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Review

Are we there yet? The state of the evidence base for guidelines on breaking bad news to cancer patients

C.L. Paul *, *T. Clinton-McHarg, R.W. Sanson-Fisher, H. Douglas, G. Webb*

The University of Newcastle, Faculty of Health, School of Medicine and Public Health, Level 2, David Maddison Building, University Drive, Callaghan NSW 2308, Australia

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ABSTRACT

The way clinicians break bad news to cancer patients has been retrospectively associated with poor psychosocial outcomes for patients. Education and practice in breaking bad news may be ineffective for improving patients' well-being unless it is informed by a sound evidence base. In the health field, research efforts are expected to advance evidence over time to inform evidence-based practice. Key characteristics of an advancing evidence base are a predominance of new data, and rigorous intervention studies which prospectively demonstrate improved outcomes. This review aimed to examine the progress of the evidence base in breaking bad news to cancer patients. Manual and computer-based searches (Medline and PsycINFO) were performed to identify publications on the topic of breaking bad news to cancer patients published between January 1995 and March 2009. Relevant publications were coded in terms of whether they provided new data, examined psychosocial outcomes for patients or tested intervention strategies and whether intervention studies met criteria for design rigour. Of the 245 relevant publications, 55.5% provided new data and 16.7% were intervention studies. Much of the intervention effort was directed towards improving provider skills rather than patient outcomes (9.8% of studies). Less than 2% of publications were rigorous intervention studies which addressed psychosocial outcomes for patients. Rigorous intervention studies which evaluate strategies for improving psychosocial outcomes in relation to breaking bad news to cancer patients are needed. Current practice and training regarding breaking bad news cannot be regarded as evidence-based until further research is completed.

1. Introduction

1.1. *The importance of an evidence base for effective and ethical practice*

Building an evidence base is an integral part of ethical care.[1] Level 1 evidence, determined by multiple randomised controlled trials reporting similar results, is accepted as the most rigorous level of evidence.[2] In general, there is an expectation that research efforts will achieve higher levels of evidence over time.[3,4]

1.2. *The need for evidence-based psychosocial or supportive cancer care*

The provision of psychosocial care is a new-comer to cancer patient care,[5] therefore Level 1 evidence for psychosocial care may take time to emerge. This may be due to a low likelihood

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* *Corresponding author*: Tel.: +61 (02) 4913 8472; fax: +61 (02) 4913 8779.
E-mail address: Chris.Paul@newcastle.edu.au (C.L. Paul).

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of harm as a result of psychosocial intervention and a lack of financial incentives for psychosocial trials. Nevertheless, Level 1 evidence is still required in order to provide best-evidence psychosocial care.

1.3. *The importance of the 'bad news' moment*

Over their career cancer oncologists will break bad news an average of 20,000 times.[6,7] However, many clinicians have difficulty or lack the necessary skills in providing this type of care.[8,9] Data gathered from studies examining interactions between patients and clinicians suggest that the consequences of breaking bad news poorly can affect both the patient[10] and the doctor involved.[11] For the doctor, stress related to these incidents can contribute to burn-out and anxiety.[12] For the patient, poorly communicated bad news can result in increased stress and anxiety, poor adjustment to the bad news, and poorer health outcomes.[10,13–15]

1.4. *The need to examine the evidence base for breaking bad news to cancer patients*

Following recognition of the importance of the issue and the lack of evidence on how to effectively break bad news to patients, a consensus approach was taken to develop practice guidelines.[16,17] The consensus guidelines recommended that the evidence base for breaking bad news be developed via rigorous intervention studies.[17] In the absence of an evidence base, it is possible that provider education in breaking bad news may be idiosyncratic or misguided. This could result in practices which are ineffective or even detrimental to patients' psychosocial health.

1.5. *Key characteristics of an advancing evidence base*

The first requirement to advance the evidence base in breaking bad news to cancer patients is *new data*. While consensus views may be based on expert opinion, an evidence base requires empirical research. Second, there is a need for *intervention studies* which describe and test strategies for improving the communication of bad news. Reviews in non-cancer healthcare fields revealed that the majority of studies had a descriptive focus.[18] Similarly, a 2004 Cochrane review exploring communication skills training for healthcare professionals working with cancer patients found only three intervention studies related to breaking bad news.[19]

A third characteristic crucial to advancing the evidence base in breaking bad news is demonstration of an *improvement in psychosocial outcomes for patients*. Guidelines have been based on an understanding of the negative effects of the way in which a clinician breaks bad news (i.e. anxiety, distress or dissatisfaction of the patient). However, the early availability of guidelines[5] and educational courses[20] may have focused researchers on skills rather than on patient benefit. Although improved skills are assumed to improve psychosocial outcomes, this association must be demonstrated in order to justify the resources required to provide training and achieve sustained improvements. Examining psychosocial impacts on providers should be contingent on establishing that it is possible to achieve psychosocial benefits for patients.

