Implementing PROVEN
PRagmatic Trial of Video Education in Nursing Homes

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UH3AG049619

Grand Rounds: A Shared Forum of the NIH HCS Collaboratory and PCORnet
Friday, March 10, 2017 — 1-2 p.m. Eastern Time
PROVEN: Objective

• To conduct a pragmatic cluster RCT of an Advance Care Planning video intervention in NH patients with advanced comorbid conditions in two NH healthcare systems
Background: Nursing Homes

• NHs are complex health care systems
  – 3 million patients admitted annually
  – Rapidly growing % post-acute care
• Patients medically complex with advanced comorbid illness
• NHs charged with guiding patient decisions by default
Background: ACP

- Advance care planning (ACP)
  - *Process* of communication
  - Align care with preferences
  - Leads to advance directives (e.g., DNR, DNH)
- Better ACP associated with improved outcomes
- ACP suboptimal in NHs
  - Not standardized
  - Low advance directive completion rates
  - Not reimbursed
  - Regional and racial/ethnic disparities
Background: Traditional ACP

• Problems with traditional ACP
  – Ad hoc
  – Knowledge and communications skills of providers variable
  – Scenarios hard to visualize
  – Health care literacy is a barrier
Background: ACP videos

• Options for care with visual images
• Broad goals of care
  – Life prolongation, limited, comfort
• Specific conditions/treatments
• Adjunct to counseling
• 6-8 minutes
• Multiple languages
PROVEN: Intervention NHs

• 18 month intervention period
• Suite of 5 ACP videos
  – Goals of Care, Advanced Dementia, Hospitalization, Hospice, ACP for Healthy Patients
• Offered facility-wide
  – All new admits, care-planning meetings for long-stay, readmission
• Flexible (who, how, which video)
• Tablet devices, internet via URL and password
• Training: corporate level, webinars, toolkit
PROVEN: Control NHs

• Usual ACP practices

• Recognize programs may be going on in background (i.e., INTERACT)
PROVEN: Primary Outcome

• Number of hospitalizations/person-days alive among patients \( \geq 65 \text{ years old} \) who are in a NH \( \geq 90 \text{ days} \) ("long-stay") and who have EITHER advanced dementia or advanced congestive heart failure/chronic obstructive lung disease

• This is our target cohort.
PROVEN: Secondary Outcomes

- Non-target cohort (for both long- and short stay):
  - Number of hospitalizations/person-days alive

- Target and non-target cohorts (for both long- and short stay):
  - Presence of advance directives: Do Not Hospitalize, Do Not Resuscitate, or no tube-feeding
  - Burdensome treatments (feeding tubes, parenteral therapy)
  - Hospice enrollment among patients
PROVEN: Outcome time frames

• For **long-stay** patients (in NH >=90 days):
  – 12-month follow-up period

• For **short-stay** patients (in NH <90 days):
  – Within 100 days of post-acute care admission
Data infrastructure in PROVEN

These have been essential to implementing and monitoring PROVEN:

1. Integrating a Video Status Report User-Defined Assessment (VSR UDA) into the healthcare systems’ EMRs to document the ACP Video Program

2. Developing systems and QA procedures for data transfers between healthcare systems and Brown (MDS, VSR UDA, advance directives)

3. Generating compliance reports for the healthcare systems

4. Uploading data to the Virtual Research Data Center (VRDC) to create finder files to match all Medicare claims, particularly hospitalization
Implementing PROVEN

• Topics for today’s presentation:

  – Challenges during implementation

  – Documenting the implementation of the intervention

  – Ongoing challenges
Challenges during implementation

• Two main challenge areas:

1. Defining compliance

2. Changes at healthcare system partners
Defining compliance

- Videos are intended to be offered in six circumstances:

<table>
<thead>
<tr>
<th></th>
<th>Events Triggering when an ACP Video is Offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>ALL PATIENTS: Within One Week of Admission</td>
</tr>
<tr>
<td>2)</td>
<td>ALL PATIENTS: Within One Week of Re-admission from Hospital</td>
</tr>
<tr>
<td>3)</td>
<td>ALL PATIENTS: Significant Change in Health Care Status</td>
</tr>
<tr>
<td>4)</td>
<td>LONG-TERM CARE RESIDENTS: Every 6 months (Align with Scheduled Care Planning Meetings)</td>
</tr>
<tr>
<td>5)</td>
<td>FAMILY MEETINGS: About Goals of Care</td>
</tr>
<tr>
<td>6)</td>
<td>SPECIFIC DECISIONS: Covered by a Video (e.g., Hospice, Hospitalization)</td>
</tr>
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</table>

From ACP Video Program toolkit
Documenting the ACP Video Program

• A Video Status Report User-Defined Assessment (VSR UDA) was programmed in the EMRs of our healthcare system partners.

