Funded by the European Union through the Structural Reform Support Programme and in cooperation with DG REFORM

REPUBLIC OF SLOVENIA
MINISTRY OF HEALTH

Support for improving quality of healthcare and patient safety in Slovenia

INCEPTION REPORT

RFS REFORM/SC2020/021

AARC - Consortium

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1. Project aims and scope

1.1. Objectives

The **overall objective** of the project**,** in line with Article 4 of the SRSP Regulation is to contribute to institutional, administrative and growth-sustaining structural reforms in Slovenia.

The **specific objectives**[1] in line with Article 5 of the SRSP Regulation, are to:

- **Support the initiatives of national authorities** to design their reforms **according to their priorities**, taking into account **initial conditions** and **expected socioeconomic impacts,**
- **Support the national authorities** in: (1) **Enhancing their capacity** to formulate, develop and implement reform policies and, (2) Defining strategies and **pursuing an integrated approach**, ensuring **consistency between goals and means** across sectors

The **specific objective** in this case of Slovenia, is to:

- **Support the Slovenian Ministry of Health (MoH)** in capacity building to develop a National strategy on quality of care (QoC), risk management (RM) and patient safety (PS), and a legal framework of no-fault compensation model

1.2. Expected results

The expected results can be differentiated into direct and indirect results:

Direct results:

- Over the longer-term, to **contribute towards improving the QoC and PS in Slovenia**

Indirect results:

- **Improved knowledge** of challenges and opportunities in **PS and QoC,**
- Strengthened **PS culture** and **patient RM,**
- Improved **strategic planning and governance** of the QoC system,
- **Revised set of indicators for QoC for hospitals, specialist outpatient care** and **primary care** available, tested and communicated.

1.3. Scope

This project aims at building capacity to develop and improve **QoC, PS and patient RM strategy,** and implementing a **no-fault patient compensation model** in Slovenia. In order to achieve the objectives and expected results, it will be crucial to take into account all the work previously carried out in the areas of QoC and PS in Slovenia.

Also, for the conduction of all the planned activities and in order to guarantee the development of a quality and complete strategy, a **strategic, operational, tactical and individual perspective** on excellence, quality and risk management will be followed.

[1] The achievement of the objectives is not solely the responsibility of the contractor and will depend partly but not only on Slovenia's action(s).

Actions will be taken at three different levels (macro, meso and micro), combining a top-down and a bottom-up approach that will allow to respond to the main needs and challenges regarding QoC and RM.

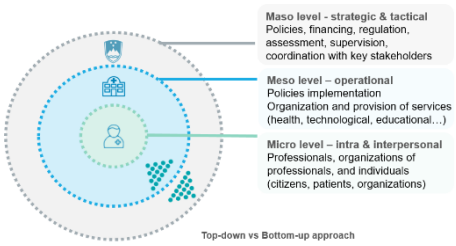


Figure 1: Systemic approach on QoC and PS

The project is expected to end with a solid national strategy, improved knowledge for the future implementation of a no-fault compensation model, and recommendations that provide building bricks for the future deployment of improvements and opportunities regarding QoC, PS and RM.

2. Methodological framework

The project will be held in 11 phases[2] during 20 months[3], starting on April 2021 and ending by October 2022.[4]

Below is presented a summary with the description of the phases, tasks and deliverables agreed in the kick-off meeting carried out in April 13th 2021 and in further contacts between MoH and the Consortium.

Summary of Phases, Tasks and Deliverables			
Phase 1: Kick-off meeting and inception report			
Task 1.1: Prepare and carry-on a kick-off meeting Task 1.2: Deliver an inception report Deliverable 1: Inception report (English)			
Phase 2: Situation analysis of the national context of PS & patient RM, patient compensation and QoC			
Task 2.1: Prepare and perform visits to 1-2 EU countries Task 2.2: Report of situation analysis (including the visit(s) report) Deliverable 2: Report of a situation analysis of the national context of PS & patient RM, patient compensation and QoC (English)			
Phase 3: Patient RM framework and action plan	**Phase 4: Improve PS and safety culture**	**Phase 5: No-fault compensation model**	
Task 3.1: Collect and review the elements of the RM system available in Slovenia Task 3.2: Conduct a comparative analysis of RM systems of PS used in other EU countries Task 3.3: Provide an analytical framework for a RM system for Slovenia Task 3.4: Formulate SMART recommendations and an action plan for the development of a safety RM system Task 3.5: Prepare and perform qualitative techniques with stakeholders (consensus building) Deliverable 3: Report on PS RM (English)	Task 4.1: Design a national action plan to strengthen PS culture Task 4.2: Support the MoH in revising and improving the guidance on how to develop local action plans Task 4.3: Develop an assessment questionnaire for PS culture, addressed to and customized for different types of healthcare providers Task 4.4: Hands-on support to selected healthcare providers drafting/finalizing their local action plans and on how to effectively use them to strengthen their PS system Task 4.5: Organize and carry out training activities addressed to healthcare providers Deliverable 4: Report on support for the preparation and implementation of a national plan and local action plans to improve PS and safety culture (English)	Task 5.1: Carry out a comparative analysis of the Slovenian compensation system and those of other EU national systems Task 5.2: Consult key players in Slovenia on selected no-fault compensation models analysed Task 5.3: Propose and describe the compensation model Task 5.4: Advise the MoH on the necessary governance and legal changes required Task 5.5: Organize communication and awareness-raising activities on the proposed compensation mechanism. Task 5.6. Elaboration of a report describing the results of the activities Deliverable 5: Report on the proposed No-fault compensation model (English)	
Phase 6: National strategy for the quality of healthcare	**Phase 7: Governance of the QoC system model**		
Task 6.1: Develop the draft national strategy for the quality of healthcare Task 6.2: Consult national stakeholders and EU experts on the draft national strategy for the quality of healthcare Deliverable 6: Report supporting the development of a national strategy for the quality of healthcare (English)	Task 7.1: Conduct a gap analysis of the current governance mechanisms or practices in the Slovene quality of healthcare system Task 7.2: Carry out a comparative analysis of governance models for the quality of healthcare from other EU countries Task 7.3: Consult national stakeholders Task 7.4: Draft the governance model for the Slovene QoC system Task 7.5: Produce a policy brief for proposing the governance model Deliverable 7: Recommendations for improving the governance of the Slovenian QoC system (English)		
Phase 8: Quality indicators	**Phase 9: IT Functional specifications**	**Phase 10: Continuous quality improvement**	**Phase 11: Communication plan**
Task 8.1: Propose an updated list of quality indicators covering all levels of healthcare provision Task 8.2: Develop methodological guidance for the use of quality indicators in quality assurance Task 8.3: Pilot the list of indicators developed previously in selected medical facilities Task 8.4: Final report elaboration Deliverable 8: Revised set of quality indicators to be applied at all levels of healthcare (English)	Task 9.1: Define business requirements Task 9.2: Define business processes for reporting and monitoring Task 9.3: Define use cases Task 9.4: Generate recommendations Deliverable 9: Functional specifications for IT systems for monitoring & reporting on quality of healthcare (English)	Task 10.1: Draft of a report including the recommendations and guidance on how to revise the existing list of indicators, propose new indicators and motivate healthcare providers to use indicators to review and improve quality of healthcare Task 10.2: Final report elaboration Deliverable 10: Recommendations and guidance on how to revise and effectively use quality indicators for continuous quality improvement (English)	Task 11.1: Draft of a report including the strategic planning of communication activities, the guidelines for action and the materials provided during communication events Task 11.2: Final version of a report including the strategic planning of communication activities, the guidelines for action and the materials provided during communication events Deliverable 11: Communication plan on the strategic report and the revised list of indicators for quality of healthcare (English)

[2] An overview of the project is provided at the end of this document.
[3] The expected duration of the project is 20 months. We expect to finish it in 16 months and count on 4 months of a safety margin against possible unforeseen circumstances.
[4] The service contract entered in force on 31/07/2020 but a contractual amendment for an extension of 5 months had to be made since the kick-off was delayed with respect to the foreseen date

2.1. Phase 1: Kick-off meeting and inception report

Aims:

- To establish adequate knowledge based on the national policy and institutional context intended to underpin the future project work in the following subjects: 1) PS and patient RM, 2) Patient compensation mechanisms and policies and, 3) The QoC system.
- To fine-tune with the MoH the activities, deliverables and timeline and take key decisions regarding the project, and deliver the inception report which will guide the implementation of the contract.
- Define the coordination, communication and validation schemes.

