

What has palliative care research already achieved?

The following broad themes of research can be identified.

Prevalence of symptoms

Prevalence of pain and of other symptoms in patients with advanced incurable illness (cancer and non-cancer).

Pain control

Assessments of the efficacy of specific approaches to pain control and evaluation of pain control programmes [e.g. validation studies of the World Health Organization (WHO) method for pain relief].

Control of other symptoms

Assessments of the efficacy of other symptom control measures (e.g. for dyspnoea, nausea and vomiting).

Needs/experiences of patients

Assessments of the unmet psychological, social, spiritual, financial or other needs of patients.

Communication skills

Assessments of the communication skills of health professionals and the efficacy of educational programmes.

Studies of carers

Studies of the care provided to dying patients as perceived by bereaved relatives/carers and studies of the needs of carers themselves.

Conventional care

Studies documenting deficiencies in conventional care both in hospitals and in the community.

Place of death

Studies assessing the proportions of patients dying at home, in hospital and in hospices (including variations over time and according to social deprivation) and studies evaluating patients' preferences regarding place of death.

Bereavement

Studies following bereavement and the development of assessment tools to identify those at high risk of protracted grief.

Specialist palliative care services

Studies documenting the evolution of specialist palliative care services and some studies documenting the effectiveness of these services (e.g. measured in terms of symptom control and satisfaction with care).

Assessment tools

Some developments in the validation of quality of life measures for use in audit and research in palliative care settings.

Policy issues

Studies which identify the impact of key policy changes on the continued development of specialist palliative care services.

One of the features of successful research in palliative care is that it has involved a wide range of disciplines including psychiatrists, sociologists and epidemiologists, as well as those working directly within the specialty.

Why has palliative care research not achieved more?

Lack of research culture

The hospice movement developed as a radical alternative to existing care for dying people, out-with the National Health Service (NHS) and reliant on charitable and voluntary support for its work. Palliative care services, both in hospices and in the community, have developed rapidly in response to the clinical needs of patients and their carers. Meeting the needs for care has, perhaps understandably, tended to take priority over the need to establish a sound evidence base.

Research skills

Until relatively recently, there has been a lack of research skills among palliative care professionals at all levels and in all disciplines. Many senior professionals in palliative care have not been trained extensively in research methodology and have not had extensive experience in conducting research. Those currently in training frequently have had little direct exposure to those who can act as mentors for research. Few research training programmes and fellowships have been available. The palliative care collaboratives under NCRI, for instance, aim to facilitate such linking and mentorship.

Isolation

Most hospices and home care teams are relatively small and lack both the critical mass and the infrastructure to conduct independent, high quality research. The geographical isolation of palliative care units from each other and from academic institutions hampers the development of a research culture and the development of links with other disciplines in the social and human sciences.

Methodological issues

The ethical and practical difficulties related to conducting research in patients with only a very limited life expectancy should not be underestimated. Staff may be ambivalent regarding the ethical justification for asking sick and dependent patients to participate in studies which require their time and effort. The presence of multiple variables in a high proportion of patients who are eligible for studies potentially increases the sample size required for statistically significant

results. Attrition (loss of) of patients during the study period, either due to deterioration in health or to death, is frequently encountered. The period of follow-up required to assess the outcome of an intervention may be longer than the duration of admissions to hospices or palliative care units. Difficulties in defining who is a palliative care patient pose problems for palliative care research and providers. Solutions include: placing more understanding and describing the patient sample in any given study, more longitudinal research to improve our understanding of needs and preferences of patients at different stages of illness, better prognostication and clearer recruitment criteria.

Research instruments

Quality of life instruments to assess outcomes of palliative care may differ from those developed for other purposes or, at the very least, require validation in a relevant patient population. Much more work on instrument development and evaluation is needed, but the absence of a perfect instrument should not be accepted as a reason for delaying research efforts.

Outcome measures

Palliative care poses particular challenges in designing outcome measures that are sensitive and relevant to patients. When evaluating how palliative care impacts upon patients, common outcome measures do not apply, as the inevitable outcome is death. Palliative care interventions are not simple and cannot easily be standardised without threatening the ethos of palliative care.

Research funding

Funding for palliative care research has, at least until recently, been scarce. However, the importance of funding for such research is now being increasingly recognized. Research topics relevant to palliative care are prominent amongst the areas given very high priority in the NHS Research and Development Programme on Cancer.

