Using Electronic Patient-Reported Outcomes to Monitor and Manage Symptoms in Cancer Care

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Background

Symptoms are common among patients with cancer
• Disease is morbid, treatments are toxic
• Interfere with physical functioning and daily activities
• Frequently lead to emergency and hospital visits

Symptom management is a cornerstone of quality care in oncology practice (and other chronic conditions)
Standard Approach to Symptom Monitoring

- Limited Time
- Forget to discuss
- Reluctance to Contact
- Problems Connecting

REACTIVE APPROACH
Alternative: Systematic Symptom Monitoring Using Electronic Patient-Reported Outcomes

PROACTIVE APPROACH
Research Findings

• Clinicians unaware of up to half of patients’ symptoms
• Systematic symptom monitoring with ePROs closes this gap
• Patients willing and able to self-report
• Clinicians trust patient-reported e-information

Integration of electronic patient-reported outcomes systems in oncology care can alert clinicians about symptoms, improve communication, and symptom control.
• Usual care vs. computer-based symptom questionnaire at oncology visits

• Results: Symptoms discussed more often during visits; significantly improved quality of life in the group that self-reported symptoms

Velikova: JCO, 2004
Early Patient Self-Reporting System

U.S. National Cancer Institute CTCAE Scale - Example: Pain

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>I have not had pain.</td>
</tr>
<tr>
<td>Grade 1 (Mild)</td>
<td>I have had mild pain, but it does not interfere with my normal functioning.</td>
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<tr>
<td>Grade 2 (Moderate)</td>
<td>I have had moderate pain, and my pain or my use of pain medications interfere with my normal functioning. But I am still able to carry out my normal daily activities.</td>
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<tr>
<td>Grade 3 (Severe)</td>
<td>I have had severe pain, and my pain or my use of pain medications severely interfere with my normal daily activities.</td>
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<tr>
<td>Grade 4 (Disabling)</td>
<td>My pain has been disabling.</td>
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</table>
Early Patient Self-Reporting System

Example: Shortness of Breath (Dyspnea)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>None</td>
<td>I have not had shortness of breath (with exercise or rest).</td>
</tr>
<tr>
<td>Grade 1 (Mild)</td>
<td>I have been short of breath with exercise, but I can walk up 1 flight of stairs without stopping.</td>
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<tr>
<td>Grade 2 (Moderate)</td>
<td>I have been short of breath with exercise but I am not able to walk up 1 flight of stairs or 1 city block without stopping.</td>
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<tr>
<td>Grade 3 (Severe)</td>
<td>I have been short of breath during my normal daily activities (dressing, showering, cleaning, cooking, etc.).</td>
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<tr>
<td>Grade 4 (Disabling)</td>
<td>I have been short of breath even when I am resting in bed or in a chair.</td>
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</tbody>
</table>
Email Alert to Clinical Nurse

From: Patient Symptom Tracking <webmaster@mskcc.org>
Date: Wednesday, June 14, 2010 at 2:16 PM
To: Microsoft Office User <[redacted]@mskcc.org>
Subject: Patient Symptom Alert

SYMPTOM REPORTED FROM HOME

Patient Medical Record Number: [redacted]
Date/Time Reported: 07/14/2010 at 2:15 PM

Symptom: DYSPNEA Grade: 3

Symptoms that have worsened since 07/07/2010:
Symptom: DYSPNEA from Grade: 1 to 3

Link to FULL REPORT
Printed Report to Oncologist at Clinic Visit

STAR SYMPTOM REPORT
Confidential PHI

Patient Name: [Redacted]
Patient MRN: [Redacted]
Primary Oncologist: [Redacted]

Worsened symptoms since July 7:
- Cough: from grade 0 to grade 1

Improved symptoms since July 7:
- Dyspnea: from grade 3 to grade 1
- Fatigue: from grade 2 to grade 1
- Pain: from grade 1 to grade 0

Below is a summary of prior reported symptoms, with most recent reports on top:

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Clinic/Chemotherapy Visit
Feasibility in Routine Cancer Care

Patients longitudinally reporting PRO symptoms (N~400):

- Most patients self-report at any given clinic visit
- Nurses respond with “clinical actions” to 75% of automated email alerts (counselling, supportive medications, referrals to ER, chemotherapy dose modifications, imaging)

## Patient Feedback on Using ePRO Systems

<table>
<thead>
<tr>
<th></th>
<th>Agree</th>
<th>Disagree</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy to use</td>
<td>98%</td>
<td>2%</td>
<td>-</td>
</tr>
<tr>
<td>Useful</td>
<td>94%</td>
<td>6%</td>
<td>-</td>
</tr>
<tr>
<td>Easier to remember symptoms at clinic visits</td>
<td>94%</td>
<td>5%</td>
<td>-</td>
</tr>
<tr>
<td>Improved discussions with my doctor/nurse</td>
<td>90%</td>
<td>10%</td>
<td>-</td>
</tr>
<tr>
<td>Improves communication with doctor and nurse</td>
<td>75%</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Would like to continue using</td>
<td>96%</td>
<td>4%</td>
<td>-</td>
</tr>
<tr>
<td>Would recommend to other patients</td>
<td>98%</td>
<td>2%</td>
<td>-</td>
</tr>
<tr>
<td>Improved quality of my care</td>
<td>65%</td>
<td>10%</td>
<td>25%</td>
</tr>
</tbody>
</table>
## Clinician Feedback on ePRO Systems