Activities (T.1.1, T.1.2):

T.1.1: Prepare and carry-on a kick-off meeting

- Videoconference briefing (carried out in December 17th 2020) with the Steering Committee previous to the kick-off meeting in order to identify the documentation and gain deep knowledge regarding what has been done so far and assure a good and deep understanding of the scope of the project and all of its components. The key and organizational aspects of the kick off were also established.
- Kick-off meeting preparation and conduction (conducted in April 13th 2021)
    1) Drafting of a detailed agenda for the kick-off meeting.
    2) Key points from the kick off meeting:
        1. Presentation of the participants and team composition
        2. Presentation of the project objectives and expected results
        3. Agreement on project calendar
        4. Agreement on the methodology of the project: main phases and deliverables
        5. Agreement on the governance model, coordination mechanisms and validation procedures
        6. Definition of next steps

T.1.2: Deliver an inception report

- Production of the inception report (D1) in English specifying: the agreements, the description of each phase, activities and deliverables according to the consensus obtained in the kick-off meeting.

Techniques:

- Structured kick-off meeting covering all the items planned

Deliverables:

- Organise a kick-off meeting (accomplished)
- D1: Deliver an inception report (deadline: 05.21)

2.2. Phase 2: Situation analysis of the national context of PS and RM, patient compensation and QoC

Aims:

- To establish an **adequate knowledge base for project** work on: 1) PS and patient RM, 2) Patient compensation mechanisms and policies and, 3) QoC system.
- To enable key Slovenian stakeholders to: 1) Better understand the **design, implementation and governance features of EU countries systems** of PS and patient RM, patient compensation and QoC, 2) **Experience first-hand how other systems manage the aspects mentioned**, 3) Discuss with and get feedback from recognised EU experts on these subjects.

Activities (T.2.1, T.2.2):

*The consortium proposes to visit 2 countries with advanced QoC and PS systems and no-fault compensation models in: **Italy (the Tuscany region)** and **Catalan health system**. Both have become benchmarks in quality throughout Europe: they are implementing a measure of measuring safety culture, they have their facilities accredited, specific agencies for quality and safety of care. In both cases direct measures of quality of clinical care and patient satisfaction with care (counting PROMs and PREMs) are included in the mandatory data requirements for organisations supplying care. Also, both have systems for internal monitoring of PS, QoC and uptake of evidence-based guidelines. Given the participation of Denmark in the previous SRSP, if convenient, this country may be included in the candidates list*[5].

Pripombe dodal [VZ1]:
?? a proposal for change this location because we were already there under the PREMs

T.2.1: Prepare and perform visits to 2 EU countries[6]

- Prepare and validate the study agendas to visit the systems of the countries selected.
- Carry out the logistical arrangements of the study visits[7] and prepare, organize and conduct the visits: coordination of the agenda and contents (1 person of the team will accompany the 10 experts).

*The **main topics of the agenda** are (non-exhaustive listing): 1) Leadership, governance and organizational models of PS & QoC, 2) Policies and regulations, 3) Institutional mechanisms, tools and processes, 4) Compensation model: legal, regulatory and financial aspects and implications to professionals and patients, 5) Indicators and instruments to monitor and assess QoC, 6) Lessons learned, facilitators and bottlenecks.*

- Elaborate and deliver the study visit report(s) with the highlights of the visit(s).

T.2.2: Report of situation analysis (including the visit(s) report)

- Elaborate an investigation protocol.

*The **items to be included in the study** are (non-exhaustive listing): 1) Main features of the healthcare systems, 2) Leadership, governance and organizational models of PS and QoC, 3) Policies and decision making process on health goals, priorities and interventions for quality and safety, 4) Regulations and legislation, 5) Institutional mechanisms, tools and processes, 6) Stakeholder involvement, 7) Compensation model: legal, regulatory and financial aspects and implications to professionals and patients, 8) Implementation, 9) Indicators and tools to monitor and assess QoC and, 10) Lessons learned, main facilitators and bottlenecks.*

- Collect information from secondary sources and through interviews to the main stakeholders.
- Structured information analysis.
- Workshop to discuss on the topics to be included in the situation analysis and also to agree on stakeholders to consult
- Workshop to comment preliminary results of the situation analysis
- Draft of a concise report (D2) identifying the main conclusions and SMART[8] recommendations[9].

Techniques:

Methodological proposal including the items to be analysed and the techniques to be used	Desk research development and preparation and conduction of interviews (n=until 10 interviews[10]): collect and analyse documentation covering the 3 main subjects of the analysis	Structured information analysis

[5] However, the support of the steering group is required to facilitate initial contacts.
[6] It has been agreed to conduct the visits from March 2022 because of the current situation of COVID-19 pandemic.
[7] All costs related to carrying out the visit(s) will be covered under the budget of this project (10 Slovenian participants).
~~Proposal: 3 physicians and 3 nurses (3ry, 2ry and 1ry level), 1 Clinical and 1 Community Pharmacist, 1 member from MoH and 1 member from the HIFS).~~ 4 MEMBERS OF MOH, 2 nurses, 2 medical doctors, pharmacist, lawyer
[8] Specific, measurable, achievable, realistic and time bound.
[9] The results are expected to be presented on September 17th, coinciding with World Patient Safety Day.
[10] To carry out this activity, the support of the counterpart is required to provide access to the people to be interviewed (online interview).

Workshop (n=2)

Deliverables:

- D2: Report of a situation analysis of the national context of PS & patient RM, patient compensation and QoC (English) (deadline of the report of situation analysis without results of the visits: 30.09.21)[11]

2.3. Phase 3: Patient RM framework and action plan

Aims:

- To assist in the development of comprehensive RM system of PS
- To analyse the system focusing on prevention and early intervention to mitigate safety risks

Activities (T.3.1, T.3.2, T.3.3, T.3.4, T.3.5):

T.3.1: Collect and review the elements of the RM system available in Slovenia

- Hold a meeting with the OWG to clarify what has been done so far and what is still needed to be done in relation to the RM system for sentinel and other adverse events.
- Elaborate an analytical framework listing the key achievements and the key outstanding issues and collect and review of key documentation using the framework and validation with the OWG.

T.3.2: Conduct a comparative analysis of RM systems of PS used in other EU countries (proposed list*: Denmark, Ireland, Australia, Italy (the Tuscany Region) and Spain – Catalan health system).

The **decision of the final list of countries will be based in the defined criteria: 1) Existence of national/regional agencies specifically dedicated to the QoC and/or to Patient Claims, 2) Existence of national plans regarding QoC and PS, 3) Mature systems of risk reporting, 4) No-fault compensation models and effective patient compensation schemes, 5) Accreditation of healthcare facilities and/or carry-out of regular audits according to relevant legislation, clinical guidelines and best practices; 6) Regular monitoring of meaningful quality and safety indicators from a perspective focused on the outcomes and the patient experience and, 7) Existence of a wide spectrum of processes and mechanisms to ensure the quality and safety of the patient, and 8) Widely professional culture of continuous improvement and performance safety.*

- Elaborate the investigation protocol to conduct the analysis (with analytical framework).
- Develop the desk research and collect the information (interviews[12]) following the protocol. MoH will facilitate the contact person in Denmark, the Consortium will facilitate the contact person in Spain and Tuscany, and for the remaining countries, support to DG Reform will be asked to contact with identified agents (The Consortium will identify the persons to interview).
- Draft of a concise report with the conclusions, strengths and weaknesses of the selected countries.

T.3.3: Provide an analytical framework for a RM system for Slovenia

- Propose an analytical framework

*The proposed **analytical framework** will be focused on **building capacity and developing mechanisms to better manage risks** (sentinel and other adverse events) to improve quality and meet objectives by: 1) Identify and categorize the existing risks: foreseeing failures, detecting sources of risk, nature of hazard, audits…, 2) Assess risks (risk rating criteria, control measures, prevention initiatives and interventions through the assessment of the severity and likelihood of the*

Pripombe dodal [VZ2]:
calculation of risk level and savings

[11] The results are expected to be presented on September 17th, coinciding with World Patient Safety Day.
[12] Collection of information from secondary sources and interviews (telephone/videoconference or face-to-face) to the main stakeholders (n=till 10 interviews).