Although the major cancer charities all contribute to research into care, this is not their first priority. The primary emphasis of the two leading cancer research charities (Imperial Cancer Research Fund and Cancer Research Campaign) is on the prevention and cure of cancer, though both have a commitment to research into the psychological consequences of cancer. The primary remit of the two largest cancer care charities (Macmillan Cancer Support and Marie Curie Cancer Care) is on the

delivery of care, though again both have now recognized the need for research and development programmes.

Further Reading:

Grande G and Ingleton C (2008) Research in Palliative Care. Chapter 32 pp 625-643. In Payne S, Seymour J and Ingleton C (eds). *Palliative Care Nursing: Principles and Evidence for Practice*. Berkshire: McGraw-Hill.

Ethical issues in palliative care research

Declaration of Helsinki states that:

- Research on human subjects must conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature;
- The design of the study must be clearly formulated and must be scientifically valid;
- The research should be carried out by scientifically qualified people or be supervised by them;
- Concerns over the interests of the subject must always prevail over the interests of science and society;
- There must be informed consent;
- In the treatment of a sick person, the physician must be free to use a new diagnostic and therapeutic measure if it offers the hope of saving life or alleviating suffering;
- In any study every patient should be assured of the best proven diagnostic and therapeutic measures;
- The refusal of a patient to participate must never interfere with the relationship of the doctor with the patient.

Need to consider:

- Benefits and risks
- Patient consent
- Deception
- Effects of methodology
- Confidentiality
- Who will have access to the data?
- Intrusion
- False hopes

Speck (2008) suggests several safeguards for protecting the interests of patients participating in palliative care research. These include:

- Monitoring procedures for gaining consent, including renegotiating consent at intervals during the research;
- Careful piloting of research methods to determine the impact of the research on participants;

- Being flexible- particularly in relation to the completeness and timing of observations to ensure that the privacy of terminally ill patients is not invaded un-necessarily.

....a study is only ethically sound if its risks are reasonable in proportion to its potential benefits, and the knowledge to be gained. Thus palliative care researchers....must demonstrate that their research questions are important, their methods are appropriate to produce valid results, and their findings are generalisable (Cassarett et al 2003: 5).

Aspects involved in process of obtaining ethical approval

1. The scientific validity of the study (already peer reviewed).
2. User involvement in research design (especially pertinent in palliative care).
3. Does the researcher/research team have the necessary skills?
4. Does the research ethics committee have the necessary skills?
5. Recruitment of participants.
6. Consent: information + consent forms.
7. Confidentiality and data protection.
8. Community considerations – relevance of any results to concerned community.

References

Casarett D, Knebel A and Helmers K (2003) Ethical challenges in palliative care research. *Journal of Pain and Symptom Management* 25: 3-5

Speck P (2008) How to gain research ethics approval. Chapter 17 pp 275-282. In Addington-Hall et al (eds) *Research Methods in Palliative Care*. Oxford University Press: Oxford.

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Babies and consent: yet another NHS scandal

But it should lead to improvements in research governance within the NHS

News p 1291

The chief medical officer of England has a slide that he often shows of a long list of scandals within the NHS. He must now add to his list the failures in the paediatric department in North Staffordshire Hospital (p 1291). A review of what happened in the hospital shows that the case is complex, but the story will probably play out in the media and in public consciousness as babies being entered into a dubious trial of a new treatment without their parents' consent.¹ The worst single accusation is that consent forms were forged, and the police and the General Medical Council are investigating that possibility. At best, the North Staffordshire episode will lead to an overdue improvement in research practice throughout the NHS. At worst, it will further undermine public confidence in the NHS and doctors and lead to a proliferation in bureaucracy that will increase the difficulties of doing research.

The North Staffordshire review started out by examining complaints about consent for a trial of continuous negative extrathoracic pressure (CNEP) in premature babies, but the panel found that it had to consider other issues. These included other research, the routine use of CNEP to treat bronchiolitis, and the use of covert video surveillance to detect Munchausen syndrome by proxy. The panel was thus struggling with several issues at once, but its greatest difficulty was working out what was acceptable at the time the CNEP research was done in the early 1990s. The world has since changed dramatically. In 1990 people were mostly happy to believe that "doctor knows best." Obtaining consent was often a formality rather than an informed, two way discussion of choices, risks, and benefits.

