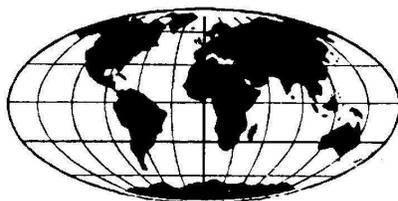


# User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice

Version: November 11, 2011

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**DISCLAIMER:** *This User’s Guide was reviewed and approved by the ISOQOL Board of Directors as an ISOQOL publication and does not reflect an endorsement of the ISOQOL membership.*

**CITATION:** *International Society for Quality of Life Research (prepared by Aaronson N, Choucair A, Elliott T, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). User’s Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version: November 11, 2011.*

## INTRODUCTION

This *User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice* was developed by a team of volunteers from the International Society for Quality of Life Research (ISOQOL). The purpose of this *User's Guide* is to help clinicians who are interested in using patient-reported outcome (PRO) questionnaires in their clinical practice as a tool in patient management. For the purposes of this *Guide*, PROs refer to patient reports on any of various outcomes, including symptom burden, functioning, health status, and health-related quality of life.

The questions addressed by this *User's Guide* include the following:

1. What are your goals for collecting PROs in your clinical practice and what resources are available? Which key barriers require attention?
2. Which groups of patients will you assess?
3. How do you select which questionnaire to use?
4. How often should patients complete questionnaires? Should it be tied to visits or a way to follow patients between visits?
5. How will the PROs be administered and scored?
6. What tools are available to aid in interpretation and how will scores requiring follow-up be determined?
7. When, where, how, and to whom will results be presented?
8. What will be done to respond to issues identified through the PROs?
9. How will the value of using PROs be evaluated?

As you will see, this *User's Guide* does not aim to provide the "right" answers to these questions. Rather, the *User's Guide* presents different options for responding to each of these questions, so that each practice can determine which approach is "right" for its own goals and needs. To that end, for each of the questions, the *User's Guide* provides the following information:

- the different options for answering each of the questions posed above,
- the resources needed to implement the various options,
- the advantages and disadvantages of the various options, and
- useful references for more information.

We hope that a wide range of practice types will find this *User's Guide* helpful. The field of assessing PROs in clinical practice is continuing to develop and evolve, and the web version of this *User's Guide* will be updated periodically. We welcome input regarding what you have found works (and doesn't work) in your practice. Please send feedback and questions to [info@isoqol.org](mailto:info@isoqol.org).

***What are your goals for collecting PROs in your clinical practice and what resources are available? Which key barriers require attention?***

Before implementing any intervention involving the use of PROs in your clinical practice, it is critical to clarify the goals of the intervention and to assess the resources available for implementing the intervention. It should be noted that the options presented below are not necessarily mutually exclusive, and that practices may be able to implement PROs in their practices to accomplish multiple objectives.

The resources involved include manpower, information systems and technical support, space, and financial investment. The level of resources required depends on how the intervention is implemented and is discussed in more detail in later sections.

In many cases the advantages and disadvantages of implementing PROs in clinical practice are similar, regardless of the particular goals. Advantages include encouraging clinicians to treat the “whole” patient rather than just the disease, facilitating communication without increasing consultation time, and engaging patients in their own care. Barriers are at the level of clinicians (lack of familiarity with the instruments, doubt about the ability of PROs to modify outcomes, time and resource constraints, disagreements over impact on patient-clinician relationship), patients (literacy, being too sick to complete questionnaires, concern about impact on relationship with clinician), and health system (reimbursement, fit within the clinical workflow).

A taxonomy of applications of PROs in clinical practice includes the following:

**A. SCREENING TOOLS**

***Resources Needed:***

- One-time PRO assessment with feedback to clinician.

***Advantages:***

- Can help identify problems that may have otherwise gone unnoticed.

***Disadvantages:***

- Provides no information on how the patient’s outcomes may be changing over time.

**B. MONITORING TOOLS**

***Resources Needed:***

- PRO data collection over time with feedback of results to clinician.

***Advantages:***

- Can track patient's outcomes over time.
- Helps evaluate whether interventions are effective.
- May facilitate modifying interventions as needed.

***Disadvantages:***

- More resource intensive.

**C. PATIENT-CENTERED CARE**

***Resources Needed:***

- PRO data collection with feedback of PRO results to patients, in addition to clinicians.

***Advantages:***

- Facilitates discussion between patients and clinicians regarding patient's issues, including their concerns and their priorities for care.
- Can lead to patients becoming more involved in their care and improved self-efficacy.
- May also produce better patient compliance, improved health outcomes, and greater patient satisfaction.

***Disadvantages:***

- May be more resource intensive to feedback results to patients in addition to clinicians.

**D. DECISION AIDS**

***Resources Needed:***

- Information about treatment options, their impact on PROs, and the probability of various PRO outcomes.
- Decision aid that presents this information to patients in an understandable manner and that allows them to clarify their values.

***Advantages:***

- Helps patients understand treatment options.
- Allows for an explicit weighing of risks and benefits.

***Disadvantages:***

- Aids are not available for all decisions.

## E. FACILITATING MULTIDISCIPLINARY TEAM COMMUNICATIONS

### **Resources Needed:**

- Method for multidisciplinary teams to share patient PRO data.

### **Advantages:**

- Provides a common data source for clinicians from diverse backgrounds to discuss patients' progress.
- Provides the patient perspective to clinicians' discussions of treatment planning and evaluation.
- May assist clinicians in agreeing on and implementing care plan.

### **Disadvantages:**

- Requires training of clinicians from multiple disciplines in interpreting PRO results.

## F. EVALUATING QUALITY OF CARE

### **Resources Needed:**

- Pooled data from patients from within the practice, preferably with normative data for comparison.

### **Advantages:**

- Can help identify strengths and weaknesses in care provided.
- May allow clinicians to compare their practice outcomes to benchmarks or other normative data.
- Provides information on effectiveness, rather than efficacy.
- If data are publicly available, enables patients and purchasers to compare providers on PROs.

