# D3.1 – PC needs analysis methodological guidelines

## WP3 – Intervention modelling through equitable multilevel needs assessment

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## List of Acronyms

| | |
|---|---|
| **AUTH** | Aristotle University of Thessaloniki |
| **CFIR** | Consolidated Framework for Implementation Research |
| **COPD** | Chronic Obstructive Pulmonary Disease |
| **HULAFE** | Fundación para la Investigación del Hospital Universitario La Fe |
| **NHS HIGHLAND** | Highland Health Board |
| **PC** | Palliative care |
| **SCMA** | Santa Casa da Misericordia da Amadora |
| **UNIVLEEDS** | University of Leeds |
| **UVEG** | University of Valencia |

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# 1. Executive Summary

The overall aim of the project InAdvance is to improve the benefit of the palliative care (PC) interventions for patients, families and informal caregivers, and front-line practitioners through the design of effective, replicable and cost-effective early PC interventions centred-on and oriented-by the patients.

This Deliverable 3.1 – *PC needs analysis methodological guidelines* – provides to clinical partners main guidelines on how to perform qualitative studies to identify what individual and contextual factors should be taken into account when PC needs are identified in older patients with non-cancer advanced diseases in their respective contexts. In order to complete the aforementioned qualitative study individual and contextual factors that impact on PC needs assessment will be identified. The qualitative study entails the involvement of several end-users of PC services, older patients with complex chronic conditions, their relatives or informal caregivers, front-line healthcare staff and managers of PC services through individual interviews or focus groups.

This deliverable presents target groups to be involved by each clinical site of the InAdvance project (HULAFE – in Spain; AUTH in Greece; SCMA in Portugal; UNIVLEEDS and NHS HIGHLAND in the United Kingdom), the methodological approach to be used as well as well main ethics aspects to be taken into consideration to perform the qualitative study. The recruitment and data collection will occur between September 2019 and January 2020, and data analysis between January and March 2020.

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## 2. Introduction

InAdvance project (*Patient-centred pathways of early palliative care, supportive ecosystems and appraisal standard*) proposes a novel model of palliative care (PC) based on early integration and personalised pathways explicitly addressed to older people with complex chronic conditions. Thus, the overall aim of InAdvance is to improve the benefit of PC through the design of effective, replicable and cost-effective early PC interventions centred-on and oriented-by the patients.

Interventions are defined for/orientated on patients, families, informal caregivers, and front-line care professionals. In this sense, the Work Package (WP) 3 of the project – *Intervention modelling through equitable multilevel needs assessment*– is aimed at developing ways to conduct equitable and prompt PC needs analysis. This will entail conducting a multi-level analysis to support timely decisions of when early PC services are needed and what would be the most appropriate way to provide such care given contextual factors and individual differences. Emphasis is placed upon equity centred supportive care for complex chronic patients. Thus, WP3 specific objectives are:

- Performing micro level analysis to identify what individual characteristics and circumstances should be taken into account when deciding what type of early PC would be needed.
- Performing meso level analysis to identify relevant contextual factors related to care organisations which may impact early PC needs assessment decisions.
- Performing meso level analysis to identify effective PC pathways from past data records.

The first task to be performed under the WP3 will be qualitative analysis aimed to identify individual and contextual factors that impact on PC needs assessment. This qualitative study entails the involvement of several end-users of PC services:

- Older patients with complex chronic conditions (primary end-user).
- Their relatives or informal caregivers.
- Front-line staff in charge of the provision of (basic and specialized) PC services.
- Managers of PC services (and complimentary services).

This study will be developed in the five clinical sites where the InAdvance clinical trials will take place under the WP5: Valencia (Spain), Amadora-Lisbon (Portugal), Thessaloniki (Greece), Leeds and Inverness (United Kingdom). We will use an experience based co-design approach with clinical staff at each site to understand barriers and facilitators to intervene on symptoms.

Within this WP a sound knowledge will be built that will be useful to inform interventions that entail adapted/individualised care pathways according to the level of complexity from which patients will be identified by the stratification model designed in the frame of the WP2. The multi-level analysis performed will subsequently:

a) inform support mechanisms in WP4;

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b) be the basis of the interventions studied under the WP5;
c) serve as the developmental evaluation – as part of the formative evaluation strategy designed under the WP6 to assess the impact and feasibility of the interventions; and
d) provide key information for the appraisal standard and dashboard (WP7).

Thus, this deliverable *PC needs analysis methodological guidelines* provides to clinical partners main guidelines on how to perform qualitative studies in their respective contexts with the aforementioned end-users.

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# 2. Protocol for qualitative interview study

## 2.1 Aim

This document is aimed to provide general guidelines to clinical partners of the InAdvance project (UVEG, HULAFE, UNIVLEEDS, AUTH, SCMA and NHS HIGHLAND) to perform qualitative studies aimed to identify what individual and contextual factors are taken into account when PC needs are identified in older patients with non-cancer advanced diseases.

