Involving Patients in Decisions When Seconds Count: A Calling

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MDM 2017
October 24, 2017
Disclosure

• Financial Disclosure: Interventional trials funded by PCORI, contracts 952 and 12-11-4435

• Unlabeled or unapproved uses: none
What is Shared Decision Making? *Interpersonal Dynamic*

*Involving* the patient in making decisions to the extent they desire.

Elwyn and Edwards 2006
What is SDM?

Key Components

Unbiased Evidence

Clinician Expertise

Patient values
## Effects of Decision Aids

<table>
<thead>
<tr>
<th>Variable</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient knowledge</td>
<td>↑</td>
</tr>
<tr>
<td>Accuracy of risk perception</td>
<td>↑</td>
</tr>
<tr>
<td>Uncertainty related to feeling uninformed</td>
<td>↓</td>
</tr>
<tr>
<td>Major elective surgery</td>
<td>↓</td>
</tr>
<tr>
<td>PSA screening</td>
<td>↓</td>
</tr>
</tbody>
</table>

*Stacey et al. Cochrane Collaboration, 2011*
User-centered design process

Evidence synthesis (ACS risk estimation tool)

Observations clinical encounter

Initial prototype

Field testing

Designers
Study team
Patients
Clinicians
Stakeholders

Modified prototype

Final Decision Aid

Evaluation (trial)

Breslin, Montori Patient Educ Counseling 2008
Anyone, Anything, Anytime

A History of Emergency Medicine
Emergency
Background

- Chest Pain 2\textsuperscript{nd} most common complaint in US EDs
- 1.5\% of patients with ACS inappropriately discharged
- Stress testing or Coronary CTA frequently obtained in low risk patients
- False positive test results, unnecessary procedures, ↑cost
Chest Pain Choice Video Demonstration
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient knowledge</td>
<td>↑</td>
</tr>
<tr>
<td>Patient engagement</td>
<td>↑</td>
</tr>
<tr>
<td>Placed in EDOU for stress testing</td>
<td>↓ (19%)</td>
</tr>
<tr>
<td>Stress testing within 30 days</td>
<td>↓ (16%)</td>
</tr>
<tr>
<td>Provider experience</td>
<td>↑</td>
</tr>
<tr>
<td>Outpatient follow-up</td>
<td>↑</td>
</tr>
<tr>
<td>Safety</td>
<td>↔</td>
</tr>
</tbody>
</table>

Hess, Kline, Stiell et al. Circulation CQO 2012
Objective

Test the effectiveness of Chest Pain Choice on validated patient centered outcome measures and resource use in a pragmatic multicenter RCT
Methods
Design

• Parallel, patient level RCT
• Allocation concealed by password-protected, web-based randomization scheme
• Dynamic randomization
• 1:1 ratio
Eligibility criteria

• Inclusion
  • Adults with chest pain considered for EDOU admission for stress testing or coronary CTA

• Exclusion
  • Ischemic ECG
  • Elevated troponin
  • Known CAD
  • Cocaine use within 72 hours
  • Unable to provide informed consent or use DA
Outcome measures

- **Decision quality**
  - Patient knowledge**
  - Degree of patient participation (OPTION scale)
  - Acceptability

- **CV endpoints**
  - Safety: 30-day MACE
  - Resource use
    - Admitted to EDOU for stress testing or coronary CT
    - 30-day rate of stress testing/coronary CT
Results
# Baseline characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n=451)</th>
<th>Intervention (n=447)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>50.6</td>
<td>459.2</td>
<td>0.57</td>
</tr>
<tr>
<td>Female</td>
<td>58%</td>
<td>56.7</td>
<td>0.41</td>
</tr>
<tr>
<td>HTN</td>
<td>55%</td>
<td>1.0</td>
<td>0.70</td>
</tr>
<tr>
<td>Dislipidemia</td>
<td>69%</td>
<td>56.9</td>
<td>0.07</td>
</tr>
<tr>
<td>Family history of premature CAD</td>
<td>59%</td>
<td>25.4</td>
<td>0.62</td>
</tr>
<tr>
<td>Mean PTP of ACS</td>
<td>3.8%</td>
<td>1,256.2</td>
<td>0.46</td>
</tr>
</tbody>
</table>
## Knowledge and Engagement