### **Disadvantages:**

- Does not necessarily involve using individuals' PRO results to aid in their management.
- Link between quality of care and PROs has been questioned, due to confounders and limitations in case mix adjustment.

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## ***Which groups of patients will you assess?***

The key considerations in determining which patients in your practice you want to complete PROs include patients' ability to self-report and the setting of care. Options include the following:

### **A. ONLY PATIENTS WHO CAN SELF REPORT**

#### ***Resources Needed:***

- Ability to identify patients capable of self-report.
- Versions of questionnaires appropriate for the languages/cultures of the patient population (translations and cultural adaptations are frequently available from instrument developers).

#### ***Advantages:***

- Individuals who self-report are providing direct assessment.

#### ***Disadvantages:***

- Some individuals may appear to be competent but may be too impaired to validly and reliably represent themselves.

### **B. PATIENTS REQUIRING ASSISTANCE (E.G., YOUNG CHILDREN, MENTALLY OR COGNITIVELY LIMITED, ETC.)**

#### ***Resources Needed:***

- Proxies need to be identified in terms of relationship to patients and it should be explicitly noted when proxy reporter varies from administration to administration.

#### ***Advantages:***

- In cases where the index patient is unable to provide responses because of incapacity, the input of significant others provides some perspective on the affected person.
- Proxies (e.g., caregivers, physicians) can provide useful information particularly on the more concrete, observable aspects of HRQOL.

#### ***Disadvantages:***

- Proxies may have a difficult time distinguishing between how their family member would respond and what they perceive that person's status to be.
- Responses from proxies may be influenced by their own feelings about and experiences of caring for the patient.

### **C. ALL AMBULATORY PATIENTS**

#### ***Resources Needed:***

- Ambulatory patients are more likely to be more independent and have more discretionary time to complete measures.
- It is recommended that a generic PRO is administered once a year.

#### ***Advantages:***

- Provides an opportunity to identify unknown problems, disabilities, and limitations.

#### ***Disadvantages:***

- Ambulatory patients may have had significant illness episodes affecting PROs between their ambulatory visits. These illness episodes may have resolved and thus not be captured in the current assessment.

### **D. AMBULATORY PATIENTS WITH SPECIFIC CONDITIONS**

#### ***Resources Needed:***

- Individuals with an identified chronic illness, whether followed in a general or specialty clinic, should complete a related PRO at least every 6 months, with weekly assessments considered for patients undergoing outpatient treatment for certain conditions (e.g., cancer).
- Ambulatory patients with specific conditions that affect vision or hand function should have access to adapted means of completing questionnaires either remotely or on site.

#### ***Advantages:***

- Focusing on patients with specific conditions allows for a more targeted measurement strategy.

#### ***Disadvantages:***

- Additional staff may be required to assist ambulatory patients with specific conditions that affect vision or hand function.

### **E. INPATIENT ACUTE CARE PATIENTS**

#### ***Resources Needed:***

- Hospitalized patients in acute medical settings will likely require help completing PROs, regardless of method of administration.
- Time to complete PROs will need to be built into the schedule.
- State of alertness will determine whether acute care patients can respond.

**Advantages:**

- Acute care patients are readily available to complete measures depending on availability of staff to help.
- Hospitalized patients will experience more rapid variation in PROs and assessments should occur more often and with appropriate recall.

**Disadvantages:**

- Acute care patients may find that completing the questionnaires is not useful during their short-term stay.
- For hospitalized patients, there will be no information to be gained about the long-term benefit of a hospitalization, if there is no post-discharge assessment.
- The environment of a hospitalized patient may influence responses.

**F. INPATIENT REHABILITATION PATIENTS**

**Resources Needed:**

- Patients hospitalized in rehabilitation settings have structured schedules and are undergoing constant evaluation for progress.

**Advantages:**

- Patients hospitalized in rehabilitation settings can have these assessments built into their schedules.

**Disadvantages:**

- If lack of progress is reflected in these measures, insurers may use the data to shorten length of stay.

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## ***How do you select which questionnaire to use?***

There are several considerations when determining which questionnaire to use. These include whether to use generic or disease-specific questionnaires, profile or preference-based measures, single or multi-item scales, or static or dynamic questionnaires. For all of the options, various attributes of the questionnaires should be evaluated, including response formats (verbal descriptor scale or numeric rating scale), focus of assessment (severity, frequency, interference, bother), time burden, and the level psychometric evidence (validity, floor/ceiling effect, etc.). One should also consider the reference period. More recent recall periods more accurately capture patient's actual experiences, but short reference periods require either more frequent assessments (meaning more burden) or may miss important symptoms between assessments.

Careful attention should be given to determining what type of patient-reported information to collect. Patient-reported data may include questions on symptoms (e.g., pain, fatigue, nausea, depressive mood), functioning (e.g., activities of daily living, cognitive functioning) or quality of life (e.g., mental, physical, and social well-being). Some questionnaires include a mix of these types of data. Selection of the content of the questionnaire should consider clinician or patient preferences. Physicians may only want to assess symptoms they know how to treat. For patients, there may be specific symptoms and quality-of-life issues they want to talk to the doctor about.

The different types of PRO questionnaires are described below.

### **A. GENERIC OR DISEASE-SPECIFIC QUESTIONNAIRES**

#### ***Resources Needed:***

- Permission to use questionnaire, if required.
- User fee, if required by instrument developers.

#### ***Advantages:***

- Generic questionnaires may capture more common domains and allow comparisons to normative populations.
- Disease-specific questionnaires may be more sensitive to specific symptoms experienced by patients.

#### ***Disadvantages:***

- Generic questionnaires may not be sensitive to changes over time.
- Disease-specific questionnaires may miss domains affecting patient but unrelated to disease under study.

## **B. NON-PREFERENCE (PROFILE) OR PREFERENCE-BASED MEASURES**

### ***Resources Needed:***

- Permission to use questionnaire, if required.
- User fee, if required by instrument developers.

### ***Advantages:***

- Profile measures provide multiple scores (and sometimes summary) measures across a broad range of PRO domains.
- Preference measures provide a single score aggregated across multiple PRO domains for an estimate of burden of disease.

