Original Articles
4 Short- and Long-Term Antireflux and Asthma Medication Use in Children After Nissen Fundoplication
12 The Falling Rate of Positive Penicillin Skin Tests from 1995 to 2007
20 Developing Minimally Invasive Surgery Centers Within Kaiser Permanente
31 An Exploratory Case Study: Effects of a Physician Organizational Socialization (Enculturation) Program

Review Article
50 Incidental Gallstones

Clinical Medicine
55 An Unusual Presentation and Etiology of Hypotension Seen in Nephrotic Syndrome
58 An Unusual Cause of Elevated Values on Liver Function Tests in a Liver Transplant Patient
61 Early and Accurate Diagnosis of Sudden Sensorineural Hearing Loss

Commentary
65 Statement to US Senate Committee Investing in Health IT: A Stimulus for a Healthier America
71 Marketing, Media, Wishful Thinking, and Conflicts of Interest: Inflating the Value of New Medical Technology
80 Dealing With Change: Using the Conditional Change Model for Clinical Research

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On the cover: “Brothers on the Cover,” written by Dr. David Kusek, MD, is a photograph taken two days after the birth of his second son. Cal, now 6 years old, is holding his newborn baby brother Alexander, his second son. Cal was born two days after the birth of his first son.

The falling rate of positive penicillin skin tests from 1995 to 2007. Eric Mary, MD; Michael Schatz, MD; CS, KIM, PhD; Kevin Yee Poon, MS

Data on the rate of positive penicillin skin test (PenST) results over time in large populations are rare. Of 5401 individuals, 251 had positive PenST. The rate declined from >10% to <5% (13 years studied) accounted for by the year of testing without contribution from patient’s age or time since reaction. Route and frequency of outpatient antibiotic use may explain this.

20 Developing Minimally Invasive Surgery Centers Within Kaiser Permanente: The Integrated Multidisciplinary Experience of Los Angeles. Gary W. Chien, MD; Mitha A. Abbas, MD, FACS, FASCRS

Although there are unique issues for each specialty, many common issues, such as anesthetic considerations, operating room standards, documentation of disposable products and electrocardiograph units, testing and implementation of new equipment, postoperative care, education, simulation, training, and research are effectively and efficiently addressed through a multidisciplinary approach and complete integration.

The four clinics in the Metro West Region. Circulation: 25,000 print readers per quarter, and accessed by 501,000 unique Web readers in 2008 from 164 countries of the world.
CASE STUDIES

55 An Unusual Presentation and Etiology of Hypotension Seen in Nephrotic Syndrome.
Anna-Maria Panagiotides, MD; Aviv Hever, MD; John J Sim, MD
The case discussed illustrates an unusual presentation of hypotension due to amyloid infiltration of the vasculature, leaving the patient susceptible to acute kidney injury even from what is generally considered mild diuresis. The kidneys are the most frequently affected organs in approximately 80% of patients with the disease. Cardiac dysfunction is the second most common presentation.

58 An Unusual Cause of Elevated Values on Liver Function Tests in a Liver Transplant Patient.
Ankur Jain, MD; Amandeep Sahota, MD; Najeeb S Alshak, MD; Jim K Tung, MD
Biliary obstruction and rejection are two of the most common causes of abnormal findings on liver function tests (LFTs) in patients who have already undergone liver transplantation. Here a post-transplant patient with jaundice, not previously vaccinated, had hepatitis B as the cause of his increased values on LFTs.

CLINICAL MEDICINE

61 Early and Accurate Diagnosis of Sudden Sensorineural Hearing Loss. Barry Rasgon, MD; Luke James Schloegel, MD
Sudden Sensorineural Hearing Loss is defined as a 30-dB hearing loss in three consecutive frequencies whose onset is less than three days. Most researchers agree it is likely to be of vascular, immunologic, or viral origin, and is regarded as an otologic emergency.

EDITORIALS

77 Isn’t it Time to Stop Accepting Handouts for our Educational Efforts? KM Tan, MD
Commercial support for continuing education risks distorting educational content, invites bias, and endangers professional commitment to evidence-based decision making. The Permanente Medical Groups are leading a ban on commercial support for accredited organizations that provide continuing education, especially because it is not the size of the gift, but the gifting itself that creates the desire to reciprocate.

