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Lay and professional stakeholder involvement in scoping palliative care issues: A comparison of methods used in seven European countries

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What is already known about the topic?

- Internationally, stakeholder (i.e. lay people and professionals with an interest in the topic) involvement in research and Health Technology Assessment (HTA) is advocated. Stakeholder involvement has the potential to ensure key shared priorities are addressed and research findings translated into practice.
- The philosophy and views about the best approaches for stakeholder involvement differ across Europe. Stakeholder consultation is seen as one of the most appropriate approaches to involvement in some countries. However, qualitative research is viewed as the most appropriate method of stakeholder involvement in other European countries.
- Few reports exist about stakeholder involvement in palliative care and the ways this informs decision making in HTA.

What this paper adds?

- This paper demonstrates that it is possible to involve lay (e.g. patients/ex-patients; family carers/ex-carers; family members and members of public organisations or groups) and professional (e.g. service commissioners, health and social care professionals / academics working in palliative care) stakeholders in HTA.
- Several approaches to stakeholder involvement in palliative care research are shown to be feasible and effective ways to identify stakeholder priorities.
- Despite the use of different methods of stakeholder involvement, stakeholders highlight a number of issues in palliative care that are 'common' across countries. The researchers used the issues raised to inform decision making for project development. Notably the issues raised informed the focus of the main HTA question and sub questions used in the assessment of specific aspects.

Implications for practice, theory or policy?

- Different methods of stakeholder involvement may be required for different palliative care stakeholder groups in different countries.

- Lay and professional stakeholder involvement is both feasible and worthwhile early in project development as this can identify key issues from the perspectives of service users and providers.

- Further guidance for stakeholder involvement in palliative care research is needed to ensure that policy and service development is more responsive to the needs of service users and providers.

Abstract

Background: Stakeholders are people with an interest in the topic. Internationally, stakeholder involvement in palliative care research and Health Technology Assessment requires -development Stakeholder involvement adds value throughout research (from prioritizing topics to disseminating findings). Philosophies and understandings about the best ways to involve stakeholders in research differ across Europe. Stakeholder involvement took place in seven European countries (England, Germany, Italy, Lithuania, The Netherlands, Norway and Poland) to inform a project that developed concepts and methods for HTA and applied these to evaluate models of palliative care service delivery.

Aims: To report on stakeholder involvement as part of the INTEGRATE-HTA project and how key issues identified informed project development.

Design: Using stakeholder consultation or a qualitative research design, stakeholders in seven countries acted as 'advisors' to aid researchers' decision making. Thematic analysis was used to identify key issues across countries.

Setting/participants: 132 stakeholders (82 professionals and 50 'lay' people) aged ≥18 participated in individual face- to- face or telephone interviews, consultation meetings or focus groups.

Results: Different methods of stakeholder involvement were used successfully to identify key issues in palliative care. Twenty-three issues common to three or more countries informed decisions about the intervention and comparator of interest; sub questions and specific assessments within the HTA.

Conclusions: Stakeholders can inform project decision making using a variety of methods of involvement. Researchers should consider local understandings about stakeholder involvement when undertaking this as views of appropriate and feasible methods vary. Methods for stakeholder involvement, especially consultation, need further development.

Keywords: Patient Involvement, palliative care, Health Technology Assessment

Introduction

Stakeholder involvement aims to gain the views and perspectives of stakeholders to inform research and HTA. Stakeholders include professionals (e.g. service commissioners, professionals and academics) and lay people (e.g. service users and their family carers). Internationally, the need for stakeholder involvement in palliative care research has been recognized[1.] Although published examples of lay stakeholder involvement in palliative care research exist[2], several barriers including a lack of time, available funds, clarity and specificity about the role of public involvement in research[2] need to be overcome.

Stakeholder involvement, including patient involvement, is established in Health Technology Assessment (HTA) as many groups have a legitimate interest in the outcome of HTA projects[3]. HTA research informs health policy decision making to ensure best value for money[4]. HTA uses a multidisciplinary approach to systematically and transparently assess the cost and clinical effectiveness, safety, organizational, ethical, legal and social issues of health technologies (e.g. medicines, devices, procedures and health care services)[4]. There is increasing recognition of the need for HTA to assess complex health technologies[5] which are imperative in dealing with the rise in numbers of people with chronic diseases. Incrementally changing, context dependent palliative care services are a good example of a complex technology[6]. However, there is a need to determine which models of palliative care service provision are most effective to inform future health policy and service decision making[7]. This is especially important as models of palliative care service provision across Europe are developing in various ways (reflecting the different cultures, religious beliefs and legal frameworks that exist)[8].