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n=451)</th>
<th>Intervention (n=447)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge (% correct)</td>
<td>44%</td>
<td>53%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Engagement (OPTION scale)</td>
<td>8</td>
<td>18</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Decision aid acceptability (patient)

- Amount of information (just right): Control 85%, Intervention 95% (P=0.01)
- Clarity of information (extremely clear): Control 70%, Intervention 80% (P=0.004)
- Helpfulness (extremely helpful): Control 70%, Intervention 80% (P=0.004)
- Would recommend to others: Control 60%, Intervention 80% (P=0.004)
Decision aid acceptability (clinician)

- Helpfulness (extremely helpful)
  - Control: P<0.001
  - Intervention: P<0.001

- Would recommend to others
  - Control: 40%
  - Intervention: 60%
  - P<0.001

- Would want to use for other decisions
  - Control: 40%
  - Intervention: 60%
  - P<0.001
### Safety

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n=451)</th>
<th>Intervention (n=447)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revascularization</td>
<td>4 (1%)</td>
<td>7 (2%)</td>
<td>0.37</td>
</tr>
<tr>
<td>MI</td>
<td>1 (0%)</td>
<td>4 (1%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>MACE within 30 days of discharge</td>
<td>0 (0%)</td>
<td>1 (0%)</td>
<td>1.0</td>
</tr>
</tbody>
</table>
Resource Use

- **Admitted to EDOU for stress test or coronary CT**: P<0.001 (Control) vs. P<0.013 (Intervention)
- **Stress test within 30 days**: P<0.001
- **Coronary CT within 30 days**: P=0.12

### Bar Chart
- Control
- Intervention

### Graphical Data
- Percentage (%) of patient resource use over time.
Main findings

Engaging patients in SDM using CPC

- ↑ patient knowledge and engagement
- Safely ↓ resource use
- Acceptable to patients and clinicians
- Takes 1 additional minute of clinician time
Pediatric Head Trauma
Pediatric Head Trauma

• Trauma leading cause of death in children > 1 yr

• Traumatic brain injury (TBI) responsible for the majority of deaths

NHAMCS 2006; Blackwell 2007; Centers for Disease Control
Controversy over CT for Minor BHT

Arguments for:

◆ Preventable morbidity/mortality due to unrecognized TBI

◆ Preverbal children difficult to evaluate

◆ When indicated, benefit of CT greatly outweighs risk, however…
Controversy over CT for Minor BHT

Arguments against:

- Among children with GCS 15, prevalence of TBI is 0-7%, surgical intervention in <1%
- Transport outside the ED, pharmacological sedation, cost
- Theoretical risk of lethal malignancy as high as 1:2500
PECARN prediction rules

• Highly sensitive for clinically-important TBI

• Rules for children < 2 and 2-18 years

• Stratify risk for clinically important TBI as low, moderate or high

Kuppermann, Lancet 2009
The PECARN TBI prediction rules

<table>
<thead>
<tr>
<th>Children &lt; 2 years</th>
<th>Children 2-18 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Severe mechanism of injury</td>
<td>1. Severe mechanism of injury</td>
</tr>
<tr>
<td>2. History of LOC &gt; 5 sec</td>
<td>2. History of LOC</td>
</tr>
<tr>
<td>3. GCS = 14 or other signs of altered mental status</td>
<td>3. GCS = 14 or other signs of altered mental status</td>
</tr>
<tr>
<td>4. Not acting normally per parent</td>
<td>4. History of vomiting</td>
</tr>
<tr>
<td>5. Palpable skull fracture</td>
<td>5. Severe headache in the ED</td>
</tr>
</tbody>
</table>
Let’s talk about concussion and your child’s risk for more serious injury such as bleeding in or around the brain.