80 Dealing With Change: Using the Conditional Change Model for Clinical Research.
Mikel Aickin, PhD
Virtually all clinical medicine is about change. In clinical research one of the most frequently used approaches—to compare changes in a treated group with corresponding changes in a control group—fails to include the baseline measurement value in the analysis. Reasons to prefer the conditional change model over the t-test are: smaller error, similar groups, and less artifact.

NARRATIVE MEDICINE

88 A Fatal Form of Contentment.
Catherine Hickie, MBBS
A 19th-century query in The Lancet into mass train travel noted vagrants as enjoying the pleasure of travel without having earned it through work—a "fatal form of contentment." The Internet has come with anxieties and fears just as the trains did. A 21st-century psychiatrist wonders if our hopes for new technology are different from the hopes of the Victorians.
Short- and Long-Term Antireflux and Asthma Medication Use in Children After Nissen Fundoplication

Steven L Lee, MD, FACS, FAAP

Abstract

Purpose: We sought to determine antireflux and asthma medication use after Nissen fundoplication (NF).

Methods: We performed a retrospective study using hospital discharge and pharmacy data from 1996 through 2005. A total of 342 pediatric patients had ≥1 NF; 336 of those had complete medication data. Use of antireflux medications and asthma medications were reviewed before and after NF.

Results: Short-term (one year after NF) use of antireflux medications decreased (odds ratio [OR] = 0.35; 95% confidence interval [CI], 0.26–0.45). During the entire study period, the decrease in antireflux medication use after NF remained in place (233 to 197 patients; OR = 0.63; 95% CI, 0.47–0.84). Use of antireflux medications decreased in neurologically healthy patients (n = 186) after NF but remained the same in neurologically impaired patients. Short-term use of inhaled and systemic asthma medications did not change (OR = 1.16 [95% CI, 0.89–1.51] and 0.90 [95% CI, 0.69–1.18]), respectively. During the entire study period, inhaled and systemic asthma medication use increased after NF (OR = 2.11 [95% CI, 1.63–2.74] and 1.85 [95% CI, 1.43–2.41]), respectively. Inhaled and systemic asthma medication use increased in both neurologically healthy and impaired children. In older children (age >5 years), short-term use of inhaled and systemic asthma medications decreased after NF (OR = 0.39 [95% CI, 0.25–0.60] and 0.31 [95% CI, 0.19–0.53]), respectively. However, during the entire study period, inhaled and systemic asthma medication use in older children remained the same.

Conclusion: NF decreased antireflux medication use in the short and long term, particularly in neurologically healthy children. Inhaled and systemic asthma medication use increased after NF in neurologically healthy and impaired children. NF provided a short-term decrease in inhaled and systemic asthma medication use in older children but showed no change in the long term.

Introduction

Excellent symptomatic results after Nissen fundoplication (NF) in children have been shown in large retrospective studies. Furthermore, laparoscopic NF has also been shown to be safe in children as small as 1.2 kg and as young as five days. However, few studies have demonstrated long-term objective outcomes after NF in children. We previously looked at the number of hospitalizations for complications related to gastroesophageal reflux disease (GERD) to determine long-term effectiveness after NF. There was no change in the number of patients hospitalized for pulmonary symptoms and failure to thrive before and after NF. We also showed that long-term use of antireflux medications decreased by 37% in children after NF. However, these studies were criticized because patients of all ages were grouped together regardless of neurologic status. Many believe that reflux disease in a young child with an underlying neurologic disorder and repeat hospitalizations for pneumonia or failure to thrive may be different from the disease in an older, neurologically healthy child with significant reactive air-
way disease. Thus, endpoints after NF may be different in such vastly dissimilar patient populations. The purpose of this study was to address this criticism by analyzing the short- and long-term effects after NF in children. Specifically, this study analyzes the use of antireflux medication and asthma medication on the basis of patient age and neurologic status.

**Materials and Methods**

The Southern California Kaiser Permanente (KP) Discharge Abstract Database (PDAB) was used to identify pediatric patients (those <19 years old) hospitalized in 12 acute-care hospitals with diagnosed GERD that was treated with NF between January 1, 1996, and December 31, 2005. Surgical therapy was determined according to the guidelines for the Current Procedural Terminology, fourth edition (CPT) procedure code for NF. This study was approved by the institutional review board of KP Southern California, protocol numbers 3934 and 5040.

