ABCs of Value Based Care – Implications for Research

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Real-World & Late Phase Research
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Dr. F.X. Campion serves as a clinical informatics consultant to the Quintiles Real-World Late Phase Research business. Previously, he served as the Director for Provider Programs at Outcome, which was acquired by Quintiles in 2011. During his tenure at Outcome, Dr. Campion was responsible for development of the COMPASS Distributed Research network, oversaw clinical applications for several national clinical registries and managed Outcome’s PQRS, Meaningful Use and Joint Commission core measure registry programs.

Dr. Campion is a member of the Department of Population Medicine at Harvard Medical School and board certified in both internal medicine and clinical informatics. He maintains his internal medicine clinical practice at the Harvard Vanguard Medical Associates, Kenmore center in Boston. He served as the Director for Clinical Information Systems at Harvard Vanguard/Atrius Health from 2005-2007, helping to roll out the EpicCare EMR across the Atrius Health Care System. From 2007-2009, he served as Medical Director of HVMA’s Complex Chronic Care disease management service. He was the Vice President for Clinical Integration of the Caritas Christi Health System from 1995-2005 and served as the Director of Quality Resources at the Lahey Clinic in Burlington, MA, 1990-1995.

He received his AB degree in biology from the College of the Holy Cross, medical degree from Harvard Medical School and completed internal medicine residency training at the New England Deaconess Hospital.
Agenda

• The affect of value and quality incentive programs on clinical practice
• The affect of large provider organizations and electronic health records (EHRs) and disease registries on research
• EHRs’ role in patient and specialty healthcare association registries for quality improvement and research
• Facilitating enrollment in clinical trials using clinical decision support (CDS) in EHRs
• Using patient portals developed for patient care in clinical trials (e.g. patient reported outcomes / PROs data collection)
• Q&A
Today’s Webinar Audience
Polling Questions

A small number of polling questions have been added to today’s webinar to make the session more interactive.
EHRs + “Value Based Purchasing” – Driving Change in Healthcare

• Value Based Purchasing – defined

“Value-based purchasing is a demand side strategy to measure, report, and reward excellence in health care delivery. Value-based purchasing involves the actions of coalitions, employer purchasers, public sector purchasers, health plans, and individual consumers in making decisions that take into consideration access, price, quality, efficiency, and alignment of incentives. Effective health care services and high performing health care providers are rewarded with improved reputations through public reporting, enhanced payments through differential reimbursements, and increased market share through purchaser, payer, and/or consumer selection.”

Federal Government Health Reform: Incentives for Change

• Physician Quality Reporting System (PQRS) – 2007
• eRX – Electronic Prescribing Incentive Program - 2008
• Health Information Technology for Economic and Clinical Health (HITECH) Act 2009
  › Standardize EHRs
• Medicare and Medicaid EHR Incentive Programs
  › “Meaningful Use” program
  › 3 stages
• Affordable Care Act 2010
  › Expanding health insurance coverage
• CMS Shared Savings Programs / Accountable Care Organizations 2012
  › Direct contracting with medical groups and hospitals
Quality Measurement: Started in private sector but now embraced by CMS

- NCQA – National Committee on Quality Assurance – health plan, claims data
- BCBSMA – “Alternative Quality Contract”
- CMS – EHR Incentive Program and ACOs
# CMS – Physicians’ Bonus Scorecard

<table>
<thead>
<tr>
<th>Year</th>
<th>eRx</th>
<th>EMR</th>
<th>PQRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>2.0%</td>
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<td>2.0%</td>
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<td>2.0%</td>
</tr>
<tr>
<td>2011</td>
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<td>$18,000</td>
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<tr>
<td>2012</td>
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<td>$12,000-$18,000</td>
<td>0.5%-1.0%</td>
</tr>
<tr>
<td>2013</td>
<td>0.5%</td>
<td>$8,000-$15,000</td>
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<td>2014</td>
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<td>$4,000-$12,000</td>
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<td>2015</td>
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<tr>
<td>2016</td>
<td>No bonus</td>
<td>$2,000-$4,000</td>
<td>No bonus</td>
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Sources: 2012 Medicare physician fee schedule; Medicare and Medicaid EHR Incentive Program Basics, Centers for Medicare & Medicaid Services
CMS – Physicians’ Evolving Penalty Box