Reviews of breaking bad news literature in other health fields have identified a fourth key characteristic of research which will advance the evidence base – *design rigour*. These reviews found that only a minority of the identified interventions met recognised criteria for good research design and methodological quality.[21] Achieving methodological rigour is vital because the quality of the methodology determines the quality of the evidence.[5] A lack of research rigour in a field may lead to conflicting results or even systematic error.

Therefore, there is a need to examine the research on breaking bad news to identify whether efforts have been directed towards achieving improved outcomes for patients.[19,22] The aims of this review were to examine the literature on breaking bad news to cancer patients published since 1995 to identify:

(1) The proportion of studies which provided new data and therefore potentially added to knowledge in the field.
(2) The proportion of studies providing new data which tested the effectiveness of intervention strategies for improving breaking bad news.
(3) The proportion of intervention studies which included a patient psychosocial outcome as one of the study measures. Psychosocial outcomes included anxiety, depression, stress, satisfaction and quality of life.
(4) The proportion of the intervention studies which measured psychosocial outcomes for patients and met accepted criteria for design rigour.
(5) Whether a positive effect on patients' psychosocial outcomes was identified as a result of rigorous interventions to improve the communication of breaking bad news.

2. Methods

2.1. *Search strategy*

A computer-based literature search was performed to identify publications on the topic of breaking bad news to cancer patients, published between January 1995 and March 2009. The year 1995 was chosen as the search start date as the consensus guidelines for breaking bad news were published in 1995.[17] Medline and PsycINFO databases were chosen for the search as both contain research publications across a wide range of health professions in the field of oncology, and are leading sources for gaining access to clinical and psychosocial cancer care related journals.

The following keyword search terms were used: 'breaking bad news'; 'guidelines for breaking bad news'; 'physician patient relations'; 'training doctors to break bad news'; 'disease and bad news'; 'delivering diagnosis'; 'communicating bad news'; 'research in breaking bad news'; 'telling patients they have cancer' or 'training to break bad news'. The search was restricted to English language articles on human subjects. Following the identification and classification of relevant publications (outlined below), a subsequent database search by relevant author name was performed. A manual search of the reference lists of identified reviews and intervention papers was performed to identify any further relevant literature.

2.2. *Inclusion and exclusion criteria*

Research studies that identified key terms in the title, abstract, article or MeSH heading were retained. All healthcare provider types (e.g. oncologists, counsellors, medical students and nurses) were included. Research articles were eligible for classification in the review if they addressed the issue of provider–patient interactions about bad news related to cancer. Publications that mentioned bad news in the title but in reference to a non-cancer related field were excluded. Books, book chapters, letters, comments on publications and dissertations were excluded.

2.3. *Publication classification*

Publications were progressively classified according to whether or not they: (1) provided new data; (2) evaluated an intervention; (3) measured the psychosocial health of patients as an outcome and (4) met criteria for design rigour as follows.

2.4. *New data*

Publications were coded according to one of the following three classifications:

1. *Non-data based*: papers which did not report any new data and did not mention a 'review'. These may have reported descriptions of methods for undertaking an intervention, about which no data were reported. This included case studies, commentaries and opinion-based papers.
2. *Data-based – no new data*: papers referred to as 'reviews' in the abstract or the title which did not contain any new data but rather collated data from previously published studies.
3. *Data-based – new data:* papers which reported new data or new analysis of data from existing sources but were not reviews.

2.5. *Intervention research*

All publications reporting new data were classified into one of the following categories:

1. *Measurement research*: studies that examined the development, analysis of quality, or testing of an instrument designed to measure a defined aspect of breaking bad news for use with cancer patients or healthcare providers.
2. *Descriptive research*: studies that examined outcomes related to breaking bad news but did not seek to implement or examine the effects of change agents, for example, describing patient satisfaction in relation to how bad news was provided, without attempting to alter provider behaviour.
3. *Intervention research*: studies that tested the effectiveness of a programme to improve the methods used by doctors for breaking bad news, the psychosocial impact on patients and providers of improved techniques, or both. Publications were classified as intervention research if both descriptive and intervention issues were examined.

2.5. *Patient psychosocial outcome*

All publications classified as intervention research were further classified in terms of the outcome measures reported.