*risk), 3) **Strategies and actions to response and mitigate risks** (activities of contingency, involved human and other resources and time for reaction), 4) Identify the **RM training needs** to manage risks, 5) Identify a **methodology for measuring PS and safety culture** among the health professionals and stakeholders (e.g. checklist questionnaire), 6) Identify **roles and levels of intervention** to ensure **compliance** with a development of a **RM organisational chart.***

T.3.4: Formulate SMART recommendations and an action plan for the development of a safety RM system

- Draft of a detailed report with the main findings and a draft of an action plan for the development of a safety RM system.

*Setting up the **action plan** to embed RM into all health providers and all organizational processes and develop a risk aware culture. The plan will take into account the political, legal and regulatory context to adapt the RM system. The following items will be addressed (non-exhaustive listing): 1) Identification of the **activities** taking into account the **objectives and strategic lines** identified in the analytical framework, 2) Identification of **responsible and roles**, 3) **Time line**, 4) **Cost-feasibility and impact analysis** of the activities to establish a prioritization and, 5) **Monitoring system** of the execution of the plan and results achieved.*

- Delivery of a final report (D3) on safety RM including: 1) The ***current status*** of the RM system available in Slovenia, 2) The ***comparative analysis*** of RM systems of PS, 3) The ***analytical framework*** for RM system for Slovenia and, 4) The ***SMART recommendations*** and ***action plan*** for the development of the system.

T.3.5: Prepare and perform qualitative techniques with stakeholders (consensus building)

- The development of consultation and consensus activities with key stakeholders will be carried out across the entire phase. Thus, it is proposed to elaborate: 1) ***Stakeholders mapping*** (identification of the key experts to consult according to the tasks to be held), 2) ***Semi-structured interviews*** with ***international stakeholders*** for the comparative analysis, 3) Delphi-like process (until 2 rounds of online survey) to build consensus on the analytical framework, on the SMART recommendations and the action plan, 4) ***Workshop*** (n=1) with key experts[13] to consensus the recommendations and the action plan (this workshop will be carried out together with a workshop of task 4.1) and, 5) ***Presentation of the results*** to a ***broad range of stakeholders***[14].

Techniques:

Development of adequate tools from Lean Six Sigma such as Ishikawa diagrams or Failure Mode and Effect Analysis (FMEA) to identify the causes of the prioritized risks and the questionnaire of RM culture, and to elaborate the action plan (e.g., quick-wins)		Desk-research, semi-structured interviews with key stakeholders and information analysis	Workshop (n=1) with key experts (consensus framework/ recommendations)
Delphi like technique (max.2 rounds): feedback on analytical framework recommendations, action plan	Investigation protocol elaboration for the conduction of a comparative analysis	Stakeholders mapping	RM organizational chart

Deliverables:

[13] E.g., directors, medical directors, nursing directors, Professional Chambers (medical, Nursing, Pharmacy, Physiotherapist), MoH, NIJZ, ZZZS.
[14] Members from: NIJZ, ZZZS, Training sector (medical, pharmacy and nursing faculties), Healthcare Facilities (Directors, Medical and nursing directors, Head of quality and PS commissions and chief financial officers, nursing directors and directors of nursing homes), Professionals Chambers (Medical, Nursing, Pharmacy), Directors of community pharmacies, Patient group (Network of patients 'organization, Mreža 25x25), MoH.

- D3: **:** Report on safety RM including the current status of the RM system available in Slovenia, the comparative analysis of RM systems of PS, the analytical framework for RM system for Slovenia and the SMART recommendations and action plan for the development of the system (English) (deadline: 30.11.21)

2.4. Phase 4: Improve PS and safety culture[15]

Aims:

- To enable MoH to build and to adopt a national plan for PS.
- To build capacity for healthcare providers on developing local action plans to assess their safety culture and to improve PS.

Activities (T.4.1, T.4.2, T.4.3, T.4.4, T.4.5):

T.4.1: Design a national action plan to strengthen PS culture (up to 5 years)

- Identify with the OWG the relevant documents to develop the project delivered in previous projects.
- Work on the identification, prioritization and consensus with the OWG and other key experts identified (if deemed necessary) on the key initiatives and interventions to be carried out over a short and medium term at a national level. This workshop will be carried out together with the workshop of phase3).

*The **national action plan on PS culture** will focus on different levels (non-exhaustive listing): 1) **System interventions**, 2) **Organisational** (institutional) **interventions**, 3) **Clinical governance**, 4) **Processes, tools and mechanisms**, 5) **Cultural interventions** (regarding decision makers, managers, professionals and patients) and, 6) **Measurement and assessment interventions.** It will include the same items described in the action plan table of the task 3.4 (including a time line).*

T.4.2: Support the MoH in revising and improving the current guidance on how to develop local action plans

- Meet with OWG to obtain and gain better understanding on the current guidance on how to develop local action plans about the essential aspects not covered, gaps and problems to resolve/improve.
- Identify and assess the different or variable points of the guidance that will need to be fine-tuned in order to guarantee its applicability to different contexts of Slovenia.
- Elaborate recommendations on fine-tuning the web-app and learning platform to different contexts.

*The **main blocks of the guidance on how to develop local action plans** are related to (non-exhaustive listing): 1) How to **collect information and diagnose** the existing **gaps**, 2) How to **define the strategies and objectives**, 3) How to **describe activities** and how to **prioritize** them, 4) How to **engage** managers, professionals and patients, 5) How to define a **realist timeline** and, 6) How to **identify and construct SMART indicators** and how to **follow-up and evaluate** them.*

T.4.3: Identify and develop an assessment questionnaire for PS culture, addressed to and customized for different types of healthcare providers

- Analyse the organizational structure, leadership, governance and characteristics of the different healthcare providers (beyond those referred in the RfS, the team proposes to add community pharmacies).
- Identify evaluated questionnaires adopted worldwide and proposal of the ones that could better respond to the Slovenian reality (e.g. AHRQ), according to, among others, the rules of translation.

[15] Note: given the logistics and local support needed, the local team of experts will carry out the main part of the face-to-face activities.

- Develop executive and friendly methodological guidance about: 1) The organisation of questionnaire-based surveys, the data analysis and interpretation of the results procedures, and 2) The understanding and use of the assessed results to improve PS culture. The guidance will include the steps to carry-out the psychometrical evaluation in a pilot and of the number of respondents needed in each level of attention in order to obtain standardized questionnaires.

T.4.4: Hands-on support to selected healthcare providers drafting/finalizing their local action plans and on how to effectively use them to strengthen their PS system (min. 5/max. 10)

- Assess the stage of preparation of the local action plan in each healthcare provider selected for the piloting to define the method of support for drafting or finalizing their plan, namely: 1) Expert on-site visits to the healthcare facilities and, 2) Remote support and assessment (phone, video, email).
- Support to each institution in fine-tuning the action plan to each particular circumstances: 1) ***Kick-off meeting*** with each healthcare provider, 2) Support in the ***assessment of the needs, institutional set up***, problems, priorities, facilitators and bottlenecks, 3) Support to identify the ***key features of an action plan*** to give response to the assessment made, 4) Support to define an effective ***implementation strategy***[16], 5) ***Continuous remote support*** to monitor the implementation and to prevent or mitigate the existence of deviations[17] and, 6) ***Periodic check-points*** (alternately remotely and in person).

T.4.5: Organize and carry out training activities addressed to healthcare providers (n=+15)

- Hold a meeting with the OWG to prepare the focus of the training activities and get deep knowledge about the context of the added 15 medical facilities to be targeted.
- Develop a methodological proposal about the techniques, contents, time frame and experts that will carry on the training activities.
- Carry-out the training activities on PS and RM, including topics such as: 1) ***Effective implementation*** of a safety management system in different types of healthcare institutions, 2) Systematic ***review of the safety management*** system at facility level and national level, 3) How to ***embed the web app and learning platform into the safety management system***, and ensure their effective use (e.g. using the learning platform for preventive action including the development of safety culture), 4) ***Inclusion of patients, caregivers and local communities*** into safety management, 5) ***Practical guidance*** on how to ***roll-out the training sessions*** in other medical facilities.

