

Integrated assessment of home based palliative care with and without reinforced caregiver support:

'A demonstration of INTEGRATE-HTA methodological guidances' – Executive Summary

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INTEGRATE-HTA



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PROJECT:

Integrated Health Technology Assessment for Evaluating Complex Technologies (INTEGRATE-HTA)

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Executive Summary



About this Executive Summary

This comprehensive executive summary reports on a case study designed to demonstrate the application of a number of the key concepts and methods developed in the INTEGRATE-HTA project to the assessment of complex technologies. The case study focuses on models of home based palliative care with and without an additional element of caregiver support, known as reinforced and non-reinforced home based palliative care respectively.

What is already known about the topic

- ▶ With changing disease patterns in Europe, increasingly complex health care technologies, such as palliative care, have gained importance.
- ▶ Current HTA methods rarely take account of wider legal, ethical and socio-cultural issues or context and implementation and are not adequately equipped to assess highly complex technologies, despite considerable progress in recent years. As a result, HTA is rarely applied to highly complex health technologies.

What this case study report adds

- ▶ The INTEGRATE-HTA project developed concepts and methods for the assessment of complex technologies, taking into account legal, ethical and socio-cultural issues as well as context and implementation.
- ▶ This case study is designed to demonstrate the application of a number of the key concepts and methods developed in the INTEGRATE-HTA project to home based palliative care, with and without an additional element of caregiver support, as an example of a complex technology; known as “reinforced” and “non-reinforced” home based palliative care respectively.
- ▶ The INTEGRATE-HTA model, developed to enable integration of relevant assessment aspects, is used to structure this report.
- ▶ The case study reports on the application of some of the concepts and methods developed within the INTEGRATE-HTA project to the assessment of effectiveness as well as economic, sociocultural, ethical, and legal aspects; patient preferences and patient-specific moderators of treatment and context and implementation issues related to reinforced and non-reinforced home based palliative care.
- ▶ The highly complex nature of reinforced and non-reinforced home based palliative care is illustrated through an assessment of complexity characteristics.

- ▶ The case study also involved extensive lay and professional stakeholder involvement, using a variety of methods, to inform the HTA process at key stages throughout the project.
- ▶ Key messages are highlighted for both HTA research and for palliative care.

The implications for research and practice

- ▶ The concepts and methods developed in the INTEGRATE-HTA project have been shown to be feasible and to have the potential to offer added value, but require further development and application in the assessment of other complex technologies.
- ▶ Reinforced and non-reinforced models palliative care are highly complex. The case study findings offer some insights into their effectiveness as well as economic, sociocultural, ethical, and legal issues; patient preferences and patient-specific moderators of treatment as well as context and implementation issues.

Foreword for the INTEGRATE-HTA Case Study

Professor Sheila Payne

Emeritus Professor, Lancaster University, UK

You may have noticed that family members are central to all aspects of our lives, from nurturing babies and young children to supporting frail older people. The availability of family members is even more important during periods of sickness and disability. Evidence suggests that they are crucial in supporting patients throughout advanced illness until death, offering to facilitate preferences such as a home death but little is known about how best to support them. Within Europe there are approximately 100 million family carers who experience considerable physical, psychological, social and financial challenges, and provide in total considerably more care than that delivered by health care workers within national health care systems. According to NICE (2004), family carers refer to all people with a close social and emotional bond, not just those related by kinship or marriage.

The case study focusing on home based palliative care, undertaken within the context of the INTEGRATE-HTA project, is therefore greatly welcomed. The case study focuses on home care, especially the additional support required by family carers to maintain a person with advanced disease in their home (called 'reinforced' home based palliative care). This is extremely topical and relevant to the work of clinicians based in primary care and also to hospital practitioners who need to discharge patients nearing the end of life to the care of their family members. A key main policy driver in the UK and many other European countries is to implement accessible and timely home based palliative and end of life care, to reduce the number of patients dying in hospitals. This is based on the assumption that most patients prefer to die at home and that hospital deaths are both more costly and potentially offer less quality on a number of indicators. Sustaining the ability of family carers to continue to provide care at home is therefore crucial. One of the major reasons for a break down in caregiving near the end of life is excessive strain and burden upon family carers.

The case study offers insights using novel HTA methodology which will be relevant to all those planning, delivering and developing new interventions to improve how we might help to prevent this.

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List of abbreviations

CICI	Context and Implementation for Complex Intervention
Cope	Committee on Publications Ethics
HBPC	Home Based Palliative Care
HTA	Health Technology Assessment
MCDA	Multiple Criteria Decision Analysis
NHS	National Health Service
PSS	Personal Social Services
rHBPC	Reinforced Home Based Palliative Care
SAP	Stakeholder Advisory Panel
TIDiER	Template for Intervention Description and Replication
UK	United Kingdom

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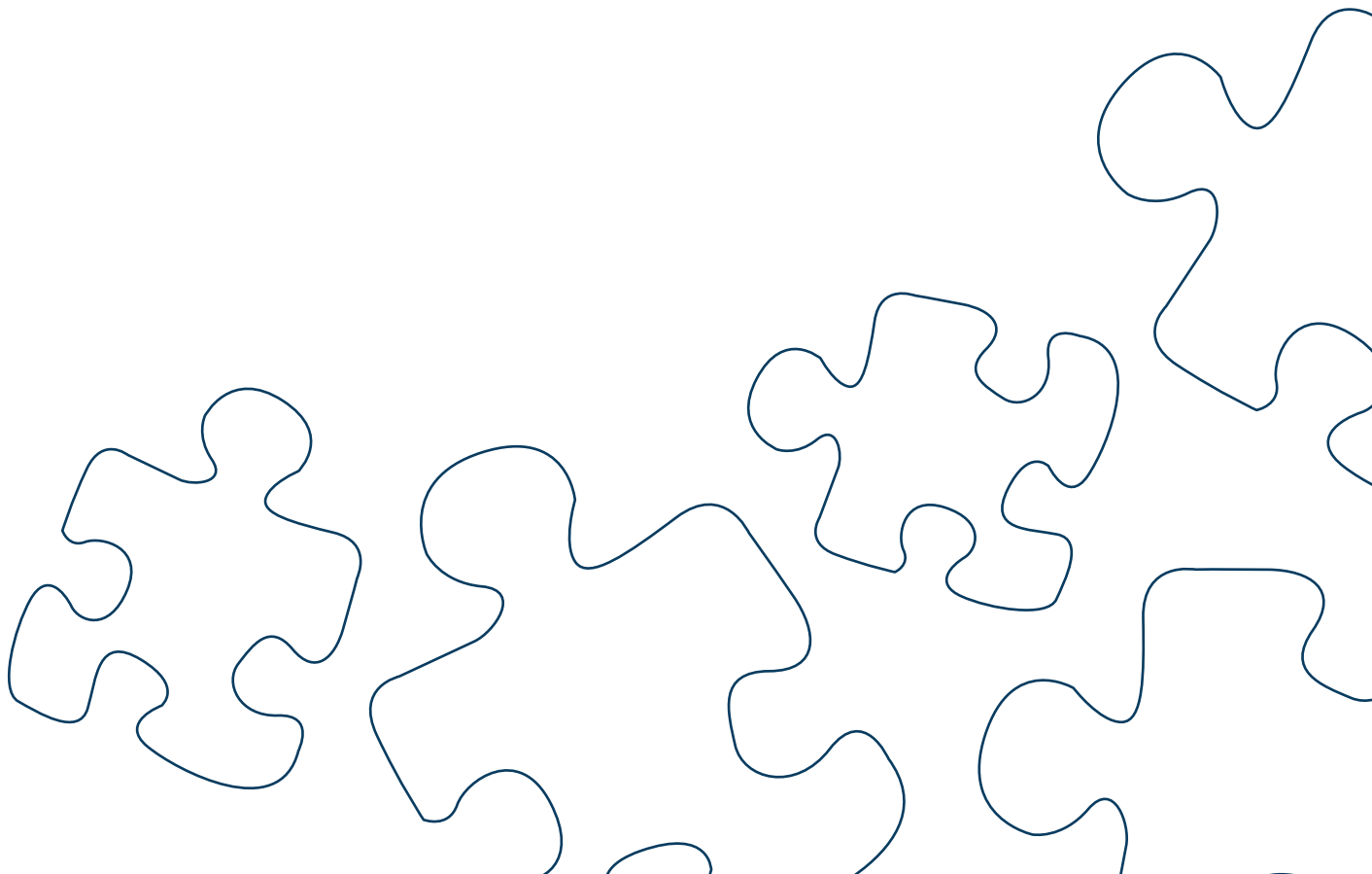
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1 ABOUT THE CASE STUDY

1.1 PURPOSE OF THE CASE STUDY: A 'DEMONSTRATION HTA'

This case study is a so-called 'Demonstration-HTA', which is used to demonstrate the application and integration of some key concepts and methods developed within the INTEGRATE-HTA project to reinforced home based palliative care as the selected complex health technology. This aims to show the feasibility and value of the concepts and methods developed within the INTEGRATE-HTA project.

