3. Ongoing dilemmas and new approaches in palliative care and end of life care research: methods, ethics, and patient and public involvement in the United Kingdom

Clare Gardiner and Emilie Couchman

The growing number of older people who live with chronic and complex conditions accentuates the significant need for robust and relevant research in palliative and end of life care (Higginson, 2016). In this chapter we outline some of the key debates in this clinical academic field. With a focus on our UK-based experience, we begin by reflecting on the challenges of how we define and recognise PEoLC needs, and the implications of this for research. Trends and patterns in PEoLC research over recent years are then outlined, including contextual issues such as research funding and debates surrounding differing epistemological approaches.

Next, we outline some of the methodological challenges which can present barriers to research. To address these challenges, best practice recommendations are emerging in the field, and some of these are highlighted and critiqued. Here we aim to further our understanding of these issues in the UK and, by doing so, identify effective strategies that address the growing complexity of research and practice in this context. Assessing the efficacy of multicomponent, complex interventions, which consider the holistic needs of patients and their families, evidently requires novel approaches to measurement and evaluation. Some such methodologies are beginning to emerge, and we discuss some examples of creative, co-produced methods and their success in accessing 'hard to reach' populations.

We then reflect on some of the ethical issues and challenges at the forefront in PEoLC research. These include conducting research in a population deemed 'vulnerable', the involvement of adults with impaired mental capacity, and reconciling informed consent with 'do no harm'. Emerging evidence that aims to address these challenges is discussed.

Finally, we touch on the importance of patient and public involvement (PPI) in PEoLC research, which has become increasingly established over recent years, both in the UK and internationally. We provide an overview of the emergence of PPI in healthcare research and discuss evidence supporting the value of PPI in research. The lack of PPI evidence specifically in PEoLC research is noted as one area where further evidence is required. Examples which demonstrate innovative and effective PPI work in the UK and internationally are beginning to emerge and centralise the role of patients and families in the research process. The challenges of applying such processes across international boundaries are touched on, including differing terminologies. The active involvement of patients and their families as research partners can go some way in addressing the challenges associated with a complex and sensitive research area, yet further evidence is required to support best practice.

In summary, several challenges persist which hamper the development of the PEoLC evidence base. Inadequate research funding and prioritisation, narrow perspectives on acceptable methods, ethical challenges, and a lack of patient representation have all contributed to the under-representation of palliative care research nationally and internationally (Abu-Odah et al., 2022). Recent developments have started to address some of these challenges, and we provide an overview of best practice guidance, novel and creative research methods, and a changing culture around research participation. Interdisciplinary research methods are also discussed, which cross traditional boundaries and can help with understanding what matters most to patients and identifying solutions in the context of rapidly changing healthcare systems.

DEFINING AND CONTEXTUALISING PEoLC IN MODERN SOCIETY

The term ‘palliative and end of life care’ is used throughout this chapter, as we encompass discussion of the holistic care of people with life-limiting conditions from diagnosis to death, throughout their illness trajectory. This term is predominantly used within the research context, but given the varying perspectives as to what constitutes palliative care amongst the general public and some professionals alike, explicit inclusion of the terms ‘palliative’ and ‘end of life’ can be useful in clinical practice too. Further, the significant contribution of informal carers and voluntary organisations within communities must not be underestimated, though this chapter focusses on PEoLC provided by healthcare professionals (see Table 3.1).

PEoLC is increasingly synonymous with holistic care. The UK charity Marie Curie describes PEoLC as meeting ‘physical, emotional, psychological, social and other needs’ as well as ‘helping with pain and other physical symptoms’ (Marie Curie, 2022). PEoLC is therefore not a linear process and may be undertaken alongside active treatment. The needs of patients and their close persons may vary throughout the illness trajectory, and health gains are possible at different holistic levels, depending on the predominant need at any given time.

The 2008 End of Life Care Strategy for England stated that ‘How we care for the dying is an indicator of how we care for all sick and vulnerable people’ (DoH, 2008). PEoLC research underpins approaches to care for people approaching the end of life, but still there are numerous factors hindering high-quality evidence in this field. The increasingly complex context of health and social care provision and the proliferation of multifaceted interventions require innovative evaluation methods.

