Implementing Models of HTE – Challenges and Opportunities

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Disclosures

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- **Copyrights/Patents:** SAQ, KCCQ, PAQ, ePRISM
- **Equity:** Health Outcomes Sciences, LLC
Presentation Goals

- Moving From Model Building to Implementation
- A Case Study of Implementing a Decision Aid
- Physician Barriers to Delivering Consistent Care
- A Case Study of Implementing a SDM Tool
- Concluding Thoughts
Delivering Precision Medicine Today

Knowledge Generation

Knowledge Translation Into Routine Clinical Care

Requires...
• Integration in workflow
• Clinically actionable information
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Using Registries to Improve Healthcare

Prospective Data Collection - NCDR

Periodic Benchmark Reports for Quality Assurance

Supports Quality Assessment through Benchmarking

Creation of Predictive Models

Requires a Novel IT Solution - ePRISM™

Improves Value with Precision Medicine

Prospectively Improve Health
Risk Models

\[ \eta = \beta_0 + \beta_1 x_{T1} + K + \beta_n x_{Tn} \]
\[ \eta = \beta x_{1T1} + K + \beta_n x_{Tn} \]
\[ \eta_i = \beta_{i0} + \beta_{i1} x_{T1} + K + \beta_{i n} x_{Tn} \]

\[ \pi_i \quad i = 1 \]
\[ \mu_i = \pi_i - \sum_{j=1}^{i=1} \pi_j \quad i = 2, K, s \text{ where } \pi_i = \Phi^{-1} (\eta_i) \]

\[ (\eta_{LO}, \eta_{HI}) = \eta \pm t_{\nu, \frac{\alpha}{2}} \sqrt{\frac{\sigma^2}{\nu}} \]

\[ \sigma^2 = \begin{bmatrix} 1 & 0 & 0 \\ x_{Tgl} & M & 0 \\ x_{Tgn} & M & 0 \end{bmatrix} \begin{bmatrix} c_{00} & c_{0} & c_{0n} \\ c_{n0} & M & 0 \\ c_{nn} & M & 0 \end{bmatrix} \begin{bmatrix} 1 & x_{Tgl} & x_{Tgn} \end{bmatrix} \]

Decision Support Tools

Implementing Tools at Point-of-Care
Traditional Consents

- Written at 16th-grade level
- Written in Legalese
- Exceedingly vague
- Does not educate
- Does not inform
- Does not help patients
- Does not help providers
Implementing Personalized Medicine
A Precision Medicine Time-Out

Unidentified Patient

ACC Risk Score for PCI 2/16/17 16:58
Risk of PCI Bleeding 7.51% / High

Acute Kidney Injury 2/16/17 16:58
Risk / Class 12.15% / Above Average
To reduce AKI risk, limit contrast to: 112 mL

Bleeding Protocol

*Exclude PCI involving native Chronic total occlusion, Atherectomy
Testing the Benefits

Kaiser-Permanente
San Francisco, CA
Ed McNulty, MD

Mayo Clinic
Rochester, MN
Henry Ting, MD

Henry Ford Hospital
Detroit, MI
Mayra Guerrero, MD

Bay State Medical Center
Springfield, MA
Aaron Kugelmass, MD

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Bay State Medical Center
Springfield, MA
Aaron Kugelmass, MD

Yale New Haven Hospital
New Haven, CT
Jeptha Curtis, MD

Prairie Heart
St. John’s Hospital
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Marc Shelton, MD

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Oklahoma City, OK
Charles Bethea, MD

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Baylor Health
Plano Heart Hospital
Plano, TX
Bradley Leonard, MD

Washington University
Barnes-Jewish Hospital
St. Louis, MO
Richard Bach, MD
Precision medicine to improve use of bleeding avoidance strategies and reduce bleeding in patients undergoing percutaneous coronary intervention: prospective cohort study before and after implementation of personalized bleeding risks

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ABSTRACT

OBJECTIVE
To examine whether prospective bleeding risk estimates for patients undergoing percutaneous coronary intervention could improve the use of bleeding avoidance strategies and reduce bleeding.