Patients’ data were then analyzed using the KP Southern California Pharmacy database for use of antireflux medications. Specifically, use of antireflux medication (H₂-blockers and proton pump inhibitors) and asthma medication (systemic steroids, inhaled β-agonists, and inhaled steroids) were analyzed. The pre-Nissen period was defined as the period from birth to first NF, and post-Nissen period was defined as the time from first NF to death or to the end of the study, whichever came first. The number of patients using antireflux and asthma medications was recorded before and after NF at six-month intervals. Short-term use was defined as restarting medication at the end of the study period, with a mean follow-up period of 4.5 years.

The data from PDAB were exported to SAS statistical software (version 9.13, SAS Institute, Inc, Cary, NC, USA) for subsequent analyses. Use of antireflux and asthma medication before and after NF was compared using χ² analysis. Odds ratios (ORs) were calculated using logistic regression. In addition to NF, age and underlying neurologic disorder were also included in the regression model. Estimates were considered statistically significant if the 95% confidence interval did not overlap 1.0 and if p values were <0.05.

**Results**

A total of 342 patients were identified as having undergone NF during the study period. Medication data were available for 336 of those, and 154 (45%) patients had an associated neurologic disorder. Mean patient age at time of NF was 3.9 ± 4.8 years (median age, one year; range, 0–17 years) with a male-to-female ratio of 1.19 to 1. Mean duration of follow-up monitoring was 4.5 years.

**Table 1. Short-term and long-term use of antireflux medication after Nissen fundoplication in children**

<table>
<thead>
<tr>
<th>Group</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All children in study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.35 (0.26–0.47)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.63 (0.47–0.84)</td>
<td>0.0015</td>
</tr>
<tr>
<td>&lt;1 year (n = 140)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.59 (0.37–0.95)</td>
<td>0.0282</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.06 (0.67–1.69)</td>
<td>0.7995</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 99)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.18 (0.10–0.34)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.28 (0.15–0.51)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>≥5 years (n = 97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.23 (0.13–0.42)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.49 (0.28–0.87)</td>
<td>0.0136</td>
</tr>
</tbody>
</table>

**Table 2. Short-term and long-term use of antireflux medication after Nissen fundoplication in neurologically healthy children**

<table>
<thead>
<tr>
<th>Group</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages (n = 186)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.22 (0.15–0.34)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.38 (0.26–0.57)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>&lt;1 year (n = 82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.45 (0.25–0.81)</td>
<td>0.0084</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.82 (0.46–1.43)</td>
<td>0.4791</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.11 (0.04–0.26)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.15 (0.06–0.35)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>≥5 years (n = 54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.09 (0.04–0.21)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.17 (0.07–0.40)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.
Antireflux Medication Use After Nissen Fundoplication

Table 1 summarizes short- and long-term use of antireflux medication after NF in all patients. Overall short-term use of antireflux medication decreased in children after NF. With respect to age, short-term use of antireflux medication decreased in children of all ages after NF. Overall, long-term use of antireflux medication remained decreased for all patients (233 to 197 patients). Of the 233 patients requiring antireflux medication before NF, 150 required medication after NF; 75.6% of all patients who restarted antireflux medication did so within one year after NF. An additional 47 patients with no prior requirement of antireflux medication were given medication after NF. With respect to age, long-term use of antireflux medications remained decreased in children one year of age and older.

Table 2 summarizes short- and long-term use of antireflux medication after NF in neurologically healthy children. Overall short-term use of antireflux medication decreased in neurologically healthy children after NF. With respect to age, short-term use of antireflux medication decreased in neurologically healthy children between the ages of 1 and 5 years. Long-term use remained the same in neurologically impaired children of all ages (93 to 96).

Table 3 summarizes short- and long-term use of antireflux medication after NF in neurologically impaired children. Overall short-term use of antireflux medication decreased in neurologically impaired children after NF. With respect to age, short-term use of antireflux medications decreased in neurologically healthy children one year of age and older. Overall, long-term use decreased in neurologically healthy patients (140 to 101).

