

5-point scale:

1. No support or buy-in
2. Little support or buy-in
3. Neutral (towards the specific action/roadmap element)
4. Initial or moderate support and buy-in
5. Full support

3. Roadmap implementation:

Is a roadmap activity/action/strategy realised (implemented)? Yes/no/N-A? Which?

Does this policy dialogue lead to the implementation of a roadmap element envisaged (phase after adoption)?

Make reference to successful action points.

Can you elaborate on why/how it got implemented?
 Have discussed proposals and solutions led to institutionalisation (already become part of the healthcare system)? Why and how? [scale-up dimension of integration]
 Have discussed proposals and solutions led to diversification, the expansion [scale-up dimension] of the ICP? Why and how?
 Have discussed proposals and solutions led to increased population or geographical coverage [scale-up dimension]? Why and how?
 What are sources of verification [for perceived scale-up dimensions]? Research findings? Organisational report? Database? News item? Word-of-mouth? From resource or implementing organisation(s)?

4. Adaptation/plasticity:

Has the roadmap (or a certain activity) been adapted?
 Can you describe the way in which the roadmap (elements) have been adapted?
 Can you indicate how this (these) adaptation(s) came about or why it is (they are) appropriate.

5. Context/elasticity:

How has the context evolved? How are contextual (political/financial/operational) barriers and facilitators to action plan/in roadmap evolving?

B. Questions about the previously organised Policy Dialogue(s)

! : All questions need to be completed for big* policy dialogues (otherwise only questions 5–9 and 19, see green boxes)

* when SCUBY is the organiser or when it is a multi-stakeholder dialogue

Please briefly comment on following items within 'Theme – Environment':

1. Suitability of room/location:

Was the room/location suitable? Why (not)?

2. Moderation/facilitation:

How was the moderation? Why good/bad?

3. Technical (material) conditions:

How were technical/material conditions? (e.g. website/video/presentation/flyers/information package/catering etc. provided?) Why good/bad?

4. Other conditions:

Please briefly comment on following items within 'Theme – Content':

5. Was it a high-priority issue (for dialogue participants)? Why?

6. Were clear meeting objectives set? Clear how? If unclear, why?

7. Do you think that sufficient information was shared with participants (in advance, during and after policy dialogue)? (Why not?)

8. Was evidence used/presented in the meeting?

If so, what kind (quant/qual/both) and what evidence specifically?

9. Was agreement reached on outcomes and action plan? How/why not?

10. Rules of engagement:

Was there a formal or informal format?

What was the set-up or rules?

1 2 3 4 5 6	<i>(e.g. online meeting, Chatham House rules, stakeholders share their perspectives one by one, scientific presentation with comments, discussion in sub-groups or plenary session, expert panel, high-level policy maker meeting)</i>
7	11. Was the policy dialogue well-prepared?
8 9 10	12. Was there proper follow-up (on next actions, next meeting, evidence/information shared)?
11	<i>Please briefly comment on following items within 'Theme – Participants':</i>
12 13 14	13. Representation: Which stakeholder groups were represented? Which were excluded?
15 16 17 18 19	14. Participation: Was participation of stakeholders during the discussion equal? Who participated more? Who participated less?
20 21 22 23 24 25 26 27	15. Collaboration How was the collaboration between stakeholders? - Very poor/poor/neutral/good/very good - Can you use a word to describe your collaboration? E.g. top-down, bottom-up, organic, spontaneous, awkward, formal, informal, ... Why do you think it was good/bad?
28 29	16. Consensus Was consensus reached between stakeholders on a certain issue? How?
30 31 32	17. Trust Was there trust between stakeholders? How did you notice?
33 34 35	18. Mutual respect Was there mutual respect? How did you notice?
36 37 38 39 40 41 42 43 44	19. Will to implement of policy-makers and/or implementers* : 1) Was there will to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? What do you think drives them to implement? Why/what is the reason to implement? Is there one direct reason or many good reasons? 2) Specify type of political commitment (expressive/financial/institutional (i.e. policy))? 3) How has COVID influenced political will towards NCD/integrated care? How, positively? How, negatively?
45	* Question only relevant if resource or implementing organisation(s) are participating
46 47 48	20. Leadership Which stakeholder displayed most leadership? + Why?
49 50 51	21. Urgency Which stakeholder displayed most urgency? + Why?
52 53 54	22. Legitimacy Which stakeholder displayed most legitimacy? + Why?
55 56 57 58 59 60	23. Ownership Which stakeholder had most ownership over the issue? + Why?

Appendix 5: Follow-up Stakeholder Interview Guide (tool 4)

Introduction

Introduction of the researcher(s)

- Name & function of researcher
- Share researcher's contact details (e.g. business card)
- In case of 2 researchers: one asking questions (mainly) and one/both taking notes

Introduction of SCUBY

- SCUBY is a 4-year research project on the scaling up of integrated care for diabetes and hypertension through co-creation with key stakeholders, such as you ... We are studying the scaling up of integrated care for diabetes and hypertension, with special attention to vulnerable people.
- The aim of this research is to engage with key stakeholders at all levels, to identify opportunities and barriers to integrated chronic care at the macro level, to implement and support best practices on a larger scale.
- Focus on integrated chronic care, diabetes, hypertension & vulnerable groups (key terms)

Explain purpose and the intent of the interview:

- **Thank you** for taking the time to provide your valuable feedback relating to the Policy Dialogue you recently attended in the context of the EU-funded SCUBY project (2019–2022), developing and implementing a scale-up roadmap for chronic diseases (specifically for diabetes type 2 and hypertension).
- **To evaluate** the effectiveness and relevance of the Policy Dialogues and consultations with experts, we kindly ask for your participation in this (follow-up) interview. Your insights and comments will help shape and strengthen future Policy Dialogues.
- Duration of interview: max 60 min
- Ensure anonymity and confidentiality
- Questions?

Informed consent

- Ask (to sign) the informed consent and permission to record the interview

Outline of interview (topics to cover)

- Policy dialogue
- Roadmap development
- Stakeholder engagement (attributes)
- Remarks and conclusion

Policy dialogue

1. What was your role and contribution in the Policy Dialogue? How was your experience?
2. Were the topics under discussion in the Policy Dialogue relevant (**high priority**) to you?
3. Was the **evidence** provided and discussed in the Policy Dialogue relevant and interesting to you? Can you use it and how?
4. How important do you think **representation** is in Policy Dialogues? Were certain groups not represented? What do you think are the benefits of a small vs big group in a Policy Dialogue?

5. How would you describe the **collaboration** between stakeholders in the Policy Dialogue? Have you collaborated before with some of these participating stakeholders? With who (not)?
6. Was a **consensus** reached on an action plan? If yes, consensus on what? And how was it reached?
7. *To policy makers:* what do you think is needed in order to implement the discussed proposal? What is your role/contribution in the scale-up of this strategy? *To other stakeholders:* Do you think policy-makers will implement the discussed proposal? Why (not)? What is your role/contribution in the scale-up of this strategy? Specify type of political commitment (expressive/financial/institutional (i.e. policy))? [**will to implement**]
8. How has **COVID** influenced political will towards NCD/integrated care? How, positively? How, negatively?
9. In your opinion, what do you think worked well and what **could be improved** from this meeting?

Roadmap

10. How **acceptable** do you think is this action/strategy/roadmap element [*specify; e.g. training/group education programme/data monitoring*] to the beneficiary (provider/patient)?
11. Can you please comment on both the **relevance** and the **feasibility** of the proposals, actions or strategies discussed/shared/agreed upon in the policy dialogue? (as one might be highly important but not a feasible action, or vice versa)
12. [**Context**] What do you see are (**financial/political/operational**) **barriers** that might hinder the implementation and scale-up of discussed proposals/actions/strategies in your National Policies?
13. [**Adaptation/plasticity**] Are changes to the roadmap or specific roadmap elements [*specify*] necessary? Which?
14. [**Costs**] What do you think are the costs related to this roadmap action/strategy [*specify*] and its implementation?
15. [later stage] Have discussed proposals and solutions led to **institutionalisation** (already become part of the healthcare system)? Why and how? [scale-up dimension of integration]
16. [later stage] Have discussed proposals and solutions led to diversification, the **expansion** [scale-up dimension] of the ICP? Why and how?
17. [later stage] Have discussed proposals and solutions led to increased population or geographical **coverage** [scale-up dimension]? Why and how?

Concluding remarks

Additional comments

- Do you have any additional remarks?

Thank

- Thank your time to participate in this interview. We truly value the information you have provided. Your responses will contribute to our analysis and help us to improve policy dialogues and scale-up in the future.

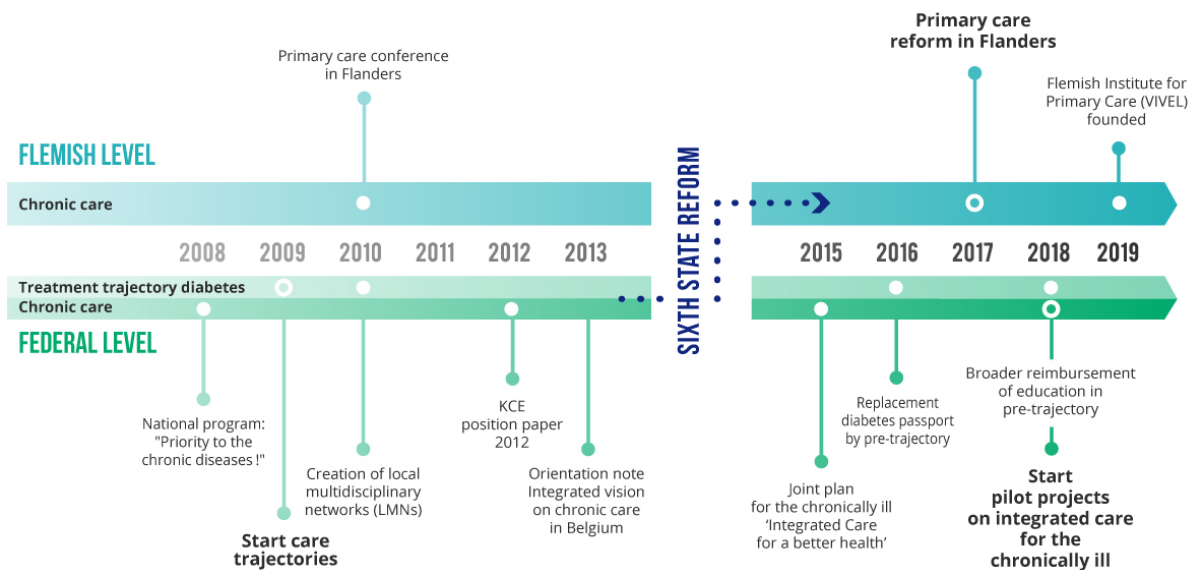
Share SCUBY brochure at the end.

Appendix 6: Template for project diary (tool 5)

Date	Event	SCUBY participant(s)	Other participants	Topic (about)	Next steps/outcomes
04/2019	Focus groups with patients				
05–09/2019	Stakeholder interviews				
23/10/2019	Launch SCUBY				
02/2020	SCUBY consortium meeting				
30/06/2020	Meeting MoH				
21/09/2020	Expert panel				

Note: The table displays activities and meetings in chronological order. Examples of activities are provided. Internal team meetings do not need to be all chronologically registered; rather the aim of the project diary is to display: (1) meetings with a stakeholder(s) on steps undertaken in the roadmap; and (2) other related network and research activities.

Appendix 7: Example of (Belgian) policy timeline on integrated care (tool 6)



Note: not updated for current corona policy developments

BMJ Open

Process evaluation of the scale-up of integrated diabetes and hypertension care in Belgium, Cambodia, and Slovenia (the SCUBY project): A study protocol

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Primary Subject Heading:	Health policy
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Process evaluation of the scale-up of integrated diabetes and hypertension care in Belgium, Cambodia, and Slovenia (the SCUBY project): A study protocol

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Abstract

Introduction: Integrated care interventions for type 2 diabetes (T2D) and hypertension (HT) are effective, yet challenges exist with regard to their implementation and scale-up. The ‘Scale-Up diaBetes and hYpertension care’ (SCUBY) project aims to facilitate the scale-up of integrated care for T2D and HT through the co-creation and implementation of contextualised scale-up roadmaps in Belgium, Cambodia, and Slovenia. We hereby describe the plan for the process and scale-up evaluation of the SCUBY project. The specific goals of the process and scale-up evaluation are to (i) analyse how, and to what extent, the roadmap has been implemented, (ii) assess how the differing contexts can influence the implementation process of the scale-up strategies, and (iii) assess the progress of the scale-up.

Methods and analysis: A comprehensive framework was developed to include process and scale-up evaluation embedded in implementation science theory. Key implementation outcomes include acceptability, feasibility, relevance, adaptation, adoption, and cost of roadmap activities. A diverse range of predominantly qualitative tools—including a policy dialogue reporting form, a stakeholder follow-up interview and survey, project diaries, and policy mapping—were developed to assess how stakeholders perceive the scale-up implementation process and adaptations to the roadmap. The role of context is considered relevant, and barriers and facilitators to scale-up will be continuously assessed.

Ethics and dissemination: Ethical approval has been obtained from The Institutional Review Board (Ref. 1323/19) at the Institute of Tropical Medicine (Antwerp, Belgium). The SCUBY project presents a comprehensive framework to guide the process and scale-up evaluation of complex interventions in different health systems. We describe how implementation outcomes, mechanisms of impact, and scale-up outcomes can be a basis to monitor adaptations through a co-creation process and to guide other scale-up interventions making use of knowledge translation and co-creation activities.

Strengths and limitations of this study

- The evaluation methods in this paper combine implementation science and scale-up theories in a joint framework.
- This identification of sequential indicators for different steps in the scale-up process is innovative and useful to conceptually advance research on scale-up.
- The insertion of mechanisms of change in the evaluation framework allows for empirical testing of theory-based concepts that facilitate scale-up.
- The set of data collection tools to track the policy dialogue and scale-up roadmaps are hands-on and can accelerate empirical scale-up research.
- A limitation of this study is the delay in data collection due to the COVID-19 pandemic, which in turn could lead to recall bias of stakeholders in interviews on the process of stakeholder collaboration in policy dialogues.

Keywords

Process evaluation, (qualitative) mixed methods, evaluation framework, scale-up, complex intervention, co-creation/policy dialogue

Introduction

To address the rising burden of chronic diseases across the world, global commitments have been made toward an integrated care approach offering multidisciplinary, non-episodic, and patient-centred care.¹⁻⁵ Integrated care leads to better care coordination and (cost) efficiency, and improves the quality of care and patient outcomes by linking services along the continuum of care.^{3 6 7} However, the scale-up of integrated care is challenging because chronic diseases pose a wicked problem⁸⁻¹² requiring multi-stakeholder action and intersectoral coordination at individual healthcare practice, organisational, and political/system levels.^{13 14}

Moreover, little is known about how to scale up complex, adaptive, and strongly contextualised interventions.¹⁴⁻¹⁶ Blueprint approaches to scaling-up health care interventions commonly described in the literature and global health initiatives are linear process models and do not fit the dynamic, emergent, and adaptive scale-up process of complex health interventions.¹⁷ Complexity is not just a property of wicked problems, but also of the intervention and the context (or system) into which the intervention takes place.¹⁸ A complex intervention can be perceived as a process of changing complex systems,¹⁹ involving multi-component, multi-stakeholder, and multi-level efforts that are tailored to the contexts in which they are delivered.^{14 20}

The 'SCale-Up diaBetes and hYpertension care' (SCUBY) project aims to develop, co-create, and assess roadmaps, which can be adapted for use in different contexts, for scaling-up of an integrated care package (ICP) for type 2 diabetes (T2D) and hypertension (HT) in dissimilar types of health systems.²¹ The ICP comprises of: (a) early detection and diagnosis, (b) treatment in primary care services, (c) health education, (d) self-management support to patients and caregivers, and (e) collaboration between caregivers.²¹⁻²⁴ These generic components are implemented via country-specific delivery models, which have been elaborated in the SCUBY protocol paper.²¹

SCUBY is a multiple case study, in which each country (Belgium, Cambodia, and Slovenia) is a case of the ICP scale-up for T2D and HT. These three countries were chosen in view of the lessons that can be drawn from these diverse health system contexts: a developing health system in a lower-middle-income country (Cambodia); a centrally steered health system in a high-income country (Slovenia); and a publicly-funded, highly privatised healthcare health system in a high-income country (Belgium).²¹ Hence, the selection of the three cases was based upon their health system characteristics, as well as current focus on scale-up strategies. Scale-up is multi-dimensional and requires various efforts to: (1) increase population coverage, (2) integrate or institutionalise ICP into health system services, and (3) expand the intervention package, i.e., diversifying the ICP with additional components.^{21 25-27} Appendix 1 provides details on this three-dimensional framework.^{21 25} The scale-up activities are specifically targeted toward improving primary (low-level) care, in all three countries. Each country focuses on a different scale-up dimension and adopts a suitable scale-up strategy that is in line with contextual needs. In Belgium, where multiple projects have been developed in several areas (current horizontal strategy), the roadmap will focus on how the ICP can be made routine practice in the Belgium health system, and which financial, policy, and regulatory reforms can support this transition (*integration*). In Cambodia, where the vertical (i.e., institutional; top-down) strategy is established, the roadmap mainly focuses on adopting a horizontal strategy to increase population *coverage* of the ICP for T2D and HT care, more specifically, increasing the number of health facilities at the primary care level providing T2D and HT care. In Slovenia, the aim

of the roadmap is to strengthen diversification (*expanding* the ICP) through enhancing the involvement of patients and informal caregivers in health care. This will be achieved by down-stepping care from health care professionals at the primary care level to patients and informal caregivers. The focus is therefore on patient empowerment and self-management of T2D and HT.

The SCUBY interventions for scale-up involve the development of evidence-based roadmaps and policy dialogues.²¹ These two methodologies—roadmaps and policy dialogues—are very much intertwined and considered to be key elements for successful stakeholder-supported scale-up.¹⁷ The first versions of the roadmaps in each country were developed based upon the findings of the formative phase and initial policy dialogues with stakeholders in each country. Subsequently, a feasible and relevant evaluation protocol was developed, in accordance with evaluations of complex interventions, which have a flexible, adaptable design.²⁸ The protocol also describes the framework to guide the evaluation of the scale-up intervention in the SCUBY project.