### ***Disadvantages:***

- Profile measures are often longer to complete.
- Preference measures may not provide clinically relevant information on the specific PRO domains affecting the patient.

## **C. SINGLE OR MULTI-ITEM SCALES**

### ***Resources Needed:***

- Permission to use questionnaire, if required.
- User fee, if required by instrument developers.

### ***Advantages:***

- Able to measure more domains if only use a single item for each.
- Multi-item scales provide more reliable/sensitive/content valid measurement.

### ***Disadvantages:***

- Single items are less reliable for tracking change.
- Multi-item scales are more burdensome (time consuming) for patients and clinicians.

## **D. STATIC OR DYNAMIC QUESTIONNAIRES**

### ***Resources Needed:***

- Permission to use questionnaire, if required.
- User fee, if required by instrument developers.
- Dynamic questionnaires require computer-based assessment and access to validated item banks and computer-adaptive test (CAT) software.

### ***Advantages:***

- Static forms can work on paper and on computer.

- CAT measures are more efficient and allow more domains to be assessed.

**Disadvantages:**

- Static forms are a burden to administer and score.
- CAT requires computer assessment

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***How often should patients complete questionnaires? Should it be tied to visits or a way to follow patients between visits?***

It is also important to consider how frequently patients will complete PROs. Options range from one-time only to frequent completion, with assessments tied to visits or a way to monitor patients between visits. These options are described in more detail below.

**A. ADMINISTRATION AT VISIT: ONE-TIME OCCURENCE**

***Resources Needed:***

- Time for patients to get familiar with measures and means for completion.
- Time for clinicians to train on the PRO's use and interpretation.
- Resources for data management and use, timely review of data, and responses to patient needs identified through PRO measurement.
- Resources to develop programs to improve patients' PROs, such as patient satisfaction and patient health-related quality of life.

***Advantages:***

- Can screen for problems and unexpected conditions.
- Provides information about what is important to the patient with regards to his/her condition and treatment.

***Disadvantages:***

- Does not enable clinicians to monitor changes.
- Assumes that decision-making about patient's treatment can occur during a single consultation.

**B. ADMINISTRATION AT VISIT: MULTIPLE VISITS**

***Resources Needed:***

- Generally requires same resources as one-time administration, but incrementally more of them.

***Advantages:***

- Allows seeing the trajectory of the disease and its treatment.
- Helps patients understand and monitor changes in their PROs, promoting their involvement and confidence and patient-centered care.
- Helps clinicians understand the use PROs.

***Disadvantages:***

- Incrementally higher costs to assess PROs at multiple visits compared to single visits.
- Requires additional workforce capacity.
- Involves increased administrative complexity.

### **C. ADMINISTRATION BETWEEN VISITS**

#### ***Resources Needed:***

- Patients need access to a website or other method to complete PROs from home.
- System requires built-in alerts so that clinicians are sent an email and/or page for issues requiring immediate attention.
- Alerts should direct clinicians to resources and personnel (e.g., nurses) available to help address problems.

#### ***Advantages:***

- Improved accessibility to health care.
- Potential of improving patient care between visits.
- Allows seeing the trajectory of the disease and its treatment.
- Helps patients understand and monitor changes in their PROs, promoting their involvement and confidence and patient-centered care.
- Helps clinicians understand the use PROs.

#### ***Disadvantages:***

- Increased burden on clinicians and healthcare infrastructure.
- Extra resources needed to ensure that critical problems reported by patients are addressed on time.
- Alerts may be burdensome.

### **D. DETERMINING FREQUENCY OF ADMINISTRATION**

#### ***Resources Needed:***

- Generally requires more resources for more frequent administration.

#### ***Advantages:***

- More frequent assessment can provide a more complete picture for patients who are very symptomatic and/or in active treatment.
- Less frequent assessment is less burdensome and may be appropriate for generally healthy patients.

#### ***Disadvantages:***

- More frequent assessments can be burdensome.
- Less frequent assessment may miss key changes in patients' outcomes.

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## ***How will the PROs be administered and scored?***

Various options for mode of administration and mode of data capture are described below. An Appendix provides a summary table of literature comparing modes of administration.

### **A. SELF-ADMINISTERED: IN CLINIC**

#### ***Resources Needed:***

- Personnel to supervise and assist, where necessary.
- Space.
- Administrative personnel for data entry.

#### ***Advantages:***

- Low-technology requirements.
- Can be implemented in any clinical setting.
- Relatively low cost.

#### ***Disadvantages:***

- Problem with low literacy patients and those with visual handicap.
- Potentially difficult with other special populations (e.g., very young, very old, severely symptomatic)
- Potentially higher rate of missing data compared to interviewer administered questionnaires

### **B. INTERVIEW ADMINISTERED: IN-CLINIC**

#### ***Resources Needed:***

- Skilled interviewer.
- Space.
- Administrative personnel for data entry.

#### ***Advantages:***

- More personal.
- Facilitates more in-depth questioning.
- Largely circumvents literacy problem and/or visual handicap.

#### ***Disadvantages:***

- Relatively expensive.
- May create problems with social desirability.
- Increased costs to dedicate staff time to administer PRO measure.

### **C. COMPUTER-ASSISTED: IN-CLINIC (including portable devices)**

#### ***Resources Needed:***

- Personnel to supervise and assist, where necessary.
- Software to collect and report the PRO data.

#### ***Advantages:***

- Efficient data capture with simultaneous data entry.

#### ***Disadvantages:***

- Potential problems finding space/providing privacy.
- Upfront costs to develop (or purchase) the PRO system and ongoing costs to maintain it.
- Potential software problems.

### **D. SELF-ADMINISTERED VIA MAIL**

#### ***Resources Needed:***

- Personnel to manage mailing.
- Administrative personnel for data entry.

#### ***Advantages:***

- Low-technology requirements.
- Potentially simpler logistics than in-clinic administration.
- Relatively low cost.

