Stanford HEALTH CARE

Stanford Children's Health | Lucile Packard Children's Hospital Stanford

Randomization and Clinical Decision Support: An EHR-based Severe Sepsis Alert

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Stanford | MEDICINE

Sepsis is costly

Table 1. Top 20 most expensive conditions treated in U.S. hospitals, all payers, 2011

Rank	CCS principal diagnosis category and name	Aggregate hospital costs, U.S. $, in millions	National costs, %	Number of hospital discharges, in thousands
1	Septicemia (except in labor)	20,298	5.2	1,094
2	Osteoarthritis	14,810	3.8	964
3	Complication of device, implant or graft	12,881	3.3	699
4	Liveborn	12,390	3.2	3,818
5	Acute myocardial infarction	11,504	3.0	612
6	Spondylosis, intervertebral disc disorders, other back problems	11,218	2.9	667
7	Pneumonia (except that caused by tuberculosis and sexually transmitted diseases)	10,570	2.7	1,114
8	Congestive heart failure, nonhypertensive	10,535	2.7	970
9	Coronary atherosclerosis	10,400	2.7	605
10	Respiratory failure, insufficiency, arrest (adult)	8,749	2.3	404

Figure: CDC

We know what to do (kind of)

Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012

Late recognition

Our approach

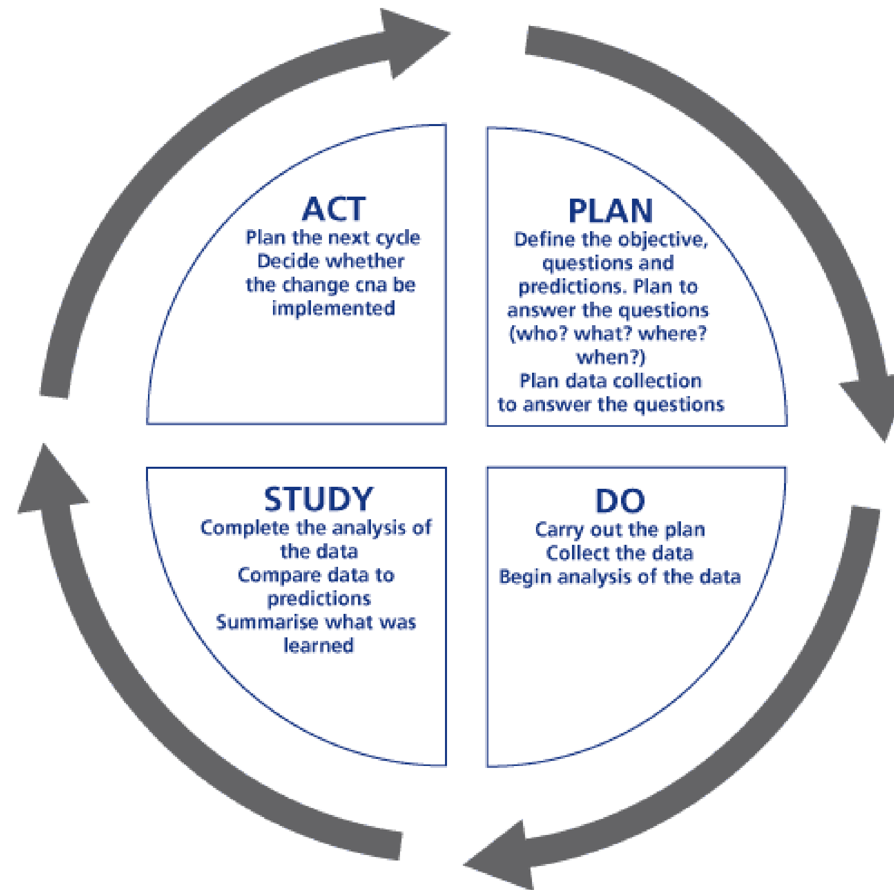
- SIRS
- Concern for infection
- Organ dysfunction

Pager text message

Document sepsis or not

- Lactate
- Blood cultures
- Antibiotics
- IVF

Quality Improvement and Confounding



Please Do Something, Anything!

Ethical? Research? Consent?

The NEW ENGLAND JOURNAL of MEDICINE

Risk, Consent, and SUPPORT

David Magnus, Ph.D., and Arthur L. Caplan, Ph.D.

HEALTH LAW, ETHICS, AND HUMAN RIGHTS

Mary Beth Hamel, M.D., M.P.H., *Editor*

Informed Consent, Comparative Effectiveness, and Learning Health Care

Ruth R. Faden, Ph.D., M.P.H., Tom L. Beauchamp, Ph.D., and Nancy E. Kass, Sc.D.

Quality Improvement vs. Research?