At the *BMJ* we can see how the world has changed by looking at the uncontrolled trial we published from North Staffordshire Hospital on the use of CNEP in premature babies in 1989.² We would reject such a study now, insisting on a randomised controlled trial. We would now expect the paper to make clear that the ethics committee approved the trial and that patients gave fully informed consent. In 1989 we didn't have such expectations. I labour this point because it has been a central difficulty for the review panel in allocating blame. By the standards of 2000 much of what has happened in North Staffordshire is clearly unacceptable, but it may be nothing like as egregious viewed through 1990 eyes. Forgery, however, was a crime in the time of Babylon.

The CNEP trial (a randomised controlled trial) was approved in 1990 and eventually published in *Pediatrics* in 1996.³ The trial can easily be criticised, not least for

having an unvalidated outcome measure. "Failure to use a validated instrument" is now one of our standard reasons for rejecting studies. But most studies published in medical journals can be easily criticised. Considerably less than 5%, for example, meet the stringent scientific criteria of the journal *Evidence-Based Medicine*.⁴

The review panel examined the work of the local research ethics committee in approving the CNEP study and found that it generally followed the guidelines of the time but might have done better in assessing the quality of the research—perhaps by using external peer review. (Ironically, the panel criticises the ethics committee for not following the latest thinking while itself placing an old fashioned faith in peer review and failing to note research that finds severe deficiencies in peer review.⁵) Again we have lots of evidence on the highly variable performance of ethics committees, not least because they are usually overworked, undertrained, and underresourced.⁶

Informed consent is at the heart of the issue, and many of the parents have no memory of giving consent. The panel was, however, presented with evidence from another well done trial where patients did not remember giving consent even though they clearly had. The panel thus concludes somewhat lamely: "It is not possible now to be sure who completed some of the consent forms or to be sure that all of them were completed as intended." Further investigations are needed, but again research shows that the standards of obtaining consent are poor.⁷

Another part of the report looks at the current use of CNEP to treat bronchiolitis. It found "that there is no substantial evidence base in support of the use of CNEP in management of bronchiolitis." This might seem shocking until we realise that there is little good evidence to support the conventional management of the condition, namely positive pressure ventilation.

The aim of showing how the deficiencies identified in the North Staffordshire review are widespread in the NHS (and all healthcare systems) is not to excuse what has happened but to explain it. The main outcome of the review is a series of recommendations on improving "research governance" within the NHS, and these are to be welcomed.

There are some basic principles that should underpin improvement. The first principle should be transparency. Patients must be fully informed of what is happening, not only in research but also in clinical practice. Similarly processes of approving research must be open to public scrutiny, and the NHS and doctors

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should be honest about the lack of evidence for so much of routine practice. Problems may have arisen in North Stafford because the doctors wanted to “protect” the patients: they thus “sold” CNEP as “a kinder, gentler treatment.” But it is neither kind nor gentle to deceive patients about the reality of their predicament.

A second principle should be partnership. Patients should be involved at all stages of designing, approving,

and carrying out research. Finally, we should promote the principle that it is good for everybody, including participants, to conduct research. The worst outcome from this tragedy would be that it becomes increasingly difficult to do research in the NHS. Then we will never know how best to treat bronchiolitis.

Richard Smith *Editor, BMJ*

- 1 NHS Executive. West Midlands Regional Office report of a review of the research framework in North Staffordshire Hospital NHS Trust. www.doh.gov.uk/wmro/northstaffs.htm (updated 8 May 2000, accessed 9 May 2000).
- 2 Samuels MP, Southall DP. Negative extrathoracic pressure in treatment of respiratory failure in infants and young children. *BMJ* 1989;299:1253-7.
- 3 Samuels MP, Raine J, Wright T, Alexander JA, Lockyer K, Spencer SA, et al. Continuous negative extrathoracic pressure in neonatal respiratory failure. *Pediatrics* 1996;98:1154-60.

- 4 Haynes B. Where's the meat in clinical journals? *ACP Journal Club* 1993;119:A23-4.
- 5 Godlee F, Jefferson T. *Peer review in health sciences*. London: BMJ Books, 1999.
- 6 Alberti KGMM. Multicentre research ethics committees: has the cure been worse than the disease? *BMJ* 2000;320:1157-8.
- 7 Tobias J, Doyal L. *Informed consent: respecting patients in research and practice*. London: BMJ Books (in press).