Internationally, the structure and content of healthcare, and the needs of populations, have changed over recent decades. In the UK, the National Health Service (NHS) was designed to manage single disease trajectories in discrete episodes of care. Nowadays, given an

Table 3.1 Definition of key terms

Term	Definition
Palliative care	This is a broad approach to care focused on quality of life for people with advanced, life-limiting conditions, to help them to live as well as possible and provide relief from distressing symptoms. (NHSE, 2023)
End of life care	Such care is a subset of palliative care provided to people nearing the end of life, the timeframe of which varies depending on factors such as diagnosis, disease trajectory, and patient preference. (NHSE, 2023)

increasingly paternalistic approach within healthcare systems, the responsibility for health outcomes lies within the professional sector to a greater extent than it does within communities. A tendency towards reactive care, leaning away from proactive and preventative action, has increased the strain on service provision. The progressive surge in multimorbidity and frailty is overwhelming. Holistic care from generalists is increasingly required, in addition to the provision of specialist care. However, factors such as subspecialisation, privatisation, inadequate staffing, and time constraints are challenging this approach. Fragmentation is an increasing problem in many healthcare systems internationally. Rising privatisation and unequal levels of staffing and funding between geographical regions mean that inconsistency in service provision compromises the ability to provide equitable care (Goodwin et al., 2011).

The UK's Department of Health and Social Care published its Major Conditions Strategy in 2023, which identified that just under half of all people dying in England receive PEoLC care, indicating considerable unmet need (DoHSC, 2023). In addition, the proportion of UK deaths in community settings has steadily increased, and then accelerated during the COVID-19 pandemic (ONS, 2021). The significant increase in people dying at home over recent years is generally viewed as a positive development, and in line with patient preferences for the majority (Lopes et al., 2024). However, the shift out of hospitals and into communities clearly demonstrates the need for high-quality community-based PEoLC, appropriate training and education, and sufficient resources to be able to deliver these services.

PEoLC is not solely provided by specialist services. Ongoing distinction between generalist and specialist PEoLC (across both primary and secondary care settings) is needed. Furthermore, recognition is required that PEoLC is often not labelled as such and is delivered within primary care by a diverse multidisciplinary team of healthcare professionals. 'Generalist' services, including general practitioners, district nurses, care home staff, or homecare workers, often provide the majority of PEoLC for people who die at home and play a critical role in enabling a good death, alongside specialist services and support from involved social networks. Given this interprofessional landscape, general practitioners, community health and care professionals, and specialist care colleagues will need to draw on concepts of interdisciplinary and collaborative practice to establish and negotiate their roles within multidisciplinary teams. As PEoLC provision continues to move 'upstream' and support individuals from an earlier stage of disease, the needs of patients and their close persons may vary, and therefore the need for involvement of a range of members of the healthcare system may be required across a much broader illness trajectory.

Ultimately, healthcare is more complex than ever before. A key priority to be addressed within both research and medical education is the management of complexity and uncertainty in populations with increasing frailty and multimorbidity. To undertake effective research that can inform future practice and policy, we also need to transcend disciplinary and institutional boundaries. The diversity of individuals within multidisciplinary teams needs to be acknowledged, valued, and engaged in order to develop new approaches to research and its outputs. Innovative approaches to research are needed in order to enable us to measure and improve upon PEoLC provision, grounded in a detailed understanding of the context.

TRENDS AND PATTERNS IN PEoLC RESEARCH

Demographic changes, including an increasing number of older people and more people living with chronic and complex conditions, mean the need for robust and relevant research in palliative care has never been greater (Higginson, 2016). Generating evidence to help maintain quality of life and support patients and their family members at the end of life remains an ongoing priority. However, several challenges exist when conducting healthcare research, many of which are exacerbated in the context of palliative care studies. First amongst these is a lack of prioritisation and research funding when compared with other disciplines. Palliative care research is one of the lowest funded (ranked 44 out of 48) areas of healthcare research in the UK (Marie Curie, 2020). Research from 2015 identified that in the UK less than 0.3% of the £500 million spent annually on cancer research was allocated to palliative care, with funding for non-cancer conditions likely to be even less (Higginson, 2016). Across Europe and internationally, similar funding challenges exist, and there are few opportunities specifically aimed at palliative care research (Kaasa, 2006). A 2018 review of international palliative care research found the field remains under-represented globally and there is limited engagement with the major health financiers, such as the World Bank, suggesting that international palliative care continues to operate outside of broader discourses of international development, global ageing, and global health (Clark et al., 2018).

Although the proportion of funding allocated to palliative care research is small, funding bodies in the UK such as Marie Curie and the National Institute for Health Research (NIHR) are helping to address this. In 2015 Marie Curie undertook a Research Prioritisation Exercise in collaboration with the James Lind Alliance to identify top research priorities for palliative care research in the UK (JLA, 2015). This patient-led exercise and its updates have been influential in focusing research into areas that will bring direct and tangible benefits to patients, their caregivers, and close persons. The exercise also led to greater acknowledgement of research gaps in palliative care and a focus on improving the evidence base to inform patient and close person choice, future practice, and guideline updates. In 2022 a major UK funder – the NIHR – announced a series of specific funding calls for palliative and end of life care, in order to address some of these gaps (NIHR, 2022). Across the European Union, funders have similarly committed financial support for palliative care research, and funding from Horizon, Erasmus+, and EU4Health has led to the development of a number of pan-European consortia with ambitious research programmes in palliative care. Despite these positive advances, funding in the area of palliative care remains disproportionate to the population's need for palliative care, and ongoing advocacy is needed to ensure PEoLC is recognised as a priority on funding agendas.

