

This is the accepted version of the following article: McConigley, Ruth and Shelby-James, Tania and Currow, David C. 2013. Promoting the consumer voice in palliative care: exploring the possibility of using consumer impact statements. Health Expectations. Advance online publication, which has been published in final form at <http://doi.org/10.1111/hex.12118>

Title: Promoting the consumer voice in palliative care: exploring the possibility of using consumer impact statements

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Source of funding: This review was conducted by the Palliative Care Clinical Studies Collaborative, which is funded by the Australian Government Department of Health and Ageing.

Conflict of interest: None

Abstract

Background: It can be difficult to engage consumers in health decision making. This is particularly so in the area of palliative care, where consumers are very unwell and are unlikely to become involved in long term programs that promote consumer input. This paper explores the possibility of using 'Consumer Impact Statements' to facilitate the inclusion of the viewpoint of people at the end of life in the process of policy and decision making, particularly in the area of subsidy of pharmaceuticals used in palliative care.

Search Strategy: A broad search was conducted to find information about the use of impact statements in any health field. The health literature and grey literature were searched to explore the use of Consumer Impact Statements to date.

Results: No papers were found describing the use of Consumer Impact Statements in the palliative care setting. Health impact assessment is used in the areas of environmental health and community health. Impact statements are less commonly used in other areas of health, especially policy development, and no formal description of a Consumer Impact Statement was found.

Discussion: There is considerable scope for developing the use of Consumer Impact Statements to promote the consumer viewpoint in health decision making, because it will allow people who are otherwise unlikely to contribute to the public debate to have their views heard by decision makers.

Conclusion: The use of Consumer Impact Statements is particularly suited to palliative care, given that consumers are often otherwise unable to contribute to the public debate.

Keywords: consumer participation; impact statements; palliative care, end of life care; pharmaceutical subsidy

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Background

Consumer involvement in health policy is highly valued by governments and policy makers¹, however, there is little empirical evidence about the best way to engage consumers and elicit a consumer perspective²⁻³. Further study is required to determine which methods of engaging consumers are successful in allowing them to have a voice in making public policy⁴.

In the hospice/palliative care setting, engaging consumers offers considerable challenges. Palliative care patients are, by definition, seriously ill and may be too frail to participate in activities that promote consumer input. However, it is important that the experiences of this group of people be heard to ensure that hospice/palliative care is appropriately funded and that policy frameworks serve consumer needs. Despite a growing interest in making hospice/palliative care services more patient focused and consumer driven, there remains little direction on how this can be achieved systematically⁵. As such, it is incumbent on the palliative care community to attempt to develop ways of engaging hospice/palliative care patients in the on-going dialogue about end of life care that allow for seriously ill people to contribute.

In Australia, the federal Government has subsidised medications since 1944⁶, but there have been limitations associated with the inclusion of medications required in palliative care. Medicines undergo a rigorous assessment process prior to being approved for inclusion in the pharmaceutical benefits scheme, which includes an initial

assessment of safety and efficacy by the Therapeutic Goods Administration followed by comparative cost effectiveness. This requires a strong evidence base and there has been no incentive for industry to support developing the evidence base just for indications for use in palliative care given that the market for palliative medications is relatively small and time limited, and most medications where additional evidence is needed are already beyond their period of patent. Therefore, the purpose of this paper is to examine ways that the literature describes consumers' (people requiring palliative care and their carers) contribution to decision making and influencing policy relating to subsidy of pharmaceutical agents used to ameliorate symptoms at the end of life. In particular, the paper aims to explore the potential use of consumer impact statements to assist with medication assessment in the palliative care context.

Search strategy

An extensive search of the literature in the areas of health and medicine was undertaken, for papers published between 2000-2012, that describe or discuss the use of consumer impact statements in the health care setting. The search was conducted using the health related databases Medline, CINAHL, EMBASE, International Pharmaceutical Abstracts, DRUG, Proquest and Current Contents. The search terms used are included in Table 1. Two key journals, Australian Health Review and Health Expectations, were identified and hand searched.