Palliative care research in the context of Health Technology Assessment (HTA) is still in its infancy. Hence, whilst knowledge and experience of stakeholder involvement is growing in a number of fields[2,9], further guidance relating specifically to stakeholder involvement in palliative care research and HTA is needed. This is particularly important as the usefulness and utilization of HTA depend on stakeholder involvement[3].

Despite recognition that stakeholder involvement is important in HTA, some hesitancy exists about how much influence stakeholders should have on scientific processes[3]. Furthermore, the extent and methods used for stakeholder involvement varies according to national and regional needs and traditions[3]. Indeed, the philosophy and understandings about the most appropriate ways to involve stakeholders (especially patients

and the public) in research differs across Europe. For example, INVOLVE, a U.K. national advisory group was set up to support public involvement (i.e. patients, carers and those using health and social services) in National Health Service (NHS), public health and social care research[10], although such mechanisms are not evident elsewhere in Europe. INVOLVE differentiate between public involvement, participation and engagement in research (see box 1). INVOLVE suggest stakeholder consultation (i.e. asking people their views) is one approach to involvement that can inform decision making in research[10]. However, qualitative research is advocated as the best approach to stakeholder involvement in several countries across Europe, although no specific methodology is recommended.

Box 1: Examples of involvement, participation and engagement.

'Involvement'	People are actively involved in research projects and in research organisations. Approaches to stakeholder involvement include: i) consultation (seeking stakeholder views to influence researcher decision making); ii)collaboration (researchers and stakeholders share decision making throughout the study) or iii) user-controlled research (stakeholders direct the research).
'Participation'	People takepart in a research study by providing data (e.g. in surveys or qualitative research interviews).
'Engagement'	Information and knowledge about research is provided and disseminated by researchers.

Source: INVOLVE (2012 p.7)

An opportunity to involve palliative care stakeholders presented itself in the context of a large European project (INTEGRATE-HTA) (see http://www.integrate-hta.eu/.) The INTEGRATE-HTA project developed concepts and methods for the integrated assessment of complex technologies as policy-makers need better tools to support their decision making regarding complex health technologies[11]. To demonstrate their feasibility and value, concepts and methods developed in the project were applied in a case study using models of palliative care service delivery as an example of a complex technology. As palliative care provision differs throughout Europe, the case study was undertaken in England for pragmatic reasons. At the outset of the INTEGRATE-HTA project, we wanted to identify key issues in palliative care in all participating countries to ensure that the project findings *may* have relevance to more than one country. Hence, we collected stakeholders' perspectives about key issues and topics of importance for palliative care as one way of involving stakeholders and influencing researchers' decision making throughout the project. A separate paper is being developed to report on the extensive stakeholder involvement that occurred throughout the project.

Aim

This paper reports on stakeholder involvement in seven European countries as part of the INTEGRATE-HTA project.

Methods

Design & settings

Lay and professional palliative care stakeholders in seven European countries acted as 'advisors' to inform project development from an early stage. As 'advisors', stakeholders provided information or data that informed researchers' decision making in the project. An experienced HTA researcher or palliative care clinician was appointed to be a local co-ordinator in each country. Local co-ordinators were given a guide to assist in establishing some consistency in planning stakeholder involvement, including example documentation (e.g. information sheets, consent forms). Additional guidance was given by the wider project team based on their knowledge of methodologically and contextually appropriate methods for each country. Methodological details are reported in tables 1, 2 and 3. As stakeholder involvement to assist project development in HTA is novel[14] and palliative care is a complex and culturally sensitive topic[6], a local co-ordinator conducted stakeholder meetings in each country. The local co-ordinator was a member of the research team or their

known associates, some of whom were experienced in palliative care research and others were HTA researchers. The local co-ordinator ensured that adequate support was available for stakeholders taking part in the project (e.g. ensuring an additional facilitator was available or allowing relatives to be present in meetings / interviews in case stakeholders became distressed). The local co-ordinator selected appropriate methods and arranged and / or conducted stakeholder meetings based on what is considered best practice for stakeholder involvement and palliative care in their own country. Across the seven countries, two approaches to stakeholder involvement were used; stakeholder consultation or a qualitative research approach.

1) Stakeholder consultation: Local co-ordinators in England, Norway and Poland adopted the U.K.'s philosophy for lay stakeholder involvement and all stakeholders were consulted as 'research advisors' to inform researchers' decision making in the project. Consultations were guided by the National Institute for Health and Care Excellence (NICE) (2012) methods for developing public health guidance[15] and the INVOLVE (2012) briefing notes for involving the public in research[2]. Information was collected and summarised using the EUnetHTA Core Model ®[14] as an overarching framework (See Table 2).

