

The Need for Regulation to Ensure Safe, High Quality Care

Halifax 8 – Winnipeg
Friday 24 October, 2008

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- History -

- Hammurabi – 4000 years ago
- Kinsman healer – Akkadian
- 282 laws – 6' high stone column
- Fee schedule for surgical services
- Means tested fees
- Full explanation of patient's rights
- Specified penalties for iatrogenic harm

- History -

	Years ago
■ Hippocrates	2,400
■ Florence Nightingale	150
■ Ernest Codman	100
■ Moser	50
■ Don Harper Mills	30
■ Lucien Leape, APSF	20
■ To Err is Human, OWAM, APSF	10
■ World Alliance for Patient Safety	4

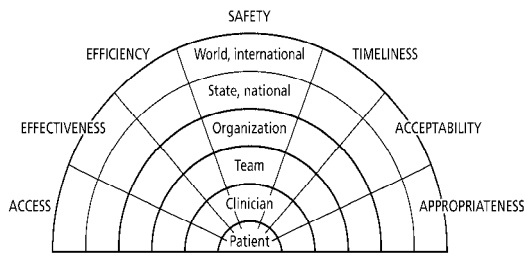
Safety

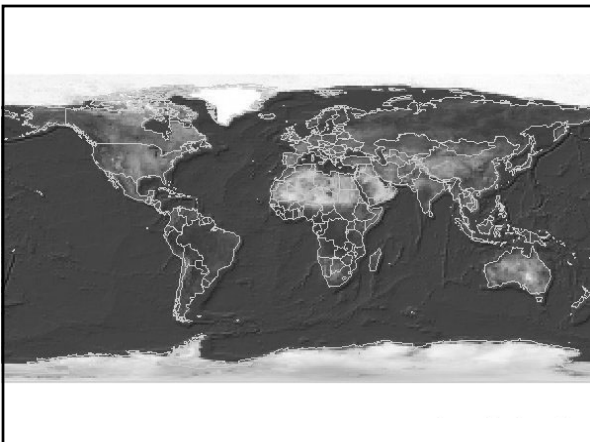
- Immediate
- Tightly Coupled
- Egregious
- Dramatic
- Unusual

Quality

- Delayed
- Loosely Coupled
- Common place
- Mundane
- Familiar

- Safety and Quality -





**- Some Reminders –
- Healthcare -**

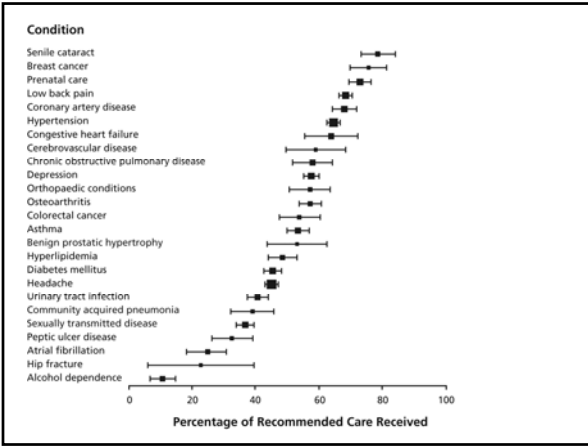
- Some great advances on many fronts
- “Lumping” all the “downside” is misleading
- Decisions should be cost-risk-benefit based
- Most practitioners are
 - Conscientious
 - Well intentioned
- Nevertheless.....

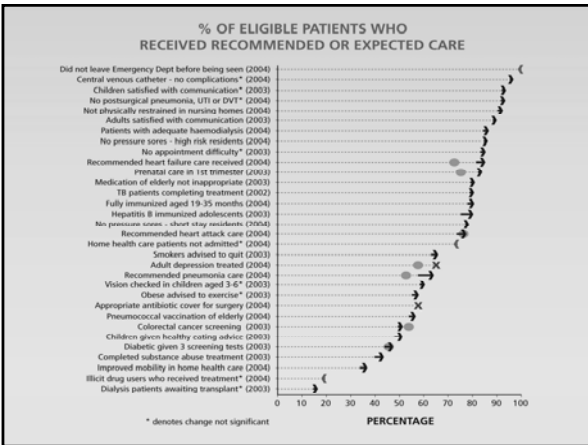
Nevertheless.....