The case study provides a synthesis of a broad range of evidence that can be used by those commissioning and developing palliative care services to support decision making in a very complex field.

1.2 AUDIENCES FOR THE CASE STUDY

This case study report may be of interest to:

- ▶ those involved in Health Technology Assessment (HTA) as it demonstrates the application of some of the key concepts and methods developed in the INTEGRATE-HTA project to the assessment of reinforced and non-reinforced home based palliative care as one complex technology.
- ▶ the palliative care community (i.e. those commissioning, delivering and using palliative care services) as it draws together a range of heterogeneous evidence that may assist decision making in a complex area of health care.

1.3 ENGLAND AS THE CONTEXT FOR THE PALLIATIVE CARE CASE STUDY

England was selected as the context for the case study because palliative care policy and services are comparatively well-developed (Centeno et al., 2013). To enhance the international relevance of the findings, in the early (scoping) stages of the case study, information was also gathered from stakeholders in the five INTEGRATE-HTA project partner countries: England, Germany, Italy, the Netherlands, Norway and our col-

laborators in Lithuania and Poland. A rapid applicability assessment was conducted to assess the applicability of HTA findings in the U.K., Poland and Germany.

2 ABOUT THE INTEGRATE-HTA PROJECT

2.1 BACKGROUND

Health Technology Assessment (HTA) is an important tool to support health policy decision making, for example whether or not to reimburse certain health technologies. However, HTAs usually focus primarily on summarising evidence about costs and effectiveness, often paying less attention to the assessment of wider issues, including, for example, ethical, socio-cultural and legal issues. Furthermore, HTA is also sub-optimally equipped for taking into account important elements such as context, implementation, patient characteristics and interactions which are often key factors when assessing complex health technologies.

Complex health technologies include multiple perspectives from the many different stakeholders, indeterminate phenomena, uncertain causality, unpredictable outcomes and time/path dependence (historicity). For complex technologies decision-makers need assessment of information to be conducted and presented in an integrated way and integration needs to start from the beginning of the assessment.

2.2 AIMS OF THE INTEGRATE-HTA PROJECT

The INTEGRATE-HTA project aims to develop concepts and methods for a comprehensive, patient-centred, and integrated assessment of complex technologies that considers

- ▶ effectiveness and economic, socio-cultural, ethical, and legal issues,
- ▶ patient preferences and patient-specific moderators of treatment,
- ▶ context and implementation issues.

2.3 CHOICE OF HOME BASED PALLIATIVE CARE AS AN EXAMPLE OF A COMPLEX INTERVENTION

A range of different models of palliative care service provision¹ are developing in different countries across Europe as many patients prefer to be cared for, and die, in their own home. Home based palliative care interventions, including both reinforced and non-reinforced models, are highly complex. The philosophy of individualised care means that home based models of palliative care involve a range of multifaceted tailored and flexible services; the effects of which are of uncertain causality. Furthermore, multiple stakeholders and unpredictable outcomes add to the complexity of palliative care.

2.4 EXPANDING THE EVIDENCE BASE ABOUT MODELS OF PALLIATIVE CARE

Some information about the effectiveness and cost effectiveness of models of palliative care exists. However, in addition to evidence about effectiveness and cost-effectiveness, policy makers also need information about the advantages and disadvantages of different models with regard to socio-cultural, ethical, and legal issues, patient preferences and patient-specific moderators of treatment. Although not traditionally seen as part of HTA, there is also a need to consider issues relating to context and implementation. These issues are important if policy makers are to choose the best palliative care provision for patients and their families as services continue to be developed and expanded in different ways across Europe.

2.5 THE OVERALL RESEARCH QUESTION

The research question reflects the intention of the INTEGRATE-HTA project to develop concepts and methods for a comprehensive, patient-centred, and integrated assessment of complex technologies. The case study focuses on informing the following question:

Are reinforced models of home based palliative care acceptable, feasible, appropriate, meaningful, effective, cost-effective models for providing patient-centred palliative care (compared to non-reinforced models of home based palliative care) in adults (defined as those aged 18 years old and over) and their families?

The focus on feasibility, appropriateness, meaningfulness and effectiveness (rather than on each individual element of assessment (i.e. ethical, socio-cultural, legal issues etc.), is intended to allow consideration of the evidence in a more integrated manner. Feasibility, appropriateness, meaningfulness and acceptability within this overall research question are interpreted as defined by the Joanna Briggs Institute and the definitions of all terms are summarised in Table 1.

2.6 REINFORCED MODELS OF HOME BASED PALLIATIVE CARE

'Reinforced models of home based palliative care' (rHBPC) refers to "existing home palliative care with an additional component of caregiver support" (Gomes et al 2013 p.19). Reinforced models of home care will always include an intentional and explicit attempt to support informal (i.e. not professional) carers in addition to the care given to patients. 'Support' is any psycho-educational intervention aimed at providing assistance to carers (e.g. individual or group counselling, education, advice or respite services which alleviate burden). This support may aim to prepare the caregiver to provide future patient care or address the psychological health burden experienced by the informal caregiver. Consequently, reinforced models do not include a single well defined intervention and some interventions to support informal carers are similar to those that may be provided within non-reinforced models.

2.7 NON-REINFORCED MODELS OF HOME BASED PALLIATIVE CARE

Non-reinforced models of home based palliative care (HBPC) do not include an intentional and explicit additional component of caregiver support. Non-reinforced models primarily focus on patients, though aspects of care may also be directed towards carers,

¹ The term 'model' of palliative care is defined with regard to its structure only as 'who delivers (e.g. professionals, paid carers) the intervention (specialist or generalist palliative care), where (setting – e.g. hospital), to whom (care recipients), when (i.e. timing and duration), how (e.g. face to face) and for what purpose (i.e. expected outcomes)?'

Table 1: Definition of research terms.

Criterion of Interest	Description
▶ Effectiveness	is defined as “The benefit (e.g. to health outcomes) of using a technology for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home” (INAHTA, 2015) Clinical effectiveness is defined as “The extent to which a specific intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions. Or more specifically, the evaluation of benefit to risk of an intervention, in a standard clinical setting, using outcomes measuring issues of importance to patients (e.g. ability to do daily activities, longer life, etc.)” (INAHTA 2015).
▶ Cost effectiveness	is defined as an economic evaluation consisting of comparing various options, in which costs are measured in monetary units, then aggregated, and outcomes are expressed in natural (non-monetary) units (INAHTA 2015).
▶ Acceptability	is defined as being agreeable to defined population groups, often those benefiting from , or target groups affected by, the intervention, those implementing an intervention and society at large (Joanna Briggs Institute 2014).
▶ Meaningfulness	is defined as “the extent to which an intervention or activity is positively experienced by the patient. Meaningfulness relates to the personal experience, opinions, values, thoughts, beliefs and interpretations of patients or clients” (Joanna Briggs Institute 2014).
▶ Appropriateness	is defined as “the extent to which an intervention or activity fits with or is apt in a situation. Clinical appropriateness is about how an activity or intervention relates to the context in which care is given (Joanna Briggs Institute 2014).
▶ Feasibility	is defined as “the extent to which an activity is practical and practicable. Clinical feasibility is about whether or not an activity or intervention is physically, culturally or financially practical or possible within a given context” (Joanna Briggs Institute 2014).
▶ Implementation	is defined as “process, constellation of processes or means of assimilating or putting into use an intervention - either evidence-based or theory-based - in an organisation or a setting” (Pfadenhauer et al., 2016).

usually on an ad hoc basis rather than as specific planned intervention. In accordance with Gomes et al’s (2013 p.10) definition, these home based models provide physical and psychological care to support patients or their family carers, or both, outside of hospitals and other institutional settings. Patients usually have severe or advanced disease (malignant or non-malignant), which is no longer responding to curative/maintenance treatment.

2.8 DIFFERENCES BETWEEN REINFORCED AND NON-REINFORCED MODELS OF HOME BASED PALLIATIVE CARE

Reinforced models of home based palliative care include an additional caregiver intervention within

an existing home care system. As such, similarities between reinforced and non-reinforced models of palliative care are inevitable. This similarity is also partly due to the holistic nature of palliative care which address the needs of the patient and their family in both reinforced and non-reinforced models, albeit that in the latter, caregiver interventions are ad hoc rather than planned, deliberate interventions.