#### ***Disadvantages:***

- Potentially high non-response rate.
- Cannot ensure patient completes questionnaire alone.
- More difficult to respond immediately if the patient reports severe symptoms and more difficult to time the assessment close to the clinical visit.
- Other limitations similar to Self-Administered In-Clinic.

### **E. TELEPHONE ADMINISTRATION: LIVE INTERVIEW**

#### ***Resources Needed:***

- Skilled interviewer.
- Administrative personnel for data entry.

#### ***Advantages:***

- More personal.
- More convenient for patient.

- Largely circumvents literacy problem and/or visual handicap.

***Disadvantages:***

- Lack of visual cues as compared to face-to-face.
- Relatively expensive.
- Potential problem with social desirability.
- Some topics may be more difficult to address.

**F. TELEPHONE INTERVIEW: VOICE ACTIVATED**

***Resources Needed:***

- Administrative personnel to oversee data collection.
- A validated and efficient interactive voice response (IVR) system.

***Advantages:***

- Relatively low cost due to automation.

***Disadvantages:***

- Automated system may be off-putting to patients.
- Upfront costs to develop (or purchase) the IVR system and ongoing costs to maintain it.
- Other disadvantages similar to Live Telephone Interview, plus impersonal nature.

**G. WEB-BASED (including portable devices)**

***Resources Needed:***

- Systems management personnel.
- Software to collect and report the PRO data.

***Advantages:***

- Efficient data capture with simultaneous data entry.
- Convenient for patient.
- Flexible timing for data collection.

***Disadvantages:***

- Difficult to ensure privacy.
- Upfront costs to develop (or purchase) the PRO system and ongoing costs to maintain it.
- Potential software problems.

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## ***What tools are available to aid in score interpretation and how will scores requiring follow-up be determined?***

Tools to aid the interpretation of PROs vary depending on whether the patient's *current* score only has been fed back to the clinicians, or whether the clinician is presented with the *change* in the patient's score. Although different options are discussed separately below for clarity, studies in this area have tended to utilize a combination of different tools to facilitate interpretation.

### **A. GENERAL WRITTEN GUIDELINES**

#### ***Resources Needed:***

- General written guidelines of score meaning (e.g., "higher scores mean better functioning").

#### ***Advantages:***

- Simple to read.
- Provides general indication of the meaning of the scores.

#### ***Disadvantages:***

- Provides no information about the clinical importance or importance to the patient.

### **B. CUT-OFF SCORE FOR "CASENESS" OR FOR LEVELS OF SEVERITY**

#### ***Resources Needed:***

- Information on what to use as the cut-off for "caseness" or for previously validated categories (e.g., no disability, moderate disability, severe disability).

#### ***Advantages:***

- Simple and easy to apply (i.e., is the patient's score above or below the threshold; or within a certain category).

#### ***Disadvantages:***

- Assumes these cut-offs and/or categories have been established for the measure in question.
- More likely to have established cut-offs and/or categories for anxiety and depression, versus quality of life measures.

- Usefulness depends on the sensitivity and specificity of cut-offs; likely to be misclassification; predictive value depends on prevalence of the condition in the population being screened.

### C. REFERENCE SCORES FROM RESEARCH STUDIES WITH SIMILAR PATIENTS

#### ***Resources Needed:***

- Information on mean endpoint scores from clinical trials/systematic reviews of patients with the same condition undergoing the same treatment.

#### ***Advantages:***

- Enables clinicians to compare their patients with patients in trials undergoing same treatment.

#### ***Disadvantages:***

- May not be available for all instruments.
- Patients in trials different from patients that clinicians may see in clinic.
- Just because it is experienced by other patients does not mean it is not a problem for this particular patient – “to be expected” is not the same as “not problematic.”
- Significantly larger error of measurement in individual, compared with group, PRO scores can make comparison with benchmarks from group data problematic.

### D. REFERENCE SCORES FROM THE GENERAL POPULATION WITH SAME CONDITION

#### ***Resources Needed:***

- Information on mean endpoint scores from the populations in the community with the same condition.

#### ***Advantages:***

- Enables the clinician to compare patient’s current score with the average of the wider population with the same condition.
- Approach can be used with both generic and disease-specific questionnaires.

#### ***Disadvantages:***

- May not be available for all instruments; needs to have been administered to a large number of patients to generate valid norms.
- Patient in front of the clinician may not be similar to the population (e.g., comorbid conditions and preferences).
- Does not provide any information about whether the patients themselves see that area as problematic – only that their score is higher/lower or the same as the reference population.

- Significantly larger error of measurement in individual, compared with group PRO scores can make comparison with benchmarks from group data problematic.

## **E. REFERENCE SCORES FROM THE HEALTHY POPULATION**

### ***Resources Needed:***

- Information on mean endpoint scores from healthy populations.

### ***Advantages:***

- Enables the clinician to compare patient's current score with the average of the healthy population.
- Can be used to determine distance from "full health."

### ***Disadvantages:***

- Only useful for generic instruments.
- Probably only useful for conditions where there is an expectation that the patient may return to full health.
- Significantly larger error of measurement in individual, compared with group, PRO scores can make comparison with benchmarks from group data problematic.

## **F. STRUCTURED INTERVIEWS TO CLARIFY SCORES**

### ***Resources Needed:***

- Personnel to review patient's scores with the patient to clarify and elaborate on problems indicated by the PROs.

### ***Advantages:***

- Can provide further information on what the patient's problems are and why.

### ***Disadvantages:***

- Resource intensive.

## **G. LINKING SCORES TO MANAGEMENT GUIDELINES**

### ***Resources Needed:***

- Recommendations for how clinicians could respond to issues identified by the PROs.
- Access to published and accepted clinical guidelines/recommendations to tie the PRO data to effective care.

**Advantages:**

- May increase the ability of PRO results to affect patient care and outcomes.

**Disadvantages:**

- May be perceived as challenging the clinician's expertise and autonomy.

**H. SIMPLE COMPARISON WITH PATIENT'S PREVIOUS SCORES**

**Resources Needed:**

- Patient's current and previous scores.

**Advantages:**

- Easy for the clinician to assess.