Health inequalities in women and men

Studies of specific causes of death should use household criteria

Women are often excluded from studies of health inequalities. The justification given for this is lack of data, but there is also a belief that health inequalities are a smaller problem for women than men. An additional problem is that it is more difficult and controversial to classify women by social class or by general standing in the community.¹⁻³

In this week's *BMJ* Sacker and colleagues show that using a particular indicator of social class or of social standing in the community influences the size of health inequalities (p 1303).⁴ They show that for women the mortality ratio comparing the bottom and the top groups in a seven step social scale is 1.75 when the Cambridge scale of occupations is used. In contrast the same ratio for men is only 1.52 with the categories in the new Office for National Statistics (ONS) socioeconomic classification. For men the contrast between top and bottom groups was greater with the ONS classification than with the Cambridge scale.

Health inequalities among women are (at least) of the same size as among men when Cambridge scores are used; the ONS classification, however, indicates that health inequalities are smaller in women. It is clear that we need to discuss the social indicators by which health inequalities in women are studied.

Similar papers in the past few years have grappled with health inequalities among women. The health outcomes in these papers comprise self perceived health, cardiovascular and other specific causes of mortality, and total mortality.⁵⁻⁹ This research has become tied to the general sociological discussion about principles of social stratification. Advocates of the Cambridge scale of occupations¹⁰ see it as an alternative to the Erikson-Goldthorpe scheme of social classes¹¹ as well as to the ONS classification. Sacker and colleagues conclude that “a better understanding of health inequality is possible when measures are used that are sensitive to the multidimensional nature of social inequality and the uneven effects of these dimensions on men and women.” This is certainly true. But it is doubtful whether the

comparison in their paper does in fact take account of this “multidimensionality.”

The ONS classification is based on job characteristics (such as whether the job is routine or needs professional qualifications) and its position in the labour market. But occupations differ in other respects, income being the most obvious one. Occupations may also form “occupational cultures,” among which smoking and drinking habits may vary systematically.¹²

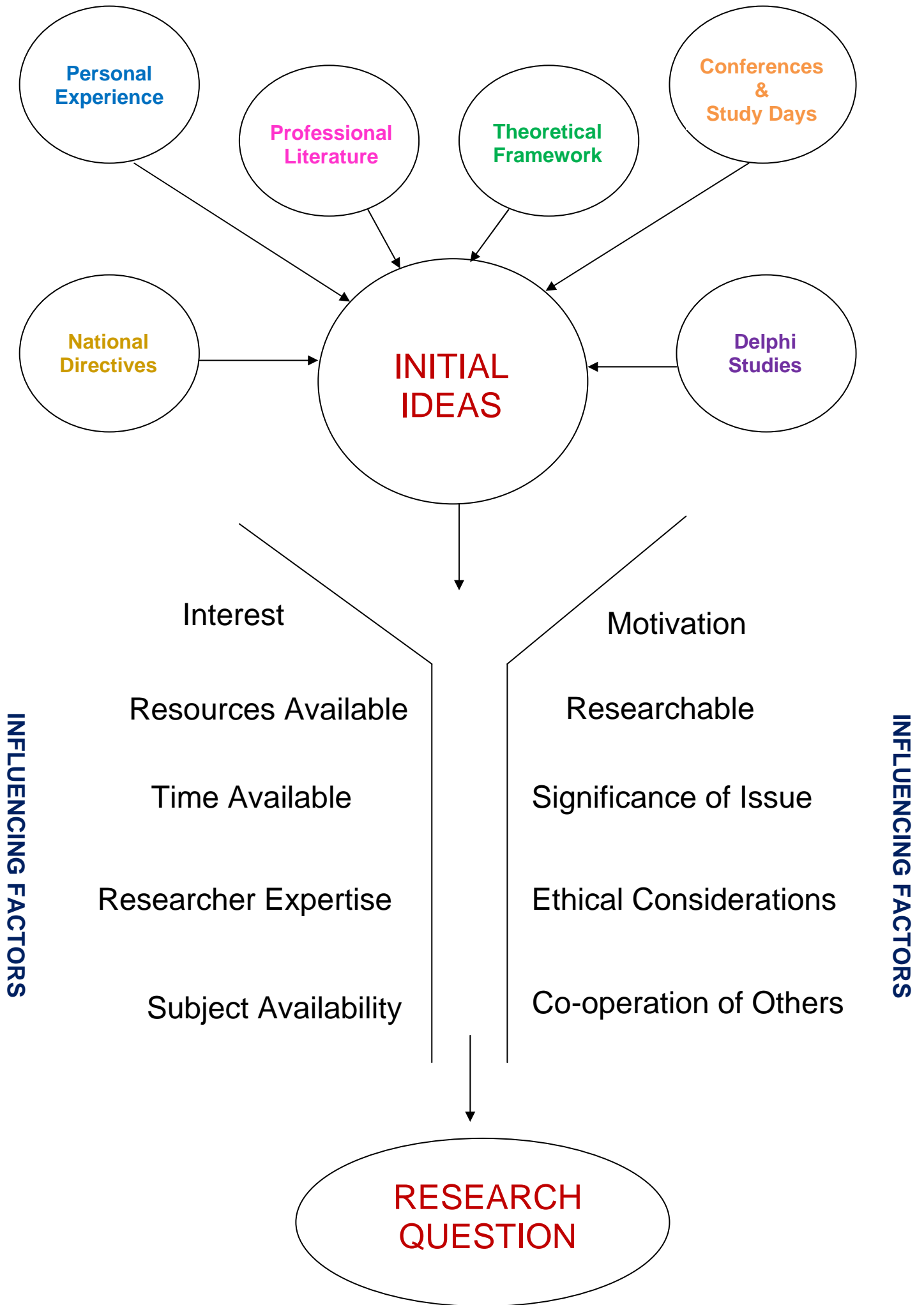
The Cambridge scale, in contrast, comes from information on friendship choices. If two friends have different occupations this is taken as an indication that the social distance between those occupations is short.¹³ Prandy explains that this is a rank order that reflects “differences in generalised advantage and disadvantage and hence in life style.”¹³

