Towards Better Cancer Diagnosis, Treatment, and Outcomes

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Evidence-Based Clinical Pathways

We will be discussing evidence-based clinical pathways to improve cancer outcomes.

Let’s use paintings to talk about how we can learn and foster creativity and innovation, rather than becoming blind servants to these clinical pathways.…..how we nurture a “learning health care system”
How to be Creative when there are Fixed Rules and “Standard Practice” Based on Evidence – Plague Art

• If you don’t use the right (academic) “symbols” and the “customer” (physician) can’t understand them, the “art” (pathway) will seem irrelevant and even disrespectful

• But within these “rules,” individual expression and creativity are possible, and the field will continue to learn and innovate
Francesco De Mura, Allegory of Charity, ca. 1743-44. Art Institute of Chicago
Carlo Coppola, The Pestilence of 1656 in Naples, Princeton University Art Museum
Templates and Mental Models – What we Bring to the Table, for Better or Worse

I showed my masterpiece to the grown-ups and asked them if my drawing frightened them.

They answered: “Why should anyone be frightened by a hat?” My drawing did not represent a hat. It was supposed to be a boa constrictor digesting an elephant. So I made another drawing of the inside of the boa constrictor to enable the grown-ups to understand. They always need explanations. My drawing No. 1 looked like this:

Try to question your mental models and observe carefully

From “The Little Prince”
you have great truths within you
if only anyone would bother to look
From Descriptive to Normative Theory ("Stages of Knowledge")
Looking for Variation that Challenges the Theory

Carlile and Christensen, HBR 2002
Now I have made some inquiries…

….and almost everything I have heard tells me that you…

• have developed a strong evidence base for effective cancer screening, diagnosis, and treatment
• have good evidence-based clinical pathways
• have world-class cancer registries
• have improved your outcomes

So I approach my talk with great respect for your profession and your work, and simply will try to help you see through a different lens and possibly become even better at serving the population of Denmark.
First Some Hard Truths - Why Academic Clinicians Are (Legitimately) Skeptical About QI

- Many associate QI with old-style, punitive QA
- QI gurus overemphasize the industrial origins of QI and its “religious” aspects
- QI experts tend to focus on non-clinical processes and outcomes
- Teams trying to do QI “by the book” get bogged down in tedious process and settle for small incremental improvements
- QI leaders are not up front about the fiscal agenda
- QI programs do not provide clinicians with the data they need to improve
- QI experts do not emphasize the academic potential of QI research
The Model for Improvement Simplified

Deming 1900-1993
System of Profound Knowledge

APPRECIATION OF A SYSTEM

THEORY OF KNOWLEDGE

UNDERSTANDING VARIATION

Psychology

Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?

Plan
Act
Do
Study

Langley et al 1997
The Model for Improvement

What are we trying to accomplish?
How will we know that a change is an improvement?
What change can we make that will result in improvement?
“Elevator Speech” on Key Attributes of Improvement Science (Model for Improvement Methodology)

- Clear, measurable aim
- A measurement framework in support of reaching the aim
- Clear description of the ideas (content) and how these ideas are expected to impact results (the causal pathway from changes to desired outcomes, and their attributable effect)
  - Conceptual or logic model, or “driver diagram”
- Clear description of the implementation strategy
  - What will be done to ensure reliable adoption of the content
- Dedication to rapid testing (PDSA) - prediction and learning from tests
- Understanding/describing/visualizing systems (process map, value stream)
- Learning from variation and heterogeneity
  - Use of time-ordered data to detect special cause and improvement
  - Understanding why results differ by ward, organization, region
- Application of behavioral and social sciences
Why Translational Research Scientists Should be Comfortable With This

• My 10 years working with a PhD scientist to develop a staph vaccine…

• Mice and PDSAs
Judge Sidney Goldmann
Sidney Goldmann and Elizabeth
We have work to do in primary care to improve screening for colon cancer…

Results from PROMISES study of patient safety in 25 primary care practices in Massachusetts

- **Regarding safety culture**
  - 36% said “difficult to report mistakes”
  - 53% felt “mistakes were held against them”
  - 43% said it is difficult to voice disagreement
  - 36% afraid to ask questions

- **Regarding referrals**
  - Only 51% thought office had reliable system for tracking referrals
  - 26% reported they had reliable system for following up with patients when a report from the consultant was not received
Understanding Patients and Providers – A Key to Implementing Effective Clinical Pathways

• The best clinical pathways will fail if providers and patients are not making decisions together
• Progress requires that we deeply understand what patients want and need, and how providers and patients can have a productive interaction
• An example of how to do this research: Gut-Check in collaboration with IDEO (Human-Centered Design), National Cancer Institute, IHI – Ethnographic inquiry

http://gutcheck.cancer.gov/screenings/home-stool-test/index.html#cgeoXrJFozw

https://www.youtube.com/watch?feature=player_embedded&amp;v=cgeoXrJFozw
Back to Clinical Pathways

