Quality in Health Care
Stage 1: Drug discovery
- 10,000 compounds

Stage 2: Pre-clinical development
- 250 compounds

Stage 3: Clinical development
- 5 compounds

Phases:
- Phase 0: Effect on body
- Phase I: Safety in humans
- Phase II: Effectiveness at treating diseases
- Phase III: Larger scale safety and effectiveness
- Phase IV: Long term safety

Regulatory approval: 1 compound

Increasing risk
- Notified Body approval required

Medical Devices:
- Class III: Examples: Pacemakers, Heart valves, Implanted cerebral stimulators
- Class IIb: Examples: Condoms, Lung ventilators, Bone fixation plate
- Class IIa: Examples: Dental filings, Surgical clamps, Tracheotomy tubes
- Class I: Examples: Wheelchairs, Stethoscopes, Spectacles

Self-assessment
- Class I medical devices will require involvement of a Notified Body if they are sterile, have a measuring function or are re-usable surgical instruments.

- Cancer: 585k
- Medical error: 251k
- COPD: 149k
- Heart disease: 611k
- Motor vehicles: 34k
- Firearms: 34k
- Suicide: 41k

All causes: 2,597k

Based on our estimate, medical error is the 3rd most common cause of death in the US.

However, we’re not even counting this - medical error is not recorded on US death certificates.

Data source:
http://www.cdc.gov/nchs/data/nvss/nvss64/nvss64_02.pdf

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Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. Martin Makary and Michael Daniel assess its contribution to mortality and call for better reporting.

Martin A Makary professor, Michael Daniel research fellow
Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA
Papillary Serous Endometrial Carcinoma, TAH + BSO + PLND + Omentectomy

CVS: regular pulse, unab
VS: S1, S2, G3
Abdo: ↑ adipose tissue, soft, tender
CNS: Awake & alert
Pulmonary edema improved but still uncontrolled

MR
LV
Ao
LA

abdominal masses
chest: hyperinflated, clear
VS: S1, S2, G3
Abdo: ↑ adipose tissue

3/12/20
Febrile
Hct 53%
circulating leukocytes
NAD

6/4/21
NAD

No fever

6/10/21
Cardiography C+/

10/6/19
Cardiography C+/

£

EM

JACCOL:
resp: GAEB
A: Abnormal sounds
VS: S1, S2
Abdo: + + adipose tissue
SNT
NS: Orientated T+P GCS 15

Today: c/o mild P.V.B. @ rest
Comatose following
GCS 6/6/1 3

9/3
MR
BfT + Echolastic signs
Abl: b clac
Abl b NAD
Abl: b NAD

9/3
G3-5cm b Vula + Vag.
G x b NAD

NAD (MT)

NAD u NAD
A. R. Marshall 5th Ave

Manhattan.

Law in
Cancor.

En.
<table>
<thead>
<tr>
<th></th>
<th>Details of prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Astrafranone - 120 mg noon</td>
</tr>
<tr>
<td></td>
<td>60 mg no night</td>
</tr>
<tr>
<td>2</td>
<td>Furosemide - 120 mg no noon</td>
</tr>
<tr>
<td></td>
<td>80 mg no night</td>
</tr>
<tr>
<td>3</td>
<td>Penendepine - 150 mg no day</td>
</tr>
<tr>
<td></td>
<td>150 mg no day</td>
</tr>
</tbody>
</table>
**DATE**: 2011-07-12 07:57

**BP**: 140/70 mmHg  
**HGG**: 10.7 mmol/l

On 7/1 repeat:

- Atenolol 12.5 mg once by mouth
- Aspirin 150 mg daily
- Omeprazole 40 mg daily
- Fosinopril 16 mg daily
- 16 mg pramipexole  
- 16 mg entacapone daily 
- 16 mg levodopa daily
1) Send stool to start.
thereafter after every loose stool.
(not more than
12mg/day, 2x/day)
2) Soral Sactets x 2.
Assessing musculoskeletal training in South Africa

