

The Leapfrog Group's Patient Safety Practices, 2003:

The Potential Benefits of Universal Adoption

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**THE LEAPFROG GROUP**  
for **Patient Safety**  
Rewarding **Higher Standards**

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## EXECUTIVE SUMMARY

The Leapfrog Group is a large coalition of more than 150 private and public sector health care purchasers working together to improve the quality of healthcare. The Leapfrog Group's quality improvement efforts highlight three main areas: 1) computer physician order entry (CPOE); 2) evidence-based hospital referral (EHR) for high-risk surgery and neonatal intensive care; and 3) ICU physician staffing (IPS).

The following report estimates the benefits that could potentially be achieved if every non-rural hospital in the United States complied fully with the 2003 Leapfrog safety standards. As in our previous analysis for the 2000 standards, we approached the analysis in two steps. First, we estimated the population at risk—the number of patients in metropolitan areas who are currently receiving care in hospitals not meeting the Leapfrog standards. Second, we estimated baseline risks in hospitalized patients, and the potential risk reductions associated with each of the safety standards. Our estimates have been updated from our previous analysis to account for both changes in the Leapfrog safety specifications and new scientific evidence since our last report.

The following Table summarizes the results of our baseline analysis:

Leapfrog Safety Initiative	Potential benefit with full implementation
Computerized Physician Order Entry	567,000 serious medication errors avoided
Evidence-Based Hospital Referral	
Five high-risk procedures	7,602 lives saved
High-risk deliveries	3,606 lives saved
ICU Physician Staffing	54,133 lives saved

Although our analysis is based on the best information currently available, there remain gaps in existing scientific knowledge. In particular, there was insufficient research to allow us to estimate the amount of morbidity (injury or disability) associated with errors in treatment, surgery, or medications. Also, as outlined later in our report, universal adoption of each standard faces several implementation challenges and would have other indirect policy implications. Nonetheless, we believe that successful adoption of The Leapfrog Group's three safety initiatives would significantly reduce the large annual toll of avoidable deaths and improve patient safety in hospitals across the United States.

### Computer physician order entry

The Leapfrog Group's standard for computer physician order entry (CPOE) requires that hospitals use a computer system that includes prescribing-error prevention software for the entry of physician medication orders. The CPOE standard has remained unchanged since our previous report. Also, there is little new evidence regarding the effectiveness of CPOE or the baseline incidence of serious medication errors. New data does suggest that hospital adoption of CPOE technology is increasing but remains low overall.

Based on a survey from 2001, 94% of US hospitals did not meet the CPOE standard, creating a population at-risk of 30 million patients. According to the best evidence, CPOE decreases serious medication errors by 55%. We estimate that universal implementation of CPOE would avert approximately 567,000 serious medication errors each year in the United States. Based on a more recent study by Bates et al. suggesting an 88% error reduction rate, a substantially greater number of

errors (907,677) could be potentially averted. Although a large proportion of serious medical errors are life threatening, the numbers that result in fatalities cannot be determined precisely from the medical literature. Accordingly, we did not calculate the number of deaths potentially avoided by CPOE. However, if only 0.1% of such errors were fatal, nearly 600 deaths would be avoided every year. If the fatality rate were 1%, nearly 6000 deaths would be avoided.

#### **Evidence-based hospital referral: High-risk surgery**

Evidence-based hospital referral (EHR) for high-risk surgery is based on the selective referral of patients to hospitals that meet certain quality standards for five operations. The quality measures previously focused only on minimum volume standards but have been expanded in 2003 to include processes of care and direct outcomes measurement. Also, because of new information on the strength of their volume-outcome relationships, Leapfrog has dropped carotid endarterectomy and added pancreatic resection to its list of operations. The 2003 standards for AAA repair, CABG and PCI now include documented adherence to certain clinical processes of care known to improve outcomes. For coronary artery bypass grafting (CABG) and percutaneous coronary interventions (PCI), risk-adjusted mortality rates have also been incorporated into the standards.

The proportion of the population at hospitals not meeting the EHR standards varied from 43% for PCI to 78% for CABG. The potential mortality reduction with EHR also differed across operations and was greatest for CABG (59%) and the smallest for AAA repair (37%). We estimate that implementation of EHR for these 5 surgical procedures would save approximately 7,602 lives each year in the US. The greatest number of deaths would be prevented with CABG (4,089 deaths annually), followed by PCI (2,800), and elective AAA repair (356). EHR would save 180 and 177 lives, respectively, with esophageal resection and pancreatic resection. The addition of process and outcomes measures to the previous volume standards has significantly increased the potential benefits of full implementation of EHR across the U.S. (2,581 in our previous analysis). The majority of the increase can be attributed to more precise classification of high quality centers using risk-adjusted mortality for CABG and PCI, by far the two most common procedures.

#### **Evidence-based hospital referral: High-risk neonatal intensive care**

The evidence-based hospital referral (EHR) standard for neonatal intensive care is based on selective referral of high-risk infants and deliveries to hospitals that meet minimum volume standards and demonstrate adherence to a new process of care measure. The EHR standard for neonatal care is directed to mothers of infants with very low birth weight (VLBW), very premature infants (<32 weeks gestational age), or those with a pre-natal diagnosis of major congenital anomaly. The newly incorporated process of care measure requires the documented use of antenatal steroids to the mothers of eligible infants.

Based on estimates from the state of California, 82% (45,954) of infants with congenital anomalies and 74% (57,737) of VLBW and/or very premature infants are born at hospitals that do not meet the standards. With EHR, there is an approximately 30% mortality reduction with referral to a higher volume NICU and a 40% mortality reduction with the use of antenatal steroids. We estimate that full implementation of EHR nationwide for high-risk neonatal intensive care would save approximately 3,606 lives each year in the U.S.. VLBW and/or very premature infants comprise the majority of lives saved (3,766 lives); infants with major congenital anomalies comprise the remainder (551 lives). Within the former group, the increased use of antenatal steroids, contributes significantly to the total number of lives saved (405 lives).

## **ICU physician staffing**

The Leapfrog Group's ICU physician staffing (IPS) standard requires that physicians with specialized experience in critical care medicine manage or co-manage patients in the ICU. These physicians, called intensivists, must be present in the ICU during daytime hours and at other times should be able to return pages within 5 minutes or arrange for on-site physicians or physician extenders who can reach ICU patients within 5 minutes. The IPS standard has changed in 2003 to include the pediatric population.

Currently in the US, 79% (1,473,085) of admissions to adult ICUs and 51% (73,500) of admissions to pediatric ICUs occur in settings that do not satisfy the IPS standard. New evidence from a structured literature review shows that a 30% reduction in mortality could be achieved with increased ICU physician staffing. We estimate that full implementation of intensivist model staffing would save approximately 54,133 lives (1,102 children and 53,031 adults) each year in the US. As expected, for both the adult and pediatric population, the number of lives saved varies according to assumptions about the effectiveness of intensivist model staffing. For example, assuming a 10% relative mortality reduction, 18,000 adult lives would be saved. In contrast, assuming a 50% mortality reduction would save over 90,000 adult lives.

## Computer physician order entry

### *Overview*

The Leapfrog Group's standard for computer physician order entry (CPOE) requires hospitals to assure that at least 75% of hospital medication orders are entered through a computer system that includes prescribing-error prevention software and can alert physicians of at least 50% of common, serious prescribing errors. Hospitals must also require that physicians electronically document a reason for overriding an interception generated by the CPOE system.

There is relatively little new evidence since our last report regarding the efficacy of CPOE or the incidence of serious medical errors in hospitalized patients. However, new data does suggest that hospital adoption of CPOE technology is increasing but remains low overall: the proportion of patients at hospitals meeting the Leapfrog CPOE standard increased from 2% to 6% between 1997 and 2001.<sup>2,3</sup>

In the updated baseline analysis, universal implementation of CPOE would avert approximately 567,000 serious medication errors each year in the United States (Figure 1). The proportion of serious medical errors that result in fatality cannot be determined precisely from the medical literature. However, if only 0.1% of such errors were fatal, nearly 600 deaths would be avoided by CPOE every year. If the fatality rate were 1%, almost 6000 deaths would be avoided every year. In the following sections, we describe the methods and assumptions used in our analysis.

### *Methods and assumptions*

The approach we used to estimate the number of serious medication errors potentially averted by full implementation of CPOE is illustrated in Figure 1. We first determined the population of inpatients who stand to benefit by the policy. We then calculated their baseline risk of serious medication errors and the reductions expected with CPOE.

Number of patients currently admitted at hospitals without CPOE. Based on data from the Nationwide Inpatient Sample (NIS),<sup>1</sup> 37,187,641 patients were admitted to non-federal, acute care hospitals in 2001. To avoid problems with health care access in rural areas, The Leapfrog Group is restricting CPOE, along with the other safety initiatives, to metropolitan areas. According to data from the NIS, hospitals in metropolitan areas accounted for 84% of all hospital admissions.<sup>1</sup>

We used new data to estimate the proportion of patients currently being treated at hospitals without CPOE. In our original report we estimated that only 2% of hospitalized patients were in hospitals with CPOE, based on a 1997 survey by Ash et al.<sup>2</sup> A more recent survey conducted in 2001 by the American Society of Health-System Pharmacists (ASHP) revealed that 4.3% of hospitals had computer physician order entry.<sup>3</sup> However, this proportion varied significantly according to hospital size. For instance, only 1.5% of hospitals with fewer than 50 beds had CPOE, compared to 20.4% at hospitals with more than 400 beds. Using data from NIS and appropriate weighting techniques, we estimate that 15% of hospitalized patients are treated in hospitals with CPOE systems on site (Table 2). Not all hospitals meet the Leapfrog Standard of having more than 75% of orders entered via CPOE. Among those hospitals with CPOE in the 2001 survey, only 35% met this requirement (Table 2). Thus, we estimate that only 6% of patients are currently treated in hospitals with CPOE systems meeting Leapfrog criteria.

