PROs and HRAs: the Hybrid Approach

Gus Gardner, Group President
• UnitedHealth Group acquired QualityMetric in March 2010
• Now Optum Outcomes, we offer tools and technology that capture the patient’s own assessment of their health (patient-reported outcomes)
• We have over 6,000 customers spanning the entire health care ecosystem
“The best measure of quality is not how well or how frequently a medical service is given, but how closely the result approaches the fundamental objectives of prolonging life, relieving distress, restoring function, and preventing disability.”

Lembke, 1952

"Anyone who can define health can transform the context of medicine."

Davis, 1987
Missing Data

• Claim Data
  - Date of service
  - Diagnosis
  - Procedure
  - Age
  - Gender
  - Frequency
  - Costs
  - Provider

• HRA/SF Data
  - Pain level
  - Depression
  - Health status
  - Vitality
  - Fall risk
  - Activities of daily living
  - Conditions
  - Symptoms
  - Cognition
  - Nutrition
  - BMI
  - Smoking
  - Substance abuse
  - Social support
  - Social functioning
  - Exercise
  - Medication adherence
How Optum can uniquely help

1. People
   - Unmatched health care expertise
   - 80,000 professionals

2. Technology
   - Comprehensive solutions
   - System-wide scale serving the unique needs of health care

3. Data
   - Insights that drive decision
   - Two decades of longitudinal data

4. Action
   - Scale to mobilize and achieve results globally
   - Helping:
     - 30 million people get the medicines they need
     - 18 federal agencies deliver technology enabled health care
     - 1 million people receive home visits to guide them to the right care
     - Process 500k documents per day by computer-assisted coding
     - 40 states expand coverage and make the most of their budgets
     - 50% of Fortune 500 companies increase employee wellness
     - 3 million people utilize health savings accounts
     - 25 million people receive services in international markets
     - 2 million people access care at local care delivery clinics
     - Tens of thousands of physicians leverage our data platform to provide smarter care

Powering Modern Healthcare
With a focus on real-world evidence (RWE) generation, insight and action, we are uniquely positioned to help our clients achieve success in directly affecting clinical care through our three core assets:

- Leading clinical, claims and consumer health care data that reveal the intricacies of your market landscape.

- Novel, first-in-class analytic platforms that turn data into insights.

- Unparalleled capabilities and proven expertise for deploying insights to change clinical care directly.
How Do We Harness All This Data?

- Good for the system™

- Decision-support tools
- Patient education tools
- Medical records that are dynamic, not just electronic
- Population health measurement
- Screening for chronic conditions
- Integrated care coordination
Turning Big Data into Smart Data

• **Velocity**
  - We are getting more and more streaming, real-time data …uninterpretable in real-time; and may take 3-6 months to rationalize.

• **Volume**
  - All large organizations are awash in data, easily amassing terabytes and petabytes of information.

• **Variety**
  - The types of data being collected are exploding… **Costs (Claims)**, **Clinical (EMR)**, **Outcomes (Biometrics)**, **Quality Measures**, **Patient-reported outcomes**, **Social Media**, **Mobile Apps**

• **Value?**
  - Does more mean more?
What We Know…

Claim Cost Distribution Analysis
Commercial Population
October 1, 2009 – September 30, 2010

• 40% of the population incurs 2% of the costs*

• 2% of the population incurs 40% of the costs*

*Cost include Prescriptions, Professional, Outpatient Facility, and Inpatient Facility

Adapted from Dr. Miles Snowden’s presentation at the Optum Health Education Conference 2011.
What We Don’t Know…

Claim Cost Distribution Analysis -- Commercial Population
October 1, 2009 – September 30, 2010

• 40% of the population incurs 2% of the costs*
• 2% of the population incurs 40% of the costs*

“Half of high costs claimants had minimal or no engagement in the prior year.”

Dr. Miles Snowden’s presentation at the Optum Health Education Conference 2011

• Adapted from Dr. Miles Snowden’s presentation at the Optum Health Education Conference 2011.
• Cost include Prescriptions, Professional, Outpatient Facility, and Inpatient Facility.
## Missing Data

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- Exercise
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“There’s a story told about a guy searching beneath a streetlight for his car keys. When asked, he admits that he lost them in a distant, dark corner of the parking lot. When asked why he isn’t looking where he lost them, he replies, ‘The light is better here.’