The critical point here is whether friendship choices are based primarily on perceived equality in social advantage or disadvantage—a claim that has not been shown empirically. A second point is whether this also implies that lifestyle makes more of a contribution to poor health than other aspects of a person's general social standing (such as income). Sacker et al do not show that lifestyle is the key explanation. A previous study by the same authors showed, however, that certain cardiovascular risk factors were closely linked to Cambridge scores.¹⁴

Which of these two stratification schemes is the better one? Most sociologists would agree that such a question must be answered with reference to general sociological problems. In the comparative European study on health inequalities the Erikson-Goldthorpe scheme, which is based on occupation, was successfully applied to a large number of (west) European countries. The researchers did not conclude that class differences in self perceived health among women were due to work—rather, this became a starting point for a whole research programme.¹⁵ How to understand the causal pathway between social position and health is a further, and different, issue than how to measure social position.

Papers p 1303

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Introduction to research in hospice and palliative care

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Read through the following research papers, then respond to the questions posed in the exercise on video Session 5, Sequence 10:

1. Cronfalk, B. S., Ternestedt, B.-M. and Strang, P. (2010), Soft tissue massage: early intervention for relatives whose family members died in palliative cancer care. *Journal of Clinical Nursing*, 19: 1040–1048. doi: 10.1111/j.1365-2702.2009.02985.x
2. Metcalfe, A., Pumphrey, R. and Clifford, C. (2010), Hospice nurses and genetics: implications for end-of-life care. *Journal of Clinical Nursing*, 19: 192–207. doi: 10.1111/j.1365-2702.2009.02935.x
3. J. Rigby, S. Payne, and K. Froggatt
Review: What evidence is there about the specific environmental needs of older people who are near the end of life and are cared for in hospices or similar institutions? A literature review
Palliat Med April 2010 24: 268-285, first published on November 19, 2009
doi:10.1177/0269216309350253
4. SJ Yardley, CE Walshe, and A. Parr
Improving training in spiritual care: a qualitative study exploring patient perceptions of professional educational requirements
Palliat Med October 2009 23: 601-607, first published on May 14, 2009
doi:10.1177/0269216309105726

Feedback from Handout 7, assigned in Session 5, Sequence 10

You may also wish to look at the published papers by Bennett (2011) and Payne (1997) detailed on your Further reading to assist you with this exercise. Also, please refer to your Glossary of Terms (Handout 10).

Paper 1: Cronfalk, Ternestedt and Strang (2009) Soft tissue massage: early intervention for relatives whose family members died in palliative cancer care.

This paper explores how bereaved relatives experienced soft tissue management during the first four months after the death of a family member who was in a palliative cancer care unit. It used a qualitative design and eighteen bereaved relatives (11 women and seven men) received soft tissue massage once a week for eight weeks. In-depth interviews were conducted after the end of the eight week periods. Interviews were analysed using a qualitative descriptive content analysis method (see Glossary). It was found that soft tissue massage proved to be helpful and generated feelings of consolation in the first four months grieving. The study was conducted in a large palliative care unit in Stockholm, Sweden.