Despite the challenges of insufficient research funding, PEoLC research has consistently improved in both quality and quantity over recent years (Clark et al., 2018). However, the disparity between high, middle, and low income countries must be acknowledged. In a bibliometric review to map the state of research trends within the field of PEoLC research internationally, the results identified a five-fold increase in the number of published articles from 2002 to 2020 (Abu-Odah et al., 2022). Articles were published from 142 countries, with the US and UK being the most productive countries in terms of the number of papers published and citations. The most common areas for research from 2002 to 2020 were related to cancer, paediatrics, quality of life, and pain. After 2014, most research focused on heart problems and dementia-related areas, along with education and training (Abu-Odah et al., 2022). The authors concluded that although research outputs have expanded significantly, there is a need for more research on non-cancer conditions and more research from low- and middle-income countries, facilitated through cross-institutional cooperation.

PEoLC research has also witnessed considerable change in terms of research methodology and study design. Whilst policymakers traditionally view randomised controlled trials as the gold standard for providing an evidence base, these are often not appropriate or possible within the context of PEoLC. This is due to ethical and recruitment issues when involving those with terminal illness in research, and the difficulty in making concrete the often complex, intangible, and patient-specific needs and outcomes. ‘Not everything that counts can be counted, and not everything that can be counted counts’ (Toye, 2015). This quotation, which has been attributed to both sociologist William Bruce Cameron and Albert Einstein in various publications, neatly expresses the challenges that researchers in PEoLC often face. The nuances, grey areas, and complexities of interactions, care needs, and priorities towards the end of life can be difficult to articulate, let alone measure and evaluate using randomised controlled trials. Consequently, there is increasing recognition of the need to adapt and develop approaches to research that permit an understanding of intangible, complex phenomena. Multiple innovative research methods and methodologies have emerged, and two examples are discussed below:

Case Studies

Walshe et al. (2004) argue that case studies are appropriate for use in the context of PEoLC under the following circumstances:

> when complex situations need to be addressed; when context is central to the study; when multiple perspectives need to be recognised; when the design needs to be flexible; when the research needs to be congruent with clinical practice; when there is no strong theory to which to appeal; and when other methodologies could be difficult to conduct. (Walshe et al., 2004: 677)

The case study approach, therefore, seems entirely appropriate to facilitate sensitive data collection from patients with PEoLC needs and those involved in their care. Yin (1994) advises that case study research enables us to answer questions about how or why things work, given their realistic context (Yin, 1994). Theory generated from case studies can help to make sense of complex relationships in healthcare practice and to tease out why efforts to improve care succeed in some contexts but not in others (Baker, 2011). Case studies help to understand the complexity that is so difficult to assess in a trial design and provide an understanding of circumstance and context (Yin, 1994). In the UK, the use of case study methods is well established in community nursing and PEoLC research, but this approach is underutilised due to misconceptions about its rigour. Its unique applicability to the PEoLC context relates to its fieldwork-based approach, which permits detailed exploration of complex settings, processes, and systems. Case study methods provide researchers with a flexible approach that is not tethered to a particular methodology and can be tailored according to the multifaceted concept being studied. However, the application of such methods must be systematic, rigorous, and reported with transparency (Brogan et al., 2019).

Realist Methodology

The realist methodology enables the evaluation of complex interventions and facilitates theory construction leading to the development of a ‘context–intervention–mechanism–outcome’ configuration (Booth et al., 2019; Hashem et al., 2019). The fundamental principle of realism involves finding a causal ‘mechanism’ between the ‘context’ and the ‘outcome’ to understand why and how something works (or does not). It is a particularly useful approach when exploring complex concepts that are not explicitly ‘measurable’ but which are common in PEoLC research. For example, a context may offer certain resources and opportunities, but it is the decision-making of participants that leads to outcomes (Rycroft-Malone et al., 2012). The realist approach may result in more useful practice and policy suggestions, given its potential to facilitate comprehension of ‘why a program works, for whom, and in what circumstances’ (Pawson and Tilley, 1997: xvi). Realist research has been increasingly utilised in PEoLC research over recent years (Wong et al., 2016).

Downey et al. (2023) argue that realist evaluation can mitigate the well-documented challenges within the existing PEoLC literature, relating to the inclusive involvement of people with PEoLC needs in research, the complexity of PEoLC services, and the inadequate depth provided by experimental studies alone. As with case study design, the methods used in realist research may be tailored depending on how they might enable the development and testing of illustrative theory (Downey et al., 2023). The RAMESES reporting standards provide guidance and support integrity, but ultimately there is no standardised approach that realist researchers must adopt (Wong et al., 2016). This mirrors the holistic, individualised style of care provision adopted by clinicians in the PEoLC field.

