Collecting Patient Reported Outcome Measures in Victoria:
Peter Mac response to DHHS
Collecting PROMS | Response from Peter MacCallum Cancer Centre | v4.0

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To The Department of Health and Human Services (DHHS)

Thank you for the opportunity to contribute to this important consultation process. Developing capacity to collect, integrate and report on PROMs is an important policy initiative and the Victorian DHHS is to be commended for initiating this consultation.

This submission has been prepared on behalf of the Peter MacCallum Cancer Centre and, as such, our responses relate specifically to PROMs in oncology settings.

David Speakman FRACS
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1 PROMS USES—SHORT AND LONG TERM

1.1 REQUEST FOR INFORMATION

The department is seeking advice on how PROMS should be used in setting policy and shaping clinical practice. For what uses should PROMS data be used and not used in Victoria, both in the short and long term?

1.2 RESPONSE

Reports coming directly from patients about symptoms, quality of life and functional status via patient-reported outcomes measures (PROMs) can provide a powerful means of understanding the impact of health conditions and the risks and benefits of medical care from the patient’s perspective. When combined with quality ancillary data, they can be used to identify unwarranted variations in the delivery and outcomes of care, as well as to achieve better experiences and outcomes for individual patients, underserved groups and the population as a whole [1-3].

Benefits of the collection and use of PROMs, however, are not guaranteed. The collection of PROMS, their integration with requisite ancillary data and reporting in ways that are meaningful to patients, the community and healthcare services present a considerable challenge. Based on our experience with PROMs in oncology settings, the likelihood of success is optimised when key stakeholders—patients, carers, multidisciplinary clinicians and health services researchers—are engaged to determine through consensus:

- The purpose and aims of PROMs collection
- The domains that matter most to patients and carers and what will likely prove clinically useful or beneficial (for example, in identifying and addressing performance concerns and knowledge gaps)
- The timing and methods of PROMs collection that are aligned with patients’ preferences and maximise the amount and quality of data collected—this must be balanced against the stresses associated with being diagnosed with cancer, as well as the sometimes high burden of disease and treatment-related morbidity
- The core ancillary data set, and
- The feasibility and ease of capturing this ancillary data

It is important to note that what matters most to patients and carers and the most pertinent clinical issues “are inherently condition-specific and multidimensional” (p. 2477) [4]; these may differ by disease type and stage, treatments received and point in the treatment trajectory. They may also change over time as clinical practices change. So, for example, in oncology consideration will need to be given to the current pace of change in adoption of new therapeutics.

Adherence to the following recommendations will help ensure the relevance and suitability of PROMs to setting policy and shaping clinical practice in oncology both in the short and the long term:

1. *The purpose and aims of PROMs and ancillary data collection are clearly and precisely defined* [5].

2. *Sufficient resources are available to support PROMs and ancillary data collection, analysis and reporting* [6].
3. Real-time feedback to patients and clinicians can be supported via electronic platforms [7]. It is ethically suspect to obtain symptom, quality of life and/or functional status data from patients if it is not used to improve care and ensure the efficient use of limited healthcare resources.

4. Chosen PROMs have been developed using robust methods [8]. Methods used to develop the PROMIS measures are a great example (for details see [9]).

5. Chosen PROMs meet minimum standards for measures to be used in patient-centred outcomes and comparative effectiveness research (for details see [10]).

6. Chosen PROMs should have minimal important difference estimates available to interpret within-individual changes and group-level differences [11].

7. Chosen PROMs can be administered to CALD and low literacy populations.

8. The method of PROMs collection does not preclude the participation of particular groups of patients (for example, those with limited access to or difficulties using technology).

9. High quality ancillary data—socio-demographic descriptors, bio-behavioural risk factors and clinical characteristics—are readily available in a consistent format for all or almost all patients [1]. For example, geographic remoteness, socio-economic disadvantage, disability status, as well as disease type and stage and treatments received. High quality ancillary data are needed to support adequate case mix adjustment [12] and to support the estimation of change in the case of non-ignorable missing data [8,13].

10. Robust case mix adjustment strategies are available [12].

11. Suitable and uniform baseline (post-diagnosis but pre-treatment) PROMs can be obtained from all (or almost all) patients. Baseline measures are needed to assess within-individual changes in cancer and treatment-related morbidity; they are also needed to facilitate the accurate interpretation of between-groups differences following any treatment or intervention for cancer and treatment-related morbidity [14].