Dr R Dachs*, MBChB(UCT), MMed(Orth)UCT, FCS(SA)Orth
Dr S Roche*, MBChB(UCT), FCS(SA) Orth, LMCC(Canada), Consultant
Dr B Vrettos*, MBChB(UCT), FCS(SA)Orth, FRCS(Eng), MMed(Orth)UCT, Consultant
Dr K MacIntyre, MBChB(Wits), MMed(Orth)Wits, FCS(SA)Orth, Arthroplasty Fellow, Groote Schuur and Life Orthopaedic Hospitals
Dr B Currin, MBChB(Wits), Intern, Groote Schuur Hospital 2010/2011
Dr N Kruger*, MBChB(UCT), FCS(SA)Orth, FRCS(Ed), Consultant
Prof J Walters*, MBChB(UCT), FCS(SA)Orth, Previous Head of Department
Prof R Dunn*, MBChB(UCT), MMed(Orth)UCT, FCS(SA)Orth, Head of Department
*Department of Orthopaedic Surgery, University of Cape Town

Correspondence:
Dr Robert Dachs
H49 Old Main Building

Tools used to assess medical students competence in procedural skills at the end of a primary medical degree: a systematic review

Marie C. Morris*, Tom K. Gallagher and Paul F. Ridgway
Department of Surgery, Trinity Centre for Health Sciences, Tallaght Hospital, Dublin, Ireland
British doctors’ experiences of working in rural South Africa: The London GP Out of Programme Experience

**Authors:**
Candice Reardon¹
Oluwatobi Enigbokan¹
Gavin George³

**Background:** A paucity of research exists that has examined temporary placements of foreign health professionals in South Africa (SA) as a possible strategy for addressing health worker shortages. The Out of Programme Experience (OOPE) initiative, run by the London GP Deanery, aims to provide a sustainable inflow of British, trainee GP doctors into rural public

The UK doctors were more inclined to want each individual to accept personal responsibility for their mistakes or problems, whilst they believed that their South African colleagues had a culture of collective responsibility and a tendency to shift blame, and that frustrated them endlessly.

In addition, three doctors stated that the poor work ethic demonstrated by some of the staff at their facilities was ‘quite depressing’ and that the focus on patient care was not as high as it should be. This latter belief was based on observations of health staff keeping the wards as low as possible and failing to include patients in their treatment decisions.
Incoherent care

• Why are we doing this?
  • Medicolegal concerns
  • Collegial opinion
  • Perverse incentives
  • Tradition
  • Inertia and linear thinking
  • Insulation from consequences (costs, harms)

• Clinical leadership – can we please step up?
Health care quality from the patients’ perspective: a comparative study between an old and a new, high-tech hospital

What patients really wanted:
- Effective pain relief
- Being seen and treated without waiting too long
- Knowing who their doctor was
- Having a comfortable bed...
Quality outcome measures

<table>
<thead>
<tr>
<th>Objective</th>
<th>Intermediate</th>
<th>Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Mortality</td>
<td>• Surrogate (e.g. HbA1c)</td>
<td>• Process</td>
</tr>
<tr>
<td>• MACE</td>
<td>• Readmission rates</td>
<td>• Cost saving</td>
</tr>
<tr>
<td>• Nosocomial infection rate</td>
<td></td>
<td>– test ordering</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Trial evidence:
- controlled environment
- homogeneous subjects

Care bundle/QI intervention:
- Cocktail
- Unpredictable interactions
- Real world
- Different patients
Effectiveness of a Bundled Intervention Including Adjunctive Corticosteroids on Outcomes of Hospitalized Patients With Community-Acquired Pneumonia
A Stepped-Wedge Randomized Clinical Trial

Melanie Lloyd, MPhtySt; Amalia Karahalios, PhD; Edward Janus, MD, PhD; Elizabeth H. Skinner, PhD; Terry Haines, PhD; Anurika De Silva, PhD; Stephanie Lowe, MPH; Melina Shackell, BPTy; So Ko, MBBS; Lucy Desmond, MD; Harin Karunajeewa, MBBS, PhD; for the Improving Evidence-Based Treatment Gaps and Outcomes in Community-Acquired Pneumonia (IMPROVE-GAP) Implementation Team at Western Health

## Corticosteroids for pneumonia

Anat Stern¹, Keren Skalsky², Tomer Avni², Elena Carrara³, Leonard Leibovici³, Mical Paul¹