1. *Skill-based outcomes*: reported outcomes in relation to provider skills in relation to breaking bad news. Outcomes could include acquisition of clinician or student skills, or perceptions regarding clinician skills. The skill outcomes measured could be itemised and specific (e.g. eliciting of emotions) or overall (e.g. performance score).
2. *Provider psychosocial outcomes*: included measures such as anxiety, depression, stress, distress, satisfaction or burnout for the provider.
3. *Patient psychosocial outcomes*: included measures such as anxiety, depression, stress, distress, satisfaction or quality of life for patients. Where a publication reported both patient and provider psychosocial outcomes, the study was coded as including patient psychosocial outcomes.

2.6. *Design rigour*

The study designs of all publications classified as intervention research and which measured patient psychosocial outcomes were classified according to The Cochrane Collaboration Effective Practice and Organisation of Care (EPOC) definitions which outline design criteria necessary for providing acceptable evidence to guide healthcare practice.[21] Publications were classified as follows:

1. *Randomised Controlled Trial (RCT)*: research that compared two or more interventions, one of which was a control intervention or no intervention, and where individuals or a defined group of individuals were randomly assigned to either an experimental or control condition.
2. *Controlled Clinical Trial (CCT)*: research that compared two or more interventions, one of which was a control intervention or no intervention, using quasi-random allocation method to assign participants to different experimental conditions.
3. *Controlled Before and After Study (CBA)*: studies which used methods other than randomisation to assign participants to intervention and control groups. Baseline and post-intervention periods of assessment were undertaken consistently for study and control groups. Study and control groups are appropriately comparable.
4. *Interrupted Time Series (ITS)*: research whereby a change over time is attributed to the implementation of an intervention that commenced at a clearly defined point in time, and was assessed at three or more data points both before and after the intervention.

Studies that did not meet any of the research design criteria were coded as non-rigorous intervention publications. These designs were not considered to meet criteria for sound intervention evaluation needed for the production of reliable evidence.[21]

2.7. *Intervention effect*

Intervention studies which were classified as meeting the standard for design rigour and which reported a patient psychosocial outcome were then examined for evidence of an intervention effect.

2.8. *Inter-rater reliability*

Ten percent of publications were independently checked by a second coder at each stage of the classification process to ensure consistency. Discrepancies were mutually resolved, with resolutions applied by one coder to all studies.

3. Results

3.1. *Publication search and exclusion*

A total of 443 publications were identified. One hundred and ninety-eight (44.7%) publications were not relevant as they: were duplicates; did not involve humans; contained non-cancer disease-specific prevalence data; were book chapters or texts; or were dissertations or conference papers. Three papers[23–25] provided additional outcome data on previously reported interventions.[26,27] Multiple papers on the same intervention with the same sample were "counted" as one study.

3.2. *Publication classification*

3.2.1. *New data*

Two-hundred and forty-five publications met the inclusion criteria and were included for classification. Of the 245 publications, 109 (44.5%) were non-data based, and 136 (55.5%) were studies which presented new data.

3.2.2. *Intervention research*

The 136 publications (55.5%) categorised as providing new data comprised 88 descriptive studies (64.7%), 41 intervention studies (30.1%) and 7 measurement studies (5.2%). The 41 intervention studies equate to 16.7% of the relevant studies (*n* = 245) regarding breaking bad news about cancer. The intervention strategies primarily included multiple workshops or group-based training sessions with a focus on education along with interaction, role playing or feedback.

3.3. *Psychosocial patient outcomes*

Of the 41 publications classified as intervention studies, 4 included at least one patient psychosocial outcome. This equated to 9.8% of the intervention studies, and 1.6% of the relevant publications about breaking bad news relating to cancer (*n* = 245). The psychosocial outcomes studied included: anxiety and depression as measured using instruments such as the Hospital Anxiety and Depression Scale and State Trait Anxiety Index; distress as measured by the general health questionnaire; satisfaction with care as measured by a range of standardised and non-standardised scales; and quality of life as measured by a range of standardised scales.

3.4. *Design rigour*

Of the 4 intervention studies identified with a patient psychosocial outcome, all used one of the accepted designs (see Fig. 1). The four rigorous intervention studies of psychosocial outcomes represent 1.6% of the total research effort on breaking bad news to cancer patients. Most of the remaining interventions did not meet the criteria due to the lack of control groups (*n* = 34, 82.9%). All of the four interventions were classified as randomised controlled trials. The four intervention studies which included a patient psychosocial outcome and met the criteria for design rigour are described in Table 1.