CHALLENGES AND BEST PRACTICE IN PEoLC RESEARCH

Due to the complexity inherent in PEoLC service delivery and research, a number of challenges exist which can present barriers to research. These include challenges related to the palliative care population and their perceived vulnerability, and methodological challenges inherent in researching a complex and multi-faceted care approach. The emergence of best practice guidance and recommendations has begun to address these challenges, which are beginning to signal a shift in research practice away from paternalistic models towards co-produced, collaborative methods.

The challenges of researching a population that is approaching the end of life are not to be underestimated. Recruitment is one example, with access to patients restricted by gatekeepers concerned about potential vulnerability. Patients may be less likely to participate if they are clinically unstable or have complex symptoms (Higginson, 2016), and patients with a limited life expectancy may, understandably, prioritise other activities over research participation. Strategies to improve recruitment have been suggested and include conducting research over multiple sites, offering flexible options for data collection (e.g. both in-person or online consultations), and capturing reasons for non-participation to inform future research (Addington-Hall, 2007). PEoLC studies are also likely to suffer from high levels of attrition, missing data, and poor compliance due to patients becoming unwell and/or dying before a study concludes (Higginson, 2016; Jordhoy, 1999; Preston, 2013). Recommendations on acceptable rates of attrition in research frequently refer to the ‘5-and-20’ rule, which suggests that attrition of less than 5% is of little concern, but attrition over 20% may lead to potentially serious threats to validity (Schulz, 2002). However, many palliative care studies report attrition rates of over 20% (Brims, 2019), and some contain attrition rates of more than 60%, with studies recruiting family caregivers experiencing similarly high levels (Addington-Hall, 1992; Brims, 2019). Reporting the cause of attrition is useful in helping to understand trial results (Oriani, 2020), and in 2013 the 'Methods Of Researching End of Life Care' (MOREcare) partnership identified five recommendations for managing missing data, attrition, and response shift. These include devising a taxonomy to define types of attrition; reporting the types and amount of missing data with details of imputation methods; investigating patterns of missing data; and devising a statistical analysis plan that accounts for high expected attrition. The partnership, which was established to develop 'best practice' methods for palliative care research, noted that whilst high rates of attrition should be assumed when planning studies and specifying analyses in palliative care research, high attrition is not indicative of poor design and a clear, pre-defined statistical analysis plan can help mitigate the impact of any missing data and of attrition (Preston, 2013).

A linked but distinct challenge within the PEoLC care population is the frequent reliance on the views of close persons and informal caregivers as a proxy for patients. In addition to providing proxy data for patients, close persons and caregivers also have their own support needs, which are increasingly recognised as an important priority for research (JLA, 2015). Involving close persons and informal caregivers in research can be challenging, yet there has been minimal exploration of the specific difficulties that may occur when conducting research with family carers in the context of palliative care (Hudson et al., 2023). Researchers have acknowledged complexities such as gatekeeping and difficulties with defining and identifying informal caregivers, who may not always identify with the terms 'carer' or 'caregiver'. Such individuals may also be reluctant to participate due to their own ill health, the emotional burden, not wanting to reflect on death/dying, or research being conducted too soon after a patient has died (Stiel, 2015). To address issues of this kind, a 2022 international expert elicitation study by the European Association for Palliative Care (EAPC) developed strategies to improve the design and conduct of research with close persons and informal caregivers. The recommendations highlight strategies for advancing scientific inquiry in research involving such individuals, including conceptual clarity of their caregiving role, more flexible and creative recruitment strategies, and incorporating caregivers themselves into the conduct of the research through PPI activity. Accompanying this, a checklist for researchers, funding bodies, and ethics committees provides practical strategies and tips for conducting high-quality research with family caregivers and close persons, and lays the foundation for further research in this important area (Hudson et al., 2022).

In addition to challenges with the palliative care population, a further issue is undertaking research which accounts for the wide range of phenomena that are central to the provision of PEoLC. Research involving a broad span of methodological approaches is necessary to address many of the challenges outlined above and to maximise the population that can benefit from PEoLC research. In addition to the case study and realist approaches we have discussed, the importance of mixed methods, qualitative, observational, co-produced, and economic designs have all been noted (Payne, 2009; Farquhar, 2013). Whilst the need for a wide range of approaches is apparent, we focus here on one particularly under-represented method – health economic evaluations and related economic research.