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<thead>
<tr>
<th>Year</th>
<th>eRx</th>
<th>EMR</th>
<th>PQRS</th>
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<tr>
<td>2012</td>
<td>-1.0%</td>
<td>No penalty</td>
<td>No penalty</td>
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<tr>
<td>2013</td>
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<tr>
<td>2014</td>
<td>-2.0%</td>
<td>No penalty</td>
<td>No penalty</td>
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<tr>
<td>2015</td>
<td>No penalty</td>
<td>-1.0%</td>
<td>-1.5%</td>
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<tr>
<td>2016</td>
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<tr>
<td>2017</td>
<td>No penalty</td>
<td>-3.0%</td>
<td>-2.0%</td>
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</table>

Note: Data for 2017 is for 2017 and beyond

Sources: 2012 Medicare physician fee schedule; Medicare and Medicaid
EHR Incentive Program Basics, Centers for Medicare & Medicaid Services
Accountable Care Organizations: “ACOs”

• Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients.

• The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors.

• When an ACO succeeds both in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program.

• Medicare Shared Savings Program — a program that helps a Medicare fee-for-service program providers become an ACO. Apply Now.

• Advance Payment ACO Model — a supplementary incentive program for selected participants in the Shared Savings Program.

• Pioneer ACO Model — a program designed for early adopters of coordinated care. No longer accepting applications.
ACO Quality 2015 Measures

- Falls: Screening for Fall Risk
- Influenza Immunization
- Pneumococcal Vaccination
- Adult Weight Screening and Follow-up
- Tobacco Use Assessment and Cessation Intervention
- Depression Screening
- Colorectal Cancer Screening
- Mammography Screening
- Percent of beneficiaries with IVD with complete lipid profile and LDL control < 100mg/dl
- Percent of beneficiaries with IVD who use Aspirin or other antithrombotic and/or LVSD
- Percent of beneficiaries with hypertension whose BP < 140/90
- Beta-Blocker Therapy for LVSD
- Percent of beneficiaries with diabetes whose HbA1c in poor control (>9 percent)
- Proportion of Adults who had blood pressure screened in past 2 years

Diabetes Composite
- ACO #22. Hemoglobin A1c Control (HbA1c) (<8 percent)
- ACO #23. Low Density Lipoprotein (LDL) (<100 mg/dL)
- ACO #24. Blood Pressure (BP) < 140/90
- ACO #25. Tobacco Non Use
- ACO #26. Aspirin Use

CAD Composite
- ACO #32. Drug Therapy for Lowering LDL Cholesterol
- ACO #33. ACE Inhibitor or ARB Therapy for Patients with CAD and Diabetes
CMS – Hospital Value Based Purchasing

• Proposed changes to the Hospital Value-based Purchasing Program (VBP)

• The Value Based Purchasing program builds upon the current Inpatient Quality Reporting (IQR) Program and uses performance data to adjust payments.

• In FY2015, the VBP will redistribute 1.50% (up from 1.25%) of hospital payments.

• CMS estimates this will allow for $1.4 billion in incentive payments.