**Concussion**
- Brain movement within the skull

- Symptoms may include headache, nausea, dizziness, or difficulty concentrating
- Symptoms should resolve in several days to a few months
- Recovery is almost always complete
- Cannot be seen on a CT scan

**Brain Injury**
- Blood

- Occurs when the head injury is severe enough to cause bleeding in or around the brain
- May require medical intervention such as a stay in the hospital or surgical procedure

In 100 children with minor head injury similar to your child:

1 will have brain injury and 99 will not

Kuppermann et al., Lancet, 2009
After monitoring your child in the emergency department for a period of time, we will find out if there is any serious bleeding in or around the brain with:

- **HEAD CT SCAN**
  You can have a head CT scan test done to determine if your child has had a brain injury.

- **OBSERVATION AT HOME**
  If your child’s symptoms are the same or better in the next 1-2 days, then there was no serious bleeding in or around the brain.

  It is very unlikely, but if your child develops new or worsening symptoms such as these, bring him/her back to the Emergency Department as soon as possible.

  - Lack of alertness (if they are becoming less and less alert within the next day)
  - Severely worsening headache (despite resting)
  - Vomiting (enough episodes to interfere with eating)
  - Unsteady or cannot walk
  - Difficulty talking or recognizing people

Your child can maintain regular activities such as sleep.
Please circle the issues that are most important to you and your child.

<table>
<thead>
<tr>
<th></th>
<th>SPEED OF DIAGNOSIS</th>
<th>RADIATION</th>
<th>SEDATION</th>
<th>COST</th>
<th>POTENTIAL DOWNSIDES</th>
<th>WAIT IN ED</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEAD CT SCAN</td>
<td>Now</td>
<td>Yes</td>
<td>Possible</td>
<td>May increase cost depending on your coverage</td>
<td>May find irrelevant things that lead to more tests</td>
<td>Typically longer</td>
</tr>
<tr>
<td></td>
<td>![CT Scan Icon]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBSERVATION AT HOME</td>
<td>Delayed</td>
<td>No</td>
<td>No</td>
<td>No added cost</td>
<td>Potential return to ED if symptoms worsen</td>
<td>Typically shorter</td>
</tr>
<tr>
<td></td>
<td>![Home Icon]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

After discussing this together, we want to do:

- [ ] HEAD CT SCAN
- [ ] OBSERVATION AT HOME
- [ ] Let the Emergency Department doctor decide what to do next

You will have the opportunity to revisit this decision with your doctor while you are in the Emergency Department.
Trial Design

- Parallel, clinician level RCT
- Allocation concealed, web-based randomization scheme
- Dynamically randomized, 1:1 ratio
  - Stratified by site and clinical training (pediatric vs. non-pediatric specialty)
- Coordinator and clinician assessed eligibility
  - If eligible, video record encounter and obtain post-visit clinician and parent surveys
Settings

• Participants recruited from EDs at 7 centers:
  • Boston Children’s, Boston, MA
  • Nationwide Children’s Hospital, Columbus, OH
  • Children’s Hospitals and Clinics of MN
  • University of Minnesota Masonic Children’s
  • Mayo Clinic, Rochester, MN
  • UC Davis, Sacramento, CA
Eligibility criteria

• **Inclusion**
  - < 18 years
  - < 24 hrs of head trauma
  - 1-2 non-high risk PECARN factors

• **Exclusion**
  - GCS < 15 or AMS
  - Signs of skull fracture
  - Brain tumor
  - Penetrating head trauma
  - Coagulopathy
  - Syncope or seizure prior to trauma
  - Pregnancy
  - Brain imaging already obtained
  - Seizure
Results
## Outcomes (n=971)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Decision aid vs usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient knowledge</td>
<td>6.2 vs 5.3, p&lt;0.001</td>
</tr>
<tr>
<td>Patient engagement</td>
<td>25 vs 13, p&lt;0.001</td>
</tr>
<tr>
<td>Decisional conflict</td>
<td>15 vs 19, p&lt;0.001</td>
</tr>
<tr>
<td>Trust in physician</td>
<td>92 vs 89, p=0.015</td>
</tr>
<tr>
<td>Safety</td>
<td>0.2% vs 0%, p=1.0</td>
</tr>
<tr>
<td>Head CT obtained</td>
<td>22% vs 24%, p=0.35</td>
</tr>
<tr>
<td>Imaging (7-days)</td>
<td>0.88 vs 0.65, p=0.045</td>
</tr>
</tbody>
</table>
Conclusions

