Using Patient Reported Outcome Measures (PROMs) in cancer care

Galina Velikova
Professor/Consultant in Medical Oncology
Section of Patient-Centred Outcomes Research
Leeds Institute of Cancer and Pathology
University of Leeds
St James’s Institute of Oncology
Can we join PROMs together?  
How? When?
Rapid learning healthcare model (Abernethy A, 2003)

- Integration of ePROMs into clinical care
- Patient-level linkage of PROMs, clinical and administrative data

- PROMs to become a part of the Big Data
Multi-Purpose PROMs
(modified Claire Snyder)

Assess PROMs

Inform Quality Improvement

Evaluate Care Quality

Build-up evidence base on symptoms or adverse events

Use in Clinical Practice to support patients
Outline

• Use of PROMs in clinical practice for individual patient care - review

• ePROMs in Leeds oncology
  • Monitoring of adverse events – eRAPID program
  • Testicular cancer follow-up

• Evaluate care quality - population studies

• Inform quality improvement?

• Existing guidelines

• Concluding remarks
Multi-Purpose PROMs
(modified Claire Snyder)

Assess PROMs

Inform Quality Improvement

Use in Clinical Practice to support patients

Evaluate Care Quality

Build-up evidence base on symptoms or adverse events
PROMs to support patient care in routine practice

Clinical method - Medical interview
Gathering of subjective information
Diagnostic aim
Not designed to monitor change or assess outcomes

Patient Reported Outcomes Measures
Quantitative information on symptoms and functioning
Track changes over time

Benefits
• Detect and monitor physical and emotional problems
• Impact on patient-doctor communication
• Facilitate patient involvement in decision making
Studies in oncology – RCT only

<table>
<thead>
<tr>
<th>Authors</th>
<th>Patient No</th>
<th>Process of care-communication</th>
<th>Decision-making</th>
<th>Patient well-being</th>
<th>Satisfaction with care</th>
</tr>
</thead>
<tbody>
<tr>
<td>McLachlan 2001</td>
<td>N=450</td>
<td>NA</td>
<td>--</td>
<td>--</td>
<td>(+ psychol)</td>
</tr>
<tr>
<td>Detmar 2002</td>
<td>N=214</td>
<td>+</td>
<td>--</td>
<td>--</td>
<td>(+ psychol)</td>
</tr>
<tr>
<td>Velikova 2004</td>
<td>N=286</td>
<td>+</td>
<td>--</td>
<td>+</td>
<td>--</td>
</tr>
<tr>
<td>Rosenbloom 2007</td>
<td>N=213</td>
<td>-/+</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Berry 2011</td>
<td>N=660</td>
<td>+</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Carlson 2010</td>
<td>N=585</td>
<td>+</td>
<td>+ Distress</td>
<td>+</td>
<td>NA</td>
</tr>
<tr>
<td>Basch 2016</td>
<td>N=766</td>
<td>NA</td>
<td>Less ER visits</td>
<td>+</td>
<td>(+ survival)</td>
</tr>
</tbody>
</table>
Measuring Quality of Life in Routine Oncology Practice Improves Communication and Patient Well-Being: A Randomized Controlled Trial

Galina Velikova, Laura Booth, Adam B. Smith, Paul M. Brown, Pamela Lynch, Julia M. Brown, and Peter J. Selby

ABSTRACT

Purpose
To examine 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.

Patients and Methods
In a prospective study with repeated measures involving 28 oncologists, 286 cancer patients were randomly assigned to either the intervention group (regular completion of European Organization for Research and Treatment of Cancer–Core Quality of Life Questionnaire version 3.0, and Hospital Anxiety
Improvement in Patient well-being

Proportions of pts with clinically significant change in FACT-G

- **Intervention**
  - Improvement: 46%
  - No change: 32%
  - Deterioration: 24%

- **Attention-control**
  - Improvement: 14%
  - No change: 61%
  - Deterioration: 31%

- **Control**
  - Improvement: 31%
  - No change: 45%
  - Deterioration: 24%
Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial

Ethan Basch, Allison M. Deal, Mark G. Kris, Howard I. Scher, Clifford A. Hudis, Paul Sabbatini, Lauren Rogak, Antonia V. Bennett, Amylou C. Dueck, Thomas M. Atkinson, Joanne F. Chou, Dorothy Dulko, Laura Sit, Allison Barz, Paul Novotny, Michael Fruscione, Jeff A. Sloan, and Deborah Schrag

See accompanying editorial on page 527

Abstract

Purpose
There is growing interest to enhance symptom monitoring during routine cancer care using patient-reported outcomes, but evidence of impact on clinical outcomes is limited.

Better QOL – EQ5D

Less emergency visits

A

Any Change $P < .001$

Change by 8 or More Points $P = .0059$

All Patients (%)

0%

100%

N = 457

Usual Care

STAR

Usual Care

Improved

Unchanged

Worsened

A

All Patients

Patients Visiting ER (%)

36%

53%

36%

29%

34%

11%

21%

Usual care

STAR

$p = .02$

Months Since Enrollment
Multi-Purpose PROMs
(modified Claire Snyder)

- Assess PROMs
- Evaluate Care Quality
- Build-up evidence base on symptoms or adverse events
- Inform Quality Improvement
- Use in Clinical Practice to support patients
Use of PROMs in clinical practice: eRAPID

Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice (NIHR programme grant)

Patients - Symptom items
Self-reporting of side effects with severity grading

Patients - Advice and alerts
- Mild self-management advice
- Serious Alerts to patients and clinicians

Electronic platform
- Functional in Real-time
- Confidential
- Well-supported

Integration in patient care pathways
- Staff training
- Patient training
Electronic platform – QTool EHR System

**Administrator/Researcher**
- Administrator Interface
- Set up studies/patient groups
- Select items/schedule questionnaires
- Combine with clinical data
- Study level reports

**Hospital Team**
- Oncologist / Nurse Interface
  - Patient monitoring
  - Review of self reports
  - Alerts

**Patient interface**
- Patient at Home
- Internet

**Software**
- QTool database
- Web based QTool data

**Data Centre**
- QTool database
- QStore database
- Electronic Patient Record (PPM)

**Patient in Clinic**
- Patient in Clinic

**Administrator Interface**
- Set up studies/patient groups
- Select items/schedule questionnaires
- Combine with clinical data
- Study level reports

**Hospital Team**
- Oncologist / Nurse Interface
  - Patient monitoring
  - Review of self reports
  - Alerts

**Electronic Patient Record (PPM)**
- Electronic Patient Record (PPM)

**UNIVERSITY OF LEEDS**
- eRAPID
- Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice

**National Institute for Health Research**
eRAPID Multi-centre programme in systemic therapy, radiotherapy and surgery

The Leeds Teaching Hospitals NHS

Prof Jane Blazeby
Elaine O’Connell
Steve Gray

Dr Alexandra Gilbert
NIHR Clinical PhD student

Dr Susan Davidson
Jacki Routledge
Matthew Barker-Hewitt

University Hospitals Bristol NHS

The Christie NHS

Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice
National Institute for Health Research