**Disadvantages:**

- Provides no information about the importance of the change either clinically or to the patient.

**I. MINIMALLY CLINICALLY IMPORTANT DIFFERENCE: DISTRIBUTION-BASED METHODS**

**Resources Needed:**

- Scores over time presented as effect sizes or standard error of measurement, along with written interpretation of what constitutes small, medium, and large changes.

**Advantages:**

- Enables the clinician to compare patient's current score with the average of the wider population with the same condition.
- Standard error of measurement remains relatively constant across ability ranges within the population.

**Disadvantages:**

- May not be intuitively meaningful to clinicians.
- Criteria for what constitutes small, medium, and large changes criticized as arbitrary.
- Meaning is improved if they are combined with anchor based measures of change.
- Minimally important differences based on the standard error of measurement is highly dependent on scale reliability, which is required to be at least 0.9 – few instruments may meet this criterion.
- Applying minimally important differences based on groups of patients to individual patients may be problematic due to the larger measurement error in individual measurements.

## J. MINIMALLY CLINICALLY IMPORTANT DIFFERENCE: ANCHOR-BASED METHODS

### **Resources Needed:**

- Data on changes in scores related to external anchors (e.g., patient global ratings of change, clinician rating of change, clinical measures).

### **Advantages:**

- Simple for the clinician to interpret, as it involves simply comparing the change in score to the point difference determined to be clinically important based on the anchor.
- Can be improved by triangulating patient and clinician ratings of important change.
- Applying minimally important differences based on groups of patients to individual patients may be problematic due to the larger measurement error in individual measurements.

### **Disadvantages:**

- Global transition questions have been criticized, as patient reports of their previous health status may be influenced by their current health status.

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## ***When will results be presented?***

Another important consideration is when and how to present the results and discuss them with patients. Option include before, during, or after a patient visit, as described below.

### **A. AT TIME OF VISIT**

#### ***Resources Needed:***

- Method to collect data at time of or prior to visit.
- Method to score PROs prior to or at time of visit.
- Method to display data.
- Clinicians willing to discuss pertinent issues identified by patients.

#### ***Advantages:***

- Information available at time of clinical encounter.
- Alerts clinicians to area of patient concern.
- Enhances patient-clinician communication.
- Helps to clarify priorities for care.

#### ***Disadvantages:***

- Possibility of omission of discussion of certain issues by clinicians due to lack of time, expertise, patient/clinician unwillingness to discuss, etc.
- Resources for scoring PROs in real time may be lacking without using e-PROs.
- Start-up costs of e-PROs may be prohibitive.

### **B. PRIOR TO VISIT**

#### ***Resources Needed:***

- Method to gather PROs from patient outside of visit.
- Method of communicating results from patient to clinician.
- Method to ensure results are also available for clinical encounter.

#### ***Advantages:***

- Time to score instruments if not e-PRO.
- Clinicians have time to prepare for discussion.

#### ***Disadvantages:***

- Clinician must respond to results prior to clinical visit.
- Need for patient to provide information outside of clinical visit.

## C. AFTER VISIT

### **Resources Needed:**

- Method to gather PROs at the time of visit.

### **Advantages:**

- PROs can be gathered at time of visit but scored and presented later.
- May work better within office work flow.

### **Disadvantages:**

- Clinician must react to results after visit decreasing usefulness.
- If patients are to receive PRO results, ensuring that they get them with appropriate interpretation may be challenging.

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## ***Where will results be presented?***

It should also be determined whether results will be presented within or outside of the clinical workflow.

### **A. WITHIN CLINICAL WORKFLOW**

#### ***Resources Needed:***

- If clinical workflow is paper-based: paper-based report that is presented to clinical staff within usual workflow.
- If clinical workflow is electronic: resources to integrate electronic PROs into electronic chart, or for non-electronic PROs, resources to add PROs to the electronic chart.

#### ***Advantages:***

- Places PROs where clinician is prepared to receive them.
- Allows integration of PRO data with other clinical data.

#### ***Disadvantages:***

- Additional information for clinicians to review.
- Electronic integration can be costly and may not be supported by electronic medical record vendor, depending on the system.

### **B. OUTSIDE OF USUAL CLINICAL WORKFLOW**

#### ***Resources Needed:***

- Clinical staff to track change in PRO status and address ongoing PRO issues which may require intervention beyond visit (e.g., phone follow-up, or self-directed supplemental information via web links).
- Electronic or paper-based system to present PROs to clinician that is reliable outside of usual workflow.

#### ***Advantages:***

- PRO presentation can be customized to clinician or group needs.
- More frequent assessment beyond episodic office visit which may enhance resolution of problems.

#### ***Disadvantages:***

- Data are outside of usual workflow.
- Documentation and retrieval may not be complete.
- Potentially time and effort consuming (e.g., nursing resources).

## KEY REFERENCES

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## ***How will results be presented?***

There are various ways to present the PRO score results, as described below.

### **A. NUMERIC PRESENTATION**

***Resources Needed:***

- Nothing beyond resources to score the PROs.

***Advantages:***

- Does not require data manipulation.
- May be easier to integrate into standard workflow.

***Disadvantages:***

- May be more difficult to interpret.

### **B. GRAPHICAL PRESENTATION**

***Resources Needed:***

- Likely requires computer manipulation of data.

***Advantages:***

- Likely easier to interpret than strict numerical presentation.
- May improve usability by patients and clinicians.

***Disadvantages:***

- More complex presentation requires data manipulation.
- Graphical representation may be more difficult to integrate into standard workflow (e.g., electronic medical record) than strict numeric.

### **C. PRESENTATION OF TRENDS OVER TIME**

***Resources Needed:***

- Requires ability to recall prior results and place them in the context of change.
- Consider presenting text with graphical information.

***Advantages:***

- Provides context for individuals over time.

- Sophisticated presentation could allow receiver of information to customize presentation format.
- Line graphs of means without extraneous information (e.g., error bars) may be clearer for patients.

***Disadvantages:***

- Same as with Graphic Presentation, plus issues with incorporating previous scores

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## ***Who will receive score reports?***

It is also important to consider who should receive the score reports, including determining which clinicians and whether the patient should see the results, as well.