Asthma Medication Use After Nissen Fundoplication

Table 4 summarizes short- and long-term use of inhaled steroids after NF in all patients. Overall short-term use of inhaled steroids remained unchanged in children after NF. With respect to age, short-term use of inhaled steroids increased in children younger than one year and remained unchanged in children older than one year after NF. Overall, long-term use of inhaled steroids increased for all patients (44 to 109). Of the 44 patients requiring inhaled steroids before NF, 31 required medication afterward; 50.5% of all patients who restarted inhaled steroids did so within one year after NF. An additional 78 patients with no prior requirement of inhaled steroids were given medication after NF. With respect to age, long-term use of inhaled steroids increased in children younger than five years and remained the same in children older than five years.

Table 5 summarizes short- and long-term use of antireflux medication after NF in neurologically impaired children. Overall short-term use of antireflux medication decreased in neurologically impaired children. With respect to age, short-term use of antireflux medication decreased in children of all ages after NF. Overall, long-term use remained decreased in neurologically healthy children (140 to 101).

Table 3. Short-term and long-term use of antireflux medication after Nissen fundoplication in neurologically impaired children

<table>
<thead>
<tr>
<th>Neurologically impaired children</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages (n = 150)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.58 (0.37–0.90)</td>
<td>0.0145</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.09 (0.71–1.68)</td>
<td>0.6961</td>
</tr>
<tr>
<td>&lt;1 year (n = 58)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.87 (0.41–1.86)</td>
<td>0.7149</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.56 (0.71–3.43)</td>
<td>0.2735</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.33 (0.17–0.73)</td>
<td>0.0061</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.62 (0.30–1.29)</td>
<td>0.2028</td>
</tr>
<tr>
<td>≥ 5 years (n = 43)</td>
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<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.52 (0.22–1.20)</td>
<td>0.1230</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.10 (0.49–2.48)</td>
<td>0.8185</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.

Table 4. Short-term and long-term use of inhaled steroids after Nissen fundoplication in children

<table>
<thead>
<tr>
<th>All children in study</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages (n = 336)</td>
<td></td>
<td></td>
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<tr>
<td>Short-term (within 1 year of NF)</td>
<td>1.31 (0.95–1.80)</td>
<td>0.1056</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>3.24 (2.34–4.49)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>&lt;1 year (n = 140)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>11.80 (4.36–31.94)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>4.96 (1.90–13.00)</td>
<td>0.0011</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 99)</td>
<td></td>
<td></td>
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<tr>
<td>Short-term (within 1 year of NF)</td>
<td>1.31 (0.80–2.13)</td>
<td>0.2842</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>3.69 (2.15–6.35)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>≥ 5 years (n = 97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.67 (0.38–1.17)</td>
<td>0.1557</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.73 (0.99–3.03)</td>
<td>0.0562</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.
long-term use of inhaled steroids after NF in neurologically healthy children. Overall short-term use of inhaled steroids remained the same in neurologically healthy children after NF. With respect to age, short-term use of inhaled steroids increased in neurologically healthy children younger than one year and remained the same in children older than one year, and long-term use increased in neurologically healthy children younger than five years and remained the same in children older than five years. Overall, long-term use of inhaled steroids increased in neurologically healthy patients (29 to 59).

Table 6 summarizes short- and long-term use of inhaled steroids after NF in neurologically impaired children. Overall, short-term use of inhaled steroids increased in neurologically impaired children after NF. With respect to age, short-term use increased in neurologically impaired children younger than five years and remained the same in children older than five years, and long-term use increased in neurologically impaired children younger than five years and remained the same in children older than five years. Overall, long-term use increased in neurologically impaired patients (15 to 50).

Table 7 summarizes short- and long-term use of inhaled β-agonists after NF in all children. Overall short-term use of inhaled β-agonists remained unchanged in children after NF. With respect to age, short-term use of β-agonists increased in children younger than one year and decreased in children older than five years after NF. Overall, long-term use of inhaled β-agonists increased for all patients (162 to 219). Of the 162 patients requiring inhaled β-agonists before NF, 131 required medication after NF; 79.0% of all

<table>
<thead>
<tr>
<th>Table 5. Short-term and long-term use of inhaled steroids after Nissen fundoplication in neurologically healthy children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurologically healthy children</td>
</tr>
<tr>
<td>All ages (n = 186)</td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>&lt;1 year (n = 82)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 50)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>≥ 5 years (n = 54)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.