The evaluation of the SCUBY intervention constitutes the third phase of the project and includes four (process, scale-up, cost, and impact) evaluations with separate research questions.²¹ This protocol comprises the first two evaluations only: the process and scale-up evaluation of the SCUBY intervention. This will increase the understanding of the process of implementing roadmaps to scale-up integrated care and to improve health outcomes, and how this is influenced by different contexts. The specific research questions we aim to address are: (i) how has the country-specific roadmap been implemented and to what extent? (ii) how can the differing contexts influence the implementation process of the scale-up strategies? and (iii) what progress has been made on each of the three axes of scale-up? Box 1 provides key definitions and their application to the SCUBY project.

Box 1. Key definitions and their application to the SCUBY project.

Concept	Definition	Application in the SCUBY project
Roadmap	An action plan delineating the targets, planning, and progression of scale-up strategies, identifying actors, actions, and timelines based upon priorities in place and time. ²¹	Scale-up Intervention In SCUBY, a scale-up roadmap constitutes an overall scale-up strategy and aim; roadmap actions or activities; a problem statement, rationale and objectives/aim(s) for each roadmap action, a timeline to plan roadmap activities within a time frame; and a description of the evidence base and key partners/stakeholders involved in the scale-up (the coordination mechanism per roadmap action).
Policy dialogue	An essential component of the policy and decision-making process, where it is intended to contribute to informing, developing, or implementing a policy change following a round of evidence-based discussions, workshops, and consultations on a particular subject. It is seen as an integrated part of the policy-making process and can be conducted at any level of the health system where a problem is perceived and a decision, policy, plan, or action needs to be made. ²⁹	Implementation strategy (to guide the roadmap development to implementation) In SCUBY, policy dialogues are used as an approach in the policy-making process to engage with key stakeholders and to develop the countries' scale-up roadmaps. They will comprise structured formal events, one-to-one interactions with key stakeholders, workshops, consultations, and joining ongoing dialogues within the context. ²⁹
Context	Complex adaptive systems that form the dynamic environment(s) in which implementation processes are situated; ³⁰ a set of characteristics and circumstances that consist of active and unique	Mediator The context in SCUBY is assessed at micro, meso, and macro levels. Since scale-up is targeting the country level, the process evaluation focuses on the macro-level context, specifically the

	factors, within which the implementation is embedded. As such, context is not a backdrop for implementation, but interacts, influences, modifies, and facilitates or constrains the intervention and its implementation. Context is usually considered in relation to an intervention, with which it actively interacts. It is an overarching concept, comprising not only a physical location but also roles, interactions, and relationships at multiple levels. ³¹	barriers and facilitators to scale-up. We look at the World Health Organization (WHO) health system building blocks ^{32 33} and broader political, economic, social, technological, environmental, and legal factors.
Scale-up	The efforts to increase the impact of health interventions so as to benefit more people and to foster policy and programme development on a sustainable basis. ²⁶	Study aim/goal Scale-up efforts in SCUBY can include various efforts to make progress on any of the three axes. Examples of efforts are: increasing coverage of existing interventions, strengthening or expanding the existing ICP package, and changing financing or monitoring systems.

The SCUBY intervention: a scale-up roadmap

The SCUBY intervention is an adaptable, evidence-based roadmap for scale-up. This roadmap comprises an action plan with steps and strategies towards a set goal—the scale-up of an ICP to improve access to affordable quality care for T2D and HT. It thus includes both processes and actions by which the ICP is brought to scale. The roadmaps can consist of a mix of scale-up strategies. The term “scale-up roadmap” is derived from the WHO/ExpandNet framework, which also provides classifications according to the degree of the intention of scale-up, formal planning, and locus of initiative:^{26 34} (a) top-down strategies whereby the central level decides to implement the innovation and institutionalises it through planning, policy changes, or legal action; (b) horizontal strategies to expand geographically or population-based; and (c) diversification strategies referring to adding new elements to an existing intervention. Thus, three major strategic scale-up options are available for roadmaps: a, b, c, or a combination of the aforementioned. The three implementing countries in the SCUBY project follow this categorisation in focus and approach: a vertical, government-steered top-down (type a) strategy in Cambodia, a horizontal strategy (type b) in Belgium, and a diversification scale-up strategy (type c) in Slovenia. In addition, countries may deviate from the dominant strategy to include other strategies to maintain progress.

Context in this multi-country study is key, as it interacts with the intervention and the implementation strategy, as well as the (implementation and scale-up) outcomes,²⁸ as shown in Figure 1. Contextual factors include barriers and facilitators to scale-up. Each context will influence the development and implementation process of the roadmap differently due to the large cultural, socio-political, and economic differences between the implementation countries, and vice versa, in each country under study, the roadmap development and implementation process will have a different impact on the context.

Figure 1. The interaction between context and the roadmap development and implementation process.

The main implementation strategy: policy dialogues

Within the SCUBY project, policy dialogues play a crucial role in the implementation of the scale-up roadmaps. Policy dialogues have been introduced by the WHO as a tool to support organisational and/or systemic changes in health and health care.²⁹ Concepts linked to policy dialogue are co-creation,³⁵⁻³⁸ co-production,³⁸⁻⁴¹ deliberative methods and processes,⁴² social and community participation,^{43 44} and collaborative governance.^{45 46}

The policy dialogue is the strategy that all implementing countries have in common. This illustrates the necessity of high-level policy engagement and multi-stakeholder collaboration. The policy dialogue can therefore be viewed as SCUBY's main implementation strategy for the development and implementation of the roadmaps in each country. Because of this ongoing engagement with stakeholders in policy dialogues, the roadmap (intervention) can continue to be adapted and amended over time.

The roadmap development and implementation process in figure 1 represents the "co-creative", emergent process towards scale-up, with multiple feedback loops from the policy dialogues to the roadmap. In addition to scientific and local evidence, the policy dialogues are literally feeding into the roadmap development and implementation; the policy dialogues provide a means to increase stakeholder (and community) support and subsequently contribute to roadmap implementation and thus the scale-up of integrated care for T2D and HT.

An overarching framework for evaluation

Figure 2 presents a comprehensive framework to guide the evaluation of the roadmap implementation. This framework has been developed to support the process and scale-up evaluation of the SCUBY intervention. It is useful to gain insight into how the key steps of the roadmap development and implementation process can be linked to outcomes and what effective measurement tools are used to capture the roadmap implementation and scale-up process.

Figure 2. An overall framework for process and scale-up evaluation. Note: Key informant interviews in SCUBY include interviews with stakeholders from resource and implementing organisations²⁶ and with SCUBY research team members in the different implementing countries.

This framework was adapted from the Medical Research Council (MRC) guidance framework for process evaluations,²⁸ emphasising the relevance of context, and its interaction with not only the intervention, but also the implementation process, the underlying mechanisms of impact, and early, midterm implementation outcomes and scale-up outcomes. As an overarching framework, it brings together the complex intervention and implementation strategy, presenting it as a process of incremental and cyclical change and adaptation, whilst linking this process to key indicators, tools, and types of evaluation.

The framework distinguishes two types of evaluation: process and scale-up evaluation. Context evaluation can be seen as a sub-part of the process evaluation, whereas context has a major influence on the development and implementation process of the complex intervention. The outcomes and measurement tools in this framework are further described in the methods section of this protocol.

Methods and analysis

Study population and design

The SCUBY study is a multiple case study, in which each country is a case. The process and scale-up evaluation in this protocol use a mixed method design, the process evaluation being qualitative and the scale-up evaluation partly quantitative.⁴⁷ The study population for the process evaluation are the stakeholders involved in the policy dialogues and the roadmap development and implementation process. The WHO/ExpandNet framework²⁶ derives two main categories: resource and implementing (user) organisations.^{48 49} Another meaningful classification for stakeholder categorisation comes from Campos and Reich.⁵⁰ These authors distinguish stakeholder groups that are likely to influence implementation: interest groups, bureaucrats (civil servants from public administration), financial decision-makers, political leaders, beneficiaries, and external actors.⁵⁰ In the SCUBY project, we distinguish one additional (seventh) group: scientific actors. The study population for the scale-up evaluation are the target population (e.g. healthcare providers; patients) living in the areas in which scale-up activities were performed.

Implementation process and scale-up outcomes

This project focuses on the implementation process and scale-up (or progression) outcomes. Their definitions, as well as their theoretical basis, application to the SCUBY project, and corresponding assessment methods and tools are described in Table 1.

Specific outcomes will be used depending on the stage of the project: early, mid, and late.⁵¹ Acceptability, feasibility, and relevance are key implementation outcomes of roadmaps in the early stage, while adaptation, adoption, and cost of roadmap activities will become more relevant from an early to mid-stage as displayed in the middle row in Figure 2. In each of these stages (early, mid, and late), the role of context will remain relevant, and barriers and facilitators to scale-up will be continuously assessed. Relevant attributes of the context and intervention used in implementation science are elasticity (of the context) and plasticity (of the intervention). Elasticity is linked to institutional fit and change in context brought about by the intervention (and implementation) process, while plasticity is related to the concept of adaptation.⁵² Measurement of the implementation outcomes is guided by multiple evaluation frames, including RE-AIM (reach, effectiveness, adoption, implementation, maintenance),⁵³ the MRC implementation fidelity,²⁸ and the NASSS (non-adoption, abandonment, scale-up, spread, sustainability) framework.^{15 54}

The mechanisms for impact refer to the effects or (causal) pathways of a specific intervention and answer the question “how does the delivered intervention produce change?” The assessment of mechanisms of impact focuses on the policy dialogue which is the major implementation strategy for the roadmap. Potential mechanisms for impact were identified through literature review on the success factors of policy dialogues⁵⁵⁻⁵⁸ and related to: (1) environment, (2) content, and (3) participants.⁵⁹ The mechanisms of impact specific to policy dialogues are presented in Table 2.

Next to implementation outcomes, scale-up outcomes (“late stage” box of the conceptual model displayed in Figure 2) will be tracked. We distinguish three scale-up outcomes: (1) Coverage, (2) Integration, and (3) expansion. In the literature some overlapping concepts are used.⁵¹ In implementation literature, the concept of reach is often used interchangeably with coverage. Similarly, maintenance, sustainability, and institutionalisation are used to assess integration.⁵¹

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3 Expansion as a third dimension—in SCUBY specifically used to indicate an extra element added in the
4 ICP—is similar to the WHO’s use of diversification in their ExpandNet strategy for scale-up.²⁶ The
5 scale-up outcomes will be assessed qualitatively and include some quantitative elements. Expansion
6 will be measured via a questionnaire with items on the five ICP components (the ICP grid). The
7 questionnaire contains items per ICP component which are scored on a five-point Likert scale. This
8 instrument—the ICP grid—was developed in collaboration between the different SCUBY country
9 teams. It was adapted from the WHO’s Innovative Care for Chronic Conditions (ICCC)⁶⁰ Framework
10 situation assessment and the Assessment of Chronic illness Care (ACIC)⁶¹ which has been validated in
11 high-income countries. This way, ICP implementation in a particular area/organisation is assessed
12 before the start of scale-up and at the end of the project. Furthermore, we can assess whether ICP
13 coverage along its five components has expanded over four years (2019 vs. 2022). To complement
14 the ICP grid, interviews with implementors will be conducted, especially if a specific programme-
15 intervention (e.g. training or new health education programme for patients) or new policy gets
16 implemented. Coverage (i.e. number of people covered by the ICP) will be measured quantitatively,
17 using a population survey or Electronic Health Records. If time and resources allow, multiple time
18 series data can be used to track ICP coverage. The axis integration will be assessed through health
19 facility stakeholder interviews, and review of policy documents and grey literature. Hence, progress
20 on integration will be reported descriptively.
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Table 1. Roadmap implementation and scale-up outcomes and measurement

Outcomes	Definition	Theoretical basis	Application to SCUBY	Assessment methods and tools
<i>Roadmap implementation outcomes</i>				
Acceptability	The perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory. ⁵¹	Cf. social validity ⁶²	Acceptable: (resource and implementation) stakeholders have mostly consensus, or at least majority on way to go.	Surveys; Key informants' interviews
Feasibility	The extent to which a new treatment, innovation, strategy, or programme can be successfully used or carried out within a given agency or setting. ⁶³	Cf. compatibility ⁶⁴	Feasibility signifies it is possible to reach the set goals specified within the roadmap.	Surveys; Key informants' interviews
Relevance	The perceived fit, appropriateness, or compatibility of the innovation or evidence-based practice (roadmap) for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem. ⁵¹	Cf. appropriateness, perceived fit ⁵¹	Fit and relevance of the proposed framework, strategies, and actions to government policy agenda and stakeholder perception/interest.	Surveys; Key informants' interviews
Adoption	The intention, initial decision, or action to try or employ an innovation or evidence-based practice. ⁵¹ Can be expressed as the absolute number, proportion, and representativeness of settings (contexts) and intervention agents (implementers) that are willing to initiate a programme (policy or intervention).	RE-AIM; ⁵³ NASSS framework, Cf. non-adoption/abandonment ^{15 54}	Uptake of the proposed roadmap (element).	Policy dialogue reporting form; Surveys; Key informants' interviews
Adaptation	The extent to which a policy or intervention is changed, the opposite of delivered as intended by its developers and in line with the programme model. It refers to the customisation and ongoing adaptation of the care package or programme model; ¹⁵ in this study, the adaptation of (preliminary and non-final versions of) the roadmap. Also linked to the concept of plasticity—"the extent to which interventions and their components are malleable and can be moulded to fit their contexts". ⁵²	MRC implementation fidelity; ²⁸ Plasticity ⁵²		Policy dialogue reporting form; Surveys; Key informants' interviews; Document reviews
Elasticity of the context	Elasticity can be defined as "the extent to which contexts can be stretched or compressed in ways that make space for intervention components and allow them to fit". ⁶⁵	Elasticity ⁵²	Changes in the context that allow an acceleration or slow-down of roadmap strategies. Example 1: COVID-19 (slow-down because of other priorities, accelerator because of increased digitalisation efforts). Example 2: government change.	Follow-up stakeholder interviews (question on B&F); Policy mapping on timeline (keep eye on policy developments and implications)
<i>Scale-up outcomes</i>				

<p>Coverage (horizontal scale)</p>	<p>The extent to which the target group is reached, in absolute and relative count.⁶⁶</p>	<p>RE-AIM,⁵³ Cf. Reach</p>	<p>Target population reached; number of people actually covered by the intervention. Example: People who have access to GPs/practices with improved ICP/ACIC score in Belgium. Number of HCs (population covered by HCs) implementing newly modified PEN package in Cambodia. Target group members reached with m-health and peer support intervention in Slovenia.</p>	<p>EHRs; Population survey; Health report/data; Health facility assessment</p>
<p>Integration</p>	<p><u>Integration</u> into health system and services (based upon Meessen et al. (2017), inspired by the universal coverage framework.⁶⁷</p>	<p>RE-AIM,⁵³ Cf. maintenance Cf. penetration, institutionalisation, sustainability⁵¹</p>	<p>The extent to which complex systems (structure and processes) allow (maintain and institutionalise) ICP implementation. Example 1: Through laws, regulation, financing. The level of institutionalisation of the recommendations in the roadmap. Example 2: In Belgium, health financing reforms and legal reform facilitating nurses in primary care. Example 3: In Cambodia, functioning NCD clinics and community-based peer support are linked to HC-PEN. Example 4: In Slovenia, integration of telemedicine and peer support for chronic patients' management to primary care.</p>	<p>Key informants' interviews; Document reviews; Health facility assessment/ICP grid, EHRs</p>
<p>Expansion</p>	<p>Expanding the intervention programme (the ICP package to cover other elements). Similar to diversification as a type of scaling up in ExpandNet, also called functional scaling up or grafting, consists of testing and adding a new innovation to one that is in the process of being scaled up, hence, exploring the possibility of pilot testing an added component to the innovation.²⁶</p>	<p>Cf. diversification²⁶</p>	<p>Additional components in ICP; addition of comorbidities to package. Example: In Belgium, addition of nurses to GP practice; in Cambodia, newly modified PEN package; in Slovenia, addition of m-health and peer support to ICP.</p>	<p>Pre-post ICP implementation evaluation via ICP grid appraisal of practices; Key informants' interviews</p>

Abbreviations: NCD: Non-communicable disease, ICP: Integrated Care Package, ACIC: Assessment of chronic illness care, GP: General Practitioner, PEN: package of essential non-communicable disease interventions, HC: Health center, EHR: Electronic Health Records, WHO: World Health Organization, B&F: barriers and facilitators.

Note: tools can be found in the Web annexes.

Table 2. Mechanisms of impact specific to policy dialogues

Policy dialogue indicators	Clarification or definition	Relating question
<i>'Theme – Environment':</i>		
Location	The location the policy dialogue takes place.	Was the room/location suitable?
Moderation/ Facilitation	How well the dialogue was moderated; this is key to having meaningful and comprehensive discussions.	How was the moderation? Who was moderating? Why was this person selected?
Technical/material conditions	Such as PowerPoint presentation, video, paper/report/information package provided, catering (lunch/snacks/reception).	How were technical/material conditions?
<i>'Theme – Content':</i>		
High-priority issue	An issue of (local, regional,) national, and international concern.	Was it a high-priority issue (for dialogue participants)?
Clear meeting objectives	This goes hand in hand with a clear vision of what outcomes and results would be expected.	Were clear meeting objectives set?
Information shared	A pre-circulated information package, including the agenda, evidence summaries, a list of policy directions to be discussed, related background information, and an evaluation form.	Which information was shared with participants (in advance, during, and after policy dialogue)?
Evidence used	Synthesis of high-quality research evidence used to identify needs and educate participants: policy dialogue discussions and participants need to be based on effective stakeholder and context analyses, part of which is evidence-based background information.	Was evidence used/presented in the meeting?
Agreement on outcomes and action plan	List of possible and tangible actions or steps.	Was agreement reached on outcomes and action plan?
Rules of engagement	The format of the meeting and rules of engagement (giving a clear overview of purpose, participants, design, method, and materials).	Was there a formal or informal format? What was the set-up or rules?
Preparation of content	The materials created for the policy dialogue and the management of the event of the meeting overall.	Was the policy dialogue well-prepared?
Follow-up	The continuation of the policy dialogue, in terms of ongoing communication of next steps and engagement, to keep the momentum alive and renew or regenerate the projects' or programme's goals. ¹⁴	Was there proper follow-up (on next actions, next meeting, evidence/information shared)?
<i>'Theme – Participants':</i>		
Representation	The stakeholder groups represented or excluded. A mix of participants and stakeholders representing all perspectives and interests: representation of decision-makers, researchers, and those affected by the issue under discussion (user/patients groups, formal and informal caregivers).	Which stakeholder groups were represented? Which were excluded?
Participation	Social participation requires all stakeholders in the participatory process to be able to adequately and fully exercise their roles. In order to do so, all stakeholders should be, as far as possible, on an equal footing with each other in terms of ability to have influence on the participation-based discussions. ⁶⁸	Was there equal participation of stakeholders during the discussion? Who participated more? Who participated less?