Strengths:

- Is relevant to clinical practice
- Palliative care aims to improve quality of life at the end of life and through to bereavement so is appropriate and significant
- Finds were positive: so good intervention
- Contribute to a growing literature in complimentary therapy (this has been a neglected area in terms of carrying out research into its effectiveness)
- Rich qualitative data.

Weaknesses:

- The sample was self-selected. So that could produce bias (see Glossary). Self selected samples are often interested in subject so may be positive anyway. So the sample may not be representative of the population
- Positive effect reported could simply be as a consequence of any interaction with a professional rather than this particular one (a common problem).

Paper 2: Metcalfe, Pumphrey and Clifford (2009) Hospice nurses and genetics: implications for end of life care.

This study aimed to determine hospice nurses' perceptions of the importance of genetics to hospice care provision and their personal level of confidence in carrying out genetics related activities within an end of life care context. The study used a survey design (see Glossary) and questionnaires were sent to a stratified (see Glossary) sample of hospice nurses ($n= 1149$) in England and Wales. Follow up telephone interviews were conducted with hospice nurse educators to explore emerging issues. Response rate to survey was 29%. Findings suggested that many nurses had not considered the relevance of genetics to hospice care and were not confident to provide it.

Strengths:

- Significant study as it is an importance and timely area of study; as 10% of people develop cancer as a result of inherited genetic disposition
- First study to explore and examine genetic education for nurses- nationally or internationally
- Highlights an important and worrying issue- that Directors of Nursing Services and senior Hospice Managers did not see genetics as relevant to hospice care
- Potentially good coverage of views as a survey was used
- Multi- method design as was followed up by telephone interviews.

Weaknesses:

- 29% response rate is extremely poor. So much so as to threaten the validity and reliability of the findings. Clearly the response rate needs to be as high as possible. If it seems likely (perhaps on the basis of pilot data) that the response rate will fall below 70%, researchers would get better estimates if they reduce the sizes and concentrate efforts on increasing the response rate.
- No steps were taken to increase the response rate (by sending follow up reminders, for example)
- No pilot study was undertaken.

Paper 3: Rigby, Payne and Froggatt (2009) What evidence is there about the specific environmental needs of older people who are near the end of life and are cared for in hospices or similar institutions? A literature review.

A narrative literature review was carried to identify and analyse evidence on this issue with twenty-nine papers meeting the inclusion criteria. Four main themes emerged: the physical environment should be 'homely'; it should support patients' needs for social interaction and privacy; it should support the caring activities of staff, family members and patients; and it should allow for spiritual expression.

Strengths:

- It explores a significant problem: the number of older people in the UK (and globally) is growing and many will suffer from chronic life-limiting illness and will require palliative care as they approach the end of life
- Focuses on a 'neglected' group, the so called 'disadvantaged dying'
- Includes both quantitative and qualitative studies
- Bears the hallmarks of a rigorous review (see reference: Gysels M and Higginson I, 2008, Chapter 8 pp 115-11135 in *Research Methods in Palliative Care* listed in your Reading List)
- Is non intrusive to patients as doesn't rely on primary data collection methods but on synthesising existing research evidence.

Weaknesses:

- Is not a systematic review (see above paper by Gysels and Higginson)

- Doesn't include a reflection on limitations. Remember from Session 5 there is so such things as 'the perfect study'!

Paper 4: Yardley, Walshe and Parr (2009) Improving training in spiritual care: a qualitative study exploring patient perceptions of professional education requirements.

The aim of this study was to describe patient suggestions for development of training to deliver spiritual care. Qualitative semi-structured interviews were carried out with twenty patients and were analysed thematically (see reference by Ingleton and Seymour 2001, on your Reading List). The study found that user opinions on training can be helpful not only in deciding objectives but also how to achieve them.

Strengths:

- The research aim is significant in that spiritual care is integral to palliative care and increased education to enhance spiritual care is needed healthcare training.
- It focuses on the patient voice' rather than relying on the perspective of bereaved carers or health care professionals
- Researcher based within the hospice, the data collection was flexible, which appeared to contribute to uptake

Weaknesses:

- Patients were from a limited demographic background
- Limited transferability of findings into different settings
- The question of who should be training the providers of spiritual care was not explored.

