Recent EORTC Experience of QoL in Cancer Survivors

NCRI Cancer Conference
6 November, 2018 – Glasgow, Scotland

Andrew Bottomley, PhD, Assistant Director,
Head, Quality of Life Department,
European Organisation for Research and Treatment of Cancer
Brussels, Belgium
Increasing number of cancer survivors in Europe – there is a need to understand the long-term effects of new cancer treatments

BUT → Regulatory and operational challenges associated with collection of long-term data internationally. Current research efforts are fragmented and require harmonization

Research on current cancer treatment-related long-term side effects has not yet reached its full potential due to lack of:

- Prospective planning
- Sustainable research infrastructure
- Funding…
Some European Union-Wide Efforts in Cancer Survivorship

• EU is motivated to help bring better standards across the EU and several initiatives are underway → EORTC, ESMO, dialogue with European Parliament

• Several EU funding calls (FP7 and H2020) have supported cancer survivorship research projects across EU member states, aiming to promote less fragmented EU research

• There is still fragmentation of standards of cancer care and survivorship across the EU member states

• Some initiatives have significantly helped, such as cancer passports or creation of bodies such as the European Cancer Patient Coalition
The Survivorship Passport is a online tool to provide eventually all European childhood cancer survivors with optimal long-term care. It provides **instant access to the medical history** of patients who ended a cancer therapy, making survivors and healthcare professionals aware of the **potential risks or late effects** stemming from the previous disease and treatment received.

Rolling out in 2018 over the next 5 years across the EU (as part of the society for Paediatric oncology 2025 plan)
EU-Wide Initiatives in Cancer Survivorship

Press releases

FOR IMMEDIATE RELEASE - 25/05/2018 - 01:30

How can cancer survivors best be supported to return to work?

To mark the European Week Against Cancer, 25-31 May 2018, the European Agency for Safety and Health at Work (EU-OSHA) publishes recent findings from its project exploring the implications of cancer for workers and workplaces across Europe. The publications identify instruments, practices, policies and interventions that can promote the successful rehabilitation and return to work of cancer survivors.

"In addition to the detrimental effects that being out of work has on an individual's well-being and finances, this situation has severe economic consequences for businesses and society as a whole."
EU-Wide Inititatives in Cancer Survivorship
European Organization for Research and Treatment of Cancer (EORTC)

• Private non-profit organization (Charity)

• Over 60 years old

• Over 3000 clinicians, researchers, etc. across the EU

• Main mission: promote and conduct research to improve cancer care and quality of life

• Core activity: conduct clinical trials (>50 currently active)
  • International
  • Develop new treatments/define new standards of care
  • Large academic trials
  • QoL outcomes in trials and development of QOL tools

• Last decade → increased interest in survivorship
EORTC Survivorship Initiatives Since 2008

- EORTC Survivorship Summits (4)
- You Protocol
- QLG Survivorship Questionnaire + Module Development
- Prospective research studies
EORTC Cancer Survivorship Summits

• Aims: unite EU-wide clinicians, researchers, social workers, patients, insurers, bankers, and policy makers with aims to:

  • Increase awareness of survivorship-related issues
  • Influence policymaking to improve health status, QoL, and social participation for cancer survivors
  • Promotion of QoL research in survivors (e.g., new measures)
  • Change social policy (e.g. better insurance for survivors)
  • 4{superscript}th Cancer Survivorship Summit is planned for 2020
QOL and Cancer Clinical Trials Conferences: Survivors and QOL as a theme increases

• A ¼ day on our 4th (2017) and 5th (May 2019) a major session is devoted to survivorship concerns.

• Plenary speakers on survivorship issues (Patti Ganz)

• Free attendance and over 40 Travel awards for patients and researchers
QoL Assessment in Cancer Survivors

• Cancer survivors face a wide range of late adverse treatment effects which can impact life expectancy and QoL and present other challenges
EORTC Approach to QoL Assessment in Cancer Survivors – Different Methods

- **EORTC core measure** (QLQ-C30) may not be fully relevant for survivors and their challenges

- **Survivorship + site-specific modules** currently under development
  - Are static measures sufficient?

- **New Item library could** be a solution
  - More flexible and efficient measures
  - Shorter, more tailored to the needs of specific populations (disease, stage, age, etc.)
EORTC Quality of Life Group Survivorship Questionnaires

• New tools intended to be used in survivors who have completed treatment with curative-intent (with the exception of maintenance treatment) at least 1 year earlier and are disease-free

• Project is currently in Phase III of development
  • Data collection expected to finish in December 2018
  • Final versions of Survivorship Core Questionnaire (QLQ-SURV) and Survivorship Site-Specific Modules (BR-SURV45, CR-SURV34, PR-SURV30) anticipated in June 2019
EORTC QLG Survivorship Questionnaires Under Development

- New EORTC QLG survivorship assessment strategy, currently under development:
  - Survivorship Core Questionnaire (QLQ-SURV)
    - Core questionnaire can be used as a standalone questionnaire or in combination with a site-specific (survivorship) module
  - Breast Survivorship Module (BR-SURV45)
  - Colorectal Survivorship Module (CR-SURV34)
  - Prostate Survivorship Module (PR-SURV30)