- We make the wrong plan half the time
- We harm a patient with 10% of admissions
- The harm is permanent or severe in 2%
- Death results in 1/300 patients
- This amounts to 4 times the road-toll
- The harm amounts to 10% of health costs

- How does this happen? -

- Making the wrong plans
- Flawed execution of plans
- In a dysfunctional milieu
 - poor behaviour
 - external factors
 - poor work practices
 - disorganised



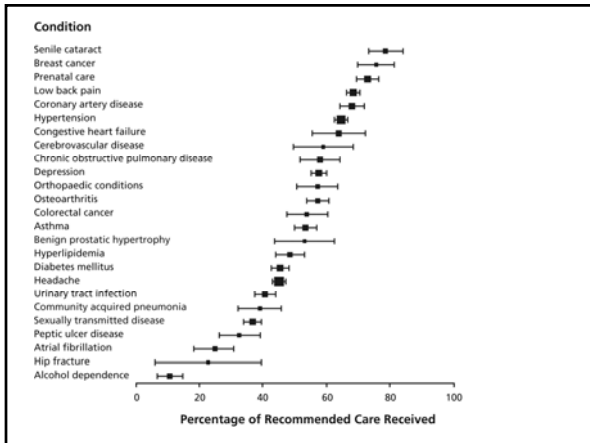


- Why? -

- Errors?
- Violations?
- Mindlines
- Work practices
- Corporate dissociation
- External influences
- Extreme patchiness

- Some examples -

- Blood pressure control
- Atrial fibrillation and stroke
- Airway management
- The wrong drug problem
- Withdrawal of treatment



Our own experience
- 5 teaching hospitals -

- INR > 4 first week
- Appropriate response (Vitamin K)
- Appropriate monitoring INR

Baseline compliance 39%

Post-intervention compliance 52%

- Atrial fibrillation and stroke -

- 149 preventable ADE's in QAHCS
- 49 anticoagulant use – 1/3 warfarin
- 5 embolic strokes, 9 bleeds
- Atrial fibrillation
 - in 5% > 65 years
 - in 10% > 75 years
- Accounts for 1 in 4 in the elderly

- Some examples -

- Blood pressure control
- Atrial fibrillation and stroke
- Airway management
- The wrong drug problem
- Withdrawal of treatment

- The wrong drug problem -

- In 1993, 7% of 2,000 incidents
- New Zealand – one in 150 injections
- In Seattle – one in 130 injections
- Can drive the “wrong drug” rate to >50% of cases in simulated situations

- Recommendations 1993 -

43. Establish a control system for organising, storing, restocking, drawing up, labelling and administering drugs.
44. Established standard protocols whenever reasonable for dilutions, labels and means of administration of drugs.
45. Adopt the ASTM colour code protocol.
46. Colour code the tips of ampoules for classes of drugs.
47. Arrange for colour coding of the plungers of syringes for classes of drugs.
48. Design and use physical templates for drug storage and stock control.



Process of Anaesthesia - Drug Trolleys -

- Standardised layout
- Racks
 - census at a glance
 - colour coded
 - stock control
 - easy to check
 - coloured ampoule tips



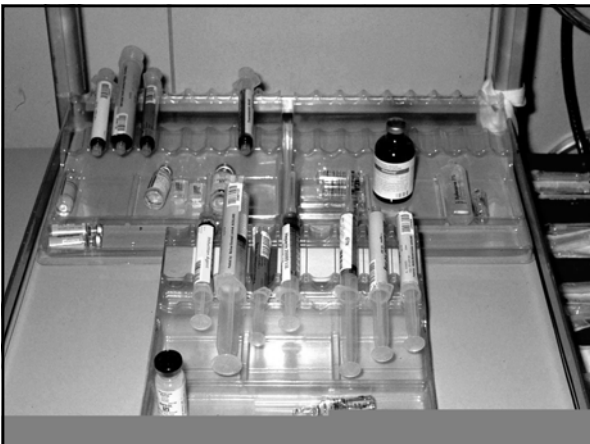
Process of Anaesthesia - Drugs -

- Prefilled syringes
- Flag labels
- Colour coded
- Bar coded
- Layout before use
- Layout after use
- Label lines
- Unique connectors









- Integrated Drug Administration System -

- Addresses every one of the problems
- 3.4 errors per million vs 7,000 per million
- Awake paralysis, wrong drug, death
- Less than \$1 per case
- Affect the safety of 2 million people per year
- 15 years laterUptake ??? Funding ???

