A Proposal to Study the Relationship Between Structure & Outcomes in the Intensive Care Unit

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Today's Agenda

- Quick review of the significance of caring for the critically ill
- Brief discussion of ICU risk stratification methodology
- Review of what's know about the relationship between ICU structure and outcomes
- Overall goals of this research effort
- Specific Research Proposal
  - soliciting suggestions relating to study design, etc.

The MAGNITUDE of ICU Care

- ICUs contain ≈ 8% of total U.S. acute hospital beds
  - 10-20% in large tertiary referral medical centers
  - compare with 2-4% in Europe and Japan
  - 2.6-fold higher per capita ICU bed use than in Canada

  [Groeger, *CCM* 20:846,1992; Dragstad, *Int J Tech Assess Health Care* 8:395,1992; Sirio, *CCM* 20:1207, 1992; Jacobs, *CCM* 18:1282,1990]

- Cost of ICU care in the U.S. -- *excluding* professional fees

  ≈ 20% of acute hospital costs ≈ 6.7% of health care dollars

  ≈ $77 billion / year ≈ 0.9% of GDP (4-fold greater than in Canada)

ICU Resource Use is Highly Skewed

- Oye *et al*. (*Chest* 99:685,1991)
  - 8% of patients consumed 50% of cumulative ICU resources (measured by TISS points)
  - this subset was sicker (by APACHE II APS)
  - 71% died in hospital -- vs. 20% of the others

- Garland *et al*. (*AJRCCM* 157:A302,1998)
  - the 5% with the longest ICU lengths of stay consumed 20-48% of various ICU resources
  - they were sicker by APACHE III, and 57% died while in the hospital -- vs. 30% of the rest

Variation in ICU Care

- No formal studies of practice variation in critical care

BUT

- Substantial variability in ICU performance, resource use:
  - APACHE II study of 13 tertiary care hospitals found ratios of ratios of actual-to-predicted hospital mortality varied from 0.59 to1.58 (Knaus, *Ann Int Med* 104:410,1986)
  - APACHE III study of 42 ICUs found actual-to-predicted ratios for mortality of 0.67-1.25 and for ICU length of stay of 0.88-1.21 (Knaus, *Ann Int Med* 118:753,1993)

THUS:

- The ICU is an economically important component of the U.S. health care system
- With death rates of 15-30% in most studies, ICU care is clearly important in human terms as well
- For these reasons it's important to improve the quality and cost-effectiveness of ICU care

Some Issues Related to Outcomes Research in the ICU

Relevant ICU Outcomes

Directly related to patient care

- ICU & hospital survival rates
- Complication rates
- – Duration of survival
- – Quality of life

} ★

- Resource consumption (including but not limited to cost of care)

★ Cost-effectiveness of care

- Effectiveness of bed utilization

★ Patient and family satisfaction

Not directly patient related

★ Staff satisfaction and retention

★ Concordance of desired to actual end of life decision-making

Some (of many) Structural Variables

Hospital variables
- size, location, teaching status
- volume, occupancy rate
- technologic availability
- patient mix
- payer mix
- physician mix

Physician practice variables
- location, size, type
- physician mix
- ★scheduling
- volume, patient mix
- payer mix

ICU variables
- type, size, volume, occupancy
- stepdown & ward bed availability
- administrative structure
- attending staffing
- nonattending staffing
- open vs. closed
- rounds
- ICU "culture"
- patient mix
- payer mix

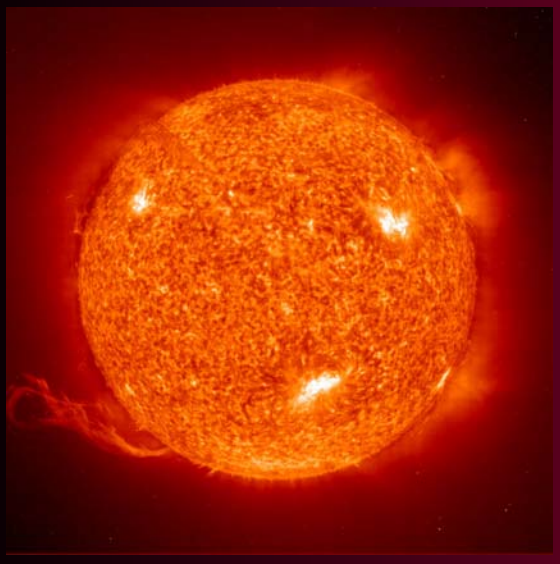
Societal/Gov't variables
- payment & practice rules
- availability of outcomes data to public &/or physicians