Collaboration	The process of two or more people or organisations working together to complete a task or achieve a goal.	How was the collaboration between stakeholders?
Consensus	General agreement on something (by most participants). Five steps in the consensus-building process are: convening, clarifying responsibilities, deliberating, deciding, and implementing agreements.	Was consensus reached between stakeholders on a certain issue?
Trust	Firm belief in the reliability (or ability) of someone, relational	Was there trust between stakeholders?
Mutual respect	Mutual respect is defined as a proper regard for the dignity of a person or position; due regard for each other's feelings, wishes, or rights.	Was there mutual respect?
Willingness to implement	Gore et al. distinguish three types of commitment, ⁶⁹ namely: expressive commitment, institutional commitment, and budgetary commitment. " <i>Expressed commitment</i> refers to verbal declarations of support for an issue by high-level, influential political leaders. <i>Institutional commitment</i> comprises the adoption of specific policies and organisational infrastructure in support of an issue. Finally, <i>budgetary commitment</i> consists of earmarked allocations of resources towards a specific issue relative to a particular benchmark. The <i>combination</i> of the three dimensions signals that a state has an explicit intention or policy platform to address this health area."	Was there willingness to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? Type of political commitment? (Expressive/financial/institutional (i.e. policy))? How has COVID-19 influenced political will towards NCD care?
Leadership	The willingness to initiate, convoke, or lead an action for or against the health reform policy. ⁷⁰	Which stakeholder displayed the most leadership?
Urgency	The degree to which stakeholder claims call for immediate attention. ⁷¹	Which stakeholder displayed the most urgency?
Legitimacy	A generalised perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions. ⁷¹	Which stakeholder displayed the most legitimacy?
Ownership	Act, right, or degree of ownership (possession) and responsibility (taken by the resource/implementing organisation, community, and/or beneficiaries) towards any programs or activities	Which stakeholder had most ownership over the issue?

Abbreviations: NCD: non-communicable diseases

Data sources and collection tools

Key data collection tools developed for the process evaluation include:

1. The policy dialogue reporting form
2. The policy dialogue survey
3. The researcher interview guide
4. The follow-up stakeholder interview guide
5. Project diaries
6. Policy mapping: document review to generate a policy timeline
7. ICP grid for implementation assessment

Most of these are used to collect data on the policy dialogue and roadmap process, as well as on context. Tools were defined based on both the indicators (as displayed in tables 1 and 2) to be included and the activities entailed in the roadmap. Some tools, in particular, the policy dialogue reporting form and the survey are based on instruments developed by CHRODIS+.⁵⁶ All methods and tools will be adapted to the specific needs and context of the countries' scale-up strategies.

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3 The policy dialogue reporting form (tool 1 in appendix 2) serves as a self-report to be filled in by the
4 research team to evaluate the policy dialogue, the roadmap progress, and contextual barriers.⁵⁶
5 Aside from a section with general questions concerning the policy dialogue, a section is foreseen for
6 the rapporteur to write the minutes of the meeting, preferably during (and/or immediately after) the
7 policy dialogue.
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10 The policy dialogue survey (tool 2 in appendix 3) is to be completed by participants at the end of each
11 policy dialogue (that is organised by SCUBY).⁵⁶ A survey link is generated through the REDCap®
12 database^{72 73} and can be made accessible to participants online using mobile telephones. A paper
13 version can be an option if country teams prefer this and if this better fits the circumstances
14 (depending on the location). Items are related to the relevance and feasibility of discussed (roadmap)
15 actions and strategies (implementation outcomes) and to barriers and facilitators for the
16 implementation and scale-up of discussed strategies (context).
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20 Qualitative, in-depth follow-up researcher interviews (tool 3 in appendix 4) with the country teams
21 will be planned regarding the reporting forms to elaborate on items related to the roadmap and
22 policy dialogue (in line with the implementation outcomes and mechanisms). Additional qualitative
23 explanatory follow-up stakeholder interviews (tool 4 in appendix 5) will be undertaken to further
24 explore perceptions of policy dialogue and roadmap processes and contextual factors in depth.
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27 The aim of the project diary (tool 5 in appendix 6) is to display key research activities undertaken for
28 roadmap development and implementation. The policy mapping (tool 6 in appendix 7) will help track
29 key policy developments and evolutions in the field of integrated care. Furthermore, as a tool, it can
30 be used to guide or contextualise the purpose of the (next) policy dialogue meeting. Both the project
31 diary (tool 5) and the policy document mapping (tool 6)—which will generate a policy timeline on
32 integrated care—assess how the context influences SCUBY's activities and vice versa. The policy
33 mapping will inform the stakeholder interview (tool 3) and vice versa, especially in relation to the
34 existing policy and political barriers and facilitators that stakeholder participants might wish to
35 further comment on. Also, other policies and political events or activities (e.g. elections) might be
36 tracked if they impact integrated chronic care policy, such as COVID-19 restrictions or new
37 regulations for the care and control of the chronically ill in COVID-19 times (e.g. different modes of
38 delivery, changed duration, materials or location, increased use of IT tools and online consultations,
39 etc.).
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44 The ICP grid at the healthcare practices (tool 7) which was used as part of context analysis in year 1,²¹
45 will be used again to evaluate expansion of the ICP grid, so that it can serve as a before-after
46 evaluation in those areas where it was used before.²¹
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49 **Data management and analysis**

50 Qualitative data will be stored as transcripts in country-specific databases as pseudonymised data.
51 The transcripts will be stored in formats that are exportable to NVivo software (NVivo qualitative
52 data analysis software; QSR International Pty Ltd.) for analysis. Primary and secondary quantitative
53 data (related to the scale-up dimensions of *coverage* and *expansion*) collected from the
54 implementation sites will be collated into the main study REDCap® database via validated electronic
55 survey forms. Anonymised data will be transferred over the internet using secured data
56 communication protocols for analyses.
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3 For the qualitative implementation outcomes, thematic analyses will be conducted based on the
4 reporting forms, interviews, and surveys. As such, evidence from different tools on policy dialogue
5 (success factors), roadmap (progress on adoption and implementation), and context (barriers and
6 facilitators to scale-up) will be triangulated, considering the various perspectives of implementors,
7 other stakeholders, and the SCUBY researchers. Themes will be deduced both from existing literature
8 and theory surrounding policy dialogues and roadmaps and grounded in the data. Many of the
9 developed tools have clear topics, relating either to underlying policy dialogue mechanisms or to
10 roadmap implementation outcomes. A theorising approach will be used to explore how context,
11 actors, roadmap activities, outcomes (cf. framework) are connected.⁷⁴

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15 The dynamic policy and political processes (events, actions, and activities) unfolding over time in
16 context will be explored using processual analysis.^{75 76} Policy document review, desk research, and
17 input from interview participants on an initial policy mapping will be triangulated and further refined
18 to enable tracking the emergence of integrated care policies from a historical perspective, resulting
19 in a more detailed chronic care policy timeline. A minor part of the analysis will consist of a
20 retrospective stakeholder analysis on the sole attribute of the position of stakeholders on the
21 roadmap development and implementation.

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25 For the analysis of the scale-up dimensions, findings from different measurement tools will be
26 triangulated. Progress on integration will be assessed qualitatively—whilst cross-checking
27 information from (policy) document review and interviews—using thick descriptions, on the ways in
28 which roadmap actions (including interventions, programmes, and reforms) have become
29 institutionalised. Quantitative data analysis on the scale-up dimensions (coverage and expansion) will
30 entail a pre-post design. For expansion, interviews with implementors and the ICP grid will be
31 analysed again at the end of the project to give an estimate on how ICP implementation has
32 improved or deteriorated across its five components, in comparison to the previous ICP
33 implementation assessment of 2019.

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37 A flowchart of how data collection tools feed into the different types of analyses can be found in
38 appendix 8. By employing multiple methods, data sources and a larger analysis team (independent
39 researchers conducting the analysis and feeding back to country research teams for discussion on the
40 findings), we cross-check information and conclusions drawn from the data via triangulation and data
41 saturation and thereby ensuring the credibility of the data.

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44 Regarding the planned start and end dates for the study, data collection commenced in year two of
45 the SCUBY project (early 2020), shortly following the development of the tools and this protocol
46 paper. Data collection will be finalised end of December 2022. Data analysis will run from October
47 2022 until March 2023.

48 49 50 **Patient and public involvement**

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52 Patients or the public were not involved in the design, or conduct, or reporting, or dissemination
53 plans of our research. The individual countries are likely to have community and patient involvement
54 (e.g. in the policy dialogues), depending on the specifics of each scale-up roadmap, and hence, their
55 involvement is beyond the scope of this current protocol.
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Discussion

This paper outlines the protocol for the evaluation of the process and scale-up of an integrated care package for type 2 diabetes and hypertension, with the roadmap being the scale-up intervention and policy dialogues as the main development and implementation strategy for the roadmaps.

Scale-up is a complex intervention. In the SCUBY scale-up, multiple components and stakeholders interact, producing emergent effects which are different from the effects of the individual elements and actors within a socio-ecological system.²⁸⁻⁷⁷ The interventions can change over time because of contextualisation and adaptation. Willis et al. highlight the importance of renewing and regenerating complex interventions.¹⁴ Recent implementation studies have therefore stressed the relevance of documenting modifications to evidence-based practices.⁷⁸⁻⁸⁰ The SCUBY scale-up intervention indeed emphasises and documents the (continuous) adaptation as a result of a co-creative process.

Our framework follows the MRC guidance framework,²⁸ emphasising the relationships between implementation, mechanisms of impact, and context. In a complex co-creative scale-up process such as in the SCUBY project, multiple indicators need to be assessed in order to identify which mechanisms lead to success. Willis et al. emphasise how process evaluations of scale-up interventions, in particular, need to support documentation of the success at key moments and at different time points, such as increased stakeholder awareness and commitment.¹⁴ Moreover, when planned early in the project, process evaluations are not only useful to understand implementation, but can also feed back into the process and thereby strengthen implementation in the project itself.

Strengths and limitations

A key strength of this evaluation protocol is the comprehensive framework to guide the evaluation and how it can serve as a guide for other scale-up interventions following knowledge translation and co-creation principles. Another strength is that the comprehensive and theoretical framework has been translated into relatively simple process evaluation tools that can be easily used and adopted by various SCUBY team members across multiple countries. This is crucial for cross-country learning. It also facilitates the use and adoption of tools for other scale-up projects.

With regard to the limitations, the research team has little control over the scale-up and the geographical areas in which the scale-up strategies will be rolled out, which implies adaptive planning for data collection. The availability of administrative data to evaluate the coverage of the scale-up is also dependent on the capacity and collaboration with government partners. The co-creation process of the scale-up intervention and subsequent strong relationships with relevant partners helps to mitigate part of this risk.

Nevertheless, in each context, stakeholders and the country research teams have differing capacities and priorities, resulting into roadmap actions with their own timelines. Their impact over time is complex and requires a detailed evaluation of health outcomes. Including the impact evaluation would be beyond the scope of the current manuscript and will be described in a separate paper. An overall challenge in this research will be, on the one hand, to collect sufficient data at various time points (dependent to some extent on the frequency of the policy dialogues in each country), and on the other hand, to analyse all collected data in an effective manner.

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3 An added value is that the research team will also use empirical findings to refine theory on scale-up,
4 to uncover how and why the adoption and implementation of the roadmaps through policy dialogues
5 lead to scale-up of integrated care. This way, a theorising approach applied in the implementation
6 and scale-up phase will advance the knowledge of mechanisms of implementation and specifically of
7 scale-up science.⁷⁴
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10 In conclusion, the SCUBY project involves complex interventions in different healthcare systems,
11 requiring multiple feedback loops to support adaptation, attention to local context, and the
12 engagement of key actors such as resource and implementing organisations. Such complex
13 interventions need an evaluation of multiple elements such as implementation processes,
14 mechanisms, intermediate outcomes, and impact. This protocol offers a theory-based framework
15 and methods to support scale-up research. It could be used in different healthcare systems for
16 context-tailored processes and scale-up interventions.
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21 **Ethics and dissemination**

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24 The Institutional Review Board (Ref. 1323/19) at the Institute of Tropical Medicine (Nationalestraat
25 155, 2000 Antwerp, Belgium) approved this study on 1 July 2021. Findings will be (1) reported to
26 national, regional, and local governments to inform policy; (2) reported to funding bodies (European
27 Commission) and networks, such as the Global Alliance of Chronic Diseases (GACD), in line with their
28 2019 Scale Up Call; (3) presented at local, national, and international conferences; and (4)
29 disseminated by peer-reviewed publications.
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34 **Declarations**

35 **Authors' contributions**

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37 The first (MM) and final (DB) authors were responsible for the conceptualisation and writing of the
38 manuscript. EW, JVO, and KKG reviewed different versions throughout the drafting process. MM, DB,
39 EW, JVO, KKG, GMK, ZKK, SrC, SaC, VB, KD, NS, CZ, APS, WVD, PI and RR were involved in the
40 development of the data collection tools. All authors contributed to the final draft of the manuscript,
41 have read the manuscript, and approved it for submission.
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50 **Competing interests**

51 The authors declare that they have no competing interests
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53

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For peer review only

List of Abbreviations

ACIC	Assessment of chronic illness care
B&F	Barriers and facilitators
CoC	Cascade of Care
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HC	Health centre
HT	Hypertension
ICCC	Innovative Care for Chronic Conditions
ICP	Integrated care package
IT	Information technology
KII	Key informant interview
MRC	Medical Research Council
NASS (framework)	Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability
NCD	Non-communicable disease
NGO	Non-Governmental Organisation
PDRF	Policy Dialogue Reporting Form
PDS	Policy Dialogue Survey
PEN	Package of essential non-communicable disease interventions
RE-AIM (framework)	Reach, Effectiveness, Adoption, Implementation, Maintenance
SCUBY	Scale-Up diabetes and hypertension care
T2D	Type 2 diabetes
WHO	World Health Organization

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interacts with intervention, implementation strategy and outcome

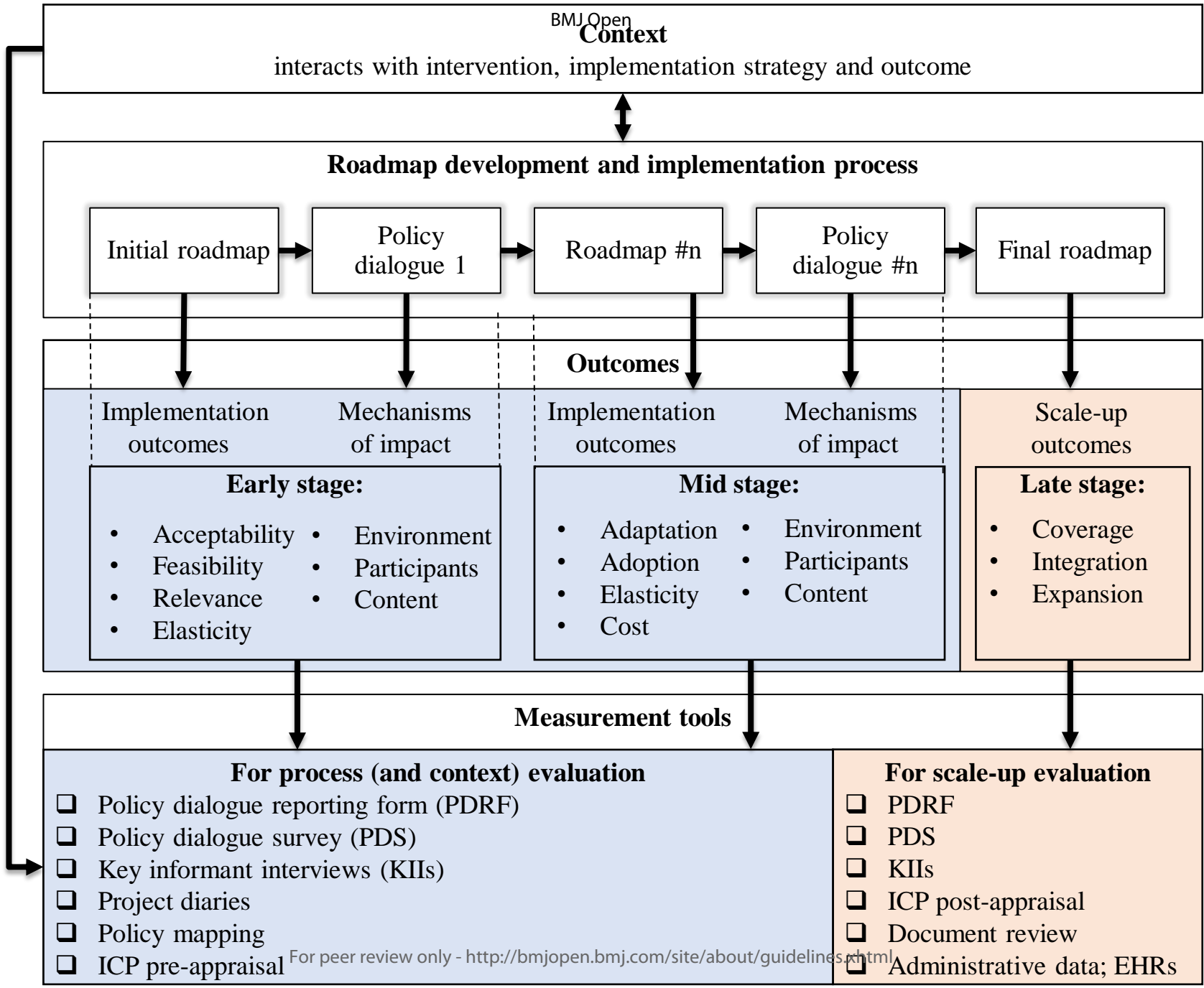


Roadmap development and implementation process



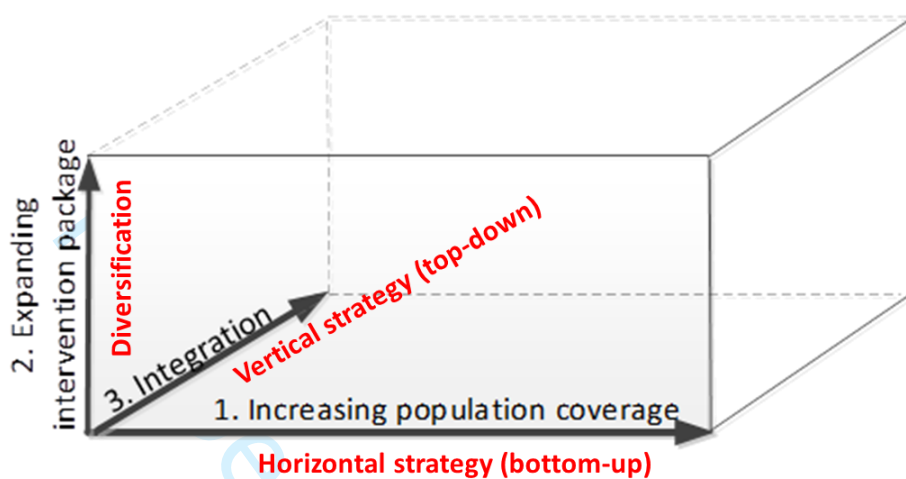
For peer review only - <http://bmjopen.bmj.com/lookup/guidelines.xhtml>