2.9 METHODS – THE INTEGRATE-HTA MODEL

The INTEGRATE-HTA Model (Wahlster et al., 2016) was developed to integrate all assessment aspects in HTAs of complex technologies. This five step model is used as a framework to present the case study results in this report.

2.9.1 Step 1 - Definition of the HTA objective and technology

Step 1 assists in the definition of the HTA objective and identification of the technologies under study.

2.9.2 Step 2 - Creation of a logic model to define evidence needs

Step 2 presents a specific logic model (Rohwer et al., 2016) (i.e. a conceptual model) for reinforced and non-reinforced home based palliative care which identifies important elements and guides evidence collection in the HTA.

Together Steps 1 and 2 assist project scoping (planning) to focus the HTA on reinforced and non-reinforced models of home based palliative care. To identify priorities in palliative care, consultations took place with 132 adult stakeholders (including commissioners, professionals, academics, patients and carers) across seven countries (England, Germany, Italy, Lithuania, the Netherlands, Norway and Poland). To ensure that the project findings have international relevance, we focused on issues of shared concern to stakeholders in the countries involved in the project. Although variability exists in palliative care services across Europe, four common themes were identified across all seven countries. Themes included recognition of palliative care needs; funding; the organisation of palliative care; and professionals' training. Within

the four themes, 23 issues were common to three or more countries, including the need to increase home care provision and provide training and support to family carers.

A review of review level evidence about models of palliative care was completed at the same time as the stakeholder consultations. Most evidence relates to specialist models of palliative care, notably home based palliative care. With greater understanding of the evidence base and stakeholder views of the key issues in palliative care, reinforced and non-reinforced models of home care were selected as the focus for the application of the INTEGRATE-HTA project methodological guidance.

The choice of home based models of palliative care reflects patient preferences for home care/death along with policy initiatives to increase the availability of home palliative care/death across several countries involved in the project.

Reinforced models of home based palliative care explicitly address two of the issues raised by Stakeholder Advisory Panels (SAPs): the need for caregiver training/support and to increase home care provision. Additionally, reinforced models reflect the philosophy of palliative care in considering the patient and caregiver as a unit of care.

2.9.3 Step 3 - Evidence assessment

Step 3 involves the application of the concepts and methods used, including further stakeholder consultation, to identify, collect and synthesise evidence for specific aspects of the HTA as follows:

Effectiveness - To compare reinforced with non-reinforced home based palliative care interventions, Gomes et al's (2013) systematic review was updated as part of the INTEGRATE-HTA project guidance to assess effectiveness aspects (Burns et al., 2016). Harvest plots were created to portray heterogeneous evidence in a clear, transparent way as meta-analysis was less appropriate. The harvest plots were used as a basis for a gap-analysis of the existing literature, which was subsequently used to inform individual semi-structured telephone consultations with four professional stakeholders from three countries (England, Germany and the Netherlands).

Economics - The economic analysis is based on a reinforced model of palliative home care, developed using a systems approach according to the INTEGRATE-HTA project guidance for economic modelling of

complex interventions in complex settings (Chilcott et al., 2016). The marginal impact on resource use and costs were modelled and should be considered in conjunction with the summary of effectiveness (presented separately). Evidence informing the model is drawn from a review of published literature and expert judgement elicited during stakeholder workshops and telephone based interviews.

Ethical - Using a procedural framework, which forms the core content of the INTEGRATE-HTA project guidance on ethical issues (Lysdahl et al., 2016b), an assessment of the complexity of, and ethical issues associated with, (reinforced) home based palliative care was completed by one researcher.

The researcher (not an HTA expert and not a trained ethicist) used 'reflective thoughts' to draw on existing knowledge, palliative care literature and advice provided by stakeholders (i.e. patients, relatives, professionals, academics and other involved parties) in seven countries during consultations at the start of the project.

Socio-cultural - Some steps from the INTEGRATE-HTA project guidance to assess socio-cultural aspects (Mozgema et al., 2016) of HBPC and rHBPC was applied through consulting nine stakeholders at different assessment steps. The group or individual consultations took part via telephone, face-to-face or via Skype. Two researchers (one with sociological and health sciences expertise (German) and one with palliative care expertise (English native speaker) were involved. The socio-cultural framework was applied in all conducted assessment steps. Culturally heterogeneous perspectives on the identified central category "the user-professional-relationship and decision making" could be identified using Cultural Theory as an example.

Legal - the INTEGRATE-HTA project guidance for assessing legal aspects (Brönneke et al., 2016) associated with reinforced and non-reinforced home based palliative care was undertaken by two researchers (one English, one German), experienced in health sciences, but with no legal training. The researchers considered nine legal issues generally of importance for different technologies in a six step process to determine the need for further legal advice or assistance in the HTA process.

Moderators of treatment outcome - the INTEGRATE-HTA project guidance on identifying patient specific moderators of treatment (i.e. factors that influence the effect of a treatment) was used (van Hoorn et al., 2016a). A search filter specifically aimed to retrieve

ve moderators of treatment outcome was combined with a modified version of Gomes et al's (2013) search strategy that was used in PubMed to find publications on home-based models of palliative care. A critical appraisal checklist tool was developed and used to critically appraise the selected full text articles.

Patient preferences - application of the INTEGRATE-HTA project guidance on identifying patient preferences (van Hoorn et al., 2016a) was used. A modified version of Gomes et al's (2013) search strategy was used in PubMed with a search filter on patient preferences for treatment outcome. Publications were subsequently evaluated on title-abstract, and full text to determine whether the papers contained information on patient preferences for treatment outcome. A critical appraisal tool specifically developed for studies on patient preferences for treatment outcomes was used to assess quality.

A summary of the results from the assessment of both patient preferences and moderators of treatment outcome was presented to an advisory panel that consisted of two ex-carers and five experienced palliative care nurses. The panel were asked to relate the findings to their daily practice: that is, to determine whether the findings made sense and were not missing important issues, whether the findings were usable and relevant.

Context and implementation - a qualitative systematic review of contextual barriers and facilitators to the implementation of home-based palliative care in Europe used the Context and Implementation for Complex Intervention (CICI) framework (Pfadenhauer et al., 2016) in evidence synthesis using the "best-fit" framework synthesis method.

Within Step 3, reinforced home based palliative care demonstrates all the described aspects of complexity, including multiple perspectives from the many different stakeholders involved, indeterminate phenomena, uncertain causality, unpredictable outcomes and time/path dependence (historicity) (see Table 2).

2.9.4 Step 4 – Mapping of the evidence

Step 4 involved extracting evidence from the evidence summaries and assigning this to the six assessment criteria (effectiveness, meaningfulness, acceptability etc.) (See Figure 1). Summary tables of the evidence informing each assessment criterion were developed in preparation for decision making. Each table provided a summary of the evidence that informs a speci-

fic assessment criterion. In addition, issues that may influence the internal/external validity of the findings were reported according to the information provided by the evidence summaries. Evidence from these summary tables was presented to the decision making committee in the case study. However, after feedback in the meeting, internal and external review, we subsequently developed the extended logic model to assist decision making (see Figure 2). The extended logic model to assist decision making is based on evidence summaries from the assessment of effectiveness, economics, acceptability, meaningfulness, feasibility and appropriateness. This was not tested in the case study but is included as an example of how the case study application assisted the development of the methods in the project. To assess the applicability of the intervention assessed in the HTA in a specific context, a

rapid applicability assessment was conducted within Step 4. A consultation guide for the applicability assessment based on the CICI framework was applied within the case study in three countries (the U.K., Germany and Poland).

2.9.5 How to read the extended logic model to assist decision making

The assessment criteria (effectiveness, meaningfulness etc.) are symbol coded (see Figure 1). Evidence relating to each assessment criterion is coded by the same symbol and assigned to either context (legal, ethical and socio-cultural evidence) or implementation outcomes (effectiveness and cost effectiveness evidence, patient preferences and moderators of treatment effect). Where

Figure 1 Structure of HTA research question taking the HTA results into account.