### 2.1.1 Objectives

The specific objectives of this qualitative study are:

1. Interview managers of PC services to determine current clinical pathways and access to care for older patients with specific non-cancer advanced diseases.

2. Interview front-line health care professionals (those in referring services and in palliative care) to understand staff barriers and facilitator accelerators for PC provision, including symptom management.

3. Interview patients, their families or caregivers to understand perspectives on the decision making process about PC and how the transition between the pathways currently occurs, and symptoms requiring support.

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# 2. Methods

This study is a qualitative study which involves one to one interviews and focus groups with both older patients (age 65 or more) and health professionals involved in the care of these patients. We would like to recruit a representative sample of male and female participants. Recruitment and data collection will occur between September 2019 and January 2020, with analysis and reporting completed by March 2020 (*Deliverable D3.3 Framework for multilevel equitable PC analysis: M15)*

Within each partner site (UNIVLEEDS, UVEG, HULAFE, AUTH, NHS HIGHLAND and SCMA), the focus of research will be on older patients with either COPD, multi-morbidities or frailty, as follows:

- In Leeds, the focus of UNIVLEEDS will be on older patients with COPD (Chronic Obstructive Pulmonary Disease).
- In Valencia, UVEG and HULAFE: older patients with chronic diseases and comorbid/multimorbid condition under case management program.
- In Lisbon, SCMA: older patients with COPD
- In Thessaloniki, AUTH: (a) patients with Interstitial Lung Disease (with emphasis in Pulmonary Fibrosis) and b) elderly with frailty and comorbidities.
- In Inverness, NHS HIGHLANDS: older patients with COPD.

This approach ensures that contextual factors and clinical pathways can be understood at each partner site, and that some common themes can be synthesized across the partner sites in order to prepare for the clinical trial later in the programme.

## 2.1 Eligibility criteria and sampling strategy

The main strategy and eligibility criteria to recruit the sample in the different end-user groups will be as follows:

**Managers:** 3-6 managers of PC services will participate in interviews.

**Health care professionals:** 8 health care professionals (doctors, nurses or social care; based in hospital or community) will participate in interviews. 4 professionals will represent disease specific service areas (e.g. COPD or heart failure services) and 4 will represent PC or case management services.

**Patients:** 12-16 patients representing a specific disease area will participate in interviews or focus groups. Half (6-8) will be patients with the specific disease that have NOT been referred to PC and half will be patients already receiving PC support. The sampling frame will focus on recruiting participants before and after a referral to PC.

**Families or informal caregivers:** 3-6 family caregivers of patients that have been interviewed will be invited to participate in interviews.

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## 2.2 Procedure

### 2.2.1 The procedure for managers and health professional participants

Health professionals will be approached to take part in the study by members of the research team (co-applicants) who work in the related clinical area. The member of the research team will introduce the study and provide the information sheet. Health professionals who are interested in taking part will be given information sheet by the research team member and will be asked to contact the local qualitative researcher using the contact details on the information sheet if they wish to participate or learn more about the study. If after contacting the researcher and haven been given the opportunity to ask questions they still wish to proceed, an individual interview or focus group will be arranged. If an individual is unable to participate in a focus group, but would like to take part, they will be given the opportunity to take part in a one to one interview instead.

The interviews will be conducted by an experienced qualitative researcher and take no longer than 60 minutes. They will be conducted in a private room at the health professional's usual workplace at a time convenient to them. The interviews will be guided by a topic guide designed to explore the professionals' perspective of how patients are identified as needing palliative care, barriers and facilitators regarding the potential decision points and understanding the role of the health professional and others in the decision making process and meeting palliative care needs.

Health professional interviews will also explore the extent to which PC provision is being delivered by non-palliative care specialists (GPs, disease specific professionals) and the rationale for this. Focus groups will be conducted at a time and location mutually convenient for participants and will take no longer than 90 minutes. On arrival at the focus group, participants will be given the opportunity to ask any questions and the ground rules for the focus group will be explained, including the fact that the discussion within the focus group should remain confidential and that participants are free to leave at any time.

### 2.2.2 The process for participants

Participants to the patient study will be recruited from disease specific services and from PC services. Recruitment will be facilitated via health professionals who will be asked to pass information on to eligible participants and ask them if they would be happy to be contacted by a researcher to discuss the study. If the researcher is not present at the time when the patient is approached, participants will be asked to sign a 'consent to contact' sheet to give their permission for a member of the research team to contact them.

Informed consent procedure: all participants will be asked to provide written consent before the interview or focus group begins and before any data is collected. Specific consent information will depend on local ethics requirements at each site. In general, this should cover the purpose and nature of the study, the process of participation (duration of interview etc.), the type of data being collected and how this data will be used and stored. It should also make clear that

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patients are able to withdraw consent to participate at any time without giving a reason.