**Baseline rate of serious medication errors.** A serious medication error is a non-intercepted error in the process of ordering, dispensing, or administering a medication that causes or has the potential to cause an adverse drug event.<sup>4</sup> In two studies by Bates et al at a single teaching hospital,<sup>4,5</sup> such errors occurred at a rate of 10.7 and 7.6 per 1,000 pt-days. Expressed in terms of incidence rates per admission, 5.1% and 3.4%, respectively, of hospitalized patients experienced at least one serious medication error. In our baseline analysis, the more conservative (lower) error rate of 7.6 per 1,000 pt-days was used. Thus, approximately 1,031,452 serious medication errors occur every year in US hospitals without CPOE.

**Efficacy of CPOE.** There is considerable literature describing the effectiveness of electronic clinical decision support systems in different contexts, as summarized recently by Kaushal et al.<sup>6</sup> A smaller number of studies have focused specifically on CPOE.<sup>6-9</sup> (Table 3) For this analysis, we relied exclusively on two studies conducted by Bates et al (Table 1), the only studies using serious medical errors as outcome measures. In the first study of over 2,000 admissions at a single academic medical center, serious medication errors fell from 10.7 to 4.9 per 1000 patient-days after implementation of CPOE (55% reduction).<sup>4</sup> In the second study (using later generation software with more advanced decision support), the proportion of patients experiencing serious medication errors fell from 7.6 to 1.1 per 1000 pt-days (88% reduction).<sup>5</sup> The more conservative estimate of CPOE efficacy (55%) was used in our baseline analysis.

## ***Results***

In our baseline analysis, we estimate that full implementation of CPOE would avert approximately 567,298 serious medication errors each year in the US. As expected, the number of errors avoided varied according to the efficacy of CPOE. (Figure 2) Although we were conservative in our baseline analysis (55% reduction in error rate with CPOE), assuming higher levels of effectiveness would have significantly increased the estimates of serious medication errors avoided. For instance, if the greater relative risk reduction (88%) seen in the more recent study by Bates et al is used for estimation, 907,677 medical errors are potentially averted (Figure 2).

## ***Cautions and policy considerations***

The number of serious medication errors that would be avoided if CPOE were implemented at all US hospitals depends on assumptions about the baseline error rate and the effectiveness of CPOE in avoiding errors. Our estimates of these parameters have several limitations. We estimated the baseline rate of serious medication errors from two studies at a single large teaching hospital (Brigham & Women's Hospital in Boston).<sup>4,5</sup> Whether errors rates from this large academic center can be safely generalized to other settings is uncertain. Because of the relatively complex case-mix at such centers, some would argue that the baseline medication error rate might be higher than the average rate at other hospitals. Alternatively, many teaching hospitals have a reputation for excellence in faculty and house staff and could have lower than expected medication error rates. To be conservative in our final estimates, we used the lower medication error rate from the two studies by Bates et al.<sup>4,5</sup>

There is also uncertainty about the effectiveness of CPOE in averting serious medication errors, which depends on both the characteristics of the software employed and each hospital's implementation skill. To be conservative in this analysis, we use the estimate that CPOE caused a 55% error reduction rate from the original report by Bates et al., which assessed a 1994-95 CPOE system. However, the quality of decision support in current CPOE systems has no doubt improved considerably, as evidenced by the follow-up study by the same group, which

demonstrated an 88% error reduction rate. For this reason, this analysis likely underestimates the number of serious medication errors that might be averted with full implementation of CPOE in US hospitals.

In focusing on its ability to reduce serious medication errors, this analysis does not provide a full accounting of the costs and benefits of CPOE. Costs are substantial and represent a significant barrier to CPOE implementation at many hospitals. As summarized previously, costs associated with implementing CPOE include system costs (establishing an appropriate information system platform and acquiring and integrating the necessary software and end-user hardware) and costs related to clinician time (content development, activation and training, and longitudinal oversight).<sup>10</sup> The total cost of implementing at an individual hospital depends on numerous variables and no doubt varies widely. Estimates of upfront costs vary from as low as \$500,000 to almost \$15 million per hospital. There is a similar spread between best- and worst-case scenarios for longitudinal costs, from \$200,000 to \$2 million per year.

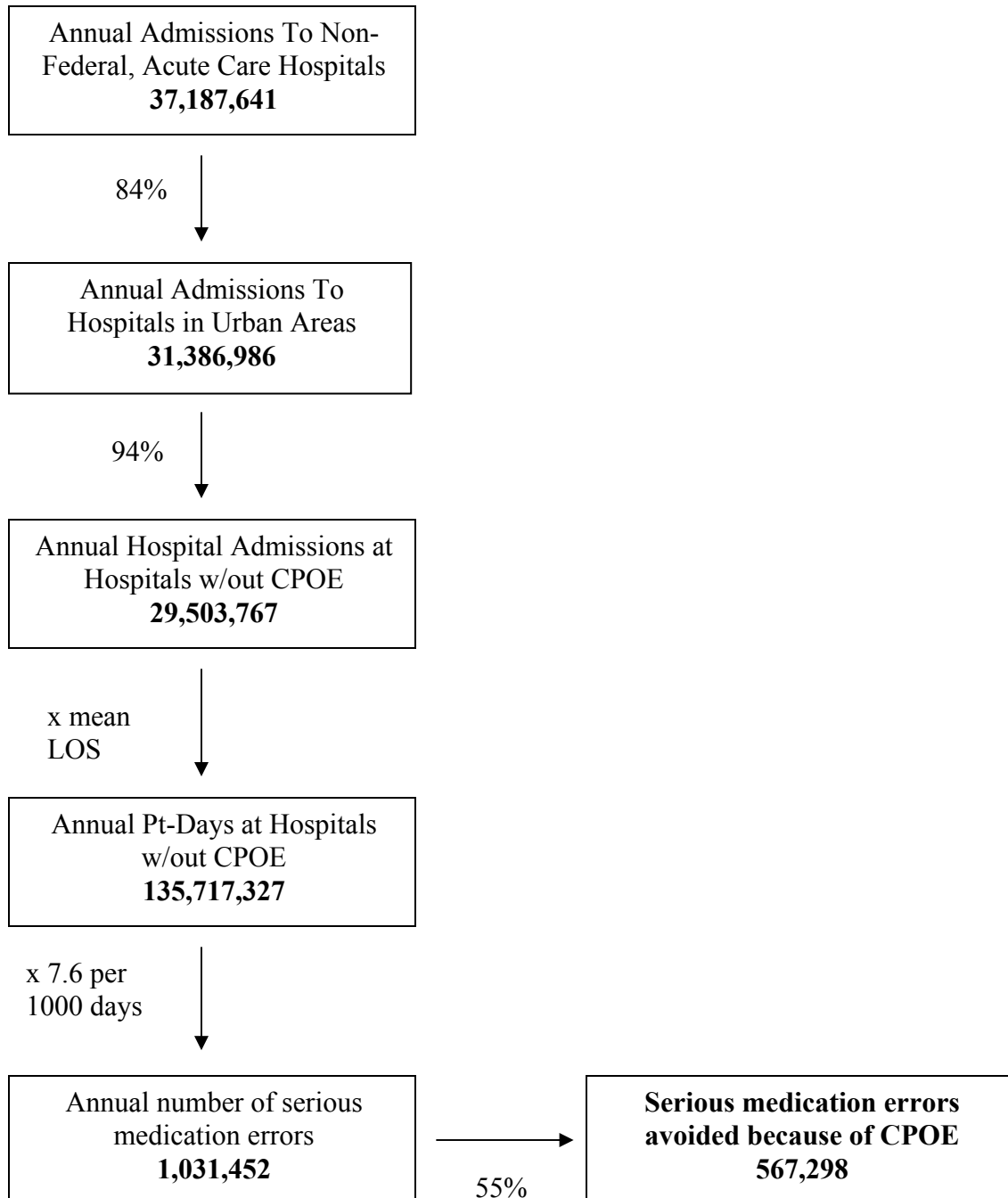
Acting to offset these costs are the potential savings from fewer medication errors and adverse drug events, estimated to range between approximately \$180,000 and \$900,000 per year, depending on hospital size.<sup>10</sup> The potential of CPOE to reduce resource utilization in other ways is likely a more important source of savings. These sources of savings include medication substitution, reduced laboratory testing and imaging, increased use of clinical pathways, and gains in clinician efficiency. Although these savings are difficult to quantify and likely vary widely by hospital, some hospitals that have implemented CPOE report annual savings exceeding \$5 million.<sup>10</sup>

A full accounting of the potential benefits of CPOE would optimally consider patient outcomes (such as mortality, injury and disability), not simply errors averted. Unfortunately, the likely effects of CPOE on patient mortality and disability rates cannot be determined directly from the literature. However, in the two studies by Bates et al,<sup>4,5</sup> more than half of all serious medication errors resulted in preventable adverse drug events. Approximately 20% of preventable adverse drug events were considered “life threatening” upon clinical review, but no patient in the two studies died as a direct result of a medication error. The two studies lacked sufficient sample size to detect a small but clinically meaningful reduction in mortality rates with CPOE. Ultimately, large, multi-center studies will be needed to better characterize relationships between medication errors and mortality. However, if only 1% of serious medication errors were fatal, we estimate that nearly 6,000 deaths would be avoided every year by full implementation of CPOE across all US hospitals.

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**Figure 1:** Calculating the number of serious medication errors avoided in the United States with universal implementation of Leapfrog’s standard for computer physician order entry (CPOE).



**Table 1:** Studies assessing the effectiveness of computer physician order entry (CPOE) in reducing serious medication errors. A serious medication error is an error in the process of ordering, dispensing, or administering a medication, that causes or has the potential to cause an adverse drug event; it does not include intercepted potential ADEs. Both studies were conducted at Brigham and Women’s Hospital, Boston, MA. <sup>3-4</sup>

Study Participants		Rate of Serious Medication Error (per 1000 pt-days)		
		Before CPOE	After CPOE	Relative Risk Reduction
6 services chosen randomly from 23 available medical, surgical and intensive care units (2491 admissions)	Same 6 services plus 2 chosen randomly from same 23 available units (2047 admissions)	10.7	4.9	55%
3 general medical services (379 admissions)	Same 3 general medical services (475 admissions)	7.6	1.1	88%

**Table 2:** Relationship of hospital bed-size and the implementation of CPOE in a national sample of hospitals. Data are from the 2001 American Society of Health-System Pharmacists (ASHP) survey of prescribing and transcribing.