• Each time a video is offered to a patient or his/her family, a VSR UDA is to be entered – even if a video is not shown.
Example VSR UDA data points

• Date video offered
• Which event triggered the video offer?
• Was a video shown?
  – If shown:
    • Date shown
    • Which video(s) shown?
    • Who showed the video?
    • Who viewed the video?
    • Any distress observed?
  – If not shown, why not?
Initial definition of compliance

- ACP Video Program compliance was initially defined as **completion of a VSR UDA** each time a **video** was offered.

**Table 1. Events Triggering when an ACP Video is Offered**

<table>
<thead>
<tr>
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<th>Event Description</th>
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<tr>
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*From ACP Video Program toolkit*
Focus on the VSR UDA

• On the regular healthcare system group “check in” calls with NHs and during formal re-training webinars, emphasis was placed on offering videos.

• NHs that were compliant with offering videos were celebrated and highlighted as program benchmarks.
Healthcare system partners’ compliance reports for admissions

- We helped our healthcare system partners develop reports in their EMRs to measure ACP Video Program compliance (videos offered) for new admissions at each center.

<table>
<thead>
<tr>
<th>Partner 1</th>
<th>Video Advance Care Planning Status Report Compliance Admissions</th>
<th>Wave: 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reporting Period: 2017-01-16 through 2017-01-29</td>
<td></td>
</tr>
<tr>
<td>Center</td>
<td>Compliant VSR UDAs</td>
<td>Noncompliant VSR UDAs</td>
</tr>
<tr>
<td>1</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Partner 2</th>
<th>Admissions VSR UDA compliance</th>
<th>Reporting Period 12/5/16 to 12/18/16</th>
<th>Reporting Period 12/19/16 to 1/1/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility 1</td>
<td>88.89%</td>
<td>91.67%</td>
<td></td>
</tr>
<tr>
<td>Facility 2</td>
<td>71.43%</td>
<td>85.71%</td>
<td></td>
</tr>
<tr>
<td>Facility 3</td>
<td>86.67%</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td>Facility 4</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Facility 5</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Facility 6</td>
<td>85.71%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Facility 7</td>
<td>87.50%</td>
<td>60%</td>
<td></td>
</tr>
</tbody>
</table>
Healthcare system partners’ compliance reports for long-stay

• Long-stay report is more difficult for NHs to program

• We are still working with the NH IT teams to help them through the construction of these reports
Also, Brown University-generated compliance reports

1. VSR UDAs completed for new admissions
   Total new admissions*

2. VSR UDAs completed for long-stay patients
   Total long-stay patients with ≥6 months of potential exposure*

* (from NH MDS data)

Finally resolved data transfer issues (e.g., bad dates, missing data from our partners) in December 2016.
Needed to redefine compliance

• HOWEVER, when we added the proportion of videos actually shown to the compliance reports....

• We found that even the NHs highly-compliant with offering videos did not have high rates of actually showing videos!
# Videos offered vs. videos shown

<table>
<thead>
<tr>
<th></th>
<th>Partner 1</th>
<th>Partner 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admissions</td>
<td>15488</td>
<td>2864</td>
<td>18352</td>
</tr>
<tr>
<td>Videos offered</td>
<td>11844</td>
<td>1697</td>
<td>13541</td>
</tr>
<tr>
<td>Videos shown</td>
<td>2549</td>
<td>1133</td>
<td>3682</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Partner 1</th>
<th>Partner 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residents EVER long stay</td>
<td>9458</td>
<td>2321</td>
<td>11779</td>
</tr>
<tr>
<td>Video EVER offered</td>
<td>3074</td>
<td>595</td>
<td>3669</td>
</tr>
<tr>
<td>Video EVER shown</td>
<td>618</td>
<td>312</td>
<td>930</td>
</tr>
</tbody>
</table>

*Data as of 12/31/2016*
Distribution of % of long-stay who were ever offered a video
Distribution of % of long-stay who were ever shown a video
Change in tune: Show the video

– Compliance reports now include videos shown.