### **A. MEMBER OF THE HEALTH CARE TEAM (physician, nurse, other ancillary personnel)**

#### ***Resources Needed:***

- Individual responsible for reacting to PROs.

#### ***Advantages:***

- Customizable to practice patterns.
- Personnel other than physician may be better able to respond to PRO.

#### ***Disadvantages:***

- Needs to be customized to practice.
- Necessitates systems based practice redesign.

### **B. FEEDBACK TO PATIENT**

#### ***Resources Needed:***

- Method to get patients information by the time of clinician discussion, either paper at time of visit or electronic communication prior to appointment.
- Follow up from the clinician after the appointment.

#### ***Advantages:***

- Patient is an active member of the care team and can participate in decision-making.

#### ***Disadvantages:***

- If results are presented without context or appropriate interpretation, may result in confused patient.
- Patients may prefer not to receive information without context.

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## ***What will be done to respond to issues identified through the PROs?***

Another important question is how to respond to issues identified through the PRO assessments. There are a variety of approaches that can be taken to address this issue, as described below.

### **A. UTILIZATION OF DISEASE MANAGEMENT PATHWAYS**

#### ***Resources Needed:***

- Useful disease management pathways applicable to the PRO.

#### ***Advantages:***

- Uniform method of addressing issue.

#### ***Disadvantages:***

- Possibility of lack of utilization of intervention as recommended.
- Pathways may not exist for all applications, resulting in burden of creating and validating pathway.

### **B. FURTHER EXPLORATION OF PRO ISSUES IDENTIFIED WITH THE PATIENT TO GAIN FULL UNDERSTANDING**

#### ***Resources Needed:***

- Time for clinicians to explore issues in greater depth.

#### ***Advantages:***

- Does not rely on PRO data as full extent of the issues.
- Allows delving deeper into issues.

#### ***Disadvantages:***

- Time consuming.

### **C. UTILIZATION OF MULTIDISCIPLINARY TEAM MEMBER EXPERTISE TO ADDRESS ISSUES**

#### ***Resources Needed:***

- Health professionals from different disciplines.

#### ***Advantages:***

- Utilization of varied skill sets.

**Disadvantages:**

- Skills may not be readily available for referrals in all settings.

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## ***How will the value of using PROs be evaluated?***

Finally, practices which implement the routine collection and use of PROs may want to assess the impact this intervention has on the quality of their care. Below, approaches to evaluate the value of using PROs in clinical practice are described, using either experimental designs and methods or quasi-experimental/quality-improvement designs and methods. For the purposes of this section, value is defined as the sum of clinical quality, service quality, and safety divided by the sum of monetary cost and time.

### **A. EXPERIMENTAL DESIGNS AND METHODS (e.g., randomized controlled trials, cluster-randomized trials)**

#### ***Resources Needed:***

- Monetary resources ranging from several hundred thousand dollars to several million dollars, depending on work scope, duration, and complexity of the trial.
- Skilled investigators.
- Robust research staff, including data managers, collectors, editors, analysts, project coordinators/managers, research clinical assistants, engaged clinicians, biostatisticians.
- Institutional support and approval, including ethics review.
- May be facilitated by health information system with a robust electronic health record, information systems analysts and programmers, and health informaticians.
- May require health economists.
- Generally requires grant support.

#### ***Advantages:***

- Minimize bias.
- Increase rigor.
- Strong internal validity – tests efficacy, not effectiveness.

#### ***Disadvantages:***

- Very complex.
- Resource intensive, in terms of monetary and personnel costs.
- Long process.
- Weak generalizability.
- Persons randomized to control condition may not benefit.
- May have insufficient follow-up time to detect impact.
- Subject to bias, including selection, differential history, differential maturation, contamination.

- May have insufficient power to detect differences.
- Designs traditionally suited to explore the efficacy of conceptually neat components of clinical practice may be inadequate to study PROs in clinical practice, or conduct improvement or implementation research.

**B. QUASI-EXPERIMENTAL, OBSERVATIONAL, SURVEY, OR QUALITY IMPROVEMENT DESIGNS AND METHODS (e.g., improvement research, realistic evaluations, plan-do-study-act cycles, time series, cross-over, case-control, etc.)**

***Resources Needed:***

- Relatively lower monetary costs.
- Quality improvement personnel.
- Health information technology frequently required, but not generally other scientists or analysts.
- May require institutional support and approval, including ethics review.

***Advantages:***

- Most health systems and community settings have well developed quality improvement programs in place.
- Improvement research is usually fast, cheap, and may be more generalizable.
- External validity may be good – tests effectiveness, not efficacy.
- Sensitive to details of implementation, organizational history, leadership, and context.
- Relies heavily on simple pre-post, uncontrolled designs with the goal of identifying how to implement effective changes.
- In the case of plan-do-study-act (PDSA), requires minimal training and involves making small changes incrementally and learning from experience while doing so.
- All subjects assessed and may benefit.

***Disadvantages:***

- Significant risk for bias and lack of validity.
- Lack of optimal experimental control.
- Difficult to determine if an intervention resulted in an improvement.
- Generalizability from one site to another is limited.