*A **non-exhaustive list of methodologies** that can be used are: 1) Assignment of **coordinators** (key experts) to supervise and validate the contents, 2) **Pre and post training questionnaires**, 3) Mix of **face-to-face and non face-to-face activities**[18], 4) Training activities **using competition techniques** among providers/ professionals, 5) **Train the trainers methodologies**, fostering the knowledge and it's transmission through each organization, 6) **Campaigns** to inform and raise awareness among healthcare professionals, patients and communities, etc.*

- Deliver of the final report (D4) describing the results of the training activities and with the national action plan for PS, the assessment questionnaire and the training materials as annexes.

Techniques:

Stakeholders mapping	Desk research and structured	Gap analysis	LSS techniques the action plans	Design thinking workshops	Train the trainers methodologies

[16] It will include a time frame and an allocation of responsibilities' for implementation and a clarification of the different procedures involved.
[17] everis has different tools in order to create team groups: Confluence or Microsoft teams.
[18] The team proposes to use the online platform as in the past projects of REFORM support.

analysis of the documentation		(e.g., quick wins)	

Deliverables:

- D4: Report on the support for the preparation and implementation of a national plan and of local action plans to improve PS and safety culture (English) (deadline: 30.06.22)[19]

2.5. Phase 5: No-fault compensation model

Aims:

- To analyse the compensation model for sentinel/ other adverse events against other national models.
- To identify a no-fault compensation model adapted to the Slovenian context.
- To build capacity for the future preparation and implementation of the identified model.

Activities[20] (T.5.1, T.5.2, T.5.3, T.5.4, T.5.5, T.5.6):

T.5.1: To carry out a comparative analysis of the Slovenian compensation system and those of other EU national systems in order to map their key features and assess their relevance and transferability to Slovenia. The proposed list of countries are: Denmark, Sweden and New Zealand.

*The analysis will include a discussion of **legislative, judicial and regulatory aspects** (non-exhaustive listing): a) **Provisions of compensation to patients injured** as a result of negligent clinical care on existing administrative and judicial proceedings, b) **Cooperation with judicial authorities**, c) **Judicial practice** concerning patient compensation (e.g., rate of out of court settlements, net costs for the complainant etc.), d) **Professional-accountability** response to meet the established standards of care (professional accountability frameworks, insurance of healthcare providers), e) **Advantages, difficulties, risks and fragilities** of the models analysed, f) **Conditions to be accomplished in the legal orders** that allow the models to operate successfully, g) The **effectiveness of the systems** chosen regarding: reporting, learning from the event to prevent a similar result in the future and sentinel and adverse-event quality review processes, h) The **sources of financing** and the **financial impact** of the system and, i) **Transparency of reporting**.*

T.5.2: Consultation of key players in Slovenia on the no-fault compensation models analysed (n=3 cases)

- The key agents[21] will be identified, together with the counterparty and, a methodological proposal will be presented with the inclusion of a focus group[22] to consensus the draft.

*To **carry out the consultation**, the key results of the comparative analysis will be presented to the experts and their opinion will be asked about: 1) The **features** they consider important to incorporate into the Slovenian model, 2) What should be introduced with **adaptations** (and what are they), 3) The **elements that would not work** or that **would require development of other areas/sectors** to assure an optimal implementation, 4) Their **prioritization of the core elements** of the different models based on a **cost-feasibility assessment** to their application in Slovenia and its potential benefits.*

[19] The results are expected to be presented on September 17th, coinciding with World Patient Safety Day.
[20] The activities under this phase will build on the information provided by MoH on the results of the TAIEX workshop (12 March 2019).
[21] We propose up to 70 people from: MoH, Association of healthcare providers; Professional Chambers (Medical, Nursing, Pharmacies, Physiotherapist), HIIS, NPHI, NGOs (Net 25x25 and at least 2 other patient organisations by choice); Patient ombudsman (organised in 9 territorial regions), Association of nursing homes; Association of spa resorts (who provide medical rehabilitation and after hospital treatment).
[22] MoH has proposed to change the Delphi like technique for a focus group given the reduced number on participants to be consulted

T.5.3: Describe, in detail, the proposed compensation model

- Propose a model based on the activities mentioned above. If needed, additional consultations of experts and stakeholders may be organized (e.g., interviews or a workshop).

*The **proposed model will address topics** such as (non-exhaustive listing): 1) The definitions of "medical injury", based on which the right to compensation is established, 2) Who is entitled to decide whether and when someone is entitled to compensation (independent commission, public institute etc.) and how to ensure neutrality/independence, 3) The organization of an appeal system (time limits for introducing claims, the applicable criteria for compensation, the minimum and maximum compensation amounts, the processes and tools needed, etc.), 4) The estimated impact with regards to court litigation, legislative and institutional changes needed, and public expenditure; 5) The sources of financing (state, insurance premiums, social contributions, etc.) and, 6) The implementation strategy (in parallel with the current system or replacement and criteria).*

T.5.4: Advice the MoH on the necessary governance and legal changes required to implement the agreed compensation model and provide support in drafting the necessary legal revisions

T.5.5: Organize communication and awareness-raising activities on the compensation mechanism

A definition will be made of the target groups, of the information needs existing in each group and of the activities and channels to better disseminate the information. These will include drafting a policy brief and organizing a high-level meeting addressed to health managers and decision-makers. Other activities can be proposed (e.g., infographics, video streaming sessions).

T.5.6: Elaboration of a report describing the results of the activities mentioned above and with annexes of: 1) Comparative analysis, 2) Proposed patient compensation model and, 3) Policy brief

Techniques:

Mapping of key players to consult	Delphi like technique (maximum of 2 rounds)	High-level meeting, policy brief, infographics (printing not included) or video streaming

Deliverables:

- D5: Report on the proposed no-fault compensation model (English) (deadline: 28.02.22)

2.6. Phase 6: National strategy for the QoC

Pripombe dodal [VZ3]: beginning in September 2021 and concluding as soon as possible

Aims:

- Provide the MoH with a draft national strategy for the QoC. Specifically, deliver a detailed report supporting the development of the national strategy for the QoC and the report on the national and EU expert's stakeholder consultation.

Activities (T.6.1, T.6.2):

T.6.1: Develop the draft of the national strategy for the QoC

- Identify the relevant stakeholders (we propose the same stakeholders included in Phase 3).
- Develop a methodological approach to draft the main items of the national strategy with the participation and consensus of the experts. It will include a governance model with the relevant stakeholders identified, in order to establish a suitable consultation methodology that facilitates consensus-building, accountability and ownership (see 6.2.).
- Prepare an executive summary of the main literature about referent national strategies for the quality of health (e.g. guidelines from WHO, national strategies from countries with advanced systems regarding QoC), identifying the key aspects in all

the items to be included in the national strategy (vision, strategies, governance, functions, guidelines, indicators, reporting …).

- Validate with the OWG and a selection of key experts[23], through a workshop, the draft of the main elements to be introduced in each chapter.

*The workshop will address the following items: 1) The **vision and strategic priorities**, 2) The **governance model** and the **institutional and organizational changes** needed to develop the vision and strategies[24], 3) The needs of development of **guidelines and standards**[25] and **quality indicators**, 4) The needs regarding **public reporting** and **performance in healthcare models** and, 5) The **key elements** about the model of PS and patient compensation.*

- Draft the national strategy based on the activities previously mentioned and revision by the OWG.

T.6.2: Consult national stakeholders and EU experts on the draft national strategy for the QoC

- Beyond the identified national actors (T6.1), identify the EU experts to consult vs areas of expertise.
- Carry-out checkpoints to systematically validate with the OWG the contents of the national strategy.
- Development of the broader stakeholder consultation[26]. The methodology proposed consists of two steps: 1) Elaborate and launch a Delphi-like consultation process to identify their opinion about the draft of the national strategy (up to 2 rounds[27]) and, 2) Integrate the feedback of the stakeholders.
- Prepare and develop a high-level workshop[28] with key experts and the OWG to integrate their feedback in the report supporting the development of a national strategy (D6).

