Overview

- The Problem: Avoidable medical error
- The Solution: Training to proficiency
- The Vehicle: The ASSERT Centre
- The Result: Proficiency based progression in practice
- Conclusions

During the time it takes to give this presentation in the US........

- 2 people have died in road accidents
- 2 people been shot dead
- 2 women have died of breast cancer
- 1 person has died of AIDS
- 11 people have died from medical errors......
That's more than the total number of US soldiers killed in World War I, Vietnam, Afghanistan & Iraq combined.

"Standard" Training is not enough

Of new Surgical Fellows:

- 21% are unprepared for the operating room
- 30% could not independently perform a laparoscopic cholecystectomy
- 66% were deemed unable to operate for 30 unsupervised minutes of a major procedure
- 56% could not perform laparoscopic suture
- 24% were unable to recognize early signs of complications.


New FDA Device Approval Guidance

10. Human Factors Validation Testing (p.23)

- Simulated ‘experience’ of device use is inadequate

  - Validation testing should be designed such that it is sufficiently sensitive to capture use-related problems that exist whether the users are aware of use errors or not.
  - Testing should facilitate identification of the root causes of use failures or problems that do occur.

June 2011
UK Department of Health

Recommendations
A. Patient-centred and service-driven
   - Recommendation 1: As part of a managed learning process and where appropriate, healthcare professionals should be ready to discuss, share and reflect in a situation where they are faced with a change of plan or other challenges.
   - Recommendation 2: Informed change management processes should be followed to ensure that these changes are effectively introduced and are driven by evidence-based practices.

29th July 2014

Graduate Medical Education That Meets the Nation’s Health Needs
Recommendations, Goals, and Next Steps

1. Graduate medical education must become outcome driven
2. Validation evidence is urgently required.

Competence in medicine – a definition?

- “... the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values and reflection in daily practice for the benefit of the individuals and communities being served.”

But...skills are directly related to clinical outcomes

Surgical Skill and Complication Rates after Bariatric Surgery

John D. Birkmeyer, M.D., Jonathan P. Finko, M.D., Amanda D’Mello, R.N., M.S., Mary O’Toole, M.S., Arthur M. Carli, M.D., Andrew H. Nunez, M.D., Justin Dembica, M.D., M.P.H., Missouri Bonadies, Ph.D., and Nancy J. Birkmeyer, Ph.D., for the Michigan Bariatric Surgery Collaborative

...bottom quartile of surgical skill, as compared with the top quartile was associated with:

<table>
<thead>
<tr>
<th>Quartile (Best)</th>
<th>1st Quartile ('worst')</th>
<th>2nd Quartile</th>
<th>3rd Quartile</th>
<th>4th Quartile (Best)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical complication rates</td>
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<tr>
<td>Re-admission rates</td>
<td></td>
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<tr>
<td>Re-operation rates</td>
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<tr>
<td>Infection rates</td>
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<td></td>
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<tr>
<td>ALL complication rates</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mortality rates</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
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<table>
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<th>Re-admission rates</th>
<th>Re-operation rates</th>
<th>Infection rates</th>
<th>ALL complication rates</th>
<th>Mortality rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st (Worst)</td>
<td>11.4%</td>
<td>6.3%</td>
<td>3.4%</td>
<td>4.6%</td>
<td>14.5%</td>
<td>0.26%</td>
</tr>
<tr>
<td>2nd</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tr>
<tr>
<td>3rd</td>
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</tr>
<tr>
<td>4th (Best)</td>
<td>-</td>
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</tbody>
</table>

**Prob. Level:**

- Surgical complication rates: 0.001
- Re-admission rates: 0.001
- Re-operation rates: 0.001
- Infection rates: 0.001
- ALL complication rates: 0.001
- Mortality rates: 0.01

The ASSERT Approach to Training

- **Clinical practice**
- **Skill characterisation**
- **Define "metrics"**
- **Validate the metrics**
- **Quantitatively Define a proficiency standard**
- **Deliberate practice - simulation training**
- **Enabling Better Safer Healthcare**
- **Proficiency based progression**
- **New skill Changing skill/Attrition**
The ASSERT Mission

ASSERT aims to decrease medical error and improve patient care by enabling health professionals and trainees to engage in the deliberate practice of skills to predefined proficiency standards in simulated clinical settings.

UNIVERSITY COLLEGE CORK

- UCC was founded in 1845
- UCC: 20,000 students
- UCC research: top 5 worldwide in food science, pharmacobiotics, nanotechnology
- UCC Alumni: George Boole

The ASSERT Centre at UCC

- State of the Art purpose built facility
- Multi-functional lab with cadaver facilities
- Hi-fi simulation suites with data management
- Research Facilities
A prospective, randomized, double-blinded clinical trial of simulation-based training

"Is there a better way to train surgical skills?"
Multicentre, prospective, randomized, double-blinded trial of proficiency-based progression simulation training for a Bankart procedure.

Residency training program

- East Amherst
- Loyola University Medical Center
- New York Medical College
- Northwestern University
- NYU Langone Health
- Ohio State University
- Philadelphia Coll of Osteopathic Medicine
- Rush University Medical Center
- St. Louis
- St. Louis University
- Tulane University
- University of Illinois at Chicago
- University of Louisville
- University of Miami School of Medicine
- University of Michigan
- University of Mississippi
- University of Tennessee
- University of Utah Medical Center
- Yale University Medical Center

Total 44

Objectively assessed intra-operative errors

<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean no. of errors and 95% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (Traditional)</td>
<td>~41%</td>
</tr>
<tr>
<td>B (Simulation training)</td>
<td>~56%</td>
</tr>
<tr>
<td>C (Simulation training with a PBP requirement (all trainees included))</td>
<td>~56%</td>
</tr>
</tbody>
</table>

\[ p < 0.01 \]

What proportion of trainees demonstrate the objectively assessed proficiency benchmark by the end of training?

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Achieved Benchmark?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>No</td>
</tr>
<tr>
<td>A (Traditional training)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>71%</td>
</tr>
<tr>
<td>B (Simulation training)</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>64%</td>
</tr>
<tr>
<td>C (PBP training)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>25%</td>
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Angelo et al. (2015) Arthroscopy

Outcomes

Achieved Benchmark?
Logistic Regression Analysis for the relative differences between a control condition (Traditional AANA Resident Course) and 2 alternative approaches to surgical training.

- Group A: Reference Group
- Group B: Odds Ratio = 1.4
- p = 0.121
- Group C: Odds Ratio = 7.4
- p = 0.036

Labour epidural: Effect of PBP on a meaningful clinical outcome

- Development of metrics
- Validation of metrics

Procedure characterised

- 74 metrics (with 12 critical errors)
- Construct validation
Principal objective: effect of PBP on incidence of epidural failure.

Novice Anaesthetic trainees (<2 years experience, < 50 epidurals)

Group S (Simulation only group)
Group P (PBP group)

Primary objective: comparison of epidural failure rate between the groups

Successful epidural analgesia administered unaided by the trainee, without ADP resulting in satisfactory analgesia by 60 minutes

Secondary outcomes:
- Impact of training on clinical performance
- Between group participant failure rates
- Patient satisfaction
- Between group participant failure rates

Data collected from first 10 epidural catheter placements

Clinical trial of effect

Epidural failure rate

- No difference in baseline variables between trainees and patients
- Primary outcome (Epidural failure rate) – 28.7% vs 13.3%
- No difference in other secondary outcomes
Conclusions

• Training of doctors must become outcome based
• This requires new evidence
• For procedural skills, proficiency-based progression works
• Important unanswered questions around skill attrition, mastery and non-technical skills.

With thanks to ...