### Table

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Risk with control</td>
<td>Risk with corticosteroids</td>
<td>RR</td>
<td>1863</td>
<td>MODERATE ¹</td>
</tr>
<tr>
<td><strong>Mortality - adults</strong></td>
<td>Study population</td>
<td>RR 0.66</td>
<td>1863 (11 RCTs)</td>
<td>MODERATE ¹</td>
<td></td>
</tr>
<tr>
<td></td>
<td>82 per 1000</td>
<td>53 per 1000 (36 to 74)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mortality - adults - severe CAP</strong></td>
<td>Study population</td>
<td>RR 0.58</td>
<td>995 (9 RCTs)</td>
<td>MODERATE ¹</td>
<td></td>
</tr>
<tr>
<td></td>
<td>131 per 1000</td>
<td>76 per 1000 (52 to 110)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mortality - adults - non-severe CAP</strong></td>
<td>Study population</td>
<td>RR 0.95</td>
<td>868 (4 RCTs)</td>
<td>MODERATE ²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>29 per 1000</td>
<td>28 per 1000 (13 to 58)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Efficacy and Safety of Corticosteroids for Community-Acquired Pneumonia: A Systematic Review and Meta-Analysis

BACKGROUND: Corticosteroids are an option in the treatment of community-acquired pneumonia (CAP). However, the benefits and adverse effects of corticosteroids, especially in severe CAP, have not been well assessed.

METHODS: PubMed, Embase, and Cochrane Library databases from inception to May 2015 were searched. Randomized controlled trials (RCTs) and cohort studies that evaluated the use of corticosteroids in adult patients with CAP were included. The quality of outcomes was evaluated using the Grading of Recommendations Assessment, Development, and Evaluation methodology. The Mantel-Haenszel method with random-effects modeling was used to calculate pooled relative risks (RRs) and 95% CIs.

RESULTS: Nine eligible RCTs (1,467 patients) and six cohort studies (4,085 patients) were identified. The mean corticosteroid dose and treatment duration were 30 mg/day methylprednisolone for 7 days. Corticosteroids did not have a statistically significant effect on mortality (RR, 0.72; 95% CI, 0.43-1.21; evidence rank, low) in patients with CAP and patients with severe CAP (RCTs: RR, 0.72; 95% CI, 0.43-1.21; evidence rank, low; cohort studies: RR, 1.00; 95% CI, 0.84-1.17). Corticosteroids treatment was associated with decreased risk of ARDS (RR, 0.21; 95% CI, 0.08-0.59) and may reduce length of hospital and ICU stay, duration of NIV antibiotic treatment, and time to clinical stability. Corticosteroids were not associated with increased rates of adverse events.

CONCLUSIONS: Short-term treatment with corticosteroids is safe and may reduce the risk of ARDS, shortening the length of the disease in patients with CAP.

CHEST 2016; 149(1):209-219

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Corticosteroids Events Total</th>
<th>Placebo Events Total</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized controlled trials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Controversial, 2005</td>
<td>0</td>
<td>24</td>
<td>7</td>
</tr>
<tr>
<td>Fernandez-Guerra, 2011</td>
<td>1</td>
<td>28</td>
<td>1</td>
</tr>
<tr>
<td>Marik, 1993</td>
<td>1</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Snijders, 2010</td>
<td>4</td>
<td>48</td>
<td>3</td>
</tr>
<tr>
<td>Torres, 2012</td>
<td>6</td>
<td>61</td>
<td>9</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>175</td>
<td>172</td>
<td>100.0%</td>
</tr>
<tr>
<td>Total events</td>
<td>12</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: τ² = 0.00; χ² = 3.95; df = 4 (P = 0.41); I² = 9%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: χ² = 1.26 (P = 0.21)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Cohort studies |
|-----------------|-----------------------------|---------------------|-------------------------------|
| Chon, 2011 | 34 | 80 | 24 | 37 | 22.3% | 0.87 (0.63-1.21) |
| Garcia-Vidal, 2007 | 5 | 70 | 13 | 238 | 2.5% | 1.31 (0.48-3.54) |
| Polverino, 2012 | 17 | 158 | 135 | 1294 | 10.3% | 0.80 (0.56-1.14) |
| Saltuk, 2011 | 18 | 61 | 16 | 50 | 7.7% | 0.90 (0.53-1.51) |
| Tang, 2012a | 167 | 943 | 147 | 943 | 53.2% | 1.14 (0.93-1.36) |
| Uygur, 2013 | 6 | 30 | 26 | 71 | 4.0% | 0.58 (0.29-1.19) |
| Subtotal (95% CI) | 1,362 | 2,733 | 100.0% | 1.00 (0.86-1.17) |
| Total events | 247 | 361 | |
| Heterogeneity: τ² = 0.00; χ² = 8.14; df = 5 (P = 0.09); I² = 3% |
| Test for overall effect: χ² = 0.00 (P = 0.99) |