DESIGN
Prospective cohort study comparing the use of bleeding avoidance strategies and bleeding rates before and after implementation of prospective risk stratification for peri-procedural bleeding.

SETTING
Nine hospitals in the United States.

PARTICIPANTS
All patients undergoing percutaneous coronary intervention for indications other than primary reperfusion for ST elevation myocardial infarction.

bleeding avoidance strategies within intervention sites increased with pre-procedural risk stratification (odds ratio 1.81, 95% confidence interval 1.44 to 2.27), particularly among higher risk patients (2.03, 1.58 to 2.61; 1.41, 1.09 to 1.83 in low risk patients, after adjustment for control sites; P for interaction=0.05). Bleeding rates within intervention sites were significantly lower after implementation of risk stratification (1.0% v 1.7%; odds ratio 0.56, 0.40 to 0.78; 0.62, 0.44 to 0.87, after adjustment); the reduction in bleeding was greatest in high risk patients. Marked variability in use of bleeding avoidance strategies was observed across sites and physicians, both before and after implementation.

CONCLUSIONS
Prospective provision of individualized bleeding risk estimates was associated with increased use of bleeding avoidance strategies and lower bleeding
Bleeding by Bleeding Risk

Fully-adjusted 45% Reduction in Bleeding (OR = 0.55 (95% CI = 0.39, 0.77))

Spertus et al. *BMJ* 2015; 350: h1302
Care is Currently Unreliable

9-Center Study of PCI and Decision Support
- 137 Operators across the 9 centers
- 7,408 Patients
- Assessed BAS use by Bleeding Risk
- Ideal Performance would look like this…

Spertus et al. BMJ 2015; 2015

Range = 1 – 100%
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Illuminating MD Behavior

= Improved Performance
= Ignorers
= Worse Performance

Outcomes from a Study

Risk Stratification
Categorizing Bival Use

Emphasizing Safety

- 52% Decreased Bleeding

De-emphasizing Safety

- 4% Decreased Bleeding

Emphasizing Costs

- 235% Increased Bleeding

De-emphasizing Costs

- 52% Decreased Bleeding

Relative Change in High-Risk Patients (OR)

8
4
2
1
0.5
0.25
0.125
0.125
0.25
0.5
1
2
4
8

Relative Change in Low-Risk Patients (OR)

Inc Safety, Dec Costs

Inc Safety, Inc Costs

Dec Safety, Dec Costs

Dec Safety, Inc Costs

8%
13%
36%
43%
Barriers to Physician Adoption of Risk Models

- Qualitative research study of 27 Interventionalists at 8 PCI centers

- 3 ‘Themes’ identified
  - Experience vs. Evidence
  - Rationing of Care
  - Perceived Value
Experience vs. Evidence

- “I think this has more to do with egos. Some physicians think that they’ve been doing this for years and years and years and they don’t need someone else’s tool to help them explain to the patient what they think is important.” (IC#: F-20; 24 years)

- “I would say that the practice habits and biases and stubbornness of cardiologists is probably the biggest obstacle” (IC#: H-23, 30 years)

Can we change physicians’ perspectives to supplement experience with evidence?
“At the end of the day, you want to do the best thing you can do for each and every patient, not just the high risk patients.” (IC#H-24; 9.5 years experience).

“Restenosis is never higher with a drug-eluting stent, never. So… why wouldn’t you put the Cadillac in everybody?” (IC# B-03; 20 years)

While we all acknowledge a need to reduce costs in healthcare, why not preferentially push for aggressive use in those who most benefit?
“..I don’t need [those] data to tell me what I already know. I already know this.” (IC# A-18; 25 years)

“The typical phrase you hear from operators is that I already know that information. That information is already in my head. Why do I need that form to tell me what to do?” (IC#: C-06, 2 years).