The grey literature was also searched. Caresearch⁷, an Australian palliative care website that includes a large anthology of palliative care related grey literature, was used as a starting point. Then, the websites of all health departments in Australia, New

Zealand, Canada, the United Kingdom and the United States of America were searched. Evidence-based practice organisations, including the Cochrane Collection, Joanna Briggs Institute and the National Institute of Clinical Excellence (NICE) were also searched. To ensure that no data were overlooked, an email was sent to each of these departments explaining the purpose of this project and requesting any relevant information. Data from consumer advocacy groups in each country were also sought, relevant websites were searched and requests for information sent. Open SIGLE, a database of grey literature from Europe, was used to search European literature available in English translation. Internet sites relating to experiences of chronic illness were also searched, with a focus on blogs and on-line fora that describe consumers' experiences.

Results

The literature search revealed almost no information about the use of impact statements in any area of health, and no information was found that related directly to the use of these statements in the area of palliative care or pharmaceutical decision making. Papers were considered relevant if they considered issues of consumer participation in pharmaceutical policy development; consumer input into any aspect of palliative care or the use of impact assessment in policy development. The search of the health-related databases resulted in a small number of articles that were relevant, albeit indirectly, to the issue of Consumer Impact Statement use in a palliative care medications context. As such, this paper presents an overview of related issues and discusses the potential of using impact statements to increase the palliative care consumer voice in pharmaceutical decision making.

Health Impact Assessments

A health impact assessment uses a variety of methods to determine what impact health projects or policies will have on the population most likely to be affected⁸. The World Health Organisation⁹ states that:

...health impact assessment is a practical approach used to judge the potential health effects of a policy, program or project on a population, particularly on vulnerable or disadvantaged groups.

Health impact assessments are widely used in the environmental health area, but can be used to guide any project that may have an impact on the health of a group of people, and are appropriate in areas as diverse as health promotion, environmental health and public health¹⁰. The main points considered in health impact assessments are the relationship between the project or policy and the health of a population; input of the population that is likely to be affected by the illness (without the ability of service providers or vendors to influence statements); expert opinion and options to minimise health risks and maximise positive health outcomes¹¹.

Health impact assessments have five key parts:

- i. Screening to assess the need for a health impact assessment;
- ii. scoping to determine what is included in the assessment;
- iii. assessing health impacts by identifying and analysing potential effects;
- iv. decision making, prioritising the issues and developing recommendations; and
- v. evaluation of the health impact assessment itself, and potentially of the health impacts described as well.^{10,12}

In relation to pharmaceutical products, the key need is for decision makers to understand the impact a disease or condition has on the lives of patients and their caregivers. Governments from a number of countries have developed guidelines for health impact assessments. The Australian Government developed Health Impact Assessment Guidelines primarily for use as part of a wider environmental health impact assessment¹³. Similar guidelines are also available in New Zealand¹⁴, England¹⁵ and Wales¹⁶. The guidelines require a health impact assessment to be conducted when developing policies, programs or projects that may impact on the health of a population, however, they are largely focused on environmental health projects such as building or industrial development.

In the public health sphere, health impact statements are used routinely when a project is likely to have an effect on a vulnerable population. The *Equity-Focused Health Impact Assessment Framework*¹⁷ assists with conducting impact assessments on proposals that are likely to affect minority sectors of the Australian community that may otherwise not be considered. The Antigonish (Canada) Community Health Impact Assessment Tool¹⁸ uses a comprehensive checklist to examine the impact of any health related project on the community, and examines a broad range of issues including child health, environmental health, community demographics, income and social status, social environment and networks, and personal health and health services. There is less information about how health impact assessment can be used in other sectors of health, including development of public policy¹².

Consumer Impact Statements

While health impact assessment is well established in some areas, there is less information about the development of impact statements that describe the effect of a policy or decision on health care consumers, or the implications for patients of a specific condition, disease, or symptom especially in relation to the subsidisation of relevant pharmaceuticals.

In Australia an Aboriginal Health Impact Statement¹⁹⁻²⁰ is required to accompany proposals for health policies, programs and strategies that will have a significant effect on Aboriginal peoples. The impact statement is accompanied by a checklist that details how consultation was undertaken and how the needs of this consumer group have been met. This method of impact statement development could form the basis of ensuring that other under-represented groups have a say in public policy setting.

