CQUEST NEWSLETTER

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UTS Cancer Quality of Life Expert Service Team (CQUEST)

In this edition:

Message from the Executive

Since our last newsletter in May, the CQUEST team has been hard at work supporting the Cancer Cooperative Trials Groups (CCTGs) to incorporate patient-reported outcome measures (PROMs) into their research.

There has been growing interest among stakeholders in a 'modular approach' to building custom PROMs. You can read more about the benefits and disadvantages of this approach below.

If you have any questions about the PROM components of your research, please get in touch via cquest@uts.edu.au or leave us a message on our resource feedback form.

CQUEST Executive team
Brendan Mulhern, Tim Luckett and Carrie-Anne Ng

CQUEST Consumer Workshop | Friday, 2 Feb 2024

More information

On Friday, 2 February, CQUEST will host an all-day in-person workshop in Sydney for consumer and community representatives working with CCTGs.

The workshop will cover ways of measuring, analysing and interpreting quality of life in cancer clinical trials. The aims of the workshop are to build consumer understanding and confidence in reviewing the PROMs components of CCTG concepts, and also to canvass consumer ideas on further resources that CQUEST should develop.

Please note:

- CQUEST will fund travel for 2 consumer/community representatives to attend from each CCTG.
- As spots are limited, **all registrants must be endorsed by their CCTG's Executive Officer**. Please contact your CCTG Executive Officer before registering.
- Any requests for travel assistance must be made by **Tuesday, 12 December** to allow sufficient time to make bookings. Please contact us at cquest@uts.edu.au to discuss travel assistance.
- If additional spots become available, we will let you know in the new year.

Modular approach to patient-reported outcome measurement

CQUEST responds to the Food and Drug Administration (FDA)'s draft guidance on core PROs in cancer trials

In June 2021, the US FDA released a draft guidance for industry on core PROs and considerations for instrument selection and trial design in cancer clinical trials. One of the key recommendations was the selection of relevant subscales or building of custom PRO measures using items from libraries ('a modular approach').

In response to this guidance, the CQUEST team, along with Jessica Roydhouse[1] of the Menzies Institute for Medical Research, published an editorial in ISOQOL's QualityTALK newsletter in August 2023. The article summarised the key challenges of using a modular approach and highlights the need for international consensus and guidance to optimise the design of custom PRO measures.

The editorial can be accessed here: https://www.isoqol.org/implementing-the-fdas-draft-guidance-on-core-pros-in-cancer-trials-the-challenge-of-a-modular-approach/

Recommendations on the modular approach by the EORTC and key stakeholders

Earlier this year, Piccinin et al. (2023) published the first international recommendations on the modular approach ('item libraries') for PROs in oncology trials. These were put forth by a working group convened by members of the European Organisation for Research and Treatment of Cancer (EORTC), and included key developers of other item libraries (e.g. FACIT, PROMIS) and representatives from industry, academic, regulatory agencies, and patient advocacy organisations.

The group identified nine primary questions aimed at informing recommendations on how to select from item libraries and implement these in oncology trials (Fig 1). These recommendations focus on methods to drive item selection, design the structure and analysis of item lists, and facilitate their use in conjunction with other measures.