That story captures quality metrics in health care today. In too many cases, we’re looking at what we can easily measure—where the light is good—instead of measuring what matters most...”

- Scott Wallace, a visiting professor at Dartmouth’s Geisel School of Medicine

Wall Street Journal, 3/22/15
Why does systematic PRO Measurement **STOP** at Regulatory approval?
SF Bibliography

Total peer-reviewed articles citing the SF tools

Total randomized controlled trials using the SF tools

Breadth and depth of SF tools by condition/disease
Patient-reported Outcomes Featured in the WSJ

1/31/2012 -- Dartmouth-Hitchcock Medical Center’s William Abdu, MD says the surveys are part of the center’s shared decision making approach:

“For us, it is as important as looking at an X-ray or an MRI.”

4/16/2012 -- The Simple Idea That Is Transforming Health Care reports on health-related quality of life and well-being. The article links to our SF-36® Health Survey.
The Hybrid (HRA-HSA) Assessment Approach
The Difference Between HRAs and SF Health Surveys

- While HRAs offer valuable information, they offer little in the way of *real-time* health status and lack standardization and comparability across individuals and populations.

<table>
<thead>
<tr>
<th>Health Risk Appraisal</th>
<th>Health Status Surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is it?</strong></td>
<td>Generally administered as part of a wellness program to identify areas for health improvement.</td>
</tr>
<tr>
<td><strong>What is measured?</strong></td>
<td>Behaviors like seatbelt usage, smoking, exercise, dietary habits, etc.</td>
</tr>
<tr>
<td><strong>What it means?</strong></td>
<td>A report of behaviors to address future health. A way to identify individuals for wellness interventions.</td>
</tr>
<tr>
<td><strong>How is it used?</strong></td>
<td>By insurers and wellness companies to engage individuals in behavioral change activities.</td>
</tr>
</tbody>
</table>
The next generation of measurement

Past

Claims data
- Offers diagnosis, procedures performed, dates of service, et al
- Represents past history and is not available in real-time

Present

Health risk appraisals
- Primarily used to educate individuals on the impact of lifestyle choices
- Behaviors identified, if changed, can impact future health

Future

Health status measures
- Scientifically valid measure of current health
- Is standardized and offers comparability across individuals and populations
The SF health surveys

The most **reliable**, rigorously validated, and widely used health status measures in the world

The surveys **measure** eight health domains and offer summary scores for **physical and mental health**

A score of 50 is considered average health, and all scores are **age, gender, and disease specific**

The scores are **standardized** so that outcomes are comparable across groups, time frames, and populations
“The Future is Already Here…”

“…it is just not very evenly distributed.”

William Gibson

The dark prophet of cyberpunk fiction
A smart measurement system for all populations

Chronic conditions, depression, barriers to care, substance abuse, comorbidities, frailty, social support, pain, vitality, disease burden, cognitive functioning, et al

• The Smart Measurement® System

Member Engagement
- Online
- Smart phone
- IVR (Phone)
- Interviewer
- Paper w/ fax back
- Alerts/Reminders

Measurement Tools
- SF surveys
- HRAs
- Disease-specific
- Pediatric
- Customized items for each population

Scoring Normative Data
- US population, n: 40,000+
- 11 countries, n: 45,000+
- 25 chronic diseases
- Medical expenditures

Reporting
- Individual
- Groups
- Providers
- Aggregate
- Trending
- Customized

Analytics
- New tool development
- Burden of disease
- Expense prediction
- Et al

Screening and Stratification
Risk Prediction
Program Evaluation
Cost/Benefit Analysis
Disease Registries
SF12/36™ scores correlate with utilization

**SF-12 MCS Scores**
- Depression Diagnosis:
  - 0%: 1x
  - 5%–10%: 3x
  - 10%–15%: 4x
  - 15%–20%: 5x
  - 20%–25%: 8x
  - 25%–30%: 10x
  - 30%–35%: 13x
  - 35%–40%: 18x

**SF-12 PCS Scores**
- Hospitalization within 6 months:
  - 15–25: 9x
  - 25–30: 4.6x
  - 30–35: 2.9x
  - 35–40: 1.7x
  - 40–45: 1x

