

# **Conflict-free Procurement and Evaluation: *The Need for Transparency***

## **Medicaid Track**

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# Today's Discussion

- 1. Good News & . . . . A Crises of Credibility**  
*- DM Industry Challenges*
- 2. Good News & . . . . A Crises of Credibility**  
*- Medicaid DM Challenges*
- 3. Medicaid Case Studies**  
*- One quick case study*
- 4. The Problem: Lack of Transparency**  
*- Methods, Interests, Results*
- 5. Proposed Solution: Credible Impact Studies**  
*- Transparency in Methods, Interests, Results*

# DM in General: On the one hand ...

## Glowing 'DM Industry News'

**“CIGNA Posts Positive Outcomes for Diabetes DM Programs (7-25-04 Health Affairs)**

**“CCIP Will Remedy Chronic Care Crisis (5-25-04)**

**“Study Documents Value of Remote Patient Monitoring for Cardiac DM (8-25-04)**

# DM in general: *On the other hand . . .*

## Troubling 'DM News'

**“Actuarial, Analytic Issues Confound DM Outcomes Data: DMOs Must Tackle Issues to Resolve Credibility Problems”** (8-04 DM News)

**“Harvard Study finds Business Case for Diabetes DM Weak”** (7-04 DM News)

**“Employers Embracing DM, Despite Lack of Outcomes Proof”** (10-03 DM News)

# Medicaid ... *on the one hand*

## Glowing 'DM Medicaid News'

**“CMS Urges States to Establish Medicaid DM Programs**

(3-10-04: DM News)

**“DMAA to Congress: DM Could Save Medicaid “Billions”**

(10-03 DM News)

**“Florida Medicaid DM Saves \$15.9 Million in First Year**

(7-10-03: DM News)

**“Many new state contracts being written by DMPC.”**

***“Successful contract renewals, not reported by media”***

Al Lewis 7-2004 & 9-2004 (private communication)

## Medicaid ... *On the other hand*

### Troubling 'DM News'

**“Florida to Pull Plug on Medicaid DM”**

(8-10-04 DM News) *re: Value-added services by pharmcos.*

**“So. Carolina Withdraws DM RFP”** (7-04 DM News).

**“Critics Question Colorado Medicaid’s Asthma DM Claims”** (3-10-04 DM News)

***Challenges to one Early Adopter  
to DM Outsourcing***

***Florida Agency for Healthcare  
Administration (AHCA)***

# *Florida's DM Experience*

## ***Rocky Waters*** **Florida Legislative Progress Reports**

Office of the Florida Legislature, (OPPAGA)  
Office of Program Policy Analysis & Government Accountability

***Nov. 2001***

***“Expected Medicaid Savings Unrealized: Performance, Cost Information Not Timely for Legislative Purposes”***

***May 2004***

***“Medicaid DM Initiative Has Not Yet Met Targeted Cost-Savings & Health Outcomes Expectations”***

**<http://www.oppaga.state.fl.us/reports/health/r04-34s.html>**

# Florida Legislative Report

*May 2004*

***“After nearly 7 years, the DM initiative . . . .***

- ***“Continues to fall short of legislative expectations & goals.”***
- ***“Health outcomes have not been sufficiently evaluated.”***
- ***“Has reportedly saved \$13.4 million, however, the agency has not finalized cost savings for several programs.”***
- ***“Cost savings are likely overstated because . . . of weak approaches to estimating baseline costs.***

# Florida Agency for Healthcare Administration: *Response*

- *Legislative Expectations were overstated.*
- *Initial agreements included savings guarantees - that insured minimal savings.*
- *Evaluation of complex medical conditions, health outcomes & corresponding financial analysis were challenging at the time.*
- *State was faced with limited resources, authority & a lack of industry standards.*
- *Evolution of programs & savings measures have achieved improved measurement methodologies.*

*Source: Private communication with AHCA staff, Sept. 21, 2004*

### **3. Our Diagnosis of the *Problem*: A ‘*Crises of Confidence*’**

**Lack of reliable, trusted Information on:**

**Comparision of different ROI Models and  
comparison of different DM results ... these  
are both necessary for a smooth functioning  
market.**

**“Transparency” is needed.**

# **Lack of Transparency:** *Problems & Solutions Elsewhere*

**Before we examine this in DM,  
we wish to examine it elsewhere  
... to put it into context.**

**Transparency of**  
**METHODOLOGY**  
***in Scientific Research***

**Problem: Verification of Findings**

**Solution:**

- Replication of studies to assess validity of findings**
  
- Requires detailed disclosure of methods used**

# Transparency of **CONFLICTS OF INTERESTS** *in Scientific Research*

## **Problem: Biased findings due to conflict of interests**

- **NEJM: Calcium Channel Antagonists (n=75 articles). 63% had Conflicts, only 2 articles disclosed conflicts** *Source: Stelfox HT et al Conflicts of Interest in the Debate Over Calcium Channel Antagonists. N Eng J Med 1998; 338: 101-105*
- **NIH: Conflict of interests disclosed among NIH scientists**  
(*source: <http://pubs.acs.org/cen/news/8219/8219ethics.html>*)
- **AHA: Conflict of interests suspected at American Heart Association on Cholesterol Guidelines (Source: 6-16-2004 AP)**
- **Journals: “Journals not policing very well.” (Source: Center for Science in the Public Interest report)**

## **Solution: Disclosure**

**Declaration of Interests & declaration of each author’s role in publication: “let the public decide”**

# Transparency of RESULTS (I)

## Problem #1

- Product claims & research findings cannot be evaluated in a vacuum.