Techniques:

Stakeholders mapping	Desk research and analysis of the documentation	Methodological approach proposal of the stakeholder consultation	Delphi-like consensus (up to 2 rounds)	Workshop with OWG and key experts (n=2)

Deliverables:

- D6: Report supporting the development of a national strategy for the QoC (English) (deadline: 31.05.22)

2.7. Phase 7: Governance of the QoC system

Aims:

- Support the MoH in developing a more detailed understanding of the current challenges in the governance of the QoC system and propose concrete options for improving it, namely: deliver a gap analysis, a comparative analysis and propose a governance model.

[23] It is proposed that the group is composed of up of two coordinators who are leading experts in the area. It's crucial that this group has the availability to participate and collaborate in each of the tasks mentioned above.
[24] E.g., new agency, roles and functions needed and main responsibilities' (for national and local levels).
[25] E.g. the Patient Safety Curriculum or the Patient Safety Research, both prepared by the WHO.
[26] We estimate a participation of a maximum of 100 people.
[27] 2 rounds means to online questionnaires, at the 2nd round, only those items that have not obtained consensus in the first round are consulted. The comments received in the first round are presented to the experts and they are asked to re-issue their opinion based on the comments of the broad group of experts, with the aim of obtaining the maximum possible consensus (see description of the technique in the chapter 2.2.2.).
[28] We propose representatives of MoH, NPHI, HII, Professional Chambers (Medical, Nursing, Pharmacy, Physiotherapist), As. healthcare organizations.

Activities (T.7.1, T.7.2, T.7.3, T.7.4, T.7.5):

T.7.1: Conduct a gap analysis of the current governance mechanisms or practices in the Slovene QoC system

- Define the methodology for the elaboration of the gap analysis (documentation collection and revision, conduction of semi-structured interviews and/ or focus groups) and the subjects:

*Define the **subjects to be addressed in the gap analysis**, such as (non-exhaustive listing): 1) **Current managerial structures** (roles, delimitation and responsibility) in **monitoring** and **assessing** QoC, 2) Existing **accountability and transparency mechanisms** and **effectiveness**, 3) Current **mechanisms** for **stakeholders management and cooperation** (for which stakeholder) and **consensus-building**, 4) Current **institutional set up** dealing with quality assurance at the level of healthcare providers, 5) **Training** and **evaluation of managers**, 6) **Procurement systems**.*

- Elaborate the gap analysis and validate it with the OWG and selected key experts.

T.7.2: Carry out a comparative analysis of governance models for the QoC from other EU countries

- Characterize the governance models of selected EU countries[29] in accordance to the subjects addressed on the gap analysis (see table above): identification of key features or other subjects to be considered in a revised governance model for Slovenia. The ***lessons learned, main facilitators and bottlenecks*** of each model and the existence of ***instruments to monitor and assess*** each one will also be identified. To elaborate this task the Consortium will conduct a desk research and carry-out interviews[30].

T.7.3: Consult national stakeholders

- Prepare, carry-out an analysis of the results of a consultation of national stakeholders[31] on the identified features of the future governance model for the QoC. The consultation process will be based on the development of an online questionnaire and interviews.

T.7.4: Draft the governance model for the Slovene QoC system

- Elaborate the skeleton of the main topics of the model and validate it with OWG and key experts.

*Based on the results of the tasks 7.1. to 7.3, the Consortium will **draft the governance model** which will cover, at least, the **following items** (non-exhaustive listing): 1) **Policies and strategic plans** based on the **vision for the future** and on the **gap analysis**, 2) **Data based process of decision making** (generate intelligence), 3) **Processes, standards, tools** for **policy implementation** (including design of health system organizational structures and their roles, powers and responsibilities; design of regulation; standard-setting; incentives; enforcement and sanctions), 4) **Participation, collaboration and engagement model and mechanisms** across sectors and with external partners, 5) **Transparency assurance and accountability mechanisms** (definition of governance structures, rules and processes for health organizations; mechanisms for independent oversight, monitoring, review and audit; availability and publication of policies, regulations, plans, reports, accounts, etc.; and openness to scrutiny), 6) **Monitoring and assessment framework** definition to measure the effectiveness of the governance model and to identify/prevent deviations and improvement model.*

- Deliver the draft of the model and validate it (through a workshop with the OWG and key experts).

T.7.5: Produce a policy brief for proposing the governance model

[29] The selected EU countries will be the same as those proposed in task 3.2
[30] Semi-structured interviews with the key responsible in each country. This activity depends on the availability of the members of the corresponding health authorities. The MoH and the PO will be asked to help establish the contacts to request the interview.
[31] MoH, Association of healthcare organizations, HIIS

- Elaborate a policy brief to explain the rationale for suggesting the governance model proposed and the advantages and requirements for adopting it.
- Elaborate a video streaming session to share the main elements of the proposed governance model.

Techniques:

Gap analysis	Methodological approach proposal of T. 7.1, 7.2. and 7.3.	Coordinate queries to the national stakeholders identified	Focus-group	Semi-structured interviews

Deliverables:

- D7: Recommendations for improving the governance of the Slovenian QoC system (English) (deadline: 30.06.22)

2.8. Phase 8: Quality indicators

Aims:

- To analyse and update the current list of quality indicators used in primary, outpatient and hospital care to be included in the institutional assessment at the providers' level.
- To develop guidance and to piloting the list of indicators, in order to acquire knowledge to improve the list to extend to other healthcare facilities.

Activities (T.8.1, T.8.2, T.8.3, T.8.4):

In order to develop T8.1 and T8.2 we propose to converge some activities:

- Previous contact with the MoH to: 1) Obtain the list of current indicators, 2) Know the results and obtain information from previous SRSP, 3) Clarify the main weak points and identified constraints, 4) Identify the list of potential key stakeholders[32] and, 5) Draft the potential list of pilot facilities.
- Elaborate the methodological approach proposal and develop a comprehensive consultation of key stakeholders[33] to obtain their opinion and vision about the indicators revision (activity 8.1.). The Consortium proposes the use of the same consultation to know their vision regarding the key elements to include in the methodological guidance for the use of quality indicators (activity 8.2.).

T.8.1: Propose an updated list of quality indicators covering all levels of healthcare provision

- We propose to review and classify the list according to a ***checklist protocol*** and to identify the gaps against: 1) ***International good practices/expertise countries***, 2) ***Relevant international frameworks*** (OECD's, HCQF, etc.) and, 3) Information collected from ***interviews*** to key national experts (we propose to create a team of experts with a coordinator to advice on this update). The ***checklist protocol*** will include the ***classification of the indicators*** (e.g., structure, process, outcome, experience, impact) and an ***assessment of parameters*** (e.g., importance, relevance, health system performance for an extended time period, feasibility, reliability, validity, specificity, measurability and time). Furthermore, each ***indicator: will be defined,*** detailed at ***which health level it should be collected, its data collection process*** and ***data sources*** identified and, if applicable, its ***sensitivity to case-mix.*** When the update list is ready and agreed with the OWG, the group of key national experts will be invited to review it. In case of divergences among the key

[32] We propose: MoH, Association of healthcare organizations, NPHI, HII, Professional Chambers (Medical, Nursing, Pharmacist, Physiotherapist) and Patient representatives.
[33] In order to carry out this activity, the support of the counterpart is essential to identify and provide access to the people.

experts in the revision process, the coordinator of the group will take the final decision on the review.

T.8.2: Develop methodological guidance for the use of quality indicators in quality assurance

- To draft, consensus of the script, development and validation of the methodological guidance.