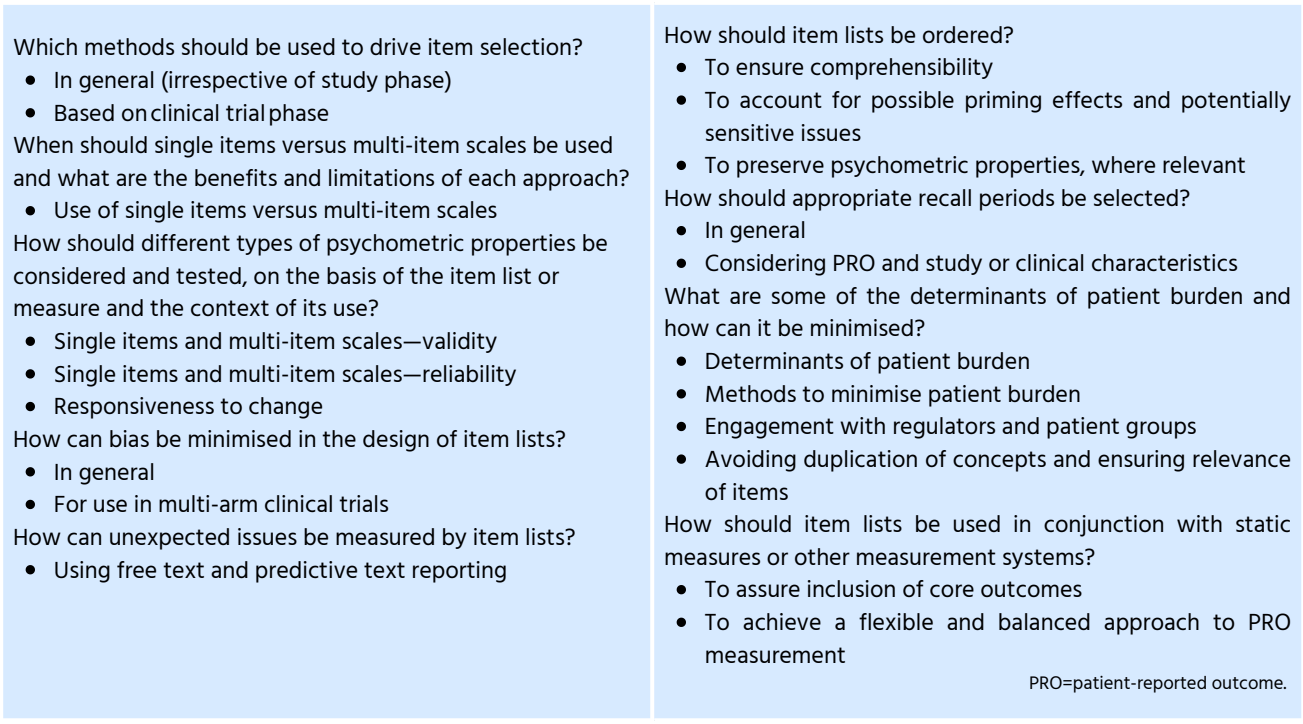

Figure 1. Research questions and topics to guide recommendations.

From: "Recommendations on the use of item libraries for patient-reported outcome measurement in oncology trials: findings from an international, multidisciplinary working group" by C. Piccinin et al., 2023, The Lancet Oncology, Panel 1. (https://doi.org/10.1016/S1470-2045(22)00654-4). Copyright by Elsevier Ltd. without changes.

[1] ISOQOL representative on the CQUEST Steering Committee

Although Piccinin et al. found insufficient evidence to provide definitive guidance on some of these questions, their paper offers an encouraging step towards improving clinical relevance and reducing response burden of PROMs. It is also worth noting that these recommendations may need to be adapted based on the specific context of use and populations being examined.

Contributed by: Carrie-Anne Ng

CQUEST Online Resources

On the CQUEST website (link below), CCTG members are able to access a number of up-to-date and practical resources to support the use of PROMs in cancer clinical trials.

We are currently developing an instructional resource on the use of conceptual frameworks to guide the selection of PROMs in clinical trials, along with a template for use in a protocol. This resource will undergo review with the authors of the Standard Protocol Items: Recommendations for Interventional Trials – Patient-Reported Outcomes (SPIRIT-PRO). Watch this space!

Please let us know what further resources would be helpful to meet your needs either via our feedback form (on the resource webpage) or email cquest@uts.edu.au.

CQUEST Resources

Save the date for our upcoming workshops

Adding value to Phase I and II Trials with Qualitative Sub-studies Wednesday, 3 April | 4 – 5 pm AEDT

This one-hour workshop is a collaboration between CQUEST and the Cancer Symptoms Trials (CST) Group / Palliative Care Clinical Studies Collaborative (PaCCSC) Qualitative Research Subcommittee, and will introduce the benefits of including a qualitative sub-study in early phase trials, along with some practical considerations. Expressions of interest will be invited for attending a further, more in-depth workshop helping you develop a qualitative sub-study for your particular trial.

Register today

Innovations in Measuring Quality of Life in Cancer Trials, Thursday, 2 May 2024 | 1 - 2 pm AEST

The increasing emphasis on PROs and methodological advancements in recent years have driven significant development in methods to effectively measure quality of life in healthcare. These include the use of computer adaptive testing, short-forms and the PRO-CTCAE. This one-hour online workshop will introduce and explore these methods in the context of cancer clinical trials.

Register today

CREST Virtual Workshop | Friday, 24 November 2023

The Cancer Research Economics Support Team (CREST) will be running a virtual workshop for CCTG members, **Understanding Health Economics in Cancer Research** on Friday, 24 November 2023.

This free, introductory, 3-hour session will focus on practical exercises to deepen participants' understanding of health economics within cancer research.

To find out more about the workshop and to register, click below. For any questions, you can reach the CREST team on crest@uts.edu.au.

Register today

Facing Fatigue seminar series

Building researcher capacity in cancer fatigue

Earlier in the year, Cancer Symptom Trials (CST) began hosting national and international presenters with expertise in fatigue as part of the Facing Fatigue Seminar Series. This seminar will continue through to June 2024.

This free, online seminar series aims to build researcher and clinician capacity to better manage fatigue for people living with, or after cancer.

Sign up to one or more sessions in the series – it's up to you! Find out more and register: uts.edu.au/facingfatigue

Upcoming CCTG events

MAR 12-15 TransTasman Radiation Oncology Group (TROG) Annual Scientific Meeting

MAR 20 Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST) Annual Research Forum

APR 17-19 Primary Care Collaborative Cancer Clinical Trials Group (PC4) Ca-PRI Conference

APR 22-24 Australia New Zealand Gynaecological Oncology Group (ANZGOG) Annual Scientific Meeting

JUL 21-23 — Australian and New Zealand Urogential and Prostate Cancer Trials Group (ANZUP) Annual Scientific Meeting

JUL 24-26 — Breast Cancer Trials (BCT) Annual Scientific Meeting

AUG 1-2 — Thoracic Oncology Group Australasia (TOGA) Annual Scientific Meeting

AUG 1-3 — Australian and New Zealand Children's Haematology and Oncology Group (ANZCHOG) Annual Scientific Meeting

OCT 24 — Melanoma and Skin Cancer Trials (MASC Trials) Annual Scientific Meeting

NOV 18-21 — Australasian Gastro-Intestinal Trials Group (AGITG) Annual Scientific Meeting