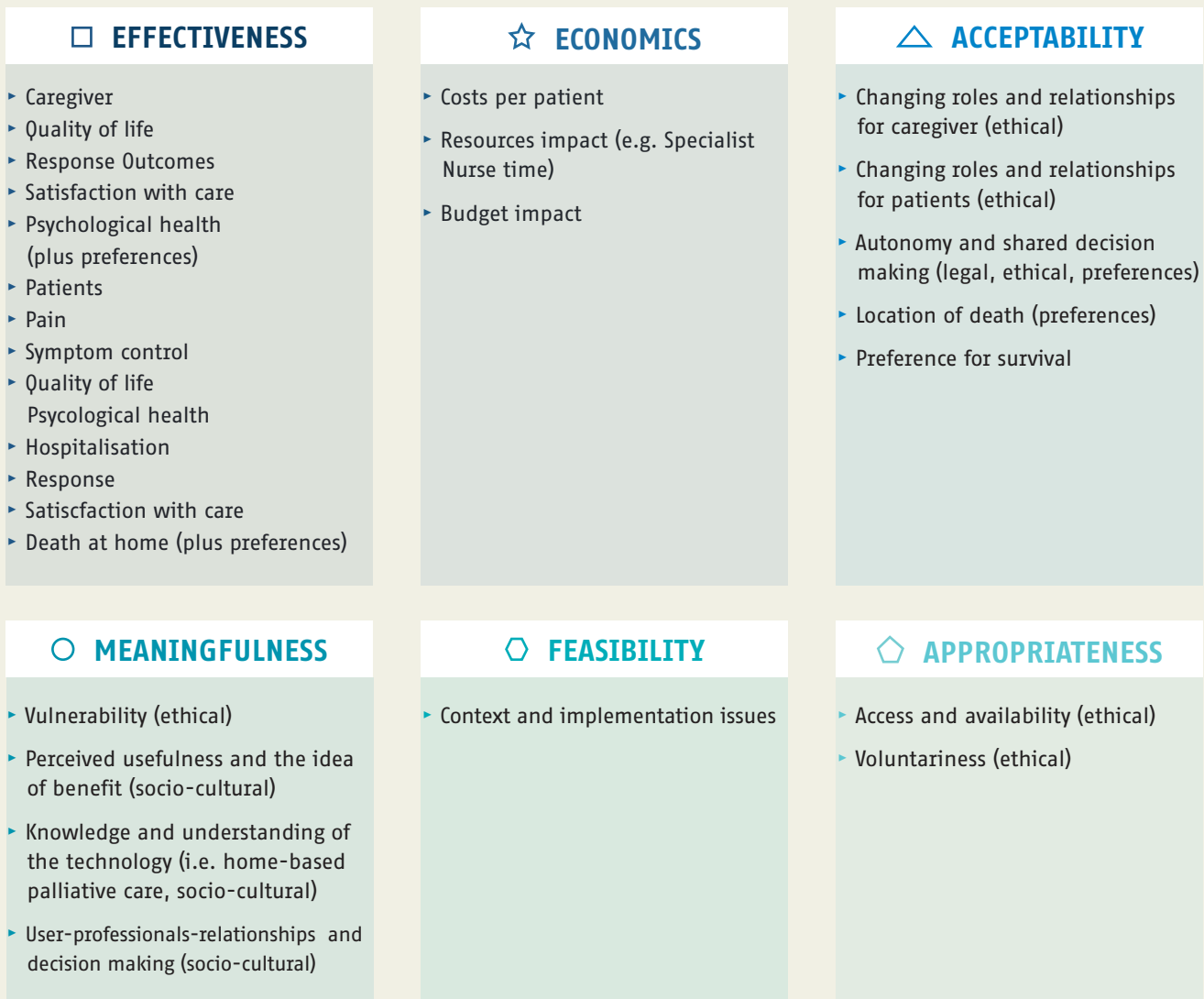


Table 2 The complexity characteristics of reinforced home based palliative care.

Characteristic	Application to palliative care
1 Multiple and changing perspectives	<p>Stakeholders include:</p> <ul style="list-style-type: none"> • Patients, carers and families. Though palliative care engages with customers holistically, each individual will have different perspectives reflected in their goals. • Health and social care professionals, people working in the charitable and voluntary sectors. • Local and national health and social care managers and policy makers, charitable and voluntary sectors agencies managers and policy makers. • All stakeholders have differing perspectives related to goals and outcomes.
2 Indeterminate phenomena	<ul style="list-style-type: none"> • The philosophy of individualised palliative care that responds to patient and caregiver preferences means that interventions should be flexible and tailored to individual need. Patient and carer needs will change over time, meaning that palliative care has to be flexible to changing circumstances. Furthermore, the concept of palliative care has evolved over time, initially being associated with cancer and more recently evolving to be appropriate for patients with any life-threatening or life-limiting illness. • Home based palliative care is not one single clearly defined/delimited intervention • Similarly reinforced carer support is not a single well defined intervention and may contain elements of support that are routinely provided within conventional care (e.g. informal training/education of carers).
3 Uncertain causality	<ul style="list-style-type: none"> • The COPE intervention within the set of reinforced home palliative care interventions was unique in having an explicit underpinning theory. However complexity of context makes the interpretation of empirical evidence base difficult, even well designed trials have difficulty determining causality. • Care providers from a range of agencies work with patients who have many different diseases and illness trajectories any combination of which may interact differently with the causal chain of the intervention. Additional difficulties for evaluation include ethical concerns about manipulating interventions considered to be beneficial to patients along with pragmatic problems of recruitment, attrition, data collection and missing data.
4 Unpredictable outcomes	<ul style="list-style-type: none"> • Over 500 outcome measures are used in palliative care. Hence, there is often a lack of consistency with regard to which outcomes are measured and the tools used to do this. • Additionally, there is uncertainty about which outcomes are most appropriate for the wide range of stakeholders, and how to balance these, especially if they are conflicting.
5 Historicity, time and path dependence	<ul style="list-style-type: none"> • Palliative care has changed over time and the philosophy of individualised care limits the generalizability and repeatability of an intervention. • The palliative care context within which the reinforced carer support intervention might act is dynamic. • Note the extent of these dynamic aspects would vary even throughout the UK. Internationally the palliative care systems would potentially commence from very different starting points.

Figure 2 The extended logic model to assist decision making showing the assessment results on Reinforced models of palliative care (sources of evidence are highlighted by numbers).



Key to numbers assigned within the symbols: Evidence informing the extended logic model resulted from the application of the following guidance: 1 = Lydahl et al. (2016a) 'Guidance for assessing effectiveness: economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies. [Online]. Available from: <http://www.integrate-hia.eu/downloads/> 2 = Van Hoor, et al. (eds). (2016a) Guidance for the assessment of treatment moderation and patients' preferences [Online]. Available from: <http://www.integrate-hia.eu/downloads/> 3 = Pfadenhauer et al. (2016) Guidance for the Assessment of Context and Implementation in Systematic Reviews and Health Technology Assessments (HTA) of Complex Interventions: The Context and Implementation for Complex Interventions (CCI) Framework [Online]. technology assessments of complex interventions & Rohwer et al. (2016) Guidance: Use of Logic Models in Health Technology Assessments of Complex Interventions [Online]. Available from: <http://www.integrate-hia.eu/downloads/>

□ EFFECTIVENESS	△ ACCEPTABILITY	◇ FEASIBILITY
☆ ECONOMICS	○ MEANINGFULNESS	◇ APPROPRIATENESS

an outcome consists of evidence from the assessment results of more than one assessment aspect (e.g. legal, ethical etc.), the outcome is assigned to several areas in the extended logic model to assist decision making. For instance, the outcome “Autonomy and shared decision making” was located in four different assessment aspects as the underlying evidence was obtained from the assessment of these four different aspects (legal issues, ethics, patient preferences, socio-cultural aspects).

2.9.6 Step 5 - HTA conclusion

Step 5 results in the HTA conclusion and recommendations. A mock decision making meeting was organised using Multiple Criteria Decision Analysis (MCDA), one method that may be used to support decision making in HTA. A group of 13 stakeholders (including 11 professionals involved in commissioning end of life services and two lay stakeholders in England) took part in

Box 1 Key results of the case study for HTA

Integration was enhanced in a number of ways within this case study. For example, use of the INTEGRATE-HTA Model provides a unifying framework for integration by organising diverse methods in a step based process. The INTEGRATE-HTA Model provides a useful structure for this report and could contribute to the future development of “integrated HTAs” by assisting the integration of different assessment aspects of complex technologies (i.e. effectiveness, economic ethical, legal and socio-cultural aspects as well as patient preferences, moderators of treatment outcomes and issues relating to context and implementation). It also assists the integration of stakeholder perspectives in HTA.

Integration was further assisted through the application of the CICI framework in the logic model and as the “best fit framework” in the qualitative review.

In the Demonstration-HTA, important aspects of home based palliative care were assessed including barriers and facilitators to the implementation of home based palliative care.

Identifying the most important assessment criteria at the outset of an HTA is valuable in assisting decisions about how to integrate subsequent evidence collection.

The logic model provided a flexible method to describe the system in which interactions between the participants, the intervention and the context occurs in home based palliative care. This enabled us to conceptualise the complexity of reinforced and non-reinforced home based palliative care.