Participants will then be contacted by the research team, given the time to ask questions and then if they still wish to proceed, an interview or focus group will be arranged. If an individual is unable to participate in a focus group, but would like to take part, they will be given the opportunity to take part in a one to one interview. This interview will have the same purpose as the focus group - to understand patient perspectives on decision making process about PC.

The semi-structured interviews will be guided by a topic guide designed to explore the patients' perspective of journey from diagnosis with particular focus on determining the potential decision points and understanding the role of the patient and others in the identifying PC needs. The focus groups will also be guided by a topic guide.

The interview will be conducted either in quiet room at the hospital or hospice or at the patients' home, whichever is most convenient for the patient. Interviews will be audio-recorded and transcribed verbatim. It is expected that interviews will last no longer than 60 minutes. On arrival at the interview, participants will be given the opportunity to discuss participation. Once all questions have been answered, patients will be asked to complete a consent form.

If a focus group is considered instead of interviews, this will take place in a quiet room at a time and location most convenient for the participants. It is expected the focus group will last no more than 90 minutes. On arrival at the focus group, participants will be given the opportunity to ask any questions and the ground rules for the focus group will be explained, including the fact that the discussion within the focus group should remain confidential and that participants are free to leave at any time.

## 2.3 Evaluation topics

### 2.3.1 Scoping review

The interview and focus groups topic guides and questions will be informed by a scoping review of current literature.

The scoping review to be performed will respond the following **research questions**:

1. Which are the needs, preferences and perceptions of older patients with complex chronic conditions about PC services?
2. Which are the needs, preferences and perception of relatives or caregivers of older patients with complex chronic conditions about PC services?
3. Which are the perceptions of care professionals about the performance of PC services?

Preliminary **search terms** have been set as follows:

- Palliative care, supportive care;

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- Needs, preferences, perceptions, values;
- Chronic conditions, multimorbidity;
- Older, ageing, elderly, seniors.

Several **databases** will be taken into consideration for the search strategy. The use of the following ones will be encouraged: PubMed, Medline, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science (WoS), Cochrane Library, PsycINFO, CINAHL or Scopus.

Articles will be deemed eligible if they meet the following **inclusion criteria**:

- Published in the last 10 years;
- Written in English;
- Peer-reviewed publications.
- Availability of full-text in English.

The **quality** of the scoping reviewed will be assured following the PRISMA checklist extension for scoping reviews [1] that contains 20 essential reporting items and 2 optional items to include when completing a scoping review.

➢ ***Current state of the work:***

Up until now a preliminary and rapid search has been carried out in order to map if potential articles relevant to identify needs of the three target groups (patients, relatives/caregivers and professionals) are available. This literature search has been carried out using a broad strategy through PubMed-Medline due to this database comprises more than 29 million citations for biomedical literature.

The selected terms used to search in the PubMed database are: Palliative care, needs, patients, families, non-formal caregivers, health care professionals, older. The final search string is shown below:

(((((palliative care [Title/Abstract]) AND needs [Title/Abstract]) AND patients [Title/Abstract]) OR caregivers [Title/Abstract]) OR professionals [Title/Abstract]) AND older [Title/Abstract]
((palliative care[Title/Abstract]) AND needs[Title/Abstract]) AND health professionals[Title/Abstract]
((palliative care[Title/Abstract]) AND needs[Title/Abstract]) AND caregivers[Title/Abstract]
(((palliative care[Title/Abstract]) AND needs[Title/Abstract]) AND older[Title/Abstract]) AND patients[Title/Abstract]

### 2.3.2 Consolidated Framework for Implementation Research

Besides the key content extracted from the literature review, the evaluation topics may be structured in the Consolidated Framework for Implementation Research

[1] Tricco, AC, Lillie, E, Zarin, W, O'Brien, KK, Colquhoun, H, Levac, D, Moher, D, Peters, MD, Horsley, T, Weeks, L, Hempel, S et al. (2018). PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Ann Intern Med. 2018,169*(7):467-473