• IQR participating hospitals submit for up to 46 selected measures across four measure sets:
  › stroke
  › venous thromboembolism
  › emergency department
  › perinatal care
# CMS – Hospital Incentives

*Cardiovascular Quality Measurement – Proposed Inpatient Prospective Payment System (IPPS) Rule*

<table>
<thead>
<tr>
<th></th>
<th>IQR: Inpatient Quality Reporting</th>
<th>VBP: Value Based Purchasing</th>
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<tr>
<td>AMI</td>
<td>• Median Time to Primary PCI • Timing of Receipt of Primary PCI</td>
<td>• Primary PCI Received Within 90 Minutes of Hospital Arrival (Note: Finalized deletion in FY2016) • Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival</td>
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<tr>
<td>Mortality</td>
<td>• Inpatient Mortality • AMI 30-Day Mortality Rate</td>
<td>• Acute Myocardial Infarction (AMI) 30-day mortality rate</td>
</tr>
<tr>
<td>Readmissions</td>
<td>• AMI 30-Day Readmission Rate</td>
<td></td>
</tr>
<tr>
<td>HF</td>
<td>• Evaluation of LVS Function • ACEI or ARB for LVSD</td>
<td>• Discharge Instructions (Note: Finalized deletion in FY2016)</td>
</tr>
<tr>
<td>Mortality</td>
<td>• HF 30-Day Mortality Rate</td>
<td>• Heart Failure (HF) 30-day mortality rate</td>
</tr>
<tr>
<td>Readmission</td>
<td>• HF 30-Day Readmission Rate</td>
<td></td>
</tr>
<tr>
<td>Total Program Measures</td>
<td>FY2015: 46 Measures (adding 11, removing 20)</td>
<td>FY2015: 19 total measures including 12 Clinical Process, 1 Patient Experience of Care Measure, 5 Mortality Outcomes and 1 Efficiency Measure</td>
</tr>
</tbody>
</table>

Poll 1

During your last visit to the doctor, did your provider use an electronic health record?

> Yes
> No
EHRs and Research - Living Side by Side

• EHR Definition

The Electronic Health Record (EHR) is a secure, real-time, point-of-care, patient-centric information resource for clinicians. The EHR aids clinicians’ decisionmaking by providing access to patient health record information where and when they need it and by incorporating evidence-based decision support. The EHR automates and streamlines the clinician’s workflow, closing loops in communication and response that result in delays or gaps in care. The EHR also supports the collection of data for (clinical analytics) uses other than direct clinical care, such as billing, quality management, outcomes reporting, resource planning, and public health disease surveillance and reporting.

• Source: http://www.himss.org/content/files/EHRAttributes.pdf
EHR Building Blocks

- Clinical data retrieval (labs, radiology, etc.)
- Problem list, medical/surgical history and medication list
- Computerized practitioner order entry (CPOE)
- Physician and nursing documentation
- Clinical decision support
- Clinical data repository
- Patient portal
- External reporting (public health applications and registries)

*required components of “certified EHR technology” for CMS incentive program
## EHR – Population Health Tools

<table>
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<tr>
<th>ID (both)</th>
<th>Patient Name</th>
<th>Home Phone</th>
<th>Last HBA1C</th>
<th>HBA1c</th>
<th>Neph Scrn</th>
<th>Last Eye Exam</th>
<th>LDL (dir)</th>
<th>Last BP</th>
<th>Systolic</th>
<th>Diastol</th>
<th>TYPE</th>
<th>PCP</th>
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<td>2000-06-0</td>
<td>2001-07-10</td>
<td>098.0 mg/dL</td>
<td>130</td>
<td>082</td>
<td>Medical</td>
<td>Self-Pa</td>
<td>Medical</td>
<td>Self-Pa</td>
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<td>16</td>
<td>RL</td>
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<td>2011-12</td>
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<td>2011-01-0</td>
<td>2012-02-03</td>
<td>132</td>
<td>080</td>
<td>Medical</td>
<td>Self-Pa</td>
<td>Medical</td>
<td>Self-Pa</td>
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<tr>
<td>16</td>
<td>N</td>
<td>543-2109</td>
<td>2002-11</td>
<td>009.1%</td>
<td>2002-10-0</td>
<td>2002-11-20</td>
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<td>080</td>
<td>Self-Pa</td>
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<td>2012-09-10</td>
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<td>086</td>
<td>Self-Pa</td>
<td>Self-Pa</td>
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EHR – Clinical Decision Support

According to the problem list, past medical history, or a diagnosis entered during this encounter, this patient has had a myocardial infarction and should be on a beta blocker unless contraindicated or currently not indicated. If either is either true, enter reason in Allergy module (pattern match to BETA-ADRENERGIC BLOCKING AGENTS & insert reason under Reaction) and consider entering in Problem List Comment for MI or CAD.