Hospital Bed-Size		Hospital Admissions According to Bed-Size Category*	Overall Percentage of Hospitals Without CPOE	Hospital Admissions without CPOE according to Leapfrog Standard**
Small	Up to 299	4,150,675 (11.2%)	98%	4,121,620
Medium	300 to 399	9,884,636 (26.6%)	90%	9,538,674
Large	≥400	23,152,330 (62.3%)	80%	21,531,667
		Total		35,122,504 (94%)

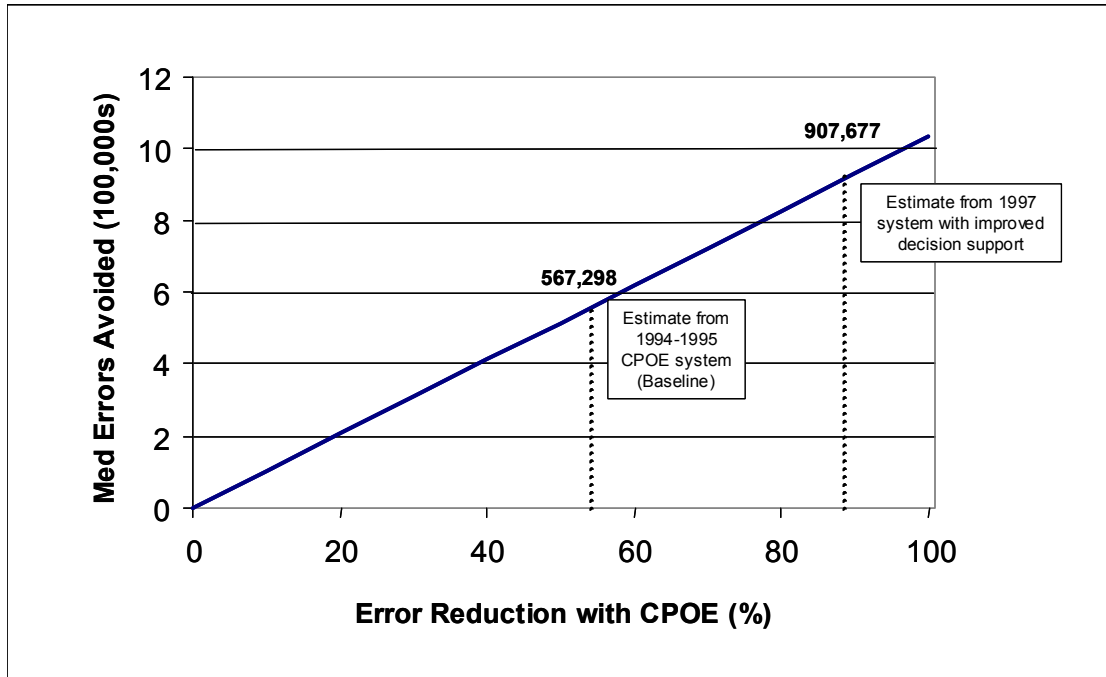
\*Data taken from 2001 version of the Nationwide Sample and national estimates calculated using hospital sampling weights.

\*\*Of hospitals that had CPOE, only 35% met the Leapfrog Standard of having more than 75% of orders entered via CPOE.

**Table 3:** Inclusive review of studies assessing the effectiveness of computer physician order entry on several different outcomes. The table was adapted from Kaushal et al.<sup>6</sup>

Study Authors	Description	Patients	Outcomes	Findings
Bates et al, 1998 <sup>4</sup>	Observational study at tertiary care center comparing event rates between units and compared to historical controls	6,771 adult inpatients on medical, surgical, and intensive care wards	Serious medication errors and adverse drug events	55% decrease in serious medication errors
Bates et al, 1999 <sup>5</sup>	Observational study at tertiary care center comparing event rates before and after implementation of CPOE	1,817 adult inpatients on 3 medical wards	Medication errors and adverse drug events	81% decrease in medication errors
Chertow et al, 2001 <sup>7</sup>	Randomized trial at a tertiary care center of CPOE with decision support to adjust drug dose and frequency with renal insufficiency	7,490 adult inpatients with renal insufficiency	Inappropriate drug dose and frequency	13% decrease in inappropriate dose and 24% decrease in inappropriate frequency
Overhage et al, 1997 <sup>8</sup>	Randomized trial at a teaching hospital assessing the impact of CPOE reminders for corollary orders	2,181 adult inpatients in a general medical ward	Omission of corollary orders (ie, drug levels when ordering gentamicin)	25% improvement in corollary orders
Teich et al, 2000 <sup>9</sup>	Observational study at tertiary center comparing event rates before and after CPOE with decision support aimed at five prescribing practices	All adult inpatients	Changes in five prescribing practices (ie, heparin for patients with bed-rest orders)	Improvement in all five prescribing practices

**Figure 2:** Sensitivity analysis demonstrating the effect of different assumptions about the effectiveness of CPOE on the number of patients avoiding medication errors each year in the United States.



## Evidence-Based Hospital Referral: High-Risk Surgery

### *Overview*

The Leapfrog Group's evidence-based hospital referral (EHR) standard for high-risk surgical procedures has undergone significant change since our previous report (Table 1).

- Leapfrog updated the list of procedures. Leapfrog added pancreatic resection, for which hospital volume has a dramatic effect on mortality. Given new evidence showing little hospital volume effect for carotid endarterectomy, Leapfrog removed it from the list. Coronary artery bypass grafting (CABG), percutaneous coronary interventions (PCI), elective abdominal aortic aneurysm (AAA) repair, and esophageal resection remain on the list.
- Incorporation of direct outcome measures. For CABG and PCI, hospitals must demonstrate acceptable risk-adjusted mortality rates, as judged by approved state- or national-level reporting systems, to satisfy the Leapfrog standards for EHR. Hospitals no longer receive full "credit" based on volume criteria alone.
- Incorporation of process of care measures. For CABG, PCI, and elective AAA repair, Leapfrog has incorporated process of care measures into its EHR standards. For these procedures, both minimum volumes and compliance with target process measures are included in the standard.

In our updated analysis, we estimate that implementation of EHR for these 5 surgical procedures would save approximately 7,602 lives each year in the United States. The greatest number of deaths would be prevented by appropriate referrals for coronary artery bypass grafting (4,089 deaths annually), followed by percutaneous coronary interventions (2,800) and elective AAA repair (356). The potential benefit of EHR for these procedures is substantially greater than estimated in our previous report, an increase largely attributable to augmenting the previous volume standards with outcome and process measures. EHR would save 180 and 177 lives, respectively, with esophageal resection and pancreatic resection.

### *Summary of Methods*

We calculated the potential benefits of EHR assuming that all patients in the US underwent surgery at a hospital that was fully compliant with the new Leapfrog EHR standards. To avoid access issues and other unintended negative consequences in rural areas, The Leapfrog Group restricts EHR implementation to urban areas. Since the standards differ for each procedure, the methods for calculating potential lives saved vary by procedure and are described separately. However, our general approach involved two steps. First, we estimated the population at-risk, which includes all patients currently having surgery at hospitals not fully adherent to the Leapfrog standards. Second, we incorporated information about the mortality reduction associated with each volume, process, or outcome standard to estimate the potential lives saved.

For most of our analyses, we relied on primary data from the 2000 Nationwide Inpatient Sample (NIS). The NIS is a 20% stratified sample of hospital discharges in the US and is maintained by the Agency for Healthcare Research and Quality (AHRQ) as part of the Healthcare Cost and Utilization Project (HCUP).<sup>1</sup> To ensure the representative nature of the database, the NIS is stratified by geographical region, hospital bed size, teaching status, urban vs. rural location, and hospital ownership.

We obtained estimates pertaining to volume and mortality using NIS data. Because information on process variables is not available from the NIS, we obtained these parameters from the literature.

### **Results**

Pancreatic Resection (Table 2). During the year 2000, there were 5,779 pancreatic resections performed in the US. Based on data from the NIS, 95% of pancreatic resections are performed in urban centers (Table 2).

The Leapfrog standard for pancreatic resection is based exclusively on minimum volume standards (11+/yr). According to 2000 NIS data, 62% of pancreatic resections were performed at hospitals not meeting this standard (Table 2).

In estimating mortality reductions likely to be achieved with EHR for pancreatic resection, we relied on risk-adjusted mortality rates derived directly from the NIS. Using the updated volume cut-offs, we calculated the adjusted rates of in-hospital death after adjusting for age, gender, race, coexisting diseases, and urgency of admission. Adjusted mortality rates were substantially lower at hospitals meeting the Leapfrog volume standard (5.0%) than at hospitals not meeting it (10.3%) (Figure 1).

We estimate that 344 deaths occur each year with this procedure at hospitals not meeting the EHR standard. Assuming the mortality rates observed at hospitals exceeding the standard, only 167 deaths would have occurred had these procedures been referred to higher volume hospitals. Thus, full implementation of EHR for pancreatic resection would save 177 lives each year in the US (Table 2).

Esophageal Resection (Table 3). As with pancreatic resection, the Leapfrog standard for esophagectomy is based exclusively on minimum volume standards. Based on 2000 NIS data, 4,350 patients undergo this procedure each year in the US with 95% in urban centers (Table 3).

Approximately 74% (3,058) of patients currently undergo esophagectomy at centers performing fewer than 13 per year. Adjusted mortality rates were markedly higher at such hospitals (11.1%) than hospitals exceeding Leapfrog volume criteria (5.2%) (Figure 1).

With these mortality rates, we would expect 339 deaths to occur without EHR and 159 deaths with EHR (Table 3). Thus, with full implementation of EHR for esophageal resection, 180 lives would be saved each year in the US (Table 3).