Our understanding of complexity and the implications for HTA methods developed through application of the economic, ethical and socio-cultural economic assessments, which enabled identification of the complexity characteristics of rHBPC and HBPC and the palliative care system.

Information and advice gathered from lay and professional stakeholders in seven countries assisted in the identification of shared issues of importance in several countries. The added value of stakeholder involvement throughout the HTA process has been illustrated through the additional insights that they provided for researchers with regard to identifying priorities in palliative care and validating some of the findings presented (e.g. patient preferences, moderators of treatment effect). Additionally, they provided colloquial (informal) evidence based on their experiential knowledge to inform gaps in the evidence (e.g. effectiveness). This colloquial evidence can complement other types of evidence to enhance understanding of the technology, its application and its implications for practice and further research.

A variety of approaches were used to involve stakeholders, some of whom were vulnerable, in this case study. Extensive lay and professional stakeholder consultation took place in a number of different ways (i.e. face-face, via telephone and email and in a Skype meeting), throughout the case study, enabling the added value of their input into HTA to be identified. In addition to assisting in identifying the topic for the case study, stakeholder advice can complement and enrich traditional forms of evidence to provide additional insights into the evidence base without creating heavy workload demands for researchers or stakeholders themselves.

Although policy directives encourage stakeholder involvement in HTA, opinion about the ‘best’ methods of stakeholder involvement vary internationally. Methods and evaluation criteria for qualitative research approaches for stakeholder involvement are well documented. However, there is scope for further development of methods and evaluation criteria for consultative approaches to stakeholder involvement.

the meeting. MCDA guides stakeholders to weight the assessment criteria (effectiveness, cost effectiveness, acceptability etc.) based on a generic description of them. Stakeholders then scored the HTA results on a scale from +5 to -5 to indicate whether the intervention (i.e. reinforced home based palliative care) is “significantly better” or “significantly worse” than non-reinforced home based palliative care. A decision could not be finalised due to the limited time available. However, participants were still able to highlight a number of important issues related to the benefit of rHBPC and the relevant evidence that we had identified in the case study. For final decision making, these issues (e.g. difficulties in differentiating between reinforced and non-reinforced home care) should be taken into account.

3 RESULTS

3.1 KEY RESULTS OF THE CASE STUDY FOR HTA

Some of the concepts and methods developed in the INTEGRATE-HTA project have been successfully applied to an assessment of rHBPC and HBPC in this case study, suggesting that these are feasible and a potentially valuable addition to HTA methods.

3.2 KEY RESULTS OF THE CASE STUDY FOR PALLIATIVE CARE

The key results relating to the Demonstration-HTA of reinforced and non-reinforced models of home based palliative care are summarised in Box 2 with reference to each assessment criterion of the HTA-research question. These findings are based on the application of some key parts of the INTEGRATE-HTA guidances for the assessment of complex health technologies. Some gaps in the assessment will mean that the findings should be considered cautiously. Due to overlaps between the assessment criteria “Meaningfulness”, “Appropriateness” and “Acceptability”, evidence related to these terms needs to be read in conjunction with each other.

4 DISCUSSION

4.1 KEY STRENGTHS OF THE CASE STUDY

The case study has several strengths. Not only is home care a timely topic of relevance to stakeholders, the case study reveals the complexity of designing intervention studies in palliative care contexts. The case study demonstrates the potential value of some of the many concepts and methods developed by a multidisciplinary HTA research team within the INTEGRATE-HTA project. This includes demonstrating the value of the INTEGRATE-HTA Model as a unifying framework for integrating evidence from a variety of sources. The updated literature review about models of palliative care is helpful to those working in the field. This case study indicates the value of using Harvest plots as a methodological approach where meta-analysis is not appropriate or feasible. The economic analysis offers a provisional costing model that HTA researchers can use when considering the design of evaluative research of palliative care interventions with elements of carer support. The ethical analysis is helpful in highlighting the assumptions about family carers and the potential for undue pressure being placed upon them to contribute to home care.

Extensive lay and professional stakeholder consultations across seven countries is a major strength as the project focuses on a topic that is potentially relevant to a number of stakeholders in several countries. The case study indicates that a variety of methods can be used to engage stakeholders, and appear to be acceptable and effective in terms of providing stakeholders with a valuable voice within HTA. The presentation of new and novel evidence about reinforced and non-reinforced models of palliative care in a comprehensive manner may direct future research activity and assist decision making about commissioning future palliative care services.

4.2 KEY LIMITATIONS OF THE CASE STUDY

Despite its strengths, the case study was hampered by not being associated with a “real world” decision making process, as the assessment criteria and integration process was not explicit at an early

Box 2 Key results of the case study for palliative care

Effectiveness: The effectiveness evidence suggests that reinforced models of home based palliative care show largely inconsistent effects. Most studies show no effect for reinforced home based palliative care interventions compared to non-reinforced home based interventions with respect to patient and caregiver outcomes. Some positive effects were seen for patient symptom control and psychological health outcomes, as well as for caregiver quality of life, psychological health and response outcomes. However, the overall impact appears to be neutral for both patient and caregiver outcomes. The gap analysis and the expert consultations complemented evidence from the primary studies, suggesting that the results may have arisen for a variety of reasons. These reasons include the heterogeneous nature of usual (i.e. non-reinforced) care, which is individually tailored for patients and informal carers throughout the illness trajectory along with the assessment of outcomes that may not reflect the purpose of the intervention and inappropriate choice of research design.

Moderators of treatment effect: The limited evidence about moderators of treatment effect for rHBPC and HBPC suggests that attention should be given to patient survival, place of death and informal caregiver's psychological health in terms of manageability and grief.

Economics: The economic analysis considered the impact of introducing a specific reinforced carer support intervention – the COPE intervention – as a new component within a home palliative care system in England. The marginal impact on resource use and costs were modelled and should be considered in conjunction with the detailed analysis of effectiveness presented separately. The economic analysis was based on a National Health Service (NHS) and Personal Social Services (PSS) perspective; patient and carer costs were not included in this case study. The results of the economic analysis suggest that the addition of reinforced carer support interventions in home-based palliative care may be cost saving, but these provisional estimates are based only on an elicitation exercise and are subject to significant uncertainty. The largest component of projected cost savings arises from the potential to reduce avoidable emergency admissions to hospital by providing formal training and support to the carer. However, many potential barriers to realising these savings exist. Interventions to support carers need to be considered within wider initiatives to provide co-ordinated palliative care, with mechanisms to review and adapt the design of the reinforcement components.

