

## Request for Changes to Safe Practice #5: Informed Consent

*Imagine...*

*Imagine a world in which clinicians delivered just the right information to their patients at precisely the right moment. Imagine that clinicians were able to focus their limited time helping well-prepared patients to put that information into perspective for their particular situations, guiding them to a decision that balances the best available scientific evidence with what matters most to them. Imagine that the collaboration continues over time, with clinicians delivering tailored information at the right time to help people consistently make informed choices and do their right things for themselves.*

*You may say that we're dreamers, but we're not the only ones...<sup>1</sup>*

### Introduction

This briefing paper provides information on Evidence-based Hospital Referral which was dropped as a Safe Practice by the Safe Practices Maintenance Committee in the 2009 Update to the Safe Practices. The Leapfrog Group has requested a temporary fix for this in the proposed Safe Practice 5: Informed Consent, with the goal of reinstatement as a separate practice in the next maintenance round. Safe Practice 5: Informed Consent currently contains the following language in the Additional Specifications:

*“Convey the risk that is associated with high-risk elective cardiac procedures and with high-risk procedures with the strongest volume-outcomes relationship.”*

The Leapfrog Group, along with other purchasers and consumers, had requested in the comment period for the 2009 update, that the language be changed to incorporate the following in the Safe Practice:

*“Convey via an 8th grade-level vocabulary the identity of any hospitals in the same medical service area, that, based on credible measurement systems known to the hospital or surgeon, offer patients a lower surgical risk for (1) high-risk cardiac procedures (CABG, PCI, AVR, AAA) and (2) for procedures (esophagectomy and pancreatectomy) where the evidence is the strongest for the volume-outcome relationship. Information disclosed to patients would include mortality rates and annual procedure volumes.*

*Medical service areas would be as defined by state government, the Dartmouth Atlas or other authoritative source.”*

Conceptually this is the direction we will continue to pursue, but we are willing to stage the impact on health care providers as we tighten the definitions on which providers must convey information to patients. In this version of the Safe Practices, we request that the existing language address esophagectomy and pancreatectomy specifically, and that the requirement for notification of patients applies to the lowest volume providers. The evidence is clear that there is at least a two-fold difference in mortality for low volume and high volume providers.

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<sup>1</sup> Joshua Seidman, PhD., President, Center for Information Therapy; and Karen Sepucha, PhD, Senior Scientist, Health Decision Research Unit, Massachusetts General Hospital/Harvard Medical School, Medical Editor, Foundation for Informed Medical Decision Making, March 19, 2008. *Navigating a Changing Health Care System: How Consumers, Clinicians and Policymakers Can Make Sense of Shared Decision Making and Information Therapy*. March 19, 2008.

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### Rationale

The Leapfrog Group, as a representative of employers and purchasers of healthcare, requests that in this year's update, there is specific language on esophagectomy and pancreatectomy, and the importance of hospital/operator volume as the mechanism for determining which providers must share volume information with their patients. In the next maintenance year, we would like a new Safe Practice which addresses patient survival/mortality. As robust mortality information is increasingly more available, it seems reasonable that this information be supplied to inform consumers making choices regarding surgical care for high risk procedures. When mortality information is not available volume information (where there is an established volume/outcomes relationship) is the next best information for consumers. In either case, consumers should be supplied with comparative information related to their medical service area, beginning specifically with esophagectomy and pancreatectomy, by those providers with low volumes.

Given the increasing availability of endorsed mortality and volume measures, and the public reporting<sup>2</sup> of such measures, healthcare providers can easily avail themselves of this information. Volume and mortality information, associated with high risk procedures and specific conditions is available from the following sources: CMS Compare Website, The Leapfrog Group Consumer Website, Consumer Reports, and state reports in PA, CA, NY, NJ, and MA. While these sources are available to both providers of healthcare and consumers, the evidence reflects<sup>3,4</sup> that consumers are often unaware of the availability of this information.

Sharing this information with consumers and answering questions regarding the variation across providers is an appropriate addition to Safe Practice 5: Informed Consent. The health care environment needs to foster *relationships based on trust, clear communication, and informed choices*. *If physicians and hospitals do not provide information that allows for informed choices, consumers will rely on "Dr. Google" instead.*<sup>5</sup>

### Volume/Outcome Relationship for High Risk Surgical Procedures

In the last two decades, there has been significant published research indicating the volume-outcomes relationship for certain high risk surgical procedures, yet the provider community historically has not supplied this information to consumers.

The Leapfrog Group asked national experts: Birkmeyer and Dimick (2003)<sup>6</sup>, Conrad and Gardner (2004)<sup>7</sup>, Lwin and Shepard (2008)<sup>8</sup>, to review the available literature and

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<sup>2</sup> Public reporting, as used in this document, refers to the definition in the "National Quality Forum Guidelines for Public Reporting"—"disclosure of information to consumers, to a community, or to a group of people who share a common interest in order to help them make better healthcare choices or to institutions to help them meet their obligations or duty to make information about their actions or performance available."