Reading list

Bennett M, Davies E, and Higginson I (2010) Delivering research in end-of-life care: problems, pitfalls and future priorities. *Palliative Medicine* 24 (5): 456-461

Grande G and Ingleton C (2008) Research in Palliative Care. Chapter 32 pp 625-643. In Payne S, Seymour J and Ingleton C (Eds) *Palliative Care Nursing: Principles and Evidence for Practice*. Open University Press: Maidenhead

Higginson I (2001) Clinical Audit and organisational audit in palliative care. In Field D, Clark D, Corner J and Davies C (Eds) *Researching Palliative Care* Chapter 16 pp 169-183. Open University Press: Buckingham.

Ingleton C and Davies S (2004) Research and scholarship in palliative care nursing. Chapter 35 pp 676-697. In Payne S, Seymour J and Ingleton C (Eds) *Palliative Care Nursing: Principles and Evidence for Practice*. Open University Press: Maidenhead.

Ingleton C and Seymour J (2001) Analysing qualitative data: examples from two studies of end-of-life care. *International Journal of Palliative Nursing* 7 (5): 227-234

Kelly L and Stone P (2007) How to develop a research question. Chapter 15 pp 249-256. In Addington-Hall J, Bruera E, Higginson I, Payne S (Eds) *Research Methods in Palliative Care*. Oxford University Press: Oxford

McDonnell A (2004) Factors which may inhibit the application of research findings into healthcare. Chapter 14 pp 199-221. In Crookes P and Davies S (Eds) *Research into Practice* Bailliere Tindall: Edinburgh

Payne S (1997) Selecting an approach and design in qualitative research. *Palliative Medicine* 11: 249-52

Seymour J and Skilbeck J (2002) Ethical issues in researching user views *European Journal of Cancer Care* 11: 215-219

Speck P (2007) How to gain research ethics approval? Chapter 17 pp 277-282. In Addington-Hall J, Bruera E, Higginson I, Payne S (Eds) *Research Methods in Palliative Care* Oxford University Press: Oxford

Todd C (2007) Writing a research proposal. In Addington-Hall J, Bruera E, Higginson I, Payne S (Eds) *Research Methods in Palliative Care* Chapter 16 pp 259-273. Oxford University Press: Oxford

Wilkie P (2001) Ethical issues in qualitative research in palliative care. In Field D, Clark D, Corner J and Davies C (Eds) *Researching Palliative Care* Chapter 7 pp 67-74. Open University Press: Buckingham

Glossary of useful terms

Abstract

Clear, concise summary of a study, usually limited to 100-250 words.

Applied research

Scientific investigations conducted to generate knowledge that will directly influence or improve practice.

Attrition

The loss of participants during the course of a study: can introduce an unknown amount of bias by changing the composition of the sample initially drawn – particularly if more subjects are lost from one group than another; can thereby be a threat to the internal validity of a study.

Bias

Any influence or action in a study that distorts the findings or slants them away from the true or expected.

Case study design

Intensive exploration of a single unit of study, such as a person, family, group, community or institution.

Causal relationship

Relationships between two variables where one variable (independent variable) is thought to cause or determine the presence of the other variable (dependent variable).

Coding

Process of transforming qualitative data into numerical symbols that can be computerized.

Cohorts

Sample in time-dimensional studies within the field of epidemiology.

Comparison group

The group not receiving a treatment or receiving the usual treatment (standard care) when non-random sampling methods are used.

Concept

A term that abstractly describes and names an object or phenomenon, thus providing it with a separate identity or meaning.

Conceptual framework

A set of highly abstract, related constructs that broadly explains phenomena of interest, expresses assumptions, and reflects a philosophical stance.

Confidentiality

Management of data in research so subjects' identities are not linked with their responses.

Confounding variables

Variables recognized before the study is initiated but cannot be controlled, or variables not recognized until the study is in process, which may have an effect on the dependent variable.

Convenience or accidental sampling

Subjects are included in the study because they happen to be in the right place at the right time; available subjects are simply entered into the study until the desired sample size is reached.

Data analysis

Conducted to reduce, organize, and give meaning to data.

Data collection

Precise, systematic, gathering of information relevant to the research purposes or the specific objectives, questions or hypotheses of a study.

Data transformation

A step often undertaken prior to the analysis of research data, to put the data in a form that can be meaningfully analysed (e.g., recording of values).

Data triangulation

Collection of data from multiple sources in the same study.

