HIGH-VALUE HEALTH CARE PROJECT

An initiative of the Quality Alliance Steering Committee

Supported by the Robert Wood Johnson Foundation
Directed by the Engelberg Center for Health Care Reform at the Brookings Institution

CLIAC Panel Meeting

Scott Endsley, Co-Chair
Expert Panel on Lab Data Integration for Diabetes Care Improvement

Min Gayles Kim
Engelberg Center for Health Care Reform at Brookings

February 10, 2010

Overview

- High-Value Health Care and Quality Alliance Steering Committee
- Project Overview
- Panel Recommendations

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Background: High-Value Health Care Activities

- Sponsored in part by the Robert Wood Johnson Foundation
- Organized across four major activities:
  - Data aggregation (joint initiative with AHIP)
  - Cost of care measures development
  - Data integration
  - Race/ethnic equities initiative

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Quality Alliance Steering Committee (QASC)

- Voluntary, multi-stakeholder collaboration formed in 2006
- Co-chairs: Carolyn Clancy, MD, and Mark McClellan, MD, PhD
- Provides national coordination to enable value-driven health care across all care settings
- Stakeholders include quality alliances, government, physicians, pharmacies/pharmacists, hospitals, health insurers, consumers, accrediting agencies, and foundations
  - Aims to advance high-value/quality, cost-effective, patient-centered health care by coordinating among entities engaged in implementing nationally-endorsed performance measures and reporting provider performance information, in an effort to enhance:
    - Performance improvement
    - Consumer decision-making
    - Effective payment policy and incentive structures for consumers
- Reviews and promulgates recommendations from the Data Integration Project

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High-Value Health Care – Lab Data Integration Project

- **Project objective:** to describe a path for practical and replicable solutions for the collection and integration of electronic lab data for direct patient care, care coordination, and performance measurement
  - Identify existing challenges and barriers to electronic exchange of lab data
  - Propose implementable recommendations to overcome these barriers and challenges
- **Project objectives to be achieved through two phases:**
  - **Phase I**: Documentation of existing public and private initiatives that are collecting and integrating electronic clinical lab data for patients with type II Diabetes Mellitus
  - **Phase II**: Engage Expert Panel to prioritize barriers and challenges and propose recommendations for overcoming barriers and challenges

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Phase I: Survey of Organizations

- Conducted semi-structured in-depth interviews (16) to document:
  - Motivation/rationale for electronic lab data collection and integration
  - Enabling factors/necessary conditions for implementation
  - Applications (primary and secondary uses) of lab data in diabetes care
  - Technical solutions implemented to enable electronic lab collection and integration
  - Challenges/barriers reported across each of these areas
- Compiled a summary of key barriers/challenges to successful electronic lab data integration:
  - Technical
  - Regulatory
  - Access
  - Financial

Phase II: Expert Panel on Lab Data Integration

Panel Membership:

Scott Endsley, MD, MSc (co-chair)
Cleveland Clinic

Mark Frisse, MD (co-chair)
Vanderbilt University

Doug Allen, MD
CareMore

Frederick Bloom, MD
Geisinger Health System

James Coates, MD
Aetna

Sarah Corley, MD, FACP
NextGen Healthcare Systems

Dave Dexter
Sonora Quest Diagnostics

Floyd Eisenberg, MD, MPH, FACP
National Quality Forum

Keith W. Hepp
HealthBridge

Donald E. Horton, Jr.
Laboratory Corporation of America Holdings

Charles Kennedy, MD
Wellpoint, Inc.

Robert Kolodner, MD
Collaborative Transformations, LLC

Benjamin Littenberg, MD
University of Vermont

Cathie Markow, BSN, MBA
Pacific Business Group on Health

Keith Michl, MD, FACP
General Practitioner/ACP

Michael W. Painter, JD, MD
Robert Wood Johnson Foundation

Elissa Passiment, EdM, CLS (NCA)
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Wes Rishel
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Sheila H. Roman, MD, MPH
Centers for Medicare & Medicaid Services

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McKesson Physician Practice Solutions

James L. Rosenzweig, MD
Boston University School of Medicine

Walter Sujansky, MD, PhD
Sujansky & Associates, LLC

Judith Yost, **MA, MT (ASCP)**
Centers for Medicare & Medicaid Services

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CLIA and Lab Data Integration

Impact of CLIA on electronic lab data integration:

- **Challenge #1**: CLIA provides that test results must be released only to "authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

State Laws Permitting Laboratories to Release Test Results to Providers

States	To person who requested test or their designee	To person authorized to use or responsible for using test	To person who requested test or person authorized to use or responsible for using test	To person as directed by person who requested test
AZ	√			
AR	√			
CA		√	√	
CT	√	√		
DC	√			
FL	√	√		
GA	√			√
HI	√		√	
IL	√			
KS	√			
ME	√			
MD	√			
MA	√			√
MO	√			
NV	√	√		
NH	√			

State Laws Permitting Laboratories to Release Test Results to Providers

States	To person who requested test or their designee	To person authorized to use or responsible for using test	To person who requested test or person authorized to use or responsible for using test	To person as directed by person who requested test
NJ	√	√		
NY	√	√	√	
OR		√	√	
PA	√		√	
RI	√			
TN	√	√		
WA	√	√	√	
WI		√		
WY	√			√

*Releasing Clinical Laboratory Test Results: Report on Survey of State Laws AHRQ Report

Expert Panel Recommendations

- **Recommendation 1:** CMS, with the assistance of the appropriate advisory panel, should develop and disseminate detailed CLIA Interpretive Guidelines. These guidelines should clarify the parties to whom a laboratory may release test results under 42 C.F.R. § 493.1291(f).
  - Expand and specify the definition of “authorized person” to be inclusive of non-ordering providers, HIEs, and other HIPAA covered entities and business associates involved in supporting direct patient care and enabling secondary use of lab data (e.g., disease management, performance measurement and reporting).
  - CLIA requirements should permit concurrent laboratory reporting of results to an authorized entity and to the lab ordering provider. CLIA must also “modernize” to more appropriately regulate technology-enabled lab data reporting and use while not standing in the way of efforts to improve, measure, and reimburse for quality.

CLIA and Lab Data Integration

Impact of CLIA on electronic lab data integration:

- **Challenge #2**: CLIA provides that the laboratory must have an adequate manual or electronic system in place to ensure test results are accurately and reliably sent from the point of data entry to final report destination. While CLIA does not specify the manner in which this verification is to be provided, laboratory personnel interpret CLIA as requiring them to certify by manual visual inspection that the EHR system to which lab results are transmitted are displaying the results consistent with CLIA reporting requirements.

Expert Panel Recommendations

- **Recommendation 2:** Guidelines should describe the verification methods that laboratories must use to ensure accurate and reliable transmission of test results to an EHR when electronic verification methods are not available.
  - Interpretation of CLIA's requirement of laboratories certifying lab results display in EHR systems should be updated to align with CMS's forthcoming certification requirements for EHRs and CMS's forthcoming meaningful use requirements.
  - This should be operationalized such that a lab will be deemed compliant with CLIA requirements if:
    1. it transmits lab result data to an EHR system in the prescribed standard messaging format; and
    2. the EHR system has been certified to manage and display lab result data in compliance with CLIA requirements.

Expert Panel Recommendations

- **Recommendation 3:** Application of CLIA regulations should be aligned with meaningful use requirements and target date for achieving meaningful use requirements. CMS should begin the process to amend the CLIA regulations accordingly.

Thank you.

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