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Appendix 1: Three-dimensional scale-up framework

Comprehensive scale-up

Types of strategy

Adapted from: van Olmen J, Menon S, Poplas Susic A, et al. Scale-up integrated care for diabetes and hypertension in Cambodia, Slovenia and Belgium (SCUBY): a study design for a quasi-experimental multiple case study. *Global health action* 2020;13(1):1824382

Appendix 2: Policy Dialogue Reporting Form (tool 1)

SCUBY Policy Dialogue Reporting Form

Policy Dialogue:

Country:

Date:

Completed by: [SCUBY team member(s)]

This sheet is used for **policy dialogue monitoring**. This document is based on the CHRODIS+ Policy Dialogue Reporting Form.

Please **also report more informal stakeholder meetings**, as we have adopted a very broad definition of policy dialogue. These reporting forms will help us keep track of the whole process.

Note: The first policy dialogue description table only needs to be **fully completed for a larger (multi-stakeholder!) dialogue** or when **SCUBY** is the organiser of the policy dialogue. Hence, for a meeting with one stakeholder group, e.g. a few policy makers, some questions do not need to be completed (as indicated in the table below).

INDEX

1. Policy Dialogue Description
2. Minutes of the Policy Dialogue
3. Action plan
4. Attachments:
 - Agenda/pre-circulated question list
 - List of documents

POLICY DIALOGUE description

General questions on Policy Dialogue	Complete fields underneath (when applicable; otherwise N/A)
1. "Title" or topic: What was the title or topic of the Policy Dialogue? [please write title between "... " to differentiate]	
2. Number of the Policy Dialogue	
3. Date: What date was the policy dialogue held on?	
4. Location: In what location did the policy dialogue take place?	
5. Main objective:	
6. Specific objectives: [please number them or use bullets]	
7. Number of participants:	
8. Members roles: Who was the <ul style="list-style-type: none"> • Organiser/coordinating team: • Moderator(s): • Keynote speaker(s): • Rapporteur(s)*: • Other Participants: <p>* mention if officially appointed in a meeting, otherwise N/A.</p>	<ul style="list-style-type: none"> • ... • ... • ... • ... • ...
9. Duration: (...h...min)	
10. Conclusions: (They should be aligned with the objectives)	

Questions about the Roadmap	Complete fields underneath (when applicable; otherwise N/A)
<p>1. Roadmap adaptation/plasticity: Has the roadmap (or a certain activity) been adapted based on the discussion(s) with stakeholders? Name all roadmap adaptations, briefly indicate how this (these) adaptation(s) came about or why it is (they are) appropriate.</p>	<p>Yes/no/N-A What/which? Why?</p>
<p>2. Context/elasticity: Please summarise (contextual) barriers to action plan/in roadmap</p>	
<p>Questions about the Policy Dialogue</p> <p>! : All questions need to be completed for big* policy dialogues (otherwise only questions 4–5 and 8, see green boxes)</p> <p>* when SCUBY is the organiser, or when it is a multi-stakeholder dialogue</p>	<p>Complete fields underneath (when applicable; otherwise N/A)</p>
<p><i>Please briefly comment on following items within 'Theme – Environment':</i></p>	
<p>1. Suitability of room/location: Was the room/location suitable? Why (not)?</p>	<p>Yes/no Why?</p>
<p>2. Moderation/facilitation: How was the moderation? Who was moderating? Why was this person selected?</p>	<p>Very poor/poor/neutral/good/very good (or N/A) Why?</p>
<p>3. Technical (material) conditions:</p>	<p>Which:</p>
<p><i>Please briefly comment on following items within 'Theme – Content':</i></p>	
<p>4. Information shared with participants in advance:</p>	<p>Yes/no Which:</p>
<p>5. Was evidence used/presented in the meeting? If so, what kind and what evidence specifically?</p>	<p>Yes/no? Qualitative/quantitative? Specify what:</p>
<p><i>Please briefly comment on following items within 'Theme – Participants':</i></p>	
<p>6. Representation: Which stakeholder groups were represented? Which were excluded?</p>	
<p>7. Participation:</p>	<p>Equal/unequal Who more?</p>

1 2 3 4 5 6 7	Was participation of stakeholders during the discussion equal? Who participated more? Who participated less?	Who less?
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	8. Will to implement of policy-makers and/or implementers* 1) Was there will to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? 2) Specify type of political commitment (expressive/financial/institutional (i.e. policy)? 3) How has COVID influenced political will towards NCD/integrated care? * Question only relevant if resource or implementing organisation(s) are participating	1) Yes/No/NA Which? Who? Comment why? 2) Expressive/financial/institutional commitment? Why? 3) How, positively? How, negatively?
25 26 27	9. Leadership Which stakeholder displayed most leadership?	Who?
28 29 30 31	10. Ownership Which stakeholder had most ownership over the issue?	Who?

Minutes of the Policy Dialogue

Narrative Minutes:

(Explain the points of discussion).

POLICY DIALOGUE ACTION PLAN

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Action	Who is responsible?	When?	What Resources?	Identified Barriers	Success/Outcome indicator(s) → Objective reached? How?

Attachments to the Policy Dialogue Reporting form

1. Agenda/Schedule

Policy dialogues should last between two and four hours.

Example:

10 mins	Welcome/Tour de Table → Policy Dialogue rules, reporting, and introduction of moderator, rapporteur, and organizer/coordinating team.
15 mins	Keynote Speech (not mandatory)
3–5 mins	Opening Statements of each participant, reflecting the various views and perspectives concerning the defined problem and policy action
60–90 mins	Guided Discussion (including consensus building on actions/next steps)
30 mins	Optional slot on EU level declaration concerning chronic diseases (Consensus Statement)
15 mins	Conclusions

2. List of shared documents and (ppt) presentations used

The research team provides here an overview of the invitation, information package(s), report(s) etc. that were shared with the policy dialogue participants as well as presentations.

Appendix 3: Policy Dialogue Survey (tool 2)

INTRODUCTION:

Thank you for taking the time to provide your valuable feedback relating to the Policy Dialogue you recently attended in the context of the EU-funded SCUBY project (2019–2022), developing and implementing a scale-up roadmap for chronic diseases (specifically for diabetes type 2 and hypertension).

To evaluate the effectiveness and relevance of the Policy Dialogues and consultations with experts, we kindly ask for your assistance in completing this feedback survey. Your insights and comments will help shape and strengthen future Policy Dialogues. The data from this survey will be combined with information from other sources; this information can be used in reports, reports, conferences and publications in professional journals

The survey should take less than **5 minutes to complete**. Responding to the survey signifies your consent. You may opt not to answer or to skip questions; however, we will not be able to remove any information you have already provided should you opt to withdraw your participation thereafter. Your responses to this survey will be kept **confidential**.

SURVEY QUESTIONS:

Please provide us with the following information about yourself:

1. You are: [Drop down menu of **occupations**]

- a policy maker/politician
- a civil servant in public health administration or at the Ministry of Health
- a civil servant in social affairs or at the Ministry of Social Affairs
- a civil servant at health insurance institute or at the Ministry of Finance
- a professional medical association
- an association of social/informal care worker
- a patient organisation
- in academia
- an NGO
- an (international) donor organisation (funder)
- a healthcare worker (nurse, GP, specialist)
- a social worker
- an informal caregiver
- a patient

[listed occupations can be contextualised per country]

2. How would you rate each of the following?

From 1-Poor to 5-Excellent

1. The location of the Policy Dialogue
2. Technical conditions (material, etc.) for the Policy Dialogue

3. Moderation
4. Background information shared in preparation for the Policy Dialogue
5. Sufficiency of evidence provided and discussed in the Policy Dialogue
6. Relevance of the topics covered [high priority issue]
7. Achievement of goals as delineated in the agenda
8. Definition and agreement of outcomes and action plan to move forward

3. What is, in your opinion, the **most relevant topic, strategy or idea covered/shared** during this Policy Dialogue for you and your country and why?
4. Which topic is **your organisation** committed to (one that was mentioned in the Policy Dialogue meeting or not mentioned)?
5. Rate the discussed topics in relation to their **relevance and feasibility** (1=low relevance/feasibility; 10=high relevance/feasibility)

Topics (strategies/roadmap elements) to be completed before/after policy dialogue by the country teams e.g. education; training; telemedicine as part of diabetes self-management; health financing (provider incentives); data monitoring; community involvement; primary care practice (integration) guidelines; etc.

6. What do you see are the **primary enhancing factors (facilitators)** for the implementation and scale-up of discussed proposals/actions/strategies agreed in this Policy Dialogue in your National Policies?
7. What do you see are the **(financial/political/operational) barriers** for the implementation and scale-up of discussed proposals/actions/strategies agreed in this Policy Dialogue in your National Policies?
8. How has **COVID influenced the will to change/adapt/improve** towards better NCD/integrated care? How, positively? How, negatively?
9. In your opinion, what do you think worked well and what **could be improved from this meeting**?
10. Overall, how would you **rate this Policy Dialogue**?
From 1-Very Poor, to 10-Excellent
11. Do you have any further comments or suggestions?

Thank you for taking the time to complete this survey. We truly value the information you have provided. Your responses will contribute to our analysis and help us to improve policy dialogues in the future.

Appendix 4: Researcher Interview Guide (tool 3)

Researcher interview guide

Interview participant(s):

Country:

Date:

Conducted by:

This guide is a complementary tool to the policy dialogue reporting form and aims to explore policy dialogue and roadmap-related indicators in more depth. Following items, based on implementation outcomes will be explored in depth:

- Adoption
- Stakeholders' support
- Implementation and scale-up dimensions
- Adaptation
- Policy dialogue environment-content-participants

Interview questions**A. Questions about the Roadmap****1. Roadmap adoption:**

Is a roadmap activity/action/strategy adopted? Yes/no/N-A? Which?

Does this policy dialogue lead to the roadmap element envisaged?

Make reference to the adopted action points.

Can you elaborate on why/how it got adopted?

2. Stakeholders' support:

Which/how many roadmap elements were discussed?

Who were the key stakeholders that gave feedback/critiqued certain roadmap elements?

Who was in full support of the roadmap element(s)?

Fill in for each discussed (roadmap) element for each key participant from resource and/or implementing organisations:

5-point scale:

1. No support or buy-in
2. Little support or buy-in
3. Neutral (towards the specific action/roadmap element)
4. Initial or moderate support and buy-in
5. Full support

3. Roadmap implementation:

Is a roadmap activity/action/strategy realised (implemented)? Yes/no/N-A? Which?

Does this policy dialogue lead to the implementation of a roadmap element envisaged (phase after adoption)?

Make reference to successful action points.

Can you elaborate on why/how it got implemented?
 Have discussed proposals and solutions led to institutionalisation (already become part of the healthcare system)? Why and how? [scale-up dimension of integration]
 Have discussed proposals and solutions led to diversification, the expansion [scale-up dimension] of the ICP? Why and how?
 Have discussed proposals and solutions led to increased population or geographical coverage [scale-up dimension]? Why and how?
 What are sources of verification [for perceived scale-up dimensions]? Research findings? Organisational report? Database? News item? Word-of-mouth? From resource or implementing organisation(s)?

4. Adaptation/plasticity:

Has the roadmap (or a certain activity) been adapted?
 Can you describe the way in which the roadmap (elements) have been adapted?
 Can you indicate how this (these) adaptation(s) came about or why it is (they are) appropriate.

5. Context/elasticity:

How has the context evolved? How are contextual (political/financial/operational) barriers and facilitators to action plan/in roadmap evolving?

B. Questions about the previously organised Policy Dialogue(s)

! : All questions need to be completed for big* policy dialogues (otherwise only questions 5–9 and 19, see green boxes)

* when SCUBY is the organiser or when it is a multi-stakeholder dialogue

Please briefly comment on following items within 'Theme – Environment':

1. Suitability of room/location:

Was the room/location suitable? Why (not)?

2. Moderation/facilitation:

How was the moderation? Why good/bad?

3. Technical (material) conditions:

How were technical/material conditions? (e.g. website/video/presentation/flyers/information package/catering etc. provided?) Why good/bad?

4. Other conditions:

Please briefly comment on following items within 'Theme – Content':

5. Was it a high-priority issue (for dialogue participants)? Why?

6. Were clear meeting objectives set? Clear how? If unclear, why?

7. Do you think that sufficient information was shared with participants (in advance, during and after policy dialogue)? (Why not?)

8. Was evidence used/presented in the meeting?

If so, what kind (quant/qual/both) and what evidence specifically?

9. Was agreement reached on outcomes and action plan? How/why not?

10. Rules of engagement:

Was there a formal or informal format?

What was the set-up or rules?

(e.g. online meeting, Chatham House rules, stakeholders share their perspectives one by one, scientific presentation with comments, discussion in sub-groups or plenary session, expert panel, high-level policy maker meeting)

11. Was the policy dialogue well-prepared?

12. Was there proper follow-up (on next actions, next meeting, evidence/information shared)?

Please briefly comment on following items within 'Theme – Participants':

13. Representation:

Which stakeholder groups were represented? Which were excluded?

14. Participation:

Was participation of stakeholders during the discussion equal?

Who participated more?

Who participated less?

15. Collaboration

How was the collaboration between stakeholders?

- Very poor/poor/neutral/good/very good
- Can you use a word to describe your collaboration? E.g. top-down, bottom-up, organic, spontaneous, awkward, formal, informal, ...

Why do you think it was good/bad?

16. Consensus

Was consensus reached between stakeholders on a certain issue? How?

17. Trust

Was there trust between stakeholders? How did you notice?

18. Mutual respect

Was there mutual respect? How did you notice?

19. Will to implement of policy-makers and/or implementers* :

1) Was there will to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? What do you think drives them to implement?

Why/what is the reason to implement? Is there one direct reason or many good reasons?

2) Specify type of political commitment (expressive/financial/institutional (i.e. policy))?

3) How has COVID influenced political will towards NCD/integrated care? How, positively? How, negatively?

*** Question only relevant if resource or implementing organisation(s) are participating**

20. Leadership

Which stakeholder displayed most leadership? + Why?

21. Urgency

Which stakeholder displayed most urgency? + Why?

22. Legitimacy

Which stakeholder displayed most legitimacy? + Why?

23. Ownership

Which stakeholder had most ownership over the issue? + Why?

Appendix 5: Follow-up Stakeholder Interview Guide (tool 4)

Introduction

Introduction of the researcher(s)

- Name & function of researcher
- Share researcher's contact details (e.g. business card)
- In case of 2 researchers: one asking questions (mainly) and one/both taking notes

Introduction of SCUBY

- SCUBY is a 4-year research project on the scaling up of integrated care for diabetes and hypertension through co-creation with key stakeholders, such as you ... We are studying the scaling up of integrated care for diabetes and hypertension, with special attention to vulnerable people.
- The aim of this research is to engage with key stakeholders at all levels, to identify opportunities and barriers to integrated chronic care at the macro level, to implement and support best practices on a larger scale.
- Focus on integrated chronic care, diabetes, hypertension & vulnerable groups (key terms)

Explain purpose and the intent of the interview:

- **Thank you** for taking the time to provide your valuable feedback relating to the Policy Dialogue you recently attended in the context of the EU-funded SCUBY project (2019–2022), developing and implementing a scale-up roadmap for chronic diseases (specifically for diabetes type 2 and hypertension).
- **To evaluate** the effectiveness and relevance of the Policy Dialogues and consultations with experts, we kindly ask for your participation in this (follow-up) interview. Your insights and comments will help shape and strengthen future Policy Dialogues.
- Duration of interview: max 60 min
- Ensure anonymity and confidentiality
- Questions?