Shared decision making in parents of children at moderate risk of clinically important TBI

- ↑ parental knowledge and engagement
- Acceptable to parents and clinicians
- ↓ ED length of stay
- ↓ Imaging at 7 days
Making sense of the findings
Next Steps: Dissemination and Implementation
How?

• Develop an implementation toolkit

• Intentionally forge resilient relationships with key stakeholders

• Conduct normalization process theory-guided focus groups

• Anticipate and weather the Valley of Despair
Patient arrival w/ complaint: chest pain

ECG testing

Ongoing active ischemia

STEMI?

Yes

No

ACS considered?

Yes

Initial troponin testing

Positive

ACS primary cause?

Yes

Admit to cardiology

Follow-up +/- advanced stress testing

Cardiology Consult

Duke score < +5

ED Observation

Treadmill stress testing

Duke score ≥ +5

No

Negative

Risk stratification

Mod/high

Low risk (HEART ≤ 3)

Risk communication

Serial troponin testing*

Positive

Negative

Discharge w/ primary care follow-up

Discharge

Shared decision making

Risk communication

Serial troponin testing*

Positive

Negative

* Serial troponin testing (for current generation Troponin T) includes a negative test ≥ 6 hours after the episode that prompted evaluation
FROM BREAKDOWN TO BREAKTHROUGH

Forging Resilient Business Relationships in the Heat of Change

MICHAEL PAPANEK

with LIZ ALEXANDER, PhD
1. Participants distinguish the intervention from current ways of working.
2. Participants collectively agree about the purpose of the intervention.
3. Participants individually understand what the intervention requires of them.
4. Participants construct potential value of the intervention for their work.
5. Key individuals drive the intervention forward.
6. Participants agree that the intervention should be part of their work.
7. Participants buy in to the intervention.
8. Participants continue to support the intervention.
9. Participants perform the tasks required by the intervention.
10. Participants maintain their trust in each other’s work and expertise through the intervention.
11. The work of the intervention is appropriately allocated to participants.
12. The intervention is adequately supported by its host organization.
13. Participants access information about the effects of the intervention.
14. Participants collectively assess the intervention as worthwhile.
15. Participants individually assess the intervention as worthwhile.
16. Participants modify their work in response to their appraisal of the intervention.
Implementation Work

Implementation Process

Feasibility, Acceptability, Appropriateness

Implementation work without catalyzing toolkit

Implementation work with catalyzing toolkit

Change in feasibility, acceptability, appropriateness
Change management Process

- Morale and Competence
  - Happiness
  - Anxiety
  - Fear
  - Threat
  - Guilt
  - Depression
  - "Valley of despair"
  - Gradual Acceptance
  - Moving Forward
  - Hostility

- Time

You are here → Denial → Defeat
What is the effect of CPC in potentially vulnerable patient populations?
Figure 1 Knowledge (%) subgroup effects. Forest plot demonstrating the effect of the Chest Pain Choice decision aid on patient knowledge in subgroups according to patient characteristics.
Figure 2 Trust in Physician Scale subgroup effects. Forest plot demonstrating the effect of the Chest Pain Choice decision aid on Trust in Physician scale scores in subgroups according to patient characteristics.
IS THERE MORE THAN ONE REASONABLE OPTION?

IS PATIENT WILLING AND ABLE TO PARTICIPATE IN DECISION?

IS THERE ENOUGH TIME TO ENGAGE PATIENT IN DISCUSSION?

No

Compassionate Persuasion
Informed Consent or Refusal

No

Physician-Directed Decisionmaking

No

SHARED DECISIONMAKING