2) Qualitative research: A variety of qualitative approaches were used in four countries (Germany, Italy, The Netherlands and Lithuania) according to local tradition and researcher preference about stakeholder involvement. These included nominal group technique[16] and categorical coding procedure following Grounded Theory methodology by Strauss and Corbin (1990)[17]; interactive evaluation and subsequently case reconstruction using constant comparison[18] and thematic analysis[19](see Table 3).

Ethical approval

Ethical approval requirements varied in each country. Where needed, local co-ordinators ensured that appropriate ethical approval was secured prior to stakeholder involvement. In England stakeholders were involved as advisors and therefore ethical approval was not required in keeping with the National Research Ethics Service (NRES) and INVOLVE (2009) joint statement[23]. In Lithuania, permission was obtained from the Director of the Hospice and verbal consent was subsequently obtained from participants. In the Netherlands, the ethics committee waived ethics approval for stakeholder discussions. In Poland, ethical approval was obtained for the meeting with family members. Ethical approval was granted from the respective committees

in Germany, Italy and all relevant institutions in Norway. In all countries, stakeholders received a letter and information sheet prior to taking part in the project. Oral and written consent was gained in all countries.

Stakeholders

Recognising different types of stakeholder expertise, both professionals and lay people were invited to participate. The aim was to ensure variation in advisors' status and healthcare settings, thus providing a 'voice' for as many stakeholders as possible. A total of 132 stakeholders (82 professionals and 50 'lay' people) aged 18 and over were recruited across the seven countries; (see Table 4). Most stakeholders were female (n=90) and (where known), white Christians.

Working with stakeholders

Researchers in each country, with varying experience of palliative care and of working with stakeholders, undertook work with stakeholders in their native language between May 2013 and June 2014. Where possible, researchers with experience of talking to patients with palliative care needs conducted meetings and interviews.

All stakeholders were well enough to take part in the project without any special arrangements being made. However, care was taken not to overtire stakeholders, especially patients and carers. Patients could have relatives or carers present in the meeting / interview if they wished, although none took up this opportunity. Additional staff (i.e. an administrator) attended some meetings to provide support in meetings. Various mechanisms were used to feedback to stakeholders, including; sending them a summary of the information they provided for verification of the issues raised and/or feeding back to stakeholders at subsequent meetings (some lay stakeholders participated in bi annual advisory meetings throughout the project in England).

Stakeholder consultation

See Table 1 for more details of methods used in England, Norway and Poland. Palliative care experts identified stakeholders. An adapted version of the EUnetHTA core model[14] domains (with some example questions for the assessment elements) (see Table 2) provided a comprehensive structure that guided individual or small group face-to-face or telephone discussions with all stakeholders. The adaptations involved specifically seeking advice about palliative care when asking about each domain and seeking stakeholder views about

heterogeneity and patient preferences. One or two questions were prepared relating to assessment elements for each domain in case a prompt was required (see Table 2). However, these questions were usually not required as the domain headings proved sufficient to stimulate 'free-flowing' discussion of key issues across domains. Audio recordings were transcribed and/or notes (all anonymised) were written up after each meeting. Each local co-ordinator undertook analysis to identify key issues within each of the EUnetHTA Core Model®[14] domains.

Table 1. Methods used in England, Norway and Poland.

