The QALY Lost index demonstrated a range of outcomes, with some arms clearly
superior. Michelle Melisko
A multicenter, phase 2 trial using response
scores, a single
Study participants were part of the I
scores.
Patients in the study were randomized to the control arm or seven experimental
arms, with patients in the control arm treated with Paclitaxel followed by
antracycline (AC).
Participants completed a validated QoL measure at baseline, prior to surgery,
and 1 month post-surgery. PROs were assessed using the NIH. Patient
Reported Outcome Measurement Information System (PROMIS®) measure and
at each time point used to calculate the PROp index, a single
utility-based index score to assess overall health-related QoL.
PROp is a preference-based summary score of health-related QoL, that is
constructed from 7 PROMIS® domains. In the current pilot study, the PROp
utility score was evaluated at three time points and used to generate a single
longitudinal QoL score or estimate of quality-adjusted life years (QALYs) lost
during treatment. For each patient, baseline QoL scores were used to calculate
the QALYs that would be experienced if they had not undergone treatment.
Nearly twenty percent (n=102, 18.5%) of patients had complete data across the
three study timepoints and were included in our analyses, and thus our data
represent a proof of concept study.

Figure 1: Example of QALY calculation using PROp scores.

Quality Adjusted Life Year – conceptually
Example:
No treatment QALY = 5 *(6.5/12) = 2.7
Baseline = 5 *(PROp), Pre-surgery = 4 *(PROp), Post-surgery = 3 *(PROp),
5.5 months: low baseline and pre-surgery, 1 month between pre and post surgery
Baseline to Pre-surgery: (5-4)/2 = 0.5 QALY
Pre-surgery to post-surgery: (-4+3)/2 = -0.5 QALY
Total QALYs = -2.5 during treatment
Lost QALYs = -0.2 during treatment - had they maintained baseline, they
would have enjoyed 0.2 QALYs more, which equates to 7.3 days at full health.

We are reporting the development of a novel, standardized assessment
that could form a routine part of clinical trials in oncology (Figure 2).

Figure 3: RCB Index, Quality of Life Lost, and Clinical Benefit Index Across
Eight Agents in the I-SPY Trial

CONCLUSIONS:
• The OCE represents a novel approach to providing summary data that
can be easily interpreted as part of clinical trial outcome data.
• Ideally, these integrated assessments would provide a more
comprehensive evaluation of investigational therapies, and ultimately
help inform treatment decisions and discussions between patients and
their providers.
• The collection of QoL data may also help motivate more timely
interventions to abrogate side effects in cancer care.
• Moving forward, electronic PRO data should be collected as part of
routine care in clinical trials, thus enabling a longitudinal QOL, and OCE
scores to be generated for every agent evaluated.