<sup>3</sup> Marshall MN, Shekelle PG, Leatherman S, et al., The public release of performance data: what do we expect to gain? A review of the evidence, *JAMA*, 2000; 283(14):1866-1874.

<sup>4</sup> Schneider EC, Lieberman T, Publicly disclosed information about the quality of health care: response of the US public, *Qual Health Care*, 2001; 10:96-103.

<sup>5</sup> Giustini D. (2005) How Google is changing medicine. *BMJ*. 331:1487-1488 (24 December).

<sup>6</sup> Birkmeyer, J.D., Dimick, J.B. The Leapfrog Group's Patient Safety Practices, 2003: The Potential Benefits of Universal Adoption. February 2004.

<sup>7</sup> Conrad, D., Gardner Updated Economic Implications of the Leapfrog Group Patient Safety Standards: Final Report to the Leapfrog Group, August 4, 2004.

<sup>8</sup> Aung K, Lwin, Donald S, Shepard. Estimating Lives and Dollars Saved from Universal Adoption of the Leapfrog Safety and Quality Standards: 2008 Update, available

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provide evidence for the impact of procedure volume in relation to patient outcomes. Three reports have been available since 2004, by the cited researchers, that summarize the evidence and quantify the impact of all urban hospitals meeting the established Leapfrog volume thresholds. See page 7 for a cumulative bibliography of the literature on the volume-outcomes relationship that The Leapfrog Group makes available online. In the next pages, we provide summary information from the most recent report produced by Lwin and Shepard (2008) and the earlier report by Birkmeyer and Dimick (2003).

The recent articles reviewed by Lwin and Shepard (2008) continue to provide evidence of a volume-outcome relationship for these high risk procedures and conditions. The studies published since the last report by Conrad (2004), reported higher volumes were associated with lower short-term, risk-adjusted mortality rates, better processes of care, and long term survival rates. Hollenbeck et al. (2007a) reported that reliance exclusively on the SEER-Medicare data set could underestimate volume-outcome relationships of some selective surgeries due to misclassifications of procedure volume. Phibbs et al. (2007) reported higher mortality rates for very-low birth-weight-infants in low volume hospitals with low levels of care. Moscucci et al. (2005) reported that lower *operator* volume for PCI was related to higher rates of major adverse cardiovascular events. Hannan et al. (2005) reported greater adverse outcomes (in-hospital mortality, higher incidence of the same-stay surgery as well as same-day surgery) in *hospitals* with low volumes of percutaneous coronary intervention (PCI). In addition, Hannan's study also reported higher incidences of same-stay and same-day surgery as adverse outcomes among low-volume *operators* performing PCI.

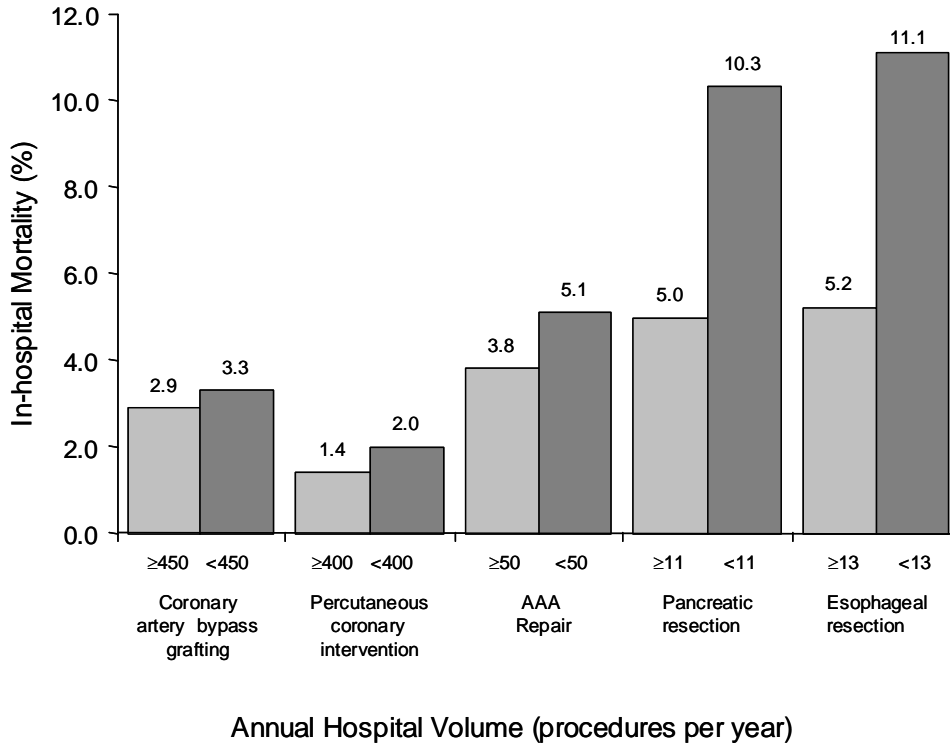
Earlier literature, produced in both the Birkmeyer and Dimick (2003) report and the Conrad and Gardner (2004) report, found substantial support in the peer-reviewed literature for the following procedures: Coronary Artery Bypass Graft (CABG), Percutaneous Cardiac Intervention (PCI), Aortic Abdominal Aneurysm (AAA) Repair, Esophagectomy and Pancreatectomy. The volume-outcomes relationship was particularly strong for Esophagectomy and Pancreatectomy. Birkmeyer and Dimick (2003) also conducted their own analysis of the volume-outcome relationship as shown in Figure 1. Two-fold differences were found for two of the five procedures, while the other three procedures were lower but statistically significant.