<table>
<thead>
<tr>
<th>Table 6. Short-term and long-term use of inhaled steroids after Nissen fundoplication in neurologically impaired children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurologically impaired children</td>
</tr>
<tr>
<td>All ages (n = 150)</td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>&lt;1 year (n = 58)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 49)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>≥ 5 years (n = 43)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.

<table>
<thead>
<tr>
<th>Table 7. Short-term and long-term use of inhaled β-agonists after Nissen fundoplication in children</th>
</tr>
</thead>
<tbody>
<tr>
<td>All children in study</td>
</tr>
<tr>
<td>All ages (n = 336)</td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>&lt;1 year (n = 140)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 99)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
<tr>
<td>≥ 5 years (n = 97)</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.
patients who restarted β-agonists did so within one year after NF. An additional 88 patients with no prior requirement for inhaled β-agonists were given medication after NF. With respect to age, long-term use of inhaled β-agonists increased in children younger than one year and remained decreased in children older than one year.

Table 8 summarizes short- and long-term use of inhaled β-agonists after Nissen fundoplication in neurologically healthy children. Overall short-term use increased in neurologically healthy children younger than one year and decreased in children older than five years, and long-term use increased in neurologically healthy children younger than one year and remained the same in children older than one year. Overall, long-term use increased in neurologically healthy patients (6% to 11%).

Table 9 summarizes short- and long-term use of inhaled β-agonists after Nissen fundoplication in neurologically impaired children. Overall short-term use increased in neurologically impaired children younger than one year and remained the same in children older than one year, and long-term use increased in neurologically impaired children younger than one year of age and remained the same in children older than one year. Overall, long-term use increased in neurologically impaired patients (77% to 108%).

Table 10 summarizes short- and long-term use of systemic steroids after NF in all patients. Overall short-term use remained unchanged in children after NF. With respect to age, short-term use increased in children younger than one year of age and decreased in children older than one year after NF. Overall, long-term use increased for all patients (102 to 150). Of the 102 patients requiring systemic steroids before NF, 70 required medication after NF; 63.3% of all patients who restarted systemic steroids did so within one year after NF. An additional 80 patients with no prior requirement of systemic steroids were given medication after NF. With respect to age, long-term use of systemic steroids increased in children younger than one year of age and remained the same in children older than one year.

Table 11 summarizes short- and long-term use of systemic steroids after NF in neurologically healthy children. Overall short-term use remained the same in neurologically healthy children after NF. With respect to age, short-term use increased in neurologically healthy children younger than one year and decreased in children older than one year, and long-term use increased in neurologically healthy children younger than one year of age and remained the same in children older than one year. Overall, long-term use increased in neurologically healthy children younger than one year and remained the same in children older than one year.
Table 10. Short-term and long-term use of systemic steroids after Nissen fundoplication in children

<table>
<thead>
<tr>
<th>All children in study</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages (n = 336)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.90 (0.69–1.18)</td>
<td>0.4630</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.85 (1.43–2.41)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>&lt;1 year (n = 140)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>3.19 (1.99–5.12)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>6.04 (3.66–9.97)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 99)</td>
<td></td>
<td></td>
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<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.57 (0.38–0.87)</td>
<td>0.0089</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.23 (0.79–1.92)</td>
<td>0.3520</td>
</tr>
<tr>
<td>≥ 5 years (n = 97)</td>
<td></td>
<td></td>
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<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.31 (0.19–0.53)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.77 (0.50–1.19)</td>
<td>0.2377</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.

Table 11. Short-term and long-term use of systemic steroids after Nissen fundoplication in neurologically healthy children

<table>
<thead>
<tr>
<th>Neurologically healthy children</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages (n = 186)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.77 (0.54–1.11)</td>
<td>0.1567</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.46 (1.03–2.06)</td>
<td>0.0343</td>
</tr>
<tr>
<td>&lt;1 year (n = 82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>2.44 (1.34–4.43)</td>
<td>0.0034</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>3.68 (1.97–6.87)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.39 (0.21–0.71)</td>
<td>0.0023</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.92 (0.51–1.66)</td>
<td>0.7814</td>
</tr>
<tr>
<td>≥ 5 years (n = 34)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.32 (0.16–0.63)</td>
<td>0.0011</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.73 (0.40–1.34)</td>
<td>0.3152</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.

