The impact of routine collection of Patient Reported Outcome Measures on patients, providers and health organisations in an oncologic setting: a rapid review

Jack Chen

An **Evidence Check** review brokered by the Sax Institute

December 2011

saxinstitute

This rapid review was brokered by the Sax Institute.

This report was prepared by Jack Chen.

December, 2011.

Enquiries regarding this report may be directed to the:
Manager
Knowledge Exchange Program
The Sax Institute
www.saxinstitute.org.au
knowledge.exchange@saxinstitute.org.au
Phone: +61 2 95145950
Fax: +61 2 95145951

Suggested Citation:
Chen JC. The impact of routine collection of Patient Reported Outcome Measures on patients, providers and health organisations in an oncologic setting: an Evidence Check rapid review brokered by the Sax Institute (http://www.saxinstitute.org.au) for the Cancer Institute NSW, 2011.

saxinstitute

Contents

EXECUTIVE SUMMARY 5

Question 1 5

Question 2 6

Question 3 7

1 Introduction 9

2 Stage One (Question One) 11

The search strategy in the current study 12

Aims, study selection and endpoints of the review 13

Inclusion and exclusion criteria 16

Data extraction and quality assessment 16

Results 17

3 Stage Two (Question Two) 32

The reliability and validity of commonly used PROs for the four most common cancers 32

The promises of PROMIS® 37

4 Stage Three (Question Three) 42

The likely impact of implementing a PROs system in NSW 42

A composite PROs tool/system that might be suitable for implementation in NSW, and factors to take into consideration when selecting and implementing the tool/system 43

Future questions and areas to address in a scoping review of existing systems that may flow from this work 45

5 Summary 47

References 48

Appendices

Appendix A. Full text search strategies used in Scopus 56

Appendix B: The web-based PROs as reviewed by Jones et al. (2007)[1] 57

Appendix C: The psychometric property appraisal criteria used in the Oxford Group Reviews 59

Appendix D: The available instruments from PROMIS 61

Appendix E: The characteristics of design and study quality 63

Appendix F: The impact and effect sizes of the studies on patients, care providers and organisations 72

Appendix G: Selected publications by the PROMIS network since 2007 76

EXECUTIVE SUMMARY

There is growing interest in and demand for integrating routinely collected patient reported outcome measures (PROs or PROMs) into clinical practice, and to place patients at the centre of care. Commissioned by the Cancer Institute NSW, we conducted a rapid review on three interlinked questions, with the following results.

Question 1

1. What are the impacts of composite measures of PROs that are collected on cancer patients during treatment on:
   a) provider behaviour so as to improve care delivered?
   b) organisational changes within health care settings to improve processes and models of care (e.g. targeting and tailoring care)?
   c) improving clinical outcomes for patients?
   d) improving patient experience of care (e.g. self-care)?
2. What mechanisms were identified as the link between PROs and the identified impacts in 1(a)?
3. What factors moderated the extent of the impacts identified as part of question 1.1?

In order to answer this question, we developed a multi-method search strategy to maximise our coverage of literature in a short period of time. We built our strategy based on three recent systematic reviews and identified an unexpected amount of new literature. We included 27 studies in our review (16 randomised controlled trials, 2 before-after controls and 9 observational studies). In comparison, the most recent review conducted in 2009 included six randomised controlled trials. We developed an outcome matrix based on the theoretical framework proposed by leading researchers in order to understand the impact of routine collected PROs on patient outcomes and the links between PROs and their impacts.

Combining results from both the randomised controlled trials and observational studies, we summarised the overall strength and direction of evidence (Table A). Overall, there is strong evidence supporting the notion that routinely collected PROs, with feedback, improve patient-provider communication and increase patient satisfaction. There is some evidence to support the notion that it improves the monitoring of treatment responses and detection of unrecognised problems. There is some positive evidence that, over time, it leads to changes in patient management. Despite some encouraging results, there is still a great degree of uncertainty regarding the impact of routinely collected PROs, with feedback, on patient health outcomes. There is little or no evidence that it has led to significant positive improvements in quality improvement initiatives, transparency, accountability, and public reporting, or in system performance at a population health or societal level. Apart from clinical trials and clinical practice, its impact on health services research and population health is largely unknown.

Table A: The overall strength and direction of evidence

Results	Strength and direction of evidence
Patient-provider communication	+++
Monitor treatment response	++
Detect unrecognised problems	++
Changes to patient health behaviour	n/a
Changes to patient management	+
Improved patient satisfaction	+++
Improved health outcomes	+/-
Strong & effective quality improvement	n/a
Increased transparency, accountability, public reporting	n/a
Better system performance (monitoring, planning, financing, evaluating, responding)	n/a

Note: ++++: the strongest positive effect; xxxx: the strongest negative effect; n/a: not available;
0: neutral (no significant effect)

Although the evidence is limited, it appears that routinely collected PROs with sufficient intensity of feedback (multiple times over a sustained period of time), targeting multiple stakeholders (doctors, nurses, allied health workers, as well as patients) with simple, clear, graphical and longitudinal meaningful interpretation of the results, and providing sufficient training for both health professionals and patients, are critical links between an intervention and the intended outcomes. There is also evidence to suggest that for some complex issues such as depression and low social functioning, routine screening and feedback may need to be integrated with other strategies such as decision-making aids, education, clear management plans and clinical pathways including referrals, to change patient outcomes. There is preliminary evidence that some of the impacts of PROs may be more pronounced among subgroups with more severe problems at baseline (e.g. depression, symptoms). More studies are needed to fully understanding these mediating and moderating effects.

Question 2

What are the psychometric properties of the composite measures of PROs that were linked to impacts in Question 1?

The Cancer Institute NSW has previously commissioned two reviews which considered the psychometric properties of PROs on pain and symptoms, distress, depression, and anxiety in cancer settings. There are also four recent well-conducted systematic reviews on psychometric properties from the Patient Reported Outcome Measurement Group in Oxford, which covered the four most common cancers (i.e. prostate, colorectal, lung and breast cancer). To avoid overlap, we summarised the key features and findings from the Oxford Group's review (Table B).

Table B: Reviews of psychometric properties of PROs of four most common cancers

Results	Breast Cancer	Prostate Cancer	Lung Cancer	Colorectal Cancer
Total references reviewed	674 + supplementary searches	186	1591	1330
Total publications included	81	76	58	35
Generic PROs Evaluated	SF-36; SF-8; SIP	SF-36; SF-12	SF-36	SF-36; SF-12
Preference-based instrument	EQ-5D	EQ-5D; HUI; QWB	EQ-5D	EQ-5D
General cancer-specific instrument	CARES-SF; EORTC QLQ-C30; FACT-G; FLIC	EORTC QLQ-C30; FACT-G	EORTC QLQ-C30; FACT-G	EORTC QLQ-C30
Condition or site specific cancer instrument	EORTC BR23; FACT-B	QLQ-PR25; FACT-P; FAPSI-8; PCTO-Q; UCLA-PCI; EPIC, revised version of UCLA-PCI; PC-QoL; Prostate Cancer Related Quality of Life; Patient Oriented Prostate Utility Scales (PORPUS)	EORTC QLQ-LC13; FACT-L; LCSS; LCSS-MESO	EORTC QLQ-CR38; FACT-C
Recommended PROs:				
Generic	SF-36	SF-36	SF-36	SF-12
Preference-based	EQ-5D	EQ-5D	EQ-5D	EQ-5D
General cancer-specific	EORTC QLQ-C30; FACT-G	EORTC QLQ-C30	EORTC QLQ-C30	EORTC QLQ-C30
Condition or cancer cite specific	FACT-B	QLQ-PR25; PACT-P (including the 4 domains from the FACT-G); UCLA-PCI & EPIC	EORTC-LC13; FACT-L	FACT-C

In our report we describe, in some detail, *The Patient Reported Outcome Management Information System (PROMIS)*, an exciting new development by the National Institute of Health and National Cancer Institute of the USA that is developing publically available PROs based on Item Response Theory (IRT) and Computer Assisted Test (CAT). We summarised its unique features of comparability, reliability (precision) and validity, flexibility, and inclusiveness in the report.

Question 3

Based on the evidence available to answer Questions 1 and 2, provide advice on:

1. Likely impacts of implementing a PROs system in NSW
2. A composite PROs tool/s that might be suitable for implementation in NSW
3. Factors that would need to be taken into consideration when selecting a PROs tool and implementing it
4. Future questions and areas to address in a scoping review of existing systems that may flow from this work.

We described the possible impact of implementing a PRO system on different stakeholders in NSW. It is likely that there will be many positive impacts of introducing such a system in NSW. Based on existing evidence, there is further potential yet to be realised and documented in the literature. We recommend that the Cancer Institute NSW further explores the feasibility of adopting the PROMIS system, possibly in combination with other validated tools/PROs systems in NSW. We outline some key issues from the literature regarding the implementation of a PROs system and outline some future areas for further investigation.

1 Introduction

Patient reported outcome measures (PROs) include health status assessments, health-related quality-of-life (HRQL), symptom reporting measures, satisfaction with care, treatment satisfaction measures, economic impact measures, and instruments for assessing specific dimensions of patient experience such as depression and anxiety.[1] The USA Food and Drug Agency (FDA) adopts a much broader definition[2]: "A PRO is any report coming directly from patients about a health condition and its treatment", meaning that PROs capture patients' perspectives about how illness or new therapies impact on, for example, their general well-being.

One of the chief obstacles to the routine collection of PROs is the difficulty of integrating the administration and analysis of PRO instruments into clinical practice. To help overcome this problem, researchers are developing and validating alternatives to traditional paper-based instruments. Alternative platforms for assessing PROs include office-based touch-screen computers, telephone-based interactive voice-response (IVR) systems, hand-held computers, mobile phones, and more recently, the Internet. The near-ubiquity of the Internet and the growing use of the World Wide Web ('the web') for delivering health-related information and healthcare interventions make Internet- based platforms a promising tool for enabling routine PRO data collection.

The Cancer Institute NSW, a government agency, has developed the NSW Cancer Plan 2011–2015, aiming for substantially improving cancer control and care through four strategic directions:

- Reducing the incidence of cancer in NSW
- Increasing the survival rate for people diagnosed with cancer
- Improving the quality of life for cancer patients and their carers
- Becoming a source of expertise on cancer and provide expert advice to patients, the public, health care professionals and the Government.

The priorities of the NSW Cancer Plan include improving the survival and quality of life of people with cancer and reducing variations in cancer outcomes across NSW. One of the ways in which the Cancer Institute NSW hopes to achieve this is by refining and using patient level outcomes to generate data feedback to drive performance improvement and improve the quality of patient experiences.

Some of the rationales put forward for measuring PROs in cancer setting include:

- Better communication and shared decision making by patients and providers
- Assessing the health status of patients entering therapy and identifying treatable problems
- Determining the degree and sources of the patient's decreased ability to function
- Distinguishing among types of problems, including physical, emotional, and social
- Detecting adverse effects of therapy
- Monitoring the effects of disease progression and response to therapy
- Informing decisions about changing treatment plans
- Predicting the course of disease and the outcomes of care.

As one step to establishing a routinely collected PROs system in NSW, the Cancer Institute NSW has commissioned a rapid review following two other reviews they commissioned previously. There were three interlinked questions raised in the Cancer Institute NSW brief. They were:

Question 1

1. What are the impacts of composite measures of PROs that are collected on cancer patients during treatment on:
   a) provider behaviour so as to improve care delivered?
   b) organisational changes within health care settings to improve processes and models of care (e.g. targeting and tailoring care)?
   c) improving clinical outcomes for patients?
   d) improving patient experience of care (e.g. self-care)?
2. What mechanisms were identified as the link between PROs and the identified impacts in 1.1?
3. What factors moderated the extent of the impacts identified as part of 1.1?

Question 2

What are the psychometric properties of the composite measures of PROs that were linked to impacts in Question 1?

Question 3

Based on the evidence available to answer Questions 1 and 2, provide advice on:

1. Likely impacts of implementing a PROs system in NSW
2. A composite PROs tool/s that might be suitable for implementation in NSW
3. Factors that would need to be taken into consideration when selecting a PROs tool and implementing it
4. Future questions and areas to address in a scoping review of existing systems that may flow from this work.

In order to answer the three questions raised by the Cancer Institute NSW, we conducted our review in three stages:

Stage 1

We reviewed the literature for Question 1 to summarise the evidence of impact of routine PROs on patients, care providers and decision-makers.

Stage 2

Based on the results of Stage 1, we further reviewed the psychometric properties of the PROs instrument and tools used in cancer setting.

Stage 3

We identified the principles and strategies recommended in the literature in choosing PROs in routine practice and considered their particular relevance to the current study.

2 Stage One (Question One)

Existing systematic reviews and the rationale for the current review

In order to develop an efficient search and review strategy, we first systematically examined existing reviews on the same or similar topics. We identified three reviews as the baseline reviews for this report.

Table 1: A comparison of three baseline reviews

First author, year	Aim and review scope	Time span and the search strategy	Search terms	Articles included in the review	Major conclusions
Luckett et al. 2009[3]	To identify future strategies for: 1. Interventions to impact patient outcomes 2. Trials to identify treatment effects.	MEDLINE and PsycINFO were systematically searched to identify reports of relevant randomised controlled trials. The time span was between 2006 and 1 August 2008. Four cancer trials were cited in a previous review (Valderas et al. 2008)[4].	1. Examined the citations of the four trials 2. Adopted the strategy used by Valderas et al.[4] and Espallargues et al.[5] which involved searching for the terms 'health status', 'functional status' or 'quality of life' and 'clinical practice', 'clinical setting', 'practice setting', 'medical practice' or 'medical consultation' anywhere in the title, abstract or keywords. Results were limited by publication date (2006–2008) and the MeSH or keyword neoplasm.	6 RCTs	Future interventions should motivate and equip health professionals to use PROs data in managing patients, training patients in self-efficacy, using more specific PROs in clinics, improving the interpretability of feedback for both medical staff and patients, and monitoring the use of PROs to intervene when problems arise. Future trials should use a cluster randomised design to control for contamination and enable systems-based interventions.
Valderas et al. 2008[4]	To summarise the best evidence regarding the impact of providing PROs information to health care professionals in daily clinical practice.	Systematic review of randomised clinical trials (Medline, Cochrane Library); reference lists of previous systematic reviews; and requests to authors and experts in the field. Time span: Articles published between 1978 and 2007.	No exact search terms provided but indicated available from the author upon request.	34 articles corres-ponding to 28 original studies; only 2 (not 4) as mentioned in the above review, are in an onco-logic setting.	Methodological concerns limit the strength of inference regarding the impact of providing PROs information to clinicians. Results suggest great heterogeneity of impact; contexts and interventions that will yield important benefits remain to be clearly defined.
Marshall et al.	To synthesize the evidence for using	Webspirs Medline was searched for	Terms used in relation to patient-reported	40 articles included in	The pattern of results suggests a general lack

First author, year	Aim and review scope	Time span and the search strategy	Search terms	Articles included in the review	Major conclusions
2006[6]	publically reported performance data to improve quality. Only articles that provided empirical evidence on the impact of public reporting on outcomes (effectiveness, patient safety, and patient-centeredness) and unintended consequences, as well as selection and quality improvement activity were included.	the years from January 1976 to November 2004. Reference lists of included studies and appropriate reviews (Greenhalgh and Meadows 1999[7]; Espallargues et al. 2000[5]; Gilbody et al. 2003[8]) were also searched for relevant articles. Finally, PubMed's 'related articles' feature was used with several background and included articles (Drury et al . 2000[9]; Velikova et al. 2004[10]) to identify publications with a high proportion of similar text in the title and abstract.	outcome measures (for example, 'self report* near2 measure*') joined with an 'and' command to terms related to routine practice outcomes (for example, 'improve* near detect*') or patient involvement in the health care process (such as 'patient* near provider* near interaction*').	the review including 5 publi-cations from an oncologic setting.	of clarity in the field, especially regarding appropriate goals for PROs and the mechanisms by which they might achieve them. To fully evaluate their role in routine practice, studies need to use PROs that capture issues of importance to patients and to measure impacts relating to the patient–provider relationship and patient contributions to their well-being. Until studies evaluate PROs as a means to facilitate patient-centred care, their full potential in clinical practice will remain unknown.

Analysing the results of the above three systematic reviews demonstrates the importance of search strategies in determining what literature will be included in the study, which in turn, may influence what conclusions will be derived. Valderas et al.'s (2008)[4] review did not include three out of the five clinical trials on cancer patients included in Marshall et al.'s (2006)[6] review. Luckett et al.'s (2009)[3] review did not include one article (i.e. Taenzer et al. (2000)[11], a before-after controlled trial) from Marshall et al.'s review.[6] Given the fact that the Stage 2 tasks depend on the results of Stage 1, we developed a comprehensive search strategy in order to capture most, if not all, the relevant studies.

The search strategy in the current study

We limited our search to the Scopus database, for the following reasons:

1. It is the largest abstract and citation database of peer-reviewed literature and quality web sources
2. It has tools to track, analyse and visualize research
3. It covers nearly 18,000 titles from more than 5,000 international publishers, including 100% coverage of Medline titles and EMBASE making any other search using Medline and EMBASE redundant
4. It has powerful and efficient features in retrieving full-text publications
5. Its references tracking feature is well suited to our top-down and bottom-up search strategy, discussed below.

We developed a mixed methodology search in order to maximise identification of recent literature in a short period of time. We conducted our search in five different ways.

1. We developed a text-based search strategy based on previous reviews. We searched for text terms 'patient reported outcome*', 'self-reported', 'self-assessed' anywhere in title, abstract and key words, combined with 'quality of life', 'symptom', 'functional status', 'health status', 'patient satisfaction', 'unmet need*' anywhere in title, abstract and key words, and with 'neoplasm' or 'cancer' in key words. The search results were restricted to between the year 2000 and October 2011. The full search strategy is listed in Appendix A
2. We reviewed all reviews (over 200 in total) and used the three baseline reviews discussed above, as the starting point for our top-down and bottom-up search strategy
3. We examined all articles that cited the 7 key randomised controlled trials[10-16] listed in the above reviews (bottom-up approach). We also tracked down references from the most recent published trials, editorials, and commentaries (a top-down approach). The powerful citation tracking feature of Scopus makes such a strategy feasible
4. We used the simplified text terms and conducted a web search in order to identify grey literature
5. We purposefully searched leading researchers and experts in the field and analysed the references and citations of their publications
6. We searched some key cancer centres' websites in order to get more detailed information. Overall, we reviewed over 2000 titles and abstracts of peer-reviewed articles and retrieved over 500 full text articles and reports.

Aims, study selection and endpoints of the review

In this review, we aim to synthesize the evidence in relation to the impact of routinely collected PROs on patients, providers, and health organisations. We adopted the frameworks proposed by Greenhalgh and colleagues (2005)[17] and by Abernethy and colleagues (2010)'s[18] to guide our evaluation of the existing literature.

Greenhalgh et al. (2005)[17] proposed a framework (Figure 1) that depicts mechanisms between the routine collection of PROs and changes in patient outcomes. The authors posit that the multilayer mediators (i.e. changes to doctor-patient communication, monitoring treatment responses, detecting unrecognised problems, changes to patient health behaviour, changes to clinicians' management plans, and improved patient satisfaction) have complex relationships among them. The studies that unveiled these complex relationships may help us understand whether and how routinely collected PROs work to improve the intended outcomes.

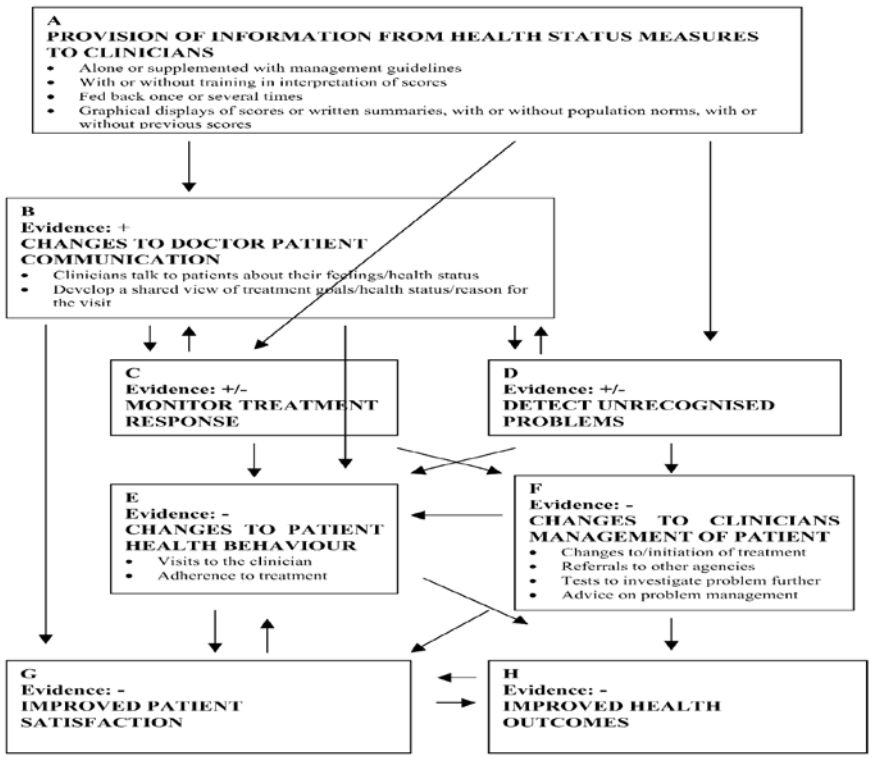

Figure 1: A hypothetical framework to understand the impact of routinely collected PROs on patient health outcomes.

(Reprinted from: Social Science and Medicine, Vol 60, Issue 4, Greenhalgh J, Long AF, Flynn R**,** *The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory?* Pages 833-843, 2005, with permission from Elsevier.)

Recently, Abernethy and colleagues[18] have argued that the routine collection of PROs has the capacity to impact not only at the patient-level, but by addressing the logistics of data linkage, could ensure that the system will grow to accommodate other clinical- and health system-level issues (e.g. evaluating comparative effectiveness of treatments, monitoring quality of care, and translating basic science findings into clinical practice, Figure 2). The integration of data systems will fuel rapid learning in cancer care at the national and societal levels (See Figures 2 and 3), making many types of research and system learning possible across institutions and health sectors. The benefits and implications of such rapid learning health care systems may include, but is not limited to, strong and effective quality improvement (QI), increased transparency, accountability, public reporting, better health system performance (monitoring, planning, financing, evaluating, responding) and better quality of care.

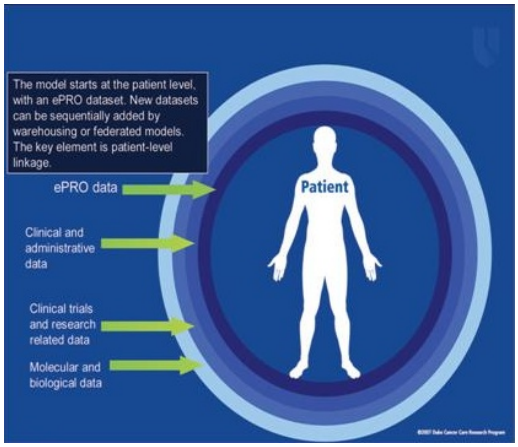

Figure 2: A data linkage framework

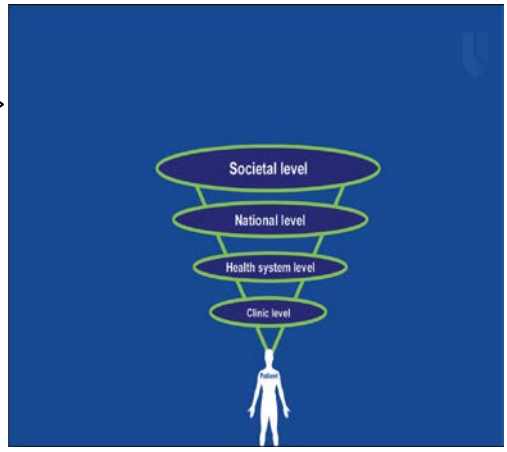

Figure 3: A learning health care system

Figures 2 and 3: adopted from Abernethy et al. (2010)

(Reprinted from: Medical Care, Vol 48, No 6, Supplement 1, Abernathy A, Ahmad A, Zafar YS et al. Electronic patient-reported data capture as a foundation of rapid learning cancer care, Pages S34 and S37, 2010, with permission from Wolters Kluwer Health.)