Methods Used	**England – lay stakeholders**	**England – Professionals**	**Norway – lay stakeholders**	**Norway – Professionals**	**Poland – lay stakeholders**	**Poland- Professionals**
Location:	Sheffield – a city in the North of England	From across England & 1 from Ireland (with experience of working in England)	Oslo	Oslo	Bydgoszcz	Bydgoszcz
Approach used	Consulting stakeholders		Consulting stakeholders		Consulting stakeholders	
Methods used to identify & approach stakeholders	The co-ordinator (LB – some experienced in palliative care research) directly approaching lay advisory groups from information provided by local experts on the INTEGRATE-HTA project team members.	The co-ordinator (LB) directly approaching individuals & managers of organizations from information provided by local experts on the INTEGRATE-HTA project team members. One professional approached the co-ordinator having heard about the study via the INTEGRATE-HTA newsletter.	A contact person from a palliative care unit assisted with the recruitment of patients and relatives as advisors.	The co-ordinator (KBL - an HTA researcher) directly approached a key person and Professor in Palliative medicine who nominated a colleague to attend. They then suggested other professionals.	The co-ordinator (WL – a palliative care expert) directly approaching individual or organizations.	The co-ordinator (WL– a palliative care expert) directly approaching individual or organizations.
Number of advisors & Total No. of meetings (Group / individual / both used)	20 patient advisors who are members of 2 established patient groups were involved in a total of 5 Individual and group meetings (1x 10; 1x5; 2x2 & 1x1)	34 professionals took part in individual and small group (up to 3 people) meetings (n=-22 - including a pilot with 3 academic experts from INTEGRATE-HTA project).	5 lay advisors took part in a total of 4 Individual and Group Meeting (1 with the patient and relative together)	5 professional experts took part in 2 group meetings.	8 participants – all members of societies or volunteers, no patients took part in one group meeting.	7 professional experts took part in one group meeting.
information collection methods **&** Interviewer's relationship with participants	One-off meetings using the EUnetHTA Core Model®[14] domains as a discussion guide. LB, at the time unknown to most stakeholders, facilitated all meetings. A female administrator took notes at some lay stakeholder meetings.		One-off meetings using the EUnetHTA Core Model®[14] domains as a discussion guide. KBL, at the time unknown to stakeholders, facilitated all meetings.		One-off meetings using the EUnetHTA Core Model®[14] domains as a discussion guide. WL, at the time known to most stakeholders, facilitated all meetings.	
Face-to-face / telephone / other	Face-to-face.	Face-to-face and telephone.	Face-to-face.	Face-to-face.	Face-to-face	Face-to-face.
Audio recorded / notes taken	Notes taken	Some were audio-recorded & notes were taken	Some were audio-recorded and notes were take	Notes taken	Audio recorded and notes taken	Audio recorded and notes taken
Setting for meeting – e.g. home office etc.	A University building.	University offices or the advisors' workplace.	Person's home, except one which was held at the hospital.	All meetings took place in the advisors' workplace.	Hospice in Bydgoszcz	Hospice in Bydgoszcz
Duration of meeting	45 minutes to 75 minutes.	60 minutes to 105 minutes.	Approximately 45 minutes.	Approximately 1 hour.	120 minutes	120 minutes
Methods used to analyse information	Anonymised advice was organised using the EUnetHTA Core Model®[14] as an overarching framework by LB		Anonymised advice was organised using the EUnetHTA Core Model®[14] as an overarching framework by KBL		Anonymised advice was organised using the EUnetHTA Core Model®[14] as an overarching framework by WL	

Table 2. Adaptions to the EUnetHTA Core Model®[14].

Domains of the EUnetHTA Core Model ®[14]:	**Adapted version used in stakeholder consultations included example questions to stimulate discussion using some assessment elements**
1. Health problem and current use of the technology (implementation level)	*Health problem and current use of palliative care (the technology)* • *What are the most important health problems that palliative care may help?* • *What palliative care services are available locally and nationally?*
2. Description and technical characteristics of technology	*Description of technical characteristics of palliative care (the technology)* • *What aspects of palliative care are most useful?*
3. Safety	*Safety* • *What types of harm may palliative care do? (These may be direct or indirect harms)* • *What safety issues need considering with palliative care?*
4. Clinical effectiveness	*Clinical Effectiveness* • *What are the health benefits of palliative care?* • *What aspects of palliative care work well?*
5. Costs and economic evaluation	*Cost Effectiveness* • *How should we pay for palliative care services?*
6. Ethical analyses	*Ethical aspects – e.g. Fairness, equity, access, autonomy, human rights.* • *What ethical concerns arise about palliative care?*
7. Organisational aspects	*Organisational aspects (Resources required, delivery / work processes, organisational culture, staffing, access, funding.)* • *How can palliative care best be organised?*
8. Social aspects	*Social aspects Lifestyle - work, family life, leisure time, religious, other activitie* • *What social impact does palliative care have on the lives of patients, their family and carer?*
9. Legal aspects	*Legal aspects* • *What legal issues are important considerations in palliative care?*
Heterogeneity (differences)	• *Heterogeneity (differencesWhat differences in people or circumstances may affect the usefulness of palliative care?*
Preferences	*Preferences* • *What preferences should be taken into account when using palliative care?* • *Is there any other aspect of palliative care that you would like to comment on?*

Qualitative research approach

See Table 3 for more details of methods used in Germany, Italy, The Netherlands and Lithuania, where procedures were undertaken in accordance with the qualitative research methodologies selected. Convenience and purposive sampling strategies were used[21] along with face-to-face data collection. In The Netherlands and Italy, individual interviews were completed; the latter were guided by the EUnetHTA Core Model®[14].. In Germany, individual interviews were used with patients and focus groups with relatives and professionals. In Lithuania, focus groups and one individual interview were conducted with professionals, some of whom were representing patient organisations. Discussions were either audio recorded and/ or notes were taken. Audio recordings were transcribed and notes were written up after each meeting. Co-ordinators undertook analysis as appropriate for their qualitative approach[20].