Abdominal Aortic Aneurysm Repair (Table 4). To comply fully with the Leapfrog standard for elective AAA repair, hospitals must perform more than 50 procedures per year and demonstrate at least 80% adherence to two process measures: beta-blockers in perioperative period and beta-blockers prescribed at discharge (Table 1). Based on 2000 NIS data, 41,667 patients underwent AAA repair in the US with 95% in urban centers (Table 4). Patients with ruptured AAAs are unstable and often need surgery at the hospital to which they first present. For this reason, the Leapfrog EHR standards do not pertain to patients with ruptured AAAs. To estimate the number of elective (non-ruptured) AAA repairs subject to EHR, we excluded patients that had a diagnosis of ruptured aneurysm or those that underwent emergent repair (22% of total AAA repairs).

As derived from the NIS, 48% of patients currently undergo AAA repair at hospitals performing fewer than 50 procedures per year. Adjusted mortality rates were significantly higher at such hospitals (5.1%) than at hospitals exceeding Leapfrog volume criteria (3.8%) (Figure 1). Thus, based on volume criteria alone, full implementation of EHR for AAA repair would potentially save 247 lives each year in the US (Table 4).

We then assessed the number of lives potentially saved by increasing the use of perioperative beta-blockers, a practice known to lower the risk of cardiac events and death after major vascular

surgery. The proportion of patients currently receiving beta-blockers with this procedure is unknown.<sup>2</sup> One large observational study found that only 30% of patients were receiving beta-blockers.<sup>3</sup> Since better processes of care likely underlie observed volume-outcome effects with AAA repair, we assumed that high volume hospitals would have a higher rate of beta-blocker use. Thus, for this analysis, we assumed a baseline adherence of 50%. The Leapfrog standard requires that at least 80% of patients receive the process of care in order for a hospital to be fully compliant. As a result, an additional 30% of patients would experience the benefit of mortality reductions associated with beta-blocker use.

How large is the benefit associated with beta-blocker use? Several randomized trials on the efficacy of beta-blockers in the perioperative period have demonstrated a 50% to 80% reduction in short-term and long-term mortality rates. However, these trials focused only on patients at high risk for cardiac events.<sup>3</sup> Thus, the benefit of perioperative beta-blockers for average-risk patients having AAA repair is not known. One large observational study demonstrated a 70% risk reduction in the combined endpoint of myocardial infarction and mortality, but did not provide risk reductions for mortality alone.<sup>4</sup> To be conservative, we assumed a relative risk reduction of 50% for our calculations. We then applied this risk reduction to an additional 30% of patients (50% baseline increased to 80%) undergoing surgery at high volume hospitals, yielding an additional 109 lives saved. Thus, a total of 356 lives would be saved each year with Leapfrog's EHR standard for AAA repair (Table 4).

Coronary Artery Bypass Grafting (Table 5). Leapfrog's updated EHR standards for coronary artery bypass grafting (CABG) are based primarily on referral to hospitals with lower risk-adjusted mortality rates. The process measures for CABG and PCI were not included in our estimates since they are not necessary for full compliance. At present, only four states (NY, NJ, PA, CA) have rigorous (e.g., audited) systems in place for assessing risk-adjusted mortality rates and reporting them publicly. In these states, hospitals must be in the best performing quartile (below the 25<sup>th</sup> percentile) of mortality rates to meet the Leapfrog EHR standard (Table 1). In other states, hospitals must meet a minimum volume standard (>450 cases per year) AND participate in the Society of Thoracic Surgeons (STS) database of risk-adjusted mortality AND have a risk-adjusted mortality rate lower than the national average to comply fully with the updated EHR standards (Table 1).

According to the 2000 NIS, 394,165 patients underwent CABG each year in the US with 97% in urban centers (Table 5). Given that the criteria for full adherence to the Leapfrog EHR standards differ according to the availability of public information on CABG outcomes, we present the results for each analysis separately.

NY, NJ, PA, CA. Given that 26% of the US population resides in these 4 states,<sup>5</sup> we estimate that 99,005 CABG operations are performed each year in these 4 states (Table 5). We determined mortality rates for each hospital in the NIS. We then divided hospitals into four equally sized groups (quartiles) based on their mortality rates. The average mortality rates within each quartile were 1.7% (1<sup>st</sup> quartile), 3.0% (2<sup>nd</sup> quartile), 4.0% (3<sup>rd</sup> quartile), and 6.1% (4<sup>th</sup> quartile). Collectively, hospitals in the last 3 quartiles (who cared for 78% of all patients) had an average adjusted mortality rate of 4.1%.

In the status quo, we would expect 3,166 deaths at hospitals in the 2<sup>nd</sup> through 4<sup>th</sup> quartiles. Assuming instead the mortality rate observed in 1<sup>st</sup> quartile hospitals, only 1,312 deaths would occur. Thus, Leapfrog's EHR standard for CABG would potentially avert 1,854 deaths in these four states alone.

Other States. Since 74% of the US population resides outside these states, we estimate that 281,785 CABG procedures occur in states without public reporting systems for cardiac

surgery (Table 5). Based on data from the 2000 NIS, approximately 39% of patients undergo CABG at hospitals that perform at least 450 cases per year AND have a mortality rate lower than the national average. The overall mortality rate for these hospitals was 2.7%. The remaining 61% of patients undergo CABG at hospitals not meeting the Leapfrog EHR standards, whose average mortality rate is 4.0%. In the status quo, 6,876 deaths occurred in this latter group. Assuming instead the 2.7% mortality observed in hospitals meeting the EHR standard, only 4,641 deaths would have occurred.

Thus, full implementation of the Leapfrog standards for CABG in these 46 states would save a total of 2,235 lives each year in the US. Including our estimates from the 4 states with public reporting systems, a total of 4,089 CABG deaths would be averted overall.

Percutaneous Coronary Intervention (Table 5). The updated EHR standards for percutaneous coronary intervention (PCI) are based on referral to hospitals that both meet minimum volume standards and also have low risk-adjusted mortality rates. However, unlike CABG, no statewide systems are currently in place for assessing risk-adjusted mortality rates for PCI. Thus, to comply fully with the EHR standard for PCI, hospitals must meet a minimum volume standard (>400 cases per year) AND participate in the American College of Cardiology (ACC) database of risk-adjusted mortality AND have a risk-adjusted mortality rate lower than the national average (Table 1). According to the 2000 NIS, 678,296 patients undergo PCI each year in the US, with 96% in urban centers (Table 5).

Based on data from the 2000 NIS, approximately 57% of patients undergo PCI at hospitals that perform at least 400 cases per year AND have a mortality rate lower than the national average. The overall mortality rate for these hospitals was 1.0%. The remaining 43% of patients undergo PCI at hospitals not meeting the Leapfrog EHR standards, whose average mortality rate is 2.0%. In the status quo, 5,600 deaths occurred in this latter group. Assuming instead the 1.0% mortality observed in hospitals meeting the EHR standard, only 2,800 deaths would have occurred. Thus, full implementation of the Leapfrog standards for PCI would save a total of 2,800 lives each year in the US.

Summary of Results. Overall, we estimate that implementation of the new EHR standards for these 5 surgical procedures would save approximately 7,602 lives each year in the United States. The greatest number of deaths would be prevented with coronary artery bypass grafting (4,089 deaths annually), followed by percutaneous coronary interventions (2,800) and elective AAA repair (356). Estimates of potential lives saved were smaller after surgery for esophageal resection (180) and pancreatic resection (177) in part because these high-risk procedures occur less frequently.

### ***Cautions and policy considerations***

The addition of process and outcomes measures to the previous volume standards has significantly increased the potential benefits of full implementation of EHR across the US. In this analysis, we estimate that 7,602 lives could be saved with EHR, compared to 2,581 in our previous analysis of the volume-only standards. The majority of the increase can be attributed to more precise classification of high quality centers using risk-adjusted mortality for CABG and PCI, by far the two most common procedures. The use of one process measure—perioperative beta-blockers—also substantially increased the benefits of EHR for elective AAA repair.

Our estimates depend on several estimated parameters and significant assumptions. In assessing procedure-specific volume-outcome relationships, we used point estimates derived directly from a recent version of the NIS, a nationally representative sample of hospitals in the United States. The magnitude of volume-outcome effects used in this analysis were generally consistent with

those used in our previous report, which were derived from the “single best” study in the literature for each procedure, as defined by Dudley et al.<sup>7</sup> Further, estimates herein of volume-related mortality reductions are similar in magnitude to those in our more comprehensive analysis based on the national Medicare population.<sup>8</sup>

When considering the effect of selective referral to hospitals based on volume standards it is also important to consider the distinction between hospital and surgeon volume. Recent evidence has emerged exploring the contribution of individual surgeon experience to the relationship of hospital volume and mortality.<sup>9</sup> For some operations, such as carotid endarterectomy, surgeon volume accounted for a large proportion of the apparent hospital volume effect. However, the importance of surgeon volume varied according to the procedure. The Leapfrog EHR standard currently does not address the importance of surgeon volume. Future updates will likely incorporate individual surgeon volume standards into the criteria.

For elective AAA repair, our estimates of the potential benefits of EHR depend on assumptions about the effectiveness of perioperative beta-blockers. As described in one recent literature synthesis, there is little doubt that this practice is associated with reduced perioperative mortality, which may persist to at least one year postoperatively.<sup>2-4</sup> However, the magnitude of the effect is somewhat uncertain. The clinical trials focus on different populations with varying baseline risk. Our estimates of lives saved by this EHR standard also require assumptions about the current prevalence of this practice and to what extent it could be increased, both of which are uncertain.

For CABG and PCI, the potential benefits of EHR depend on the reliability of risk-adjusted mortality rates. No matter how rigorously they are assessed and risk-adjusted, estimates of a hospital’s mortality rate will always be somewhat imprecise, particularly when baseline event rates are low. The net effect is that a high proportion of hospitals just above or below a given mortality standard will have confidence intervals that overlap the standard. Stated a different way, chance dictates that some hospitals with mortality rates below the standard will actually have a worse true mortality rate than some hospitals above it. Our analysis does not adequately deal with this issue—it assumes that measured mortality rates perfectly reflect performance. Thus, we have to some degree overestimated the lives likely to be saved by EHR for CABG and PCI.