“I always try to minimize the bleeding risk regardless of what the person’s risk is up front in radial artery cases, when appropriate. And to see a number spelled out doesn’t really help me much in terms of what I would do.” (IC# D-19; 21 years)
5 Steps to Success

Step 1 – Identifying a Clinical Champion
Identify a Cath Lab Leader to Drive Change

Step 2 – Creating a Protocol
Create a Risk-based Protocol

Step 3 – Implementing a Standardized Time-out
Creating a Structured Time-Out

Step 4 – Measuring and Sharing Performance
Feedback and Accountability

Step 5 – Celebrating Success
Develop Rewards
Impact of Accountability

SLH 2012

SLH 2013

- Predicted Bleeding Rate in 2013: 6.5%
- Observed Bleeding in 2013: 2.4%
  - A third of predicted!
The Benefits of Greater Consistency

Incidence of PCI-Related Bleeding

- Implementation of the Risk Model
- Unblinded Feedback
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PCORI Grant to Implement SDM for Stents

◆ Development of a Decision Aid with Patients
  – Personalized benefits embedded

◆ 3 Phases of Implementation
  – Usual Care with Personalized Consents
  – Personalized Consents + SDM Aid + Decision Coach
  – Personalized Consents + SDM Aid

◆ Outcomes
  – Participating in the Decision
  – Having a Stent Preference
### Adjusted analyses of knowledge transfer and shared decision making

<table>
<thead>
<tr>
<th></th>
<th>Effect Measure</th>
<th>Post-Coach vs. Pre</th>
<th>Post-Coach vs. Post-No Coach</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Effect (95% CI)</td>
<td>P-value</td>
</tr>
<tr>
<td><strong>Knowledge Transfer</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total correct (out of 6)</td>
<td>Mean Difference</td>
<td>1.8 (1.5, 2.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>All questions correct</td>
<td>Risk Ratio</td>
<td>11.7 (4.9, 27.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Process of SDM</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussed stent types with nurse</td>
<td>Risk Ratio</td>
<td>3.7 (2.8, 4.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Perceived autonomy support from nurse (0-7)</td>
<td>Mean Difference</td>
<td>0.6 (0.2, 1.1)</td>
<td>0.006</td>
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<tr>
<td>Discussed stent types with physician</td>
<td>Risk Ratio</td>
<td>1.50 (1.26, 1.79)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Perceived autonomy support from physician (0-7)</td>
<td>Mean Difference</td>
<td>0.7 (0.3, 1.1)</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>Participation in SDM</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stated a stent preference</td>
<td>Risk Ratio</td>
<td>1.91 (1.57, 2.33)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Shared/kept stent choice decision</td>
<td>Risk Ratio</td>
<td>2.87 (1.84, 4.49)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Correctly recalled stent type received†</td>
<td>Risk Ratio</td>
<td>1.45 (1.14, 1.83)</td>
<td>0.002</td>
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<tr>
<td>Stent preference concordant with actual**†</td>
<td>Risk Ratio</td>
<td>0.97 (0.87, 1.08)</td>
<td>0.56</td>
</tr>
</tbody>
</table>

† For patients who received a stent; * For patients who voiced a stent preference

SDM = shared decision making
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Concluding Thoughts

◆ Models are Meaningless w/o Effective Implementation
  – Must be integrated within routine workflow
  – Simpler models are better

◆ Physician Acceptance is Critical
  – Compelling evidence is important, but not sufficient
  – Proof of benefit is important, but not sufficient
  – Accountability and incentives are critical

◆ Implementing SDM Requires Investing in Infrastructure
Rethinking Medical Decision-Making

From Mindless to Mindful Practice — Cognitive Bias and Clinical Decision Making
Pat Croskery, M.D., Ph.D.
2 Types of Human Decision-Making

Type 1: Automatic, Intuitive, Based on Past Experiences
- Easy to Use, Reflexive
  - Not always right

Type 2: Logical, Precise, Analytic, Organized
- Hard, Resource Intensive
  - Almost always right

2+2=??

17*23=??

Strongly Preferred

Used Only when Forced

The Challenge is to Make Type 2 Decisions Easy and Reflexive