## Solution #1

- Literature review / critique in scientific publications
  - Benchmarking in many industries (e.g. JD Powers, Insurance Institute for Highway Safety, CMS, HEDIS, USN&WR)
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## Problem #2

- Publication bias: “positive findings more often reported than negative or inconclusive findings”

## Solution #2

In clinical industry .. A novel, widely agreed-upon solution

**Next pages:**

# Transparency of RESULTS (II)

**Pharmaceutical Research & Manufactures Assoc.**

## **Executive Committee of PhRMA (June 2004):**

- Unanimously adopted a set of principles for conduct of clinical trials and communication of results.

## **Principles:**

- PhRMA companies commit to the timely communication of all meaningful results of clinical trials, whether those results are positive or negative.
- Further, results are always to be communicated in an objective, accurate, balanced and complete manner.

# Transparency of RESULTS (III) Medical Journals Statement

**“Honest reporting begins with revealing the existence of all clinical studies, even those that reflect unfavorably on a research sponsor’s product” (September 16, 2004)**

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS



## Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors

Altruism and trust lie at the heart of research on human subjects. Altruistic individuals volunteer for research, clinicians, other researchers, and experts who write practice guidelines or decide on insurance-coverage

# Conclusions ... *in Other Industries*

## Three Areas Where Transparency is Warranted

1. Methods
2. Interests
3. Results

# Implications for DM

## 1. Methods

Disclosure of methods used to assess impact are needed.

## 2. Interests

Disclosure of potential conflicts of interest among those funding impact studies and conducting impact studies are needed.

## 3. Results

Next pages.

# Implications for DM

## Results

### *Make public all results?*

**No:** *There is no “gold standard” for assessing impact (like randomized trials in medicine).*

**Benchmarking** *(anonymous or not)?*

**Yes.** Two ways:

- *Similar DM programs to each other, using the same impact model.*
- *Different impact models using the same DM programs*

# IMPACT/ROI Models (I)

## *Individual Efforts*

Individual Efforts	Affiliation	Peer Review Articles
Selby, et al	<b>Individual</b> <i>(Kaiser - No Calif.)</i>	Determining the Value of DM Programs JCJQS
Linden, et al	<b>Individual</b> <i>(Linden Consulting)</i>	Numerous Papers <a href="http://www.LindenConsulting.org">www.LindenConsulting.org</a>
Wilson et al	<b>Individuals</b> <i>(Wilson Research, LLC)</i>	<b>ROI in State Programs</b> <b>RWJF</b>
Fetterolf et al	<b>As Individuals</b> <i>(e.g., Highmark &amp; Maine Medical Center)</i>	<b>Estimating ROI in DM Using Pre-Post Analysis</b> DMAA
Duncan et al	Lotter Actuarial Partners, Inc.	<b>An Actuarial Methodology for Evaluating DM Outcomes</b> (SOA - In press)

# IMPACT / ROI Models (II)

## *Industry Efforts*

Industry Efforts	Affiliation	Product
Disease Management Association of America	Trade Group	White Papers DM (in press)
Healthways – Hopkins	Vendor Sponsored	White Paper DM (Fall 2003)
Disease Management Purchasing Consortium	Privately Operated Consortium	White Papers, Training & ROI Certifications Available from DMPC
NMHCC DM ROI Workgroup	Independent Ad Hoc Group	Paper in JCAHO's J. of Quality & Patient Safety

# IMPACT / ROI

## Our Conclusions

### 1. No agreed upon method

*DMAA & NMHCC workgroup state “follow principles and recommendation” with any study design*

### 2. Do assessments in multiple ways

### 3. Benchmark reports needed ... apples-to apples comparisons.

# Need for ROI Benchmarking

## **METHODS:**

To provide credible, expert-based, assessments of impact / ROI models ( “methodology crash tests” ) to buyers, sellers, and users of evaluation information.

## **RESULTS:**

To provide credible, expert-based, assessments ( “program crash tests” ) the value of defined population health management programs.

***DISCLOSE POTENTIAL CONFLICTS OF INTEREST***

# Our Conclusion on ROI Assessments

**‘One standard’ can not become  
‘generally accepted’ or broadly  
‘adopted’**

**Because we cannot, currently,  
compare:**

- **Methods or**
- **Results . . .**

**Because of a lack of transparency.**

***Therefore, here is our proposal . . . .***

# Population Health Impact Institute

## *Key Principles*

- **Transparency**  
= methods and metrics
- **Fostering cooperation and collaboration**  
= sharing research results (*blinded and reported by client*)
- **Scientific Credibility**  
= recognized experts, publications, peer reviews
- **Independence & Accountability**  
= balanced industry leadership / Board
- **Methodology convergence**  
= convergence of statistical, epidemiological, and actuarial models

# **Population Health Impact Institute**

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# Conclusion

- **Crises of confidence in DM and Medicaid DM**
- **Similar crises have been dealt with in other industries, through more transparency.**
- **We argue for transparency in: methods, interests, and results**
- ***If you'd like to learn more about the Institute... feel free to contact us for more information:  
twilson@wilsonresearch-llc.com (513-289-3743)***