Infection Prevention and Social Change
Prof. Elaine Larson, Columbia University
A Webber Training Teleclass

Infection Prevention and Social Change
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What We’ll Talk About

• Summarize social changes relevant to infection prevention and control
  – Reimbursement strategies
  – Mandatory reporting and increasing consumer involvement
  – Increasing regulation of research
• Examine the role of leadership in prevention behaviors

Social changes relevant to infection prevention and control

• Reimbursement strategies (CMS)
• Mandatory public reporting; increasing transparency and patient/consumer involvement
• Increasing regulation of research

SOCIAL CHANGES
REIMBURSEMENT STRATEGIES

Deficit Reduction Act P.L. 109-171

• Secretary of HHS must identify high cost, high volume preventable conditions that result in higher payment
• As of October 1, 2008 CMS denies payment for 10 hospital acquired conditions, 3 of which are HAIs
  – Selected surgical site infections
  – Vascular catheter associated infections
  – Catheter associated urinary tract infections

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Declarations:
Research funding from Deb Healthcare
Consultant: GOJO Industries
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A report of a conference funded by AHRQ (R13018099) and held in April 2009, New York City

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• Morning Presentations
  – “CMS Progress toward Value-based Purchasing” T. Valuck
  – “Measuring Healthcare-associated Infections” T. Horan
  – “Using Incentives to Reduce the Rate of HAI” A. Dudley

• Afternoon Presentations
  – “Creating an Environment for Learning, Innovation, and Successful Implementation in Organizations” I. Nembhard
  – “Other Payer and Provider Responses to the CMS HAI Rule” S. Glied

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Results

• All agreed that research should be theory driven
• Clinician’s response may be predicted using behavioral theory
  – The incentive can serve as a stimulus
  – Environmental, organizational, provider and patient characteristics are mediating variables that impact outcomes
• Organizational theory and management research acknowledges the relationship between organizational culture and staff behavior

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Stone, et al., Med Care 2010; 48:413-9

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SOCIAL CHANGES
MANDATORY PUBLIC REPORTING, INCREASING TRANSPARENCY AND PATIENT/CONSUMER INVOLVEMENT

CMS Hospital Inpatient Quality Reporting Program

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Variation in State Laws

- Number of and types of HAIs needed to report
- Process measures
- Public reporting versus health department reporting
- Mandatory versus voluntary

California Infection Prevention and Control Departments’ Resources and Effectiveness


Study and Political Timeline

- Survey 1: 207 hospitals participated, 69% recruitment rate
- Survey 2: 213 hospitals participated, 71% recruitment rate
- There were no differences in hospital demographics from time 1 to time 2

Results

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Infection Preventionist Time

- More time on surveillance
  (37% versus 41%, p = 0.02)
- Less time on education of staff
  (11% versus 9%, p < 0.01)
- More time in office
  (47% versus 53%, p = 0.03)

HAI Rates Decreased in Medical/Surgical ICUs

- **CLABSI rate**
  - Time 1 (n = 92) 2.3/1000 line days
  - Time 2 (n = 99) 1.1/1000 line days
- **VAP rate**
  - Time 1 (n = 92) 2.6 /1000 ventilator days
  - Time 2 (n = 94) 1.3 /1000 ventilator days