*Develop an **executive and friendly document** with very clear content on the main aspects that providers must keep in mind to ensure effective use of the indicators list. It must answer the main FAQs[34]. The following items will be included (non-exhaustive listing): 1) How to **embed** the revised list of indicators in the **regulatory and governance framework** of the healthcare facilities, 2) **Appropriate and effective use** of the indicators, 3) Definition of which and how to use them for allowing **comparisons of specialities** within a healthcare institution, and for **benchmarking by specialities among providers**, 5) How to **assess the indicators**, 6) **Recommendations about the roles, functions and training** necessary to assure the optimal use, 7) Identification and assurance of key elements regarding the **supporting collection, reporting and information systems**.*

T.8.3: Pilot the list of indicators developed previously in selected medical facilities[35]

- To start the pilot, a **kick-off session** in each institution is proposed to be carried out to: 1) ***Present the project***, 2) ***Train*** on knowledge of the **indi*cators, their use and evaluation***, 3) ***Review the data collection and reporting procedures*** and, 4) Identify possible ***risks and mitigation actions*** and, 5) Identify those ***responsible*** and the method of ***coordination*** with the project team. The duration of the pilot will be defined together with the OWG[36], and during it, there will be a ***help-desk*** to give support and ***biweekly online control points*** to ***identify risks or deviations and improvement measures.*** At the end, ***1 workshop*** will be held with the key agents (identify paint points and recommendations).
- To test and evaluate the list of indicators it will be necessary to: 1) ***Calculate the values of the indicators***, 2) ***Analysis of the IT systems*** (appropriateness, completeness and user friendliness) used to monitor and assess, 3) ***Analysis of the results*** and, 4) Identify ***challenges and bottlenecks*** that can affect the quality of data, or the process of data collection and assessment.

T.8.4: Final report elaboration

- Delivery of the final report (D8) with the results of all the activities: 1) Updated list of quality indicators, 2) Methodological guidance for the use of the quality indicators, 3) The results of the pilot.

Techniques:

Key stakeholders map	Desk research and structured analysis	Semi-structured interviews and interaction process of review with key experts	Methodological approach proposal for stakeholder consultation

Participative process with the pilots to establish the base for starting and to evaluate the results	Help-desk support to the healthcare facilities piloting the indicators and biweekly check-points	Dash-board with main indicators of execution and results of the pilots

Deliverables:

[34] We propose to identify the main FAQs in the key stakeholder's consultation process.
[35] The selection of around 5 hospitals and 5 primary healthcare facilities will be held by MoH.
[36] The proposal is to carry it out in 6 months, although this period must be agreed with all the parts involved.

- D8: Revised set of quality indicators to be applied at all levels of healthcare (English) (deadline: 29.07.22)

2.9. Phase 9: IT functional specifications

Aims:

- Build the functional specifications for IT systems used to monitor and assess QoC at the level of different healthcare providers.
- Get a MoSCoW-based sheet of IT systems, detailed enough to define the main pillars and key specifications to ensure quality and PS but open enough to be adapted and customized.
- Prepare the list of business processes/functional use cases (monitoring and reporting perspective).

Activities (T.9.1, T.9.2, T.9.3, T.9.4):

T.9.1: Define business requirements

- Our proposal is to prepare a business requirements catalogue, which will contain the high-level requirements prioritized using MoSCoW scale (Must, Should, Could, Won't). The approach to gather these requirements will be mainly based on: 1) The analysis to be done in Phase 8 regarding the appropriateness, completeness and user friendliness of the IT systems currently used in Slovenia to monitor and assess QoC, 2) The previous work done as part of the project on sentinel and other adverse events, and the project on PREMs and PROMs and, 3) everis expertise gathered from previous projects/initiatives related to PS and RM monitoring and reporting (see https://www.ehcos.com/en/products/ehcos-empi/). Some of the **key requirements** will cover, among others: 1) ***Assessment of the safety culture***; 2) ***Assessment of the knowledge about the risk map*** to be considered by healthcare professionals; 3) Analysis of the ***adverse effects notified*** and, 4) ***Key information to be shown in dashboards/executive reports.***
- The **business requirements sheet** will include (non-exhaustive listing): 1) ***Requirement ID*** (traceability), 2) ***Business process reference*** (see T.9.2), 3) ***Requirement and description***, 4) ***MoSCoW-based value***, 5) ***Dependencies*** with other business requirements, 6) ***Requirement motivation/origin*** and, 6) ***Business topic.***
- The definition will be done by applying an **agile approach**, to generate iterative versions validating them with the key stakeholders until the generation of the final version.

T.9.2: Define Business Processes for reporting and monitoring

- Once the business requirements are clearly defined in T.9.1., the specific business processes will be created. The process will be defined by using BPMN2 standard and will model: business events, actor swim lanes, user driven activities, unhappy/ exception paths (where applicable), other dependencies, interoperability with other systems (both within the same facility or external) and traceability with business requirements and use cases (see T.9.3).

T.9.3: Define the Use Cases (UC)

- The use cases will model how the users will use the system to accomplish the particular goals–system interaction steps. They will include: 1) ***Links to requirements*** that are realised via the use case (UC), 2) ***Description of the UC***, 3) ***Pre and post conditions***, 4) ***Permissions*** required to fulfil the goal, 5) ***UC flow*** with main flow (happy path) and alternative paths in the form of a diagram and a scenario (narrative), 6) ***UC steps for each flow*** in the form of user actions – system

Pripombe dodal [VZ4]:
financial aspect, application costs, system costs

responses, 7) Indicative system ***mock-ups*** that provide a visual illustration of the data presented and, 8) ***Data specifications***.

T.9.4: Generate recommendations

- To properly implement and integrate the functional specifications defined, some **detailed recommendations** will be prepared for any IT provider / system. Among others, it will be included:
  1) ***Suggested roadmap*** for implementation and deployment (prioritization of UC), 2) ***High-level testing strategy***, including functional and performance and interoperability and security testing and, 3) ***Quality criteria*** for implementation and deployment acceptance (conformity certification).

Techniques:

BABOK® for business analysis	MoSCoW for business requirements	BPMN2 & UML for modelling	Agile

Deliverables:

- D9: Functional specifications for IT systems for monitoring and reporting on QoC (English) (deadline: 30.12.21)

2.10. Phase 10: Recommendations and guidance for continuous quality improvement

Aims:

- To elaborate SMART[37] recommendations and guidance to enhance the capacity of stakeholders to revise the list of indicators or propose new ones to the future.
- To identify incentives to motivate healthcare providers to use quality indicators with the aim of guaranteeing continuous quality improvement.

Activities (T.10.1, T.10.2):

T.10.1: Draft of a report including the recommendations and guidance on how to revise the existing list of indicators, propose new indicators and motivate healthcare providers to use indicators to review and improve QoC (incentive mechanism)

- Develop a **step-by step guide** to help the revision or inclusion of new indicators with a clarification of the organization, roles and responsibilities' of actors. This guide will be based in the: 1) Analysis of the findings of the most salient issues from relevant deliverables developed previously, 2) The experience learnt in the previous Phase of the project. It will include a ***check-list of the key items*** that must be assured to effectively review and use them and the ***knowledge and skills*** needed.
- Prepare and carry-out a **design thinking session** with the OWG and other relevant key experts, to draft a proposal of incentives to be implemented at national or local level, taking into account: 1) The ***lessons learned*** from the pilots, 2) ***Good practices in EU countries*** adapted to their viability, timeline and sustainability in the Slovenia context and, 3) The ***strategic lines*** defined for the Slovenia in terms of safety RM and QoC. This incentives will be proposed within a ***holistic and systemic approach***, including different areas (clinical, legislative, financial, organizational, technological, etc.). For each proposal the ***main benefits and risks*** will be identified and a **quick-win prioritization** will be developed in order to define the best balanced cost-effective incentives.

T.10.2: Final version of the report

[37] Specific, measurable, achievable, realistic and time bound.

- Draft the final version of the D10 based on the suggestions from the OWG and the key experts.

Techniques:

Design thinking meeting with key experts (lessons learnt from pilots, good practices in EU…)	Prioritization matrix	PERT and Gant Planning

Deliverables:

- D10: Recommendations and guidance on how to revise and effectively use quality indicators for continuous quality improvement (English) (deadline: 30.06.22)

2.11. Phase 11: Communication plan

Aims:

- Effectively disseminate the results and knowledge acquired using positive and clear messages adapted to the different audiences and develop accountability, commitment and ownership.
- Reduce the uncertainty and resistance to the changes and innovations regarding the QoC and PS RM.