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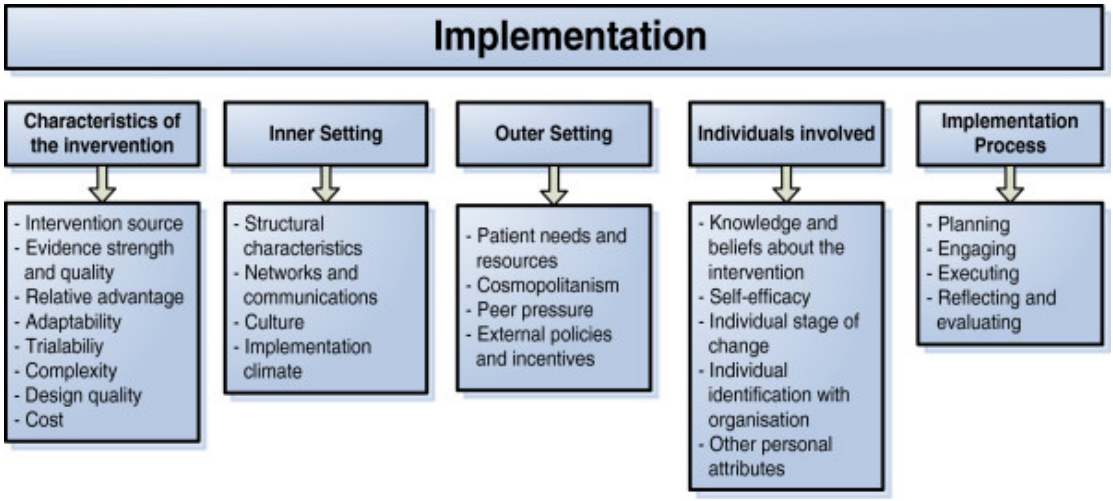
(CFIR) that provides a menu of constructs that have been associated with effective implementation[2]. The CFIR provides a menu of constructs (see Figure 1) that can be used in a range of applications – as a practical guide for systematically assessing potential barriers and facilitators in preparation for implementing an innovation, to providing theory-based constructs for developing context-specific logic models or generalizable middle-range theories.

**Figure 1 CFIR constructs**




## 2.4. Data analysis

Independently of the data collection method used (focus group or individual interviews), qualitative analysis will be performed at each site following a six-stage procedure[3]:

1. Transcription. A good quality audio recording and a *verbatim* (word for word) transcription of the interview is needed.

2. Familiarization with the interview. Becoming familiar with the whole interview using the audio recording and/or transcript and any contextual or reflective notes that were recorded by the interviewer is a vital stage in interpretation.

3. Coding. Application of labels (codes) that describe what researchers are interpreting in the passage as important.

4. Developing a working analytical framework. After coding a few interviews, comparison of the labels applied by researchers should be done in order to agree a set of codes to apply to all subsequent transcripts.

[2] https://cfirguide.org/

[3] Gale, N.K., Heath, G., Cameron, E., Rashid, S. & Redwwod, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology, 13*: 117.

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5. Applying the analytical framework. Application of the working analytical framework by indexing subsequent transcripts using the existing categories and codes.

6. Charting data into the framework matrix. Due to qualitative data are voluminous, it is useful to generate a matrix and data are 'charted' into the matrix in order to being summarized.

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# 3. Data management

## 3.1. Analysis

Interview and focus group transcripts will be analysed using framework analysis draw out key themes from the data. The framework analysis process involves 5 key stages:

1. Familiarisation: getting an overview of the issues raised during the interviews;
2. Identifying a thematic framework: making notes on the key issues discussed;
3. Indexing: applying the thematic framework to the data;
4. Charting: moving data from individual interviews and putting sections into the framework; and
5. Mapping and interpretation: the researcher attempts to make sense of the data and interpret the key themes and issues discussed.

Final data analyses and summaries can be shared between programme partners but combined analysis will be limited because of different health care systems, different interview topic guides and studying different disease areas. However, some meta-level synthesis may be possible.

## 3.2. Data storage

Hard copies of participant data will be stored in locked filing cabinets. Electronic participant data will be stored on university firewall protected computers. Audio recordings of interviews will be transcribed by a member of the research team. All interview transcripts and recordings will be kept for five years after completion of recruitment when it will then be destroyed. Data analysis will be carried out at the local research team.

## 3.3. Anonymity and confidentiality

All data collected for this study will be anonymised and stored confidentially. Participants will be given a study number and no reference to personal identifiable data will be made. None of the information provided by patients will be linked to their medical record.

## 3.4. Ethical issues

Each clinical partner will need to follow their local research ethical committee procedures to obtain approval for the conduct of the research at each site before recruitment and data collection begins. The necessary documentation for this approval will depend on local ethics committee requirements.

It is not considered that there are any risks for the participants by being involved in this study and it is anticipated that no harm will come to participants. Some patients, particularly those who have not yet been referred to PC may find the issue of PC upsetting. Participants will be made fully aware of the topic of discussion before deciding whether they would like to take part and they will be made aware that they are free to withdraw at any time. If participants choose to withdraw from the study, any data they have already provided will remain strictly

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confidential. If patients become upset during the interview or focus group or raises any specific concerns, we will ask them if they mind if we speak to the clinical team about their experiences. The clinical team could then assess and provide additional support or information. The interviewer has previous experience of discussing sensitive issues with patients and will ask questions in a thoughtful manner.

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