Optimizing Clinical Quality and Economic Value: Mutually Rewarding Goals for Payers, Providers and Patients

Spring Managed Care Forum
April 24, 2015
David Gregory, FACHE
Principal

Agenda/Learning Objectives

> To balance clinical and economic value in meaningful ways for all stakeholders with a focus on population health
> To develop and assess new protocols in Breast Cancer, Heart Failure, Depression and GERD
> To focus on the essential elements of performance-based program development using these disease categories
> To learn the requirements for developing a foundation for a performance-based payment program, including financial alignment
> To understand how new medical technologies can be ACO-friendly and mitigate risk for certain patient cohorts
The Future of Performance-Based Reimbursement

> No longer a “fad” for only the most sophisticated systems
> Implemented by government payers; private payers adopting similar models
> Rewards providers for quality of care improvements/health outcomes and cost containment
> Requires providers to work collaboratively to coordinate care, manage costs and produce quality outcomes
> Payment for value rather than volume
> Initial models are “no risk” – providers shared in upside savings only
> Full continuum of care connections are a big challenge
> What is the next generation once benchmarks are achieved?

Health Care Reform Changes Integration and Financial Risk

<table>
<thead>
<tr>
<th>Small % Financial Risk</th>
<th>Moderate % of Financial Risk</th>
<th>Large % of Financial Risk</th>
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<tbody>
<tr>
<td>FFS</td>
<td>Per Diem Payment</td>
<td>Value Based Purchasing</td>
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<td></td>
<td>Bundled Payments</td>
<td>ACO/Shared Risk Contracts</td>
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<td>Capitation</td>
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<tr>
<td>Limited Provider Integration</td>
<td>More Developed Provider Integration</td>
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Healthcare Reform Prompts CV Service Line Changes

<table>
<thead>
<tr>
<th>Traditionally</th>
<th>Reformed</th>
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<tbody>
<tr>
<td>Fee-for-service payment</td>
<td>Pay-for-performance, at-risk, shared savings, penalties</td>
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<tr>
<td>Focus on QUANTITY of services</td>
<td>Focus on QUALITY of services</td>
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<tr>
<td>Length-of-stay reduction</td>
<td>Balancing length of stay and readmission reductions</td>
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<tr>
<td>Index admission focus</td>
<td>Episode of care, long-term focus</td>
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<tr>
<td>Individual patient utilization and costs</td>
<td>Population utilization and costs</td>
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Health Plan/Accountable Care Perspectives

> The inter-relationship of medical and behavioral health care is a significant key
> Health plan outsourcing of key line items to benefit managers is on-going
> Incentives for “non-billable” case management services must be present
> Patient education/engagement assistance by the life sciences sector is in play
> Transitions of care nodes are ripe for improvement
  – Post acute utilization (e.g., readmissions) remain an opportunity for improvement
Case Study:
Faster testing of margins during lumpectomies can assist accountable care delivery systems to more effectively manage breast cancer patients.

Breast Cancer Treatment
MarginProbe Overview

> The MarginProbe™ System delivers real-time cancer detection in the operating room allowing for an immediate assessment of cancer on the margin of excised tissue
>
> MarginProbe detects cancer by assessing the electromagnetic response of tissue; the system allows the surgeon to apply external fields to suspect tissue, capturing the minute differences in electromagnetic properties
>
> The system characterizes the tissue’s electromagnetic signature and then compares those responses to an internal database of known signatures in healthy and cancerous tissues

MarginProbe Overview, Cont.

Fits easily into current practice

> MarginProbe is applied to all six margins of the excised tissue immediately following excision
>
> No contrast agents or markers are required
>
> Measurements take three to five minutes on average
MarginProbe Results

> Real-time results allow surgeons to evaluate margins for the presence of cancer and, if necessary, immediately excise additional tissue, potentially avoiding a second surgery

> MarginProbe detects both Ductal carcinoma in situ (DCIS) and invasive cancer

> In a randomized study of 300 breast cancer patients in Israel, the reoperation rate was reduced by 56% vs. standard of care when the MarginProbe System was employed

Economic Impact of the Use of MarginProbe

**Payers**
> Reduced repeat lumpectomies
> Reduced follow-up mastectomies

**Providers**
> Increased radiation treatments
> Reduced re-admissions
> Potential additional OR time for other procedures
MarginProbe Economic Impact Model

The model measures:

> The projected impact of an overall increase in the volume of breast cancer episodes
> Changes in the ratio of desirable lumpectomies to mastectomies that can result in an increase in favorable radiation volume
> The projected impact of lower re-excision rates due to the real-time margin testing power delivered by the MarginProbe

Population Health Implications

> The lumpectomy/radiation pathway is more desirable than the mastectomy pathway for all parties
  - Patients have less radical procedures with equally good outcomes (if not better)
  - Hospitals generate more profits
  - Payers/ACOs enjoy fewer repeat procedures
Case Study: Percutaneous ventricular assist devices can assist accountable care delivery systems to more effectively manage high-risk heart failure patients.