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**APPENDIX: LITERATURE COMPARING MODES OF ADMINISTRATION**

<b>Author</b>	<b>Sample</b>	<b>N</b>	<b>Modes of administration</b>	<b>Topic/questionnaire</b>	<b>Results</b>	<b>Conclusion</b>	<b>Comments</b>
Barry, 1995 (1)	Visually impaired or illiterate men with history of BPH	124	Self-administration vs interviewer administration	American Urological Association Symptom Index (AUASI)	No significant difference between group mean scores	Although it should be self-administered when possible, interviewer administration appears to be acceptable.	
Beebe, 2007 (2)	Primary care and specialty internal medicine physicians	500	Web vs mail	Electronical Medical Record	Two different mixed-mode combinations. Overall response rates higher in the mail/web condition than in web/mail condition. Median response time was 2 days faster in the web/mail condition.	Key outcome variables appear to be unaffected by the data collection method.	
Bushnell, 2003 (3)	Persons with asthma and caregivers	154 (51 adults, 52 children, 51 caregiver s)	Paper and pencil vs computer	AQLQ(S), PAQLQ(S)), PACQLQ	Differences between paper and electronic version. ICC ranged from 0.72 to 0.96. Test-retest reliability of the electronic version yielded ICC ranging between 0.66 and 0.90. Patients preferred the electronic version.	Statistical evidence to support the use of electronic data capture for populations with asthma.	
Chambers, 1987 (4), No full text available online	Patients in a physiotherapy clinic	96	Self-completion vs telephone interview vs personal interview	MHIQ	Physical function, social function, and emotional function test-retest scores obtained by self-completion within a 1-week interval were most stable. Changes reflected by the physical function scores correlated with changes in physical function reported by a patient's physiotherapist.	Physical function scores on all three modes of administration were sensitive to change, but the mode of administration did not affect the size of the change scores.	
Cheung, 2006 (5)	Cancer patients	1265	Paper and pencil vs interview	FACT-G, FLIC, EORTC QLQ-C30	Except for one, all scales showed higher mean values in patients who were interviewed than patients who self-administered the questionnaires.  No interaction between modes of administration and respondents' educational level.	Physical aspect of quality of life is not sensitive to interviewer administration but psychological aspect is.	Statistical adjustment for some scales is recommended.
Day, 2003 (6)	Participants who used	80	Face-to-face vs telephone	Rehabilitation, "Life	No statistically significant differences in mean scores on	It should not be assumed that all	

	eyeglasses as primary visual assistive device			Orientation Test", and "Psychosocial Impact of Assistive Devices Scale"	the questionnaire between the face-to-face and telephone mode of administration.	questionnaires will yield the same results regardless of the mode of administration used.	
Fouladi, 2002 (7), No full text available online	College students	?	Paper and pencil vs online	Inventory of Parental and Peer Attachment (IPPA), Negative Mood regulation Scale (NMRS), Trait Meta-Mood Scale (TMMS)	Statistically significant mode of administration effects, but the magnitude of the effects was small.	The basic similarity of the properties of the measures using paper and pencil and online modes of administration suggest the viability of the internet for assessing these and other psychological phenomena.	
Garcia-Losa, 2001 (8)	Benign prostatic hyperplasia (BHP) patients	926	Self-administered vs interview-administered	I-PSS	Interview-administration results in slightly lower scores.  Reliability is higher with same mode of administration at two recurrent visits.	Slight mode of administration effect. Measurement reliability can be increased by using the same mode of administration at baseline and follow-up visits.	
Grootendorst, 1997 (9)	Respondents and proxy respondents in the Ontario Health Survey	24215 paired assessments of emotion and 23953 of pain.	In person interviews vs self-completed written questionnaires	Ontario Health Survey.  Emotion, pain, labor force participation	High level of disagreement observed in responses. For emotion, percent agreement was 79, unweighted kappa 0.42. For pain these values were 47 and 0.19, and for labor force participation 96 and 0.91 respectively. Low kappa's may be an indication that mode of administration affected the responses.	Levels of morbidity reported by subjects to interviewer-administered questionnaires may underestimate morbidity relative to morbidity reported by subjects using self-administered questionnaires.	-
Gundy, 2010 (10)	Cancer patients	314	Paper and pencil vs telephone vs mail	EORTC QLQ-C30	Significant differences in group means for Emotional Functioning scale.  Minor significant difference in Cronbach's alpha between modes of administration for Role Functioning scale.	Mode of administration had little effect on reliability or mean scores, with exception of the Emotional Functioning scale.	
Hanmer, 2007 (11)	Noninstitutionalized US adult population	35667	Telephone vs mail vs self-administered	HRQoL: EQ-5D, HUI Mark 3,	In general, responses were more likely to be at the ends of the scale in telephone	When choosing survey-collected HRQoL scores for comparative	Older age groups and females

			with interviewer present	EVGFP	administration.  The percent who reported 'excellent' health is larger in telephone- than in the self-administered administration questionnaires.  Telephone administration yielded more positive HRQoL estimates than self-administration in older-age groups.	purposes, mode of administration has to be taken into account.	reported lower HRQoL than younger age groups and males, regardless of mode of administration.
Hepner, 2005 (12)	Patients receiving care from medical provider groups	880 (537 phone, 343 mail)	Telephone vs mail	Consumer Assessment of health Plans Study (G-CAHPS)	Only one significant mode-difference in item and composite means by mode after adjusting for case-mix differences.  No significant differences in internal consistency by mode.	Mail and telephone modes of data collection for the G-CAHPS survey produce similar results.	
Jorngarden, 2006 (13)	Persons aged 13-23 years	585	Telephone interview vs postal questionnaire	SF-36, Hospital Anxiety and Depression Scale (HADS)	The 16-23 year-olds reported higher scores on telephone interview. This difference was more marked among females. For the 13-15 year-olds there were less differences on mean scores on the scales between the modes of administration than for the other age-groups.	Mode of administration has to be taken into account when planning studies and comparing results from different groups.	
Kurt, 2004 (14)	Older primary care patients	54	Computer-assisted vs paper and pencil	CESDR20, GDS15, ADL, IADL	Correlation between computer and paper versions of GDS15 and CESDR20 were good, Pearson correlation coefficients 0.719 and 0.740 respectively. Intra-method reliability for the computer versions of GDS15 and CESDR20 yielded correlation coefficients of 0.697 and 0.849 respectively. Intra-method reliability for the paper versions was lower. Inter-method reliability and efficiency of computer assisted questionnaires compared to the paper and pencil versions were good or better.	Computer administered rating scales offer a reliable means of assessing health related data.	
Maisto, 2008 (15)	HIV positive and HIV	6000	Self-administration	Timeline followback	No significant differences in median total number of drinks	Data from this study provide strong	