UNIVERSITY OF LEEDS
### AEs items severity grades

<table>
<thead>
<tr>
<th>AEs Item</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Standard</th>
<th>Dropdown</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Have you had pain or discomfort anywhere on your body?</td>
<td>No</td>
<td>I had mild pain or discomfort</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I had moderate pain or discomfort and I was not able to do some of the things I normally do (e.g. household chores, shopping)</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I had severe pain or discomfort and I was not able to care for myself (e.g. getting out of bed, bathing, dressing)</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Nausea</td>
<td>Have you felt sick (nauseous or queasy)?</td>
<td>No</td>
<td>I felt sick but I was able to eat and drink the same amount and type of foods as usual</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I felt sick and I ate or drank less than usual or changed what I ate or drank</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I felt sick and was not able to eat or drink</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Sleep</td>
<td>Have you had difficulty sleeping? OR What was the severity of your difficulty sleeping?</td>
<td>No</td>
<td>I occasionally have difficulty falling asleep, staying asleep or I wake too early</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I often have difficulty falling asleep, staying asleep or I wake too early</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I always have difficulty falling asleep, staying asleep or I wake too early</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>Have you had tingling or numbness in your fingers or toes? OR What was the severity of the tingling or numbness in your fingers or toes?</td>
<td>No</td>
<td>I had a bit of tingling or numbness (perhaps when handling cold or hot objects)</td>
<td>Dropdown</td>
<td>Standard</td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I had tingling or numbness and I was not able to do some of the things I normally do (e.g. buttoning up or using cutlery)</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>I had tingling or numbness and I was not able to carry out daily activities (e.g. I had difficulty walking, dropped things or stepped on things by accident)</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>
Welcome to the home page of the University of Leeds and Leeds Teaching Hospitals, eRapid research project funded by a National Institute for Health Research (NIHR) Programme Grant (RP-PG-0611-20008).

eRapid stands for “Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice”.

The aim is to develop an integrated web-system for patients to report symptoms and side effects during and after cancer treatment. Data that is reported by patients using the web-system (called QTool) will be documented in individual patient electronic health records. Where patients report mild side effects they will receive advice on how to manage them and to seek timely medical advice.

If you have any queries regarding the content of this website, please contact The Patient Reported Outcomes Group (POG) on (0113) 20 68968.

Please visit our Patient Reported Outcomes website www.pogweb.org to view our other studies. Our research primarily involves developing and evaluating web based systems for cancer patients to report information about their health and wellbeing.
Have you had pain or discomfort anywhere on your body?

- No
- I had mild pain or discomfort
- I had moderate pain and discomfort and was not able to do some of the things I normally do (for example, household chores/ shopping)
- I had severe pain and discomfort and was not able to care for myself (for example getting out of bed, bathing, dressing)
eRAPID demo questionnaire

For your Pain:

If you have been prescribed painkillers (also known as analgesics) by your doctor, take the maximum dose that you have been recommended as soon as you first feel you have pain. Make sure that you take your painkillers regularly, even if you have mild pain, which you think you can cope with. It is easier to prevent the pain than to treat existing pain. Do not exceed the maximum dose that you have been prescribed.

If you haven’t been prescribed any painkillers by your doctor and you have mild pain, there are certain painkillers that you can take which can be bought without a prescription. Painkillers suitable for mild pain include:

* Paracetamol

* Ibuprofen

Take the dose that is advised by the pharmacist or indicated on the drug information as soon as you feel that you first have pain. Make sure that you take your painkillers regularly, even if you have mild pain, which you think you can cope with.
Clinician view EHR - graphs

- Integration with Electronic Patient records in real time
**eRapid Systemic RCT diagram**

**Endpoints and analysis**
- Recruitment, attrition, missing data
- Quality of life (FACT-G), EORTC QLQ-C30
- Clinical process measures - number of hospital contacts, alerts and hospital admissions, clinician records of symptoms, changes to treatment
- Use of resources - hospital and community contacts, medications and treatment related expenses
- End of study interviews with participants and clinical staff
N=87 over 6 months
80% Consent rate
15% Attrition rate
## Activation of clinical algorithms

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Breast</th>
<th>Ovarian</th>
<th>Colorectal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total QTool completions</td>
<td>382</td>
<td>73</td>
<td>85</td>
</tr>
<tr>
<td>A1-Alert - contact the hospital immediately</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>A2 – serious symptoms improved, contact when convenient</td>
<td>10%</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>B-3 or more moderate symptoms, contact when convenient</td>
<td>17%</td>
<td>22%</td>
<td>4%</td>
</tr>
<tr>
<td>C- mild symptoms, self-management advice</td>
<td>69%</td>
<td>67%</td>
<td>91%</td>
</tr>
<tr>
<td>D – no problems</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>
Multi-Purpose PROMs
(modified Claire Snyder)