Informed consent

- Ask (to sign) the informed consent and permission to record the interview

Outline of interview (topics to cover)

- Policy dialogue
- Roadmap development
- Stakeholder engagement (attributes)
- Remarks and conclusion

Policy dialogue

1. What was your role and contribution in the Policy Dialogue? How was your experience?
2. Were the topics under discussion in the Policy Dialogue relevant (**high priority**) to you?
3. Was the **evidence** provided and discussed in the Policy Dialogue relevant and interesting to you? Can you use it and how?
4. How important do you think **representation** is in Policy Dialogues? Were certain groups not represented? What do you think are the benefits of a small vs big group in a Policy Dialogue?

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5. How would you describe the **collaboration** between stakeholders in the Policy Dialogue? Have you collaborated before with some of these participating stakeholders? With who (not)?
 6. Was a **consensus** reached on an action plan? If yes, consensus on what? And how was it reached?
 7. *To policy makers:* what do you think is needed in order to implement the discussed proposal? What is your role/contribution in the scale-up of this strategy? *To other stakeholders:* Do you think policy-makers will implement the discussed proposal? Why (not)? What is your role/contribution in the scale-up of this strategy? Specify type of political commitment (expressive/financial/institutional (i.e. policy))? [**will to implement**]
 8. How has **COVID** influenced political will towards NCD/integrated care? How, positively? How, negatively?
 9. In your opinion, what do you think worked well and what **could be improved** from this meeting?

Roadmap

10. How **acceptable** do you think is this action/strategy/roadmap element [*specify; e.g. training/group education programme/data monitoring*] to the beneficiary (provider/patient)?
11. Can you please comment on both the **relevance** and the **feasibility** of the proposals, actions or strategies discussed/shared/agreed upon in the policy dialogue? (as one might be highly important but not a feasible action, or vice versa)
12. [**Context**] What do you see are (**financial/political/operational**) **barriers** that might hinder the implementation and scale-up of discussed proposals/actions/strategies in your National Policies?
13. [**Adaptation/plasticity**] Are changes to the roadmap or specific roadmap elements [*specify*] necessary? Which?
14. [**Costs**] What do you think are the costs related to this roadmap action/strategy [*specify*] and its implementation?
15. [later stage] Have discussed proposals and solutions led to **institutionalisation** (already become part of the healthcare system)? Why and how? [scale-up dimension of integration]
16. [later stage] Have discussed proposals and solutions led to diversification, the **expansion** [scale-up dimension] of the ICP? Why and how?
17. [later stage] Have discussed proposals and solutions led to increased population or geographical **coverage** [scale-up dimension]? Why and how?

Concluding remarks

Additional comments

- Do you have any additional remarks?

Thank

- Thank your time to participate in this interview. We truly value the information you have provided. Your responses will contribute to our analysis and help us to improve policy dialogues and scale-up in the future.

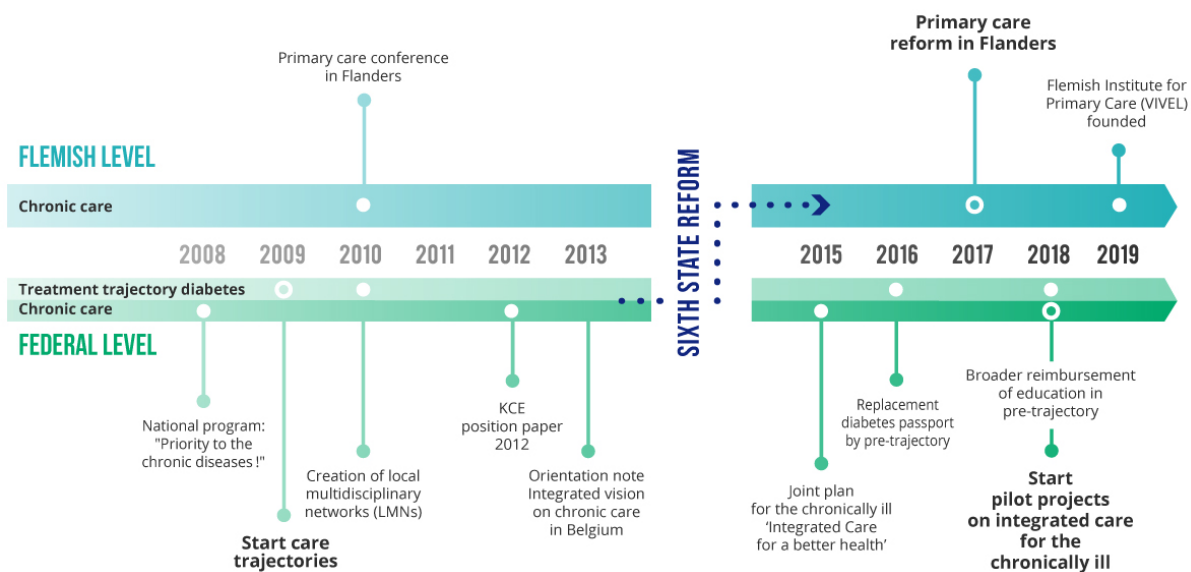
Share SCUBY brochure at the end.

Appendix 6: Template for project diary (tool 5)

Date	Event	SCUBY participant(s)	Other participants	Topic (about)	Next steps/outcomes
04/2019	Focus groups with patients				
05–09/2019	Stakeholder interviews				
23/10/2019	Launch SCUBY				
02/2020	SCUBY consortium meeting				
30/06/2020	Meeting MoH				
21/09/2020	Expert panel				

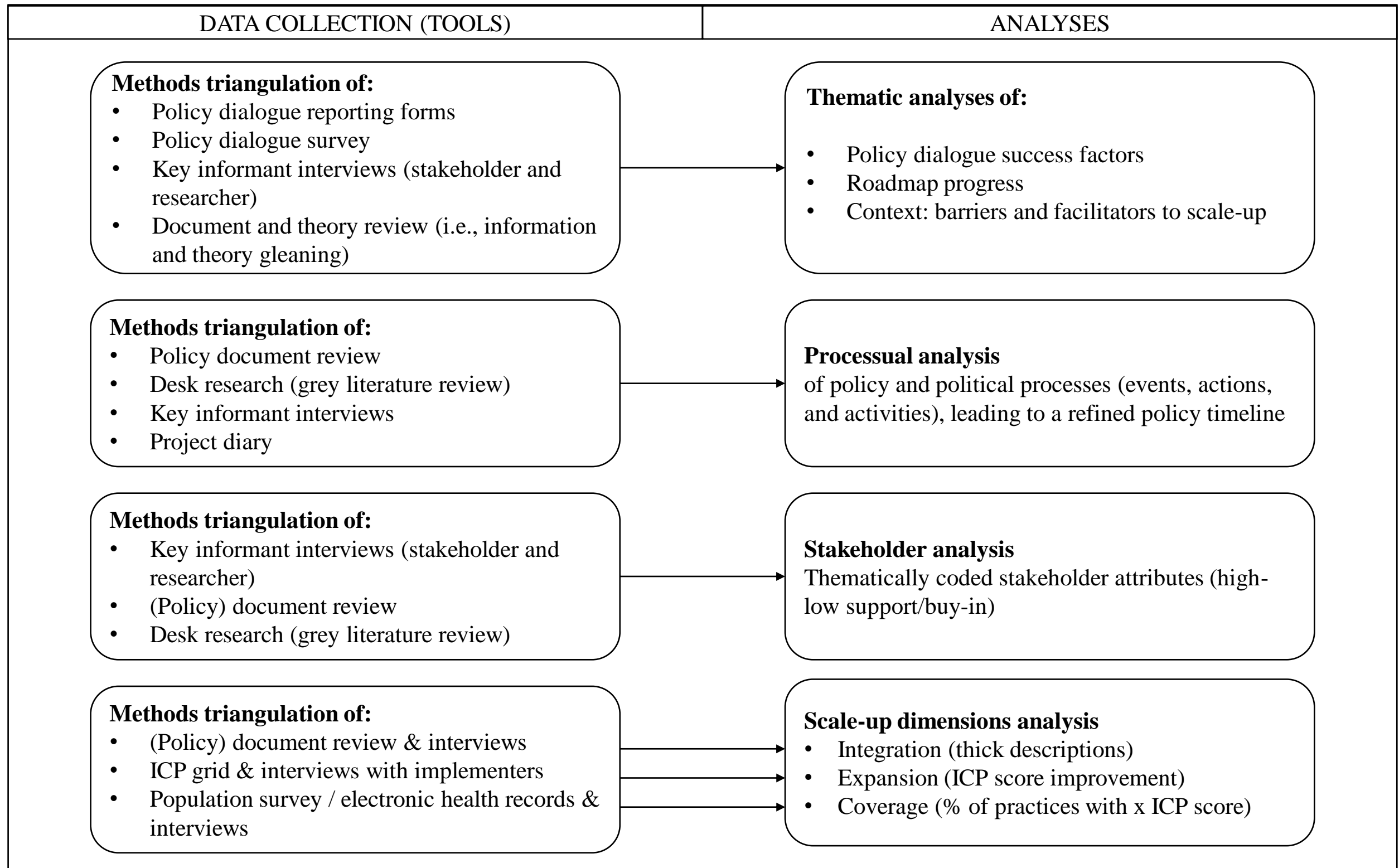
Note: The table displays activities and meetings in chronological order. Examples of activities are provided. Internal team meetings do not need to be all chronologically registered; rather the aim of the project diary is to display: (1) meetings with a stakeholder(s) on steps undertaken in the roadmap; and (2) other related network and research activities.

Appendix 7: Example of (Belgian) policy timeline on integrated care (tool 6)



Note: not updated for current corona policy developments

Appendix 8: Flowchart depicting how data collection tools feed into different types of analyses



BMJ Open

Process evaluation of the scale-up of integrated diabetes and hypertension care in Belgium, Cambodia, and Slovenia (the SCUBY project): A study protocol

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Primary Subject Heading:	Health policy
Secondary Subject Heading:	Qualitative research
Keywords:	QUALITATIVE RESEARCH, PUBLIC HEALTH, PRIMARY CARE, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Manuscripts

Process evaluation of the scale-up of integrated diabetes and hypertension care in Belgium, Cambodia, and Slovenia (the SCUBY project): A study protocol

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Abstract

Introduction: Integrated care interventions for type 2 diabetes (T2D) and hypertension (HT) are effective, yet challenges exist with regard to their implementation and scale-up. The ‘Scale-Up diaBetes and hYpertension care’ (SCUBY) project aims to facilitate the scale-up of integrated care for T2D and HT through the co-creation and implementation of contextualised scale-up roadmaps in Belgium, Cambodia, and Slovenia. We hereby describe the plan for the process and scale-up evaluation of the SCUBY project. The specific goals of the process and scale-up evaluation are to (i) analyse how, and to what extent, the roadmap has been implemented, (ii) assess how the differing contexts can influence the implementation process of the scale-up strategies, and (iii) assess the progress of the scale-up.

Methods and analysis: A comprehensive framework was developed to include process and scale-up evaluation embedded in implementation science theory. Key implementation outcomes include acceptability, feasibility, relevance, adaptation, adoption, and cost of roadmap activities. A diverse range of predominantly qualitative tools—including a policy dialogue reporting form, a stakeholder follow-up interview and survey, project diaries, and policy mapping—were developed to assess how stakeholders perceive the scale-up implementation process and adaptations to the roadmap. The role of context is considered relevant, and barriers and facilitators to scale-up will be continuously assessed.

Ethics and dissemination: Ethical approval has been obtained from The Institutional Review Board (Ref. 1323/19) at the Institute of Tropical Medicine (Antwerp, Belgium). The SCUBY project presents a comprehensive framework to guide the process and scale-up evaluation of complex interventions in different health systems. We describe how implementation outcomes, mechanisms of impact, and scale-up outcomes can be a basis to monitor adaptations through a co-creation process and to guide other scale-up interventions making use of knowledge translation and co-creation activities.

Strengths and limitations of this study

- The evaluation methods in this paper combine implementation science and scale-up theories in a joint framework.
- This identification of sequential indicators for different steps in the scale-up process is innovative and useful to conceptually advance research on scale-up.
- The insertion of mechanisms of change in the evaluation framework allows for empirical testing of theory-based concepts that facilitate scale-up.
- The set of data collection tools to track the policy dialogue and scale-up roadmaps are hands-on and can accelerate empirical scale-up research.
- A limitation of this study is the delay in data collection due to the COVID-19 pandemic, which in turn could lead to recall bias of stakeholders in interviews on the process of stakeholder collaboration in policy dialogues.

Keywords

Process evaluation, (qualitative) mixed methods, evaluation framework, scale-up, complex intervention, co-creation/policy dialogue

Introduction

To address the rising burden of chronic diseases across the world, global commitments have been made toward an integrated care approach offering multidisciplinary, non-episodic, and patient-centred care.¹⁻⁵ Integrated care leads to better care coordination and (cost) efficiency, and improves the quality of care and patient outcomes by linking services along the continuum of care.^{3 6 7} However, the scale-up of integrated care is challenging because chronic diseases pose a wicked problem⁸⁻¹² requiring multi-stakeholder action and intersectoral coordination at individual healthcare practice, organisational, and political/system levels.^{13 14}

Moreover, little is known about how to scale up complex, adaptive, and strongly contextualised interventions.¹⁴⁻¹⁶ Blueprint approaches to scaling-up health care interventions commonly described in the literature and global health initiatives are linear process models and do not fit the dynamic, emergent, and adaptive scale-up process of complex health interventions.¹⁷ Complexity is not just a property of wicked problems, but also of the intervention and the context (or system) into which the intervention takes place.¹⁸ A complex intervention can be perceived as a process of changing complex systems,¹⁹ involving multi-component, multi-stakeholder, and multi-level efforts that are tailored to the contexts in which they are delivered.^{14 20}

The 'SCale-Up diaBetes and hYpertension care' (SCUBY) project aims to develop, co-create, and assess roadmaps, which can be adapted for use in different contexts, for scaling-up of an integrated care package (ICP) for type 2 diabetes (T2D) and hypertension (HT) in dissimilar types of health systems.²¹ The ICP comprises of: (a) early detection and diagnosis, (b) treatment in primary care services, (c) health education, (d) self-management support to patients and caregivers, and (e) collaboration between caregivers.²¹⁻²⁴ These generic components are implemented via country-specific delivery models, which have been elaborated in the SCUBY protocol paper.²¹

SCUBY is a multiple case study, in which each country (Belgium, Cambodia, and Slovenia) is a case of the ICP scale-up for T2D and HT. These three countries were chosen in view of the lessons that can be drawn from these diverse health system contexts: a developing health system in a lower-middle-income country (Cambodia); a centrally steered health system in a high-income country (Slovenia); and a publicly-funded, highly privatised healthcare health system in a high-income country (Belgium).²¹ Hence, the selection of the three cases was based upon their health system characteristics, as well as current focus on scale-up strategies. Scale-up is multi-dimensional and requires various efforts to: (1) increase population coverage, (2) integrate or institutionalise ICP into health system services, and (3) expand the intervention package, i.e., diversifying the ICP with additional components.^{21 25-27} Appendix 1 provides details on this three-dimensional framework.^{21 25} The scale-up activities are specifically targeted toward improving primary (low-level) care, in all three countries. Each country focuses on a different scale-up dimension and adopts a suitable scale-up strategy that is in line with contextual needs. In Belgium, where multiple projects have been developed in several areas (current horizontal strategy), the roadmap will focus on how the ICP can be made routine practice in the Belgium health system, and which financial, policy, and regulatory reforms can support this transition (*integration*). In Cambodia, where the vertical (i.e., institutional; top-down) strategy is established, the roadmap mainly focuses on adopting a horizontal strategy to increase population *coverage* of the ICP for T2D and HT care, more specifically, increasing the number of health facilities at the primary care level providing T2D and HT care. In Slovenia, the aim

of the roadmap is to strengthen diversification (*expanding* the ICP) through enhancing the involvement of patients and informal caregivers in health care. This will be achieved by down-stepping care from health care professionals at the primary care level to patients and informal caregivers. The focus is therefore on patient empowerment and self-management of T2D and HT.

The SCUBY interventions for scale-up involve the development of evidence-based roadmaps and policy dialogues.²¹ These two methodologies—roadmaps and policy dialogues—are very much intertwined and considered to be key elements for successful stakeholder-supported scale-up.¹⁷ The first versions of the roadmaps in each country were developed based upon the findings of the formative phase and initial policy dialogues with stakeholders in each country. Subsequently, a feasible and relevant evaluation protocol was developed, in accordance with evaluations of complex interventions, which have a flexible, adaptable design.²⁸ The protocol also describes the framework to guide the evaluation of the scale-up intervention in the SCUBY project.

The evaluation of the SCUBY intervention constitutes the third phase of the project and includes four (process, scale-up, cost, and impact) evaluations with separate research questions.²¹ This protocol comprises the first two evaluations only: the process and scale-up evaluation of the SCUBY intervention. This will increase the understanding of the process of implementing roadmaps to scale-up integrated care and to improve health outcomes, and how this is influenced by different contexts. The specific research questions we aim to address are: (i) how has the country-specific roadmap been implemented and to what extent? (ii) how can the differing contexts influence the implementation process of the scale-up strategies? and (iii) what progress has been made on each of the three axes of scale-up? Box 1 provides key definitions and their application to the SCUBY project.

Box 1. Key definitions and their application to the SCUBY project.