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EHR – CDS Medication Prescribing

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**OutOfRange**

From **BestPractice**: According to the problem list, past medical history, or a diagnosis entered during this encounter, this intervention is indicated. If either of latter true, enter reason in Allergy module (pattern match to BETA-ADRENERG CAD).

### Beta Blocker post MI

#### Medications

- **ATENOLOL TABLET 25MG 1 PO QD**
  - 1 tab po qd, Disp-30 Tab, R-1
- **ATENOLOL TABLET 50MG 1 PO QD**
  - 1 tab po qd, Disp-30 Tab, R-1
- **ATENOLOL TABLET 100MG 1 PO QD**
  - 1 po qd, Disp-30 Tab, R-1
- **METOPROLOL TARTRATE TABLET 50MG 1 PO QD**
  - 1 po qd, Disp-30 Tab, R-1
- **METOPROLOL TARTRATE TABLET 100MG 1 PO QD**
  - 1 po qd, Disp-30 Tab, R-1
- **PROPRANOLOL HCL TABLET 40MG 1 PO BID**
  - 1 po bid, Disp-60 Tab, R-1

#### Procedures

- **BETA BLOCKER CONTRAINDICATED [322520]**
  - Qty-1
- **BETA BLOCKER NOT CURRENTLY INDICATED [323304]**
  - Qty-1

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Advantages of Clinical Research Studies Using Electronic Health Record Databases

• Data acquisition is less expensive and less time-consuming

• Understand “real world practice”
  › Limit inclusion/exclusion criteria to study all patients with a given diagnosis or treatment or medical device
  › Compare effectiveness of different treatments for similar populations
  › Off-label and Over-The-Counter (OTC) treatments

• Can be conducted in situations where RCT are impractical or not feasible
  › Patient compliance and adherence
  › Follow-up for long-term benefits or delayed complications under conditions of real-world use
  › Include special patient subgroups and heterogeneous patient populations,
  › Events that occur with low frequency (condition or outcome)
  › Safety studies - both short term and long term retrospective analysis
EHR Data Analytic Capabilities Across the Pharma Life Cycle

- **Pre Clinical**
  - Unmet needs/Gap Analysis
  - Competitive Landscape Exploratory Research
  - Probe for new indications
  - Target Product Profiling Analysis
  - Physician/Patient Profiles

- **Phase I, II, III**
  - Product Profile Testing
  - Unmet Needs / Gap Analysis
  - Patient Recruitment
  - Protocol Feasibility
  - Research Site Recruitment
  - Adaptive Trial support

- **Phase IIIb, Launch**
  - Product Testing and Positioning
  - Patient/Physician profiles
  - Comparative Effectiveness Studies
  - Customizable Research
  - Probe for Safety and Side Effects
  - Patient Recruitment
  - Protocol Feasibility

- **Phase IV, Post Launch**
  - Observational Studies
  - ‘Real-world’ prescribing patterns
  - Comparative Effectiveness Studies
  - Longitudinal Adverse Event Monitoring
  - New Indication Research
  - Patient Registries
  - Safety Studies
  - QOL Studies
  - Comorbidity Studies
  - PRO Studies
  - QoC Studies

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**Pre Market**

**Post Market**
**Benefits of QEMR Database**

**Setting**
- National Coverage
- Large & Growing
- Majority Primary Care

**EMR Database**
- Nightly Uploads
- Uses Existing Data
- Reports All Data
- Ongoing Enhancements

**Quintiles Analytics**
- Flexible expertise
- Experience

**Providers**
- Responsive

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*Similar to U.S.*

Large numbers and increasing

Front line clinical data

Near real-time

Flexible, allows for ‘What if’