- Assess PROMs
- Use in Clinical Practice to support patients
- Build-up evidence base on symptoms or adverse events
- Evaluate Care Quality
- Inform Quality Improvement
## Patient Reported Symptoms Report

(eRapid RCT in systemic cancer treatment - report date: 28 Sep 2015)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency of symptoms reported (by subject)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 3</td>
<td>Level 2</td>
</tr>
<tr>
<td>Physical Ability</td>
<td>19 (10)</td>
<td>84 (26)</td>
</tr>
<tr>
<td>Indigestion</td>
<td>12 (4)</td>
<td>26 (13)</td>
</tr>
<tr>
<td>Pain</td>
<td>11 (4)</td>
<td>94 (28)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>11 (6)</td>
<td>100 (28)</td>
</tr>
<tr>
<td>Nausea</td>
<td>10 (5)</td>
<td>73 (24)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>9 (6)</td>
<td>10 (7)</td>
</tr>
<tr>
<td>Appetite</td>
<td>8 (4)</td>
<td>98 (20)</td>
</tr>
<tr>
<td>Constipation</td>
<td>4 (3)</td>
<td>36 (13)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4 (4)</td>
<td>5 (4)</td>
</tr>
<tr>
<td>Chills</td>
<td>3 (2)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Sore Mouth</td>
<td>1 (1)</td>
<td>60 (17)</td>
</tr>
<tr>
<td>Sleeping</td>
<td>0 (0)</td>
<td>14 (10)</td>
</tr>
<tr>
<td>Taste</td>
<td>0 (0)</td>
<td>12 (7)</td>
</tr>
<tr>
<td>Short Breath</td>
<td>0 (0)</td>
<td>10 (4)</td>
</tr>
<tr>
<td>Sore Hands</td>
<td>0 (0)</td>
<td>6 (3)</td>
</tr>
<tr>
<td>Temperature</td>
<td>0 (0)</td>
<td>5 (4)</td>
</tr>
<tr>
<td>Reaction Injection</td>
<td>0 (0)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Nail Changes</td>
<td>0 (0)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Ascites</td>
<td>0 (0)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>0 (0)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Depression</td>
<td>0 (0)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0 (0)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Skin rash</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Nose Bleeds</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>92 (49)</td>
<td>649 (222)</td>
</tr>
</tbody>
</table>

## Alerts (by subject)

- Indigestion: 5 (1)
- Pain: 4 (2)
- Nausea: 2 (1)
- Lack of appetite: 1 (1)
- Constipation: 1 (1)
- Diarrhoea: 1 (1)
Internal Pilot - Patient-reported AEs via QTool

Breast - Highest level of symptom during cycle 1 Docetaxel (and EC90 below)

Gynae - Highest level of symptom during cycle 1 (Colorectal below)

Neuropathy

Sleep

# patients Level 0  # patients Level 1  # patients Level 2  # patients Level 3

Temperature  Olias  Pain  Vomiting  Nausea  Diarrhea  Constipation  Fatigue  Physical  Appetite  Sore Mouth  Sleep

Temperature  Olias  Pain  Vomiting  Nausea  Diarrhea  Constipation  Fatigue  Physical  Appetite  Sore Mouth  Sleep
Testicular cancer
Community Follow-up
Service development project

Dr Dan Stark
Consultant Medical Oncology
Lead for Teenage and Young Adult Oncology Unit
Testicular cancer

Community Follow-Up

- **Standard Follow-up**
  - 13 surveillance pathways
  - OPA, Blood tests, X-rays, CT scans,
  - Done & interpreted in Cancer Centre
  - Patients from across Yorkshire
  - Multiple OP visits (2-12 in first year)

- **Community Follow-up**
  - Same pathways
  - **QTool instead of OPA**
  - OPA face to face once per year or for CT results
  - Blood tests, X-rays closer to home

- Started 2013, currently 168 patients
Online PROMs – Testicular Cancer
### Evaluation of Community Follow-up