Synthesising the findings from all stakeholders

There is an absence of evidence based guidance on synthesising findings across different qualitative and stakeholder consultation paradigms. As the project developed concepts and methods for HTA, we used the EUnetHTA Core Model®[14] domains to structure the findings from stakeholder involvement in an attempt to identify issues that could inform as many HTA assessment aspects and sub questions as possible. Therefore, a table listing the key issues within each of the EUnetHTA Core Model®[14] domains was developed and populated with the results from each of the seven countries (see Table 5). The list of issues was clustered into four broad 'themes' using an approach guided by thematic analysis in qualitative research[20]. This approach was intentionally reductive for pragmatic reasons, reflecting the need to produce a coherent synthesis, whilst recognising that different philosophies underpinned the various approaches used[21]. .

The COREQ checklist[22] was used for reporting on qualitative research and the GRIPP checklist[23] for reporting on patient and public involvement in research.

Table 3. Methods used in Germany, Italy, The Netherlands and Lithuania.

Methods Used	**Germany – lay stakeholders**	**Germany– Professionals**	**Italy – lay stakeholders**	**Italy – Professionals**	**The Netherlands – lay stakeholders**	**The Netherlands - Professionals**	**Lithuania Professionals, including representatives of patient organisations**
Location:	A city & 2 small towns in northern Germany	A city & 2 small towns in northern Germany	Rome (Lazio Region) & Lecce (Puglia Region)	Rome (Lazio Region) & Lecce (Puglia Region)	Nijmegen	Nijmegen	Kaunas
Qualitative methodology used	Qualitative research: nominal group technique and categorical coding procedure informed by a Grounded Theory approach.		Qualitative research: using EUnetHTA Core Model®[14]as a framework.		Qualitative research: Interactive evaluation and subsequently case reconstruction using constant comparison.		Qualitative research & Thematic analysis.
Sampling strategy	A mixture of convenience and purposeful sampling. The co-ordinator directly approached individual or organizations and asked palliative care experts in pre-informer consultations to identify important stakeholders. Professionals recruited patients and relatives.	A mixture of convenience and purposive sampling, the co-ordinator directly approached individual or organizations.	Convenience sampling Co-ordinator directly approaching individual or organizations.		Co-ordinator directly approaching individual or organizations Physicians were asked to recruit patients.	Purposeful sampling Co-ordinator directly approaching individual or organizations Professionals nominated other professionals working in the field of palliative who were willing to participate.	Purposeful sampling Co-ordinator directly approaching individuals
Total No. of Group / individual meeting / both used	4 Individual interviews with patients (n=4) and 1 focus group separately with relatives (n=4).	1 focus group separately with professionals (n=7).	7 Individual interviews (n=8)	8 Individual interviews (n=8)	2 Individual interviews (n=2)	12 Individual interviews (n=12) – one professional was interviewed twice due to her expertise.	2 focus groups and 1 individual interview (1x6, 1x2, 1x1) (n=9)
Data collection: Interviewer's relationship with participants	Face-to-face interviews with patients & focus group with relatives (All audio recorded & notes taken). Moderation cards were used and prioritization of points took place in the focus groups and in the interviews	Focus group (All audio recorded & notes taken).	Individual, face-to-face / telephone interviews (All audio recorded & notes taken).		Face-to-face interviews (Notes taken)	Face-to-face interviews (Notes taken). Some were contacted by email post meeting for clarification of their responses.	Face-to-face interview & 2 focus groups (All audio recorded)
	AD, KH & KM (all HTA researchers) at the time unknown to stakeholders, completed data collection.		MDN (researcher in palliative care) at the time unknown to stakeholders, completed data collection.		MT & GJvdW (HTA researchers) at the time unknown to half of the stakeholders, completed data collection.		AB (palliative care researcher) known to most stakeholders, completed data collection.
Location – e.g. home office etc.	In the patients´ home, a nursing home and at a palliative care unit. Focus group with relatives and professionals took place in the premises of the University of Bremen.	The University of Bremen.	Home	The University or the stakeholder's workplace.	Patients chose the location of the interview which were held in familiar surroundings (home / hospice).	Radboud university medical center or at the stakeholder's workplace.	Kaunas Nursing Hospital, Republican Hospital of Kaunas Palliative care unit & Oncology Hospital Palliative care unit. in Kaunas
Length of interview / meeting	Interviews: 30-46 minutes Focus group relatives: 2.5	3.5 hours	45min – 60 min		60 minutes approximately		60 minutes