• We need to start by being completely honest about what we do and don’t know

• We must understand when we want strong adherence to elements of the pathway and when we hope that physicians will use their judgment and depart from the pathway
  – Remember what we said about learning from anomalies

• Think about how much we really know – the “stages of knowledge”
## Stages of Knowledge

<table>
<thead>
<tr>
<th>Stage</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ignorance</td>
<td>Phenomenon not recognized or the variable’s effects seem random</td>
</tr>
<tr>
<td>2</td>
<td>Awareness</td>
<td>Variable known to be influential but can be neither measured nor controlled</td>
</tr>
<tr>
<td>3</td>
<td>Measure</td>
<td>Variable can be measured but not controlled</td>
</tr>
<tr>
<td>4</td>
<td>Control of the mean</td>
<td>Control of the variable possible but not precise; control of variance around the mean impossible</td>
</tr>
<tr>
<td>5</td>
<td>Process capability</td>
<td>Variable can be controlled across entire range</td>
</tr>
<tr>
<td>6</td>
<td>Process characterization</td>
<td>Known how small changes in the variable will affect the result</td>
</tr>
<tr>
<td>7</td>
<td>Know why</td>
<td>Fully characterized scientific model of causes/effects, including secondary variables</td>
</tr>
<tr>
<td>8</td>
<td>Complete knowledge</td>
<td>Knowledge of all interactions so that problems can be prevented</td>
</tr>
</tbody>
</table>

*After Bohmer, Harvard Business School, *Designing Care*, and RE Bohn, MIT*
<table>
<thead>
<tr>
<th>Stage</th>
<th>Name</th>
<th>Time</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ignorance</td>
<td>Until 18th Century</td>
<td>High mortality from wasting disease with sweet urine, no treatment</td>
</tr>
<tr>
<td>2</td>
<td>Awareness</td>
<td>Early 20th Century</td>
<td>Starvation diet improves longevity</td>
</tr>
<tr>
<td>3</td>
<td>Measure (but cannot control)</td>
<td>1914</td>
<td>Sugar in urine measured by FeCl (30 min.) then Benedict test (5 min.)</td>
</tr>
<tr>
<td>4</td>
<td>Control of the mean</td>
<td>1921-mid 20th Century</td>
<td>Impure insulin variably controls blood glucose</td>
</tr>
<tr>
<td>5</td>
<td>Process capability (variable controlled across range)</td>
<td>Mid-late 20th Century</td>
<td>Pure insulin with daily urine testing and dosing controls blood glucose</td>
</tr>
<tr>
<td>6</td>
<td>Process characterization (small changes in variable affect result)</td>
<td>1993</td>
<td>Multiple testing and customized insulin dosing controls glucose all day and reduces complications</td>
</tr>
<tr>
<td>7</td>
<td>Know why (secondary variables)</td>
<td>1990s</td>
<td>Other risk factors (diet, cholesterol) specified, controlled</td>
</tr>
<tr>
<td>8</td>
<td>Complete knowledge</td>
<td>Now-future</td>
<td>Artificial pancreas or islet cell transplant</td>
</tr>
</tbody>
</table>
### Observing and Learning in Clinical Practice

<table>
<thead>
<tr>
<th>Stage of Knowledge</th>
<th>1,2</th>
<th>3,4,5</th>
<th>6,7,8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Problem type</strong></td>
<td>Unstructured</td>
<td>Semi-structured</td>
<td>Highly structured</td>
</tr>
<tr>
<td>Problem-solving mode</td>
<td>Unstructured problem solving</td>
<td></td>
<td>Rules application</td>
</tr>
<tr>
<td>Knowledge type</td>
<td>Tacit</td>
<td>Pattern matching</td>
<td>Explicit</td>
</tr>
<tr>
<td>Testing strategy</td>
<td>Hypothesis generation, trial and error, serendipitous observation</td>
<td>Testing, directed, probe and learn cycles</td>
<td>Verification (quality control)</td>
</tr>
<tr>
<td>Test type</td>
<td>Exploratory</td>
<td>Discriminatory</td>
<td>Confirmatory</td>
</tr>
<tr>
<td>Number of iterations</td>
<td>Many</td>
<td>Few</td>
<td>One</td>
</tr>
<tr>
<td>Practitioner expertise</td>
<td>Expert</td>
<td></td>
<td>Novice</td>
</tr>
<tr>
<td>Management focus</td>
<td>Individual patient and problem, efficient experimentation, learning mode, solution discovery</td>
<td></td>
<td>Class problems, solutions, reliable execution/implementation</td>
</tr>
</tbody>
</table>

Adapted from Bohmer, Designing Health Care
What does this have to do with implementing evidence-based clinical pathways??