Variable Elements of Intensivist Practice Structure

- Location
- Group size
- Practice type (solo, group, institutional, academic)
- Involvement of ICU Fellows
- Involvement of other health care workers (e.g. PAs, ANPs)
- Nature of interaction with nurses, residents, etc. (e.g. structured ICU rounds)
- Clinical load of ICU patients (daily avg, yearly load)
- Scheduling
  - daily rotation for attendings
  - evening, weekend coverage
  - info transfer over transitions
- Concurrent clinical obligations (inpt vs. outpt; ICU vs. non-ICU)
- Concurrent nonclinical obligations (teaching, research, administration)
- Time spent in ICU (per day, per patient)
- Payer mix

Prospective Severity Stratification Systems

- Best developed for ICU care
  - APACHE, SAPS, MPM, PRISM, specialized systems for trauma, cardiac surgery, a few others
  - custom systems for specific purposes (e.g. CHQC, SUPPORT)
  - much less developed out of ICU or specialized patient types
- Validated, published prediction equations within the widely used systems exist only for:
  - short-term mortality rates, ICU LOS, ventilator-days
- These currently available prediction systems are imperfect:
  - ignore racial, socioeconomic, insurance, other factors
  - can't account for changes over time in medical care
  - variable performance across diagnoses & countries



What's Known About the Effect of ICU Structure on ICU Outcomes?

"Open" vs. "Closed" ICUs

- Definitions not simple - made up of many elements
- 15 studies (at least)
  - span MICU, CCU, SICU, PICU
  - most from U.S., one from Canada, one from Singapore
- Interpretation complicated by:
  - major differences in structure of the open & closed systems (various "degrees" of open and closed)
  - comparison across disease states vs. restricted diagnoses
  - possibility of publication bias
  - ★ large differences in study design, outcome parameters assessed, case-mix adjustment, reporting of data

Open vs. Closed ICUs - Summary

- In ICUs which were closed or had more clinical control or involvement by Intensivists:
  - 7 of 11 studies found lower hospital mortality rates
  - 6 of 9 found shorter ICU lengths of stay
  - 5 of 8 found shorter hospital lengths of stay
- No published study has identified worse outcomes from more involvement by Intensivists in care of ICU patients
- Estimated (*Eff Clin Pract* 6:284, 2000) that >53,000 lives/year would be saved in U.S. by full implementation of the Leapfrog Group requirements of Intensivist-model ICU care
- Yet the debate continues -- driven primarily by nonmedical issues
- More research is needed to clearly identify which aspects of the closed ICU system are key to improved outcomes

Beyond Open vs. Closed ICUs: Influence of Continuous Attending Intensivist Coverage

[Blunt *Lancet* 356:735, 2000]

- *Before* vs. *After* study in the closed ICU of a university-affiliated hospital in the U.K.
- After -- an Intensivist stayed in house 24 hrs/day
- Before -- an Intensivist was present during weekdays, and 45% of evenings and weekends
- APACHE II for Actual:Predicted Hospital Mortality Ratios.

	Before	*After*
N	**452**	**372**
APACHE II score	**19.3**	**17.9 ***
Actual:predicted hosp. mortality ratio	**1.11**	**0.81 ***

Beyond Open vs. Closed ICUs: Telemedicine

[Rosenfeld *CCM*. 28(12): 392, 2000]

- *Before* vs. *After* study in open SICU at a Hopkins affiliate; housestaff team; surgical Intensivist with an informal role, APACHE III for severity adjustment.
- After -- consulting Intensivist doing remote monitoring 24 hrs/day on all patients; talking daily by phone with resident &/or attending; spoke to nurses bid.
- Telemedicine led to:
  - reduction in ICU SMR -- from 1.75 to 0.56
  - reduction in hospital SMR -- from 1.07 to 0.71
  - reduction in ICU LOS ratio -- from 0.96 to 0.86
  - 25% reduction in ICU costs
  - trends to lower hosp costs (12%), ICU complications (15.1 vs 9.5%); no difference in hospital LOS ratio