Our estimates also raise a basic practical consideration: Is full implementation of EHR realistically feasible? For some procedures, the answer is yes. When hospitals in rural areas are excluded, all or most patients undergoing pancreatic resection or esophagectomy could be referred to hospitals meeting Leapfrog volume standards without imposing unreasonable travel burdens on patients.<sup>10</sup> These operations are also uncommon enough that EHR would not imply redistribution of large numbers of patients creating capacity problems at high volume hospitals. For elective AAA repair, there is little doubt that hospitals sufficiently motivated could increase the proportion of patients receiving perioperative beta-blockers. In contrast, the feasibility of full implementation of CABG and PCI is doubtful. Even if rigorous information about risk adjusted mortality rates were available for all hospitals, it would not be practical to move all patients to the 25% of hospitals with the best results. This would involve referral of hundreds of thousands of patients and present obvious capacity issues at receiving centers.

For this reason, incentives created by The Leapfrog Group for hospitals to measure and report their outcomes should be viewed in an additional context: quality improvement. Previous efforts in cardiac surgery and in the Department of Veterans Affairs suggest that the basic act of outcomes measurement and feedback of performance data to providers can result in dramatic reductions in surgical morbidity and mortality rates.<sup>11-12</sup> For some procedures, outcomes may be best improved by efforts aimed simply at getting patients to the best hospitals. For other procedures, however, it is important not to overlook the value of incentives that will stimulate improvement of quality at all hospitals.

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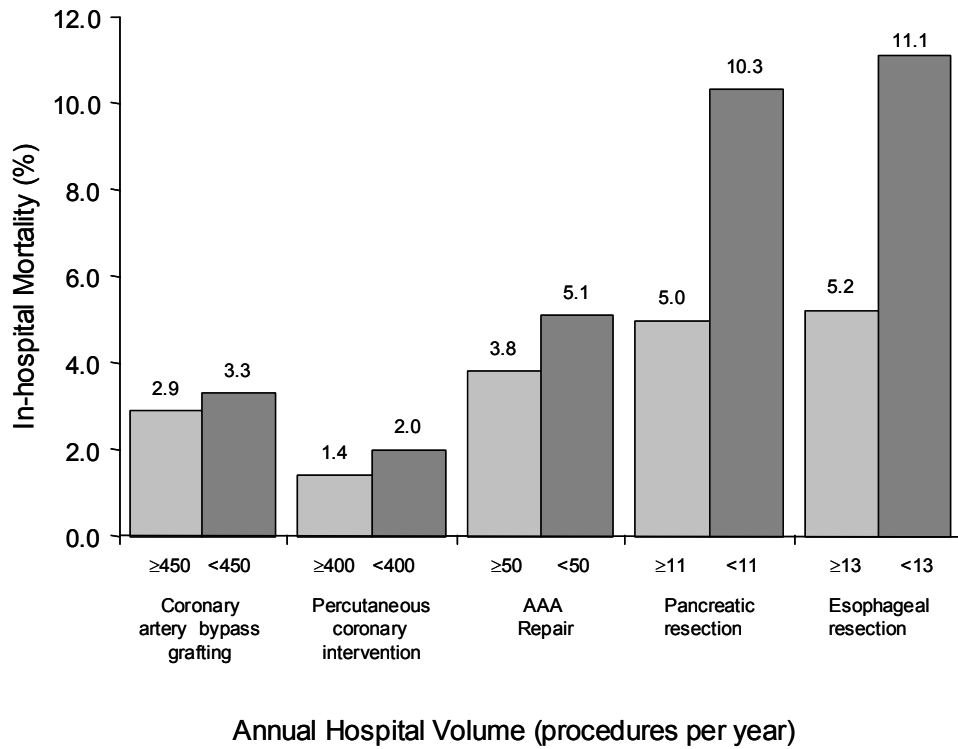
**Table 1:** Criteria for Full Adherence to the 2003 Leapfrog EHR Safety Standards.

Procedure	Volume Standard	Process Measures	Outcomes Measures
Pancreatic Resection	11/yr	None	None
Esophageal Resection	13/yr	None	None
AAA Repair	50/yr	Perioperative beta-blockers Beta-blockers prescribed at discharge	None
Coronary Artery Bypass Grafting			
NY, NJ, PA, CA*	None	(beta-blockers, use of IMA, aspirin, lipid lowering therapy and early extubation when appropriate)**	Must be in the lowest quartile of mortality rates in the state
Other States	450/yr	(beta-blockers, use of IMA, aspirin, lipid lowering therapy and early extubation when appropriate)**	Must participate in STS database <u>AND</u> have mortality rate below the national average
Percutaneous Coronary Intervention	400/yr	(Aspirin on discharge, intervention within 90 minutes for AMI)**	Must participate in ACC database <u>AND</u> have mortality rate below the national average

\*NY, NJ, PA, CA have prospective outcomes registries for coronary artery bypass grafting and percutaneous coronary interventions.

\*\*Used in partial credit algorithms for hospitals not meeting the criteria for full adherence to the Leapfrog EHR standards.

**Figure 1:** Adjusted mortality rates at hospitals above and below Leapfrog volume criteria. Analysis based on data from the Nationwide Inpatient Sample (2000). Mortality rates are adjusted for age, gender, race, admission acuity, and coexisting diseases. The differences between high and low volume hospitals are statistically significant ( $P < .05$ ) for all five procedures.



**Table 2:** Number of lives potentially saved by implementation of EHR for pancreatic resection.

Pancreatic Resection		
	Inputs and Assumptions	Annual Number
Number of annual cases in US hospitals	2000 NIS	5,779
Number in urban hospitals	96% in urban setting (2000 NIS)	5,548
Patients at low volume hospitals (LVHs) (population at-risk)	62% of patients (2000 NIS)	3,340
Expected deaths without EHR	10.3% (mortality rate at LVHs) of 3,340	344
Expected deaths with EHR	5.0% (mortality rate at HVHs) of 3,340	167
Lives saved by EHR		177

**Table 3:** Number of lives potentially saved by implementation of EHR for esophageal resection.

Esophageal Resection		
	Inputs and Assumptions	Annual Number
Number of annual cases in US hospitals	2000 NIS	4,350
Number in urban hospitals	95% in urban setting (2000 NIS)	4,132
Patients at low volume hospitals (LVHs) (population at-risk)	74% of patients (2000 NIS)	3,058
Expected deaths without EHR	11.1% (mortality rate at LVHs) of 3,058	339
Expected deaths with EHR	5.2% (mortality rate at HVHs) of 3,058	159
Lives saved by EHR		180

**Table 4:** Number of lives potentially saved by implementation of EHR for abdominal aortic aneurysm repair.

### Abdominal Aortic Aneurysm Repair

	Inputs and Assumptions	Annual Number
Number of annual cases in US hospitals	2000 NIS	41,667
Number in urban hospitals	95% in urban setting (2000 NIS)	39,586
Patients at low volume hospitals (LVH) (population at-risk)	48% in LVHs (2000 NIS)	19,001
Expected deaths without EHR	5.1% (mortality at LVHs) of 19,001	969
Expected deaths with implementation of volume standard	3.8% (mortality at HVHs) of 19,001	722
Expected deaths after implementation of beta-blocker standard	30% of patients experience additional 50% relative mortality reduction	613
Lives saved by volume standards		247
Lives saved from beta-blockers		109
Total lives saved with EHR		356

**Table 5:** Number of lives potentially saved by implementation of EHR for coronary artery bypass grafting surgery.

Coronary Artery Bypass Surgery		
	Inputs and Assumptions	Annual Number
Number of cases in US hospitals	2000 NIS	394,165
Number in urban hospitals	97% in urban setting (2000 NIS)	380,790
<b>NJ, NY, PA, CA</b>		
Number of cases in these states	26% of US population (US census data)	99,005
Number of cases at hospitals with mortality > 25 <sup>th</sup> percentile	78% of patients (2000 NIS)	77,224
Expected deaths without EHR	4.1% (mortality rate at all hospitals above 25 <sup>th</sup> percentile) of 77,224	3,166
Expected deaths with EHR	1.7% (mortality rate at hospitals below 25 <sup>th</sup> percentile) of 77,224	1,312
Lives saved by EHR		1,854
<b>Other States</b>		
Number of cases in other states	74% of US population (US census data)	281,785
Number of cases at hospitals not meeting EHR standards*	61% of patients (2000 NIS)	171, 889
Expected deaths without EHR	4.0% (mortality rate at hospitals not meeting EHR standard) of 171, 889	6,876
Expected deaths with EHR	2.7% (mortality rate at hospitals meeting EHR standard) of 171, 889	4,641
Lives saved by EHR	6,876 (deaths without EHR) x 0.33 (RRR) =	2,235
Total lives saved with EHR		4,089

\*Hospitals must meet the volume threshold (>450 cases/year) and have mortality rates lower than the national average.

**Table 6:** Number of lives potentially saved by implementation of EHR for percutaneous coronary interventions.

### Percutaneous Coronary Interventions

	Inputs and Assumptions	Annual Number
Number of cases in US hospitals	2000 NIS	678,296
Number in urban hospitals	96% in urban setting (2000 NIS)	651,164
Number of cases at hospitals that don't meet EHR standards*	43% of patients (2000 NIS)	280,000
Expected deaths without EHR	2.0% (mortality rate at hospitals not meeting EHR standard) of 207,201	5,600
Expected deaths with EHR	1.0% (mortality rate at hospitals meeting EHR standard) of 207,201	2,800
Lives saved by EHR		2,800

\*Hospitals must meet the volume threshold (>400 cases/year) and have mortality rates lower than the national average.