Combining both frameworks, we developed a list of outcome indicators (Table 2) against which we assessed each eligible study. To include not only the doctors' but also other health service providers' (such as nurses, allied health workers) experience with patients after adopting a PROs system, we used the term 'Patient-provider communication' instead of 'doctor patient communication' as proposed by Greenhalgh et al. (2005)[17] in the current study. We also examined the possible modification and subgroup effects as stipulated by the Cancer Institute NSW.

Table 2: Outcome indicators assessed for each eligible study included in the review

No.	Outcomes
1	Patient-provider communication
2	Monitor treatment response
3	Detect unrecognised problems
4	Changes to patient health behaviour
5	Changes to patient management
6	Improved patient satisfaction
7	Improved health outcomes
8	Strong & effective quality improvement
9	Increased transparency, accountability, public reporting
10	Better system performance (monitoring, planning, financing, evaluating, responding)
11	Modify variables on the effect (both at individual and organisation level)
12	Possible subgroup effects

Note: We combined both 11 & 12 in the summarising tables as few studies have explored such issues.

Inclusion and exclusion criteria

The inclusion criteria were: (1) Substantial content in presenting empirical evidence on the impact of routinely collected PROs on at least one of the outcomes listed in Table 2; (2) Adult cancer patients; (3) Conducted in an oncologic setting including inpatient, outpatient and outreach services; and (4) Studies using a composite PROs system. We excluded studies on child cancer patients, non-English language articles, opinion and theoretical articles, historical descriptions, review articles, and feasibility studies of some PROs collection devices. To reflect the demanding and complex nature of evaluating the impact of routinely collected PROs, eligible studies included a variety of designs including, but not limited to, randomised controlled trials (RCTs), controlled before-after trials (CBA) and interrupted time series (ITS). ITS designs have a longitudinal character, with repeated measurements and at least 3 data points before and after the intervention point. We also included surveys and clinical audits, if the studies provided quantitative results relevant to the listed outcomes.

Data extraction and quality assessment

All studies were classified into two domains. The first correlated sample characteristics and population wide characteristics and the second focused on study design. The data extraction form was adapted from other review studies using the outcome measures discussed above (Table 2). For each eligible study, we listed the leading author, country and jurisdiction, design, sample, outcome measures, the PROs used, times of feedback and intervention, members of medical teams given feedback, management plans offered to the teams, and training (see Appendix E). We also listed all qualifying studies chronologically and the outcome indicators (see Appendix F).

We classified the application of routinely collected PROs in particular participants or samples as domain one and rated it on a four-point scale representing how closely the participants or samples overlapped with the characteristics and needs of the intended study populations. For example, for a study conducted in the USA on a sample of lung cancer patients, we assessed the degree of overlap of the study sample with the characteristics of lung cancer patients in the USA overall, by considering the study setting, sample size and sampling frame, response rate, loss-to-follow-up, and the characteristics of the study sample. We classified study design as domain two and rated it on four categories with one star indicating the weakest design and four stars indicating the strongest design. Four stars indicates a randomised trial or experimental study; three stars indicates a controlled trial, pre-post trial with control (controlled before–after trial), time series, or observational cohort with multivariable adjustment; two stars indicates a pre–post trial without control, observational cohort study without multivariable adjustment, cross-sectional study without multivariable adjustment, analysis of time trends without control, or well-designed qualitative study; and one star indicates a case series, other qualitative study, or survey (descriptive) study.

We used revised appraisal criteria adapted from the guidelines on the assessment of quality improvement interventions.[19,20] We also created a global rating after the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system.[21] The BMJ has recommended the GRADE system since 2006 (through its 'Instructions to Authors' on bmj.com) for grading evidence when submitting a clinical guidelines article. It has multiple advantages and is useful for systematic reviews and health technology assessments, as well as for evaluating research on clinical guidelines. The global rating we created was based on the integration of domain one and domain two ratings, as well as the intervention fidelity (the degree of success of the interventional strategy, the patients' and providers' adherence to the intervention strategy), dose-response gradient, precision and validity of outcomes (potential confounding factors and biases), uncertainty of direction of the results. The global rating has three categories. We indicate

that the study should carry great (three checks), moderate (two checks), or little (one check) weight when considering the strength of evidence. An illustration of the rating scheme is presented (Table 3).

Table 3: The components, rating criteria and symbol, and categories used in summarising the study evidence in the current study

	Domain 1	Domain 2	Global (GRADE)
Decision components	Subject of public reporting (or study population) and study participants (sample).	Types of study (i.e. study designs).	Components from Domain 1 & 2 as well as implementation and adherence to intervention, dose-response gradient, precision and validity of the outcomes, uncertainty of direction of the results.
Rating criteria	How well does the study sample represent the study population?	How strong is the study design both in terms of its external and internal validity?	How much weight does the current study add to the evidence-base taking into considerations of all the components above?
Symbol used & categories of rating	1* : no overlap 2*: modest overlap 3*: large overlap 4*: complete overlap	1*: weakest design 2*: moderate design 3*: strong design 4*: strongest design	√: little weight √√: moderate weight √√√: great weight

We made no attempt to quantitatively synthesise the results and the data were too heterogeneous to support pooling.

Results

Our multi-method search strategy yielded 27 publications that were eligible to be included in our review – a significant increase compared with the most recent reviews. We identified 16 randomised controlled trials and 2 before-after trials with 11 published before 2009. We presented the characteristics and the quality of the studies in Appendix E and their impact on outcome indicators in Appendix F.

An overview of the study quality

There has been a marked increase in the volume and quality of studies published recently in this area. Of the 16 randomised controlled trials included in this review, seven were published between 2010 and 2011. The quality of studies published since 2010 is also demonstrably better with much larger sample sizes, and with three trials[22-24] having a sample size of more than 200 and two trials having a sample size over 580.[25,26]

However, despite the increased volume and improved quality of studies, there were still no large cluster randomised controlled design studies recommended by Fayers[27], who argues that cluster RCTs are well suited to overcoming the limitations of simple RCTs. It is well-known that system intervention trials such as routine collection of PROs, and feedback to the clinicians and systems, are prone to cross-contamination and to introducing investigator and participant biases. Two recently published studies[22,23] were the continuation of an earlier study published by Velikova et al. (2004)[10]. Most studies did not systematically examine outcomes and mechanisms, and placed more emphasis on processes instead of outcome measures.[12] All studies were conducted in a limited setting (often in a single centre) thus restricting the generalisation of the findings.

Another significant limitation of the current evidence is that no studies have adopted a comprehensive theoretical model and framework, despite the repeated demand from leading researchers in the area.[17,28-30] All studies concentred on the level of patients and health professionals in clinic settings and no study examined the impact of collecting PROs on health care organisations, health system improvement, quality improvement or population health at a system or societal level.

An overview of the study findings

The 16 randomised controlled trials and 9 before-after controlled trials

We present the design and major findings from each of the RCTs in chronological order below. A full assessment of their impact on outcome indicators is provided in Appendices E and F.

Trowbridge et al. (1997)[16] conducted a randomised controlled trial on 510 cancer outpatients to determine the effectiveness of a clinical-practice intervention in improving pain control at 23 clinics in Indiana, the USA. All the patients completed assessments of their pain, their pain regimens, and the degree of relief received. The patients were surveyed again by mail four weeks after their clinic visits. The intervention group's clinical charts contained a summary of the completed pain scales. The oncologists who treated these patients were instructed to review the summary sheet prior to an evaluation. This summary was not available for the oncologists treating the patients in the control group. A significant difference ($p = .0162$) in the physicians' prescription patterns was found. In the control group, prescriptions for 86% of the patients did not change, with no decrease in analgesic prescriptions; for 14% of the patients analgesic prescriptions increased. In the intervention group; analgesic prescriptions changed for 25% of the patients, decreasing for 5% and increasing for 20%. A decrease in the incidence of pain described as more than life's usual aches and pains was found for the intervention group ($p = .05$). The authors reported that although analgesic regimens were altered significantly when the physicians understood more about the patient's pain, cancer pain management remains a complex problem.

Comments: This study is one of the first RCTs demonstrating a significant impact of PROs on improved detection of unrecognised problems, changes to patient management plans as well as a modest improvement on selected health outcomes.

Using a sample of 450 cancer patients and standardised questionnaires via a touch-screen computer, McLachlan and colleagues (2001)[15] tested the hypothesis that making patient-reported cancer needs, quality-of-life (QL), and psychosocial information available to the health care team, allowing coordinated specifically targeted psychosocial interventions will result in reduced cancer needs, improved QL, and increased satisfaction with care received. For a randomly chosen two thirds, this information was made available to the health care team who coordinated the targeted psychosocial interventions. Information from the remaining one third was not seen. Patients were assessed two and six months after randomisation for changes in their cancer needs, QL, psychosocial functioning, and satisfaction with overall care received. The authors reported that there were no significant differences between the two arms with respect to changes in cancer needs, QL, or psychosocial functioning between the baseline and follow-up assessments, nor with respect to satisfaction with care. However, for the subgroup of patients who were moderately or severely depressed at baseline, there was a significant reduction in depression for the intervention arm relative to the control arm at the six month assessment. The study also demonstrated no consultation time differences between two-arms. Only 37% of the patients received anticancer therapy at baseline that may have marked potential effect.

Comments: Making patient-reported cancer needs, QL, and psychosocial data available to the health care team at a single consultation together with coordinated psychosocial interventions does not seem to reduce cancer needs nor improve QL, psychosocial functioning, or satisfaction

with the care received. However, identification of patients with moderate or severe levels of depression at baseline may be valuable in reducing subsequent levels of depression.

Detmar et al. (2002)[14] evaluated the efficacy of standardised HRQL assessments in facilitating patient-physician communication and increasing physicians' awareness of their patients' HRQL-related problems on ten physicians and 214 patients in an outpatient clinic of a cancer hospital in the Netherlands in a prospective RCT. At three successive outpatient visits, patients completed an HRQL questionnaire (EORTC QLQ-C30). The responses were computer scored and transformed into a graphic summary. Physicians and patients received a copy of the summary before the consultation in intervention group. The investigators audio taped the consultations and analysed content to evaluate patient-physician communication. The study also assessed physicians' awareness of their patients' health problems. The authors found that the HRQL-related issues were discussed significantly more frequently in the intervention than in the control group. Physicians in the intervention group identified a greater percentage of patients with moderate-to-severe health problems in several HRQL domains than did those in the control group. All physicians and 87% of the patients believed that the intervention facilitated communication and expressed interest in its continued use.

Comments: The study demonstrated the positive impact on communication, detection of unrecognised problems, changes to patient management, improved patient satisfaction and modest improvement on selected health outcome (i.e. SF-36, before-after in intervention group).

Velikova and colleagues (2004)[10] examined the effects on process of care and patient well-being, of the regular collection and use of health-related quality-of-life (HRQL) data in oncology practice involving 28 oncologists. In total, 286 cancer patients were randomly assigned to either the intervention group (completion of questionnaires on touch-screen with feedback); attention-control group (completion of questionnaires, but no feedback); or control group (no HRQL measurement in clinic before encounters). Primary outcomes were patient HRQL over time, measured by the Functional Assessment of Cancer Therapy-General questionnaire, physician-patient communication, and clinical management, measured by content analysis of tape-recorded encounters. The authors found that patients in the intervention and attention-control groups had better HRQL than the control group (P = .006 and P = .01, respectively), but the intervention and attention-control groups were not significantly different. A positive effect on emotional well-being was associated with feedback of data, but not with instrument completion. A larger proportion of intervention patients showed clinically meaningful improvement in HRQL. More frequent discussion of chronic nonspecific symptoms was found in the intervention group, without prolonging encounters. There was no detectable effect on patient management. In the intervention patients, HRQL improvement was associated with explicit use of HRQL data, discussion of pain, and role function.

Comments: The study showed that routine assessment of cancer patients' HRQL had a positive impact on physician-patient communication, detect unrecognised problems (64% encounters involving referring to HRQL by physicians) and resulted in better patient management (11% of encounters in intervention arm) and better patient outcomes (HRQL and emotional functioning).

Boyes et al. (2006)[13] examined the effectiveness of giving medical oncologists immediate feedback about cancer patients' self-reported psychosocial well-being in reducing those patients' levels of anxiety, depression, perceived needs and physical symptoms in a RCT. Cancer patients attending one cancer centre for their first visit were randomly allocated to intervention (n = 42) or control (n = 38) groups. All patients completed a computerised survey assessing their psychosocial well-being while waiting to see the oncologist. Intervention patients' responses were immediately scored and summary reports were placed in each patient's file for follow-up. Intervention patients who reported a debilitating physical symptom at visit 2 were significantly less likely to report a debilitating physical symptom at visit 3 compared with control patients. Reductions in levels of anxiety, depression and perceived needs among intervention patients

were not significantly different to control patients. Half the oncologists in the intervention group referred to patients' reported outcomes during the consultations.

Comments: The study showed that repeated collection and immediate feedback of patient-reported health information to oncologists has potential to improve communication and patients' symptom control, but has little impact upon emotional well-being, including those at high risk.

Hoekstra et al. (2006)[31] investigated the effect of reporting physical symptoms by using a systematic symptom monitoring instrument, the Symptom Monitor, on symptom prevalence and severity among 146 palliative cancer patients (intervention group = 69 with Symptom Monitor or control group = 77 without Symptom Monitor). Ten physical symptoms with regard to prevalence and severity were monitored. After 2 months, the prevalence of symptoms was lower in the intervention group compared to the control group (prevalent differences 2.1–24.3%) for 9 out of 10 symptoms (except coughing). The intervention group scored a statistically significantly lower prevalence in constipation and vomiting (prevalence differences 24.3% and 18.0%, respectively). In four symptoms (fatigue, lack of appetite, shortness of breath, and nausea), the intervention group had a lower, although not statistically significant, severity score (median differences 0.5–1). In four symptoms (pain, coughing, sleeplessness, and diarrhoea), the severity score was the same in both groups (medians 2–4). In two symptoms (constipation and vomiting), the severity score was lower in the control group (median differences -1 and -2). A comparison between the study groups on improved, deteriorated, or steady-state cases showed that the severity score had deteriorated less for 8 out of 10 symptoms in a larger proportion of patients in the intervention group.

Comments: The study showed some minimum impact on communication (one in five patients used it to enhance communication with doctors) and decreased prevalence in 9 out of 10 symptoms and such beneficial effects were more pronounced in the deteriorated group.

Korniblith and colleagues (2006)[32] examined whether distress in older patients (aged 65 years and older) would be reduced with educational materials (EM), supplemented by monthly telephone monitoring (TM) (TM + EM) compared with the use of EM alone because of more timely referrals to appropriate health professionals. One hundred and ninety-two older patients who had advanced disease and were currently receiving treatment were randomised to receive either TM + EM or EM alone. One hundred and thirty-one patients were evaluated by telephone interview for psychological and physical distress and for social support at baseline and at six months using HADS, EORTC QLQ-C30 and MOS Social Support Survey items. Patients who in the TM + EM group were called monthly for six months to monitor their distress. Those patients who scored above the cut-off levels were referred to their oncology nurse for referral to the appropriate professional. Patients in the EM group received written materials regarding cancer-related psychosocial issues and available resources. The authors found that at 6 months, patients in the TM + EM group reported significantly less anxiety, depression, and overall distress compared with patients in the EM group.

Comments: The study showed that monthly monitoring of older patients' distress with TM + EM with referral for appropriate help was found to be an efficient means of reducing patients' anxiety and depression compared with patients who received only EM. Both arms improved communication but the TM + EM arm detected more unrecognised problems.

Rosenbloom and colleagues (2007)[12] examined whether offering interpretive assistance of HRQL results would improve patient outcomes. Two hundred and thirteen participants with metastatic breast, lung or colorectal cancer were randomly assigned to one of three conditions: usual care; HRQL assessment or HRQL assessment followed by a structured interview and discussion. Interviews about patients' assessment responses were conducted by a research nurse, who then presented HRQL information to the treating nurse. HRQL and treatment satisfaction outcomes

were assessed at three and six months. No significant differences were found between study conditions in HRQL or satisfaction.

Comments: The study suggests that routine HRQL assessment, even with description of results, is insufficient to improve patient HRQL and satisfaction. Positive effects may require supplementing assessment results with specific suggestions for clinical management changes.

Given and colleagues (2008)[33] compared symptom response and times to response among 129 breast cancer patients who were assigned to either a cognitive behavioural Nurse-Administered Symptom Management intervention or an Automated Telephone Symptom Management (ATSM) intervention. Anchor-based definition of response using mild, moderate, and severe categories of symptom severity were used. Responses and times to response for 15 symptoms were investigated in relation to trial arm, comorbid conditions, treatment protocols, and metastatic versus localised disease. The authors found that the ATSM arm was more effective among patients with metastatic disease. Compared with patients receiving combination chemotherapy protocols, those patients treated with single agents had greater response and shorter time to response.

Comments: An educational information intervention delivered via an automated voice response system that assesses symptoms and refers patients to a Symptom Management Guide is more effective than a complex cognitive behavioural approach in terms of producing greater symptom responses in shorter time intervals among patients with metastatic disease. The ATSM arm also improves monitoring treatment response and detection of unrecognised problems.

Kearney and colleagues (2009)[34] conducted a RCT to evaluate the impact of a mobile phone-based, remote monitoring, advanced symptom management system (ASyMS©) on the incidence, severity and distress of six chemotherapy-related symptoms (nausea, vomiting, fatigue, mucositis, hand-foot syndrome and diarrhoea) in 112 patients receiving outpatient chemotherapy with lung, breast or colorectal cancer (56 patients for both control group and intervention group) in seven clinical sites in the UK. The authors used a paper version of chemotherapy-related morbidity of six common chemotherapy-related symptoms (nausea, vomiting, fatigue, mucositis, hand-foot syndrome and diarrhoea) as the outcome measures and used an electronic version of ASyMS© to monitor the symptoms in the intervention arm at least twice a day (i.e. morning and evening, or as necessary). The authors found that there were significantly higher reports of fatigue in the control group compared to the intervention group. Reports of incidence, severity and distress level of hand-foot syndrome were on average lower in the control group.

Comments: This pilot study demonstrates that ASyMS© can support the management of symptoms in patients with lung, breast and colorectal cancer receiving chemotherapy. It demonstrates that this mobile phone-based technique may improve the management of fatigue and identified hand-foot syndrome which may have been underreported in a routine care model. However, the authors also suggested that a large trial with sufficient power is needed in order to ascertain the impact of adopting such a technology.

Carlson et al. (2010)[26] evaluated a routine online distress screening program on 585 breast cancer and 549 lung cancer patients. Patients were randomly assigned to one of three conditions: (1) Minimal screening: the distress thermometer (DT) only plus usual care; (2) Full screening: DT, problem checklist, Psychological Screen for Cancer Part C measuring anxiety and depression, a personalised report summarising concerns and the report on the medical file; or (3) Triage: full screening plus optional personalised phone triage with referral to resources. Patients in all conditions received an information packet and were reassessed 3 months later with the full screening battery. The authors found that high prevalence of baseline distress was found across patients. Twenty percent fewer patients with lung cancer in triage continued to have high distress at follow-up compared to those in the other two groups, and patients with breast cancer in the

full screening and triage conditions showed lower distress at follow-up than those in minimal screening. The best predictor of decreased anxiety and depression in full screening and triage conditions was receiving a referral to psychosocial services.

Comments: The authors showed routine online screening is feasible in a large cancer centre and may help to reduce future distress levels, particularly when coupled with uptake of appropriate resources.

Ruland et al. (2010)[35] examined the effects of a computer-assisted, interactive tailored patient assessment (ITPA) tool in oncology practice on: documented patient care, symptom distress, and patients' need for symptom management support during treatment and rehabilitation using a sample of 145 patients treated for leukaemia or lymphoma (intervention group, n = 75 or control group, n = 70). Both groups used the ITPA for symptom assessments prior to inpatient and outpatient visits for up to one year. The assessment summary, which displayed patients' self-reported symptoms, problems, and distress in rank-order of the patient's need for support, was provided to physicians and nurses in the intervention group only but not in the control group. The study found that significantly more symptoms were addressed in the intervention group patient charts versus those of the control group. Symptom distress in the intervention group decreased significantly over time in 11 (58%) of 19 symptom/problem categories versus 2 (10%) for the control group. Need for symptom management support over time also decreased significantly more for the intervention group than the control group in 13 (68%) symptom categories.

Comments: This is the first study to show that an ITPA used in an interdisciplinary oncology practice can significantly improve patient-centred care and patient outcomes, including reduced symptom distress and reduced need for symptom management support.

Velikova and colleagues (2010)[23] presented the results of follow-up of a previous trial[10] and investigated the effects of regular use of health-related quality of life (HRQL) in oncology practice, focusing on the secondary aims of the trial: patient satisfaction and patients' perspectives on continuity and coordination of their care. Two hundred and eighty six cancer patients were randomised to: (1) Intervention arm: regular touch-screen completion of HRQL with feedback to physicians; (2) Attention-control arm: completion of HRQL without feedback; and (3) Control arm: no HRQL assessment. Secondary outcomes were patients' experience of continuity of care (Medical Care Questionnaire (MCQ)) including 'Communication', 'Coordination' and 'Preferences to see usual doctor' subscales, patients' satisfaction, and patients' and physicians' evaluation of the intervention. The study found that patients in the intervention arm rated their continuity of care as better than the control group for the 'Communication' subscale. No significant effects were found for 'Coordination' or 'Preferences to see usual doctor'. Patients' evaluation of the intervention was positive. More patients in the intervention group rated the HRQL assessment as useful compared to the attention-control group (86% versus 29%), and reported that their doctors considered daily activities, emotions and quality of life.

Comments: The study showed that use of HRQL measures in oncology practice brought changes to doctor-patient communication and improved patient satisfaction.

Berry and colleagues (2011)[25] conducted a trial in 660 patients with various cancer diagnoses to determine the effect of the Electronic Self-Report Assessment-Cancer (ESRA-C) on the likelihood of symptoms and quality-of-life issues (SQLIs) discussed between clinicians and patients with cancer in ambulatory clinic visits. Secondary objectives included comparison of visit duration between groups and usefulness of the ESRA-C as reported by clinicians. In the intervention group, patient-reported SQLIs were automatically displayed on a graphical summary and provided to the clinical team before an on-treatment visit (n = 327); in the control group, no summary was provided (n = 333). SQLIs were scored for level of severity or distress. One on-treatment clinic visit was audio recorded for each participant and then scored for discussion of each SQLI. The study found that the likelihood of SQLIs being discussed differed by randomised group and depended

on whether an SQLI was first reported as problematic. Clinic visits were similar with regard to duration between groups, and clinicians reported the summary as useful.

Comments: The study showed that using ESRA-C in the setting can improve communication and the effect was more pronounced among patients whose baseline SQLIs level was problematic.

Cleeland et al. (2011)[36] examined whether at-home symptom monitoring plus feedback to clinicians about severe symptoms contributed to more effective postoperative symptom control among 79 patients receiving thoracotomy for lung cancer or lung metastasis in a two-arm randomised controlled trial. After hospital discharge, patients rated symptoms twice weekly for four weeks via automated telephone calls. For intervention group patients, an e-mail alert was forwarded to the patient's clinical team for response if any of a subset of symptoms (pain, disturbed sleep, distress, shortness of breath, or constipation) reached a predetermined severity threshold. The study found that the intervention group experienced greater reduction in symptom threshold events than did controls (19% v 8%, respectively) and a more rapid decline in symptom threshold events. The difference in average reduction in symptom interference between groups was -0.36 (SE, 0.078; P = .02). Clinicians responded to 84% of e-mail alerts. Both groups reported equally high satisfaction with the automated system and with postoperative symptom control.