Methods used to analyse information / data	hours Transcribed anonymised & open coding following Grounded Theory & nominal group technique	Interviews transcribed anonymously & thematically analysed using key-words or key concepts within different domains. Presented in a descriptive manner	Reconstruction of interpretive frames	Thematic analysis -

Findings

Stakeholders identified twenty three key issues that were common to three or more countries. These issues were categorised under four themes (see Table 5) to identify similarities in findings across different countries. Whilst word limits preclude presenting separate lay and professional findings in this paper, lay contributions primarily provided insights into patients' and carers' experiences of services whereas professionals were able to draw on their experiences of service provision to a wide range of clients and situations. We used the issues to identify both an intervention and comparator model of service provision for the main HTA question. We also used the issues to inform sub questions for the assessment of specific aspects (e.g. ethical, socio-cultural aspects). Two of the issues raised by stakeholders; the need to increase home care provision and for caregiver training/support resonated with the findings of a review of review level evidence about models of service provision that had been completed at the same time as the initial stakeholder involvement. (The review was undertaken to assist decision making about intervention and comparator models that could be used to test concepts and methods developed in the project within the palliative care case study).

Insights from the evidence base and stakeholder views of the key issues in palliative care allowed us to select home based models of palliative care with and without an additional component of informal carer support as the focus for the case study. These models, known as 'reinforced' and 'non-reinforced' models of home care[24] respectively, provided the intervention and comparator models for the main HTA research question. Reinforced models of home palliative care explicitly address two of the issues raised by stakeholders in several countries (i.e. the need for caregiver training/support and the need to increase home care). The remaining issues helped to sensitize the team to key issues in palliative care; assisted the development of sub questions (e.g. for the socio-cultural aspects which focused on the user-professional-relationship and decision making) and subsequently informed specific assessments (e.g. the ethical assessment) within the HTA.

Table 4. Background details of the stakeholders involved in each country.

	Lay stakeholders							**Professional stakeholders**						
	E n=20	**G n=8**	**I n= 7**	**Ne n= 2**	**No n= 5**	**Pn= 8**	**L***	**E n=34**	**G n=7**	**I n=8**	**Ne n=12**	**No n=5**	**P n=7**	**L n=9***
Location	Sheffield – a city in the North of England	City & small town in northern Germany	6 Rome (Lazio Region) 1 Lecce (Puglia Region)	Nijmegen	Oslo	Bydgoszcz		Across England & 1 from Ireland	City & small town in northern Germany	6 Rome (Lazio Region) 1 Lecce (Puglia Region)	Nijmegen	Oslo	Bydgoszcz	Kaunas
Sex	M -10 F-10	M-3 F-5	M-2 F-5	M-1 F-1	M-2 F-3	M-0 F-8		M-9 F25	M-1 F-6	M-3 F-5	M-6 F-6	M-1 F-4	M-4 F-3	F-9
Age – range (mean)	32-89	40-69	33-72	Did not ask	27-81	25-65		28-66	40-69	33-67	Did not ask	50-59	38-52	28-66
Advisor	P-2 P & C -1 C– 2 Ex-C- 2 FM – 6 Fr -2 PC group -5	P-4 FM – 4	FM –7	P-2	P - 3 C – 2	PC group - 3 V - 5		Cl-22 R -6 Cl & R - 5 M -1	Cl -4 + 1 (retired) Cl& R - 1 M- 1	Cl – 4 R – 3 V - 1	Cl – 6 Cl& R - 6	Cl& R – 5	Cl – 3 Cl & R– 4	Cl 6 (4 managers) Cl& R – 1 SW & PCS – 2
Ethnicity:	White - 19 Asian– Indian – 1	No details available	White – 7	White – 2	White – 4 Other Asian – 1	White - 8		White-31 African-2 Caribbean - 1	No data available	White-8	White-12	White-5	White-7	White-9
Religion:	Christian – 13 Hindu -1 None / Neutral – 3 Non response - 3	Catholic – 2 Protestant – 2 None / Neutral – 2 Non response – 2	Catholic – 7	Did not ask	Christian – 1 Muslim – 1 None / Neutral – 1 Did not ask – 2	Catholic – 8		Christian - 19 Jewish None- 12 3 (pilot) not asked	Catholic 1 Protestant – 3 Jewish – 1 2 preferred not to say	Roman Catholics 8	Not asked	Christian 3 Not asked – 2	Catholics 7	Christian 9
year's' experience of palliative care: Range (Mean)	1-26 years (8.86 (based on 15 responses)	All 4 patients had less than 6 months' experience & relatives had 6 months – 3 years	1-24months (5.1 months based on 7 responses)	-	2weeks – approximately 2 years	3-20 (10) years based on 8 responses		3 months-43 years (18.8 years based on 31 responses)	5-18 years (10 years based on 7 responses)	2-15 (10 years based on 8 responses)	Not known	Not known	4-25 (15 years based on 7 responses)	15