Unbiased

Additional data/data sources

Responsive to changing needs

Program engagement

Innovative consortium
Quintiles EMR Data

36 Million Unique Patients in Quintiles’ EMR Dataset, with over 17 million available for research (4+ activity days and at least 1 office visit)

- Data de-identified and HIPAA compliant
- Organized by practice to provide longitudinal medical record for each patient
- Available information includes demographics, vital signs, lifestyle characteristics, medical diagnoses, patient complaints, diagnostic and lab tests/results, procedures, insurance, and prescription detail

652 MQIC Institutions*
39,900 Providers (M.D., D.O., D.P.M., PA-C, RN-NP)
49 States and DC
EMR Geographic Coverage

QEMR Database: Patient Locations
2013-Q4, Research Patients*
17,113,223 Patients among 657 Provider Organizations in 341 Zip 3-digit Areas

*Research Patients: 4+ Activity Days Including at least 1 office visit (2004-2013)
QEMR Database Patients & US Population

Geographic areas served by the QEMR (Blue) are similar to the overall US population (Purple). QEMR patient demographic characteristics (Green) are similar to what we know about utilizers of healthcare--older, female, non-Hispanic (from National Ambulatory Medical Care Survey, NAMCS).

* ZIP codes with at least one Centricity EMR site
Publications Using the MQIC Database

Top Topic Areas
- Diabetes
- CV-Hypertension
- CV-Metabolic
- CV
- Database/Informatics
- Psychiatric
- COPD
- Health Management
- Population Health
Example publications from EHR database research

• Evaluating diagnosis and treatment patterns of COPD in primary care
• Patterns of use of antithrombotic therapy and quality of anticoagulation among
  with non-valvular atrial fibrillation in clinical practice
• New diagnosis of hypertension among celecoxib and nonselective NSAID
  users: a population-based cohort study
• Blood pressure outcomes in patients receiving angiotensin II receptor blockers
  in primary care: a comparative effectiveness analysis
• Association between oral antidiabetic use, adverse events and outcomes in
  patients with type 2 diabetes
• Six-month outcomes on A1C and cardiovascular risk factors in patients with
  type 2 diabetes treated with exenatide in an ambulatory care setting
EHRs and Registries – A Powerful Combination for Research

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<thead>
<tr>
<th>Characteristic</th>
<th>EHRs</th>
<th>Registries</th>
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<tbody>
<tr>
<td>Data collected for…</td>
<td>Individual patient health tracking &amp; physician orders support</td>
<td>Population research</td>
</tr>
<tr>
<td>Patients included</td>
<td>All in practice</td>
<td>Selected based on protocol</td>
</tr>
<tr>
<td>Provider-induced variability in data collection</td>
<td>Lots</td>
<td>None</td>
</tr>
<tr>
<td>Practice-based customization of data collection</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Data formats</td>
<td>Structured &amp; unstructured</td>
<td>Structured &amp; controlled vocabularies</td>
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<tr>
<td>Timing of data collection</td>
<td>Tied to patient encounters</td>
<td>Tied to protocol</td>
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<tr>
<td>Data quality assurance</td>
<td>Limited</td>
<td>Research specific validation rules</td>
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<td>Data standards</td>
<td>HL7</td>
<td>CDISC</td>
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</table>
American Heart Association – Get With the Guidelines® Registries

- Web-based, point of care registry that reinforces evidence based guidelines
- Over 3,000,000 patients prospectively enrolled in four disease modules
- 2,000+ participating U.S. hospitals
- Stroke, Heart Failure, Resuscitation, Afib
- Significant changes in behavior following introduction of the registry
- 80,000 impacted annually
- Continued improvement in all quality measures over years.