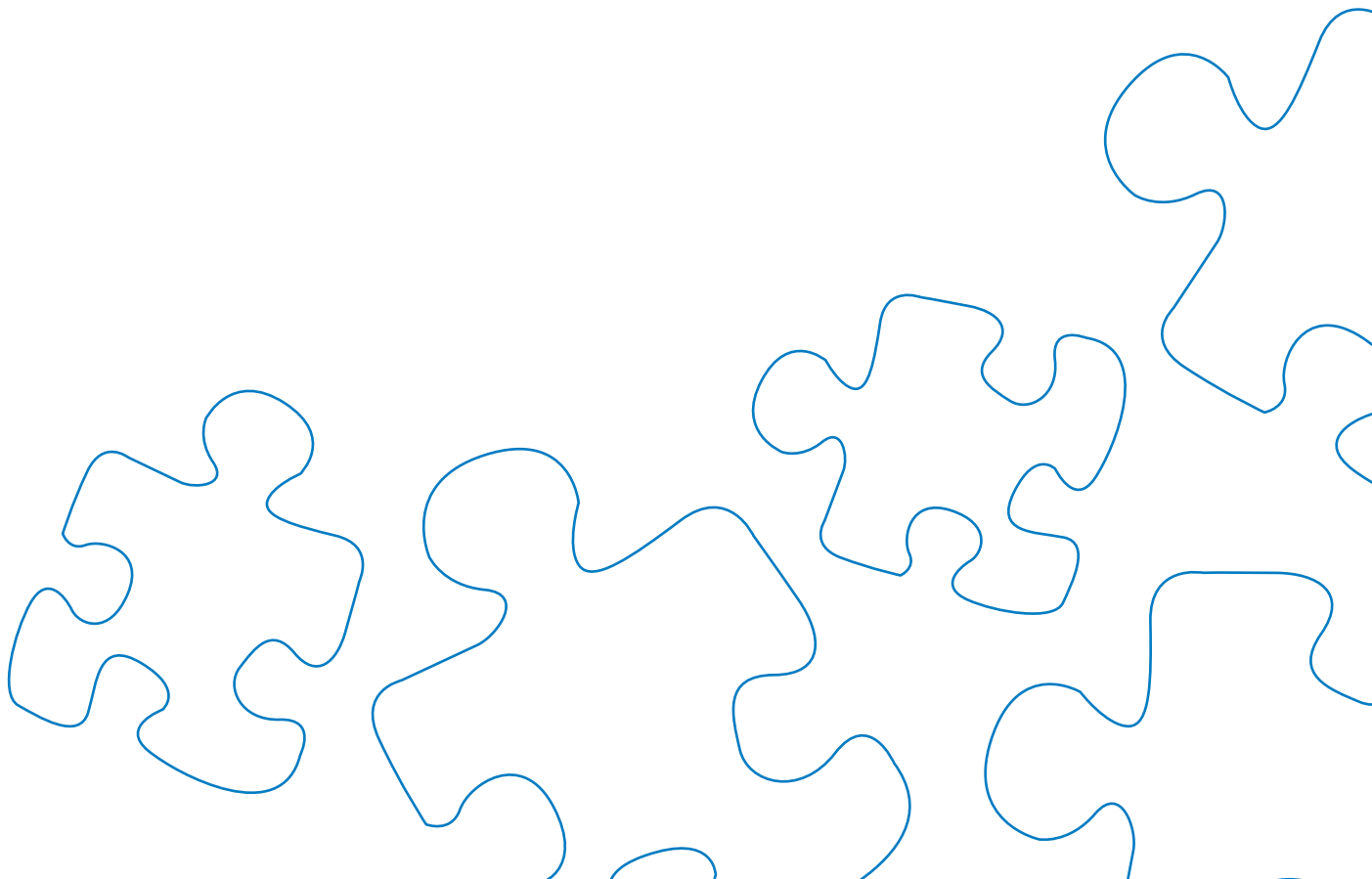
Acceptability: Evidence for acceptability comes from the ethical, legal, socio-cultural assessments and the assessment of patient preferences, including both patient preferences for how care is provided and for specific treatment outcomes. Most patients prefer quality rather than quantity of life and would prefer to die at home. The ethical assessment identified access and availability as issues influencing the acceptability of rHBPC and HBPC. Both the ethical and socio-cultural assessments identified that rHBPC and HBPC results in changing roles and relationships for patients and informal carers, both of whom may experience stigma and loss of social status. Additionally, relationships with healthcare professionals may also change. Findings from the assessment of socio-cultural aspects indicate that informal carers may lack clarity about their responsibilities, lack training for their role, experience role conflict and suffer illness as a result of care giving which may be influenced by additional caregiver support in rHBPC. rHBPC and HBPC pose challenges to carer voluntariness (willingness to take on the role), shared decision making and patient and carer autonomy and conflicts of interest can arise between patients and family carers the latter also being raised as a concern in the legal assessment. Reducing the burden on families is important as is the desire to preserve autonomy. rHBPC aims to provide support to informal carers and could change the way informal carers deal with the situation as well as how professional carers value the role of informal carers and the related burden. The socio-cultural assessment indicated that rHBPC may empower informal carers to make an informed decision about taking over or continuing the caring role. However, these effects are uncertain and rHBPC may be problematic in terms of ensuring informed consent and preserving patient autonomy. Not only is there a risk that family pressure may oppose the patient's free informed consent or dissent, conflicts of interest can arise between patients and family carers. The dual role of family members as carers as well as a source for substituted informed consent and the higher number of people that might be involved and need access to the patient's data may also influence acceptability.

Meaningfulness: Evidence for meaningfulness also comes from the ethical and socio-cultural assessment. Both assessments identified that patients requiring rHBPC and HBPC are vulnerable as palliative care is associated with stigma. The patient centred approach and individual relationships that rHBPC and HBPC offers patients, carers and professionals are valued by stakeholders. rHBPC and HBPC offer benefits for patients who feel safe and secure, as well as for relatives who can be close to the patient and manage their lives without the added burden of hospital visits. rHBPC and HBPC allow professionals to provide individualised care. Although much of the information collected was positive, it is worth noting that concerns were expressed in the socio-cultural assessment about the lack of understanding about the term palliative care and lack of clarity about when and how to access palliative care. Additionally carers reported concerns that their request for services was limited to what they know about and the 'battles' to gain information and funding had negative consequences for their own health. These issues may be positively influenced by additional support through rHBPC.

Appropriateness: Evidence from the ethical and the socio-cultural assessment informs appropriateness. Concerns exist about fairness and equity in terms of the just distribution of palliative care services and the access and availability of palliative care, particularly HBPC due to the lack of availability of services and specific professionals. This is compounded by concerns about defining "end of life care" which can lead to uncertainties concerning access to rHBPC and HBPC. Service access may vary geographically. Easy (e.g. out of hours), equitable (e.g. to all groups, irrespective of diagnosis) and timely (e.g. not restricted only to the last months of life) access to palliative care and support for family carers post bereavement is required. Home based palliative care may challenge carer autonomy with regard to voluntariness of role acquisition and the implementation, use and withdrawal of home based palliative care services. The socio-cultural assessment highlights a number of reasons for difficulties in access to palliative care, raising concerns that access to HBPC and rHBPC can become an issue of social inequality.

Feasibility: Evidence from the qualitative review, ethical and socio-cultural assessments inform feasibility. The successful delivery of home based palliative care relies on the provider, the organisation and structure in which they are embedded, as well as the micro-context of the family and home in which a palliative care patient and his family are living. A number of barriers and facilitators to the implementation of home based palliative care were identified in a qualitative review. Additionally, the ethical assessment highlighted the need for shared decision making at the outset of HBPC, acknowledging that this challenges patient and carer autonomy as the result of communication difficulties arising from a variety of causes (e.g. patient capacity, physician / staff paternalism or restrictions on choices available). All three assessments indicated that informal care imposes a burden on the lay caregiver, who needs to be willing to undertake the role and supported in it. However, the informal carer's needs for support fail to be identified or addressed for a variety of reasons; some related to informal carers' lack of willingness to disclose their needs and others relating to professional carers' inability to identify caregiver needs, lack of training, resources and structural barriers. The socio-cultural assessment suggests that the feasibility of HBPC is associated with the number of agencies involved in providing care and the degree to which services are co-ordinated, which may be influenced by professional training, cultures and co-operation styles. Furthermore, access of the informal caregiver to the health and social system, difficulties in navigating the system as well as barriers to actually utilizing them were recurrent themes in the qualitative review.

stage. This made integration more difficult after the identification and synthesis of evidence. Resource constraints influenced the degree to which the concepts and methods developed within the INTEGRATE-HTA project have been tested. Limited quantity and quality of evidence exists about reinforced and non-reinforced models of home based palliative care and there was little directly relevant evidence in some aspects of the assessment. Consequently, the case study findings are heavily reliant on a limited number of a number of lay and professional stakeholders with experience and expertise in palliative care. Difficulties arose in achieving a shared understanding about palliative care terms and the interventions of interest among the research team and with the diverse range of international stakeholders. For example, the term 'reinforced' care is not widely recognised by clinicians or policy makers. Similarities and overlaps between reinforced and non-reinforced home-based models of palliative care and the fact that these terms are not widely recognized or used in practice made assessment particularly difficult. This, coupled with poor descriptions of the heterogeneous models in the literature, resulted in some lack of clarity about the intervention and comparator for stakeholders. The U.K. focus for the case study means that there needs to be careful consideration before it can be generalised to other countries in Europe or beyond. Palliative care needs to be understood in the cultural, economic and healthcare system in which it is embedded as acknowledged in the analysis of socio-cultural aspects of HTA.



5 CONCLUSIONS

Box 3 Conclusions for HTA

The case study demonstrates the application of some of the concepts and methods developed within the INTEGRATE-HTA project to the assessment of rHBPC and HBPC, as one example of a complex health technology. Findings suggest that all of the concepts and methods applied in this case study appear to be feasible and potentially valuable additions to HTA methods.

However, a number of shared difficulties undermined the development of an integrated HTA, including similarities between, and poor descriptions of, both intervention and comparator models within the evidence base. This created uncertainty for researchers trying to differentiate between rHBPC and HBPC for assessment using evidence review. Furthermore, the heterogeneous nature of rHBPC and stakeholders' lack of familiarity with the term 'reinforced' palliative care resulted in lack of clarity and shared understandings of rHBPC and HBPC.

The limited amount and quality of evidence available about rHBPC and HBPC restrict the conclusions that can be drawn from the case study. As such, careful interpretation is required when considering the case study results. Further application of the concepts and methods developed within the INTEGRATE-HTA project in the assessment of other complex technologies is warranted.

Box 4 Conclusions for palliative care

Reinforced and non-reinforced home-based palliative care have all the characteristics of complex health technologies. The existing evidence about rHBPC and HBPC is limited in terms of quantity and quality. The evidence that does exist is too limited to draw firm conclusions about whether reinforced models are more acceptable, feasible, appropriate, meaningful, effective, cost-effective and patient-centred models than non-reinforced models of home based palliative care for adults.