- Safe Use Of Anticoagulants In 5 Major Hospitals -

- Guideline development
 - Recent “gold standards”
 - Accessibility, brevity, clarity
 - Standardise across all hospitals
- Clinician involvement -
 - Respected, hands-on
 - Recruit for ownership

- Safe Use Of Anticoagulants In 5 Major Hospitals -

- Get baseline practice data
 - To define current practice
 - To enable feedback to clinicians
- Carry out academic detailing
 - To identify deficiencies in practice
 - To impart part desired practice
- 3-month post-intervention data

- Warfarin initiation -

- INR >4 in First Week -

■ Pre-intervention	31%
■ Post-intervention	20%
■ Relative improvement	40%

- Warfarin Overanticoagulation -

- Appropriate use of Vitamin K for INR >6 -

■ Pre-intervention	49%
■ Post-intervention	75%
■ Relative improvement	56%

- Warfarin Overanticoagulation -

- Follow-up INR Within 24 Hours -

■ Pre-intervention	48%
■ Post-intervention	61%
■ Relative improvement	28%

- Warfarin anticoagulation -
- Patients with Bleeding Given Vitamin K -

- Pre-intervention 39%
- Post-intervention 66%
- Relative improvement 66%

- Good Things -

- Academic detailing
 - Enthusiastic positive response
 - Especially from junior doctors
- Many requests for guidelines
- Keen interest in the process
- Relative improvement: 26-66%

- Bad Things -

- Staff turnover - ongoing burden
- Idiosyncratic practices from a bad experience
- “Seniority and autonomy seem to entitle prescribers to practice non-evident based medicine”
- Pre-intervention: 35-52%

- Summary -

- Over 300 studies assessed (1997 – 2007)
- Economic evaluations non-existent or poor
- “Back of the envelope” calculations:
 - the cure often costs more than the problem with intensive single issue interventions
 - interprofessional education?
 - audit and feedback
 - guidelines
- Barriers to guideline use by senior and junior doctors
- Standards and responsive regulation

- Audit and feedback -

- 118 studies, 88 comparisons
- Effects ranged from a 16% decrease in compliance to a 70% increase
- Low baseline compliance with recommended practice and a higher intensity of feedback were associated with greater effectiveness
- *This should take place regularly, by peers, using good tools*

- Use of guidelines by professions allied to medicine -

- 18 studies, 467 health professionals
(17 studies of nurses, 1 of dieticians)
- 3/5 – improved processes of care
- 6/8 – improvements in outcomes of care
- Studies supported the hypothesis that there is no difference between care given by nurses using clinical guidelines and standard physician care
- *Effective, but need forcing functions*

- Areas of deficiency -

RAND	25
ARQH	42
QAHCS	20
NICS	23
NICE	32
STANFORD	25
Summary	172

- Some principles -

- Evidence where there is some
- Standardisation where there isn't
- Tools, not guidelines
 - developed by users
 - attention to workflow
 - standard explicit or implicit
 - documents process
 - easy to audit – data base
- Part of professional life necessary for credentialling and accreditation

- Conclusion -

- Current baselines are unacceptable
- Current rate of change is unacceptable
- Most existing approaches are not realistic or cost effective
- There is a large reservoir of goodwill and professional aspiration
- Properly planned responsive regulation is needed
- Clearly defined responsibilities
- Standardisation at the point of care and accountability at the individual level

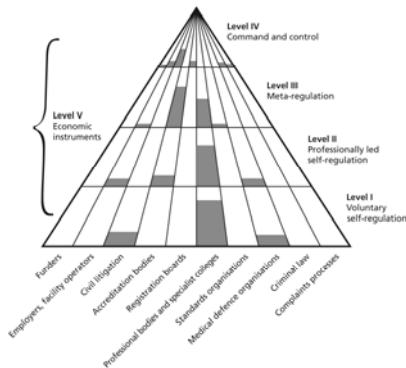
Where are we at in 2007?