*Survey of MDs & RNs*

<table>
<thead>
<tr>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discuss PRO reports with patients</td>
<td>90%</td>
</tr>
<tr>
<td>PROs accurately reflect patient clinical status</td>
<td>90%</td>
</tr>
<tr>
<td>PROs are useful during treatment for adverse event monitoring</td>
<td>95%</td>
</tr>
<tr>
<td>PROs are a potential source of research-grade data</td>
<td>90%</td>
</tr>
</tbody>
</table>
“STAR” Study: ePRO Impact on Clinical Outcome

Patients receiving chemotherapy for metastatic breast, lung, GU, GYN cancer at MSKCC

INTERVENTION ARM
- Self-report 12 common symptoms
  - Prior to / between visits, by web
  - Weekly email reminders to patients
  - Alerts to nurses (by email)
  - Reports to oncologists (at visits)

CONTROL ARM
- “Standard” symptom monitoring

Outcomes
- QOL
- ER visits
- Survival

Stratified by level of prior computer use
Randomized 2:1 for those w/o prior use

Treatment discontinuation, withdrawal, hospice, death

Basch: JAMA, 2017; JCO 2016; ASCO 2017
Results

766 patients enrolled between June 2007 and January 2011

Overall survival analysis June 2016

• Median follow-up 7 years
• 517/766 (67%) participants had died

Basch: JAMA, 2017; JCO 2016; ASCO 2017
Quality of Life

- Assessed at 6 months, compared to baseline
- Compared to standard care, 31% more patients in the self-reporting arm experienced QOL benefits ($P<0.001$)
Emergency Room Visits

- Compared to standard care, 7% fewer patients in the self-reporting arm visited the Emergency Room, with durable effects throughout the study ($P=0.02$).
Overall Survival

• Compared to standard care, median survival was 5 months longer among patients in the self-reporting arm (31.2 vs. 26.0 months) ($P=0.03$)

• Remained significant in multivariable analysis: Adjusted hazard ratio 0.832 (95% CI; 0.696, 0.995)

• 5-year absolute survival benefit of 8%
**ASCO 2018 Abstract #6500**

**Fabrice Denis et al.**

N = 133

- NSCLC and SCLC
- Stages II (N+ only) - IV
- SCLC and NSCLC
- TKI or maintenance therapy allowed

**INTERVENTION:** Weekly web-based symptom reporting w/ less frequent imaging surveillance

<table>
<thead>
<tr>
<th>Stage</th>
<th>3 mo</th>
<th>6 mo</th>
<th>9 mo</th>
<th>12 mo</th>
<th>15 mo</th>
<th>18 mo</th>
<th>21 mo</th>
<th>24 mo</th>
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<tbody>
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**CONTROL:** No symptom reporting and more frequent imaging surveillance

<table>
<thead>
<tr>
<th>Stage</th>
<th>3 mo</th>
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**PRIMARY OUTCOME:** OVERALL SURVIVAL
Key Result

7.6 month OS benefit in web symptom-reporting arm vs. control

Likely mechanisms:
- Better symptom management
- Catching relapse earlier

Conclusion: Compelling evidence for web-based symptom monitoring during cancer care - reinforces data from ASCO 2017

Median OS
- Web-application arm (n = 60) 22.5 months
- Control arm (n = 61) 13.5 months

12 mo OS
- Web-application arm (n = 60) 75%
- Control arm (n = 61) 53%

24 mo OS
- Web-application arm (n = 60) 50%
- Control arm (n = 61) 26%

P=0.004,
HR 0.496 (0.305 ; 0.806); p=0.005
New Generation of Systems

Web

Automated Telephone Systems

Mobile
Severe symptoms on 6/19/2017: Activity Level, Appetite, Nausea, Vomiting, Dyspnea, Diarrhea, Constipation, Pain, Insomnia, Depression.

Worsened symptoms between 6/12/2017 and 6/19/2017: Activity Level, Appetite, Nausea, Vomiting, Dyspnea, Diarrhea, Constipation, Pain, Insomnia, Depression.

Falls: 6/12/2017

Improved symptoms between 6/12/2017 and 6/19/2017: Activity Level, Appetite, Nausea, Vomiting, Dyspnea, Diarrhea, Constipation, Pain, Insomnia, Depression.

Food/Fluid Intake
(0 = no change; 3 = decreased a lot or totally)

Patient ECOG Performance Status
(0 = normal; 4 = bedridden)

Pain
(0 = none; 3 = severe +/- frequent +/- debilitating)

Dyspnea
(0 = none; 3 = severe +/- debilitating)
What can I do to manage my sleep problems?