Site-specific survivorship modules
Your Outcome Update (YOU) Protocol and Infrastructure

• Your Outcome Update → An EORTC coordinated infrastructure

• To evaluate the overall survival and key long-term clinical outcomes (e.g., second primary cancers, long-term toxicities, comorbidities) among cancer survivors

• To evaluate patient-reported outcome measures (PROMs) among long-term cancer survivors

• To address other issues of survivorship
YOU Data Collection

Baseline Data
- Baseline Patient and tumour characteristics from parental study
- Clinical outcomes at end of study of parental study
- Adverse effects at end of study of parental study
- PROMs at end of study of parental study
- Existing Comorbidities

Clinical Data
- Overall survival
- Second primary cancers
- Relapse
- Long-term adverse effects (e.g. cardiovascular events)
- Comorbid conditions

PROMs
- Functional challenges
- Distress, fear of recurrence, cognitive function, depression, etc.
- Social economic issues
- *Selected from EORTC QLG Survivorship Questionnaire (QLQ-SURV)*

Project-specific data
- If needed, additional clinical or PROMs not pre-specified in the YOU core data set

Retrospective data collection of existing data

Prospective data collection (core data set)
Prospective EORTC Quality of Life Group Survivorship Studies

• **Long-term views of women with Gyn cancer patients on follow-up (2016-…)**
  
  • to provide a comprehensive evaluation of both the physical and psychosocial effects of gynecologic cancer survivors.
  
  • Addressing NCRI/James Lind Alliance priority 5 (i.e. what are the short term and long term psychological impacts of cancer and its treatment) and priority 25 (what is the optimal follow-up to “detect when a cancer has come back”)

• **Long-term views in early and locally advanced breast cancer patients on follow-up (2016…)**
  
  • to identify physical and psychosocial problems during follow-up after primary treatment in breast cancer patients. Addressing NCRI/James Lind Alliance priority 5…

• **Long-term toxicity in Head and Neck survivors (2017…)**
  
  • Long term psychosocial and physical impact on people who have survived more than 5 years after a head/neck cancer diagnosis
Retrospective Studies

- **Patient Reported Outcomes and Behaviour Evidence (PROBE)** – from 2008-2016

- A Consortium of global researchers from EORTC, UK MRC, NCIC, and AGO representatives with a set of pre-determined QoL (PRO) research questions to help better understand the use of QoL from closed RCTs

- Resulted in a database of over 40,000 patients with QoL and clinical data from fully published cancer clinical trials.

- This led to 14 publications which addressed questions of cancer patients and survivors e.g.
  - Whether QoL is prognostic? Findings: Yes
  - Are symptom clusters prognostic? Findings: Yes
  - Do patient vs. doctors’ assessments of wellbeing differ in RCTs? Findings: Yes
  - What’s different between clinical and statistical significance? Findings: Major

- This shows QoL data has a value post completion of the original trials and in long-term. EORTC is happy to share the data.
Improving standards in QOL research

- **Setting International Standards in the Analysis of Quality of Life (SISAQOL)** is an international Consortium created in 2016

- Concerns were raised about poor standards of analysis of QOL in RCTs.

- Shared interest in improving the standards of PRO analysis in cancer RCTs in order to improve patient outcomes
SISAQOL Consortium

<table>
<thead>
<tr>
<th>Academic Researchers / Statisticians / Clinicians</th>
<th>Regulatory Bodies</th>
<th>Medical Institutes</th>
<th>Industry Representatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>FDA</td>
<td>MD Anderson</td>
<td></td>
</tr>
<tr>
<td>Austria</td>
<td>MHRA/EMA</td>
<td>Mayo Clinic</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>Health Canada</td>
<td>National Cancer Institute</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>Institute for Quality and Efficiency in Health Care</td>
<td>EORTC</td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>France</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Academic / Learned Societies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Society for Quality of Life Research (ISOQOL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consolidated Standards of Reporting Trials (CONSORT-PRO)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Society for Pharmaceutics and Outcomes Research (ISPOR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multinational Association of Supportive Care in Cancer (MASCC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Journal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lancet Oncology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Representative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Brain Tumour Alliance</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Regulatory Bodies
- FDA
- MHRA/EMA
- Health Canada
- Institute for Quality and Efficiency in Health Care

Medical Institutes
- MD Anderson
- Mayo Clinic
- National Cancer Institute
- EORTC

Industry Representatives
- Adelphi
- Boehringer-Ingelheim
- Genentech
SISAQOL have now provided evidence of poor standards of analysis of QOL in RCTs via published systematic reviews.

- Consensus has been reached, based on systematic literature reviews, and consensus meetings on several key QOL analysis methods.

- SISAQOL analysis consensus recommendations to be released in early 2019.

- New work planned for 2019 - is questions of RCTs are poor what about analysis standard for survivorship studies?
Summary

• Survivorship research is gaining its important position in cancer care

• Research efforts remain fragmented and require harmonization to reduce research waste and promote international collaboration

• The EORTC is very open and supportive of future collaboration on all of the recently identified research priorities