Figure 1 – Mortality of patients with CAP according to treatment arm. The size of the squares denotes the point estimate in each study are proportional to the weight of the study. The diamonds represent the overall findings in each plot, for all study names, see the cited references. CAP = community-acquired pneumonia; M-H = Mantel-Haenszel.

Figure 4 – Trial sequential analysis of studies with patients with severe CAP. Trial sequential analysis, assuming a 15% mortality rate in the control group and a 25% relative risk reduction with 80% power and a two-sided α of 0.01, found that the optimal sample size needed to reliably detect a plausible effect of treatment on the mortality of patients with severe CAP was 2,546 patients. The sequential monitoring boundary has not been crossed, indicating that the cumulative evidence is stable and inconclusive. See Figure 1 for legend for expansion of abbreviations.
Quality yardsticks

Guideline quality

Matching guidelines to clinical settings

Intervention interactions

Measuring quality or guideline discordance?
Quality improvement
System strengthening
QI exponential growth

Healthcare QI hits in Google Scholar per year

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of articles</th>
<th>Exponential (Number of articles)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Fig 3. Number and risk of bias of studies with acceptable research designa over time.

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0217617
Do quality improvement initiatives work?
Deming
Shewhart cycles
PDCA
PDSA
Lean manufacturing
Performance jumps vs Kaizen
Analysis paralysis
Effectiveness of a national quality improvement programme to improve survival after emergency abdominal surgery (EPOCH): a stepped-wedge cluster-randomised trial

Carol J Peden, Tim Stephens, Graham Martin, Brennan C Kahan, Ann Thomson, Kate Rivett, Duncan Wells, Gerry Richardson, Sally Kerry, Julian Bion, Rupert M Pearse, on behalf of the Enhanced Peri-Operative Care for High-risk patients (EPOCH) trial group*

Summary
Background Emergency abdominal surgery is associated with poor patient outcomes. We studied the effectiveness of a national quality improvement (QI) programme to implement a care pathway to improve survival for these patients.

Figure 2: All-cause mortality within 90 days of emergency abdominal surgery

Figure 3: Duration of hospital stay after emergency abdominal surgery

*Published Online April 25, 2019
Lancet 2019; 393: 2213-21
The effectiveness of interventions to improve laboratory requesting patterns among primary care physicians: a systematic review

Sharon L. Cadogan¹*, John P. Browne¹, Colin P. Bradley² and Mary R. Cahill³
Fig. 1 Flow diagram of the search strategy for review

PubMed (N=2,386)  Cochrane Library (N=837)  SCOPUS (N=681)  EMBASE (N=2,262)

6,166 total records

386 Studies identified for abstract review: 165 (PubMed) 191 (Scopus) 9 (Cochrane) and 21 (Embase)

5,780 excluded: Duplicates (N=504), Title review (N=5,276)

299 excluded based on abstract review

87 Studies considered potentially relevant

76 papers excluded based on inclusion/exclusion criteria

11 Studies included in the review
<table>
<thead>
<tr>
<th>Study type</th>
<th>Low risk of bias</th>
<th>High risk of bias</th>
</tr>
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<tbody>
<tr>
<td>Interrupted time series</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Controlled before after</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Randomised controlled trial</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>
Interventions

Guidelines, education, and feedback
Guidelines and feedback
Guidelines
Education and feedback
Education
Change order form