Here’s my take on how to make the most of them as part of a “learning health care system”
What’s Wrong with Clinical Practice Guidelines?

• Long, tedious

• Not much guidance regarding:
  – Relative importance and impact of each element
  – What do to about important recommendations for which the evidence is weak
    – Lack of relationship to a “learning healthcare system”
  – Sequencing
  – Implementation
  – Measurement

• Not written with decision support at the point of care in mind
What’s in a Clinical Pathway?

• Specification of a relatively homogeneous population
• Evidence review
  – Method to reach consensus (e.g., expert meeting, Delphi)
  – Which evidence is solid, which is not (evidence grading)
• Clear boundaries in time (start/stop) and place
• Measurement framework for key processes and outcomes
Rigorous Pathway Development

- Create **standardized clinical pathways** for major conditions that together comprise the majority of clinical care
  - Respect both the **production system** (“value stream” from the point of view of the health care system) and the **consumption system** (“Lean consumption” or “value stream” from the point of view of the patient)
  - Be clear about the **boundaries** (when the pathway begins and when it ends) and **process and outcome measures**
    - Specify a relatively homogeneous population
    - Start point should include the decision regarding whether or not to perform a test, do a procedure, or recommend a treatment – a key step in removing unhelpful “waste” from the system and insuring improved prevention, treatment and outcomes
    - End point should be distant enough to assess meaningful outcomes (including **patient-reported outcomes**)
    - Clearly indicate who does what happens when and where (in process maps, these are called “swim lanes” for each category of provider)
Pathway Challenges and Opportunities

- Lots of work to create just one
- Generally cover only a fraction of processes that need to be improved, so prioritization critical
- Analysis and revision very time consuming
- Most electronic medical records do not support automated learning
- Ambiguities in evidence may not be resolved
Pathway Challenges and Opportunities

• Even if all steps are solidly evidence-based and executed reliably, outcome may not move dramatically
  – “Attributable effect” usually lower than assumed
  – Reliability rarely is as high as needed to change outcomes

• Pathways started as nursing tools – they must be multi-disciplinary and inter-professional
  – But hard to get MDs, nurses, clinical pharmacists to communicate and round together
Challenges and Opportunities

• Clearly indicate to whom the pathway does and does not apply
  – Use cautiously in patients with do-morbidities and the frail elderly
• Incorporate checklists at critical points in the pathway
• Build in stop checkpoints (e.g., antibiotic “time out”)
• Use standardized order sets liberally to drive evidence-based prescribing and testing
Challenges and Opportunities

• Allow clinicians to opt out of any aspect of the pathway based on their experience and judgment
  – Require documentation of the reason for deviating from the pathway
    – Foundation for a learning healthcare system, but automation is needed to do this efficiently
    – Protection against litigation
  – Be *skeptical* when the level of knowledge is high (*explicit, rules-based knowledge*) and *permissive* when the level of knowledge is low (*tacit knowledge*)

• Draw on guidelines from professional societies, but respect need for local adaptation and complexity of implementation

• Be realistic about what it takes to maintain clinical pathways
Challenges and Opportunities

• Embed quality metrics into clinical pathways so that data can be collected as part of routine work
  – Feedback data and make it visible
  – If this looks impossible, reconsider the prevailing system of care

• Adopt and monitor “balancing measures”
  – The pneumonia treatment core metric
  – 100% compliance with isolation precautions
Let’s Pause Here…

• How will you learn together and continue to innovate?
Problems and Paradoxes

• Do efforts to achieve reliable processes and care pathways stifle innovation?
  – Possibly, but there are ways to help the front line innovate as part of their routine work
Innovating at the Front Line

- Look for the “pain”
  - An example from radiology and the emergency department
- Align with institutional and microsystem priorities and passion
- Harvest intrinsic motivation
- Carve out protected time (or even financial support)
  - Most innovative industries spend >5% on innovation
- Provide data and rush expertise to the point of care to support innovation
  - QI, behavioral science, qualitative/ethnographic methods expertise; research assistance
Innovating at the Front Line

• Tolerate risk
  – Fail frequently, quickly, and well
  – “Culture of safety”
  – Build trust

• Celebrate and reward success (and failure) – make innovation highly visible

• Embrace a “not invented here” mentality
  – What does innovation mean for your team in your context?
Innovating at the Front Line

• Notice, test, adopt and reward disruptive innovation
• Promote and celebrate positive deviance
  – Respecting those quirky folks with strange ideas
• Brainstorm
• Walk about and observe closely
• Perform site visits to observe promising innovations first-hand (internally and externally)
• Borrow from other settings, countries, industries
Innovating at the Front Line