Economic arguments are often central to debates that seek to expand palliative care as a cost-effective 'solution' to patient care (Smith, 2014), yet our understanding of cost-effectiveness is limited by the poor-quality evidence base and low certainty of findings (Bajwah, 2020). Debates persist around the appropriateness of 'standard' methods of economic evaluation within the specialist context of PEoLC. For example, the applicability of Quality Adjusted Life Years (QALYs) as a measure of outcome for people with life-limiting illness has been questioned, amidst concerns that these fail to demonstrate cost-effectiveness in palliative care (Preston, 2012; Normand, 2009). Others argue that QALYs are the most widely used method, and until alternative measures for palliative care are available, their use should continue (Round, 2012). Debates also persist about the appropriateness of standard models of economic evaluation and the choice of economic dimensions which are typically assessed in palliative care research (Gardiner, 2017). A 2011 study from Canada noted that the majority of economic studies in palliative care take a narrow perspective and are mostly focused on measuring publicly financed healthcare, without considering the considerable costs that are faced by others including patients, families, and charities (Guerriere, 2011). A systematic review in 2017 highlighted the importance of considering costs from a variety of economic viewpoints, particularly noting that palliative care interventions often 'shift' costs from publicly financed care to individual patients and their families. The authors provided a framework of relevant cost components and suggested economic perspectives to guide future research and promote the use of broader economic viewpoints within the context of palliative care (Gardiner, 2017). However, further research is required to develop and refine methodologies which account for multiple economic viewpoints, particularly those which enable international comparisons to be made.

Whilst the issues outlined above highlight the difficulties of conducting research with a complex population in a challenging methodological context, progress is being made in developing strategies to address this. In 2013, the MORECare collaboration used evidence-based approaches to produce the 'MORECare Statement', a checklist of components that require consideration when designing and conducting palliative care intervention studies. In parallel, the partnership also developed the national/international MORECare recommendations to improve the environment for the development and evaluation of interventions in palliative care. Further recommendations have subsequently been published, including on mixed methods research, ethical issues, and health economics. The MORECare outputs set clear standards on good research practice in evaluating services and treatments in palliative care and are relevant to those designing, funding, and reviewing studies. They have underpinned many subsequent developments in palliative care research and support the development of standards for research in this context (Higginson et al., 2013).

INTERDISCIPLINARY APPROACHES TO PEoLC RESEARCH

In an ideal world, PEoLC research should acknowledge and transcend disciplinary boundaries on three key levels in order to deepen understanding, attract the attention of policymakers, and implement effective change. First, methods should permit researchers to reach the relevant multidisciplinary teams within a study's context. Second, barriers between the primary, secondary, and tertiary care interfaces should be surmounted. These approaches are fundamental as a patient's experience of healthcare becomes increasingly fragmented and multifaceted. Third, healthcare research should be linked with other wider disciplines, such as the arts, humanities, and social sciences, in order to deepen the potential for participant engagement, extend dissemination of findings with the public, and promote dialogue with policymakers. The greater inclusion of such disciplines would permit a more holistic view of study participants, appreciating them as far more than solely a patient.

Multidisciplinary Teamworking

'A multidisciplinary team (MDT) is a group of healthcare professionals of varied disciplines and roles, working together towards a common goal of providing optimal care for a patient' (Bowen, 2014: 142). PEoLC is often provided by non-specialists and delivered by a diverse group of professionals, including general practitioners, district nursing teams, care home staff, homecare providers, and family caregivers. As previously mentioned, informal caregivers and voluntary organisations within communities must not be underestimated, though a focus remains on the professional provision of care. Community-based multidisciplinary teams provide the majority of PEoLC for people who die at home, and they play a critical role in enabling a good death in the community, alongside specialist PEoLC care services. Evidence suggests that the multidisciplinary team (MDT) approach to PEoLC has positive impacts on a range of patient and close person or informal caregiver outcomes. For example, in China, Liu et al. (2023) conducted a randomised controlled trial comparing 'conventional' palliative nursing care with a multidisciplinary collaborative approach to such care. Patients receiving the multidisciplinary approach reported fewer adverse mental health symptoms, perceived higher levels of social support, and outcome measures relating to quality of life improved.

The MDT context is not just applicable to research focusing on the experiences of patients and their close persons. Borgstrom et al. (2024) highlight the potential benefits to healthcare professionals of the increasingly MDT style of working. The authors advocate for further research to understand how such healthcare models affect 'individual and collective decision-making and processes of sharing emotional burdens' (Borgstrom et al., 2021: 1). Further, although on paper, teamworking involves members working towards a common goal with a common purpose, this does not always translate into clinical practice. Effective teamworking cannot happen if a system is overwhelmed. Appropriate time and resources must be factored in for individuals to be able to focus both on their own work, and on collaboration and cooperation (Hoban, 2023).