Only one study at low overall risk of bias: Educational activities reduced test volume 12%
A hospital-randomized controlled trial of a formal quality improvement educational program in rural and small community Texas hospitals: one year results

GIOVANNI FILARDO1, DAVID NICEWANDER1, JEPH HERRIN2, JANINE EDWARDS3, PERCY GALIMBERTI4, MARI TETZE4, SUSAN MCBRIDE4, JULIE GUNDERTON1, ASHLEY COLLINSWORTH1, ZIAD HAYDAR1, JOSIE WILLIAMS3 AND DAVID J. BALLARD1

1Institute for Health Care Research and Improvement, Baylor Health Care System, 8080 N. Central Expressway, Suite 500, Dallas, TX 75206, USA, §Section of Cardiovascular Medicine, Yale University School of Medicine, 333 Cedar Street, New Haven, CT 06510, USA, 2Texas A&M University Health Science Center, 3833 Texas Avenue, Suite 150, Bryan, TX 77802, USA, and §Dallas Fort Worth Hospital Council, 250 Decker Drive, Irving, TX 75062, USA

Abstract

Objective. To investigate the effectiveness of a quality improvement educational program in rural hospitals.

Design. Hospital-randomized controlled trial.

Setting/Participants. A total of 47 rural and small community hospitals in Texas that had previously received a web-based benchmarking and case-review tool.

Intervention. The 47 hospitals were randomized either to receive formal quality improvement educational program or to a control group. The educational program consisted of two 2-day didactic sessions on continuous quality improvement techniques, followed by the design, implementation and reporting of a local quality improvement project, with monthly coaching conference calls and annual follow-up conferences.

Main Outcome Measures. Performance on core measures for community-acquired pneumonia and congestive heart failure were compared between study groups to evaluate the impact of the educational program.

Results. No significant differences were observed between the study groups on any measures. Of the 23 hospitals in the intervention group, only 16 completed the didactic program and 6 the full training program. Similar results were obtained when these groups were compared with the control group.

Conclusions. While the observed results suggest no incremental benefit of the quality improvement educational program following implementation of a web-based benchmarking and case-review tool in rural hospitals, given the small number of hos-
“It worked for me” and the epidemic of reporting site-specific QI interventions

But does it travel well?
“Health care is characterized by optimistic reliance on the excellence of individual performers, an attitude that tends to underestimate the possibility or failure and fails to think of operational changes as protective against poor outcomes.”
Knock on harms of projects versus system approaches – gaming the system

• Waiting times – fewer patients/day – longer time to appt – higher attrition rate/emergency unit presentation rate

• Ambulance response times

• Most ‘successes’ are limited projects rather system wide improvements

• Counting HbA1cs...
Gaming the system: 
1/3 ‘corrected’ their data
The moderate success of quality of care improvement efforts: three observations on the situation

TAL KATZ-NAVON¹, EITAN NAVEH² AND ZVI STERN³

Clinical autonomy vs conformity

Better or quicker?

Qi in silos
Doctors aren’t pilots

- High reliability versus multi-variable uncertainty
- SoPs versus flexibility and responsiveness
- Professional versus organizational norms
Organisations preach quality but practice productivity

- Do it excellently, but do it really, really fast (and cheaply)

PROMOTE:
- Quality
- Safety

REWARD:
- Productivity
- Efficiency
QI in silos

- “Only applies to our area”
- No time to share
- Not placed in a strategy of improvement
“Cosmetic QI”

• First movers want technical efficiency
  • Find and solve problems

• Second movers want legitimacy
  • Formulaic adoption of ‘best practice’
  • Conform to institutional pressures
What characterizes useful interventions?

• Interest and enthusiasm and support from leaders/organisation
• Sustainable
• Make a clinically important difference
• Exportable
• Active participation/collaboration of end-users in audit cycle.
• Fosters sense of agency in participants
Quality in Care

• Implementation:
  • Professionalism
  • Taking back clinical leadership
  • Educating for quality in all environments, not just tertiary centres

• Outcomes – are we focusing on the right things?
• Metrics/yardsticks – are our guidelines fit for purpose?
• Quality improvement and audit linked to system change