12. The relative completeness of follow-up PROMs data can be guaranteed. In oncology, PROMs compliance can be poor [15] and missingness informative [13]. To ensure the completeness of follow-up data, services will require adequate resourcing as follow-up strategies are notoriously expensive; and feasibility testing will be crucial, in some cases missing data may be unavoidable.

Well-resourced, comprehensive feasibility assessment will be crucial to appraise processes, resources, management and scientific/clinical utility (for details see [16]).
2 WHICH DISEASES AND CONDITIONS?

2.1 REQUEST FOR INFORMATION 1

The department is seeking advice on which diseases and conditions [“instruments” removed by respondent] should be collected in the pilot trial and for a subsequent expansion. Generally, consideration will be given to the scope for PROMs to improve:

- clinical practice
- health outcomes
- resource allocation.

2.2 RESPONSE 1

It is imperative that the pilot (proof-of-concept) trials assess feasibility of PROMs and ancillary data collection across the condition/disease complexity and prognosis spectrum. Generalisability of results will be severely limited by tests of methods and procedures limited to less complex, better prognosis conditions/diseases. For example, the success of PROMs and ancillary data collection in prostate cancer (5-year survival: 94%) will not provide an adequate test of the likely success of PROMs and ancillary data collection in lung cancer (5-year survival: 15%).

It is also imperative that a thorough scoping study be undertaken within each condition/disease group to map existing PROMs collection. In oncology, there is a great deal of research activity (including quality improvement activities) and patients may receive requests to complete PROMs from multiple organisations. So, for example, a patient could be asked to complete the same PROM two or more times or they could be asked to complete multiple PROMs covering the same or different domains. Within each condition/disease, a strategic approach is crucial to minimise patient burden and bother, to ensure limited resources are utilised efficiently and effectively and to ensure ongoing stakeholder support.

If appropriate, lung cancer may be a prudent choice for the pilot trial, because:

- Lung cancer is the fifth most commonly diagnosed cancer, yet accounts for the highest number of cancer deaths in Australia (https://lung-cancer.canceraustralia.gov.au/statistics)
- It is a disease that affects both sexes, although prognosis is poorer for men [17]
- Disease outcomes are highly variable—ranging from cure to rapid progression to palliation
- The burden of the disease and its treatment may be high, with some patients experiencing rapid functional and emotional decline, and
- Lung cancer patients receive a variety of treatments, including newer targeted and personalised therapies.

In this context, high quality PROMs and ancillary data could help understand:

- The short- and longer-term benefits and drawbacks of different treatment regimens/approaches on domains that matter most to patients
- The benefits and drawbacks of non-medical clinical practice innovations—for example, prehabilitation, as well as other nursing and allied health interventions

They could also help guide the improvement of care processes and systems to ensure services are targeted and tailored to those that need it most.
2.3 REQUEST FOR INFORMATION 2

Advice is also sought on which chronic diseases and conditions could be suitably collected from community settings.

2.4 RESPONSE 2

No response.

For the pilot program, consideration will be given to those diseases and treatments for which a PROMs collection can be implemented in time for 1 July 2017.
3 WHICH PROMS?

3.1 REQUEST FOR INFORMATION

The department is seeking advice on which generic and condition-specific instruments are currently being used or developed by health services, clinical registries and associations including for those diseases and conditions described in section 3.1.

In recommending a suite of instruments, the department will have regard to:

- the appropriateness of the instruments
- the extent to which the instruments are currently in use or are being developed
- the extent to which the instruments will permit benchmarking across Australia and internationally
- whether the instruments can be implemented by 1 July 2017.

3.2 RESPONSE

The appropriateness of instruments will depend on their intended use and planned analyses. Instruments and meaningful times for their administration should be determined through consensus. At a minimum, cancer patients, carers, clinicians and healthcare researchers should be actively engaged in this process. This will maximise the likelihood that measures reflect what truly matters most to patients and what will likely prove clinically useful and/or beneficial. Further, only then can the level of respondent and clinician burden associated with candidate measures be determined.