Comments: Frequent symptom monitoring with alerts to clinicians when symptoms became moderate or severe reduced symptom severity and increased patient satisfaction. However, these results should be confirmed in a larger study.

Takeuchi and colleagues (2011)[22] used the new data from a previously published trial[10,23] to examine how PROs feedback had an impact on patient-physician communication over time to gain a better understanding of how it may influence patient care. Patients were randomly assigned to intervention (regular completion of EORTC QOL-C30 and HADS with feedback to oncologists), attention-control (completion of same questionnaires without feedback), and control (standard care) arms. The content of consultation audio recordings between 28 oncologists and 198 patients over four consecutive visits (792 consultations) was analysed. The longitudinal impact of the intervention on patient-physician communication, dynamics of patient-physician interaction, and the association between PROs and the content of clinic discussion were analysed. The study found that patients in the intervention arm discussed more symptoms over time compared with patients in the attention-control and control arms. No study arm effect was observed for function discussions. Discussion topics were predominantly raised by patients/relatives, regardless of arm allocation. Clinic discussions were associated with severity of patient-reported symptoms but not with patient-reported functional concerns.

Comments: A positive longitudinal impact of the intervention on symptom discussion was observed, but not for function discussion, suggesting that potentially serious problems may remain unaddressed. Physicians may need to play a more proactive role in initiating the discussion topics.

The two before-after trials

Apart from the 16 RCTs discussed above, Taenzer and colleagues (2000)[11] conducted an earlier before-after trial with the period before intervention as a historical control to determine if providing patient specific Quality of Life (QL) information to clinic staff before a clinic appointment improved patient care in a lung cancer outpatient clinic. Patients were sequentially assigned to either a usual care control group or the experimental group, which completed a computerised version of EORTC QLQ-C30 questionnaire in order to provide the clinic staff with QL information prior to the clinic appointment. The control group completed the EORTC QLQ-C30 paper version after the clinic appointment. Outcome measures were patient satisfaction, the degree to which issues identified on the QL questionnaire were addressed in the appointment, and a chart audit, which measured charting of QL issues and actions taken by the clinician

relating to QL. The study found that in the experimental group, more QL issues identified by the patient on the EORTC QLQ-C30 were addressed during the clinic appointment than in the control group. More categories were charted and a trend towards more actions being taken was seen in the experimental group. Patients reported being equally and highly satisfied with the treatment in both groups.

Comments: This is an earlier before-after trial which demonstrated that routine collection of PROs and feedback is a simple, time-effective and acceptable means of improving patient-provider communication. It also showed high patient satisfaction and improved detection of unrecognised problems.

Hilarius et al. (2008)[37] evaluated the efficacy of incorporating standardised health-related quality of life (HRQL) assessments as a routine part of the outpatient chemotherapy treatment of cancer patients in a community hospital in terms of: (1) Facilitating nurse-patient communication; (2) Increasing nurses' awareness of patients' HRQL; (3) Patient management; (4) Patients' satisfaction; and (5) Patients' HRQL in a sequential cohort study with repeated measures (using before 'washing-out' period as control). The intervention involved patients completing standardised HRQL questionnaires via a touch-screen computer, the results of which were provided to nurses and patients in a graphic summary. Questionnaire and medical record data were used to assess outcomes. The study found that HRQL-related topics were discussed significantly more frequently in the intervention group than in the control group. Nurses' awareness of patients' levels of daily activity, pain, and overall quality of life was significantly better in the intervention than in the control group. The mean number of HRQL-related notations in the medical records was significantly higher in the intervention group. However, only modest effects were observed in patient management (counselling behaviour), and no significant effects were found in patient satisfaction or changes in HRQL over time.

Comments: Incorporating standardised HRQL assessments in daily clinical oncology nursing practice primarily facilitates the discussion of HRQL issues and increases nurses' awareness. It also had a positive impact on identification of unrecognised problems and a modest impact on patient management.

The nine observational studies

We included nine observational studies in our review. The studies had been conducted in variety of settings on different study populations.

Brinbridge et al. (2011)[38] assessed how standardised symptom assessment (i.e. The Edmonton Symptom Assessment System (ESAS)) can enhance multidisciplinary care through self-completed surveys to clinical teams at various disease-site clinics at a cancer centre in Ontario, Canada. The study found that although most of the nurses and allied health professions found the ESAS to enhance patient care, help patients articulate their symptom issues, and facilitate follow-up with patients with past symptom issues, only approximately half of the physicians agreed with these statements.

In a small study, Halkett and colleagues (2010)[39] evaluated the use of a touch-screen system in comparison to written questionnaires in a large tertiary hospital in Western Australia (WA). The study found that the technology was not very reliable with some significant practical problems. However, around a quarter of patients found the touch-screen system improved the communication and 10% reported a positive impact on health outcomes. Patients were generally satisfied with both methods.

Dinkel et al. (2010)[40] implemented distress screening in routine radiotherapy practice and compared computerised and paper-and-pencil screening in terms of acceptability and utility in a large study (n = 3,450). Physicians received immediate feedback of the psycho-oncological

results. The study found that agreement between the computerised and the paper assessment was high. Patient satisfaction did not differ between the two administration modes. Nurses and radiographers rated the computerised assessment less time consuming. Physicians valued the psycho-oncological results as interesting and informative (46.7%). However, patients and staff agreed that the distress screening did not lead to an increase in discussion of psychosocial issues in clinician-patient encounters.

Mark and colleagues (2010)[41] evaluated The Patient Assessment, Care and Education (PACE) System™ - an electronic patient symptom screening and reporting system for oncology, in order to determine provider and patient opinions of the system and documented evidence as to whether symptom assessment rates increased after this system was implemented. The study found that providers seemed to value the system. In particular, they reported that the screening and reporting system helped them to identify, track, and document the patients' most important symptoms. The patient survey indicated that the majority of patients found the system easy to use and generally helpful and would recommend it to others. The chart review indicated that assessment rates for depression, fatigue, and pain increased after the system was implemented.

Butt and colleagues (2008)[42] sought to learn about patient perceptions of their symptoms and treatment through a baseline assessment and two monthly follow-up assessments via standardised questionnaires and semi-structured interviews. The study found that across all assessments, at least half of the sample experienced at least some fatigue, pain, or distress. On the whole, patients and providers did communicate about these concerns, and at least 75% of patients found these discussions helpful when they occurred, supporting the notion that symptom identification and communication may optimise the detection of those at risk of morbidity and decreased quality of life because of excess symptom burden.

Weaver et al. (2007)[43] reported a feasibility study to examine the utility of home monitoring of patients' symptoms via a mobile phone. Six colon cancer patients receiving adjuvant chemotherapy, entered symptom data onto user friendly screens on a mobile phone twice daily. This 'real time' data was sent via a secured connection to a remote computer. In the event of moderate or severe symptoms (generating amber and red alerts respectively), the nurse was immediately alerted by the computer, via a pager. The nurse then contacted the patient to reinforce the automatic advice sent to the patient on their phone and to assess the patient using clinical algorithms. The study found that both patients and staff felt confident in this approach to symptom management and the technology for monitoring patients' symptoms worked well. The patients felt secure in the knowledge that their symptoms were being closely monitored and that they were participating effectively in their own care management.

Basch and colleagues (2005, 2007)[44,45] evaluated the patient reported Common Terminology Criteria for Adverse Events (CTCAE) which is the mandated instrument for tracking patient toxicity symptoms in National Cancer Institute (NCI)-sponsored cancer treatment trials and were often reported by clinicians. The investigators adapted CTCAE symptom items into patient language and uploaded these to an online platform. Cancer outpatients receiving chemotherapy were invited to self-report selected symptoms at visits via waiting area computers or optional home access. Symptom reports were printed for nurses at visits, but no instructions were given with regard to use of this information. The study found that at each consecutive visit, most patients logged in without significant attrition. Whether patients logged in at home was related to previous internet experience. Satisfaction with the system was high, but only half felt communication was improved. All participating nurses understood the reports and felt this information was useful for clinical decisions, documentation, and discussions. However, only one of seven nurses discussed reports with patients frequently, with insufficient time being the most common barrier to discussions.

Mooney and colleagues (2002)[46] were among the earlier researchers to explore the feasibility of using a telephone-based computerised system to monitor post-chemotherapy symptoms and to

test the mechanism of generating alert communications to healthcare providers about symptoms that were poorly controlled. By asking 27 cancer patients to call the telephone-linked care (TLC) system daily during a single cycle of chemotherapy and report on seven common chemotherapy-related symptoms, the study found that the TLC was easy to learn and use and that it captured daily symptom information from patients in their homes. A majority of patients experienced symptoms that were severe enough to generate symptom-alert faxes. Patient satisfaction with TLC was high. The technique, TLC voice, and the duration of the calls were acceptable to patients and there were few technical problems.

A summary of impact on outcome matrix indicators

Impact on patient-provider communication

Over the 27 studies (i.e. 16 randomised controlled trials, 2 before-after trials and 9 observational studies) included in this review, four studies[16,26,33,35] did not examine or report on the effect of routinely collected PROs on patient-provider communication. Of the 23 studies that did report such an impact, 21 studies (91.3%) reported a positive effect including well-designed and conducted large RCTs.[10,11,14,22,23,25] One study reported no significant improvement of patient-provider communication possibly due to low level of symptoms (only 37% of patients received anticancer therapy, hence the reduced need for communication about treatment) [15]. Another study had an already high communication level at baseline (hence a ceiling effect that there was little room for further improvement).[12] Our finding of positive effect on patient-provider communication is also consistent with previous reviews conducted in both cancer[3] and non-cancer settings.[4,6,17]

In summary, there is very strong evidence supporting the notion that routinely collected PROs, with timely feedback, enhance patient-provider communication.

Impact on monitoring of treatment response

Although most of the 27 studies did not include an explicit study objective about monitoring treatment response, 11 studies did report on the impact of introducing routinely collected PROs on monitoring of treatment responses (Appendix F).[10,26,33,34,36,37,41–44,46] These studies showed a strong or moderate effect on increasing monitoring activities of treatment response. The strongest effect seems to occur in the studies which focused on monitoring patient symptoms, side effects and toxicity collected during and after chemotherapy for outpatients. In particular, real-time patient-reported symptoms and toxicity through innovative mobile phone-based, web-based or IVR systems, significantly improved the monitoring of treatment response.

In summary, there is strong evidence to support the notion that routinely collected PROs significantly improve the monitoring of treatment response.

Impact on detecting unrecognised problems

Although the idea that routinely collected PROs may provide better opportunities for service providers, as well as patients, to detect unrecognised problems through increased awareness, improved communication and monitoring seems intuitively plausible, only 16 of the 27 studies reported results related to the detection of unrecognised problems (Appendix F). Of the 16 studies, 15 studies[10,11,14,16,32–37,41–44,46] reported either a strong or moderate positive impact on detecting unrecognised problems. However, the study by McLachlan and colleagues[15] did not find any difference between the intervention arm and the control arm.

Within the studies that reported results related to unrecognised problems, there seems to be a need to develop more comprehensive and valid measures in order to understand specifically PROs' impact on identifying underreported and unrecognised problems for different cancer patients in different settings.

In summary, there is reasonably strong evidence supporting the notion that routinely collected PROs are helpful in identifying unrecognised problems in a variety of settings.

Impact on changes to patient health behaviour

No study provided systematic evaluation on the impact. Whether and how patient health behaviours are changed is unknown.

Impact on changes to patient management

Of the 17 studies that provided some evidence, 13 studies[11,14,16,34–43] reported either a strong or modest positive effect on changes to patient management, while 4 studies[10,12,13,23] found no such effect. However, it is worth noting that 10 studies did not provide any information about changes to patient management and descriptions of the impact on patient management, when reported, were often incomplete. There is evidence to indicate that simple routine feedback of PROs may not be sufficient to improve patient outcomes. Other resources may be needed such as education, referral services and a detailed patient management plan following the PROs.[32] There is also a need to develop better measures of changes to patient management, as it is often complex and difficult to quantify.[22]

Overall, there is reasonable evidence supporting the hypothesis that implementing a routinely collected PROs system brings positive changes to patient management, in settings where a patient management plan is an integral part of the system.

Impact on patient satisfaction

Of the 16 studies which reported results related to this impact, 13 studies[14,23,32,36,37,39–46] reported a very strong to moderate positive effect on improved patient satisfaction. For the three studies[11,12,15] that did not find such a positive effect, one study[11] reported a possible ceiling effect which means that both intervention group and control group had a very high baseline patient satisfaction level that may have impeded the demonstration of a significant difference between the two arms during the following up period.

It is also worth noting that there may be improved experience and satisfaction for other stakeholders such as patients' family members, caregivers, as well as health professionals, that were not measured or reported. Research to better understand all stakeholders' experiences after implementing routinely collected PROs is needed.

In general, it seems that there is strong evidence to support the notion that routinely collected PROs, with timely feedback, significantly enhance patients' experiences and satisfaction.

Impact on health outcomes

Of the 15 studies that reported results related to impact on health outcomes, 13 studies[10,13,14,16,26,31-36,43,44] reported some positive improvement, ranging from moderate to strong, while 2 studies[12,15] failed to find any such effect. It appears that symptoms, side effects and toxicity are most likely to be improved, followed by emotional wellbeing. There is little evidence on improvement on both overall HRQLs as well as social wellbeing. There is also a need to understand the impact on long-term health outcomes such as survival rate.

Most of the studies included in the review did not focus on health outcomes and some of the positive improvements on outcomes only occurred on selective measures. It is not clear how these positive improvements can be generalised to different settings.

In summary, there is weak but positive evidence supporting the notion that routinely collected PROs may improve health outcomes. However, such observation needs to be confirmed by better designed studies covering a large set of well-developed outcome measures.

Impact on quality improvement

No study provided relevant evidence on the potential impact of routinely collected PROs on quality improvement.

Impact on transparency, accountability and public reporting

No relevant results were provided in any of the included studies.

Impact on better system performance (monitoring, planning, financing, evaluating, responding)

No relevant results were provided in any of the included studies.

Overall strength and direction of evidence

Combining results from both randomised controlled trials and observational studies, we summarised the overall strength and direction of evidence (Table A). Overall, there is strong evidence supporting the notion that routinely collected PROs, with feedback, improve doctor-patient communication and increase patient satisfaction. There is some evidence to support the notion that they improve the monitoring of treatment responses and detection of unrecognised problems. There is weak but positive evidence that, over time, they lead to changes in patient management. Despite some encouraging results, there is still a great degree of uncertainty regarding the impact of routinely collected PROs, with feedback, on patient health outcomes. There is little or no evidence that they have led to significant positive improvements in quality improvement, transparency, accountability, and public reporting, or in system performance at a population health or societal level. Apart from clinical trials and clinical practice, their impact on health services research and population health is largely unknown.

There is a variety of models on how to routinely collect PROs and how to feed back the data to different stakeholders. We also need to bear in mind that cancer patients are vastly different given their background, type and stage of cancer, prognosis, treatment, and position on the life course continuum. Thus, such general observation above may not apply to each and every different setting. For example, recent studies demonstrated a positive impact of routinely collected PROs on symptom control through either web-based or mobile phone based approaches. Such positive impacts were less pronounced on HRQL.

Table 4: The overall strength and direction of evidence

Results	Strength and direction of evidence
Patient-provider communication	+++
Monitor treatment response	++
Detect unrecognised problems	++
Changes to patient health behaviour	n/a
Changes to patient management	+
Improved patient satisfaction	+++
Improved health outcomes	+/-
Strong & effective quality improvement	n/a
Increased transparency, accountability, public reporting	n/a
Better system performance (monitoring, planning, financing; evaluating, responding)	n/a

Note: ++++: the strongest positive effect; xxxx: the strongest negative effect; n/a: not available; 0: mutual (no significant effect).

Recent studies on the validation and feasibility of adopting an electronic PROs system in cancer settings

Many recent studies have validated and tested the feasibility of an electronic PROs system among different types of cancer patients and in different settings.

Abernethy and colleagues (2010)[47] validated the Patient Care Monitor (PCM, version 2) in the academic setting involving 275 cancer patients (breast = 65, gastrointestinal = 113 and lung = 97). The study found that the construct validity was well validated against well-established instruments (FACT-G, MDASI & FACIT-F) and both previous and current studies indicated high patient satisfaction with the system and high feasibility in implementing such a system in similar settings. This study further established the feasibility and acceptability of PCM by both patients and health professionals in an earlier published study in 2008.[48]

Through following a total of 163 cancer patients for an average of 12 month periods, Basch et al. (2009)[49] also demonstrated that the longitudinal collection of clinician CTCAE (National Cancer Institute's Common Terminology Criteria for Adverse Events) assessments better predict unfavourable clinical events, whereas patient reports better reflect daily health status, indicating clinical utility of such measures and arguing for the need to include both clinicians' and patients' reported measures in clinical trials. This result also added further evidence of the utility of such a system from a previous study.[50]

Snyder et al. (2009)[51] reported their study results on the work of developing a prototype website (PatientViewpoint) to collect patient-reported outcomes in outpatient clinical oncology, and linking the data with electronic medical records (EMR). Clinicians reported that the website could improve clinical practice if it was not burdensome and were most interested in tracking change over time. Patients were interested in using the website because of the potential to facilitate communication with their clinicians. The usability testing suggested that patients had few problems accessing and using the site.

Fellingen and colleagues (2009)[52] explored the ability of cancer patients who were primarily receiving palliative care to use a touch screen computer for assessment of symptoms and

mobility and to investigate which factors predicted the need for assistance during the assessment. The patients responded to 60 items on symptoms and mobility directly on the computer and found that in a pilot study, 11 patients (55.0%) preferred computerised assessment over paper and pencil, whereas five (25.0%) had no preference. In the main data collection, only 86 patients (23.2%) required assistance. Patients requiring assistance were significantly older, had worse performance status, and poorer cognitive function than those not requiring assistance. The study showed the feasibility of using touch screen computer in a palliative care setting and suggested the assessment tools should be short and user-friendly.

Apart from the conventional HRQL, symptom and satisfaction with the care, other instruments have been developed to measure less common concepts. Using a sample of 150 head and neck cancer patients, Rogers et al. (2009)[53] explored the utility of using a touch-screen computer to administer a Patients Concerns Inventory (PCI) which covers a range of issues including hearing, intimacy, fatigue, financial burden, regret, support for family, and wound healing. The authors found that PCI helped focus the consultation onto patient needs and promoted multidisciplinary care. From the Peter MacCallum Cancer Centre, in Melbourne, Pigot and colleagues (2009)[54] argued that a diagnosis of cancer can have a profound impact on the physical, emotional, psychological, social and spiritual areas of a person's life. Supportive care services are directed towards this full range of issues associated with cancer. Identification of need is the first step in meeting supportive care concerns, but there is a lack of tools and processes regularly used in clinical practice. The authors discussed the steps in the development of a supportive needs screening tool (SNST) appropriate for use in an oncology outpatient setting. The authors reported that the SNST has face validity and demonstrated usability in an ambulatory care oncology stetting and patients and staff also reported high acceptability.

Screening for distress, depression and anxiety has been another important area of PROs application and is the subject of recent research.[55-73] In a recent review, Mitchell and Vhabzadeh (2011)[55] provided a succinct summary of ten key learning points from 40 years of primary-care research on screening for distress and depression in cancer settings: (1) Primary care is an important partner in psychosocial care; (2) Both over and under detection are problematic; (3) Barriers to identification involve patient and clinician factors; (4) Acceptability of screening is critical to implementation; (5) Underserved groups need special attention in screening; (6) Patient-clinician trust is an important modifiable variable; (7) Greater contact influences detection; (8) Clinician confidence/skills influence screening success and subsequent action; (9) Training may improve confidence but effects upon long-term outcomes are modest; and (10) Screening is generally ineffective without aftercare. The authors concluded that the 40 years of primary-care research has shown largely what does not work in relation to screening, namely relying on clinicians' unassisted judgment without infrastructure support, using over-complex scales with low acceptability, looking for depression alone, using screening without linked treatment, treating in the absence of follow-up and failing to engage patients in their own care. These points need to be carefully considered before the design and administration of a screening tool.

There are several studies that explored a web-based platform for collecting PROs in cancer settings.[1,44,51,65,74-81] For example, based on a sample of 627 adult and older adult patients from various oncology clinics who completed an electronic symptoms survey, Tariman et al. (2011)[74] tested the performance of the Acceptability E-scale. The authors reported that the revised Acceptability E-scale has strong psychometric properties and can be useful in assessing the acceptability and usability of computerised health-related programs in oncology and other health populations. From the School of Public Health, China Medical University in Taiwan, Lin and colleagues (2011)[75] reported that the results from a study on a real-time clinical decision support system (RTCDSS) with interactive diagrams enables clinicians to instantly and efficiently track patients' clinical records (PCRs) and improves their quality of clinical care. The authors proposed a RTCDSS to process online clinical informatics from multiple databases (including ePROs) for clinical decision making in the treatment of prostate cancer, based on Web Model-View-

Controller (MVC) architecture, by which the system can easily be adapted to different diseases and applications. The authors believe that the proposed framework supports online clinical informatics, evaluates treatment risks, offers interactive guidance, provides real-time reference for decision making in the treatment of prostate cancer, and can be readily adapted to an existing hospital information system.

Donaldson (2007)[79] describes how practices might create continuous healing relationships using methods that are independent of patient visits, to monitor and address problems that may occur during cancer care. The author posits that such a system would be based on patient report, be timely and useful, sensitive to change, and a low burden for patients, clinicians, and administrative staff. Furthermore, it would be built into the delivery of care and be integrated with other data systems such as patient records, decision support, and community or other resources. Using reports for patients that are presented in a format that is easily understandable, patients should be able to monitor their own progress. The web-based platform holds a great deal of promise. Jones & Snyder (2007)[1] produced a review on issues in the design of internet-based systems for collecting patient-reported outcomes. The authors discussed the rationale for using the Internet for routine PROs collection, summarised relevant literature and ongoing projects, and raised several key design and development issues that should guide further efforts in this area. They argued that PROs via the Internet has the potential to overcome many of the challenges associated with efforts to routinely use PROs in the clinical encounter such as being difficult to administer, score and interpret and lack of patient control. The authors also provided an overview of the key websites in the USA at that time and the summary table is attached in Appendix B.

Potential links between and moderating factors in the routine collection of PROs with feedback, and patient outcomes

Although the evidence is limited, it appears that routine collected PROs with sufficient intensity of feedback (multiple times over a sustained period of time), targeting multiple stakeholders (doctors, nurses, allied health workers, as well as patients) with simple, clear, graphical and longitudinal meaningful interpretation of the results, and providing sufficient training for both health professionals and patients, are critical links between an intervention and the intended outcomes. There is also evidence to suggest that for some complex issues such as depression and low social functioning, routine screening and feedback may need to be integrated with other strategies such as decision-making aids, education, clear management plans and clinical pathways including referrals, to change patient outcomes. There is preliminary evidence that some of the impacts of PROs may be more pronounced among subgroups with more severe problems at baseline (e.g. depression, symptoms). More studies are needed to fully understand these mediating and moderating effects.