Declaration of Helsinki

Ethical code based on the Nuremberg code that differentiated therapeutic from non-therapeutic research.

Delphi technique

A method of measuring the judgements of a group of experts for assessing priorities or making forecasts.

Dependent variable

The response, behaviour, or outcome that is predicted or explained in research; changes in the dependent variable are presumed to be caused by the independent variable.

Ethical principles

Principles of respect for persons, beneficence, and justice relevant to the conduct of research.

Experimental design

Designs that provide the greatest amount of control possible in order to more closely examine causality.

Focus group interview

An interview in which the respondents are a group of individuals assembled to answer questions on a given topic.

Generalization

Extends the implications of the findings from the sample that was studied to the larger population or from the situation studies to a larger situation.

Grounded theory research

An inductive research technique based on symbolic interaction theory, which is conducted to discover what problems exist in a social scene and the process persons use to handle them. The research process involves formulation, testing and redevelopment of propositions until a theory is developed.

Hawthorne effect

A psychological response in which subjects change their behaviour simply because they are subjects in a study, not because of the research treatment.

Inclusion criteria

Sampling requirements identified by the researcher that must be present for the element or subject to be included in the sample.

Informed consent

The prospective subject's agreement to voluntarily participate in a study, which is reached after assimilation of essential information about the study.

Interviews

Structured or unstructured verbal communication between the researcher and subject, during which information is obtained for a study.

Limitations

Theoretical and methodological restrictions in a study that may decrease the generalizability of the findings.

Longitudinal study

A study designed to collect data at more than one point in time, in contrast to a cross-sectional study.

Natural settings

Field settings or uncontrolled, real-life situations examined in research.

Pilot study

A smaller version of a proposed study conducted to develop and/or refine the methodology, such as the treatment, instrument, or data collection process.

Population

All elements (individuals, objects or events) that meet sample criteria for inclusion in a study. Sometimes referred to as a target population.

Principal investigator (PI)

In a research grant, the individual who will have primary responsibility for administering the grant and interacting with the funding agency.

Proposal, research

Written plan identifying the major elements of a study, such as the problem, purpose, and framework, and outlining the methods to conduct the study. A formal way to communicate ideas about a proposed study to receive approval to conduct the study and seek funding.

Purposive sampling

Judgemental sampling that involves the conscious selection by the researcher of certain subjects or element to include in a study.

Qualitative research

A systematic, interactive, subjective approach used to describe life experiences and give them meaning.

Quantitative research

A formal, objective, systematic process to describe, test relationships, and examine cause and effect interactions among variable.

Questionnaire

A printed self-report form designed to elicit information that can be obtained through written responses of the subject.

Reliability

Represents the consistency of the measure obtained.

Research hypothesis

The alternative hypothesis to the null hypothesis that states there is a relationship between two or more variables.

Research objectives

Clear, concise, declarative statements that are expressed to direct a study and are focused on identification and description of variables and/or determination of the relationships amongst variables.

Research questions

Concise, interrogative statements developed to direct studies that are focused on description of variables, examination of relationships among variables, and determination of differences between two or more groups.

Rigour

The striving for excellence in research through the use of discipline, scrupulous adherence to detail, and strict accuracy.

Sample

A subset of the population that is selected for a study.

Sampling

Includes selecting group of people, events, behaviours, or other elements with which to conduct a study.

Sampling method

The process of selecting a group of people, events, behaviours, or other elements that are representative of the population being studied.

Scientific method

Incorporates all procedures that scientists have used, currently use, or may use in the future to pursue knowledge, such as quantitative research, qualitative research, and outcomes research.

Setting

Location for conducting research, such as a natural, partially controlled, or highly controlled setting.

Simple hypothesis

States the relationship (associative or causal) between two variables.

Survey

Technique of data collection using questionnaires or personal interviews to gather data about an identified population.

Survey design

A design to describe a phenomenon by collecting data from a large sample using questionnaires or personal interviews.

Unstructured interviews

Initiated with a broad question and subjects are usually encouraged to further elaborate on particular dimensions of a topic.

Unstructured observations

Involve spontaneously observing and recording what is seen with a minimum of prior planning.

Validity, design

The strength of a design to produce accurate results or findings may be determined by examining statistical conclusion validity, internal validity, construct validity, and external validity.

Variables

Qualities, properties, or characteristics of persons, things, or situations that change or vary and are manipulated or measured in research.