Percutaneous Cardiac Assist Devices

- pVAD is a minimally invasive percutaneous catheter-based device that is powered and controlled by its console and is designed to provide partial circulatory support.
- The Impella pump pulls 2.5 L/min of blood from the left ventricle through an inlet area near the tip and expels blood from the catheter into the ascending aorta; TandemHeart is another pVAD option that requires a transseptal puncture.
- The motor pump can be inserted via a standard catheterization procedure through the femoral artery, into the ascending aorta, across the valve, and into the left ventricle.
- Key to pVAD is its ability to directly unload the left ventricle, thereby augmenting coronary flow and providing better hemodynamic support compared with the traditional IABP.

pVADs (Impella and TandemHeart)

PROTECT II Key Clinical Findings
90-Day Per-Protocol Analysis

Abbreviations: MACCE: Major adverse cardiac and cerebrovascular event; MAE: Major adverse event.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>IABP (n=211)</th>
<th>pVAD (n=216)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat Revascularization</td>
<td>12.4%</td>
<td>6.0%</td>
<td>0.024</td>
</tr>
<tr>
<td>MAE Rate</td>
<td>51.0%</td>
<td>40.0%</td>
<td>0.023</td>
</tr>
<tr>
<td>MAE Rate Post-Hospital Discharge</td>
<td>18.1%</td>
<td>7.9%</td>
<td>0.002</td>
</tr>
<tr>
<td>MACCE</td>
<td>31.0%</td>
<td>21.9%</td>
<td>0.033</td>
</tr>
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</table>

Significant Functional Status Improvement

New York Heart Association Functional Class Changes

Baseline

NYHA Class Distribution


N=223 patients with NYHA assessment available at baseline and 90 days

Payer Impact: Minimal Per Member Per Month Outlays

Non-Emergent Care Model
Mean cost per case for 12-month EOC

Emergent Care Model
Mean cost per case for 12-month EOC

Case Study:
Faster determination of appropriate psychotropic drugs via a pharmacogenomic assay can assist accountable care delivery systems to more effectively manage drug utilization and depression symptoms.
GeneSight Pharmacogenomic Assay From Assurex Health

Phase 1: Laboratory Analysis of Genotype
Phase 2: Creation of Composite Phenotype
Phase 3: Integration with Psychiatric Pharmacology
Phase 4: Interpretive Report Classification

Use as Directed
Use with Caution
Use with Caution and More Frequent Monitoring

Genesight Sample Report

Antidepressants

USE AS DIRECTED
- Sertraline (Zoloft®)
- Citalopram (Celexa®)
- Escitalopram (Lexapro®)

USE WITH CAUTION
- Do not exceed maximum dose.
- Measure drug levels frequently.
- Limited data on long-term safety.
- Use with caution in patients with liver disease.
- Use with caution in elderly patients.

Antipsychotics

USE AS DIRECTED
- Ziprasidone (Geodon®)
- Olanzapine (Zyprexa®)
- Quetiapine (Serentil®)
- Clozapine (Clozaril®)

USE WITH CAUTION
- Measure drug levels frequently.
- Use with caution in patients with a history of suicide.
- Use with caution in patients with liver disease.
- Use with caution in elderly patients.

Use of this drug may increase risk of side effects. Use with caution in patients with a history of suicide. Use with caution in patients with liver disease. Use with caution in elderly patients.
GeneSight Clinical Studies

GeneSight Psychotropic has been clinically validated in patients who have failed one or more psychiatric medications:

3. Furmaga KM, Achytes E, Smart L. The clinical impact of an antidepressant pharmacogenomic algorithm. Poster presentation; NCDEU 2012; Phoenix, AZ.

Cost Effectiveness: Pine Rest and UHS

> 30% of patients are currently prescribed medication incompatible with their pharmacogenomic profile (“red bin medications”) – Pine Rest
> Taking “red bin medications” results in minimal symptom improvement over 8 weeks – Pine Rest
> Taking “red bin medications” results in a 69% increase in healthcare utilization, 3-fold more medical absence days from work and 4-fold greater number of disability claims over one year – UHS
> Taking “red bin medications” results in an increase of $5188 in healthcare utilization costs annually – UHS
> Since 30% of patients are taking “red bin medications” the healthcare saving of testing all subjects to help these patients is $1556 annually
Cost Effectiveness – Predict Psymeds

The PREDICT PSYMEDs study was a prospective study of 2,176 GeneSight test subjects and 10,880 un-tested propensity matched controls who had initiated two different psychotropic medications within 90 days prior to GeneSight testing. Pharmacy claims were monitored prospectively for one year and used to analyze medication utilization and drug spend.