Impact statements that describe the impact of a disease or symptom are not common and only one was found in this search. The Joint Epilepsy Council of Australia prepared an impact statement that involved extensive consultation with people with epilepsy (n=467) and caregivers of people with epilepsy (n=496)²¹. The four page report covers a range of topics relating to life with epilepsy, including information about diagnosis, treatment, and the impact of epilepsy on everyday life, worklife and psychosocial issues, and demonstrates the effectiveness of using a concise impact statement to illustrate the effects of living with a disease. A similar format could be used to describe other diseases or troublesome symptoms. No information is available about the most appropriate process for developing a disease-specific impact statement.

Impact Statements in Palliative Care

We have been unable to find any evidence that impact statements are in use in the hospice/palliative care setting. Despite this, there are a number of reasons to consider impact statements as an option for increasing the input of seriously ill people into policy decisions. In particular, the lack of a consumer voice in this area suggests the need for other ways of compiling and presenting information about the experiences of seriously ill people and their caregivers. An impact statement may consider data from a number of sources, including research and other professional literature, personal accounts and data collected by survey, interview or other means. A considerable advantage of developing structured impact statements relating to palliative care is that data collection could be brief in order to minimise patients' and families' burden.

The perceived vulnerability of the palliative care patient group means that there are specific issues to be considered if health impact statements are used as a means of promoting consumer input in hospice/palliative care policy making and practice. While impact statements have the potential to provide a voice to a largely unheard group, the collection of data for the impact statements needs to be considered in terms of ethical issues. The timing of data collection is crucial if the true impact of a symptom experienced by a seriously ill person is being measured, however there are obvious limitations to collecting data in the terminal phase of illness. Therefore, it should be noted that it is unlikely that any impact statement can reflect accurately the entire experiences of someone very close to death.

Palliative care considers the patient and their family as the 'unit of care'²². When considering the impact of a condition, disease or symptom it is appropriate to consider the effect on the family and/or caregiver as well. Including the caregivers' perspectives in a consumer impact statement relating to end of life experiences is of benefit for at least two reasons. Firstly, caregivers and close family members may be able to act as a proxy for some key parameters, providing accurate information about the patient's experience²³⁻²⁴. Secondly, the implications of the phenomena being examined on the caregiver and close family is of relevance in this setting, both for their willingness to continue care for this person and the willingness to potentially provide care in the same circumstances again.²⁵

The development of impact statements that relate to the use of medicines in the hospice /palliative care setting offers a unique opportunity to include a consumer voice in the medication subsidy debate that may otherwise not be heard. Much of the information provided about the need for government subsidy of medications is provided by pharmaceutical companies with a vested interest in having a product under patent made more readily available for consumers. Completing an impact statement that is demonstrably independent of pharmaceutical company interests ensures patients and families have the chance to describe their experiences, the impact of this illness and its symptoms on each of them and highlight issues that are of importance to them. When completed by an independent body, an impact statement is a patient-centred statement of experience and can subsequently help inform decision makers about the potential impact of an illness on individuals and their families.

Gathering Evidence for an Impact Statement

There is little information about how best to gather data to inform a health impact statement. While it is likely that the tenets underpinning health impact assessments are suitable for use in the development of consumer impact statements as well, there is a need to consider specific methodologies suitable for collecting information from seriously ill patients. The health literature has a large amount of information about the experiences of patients and their families using different methods and presented in different ways. Each is likely to have some utility in terms of gathering data that are useful for inclusion in an impact statement.

There are lots of quantitative studies that describe conditions or symptoms suffered by people with specific diseases and a plethora of instruments designed to measure symptoms and the impact of symptoms on patients. These are useful for preparing an impact statement as they can offer a range of methods and samples on which to base the impact statement. In addition, they may offer insights into the effects of the condition on the activities of daily living, physical and psychosocial wellbeing or quality of life. For example, a study of symptoms experienced by people with dementia used both patient and caregiver reports of symptoms, using a range of instruments including the Edmonton Symptom Assessment Scale and the End of Life Dementia Scale – Symptom Management²⁶. The study showed that the most commonly reported symptoms by patients were pain (42%) and depression (11%) and that caregivers reported cognitive deficit as being most prevalent (47%). Activity disturbance was reported by 15% of caregivers.