Table 12. Short-term and long-term use of systemic steroids after Nissen fundoplication in neurologically impaired children

<table>
<thead>
<tr>
<th>Neurologically impaired children</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages (n = 150)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.77 (0.54–1.11)</td>
<td>0.1567</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>1.46 (1.03–2.06)</td>
<td>0.0343</td>
</tr>
<tr>
<td>&lt;1 year (n = 58)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>2.44 (1.34–4.43)</td>
<td>0.0034</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>3.68 (1.97–6.87)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1 year ≤ age &lt; 5 years (n = 49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.39 (0.21–0.71)</td>
<td>0.0023</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.92 (0.51–1.66)</td>
<td>0.7814</td>
</tr>
<tr>
<td>≥ 5 years (n = 43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term (within 1 year of NF)</td>
<td>0.32 (0.16–0.63)</td>
<td>0.0011</td>
</tr>
<tr>
<td>Long-term (&gt;1 year after NF)</td>
<td>0.73 (0.40–1.34)</td>
<td>0.3152</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio; NF = Nissen fundoplication.

Revision Fundoplication and Mortality

Twenty-six (7.6%) patients had more than one fundoplication operation performed. Fifty-one patients (14.9%) died during the study period. The causes of death included aspiration pneumonia for one patient, other pneumonia for one patient, and respiratory distress for two patients. All other deaths did not appear to be associated with GERD-related complications.

Discussion

Antireflux surgery has been a mainstay in the treatment of GERD for many decades. However, with new and more potent antireflux medications available, the long-term outcome after antireflux procedures has recently come into question.6 Previous studies have shown that antireflux procedures are successful in relieving reflux symptoms in children.4 In a multi-institutional review of 7467 patients, good to excellent resolution of symptoms was reported in 95% of neurologically healthy children and 85% resolution in neurologically healthy patients (59 to 75).

Table 12 summarizes short- and long-term use of systemic steroids after NF in neurologically impaired children. Overall short-term use remained the same in neurologically impaired children after NF. With respect to age, short-term use increased in neurologically impaired children younger than one year of age and decreased in children older than one year, and long-term use increased in neurologically impaired children younger than one year and remained the same in children older than one year. Overall, long-term use of systemic steroids increased in neurologically impaired patients (43 to 75).
in neurologically impaired children after NF. However, these subjective outcomes were not clearly defined, and there were no objective outcomes measures in that study.

Few studies have documented objective endpoints after NF in children. Conversely, in adult patients, long-term follow-up monitoring that compared medical and surgical management of GERD showed no difference in grade of esophagitis, frequency of treatment of esophageal stricture, scores on the Medical Outcomes Study 36-Item Short-Form Health Survey, and overall satisfaction with antireflux therapy. Such endpoints after NF are difficult to reproduce in children because not all children being treated for GERD routinely undergo endoscopy to document esophagitis or stricture. Furthermore, existing quality-of-life surveys used in adults are not applicable to children.

In an attempt to provide objective follow-up after NF, we previously looked at the number of hospitalizations for GERD-related complications to determine long-term effectiveness after NF. There was no change in the frequency of hospitalizations, number of hospitalizations, or number of patients hospitalized for pulmonary symptoms and failure to thrive before and after NF. Similar results were seen in a population-based study. In another attempt to look at objective outcomes after NF, we studied the long-term use of antireflux medications after NF and showed that NF decreased use of antireflux medications by 57%. However, both of these studies were criticized because all patients were grouped together. Many suggested that GERD may affect children differently depending on age and underlying neurologic status. In addition, the goals of treatment may also be significantly different because of age and associated comorbidities. It is well known that patients with underlying neurologic disorders have a higher complication rate after NF, including a higher reoperation rate for wrap disruption and increased risk of hospitalization for GERD-related complications after NF. Thus, to address these issues, we specifically looked at short- and long-term use of antireflux medications and asthma medications on the basis of age and neurologic status.

Antireflux medication use significantly decreased in both the short term and the long term for all patients. Only neurologically healthy children older than one year had significant long-term decrease in medication use. Children with associated neurologic impairment and who were younger than one year of age demonstrated a short-term decrease in antireflux medication use, but this trend did not continue over the long term. Although these findings are significant and provide valuable information to better counsel parents regarding antireflux medication use in their children after NF, we still have not answered the question of whether the goals of the antireflux procedure, as determined by the parents or caregivers, were met. It may be that parents of children younger than one year or children with associated neurologic impairment consider NF to be successful despite the need to restart antireflux medications as long as other benefits of NF, such as improved weight gain or administration of bolus feedings, are achieved. Further study is needed to develop and validate quality-of-life indicators and surveys specifically for parents of these children.