Communication and Coordination Across Interfaces

In an ideal scenario, at present occurring more often in high-income countries, people who are approaching the end of life typically access care across multiple settings and organisations. Even in such countries, there are often large discrepancies between people who may benefit from PEoLC and those who receive it in a timely manner. It is vital that this care is effectively coordinated, and it is often the role of primary care clinicians to facilitate this (National Palliative and End of Life Care Partnership, 2021). In the UK, general practitioners and primary care teams are supporting more people to die in the community. There has been a concerted long-term policy and clinical emphasis on providing more PEoLC outside hospitals, and the proportion of deaths in community settings has steadily increased (ONS, 2016). Poor interprofessional communication hinders the delivery of PEoLC by general practitioners (Carey et al., 2019), yet relatively simple solutions such as Electronic Palliative Care Coordination Systems (EPaCCS) and shared healthcare records can facilitate PEoLC (Leniz et al., 2020). In addition, MDT meetings have been found to support the integration and coordination of care (Dudley et al., 2019; Borgstrom et al., 2021). There is undoubtedly a focus on specialist PEoLC delivery in current studies. Uncertainty surrounding the role of primary care professionals in PEoLC and their delivery of such care that is often not labelled as such are possible reasons for this bias. Research needs to cross the primary and secondary care interface, as well as the interdisciplinary interface.

Interdisciplinary Working

The multiple interrelations between disciplines such as the humanities, social science, natural science, formal science, and applied science have never been more apparent. Palliative and end of life care research that adopts techniques from relevant disciplines could facilitate greater understanding, wider engagement, and more tangible outcomes. Further, there is evidence that such approaches to research can benefit study participants. For example, Budig et al. (2018) found that after using the Photovoice visual research methodology (which incorporates the use of photographic images to prompt reflection and comment), participants felt empowered in terms of gains in knowledge and skills, changes in self-perception, and their access to and use of resources.

Ultimately, multiple individuals can be involved in the care of patients with PEoLC needs. Arguably, any research undertaken in the healthcare sphere needs to be designed creatively, but the MDT context makes this particularly necessary. Exploration of this collaborative way of working is essential if we are to improve both patient and healthcare professional experience. New research approaches are emerging, which aim to capture understanding across different dimensions, many of which are described elsewhere in this *Handbook*. This contextualisation of findings within their natural habitats permits the creation of a stable foundation from which to make practical recommendations for future service provision.

ETHICAL ISSUES IN PEoLC RESEARCH

In recent years compelling moral and ethical arguments have been made to support the involvement of terminally ill individuals in research. Providing individuals with an opportunity to participate in research protects a patient's right to autonomy, and patients may choose to be involved in research, volunteering their consent to do so. In addition to moral and ethical debates, evidence now suggests that research participation can confer considerable benefits to those receiving PEoLC. These include a sense of altruism and contributing to others, an opportunity to derive meaning from illness, and an opportunity to be heard (Gysels, 2008; Dean and McClement, 2002). A rights-based argument has proposed that dying persons have just as much right to participate in research as any other individuals (Benioliel, 1980).

A consensus has therefore emerged across the research community that people receiving PEoLC should not be prevented from participating in research if studies are carefully designed and executed to ensure sensitivity to participants' needs and concerns, and key ethical principles are upheld (Gysels, 2013). These include ensuring autonomous decision-making, the appropriate balance of potential benefits and harms, the provision of informed consent, and the promotion of collaborative research approaches. Nonetheless, upholding these principles can be particularly challenging in some circumstances, particularly when involving people who have reduced capacity to consent.

Ethical issues are therefore at the forefront in PEoLC research, and this section considers three key areas: conducting research in a population deemed ‘vulnerable’; reconciling informed consent with ‘do no harm’; and the involvement of adults with impaired mental capacity.

People approaching the end of life are often deemed ‘vulnerable’ due to their complex and debilitating symptoms, high levels of distress, and physical decline (Dean and McClement, 2002). This, in combination with the emotional intensity of impending death and the reality of diminishing time, has led many to argue that people approaching the end of life should never be invited to participate in research (de Raeve, 1994). Historically, some authors have argued that strong moral grounds exist for objecting to research in the field of PEoLC. In 1980 Benoliel suggested that ‘There maybe merit in raising the general question as to whether dying patients should ever properly be subjects for scientific study’ (Benoliel, 1980: 120). Conducting research into the needs and experiences of these individuals has been said to be ‘an affront to the dignity of those people who are terminally ill and an expression of profound disrespect for the emotional and physical state of such patients’ (deRaeve, 1994: 299). However, in order to eliminate the potentially disempowering effects of the ‘vulnerability’ label, such populations may be considered to be ‘structurally vulnerable’ given their prognosis, but may not identify with this vulnerability on an individual level (Chung, 2021). In addition, and also in taking a rights-based approach, whilst concerns about vulnerability are legitimate, they do not justify special restrictions for PEoLC research (Casaret and Karlawish, 2000).