6 RECOMMENDATIONS FOR HTA

The case study report has provided useful insights in the application of the methods and concepts developed in the INTEGRATE-HTA project report. Based on the results of the Demonstration-HTA, recommendations for HTA are shown in Box 5.

Box 5 Recommendations for HTA

- 1 **Integration should be taking place from the very beginning:** Framing of the HTA question, and developing this in light of the understanding of the system within which the intervention will be implemented, is the very first step for an integrated HTA. In particular, consideration should be given to how the assessment criteria of the HTA research question will be informed by the evidence collected. Accordingly, the different assessment aspects should be considered to address overlaps between the assessment results (e.g. assessment results regarding patient characteristics can feed into the assessment of effectiveness). A "real world" decision making process will assist in making the assessment criteria and process explicit at an early stage.

Further work is needed to ensure that consideration has been given to the integration process well before specific elements of the evidence required for the HTA are identified.

Stakeholder consultation is required to develop an understanding of the most important issues to address in the HTA. Involving stakeholders throughout the HTA process is important for researchers to gain additional perspectives that assist in the interpretation of evidence. Stakeholder consultation provides insights into the criteria that they consider to be important in decision making; information that could assist decision makers within each context and for each HTA question posed.

2 Complexity characteristics of the intervention should be assessed and taken into consideration throughout HTA: The complexity characteristics of the intervention may not be apparent at the outset and their relevance and significance may emerge during the evidence synthesis process. It is important that an assessment of complexity characteristics is undertaken and a common understanding of the intervention's complexity is established in the research team.

3 Stakeholder involvement throughout the HTA process should be encouraged: Researchers should involve stakeholders throughout the HTA process to ensure that their experience and expertise informs the focus of the HTA, the evidence and interpretation of the the evidence. This includes careful consideration of the range and diversity of different stakeholders who may usefully inform the HTA process.

Stakeholder involvement should be planned at the outset of the project. Attention should be given to the most appropriate methods of stakeholder involvement and the co-ordination of stakeholder involvement in HTA. Co-ordination issues should specifically consider whether stakeholder input can be shared amongst the assessment aspects (e.g. for the assessment of economic and ethical aspects) or whether each aspect requires separate stakeholder involvement. Stakeholder involvement also needs to be timely with regard to the activity (e.g. to coincide with development of the project scope or analysis of the findings).

International stakeholder consultation requires understanding of different philosophies and recommendations about the best approaches to stakeholder involvement in each country. Different approaches to involvement require different ethical approvals; the use of different methods and language to describe research / involvement activities. International research teams involving stakeholders in different countries should pay particular attention to methods used for the synthesis of information obtained through stakeholder consultation and the interpretation of the findings. The advice provided by stakeholders should be viewed as colloquial (informal) evidence based on experiential knowledge. Methods need to be developed to evaluate the impact of stakeholder involvement in HTA, especially in areas where both the quantity and quality of the evidence is limited.

The purpose, timing and methods of stakeholder involvement are crucial if it is to be feasible, acceptable and effective. Better understanding should be developed, through further research, of the value of lay stakeholder input into HTA and how best to elicit their views by developing a range of methods and evaluation criteria. For example, lay and professional stakeholders provide heterogeneous perspectives and valuable insight and understanding of the technology, which saves time. Stakeholder contributions to the HTA should be adequately resourced in terms of manpower, time and finance to ensure realistic expectations of what can achieve.

The purpose and potential impact of stakeholder consultation should be clearly articulated to all stakeholders so that everyone involved has realistic and shared expectations about this. Consideration should be given to the potential positive, negative, short and long term impact of stakeholder involvement in terms of reach and significance. A dialogue should be established with stakeholders throughout the project. Feedback should be given to stakeholders about the value of their input into the HTA process and the changes made as a result of the advice or information they provide. An explanation should be given to stakeholders for decisions made, particularly if this conflicts with the advice and information they provide.

- 4 **The methods and concepts developed within the INTEGRATE-HTA project should be applied to other complex technologies:** The methods developed in the INTEGRATE-HTA project should be applied to other complex technologies by HTA researchers. This is essential to demonstrate their value in an HTA undertaken in a “real world” rather than a methodological research project setting. Further case studies could also test their value in different types of HTA and in assessing different technologies and evaluate the extent to which they are found to be feasible and useful by both those undertaking, and acting on, the findings of more integrated, patient-centred HTA methods.

7 KEY MESSAGES AND RECOMMENDATIONS FOR PALLIATIVE CARE

A number of key messages were identified for service commissioners, health and social care practitioners, academics, carers and service users in the case study. The messages are of interest to all stakeholders (not exclusive to each group), although some may have more relevance to specific groups.

Before reading the key messages and recommendations arising from the study (see box 6), we provide an overview of what is known about palliative care for readers who are not familiar with this (see bullet points below).

- ▶ European populations are ageing; people are living with more complex, chronic conditions and a greater number of co-morbidities. Many people with chronic conditions have palliative care needs.
- ▶ Palliative care aims to relieve suffering and improve quality of life for both patients and families throughout a life limiting illness, not just at the end of life. Palliative care is highly complex as it is interdisciplinary and holistic in nature (i.e. addresses physical, psychological, social, spiritual and emotional needs) and treats the patient and family as the ‘unit of care’. Palliative care also provides support for family carers post bereavement.
- ▶ In the U.K. (the context for the case study), palliative care is delivered by two distinct categories of health and social care professionals: specialist and generalist palliative care providers. ‘Generalist palliative care’ providers are health professionals who have not received specific training in palliative care, but routinely provide health care for patients at the end of their lives, which may include general practitioners, community nurses, nursing home staff and hospital staff. ‘Specialist palliative care’ is provided by teams of multidisciplinary palliative care professionals who have undertaken specialist training in palliative care and work only within the field of palliative care.
- ▶ Informal carers have a key role in supporting people with palliative care needs, including those approaching their end of life. Informal carers are lay people in a close supportive role who undertake vital care work and emotional management, although they may or may not be family members. Care is often provided by a complex network of family, friends and neighbours, each contributing different aspects of practical and emotional care, and economic resources. Not all families may be functional or supportive and not all homes may be safe, comfortable or well equipped for end of life care. Much evidence shows patients have a preference for care and death at home. Interventions should, therefore, reflect this preference by aiming to deliver care outside institutional settings where possible to enable patients to remain at home if desired.
- ▶ Care at home can be rewarding for those closest to the patient, including the informal caregiver. However, the role of informal carers differs in each family and is known to change over time. Providing home care may increase the burden of informal caregivers close to the patient, causing physical, psychological and social stress both during care and after the death of the patient.
- ▶ Providing support for informal carers is important is important as informal carers are known to suffer high levels of stress and burden as a result of their caregiving responsibilities. Caregiver stress and burden may result in a breakdown of informal caregiving and increase costs and health service use should the carer become ill themselves or unable to continue in their role.
- ▶ The need to support informal carers in their caregiving role is important and widely acknowledged in policy and service commissioning documents.
- ▶ There may be a limited window of opportunity to support informal carers, whose needs may change over time and with the patient’s condition and their own healthcare needs. Additionally, the provision of support for informal caregivers relies on them being identified and many people do not consider themselves to be ‘carers.’
- ▶ Practitioners should assess each individual’s willingness (voluntariness) to take on the informal caregiving role and their needs for support before they commence in role.

Box 6 Key messages and recommendations for palliative care

1 Home based palliative care services have been developed with and without an additional component of caregiver support. These models are known as “reinforced” (rHBPC) and “non-reinforced” home based palliative care (HBPC) respectively. Although diverse (heterogenous) in nature, reinforced (rHBPC) and non-reinforced models of home based palliative care (HBPC) may be similar in several respects. HBPC models primarily focus on patients, though support may also be directed towards caregivers on an ad hoc basis rather than as specific planned intervention. rHBPC will always include an intentional, explicit attempt to support informal caregivers in addition to the care given to patients. ‘Support’ is broadly defined as any psycho-educational intervention aimed at providing assistance to caregivers (e.g. individual or group counselling, education, advice or respite services). Hence, this support may be more active in nature, aiming to prepare the caregiver for the patient care to come, by teaching the necessary skills, or it may be reactive in nature, aiming to address psychological health burden of the lay caregiver resulting from care. Some reinforced models are underpinned by specific theories, such as stress-coping while others may not be based on theory.