An obvious goal for performing NF in patients with GERD and severe reactive airway disease is to eliminate or decrease the use of asthma medications. Our study showed that use of inhaled steroids increased in the long term for all patients. This increase was seen more in neurologically healthy children younger than one year of age and neurologically impaired children younger than five years of age. With respect to inhaled β-agonists, there was a decrease in use in the short term for older, neurologically healthy children. Similar findings were seen with respect to systemic steroids use. These findings indicate that it is unlikely that asthma medication use will be eliminated after NF, but there is a trend toward decreased use of rescue asthma medications (systemic steroids and inhaled β-agonists) in the short term. These findings further support the belief that outcomes after NF vary with patient age and neurologic status.

Our study had several limitations. Our data came from a discharge abstract database, and the CPT coding or coding according to the International Classification of Diseases, ninth revision (ICD-9), of each diagnosis and procedure was not independently validated. Thus, we were not able to determine the exact indications for NF. Some patients with underlying neurologic or cardiac anomalies underwent NF because of their perceived risk of developing GERD. Also, technical details of the procedure were not available, such as length of wrap, crural approximation, or open versus laparoscopic. Another limitation of this study was that indications for administration of antireflux and asthma medications were not reviewed and are not known.
Previous studies have shown that antireflux medications may be over-prescribed in children,\textsuperscript{12,13} they have been prescribed without adequate workup and without documented GERD. Although not previously studied, this may also be the case with respect to asthma medications. In our study, we also did not know how compliant patients were in taking the antireflux and asthma medications. Our pharmacy database represents dispensed medications, so we cannot be sure that the patients were taking what was prescribed.

Overall, our findings demonstrated a slight decrease in antireflux medication use after NF. In children with neurologic impairment, there was no decrease in antireflux medication use after NF. Thus, NF should not be performed with the expectation that patients will no longer need antireflux medications. Furthermore, with respect to asthma medications, it appears that only older, neurologically healthy children may potentially benefit from NF. These findings suggest that GERD and GERD-related complications may be significantly different depending on age and associated neurologic status. Finally, endpoints indicating successful NF may also be different depending on age and neurologic status. ○

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

Acknowledgment
Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References

All States of Life
The first fit of the asthma has been experienced at all times, from the earliest infancy to extreme old age, and in every intermediate stage of life.

— Commentaries on the History and Cure of Diseases, William Heberden, 1710-1801, English physician
The Falling Rate of Positive Penicillin Skin Tests from 1995 to 2007

Eric Macy, MD
Michael Schatz, MD, MS
CK Lin, PhD
Kwun-Yee Poon, MS

Abstract

Background: Data on the rate of positive penicillin skin test (PenST) results over time in large populations are rare. The factors that influence positive PenST results are incompletely understood.

Objectives: We sought to correlate demographic variables to the rate of positive PenST results over time in a large group of patients with a history of penicillin allergy.

Methods: Results from the first test for all patients tested for penicillin allergy in the Kaiser Permanente Health Care Program in San Diego County, CA, between 1995 and 2007 are reported. All patients were tested with penicillin, penicilloyl-poly-lysine, penilloate, penicilloate, and amoxicillin.

Results: There were 255 positive PenST results in 3469 individuals. The rate of positive PenST results declined from >10% to <5% during the 13 years studied. The positive PenST result rate could be accounted for by the year of testing ($R^2 = 0.56$; $p = 0.003$) without any significant contribution from the patient’s age or the time since reaction (TSR). If the TSR was $\leq 13$ years, the relative risk of a positive PenST result was 2.1 (95% confidence interval = 1.6–2.8). If the study subject’s age was $\leq 38$ years, the relative risk of a positive PenST result was 2.1 (95% confidence interval = 1.6–2.7). Females reported higher rates of penicillin allergy history than males did (11% compared with 6.6%; $p < 0.0001$), but there were no significant sex differences in the rate of positive PenST results.

