There are vast amounts of research findings demonstrating the effectiveness of electronic clinical outcome assessment (eCOA) in improving clinical trial data quality and completeness. Further, a host of published literature on the benefits of patient-reported outcomes (PRO) data—such as reporting symptom occurrence on a near real-time basis, medication compliance tracking, understanding shifts in quality of life, etc.—is driving the rapid adoption of technology for collecting PRO data and supporting regulators’ guidance to trial sponsors on collecting these important data electronically.

Additionally, much research has demonstrated the equivalence of electronic PRO (ePRO) to its traditional paper counterparts, as well as patients’ preferences for ePRO over paper-and-pencil approaches. A survey by Industry Standard Research found that 55% of respondents strongly prefer ePRO systems over paper diaries and that 86% “somewhat prefer” them. Less publicized research demonstrates how eCOA positively impacts interactions between patients and their clinicians.

Here we summarize some of the research findings on how the use of electronic devices promotes patient/clinician interactions and enables better care.

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ePRO/eCOA Increases Patient/Clinician Interactions

Highly engaged and well-informed patients enable more efficient clinical visits and greater patient retention. The technology behind ePRO/eCOA can enable patients to think through their symptoms prior to meeting with site staff. As a result, patients are more likely to bring up health-related issues in discussions during the clinical visit, since the eCOA completion prompts memory. The following are some examples of research highlighting these factors:

- In a head-to-head comparison of electronic vs. paper diary completion using the EORTC-QLQ-C30 (from the European Organization for Research and Treatment of Cancer), 48.9% of the symptoms reported electronically were addressed at the clinic visit vs. only 23.6% documented on paper.¹
- In a study of 660 cancer patients, trial participants were given touch-screen tablets to complete the Electronic Self-Report Assessment–Cancer (ESRA-C), which includes items on symptoms and health-related quality of life. The ePRO reports to clinicians fostered discussions with patients during visits, clinicians were more likely to discuss issues flagged by the automated system during visits, and visit duration was unaffected.²
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**ePRO/eCOA Decreases Post-Operative Symptom Severity**

Use of ePRO/eCOA has proven to foster additional communication between patients and clinicians and improve patient care and post-operative symptom control. ePRO/eCOA has been shown to decrease post-operative symptom severity by having a standard programmed methodology for monitoring symptoms, as summarized here:

- Standard post-operative care was compared to the inclusion of e-mail alerts to the clinical team if specific symptoms crossed a threshold. In the e-mail alerts group, there was a 50% reduction in pain and an overall 11% decrease in severe symptoms. Eighty-four percent of clinicians responded to the e-mail alerts within 24 hours; there was no impact on clinical workflow. Sixty percent of alerts generated a call to the patient, 15% of the calls resulted in a medication change, and most calls educated patients about symptom control or reinforced use of prescribed medications.

**ePRO/eCOA Increases Patient Candor and Reporting of More Events and More Severe Events**

ePRO/eCOA also has been proven to increase patient candor, as patients are more likely to report more events and more severe events electronically than on paper. This principle applies across a spectrum of indications, and is generally applicable to patient-reported data. Patient reporting on diverse topics such as medication compliance and blood glucose levels are common examples, as detailed here:

- Diabetes subjects under-report hypoglycemic and hyperglycemic events on paper COAs 67% of the time. Further, diabetic patients using paper COA create blood glucose values and fail to record them. A systematic review encompassing 11 diabetes studies showed that among these three categories of errors, nearly 50% of paper COA data are inaccurate. eCOA mitigates any such errors.

- Several studies examined the impact of electronic and paper patient diaries on glycemic control and HbA1c levels. These studies found that increased monitoring in the electronic version may have encouraged positive behavioral changes and/or provided additional information on which patients could take action to improve their glycemic control.

The use of a mobile electronic diary vs. conventional clinic visits were compared in patients from a diabetes clinic in a crossover design study for 12 weeks. In the electronic diaries, subjects recorded meals and blood glucose levels, and they received immediate feedback on their nutritional intake. There was a significant improvement in HbA1c for the time that subjects were using the electronic diary vs. control period (HbA1c levels reduced 0.83%). Overall, the authors concluded that use of eCOA improved HbA1c levels.