E: England; G: Germany; I: Italy; Ne: The Netherlands; No: Norway; P: Poland; L: Lithuania

*In Lithuania, the professionals approached included 3 representatives of patient organisations provided information in lieu of approaching lay stakeholders for two reasons; 1) Patients receiving palliative care have a serious health condition and 2) palliative care in Lithuania is relatively new field and competent opinion can express may be more specialist.Lay stakeholders: P:Patient; P&C: patient & carer; C: Carer; Ex-C: Ex Carer; FM: Family member ; Fr: Friend; PC Group : Member of palliative care group / associations; V: volunteers (among lay stakeholders in Poland). Professional stakeholders: Cl: Clinicians; R: Researchers; Cl & R: Clinician & Researcher (dual role); M: Manager, SW & PCS: Social worker and Pastoral Care Specialist; V: volunteers (among professional stakeholders in Italy).

Table 5. Common Issue identified by stakeholders across seven countries (England, Germany, Italy, The Netherlands, Norway, Lithuania & Poland).

Countries	Common Issue identified by stakeholders
	Theme 1: knowledge and understanding
	Information about issues related to the knowledge and understanding of palliative care were clustered within this theme.
E, G, I, L, Ne, No, P	Improve professional's ability to recognise patients with palliative care needs & transition to palliative care.
E, G, I, L, Ne, No, P	Ensure practitioners are adequately trained to deliver palliative care including providing support for generalists providing palliative care.
E, G, I, L, No, P	Improve understanding of the definition & nature of palliative care by professionals, patients and the public / society.
E, I, L, Ne, P	Reduce stigma of death and palliative care in society
E, I, L, No, P	Develop greater understanding (for professionals, patients and the public) about harms, & reduce, physical, psychological, social & economic harms for patients (e.g side effects of treatments/ medicalization of dying), families (e.g. stress of caring / bereavement / economic problems) & staff (e.g. burnout).
E, I, L, P	Provide training and support for family carers.
E, G, I, L, No, P	Identify what effectiveness means for palliative care services (QoL, symptom control are the focus for effectiveness).
E, L, No	Improve patient and carer understanding of ethical issues (e.g. discontinuation of futile treatments).
E, G, I	Increase patients', carers' and professionals' understanding of a range of legal issues relating to palliative care (e.g. the right to live or die, euthanasia, safeguarding, capacity, advanced directives, patient's autonomy).
E, G, I, L	Develop an understanding of how different social & cultural backgrounds of patients and staff influence the provision of palliative care.
	Theme 2: organisational dependent availability and access
	Information about issues related to the availability and access to palliative care were clustered under this theme.
E, G, I, L, No, P	Increase availability of palliative care– e.g. increase bed numbers & service to all disease types, more patients –elderly MH LD & in a variety of geographical and care settings – e.g. rural areas / nursing homes / home.
E, G, I, L, No, P	Enhance recognition of palliative care as a speciality.
E, G, I, L, Ne, No, P	Funding of palliative care requires attention (to ensure funding continues or to reduce costs).
E, G, I, L, No, P	Equity of access to palliative care is a concern due to availability of palliative care, specific professions and eligibility criteria.
E, G, I, No, P	Ensure easy (e.g. out of hours),equitable (e.g. to all groups) and timely (e.g. not restricted only to the last months of life) access to palliative care.

E, G, I, L, No, P	Possible over-treatment (if death seen as a defeat by professionals) or under-treatment (because of failure to identify palliative care needs).
E, I, No, P	Improve availability of specific disciplines within the palliative care – eg dieticians, psychologists, Occupational therapists, music therapists.
E, G, I, P	Provide support for family carers post bereavement.
	Theme 3: attitudes and clinical decision-making
	Information about issues such as communication which reflect attitudes and affect decision making.
E, G, I, L, No, P	Need for information–giving to patients and carers about a range of issues to improve patient decision making and autonomy.
E, G, I, Ne, No	Communication recognised as important – Overcome communication difficulties with patients and carers (e.g. re prognosis, to avoid deception & to ensure informed consent).
	Theme 4: continuity of care (outcome which is dependent of the three above preconditions)
	Information about issues influencing the continuity of care both at an organisational and individual level were included in this theme.
E, G, I, L, Ne, No, P	Improve the organisation of palliative care in terms of co-ordination of, communication & co-operation between services to ensure continuity of patient care.
E, G, I, Ne, No	Withdrawal of treatment & the transition from active to palliative care is an area of concern.
E, I, No, P	Reduce hospitalisation and increase home care.