3 Stage Two (Question Two)

The reliability and validity of commonly used PROs for the four most common cancers

The extended search strategy we adopted identified many measurement instruments in the listed studies (see Appendix E). In some studies multiple instruments were used. To provide an assessment of the psychometric properties for each of these instruments is beyond the scope of the current review. A lot of studies used well-validated instruments such as EROTC QLQ-C30, HADS for the routine collection of patient outcomes; other studies used instruments with little or no psychometric validation (such as NCI CTCAE based web system). Fortunately, the two reviews commissioned by the Cancer Institute NSW previously, provide a solid base for understanding the psychometric properties of commonly used PROs in measuring psychological distress, depression and anxiety as well as pain and symptom measures. As many more PROs have been used in cancer settings for other purposes (such as one of the endpoints in clinical trials) and in other settings (such as for aging patients with multiple chronic diseases), it would be more useful to examine the best available PROs measures and their psychometric properties on cancer patients as a whole.

Recently, the researchers from the Patient Reported Outcome Measurement (PROM) Group in Oxford have conducted a series of structured reviews on the psychometric properties of PROs in four leading cancer groups: colorectal cancer (2010)[82], lung cancer (2010)[83], prostate cancer (2009)[84] and breast cancer (2009).[85] The structured review was conducted mainly based on the University of Oxford PROs bibliography database which was searched up to December 2005 using specific keywords. This search was combined with other extensive systematic searches reported in both published and grey literature since 2006. This database was compiled by the Oxford PROM Group with funding from the Department of Health and the Information Centre, and hosted by the University of Oxford. The Ovid search engine was used to explore a number of relevant databases from January 2006 until February 2010, using a comprehensive search strategy.

For each cancer type, a common methodology was used as:

Inclusion criteria

Sample:

- Patient with the particular cancer type (i.e. lung, breast, prostate, colorectal, respectively)
- English-speaking populations

Study design:

- Studies where a principal PRO is being evaluated
- Studies evaluating several PROs concurrently
- Applications of PROs with sufficient reporting of methodological issues

Specific inclusion criteria for generic and disease-specific instruments:

- The instrument is patient-reported
- There is published evidence of measurement reliability, validity or responsiveness following completion in the specified patient population
- The instrument will ideally be multi-dimensional (it is at the reviewer's discretion to include PROs which are specific to a health condition but have a narrow focus e.g. a specific dimension of health, such as symptoms)

- Evidence is available from English language publications, and instrument
- Evaluations conducted in populations within UK, North America, Australasia.

Exclusion criteria

- Clinician-assessed instruments
- Studies evaluating the performance of non-patient reported measures of functioning or health status where a PROM is used as a comparator indicator
- Studies with very small sample sizes (i.e. n≤40 or n≤50; and)
- Studies using incomplete versions of instruments.

Two reviewers assessed and evaluated the methodological quality of PROs based on modified London School of Hygiene appraisal criteria (Smith et al. 2005)[86] which is listed in Appendix C. Data were extracted on the psychometric performance and operational characteristics of each PRO.

We summarised the four review results (Table 5). For each type of cancer, we compared the total references reviewed, total publications included in the review, generic PROs evaluated during the review, preference-based instrument, cancer-specific instrument, condition-specific (or site-specific) instruments reviewed, and the reviewers' recommendation on choosing different types of instruments based on the review results. A detailed appraisal of psychometric properties for each instrument is also presented (Tables 6–13).

Table 5: The review results for four most common cancers from the Oxford Group[82-85]

Results	Breast Cancer	Prostate Cancer	Lung Cancer	Colorectal Cancer
Total references reviewed	674 + supplementary searches	186	1591	1330
Total publications included	81	76	58	35
Generic PROs evaluated	SF-36; SF-8; SIP	SF-36; SF-12	SF-36	SF-36; SF-12
Preference-based instrument	EQ-5D	EQ-5D, HUI, QWB	EQ-5D	EQ-5D
General cancer-specific instrument	CARES-SF; EORTC QLQ-C30; FACT-G; FLIC	EORTC QLQ-C30; FACT-G	EORTC QLQ-C30; FACT-G	EORTC QLQ-C30
Condition or site specific cancer instrument	EORTC BR23; FACT-B	QLQ-PR25; FACT-P; FAPSI-8; PCTO-Q; UCLA-PCI; EPIC, revised version of UCLA-PCI; PC-QoL; Prostate Cancer Related Quality of Life; Patient Oriented Prostate Utility Scales (PORPUS)	EORTC QLQ-LC13; FACT-L; LCSS; LCSS-MESO	EORTC QLQ-CR38; FACT-C
Recommended PROs				
Generic	SF-36	SF-36	SF-36	SF-12
Preference-based	EQ-5D	EQ-5D	EQ-5D	EQ-5D
General cancer-specific	EORTC QLQ-C30; FACT-G	EORTC QLQ-C30	EORTC QLQ-C30	EORTC QLQ-C30
Type or cancer site specific	FACT-B	QLQ-PR25; PACT-P(including the 4 domains from the FACT-G); UCLA-PCI & EPIC	EORTC-LC13; FACT-L	FACT-C

Table 6: The psychometric instruments included in the review for breast cancer patients from the Oxford review

Three generic instruments

1. Medical Outcomes Study 36-Item Health Survey (SF-36)
2. Medical Outcomes Study 8-Item Health Survey (SF-8)
3. Sickness Impact Profile (SIP)

One preference-based measure

1. European Quality of Life Questionnaire (EuroQol; EQ-5D)

Six cancer-specific instruments with two specific to breast cancer (EORTC BR23, FACT-B):

1. Cancer Rehabilitation Evaluation System – Short-Form (CARES-SF)
2. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
3. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer module EORTC BR23
4. Functional Assessment of Cancer Therapy – General (FACT-G)
5. Functional Assessment of Cancer Therapy – Breast (FACT-B)
6. Functional Living Index – Cancer (FLIC)

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Table 7: Appraisal of generic, cancer specific or condition specific PROs included in the Oxford breast cancer review

PROM	Repro-ducibility	Internal consistency	Validity – content	Validity – construct	Responsive-ness	Interpret-ability	Precision	Accept-ability	Feasibility
Generic PROs									
SF-36	0	++	+++	++	++	+++	+	++	++
SF-8	0	0	+	+	0	+++	0	+	+
SIP	0	+	+	+	+	0	0	+	0
EQ-5D	0	n/a	+	+	+	+	+/-	0	0
CARES-SF	+	+	++	++	+	0	0	+	+
Cancer specific or condition specific PROs									
EORTC QLQ-C30	0	++	+++	+++	+	++	-	++	++
FACT-G	+	+++	+++	+++	++	++	0	++	+
FACT-B	+	+++	+++	++	+++	+	0	+++	+
FLIC	0	+	++	+	+	0	0	+	0

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Table 8: The psychometric instruments included in the review for prostate cancer patients from the Oxford review

One generic measure

1. Medical Outcomes Study Health Survey instruments (SF-36 & SF-12)

Three preference-based measures

1. European Quality of Life Questionnaire (EuroQol EQ-5D)
2. Health Utilities Index (HUI)
3. Quality of Well Being Scale (QWB)

Two general cancer and 9 prostate cancer-specific specific PROs

1. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
2. EORTC Prostate-specific module (QLQ-PR25)
3. Functional Assessment of Cancer Therapy – General (FACT-G)
4. Functional Assessment of Cancer Therapy – Prostate (FACT-P)
5. FACT Advanced Prostate Symptom Index (FAPSI-8)
6. Prostate Cancer Treatment Outcomes – Questionnaire (PCTO-Q)
7. University of California-Los Angeles Prostate Cancer Index (UCLA-PCI)
8. Expanded Prostate Index Composite (EPIC, revised version of UCLA-PCI)
9. Prostate Cancer – Quality of Life (PC-QoL)
10. Prostate Cancer Related Quality of Life
11. Patient Oriented Prostate Utility Scales (PORPUS)

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Table 9: Appraisal of generic, cancer specific or condition specific PROs included in the Oxford prostate cancer review

PROM	Repro-ducibility	Internal consistency	Validity – content	Validity – construct	Responsive-ness	Interpret-ability	Precision	Accept-ability	Feasibility
Generic PROs									
SF-36	0	++	+	++	+	0	0	0	0
EQ-5D	0	n/a	-	0	+	+	0	0	0
HUI	0	0	-	+	+	+	0	0	0
QWB	0	0	0	+	+	+	0	0	0
Cancer specific or condition specific PROs									
EORTC QLQ-C30	+	+	+	+++	++	0	0	0	0
EORTC QLQ-PR25	0	+	++	+	+	0	-	0	+
FACT-G	+	++	+	+++	+++	++	0	0	0
FACT-P	0	+	++	++	+++	+	0	-	+
FAPSI-8	0	+	+	+	+	+	0	0	+
PCTO-Q	+	0	0	++	0	0	0	0	0
UCLA-PCI	+	+	++	+++	++	+	-	0	0
EPIC	+	0	++	++	++	++	-	+	0
PC-QoL	+	+	++	++	0	0	-	+	+
PCRQL	0	++	+	++	0	0	-	0	0
PORPUS	+	0	+	+	+	0	0	0	0

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Table 10: The psychometric instruments included in the review for lung cancer patients from the Oxford review

One generic instrument

1. Medical Outcomes Study 36-Item Health Survey (SF-36)

One preference-based measure

1. European Quality of Life Questionnaire (EuroQol; EQ-5D)

Two general cancer-specific PROs

1. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
2. Functional Assessment of Cancer Therapy - General (FACT-G)

Four lung cancer specific PROs

1. European Organization for Research and Treatment of Cancer Quality of Life Lung-specific Questionnaire (EORTC QLQ-LC13)
2. Functional Assessment of Cancer Therapy -Lung (FACT-L)
3. Lung Cancer Symptom Scale (LCSS)
4. Lung Cancer Symptom Scale – Mesothelioma (LCSS-Meso)

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Table 11: Appraisal of PROs included in the Oxford lung cancer review

PROM	Repro-ducibility	Internal consistency	Validity – content	Validity – construct	Responsive-ness	Interpret-ability	Floor/ ceiing/ Precision	Accept-ability	Feasibility
Generic measures									
SF-36	0	0	0	+	+	0	0	0	0
Preference-based measures									
EQ-5D	0	n/a	0	+	0	0	0	+	+
Cancer-specific measures									
EORTC C-30	0	0	++	+	+	0	0	+	+
FACT-G	0	0	++	+	0	0	0	0	0
Lung cancer-specific measures									
EORTC QLQ-LC13	0	0	++	+++	+++	0	0	+	+++
FACT-L	0	++	++	++	++	0	0	++	++
LCSS	0	+	+	++	+	0	0	+	0

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Table 12: The psychometric instruments included in the review for colorectal cancer patients from the Oxford review

Two generic instruments

1. Medical Outcomes Study 36-Item Health Survey (SF-36)
2. Medical Outcomes Study 12-Item Health Survey (SF-12)

One preference-based measure

1. European Quality of Life Questionnaire (EuroQol; EQ-5D)

One general cancer-specific PROs

1. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)

Two lung cancer specific PROs

1. European Organization for Research and Treatment of Cancer Quality of Life Colorectal-specific Questionnaire (EORTC QLQ-CR38)
2. Functional Assessment of Cancer Therapy -Colorectal (FACT-C)

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Table 13: Appraisal of PROs included in the colorectal review

PROM	Repro-ducibility	Internal consistency	Validity – content	Validity – construct	Responsive-ness	Interpret-ability	Precision	Accept-ability	Feasibility
Generic measures									
SF-36	0	0	0	+	+	0	0	0	0
SF-12	0	0	0	++	+	0	0	++	0
Preference-based measures									
EQ-5D	0	n/a	0	++	+	0	0	+	0
Cancer-specific measures									
EORTC QLQ C-30	0	0	0	++	++	0	0	++	0
Colorectal cancer-specific measures									
EORTC CR-38	0	0	0	+	+	0	0	+	0
FACT-C	0	++	0	++	++	0	0	+	0

Note: 0: not reported (no evaluation completed); - evaluation evidence available indicating poor performance of instrument; + some limited evidence in favour; ++ good evidence in favour; +++ Excellent evidence in favour
(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

The promises of PROMIS®

Despite a growing interest in the integration of PROs into clinical practice, efforts have been hampered by a number of challenges. These include: (1) Floor and ceiling effects that limit sensitivity to change; (2) Lengthy questionnaires that increase patient burden; (3) A proliferation of measures of the same outcome limiting the ability of decision makers to compare results across studies; (4) Some promising PROs have not been validated specifically in the clinical population under study; and (5) A scarcity of evidence regarding the validity of PROs, despite the US Food and Drug Administration urging that special attention be paid to this in its guideline on the use of PROs for pharmaceutical labelling claims[2]. Collectively, these challenges have limited the use of patient-reported outcomes as endpoints within clinical trials and clinical practice and have inhibited the adoption of key trial findings by practitioners. Due to the lack of standardised instruments that have been validated in large heterogeneous populations, clinicians and policy makers believe that some instruments may not have decision making relevance (external validity) in clinical practice.

> *"The clinical outcomes research enterprise would be enhanced greatly by the availability of a psychometrically validated, dynamic system to measure PROs efficiently in study participants with a wide range of chronic diseases and demographic characteristics."*
> National Institutes of Health, 2003

The Patient Reported Outcome Management Information System (PROMIS®) Network, a component of the National Institutes of Health's Re-engineering the Clinical Research Enterprise program, seeks to overcome limitations in existing PRO instruments by (1) Developing and testing large PRO item banks based on Item Response Theory (IRT) covering a wide range of concepts and constructs such as pain, fatigue, physical functioning, emotional distress, and social role participation that have a major impact on quality-of-life across a variety of chronic diseases; (2) Creating a computer adaptive test (CAT) system for the assessment of PROs in clinical research; and (3) Creating a publicly-available and updatable system for accessing and using the item bank via the CAT system, known as Assessment Center (www.assessmentcenter.net).

This initiative applies to a wide range of disorders including cancer, congestive heart failure, depression, arthritis, and multiple sclerosis, as well as chronic pain conditions. PROMIS® is creating new paradigms for how clinical research information is collected, used, and reported. The PROMIS® initiative addresses a need in the clinical research community for a rigorously tested PROs measurement tool that utilises recent advances in information technology, psychometrics, and qualitative, cognitive, and health survey research.

PROMIS® has many assessment options available to measure self-reported health for clinical research and practice. PROMIS® assessment instruments are drawn primarily from calibrated item banks (sets of well-defined and validated items) measuring concepts such as pain, fatigue, physical function, depression, anxiety and social function. These calibrated item banks can be used to derive short forms (typically requiring 4–10 items per concept), or computerised adaptive testing (CAT; typically requiring 4–7 items per concept for more precise measurement). Assessments are available for children and adults. Most PROMIS® instruments are available through Assessment Center (www.assessmentcenter.net). Those which are not yet available on Assessment Center can be obtained by contacting the PROMIS® statistical centre through help@assessmentcenter.net. The Assessment Center can be utilised for online or offline computer-based administration or instruments can be downloaded for paper administration or entry into other data collection platforms. For registered users, all the instruments, documentation, and necessary computer platforms are free at the writing of this report.

The instruments from PROMIS® are available in the form of item banks, short forms and profiles. Item banks are calibrated items from which a summary score can be obtained from a subset of items (i.e. via CAT or short form) whereas scales are calibrated items from which a summary score should be obtained only from the complete set of items. Item pools are collections of related items that are not intended to produce a summary score but instead are to be used as single items. Short forms are static subsets of item banks, and profiles are fixed collections of short forms measuring multiple concepts.

During the first phase of the initiative (2004–2009), PROMIS® formed a network of researchers that developed questions or 'items' to analyse five outcomes or 'domains' (See Appendix D for detailed instruments). PROMIS® is creating a psychometrically-robust CAT system, based on IRT, to administer these items. In addition, it has developed a web-based system to give clinical researchers access to the item banks and the CAT system. Whether administered through an iterative CAT system that allows research flexibility, or by paper version short forms, PROMIS® has already demonstrated improved efficiency and sensitivity in comparison with existing PROs. Long-term trials are planned to address issues of validity and sensitivity to changes in clinical populations. The efficiency, flexibility, and sensitivity of PROMIS® has the potential to become a widely-accepted, standardised PROs measurement tool that will allow greater comparability of studies, with reduced burden on patients.

As the PROMIS® initiative moves to a second phase (2009–2013) of Roadmap support, it will continue to advance the field of patient self-reporting in clinical research and practice, by:

- Developing new items and domains
- Translating current and future items and domains into other languages such as Spanish and Chinese to facilitate international studies
- Conducting validation studies in large-scale clinical trials in a variety of clinical populations
- Making PROMIS® tools accessible to a wider range of clinical researchers and patient-care communities, and optimising its usability for rapid adoption

- Providing on-going education and outreach to familiarise users with new developments in PROMIS®
- Improving PROMIS® tools to allow for better outcomes in clinical trials, and, potentially, better individual and clinical decisions
- Engaging stakeholders at all levels, by including interactions with other health-related federal agencies, forging new relationships with patients and patient organizations, and establishing public-private partnerships to sustain PROMIS® once Roadmap funding ends.

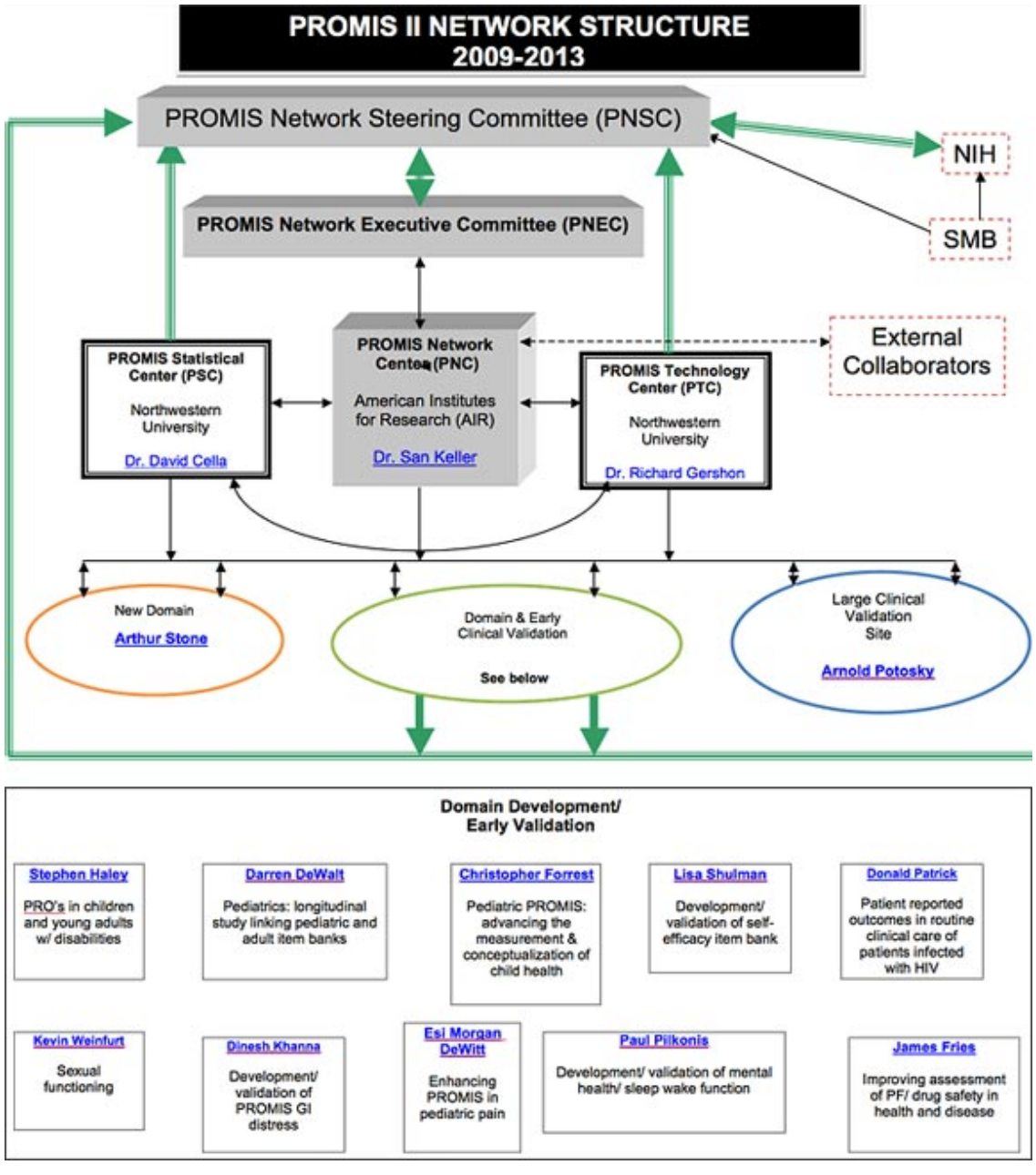

Figure 4: Diagram of the PROMIS Network Structure

(Source: http://commonfund.nih.gov/promis/)

In an ambitious move, the PROMIS® initiative aims to achieve four values which almost all previous attempts to develop PROs have failed to address:

Comparability: the measures can be used and compared across different diseases, conditions and different populations, and across life course

Reliability (precision) and validity: being extensively tested against existing and legacy instruments such as SF-36 in different formats (i.e. short-form, profile, scale) under different study populations and conditions and across the score continuum of the concept; it is extremely helpful in understanding the responsiveness, floor and ceiling effect of the instruments

Flexibility: it can be administrated through paper-pen, touch-screen, smart phone, PDA and web. It can also incorporate specific instrument developed or adopted by individual research. It is also linkable to EHR and other databases

Inclusiveness: Items were written simply at elementary-school reading level and cognitive interviews for all items were conducted. Every item was pre-tested and then field tested in individuals with low literacy. Items have been translated into Spanish and 33 countries requested the translation. The PROMIS II will have a focus on children's measures.

The National Cancer Institute (NCI) provided supplementary funding to the PROMIS Network to ensure that the network's measures were valid for cancer patients and survivors across the continuum of care, and that its measurement tools addressed the needs of cancer researchers.

According to Garcia, Cella and their colleagues[87], the NCI provides support on the three fronts:

The NCI supplement made possible the collection of data for item calibration and norming from more than 2,000 patients with cancer (reflecting multiple tumour sites and different stages of treatment). In addition, expert and patient input on domains was obtained to enhance the cancer relevance of PROMIS'® measures of pain, fatigue, emotional distress, and physical function; the same will later be done for social function. Together, these quantitative and qualitative approaches provide greater confidence that the PROMIS® measures have precise and valid interpretations for patients and survivors along the continuum of cancer care

The NCI supplementary funding is supporting the development of PROs measures by assessing additional domains that are especially relevant for cancer patients and survivors. Researchers at NCI (Bethesda, MD), Northwestern University (Evanston, IL), and Duke University (Durham, NC) are focusing on four important self-reported health domains for which there are no well-accepted measures: cognitive function, the negative and positive psychosocial impacts of illness (ie, stress response and coping; shifts in self-concept, social interactions, and spirituality), sleep/wake function, and sexual function

The NCI is providing support to identify and address barriers to the adoption of PROMIS® measures in oncology clinical trials. Their supplement to augment the utility of PROMIS® measures in oncology by: identifying minimally important differences (MIDs) in scores on PROMIS measures used in cancer populations; gathering clinician feedback on formats for reports of patients' scores on PROMIS® measures; working collaboratively with NCI-funded cooperative groups to select optimal PRO measures for use in clinical trials that include HRQL components. An MID on a PROs measure represents the smallest score difference (either improvement or deterioration) that patients perceive as important and which would lead clinicians to consider a change in care. By representing the smallest clinically significant score changes, MIDs increase the utility of PROs scores for clinicians and clinical researchers (i.e. facilitating interpretation of patients' responses to treatment and other changes over time). Likewise, incorporating clinician input in designing graphical reports of patients' PROs scores helps to ensure the interpretability of assessment results, which researchers have emphasised is fundamental in symptom monitoring and management trials.

Together, these efforts are expected to improve substantially the ability of oncology researchers to assess PRO end points that are important to patients and clinicians with greater efficiency and precision.