2 Professionals should be alert to carer’s needs for support and consider ways that their needs can be met.

3 Decision makers need to further consider how best to support informal carers and where possible, support should reflect the needs and preferences of both patients and carers. There is a limited amount and quality of research evidence about all aspects of reinforced (rHBPC) and non-reinforced home based palliative care (HBPC) on which to base decisions about which services should be commissioned. Poor reporting about the components of rHBPC and HBPC hinders comparisons of the interventions, increasing limitations relating to the volume of available evidence. Additionally, stakeholders’ lack of familiarity with the term ‘reinforced’ palliative care resulted in lack of clarity and shared understandings of rHBPC and HBPC.

Reinforced home-based palliative care interventions were neither better nor worse than non-reinforced home-based care with respect to patient outcomes and most showed no effect across caregiver outcomes. It is possible that the outcome measures used are not sensitive enough to detect relevant effects in this population.

In the absence of cost effectiveness data, expert elicitations provided insight into costs of reinforced home based palliative care. Cost data supports the implementation of home based models of palliative care with the potential to be cost saving, largely because of an expected reduced need for hospitalization of the patient who is being cared for by the recipient of rHBPC.

4 In addition to cost and clinical effectiveness evidence, decision makers should take account of other types of evidence that may assist in capturing the complexity of palliative care. Decision makers indicated their desire to take account of a wider range of evidence. Doing so relies on HTA researchers’ ability to undertake assessments of a variety of aspects (e.g. socio-cultural, legal and ethical issues; context and implementation issues as well as patient preferences).

5 Although most patients prefer quality rather than quantity of life and to die at home, evidence suggests that single patients who live alone are less likely to die at home. Patients without caregivers; with uncontrollable physical symptoms; where physicians may not be available or where concerns exist about responding to sudden changes are also less likely to die at home.

6 Although most patients prefer to die in the security of their own home, determining the acceptability, meaningfulness and appropriateness of rHBPC and HBPC proved challenging in light of the limited quality and quantity of evidence about models of home based palliative care and challenges associated with HBPC.

7 In terms of acceptability, the challenges associated with home based palliative care for informal caregivers include adapting to changing roles and relationships amongst the patient-carer dyad and professionals; preserving patient and informal caregiver independence in decision making (autonomy) and avoiding caregiver burden.

- 8 Practitioners, informal carers and patients should be alert to the effects of home based palliative care in terms of changing roles and relationships, the possible stigma and loss of social status experienced and burden that this may impose on the lay carer.

- 9 In terms of meaningfulness, the challenges associated with home based palliative care relate to alleviating the carer burden and subsequent ill health.

- 10 As a priority, informal carers need equitable access to high quality, flexible services that are able to respond to individual needs and circumstances. A number of interventions and services have been developed to support informal carers. However, concerns exist regarding the availability, accessibility and equity of palliative care provision and the challenges this poses to carer autonomy. Tailored, responsive support may be needed because each family and caregiving situation is unique.

- 11 In terms of feasibility, a number of barriers and facilitators exist to the implementation of home based palliative care, notably in supporting informal carers in their role. These barriers and enablers related to the provider; the organisation and structure in which they are embedded as well as the micro-context of the family and home in which a palliative care patient and his family are living. For example, communication difficulties arise from a variety of causes (e.g. patient capacity, physician / staff paternalism or service restrictions on choices available). Lay carers' willingness to undertake the role and be supported in it influences the situation. Some barriers related to informal carers' lack of willingness to disclose their needs and other barriers related to professional carers' inability to identify carer needs, lack of training or resources. The feasibility of HBPC is associated with the number of agencies involved in providing care and the degree to which services are co-ordinated, which may be influenced by professional training, cultures and co-operation styles. Furthermore, access of the informal carer to the health and social system, difficulties in navigating the system as well as barriers to actually utilizing them were often reported. All these issues need to be considered when making decisions about how best to support patients and their carers.

- 12 Decision makers, service providers, practitioners, informal carers and patients require a clear understanding of the potential barriers and facilitators of home based palliative care and strategies need to be developed to overcome the barriers (e.g. equity of access, providing information and assisting informal carers to navigate the health care system).

- 13 Interventions to support carers need to be considered within wider initiatives to provide co-ordinated palliative care, with mechanism to review and adapt the design of the reinforcement components.

- 14 The limited amount and quality of evidence that was available about rHBPC and HBPC and the lack of directly relevant evidence in some aspects of the assessment impeded the conclusions that can be drawn from the application of the application in this case study. As a result, the case study findings are heavily reliant on a limited number of experts. Careful interpretation is required when considering the case study results.

- 15 Differences in palliative care provision across Europe means that careful consideration is required in order to determine which, if any, of the findings could be potentially applicable across Europe.

- 16 Further evidence is required about all aspects of home based models of palliative care assessed in this HTA case study. With regard to research examining the effectiveness of home based models of palliative care, careful consideration should be given to outcome measures to ensure that these reflect the purpose of the intervention, the choice of research design and patient and carer perspectives about what is important. There is a need for more research to understand how support might best be tailored to meet the different circumstances and specific needs of different patients and carers.

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- 17 Service commissioners should consider the use of mixed methods, qualitative research and action research as a potential way of evaluating services. Randomised controlled trials and other types of experimental evidence are often not feasible in palliative care and action research methods are also a useful way to engage with local clinicians, patients and informal carers, who are key stakeholders, in the process of service development.
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- 18 Better reporting of the components of reinforced and non-reinforced models of palliative care is required in primary studies and for review level evidence. With some adaption of the tool, this could be achieved using the TIDiER framework (Hoffmann et al., 2014) in primary research studies as well as reviews. This will enable decision makers to determine the resource implications associated with replicating models

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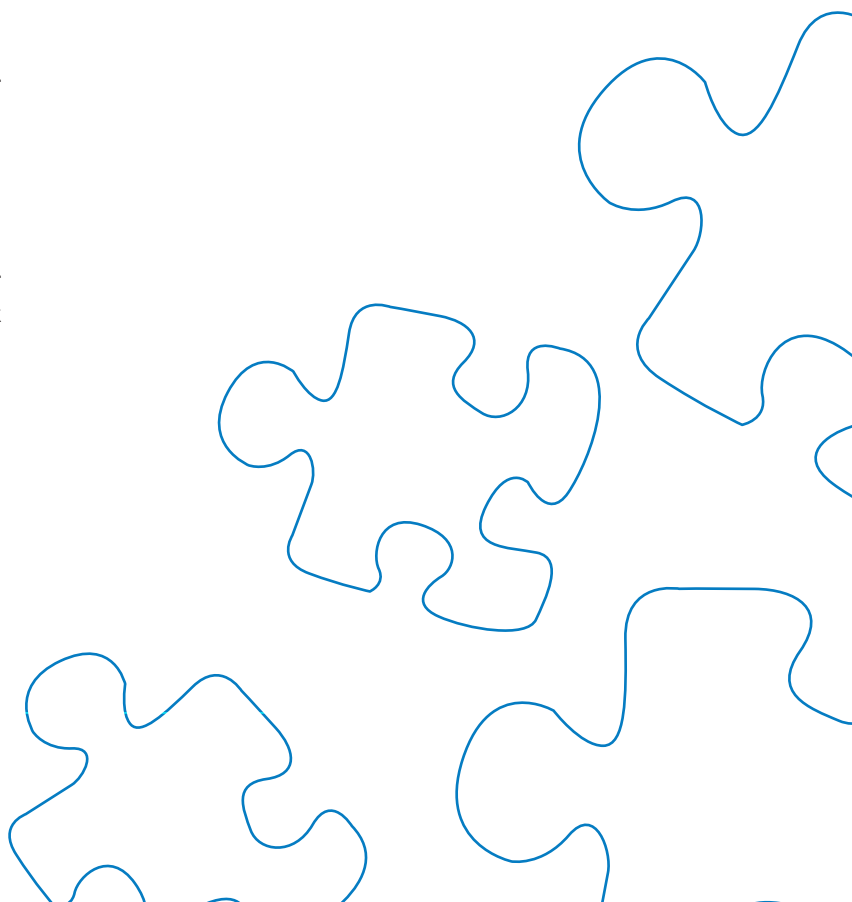
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- 1 Integrated health technology assessment for evaluating complex technologies (INTEGRATE-HTA): An introduction to the guidances
- 2 Guidance on the integrated assessment of complex health technologies – The INTEGRATE-HTA Model
- 3 Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies
- 4 Guidance for the assessment of treatment moderation and patients' preferences
- 5 Guidance for the Assessment of Context and Implementation in Health Technology Assessments (HTA) and Systematic Reviews of Complex Interventions: The Context and Implementation of Complex Interventions (CICI) Framework
- 6 Guidance on the use of logic models in health technology assessments of complex interventions
- 7 Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex intervention



INTEGRATE-HTA



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