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at: [http://www.leapfroggroup.org/media/file/Lives\\_Saved\\_Leapfrog\\_Report\\_2008-Final\\_%282%29.pdf](http://www.leapfroggroup.org/media/file/Lives_Saved_Leapfrog_Report_2008-Final_%282%29.pdf), accessed on 8/3/09.

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**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.



### Potential Lives Saved

In the most recent update, “the [potential] lives saved from evidence-based hospital referral are based on the number of procedures per year for the specific procedure, times the difference in mortality rates per procedure. Lwin and Shepard (2008) used the results of procedure-specific studies (Hannan et al., 2005, Marcin et al., 2008, Brooke et al., 2008, Nguyen et al., 2004, Dimick et al., 2005) to estimate the national total lives saved from evidence-based hospital referral. Only the studies done for the US population are included. Only statistically significant findings matched for the hospital volume criteria of Leapfrog’s endorsed standards were adopted for extrapolating the national estimate. Lwin and Shepard (2008) updated the annual number of cases, the proportion of procedures that were performed in urban hospitals, and the proportion of procedures in low-volume hospitals for each high-risk surgery in the evidence-based standards. “

Their estimate (Table 5 below) is much lower than the previous estimate based on the 2000 NIS (Birkmeyer and Dimick., 2003), where the number of lives saved was estimated to be 7,602.

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**Table 5: Annual lives saved from evidence-based hospital referral, by procedure**

High risk procedure	Share of low-volume procedures	Mortality rate of procedures under low volume	Mortality rate of procedures under high volume	No. of procedures performed	Lives saved
Pancreatic resection	37%	9.2%	2.7%	6,616	160
Esophageal resection	64%	20.7%	10.7%	3,312	210
AAA	62%	4.4%	2.2%	43,048	283
CABG	59%	2.9%	1.7%	239,043	1,710
PCI	13%	1.2%	0.6%	794,492	638
Bariatric surgery	11%	1.2%	0.3%	1,850	17
<b>Total</b>	<b>25%</b>			<b>1,088,361</b>	<b>3,018</b>

However, as a different way of expressing the potential lives saved from each high-risk surgery, the authors used a baseline number of 100 procedures to calculate how many lives per 100 procedures could be saved if done in hospitals meeting the Leapfrog EHR standards (Table 7).

**Table 7: Potential lives saved based on weighted averages**

Weighted saving (100 procedures)	New estimate (2006 NIS)	Old estimate (2000 NIS)
Pancreatic resection	0.04	0.03
Esophageal resection	0.03	0.02
AAA	0.09	0.05
CABG	0.27	0.46
PCI	0.45	0.60
Bariatric surgery	0.00	0.00
Average saving among 100 procedures	0.87	1.16
<b>Potential lives saved</b>	<b>9,527</b>	<b>12,514</b>

Their estimate based on 2006 NIS data was 0.9 lives saved for 100 procedures of all high risk surgeries performed by hospitals meeting the Leapfrog standard. The previous estimate (based on 2000 NIS) reflects savings of 1.2 lives per 100 procedures. As an approximation, one life out of 100 procedures can be saved for the high risk operations currently meeting the EBHR performance standards.

The authors extrapolated this figure, and suggest that it could be assumed that if all hospitals performing these high risk surgeries had adopted the EBHR standards in 2006, an average number of 9,500 to 12,500 lives could have been saved in a single year.

### Summary

We believe the evidence related to volume-outcomes relationship is clear for the specified high risk procedures. In addition, the presence of mortality data in the public domain has increased dramatically. These two metrics are now accessible to providers to discuss with their patients.

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Thus, The Leapfrog Group, along with other purchasers, and consumer groups, request that the Safe Practices Maintenance Committee re-instate more specific language related to risks for patients in Safe Practice #5: Informed Consent. This information should include comparative hospital mortality and volume of esophagectomy and pancreatectomy for the hospitals in the patient's medical service area by those providers with the lowest volumes. We also request that in the next update to the Safe Practices, that a separate safe practice be incorporated that addresses patient survival for the remaining cardiac procedures.

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