3.5. *Intervention effect*

Table 1 describes the four intervention studies with patient psychosocial outcomes which met the criteria for adequate design rigour. The studies of the effect of intensive skills training and consolidation on patient anxiety[24,25,27] found no effect. However, reduced patient distress[28] was found in an earlier study including training in skills for emotion handling and problem defining. Betz Brown et al.[29] and Delvaux et al.[23] produced conflicting findings regarding the impact of improved physician communication skills on patient satisfaction, with the more intensive training intervention providing a positive benefit for patient satisfaction.[23]

4. Discussion

The review revealed that an extremely small proportion (1.6%) of the published studies in the field of breaking bad news involved studies which provided an evidence base for practice. Of all publications addressing the issue of breaking bad news to cancer patients, approximately half provided new data and less than one-fifth involved an intervention trial. More than 90% of the intervention effort failed to measure psychosocial outcomes for patients. This is despite the published observation in 1995 that the field had yet to demonstrate improved

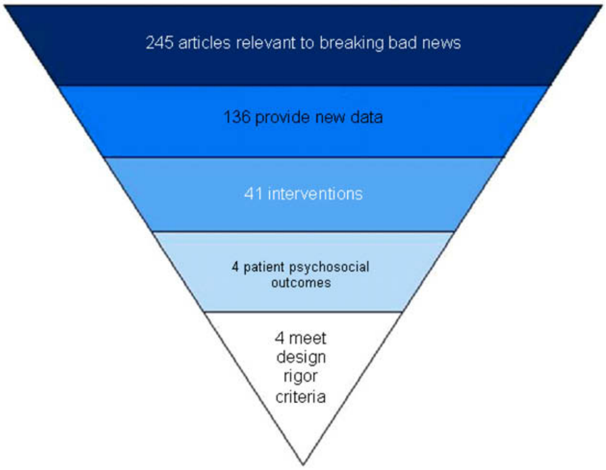

Fig. 1 – Progressive classification of the proportion of relevant literature addressing each of the study aims regarding breaking bad news issues.

Table 1 – Description of intervention studies which included a patient psychosocial outcome and which met criteria for design rigour.

Author and year	Participant group	Design and follow-up	Intervention	Control	Measures	Outcomes evaluated	Improvements	No differences
Lienard et al., 2006[29]Merckaert et al., 2005[28]Razavi et al., 2003[31]	30 intervention and 30 control physicians. 1 cancer patient per physician	RCT Baseline, 1 month follow-up	2.5 day basic communication skills training + 6 × 3 h consolidation workshops	2.5 d basic training programme	(i) Cancer Research Campaign Workshop Evaluation Manual (CRCWEM) via real and simulated patient interview (ii) Perception of the interview Qaire for both provider and patient (iii) Hospital Anxiety and Depression (HADS), State Trait Anxiety Inventory (STAI) for patients	(i) Communication skills-Physician ability to detect patient distress (ii) Evolution of patient anxiety (iii) Associations among patient and provider factors	(i) Some skills (eg Open and directive questioning, alerting patients to reality, decrease in premature reassurance, empathy) (ii) Consolidation workshop associated with use of assessment skills and supportive skills	(i) Some skills ($n = 19$) (ii) Physician ability to detect distress (iii) Patient anxiety
Delvaux et al., 2004[27], Razavi et al., 02[30]	53 intervention and 58 control oncology nurses, 57 intervention and 58 control nursing managers from 88 hospitals	RCT Baseline, immediate, 1 week, and 3 month follow-up	105 h (3 × 1 week) training programme including information, case presentations and role playing	Measurement only	(i) Cancer Research Campaign Workshop Evaluation Manual (CRCWEM) with Simulated and real patient interviews (ii) Nurse stress and satisfaction (iii) Patient satisfaction (SIAQ) and Quality of Life (EORTC QLQ C30) (control) (iv) Harvard Psychosocial and Martindale Regressive Imagery Dictionaries	(i) Provider facilitative behaviours, evaluative functions and inhibitory behaviours (ii) Nurse stress and satisfaction (iii) Patient satisfaction and QoL (iv) Emotional word frequency and emotional depth for providers and patients	(i) Provider facilitative behaviours, evaluative functions and inhibitory behaviours in simulated interviews (ii) Nurse stress (iii) Patient satisfaction (iv) Frequency and depth of emotional words for intervention group with simulated patient	(i) Most scales for real patient interviews (ii) Nurse satisfaction (iii) Use of emotional words with real patients (iv) No group by time effect for functioning, physical symptoms or financial impact (EORTC QLQ C30)
Roter et al., 1995[32]	Primary care physicians and patients: 22 and 207 in intervention 1, 23 and 214 in intervention 2, 24 and 227 in intervention 3	RCT Baseline and Immediate follow-up	2 × 4 h sessions including information, discussion, role play and later practice 1: Emotion handling skills (EH) 2: Problem defining skills (PD)	Measurement only	(i) Simulated patient interviews (ii) Physician questionnaires (iii) Real patient audiotapes (iv) Patient general health questionnaire (GHQ)	(i) EH and PD skills with simulated and real patients (ii) Recognition and management (EH and PD) in real patients with positive GHQ (iii) Reduction in patient distress	(i) At follow-up Intervention physicians used significantly more EH and PD skills and had higher clinical proficiency than controls (ii) Intervention patients had significantly reduced distress compared to controls up to 6 months	
Betz Brown et al., 1999[33]	32 intervention and 29 control clinicians, approx. 81 patients per clinician	RCT Baseline and 1–6 month follow-up	2 × 4 h workshops and homework including education and role play	Measurement only	(i) Clinician self-rated communication skills (ii) Art of Medicine (patient perception) survey	(i) Mean self-rated skills (ii) Relative difference in patient satisfaction	Self rated skills	Patient satisfaction