## Evidence-Based Hospital Referral: High-Risk Neonatal Intensive Care

### *Overview*

The Leapfrog evidence-based hospital referral (EHR) standard for neonatal intensive care requires that high-risk deliveries be managed in neonatal ICUs (NICUs) with average daily census levels of 15 or more. Neonatal EHR applies to infants with very low birth weights (less than 1500g), infants delivered at gestational age less than 32 weeks and those with a pre-natal diagnosis of major congenital anomalies. Leapfrog's standards now requires adherence to a process of care measure for full compliance: the administration of antenatal steroids to mothers of eligible infants (Table 1).

We estimate that full implementation of EHR nationwide for high-risk neonatal intensive care would save approximately 3,606 lives each year in the US. Very low birth weight and/or very premature infants comprise the majority of lives saved (3,055 lives). Infants with major congenital anomalies comprise the remainder (551 lives) of lives saved. Within the former group, the increased use of antenatal steroids (405 lives) contributes significantly to the total number of lives saved.

### *Methods and Results*

The number of lives potentially saved by full implementation of EHR for high-risk deliveries was calculated by first determining the number of deliveries (population at-risk) potentially affected by the policy. We then estimated baseline mortality risks for the high-risk groups and the potential mortality reductions associated with selective referral and use of antenatal steroids. According to the national birth report for 2001, there were 4,025,933 live births in the US. The high-risk infants included in the Leapfrog EHR standard are considered as two separate groups: 1) infants with major congenital anomalies and 2) very low birth weight (VLBW) and/or very premature infants. The number of lives saved with EHR for high-risk neonatal care was estimated for each group separately.

Infants with Congenital Anomalies (Table 2). The combined incidence of the congenital anomalies targeted by The Leapfrog Group is 1.6% (64,415 births) of live births each year in the US.<sup>2</sup> According to the Nationwide Inpatient Sample (NIS) for 2000, 87% of all births occur in urban hospitals. Based on data from the state of California, 82 percent of births involving major congenital anomalies occurred in non-regional (level 1, II, or II+) NICUs or in regional NICUs with average daily census rates below 15.<sup>2</sup>

Since 60% of deliveries involving major congenital anomalies are not detected by prenatal ultrasound<sup>3-4</sup>, all of the births currently occurring in other settings would not be eligible for transfer to large regional NICUs prior to delivery. Thus, we assumed that only 40% of such deliveries could be moved to large regional NICUs (Table 2).

Our estimates of the efficacy of evidence-based hospital referral rely on one study examining mortality rates for high-risk deliveries in high volume and low volume NICUs.<sup>5</sup> The adjusted odds ratio of death at regional NICUs with an average daily census of 15 or more compared to all other facilities was approximately 0.67. Because the study did not present stratified results, we assumed the same relative benefit for the two high-risk subgroups.<sup>2</sup>

The mortality rate (within the first 28 days of life or first year of life if continuously hospitalized) for infants with congenital anomalies was 9.25%.<sup>2</sup> We determined mortality rates at non-regional NICUs (9.8%) and regional NICUs with average daily census of 15 or more (6.8%) based on the overall mortality rates and the mortality reduction associated with EHR as previously described.<sup>2</sup> Full implementation of EHR for infants with prenatal diagnosis of a major congenital anomaly would result in 551 lives saved each year in the US (Table 2).

Very Low Birth Weight and/or Very Premature Infants (Table 3). There is considerable overlap in the occurrence of VLBW and very preterm births. The incidence of very low birth weight (<1500g) and very premature infants (<32 weeks gestation) as determined from the 2001 National Birth Report were 1.44% (57,973 births) and 1.95% (78,506 births), respectively.<sup>1</sup> There is, of course, substantial overlap between these two groups. Based on stratified data from the National Birth Report<sup>1</sup>, we estimated that 2.23% of live births have at least one of the two conditions.

Approximately 74 percent of births of VLBW and/or very premature infants occurred in NICUs with an average daily census rates below 15.<sup>2</sup> Most mothers experiencing premature labor will present to the nearest hospital or facility at which they have received prenatal care. Some with particularly advanced or precipitous labor will not be appropriate candidates for transfer for safety reasons. As in our previous report<sup>2</sup>, we assumed that 10% of such women would not be appropriate for transfer (Table 1).

The mortality rate for VLBW and/or very premature infants, based on data from the state of California, was 16.8%.<sup>2</sup> We estimated mortality rates at non-regional NICUs (18.1%) and regional NICUs with average daily census of 15 or more (13.0%) based on the overall mortality rates and the mortality reduction associated with this volume-based EHR standard, as previously described (Table 2).<sup>2</sup> Full implementation of the standard for VLBW and/or very premature infants would result in 2,650 lives saved each year in the US (Table 2).

Adherence to antenatal steroids (Table 3). The Leapfrog EHR standard includes adherence to a new process measure for appropriate infants (Table 1). All mothers delivering between 24 and 33 6/7 weeks of gestational age should receive at least one dose of antenatal steroids.

Several randomized clinical trials have shown significant reductions in mortality among premature infants receiving antenatal steroids. A meta-analysis of 15 trials demonstrated an average mortality reduction of 40% when combined across trials.<sup>7</sup> For our calculations, the population at-risk is VLBW infants not currently receiving antenatal steroids. Recent data from the Vermont Oxford Network of NICUs demonstrated that 75% of VLBW infants received antenatal steroids.<sup>8</sup> Since predominantly large NICUs participate in this network, we applied this baseline rate of steroid use to NICUs meeting the volume-based EHR standard.

For our calculations, we assumed that the rate of adherence could be increased from 75% to 90% (not 100%). We made this conservative assumption for the following two reasons: 1) eligibility criteria for the volume-based standards and process measures are similar but not identical and 2) some infants may not be eligible for the process measures for other reasons. Thus, we assumed that an additional 15% of infants would be receiving antenatal steroids. Given a further mortality reduction of 40% among the 15% of infants, we estimate an additional 405 lives saved each year (Table 3).

### ***Cautions and policy considerations***

Estimates of the potential benefits of EHR for high-risk deliveries should be viewed cautiously. Compared to the evidence underlying other Leapfrog safety standards, research examining the variation in mortality rates across NICUs is relatively scant. By necessity, our analysis relied primarily on a single study based on California hospital discharge data.<sup>5</sup> Thus, it is important to consider the external validity of this study with regards to both the distribution of high-risk deliveries and the potential efficacy of volume-based hospital referral.

The calculation of lives saved due to use of antenatal steroids required several assumptions. Eligibility criteria for volume-based referral and antenatal steroids are similar but not identical. Because we could not determine the size of eligible population more precisely, we made conservative assumptions about the proportion of infants eligible. Despite the uncertainty in these assumptions,

however, our results suggest that a modest increase in the use of antenatal steroids will substantially increase the potential benefits of EHR.

Mechanisms underlying relationships between volume and outcome with neonatal intensive care are largely unknown. Mechanisms no doubt include greater utilization of specific processes of care (such as use of antenatal steroids) at higher volume centers. In our analysis, however, we assumed independent effects of volume-based referral and the greater adherence to the process measure. To the extent that the two may be related, however, our estimates may reflect some degree of “double-counting” in determining lives saved.

Although current evidence suggests that the Leapfrog EHR standards for NICU care could save many lives, further research on the epidemiology of high-risk deliveries and the efficacy of referral to higher volume NICUs is warranted. Studies should also strive to understand how differences in processes of care contribute to observed variation in mortality rates across neonatal ICUs.

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**Table 1:** Criteria for full adherence to the 2003 Leapfrog EHR Safety Standards for high-risk neonatal intensive care.

Condition	Volume Standard	Process Measures
Major congenital anomalies	Neonatal ICU with average daily census >15	None
Very low birth weight (<1500g) and/or very premature (<32 weeks)	Neonatal ICU with average daily census >15	Antenatal steroids*

\*Infants born between 24 and 33 6/7 weeks are eligible.

**Table 2:** Number of lives potentially saved by implementation of EHR for infants with congenital anomalies.

### Infants with Congenital Anomalies

	Inputs and Assumptions	Annual Number
Deliveries in US hospitals with congenital anomalies	1.6% of live births (CA state data)	64,415
Number in urban hospitals	87% in urban setting (2000 NIS)	56,041
Deliveries in urban hospitals that don't meet Leapfrog Standards	82% (CA state data)	45,954
Deliveries eligible for referral to NICU with average daily census of 15 or more	40% (detected on prenatal ultrasound)	18,382
Expected deaths without referral	9.8% (mortality rate before EHR)	1,801
Expected deaths with referral	6.8% (mortality rate after EHR)	1,250
Lives saved by EHR		551

**Table 3:** Number of lives potentially saved by implementation of EHR for very low birth weight and/or very premature infants.

**Very Low Birth Weight and/or Very Premature Infants**

	Inputs and Assumptions	Annual Number
Deliveries in US hospitals	2.23% (National birth report)	89,681
Number in urban hospitals	87% in urban setting (2000 NIS)	78,022
Deliveries in urban hospitals that don't meet Leapfrog Standards	74% (CA state data)	57,737
Deliveries eligible for referral to NICU with average daily census of 15 or more	90% (based on "clinical grounds")	51,963
Expected deaths without volume-based referral	18.1% (mortality rate before EHR)	9,405
Expected deaths with volume-based referral	13.0% (mortality rate after EHR)	6,755
Expected deaths after implementation of antenatal steroids standard	15% of patients experience additional 40% relative mortality reduction	6,350
Lives saved by volume standards		2,650
Lives saved from antenatal steroids		405
Total lives saved		3,055

## ICU Physician Staffing

### *Overview*

The Leapfrog Group's IPS safety standard requires that physicians with specialized experience in critical care medicine manage or co-manage patients in the ICU. These physicians, called intensivists, must be present in the ICU during daytime hours and provide clinical care exclusively in the ICU. At other times (at least 95% of the time), they should be able to return pages within 5 minutes or arrange for on-site physicians or physician extenders who can reach ICU patients within 5 minutes.

Updates since the publication of our previous report account for changes in the IPS Standard itself and publication of data on the efficacy of IPS from a structured literature review. A national advisory panel recently met to update the IPS Standard resulting in an expansion of the initiative to include pediatric ICUs. Thus, the current report includes estimates of potential lives saved for both adult and pediatric ICUs.