Tips to help you sleep:

- **Tell your cancer care team about problems that are getting in the way of your sleep.** Getting treatment to lower side effects such as pain or bladder or bowel problems may help you sleep better.

- **Set good bedtime habits.**
  - Go to bed only when sleepy, in a quiet and dark room, and in a comfortable bed.
  - Go to bed and wake up at the same time.
  - Avoid napping if possible.
  - Make sure your bedroom is not overly hot or cold.
  - Stop watching television or using devices with screens a couple of hours before going to bed.
    - Devices like: iPads, laptops, and smart phones.
  - Don’t drink or eat a lot starting about 2-3 hours before bedtime.
  - Exercising too close to bedtime may make sleep more difficult.
    - Exercise before 2:00pm promotes sleep.
  - Don’t watch the clock at night.
  - Keep out pets who wake you up.

- **Don’t stay awake in bed for more than 5-10 minutes.** If you do not fall asleep, get out of bed, sit in a chair in the dark until you are sleepy. It’s okay if this happens several times a night.

- **Avoid caffeine after midday.** Also cigarettes, alcohol and some ‘over-the-counter’ medications may interfere with sleep.

- **Sleep medicine may be prescribed** by your cancer care team for a short period if other strategies don’t work.

- **Cognitive behavioral therapy (CBT) and/or relaxation therapy may help.** For example, a CBT therapist can help you learn to change negative thoughts and beliefs about sleep into positive ones.
  - Muscle relaxation, guided imagery, and self-hypnosis may help.

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**PAIN**

- **Assess pain medication history:**
  - What is prescribed, what is the patient actually taking, how is it working?
  - Is the patient taking opioids, and are they long acting, short acting, or both?
  - How long has the patient been on their pain regimen?

- **Conduct comprehensive pain assessment:**
  - Location of pain (Where does pain originate? Does it radiate to another area of the body?)
  - Intensity of pain (Use pain scale of 0-10 with 10 being the worst pain imaginable).
  - Quality of pain (sharp, stabbing, burning, aching).
  - Using scale of 1-10 being the worst pain imaginable: What is your pain at its best? What is it at its peak? What is your pain after taking your pain medications?
  - Assess for breakthrough pain (Does the pain return or increase in intensity before the next dose?).
  - Great, duration and aggravating/diminishing factors (When does it start? What makes it worse/better? How often does it occur? How long does it last?)
  - Assess for changes in activity level, sleep, general activities of daily living, depression.
  - If taking opioids, assess for constipation.

**Management of Pain:**

1. **Non-opioids (acetaminophen, COX-2 inhibitor, NSAID).** Note that COX-2 inhibitor (celecoxib, meloxicam) does not inhibit platelet aggregation; NSAID toxic effects can include acute renal failure, gastrointestinal toxicity, cardiovascular toxicity, and CNS toxicity such as memory loss and confusion. NSAIDs should be avoided in patients with stomach or intestinal ulcers, cardiovascular disease and/or hypertension; kidney disease; bleeding disorders; pregnancy; taking other prescription anti-coagulants such as warfarin (Coumadin) or heparin, phosphonyl (Dilaudid), and/or cyclosporine; use of anticoagulants may cause hepatic injury; use caution with liver disease.

2. **Opioids such as morphine when pain persists or increases and cannot be controlled by non-opioids.**

3. **Non-medication treatments should be offered for all patients with pain.** These include emotional support, distraction (music, social engagement), appropriate physical activity (pilates, tai chi, supportive devices, exercise therapy), physical therapy, and topical application of heat or cold.

**Considerations:**

- Pain medication scheduled “around the clock” when pain is constant. Consider long-acting agents.
- Use the simplest route of administration possible.
- Consider additional supportive drugs to address anxiety, depression, or neuropathic pain symptoms.
- Provide patient/family/caregiver education about treatment approaches and safe medication use.
- Consider suggesting a pain diary to monitor characteristics of pain, medications regimen, and response to medication.
- No driving when using opioids.

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*This form and its contents can be used in its entirety or adapted to your specific needs. It is based on general health information and is not intended to replace or substitute medical advice or treatment. It is for educational purposes only and is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of a healthcare professional who is familiar with the particular patient situation.*
Ongoing ePRO Trial in Routine Cancer Care

PRO-TECT U.S. national trial – currently enrolling patients
- 1000 patients receiving cancer treatment across U.S. community oncology sites
- Evaluating processes for integrating PROs into workflow
PATIENT

PRO SYSTEM

CLINICIANS  RESEARCHERS  HEALTHCARE SYSTEMS  FUTURE PATIENTS

PATIENT CARE  REAL WORLD EVIDENCE  QUALITY ASSESSMENT  DECISION MAKING

SELF-EFFICACY
Resources for Health Systems/Clinics


Summary of ePRO Use in Routine Care

Integration of patient-reported symptoms into cancer care is feasible and is associated with clinical benefits.

This approach may be considered for inclusion as a part of standard symptom management to improve and measure quality of care.

Future efforts should focus on strategies for implementing self-reporting into clinical workflow and electronic health records.