Activities (T.11.1, T.11.2):

T.11.1: Draft of a report including the strategic planning of communication activities, the guidelines for action and the materials provided during communication events

- Map the main stakeholders: identify the target audiences.
- Develop an online and written survey aimed at professionals, patients, policy makers and management level of healthcare providers (n= until 20 people per group[38]) to inquire the current level of knowledge, their expectation regarding information about QoC and the best channels.
- Hold an internal meeting with the OWG and key experts to define the key messages to each audience.
- Draft a **strategic plan** including the communication activities, the guidelines for action, audiences to be target, the channels to be used, the engagement techniques and the assessment and follow-up of the activities. This plan will address, at least, the following items: 1) How to ***motivate*** healthcare providers to support the implementation of the proposed changes, 2) How to effectively ***communicate information*** to patients, including by presenting the indicators in the most effective way, 3) How to ***raise awareness*** among key stakeholders about the importance of quality assessment and monitoring, 4) Which are the ***best indicators to follow-up*** the result of the activities and, 5) The ***key elements*** of mature healthcare systems in this matter (accountability, transparency, etc.).
- Organization of communications events (stream session and infographics) targeting both healthcare professionals and policymakers (one high-level workshop with relevant authorities[39]).

T.11.2: Final version of the report

- Draft the final version of the report D11 (in English).

[38] The OWG will select the people to be consulted in each group and will facilitate the contacts to the Consortium, respecting the GDPR laws.
[39] MoH, NPHI, Association of healthcare organization, HIIS, Chambers (Medical, Nursing, Pharmacist, Physiotherapist), Patient representatives.

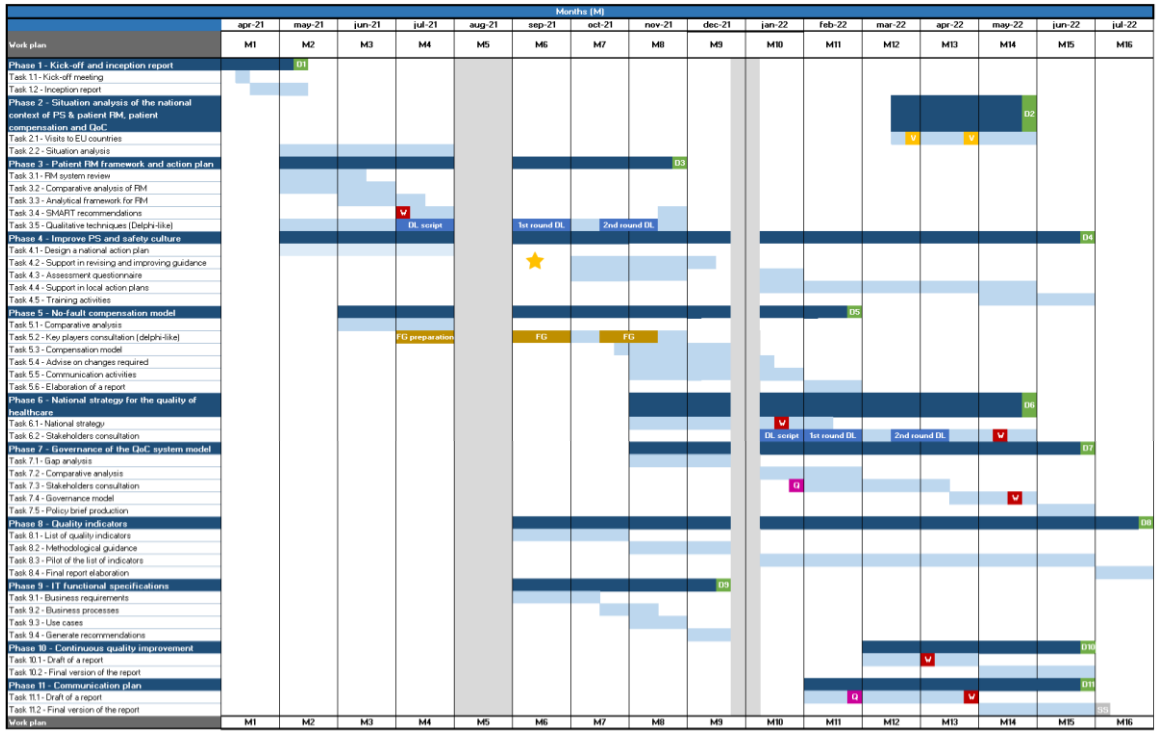
Techniques:

Survey to stakeholders	Internal design thinking meeting	High-level workshop	Streaming session (providers, professionals, patients)	Infographics (printing not included)

Deliverables:

D11: Communication plan on the strategic report and revised list of indicators for QoC (English) (deadline: 30.06.22)

3. Overall project GANTT chart[40]



D Deliverable | V Visits to EU countries | DL Delphi-like | W Workshops | FG Focus group | Q Questionnaires | SS Streaming session | World Patient Safety Day

[40] Compliance with the calendar is subject to the ability of MoH to articulate their assigned and scheduled tasks

4. Governance model and coordination mechanisms

4.1. Steering Committee

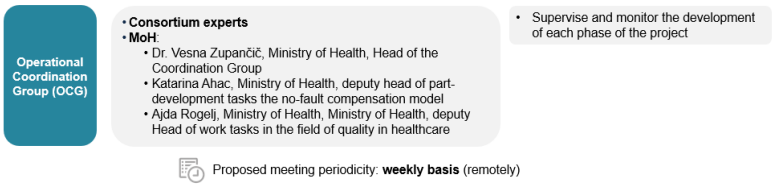
The proposed monitoring mechanism is based on SC responsible for providing directions to the project. Below is presented the involved members and main functions of the SC. The proposed meeting periodicity is on a quarterly basis and, whenever deemed necessary, any member of the SC may request a meeting.

Pripombe dodal [VZ5]:

Steering comitee
Bogdan Tušar, General director, Ministry of health, head of the Steering Committee
Biserka Simčič, secretary, Ministry of health
Miriam Komac
Anka Bolka
Tit Albreht
Bojana Beović

4.2. Operational Coordination Group

To work closely, an OCG has been established. Below is presented the involved members and main functions of the OCG. The proposed meeting periodicity is in a weekly basis.



Pripombe dodal [VZ6]:

Dr. Vesna Zupančič, Ministry of health, Head of the Coordination Group
Alenka Kovač Arh, Ministry of health, deputy head of part-development tasks the non-fault….
Denis Perko, National institute of Public Health, deputy Head of work tasks in the field of quality in health care

4.3. Operational working groups

To work closely, three OWG have been set up for each dimension of the project, which are shown below:

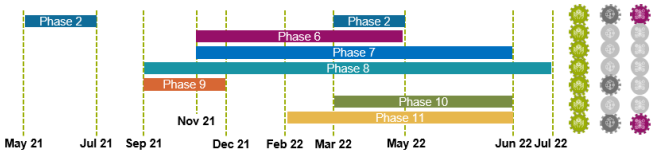
	Composition	Main functions
Operational Working Groups (OWG)	• **MoH** • **The Consortium representatives** • **Consortium experts**	• To guarantee the delivery of all planned outputs. The OWGs will have a different composition, depending on the phase of the project to which they are dedicated
OWG 1: Quality of Healthcare	• Dr. Denis Perko, National Institute of Public Health, member • Aleš Fischinger, Medical Chamber of Slovenia, member • Krunoslav Pavlovič, Medical Chamber of Slovenia, deputy member • Saša Kadivec, Chamber of Nursing and Midwifery of Slovenia, member • Boštjan Kersnič, General Hospital Novo mesto, member • Viki Kotar, University Rehabilitation Center Soča, member • Ana Ogrič, Community Health Centre Idrija, member	
OWG 2: Patient Safety and risk management	• Jelka Mlakar, University Clinical Center Ljubljana, member • Rok Accetto, University Clinical Center Ljubljana, deputy member • Milena Radoha Bergoč, Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, member • Marjetka Plementaš, Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, deputy • Robertina Benkovič, Community Health Centre Ljubljana, member	
OWG 3: No-fault compensation model	• Mihaela Bevc, Ministry of Justice, member • Minika Naumovski, Ministry of Justice, member • Nataša Čarman Korenjak, Health Insurance Institute, member • Peter Renčel, Medical Chamber of Slovenia, member	

Pripombe dodal [VZ7]:

~~Natasa Čarman Korenjak~~ (remove) I announce additional names

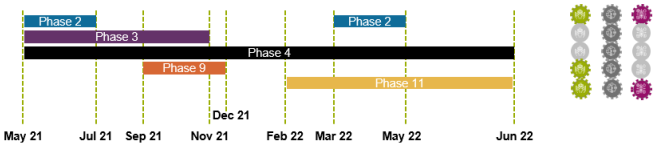
As there are different OWG, good coordination mechanisms are crucial to guarantee the quality of the project. Below is presented the different phases in which each OWG participates and their meeting periodicity.