E: England; G: Germany; I: Italy; Ne: The Netherlands; No: Norway; P: Poland; L: Lithuania

Discussion

Despite differences in palliative care provision throughout Europe[7] and the use of various locally sensitive consultation methods, stakeholders in seven European countries identified common issues in palliative care. Stakeholders' advice informed the project in several ways, notably enhancing our understanding of palliative care and enabling the team to select 'reinforced' and 'non-reinforced' models of home based palliative care[24] as the intervention and comparator of interest for the application of the HTA methods developed in the project. Additionally, stakeholder involvement sensitized the team to key issues in palliative care (e.g. the philosophy of palliative care re patient and caregiver as a unit of care; patient preferences of home care/death which is reflected in Policy initiatives to increase availability of home palliative care/home death across several countries involved in the project). As a result, stakeholder involvement also subsequently informed sub questions and specific assessments within the HTA (e.g. the ethical and socio-cultural assessments).

We learned that both lay and professional stakeholders can contribute much experiential knowledge of palliative care, assisting project development. Involving stakeholders required consideration of their needs for access, support; appropriate project information and questioning in a manner that enhanced their confidence in providing information / data. The methodological, ethical and practical issues for stakeholder involvement in palliative care research vary between countries. There is no recommended approach to stakeholder involvement and, although clear methodologies exist when using qualitative research approaches, this is not the case for stakeholder consultation. Sharma et al (2015)[25] assert, stakeholder perspectives can be viewed as "colloquial evidence" that provides additional knowledge and has a different role to that of other types of evidence. Hence, as Sharma et al (2015)[25] suggest, this type of knowledge should not be judged in the same way as other evidence because it is not collected in the same rigorous and systematic manner.

Whilst no consensus exists about the best methods of stakeholder consultation[13], by using locally sensitive methods of stakeholder involvement, we ensured that a variety of stakeholder perspectives of palliative care were integrated into the project design. This adds to the body of evidence that stakeholders, including patients and the public, can assist in designing research[9] which changes their roles and relationships with researchers[26]. Given the different stakeholder roles and relationships with researchers, we had to overcome uncertainty about ethical requirements which vary in each country when undertaking stakeholder involvement, especially when using a consultation

approach. Furthermore, systematic methods for identifying common topics proved challenging, although similar issues arose across countries.

Despite interest in palliative care amongst European policy makers[27], there has been a lack of international comparative perspectives on service developments[28]. Differences in the amount and source of data and the difficulties of cross country comparative analysis have previously been recognised[27]. However, including the perspectives of patients and the public adds a new dimension to these complexities.

Strengths and limitations

Involving stakeholders early in project development in seven European countries was a major strength as it assisted the identification of issues that were common across countries. This provides 'added value' as it enhances the likelihood of the findings having international relevance. However, whilst using different methods of stakeholder involvement was a strength in terms of being locally appropriate, it proved challenging in terms of synthesis. Limitations exist in the reporting of differences in professional and lay perspectives across countries. Almost all stakeholders were white Christians which limits identification of the views of ethnic minority groups who are known to have specific palliative care needs[29].

Conclusion

There are no gold standard approaches for stakeholder involvement across Europe. However our findings indicate this can be done successfully in a variety of different ways, using a variety of different approaches/methods. Researchers should consider understandings about stakeholder involvement in the local context when undertaking this in more than one country as some approaches/methods may be considered more appropriate than others. Although it may not be straightforward, it is both feasible and worthwhile to invest in palliative care stakeholder consultation when undertaking research. Irrespective of the method used, the added value of international stakeholder involvement is evident. Stakeholder involvement enhanced the project team's understanding of issues in palliative care that were common across countries. Stakeholder information can inform project decision making about both the intervention and comparator used in the main HTA research question and the focus of sub questions used to assess other aspects in the project. Such widespread stakeholder involvement potentially enhances the applicability of the project findings. Methods for stakeholder involvement need further development, especially with reference to stakeholder consultation and synthesis of information from the different approaches that can be used.

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The authors declare that there is no conflict of interest.

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