An enormous number of PROMs have been developed for use with cancer populations. The two most widely used suites of instruments, however, are the EORTC and FACIT measures [18]; both include a ‘core’ cancer-specific measure and disease-specific modules. The ‘core’ measures are composed of a similar number of items (EORTC QLQ-C30: 30 items; FACT-General: 27 items), but there are important differences in the scale structure and social domains [18] and the two instruments differ in responsiveness and relative efficiency [19]. Critically, however:

- Neither suite of instruments was developed using robust modern methods like those used to develop the PROMIS measures. Measures developed using modern psychometric methods provide statistics on the discriminating power of items. Measures developed using traditional methods do not. This information is critical, as it helps choose items/scales that can improve the certainty of test score-based decisions [20].
- Enhanced sensitivity to disease and treatment effects relies on the administration of disease/treatment-specific modules [18], adding to patient burden, and
- Perhaps most importantly, constituent items and scales simply do not possess the necessary properties to support high-stakes clinical decision-making; in this case, they are comprised of a very small number of items (often only one item) per domain. With fewer items per domain, domain coverage cannot be guaranteed [21] and measurement error tends to have a much greater influence on test scores and the decisions then based on these scores [20].

For any one PROM and ancillary data set to be suitable for multiple purposes in oncology, higher levels of burden would need to be acceptable to patients and clinicians. For clinical practice, however, larger sets may be required to ensure robust assessment of cancer and treatment-related morbidity across the cancer trajectory. For benchmarking, smaller sets may be acceptable (e.g., PROMIS Global Health v1.2); nevertheless, all of the International Consortium for Health Outcomes Measurement (ICSHOM) standard sets for cancer, excepting prostate cancer, include the ‘core’ EORTC measure and modules (see Standard Sets Overview: http://www.ichom.org/).
In lieu of the arguments outlined above and in line with recommendations 4 through 9 outlined in the section titled *PROMs uses—short and long term*, measures from the NIH-funded PROMIS suite are highly recommended ([http://www.healthmeasures.net/explore-measurement-systems/promis](http://www.healthmeasures.net/explore-measurement-systems/promis)). Note, however, the PROMIS suite does not provide complete coverage of disease-specific symptoms, as these are many and varied.

In the event that disease-specific symptom measures are required, content covered by scales/items comprising the EORTC and FACIT disease-specific modules may be useful, provided alternative response formats are developed and tested—in this case, seven point Likert-type scales with word anchors for each point [22]—and appropriate cut-points are identified to guide clinical decision-making.
4 WHAT ROLES?

4.1 REQUEST FOR INFORMATION 1

The department invites health services, clinical registries and networks to participate in the PROMs collection both for the pilot program and for subsequent collections.

It is seeking advice on:

• what roles health services, clinical registries and networks, and other bodies should have in collecting, storing and supplying PROMs data

4.2 RESPONSE 1

Careful consideration needs to be given to data curation. Specifically, which organisations or model (health service or clinical registry) is best placed to gather and be responsible for PROMs and ancillary data, as this has implications— for example, security, custodian responsibilities and ethical requirements. While it appears reasonable to leverage off existing collections for a state-wide collection, each registry, network and health service has its own specific purpose and scope and bespoke PROMs and ancillary data collections. Thus, there may be little consistency across existing collections.

In oncology, involvement of health services will be crucial to ensure data quality and consistency. Patients will need to be identified and PROMs administered within specified and often tight timeframes. Further, health services are best placed to manage overall PROMs burden to individual patients—in this case, PROMs forming part of the pilot program, as well as routine and research collections.

Lessons learnt from the design and implementation of a feasibility study to gather PROMs data in a sub-cohort of lung cancer patients at Peter Mac highlighted the importance of the timing and methods of PROMs collection. If collection times are close together (for example, baseline and 2 month follow-up) defined windows (plus or minus two weeks) and appropriate systems need to be set up to facilitate timely collection. Further, if there are multiple follow-ups, maintenance of up-to-date records is crucial to ensure that instruments are not sent to deceased patients or their families, as this can be distressing. No matter which organisation is responsible for PROMs collection, a link with the National Death Index will be required to ensure systematic notification of deaths (other than trying to contact the patient and then being notified by family).