**SF-36 PCS Scores**
- Total Mean Monthly Expenditures:
  - 55–65: 1x
  - 45–55: 3x
  - 35–45: 6x
  - 25–30: 10x

**SF-36 PCS Scores**
- Job Loss Due to Health:
  - 9–35: 4.6x
  - 35–45: 2.9x
  - 45–55: 1.7x
  - 55–65: 1x

**SF-36 PCS Scores**
- Total Mean Monthly Expenditures:
  - 55–65: 1x
  - 45–55: 3x
  - 35–45: 6x
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**SF-12 MCS Scores**
- Depression Diagnosis:
  - 0%: 1x
  - 5%–10%: 2x
  - 10%–15%: 8x
  - 15%–20%: 10x
  - 20%–25%: 24x
  - 25%–30%: 35x
  - 30%–35%: 42x
  - 35%–40%: 51x
  - 40–45: 60x

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  - 0%: 1x
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SF12/36™ scores highly correlate with utilization

- Adding **SF-12** scores to regression models improved prediction of subsequent medical expenditures (increased $R^2$ from 0.26 to 0.29).

(Fleischman, Cohen, Manning and Kosinski 2006)
Smart Measurement® System Dashboards

Screen New Members

Understand Future Risk

Evaluate Treatments

Track Trends

Plan Interventions

Refine Data/Sort
PROs help facilitate patient-doctor communication

- Real-time data collection and reporting
Real Time, Automated Decision-support Tools

Look at health from every angle
SF health surveys predict utilization and costs

1. SF-12 scores significantly improve the prediction of hospitalization, institutionalization, and mortality in the elderly over complex comorbidity indices (Mayo NE et al, 2005)

2. SF-36 predicts use of post discharge medical services or long-term care placement among general medical patients (Fairchild DG et al. 1998)

3. PCS-36 predicts subsequent utilization of primary care, hospitalization, diagnostic services, and specialty care over 1-year (Bertakis KD et al. 2010)

4. SF-36 predicts emergency room visits among migraine patients, especially MCS-36 (Freitag FG et al. 2005)

5. Pre-admission SF-36 scores predict 6-month mortality among patients entering ICUs (Hofhuis JG et al, 2007)


7. SF-36 predicts mortality and hospitalizations among end stage renal disease patients (Parkerson GR et al. 2000)

8. SF-36 improves prediction of medical expenditures and hospitalization in general Dutch population (Stam PJ et al. 2010)

9. PCS and MCS scores were significant predictors of both hospitalization and death. For respondents with PCS scores in the lowest quartile (versus those in the highest), risk of death was 5.99 times as great (95% CI=1.90-18.95). (Dorr et al., 2006)

10. SF-12 improves prediction of total annual medical expenditures over 1-year in the general population (Fleischman et al 2006)
Addenda
The Science
Our scientific heritage: the test of time

Health Insurance Experiment:
- The first use of psychometrics in health surveys
- Demonstrated that self-administered surveys are reliable and valid

1974

Medical Outcomes Study:
- Four-year observational study of practice style for over 23,000 chronically ill patients
- Surveys measured 40 health concepts and became the basis for the SF-36 Health Survey

1986

The Medicare Health Outcomes Study:
- The 1997 Balance Budget Act directed Medicare to focus on the health status of beneficiaries
- The SF-36 was recommended as a core measure in an annual assessment of physical and mental health

1998

Improved versions of the SF surveys:
- The SF-36v2® and the SF-12v2® Health Surveys are made available
- Improvements were made to item wording and response choices

2000

QualityMetric founded:
- Our mission was to expand the application of PRO measures. Using emerging technologies, we set out to make these health surveys more accessible to patients, and the results more meaningful and useful for decision-makers.

2003

Asthma Control Test:
- The Asthma Control Test™ is a five question health survey used to measure asthma control in individuals 12 years of age and older.
- The survey measures the elements of asthma control as defined by the National Heart, Lung and Blood Institute (NHLBI).