Presence of Evidence-Based Policies

<table>
<thead>
<tr>
<th>Policy</th>
<th>Survey 1</th>
<th>Survey 2</th>
<th>p-value</th>
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<tbody>
<tr>
<td><strong>CLABSI</strong></td>
<td></td>
<td></td>
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<tr>
<td>- Chlorhexidine use</td>
<td>93</td>
<td>90</td>
<td>0.003</td>
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<tr>
<td>- Barrier precautions</td>
<td>97</td>
<td>93</td>
<td>0.007</td>
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<td>- Optimal site selection</td>
<td>97</td>
<td>94</td>
<td>0.001</td>
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<tr>
<td>- Daily infection check</td>
<td>94</td>
<td>97</td>
<td>0.02</td>
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<tr>
<td>- Raising of head</td>
<td>99</td>
<td>96</td>
<td>0.06</td>
</tr>
<tr>
<td>- IVT prophylaxis</td>
<td>93</td>
<td>95</td>
<td>0.11</td>
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<tr>
<td>- Stool flora prophylaxis</td>
<td>96</td>
<td>97</td>
<td>0.17</td>
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<td>- Sedation vacation</td>
<td>91</td>
<td>92</td>
<td>0.17</td>
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<tr>
<td>- Prevalent isolation</td>
<td>72</td>
<td>83</td>
<td>0.016</td>
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<tr>
<td>- Bathroom isolation</td>
<td>87</td>
<td>98</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Respiratory isolation</td>
<td>35</td>
<td>28</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>VAP</strong></td>
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<td></td>
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<tr>
<td>- Nasogastric feeding</td>
<td>90</td>
<td>87</td>
<td>0.22</td>
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<tr>
<td>- DVT prophylaxis</td>
<td>87</td>
<td>96</td>
<td>0.19</td>
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<tr>
<td>- Stomach ulcer prophylaxis</td>
<td>80</td>
<td>90</td>
<td>0.19</td>
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<tr>
<td>- Sedation vacation</td>
<td>91</td>
<td>92</td>
<td>0.17</td>
</tr>
<tr>
<td>- Positioning of patients</td>
<td>93</td>
<td>94</td>
<td>0.001</td>
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<tr>
<td><strong>CAUTI</strong></td>
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<tr>
<td>- Portable sonograms</td>
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<td>83</td>
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<td>- Condom catheters</td>
<td>87</td>
<td>98</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>- Reminder/stop order</td>
<td>35</td>
<td>28</td>
<td>&lt;0.001</td>
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<tr>
<td>- Disconnection by nurse</td>
<td>45</td>
<td>25</td>
<td>0.019</td>
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<tr>
<td>- Selection of prophylactic antibiotics</td>
<td>86</td>
<td>83</td>
<td>0.36</td>
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<tr>
<td>- Disconnection w/in 24 hrs</td>
<td>87</td>
<td>86</td>
<td>0.82</td>
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<tr>
<td>- Glucose control</td>
<td>90</td>
<td>87</td>
<td>0.02</td>
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<td>- Hair removal</td>
<td>88</td>
<td>71</td>
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<tr>
<td>- Normothermia</td>
<td>79</td>
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Methods

- Purposive sample of 6 hospitals, all participating in CHAIPI was recruited to gain regional representation across the state
- Open ended questions structured around Donabedian’s framework
- Interviewed 25 professionals during the summer of 2009. Interviews typically lasted one hour.

Data Analysis

- Interviews audiotaped and transcribed; transcripts entered into NVivo 8® to facilitate content analysis
- Bi-weekly meetings with expert qualitative researcher
- Two coders—developed initial set of core and secondary codes
- Iterative process of re-reading and coding until general consensus of coding scheme
- To maintain consistency, 30% of the transcripts were double coded.
- Inter-rater agreement > 90%

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Outcomes not always clear cut

- **S. aureus BSI and hand hygiene rates subject to public reporting in Australia**


Why?

- Better ‘washers’ are also more accurate and careful reporters and do better surveillance
- Causes of BSI are multiple; HH may have an impact but not the only factor
- No causal relationship between HH and BSI
- Even if there were a causal relationship, sophisticated multivariable analyses are essential to tease out confounders and effect modifiers

Conclusions

- While there is some evidence that state and federal policies may be working, there is likely to be both intended and unintended consequences related to the recent policy changes
- Rigorous evaluation of these policies are needed to inform decision-makers
- Not only do we need evidence-based clinical processes
- We also need evidence-based policy making!

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IRONY

• US is way behind EU in controlling antibiotic use in animals
• Although fluoroquinolones were banned from US poultry production in 2005, 70% of its use in 2010 was still in animals that are healthy but vulnerable to diseases because of crowded, unsanitary conditions

NY Times, 4/18/10

SOCIAL CHANGES

INCREASING REGULATION OF RESEARCH

Eliminating Catheter-Associated BSI in an ICU

• Study design: Prospective study in a surgical ICU, Johns Hopkins Hospital.
• Measurement: CA-BSIs and guideline adherence.
• Results: CA-BSI rate decreased from 11.3 to 0 per 1,000 catheter-days. 43 CA-BSIs, 8 deaths, and $1,945,922 saved.


Keystone Project

• Michigan Hospital Association
• 127 intensive care units (ICUs) in Michigan and five other states.
• 68 ICUs totally eliminated CA-BSIs.
• For 6 months, they eliminated VAP.
• Estimates that they saved >1,578 lives, reduced 81,000 hospital days, and saved $165 million.
• Hospitals in Rhode Island, New Jersey and Maryland are replicating the Keystone Project locally and others will follow.

Pronovost, et al. NEJM 2006;355:2725-32

Sequence of Events

• 10/03. Project determined to be Exempt by Hopkins IRB
• 3/04-9/05. Project data collection
• 12/06. Results published
• 2/07. OHRP notifies Hopkins of concerns
• 8/07. Project suspended by OHRP

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Key Questions*

• Was this quality improvement project also human subjects research?
• If so, could the IRB approval been expedited?
• Was informed consent required?