In our updated baseline analysis, we estimate that full implementation of IPS would save approximately 54,134 lives each year in the US. The effectiveness of IPS is due to the large number of deaths that occur in the ICU each year (over 200,000). Given the magnitude of the population at risk, even small improvements in ICU mortality rates save many lives. Although our analysis is based on the best data currently available, many of the variables used in our calculations cannot be estimated precisely. In instances of uncertainty, we selected values that biased our calculations downward. Thus, we believe our estimate of the number of lives likely to be saved by IPS is conservative. In following sections, we describe the methods and assumptions we used in our analysis.

### *Methods and Assumptions*

The general strategy used to calculate the number of lives saved by full implementation of intensivist model ICUs is shown in Figure 1. The first step was determining the adult and pediatric populations at risk. Next, the baseline in-hospital mortality risks for each population and the potential mortality reductions associated with implementing intensivist model ICUs were estimated.

Current number of ICU admissions. To estimate the number of patients that could potentially benefit from the policy initiative we determined the number of patients admitted each year to non-intensivist ICUs (Figure 1). We could not directly determine the overall number of patients admitted to ICUs in the United States. Therefore, we determined ICU utilization rates for one state (Maryland) and extrapolated to the entire US. This method is different from that used in our previous report, which was based on the Medicare population and may have been an overestimate since the data include admissions to the postoperative recovery unit.

The total number of adult hospitalizations (18 or more years old) and children (<18 years) in the US were determined using weighted estimates from the Nationwide Inpatient Sample.<sup>2</sup> To avoid problems with health care access in rural areas, the Leapfrog Group is restricting the IPS Standard, along with the other safety initiatives, to metropolitan areas. In the Nationwide Inpatient Sample in 2001, 84% of patients were admitted to hospitals in urban areas.<sup>2</sup> The Maryland state data from 2002 revealed that 2.7% of children and 7.2% of adults were admitted to the ICU. Based on these calculations, we assumed in our analysis that 1,864,664 adults and 144,118 children are admitted to urban ICUs each year in the US.

The current proportion of ICUs in the US with intensivist models is unknown, but is thought to be low. In a 1991 national survey, only 22% of hospitals indicated that ICU order writing was restricted to unit staff (i.e., a “closed unit”).<sup>3</sup> In a follow-up survey, the same group reported that 17% of ICUs had closed units with respect to order writing.<sup>4</sup> Neither study described the proportion of closed units in which all ICU staff were board-certified (or -eligible) in critical care medicine, or met other Leapfrog criteria. In the hospital survey (~60% response rate) conducted by the Leapfrog group, 21.4% (110 of 515) of hospitals in rollout areas responded that they fully meet the IPS standard.<sup>5</sup> In our baseline analysis, we assumed that 21% of all adult ICU patients are currently treated in ICUs meeting the Leapfrog standard. This assumption is likely an overestimate given that hospitals with IPS already in place are more likely to respond to the Leapfrog’s survey.

In contrast to adults in ICUs, the pediatric population is more likely to be covered by a critical care specialist. In a national survey conducted in 1993 by Pollack et al, 201 of 301 hospitals with pediatrics ICUs responded and 48.5% of hospitals stated that they had a dedicated ICU physician available 24 hours per day.<sup>6</sup>

Current ICU Mortality. We estimated average in-hospital mortality rates for both adult and pediatric ICU patients from large cohort studies specific to each population. For adults, Zimmerman et al.<sup>7</sup> noted an overall 12.4% in-hospital mortality rate in 38,000 patients admitted to 161 hospitals between 1993 and 1996. In another study of adults by Shortell et al., in-hospital mortality for 17,000 patients at 42 randomly selected ICUs was 16.6% between 1988 and 1990.<sup>8</sup> In our baseline analysis, we selected 12% since it is the lower, more conservative of these two estimates. For pediatric ICUs the overall mortality is lower on average and was approximately 5% in two large cohort studies.<sup>9,10</sup>

Mortality reductions with implementing the intensivist model. Several previous studies have evaluated the effectiveness of higher intensity staffing models in reducing ICU mortality. In our previous report, we used the estimate from the single study showing the lowest efficacy, which showed a 15% relative mortality reduction. Using this low-end assumption regarding effectiveness provided a conservative estimate of the number of potentially averted deaths.

Since our last report on the benefits of universal adoption, high quality information synthesizing the previous evidence has become available. In a recent systematic review by Pronovost and colleagues, the mortality reduction for all studies combined was estimated and was found to be higher than the conservative estimate we used for the previous analysis.<sup>1</sup>

Pronovost’s structured review found that 16 of 17 (94%) studies demonstrated a reduction in hospital mortality (Figure 2).<sup>1,11-23</sup> The weighted relative risk for in-hospital mortality with high intensity vs. low intensity IPS was 0.71 (95% CI, 0.62 to 0.82) (Figure 2). This combined estimate of a 30% risk reduction was used in our baseline analysis. The systematic review also estimated a 40% reduction in ICU mortality for studies that included this endpoint. In our analysis, we used the lower (more conservative) estimate of efficacy based on the overall hospital mortality analysis.

Two studies in the systematic review included pediatric patients and these both demonstrated larger mortality reductions than the combined estimate. Only one of these used in-hospital mortality as an endpoint yielding a relative risk reduction of 47%. To avoid an unstable estimate, the more conservative overall estimate of a 30% reduction was applied to the pediatric population as well (Figure 1).

## ***Results***

In our baseline analysis, we estimate that full implementation of intensivist model staffing would save approximately 54,134 lives (1,102 children and 53,031 adults) each year in the US (Figure 1). As expected, for both the adult and pediatric population, the number of lives saved varies according to assumptions about the effectiveness of intensivist model staffing (Figure 3 and Figure 4). For example, assuming a 10% relative mortality reduction, 18,000 adult lives would be saved with universal adoption of the IPS standard. In contrast, assuming a 50% mortality reduction would estimate over 90,000 adult lives saved.

## ***Cautions and policy considerations***

Given the large number of deaths that occur in ICUs each year in the United States (more than 200,000), even small reductions in ICU mortality rates would save many lives. Based on our updated analysis, if the Leapfrog initiative is successful in effecting full implementation of intensivist model ICU staffing in metropolitan areas nationwide, we estimate that approximately 53,031 adult's lives and 1,102 children's lives could be saved each year in the US. Despite changes in our assumptions regarding the effectiveness of IPS, the number of potential lives saved is similar to the estimate from our previous report. The smaller population at-risk in the current report offset the larger mortality reduction associated with IPS used in the baseline analysis.

The estimate of the effectiveness of IPS from the structured literature review is only as accurate as the original studies, which have several shortcomings in methodology that should be considered. First, many of them use historical controls and are limited by secular trend bias, with the mortality falling at those hospitals for reasons other than implementation of intensivist model staffing. The hospitals in these studies may have changed other aspects of care not directly related to physician staffing changes. Although there is no evidence that ICU mortality rates are declining, mortality rates with many clinical conditions are improving over time with advances in science and technology. However, given the magnitude of decline in mortality seen in many of these studies, it is very unlikely that improvements can be attributed to secular trend bias alone.

Second, estimates from studies with cross-sectional designs may suffer from imperfect risk-adjustment. Thus, their results may be partially confounded by unmeasured differences in characteristics of both patients and providers between control and intensivist model groups. For instance, few studies used physiologic data for risk adjustment, which is important given the severity of illness in the critically ill population. Also, hospitals with and without IPS may differ in other important areas such as availability of technology, nurse staffing, and hospital caseload. Third, most of these studies are from single hospitals or, at the most, limited geographic areas, and caution is required in generalizing these results to the entire US. Finally, there was substantial heterogeneity in the amount of intensivist involvement across the original studies. Some studies involved simply adding co-management by a single intensivist to a system primarily run by non-ICU based physicians; others described extensive changes in staff organization, including complete replacement of ward-based teams by intensivists and ICU-based house staff. It is important to note, however, that the Leapfrog IPS standard falls on the latter, "stricter" side of the spectrum, and thus is likely to be more efficacious.

Although the potential benefits are large, several barriers must be overcome to realize full implementation of intensivist model ICU staffing. Although workforce issues have not been studied carefully, it is unlikely that there are currently enough board-certified intensivists to staff ICUs fully at all hospitals.<sup>24</sup> In hospitals with small units, meeting the Leapfrog standard may increase net cost per stay. For these reasons, broad implementation of intensivist model ICU

staffing may require a blend of increased fellowship training slots in critical care, consolidation of small ICUs, and advances in telemedicine.

Many would argue that lives saved by intensivist model ICU staffing are not equivalent to lives saved by other public health interventions (e.g. seat belt laws). ICU patients often have substantial limitations in functional status and shortened life expectancies compared to the general population. For this reason, further research should consider how improvements in ICU care affect quality of life after hospital discharge and long-term survival.

Another significant barrier to full implementation of IPS is the expense of hiring additional staffing at each hospital. Salaries for intensivists, nurse practitioners, and physician assistants will result in large expenditures for hospitals. These costs, however, will be offset by savings from reductions in inappropriate ICU admissions, shortened ICU and hospital length of stay, and lower complication rates. Further, given the more than 50,000 lives saved from IPS, conservative estimates of life expectancy yield a potential savings of \$5.3 billion dollars from a societal perspective.<sup>25</sup>

Despite these considerations, given the large number of ICU deaths in the US each year, it is evident that universal implementation of the Leapfrog Group's IPS Standard will save a large number of lives. Our analysis demonstrates that the majority of the avoided deaths are in the adult population but many lives will also be saved each year in pediatric ICUs. Future research should determine strategies to overcome barriers to the widespread implementation of intensivist management of ICUs.