Effects of Other Structural Aspects of ICU Care on Clinical Outcomes

- Managed care ⇒ ↓ resource use or ↓ hospital mortality
  [Rapoport, *Arch Int Med* 152:2207,1992; Angus, *JAMA* 276:1075,1996]
- ↑ICU technologic availability ⇒ ↓ hospital mortality
  [Bastos, *Int Care Med* 22:664,1996]
- Contradictory results about ↓ hospital mortality with ↓ task diversity [Shortell, *Med Care* 32:508,1994; Bastos, *Int Care Med* 22:664,1996; Mitchell, *Am J Crit Care* 5:353,1996]

ICU Outcomes & Structure - 2

- ↓ ICU bed availability or ↑stepdown bed availability ⇒ more efficient ICU bed utilization [Byrick, *Chest* 104:876,1993; Franklin, *Arch Int Med* 148:1403,1988; Strauss, *JAMA* 255:1143,1986]
- Contradictory results about whether ↑nurse workload increases LOS, mortality or complication rates
  [(-)Shortell, *Med Care* 32:508,1994; (+)Vicca, *J Hosp Infec* 43:109, 1999; (+)Tarnow-Mordi, *Lancet* 356:185, 2000; (+)Amaravadi, *Int Care Med* 26:1857, 2000]
- Ventilator team ⇒ ↓ventilator-days and costs
  [Cohen, *CCM* 19:1278,1991]

ICU Outcomes & Structure - 3

- Pharmacist involved in ICU rounds ⇒ 66%↓ in avoidable adverse drug reactions [Leape, *JAMA* 282:267,1999]

- Multicenter retrospective study (N=7196) found ↓ severity-adjusted rate of Swan-Ganz use in ICUs having full-time Intensivist staffing model [Rapoport, *JAMA* 283:2559,2000]

- Eliminated standing CXR orders in a PICU ⇒ 37% fewer CXRs per ICU-day with no change in LOS, or mean # of ventilator-days [Price, *CCM* 27:1588,1999]

ICU Outcomes & Structure - 4

- Supplied daily, itemized lab and pharmacy charges in a PICU ⇒ ↓ in PRISM and TISS-adjusted lab and pharmacy charges with no change in mortality or ICU LOS
  [Sachdeva, *CCM* 24:501,1996]

- Availability of private physician in a closed ICU ⇒ *less* frequent withdrawal of life support
  [Kollef, *CCM* 24:968,1996 & *CCM* 27:2125,1999]

- Switch to a proactive process of end-of-life communication with a formal, multidisciplinary meeting <72 hrs after MICU admission involving attending doc ⇒ 1 day shorter median ICU LOS [Lilly, *AJM* 109:469,2000]

ICU Outcomes & Structure - 5

- Better ICU "culture" (= leadership, coordination, communication, conflict management) ⇒ ↓ ICU LOS and RN turnover in one study, but not another [Shortell, *Med Care* 32:508,1994; Zimmerman, *CCM* 21:1443,1993]

- 5 year TQM implementation in ICU at Intermountain LDS, with many computer-driven protocols ⇒ reduced per-patient hospital costs by $4,500-5,000 [Clemmer, *CCM* 27:1768,1999]

Continuity & Weekend Issues in the ICU

- Little data relating specifically to ICU care
- Blunt's study of 24 hr Intensivist coverage ⇒ ↓SMR must have had "poor" day-to-day continuity [*Lancet* 356:735, 2000]
- Iatrogenic complication rates in 2 French ICUs were *not* more common on weekends [Giraud, *CCM* 21:40, 1993]
- Goldfrad showed using large ICU databases from the UK that "premature" discharge at night was associated with higher hospital mortality (OR=1.35, CI=1.10-1.65) [*Lancet* 355:1138, 2000]
- Central line placement in ICU patients performed at night was associated with more complications (OR=2.06, CI=1.04-4.08) [Merrer, *JAMA* 286:700, 2001]

Continuity & Weekend Issues - NonICU

- Study of 3.7M admissions to Ontario hospitals found adjusted hospital mortality of those admitted on weekends higher for many diagnoses, not lower for any [Bell, *NEJM* 345:663,2001]
- Hospitalist study by Diamond showing improved outcomes had coverage only during weekdays [*Ann Int Med*, 129:197,1998]
- ∃ modest amount of outpatient continuity studies, most of poor methodologic quality and with conflicting conclusions
  - best one is of VA outpatients randomized to clinics with good vs. poor visit-to-visit continuity --- found that better continuity had no effect on hospitalizations/year, but did improve patient satisfaction and reduce hospital LOS, ICU LOS and # of outpatient x-rays and ECGs [Wasson, *JAMA* 252:2413,1984]