- We make the wrong plan nearly 50% of the time
- We harm a patient with 10% of admissions
- The harm is permanent or severe with 2% of admissions
- Death is associated with the harm in 1/300 patients
- This amounts to 100,000 preventable deaths since the QAHCS in 1995
- Iatrogenic harm costs as much as \$1 million /hour

What currently dictates practice?

- Collectively constructed 'mindlines' rather than evidence-based guidelines (BMJ 2004;329;1013-)
- Communities of practice, cohesive, loyal
- Mutual reinforcement of ritualistic behaviour
- Normalisation of deviance
- Us and them – binary thinking, autonomy
- Standards?.....“But we are different”

Regulation in Health Care



What to do?

Harness the natural properties and behaviours which emerge spontaneously at socio-technical interfaces of the complex system which constitutes healthcare

What are these?

- Natural networks, hubs, connectivity
- Natural appeal and stickiness
- Natural propagation and tipping points
- Natural categories and natural mapping
- Natural surveillance and collegial behaviour

A historical accident

- 1987 – Monitoring and Patient Safety
- 1988 – 37 papers A&IC 16(1), 5-116
- Natural network – hubs
- Natural appeal – stickiness
- From guidelines to standards
- Tools – endorsement
- Tipping point – natural propagation
- International spread and endorsement
- Anaesthesia and Patient Safety, A&IC 2005; 33(3): 297-300

Collaborations for Translating Evidence into Practice - CTEP -

- Coogee Charter – 30 key people
- Clinician-led reform of healthcare
- Guideline review – Map of Medicine, JBI
- Standards development
- Tools - standard implicit or explicit
 - the record of implementation
 - the means for audit
- Random audit by peers
- Required for credentialling and accreditation

Clear responsibilities and accountabilities

- For
- priority setting
 - guideline review
 - standards development
 - endorsement
 - validation of tools
 - implementation (top down)
 - audit, credentialling, accreditation

Areas of deficiency

QAHCS	20
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Setting Priorities

- Choose well documented problems that are common
- Choose problems for which there is a solution
- Form collaborations
- Review, to standards, to tools, to audit, to credentialling, to accreditation

General Practice - Preventive

- Smoking 2
- Obesity 1
- Lipids 2
- Blood pressure 2

Basic Health Record

	Identity of HCP	Date
Smoking - Do you smoke?		
- Do you want to quit?		
- Materials provided		
Diet/eating - weight		
- BMI		
- Do you want to lose weight?		
- Materials provided		
Exercise - Average hours/day		
- Average intensity		
- Do you want advice?		
- Materials provided		
Blood lipids - Comment		
- Plan		
Blood pressure - Reading		
- Plan		
Alcohol - Drinks per week		
- Advice given?		
- Materials provided		

General Practice – Common conditions

- Headache 1
- Back pain 2
- Dyspepsia 2
- Antenatal care 3

Medicine

- Acute coronary syndrome 5/6
- Heart failure 5/6
- Diabetes 5/6
- Atrial fibrillation-warfen 4/6
- Community acquired pneumonia 2/6
- Asthma 4/6

Surgery

- Thromboembolism prophylaxis 5/6
- Prophylactic antibiotics 3/6
- Pain management 2/6
- Cancer of the colon 4/6
- Wrong side/site/patient surgery

CORRECT PATIENT, SITE & PROCEDURE
(18 steps, 6 people)

	Identity of Healthcare professional	Time & date
Consent form – Patient's name		
- Procedure site		
- Procedure name		
- Procedure reason		
Site marked		
Patient ID in OR– Name stated		
- DOB stated		
- Site stated		
- Procedure stated		
Response checked – ID band		
- Marked site		
- Consent form		
Time out		
- Correct patient		
- Correct site		
- Correct procedure		
- Correct implant		
- Images correct		
- Images labelled		

Nursing

- Pressure ulcers 4/6
- Falls 2/6
- Vascular access 4/6
- Ventilator associated pneumonia 3/6

Summary – some principles

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