As of early 2011, there were over 2,600 investigators in 45 countries registered for PROMIS® software. Over 9000 study participants were assessed in 2010 using PROMIS® software, with over 22,000 study participants assessed since creation of the software. PROMIS® has been used in successful NIH grant applications, producing over 100 journal articles, including cancer-related publications. PROMIS® researchers have also made over 100 presentations on the topic worldwide in the last two years. Selected publications by the PROMIS® network since 2007[88-148] are listed in Appendix G.

4 Stage Three (Question Three)

The likely impact of implementing a PROs system in NSW

The field of developing, choosing and implementing PROs systems is advancing rapidly. Based on a growing body of evidence, the routine collection of PROs, especially in cancer patients is likely to have positive impacts, as we found in Stage One. There are several trends worth noting when considering implementation of such systems.

Building a 'rapid learning health care system' as those urged by Olsen et al. (2007)[149] (See the key points below)

Learning health system characteristics
Culture: participatory, team-based, transparent, improving
Design and processes: patient-anchored and tested
Patients and public: fully and actively engaged
Decisions: informed, facilitated, shared, and coordinated
Care: starting with the best practice, every time
Outcomes and costs: transparent and constantly assessed
Knowledge: ongoing, seamless product of services and research
Digital technology: the engine for continuous improvement
Health information: a reliable, secure, and reusable resource
The Data utility: data stewarded and used for the common good
Trust fabric: strong, protected, and actively nurtured
Leadership: multi-focal, networked, and dynamic

Figure 5: Adapted from The Learning Healthcare System (Olsen et al. 2007)

Renewed commitment to building patient-centred care ('nothing about me without me')

Building a digital and information infrastructure in health care including electronic medical records

Increased recognition of the state-of-art measurement science (i.e. Item Reponses Theory and CAT technology) within the health sector.

Properly planned, a well-implemented PRO system will conform and be integral to these convergent trends, and will make a significant contribution towards the building of a 'rapid learning health system'. The literature has already shown that a well-planned PROs system could greatly improve patient-provider communication and patient satisfaction. It may also contribute to the effective monitoring of treatment responses, detection of unrecognised problems, creating patient-centred care management plans and eventually lead to better health outcomes. Despite a lack of empirical evidence, such real-time and life trajectory data, if properly linked with other population databases, could be harnessed to develop new drugs or therapies, improve quality of care, and contribute to population health and health services research.

The literature reflects that patients in general understand the technology, are willing to use it, feel it will help them with their communication with doctors and improve their well-being.

Even more encouraging, many electronic PROMs systems could be implemented for palliative cancer patients. Most nurses and allied health professionals are very positive about such systems. Despite the acknowledged usefulness and importance of the information, physicians may still require assistance to fully integrate the information into their decision-making and clinical practice processes.

We envisage that many clinical, public health and health services researchers will embrace and endorse PROs if the data collected are of high research quality. There will be new research questions formed given the unique nature of the linked data and unprecedented opportunities afforded. As the US FDA has advocated the PROs guideline on evaluating PROs-based labelling claims for oncology drugs, many clinical trialists and their industry partners may have a keen interest in every aspect of an adopted PROs system. In contrast to the extensive and prescriptive views on PRO claims by the FDA, the European Medicines Agency (EMA) has conducted authorisations without an explicitly defined approach for evaluating HRQL data. However, any change in their position will also have an impact on the responses of clinical researchers and trialists on the implemented PROs system.[150]

The rationale and practices of data linkage have been well accepted within the NSW health sector. We do not envisage any significant negative responses from the decision-makers within the sector.

A composite PROs tool/system that might be suitable for implementation in NSW, and factors to take into consideration when selecting and implementing the tool/system

There is a proliferation of tools/systems and PROs (well over 2000). It is important to know that any recommendation of a suitable tool/system will depend on the precise purpose of the PROs. For example, a PROs tool/system suitable for screening will be different from one best suited for diagnosis. It is difficult to recommend one PROs system without knowing the vision, aims and intended use. Similarly, the scope and content of a composite PROs system will also depend on its purpose. For example, should it cover both HRQL and symptoms? Or is an HRQL only instrument sufficient? Other parameters to consider in choosing a PROs system include cost, infrastructure support and other resources. This kind of complexity has been well-documented by Basch et al. (2007)[50] during the development of the web-based CTCAE system (see Table 14 below).

Table 14: Questions and considerations when developing an electronic PRO questionnaire platform

Catagory	Questions	Considerations
Questionnaire platform	Paper vs. electronic?	Cost, development time, data volume
	If electronic, what hardware type (Web, PDA, IVR)?	Cost, hardware availability, training, maintenance
	Internal software development vs. third-party product?	Cost, time, technical support, updates
	Data storage in standard/exportable format?	Yes, because cannot anticipate future needs
Questionnaire content	Use existing instrument vs. original development?	Objectives of research/data use
	Verify adequate validation of instrument?	Re-validation for major modifications
	Appropriate to target population?	Prior use in similar patients or disease
PHI privacy	Institutional privacy review?	Privacy board or IRB, HIPAA officer
	Security (polarized) screens on monitors?	Computer locations
	Password protection?	Encryption, user modification, secure recovery
	Remote access to system vs. limited local access?	Objectives of research
	Disclaimer at login?	Legal/liability issues
Data security	Institutional security review?	IRB, IS department
	Secure system configuration and database?	System validation, automated audit trail
	Login timeout?	Functionality, institutional requirements
Patient safety	Automated warnings for concerning responses?	Content of questionnaire items, liability, safety
	Remote access to previously entered data?	Objectives of system, privacy, security

PRO = patient reported outcomes; PDA = personal digital assistant; IVR = integrated voice response; PHI = protected health information; IRB = institutional review board; HIPAA = Health Insurance Portability and Accountability Act; CAT = computerized adaptive testing; IRT = item response theory; IS = Information Services; UAT = user acceptance testing.

(Reproduced from Evaluation of an Online Platform for Cancer Patient Self-reporting of Chemotherapy Toxicities. Basch E, Artz D, Iasonos A, Speakman J, Shannon K, Lin K et al. Am Med Inform Assoc. 2007; 14(3):264–268. doi: 10.1197/jamia.M2177. Copyright © 2007, American Medical Informatics Association, with permission from BMJ Publishing Group Ltd.)

However, based on our review of the literature, we would recommend that the PROs system should:

1. Be based on an electronic platform but be amendable to paper-pen format (see Table 15 below for an example of potential advantages of e-form)
2. Be based on the state-of-the-art measurement science (i.e. IRT and CAT)
3. Be comprehensive in terms of domains, concepts, and constructs
4. Ensure comparability
5. Have established reliability (precision) and validity
6. Ensure flexibility
7. Ensure inclusiveness
8. Be low cost or free.

Table 15: Comparison of web-based vs. traditional methods of completing tasks necessary for collecting patient-reported outcomes

PROs collection task	Internet-based approach	Paper-based approach
Instrument selection	Web-based program helps physician identify domains of interest and guides physician through instrument selection based on selected criteria	Physician conducts ad-hoc search for available instrument
Administration	Asynchronous -patient can complete the instrument in the physician's office, at home, or via any Internet-connected appliance (mobile phone, handheld, etc); the physician and/or staff need not be present	Physician and/or staff administer during an office visit
Scoring	Automatically, immediately after patient completes the form; no data entry required	Done by physician and/or staff according to an algorithm; data must be entered by hand into database
Normalizing	Comparison scores immediately available for population and subgroup comparisons	Physician and/or staff must locate data and make manual comparisons
Analysis	Physician can conduct practice-level and patient-level analysis using built-in reporting tools	Physician and/or staff must do analyses manually or enter data separately into

PROs collection task	Internet-based approach	Paper-based approach
		an analysis program
Follow-up Access	Reminders and decision support can be built into the Internet-based application Data accessible anytime by any treating physician	No real-time decision support Data only available when paper-based record available
Tracking	Reports can be generated automatically according to criteria selected by the patient or physician	Any historical comparisons must be assembled from paper-based results, if available

Adopted from Jones et al. 2007[1]

(With kind permission from Springer Science+Business Media: Quality of Life Research, Vol 16 No 8,2007, Page 1409. Issues in the design of Internet-based systems for collecting patient-reported outcomes. Jones JB, Snyder CF, Wu AW. Table 1.)

The only PROs system that fully met our criteria is the PROMIS®. We recommend that the Cancer Institute NSW further explore the suitability of adopting the PROMIS® platform. Two added advantages of PROMIS are that it is developing comparable instruments for children, and that it can also be used in population health research.

One of the limitations of the PROMIS is that some of cancer-specific instruments are still under development. If necessary, we recommend the integration of some of the instruments recommended in the two reviews commissioned previously by the Cancer Institute NSW and the four reviews by the Oxford group as discussed in this report.

Factors that may need to be considered when implementing a PROs system include:

1. Ensuring data security and developing an effective data sharing and dissemination strategy
2. Sufficient training for patients and health professionals
3. Ensuring the intensity of feedback and fidelity of the intervention (right time, right amount, right people, right content)
4. Developing and summarising the best ways to help clinicians to interpret PROs results and apply them in clinical care
5. Combing research, screening and routine QI, and linking different databases
6. Paying attention to the continuum of care among cancer patients and including suitable tools for cancer patients under palliative care
7. Enabling linkages between the ePROs system and electronic medical records
8. Making necessary system changes and redesigning the model of care if required
9. Integrating the ePROs system with other information sources, such as education, referral, and allied health
10. Encouraging an action research approach to continuously monitor and improve the implementation and outcomes of the PROs system.

Future questions and areas to address in a scoping review of existing systems that may flow from this work

There are some areas that may need further clarification and investigation. Some of these questions are:

1. What is the Cancer Institute NSW's vision in establishing a routinely collected PROs? What is the exact purpose of the planned routine collection of PROs? What is the long-term business model?
2. How does the ePROs system contribute to national digital infrastructure and e-Health, the rapid learning system and patient-centred care?
3. What system changes should be made in order to make this exercise useful and valuable?
4. How can the confidentiality of the data system be guaranteed, when linked with other data sources?
5. What other components, apart from HRQL or symptom, should be included in the ePROs system (e.g. patient satisfaction, patient needs, and patient concerns)(see Figure 5 below for other possible components)?
6. What are the best ways to present information to different stakeholders?
7. How should the system best be designed to respond to new oncologic drug developments and to conducting comparative effectiveness research?
8. Can the response shift be measured and interpreted in a clinically meaningful way?
9. If combining curative and palliative care: what types of PROs should be applied, for whom and for what purpose?
10. Can a palliative care outreach service (both for inpatients and outpatients) be integrated into the current ePROs system?

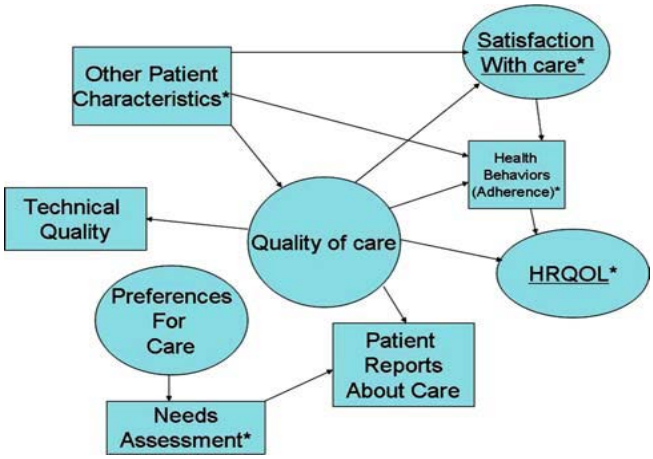

Figure 6: Hypothetical relationships among different kinds of patient-reported measures

Circles denote latent constructs (i.e. multiple indicators define the construct) and boxes represent observed indicators (i.e. construct is manifest or measured directly). * Patient-reported Measures (adopted from Fung et al. (2008) [151]

(With kind permission from Springer Science+Business Media: Quality of Life Research, Vol 17, Issue 10, 2008, Page 1298. Prospects and challenges in using patient-reported outcomes in clinical practice. Fung CH.)

5 Summary

There is growing evidence supporting the routine collection of ePROs to enable better and patient-centred care, especially in cancer settings. The Cancer Institute NSW is uniquely positioned to leverage on the rapid advancement of different ePROs models over the last decade, on the progress in applying IRT and CAT in developing ePROs systems, and on the acceptance of such technology by patients and health professionals. More importantly, real-time and routinely collected PROs will enable the development of a rapid learning health system which will have great potential to advance our knowledge of drug development, best models of cancer patient care, and a much more patient-centred health care system.

In 1963, the geneticist J. B. S. Haldane[152 (p.464)] described four stages of acceptance for new ideas or methods: (1) This is worthless nonsense; (2) This is an interesting, but perverse point of view; (3) This is true, but quite unimportant; (4) I always said so. There is every reason to believe that, with wise implementation by the Cancer Institute NSW, the use of ePROs in cancer settings can reach Haldane's stage 4.

References

1. Jones JB, Snyder CF, Wu AW. Issues in the design of Internet-based systems for collecting patient-reported outcomes. J Clin Oncol. 2007; 16(8):1407–1417.

2. Guidance for industry patient-reported outcome measures: use in medical product development to support labeling claims. U.S. Department of Health and Human Services FDA December, 2009.

3. Luckett T, Butow PN, King MT. Improving patient outcomes through the routine use of patient-reported data in cancer clinics: future directions. Psychooncology. 2009; 18(11):1129–1138.

4. Valderas JM, Kotzeva A, Espallargues M, Guyatt G, Ferrans CE, Halyard MY et al. The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. Qual Life Res. 2008; 17(2):179–193.

5. Espallargues M, Valderas JM, Alonso J. Provision of feedback on perceived health status to health care professionals: a systematic review of its impact. Med Care. 2000; 38(2):175–186.

6. Marshall S, Haywood K, Fitzpatrick R. Impact of patient-reported outcome measures on routine practice: a structured review. J Eval Clin Pract. 2006; 12(5):559–568.

7. Greenhalgh J, Meadows K. The effectiveness of the use of patient-based measures of health in routine practice in improving the process and outcomes of patient care: a literature review. J Eval Clin Pract. 1999; 5(4):401–416.

8. Gilbody SM, House AO, Sheldon TA. Outcome measures and needs assessment tools for schizophrenia and related disorders. Cochrane Database Syst Rev. 2003; (1):CD003081.

9. Drury M, Yudkin P, Harcourt J, Fitzpatrick R, Jones L, Alcock C et al. Patients with cancer holding their own records: a randomised controlled trial. Br J Gen Pract. 2000; 50(451):105–110.

10. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. J Clin Oncol. 2004; 22(4):714–724.

11. Taenzer P, Bultz BD, Carlson LE, Speca M, DeGagne T, Olson K et al. Impact of computerized quality of life screening on physician behaviour and patient satisfaction in lung cancer outpatients. Psychooncology. 2000; 9(3):203–213.

12. Rosenbloom SK, Victorson DE, Hahn EA, Peterman AH, Cella D. Assessment is not enough: a randomized controlled trial of the effects of HRQL assessment on quality of life and satisfaction in oncology clinical practice. Psychooncology. 2007; 16(12):1069–1079.

13. Boyes A, Newell S, Girgis A, McElduff P, Sanson-Fisher R. Does routine assessment and real-time feedback improve cancer patients' psychosocial well-being? Eur J Cancer Care (Engl). 2006; 15(2):163–171.

14. Detmar SB, Muller MJ, Schornagel JH, Wever LDV, Aaronson NK. Health-related quality-of-life assessments and patient-physician communication: a randomized controlled trial. JAMA. 2002; 288(23):3027–3034.

15. McLachlan SA, Allenby A, Matthews J, Wirth A, Kissane D, Bishop M et al. Randomized trial of coordinated psychosocial interventions based on patient self-assessments versus standard care to improve the psychosocial functioning of patients with cancer. J Clin Oncol. 2001; 19(21):4117–4125.

16. Trowbridge R, Dugan W, Jay SJ, Littrell D, Casebeer LL, Edgerton S et al. Determining the effectiveness of a clinical-practice intervention in improving the control of pain in outpatients with cancer. Acad Med. 1997; 72(9):798–800.

17. Greenhalgh J, Long AF, Flynn R. The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory? Soc Sci Med. 2005; 60(4):833–843.

18. Abernethy AP, Ahmad A, Zafar SY, Wheeler JL, Reese JB, Lyerly HK. Electronic patient-reported data capture as a foundation of rapid learning cancer care. Med Care. 2010; 48(6Suppl):S32–S38.

19. Grimshaw J, McAuley LM, Bero LA, Grilli R, Oxman AD, Ramsay C et al. Systematic reviews of the effectiveness of quality improvement strategies and programmes. Qual Saf Health Care. 2003; 12(4):298–303.

20. Wagstaff A. Inequality aversion, health inequalities, and health achievement. J Health Econ. 2002: 21(4):627–641

21. Guyatt GHO, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008; 336:924–926.

22. Takeuchi EE, Keding A, Awad N, Hofmann U, Campbell LJ, Selby PJ et al. Impact of patient-reported outcomes in oncology: a longitudinal analysis of patient-physician communication. J Clin Oncol. 2011; 29(21):2910–2917.

23. Velikova G, Keding A, Harley C, Cocks K, Booth L, Smith AB et al. Patients report improvements in continuity of care when quality of life assessments are used routinely in oncology practice: secondary outcomes of a randomised controlled trial. Eur J Cancer. 2010; 46(13):2381–2388.

24. Santana MJ, Feeny D, Johnson JA, McAlister FA, Kim D, Weinkauf J et al. Assessing the use of health-related quality of life measures in the routine clinical care of lung-transplant patients. Qual Life Res. 2010; 19(3):371–379.

25. Berry DL, Blumenstein BA, Halpenny B, Wolpin S, Fann JR, Austin-Seymour M et al. Enhancing patient-provider communication with the electronic self-report assessment for cancer: a randomized trial. J Clin Oncol. 2011; 29(8):1029–1035.

26. Carlson LE, Groff SL, Maciejewski O, Bultz BD. Screening for distress in lung and breast cancer outpatients: a randomized controlled trial. J Clin Oncol. 2010; 28(33):4884–4891.

27. Fayers PM. Evaluating the effectiveness of using PROs in clinical practice: a role for cluster-randomised trials. Qual Life Res. 2008; 17(10):1315–1321.

28. Basch E, Abernethy AP. Supporting clinical practice decisions with real-time patient-reported outcomes. J Clin Oncol. 2011; 29(8):954–956.

29. Abernethy AP, Wheeler JL, Zafar SY. Management of gastrointestinal symptoms in advanced cancer patients: the rapid learning cancer clinic model. Curr Opin Support Palliat Care. 2010; 4(1):36–45.

30. Berry DL. Patient-reported symptoms and quality of life integrated into clinical cancer care. Semin Oncol Nurs. 2011; 27(3):203–210.

31. Hoekstra J, De Vos R, Van Duijn NP, Schadé E, Bindels PJE. Using the symptom monitor in a randomized controlled trial: the effect on symptom prevalence and severity. J Pain Symptom Manage. 2006; 31(1):22–30.

32. Kornblith AB, Dowell JM, Herndon JE, Engelman BJ, Bauer-Wu S, Small EJ et al. Telephone monitoring of distress in patients aged 65 years or older with advanced stage cancer: a cancer and leukemia group B study. Cancer. 2006; 107(11):2706–2714.

33. Given CW, Sikorskii A, Tamkus D, Given B, You M, McCorkle R et al. Managing symptoms among patients with breast cancer during chemotherapy: results of a two-arm behavioral trial. J Clin Oncol. 2008; 26(36):5855–5862.

34. Kearney N, McCann L, Norrie J, Taylor L, Gray P, McGee-Lennon M et al. Evaluation of a mobile phone-based, advanced symptom management system (ASyMS©) in the management of chemotherapy-related toxicity. Support Cancer Care. 2009; 17(4):437–444.

35. Ruland CM, Holte HH, Røislien J, Heaven C, Hamilton GA, Kristiansen J et al. Effects of a computer-supported interactive tailored patient assessment tool on patient care, symptom distress, and patients' need for symptom management support: a randomized clinical trial. J Am Med Inform Assoc. 2010; 17(4):403–410.

36. Cleeland CS, Wang XS, Shi Q, Mendoza TR, Wright SL, Berry MD et al. Automated symptom alerts reduce postoperative symptom severity after cancer surgery: a randomized controlled clinical trial. J Clin Oncol. 2011; 29(8):994–1000.

37. Hilarius DL, Kloeg PH, Gundy CM, Aaronson NK. Use of health-related quality-of-life assessments in daily clinical oncology nursing practice: a community hospital-based intervention study. Cancer. 2008; 113(3):628–637.

38. Bainbridge BD, Seow H, Sussman J, Pond G, Martelli-Reid L, Herbert C et al. Multidisciplinary health care professionals' perceptions of the use and utility of a symptom assessment system for oncology patients. J Oncol Pract 2011; 7(1):19–23.

39. Halkett G, Jiwa M, Tanner P, Fournier C, Katris P. Trialling computer touch-screen technology to assess psychological distress in patients with gynaecological cancer. Australas Med J 2010; 3(12):781—785.

40. Dinkel A, Berg P, Pirker C, Geinitz H, Sehlen S, Emrich M et al. Routine psychosocial distress screening in radiotherapy: implementation and evaluation of a computerised procedure. Br J Cancer. 2010; 103(10):1489–1495.

41. Mark TL, Fortner B, Johnson G. Evaluation of a tablet PC technology to screen and educate oncology patients. Support Cancer Care. 2008; 16(4):371–378.

42. Butt Z, Wagner LI, Beaumont JL, Paice JA, Straus JL, Peterman AH et al. Longitudinal screening and management of fatigue, pain, and emotional distress associated with cancer therapy. Support Cancer Care. 2008; 16(2):151–159.

43. Weaver A, Young AM, Rowntree J, Townsend N, Pearson S, Smith J et al. Application of mobile phone technology for managing chemotherapy-associated side-effects. Ann Oncol. 2007; 18(11):1887–1892.

44. Basch E, Artz D, Dulko D, Scher K, Sabbatini P, Hensley M et al. Patient online self-reporting of toxicity symptoms during chemotherapy. J Clin Oncol. 2005; 23(15):3552–3561.

45. Basch E, Iasonos A, Barz A, Culkin A, Kris MG, Artz D et al. Long-term toxicity monitoring via electronic patient-reported outcomes in patients receiving chemotherapy. J Clin Oncol. 2007; 25(34):5374–5380.

46. Mooney KH, Beck SL, Friedman RH, Farzanfar R. Telephone-linked care for cancer symptom monitoring: a pilot study. Cancer Pract. 2002; 10(3):147–154.

47. Abernethy AP, Zafar SY, Uronis H, Wheeler JL, Coan A, Rowe K et al. Validation of the patient care monitor (version 2.0): a review of system assessment instrument for cancer patients. J Pain Symptom Manage. 2010; 40(4):545–558.

48. Abernethy AP, Herndon 2nd JE, Wheeler JL, Patwardhan M, Shaw H, Lyerly HK et al. Improving health care efficiency and quality using tablet personal computers to collect research-quality, patient-reported data. Health Serv Res. 2008; 43(6):1975–1991.

49. Basch E, Jia X, Heller G, Barz A, Sit L, Fruscione M et al. Adverse symptom event reporting by patients vs clinicians: relationships with clinical outcomes. J Natl Cancer Inst. 2009; 101(23):1624–1632.

50. Basch E, Artz D, Iasonos A, Speakman J, Shannon K, Lin K et al. Evaluation of an Online Platform for Cancer Patient Self-reporting of Chemotherapy Toxicities. J Am Inform Assoc. 2007; 14(3):264–268.

51. Snyder CF, Jensen R, Courtin SO, Wu AW, Aaronson N, Brundage M et al. PatientViewpoint: a website for patient-reported outcomes assessment. Qual Life Res. 2009; 18(7):793–800.