2015

QualityMetric acquired
- In March QualityMetric was acquired by UnitedHealth Group and is now part of Optum.
The Technology
Data management capabilities

Stable
- 2001 – Health Status portal
- 2005 – ePRO system
- 2010 – EDC
- 2012 – Integrated w/CTMS, eTMF
- 2013 – 24 LP up & running
- 2014 – AbsTrak Integration & Dashboards

Scalable
- Total Groups: 921
- Total Sites: 47,165
- Total Patients: 3,007,367
- Total Surveys/Forms: 608
- Surveys/Month: 46,039 (Avg. Jan-Sep 2014)

Secure
- HIPAA
- FDA 21 CFR Part 11
- SAS 70, ISO 27001: 2005
- SSAE 16

Annual Survey Administrations
Other Health Related Outcomes

General health status was assessed by the Short Form health survey (SF-36). In studies I, IV, and V, patients receiving XELJANZ 5 mg twice daily or XELJANZ 10 mg twice daily demonstrated greater improvement from baseline compared to placebo in physical component summary (PCS), mental component summary (MCS) scores and in all 8 domains of the SF-36 at Month 3.
Oral SOLO and Oral STEP Trials*

**Oral Solo**

**Oral Step**

*Calculated from tabulated data posted on clinicaltrials.gov*
Our Recent Interactions with the FDA (SEALD and DPARP)

• We have been invited to submit the SF-36v2 Health Survey to be a qualified endpoint for RA trials
  • Invitation came during Pfizer’s negotiations for Xeljanz label
  • Submission in progress…

• Emphasis on standardization
  • In administration and scoring
  • In interpretation and display of results
  • In labeling language across the SF-36 profile

• Also working with regulators (US and EU) to protect intellectual property and trade secrets related to PRO endpoints and analysis
  • Hold our SF scoring algorithms as a “trade secret” so sponsors don’t need to include the algorithms in submissions
SF-36 and Labeling

• FDA confidential commentary:
  – “[SF-36]…is a legacy measure of general health status that has been used across many rheumatologic conditions, particularly across multiple RA clinical trials, including clinical development trials in RA used to support approval and labeling. Its prior acceptance and usage has provided an extensive experiential basis to support its comparative utility due to a long tradition of use as a general measure of health status in RA. After much consideration, CDER made the decision that there was adequate justification to begin to again include SF-36 in RA labeling.”

• FDA stance on SF-36 as an acceptable endpoint across all conditions
  – “Findings from the SF-36 in clinical trials would need to be evaluated on a case by case basis. The appropriateness of including the SF-36 in labeling will depend on, among other things, the context of use (e.g., indication, patient population), whether the assessment of general health status provides additional important information that is not redundant to other assessments described in labeling, and whether other preferred assessments exist for that context of use.”
  – Has some limitations but long history of use provides sufficient comfort to support labeling claims that are meaningful to patients and clinicians
  – FDA encourages sponsors to think carefully about instrument selection and work with the Agency early in drug development to identify and select appropriate outcome assessments
NCQA HRA Certification

NCQA HRA Certification Entails Meeting 3 Requirements

Privacy and Confidentiality:

Physical and Electronic Access
Uses and Disclosures
Informing Individuals

Health Appraisal minimums:

Components and Scope
Frequency
Review and Update

Measuring Effectiveness

Participant/client experience
Opportunities for Improvement
Take Action to Improve and Evaluate

Certification involves a 6 Month “look back” from date of submission

Documentation submissions/audit of requirements
CDC HRA Plus Model

“CMS strongly encourages MAOs (Medicare Advantage Orgs) to adopt the components in the CDC Model HRA beginning in CY 2016.” CMS Call Letter Feb. 20, 2015.

CDC HRA Plus Model two-fold:

Assessment of:

- Physical Activity
- General Health
- Seat Belt Use
- Tobacco/Alcohol Use
- Nutrition
- Depression/Anxiety/High Stress
- Social/Emotional Support
- Pain
- ADLs/Instrumental ADLS
- Sleep
- Self Reported Biometrics
- Follow CMS (42 CFR 410.15)

“HRA PLUS”:
Employ health education, access to activities, healthy eating, environmental changes, smoking cessation, use of incentives and competitions in the workplace, etc. to achieve better outcomes compared to an HRA with feedback alone.
CMS - 42 CFR 410.15

Annual Wellness Visits

First Annual Wellness Visit:
- Medical and Family History
- List of Providers/Suppliers of care/services
- Biometric Measures
- Detection of any cognitive impairment
- Risk factors for depression
- Functional ability
- Screening schedule for 5-10 years
  - incl. risk factors & conditions (Incl. MH) requiring interventions
- Furnish advice/education/referral(s) as appropriate

Subsequent Annual Wellness Visits:
- Repeat and update
Thank You!