Final Outcome

• 11/07. OHRP changed their mind; waiver of consent appropriate
• See Miller FG, Emanuel EJ. Quality-improvement research and informed consent. NEJM 2008; 358:8-769

Differentiating QI and Research


• Testing beyond current knowledge
• Random allocation of participants
• Delaying feedback to avoid biasing interpretation of data
• Researchers with less commitment to improvement of local situation
• Funding/participation by parties outside the project setting/organization

Final, final outcome

• OHRP has rescinded its decision and now agrees with the Hopkins IRB that this is not research (because it has now been shown to work)
• AHRQ has funded the ‘checklist’ study to expand to other states

If I plan to carry out a quality improvement project and publish the results, does the intent to publish make my quality improvement project fit the regulatory definition of research?

No. The intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.
A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

Haynes, et al. NEJM 2009; 360:491-499

WHO Safe Surgery Program

- Death rate declined from 1.5 to 0.8% (p=0.003)
- Inpatient complications went from 11 to 7% (p<0.001)

“The human subjects committees of Harvard School of Public Health, the WHO, and each participating hospital approved the study and waived the requirement for written informed consent.”

Striking the Balance

- What is the evidence that increasing regulation yields better protections and improved understanding among research participants? (Not much)

“The degree of scrutiny, the extent of continuing oversight, and the safety monitoring procedures for research proposals should be calibrated to a study’s degree of risk. Minimal risk studies should be handled diligently, but expeditiously, while studies involving high risk should receive the extra time and attention they require.”


“Proposed changes in the ‘Common Rule’ to simplify the process and put the emPHASIS on the right syllABLE
- Advance Notice of Proposed Rulemaking published July, 2011 designed to expand federal protections and reduce oversight burden on investigators and IRBs for low risk research

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So what do we do?

We need simple rules...

- No patient should be harmed by an HAI
- Targeting zero infections is a laudable goal
- Infection prevention must be an organizational goal
- Chief executives must deliver clear expectations, set goals and provide necessary resources
- Everyone is responsible

— Alvarado, APIC, 2007

Be a Leader:
Successful Leaders...

— Cultivate a culture of excellence
— Communicate this to staff
— Focus on overcoming barriers
— Deal directly with resistant staff
— Inspire
— Think strategically, act locally
— Leverage personal prestige
— Form interdisciplinary partnerships

Saint, et al. Importance of leadership in preventing HAI. Infect Control Hosp Epidemiol 2010; 31:901

Role model

Health-care workers in a room with a higher ranking medical staff person or peer who did not wash hands were significantly less likely to wash their own hands
(odds ratio 0.2; 95% CI: 0.1 to 0.5; p<0.001)

Lankford, EID 2003; 9:217

Local Culture More Important than Discipline

- Physician hand hygiene varied from 4 (gynecology)-96 (neonatal ICU)% within a single hospital
- Varied by a mean of 33% and 77% between hospitals
- “consistent with an important role of the local ward culture”

— Cantrell, et al. 2008 Jul 9; AJIC

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Target the Leaders

- During a multifaceted hand hygiene promotional program (performance feedback, pocket bottles of sanitizer, etc) on 35 wards...
- Patient-nurse ratio did not affect adherence
- Job seniority (≥30 years) was an independent predictor of improved adherence

Target the Message

- Four MD focus groups to understand determinants of hand hygiene
- Three with MDs with various levels of training in anesthesiology, surgery, emergency/critical care; one with internal medicine residents

Themes

- Overestimate their knowledge but are skeptical of expert recommendations
- Concerned about patient perceptions
- Emphasize the role of funding to improve hand hygiene
- Medical hierarchy is critical in their behavior


Moving beyond the simplistic

- “..even though..hands are substantially cleaner, the benefit..is uncertain”
- “Our focus on building better hand hygiene programmes has misled us into believing we are doing something about a problem that remains intractable.”

seen in geological perspective, we are fossils in the making, to be buried and eventually exposed again for the puzzlement of creatures of later eras...One of us doesn’t differ that much from another, each generation repeats its parents, the works we build to outlast us are not much more enduring than anthills, and much less so than coral reefs. Here everything returns upon itself, repeats and renews itself.

Wallace Stegner, Crossing to Safety, 1987

“The time has come for the infection control community to move on...we must reacquaint ourselves with that lonely feeling familiar to clinicians when they realize a case is much more difficult than it appeared...we should embrace the intellectual audacity of our beloved Semmelweis but let go of his how-to manual.”


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Folks, I’m telling you, birthing is hard
And dying is mean—
So get yourself a little loving
In between

Langston Hughes