	negative adults		vs telephone administration	(TLFB), daily alcohol consumption	between modes or sequence of mode administration. Good to excellent test-retest reliability of self reports for both modes of administration.	experimental evidence for the utility of the self-administered TLFB.	
Perkins, 1998 (16)	Community member list	1110 (495 telephone, 615 mail)	Telephone vs mail	SF-36	Significantly higher consent rate for telephone administration. Also, costs were lower and health ratings were more favourable for the telephone administration. Comparable levels of completed data and internal consistency reliability were found between the modes. T-test mean scores across modes differed significantly on four scales: Bodily Pain (P = 0.02), Social Functioning (P = 0.002), Role-Emotional (P < 0.001), and Mental Health (P = 0.007). Significant differences in internal consistency reliability estimates between modes.	Choice of survey administration mode should not be made on the basis of cost alone, as there are issues relevant to data quality that relate to the mode of administration.	Results are discussed in light of the advantages and disadvantages of each administration mode.
Pinnock, 2005 (17)	Adults with asthma	96	Postal administration vs supervised self-completion	Mini Asthma Quality of Life Questionnaire (MiniAQLQ) and Asthma Control Questionnaire (ACQ)	No significant differences in mean scores between both groups and a high degree of concordance and correlation (r = 0.96 for the MiniAQLQ, r = 0.94 for the ACQ).	Users may confidently choose the mode of administration most appropriate to their needs.	
Raat, 2007 (18)	Adolescents	933 (458 internet, 475 paper)	Internet administration vs paper version	Child Health Questionnaire Child Form (CHQ-CF)	Paper administration resulted in significantly higher scores on 4 of 10 CHQ-CF scales compared with internet administration (P<0.05), but Cohen's effect sizes were ≤ 0.21. This is a small effect. Mode of administration did not interact significantly with gender nor with age (P>0.05), except for the scales 'role-functioning-emotional/behavioural', 'mental health', 'self esteem', and 'general health'.	Differences between paper and internet administration can be considered as negligible or small.	
Rhodes,	Community	475	self-	American	Mean symptom scores were	Standardized method	

1995 (19)	men		administered vs face to face interview vs telephone interview	Urological Association Symptom Index (AUASI)	lower in the oral interview mode than in the self-administered mode of administration. In telephone interviews the scores were much lower than with self-administration.	of questionnaire administration should be used at baseline and follow-up.	
Ryan, 2002 (20)	Healthy individuals and chronic pain patients	115 (79 healthy, 36 chronic pain patients)	Electronic vs paper	SF-36	Less than 4% inter-version difference for any of the SF-36 sub-scales. Significant version effect only for the subscale 'social function', significant order effect for subscales 'vitality' and 'mental health'.	Electronic SF-36 is equivalent in performance and more effective than the paper version.	
Sikorskii, 2009 (21)	Patients with chronic conditions	386 (200 in nurse arm, 186 in AVR arm)	Automated voice response (AVR) vs live telephone interview with nurse	14 cancer related symptoms	Patients contacted by the AVR reported higher scores for several cancer-related symptoms controlling for prior intake symptom assessment that was free of mode effect. Symptom reporting varied by age.	Mode effect needs to be considered in designing trials for symptom management and in symptom monitoring in clinical practice.	
Vereecken, 2006 (22)	Adolescents	5092 (4083 paper and pencil, 1008 computer)	Computer-administered vs paper-and-pencil-administered	Health Behaviors in School-aged Children (HBSC) survey. Health and lifestyle behaviours (nutrition, substance use, physical inactivity, sexual behavior)	No significant differences for the majority of lifestyle behaviors. For questions about feelings/affective states, more socially desirable responses in the paper-and-pencil format.	Present findings suggest a need for further exploration of potential mode effects.	
De Vries, 2005 (23)	Hospital patients	20826	Mail vs telephone	CAHPS (ratings of hospital care)	Significant mode-effects for 13 of the 21 questions in the study. Compared with mail respondents, telephone respondents were more likely to rate care more positively and health status negatively.	Mode of administration should be standardized or carefully adjusted for.	
Webb, 1999 (24)	Adolescents (13-20 years) receiving services at community	671 (348 CASI, 323)	Computer-assisted self interview (CASI) vs written self-	Health behavior information (health protective	194 CASI were matched with 194 SAQ. No significant difference. Girls reported greater frequency and boys reported lower frequency of alcohol and	Maybe gender-related differences between modes of administration of specific health	Adolescents' attitude and comfort levels toward completing

	adolescent health clinics	SAQ)	administered questionnaire (SAQ)	behaviours, substance use, and sexual behaviours)	marijuana use on CASI than on SAQ.	behaviours.	different modes of data collection should be asked out directly in future studies.
Weinberger, 1996 (25)	Veterans in General Medical Clinic	172	Telephone vs face-to-face vs self-administration	SF-36	More positive ratings of HRQOL for face to face administration. Large variation in SF-36 scores over short intervals for all modes of administration.  No significant differences in mean scores and high internal consistency regardless of mode of administration.	SF-36 showed high internal consistency regardless of mode of administration, but large variation in SF-36 scores over short intervals may reduce its usefulness as an evaluative instrument.	
Wu, 1997 (26)	HIV patients and proxy respondents	68	Paper and pencil vs telephone vs interview	Medical Outcomes Study HIV Health Survey (MOS-HIV), EuroQol	Few differences in scores between self and interview administration and type of interview.	Data from self-administered questionnaires, face to face interviews and telephone administration can be pooled without compromising data quality.	
Young, 2009 (27)	Children (8-13 years) with cerebral palsy (5), spina bifida (23), and cystic fibrosis (27)	69	Paper vs web-based	Activities Scale for Kids (ASK), Pediatric Quality of Life Inventory (PedsQL)	Indeterminate, not enough power for statistical significance testing. Mean ASK score was 77.5 and mean PedsQL score was 69.1. Intermethod intraclass correlation coefficients for web-based administration were 0.98 for the ASK and 0.64 for the PedsQL, for paper they were 0.99 and 0.94 respectively. Both ASK and PedsQL were highly reliable on paper and on the web.	Web AKS was valid in comparison to the paper format. Mode of administration may be more important when using the PedsQL.	