– On the regular healthcare system group “check in” calls with NHs and during formal re-training webinars, emphasis is now placed on showing the video.

– NHs that are compliant with showing the video are celebrated and highlighted as program benchmarks.

– Target set for each center to have a “video shown” rate of at least 50%.
Challenges during implementation

• Two main challenge areas:

  1. Defining compliance

  2. Changes at healthcare system partners
Healthcare system partners

• **CHALLENGE #1: Turnover in key partner staff.**
  
  – With one of our two healthcare system partners, there was turnover **twice** in the implementation liaison role.

• **SOLUTIONS:**
  
  – Kept engaged with senior leadership in our healthcare system partners.
  
  – Provided one-on-one trainings and orientations with newly-hired implementation liaisons.
  
  – Began including implementation liaisons on our monthly Steering Committee calls.
Healthcare system partners

- **CHALLENGE #2: Turnover in ACP Champion staff →** More than half of NHs had at least one Champion turnover.

<table>
<thead>
<tr>
<th></th>
<th># of NHs</th>
<th>% of NHs</th>
</tr>
</thead>
<tbody>
<tr>
<td>No turnover in ACPCs</td>
<td>55</td>
<td>46.22%</td>
</tr>
<tr>
<td>1 ACPC loss</td>
<td>39</td>
<td>32.77%</td>
</tr>
<tr>
<td>2 ACPC losses</td>
<td>22</td>
<td>18.49%</td>
</tr>
<tr>
<td>3 ACPC losses</td>
<td>2</td>
<td>1.68%</td>
</tr>
<tr>
<td>5 ACPC losses</td>
<td>1</td>
<td>0.84%</td>
</tr>
</tbody>
</table>

Total intervention NHs 119

*Data as of 2/15/2017*
Relationship between turnover and ACP Video Program compliance for admissions

Data as of 12/31/2016
Relationship between turnover and ACP Video Program compliance for long-stay

Data as of 12/31/2016
Healthcare system partners

• CHALLENGE #3: Divestitures

  – At one partner, a total of 8 NHs (2 intervention, 6 control) were divested after they were randomized to the study sample.

  – These divestitures occurred after the ACP Video Program had launched.
Healthcare system partners

• **CHALLENGE #3: Divestitures**

• **SOLUTION:**
  - We accrued the cohort of patients in NHs until the date of divestiture.
  - Although we stopped accruing patients in those NHs upon the date of divestiture, we can keep following their patient outcomes for up to 12 months afterward.
Documenting implementation

• ACP Champions are critical to the success of the ACP Video Program
  – These are key staff (usually Social Workers) appointed by senior leadership to lead the implementation in each NH
  – Each NH has at least two Champions: primary, secondary

• We designed telephone interviews to be conducted with Champions at three timepoints during the 18-month implementation period:
  – Baseline ➔ 4 months after launch
  – Intermediate ➔ 9 months after launch
  – Final ➔ 15 months after launch
ACP Champion interview themes

• What were the NH’s ACP practices before the video program?

• Feedback on the ACP video program training

• How is the implementation going (e.g., what’s gone well, challenges, reactions)?

• Any distress among viewers? (DSMB request)
So, How Pragmatic is PROVEN now?

• Each Change to the Intervention Implementation model considered in light of PRECIS-2 principles

• Clearly even a multi-facility pilot doesn’t uncover all operational implementation impediments

• In “real” world health systems test new programs with pilots as well
* PRECIS-2 diagram from Loudon et al, BMJ, 2015 with adapted formatting.
## Implementation RT vs. HCS: ORGANIZATION