Ethics approval will need to be sought for new collections or amendments lodged for existing collections. Custodianship, quality assurance procedures and reporting outputs would need to have consensus agreement and adherence to national guidelines [6, 23] for each health condition for a state-wide strategy to be standardised. As per the ACSQHC guidelines, any Australian Clinical Quality Registry should demonstrate sufficient funding is allocated for these activities [23].

4.3 REQUEST FOR INFORMATION 2

The department is seeking advice on:

• how PROMs should be collected for those diseases and conditions for which there are no existing data collection frameworks.

4.4 RESPONSE 2

No response.
4.5 REQUEST FOR INFORMATION 3

The department invites clinical registries wishing to participate to propose how patient-level registry data might be made available to the department on an ongoing basis.

4.6 RESPONSE 3

No response.
5 ANCILLARY DATA

5.1 REQUEST FOR INFORMATION
The department will also be taking advice from participants on what other data are necessary for it to collect.

5.2 RESPONSE
On their own, high quality ancillary data—socio-demographic descriptors, bio-behavioural risk factors and clinical characteristics—are fundamental to efforts to better understand and serve Australia’s diverse cancer population [1-3]. In the context of PROMs collection and use, at a minimum, this data is needed to support adequate case mix adjustment [12]. Like the choice of PROMs themselves, the choice of ancillary data should be determined by relevant stakeholders and supported by insights in the relevant professional literature.

Despite general consensus regarding their utility, there is no minimum data set (MDS) with data definitions covering essential descriptors, risk factors and clinical characteristics. An MDS approach is imperative to ensure the production of useful and useable data; in this case, state- and/or nationally-comparable, consistent information.

At present, if recorded at all, only the most basic ancillary data is routinely recorded in hospital records—“the presumption of detailed clinical data is often at odds with the nature of existing data sources” (p. 775) [24]—and such data rarely exists in a readily extractable format. Most hospital records (both paper and electronic) only support manual searches, which are incredibly time-consuming and laborious. Moreover, in some cases, due to the unavailability or incompleteness of information, clinician input would be required.

The following data could be supplied by the Victorian Cancer Registry:

- Basic demographics including date of birth, date of death (if relevant), age at diagnosis, sex, country of birth, Aboriginality, ICS region, LGA/SLA and statistical division, and
- Tumour characteristics including primary site, morphology, behaviour, grade and date of diagnosis.

Notably, however, critical clinical data—stage, treatment and recurrence, which is the focus of Cancer Australia’s STaR program [25]—are not currently available.
6 CENSUS OR SURVEY

6.1 REQUEST FOR INFORMATION

The department invites advice on whether data should be collected as a sample survey or a census of the participating patient and hospital population.

6.2 RESPONSE

A census.
7 COLLECTING METHODS

7.1 REQUEST FOR INFORMATION

The department invites advice on options for online data capture, storage and retrieval that meets the requirements of patients, clinicians, and the department.

- What are some of the possible functions of an online portal?
- What are the costs of establishing and operating an online portal?
- What are the legal implications of data security and patient confidentiality for an online portal?

7.2 RESPONSE

An electronic platform (or system) will be central to the success of the collection and use of PROMs and ancillary data in Victoria. The provision of real-time feedback to patients and clinicians and the supply of relevant data to the department will be impeded by a paper-based system. Electronic systems allow “efficient standardized assessments, decrease response burden, increased satisfaction, improved ease of use, and fewer missing data compared with paper-based PRO measures” (p. e215) [7]. They obviate the need to manually calculate PROMs scores and appropriate programming can facilitate comparisons with evidence-based cut-scores and minimal important difference estimates.

Nevertheless, electronic platforms are not without their challenges. For instance:

- Potential bias—some patients may not have access to a computer; some may have difficulty using technology (for example, inadequate broadband, visual impairment, not familiar with technology). When testing follow-up collection methods (paper and electronic) for our feasibility study in a sub-cohort of lung cancer patients at Peter Mac, we discovered that half of the sample did not have an email address.