Concept	Definition	Application in the SCUBY project
Roadmap	An action plan delineating the targets, planning, and progression of scale-up strategies, identifying actors, actions, and timelines based upon priorities in place and time. ²¹	Scale-up Intervention In SCUBY, a scale-up roadmap constitutes an overall scale-up strategy and aim; roadmap actions or activities; a problem statement, rationale and objectives/aim(s) for each roadmap action, a timeline to plan roadmap activities within a time frame; and a description of the evidence base and key partners/stakeholders involved in the scale-up (the coordination mechanism per roadmap action).
Policy dialogue	An essential component of the policy and decision-making process, where it is intended to contribute to informing, developing, or implementing a policy change following a round of evidence-based discussions, workshops, and consultations on a particular subject. It is seen as an integrated part of the policy-making process and can be conducted at any level of the health system where a problem is perceived and a decision, policy, plan, or action needs to be made. ²⁹	Implementation strategy (to guide the roadmap development to implementation) In SCUBY, policy dialogues are used as an approach in the policy-making process to engage with key stakeholders and to develop the countries' scale-up roadmaps. They will comprise structured formal events, one-to-one interactions with key stakeholders, workshops, consultations, and joining ongoing dialogues within the context. ²⁹
Context	Complex adaptive systems that form the dynamic environment(s) in which implementation processes are situated; ³⁰ a set of characteristics and circumstances that consist of active and unique	Mediator The context in SCUBY is assessed at micro, meso, and macro levels. Since scale-up is targeting the country level, the process evaluation focuses on the macro-level context, specifically the

	factors, within which the implementation is embedded. As such, context is not a backdrop for implementation, but interacts, influences, modifies, and facilitates or constrains the intervention and its implementation. Context is usually considered in relation to an intervention, with which it actively interacts. It is an overarching concept, comprising not only a physical location but also roles, interactions, and relationships at multiple levels. ³¹	barriers and facilitators to scale-up. We look at the World Health Organization (WHO) health system building blocks ^{32 33} and broader political, economic, social, technological, environmental, and legal factors.
Scale-up	The efforts to increase the impact of health interventions so as to benefit more people and to foster policy and programme development on a sustainable basis. ²⁶	Study aim/goal Scale-up efforts in SCUBY can include various efforts to make progress on any of the three axes. Examples of efforts are: increasing coverage of existing interventions, strengthening or expanding the existing ICP package, and changing financing or monitoring systems.

The SCUBY intervention: a scale-up roadmap

The SCUBY intervention is an adaptable, evidence-based roadmap for scale-up. This roadmap comprises an action plan with steps and strategies towards a set goal—the scale-up of an ICP to improve access to affordable quality care for T2D and HT. It thus includes both processes and actions by which the ICP is brought to scale. The roadmaps can consist of a mix of scale-up strategies. The term “scale-up roadmap” is derived from the WHO/ExpandNet framework, which also provides classifications according to the degree of the intention of scale-up, formal planning, and locus of initiative:^{26 34} (a) top-down strategies whereby the central level decides to implement the innovation and institutionalises it through planning, policy changes, or legal action; (b) horizontal strategies to expand geographically or population-based; and (c) diversification strategies referring to adding new elements to an existing intervention. Thus, three major strategic scale-up options are available for roadmaps: a, b, c, or a combination of the aforementioned. The three implementing countries in the SCUBY project follow this categorisation in focus and approach: a vertical, government-steered top-down (type a) strategy in Cambodia, a horizontal strategy (type b) in Belgium, and a diversification scale-up strategy (type c) in Slovenia. In addition, countries may deviate from the dominant strategy to include other strategies to maintain progress.

Context in this multi-country study is key, as it interacts with the intervention and the implementation strategy, as well as the (implementation and scale-up) outcomes,²⁸ as shown in Figure 1. Contextual factors include barriers and facilitators to scale-up. Each context will influence the development and implementation process of the roadmap differently due to the large cultural, socio-political, and economic differences between the implementation countries, and vice versa, in each country under study, the roadmap development and implementation process will have a different impact on the context.

Figure 1. The interaction between context and the roadmap development and implementation process.

The main implementation strategy: policy dialogues

Within the SCUBY project, policy dialogues play a crucial role in the implementation of the scale-up roadmaps. Policy dialogues have been introduced by the WHO as a tool to support organisational and/or systemic changes in health and health care.²⁹ Concepts linked to policy dialogue are co-creation,³⁵⁻³⁸ co-production,³⁸⁻⁴¹ deliberative methods and processes,⁴² social and community participation,^{43 44} and collaborative governance.^{45 46}

The policy dialogue is the strategy that all implementing countries have in common. This illustrates the necessity of high-level policy engagement and multi-stakeholder collaboration. The policy dialogue can therefore be viewed as SCUBY's main implementation strategy for the development and implementation of the roadmaps in each country. Because of this ongoing engagement with stakeholders in policy dialogues, the roadmap (intervention) can continue to be adapted and amended over time.

The roadmap development and implementation process in figure 1 represents the "co-creative", emergent process towards scale-up, with multiple feedback loops from the policy dialogues to the roadmap. In addition to scientific and local evidence, the policy dialogues are literally feeding into the roadmap development and implementation; the policy dialogues provide a means to increase stakeholder (and community) support and subsequently contribute to roadmap implementation and thus the scale-up of integrated care for T2D and HT.

An overarching framework for evaluation

Figure 2 presents a comprehensive framework to guide the evaluation of the roadmap implementation. This framework has been developed to support the process and scale-up evaluation of the SCUBY intervention. It is useful to gain insight into how the key steps of the roadmap development and implementation process can be linked to outcomes and what effective measurement tools are used to capture the roadmap implementation and scale-up process.

Figure 2. An overall framework for process and scale-up evaluation. Note: Key informant interviews in SCUBY include interviews with stakeholders from resource and implementing organisations²⁶ and with SCUBY research team members in the different implementing countries.

This framework was adapted from the Medical Research Council (MRC) guidance framework for process evaluations,²⁸ emphasising the relevance of context, and its interaction with not only the intervention, but also the implementation process, the underlying mechanisms of impact, and early, midterm implementation outcomes and scale-up outcomes. As an overarching framework, it brings together the complex intervention and implementation strategy, presenting it as a process of incremental and cyclical change and adaptation, whilst linking this process to key indicators, tools, and types of evaluation.

The framework distinguishes two types of evaluation: process and scale-up evaluation. Context evaluation can be seen as a sub-part of the process evaluation, whereas context has a major influence on the development and implementation process of the complex intervention. The outcomes and measurement tools in this framework are further described in the methods section of this protocol.

Methods and analysis

Study population and design

The SCUBY study is a multiple case study, in which each country is a case. The process and scale-up evaluation in this protocol use a mixed method design, the process evaluation being qualitative and the scale-up evaluation partly quantitative.⁴⁷ The study population for the process evaluation are the stakeholders involved in the policy dialogues and the roadmap development and implementation process. The WHO/ExpandNet framework²⁶ derives two main categories: resource and implementing (user) organisations.^{48 49} Another meaningful classification for stakeholder categorisation comes from Campos and Reich.⁵⁰ These authors distinguish stakeholder groups that are likely to influence implementation: interest groups, bureaucrats (civil servants from public administration), financial decision-makers, political leaders, beneficiaries, and external actors.⁵⁰ In the SCUBY project, we distinguish one additional (seventh) group: scientific actors. The study population for the scale-up evaluation are the target population (e.g. healthcare providers; patients) living in the areas in which scale-up activities were performed.

Implementation process and scale-up outcomes

This project focuses on the implementation process and scale-up (or progression) outcomes. Their definitions, as well as their theoretical basis, application to the SCUBY project, and corresponding assessment methods and tools are described in Table 1.

Specific outcomes will be used depending on the stage of the project: early, mid, and late.⁵¹ Acceptability, feasibility, and relevance are key implementation outcomes of roadmaps in the early stage, while adaptation, adoption, and cost of roadmap activities will become more relevant from an early to mid-stage as displayed in the middle row in Figure 2. In each of these stages (early, mid, and late), the role of context will remain relevant, and barriers and facilitators to scale-up will be continuously assessed. Relevant attributes of the context and intervention used in implementation science are elasticity (of the context) and plasticity (of the intervention). Elasticity is linked to institutional fit and change in context brought about by the intervention (and implementation) process, while plasticity is related to the concept of adaptation.⁵² Measurement of the implementation outcomes is guided by multiple evaluation frames, including RE-AIM (reach, effectiveness, adoption, implementation, maintenance),⁵³ the MRC implementation fidelity,²⁸ and the NASSS (non-adoption, abandonment, scale-up, spread, sustainability) framework.^{15 54}

The mechanisms for impact refer to the effects or (causal) pathways of a specific intervention and answer the question “how does the delivered intervention produce change?” The assessment of mechanisms of impact focuses on the policy dialogue which is the major implementation strategy for the roadmap. Potential mechanisms for impact were identified through literature review on the success factors of policy dialogues⁵⁵⁻⁵⁸ and related to: (1) environment, (2) content, and (3) participants.⁵⁹ The mechanisms of impact specific to policy dialogues are presented in Table 2.

Next to implementation outcomes, scale-up outcomes (“late stage” box of the conceptual model displayed in Figure 2) will be tracked. We distinguish three scale-up outcomes: (1) Coverage, (2) Integration, and (3) expansion. In the literature some overlapping concepts are used.⁵¹ In implementation literature, the concept of reach is often used interchangeably with coverage. Similarly, maintenance, sustainability, and institutionalisation are used to assess integration.⁵¹

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3 Expansion as a third dimension—in SCUBY specifically used to indicate an extra element added in the
4 ICP—is similar to the WHO’s use of diversification in their ExpandNet strategy for scale-up.²⁶ The
5 scale-up outcomes will be assessed qualitatively and include some quantitative elements. Expansion
6 will be measured via a questionnaire with items on the five ICP components (the ICP grid). The
7 questionnaire contains items per ICP component which are scored on a five-point Likert scale. This
8 instrument—the ICP grid—was developed in collaboration between the different SCUBY country
9 teams. It was adapted from the WHO’s Innovative Care for Chronic Conditions (ICCC)⁶⁰ Framework
10 situation assessment and the Assessment of Chronic illness Care (ACIC)⁶¹ which has been validated in
11 high-income countries. This way, ICP implementation in a particular area/organisation is assessed
12 before the start of scale-up and at the end of the project. Furthermore, we can assess whether ICP
13 coverage along its five components has expanded over four years (2019 vs. 2022). To complement
14 the ICP grid, interviews with implementors will be conducted, especially if a specific programme-
15 intervention (e.g. training or new health education programme for patients) or new policy gets
16 implemented. Coverage (i.e. number of people covered by the ICP) will be measured quantitatively,
17 using a population survey or Electronic Health Records. If time and resources allow, multiple time
18 series data can be used to track ICP coverage. The axis integration will be assessed through health
19 facility stakeholder interviews, and review of policy documents and grey literature. Hence, progress
20 on integration will be reported descriptively.
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Table 1. Roadmap implementation and scale-up outcomes and measurement

Outcomes	Definition	Theoretical basis	Application to SCUBY	Assessment methods and tools
<i>Roadmap implementation outcomes</i>				
Acceptability	The perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory. ⁵¹	Cf. social validity ⁶²	Acceptable: (resource and implementation) stakeholders have mostly consensus, or at least majority on way to go.	Surveys; Key informants' interviews
Feasibility	The extent to which a new treatment, innovation, strategy, or programme can be successfully used or carried out within a given agency or setting. ⁶³	Cf. compatibility ⁶⁴	Feasibility signifies it is possible to reach the set goals specified within the roadmap.	Surveys; Key informants' interviews
Relevance	The perceived fit, appropriateness, or compatibility of the innovation or evidence-based practice (roadmap) for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem. ⁵¹	Cf. appropriateness, perceived fit ⁵¹	Fit and relevance of the proposed framework, strategies, and actions to government policy agenda and stakeholder perception/interest.	Surveys; Key informants' interviews
Adoption	The intention, initial decision, or action to try or employ an innovation or evidence-based practice. ⁵¹ Can be expressed as the absolute number, proportion, and representativeness of settings (contexts) and intervention agents (implementers) that are willing to initiate a programme (policy or intervention).	RE-AIM; ⁵³ NASSS framework, Cf. non-adoption/abandonment ^{15 54}	Uptake of the proposed roadmap (element).	Policy dialogue reporting form; Surveys; Key informants' interviews
Adaptation	The extent to which a policy or intervention is changed, the opposite of delivered as intended by its developers and in line with the programme model. It refers to the customisation and ongoing adaptation of the care package or programme model; ¹⁵ in this study, the adaptation of (preliminary and non-final versions of) the roadmap. Also linked to the concept of plasticity—"the extent to which interventions and their components are malleable and can be moulded to fit their contexts". ⁵²	MRC implementation fidelity; ²⁸ Plasticity ⁵²		Policy dialogue reporting form; Surveys; Key informants' interviews; Document reviews
Elasticity of the context	Elasticity can be defined as "the extent to which contexts can be stretched or compressed in ways that make space for intervention components and allow them to fit". ⁶⁵	Elasticity ⁵²	Changes in the context that allow an acceleration or slow-down of roadmap strategies. Example 1: COVID-19 (slow-down because of other priorities, accelerator because of increased digitalisation efforts). Example 2: government change.	Follow-up stakeholder interviews (question on B&F); Policy mapping on timeline (keep eye on policy developments and implications)
<i>Scale-up outcomes</i>				

<p>Coverage (horizontal scale)</p>	<p>The extent to which the target group is reached, in absolute and relative count.⁶⁶</p>	<p>RE-AIM,⁵³ Cf. Reach</p>	<p>Target population reached; number of people actually covered by the intervention. Example: People who have access to GPs/practices with improved ICP/ACIC score in Belgium. Number of HCs (population covered by HCs) implementing newly modified PEN package in Cambodia. Target group members reached with m-health and peer support intervention in Slovenia.</p>	<p>EHRs; Population survey; Health report/data; Health facility assessment</p>
<p>Integration</p>	<p><u>Integration</u> into health system and services (based upon Meessen et al. (2017), inspired by the universal coverage framework.⁶⁷</p>	<p>RE-AIM,⁵³ Cf. maintenance Cf. penetration, institutionalisation, sustainability⁵¹</p>	<p>The extent to which complex systems (structure and processes) allow (maintain and institutionalise) ICP implementation. Example 1: Through laws, regulation, financing. The level of institutionalisation of the recommendations in the roadmap. Example 2: In Belgium, health financing reforms and legal reform facilitating nurses in primary care. Example 3: In Cambodia, functioning NCD clinics and community-based peer support are linked to HC-PEN. Example 4: In Slovenia, integration of telemedicine and peer support for chronic patients' management to primary care.</p>	<p>Key informants' interviews; Document reviews; Health facility assessment/ICP grid, EHRs</p>
<p>Expansion</p>	<p>Expanding the intervention programme (the ICP package to cover other elements). Similar to diversification as a type of scaling up in ExpandNet, also called functional scaling up or grafting, consists of testing and adding a new innovation to one that is in the process of being scaled up, hence, exploring the possibility of pilot testing an added component to the innovation.²⁶</p>	<p>Cf. diversification²⁶</p>	<p>Additional components in ICP; addition of comorbidities to package. Example: In Belgium, addition of nurses to GP practice; in Cambodia, newly modified PEN package; in Slovenia, addition of m-health and peer support to ICP.</p>	<p>Pre-post ICP implementation evaluation via ICP grid appraisal of practices; Key informants' interviews</p>

Abbreviations: NCD: Non-communicable disease, ICP: Integrated Care Package, ACIC: Assessment of chronic illness care, GP: General Practitioner, PEN: package of essential non-communicable disease interventions, HC: Health center, EHR: Electronic Health Records, WHO: World Health Organization, B&F: barriers and facilitators.

Note: tools can be found in the Web annexes.

Table 2. Mechanisms of impact specific to policy dialogues

Policy dialogue indicators	Clarification or definition	Relating question
<i>'Theme – Environment':</i>		
Location	The location the policy dialogue takes place.	Was the room/location suitable?
Moderation/ Facilitation	How well the dialogue was moderated; this is key to having meaningful and comprehensive discussions.	How was the moderation? Who was moderating? Why was this person selected?
Technical/material conditions	Such as PowerPoint presentation, video, paper/report/information package provided, catering (lunch/snacks/reception).	How were technical/material conditions?
<i>'Theme – Content':</i>		
High-priority issue	An issue of (local, regional,) national, and international concern.	Was it a high-priority issue (for dialogue participants)?
Clear meeting objectives	This goes hand in hand with a clear vision of what outcomes and results would be expected.	Were clear meeting objectives set?
Information shared	A pre-circulated information package, including the agenda, evidence summaries, a list of policy directions to be discussed, related background information, and an evaluation form.	Which information was shared with participants (in advance, during, and after policy dialogue)?
Evidence used	Synthesis of high-quality research evidence used to identify needs and educate participants: policy dialogue discussions and participants need to be based on effective stakeholder and context analyses, part of which is evidence-based background information.	Was evidence used/presented in the meeting?
Agreement on outcomes and action plan	List of possible and tangible actions or steps.	Was agreement reached on outcomes and action plan?
Rules of engagement	The format of the meeting and rules of engagement (giving a clear overview of purpose, participants, design, method, and materials).	Was there a formal or informal format? What was the set-up or rules?
Preparation of content	The materials created for the policy dialogue and the management of the event of the meeting overall.	Was the policy dialogue well-prepared?
Follow-up	The continuation of the policy dialogue, in terms of ongoing communication of next steps and engagement, to keep the momentum alive and renew or regenerate the projects' or programme's goals. ¹⁴	Was there proper follow-up (on next actions, next meeting, evidence/information shared)?
<i>'Theme – Participants':</i>		
Representation	The stakeholder groups represented or excluded. A mix of participants and stakeholders representing all perspectives and interests: representation of decision-makers, researchers, and those affected by the issue under discussion (user/patients groups, formal and informal caregivers).	Which stakeholder groups were represented? Which were excluded?
Participation	Social participation requires all stakeholders in the participatory process to be able to adequately and fully exercise their roles. In order to do so, all stakeholders should be, as far as possible, on an equal footing with each other in terms of ability to have influence on the participation-based discussions. ⁶⁸	Was there equal participation of stakeholders during the discussion? Who participated more? Who participated less?