Decision-making capacity describes the ability to understand information and to make a rational choice. This capacity may be impaired in patients near the end of life due to cognitive impairment or extreme frailty (Perrels et al., 2014). As a consequence, decision-making and informed consent for these patients will be more difficult and sometimes impossible (Casaret and Karlawish, 2000). The challenge of involving those with reduced mental capacity in research has been considered in other contexts such as dementia and psychiatric illness but only more recently in PEoLC research. The MORECare capacity statement, developed in 2020, provides evidence-based guidance on how best to include individuals in research when they have impaired capacity and are nearing the end of life (Evans et al., 2020). Informed by systematic review and expert consultation, the MORECare Statement promotes individuals’ autonomy and decisional capacity in the consent process and highlights the need for different approaches across the capacity spectrum, from mild to severe impairment. The statement includes consideration of ethics, involvement of consultees, maximising individual autonomy, tailoring recruitment strategies, ensuring sufficient time is given, and enhancing the research culture and infrastructure (Evans et al., 2020). Evidence from multiple studies now concludes that conducting research involving adults with impaired capacity at the end of life is feasible and acceptable (Kotze et al., 2021). However, the adoption of key principles and a robust ethical framework is required to accommodate variable and changeable levels of capacity, in order to adequately protect participants (Evans et al., 2020).

Informed consent is central to the conduct of ethical research and concerns the permission granted by an individual in full knowledge of what the research involves, as well as the possible consequences and any risks and benefits. The process of informed consent requires a researcher to openly communicate all aspects of a research study, paying particular attention to any risks or benefits, and to seek written or verbal affirmation from the participant that they agree to continue. Whilst informed consent is a cornerstone of ethical research, in trying to obtain informed consent, an inadvertent clash of ethical imperatives may occur. A useful example comes from a study which explored the PEoLC needs of people with advanced Chronic Obstructive Pulmonary Disease (COPD) (Gardiner et al., 2010). Here, patients with advanced COPD were recruited to participate in surveys and interviews detailing their care needs as they approached the end of life. The Research Ethics Committee (REC) designated to review the project requested that the words ‘palliative care’ and ‘COPD’ be removed from all patient materials to avoid any potential distress. Thus, the content of the study documentation migrated from ‘palliative care needs in COPD’ to ‘care needs in people with chest problems’ (Gardiner et al., 2010). In this instance, it can be argued that by upholding the principle of ‘do no harm’ the REC directly contravened the principle of informed consent, as participants were left unaware of the true study aim. Other authors have highlighted the damaging impact of the ‘over-protectiveness’ of RECs, which can distort their gatekeeping role (Lee and Kristjanson, 2013; Gysels et al., 2013). These examples reinforce the importance of ethical policy which is informed by emerging research, and which incorporates expert guidance and, more crucially, user perspectives, in order to promote ethical best practice.

PATIENT AND PUBLIC INVOLVEMENT IN PEoLC RESEARCH

Incorporating user perspectives in research is central to ensuring that research is ethical, feasible, and relevant to the populations in which it is conducted. In the UK the term ‘patient and public involvement (PPI)’ has emerged to describe the active involvement of patients, their families, and interested members of the public in research. The INVOLVE initiative, funded by the NIHR to support such involvement within England, defines PPI as research carried out with or by members of the public rather than to, about, or for them (NIHR, 2012). PPI can include a wide range of activities, such as identifying research priorities, planning study designs, collecting, analysing, and interpreting data, and disseminating and/or implementing research findings (NIHR, 2021; Johnson et al., 2021).

In the UK, PPI is now an established element of research culture and is recognised as a key prerequisite for high-quality health research (NIHR, 2021). The vast majority of research funders require consideration of PPI in grant applications, and funding decisions are made in collaboration with PPI representatives. Internationally PPI has begun to increase in priority, and it is recognised as a key component across a range of research activities, including ethical review, clinical guidance development, and more recently PEoLC research (Boivin et al., 2010; Heckel et al., 2010). Nonetheless, although there is general consensus that PPI adds value throughout research, philosophies and understandings about the best ways to involve patients and the public in this way differ internationally (Brereton et al., 2017). This 2017 study involving PPI activities across seven European countries identified a range of different involvement methods, each tailored to the specific cultural and social situations of the countries involved. In this study, there was little consensus on an acceptable international standard for PPI in PEoLC research, highlighting the importance of careful planning, early engagement, and development of an evidence base to ensure PPI methods are appropriate (Brereton et al., 2017).