- Shadow other professionals and patients
- Pretend to be another professional or better yet, a patient
- Leverage ethnographic inquiry methods, such as video ethnography, to deeply understand needs and perceptions
- Include patients on the innovation team
Video Ethnography

Potential Benefits:

- Creates the will to change and excitement to change
- Identifies patterns of the member, staff, and/or physician experience
- Uncovers "why" something is happening the way it is
- Explains discrepancies between what people say and do
- Identifies needs that people can't always articulate explicitly

Adapted from Kaiser Permanente Video Ethnography Program
The ‘Ethnographic’ Mindset

**Vuja de** – Seeing the familiar in unfamiliar ways

- Openness and curiosity
- Deep listening
- Positioning the patient, staff or physician as the expert
- Asking Why? How?
- Picking up on the patients or staff use of language
- Observing in addition to listening
- Being present!

Adapted from Kaiser Permanente Video Ethnography Program
Power of Observation and Shadowing

“What people say, what people do, and what they say they do are entirely different things.”

- Margaret Mead
GPS (Global Positioning System)
Which is Better?
What Would Make Both of Them Better?

• Real time “hot links” (Memphis-style barbecue)
• Real time feedback (potholes, accidents, traffic – some of this happens already)
• Learning from drivers who took another route
How “Primitive” Telemedicine saved Uncle Harold
Uncle Harold
Innovative Technologies

• Nanotechnology – wearable microsensors
  – ASSIST - Advanced Self-Powered Systems of Integrated Sensors and Technologies (NSF-funded, NC State and 8 other universities)
  – Biodegradable ultra-flexible sensors and drug dispenser systems
• Wellness apps – Jawbone UP, Fitbit, Nike Fuelband for exercise, sleep, nutrition
• Apple iPhone HealthBook (combines sensors and health apps)
  – Ear infection remote diagnosis
  – Skin mole diagnosis
• “ICU on the wrist”
• Contact lenses to track glucose, intra-ocular pressure
• Stockings that monitor gait (Parkinson’s)
• Head bands to monitor brain wave activity
• FDA-approved remote EKG, BP. glucose, ultrasound
Innovative Technologies

• Blood micro-sampling/testing (Theranos)
• Pills that signal when they have been swallowed (Proteus)
• Nano-sensors floating in bloodstream or attached to blood vessel to monitor any organ
• Mood sensing in mental health (tone and inflection of voice, facial expression, breathing pattern, heart rate, galvanic skin response, BP)
Innovative Technologies

• Automated patient scheduling (ZocDoc)
• Primary care – specialist referral (eReferral)
• On-line MD services (Dr. Thom, Teladoc, MDLIVE, Zipnosis, NowClinic, etc.)
• Second opinions (Cleveland Clinic, Mayo)
• Online communities to share drug side effects and other data, serve as big data source to find determinants of health behaviors
  – PatientsLikeMe Open Research Exchange
• Mobile technologies and provider-patient-researcher networks
  – Self-management and tracking
    – Downloadable statistical process control charts for IBD, n=1 experiments, hypothesis generation (C3N)
A Futuristic Asthma Scenario…

• A teenager prone to wheezing in gym gets data on environmental exposures, air quality, pollen count
• She gets real-time data on physical activity, oxygen concentration in the blood, vital signs, chest motion
• Lung function is assessed by smart phone microphone
• Nitric-oxide sampled in her breath
• A warning is delivered by voice mail or text that an attack is imminent and to use an inhaler
  – But: will this be better than the patient could have done by “knowing herself?”
• Data for research aggregated from many tracked patients

Adapted from Eric Topol, Wall Street Journal, Jan. 10-11, 2015
Uncle Harold - Futurecast

What Uncle Harold could expect today (or soon)

- Video-enhanced apartment safety check
- Safety alerts for falls, inactivity
- Automated care plan – just the right service at just the right time, drawing on medical and community resources
  - GIS enabled links to services near Uncle Harold
- Wearable sensing, painless biomonitoring (B-type Natriuretic Peptide (BNP))
- Automated med adherence reminders and even detection (Proteus); automated refills
Uncle Harold - Futurecast

- Virtual video appointments and daily check-in with appropriate team provider (he does not have reliable transportation, though Village-to-Village helps)
  - Group visits
- Remote specialty consultation with cardiologist, dermatologist, ophthalmologist*
- TeleStroke for his embolic stroke
- Social network with other “live alone” patients
  - Social support
  - Information, tips
  - Job one – Create social and bridging capital where little or none exists
    - Chicago heat wave

* 1/6 US doctor visits now virtual - Deloitte