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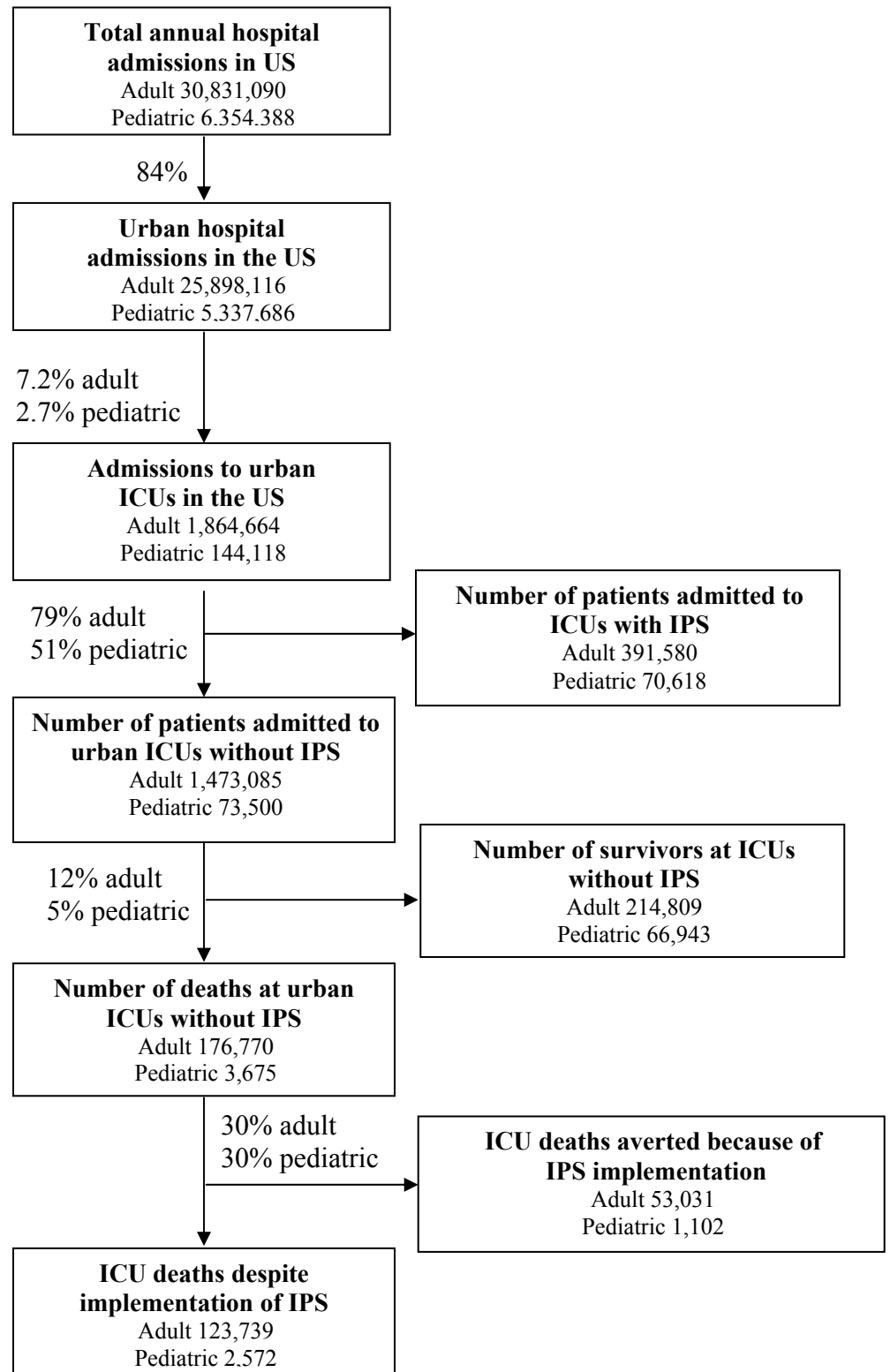
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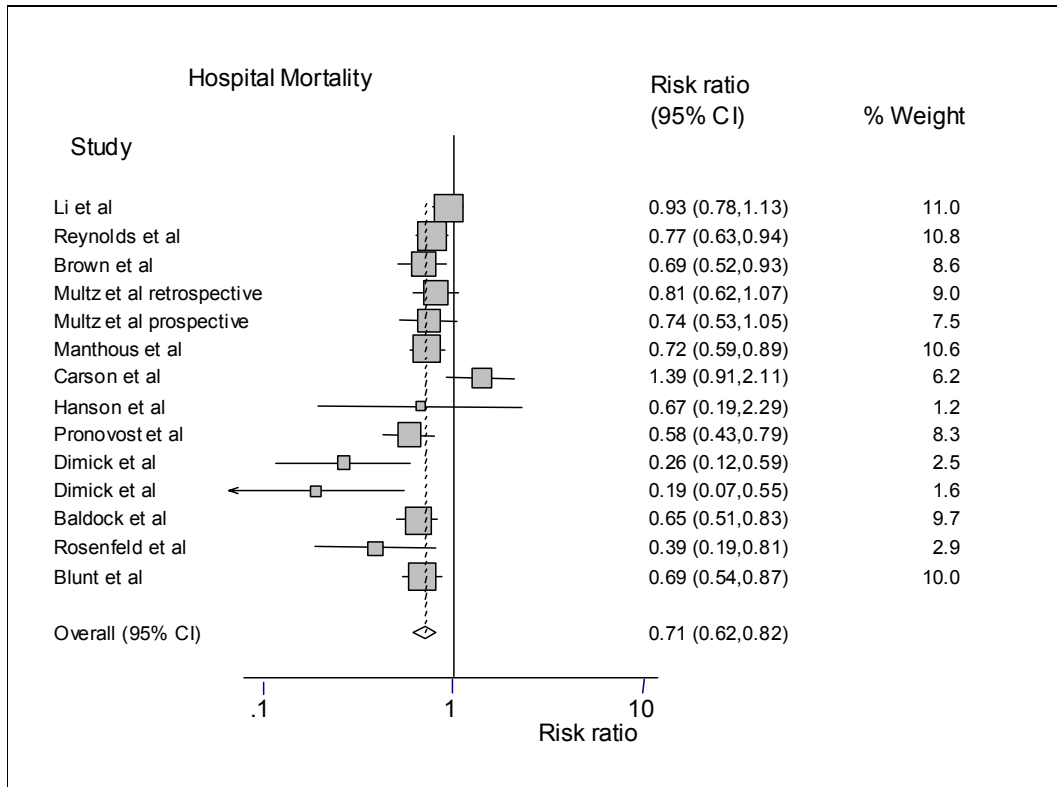
**Table 1.** Studies included in the systematic review of ICU physician staffing. The table has been modified from Pronovost et al.<sup>1</sup>

<b>Source</b>	<b>Population</b>	<b>Study Design</b>	<b>ICUs Studied</b>
Li et al, 1984 <sup>11</sup>	Medical or surgical	Cohort with historical controls	1
Reynolds et al, 1988 <sup>12</sup>	Medical (sepsis)	Cohort with historical controls	1
Brown et al, 1989 <sup>13</sup>	Medical or surgical	Cohort with historical controls	1
Multz et al retrospective, 1998 <sup>14</sup>	Medical	Cohort with historical controls	1
Multz et al prospective, 1998 <sup>14</sup>	Medical	Cohort with historical controls	2
Manthous et al, 1997 <sup>15</sup>	Medical	Cohort with historical controls	1
Carson et al, 1996 <sup>16</sup>	Medical	Cohort with historical controls	1
Hanson et al, 1999 <sup>17</sup>	Surgical	Cohort with concurrent controls	1
Pronovost et al, 1999 <sup>18</sup>	Surgical (AAA repair)	Cross-sectional	39
Dimick et al, 2001 <sup>19</sup>	Surgical (esophagectomy)	Cross-sectional	35
Dimick et al, 2002 <sup>20</sup>	Surgical (hepatectomy)	Cross-sectional	32
Baldock et al, 2001 <sup>21</sup>	Medical or surgical	Cohort with historical controls	1
Rosenfeld et al, 2000 <sup>22</sup>	Surgical	Cohort with historical controls	1
Blunt et al, 2000 <sup>23</sup>	Medical	Cohort with historical controls	1

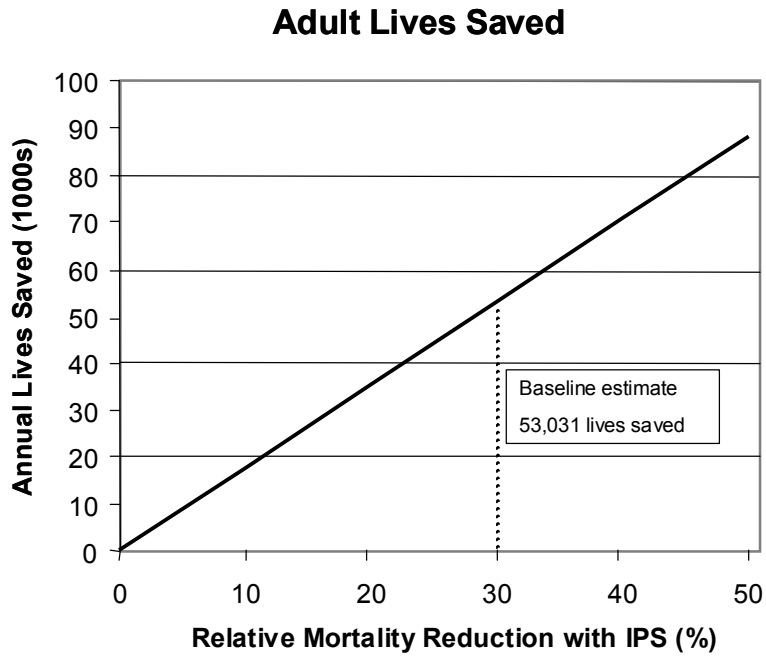
**Figure 1:** Number of lives that would be saved each year by full implementation ICU physician staffing (IPS) nationwide.



**Figure 2:** Mortality for high intensity vs. low intensity ICU physician Staffing. The figure has been modified from Pronovost et al.<sup>1</sup>



**Figure 3:** Sensitivity analysis demonstrating the effect of different assumptions about the effectiveness of IPS on the number of adult lives saved each year in the US.



**Figure 4:** Sensitivity analysis demonstrating the effect of different assumptions about the effectiveness of IPS on the number of children's lives saved each year in the US.