<table>
<thead>
<tr>
<th>Pre-Testing (180 Days)</th>
<th>Post-Testing (365 Days)</th>
<th>Group Change</th>
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<tbody>
<tr>
<td>Tested</td>
<td>Tested</td>
<td>Tested</td>
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<tr>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
</tr>
<tr>
<td>$644.33</td>
<td>$764.04</td>
<td>$701.80</td>
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<tr>
<td>Non-Tested</td>
<td>Non-Tested</td>
<td>Non-Tested</td>
</tr>
<tr>
<td>mean/pat-month</td>
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<tr>
<td>$701.80</td>
<td>$907.80</td>
<td>$565.00</td>
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<tr>
<td>Tested</td>
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<td>Tested</td>
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<tr>
<td>mean/pat-month</td>
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<td>mean/pat-month</td>
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<tr>
<td>$907.80</td>
<td>$1572.80</td>
<td>$665.00</td>
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<tr>
<td>Non-Tested</td>
<td>Tested</td>
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<tr>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
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<tr>
<td>$1572.80</td>
<td>$1835.60</td>
<td>$262.80</td>
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<tr>
<td>Tested</td>
<td>Non-Tested</td>
<td>Tested</td>
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<tr>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
</tr>
<tr>
<td>$1835.60</td>
<td>$2591.60</td>
<td>$755.00</td>
</tr>
<tr>
<td>Non-Tested</td>
<td>Tested</td>
<td>Non-Tested</td>
</tr>
<tr>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
<td>mean/pat-month</td>
</tr>
<tr>
<td>$2591.60</td>
<td>$3384.40</td>
<td>$792.80</td>
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> After testing with GeneSight patients spend $1,035.60 less annually on medications.
GeneSight: Population Health Implications

> In Cost Effectiveness Analysis (CEA) across a broad range of test pricing, GeneSight reduces total healthcare spend. Contributors:

– UHS Study: patients unknowingly on red bin meds experienced:
  » 69% more total healthcare visits (p=0.005)
  » 67% more general medical visits (p=0.02)
  » >3-fold more medical absence days (p=0.06)
  » >4-fold more disability claims (p=0.004)
  » Annual costs ↑ $5,188 (p=0.03) for these patients (2010 US$)

– Emerging Medco (PREDICT PSYMEDS) study data (n~13K)
  » GeneSight-guided patients ↓ drug spend by $86.30 per pat/mo (p<0.0001)
  » Equates to $1,035.60 annual savings when meds are GeneSight-guided

Conclusion: Magnitude and timing of GeneSight cost savings generates a rapid ROI to the healthcare payer, while delivering the appropriate treatment to the patient sooner.

Case Study:
The use of a non-invasive device to strengthen the gastro-esophageal sphincter can assist accountable care delivery systems to more effectively manage Refractory GERD patients
GERD

> *AGA REPORT 2006 – “..MOST COSTLY GI DISORDER IN U.S…”
> Over 20 MILLION PEOPLE IN U.S. HAVE GERD = TOTAL COST OF WELL OVER $30 BILLION+
> Prevalence of GERD in population based studies has ranged from 25 – 40% - based on severity, frequency and duration

* Reference: Wahlqvist et al 2006

Stretta System by Mederi Therapeutics

> A minimally invasive endo-luminal treatment of gastroesophageal reflux disease (GERD), indicated for patients who remain symptomatic despite a trial of high dose or a minimum of twice daily dose of proton pump inhibitors (PPI), or in patients who are unable to tolerate PPI therapy
> Not considered an alternative to effective PPI therapy, but rather is intended for those patients who remain unsuccessfully treated and whose only alternative option is anti-reflux surgery (surgical fundoplication)
> Target group of patients consists of those with moderate GERD symptoms despite maximal PPI therapy
> Fundoplication is indicated in patients with severe GERD symptoms, severe esophagitis or Barrett’s esophagus, and also in patients with a hiatal hernia greater than 3 cm
> Offers a “middle” therapy which may avoid a major surgical intervention, especially for those who are not good surgical candidates due to co-morbidities
The "Gap" That Stretta Fills

The Treatment "Gap" That Stretta Fills

PPI  The "gap"  ARS

65-70%  25-30%  5%

"Gap": % of patients refractory to PPI not pursuing ARS; ARS: Anti-reflux surgery