psychosocial outcomes as a result of appropriate communication skills.

4.1. *The need for new data*

The fact that only slightly more than half of the published work examined in this review provided new data suggests that a disproportionate effort is directed towards commentary and opinion rather than empirical work. This finding is not confined to the field of breaking bad news to cancer patients.[18] It is concerning that publications do not reflect a focus on building an evidence base.

4.2. *A focus on interventions*

An examination of the intervention studies in the field of breaking bad news highlights the difficulties in developing an evidence base. Only 41 publications (16.7%) between 1995 and 2008 were classified as interventions. It must be acknowledged that there are complexities in undertaking intervention research in this field. Intervention research is more difficult to accommodate; requires unique expertise, multidisciplinary input, and management skills, takes longer to complete and poses a risk to researchers who may have reduced publication opportunities. If interventions continue to appear at the current rate, a sound evidence base looks like a distant goal.

4.3. *The importance of psychosocial outcomes*

Only 9.8% of the intervention studies identified here measured a patient psychosocial outcome, suggesting an assumption that improved provider skill is beneficial to patients. Given the small evidence base addressing this point, and the equivocal data produced by the rigorous evaluations of psychosocial outcomes, a health benefit has yet to be reliably demonstrated. Therefore, future studies must include measurement of patient psychosocial outcomes. The wide range of outcomes measured, including anxiety, depression, quality of life, satisfaction and general well-being, suggests a lack of clarity about the mechanism by which appropriately breaking bad news is likely to influence patient outcome. Without consistent evidence of improved psychosocial outcomes, considerable resources may be expended on programmes which provide no real benefit to the patient. Further, clinicians perceiving that current methods improve psychosocial outcomes may be resistant to changing, should other approaches be found effective.

4.4. *Evidence from rigorous studies*

Less than 2% of all publications in the field were directed towards rigorous evaluation of strategies for improving psychosocial patient outcomes. There is little literature supporting a change in patient outcomes as a result of training healthcare providers in breaking bad news. Two studies found increased satisfaction[23] and reduced distress.[28] However other studies failed to find an effect on patient anxiety[24] or satisfaction.[29] Therefore, the literature does not provide sufficient evidence for making recommendations on how to improve psychosocial outcomes for cancer patients when breaking bad news. Consequently, current training and practice in breaking bad news is not evidence-based and may not be having the desired positive effect on patients' psychosocial health.

4.5. *Review limitations*

The limitations of this review include the literature search strategy, which was designed to elicit only published literature. Given the nature of publication bias[30], it is unlikely that many rigorous studies finding a positive intervention effect exist in the unpublished literature. Further, published work may not correspond directly to research effort. Therefore, the number of published intervention studies may underestimate the overall proportion of resources directed towards intervention. However, the small number of intervention studies with a patient outcome ($n = 4$) suggests the overall conclusion that there is insufficient focus on interventions with patient psychosocial outcomes is still valid.

4.6. *The way ahead*

In order to change the research effort in fields like breaking bad news, a more strategic approach to the allocation of research funding could be used. One challenge for the field is producing studies of sufficient quality. These studies may require multidisciplinary teams with links to treatment centres. Design challenges arising from the need to randomise either patients or providers are also soluble. Another methodological challenge in the field involves agreeing on key robust outcome measures. There is a need for a series of rigorous intervention studies which address strategies for improving psychosocial outcomes for cancer patients receiving bad news from clinicians. Changes to current approaches to research funding and access to patients for research would assist in achieving this goal.

Conflict of interest statement

None declared.

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