Collaboration	The process of two or more people or organisations working together to complete a task or achieve a goal.	How was the collaboration between stakeholders?
Consensus	General agreement on something (by most participants). Five steps in the consensus-building process are: convening, clarifying responsibilities, deliberating, deciding, and implementing agreements.	Was consensus reached between stakeholders on a certain issue?
Trust	Firm belief in the reliability (or ability) of someone, relational	Was there trust between stakeholders?
Mutual respect	Mutual respect is defined as a proper regard for the dignity of a person or position; due regard for each other’s feelings, wishes, or rights.	Was there mutual respect?
Willingness to implement	Gore et al. distinguish three types of commitment, ⁶⁹ namely: expressive commitment, institutional commitment, and budgetary commitment. “ <i>Expressed commitment</i> refers to verbal declarations of support for an issue by high-level, influential political leaders. <i>Institutional commitment</i> comprises the adoption of specific policies and organisational infrastructure in support of an issue. Finally, <i>budgetary commitment</i> consists of earmarked allocations of resources towards a specific issue relative to a particular benchmark. The <i>combination</i> of the three dimensions signals that a state has an explicit intention or policy platform to address this health area.”	Was there willingness to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? Type of political commitment? (Expressive/financial/institutional (i.e. policy))? How has COVID-19 influenced political will towards NCD care?
Leadership	The willingness to initiate, convoke, or lead an action for or against the health reform policy. ⁷⁰	Which stakeholder displayed the most leadership?
Urgency	The degree to which stakeholder claims call for immediate attention. ⁷¹	Which stakeholder displayed the most urgency?
Legitimacy	A generalised perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions. ⁷¹	Which stakeholder displayed the most legitimacy?
Ownership	Act, right, or degree of ownership (possession) and responsibility (taken by the resource/implementing organisation, community, and/or beneficiaries) towards any programs or activities	Which stakeholder had most ownership over the issue?

Abbreviations: NCD: non-communicable diseases

Data sources and collection tools

Key data collection tools developed for the process evaluation include:

1. The policy dialogue reporting form
2. The policy dialogue survey
3. The researcher interview guide
4. The follow-up stakeholder interview guide
5. Project diaries
6. Policy mapping: document review to generate a policy timeline
7. ICP grid for implementation assessment

Most of these are used to collect data on the policy dialogue and roadmap process, as well as on context. Tools were defined based on both the indicators (as displayed in tables 1 and 2) to be included and the activities entailed in the roadmap. Some tools, in particular, the policy dialogue reporting form and the survey are based on instruments developed by CHRODIS+.⁵⁶ All methods and tools will be adapted to the specific needs and context of the countries’ scale-up strategies.

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3 The policy dialogue reporting form (tool 1 in appendix 2) serves as a self-report to be filled in by the
4 research team to evaluate the policy dialogue, the roadmap progress, and contextual barriers.⁵⁶
5 Aside from a section with general questions concerning the policy dialogue, a section is foreseen for
6 the rapporteur to write the minutes of the meeting, preferably during (and/or immediately after) the
7 policy dialogue.
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10 The policy dialogue survey (tool 2 in appendix 3) is to be completed by participants at the end of each
11 policy dialogue (that is organised by SCUBY).⁵⁶ A survey link is generated through the REDCap®
12 database^{72 73} and can be made accessible to participants online using mobile telephones. A paper
13 version can be an option if country teams prefer this and if this better fits the circumstances
14 (depending on the location). Items are related to the relevance and feasibility of discussed (roadmap)
15 actions and strategies (implementation outcomes) and to barriers and facilitators for the
16 implementation and scale-up of discussed strategies (context).
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20 Qualitative, in-depth follow-up researcher interviews (tool 3 in appendix 4) with the country teams
21 will be planned regarding the reporting forms to elaborate on items related to the roadmap and
22 policy dialogue (in line with the implementation outcomes and mechanisms). Additional qualitative
23 explanatory follow-up stakeholder interviews (tool 4 in appendix 5) will be undertaken to further
24 explore perceptions of policy dialogue and roadmap processes and contextual factors in depth.
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27 The aim of the project diary (tool 5 in appendix 6) is to display key research activities undertaken for
28 roadmap development and implementation. The policy mapping (tool 6 in appendix 7) will help track
29 key policy developments and evolutions in the field of integrated care. Furthermore, as a tool, it can
30 be used to guide or contextualise the purpose of the (next) policy dialogue meeting. Both the project
31 diary (tool 5) and the policy document mapping (tool 6)—which will generate a policy timeline on
32 integrated care—assess how the context influences SCUBY's activities and vice versa. The policy
33 mapping will inform the stakeholder interview (tool 3) and vice versa, especially in relation to the
34 existing policy and political barriers and facilitators that stakeholder participants might wish to
35 further comment on. Also, other policies and political events or activities (e.g. elections) might be
36 tracked if they impact integrated chronic care policy, such as COVID-19 restrictions or new
37 regulations for the care and control of the chronically ill in COVID-19 times (e.g. different modes of
38 delivery, changed duration, materials or location, increased use of IT tools and online consultations,
39 etc.).
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44 The ICP grid at the healthcare practices (tool 7) which was used as part of context analysis in year 1,²¹
45 will be used again to evaluate expansion of the ICP grid, so that it can serve as a before-after
46 evaluation in those areas where it was used before.²¹
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49 **Data management and analysis**

50 Qualitative data will be stored as transcripts in country-specific databases as pseudonymised data.
51 The transcripts will be stored in formats that are exportable to NVivo software (NVivo qualitative
52 data analysis software; QSR International Pty Ltd.) for analysis. Primary and secondary quantitative
53 data (related to the scale-up dimensions of *coverage* and *expansion*) collected from the
54 implementation sites will be collated into the main study REDCap® database via validated electronic
55 survey forms. Anonymised data will be transferred over the internet using secured data
56 communication protocols for analyses.
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3 For the qualitative implementation outcomes, thematic analyses will be conducted based on the
4 reporting forms, interviews, and surveys. As such, evidence from different tools on policy dialogue
5 (success factors), roadmap (progress on adoption and implementation), and context (barriers and
6 facilitators to scale-up) will be triangulated, considering the various perspectives of implementors,
7 other stakeholders, and the SCUBY researchers. Themes will be deduced both from existing literature
8 and theory surrounding policy dialogues and roadmaps and grounded in the data. Many of the
9 developed tools have clear topics, relating either to underlying policy dialogue mechanisms or to
10 roadmap implementation outcomes. A theorising approach will be used to explore how context,
11 actors, roadmap activities, outcomes (cf. framework) are connected.⁷⁴

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15 The dynamic policy and political processes (events, actions, and activities) unfolding over time in
16 context will be explored using processual analysis.^{75 76} Policy document review, desk research, and
17 input from interview participants on an initial policy mapping will be triangulated and further refined
18 to enable tracking the emergence of integrated care policies from a historical perspective, resulting
19 in a more detailed chronic care policy timeline. A minor part of the analysis will consist of a
20 retrospective stakeholder analysis on the sole attribute of the position of stakeholders on the
21 roadmap development and implementation.

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25 For the analysis of the scale-up dimensions, findings from different measurement tools will be
26 triangulated. Progress on integration will be assessed qualitatively—whilst cross-checking
27 information from (policy) document review and interviews—using thick descriptions, on the ways in
28 which roadmap actions (including interventions, programmes, and reforms) have become
29 institutionalised. Quantitative data analysis on the scale-up dimensions (coverage and expansion) will
30 entail a pre-post design. For expansion, interviews with implementors and the ICP grid will be
31 analysed again at the end of the project to give an estimate on how ICP implementation has
32 improved or deteriorated across its five components, in comparison to the previous ICP
33 implementation assessment of 2019.

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37 A flowchart of how data collection tools feed into the different types of analyses can be found in
38 appendix 8. By employing multiple methods, data sources and a larger analysis team (independent
39 researchers conducting the analysis and feeding back to country research teams for discussion on the
40 findings), we cross-check information and conclusions drawn from the data via triangulation and data
41 saturation and thereby ensuring the credibility of the data.

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44 Regarding the planned start and end dates for the study, data collection commenced in year two of
45 the SCUBY project (early 2020), shortly following the development of the tools and this protocol
46 paper. Data collection will be finalised end of December 2022. Data analysis will run from October
47 2022 until March 2023.

48 49 50 **Patient and public involvement**

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52 Patients or the public were not involved in the design, or conduct, or reporting, or dissemination
53 plans of our research. The individual countries are likely to have community and patient involvement
54 (e.g. in the policy dialogues), depending on the specifics of each scale-up roadmap, and hence, their
55 involvement is beyond the scope of this current protocol.
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Ethics and dissemination

The Institutional Review Board (Ref. 1323/19) at the Institute of Tropical Medicine (Nationalestraat 155, 2000 Antwerp, Belgium) approved this study on 1 July 2021. Findings will be (1) reported to national, regional, and local governments to inform policy; (2) reported to funding bodies (European Commission) and networks, such as the Global Alliance of Chronic Diseases (GACD), in line with their 2019 Scale Up Call; (3) presented at local, national, and international conferences; and (4) disseminated by peer-reviewed publications.

Declarations

Authors' contributions

The first (MM) and final (DB) authors were responsible for the conceptualisation and writing of the manuscript. EW, JVO, and KKG reviewed different versions throughout the drafting process. MM, DB, EW, JVO, KKG, GMK, ZKK, SrC, SaC, VB, KD, NS, CZ, APS, WVD, PI and RR were involved in the development of the data collection tools. All authors contributed to the final draft of the manuscript, have read the manuscript, and approved it for submission.

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Competing interests

The authors declare that they have no competing interests

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List of Abbreviations

ACIC	Assessment of chronic illness care
B&F	Barriers and facilitators
CoC	Cascade of Care
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HC	Health centre
HT	Hypertension
ICCC	Innovative Care for Chronic Conditions
ICP	Integrated care package
IT	Information technology
KII	Key informant interview
MRC	Medical Research Council
NASS (framework)	Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability
NCD	Non-communicable disease
NGO	Non-Governmental Organisation
PDRF	Policy Dialogue Reporting Form
PDS	Policy Dialogue Survey
PEN	Package of essential non-communicable disease interventions
RE-AIM (framework)	Reach, Effectiveness, Adoption, Implementation, Maintenance
SCUBY	Scale-Up diabetes and hypertension care
T2D	Type 2 diabetes
WHO	World Health Organization

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For peer review only

interacts with intervention, implementation strategy and outcome

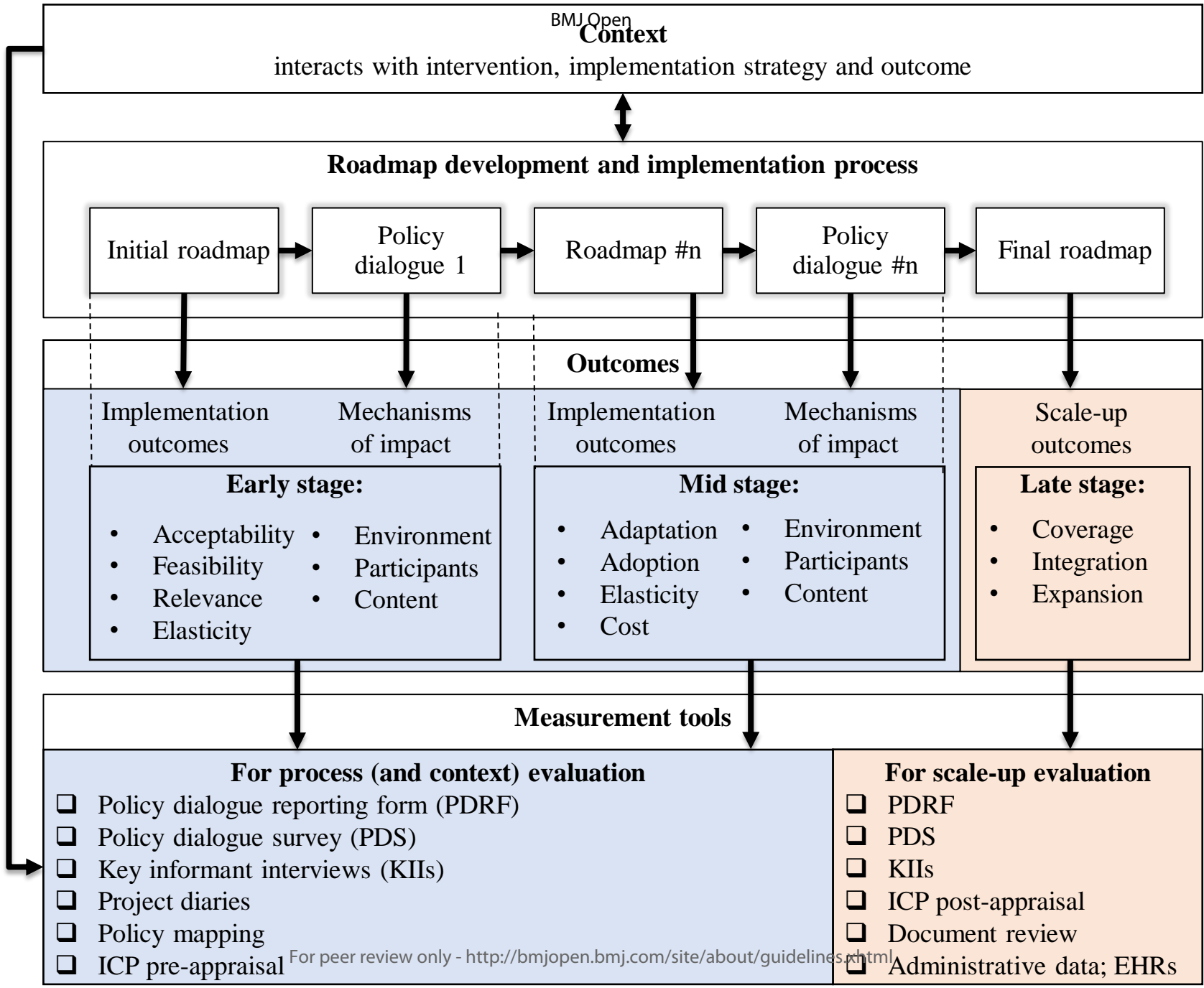


Roadmap development and implementation process



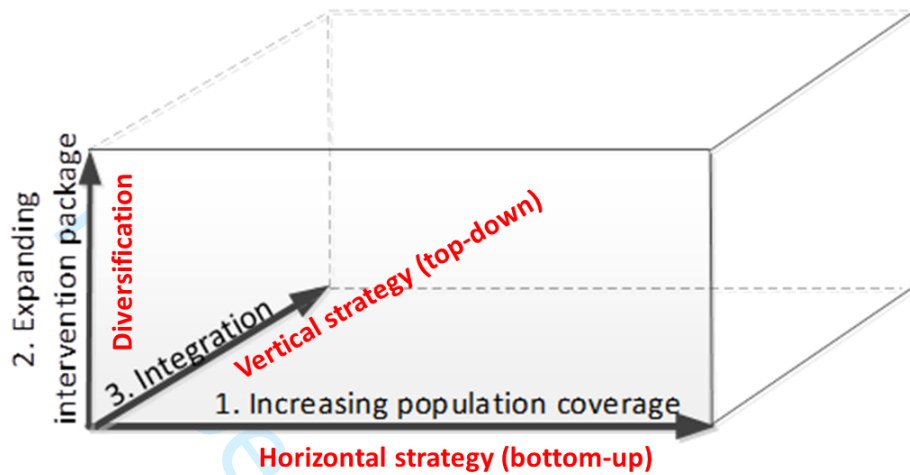
For peer review only - <http://bmjopen.bmj.com/lookup/guidelines.xhtml>

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Appendix 1: Three-dimensional scale-up framework

Comprehensive scale-up

Types of strategy

Adapted from: van Olmen J, Menon S, Poplas Susic A, et al. Scale-up integrated care for diabetes and hypertension in Cambodia, Slovenia and Belgium (SCUBY): a study design for a quasi-experimental multiple case study. *Global health action* 2020;13(1):1824382

Appendix 2: Policy Dialogue Reporting Form (tool 1)

SCUBY Policy Dialogue Reporting Form

Policy Dialogue:

Country:

Date:

Completed by: [SCUBY team member(s)]

This sheet is used for **policy dialogue monitoring**. This document is based on the CHRODIS+ Policy Dialogue Reporting Form.

Please **also report more informal stakeholder meetings**, as we have adopted a very broad definition of policy dialogue. These reporting forms will help us keep track of the whole process.

Note: The first policy dialogue description table only needs to be **fully completed for a larger (multi-stakeholder!) dialogue** or when **SCUBY** is the organiser of the policy dialogue. Hence, for a meeting with one stakeholder group, e.g. a few policy makers, some questions do not need to be completed (as indicated in the table below).

INDEX

1. Policy Dialogue Description
2. Minutes of the Policy Dialogue
3. Action plan
4. Attachments:
 - Agenda/pre-circulated question list
 - List of documents

POLICY DIALOGUE description

General questions on Policy Dialogue	Complete fields underneath (when applicable; otherwise N/A)
1. "Title" or topic: What was the title or topic of the Policy Dialogue? [please write title between "... " to differentiate]	
2. Number of the Policy Dialogue	
3. Date: What date was the policy dialogue held on?	
4. Location: In what location did the policy dialogue take place?	
5. Main objective:	
6. Specific objectives: [please number them or use bullets]	
7. Number of participants:	
8. Members roles: Who was the <ul style="list-style-type: none"> • Organiser/coordinating team: • Moderator(s): • Keynote speaker(s): • Rapporteur(s)*: • Other Participants: <p>* mention if officially appointed in a meeting, otherwise N/A.</p>	<ul style="list-style-type: none"> • ... • ... • ... • ... • ...
9. Duration: (...h...min)	
10. Conclusions: (They should be aligned with the objectives)	

Questions about the Roadmap	Complete fields underneath (when applicable; otherwise N/A)
<p>1. Roadmap adaptation/plasticity: Has the roadmap (or a certain activity) been adapted based on the discussion(s) with stakeholders? Name all roadmap adaptations, briefly indicate how this (these) adaptation(s) came about or why it is (they are) appropriate.</p>	<p>Yes/no/N-A What/which? Why?</p>
<p>2. Context/elasticity: Please summarise (contextual) barriers to action plan/in roadmap</p>	
<p>Questions about the Policy Dialogue</p> <p>! : All questions need to be completed for big* policy dialogues (otherwise only questions 4–5 and 8, see green boxes)</p> <p>* when SCUBY is the organiser, or when it is a multi-stakeholder dialogue</p>	<p>Complete fields underneath (when applicable; otherwise N/A)</p>
<p><i>Please briefly comment on following items within 'Theme – Environment':</i></p>	
<p>1. Suitability of room/location: Was the room/location suitable? Why (not)?</p>	<p>Yes/no Why?</p>
<p>2. Moderation/facilitation: How was the moderation? Who was moderating? Why was this person selected?</p>	<p>Very poor/poor/neutral/good/very good (or N/A) Why?</p>
<p>3. Technical (material) conditions:</p>	<p>Which:</p>
<p><i>Please briefly comment on following items within 'Theme – Content':</i></p>	
<p>4. Information shared with participants in advance:</p>	<p>Yes/no Which:</p>
<p>5. Was evidence used/presented in the meeting? If so, what kind and what evidence specifically?</p>	<p>Yes/no? Qualitative/quantitative? Specify what:</p>
<p><i>Please briefly comment on following items within 'Theme – Participants':</i></p>	
<p>6. Representation: Which stakeholder groups were represented? Which were excluded?</p>	
<p>7. Participation:</p>	<p>Equal/unequal Who more?</p>

1 2 3 4 5 6 7	Was participation of stakeholders during the discussion equal? Who participated more? Who participated less?	Who less?
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	8. Will to implement of policy-makers and/or implementers* 1) Was there will to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? 2) Specify type of political commitment (expressive/financial/institutional (i.e. policy)? 3) How has COVID influenced political will towards NCD/integrated care? * Question only relevant if resource or implementing organisation(s) are participating	1) Yes/No/NA Which? Who? Comment why? 2) Expressive/financial/institutional commitment? Why? 3) How, positively? How, negatively?
25 26 27	9. Leadership Which stakeholder displayed most leadership?	Who?
28 29 30 31	10. Ownership Which stakeholder had most ownership over the issue?	Who?