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No Patients</td>
<td>1559</td>
<td>759</td>
</tr>
<tr>
<td>No (%) in FU</td>
<td>489 (31%)</td>
<td>220 (29%)</td>
</tr>
<tr>
<td>No accepted CFU</td>
<td>123 (25%)</td>
<td>168 (78%)</td>
</tr>
</tbody>
</table>

N withdrawn = 18

33 patients interviews
2/3 in favour of Community Follow-up in principle
Reduces the time taken for clinic (travel + waiting)
Reduces the impact upon work/education
• An innovative approach for remote monitoring and support of ovarian cancer patients using ePROMs and re-designed care pathways

No symptoms AND/OR CA125 normal.

Mild/moderate symptoms AND/OR CA125 normal – system advice provided only.

Mild/moderate symptoms AND/OR CA125 raised – patient contacted by clinician.

Serious symptoms AND/OR CA125 raised – patient contacted by clinician.

Note: This is an example algorithm and the exact detail – including thresholds, use of CA125 monitoring (for all/subset of patients) and action taken will be determined during the Development Phase work.
Multi-Purpose PROMs
(modified Claire Snyder)

Assess PROMs

Inform Quality Improvement

Evaluate Care Quality

Use in Clinical Practice to support patients

Build-up evidence base on symptoms or adverse events
Evaluate care quality

Pain
Nausea
Neuropathy

Hospital 1
Hospital 2
Hospital 3
PROMs in NHS populations

- NHS PROMs elective surgery
- National cancer survivors pilot

Patient-reported outcomes of cancer survivors in England 1–5 years after diagnosis: a cross-sectional survey


ABSTRACT

Objectives: To determine the feasibility of collecting population-based patient-reported outcome measures (PROMs) in assessing quality of life (QoL) to inform the future direction of cancer research and care.

ARTICLE SUMMARY

Article focus
- To determine the feasibility of routinely collecting patient-reported outcome measures (PROMs) for cancer patients.
2015 NHS England Independent Cancer Taskforce report

Achieving World-Class Cancer Outcomes

• Recommendation 64
• To develop a national metric on quality of life by 2017 which would enable better evaluation of long-term quality of life after treatment.

• PROMs should be rolled out across breast, colorectal and prostate cancer by 2020, with evaluation and further rollout across other cancer types.
Quality of Life on the Cancer Dashboard
Outline

• Use of PROMs in clinical practice for individual patient care - review

• ePROMs in Leeds oncology
  • Monitoring of adverse events – eRAPID program
  • Testicular cancer follow-up

• Evaluate care quality - population studies

• Inform quality improvement?

• Existing guidelines

• Concluding remarks
Helps clinicians and researchers interested in implementing PRO assessment to aid patient care

Includes
- Considerations
- Options
- Resource requirements
- Relative advantages and disadvantages

Review

The use of EORTC measures in daily clinical practice—A synopsis of a newly developed manual

Lisa M. Wintner a, *, Monika Sztankay a, Neil Aaronson b, Andrew Bottomley c, Johannes M. Giesinger a, Mogens Groenvold d, Morten Aa Petersen d, Lonneke van de Poll-Franse e, Galina Velikova f, Irma Verdonck-de Leeuw g, Bernhard Holzner a on behalf of the EORTC Quality of Life Group
Users’ Guide to Integrating Patient-Reported Outcomes in Electronic Health Records

Prepared For PCORI By:
Johns Hopkins University, Baltimore, MD

May 2017

Concluding thoughts on implementation in patient care

- eHealth
  - Patient portals
  - Levels of integration with EPR
  - Mobile reporting by patients
- Engaging professionals in responding to PROMs data
- Evaluation and Health economics
- Integrated care pathways
  - Referral pathways based on patient self-reports
- Organizational changes
  - Central IT support
Acknowledgements

• We wish to thank the patients, oncologists and clinic staff who made this work possible

• National Institute for Health Research of England

• Yorkshire Cancer Research

• Section of Patient-Centred Outcomes Research

• POG - Patient-reported Outcomes Group

• Clinical Trials and Research Unit, University of Leeds