<table>
<thead>
<tr>
<th>ASPECT</th>
<th>Approach</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRAINING</td>
<td><strong>RT:</strong> Developed training materials - e.g., printed toolkit, webinars, laminated card</td>
<td>• HCS’ had different preferred modalities:</td>
</tr>
<tr>
<td></td>
<td><strong>HCS:</strong> Leveraged existing corporate infrastructures to do trainings</td>
<td>HCS1: Centralized, in-person</td>
</tr>
<tr>
<td></td>
<td><strong>RT &amp; HCS:</strong> Co-led trainings</td>
<td>HCS2: Multiple Webinars</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Turnover of NH champions required multiple re-trainings</td>
</tr>
<tr>
<td>PERSONNEL</td>
<td><strong>RT:</strong> Dedicated one PI and one PD</td>
<td>• Turnover of both corporate leaders</td>
</tr>
<tr>
<td></td>
<td><strong>HCS:</strong> Corporate-level leader appointed to oversee project; Site champion(s) at each NH</td>
<td>• Extensive champion turnover</td>
</tr>
<tr>
<td>RESOURCES</td>
<td><strong>RT:</strong> Developed intervention; supplied tablets with videos</td>
<td>• Two sites had mostly Navajo patients so RT created new videos</td>
</tr>
<tr>
<td></td>
<td><strong>HCS:</strong> Provided training venues; embedded video status report into EMR</td>
<td>• Tablets stolen at one site so RT replaced them</td>
</tr>
</tbody>
</table>

*RT=research team; HCS=health care system*
## Implementation: FLEXIBILITY (DELIVERY)

<table>
<thead>
<tr>
<th>ASPECT</th>
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<th>Challenges</th>
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</table>
| **PROTOCOL-DRIVEN** | **RT:** Prescribed guidelines for timing of video OFFERING (7 days from admission, q6 months for long-stay)  
**RT:** Flexible guidelines for:  -which videos to offer which patient  -who shows videos (mostly SW) | • Higher adherence for admissions vs. LTC  
• Competing responsibilities a barrier  
• LTC-patients hard to find “right time”, family often not at care planning meeting |
| **CO-INTERVENTIONS** | **RT:** Did not dictate how other ACP modalities could be used (e.g., MOLST)  
**HCS:** Allowed other ongoing ACP activities to continue in NHs | • Other ACP programs highly variable & not easily measured  
• ++ external initiatives to ↓hospitalizations (1º outcome) |
| **MONITORING**      | **RT:** Designed Video Status Report (VSR)  
**HCS:** Embeds VSR into EMR at all NHs  
**RT & HCS:** Instruct VSR completion when video OFFERED (i.e., patient or family could refuse) | • Champions interpreted compliance as offering (i.e., VSR completion) vs showing video |

*RT=research team; HCS=health care system*
### Implementation: FLEXIBILITY (ADHERENCE)

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<tr>
<td><strong>PRE-SCREENING</strong></td>
<td><strong>HCS:</strong> Excluded sites with major organizational or regulatory difficulties</td>
<td>• Determination of ‘dysfunctional’ sites was subjective based on corporate leaders’ assessments</td>
</tr>
<tr>
<td><strong>SITE WITHDRAWAL</strong></td>
<td><strong>RT:</strong> NHs with low implementation adherence rates were NOT dropped</td>
<td>• HCS divested several NHs mid-implementation</td>
</tr>
<tr>
<td><strong>SITE MONITORING</strong></td>
<td><strong>HCS:</strong> Internal monthly reports for VSR completion for admissions only</td>
<td>• HCS internal reports for admissions only and based on offering videos, so missed low compliance in LTC and show rate</td>
</tr>
<tr>
<td></td>
<td><strong>RT:</strong> Quarterly reports were completed for admissions and LTC; champion interviews uncovered issues (lack of focus on LTC, champion turnover)</td>
<td>• RT reports delayed due to data transfer; 01/17 added ‘show’ rate and increased to monthly</td>
</tr>
<tr>
<td></td>
<td><strong>RT &amp; HSC:</strong> monthly ACP champions calls; problem-solve low performers</td>
<td></td>
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*RT=research team; HCS=health care system*

Implementing PROVEN – March 10, 2017
E=Explanatory; P=Pragmatic
Ongoing challenges

- Implementing PROVEN as one of a multiplicity of quality improvement initiatives and responses to regulatory demands

- Integrating the video and ACP into centers’ standard operating procedures

- Continued market stressors on the NH industry (e.g., reduced Medicare days and higher acuity of patients) that diminish revenue, increase pressure, and reduce staffing levels (including ACP Champions)
Lessons & Implications

• ACP Videos Selected because standardized and ready for broad implementation

• Unanticipated Complications in the “mechanics” of introducing Videos into daily operations – seemed so simple!

• Now considering implications for projected effect size on the outcome