A PROPOSAL FOR OUTCOMES RESEARCH IN THE MICU AT METRO

Statement of the Problem

- Understanding the relationship between ICU structure and ICU outcomes is important
- Little is known of what works better in ICUs, or why
- What is missing in the existing literature is high quality data derived from prospective, interventional studies
- Reason = they're difficult, inconvenient and require a lot of buy-in
- Such work has important policy implications (e.g. Leapfrog)
- Metro is perfect for this sort of work
  - few institutional impediments; tradition of clinical research and collaboration between HSR and MICU groups

Long-Term Plan

- Turn our MICU into a laboratory for investigating how structural change affects important outcomes
- Do studies having important implications beyond Metro
  - collaborations with other ICUs
- Use outcomes that are important to diverse groups, e.g:
  - mortality (short-term, long-term)
  - resource use (costs, LOS, TISS)
  - quality of life (QALY)
  - complication rates, error rates
  - satisfaction (nurses, doctors, RRTs, families/patients)
  - ★ worker retention
  - medical education

>>> Intensivist Weekend Coverage Study <<<

- Transitions between attending Intensivists represent an opportunity for inefficiency in ICU care
- Our current ICU coverage system has ≈10 transitions/month
  - some ICU groups send a different physician to the ICU or hospital each day (e.g. A B C A B C A B C)
  - some do 30 days in a row (!)
- **Hypothesis**: Attending Intensivist scheduling schemes that reduce # of transitions will lead to improved quality of care
- The findings (whether + or -) have important implications

Outcome Variables

- Hospital and ICU lengths of stay
- Hospital and ICU costs
- Hospital and ICU mortality rates
- End-of-life decision making:
  - rate of DNR and withdrawal of life support decisions
  - interval between ICU admission and end-of-life decisions
- Satisfaction surveys:
  - Intensivists
  - ±nurses, residents, patients/families, respiratory therapists

Study Design - 1

- 3 consecutive periods: A ---- B ---- A (ABAB??)
- Schedule A designed to maximize # of monthly transitions
  - ½ month blocks, cross-coverage for all weekends
  - average of 10.7 transitions/month
- Schedule B designed to minimize them
  - ½ month blocks, no weekend cross-coverage
  - 2 transitions/month

Study Design - 2

- Sample size calculation: effect size Δ=½ day of ICU LOS endpoint (log transformed), unpaired t-test, α=.05, power=80%, AG's NJ ICU database having mean ICU LOS = 4.5 days $\Rightarrow$ N = 709 for each group
  - $\approx$1300 MICU admission/year --- so study length $\approx$ 1 year
- Exclusions:
  - transferred to/from MICU from/to a different ICU
  - chronic mechanical ventilation (i.e. out of hospital)
  - reason for MICU admission not contained within APACHE III (e.g. rule out MI that actually rules out)

Covariates/Confounders

- Demographics
  - age, race, gender, insurance type
- Disease-related
  - reason for ICU admission
  - severity of illness (APACHE III)
  - need for mechanical ventilation within first 24 or 48 hrs
  - comorbid conditions
- Miscellaneous
  - source of hospital admission
  - source of ICU admission
  - readmission to MICU
  - existence of advance directives upon ICU admission
- Hospital-related
  - MICU bed occupancy
  - MICU nurse:patient ratios
  - availability of floor and stepdown beds

Analyses for Each Outcome Variable

- If patients under Scheduling Schemes A and B are similar at MICU admission $\Rightarrow$ unpaired t-tests, χ^2-tests
- Multivariate modeling adjusting for confounding variables
  - ? include Schedule Scheme A/B as a dummy variable OR include the actual # (rate?) of transitions for each patient?

? Since there might well be differences between Intensivists, do we need to adjust for any unbalanced distribution of individuals in periods A vs. B?

Questions/Uncertainties

? ABA or ABAB

? Since the current Scheme is A, does it minimize artifact to start the study by changing to B (BAB, or BABA)?

? Need to adjust sample size calculation for expected % of patients in each Scheduling Scheme that won't be in MICU over any transitions?

e.g. <LOS>=4.5 days, then the average patient admitted on Monday won't be in MICU over any weekend transition

? Use mean or median?

? If we do this simultaneously in 2 (or 3) different ICU's, does it lessen problems by doing ABA at one site while doing BAB at the other? Does this depend on which Scheduling Scheme is in use at each location pre-study?

? Fellow issues

? Will having Intensivists keep track of time spent on ICU care each day of the study alter that potential confounder?