The Treatment "Gap" That Stretta Fills

PATIENT SELECTION CRITERIA - THE SPECTRUM OF GERD TREATMENTS

Medications (PPIs)

70% Respond to Meds
- Mild GERD symptoms
- Functioning LES
- Highly motivated patient
- Compliant to routine
- Tolerant of medication
  - No side effects
  - No drug interactions

25-30% Refractory GERD
- Mild to moderate GERD
- <2 cm hiatal hernia
- Partial response to meds
- Non-compliant to med routine
- Intolerant of long-term use of medication
  - Side effects
  - Drug interactions
- Post-bariatric surgery with GERD symptoms
- Non-erosive reflux disease
- Post antisinus surgery with GERD symptoms
- Extra-esophageal symptoms of GERD

5% Have Anti-Reflex Surgery
- Severe GERD
- Intolerant of long-term use of medication
  - Side effects
  - Drug interactions
- Post-Stretta procedure with GERD symptoms
- Erosive esophagitis
- >2 cm hiatal hernia (ARS)

SPECIAL INDICATIONS
TRANSORAL FUNDOPICATION
- <2 cm hiatal hernia
- <35 Body mass index

SPECIAL CONSIDERATIONS
IMPLANTED DEVICES
- Magnetic implants are not considered safe for MRI
RFE Mechanism of Action

**RFE MECHANISMS OF ACTION**

**INCREASED WALL THICKNESS**

"EUS demonstrates that LES muscle is significantly thickened after RF delivery. Thickening may result in reduced compliance of the LES junction and contribute to its mechanism of action."  


**INCREASED LES PRESSURE - DECREASED TLESRs**

"We reduced the rate of postprandial transient LES relaxations from 6.8 (3.7-9.6) (median [interquartile range]) per hour to 5.2 (4.2-5.8) per hour (p=0.01), and increased mean baseline LES pressure from 15.2 (SEM 6.3) mm Hg to 18.5 (SEM 4.8) mm Hg (p<0.01)"  


**DECREASED TISSUE COMPLIANCE**

"Stretta improved GERD symptoms and decreased GEJ compliance. Decreased GEJ compliance, which reflects altered LES neurovascular function, may contribute to symptomatic benefit by decreasing refluxate volume."  


**DECREASED ACID EXPOSURE**

"At 12 months, the mean 24 h pH scores, the LES basal pressure, the 24-h pH scores, and the proton pump inhibitor (PPI) daily dose consumption were significantly improved from baseline."  

Stretta Evidence of Improvement in Health Outcomes: 13 Years of Clinical Studies Safe, Effective + Durable

> 20,000 patients treated to date
  - > 3000 patients involved in Clinical Study
  - Demonstrated improvement outside of investigational setting
> 10 Year outcomes study published in Surgical Endoscopy
> 33+ published peer-reviewed studies
  - Consistency of reported results (US, EU, Japan, China)
  - Uniform protocols and inter-trial consistency
  - Use of validated clinical surveys
> Level I Evidence
  - 3 Randomized Sham Control trials
    » 158 total patients followed 3-12 months
    » Significant improvement in symptom scores or quality of life compared to Sham group
  - 1 Randomized vs. PPI

Stretta Budget Impact Model

> Objective of the model was to assess the budget impact of Stretta as an alternative to patients with Refractory GERD who either received a Nissen Fundoplication (Fundoplication cohort) or who are currently managing their condition medically and are considering a surgical intervention (medically managed cohort)
> The average costs associated with three major time points are captured:
  - 12 months prior to the procedure
  - The procedure itself
  - 12 months post-procedure for each patient cohort
> The pre-procedure and post-procedure average costs were categorized into Inpatient, Outpatient, Emergency Room, Professional and Pharmacy
> The model shows that no matter the amount of re-distribution from Fundoplication IP/OP and Refractory GERD to Stretta, there will be a PMPM savings; the amount of savings is dependent on both the size and type of the allocation along with the number of covered lives considered
Population Health Implications

> For patients with refractory GERD, Stretta is more desirable than the Nissen Fundoplication pathway for all parties
  – Patients have less radical procedures with equally good outcomes (if not better)
  – Payers/ACOs enjoy lower downstream costs

Lessons Learned/Recommendations

Goal: The right services at the right level of care, delivered at the right cost, will generate the right outcomes

> Provider engagement and financial alignment
> Timely communication and feedback
> Provider accountability
> Monitoring and control mechanisms
  – Documentation
  – Case management
  – Proactive responses to budget exceptions
  – Program administration
> Maintain and expand market share for all parties
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