Stanford University HRPP	**Notice of Determination of Human Subject Research**	NOT-H3 1/1

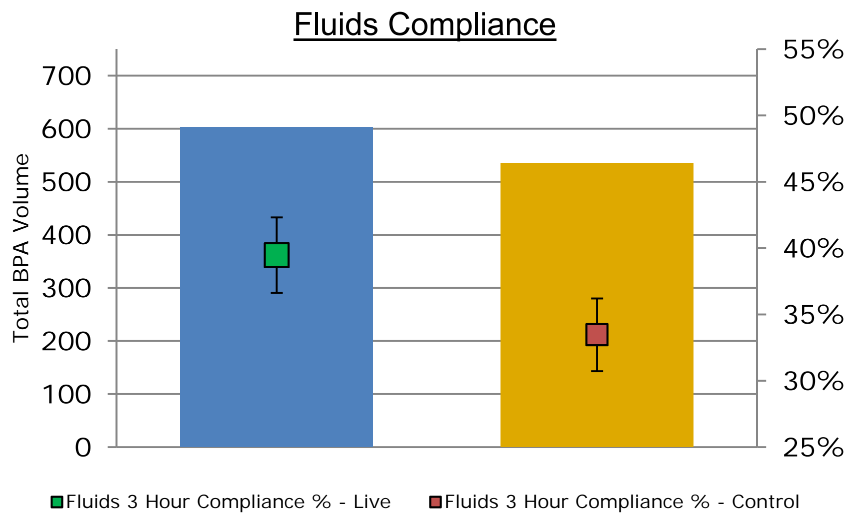
☒ **THIS PROJECT DOES NOT REQUIRE SUBMISSION TO THE STANFORD IRB, BECAUSE:**

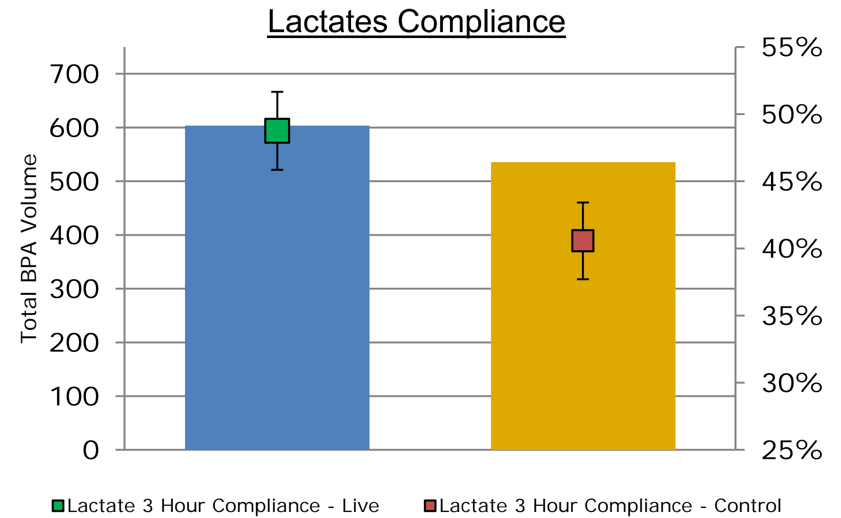
☒ **This project does not meet the Federal definition of *research*** [DHHS 45 CFR 46.102(d)] **or *clinical investigation*** [FDA 21 CFR 50.3(c), 56.102(c)]. See Is My Project "Research"? [AID-H8].

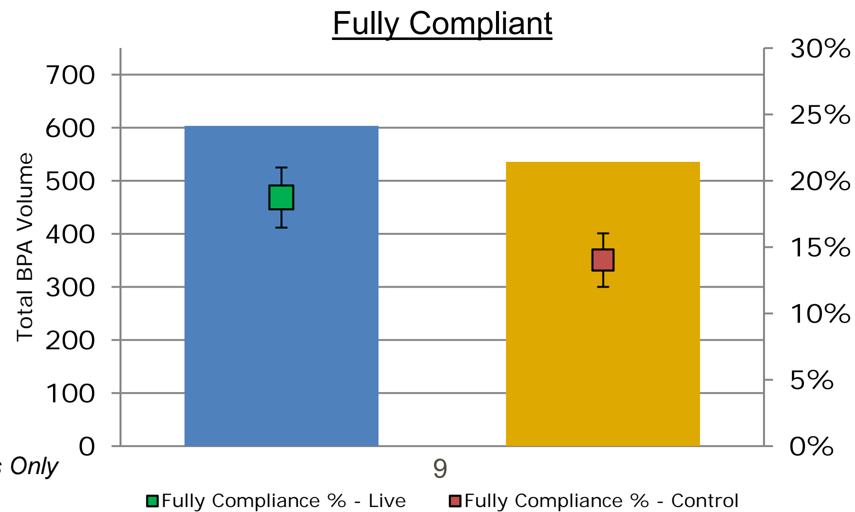
- Exempt from IRB as QI initiative
- 1:1 encounter-level randomization
- Performance metric endpoints: antibiotics, IVF, lactate, blood cultures
- Expected randomization period of 7 months to see 10% difference

Results at 6 months

- **1138 encounters randomized**
- **2 of 4 process metrics statistical improvement**







An Argument for Randomization