The evidence base for PPI in PEoLC research therefore remains relatively limited (Chambers et al., 2019). Whilst research from other disciplines has highlighted the value of involvement, both for researchers and for patients and the public (Ocloo and Matthews, 2016), few studies have addressed the specific benefits or challenges for PEoLC research. Moreover, misconceptions persist around the involvement of people with life-limiting and terminal illness (NIHR, 2012). A review of evidence in 2020 reported that involvement in PEoLC research was perceived as complex and challenging, and concerns were voiced about the vulnerability of patients and their close persons (Chambers, 2019). However, the findings showed that although involvement in PEoLC research is demanding, it is not dissimilar to that in other fields, a finding confirmed in a recent qualitative study (Johnson et al., 2021). Some evidence has also begun to emerge highlighting the positive impacts of involvement in PEoLC research; for example, PPI can help demystify PEoLC and raise awareness about PEoLC research (Daveson et al., 2015). Furthermore, through the experiences of the communities they are working with, researchers can gain greater insights into health conditions and what it is like to receive PEoLC (Chambers et al., 2019). In the UK, PPI has been associated with a higher likelihood of funding success, underlining the importance of early engagement with PPI throughout the research cycle (Gardiner, 2018).

Nonetheless, challenges remain and issues concerning power, diversity, and emotions may be magnified in PEoLC, leading to a reluctance among researchers to undertake involvement (Chambers et al., 2019). Practical problems also exist, including sourcing adequate funding to provide staff training, administrative support, and financial recompense for involvement (Heckel et al., 2020). When PPI first emerged in healthcare research, PPI activities were built on a volunteer model with patients and the public expected to give their time for free, whilst professionals often receive money for their time spent. More recently, payment guidance and suggested rates of pay have been recommended for patients and the public, in recognition of the value of their input and to increase inclusivity (NIHR, 2021). Whilst laudable, many researchers lack the funds to provide payment for PPI (particularly in the pre-funding stage of research), and this should be urgently addressed by research funders and academic institutions to avoid an absence of PPI in early-stage research development. In addition to adequate funding, patients, caregivers, and the public require guidance from researchers on how to help improve research productivity, quality, and relevance (Daveson et al., 2015), albeit the best ways to achieve this have yet to be identified. Creative and diverse methods have proved useful for maximising inclusivity and supporting those who are frail or unwell to undertake PPI. One recent example highlighted the benefits of an online forum for PPI, which facilitated virtual communication between researchers and PPI representatives. An evaluation of the forum suggested it provided greater flexibility for those who wished to be involved and was received positively by both PPI members and researchers (Brighton et al., 2018).

Guidance is now available for improving PPI activities in health and social care research. The UK Standards for Public Involvement have been designed to improve the quality and consistency of public involvement in research. They describe what ‘good’ public involvement looks like and encourage specific approaches and behaviours, including flexibility, sharing, learning, and respect (NIHR, 2017). Other guidance is also available to support the reporting of PPI activities; for example, the GRIPP2 checklist is an evidence-based statement which supports researchers in reporting PPI activity within research projects (Staniswescka et al., 2017). Guidance has also emerged for evaluating PPI and capturing impacts in healthcare research. The Public Involvement in Research Impact Toolkit (PIRIT) is a set of pragmatic tools which aims to support researchers, working with public contributors, to plan and integrate their involvement in research, track public contributions and the difference they make to the research, and demonstrate impact against the UK Standards for Public Involvement (Marie Curie, 2023). Despite the recent proliferation of PPI toolkits and guidance, specific advice to support both researchers and PPI members in PEoLC research remains lacking (Gardiner, 2018). Further research is therefore required to provide PPI guidance for those undertaking research in this context and to address issues such as emotional support, discussion of sensitive topics, unpredictable circumstances, and flexible working to enhance diversity and inclusivity (Johnson et al., 2021). Such guidance could build on principles that have been identified as central to PPI in PEoLC research. These include: building and maintaining relationships; flexible approaches to involvement; and finding the 'right' people to engage in PPI (Johnson et al., 2021). Wider national and international development of standards and guidance will be important, but crucially any such material and support should be co-produced with PPI representatives to ensure patients and the public remain at the heart of the research process.

CONCLUSION

A key theme in healthcare policy and practice, both in the UK and internationally, is how we can manage uncertainty given longer and more unpredictable illness trajectories. This is also a pressing issue for academics, who need to be able to contextualise patient care against a backdrop of changing healthcare systems. The complexity of the care needs of individual patients and of specific populations, and the characteristics of the overarching healthcare system, must all be acknowledged and addressed by researchers. Assessing the efficacy of multicomponent, complex interventions, which consider the holistic needs of patients and their families, evidently requires novel approaches to measurement and evaluation.

Context is everything. Research must be co-produced with patients and the public to produce outcomes that will directly relate to the complex systems that service users have to negotiate. To undertake effective research that allows us to truly understand what is happening, why, and in what circumstances, and to inform future practice and policy, we need to cross disciplinary and institutional boundaries and break down the barriers to doing so. Though this chapter focused on the PEoLC provided by healthcare professionals, the importance of community-based voluntary organisations and informal caregivers in providing such care must not be underestimated. Not all care needs to be delivered by healthcare professionals, and the added value in health delivery from informal providers must not be overlooked. As the strain on healthcare systems continues to grow, the voice of such care sectors needs to be increasingly prominent in research.

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