Winner of Secretary of Health and Human Services 'Innovation in Prevention Award'
AHA GWTG Stroke Registry

• >1,700 hospitals, >2 million stroke patients since 2004
• Impact on Stroke clinical guideline and evidence-based practice
• Implementation of the guidelines in conjunction with participation in the registry enables hospitals to:
  › Guide hospital team to practice evidence-based quality stroke care
  › Deliver thrombolytic therapy on time
  › Qualify as a “primary stroke center” – required for some EMS systems
  › Perform favorably on CMS quality measures and Joint Commission performance standards
Cystic Fibrosis Foundation

• Disease-based patient registry
• 115+ CF Care Centers in U.S.
• Support for global CF groups
• 27,000+ patients
• Promoting research and quality of care
• Integrated platform for enabling clinical trials
• Portal for all stakeholders including patients/caregivers
  › Information resource
  › Communication
Median Predicted Survival Age, 1988-2012

Source: Cystic Fibrosis Foundation Patient Registry 2012 Annual Data Report
### CF Drug pipeline

http://www.cff.org/research/DrugDevelopmentPipeline/

<table>
<thead>
<tr>
<th>CFTR Modulation</th>
<th>Pre-clinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>To Patients</th>
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<tbody>
<tr>
<td>Kalydeco™ (also known as ivacaftor)</td>
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</tr>
<tr>
<td>Ataluren (formerly known as PTC124)</td>
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<tr>
<td>Lumacaftor + ivacaftor</td>
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Data Interoperability – enabling Secondary Use of EHR Data

- **Primary Use**
  - Electronic Health Records
  - Care Givers

- **Secondary Use**
  - Quality
  - Research
    - Drug Safety
    - Clinical Research
    - Disease Registry
  - Public Health
Example – EHR View of a Gout Patient with Elevated Uric Acid

<table>
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<tr>
<th>Test</th>
<th>Value</th>
<th>Reference Interval</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron, Total</td>
<td>43 mcg/dL</td>
<td>40-175 mcg/dL</td>
<td>X0</td>
</tr>
<tr>
<td>LD</td>
<td>205 U/L</td>
<td>100-200 U/L</td>
<td>X0</td>
</tr>
<tr>
<td>Phosphate (as phosphorus)</td>
<td>4.2 mg/dL</td>
<td>2.5-4.5 mg/dL</td>
<td>X0</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>10.1 mg/dL</td>
<td>2.5-7.0 mg/dL</td>
<td>X0</td>
</tr>
<tr>
<td>Comprehensive Metabolic Panel w/EGFR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td>100 mg/dL</td>
<td>65-99 mg/dL</td>
<td>X0</td>
</tr>
<tr>
<td>Urea Nitrogen (BUN)</td>
<td>9 mg/dL</td>
<td>7-25 mg/dL</td>
<td>X0</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1.8 mg/dL</td>
<td>0.50-1.20 mg/dL</td>
<td>X0</td>
</tr>
<tr>
<td>eGFR Non-AFR. American</td>
<td>&gt;60 mL/min/1.73m2</td>
<td>&gt; OR = 60 mL/min/1.73m2</td>
<td>X0</td>
</tr>
<tr>
<td>eGFR African American</td>
<td>&gt;60 mL/min/1.73m2</td>
<td>&gt; OR = 60 mL/min/1.73m2</td>
<td>X0</td>
</tr>
<tr>
<td>BUN/Creatinine Ratio</td>
<td>15 (calc)</td>
<td>6-22 (calc)</td>
<td>X0</td>
</tr>
<tr>
<td>Sodium</td>
<td>141 mmol/L</td>
<td>135-146 mmol/L</td>
<td>X0</td>
</tr>
<tr>
<td>Potassium</td>
<td>3.0 mmol/L</td>
<td>3.5-5.3 mmol/L</td>
<td>X0</td>
</tr>
<tr>
<td>Chloride</td>
<td>105 mmol/L</td>
<td>98-110 mmol/L</td>
<td>X0</td>
</tr>
<tr>
<td>Carbon Dioxide</td>
<td>21 mmol/L</td>
<td>21-33 mmol/L</td>
<td>X0</td>
</tr>
<tr>
<td>Calcium</td>
<td>9.3 mg/dL</td>
<td>8.6-10.2 mg/dL</td>
<td>X0</td>
</tr>
<tr>
<td>Protein, Total</td>
<td>7.5 g/dL</td>
<td>6.2-8.3 g/dL</td>
<td>X0</td>
</tr>
<tr>
<td>Albumin</td>
<td>4.9 g/dL</td>
<td>3.6-5.1 g/dL</td>
<td>X0</td>
</tr>
<tr>
<td>Globulin</td>
<td>2.6 g/dL (calc)</td>
<td>2.2-3.9 g/dL (calc)</td>
<td>X0</td>
</tr>
<tr>
<td>Albumin/Globulin Ratio</td>
<td>1.0 (calc)</td>
<td>1.0-2.1 (calc)</td>
<td>X0</td>
</tr>
</tbody>
</table>
Within the EHR – Select Gout Registry Electronic Form
Gout Registry
“Pre-populate” Registry Form with EHR Data Leveraging Interoperability
Patient Reported Outcomes (PROs) – Expanded Research Impact