52. Fyllingen EH, Oldervoll LM, Loge JH, Hjermstad MJ, Haugen DF, Sigurdardottir KR et al. Computer-based assessment of symptoms and mobility in palliative care: feasibility and challenges. J Pain Symptom Manage. 2009; 38(6):827–836.

53. Rogers SN, El-Sheikha J, Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. Oral Oncol. 2009; 45(7):555–561.

54. Pigott C, Pollard A, Thomson K, Aranda S. Unmet needs in cancer patients: development of a supportive needs screening tool (SNST). Support Cancer Care. 2009; 17(1):33–45.

55. Mitchell AJ, Vahabzadeh A, Magruder K. Screening for distress and depression in cancer settings: 10 lessons from 40 years of primary-care research. Psychooncology. 2011; 20(6):572–584.

56. Johns SA, Kroenke K, Theobald DE, Wu J, Tu W. Telecare management of pain and depression in patients with cancer: patient satisfaction and predictors of use. J Ambul Care Manage. 2011; 34(2):126–139.

57. Husson O, Mols F, van de poll-franse LV. The relation between information provision and health-related quality of life, anxiety and depression among cancer survivors: a systematic review. Ann Oncol. 2011; 22(4):761–772.

58. Mitchell AJ, Meader N, Symonds P. Diagnostic validity of the Hospital Anxiety and Depression Scale (HADS) in cancer and palliative settings: a meta-analysis. J Affect Disord. 2010; 126(3):335–348.

59. Luckett T, Butow PN, King MT, Oguchi M, Heading G, Hackl NA et al. A review and recommendations for optimal outcome measures of anxiety, depression and general distress in studies evaluating psychosocial interventions for english-speaking adults with heterogeneous cancer diagnoses. Support Cancer Care. 2010; 18(10):1241–1262.

60. Verdonck-de Leeuw IM, de Bree R, Keizer AL, Houffelaar T, Cuijpers P, van der Linden MH et al. Computerized prospective screening for high levels of emotional distress in head and neck cancer patients and referral rate to psychosocial care. Oral Oncol. 2009; 45(10):e129–e133.

61. Fann JR, Berry DL, Wolpin S, Austin-Seymour M, Bush N, Halpenny B et al. Depression screening using the Patient Health Questionnaire-9 administered on a touch screen computer. Psychooncology. 2009; 8(1):14–22.

62. Mitchell AJ, Kaar S, Coggan C, Herdman J. Acceptability of common screening methods used to detect distress and related mood disorders—Preferences of cancer specialists and non-specialists. Psychooncology. 2008; 17(3):226–236.

63. Becker J, Fliege H, Kocalevent RD, Bjorner JB, Rose M, Walter OB et al. Functioning and validity of a computerized adaptive test to measure anxiety (A-CAT). Depress Anxiety. 2008; 25(12):E182–E94.

64. Frick E, Tyroller M, Panzer M. Anxiety, depression and quality of life of cancer patients undergoing radiation therapy: a cross-sectional study in a community hospital outpatient centre. Eur J Cancer Care (Engl). 2007; 16(2):130–136.

65. Crane HM, Lober W, Webster E, Harrington RD, Crane PK, Davis TE et al. Routine collection of patient-reported outcomes in an HIV clinic setting: the first 100 patients. Curr HIV Res. 2007; 5(1):109–118.

66. Cabañero-Martínez MJ, Cabrero-García J, Richart-Martínez M, Muñoz-Mendoza CL, Reig-Ferrer A. A structured review of the depression scales in elderly people. *Revisión estructurada de las escalas de depresión en personas mayores.* Int J Clin Health Psychol. 2007; 7(3):823–846.

67. Williams S, Dale J. The effectiveness of treatment for depression/depressive symptoms in adults with cancer: a systematic review. Br J Cancer. 2006; 94(3):372–390.

68. Tsutsumi S, Yamaki S, Yamaguchi S, Asao T, Kuwano H. Anxiety in outpatients receiving chemotherapy for solid cancer. Hepatogastroenterology. 2006; 53(72):828–830.

69. Akechi T, Okuyama T, Sugawara Y, Shima Y, Furukawa TA, Uchitomi Y. Screening for depression in terminally ill cancer patients in Japan. J Pain Symptom Manage. 2006; 31(1):5–12.

70. Shimizu K, Akechi T, Okamura M, Oba A, Fujimori M, Akizuki N et al. Usefulness of the nurse-assisted screening and psychiatric referral program. Cancer. 2005; 103(9):1949–1956.

71. Lee SJ, Loberiza FR, Antin JH, Kirkpatrick T, Prokop L, Alyea EP et al. Routine screening for psychosocial distress following hematopoietic stem cell transplantation. Bone Marrow Transplant. 2005; 35(1):77–83.

72. King DA, Heisel MJ, Lyness JM. Assessment and psychological treatment of depression in older adults with terminal or life-threatening illness. Clin Psychol Sci Pract. 2005; 12(3):339–353.

73. Francoeur RB. The relationship of cancer symptom clusters to depressive affect in the initial phase of palliative radiation. J Pain Symptom Manage. 2005; 29(2):130–155.

74. Tariman JD, Berry DL, Halpenny B, Wolpin S, Schepp K. Validation and testing of the Acceptability E-scale for web-based patient-reported outcomes in cancer care. Appl Nurs Res. 2011; 24(1):53–58.

75. Lin HC, Wu HC, Chang CH, Li TC, Liang WM, Wang JYW. Development of a real-time clinical decision support system upon the web mvc-based architecture for prostate cancer treatment. BMC Med Inform Decis Mak. 2011; 11(1).

76. Hacker ED. Technology and quality of life outcomes. Semin Oncol Nurs. 2010; 26(1):47–58.

77. Fleisher L, Buzaglo J, Collins M, Millard J, Miller SM, Egleston BL et al. Using health communication best practices to develop a web-based provider-patient communication aid: the CONNECT™ study. Patient Educ Couns. 2008; 71(3):378–387.

78. Podichetty VK, Weiss LT, Fanciullo GJ, Baird JC. Web-based health survey systems in outcome assessment and management of pain. Pain Med. 2007; 8(Suppl.3):S189–S198.

79. Donaldson MS. Use of patient-reported outcomes in clinical oncology practice: a nonvisit approach to patient care based on the IOM report. J Ambul Care Manage. 2007; 30(4):302–307.

80. Karras BT, Wolpin S, Lober WB, Bush N, Fann JR, Berry DL. Electronic Self-report Assessment--Cancer (ESRA-C): working towards an integrated survey system. Stud Health Technol Inform 2006; 122:514–518.

81. Bush N, Donaldson G, Moinpour C, Haberman M, Milliken D, Markle V et al. Development, feasibility and compliance of a web-based system for very frequent QOL and symptom home self-assessment after hematopoietic stem cell transplantation. Qual Life Res. 2005; 14(1):77–93.

82. Hadi M, Gibbons E, Fitzpatrick R. A structured review of patient-reported outcome measures for colorectal cancer: Patient-reported Outcome Measurement Group. Department of Public Health, University of Oxford, 2010.

83. Comabella CCi, Gibbons E, Fitzpatrick R. A structured review of patient-reported outcome measures for patients with lung cancer: Patient-reported Outcome Measurement Group. Oxford: Department of Public Health, University of Oxford, 2010.

84. Morris C, Gibbons E, Fitzpatrick R. A structured review of patient-reported outcome measures for men with prostate cancer: Patient-reported Outcome Measurement Group. Oxford: Department of Public Health, University of Oxford, 2009.

85. Davies N, Gibbons E, Mackintosh A, Fitzpatrick R. A structured review of patient-reported outcome measures for women with breast cancer: Patient-reported Outcome Measurement Group. Oxford: Department of Public Health, University of Oxford, 2009.

86. Smith S, Cano S, Lamping DL, Staniszewska S, Browne J, Lewsey J et al. Patient-Reported Outcome Measures (PROMs) for routine use in Treatment Centres: recommendations based on a review of the scientific evidence. Final Report to the Department Health, University of Oxford December 2005 ed: Health Services Research Unit, London School of Hygiene &Tropical Medicine, London, UK, 2005.

87. Garcia SF, Cella D, Clauser SB, Flynn KE, Lad T, Lai JS et al. Standardizing patient-reported outcomes assessment in cancer clinical trials: a patient-reported outcomes measurement information system initiative. J Clin Oncol. 2007; 25(32):5106–5112.

88. Varni JW, Thissen D, Stucky BD, Liu Y, Gorder H, Irwin DE et al. PROMIS® Parent Proxy Report Scales: an item response theory analysis of the parent proxy report item banks. Qual Life Res. 2011: 1–18.

89. Thissen D, Varni JW, Stucky BD, Liu Y, Irwin DE, DeWalt DA. Using the PedsQL™ 3.0 asthma module to obtain scores comparable with those of the PROMIS pediatric asthma impact scale (PAIS). Qual Life Res. 2011; 1–9.

90. Sung VW, Marques F, Rogers RR, Williams DA, Myers DL, Clark MA. Content validation of the patient-reported outcomes measurement information system (PROMIS) framework in women with urinary incontinence. Neurol Urodyn. 2011; 30(4):503–509.

91. Preston K, Reise S, Cai L, Hays RD. Using the nominal response model to evaluate response category discrimination in the PROMIS emotional distress item pools. Edu Psychol Meas. 2011; 71(3):523–550.

92. Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item banks for measuring emotional distress from the Patient-Reported Outcomes Measurement Information System (PROMIS®): depression, anxiety, and anger. Assessment. 2011; 18(3):263–283.

93. Magasi S, Ryan G, Revicki D, Lenderking W, Hays RD, Brod M et al. Content validity of patient-reported outcome measures: perspectives from a PROMIS meeting. Qual Life Res. 2012; 21(5):739–746.

94. Lai JS, Cella D, Choi S, Junghaenel DU, Christodoulou C, Gershon R et al. How item banks and their application can influence measurement practice in rehabilitation medicine: a PROMIS fatigue item bank example. Arch Phys Med Rehabil. 2011; 92(10Suppl.):S20–S27.

95. Junghaenel DU, Christodoulou C, Lai JS, Stone AA. Demographic correlates of fatigue in the US general population: results from the patient-reported outcomes measurement information system (PROMIS) initiative. J Psychosom Res. 2011; 71(3):117–123.

96. Irwin DE, Stucky BD, Langer MM, Thissen D, DeWitt EM, Lai JS et al. PROMIS Pediatric Anger Scale: an item response theory analysis. Qual Life Res. 2012; 21(4):697–706.

97. Hung M, Clegg DO, Greene T, Saltzman CL. Evaluation of the PROMIS physical function item bank in orthopaedic patients. J Orthop Res. 2011; 29(6):947–953.

98. Gibbons LE, Feldman BJ, Crane HM, Mugavero M, Willig JH, Patrick D et al. Migrating from a legacy fixed-format measure to CAT administration: calibrating the PHQ-9 to the PROMIS depression measures. Qual Life Res. 2011; 20(9):1349–1357.

99. Fries JF, Krishnan E, Rose M, Lingala B, Bruce B. Improved responsiveness and reduced sample size requirements of PROMIS physical function scales with item response theory. Arthritis Res Ther. 2011; 13(5):R147

100. Fries J, Rose M, Krishnan E. The PROMIS of better outcome assessment: responsiveness, floor and ceiling effects, and internet administration. J Rheumatol. 2011; 38(8):1759–1764.

101. Flynn KE, Jeffery DD, Keefe FJ, Porter LS, Shelby RA, Fawzy MR et al. Sexual functioning along the cancer continuum: focus group results from the Patient-Reported Outcomes Measurement Information System (PROMIS®). Psychooncology. 2011; 20(4):378–386.

102. Cook KF, Bamer AM, Roddey TS, Kraft GH, Kim J, Amtmann D. A PROMIS fatigue short form for use by individuals who have multiple sclerosis. Qual Life Res. 2012; 21(6):1021–1030.

103. Cella D, Lai JS, Stone A. Self-reported fatigue: one dimension or more? Lessons from the functional assessment of chronic illness therapy-fatigue (FACIT-F) questionnaire. Support Cancer Care. 2011; 19(9):1441–1450.

104. Bajaj JS, Thacker LR, Wade JB, Sanyal AJ, Heuman DM, Sterling RK et al. PROMIS computerised adaptive tests are dynamic instruments to measure health-related quality of life in patients with cirrhosis. Aliment Pharmacol Ther. 2011; 34(9):1123–1132.

105. Amtmann D, Cook KF, Johnson KL, Cella D. The PROMIS initiative: involvement of rehabilitation stakeholders in development and examples of applications in rehabilitation research. Arch Phys Med Rehabil. 2011; 92(10 Suppl.):S12–S19.

106. Yeatts KB, Stucky B, Thissen D, Irwin D, Varni JW, Dewitt EM et al. Construction of the Pediatric Asthma Impact Scale (PAIS) for the Patient-Reported Outcomes Measurement Information System (PROMIS). J Asthma. 2010; 47(3):295–302.

107. Varni JW, Stucky BD, Thissen D, Dewitt EM, Irwin DE, Lai JS et al. PROMIS Pediatric Pain Interference Scale: an item response theory analysis of the pediatric pain item bank. J Pain. 2010; 11(11):1109–1119.

108. Rothrock NE, Hays RD, Spritzer K, Yount SE, Riley W, Cella D. Relative to the general US population, chronic diseases are associated with poorer health-related quality of life as measured by the Patient-Reported Outcomes Measurement Information System (PROMIS). J Clin Epidemiol. 2010; 63(11):1195–204.

109. Riley WT, Rothrock N, Bruce B, Christodolou C, Cook K, Hahn EA et al. Patient-reported outcomes measurement information system (PROMIS) domain names and definitions revisions: further evaluation of content validity in IRT-derived item banks. Qual Life Res. 2010; 19(9):1311–1321.

110. MacLaren VV, Best LA. Multiple addictive behaviors in young adults: student norms for the Shorter PROMIS Questionnaire. Addict Behav. 2010; 35(3):252–255.

111. Liu H, Cella D, Gershon R, Shen J, Morales LS, Riley W et al. Representativeness of the patient-reported outcomes measurement information system internet panel. J Clin Epidemiol. 2010; 63(11):1169–1178.

112. Irwin DE, Stucky BD, Thissen D, DeWitt EM, Lai JS, Yeatts K et al. Sampling plan and patient characteristics of the PROMIS pediatrics large-scale survey. Qual Life Res. 2010; 19(4):585–594.

113. Irwin DE, Stucky B, Langer MM, Thissen D, DeWitt EM, Lai JS et al. An item response analysis of the pediatric PROMIS anxiety and depressive symptoms scales. Qual Life Res. 2010; 19(4):595–607.

114. Henly SJ. Editorial: The promise of PROMIS. Nurs Res. 2010; 59(2):77.

115. Henly SJ. The promise of PROMIS. Nurs Res. 2010; 59(2):77.

116. Hays RD, Bode R, Rothrock N, Riley W, Cella D, Gershon R. The impact of next and back buttons on time to complete and measurement reliability in computer-based surveys. Qual Life Res. 2010; 19(8):1181–1184.

117. Hahn EA, DeVellis RF, Bode RK, Garcia SF, Castel LD, Eisen SV et al. Measuring social health in the patient-reported outcomes measurement information system (PROMIS): item bank development and testing. Qual Life Res. 2010; 19(7):1035–1044.

118. Gershon RC, Rothrock N, Hanrahan R, Bass M, Cella D. The use of PROMIS and assessment center to deliver Patient-Reported Outcome Measures in clinical research. J Appl Meas. 2010; 11(3):304–314.

119. Flynn KE, Shelby RA, Mitchell SA, Fawzy MR, Hardy NC, Husain AM et al. Sleep-wake functioning along the cancer continuum: focus group results from the Patient-Reported Outcomes Measurement Information System (PROMIS®). Psychooncology. 2010; 19(10):1086–1093.

120. Eisenstein EL, Diener LW, Nahm M, Weinfurt KP. Impact of the Patient-Reported Outcomes Management Information System (PROMIS) upon the design and operation of multi-center clinical trials: a qualitative research study. J Med Syst. 2010:1–10.

121. Choi SW, Reise SP, Pilkonis PA, Hays RD, Cella D. Efficiency of static and computer adaptive short forms compared to full-length measures of depressive symptoms. Qual Life Res. 2010; 19(1):125–136.

122. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. J Clin Epidemiol. 2010; 63(11):1179–1194.

123. Amtmann D, Cook KF, Jensen MP, Chen WH, Choi S, Revicki D et al. Development of a PROMIS item bank to measure pain interference. Pain. 2010; 150(1):173–82.

124. Aletaha D. From the item to the outcome: the promising prospects of PROMIS. Arthritis Res Ther. 2010; 12(1):104–106.

125. Revicki DA, Kawata AK, Harnam N, Chen WH, Hays RD, Cella D. Predicting EuroQol (EQ-5D) scores from the Patient-Reported Outcomes Measurement Information System (PROMIS) global items and domain item banks in a United States sample. Qual Life Res. 2009; 18(6):783–791.

126. Revicki DA, Chen WH, Harnam N, Cook KF, Amtmann D, Callahan LF et al. Development and psychometric analysis of the PROMIS pain behavior item bank. Pain. 2009; 146(1–2):158–169.

127. Klem M, Saghafi E, Abromitis R, Stover A, Dew MA, Pilkonis P. Building PROMIS item banks: librarians as co-investigators. Qual Life Res. 2009; 18(7):881–888.

128. Jeffery DD, Tzeng JP, Keefe FJ, Porter LS, Hahn EA, Flynn KE et al. Initial report of the cancer Patient-Reported Outcomes Measurement Information System (PROMIS) sexual function committee: review of sexual function measures and domains used in oncology. Cancer. 2009; 115(6):1142–1153.

129. Jansky LJ, Huang JC. A multi-method approach to assess usability and acceptability: a case study of the Patient-Reported Outcomes Measurement System (PROMIS) workshop. Social Science Computer Review 2009; 27(2):262–270.

130. Irwin DE, Varni JW, Yeatts K, DeWalt DA. Cognitive interviewing methodology in the development of a pediatric item bank: a Patient Reported Outcomes Measurement Information System (PROMIS) study. Health Qual Life Outcomes. 2009; 23(7):3

131. Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the Patient-Reported Outcomes Measurement Information System (PROMIS) global items. Qual Life Res. 2009; 18(7):873–880.

132. Fries JF, Krishnan E, Bruce B. Items, instruments, crosswalks, and PROMIS. J Rheumatol. 2009; 36(6):1093–1095.

133. Fries JF, Krishnan E. What constitutes progress in assessing patient outcomes? J Clin Epidemiol. 2009; 62(8):779–780.

134. Fries JF, Cella D, Rose M, Krishnan E, Bruce B. Progress in assessing physical function in arthritis: PROMIS short forms and computerized adaptive testing. J Rheumatol. 2009; 36(9):2061–2066.

135. Fortune-Greeley AK, Flynn KE, Jeffery DD, Williams MS, Keefe FJ, Reeve BB et al. Using cognitive interviews to evaluate items for measuring sexual functioning across cancer populations: improvements and remaining challenges. Qual Life Res. 2009; 18(8):1085–1093.

136. Walsh TR, Irwin DE, Meier A, Varni JW, DeWalt DA. The use of focus groups in the development of the PROMIS pediatrics item bank. Qual Life Res. 2008; 17(5):725–735.

137. Rose M, Bjorner JB, Becker J, Fries JF, Ware JE. Evaluation of a preliminary physical function item bank supported the expected advantages of the Patient-Reported Outcomes Measurement Information System (PROMIS). J Clin Epidemiol. 2008; 61(1):17–33.

138. Neary PC, Boyle E, Delaney CP, Senagore AJ, Keane FBV, Gallagher AG. Construct validation of a novel hybrid virtual-reality simulator for training and assessing laparoscopic colectomy; results from the first course for experienced senior laparoscopic surgeons. Surgical Endoscopy and Other Interventional Techniques 2008; 22(10):2301–2309.

139. Christodoulou C, Junghaenel DU, DeWalt DA, Rothrock N, Stone AA. Cognitive interviewing in the evaluation of fatigue items: results from the Patient-Reported Outcomes Measurement Information System (PROMIS). Qual Life Res. 2008; 17(10):1239–1246.

140. Castel LD, Williams KA, Bosworth HB, Eisen SV, Hahn EA, Irwin DE et al. Content validity in the PROMIS social-health domain: a qualitative analysis of focus-group data. Qual Life Res. 2008; 17(5):737–749.

141. Reeve BB, Hays RD, Bjorner JB, Cook KF, Crane PK, Teresi JA et al. Psychometric evaluation and calibration of health-related quality of life item banks: plans for the Patient-Reported Outcomes Measurement Information System (PROMIS). Med Care. 2007; 45(5Suppl.1):S22–S31.

142. Hays RD, Liu H, Spritzer K, Cella D. Item response theory analyses of physical functioning items in the medical outcomes study. Med Care. 2007; 45(5Suppl.1):S32–S38.

143. DeWalt DA, Rothrock N, Yount S, Stone AA. Evaluation of item candidates: the PROMIS qualitative item review. Med Care. 2007; 45(5Suppl.1):S12–S21.

144. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH roadmap cooperative group during its first two years. Med Care. 2007; 45(5Suppl.1):S3–S11.

145. Cella D, Gershon R, Lai JS, Choi S. The future of outcomes measurement: item banking, tailored short-forms, and computerized adaptive assessment. Qual Life Res. 2007; 16(Suppl.1):133–141.

146. Ader DN. Developing the Patient-Reported Outcomes Measurement Information System (PROMIS). Med Care. 2007;45(Suppl.1):S1–S2.

147. Pallanti S, Bernardi S, Quercioli L. The Shorter PROMIS Questionnaire and the Internet Addiction Scale in the assessment of multiple addictions in a high-school population: prevalence and related disability. CNS Spectr. 2006; 11(12):966–974.

148. Fries JF, Bruce B, Cella D. The promise of PROMIS: using item response theory to improve assessment of patient-reported outcomes. Clin Exp Rheumatol. 2005; 23(5Suppl.39):S53–S57.

149. Olsen LA, Aisner D, Michael J. The learning healthcare system: workshop summary (IOM Roundtable on Evidence-Based Medicine), 2007.

150. Hao Y. Patient-reported outcomes in support of oncology product labeling claims: regulatory context and challenges. Expert Rev Pharmacoecon Outcoms Res. 2010; 10(4):407–420.

151. Fung CH, Hays RD. Prospects and challenges in using patient-reported outcomes in clinical practice. Qual Life Res. 2008; 17(10):1297–1302.

152. Haldane JBS. The truth about death. J Genet. 1963; 58:(2):464.

Appendix A: Full text search strategies used in Scopus

Strategy A.

A more extensive search covering a larger literature: 6095 hits

(TITLE-ABS-KEY (patient reported outcome) OR TITLE-ABS-KEY (self-reported) OR TITLE-ABS-KEY (self-assessed)OR TITLE(routine))
AND (TITLE-ABS-KEY(quality of life) OR TITLE-ABS-KEY(symptom) OR TITLE-ABS-KEY(functional status) OR TITLE-ABS-KEY(health status) OR TITLE-ABS-KEY(patient satisfaction) OR TITLE-ABS-KEY(unmet need*))
AND (KEY(neoplasm) OR KEY(cancer))
AND PUBYEAR > 1999 : (This more specific search strategy had 489 hits.)

Strategy B.