Minutes of the Policy Dialogue

Narrative Minutes:

(Explain the points of discussion).

Attachments to the Policy Dialogue Reporting form

1. Agenda/Schedule

Policy dialogues should last between two and four hours.

Example:

10 mins	Welcome/Tour de Table → Policy Dialogue rules, reporting, and introduction of moderator, rapporteur, and organizer/coordinating team.
15 mins	Keynote Speech (not mandatory)
3–5 mins	Opening Statements of each participant, reflecting the various views and perspectives concerning the defined problem and policy action
60–90 mins	Guided Discussion (including consensus building on actions/next steps)
30 mins	Optional slot on EU level declaration concerning chronic diseases (Consensus Statement)
15 mins	Conclusions

2. List of shared documents and (ppt) presentations used

The research team provides here an overview of the invitation, information package(s), report(s) etc. that were shared with the policy dialogue participants as well as presentations.

Appendix 3: Policy Dialogue Survey (tool 2)

INTRODUCTION:

Thank you for taking the time to provide your valuable feedback relating to the Policy Dialogue you recently attended in the context of the EU-funded SCUBY project (2019–2022), developing and implementing a scale-up roadmap for chronic diseases (specifically for diabetes type 2 and hypertension).

To evaluate the effectiveness and relevance of the Policy Dialogues and consultations with experts, we kindly ask for your assistance in completing this feedback survey. Your insights and comments will help shape and strengthen future Policy Dialogues. The data from this survey will be combined with information from other sources; this information can be used in reports, reports, conferences and publications in professional journals

The survey should take less than **5 minutes to complete**. Responding to the survey signifies your consent. You may opt not to answer or to skip questions; however, we will not be able to remove any information you have already provided should you opt to withdraw your participation thereafter. Your responses to this survey will be kept **confidential**.

SURVEY QUESTIONS:

Please provide us with the following information about yourself:

1. You are: [Drop down menu of **occupations**]

- a policy maker/politician
- a civil servant in public health administration or at the Ministry of Health
- a civil servant in social affairs or at the Ministry of Social Affairs
- a civil servant at health insurance institute or at the Ministry of Finance
- a professional medical association
- an association of social/informal care worker
- a patient organisation
- in academia
- an NGO
- an (international) donor organisation (funder)
- a healthcare worker (nurse, GP, specialist)
- a social worker
- an informal caregiver
- a patient

[listed occupations can be contextualised per country]

2. How would you rate each of the following?

From 1-Poor to 5-Excellent

1. The location of the Policy Dialogue
2. Technical conditions (material, etc.) for the Policy Dialogue

3. Moderation
4. Background information shared in preparation for the Policy Dialogue
5. Sufficiency of evidence provided and discussed in the Policy Dialogue
6. Relevance of the topics covered [high priority issue]
7. Achievement of goals as delineated in the agenda
8. Definition and agreement of outcomes and action plan to move forward

3. What is, in your opinion, the **most relevant topic, strategy or idea covered/shared** during this Policy Dialogue for you and your country and why?
4. Which topic is **your organisation** committed to (one that was mentioned in the Policy Dialogue meeting or not mentioned)?
5. Rate the discussed topics in relation to their **relevance and feasibility** (1=low relevance/feasibility; 10=high relevance/feasibility)

Topics (strategies/roadmap elements) to be completed before/after policy dialogue by the country teams e.g. education; training; telemedicine as part of diabetes self-management; health financing (provider incentives); data monitoring; community involvement; primary care practice (integration) guidelines; etc.

6. What do you see are the **primary enhancing factors (facilitators)** for the implementation and scale-up of discussed proposals/actions/strategies agreed in this Policy Dialogue in your National Policies?
7. What do you see are the **(financial/political/operational) barriers** for the implementation and scale-up of discussed proposals/actions/strategies agreed in this Policy Dialogue in your National Policies?
8. How has **COVID influenced the will to change/adapt/improve** towards better NCD/integrated care? How, positively? How, negatively?
9. In your opinion, what do you think worked well and what **could be improved from this meeting**?
10. Overall, how would you **rate this Policy Dialogue**?
From 1-Very Poor, to 10-Excellent
11. Do you have any further comments or suggestions?

Thank you for taking the time to complete this survey. We truly value the information you have provided. Your responses will contribute to our analysis and help us to improve policy dialogues in the future.

Appendix 4: Researcher Interview Guide (tool 3)

Researcher interview guide

Interview participant(s):

Country:

Date:

Conducted by:

This guide is a complementary tool to the policy dialogue reporting form and aims to explore policy dialogue and roadmap-related indicators in more depth. Following items, based on implementation outcomes will be explored in depth:

- Adoption
- Stakeholders' support
- Implementation and scale-up dimensions
- Adaptation
- Policy dialogue environment-content-participants

Interview questions**A. Questions about the Roadmap****1. Roadmap adoption:**

Is a roadmap activity/action/strategy adopted? Yes/no/N-A? Which?

Does this policy dialogue lead to the roadmap element envisaged?

Make reference to the adopted action points.

Can you elaborate on why/how it got adopted?

2. Stakeholders' support:

Which/how many roadmap elements were discussed?

Who were the key stakeholders that gave feedback/critiqued certain roadmap elements?

Who was in full support of the roadmap element(s)?

Fill in for each discussed (roadmap) element for each key participant from resource and/or implementing organisations:

5-point scale:

1. No support or buy-in
2. Little support or buy-in
3. Neutral (towards the specific action/roadmap element)
4. Initial or moderate support and buy-in
5. Full support

3. Roadmap implementation:

Is a roadmap activity/action/strategy realised (implemented)? Yes/no/N-A? Which?

Does this policy dialogue lead to the implementation of a roadmap element envisaged (phase after adoption)?

Make reference to successful action points.

Can you elaborate on why/how it got implemented?
 Have discussed proposals and solutions led to institutionalisation (already become part of the healthcare system)? Why and how? [scale-up dimension of integration]
 Have discussed proposals and solutions led to diversification, the expansion [scale-up dimension] of the ICP? Why and how?
 Have discussed proposals and solutions led to increased population or geographical coverage [scale-up dimension]? Why and how?
 What are sources of verification [for perceived scale-up dimensions]? Research findings? Organisational report? Database? News item? Word-of-mouth? From resource or implementing organisation(s)?

4. Adaptation/plasticity:

Has the roadmap (or a certain activity) been adapted?
 Can you describe the way in which the roadmap (elements) have been adapted?
 Can you indicate how this (these) adaptation(s) came about or why it is (they are) appropriate.

5. Context/elasticity:

How has the context evolved? How are contextual (political/financial/operational) barriers and facilitators to action plan/in roadmap evolving?

B. Questions about the previously organised Policy Dialogue(s)

! : All questions need to be completed for big* policy dialogues (otherwise only questions 5–9 and 19, see green boxes)

* when SCUBY is the organiser or when it is a multi-stakeholder dialogue

Please briefly comment on following items within 'Theme – Environment':

1. Suitability of room/location:

Was the room/location suitable? Why (not)?

2. Moderation/facilitation:

How was the moderation? Why good/bad?

3. Technical (material) conditions:

How were technical/material conditions? (e.g. website/video/presentation/flyers/information package/catering etc. provided?) Why good/bad?

4. Other conditions:

Please briefly comment on following items within 'Theme – Content':

5. Was it a high-priority issue (for dialogue participants)? Why?

6. Were clear meeting objectives set? Clear how? If unclear, why?

7. Do you think that sufficient information was shared with participants (in advance, during and after policy dialogue)? (Why not?)

8. Was evidence used/presented in the meeting?

If so, what kind (quant/qual/both) and what evidence specifically?

9. Was agreement reached on outcomes and action plan? How/why not?

10. Rules of engagement:

Was there a formal or informal format?

What was the set-up or rules?

(e.g. online meeting, Chatham House rules, stakeholders share their perspectives one by one, scientific presentation with comments, discussion in sub-groups or plenary session, expert panel, high-level policy maker meeting)

11. Was the policy dialogue well-prepared?

12. Was there proper follow-up (on next actions, next meeting, evidence/information shared)?

Please briefly comment on following items within 'Theme – Participants':

13. Representation:

Which stakeholder groups were represented? Which were excluded?

14. Participation:

Was participation of stakeholders during the discussion equal?

Who participated more?

Who participated less?

15. Collaboration

How was the collaboration between stakeholders?

- Very poor/poor/neutral/good/very good
- Can you use a word to describe your collaboration? E.g. top-down, bottom-up, organic, spontaneous, awkward, formal, informal, ...

Why do you think it was good/bad?

16. Consensus

Was consensus reached between stakeholders on a certain issue? How?

17. Trust

Was there trust between stakeholders? How did you notice?

18. Mutual respect

Was there mutual respect? How did you notice?

19. Will to implement of policy-makers and/or implementers* :

1) Was there will to implement a discussed strategy or action? If yes, which strategy and who showed this will to implement? What do you think drives them to implement?

Why/what is the reason to implement? Is there one direct reason or many good reasons?

2) Specify type of political commitment (expressive/financial/institutional (i.e. policy))?

3) How has COVID influenced political will towards NCD/integrated care? How, positively? How, negatively?

*** Question only relevant if resource or implementing organisation(s) are participating**

20. Leadership

Which stakeholder displayed most leadership? + Why?

21. Urgency

Which stakeholder displayed most urgency? + Why?

22. Legitimacy

Which stakeholder displayed most legitimacy? + Why?

23. Ownership

Which stakeholder had most ownership over the issue? + Why?

Appendix 5: Follow-up Stakeholder Interview Guide (tool 4)

Introduction

Introduction of the researcher(s)

- Name & function of researcher
- Share researcher's contact details (e.g. business card)
- In case of 2 researchers: one asking questions (mainly) and one/both taking notes

Introduction of SCUBY

- SCUBY is a 4-year research project on the scaling up of integrated care for diabetes and hypertension through co-creation with key stakeholders, such as you ... We are studying the scaling up of integrated care for diabetes and hypertension, with special attention to vulnerable people.
- The aim of this research is to engage with key stakeholders at all levels, to identify opportunities and barriers to integrated chronic care at the macro level, to implement and support best practices on a larger scale.
- Focus on integrated chronic care, diabetes, hypertension & vulnerable groups (key terms)

Explain purpose and the intent of the interview:

- **Thank you** for taking the time to provide your valuable feedback relating to the Policy Dialogue you recently attended in the context of the EU-funded SCUBY project (2019–2022), developing and implementing a scale-up roadmap for chronic diseases (specifically for diabetes type 2 and hypertension).
- **To evaluate** the effectiveness and relevance of the Policy Dialogues and consultations with experts, we kindly ask for your participation in this (follow-up) interview. Your insights and comments will help shape and strengthen future Policy Dialogues.
- Duration of interview: max 60 min
- Ensure anonymity and confidentiality
- Questions?

Informed consent

- Ask (to sign) the informed consent and permission to record the interview

Outline of interview (topics to cover)

- Policy dialogue
- Roadmap development
- Stakeholder engagement (attributes)
- Remarks and conclusion

Policy dialogue

1. What was your role and contribution in the Policy Dialogue? How was your experience?
2. Were the topics under discussion in the Policy Dialogue relevant (**high priority**) to you?
3. Was the **evidence** provided and discussed in the Policy Dialogue relevant and interesting to you? Can you use it and how?
4. How important do you think **representation** is in Policy Dialogues? Were certain groups not represented? What do you think are the benefits of a small vs big group in a Policy Dialogue?

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5. How would you describe the **collaboration** between stakeholders in the Policy Dialogue? Have you collaborated before with some of these participating stakeholders? With who (not)?
 6. Was a **consensus** reached on an action plan? If yes, consensus on what? And how was it reached?
 7. *To policy makers:* what do you think is needed in order to implement the discussed proposal? What is your role/contribution in the scale-up of this strategy? *To other stakeholders:* Do you think policy-makers will implement the discussed proposal? Why (not)? What is your role/contribution in the scale-up of this strategy? Specify type of political commitment (expressive/financial/institutional (i.e. policy))? [**will to implement**]
 8. How has **COVID** influenced political will towards NCD/integrated care? How, positively? How, negatively?
 9. In your opinion, what do you think worked well and what **could be improved** from this meeting?

Roadmap

10. How **acceptable** do you think is this action/strategy/roadmap element [*specify; e.g. training/group education programme/data monitoring*] to the beneficiary (provider/patient)?
11. Can you please comment on both the **relevance** and the **feasibility** of the proposals, actions or strategies discussed/shared/agreed upon in the policy dialogue? (as one might be highly important but not a feasible action, or vice versa)
12. [**Context**] What do you see are (**financial/political/operational**) **barriers** that might hinder the implementation and scale-up of discussed proposals/actions/strategies in your National Policies?
13. [**Adaptation/plasticity**] Are changes to the roadmap or specific roadmap elements [*specify*] necessary? Which?
14. [**Costs**] What do you think are the costs related to this roadmap action/strategy [*specify*] and its implementation?
15. [later stage] Have discussed proposals and solutions led to **institutionalisation** (already become part of the healthcare system)? Why and how? [scale-up dimension of integration]
16. [later stage] Have discussed proposals and solutions led to diversification, the **expansion** [scale-up dimension] of the ICP? Why and how?
17. [later stage] Have discussed proposals and solutions led to increased population or geographical **coverage** [scale-up dimension]? Why and how?

Concluding remarks

Additional comments

- Do you have any additional remarks?

Thank

- Thank your time to participate in this interview. We truly value the information you have provided. Your responses will contribute to our analysis and help us to improve policy dialogues and scale-up in the future.

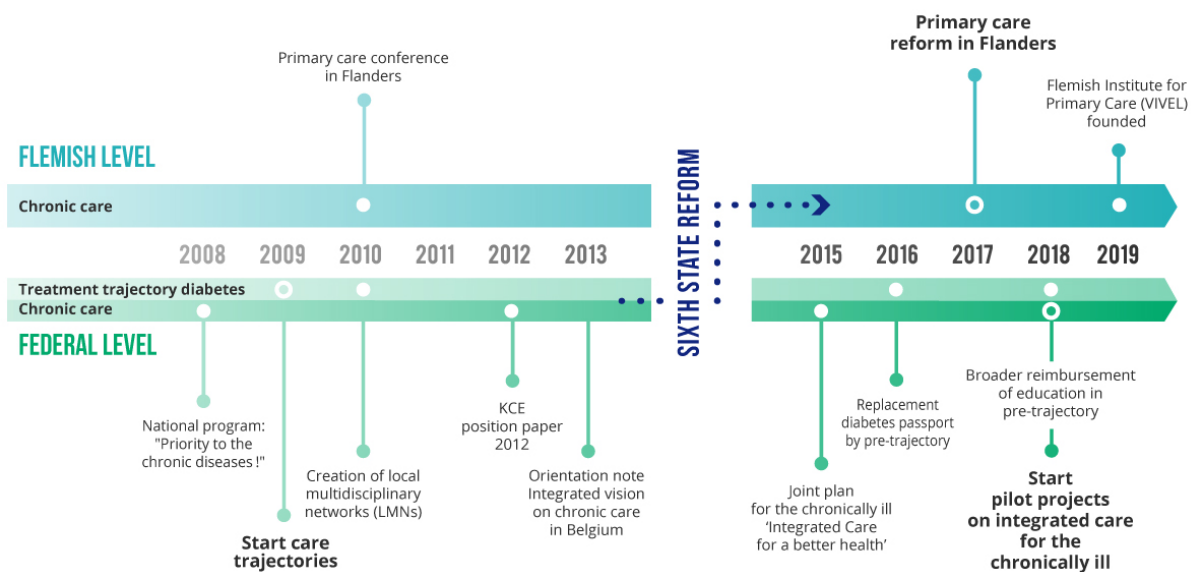
Share SCUBY brochure at the end.

Appendix 6: Template for project diary (tool 5)

Date	Event	SCUBY participant(s)	Other participants	Topic (about)	Next steps/outcomes
04/2019	Focus groups with patients				
05–09/2019	Stakeholder interviews				
23/10/2019	Launch SCUBY				
02/2020	SCUBY consortium meeting				
30/06/2020	Meeting MoH				
21/09/2020	Expert panel				

Note: The table displays activities and meetings in chronological order. Examples of activities are provided. Internal team meetings do not need to be all chronologically registered; rather the aim of the project diary is to display: (1) meetings with a stakeholder(s) on steps undertaken in the roadmap; and (2) other related network and research activities.

Appendix 7: Example of (Belgian) policy timeline on integrated care (tool 6)



Note: not updated for current corona policy developments

Appendix 8: Flowchart depicting how data collection tools feed into different types of analyses