• PROs tremendously improve the relevance of clinical research

• Unlock important patient factors related to clinical effectiveness
  › Patient compliance with treatment regimen
  › Reporting of medication adverse effects
  › Identify patient beliefs regarding treatment effect
  › Monitor patient symptoms and understand relevance to their lives.

• Meaningful Use incentive program requires providers to offer patient portals for communication with providers

• This gives an opportunity to collect PROs via the EHR

• Some PRO instruments now include discrete, coded data
  › SNOMED and LOINC codes related to questionnaire responses
  › Pain scales
  › Functional status measures
  › Symptom scores
Patient Portals – links patients and providers
Poll 2

Have you every logged on to an EHR patient portal to retrieve test results, make an appointment, refill medications or ask for medical advice?

> Yes
> No
Patient Reported Outcomes

eSource Data Capture

• Site based ePRO using site computer or iPad
• Home-based ePRO by email
• SMS patient reminder messages
Value Based Purchasing - 17 States “All Payer” Data Sets Now Available

Interactive State Report Map
Learning Health Care System

...a vision of what is possible ... to transform the effectiveness and efficiency of care—to produce high-quality health care that continuously learns to be better.”

Best Care at Lower Cost: The Path to Continuously Learning Health Care in America

Mark Smith, Robert Saunders, Leigh Stuckhardt, J. Michael McGinnis, Editors; Committee on the Learning Health Care System in America; Institute of Medicine


450 pages

6 x 9

HARDBACK (2012)
Conclusions

› EHR adoption and “Value Based Purchasing” are transforming the U.S. healthcare system and have potential to accelerate major improvements in care
› Increasing volume and detail of clinical information available for analysis
› Increasing complexity of care – in pts with multiple chronic conditions
› All make real-world, EHR data increasingly valuable for clinical research
   » Can only achieve a portion of needed knowledge from RCTs
   » Expect combination of EHRs and Registries to accelerate using data interoperability standards
› Need thoughtful coordination and research plan for phase 3 through phase 4, then continuous cycle of data use and re-use for real-world knowledge and refinement
› Simultaneous initiative are underway to expand availability and access to large claims data sets and for the creation of “learning health care systems” focused on the continuous analysis and application of new knowledge to improve the safety and effectiveness of care.
› We are just at the beginning of great things to come.
Thank you
Previous & Upcoming Events

Quintiles experts run regular webinars on Real-World & Late Phase services. Topics include:

- OBSERVATIONAL RESEARCH & REGISTRIES
- SAFETY & RISK MANAGEMENT
- HTA & MARKET ACCESS
- MAXIMIZING VALUE AND QUALITY IN PHASE IV
- RARE DISEASE REGISTRIES
- COMPARATIVE EFFECTIVENESS RESEARCH
- CLINICAL OUTCOME ASSESSMENTS

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- SCOPE SUMMIT
- MEDICAL AFFAIRS LEADERS FORUM
- ISPE MID-YEAR SYMPOSIUM
- WORLD ORPHAN DRUG CONGRESS

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