A more restricted search with some search terms being restricted to titles: 489 hits

(TITLE(patient reported outcome) OR TITLE(self-reported) OR TITLE(self-assessed)OR TITLE(routine))
AND (TITLE-ABS-KEY(quality of life) OR TITLE-ABS-KEY(symptom) OR TITLE-ABS-KEY(functional status) OR TITLE-ABS-KEY(health status) OR TITLE-ABS-KEY(patient satisfaction) OR TITLE-ABS-KEY(unmet need*))
AND (KEY(neoplasm) OR KEY(cancer))
AND PUBYEAR > 1999 :

Appendix B: The web-based PROs as reviewed by Jones et al. (2007)[1]

Table 2 Characteristics of web-based tools for collecting patient reported outcomes

Tool/*Author*	Target Population	Instruments (*total number of items*)	Response Rate	Purpose	Intended Use	Usability Features/ Characteristics	Reporting Capabilities	Educational Features	Evaluations
Fred Hutchinson Cancer Research Center *Bush et al., Qual Life Research (2005)*	Cancer patients undergoing hematopoietic stem cell transplantation	•EORTC-QLQC30 •HSCT symptom inventory •Health Perceptions Questionnaire •Demands of BMT Inventory •Profile of Mood States *(5 items per day drawn from 38-item bank)*	119 patients enrolled; 30 completed 52 weeks of participation, 46 completed <52 weeks; 39 still actively participating	•Develop system for frequent (daily) home-based assessment of QOL, symptoms •Detect early onset of relapse	Patients log in daily/several times per week to complete QOL assessment	Integrated administration component of website	•Linked to electronic medical record •Graphical displays of all online activities •Log of all responses •Symptom alerts	Public section of website has detailed tutorial; instructions on website use for beginners	•Access •Accrual and attrition •Compliance •Usage •Patient satisfaction
CHADIS - Child Health and Development Interactive System *Unpublished proceedings; abstracts*	General pediatric care	Operationalized DSM-PC Child and Adolescent version *(Number of items varies)*	Not reported	Pediatric diagnostic decision support	Parent completes web-based assessment prior to visit	Can be incorporated in EHR	•Can be linked to EHR •Identifies chief problem areas •Provisional diagnoses	Extensive localized resource database	Not reported
WHOMS - Wireless Health Outcomes Monitoring System *Bielli et al., BMC Med Inform & Dec Making (2004)*	Cancer patients	Pain questionnaire based on MSAS-SF *(10 items)*	56/97 (58%) patients completed the assessment	Allow patients to self-report cancer pain; allow physician tracking of results	Patient completes questionnaire on mobile phone or Internet	•Physician can create and manage instruments •Physicians can customize alertable response levels	Graphical, color-coded output for physician	Not reported	Not reported
STAR (Memorial Sloan-Kettering) *Basch et al., J Clin Onc (2005)*	Cancer patients w/gynecologic malignancy	•CTCAE •EQ-5D •Performance Status *(13 items)*	80 patients enrolled; 49 (67%) used system at 81 100% of visits (8 week period)	•Assess feasibility of patient symptom self-reporting •Assess use of Internet for PRO	Patients enter and track symptoms using standard instrument	•Longitudinal reports accessible to patient and clinician •Free-text diary available to patients	•System for handling out of range results •Results printed and given to clinician for optional use during visit	•10 min instruction •Wallet card w/ support line, unique password	•Patterns of use •Patient Impressions •Clinician Feedback
Hows Your Health *Unpublished data; interviews, www.howsyourhealth.org*	Primary care patients	QOL, overall health, pain, feelings, social support, physical activity, diagnoses, etc *(Approximately 30 items, depending on patient responses)*	Not reported	Allows patients to self-report issues of importance so as to improve clinical communication and aid self-management	Completed by patients prior to visit; resulting reports/letters can be shared with doctor during visit	•Simple, easy to understand interface •Pictorial representations of health issues improve understanding	•Printable results, letters to share with physician •Physician can track aggregate results (no identifiable information obtained from patients)	Customized feedback depending on responses	Not reported

Tool/*Author*	Target Population	Instruments (*total number of items*)	Response Rate	Purpose	Intended Use	Usability Features/ Characteristics	Reporting Capabilities	Educational Features	Evaluations
WB-DAT (Web-based Depression & Anxiety Test) *Farvolden et al., JMIR (2003)*	Major depressive disorder, anxiety disorder	DSM-IV-based screening tool with follow-up questions for anxiety disorders *(11 standard items plus additional questions based on patient response)*	Administered to 193 participants	Self-report screening tool for depression	Improve communication between patient and clinician by providing summary of standard diagnostic information	WB-DAT results are NOT longitudinal, but other tools (Mood Tracker) can be accessed on subsequent visits	•Summary report can be printed by patient to present to clinician •Report summarizes responses to major diagnostic categories	•Educational component available on site •Forum support group on site	Preliminary validation study conducted (vs. standard diagnostic tool)
UCSD Center for Innovative Therapy Patient Self-Assessment Questionnaire *Athale et al, J Rheum (2004)*	Rheumatoid Arthritis (RA)	UCSD Center for Innovative Therapy Patient Self-Assessment Questionnaire *(21 items)*	56 patients completed the computerized assessment	Allow patients to self-report RA and physicians to monitor via Internet	Patient completes instrument in clinic	Patients can use mouse, touchball, touchscreen to complete	Printed report that patient can take to physician	Software has optional instructions	Instrument validation
University of Washington - Cancer Website Research Project *Berry et al., Onc Nurs Forum (2004); Mullen et al., Onc Nurs Forum (2004*	Cancer patients treated with radiation therapy	•SF-8 •SDS-13 •Pain intensity scale •Fever & chills •Sexual interest//function *(24 total items)*	Administered to 101 patients for pilot testing; 45 patients completed for usability testing	QOL assessment in cancer patients evaluated for radiation therapy	Complete in physician's office	Internet-based application administered using a touchscreen	Graphical output only (no scores)	Not described	•Acceptability •Usability •Focus groups

(With kind permission from Springer Science+Business Media: Issues in the design of Internet-based systems for collecting patient-reported outcomes. Quality of Life Research. Vol 16, 2007, No. 8, Pages 4–6. Jones JB, Snyder CF, Albert WW. Figure 2.)

Appendix C: The psychometric property appraisal criteria used in the Oxford Group Reviews

Appraisal component	Definition/test	Criteria for acceptability
Reliability		
Test-retest reliability	The stability of a measuring instrument over time; assessed by administering the instrument to respondents on two different occasions and examining the correlation between test and re-test scores	Test re-test reliability correlations for summary scores 0.70 for group comparisons
Internal consistency	The extent to which items comprising a scale measure the same construct (e.g. homogeneity of items in a scale); assessed by Cronbach's alpha's and item-total correlations	Cronbach's alphas for summary scores 0.70 for group comparisons Item-total correlations 0.20
Validity		
Content validity	The extent to which the content of a scale is representative of the conceptual domain it is intended to cover; assessed qualitatively during the questionnaire development phase through pre-testing with patients. Expert opinion and literature review	Qualitative evidence from pre-testing with patients, expert opinion and literature review that items in the scale represent the construct being measured Patients involved in the development stage and item generation
Construct validity	Evidence that the scale is correlated with other measures of the same or similar constructs in the hypothesised direction; assessed on the basis of correlations between the measure and other similar measures	High correlations between the scale and relevant constructs preferably based on a priori hypothesis with predicted strength of correlation
The ability of the scale to differentiate known-groups; assessed by comparing scores for sub-groups who are expected to differ on the construct being measured (e.g. a clinical group and control group)	Statistically significant differences between known groups and/or a difference of expected magnitude	
Responsiveness	The ability of a scale to detect significant change over time; assessed by comparing scores before and after an intervention of known efficacy (on the basis of various methods including t-tests, effect sizes (ES), standardised response means (SRM) or	Statistically significant changes on scores from pre to post-treatment and/or difference of expected magnitude

Appraisal component	Definition/test	Criteria for acceptability
	responsiveness statistics	
Floor/ceiling effects	The ability of an instrument to measure accurately across full spectrum of a construct	Floor/ceiling effects for summary scores <15%
Practical properties		
Acceptability	Acceptability of an instrument reflects respondents' willingness to complete it and impacts on quality of data	Low levels of incomplete data or non-response
Feasibility/burden	The time, energy, financial resources, personnel or other resources required of respondents or those administering the instrument	Reasonable time and resources to collect, process and analyse the data

(Used with permission of the Patient Reported Outcome Measurement Group, Department of Public Health, University of Oxford.)

Appendix D: The available instruments from PROMIS

Domain	Adult – # items		Pediatric – # items	
	Bank/ Scale	Short Forms	Bank/ Scale	Short Form
Emotional Distress – Anger	29	8	6	
Emotional Distress – Anxiety	29	4, 6, 7, 8	15	8
Emotional Distress – Depression	28	4, 6, 8a, 8b	14	8
Applied Cognition – Abilities	33	4, 6, 8		
Applied Cognition – General Concerns	34	4, 6, 8		
Psychosocial Illness Impact – Positive	39	4, 8		
Psychosocial Illness Impact – Negative	32	4, 8		
Fatigue	95	4, 6,7, 8	23	10
Pain – Behaviour	39	7		
Pain – Interference	41	4, 6a, 6b, 8	13	8
Pain Intensity	3			
Physical Function	124	4, 6, 8, 10, 20		
Mobility			23	8
Upper Extremity			29	8
Physical Function for Samples with Mobility Aid Users	114	12		
Sleep Disturbance	27	4, 6, 8a, 8b		
Sleep-Related impairment	16	8		
Sexual Function: Global Satisfaction with Sex Life	7			
Sexual Function: Interest in Sexual Activity	4			
Sexual Function: Lubrication	8			
Sexual Function: Vaginal Discomfort	10			
Sexual Function: Erectile Function	8			
Sexual Function: Orgasm (uncalibrated item pool)	3			
Sexual Function: Therapeutic Aids (uncalibrated item pool)	9			
Sexual Function; Sexual Activities (uncalibrated item pool)	12			
Sexual Function: Anal Discomfort (uncalibrated item pool)	5			
Sexual Function: Interfering Factors (uncalibrated item pool)	10			
Sexual Function Screener Questions (uncalibrated item pool)	3			
Satisfaction with Participation in Discretionary Social Activities (v1.0)	12	7		
Satisfaction with Participation in Social Roles (v1.0)	14	4, 6, 7, 8		
Satisfaction with Social Roles and Activities (v2.0)	44	4, 6, 8		
Ability to Participate in Social Roles and Activities	35	4, 6, 8		
Companionship	6	4, 6		
Informational Support	10	4, 6, 8		
Emotional Support	16	4, 6, 8		
Instrumental Support	11	4, 6, 8		
Social isolation	14	4, 6, 8		
Peer Relationships			15	8
Asthma Impact			17	8
Global Health	10			

(Reproduced with permission of the PROMIS Health Organization and the National Institutes of Health. See www.nihpromis.org for further information.)

PROMIS profile instruments available on Assessment Care

Domain	PROMIS-29	PROMIS-43	PROMIS-57
	# Items		
Emotional Distress - Anxiety	4	6	8
Emotional Distress – Despression	4	6	8
Fatigue	4	6	8
Pain – Interference	4	6	8
Pain – Intensity	1	1	1
Physical Function	4	6	8
Sleep Disturbance	4	6	8
Satisfaction with Social Participation (Social Roles v1.0)	4	6	8

(Reproduced with permission of the PROMIS Health Organization and the National Institutes of Health. See www.nihpromis.org for further information).

Appendix E: The characteristics of design and study quality

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
Trowbridge et al. (1997)[16]	USA (Indiana Community Cancer Centre, Indianapolis)	RCT: Intervention/ Control	320 cancer outpatients, 13 oncologists and 23 clinics	Pain Management Index (ref); pain medication level (0–3) minus pain level. Patient assessment of pain, pain regiments and relief received. Patterns of analgesic prescription	Estimates of average and worst pain over the previous 7 days, satisfaction with current pain regimens and degree of relief received	One	Doctors only (12)	No	No	**	***	√√
Tazenzer et al. (2000)[11]	Canada (Tom Baker Cancer Centre , Calgary, Alberta)	Before-after trial: usual care group /Intervention group with before as control	53 lung cancer patients attending an outpatient lung cancer clinic	EORTIC QLQ-C30 11-item Patient Satisfaction Questionnaire (PDIS) (adapted through Falvo and Smith, 1983). Exit Interview (patient's perception if QL issues had been addressed during the visit). Medical Record Audit on patients' care plan	EORTC QLQ-C30 (on a PC)	Once	Doctors and nurses	No	Ground round intro-duction and training	*	***	√√
McLachlan et al. (2001)[15]	Australia (Peter MacCallum Cancer Institute, Melbourne)	RCT: Intervention /control (ratio: 2:1)	450 cancer patients attending ambulatory clinics	Patient HRQL (EORTC QLQ-C30) 32-item Patient needs (Cancer Needs Questionnaire Short Form [CNQ]. Patient distress (Beck Depression Inventory [BDI]. Patient satisfaction (in 6-month). Services provided for those identified as required by	EORTC QLQ-C30, CNQ, BDI (through a touch-screen PC)	One	Doctor and coordi-nation nurse (numbers not reporter)	Individualised plan developed by coordination nurse in accordance with generic psycho-social guidelines	No	**	***	√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
				coordination nurse								
Detmar et al. (2002)[14]	Netherland (Netherlands Cancer Institute, Amsterdam)	RCT: (Cross-over design) Intervention/ control	214 palliative cancer patients in a outpatient clinic of a cancer hospital	Patient-doctor communication. Doctor's awareness of patient HRQL Patient management. Patients'/doctors' satisfaction. Patient HRQL (SF-36). Patients'/doctors' evaluation of intervention	EORTC QLQ-30	Three	Doctors (n=10)	No	Doctors given 30-mins training and patient mailed a leaflet	***	****	√√√
Mooney et al. (2002)[46]	USA (University of Utah, Salt Lake City, Utah)	A pilot Prospective study over a month period with daily measures	27 patients receiving cancer chemotherapy at a cancer centre outpatient clinic	Telephone-Linked Care system for Chemotherapy [TLC-Chemo Alert]. Seven symptoms (nausea and vomiting, fatigue, trouble sleeping, sore mouth, fever, feeling blue, feeling anxious). Exit interview	TLC-Chemo Alert	Patients asked to report daily during the cycle and the alerts were sent to providers	Doctors (n=2)	Yes	Patients trained (10 minutes TLC orien-tation)	**	**	√
Velikova et al. (2004)[10]	UK (Cancer Research UK Clinical Centre – Leeds)	RCT: Intervention /control-attention/control in a ratio of 2:1:1	286 cancer outpatients attending a large cancer centre of a teaching hospital	Patient HRQL (FACT-G). Discussion of HRQL issues in consultation. Medical actions (decisions on cancer treatment, symptomatic/ supportive treatment, investigations and referrals). Non-medical actions (advice on lifestyle, coping and reassurance).	EORTC QOQ-C30 Hospital Anxiety and Depression Scale [HADS]	Regular clinic visit over an average of 6 months	Doctor (n=28)	No	One to one training and manual provi-ded	***	****	√√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
				Physician checklist assessing the clinical usefulness of PROM data								
Basch et al. (2005)[44]	USA (Memorial Sloan-Kettering Cancer, New York)	Prospective pilot study of patient online self-reporting of toxicity symptoms	80 patients diagnosed with a gynaecologic malignancy starting a new chemotherapy regimen	Pattern of use of a self-reported online Symptom Track and Reporting [STAR] system. Patient impression of such system based on an exit questionnaire survey. Clinician feedback (through survey and team debriefing)	Symptom Track and Reporting [STAR] based on NCI CATCAE system	Any clinic visits during 8-week study period (mean=3, range 1–6), also possible log in at home during the period	Doctors and study team (n =un-reported)	Yes	Training pro-vided to patients but un-reporte d to staff	**	**	√
Boyes et al. (2006)[13]	Australia (Centre for Health Research & Psycho-oncology, University of Newcastle)	Pilot controlled trial: Intervention /control	80 cancer outpatients attending one cancer centre	Patient symptoms. Patient anxiety/ depression[HADS]. Patient needs (Supportive Care Needs Survey [SCNS]. Acceptability of intervention to patient and doctors	Symptoms, HADS SCNS	1st consul-tation:100 % patients; 2nd: 83%; 3rd: 71%; 4th: 60%	Doctors (n=4)	List of patients needs accompanied by suggestions for appropriate referral	None	**	***	√√
Hoeskstra et al. (2006)[31]	Netherlands (Academic Medical Centre, University of Amsterdam)	RCT: Intervention group with symptom monitoring / control	146 palliative cancer patients recruited through two hospitals and local GPs	10 symptoms from the Symptom Monitor. Severity of the reported symptom (0–10 score)	Symptom Monitor Extensive Questionnaire	Weekly self-assessed Symptom Monitor at home; Extensive question-naire every 2-months	GPs (98 times) and medical specialists (96 times)	No	No	**	***	√√
Korniblith et	USA (Dona-	RCT: Telephone	192 cancer	EORTC-QLQ-30 HADS	EORTC-QLQ-30‡	Once a	Ontological	Yes	Yes	***	****	√√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
al. (2006)[32]	Farber Cancer Institute, Boston)	Monitoring (TM) versus TM+Education Material (EM)	patients with advanced disease and receiving active treatment		HADS MOS-SS GDS (short form) QARSQ-PH UMPSI GSRE Patient Satisfaction with the Research Program BOMC test	month over 6 months	nurses					
Basch et al. (2007)[45]	USA (Memorial Sloan-Kettering Cancer, New York)	Prospective pilot study of a patient online self-reporting of toxicity symptoms	107 patients diagnosed with thoracic gynaecologic malignancy starting a new chemotherapy regimen	Feasibility/Pattern of use of a self-reported online Symptom Track and Reporting [STAR] system. Patient satisfaction survey (an exit questionnaire survey). Nursing survey (through an exit survey)	Symptom Track and Reporting [STAR] based on NCI CATAE system	Any clinic visits during 42-wk study period (mean=12, range 1–40), also possible log in at home during the period	Nurses and study team (n=un-reported)	No	Training pro-vided to patients but un-reporte d to staff	**	**	√
Rosen-bloom et al. (2007)[12]	USA (Center on Outcomes, Research and Education, Evanston Northwestern Healthcare	RCT: Structured interview and discussion / assessment control / standard care	213 patients with advanced breast, lung or colorectal cancer	Patient HRQL (Functioning Living Index – Cancer [FLIC]). Patient affect (Brief Profile of Mood States [Brief POMS]). Patient satisfaction [PSQ-III]. Clinical treatment changes as reported by nurse (supportive care changes, referrals, 'other' clinical changes and changes in standard dose of chemotherapy as a result of PROs)	FACT-G and a single item asking patients whether a particular symptom or problem was better than, worse than, or as expected	Clinic visits at baseline, and 1, 2, 3 and 6 months	Treating nurses (n=not reported)	No	No	***	****	√√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
Weaver et al. (2007)[43]	UK (Oxford Radcliffe Hospitals NHS Trust	A pilot study of novel mobile phone technology	6 colon cancer patients	Questionnaire on symptoms derived from the Common Terminology Criteria for Adverse Events (CTCAE) grading system	Questionnaire derived from the Common Terminology Criteria for Adverse Events (CTCAE) grading system	Twice daily during the chemo-therapy circle (one morning, one evening)	Nurses (n= not reported)	Yes	Yes	**	**	√
Butt et al. (2008)[42]	USA (Center on Outcomes, Research and Education (CORE), Evanton Northwestern Healthcare)	Prospective study to explore the longitudinal screening and management of fatigue, pain, and emotional distress	99 cancer patients with solid tumor of lymphoma undergoing cancer undergoing cancer treatment	FACT-G FACT-Fatigue subscale Brief Pain Inventory [BPI] HADS. Structured interview with patients on HRQL and symptom management	FACT-G FACT-Fatigue subscale Brief Pain Inventory [BPI] HADS	Baseline, 1 month and 2 months after the baseline	Doctors and nurses	?	?	**	**	√
Given et al. (2008)[33]	USA (Michigan State University)	RCT: Nurse-Administrated Symptom Management (NASM) vs Automated Telephone Symptom Management (ATSM) intervention	129 breast cancer patients	Outcomes measured at 10–16 wks: 15 symptoms (0–10 scale). Responses & Non-responses of symptoms. Time to response	15 symptoms (0–10 scale) Severity of the symptoms	6 contacts or self-reporting (1-4 wk, 6wk, 8wk)	Nurses or ATSM system	Yes	Yes	**	****	√√√
Hilarius et al. (2008)[37]	Netherland (Hospital Pharmacy, Red Cross Hospital, Beverwijk)	A sequential cohort design with repeated measures to evaluate the use of HRQL assessments in daily clinical oncology nursing practice	10 nurses and 219 patients cancer patients with either adjuvant or palliative chemotherapy in a community hospital	Dartmouth Primary Care Cooperative Information Functional Health Assessment (COOP charts). Patient Management extracted from medical record. Patient satisfaction (an exit survey based on	EORTC QLQ-C30 EORTC QLQ-BR23 EORTC QLQ-CR38 EORTC QLQ-LC13	Four consecutive visits after baseline for both pre (control arm) and post (inter-vention arm) with a	Patients and nurses before consul-tations	No	Yes	***	***	√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
				PSQ, Form II). Patients' self-reported HRQL (SF-36, FACT-BCS, FACT-C, FACT-L). Nurse and patient evaluation of the intervention (an exit survey)		two-month 'wash-out' period						
Mark et al. (2008)[41]	USA (Thomson Healthcare, Washington DC)	A cross-sectional survey of the of both patients' and health professionals' experience; A before-after patient chart review	100 cancer patients and 92 health professionals on the experience of The Patient Assessment, Care and Education [PACE] System, including PCM instrument and an education component	Questionnaire survey of 102 providers. The patients satisfaction survey (n=100) including 8-item on PCM 200 patient chart reviews (100 charts before and 100 charts after the PACE system)	PCM An education component (not reported in this study)	Each visit to clinic	Clinicians (n=un-reported)	No	?	**	***	√√
Kearney et al. (2009)[34]	UK (Cancer Care Research Centre, University of Stirling, Stirling)	RCT: Control group versus intervention group (mobile phone-based remote monitoring of symptoms) over five time points	56 patients with lung, breast or colorectal cancer for each group (total 112 patients)	Paper version of electronic, mobile phone-based Advanced Symptom Management Systems [ASyMS©] based on Common Terminology Criteria Adverse Events [CTCAE] grading system and the Chemotherapy Symptom Assessment Scale	Mobile phone-based [ASyMS©] including chemotherapy-related morbidity of six common symptoms (nausea, vomiting, fatigue, mucositis, hand-foot syndrome and diarrhoea)	Five times including baseline and each of four chemo-therapy cycles over a period of 14 days	Doctors only (n=un-reported)	Yes	Yes	**	****	√√
Carlson et al. (2010)[26]	Canada (Tom Baker Cancer Centre, University of Calgary,	RCT: minimum screening (distress)/full screening/Triage : full screening +	585 breast cancer patients + 549 lung cancer patients	Patient distress at 3-month follow-up. Depression and anxiety at 3-month follow-up	Minimum screening: Distress thermometer [DT]. Full screening: DT + Psychological scan	Baseline	Screening team member (n=un-reported)	Yes	Yes	****	****	√√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
	Alberta)	referring to appropriate services			for cancer part C [PSSCAN]							
Dinkel et al. (2010)[40]	German (Department of Psychotherapy and Psychosomatic Medicine, Technische University Munchen)	Paired comparison: a computerised and a paper version of Stress Index Radio Oncology (SIRO) tool Prospective survey	177 cancer patients in study 1,273 cancer patients in study 2 (n=142 for computerised version and n=131 for paper version of SIRO) 27 Patients, nurses/radiographs and 15 physicians evaluated the screening procedure	Agreement between computer and paper version of SIRO Patient satisfaction. Time need for both modes. Perceived utility. Perceived impact on communication. Perceived impact on patient outcome	SIRO	Any visit	Doctors and nurses (n=un-reported)	No	No	***	**	√√
Halkett et al. (2010)[39]	Australian (WA Centre for Cancer and Palliative Care, Curtin Univesity)	Pilot study of using computer touch-screen technology to asses psychological distress in patients	60 patients with various gynaecological cancers	Patient satisfaction with both touch-screen and paper questionnaire. Perceived utility of both modes by patients and health professionals	EORTC QLQ-C30 HADS The Supportive Care Needs Scale The Distress Thermometer Follow questionnaire survey on perceived utility of both modes	Once	Nurses and doctors	Yes	Yes	*	**	√
Ruland et al. (2011)[35]	Norway (Centre for Shared Decision Making and Nursing Research, Oslo University	RCT: a computer-assisted, interactive tailored assessment (ITPA) with feedback vs ITPA only in	145 patients treated for leukaemia or lymphoma	Number of patient symptoms and problems addressed. Changes in symptom distress. Changes in patients' need for symptom	Choice ITPA(19 symptoms (0–4 scale on bothersome) and a severity scale of 0–10)	Every inpatient admission with up to four follow-up visits	Doctors and nurses (n=un-reported)	No (as seen appropriate)	Yes	***	****	√√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
	Hospital, Oslo)	oncology practice		management support over time. SF-36, Center for Epidemiological Studies Depression Scale [CES-D]. Medical Outcome Study Social Support Scale [MOS – SS]								
Velikova et al. (2010)[23]	UK (Cancer Research UK Clinical Centre, Leeds)	RCT: Intervention/ control-attention/ control in a ratio of 2:1:1	286 cancer patients commencing treatment at the Medical Oncology Clinic at St James Hospital	Medical Care Questionnaire [MCQ]: 15-item three subscales: Communication, Coordination, Patient preferences Satisfaction with care. Patients' and physicians' evaluation of the intervention K-index (Continuity of care: K=[number of visits – number of doctors)/(number of visits -1])	EORTC QOQ-C30 Hospital Anxiety and Depression Scale [HADS]	Regular clinic visit over an average of 6 months	Doctor (n=28)	No	One to one training and manual pro-vided	***	****	√√√
Bainbridge et al. (2011)[38]	Canada (Juravinski Cancer Centre, McMaster University, Hamilton, Ontario)	Survey on the utility of	128 nurses, physicians, and allied health professionals	Perceptions of use and utility of the Edmonton Symptom Assessment System [ESAS] adopted by Ontario's cancer centres since 2007	ESAS	Every clinic visit	Doctors and nurses	Yes	Yes	*	*	√
Berry et al. (2011)[25]	USA (Dan-Faber Cancer Institute, Boston)	RCT: Intervention/ Control	660 cancer patients with various cancer diagnoses and stages at two institutions of a comprehensive	Audio-recorded content of all communication between clinicians, patients and accompanying friends or family members at each T2 visit (4–6 wks after	Patient reported symptoms and quality-of-life [SQLIs] from the Electronic Self-Report Assessment-Cancer [ESRA-C]	Every clinic visit during the study period	Doctors (n=76 principle physicians and other) or incorp-orated into	No	Yes	***	****	√√√