- The eCOA diary has proven to be an important and better tool than paper for patients and healthcare providers to improve clinical care. It is well recognized that, for patients with diabetes, a key element to attenuating disease progression is good control of blood glucose levels. Studies show that for each percentage point decrease in HbA1c, microvascular complications are decreased by 35%.

- Patients reporting study medication intake on paper tend to report near 100% compliance, whereas these same patients reporting medication intake in an ePRO diary not only report doses taken, but also report missed doses as well as overdoses. Having an accurate picture of dosing is critical to determining drug efficacy and safety, as well as for interpreting pharmacokinetic and pharmacodynamics profiles (data on file with the author’s company).

**ePRO/eCOA Increases Patient Candor in Suicidal Ideation and Behavior**

Self-reported electronic data capture enables increased patient candor in suicidal ideation and behavior (SIB). Patients are more likely to reveal a higher frequency and severity of symptoms than site interviewer-ascertained. These phenomena are also well documented for other topics, including sexual activity, drug/alcohol abuse, obesity, HIV, and mental health. Some studies that focused on this area include the following:

- In major depressive disorder and bipolar disorder, self-reported questionnaires were two to four times more likely to reveal higher frequency and severity of suicidal ideation than clinician-ascertained. In an eight-year study in children and adolescents, 98 families were followed. Subjects completed a youth clinical interview and youth self-report assessments on suicidal ideation. Reports of suicidality were higher for the youth self-report (25% and 30% in the younger and older cohorts, respectively) than the interview version (11% and 24% in the younger and older cohorts, respectively).
Sixty-eight in-patients being treated for mood or anxiety disorders completed the self-reported Beck Depression Index (BDI) and clinician interview. Nine of the 50 participants (18%) who responded positively on the self-reported BDI were rated by clinicians as negative for suicidal ideations following the face-to-face interviews.10

In primary care, clinicians reported that an online electronic monitoring tool helped with engaging their patients, who were more willing to share how they were feeling in terms of symptoms, side effects, and their suicidal ideation online. Clinicians reported that this enabled them to better address patients’ health issues.11

Psychiatric patients who previously responded to questions on suicidal ideation and behavior indicated that they would be more likely to honestly report via self-report vs. via sharing their thoughts during a face-to-face clinical interview. The data showed that by using self-report instead of a clinical interview, one in five patients could potentially be prevented from a missed SIB event at a clinical visit because they are more likely to be honest through self-report. Moreover, SIB events might be prevented in one in four patients who are women and one in three patients who are under the age of 4512 (see Figure 1).

**NOTE:** Survey respondents were asked “If you were having thoughts of suicide or acts of self-harm, how likely would you be to HONESTLY answer questions in person vs. on an electronic device?”

**Conclusion**

ePRO and eCOA data capture methods serve science and clinical study operations in multiple ways. Attributable collection of symptom occurrence, medication compliance, and patient quality-of-life data continue to provide sponsors with more reliable insights into patient experiences during treatment, which supports regulators’ recommendations. Further, eCOA has proven to enable greater patient engagement with the clinician and the study, supporting greater candor during reporting on both the number and severity of events.

While the combination of improved data accuracy and quality—along with patient preference for electronic collection—is driving rapid adoption of the technology, some clinical trial sponsors persist in using outdated, familiar, paper-based methods. Since it is forecasted that ePRO/eCOA will become the norm and supersede paper diaries and questionnaires in the near future, clinical trial sponsors, as well as investigative site personnel and other trial stakeholders, would benefit from embracing the technology now, so as to not end up at a competitive disadvantage.

**REFERENCES**


**FIGURE 1: Likelihood of Honestly Answering Questions in Person vs. Electronically**

<table>
<thead>
<tr>
<th>Percent of Respondents</th>
<th>In Person</th>
<th>Electronically</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likely</td>
<td>74%</td>
<td>92%</td>
</tr>
<tr>
<td>Unlikely</td>
<td>26%</td>
<td>8%</td>
</tr>
</tbody>
</table>

**Source:** ERT, 2017

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