Describing the experience of an illness using qualitative research methods such as phenomenology, grounded theory or case study methods is common. Phenomenology in particular may be of benefit when preparing an impact statement because it examines the lived experience of the phenomena in question, generally using one-to-one interviews as the method of data collection²⁷. Examples of phenomenological studies of the impact of a disease include Ek and Ternestedt's²⁸ study of people with end-stage chronic obstructive pulmonary disease (COPD) (n=8). The findings of the study described living with COPD as being a life dominated by a lack of physical strength that led to a reduction in activities and in turn social isolation because of the inability to participate in social activities. Participants described emotional distress and feelings of meaninglessness that accompanied physical limitations. Donovan and Flynn's study of the experiences of men with breast cancer (n=15) also used a phenomenological approach, using interviews and email conversations to collect data²⁹. The findings of this study described the emotional difficulties men experienced suffering what they considered a 'woman's disease' and the effect that this had on their personal relationships and sexuality. The findings of these two studies highlight the strength of using a qualitative method to gather data about living with a specific condition. However, sample sizes are small and sampling techniques are purposive, potentially limiting generalizability of findings.

Systematic and other reviews of literature are useful for preparing impact statements, in that much of the hard work finding appropriate sources of information has already been done. Review papers are able to provide a much deeper insight into the experiences of people with a specific condition, but do not offer the personal insights

found in qualitative research papers. Embrey's review of the literature describing the experiences of people with multiple sclerosis who require palliative care is an example of the efficacy of a literature review in describing disease/symptom impact³⁰. This paper describes the nature of multiple sclerosis, the nature of palliative care for people with multiple sclerosis and evaluates palliative care services provided for this group of people.

The Internet is also a rich source of patient-centred literature and has a large number of sites that relate to the experiences of people with illnesses but there is a question as to how representative such fora are. The most useful of these for preparing impact statements are blogs and forums, where people post entries about their own experiences. The quality of these is variable and it is difficult to locate specific information when required. However, an excerpt from a blog about life with Parkinson's Disease demonstrates that the Internet could be a useful source of information in this area especially with emerging context monitors for trends and patterns of interaction:

You think you don't entertain me anymore because I'm not grinning or laughing. If I appear to stare at you, or have a wooden expression, that's the Parkinson's, I hear you. I have the same intelligence; it just isn't easy to show facial expressions. If swallowing, I may drool. This bothers me, so I will mop it up.....

(http://katekelsall.typepad.com/my_weblog/).

Statements such as these could form a useful adjunct to an impact statement and could be used to gather qualitative data about a disease or symptom. However, the

nature of the Internet makes it difficult to verify the accuracy and completeness of these accounts and searching can be cumbersome and slow.

The Role of Consumer Impact Statements in Pharmaceutical Policy Development

Preparation of Consumer Impact Statements is likely to be led by the palliative care research community aiming to build a body of evidence to support the need for greater access to medications for people requiring palliative care. The data required for completing a consumer impact statement needs to be collected from a range of sources using a range of methods, so that a comprehensive and balanced account of the impact on patients and their caregivers of a condition, disease or symptom is compiled. As yet, there are few data about the appropriateness of specific methodologies that are suitable for use in this population and it is important that methods used do not prove burdensome to patients and families. The next logical step is to determine ways in which data can be collected to develop impact statements that are suitable for patients and families close to the end of life and that will result in high quality, useful data being available to inform healthcare decision making.

Conclusion

Health impact assessment is becoming more widely accepted as a method of assessing the impact of a government policy, but as yet there is no precedent for using an impact statement in the palliative care setting or pharmaceutical subsidy decision making process. However, it is reasonable to expect that consumers will get a say in the decision that is made and will be able to inform decision makers of their experiences and needs. In the palliative care setting, where people are often seriously ill and perceived to be vulnerable, participating in research is justified if it will benefit

the participants and others and, as such, being a part of developing an impact statement is an appropriate way for people at the end of life to contribute to health care decision making.

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Table 1: Search terms for literature review

Mesh Heading	Alternative Terms
Consumer participation	Consumer involvement Patient participation Patient involvement Public participation Public involvement Engaging consumers Engaging patients Engaging public Consumer advocacy Patient advocacy
Drug approval	New drug approval Drug approval process Drug policy Pharmaceutical policy
	Health impact statement/health statement Consumer impact statement/consumer statement Symptom impact statement Disease impact statement
	Lived experience /symptom/disease Living with/symptom disease Describing symptom/disease

Carer/caregiver/lived experience

Patient story

Patient anecdote

Patient experience