- **OWG 1: QoC**



There are 7 phases where this OWG participates. In case of phase 2 and phase 11 weekly meetings with representatives of the 3 OWG will be defined. For phase 9, weekly meetings with representatives of the OWG 1 and 2 will be defined. We recommend: 1) to assign a coordinator/small team members within OWG for each one of the phases, 2) weekly basis meetings starting from **September 2021 until July 2022** to carry out phase 6, 7, 8 and 10 (when phases coincide, meetings will be of 2h, 30' to each phase).

- **OWG 2: PS and RM**



Starting from May 2021, there are 3 phases to be carried out with a very intensive dedication need. In case of phase 2 and phase 11 weekly meetings with representatives of the 3 OWG will be defined. For phase 9, weekly meetings with representatives of the OWG 1 and 2 will be defined. We recommend: 1) to define a coordinator/ small team members within OWG for each one of the phases, 2) weekly basis meetings to carry out phase 3 and 4 (when both phases coincide meetings will be of 1h, 30' to each phase).

- **OWG 3: No-fault compensation model**

There are 3 phases to be carried out: phase 2 (starting on May), phase 5 (starting on June), phase 11 (starting on February). In case of **phase 2 and phase 11** weekly meetings with representatives of the 3 OWG will be defined. It is crucial to define: 1) a coordinator/ small team members within OWG for each one of the phases, 2) weekly basis meetings to carry out phase 5.

4.4. Coordination scheme

4.4.1. Coordination between the REFORM and the contractor

In order to guarantee the coordination between the REFORM and the Consortium, it is appointed the figure of the Project Officer (PO) (Florin Popa), who will act as the main contact point for the contract.

	Description
Project officer	• Act as the main contact point for the contract • Play an active role in the design and implementation of the project following the contract • Have access to draft deliverables and provide feedback thereon • Be invited to all meetings and any major activity.

Moreover, in order to report all the activities and tasks done by the project, the Consortium will send a **progress report** after 5, 10 and 15 months starting from the date of signature of the contract, with the objectives of: 1) Presenting the main updates on the development of the planned activities and the expected results, 2) Identifying the delays (if any) and strategies to manage them. This report will be no longer than five pages and will be written in English.

4.4.2. Coordination with key stakeholders

A clear interaction with the main stakeholders is key for the success of our engagement method. Well-defined communication with stakeholders on the need of their involvement in the project will be followed. It is crucial to explain why their participation within the project (via consultations, interviews, surveys, workshops…) is needed and how the project is taking stakeholders' views into account. Giving feedback to stakeholders that participated in the processes in a way that clarifies how the outcome was reached and reporting on the next steps of the process are key to our approach. Our stakeholders' engagement and participatory approach is based on **five pillars** which work together to ensure the achievement of the objectives of the project: 1) **Engagement strategy:** Set the vision and ambition by group of stakeholders, 2) **Stakeholder mapping:** Define criteria for identifying and prioritising stakeholders and select engagement mechanisms, 3) **Preparation:** Determine details and logistics for the engagement and set the rules, 4) **Engagement:** Conduct the engagement itself, ensuring equitable and relevant stakeholder contribution and, 5) **Action plan:** Identify opportunities from feedback, determine actions, revisit goals and plan next steps for follow-up and ongoing engagement.

The coordination scheme will have the following characteristics:

- **Deliverable/document validation**

In order to review and validate different deliverables (draft and final version), the following methodology is proposed:

1) **Compilation of information** for the elaboration of the document (the consortium)
2) Presentation of an **index proposal** including the description of the general content that the document will contain in each section (the consortium)
3) 1 week will be given to the OWG to validate the proposed index
4) **Elaboration of the draft** of the document (the consortium)
5) Until 2 weeks max. will be given to MoH to **validate the draft document**
6) Introduction of suggestions and **elaboration of the final version.** Until 2 weeks max. will be given to the consortium to introduce changes and elaborate the final document[41]
7) Final **revision and approval** of the document (1 week)

- **Techniques validation**

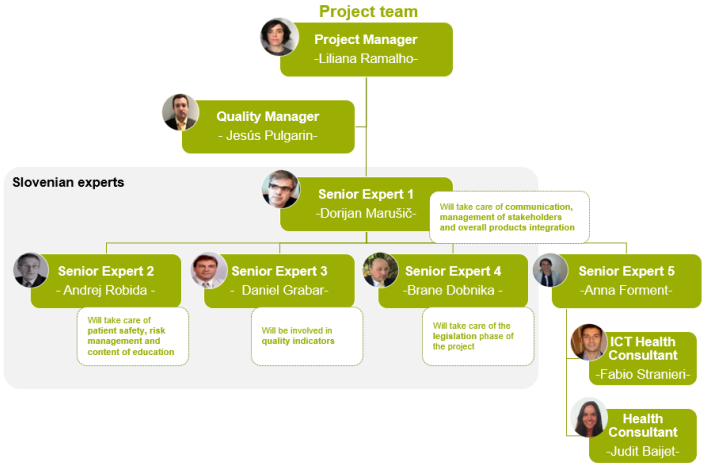
In order to guarantee the optimal and successful conduction of the techniques, the following methodology is proposed:

1) Given the need to carry out questionnaires and structured interviews throughout the project, we propose the following methodology to review and validate the different steps of the elaboration and conduction of techniques[42]:
2) Presentation to MoH of a **methodological approach** of the technique to be carried out (the consortium)
3) MoH **identifies the stakeholders** who will be consulted
4) Elaboration of a **script** (e.g. of the Delphi, interviews, questionnaire…) (the consortium)
5) **Validation** of the script (MoH) – until 1 week
6) **Launch** of the technique (e.g. of the Delphi, interviews, questionnaire…)
7) **Analysis of the results**
8) Draft report of results (inside the *deliverable validation procedure*)

[41] It will be adjusted as the project moves forward, according to the context and particular casuistry (e.g. changes in the scope, requested changes of high impact…)
[42] MoH is expected to select the agents to be contacted to carry out the scheduled activities. The facilitation of personal contacts must comply with RGPD.

5. Project team

The team in charge of project execution is detailed below:



6. Overview of deliverables for the project

Deliverable	Description	Indicative timetable
Deliverable 1 (ENG)	Inception report	30.05.2021
Deliverable 2 (ENG)	Report of a situation analysis of the national context of PS & patient RM, patient compensation and QoC	31.05.2022
Deliverable 3 (ENG)	Report on safety RM including the current status of the RM system available in Slovenia, the comparative analysis of RM systems of PS, the analytical framework for RM system for Slovenia and the SMART recommendations and action plan for the development of the system	30.11.2021
Deliverable 4 (ENG)	Report on the support for the preparation and implementation of a national plan and of local action plans to improve PS and safety culture	30.06.2022
Deliverable 5 (ENG)	Report on the proposed no-fault compensation model	28.02.2022
Deliverable 6 (ENG)	Report supporting the development of a national strategy for the QoC	31.05.2022
Deliverable 7 (ENG)	Recommendations for improving the governance of the Slovenian QoC system	30.06.2022
Deliverable 8 (ENG)	Revised set of quality indicators to be applied at all levels of healthcare	29.07.2022
Deliverable 9 (ENG)	Functional specifications for IT systems for monitoring and reporting on QoC	30.12.2021

Pripombe dodal [VZ9]: we need a proposal for a strategy as soon as possible, postponing the start of work to September,

Pripombe dodal [VZ8]:

Deliverable	Description	Indicative timetable
Deliverable 10 (ENG)	Recommendations and guidance on how to revise and effectively use quality indicators for continuous quality improvement	30.06.2022
Deliverable 11 (ENG)	Communication plan on the strategic report and revised list of indicators for QoC	30.06.2022