Reference	Country / Jurisdiction	Design	Sample / Population	Outcome measures	PROS used	Inter-vention/ Number of times feedback	Members of medical team given feedback	Manage-ment plan offered to team	Training to staff	Do-main 1	Do-main 2	Glo-bal Rating
			cancer centre	the treatment). Clinic visit duration. Physician exit questionnaire survey			charts (n=un-reported)					
Cleeland et al. (2011)[36]	USA (MD Anderson Cancer Center, The University of Texas)	RCT: e-mail alert of symptom to patients' clinical team versus no e-mail alert	79 lung cancer patients receiving thoracotomy	Four targeted symptoms: pain, distress, disturbed sleep, and shortness of breath, constipation (no fatigue as no effective response). MDASI at follow-up clinic visit. An exit questionnaire survey	Automated telephone calls (IVR system): MD Anderson Symptom Inventory (13 common cancer related symptoms)	Twice weekly, up to 4 wks after discharge	Nurses (n=un-reported)	Yes	Training to patients pro-vided	**	****	√√
Takeuchi et al. (2011)[22]	UK (St James' Institute of Oncology, Leeds)	Longitudinal study of data as part of Velikova et al (2004, 2010) RCT	286 cancer patients commencing treatment at the Medical Oncology Clinic at St James Hospital	Audio-recorded content of Patient-physician communication. Longitudinal impact of PRO intervention. Dynamics of communication. Association between severity of symptoms/ functions and clinic discussion	EORTC QOQ-C30 Hospital Anxiety and Depression Scale [HADS]	Four con-secutive visits from baseline	Doctor (n=28)	No	One to one training and manual prov-ided	***	****	√√√

§ Four stars indicate a randomised trial or experimental study; three stars indicate a controlled trial, pre–post trial with control (controlled before–after trial), time series, or observational cohort with multivariable adjustment; two stars indicate a pre–post trial without control, observational cohort study without multivariable adjustment, cross-sectional study without multivariable adjustment, analysis of time trends without control, or well-designed qualitative study; and one star indicates a case series, other qualitative study, or survey (descriptive) study.

Φ Three checks indicate great weight in the stratum's body of evidence; two checks indicate moderate weight; and one check indicates little weight.

ǂ MOS-SS: Medical Outcomes Study Social Support Survey; GDS: Geriatric Depression Scale (short form); QARSQ-PH: Physical Health subscale of the Older American Resources and Services Questionnaire (OARSQ); UMPSI: Utilisation of Mental Health and Psychosocial Services Instrument; GSRE: Geriatric Schedule of Recent Experience Instrument.

Appendix F: The impact and effect sizes of the studies on patients, care providers and organisations

Studies	Doctor-patient communication	Monitor treatment response	Detect unrecognised problems	Changes to patient health behaviour	Changes to patient management	Improved patient satisfaction	Improved health outcomes	Feasibility of the implementation	Moderating and subgroup effect
Trowbridge et al. (1997)[16]			++		++		+ (but no change in PMI)	+++	
Tazenzer et al. (2000)[11]	+++		++		+	–		+++	
McLachlan et al. (2001)[15]	– (no time differences in consultation between two arms)		– (only 37% patients receiving anticancer therapy at baseline)			–	–	+++	+ (on high BDI score subgroup)
Detmar et al. (2002)[14]	+++ (10 out of 12 HRoL measures, especially on social functioning and fatigue)		++		+ (increased patient counselling) + (25% with family members and primary care physicians)	+ (emotional support) ++ (information sharing & communication)	+ (SF-36)	+++	+ (before-after improvement by intervention group)
Mooney et al. (2002)[46]	+++	++	++			+++		++	
Velikova et al. (2004)[10]	+++		++ (64% encounters involving referring to HRoL by physicians)		– (possible due to simple coding between two arms) + (contributed to patient manage-ment in 11% of encounters intervention arm)		++ (overall quality of life and emotional functioning)	++ (response rate 70%)	+ (more discussion of HRoL subgroup had better outcome within intervention group)

Studies	Doctor-patient communication	Monitor treatment response	Detect unrecognised problems	Changes to patient health behaviour	Changes to patient management	Improved patient satisfaction	Improved health outcomes	Feasibility of the implementation	Moderating and subgroup effect
Basch et al. (2005)[44]	+++	+	++			+++	+	++ (65% patient log in before any verbal encouragement)	
Boyes et al. (2006)[13]	+ (50% oncologists in intervention group talked with patients)				-		++ (fewer deliberating symptoms) – (anxiety and depression)	+	-
Hoekstra et al. (2006)[31]	+/– (Only 18% patients used it enhancing communication)			-			++ (lower prevalence in 9 out of 10 symptoms; deteriorated less in 8 out of 10 symptoms)	+	The beneficial effects were pronounced in the deteriorated group
Korniblith et al. (2006)[32]	+++ (both arms)		++ (more from TM+EM arm)			++ (both arms)	++ (better in TM+EM arm – reduction of psychological distress)	++	
Basch et al. (2007)[45]	+					++		++ (can be improved through reminder)	
Rosenbloom et al. (2007)[12]	– (Possible Ceiling effect)				–	–	–	++	No effect even among the most highly distressed patients
Weaver et al. (2007)[43]	+ (nurse-patient communication)	+	+		+	+	+	++	
Butt et al. (2008)[42]	++	+	+		+	++		++	

Studies	Doctor-patient communication	Monitor treatment response	Detect unrecognised problems	Changes to patient health behaviour	Changes to patient management	Improved patient satisfaction	Improved health outcomes	Feasibility of the implementation	Moderating and subgroup effect
Given et al. (2008)[33]		+	+				++ (ATSM more likely to generated responses in symptom management and required less time to do so)	++	+ (Compared with patients receiving combination chemotherapy protocols, those patients treated with single agent had greater response and shorter time to response)
Hilarius et al. (2008)[37]	++	+	++		+	++		++	
Mark et al. (2008)[41]	++	+	+		+	++		++	
Kearney et al. (2009)[34]	++	+	++		++		++ (Fatigue)	+++	
Carlson et al. (2010)[26]							+++ (distress) ++ (decreased depression and anxiety related to referral to services)	+++	
Dinkel et al. (2010)[40]	+				+	+		++	
Halkett et al. (2010)[39]	+ (around 25% of doctors)				+ (10% patients reported changed outcomes)	+ (patients is generally happy with both methods) – (Health professionals found some issues)		+/– (some issues identified but nothing fundamental and patients were generally happy)	
Ruland et al.			++		++		++	++	

Studies	Doctor-patient communication	Monitor treatment response	Detect unrecognised problems	Changes to patient health behaviour	Changes to patient management	Improved patient satisfaction	Improved health outcomes	Feasibility of the implementation	Moderating and subgroup effect
(2010)[35]									
Velikova et al. (2010)[23]	++				(no difference in coordination of care & 'preferences to see usual doctor' subscale)	++ (86% in intervention vs 29% in the attention-control group)		++	
Bainbridge et al. (2011) [38]	+	+			+			++	+ 89% of nurses and 55% of physicians referred to the ESAS in clinics 'always' or ' most of the time'
Berry et al. (2011)[25]	++ (25% physician explicitly referred to SQLI summary)							++	++ (the treatment effect on communication is evident on over threshold group on cognitive function, impact on sex and social function)
Cleeland et al. (2011)[36]	++	+	+		+	+	++	++	
Takeuchi et al. (2011)[22]	++ (on symptom but not function)							++	

Note: +++ very strong effect; ++ strong effect; + some effect; +/- uncertain effect; –No effect; blank :untested or reported; * impact on quality improvement, increased transparency, accountability, public reporting, better population and system performance (monitoring, planning, financing, evaluating, etc).

Appendix G: Selected publications by the PROMIS network since 2007

Varni JW, Thissen D, Stucky BD, Liu Y, Gorder H, Irwin DE et al. PROMIS® Parent Proxy Report Scales: an item response theory analysis of the parent proxy report item banks. Qual Life Res. 2012; 21(7):1223–12401.

Thissen D, Varni JW, Stucky BD, Liu Y, Irwin DE, DeWalt DA. Using the PedsQL™ 3.0 asthma module to obtain scores comparable with those of the PROMIS Pediatric Asthma Impact Scale (PAIS). Qual Life Res. 2011:1–9.

Sung VW, Marques F, Rogers RR, Williams DA, Myers DL, Clark MA. Content validation of the Patient-Reported Outcomes Measurement Information System (PROMIS) framework in women with urinary incontinence. Neurol Urodyn. 2011; 30(4):503–509.

Preston K, Reise S, Cai L, Hays RD. Using the nominal response model to evaluate response category discrimination in the PROMIS emotional distress item pools. Edu Psychol Meas. 2011; 71(3):523–550.

Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item banks for measuring emotional distress from the Patient-Reported Outcomes Measurement Information System (PROMIS®): depression, anxiety, and anger. Assessment. 2011; 18(3):263–283.

Magasi S, Ryan G, Revicki D, Lenderking W, Hays RD, Brod M et al. Content validity of patient-reported outcome measures: perspectives from a PROMIS meeting. Qual Life Res. 2012; 21(5):739–746.

Lai JS, Cella D, Choi S, Junghaenel DU, Christodoulou C, Gershon R et al. How item banks and their application can influence measurement practice in rehabilitation medicine: a PROMIS fatigue item bank example. Arch Phys Med Rehabil. 2011; 92(10Suppl.):S20–S27.

Junghaenel DU, Christodoulou C, Lai JS, Stone AA. Demographic correlates of fatigue in the US general population: results from the patient-reported outcomes measurement information system (PROMIS) initiative. J Psychosom Res. 2011; 71(3):117–123.

Irwin DE, Stucky BD, Langer MM, Thissen D, DeWitt EM, Lai JS et al. PROMIS Pediatric Anger Scale: an item response theory analysis. Qual Life Res. 2012; 21(4):697–706.

Hung M, Clegg DO, Greene T, Saltzman CL. Evaluation of the PROMIS physical function item bank in orthopaedic patients. J Orthop Res. 2011; 29(6):947–953.

Gibbons LE, Feldman BJ, Crane HM, Mugavero M, Willig JH, Patrick D et al. Migrating from a legacy fixed-format measure to CAT administration: calibrating the PHQ-9 to the PROMIS depression measures. Qual Life Res. 2011; 20(9):1349–1357.

Fries JF, Krishnan E, Rose M, Lingala B, Bruce B. Improved responsiveness and reduced sample size requirements of PROMIS physical function scales with item response theory. Arthritis Res Ther. 2011; 13(5):R147

Fries J, Rose M, Krishnan E. The PROMIS of better outcome assessment: responsiveness, floor and ceiling effects, and internet administration. J Rheumatol. 2011; 38(8):1759–1764.

Flynn KE, Jeffery DD, Keefe FJ, Porter LS, Shelby RA, Fawzy MR et al. Sexual functioning along the cancer continuum: Focus group results from the Patient-Reported Outcomes Measurement Information System (PROMIS®). Psychooncology. 2011; 20(4):378–386.

Cook KF, Bamer AM, Roddey TS, Kraft GH, Kim J, Amtmann D. A PROMIS fatigue short form for use by individuals who have multiple sclerosis. Quality Life Res. 2012; 21(6)1021–1030.

Cella D, Lai JS, Stone A. Self-reported fatigue: one dimension or more? Lessons from the functional assessment of chronic illness therapy-fatigue (FACIT-F) questionnaire. Support Cancer Care. 2011; 19(9):1441–1450.

Bajaj JS, Thacker LR, Wade JB, Sanyal AJ, Heuman DM, Sterling RK et al. PROMIS computerised adaptive tests are dynamic instruments to measure health-related quality of life in patients with cirrhosis. Aliment Pharmacol Ther. 2011; 34(9):1123–1132.

Amtmann D, Cook KF, Johnson KL, Cella D. The PROMIS initiative: involvement of rehabilitation stakeholders in development and examples of applications in rehabilitation research. Arch Phys Med Rehabil. 2011; 92(10Suppl.):S12–S19.

Yeatts KB, Stucky B, Thissen D, Irwin D, Varni JW, Dewitt EM et al. Construction of the Pediatric Asthma Impact Scale (PAIS) for the Patient-Reported Outcomes Measurement Information System (PROMIS). J Asthma. 2010; 47(3):295–302.

Varni JW, Stucky BD, Thissen D, Dewitt EM, Irwin DE, Lai JS et al. PROMIS Pediatric Pain Interference Scale: an item response theory analysis of the pediatric pain item bank. J Pain. 2010; 11(11):1109–1119.

Rothrock NE, Hays RD, Spritzer K, Yount SE, Riley W, Cella D. Relative to the general US population, chronic diseases are associated with poorer health-related quality of life as measured by the Patient-Reported Outcomes Measurement Information System (PROMIS). J Clin Epidemiol. 2010; 63(11):1195–1204.

Riley WT, Rothrock N, Bruce B, Christodolou C, Cook K, Hahn EA et al. Patient-Reported Outcomes Measurement Information System (PROMIS) domain names and definitions revisions: further evaluation of content validity in IRT-derived item banks. Qual Life Res. 2010; 19(9):1311–1321.

MacLaren VV, Best LA. Multiple addictive behaviors in young adults: Student norms for the Shorter PROMIS Questionnaire. Addict Behav. 2010; 35(3):252–255.

Liu H, Cella D, Gershon R, Shen J, Morales LS, Riley W et al. Representativeness of the Patient-Reported Outcomes Measurement Information System internet panel. J Clin Epidemiol. 2010; 63(11):1169–1178.

Irwin DE, Stucky BD, Thissen D, DeWitt EM, Lai JS, Yeatts K et al. Sampling plan and patient characteristics of the PROMIS pediatrics large-scale survey. Qual Life Res. 2010; 19(4):585–594.

Irwin DE, Stucky B, Langer MM, Thissen D, DeWitt EM, Lai JS et al. An item response analysis of the pediatric PROMIS anxiety and depressive symptoms scales. Qual Life Res. 2010;19(4):595–607.

Henly SJ. Editorial: The promise of PROMIS. Nurs Res. 2010; 59(2):77.

Henly SJ. The promise of PROMIS. Nurs Res. 2010; 59(2):77.

Hays RD, Bode R, Rothrock N, Riley W, Cella D, Gershon R. The impact of next and back buttons on time to complete and measurement reliability in computer-based surveys. Qual Life Res. 2010; 19(8):1181–1184.

Hahn EA, DeVellis RF, Bode RK, Garcia SF, Castel LD, Eisen SV et al. Measuring social health in the Patient-Reported Outcomes Measurement Information System (PROMIS): item bank development and testing. Qual Life Res. 2010; 19(7):1035–1044.

Gershon RC, Rothrock N, Hanrahan R, Bass M, Cella D. The use of PROMIS and assessment center to deliver Patient-Reported Outcome Measures in clinical research. J Appl Meas. 2010; 11(3):304–314.

Flynn KE, Shelby RA, Mitchell SA, Fawzy MR, Hardy NC, Husain AM et al. Sleep-wake functioning along the cancer continuum: focus group results from the Patient-Reported Outcomes Measurement Information System (PROMIS®). Psychooncology. 2010; 19(10):1086–1093.

Eisenstein EL, Diener LW, Nahm M, Weinfurt KP. Impact of the Patient-Reported Outcomes Management Information System (PROMIS) upon the design and operation of Multi-center Clinical Trials: a Qualitative Research Study. J Med Syst. 2011; 35(6):1521–1530.

Choi SW, Reise SP, Pilkonis PA, Hays RD, Cella D. Efficiency of static and computer adaptive short forms compared to full-length measures of depressive symptoms. Qual Life Res. 2010; 19(1):125–136.

Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. J Clin Epidemiol. 2010; 63(11):1179–1194.

Amtmann D, Cook KF, Jensen MP, Chen WH, Choi S, Revicki D et al. Development of a PROMIS item bank to measure pain interference. Pain. 2010; 150(1):173–182.

Aletaha D. From the item to the outcome: the promising prospects of PROMIS. Arthritis Res Ther. 2010; 12(1):104–106.

Revicki DA, Kawata AK, Harnam N, Chen WH, Hays RD, Cella D. Predicting EuroQol (EQ-5D) scores from the Patient-Reported Outcomes Measurement Information System (PROMIS) global items and domain item banks in a United States sample. Qual Life Res. 2009; 18(6):783–791.

Revicki DA, Chen WH, Harnam N, Cook KF, Amtmann D, Callahan LF et al. Development and psychometric analysis of the PROMIS pain behavior item bank. Pain. 2009; 146(1–2):158–169.

Klem M, Saghafi E, Abromitis R, Stover A, Dew MA, Pilkonis P. Building PROMIS item banks: librarians as co-investigators. Qual Life Res. 2009; 18(7):881–888.

Jeffery DD, Tzeng JP, Keefe FJ, Porter LS, Hahn EA, Flynn KE et al. Initial report of the cancer Patient-Reported Outcomes Measurement Information System (PROMIS) sexual function committee: review of sexual function measures and domains used in oncology. Cancer. 2009; 115(6):1142–1153.

Jansky LJ, Huang JC. A multi-method approach to assess usability and acceptability: a case study of the Patient-Reported Outcomes Measurement System (PROMIS) workshop. Social Science Computer Review. 2009; 27(2):262–270.

Irwin DE, Varni JW, Yeatts K, DeWalt DA. Cognitive interviewing methodology in the development of a pediatric item bank: a Patient Reported Outcomes Measurement Information System (PROMIS) study. Health Qual Life Outcomes. 2009; 23(7):3.

Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the Patient-Reported Outcomes Measurement Information System (PROMIS) global items. Qual Life Res. 2009; 18(7):873–880.

Fries JF, Krishnan E, Bruce B. Items, instruments, crosswalks, and PROMIS. J Rheumatol. 2009; 36(6):1093–1095.

Fries JF, Krishnan E. What constitutes progress in assessing patient outcomes? J Clin Epidemiol. 2009; 62(8):779–780.

Fries JF, Cella D, Rose M, Krishnan E, Bruce B. Progress in assessing physical function in arthritis: PROMIS short forms and computerized adaptive testing. J Rheumatol. 2009; 36(9):2061–2066.

Fortune-Greeley AK, Flynn KE, Jeffery DD, Williams MS, Keefe FJ, Reeve BB et al. Using cognitive interviews to evaluate items for measuring sexual functioning across cancer populations: improvements and remaining challenges. Qual Life Res. 2009; 18(8):1085–1093.

Walsh TR, Irwin DE, Meier A, Varni JW, DeWalt DA. The use of focus groups in the development of the PROMIS pediatrics item bank. Qual Life Res. 2008; 17(5):725–735.

Rose M, Bjorner JB, Becker J, Fries JF, Ware JE. Evaluation of a preliminary physical function item bank supported the expected advantages of the Patient-Reported Outcomes Measurement Information System (PROMIS). J Clin Epidemiol. 2008; 61(1):17–33.

Neary PC, Boyle E, Delaney CP, Senagore AJ, Keane FBV, Gallagher AG. Construct validation of a novel hybrid virtual-reality simulator for training and assessing laparoscopic colectomy; results from the first course for experienced senior laparoscopic surgeons. Surgical Endoscopy. 2008; 22(10):2301–2309.

Christodoulou C, Junghaenel DU, DeWalt DA, Rothrock N, Stone AA. Cognitive interviewing in the evaluation of fatigue items: results from the Patient-Reported Outcomes Measurement Information System (PROMIS). Qual Life Res. 2008; 17(10):1239–1246.

Castel LD, Williams KA, Bosworth HB, Eisen SV, Hahn EA, Irwin DE et al. Content validity in the PROMIS social-health domain: a qualitative analysis of focus-group data. Qual Life Res. 2008; 17(5):737–749.

Reeve BB, Hays RD, Bjorner JB, Cook KF, Crane PK, Teresi JA et al. Psychometric evaluation and calibration of health-related quality of life item banks: plans for the Patient-Reported Outcomes Measurement Information System (PROMIS). Med Care. 2007; 45(5Suppl.1):S22-S31.

Hays RD, Liu H, Spritzer K, Cella D. Item response theory analyses of physical functioning items in the medical outcomes study. Med Care. 2007; 45(5Suppl.1):S32-S38.

DeWalt DA, Rothrock N, Yount S, Stone AA. Evaluation of item candidates: The PROMIS qualitative item review. Med Care. 2007; 45(5Suppl.1):S12-S21.

Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B et al. The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH roadmap cooperative group during its first two years. Med Care. 2007; 45(5Suppl.1):S3–S11.

Cella D, Gershon R, Lai JS, Choi S. The future of outcomes measurement: item banking, tailored short-forms, and computerized adaptive assessment. Qual Life Res. 2007; 16(Suppl.1):133–141.

Ader DN. Developing the Patient-Reported Outcomes Measurement Information System (PROMIS). Med Care. 2007; 45(5Suppl.1):S1–S2.

Pallanti S, Bernardi S, Quercioli L. The Shorter PROMIS Questionnaire and the Internet Addiction Scale in the assessment of multiple addictions in a high-school population: prevalence and related disability. CNS Spectr. 2006; 11(12):966–974.

Fries JF, Bruce B, Cella D. The promise of PROMIS: using item response theory to improve assessment of patient-reported outcomes. Clin Exp Rheumatol. 2005; 23(5Suppl.39):S53–S57.