- Security and confidentiality—PROMs data needs to be identifiable for linkage purposes; in this case, linking PROMs data to ancillary data. Thus, any electronic platform would need to maintain a high level of security in order to protect patients’ privacy and fall within the legal exceptions to protecting the confidentiality of identifying patient health information. For example, the Health Services Act 1988 permits the giving of health information for the purposes of medical or social research if the use has been approved by a HREC and is in accordance with HPP 2.2.(g) of the Health Privacy Principles in the Health Records Act 2001 ‘if the use or disclosure is necessary for research, or the compilation or analysis of statistics, in the public interest’—

(i) it is impracticable for the organisation to seek the individual’s consent before the use or disclosure; and

(ii) that purpose cannot be served by the use or disclosure of information that does not identify the individual or from which the individual’s identity cannot reasonably be ascertained; and

(iii) the use or disclosure is in accordance with guidelines issued or approved by the Health Services Commissioner under section 22 for the purposes of this subparagraph; and

(iv) in the case of disclosure—
(A) the organisation reasonably believes that the recipient of the health information will not disclose the health information; and

(B) the disclosure will not be published in a form that identifies particular individuals or from which an individual’s identity can reasonably be ascertained; or

and

(h) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent—

(i) a serious and imminent threat to an individual’s life, health, safety or welfare; or

(ii) a serious threat to public health, public safety or public welfare—

and the information is used or disclosed in accordance with guidelines, if any, issued or approved by the Health Services Commissioner under section 22 for the purposes of this paragraph’

Patient informed consent to the linking of identifiable health information is the best way to overcome the risk of a breach of the obligation of confidentiality.

• Data linkage—if responses to PROMs are gathered via an online portal, functionality and interoperability with other relevant systems (health services, clinical registries and networks) will be required to link patient-level PROMs data to ancillary data.

Finally, the merits of a local versus central system will need to be considered. Dependent on the requirements and design (i.e., network, infrastructure, software, database, reporting/analytic tools, project team, support team and managing access to ensure appropriate security), establishment and operating costs will vary. As will management of logon and system updates.

Other important requirements are discussed and resources are provided on the Australian Commission on Safety and Quality in Healthcare website (National arrangements for clinical quality registries): https://www.safetyandquality.gov.au/our-work/information-strategy/clinical-qualityregistries/
8 RESOURCES REQUIRED

8.1 REQUEST FOR INFORMATION

The department invites health services, clinical registries and networks to describe their existing data collection, storage and supply methods.

8.2 RESPONSE

PROMs and ancillary data collection is a resource intensive, ongoing activity. It can take years to develop and refine large-scale PROMs and ancillary data collections. Currently, there are no excess resources in health services to support these activities. Health services would require additional funding to support development, establishment and feasibility testing, as well as ongoing activities.

More specifically, health services would require adequate resourcing—time, technology (software and equipment) and labour (project manager, SQL server-proficient data analyst and IT developer)—to support development, establishment and feasibility testing of the core data set (including a MDS with data definitions for ancillary data), as well as the data collection and supply systems [6]. They would also require adequate resourcing—time, technology and labour—to support collection, cleaning and data quality checks, storage (including SQL server space), supply, governance, analysis and reporting on PROMs and ancillary data [6]. Notably, while PROMs data may be collected via electronic systems, as stated previously, requisite ancillary data rarely exists in a readily extractable format, if it exists at all. A team of appropriately trained staff would be required to collect, clean and enter ancillary data into an electronic system.

We provide, as an example, the main development and implementation steps for the feasibility study mentioned previously (PROMs data collection in a sub-cohort of lung cancer patients at Peter Mac). Each step required adequate resourcing.

Set-up:

- Protocol development
- Ethics and ongoing amendments
- Develop operating procedures for the registry
- Build Microsoft Access database and REDCap to ensure linkage to clinical data
- Set-up and test ongoing cost to track patient follow-up

Implementation:

- Identifying eligible patients
- Consenting patients (includes phone calls, cost to print PICFs and return envelopes)
- Collecting data from patients (paper and electronic), as well as one reminder if not returned (cost of an SMS reminder)
- Administration time to identify if patients have withdrawn, died or are too sick to complete PROMs
- Collecting and linking data from medical records
- Data entry of paper-based PROMs
- Cleaning data
- Analysis
- Reporting
- Governance meetings
9 ACCESS TO DATA

9.1 REQUEST FOR INFORMATION

*The department invites suggestions on how to ensure that patient confidentiality is protected while at the same time promoting accessibility to potentially useful and valuable data.*

9.2 RESPONSE

10 REFERENCES