Conclusions: There has been a steady decline in the proportion of positive PenST results between 1995 and 2007, independent of study subject age and TSR. Increasing age and increasing TSR were associated with a lower rate of positive PenST results.

Introduction

Penicillin skin testing has been done in advance of need in large groups of people since penicilloyl-polylysine (PPL) became commercially available in the 1970s.$^{1,2}$ There have been higher rates for positive penicillin skin test (PenST) results reported in recent studies from Europe and the Middle East compared to most recent studies from the US.$^{3-7}$ The literature on IgE-mediated penicillin allergy has become increasingly difficult to analyze$^8$ for the following reasons: 1) reports of PenST results are marked by differences in populations studied, testing criteria, reagents, and testing methods; 2) some studies have very small sample sizes and include individuals with histories of reactions to nonpenicillin $\beta$-lactams; 3) there are significant disagreements on the concentration of native amoxicillin that should be used for testing,$^{10-12}$ and 4) there is no international consensus on what constitutes an appropriate panel of PenST reagents.

Another factor contributing to this confusing state is that there may be population variation in the rate of positive PenST results over time. The positive PenST result rate in children in the US has markedly declined since the early 1990s.$^7$ We present data here that was derived from a large population, including both children and adults, studied by a single group of investigators for more than 13 years using the same method of skin testing with a extensive panel of chemically well-defined PenST reagents. In addition to determining variation over time of positive PenST results, we identified clinical predictors of positive results in this population.

Methods

This study was reviewed and approved by the Kaiser Permanente (KP) Southern California institutional review board. All PenSTs were performed by registered
nurses from the KP San Diego Allergy Department. Patients were tested either in the outpatient setting or in the hospital. The KP Health Care Program maintains a single comprehensive medical record for each member. The medical records since 2007 are completely electronic. This report complies with the position paper of the European Academy of Allergology and Clinical Immunology on nomenclature for allergy.13

Penicillin Skin Test Reagents
All patients were tested with penicillin (0.01 molar), penicilloyl-poly-lysine (PPL) in the form of Pre-Pen or self-produced PPL (6 × 10^{-5} molar), penilloate (0.01 molar), penilloate (0.01 molar), and amoxicillin (0.01 molar).12 Commercially produced PPL (Pre-Pen) became unavailable in the US after September 2004. Penicillin skin testing was done between October 2004 and October 2006 using outdated Pre-Pen, as previously reported.14 Almost all patients with a negative result after July 16, 2006, were given an oral amoxicillin (250 mg) or penicillin (500 mg) challenge and observed for one hour.

Penicillin Skin Test Method
A buffered saline negative control and a histamine (1 mg/mL for prick tests and 0.1 mg/mL for intradermal tests (ID)) positive control were placed at the start of each round of tests. Drops of each reagent were placed on the outer surface of the upper arm and pricked using a different Duotip-Test device (Lincoln Diagnostics, Inc, Decatur, IL, USA) for each drop. After a 15-minute waiting period, skin prick reactions were read and recorded. The mean diameter of the wheal over the mean diameter of the flare or surrounding erythema was measured in millimeters. Positive responses consisted of a wheal of ≥5 mm in diameter with surrounding erythema greater than the wheal, a negative response to the control solution, and a positive response to histamine. If all test responses were negative by skin prick, then ID testing was performed using the outer surface of the other upper arm. Using the same reagents, we administered 0.02 mL of each reagent intradermally through individual 27-gauge tuberculin syringes. ID test results were also read and recorded after 15 minutes. Positive responses consisted of a wheal of ≥5 mm in diameter with surrounding erythema greater than the wheal, a negative response to the control solution, and a positive response to histamine. If any puncture test result was positive, no ID tests were done with any of the remaining negative reagents.

Oral Challenges
An oral amoxicillin challenge was given to 215 individuals tested between November 16, 1994, and May 28, 1996, who had negative results on PenSTs, as previously reported.12,15 Almost all patients with a negative result after July 16, 2006, were given an oral amoxicillin (250 mg) or penicillin (500 mg) challenge and observed for one hour.

Inclusion and Exclusion Criteria
Patients were offered a PenST if they had a history of a penicillin-associated adverse drug reaction and if it was thought that knowing whether they had positive or negative test results on PenSTs would help in their future clinical treatment. Most patients were tested in advance of acute need for a penicillin-class antibiotic. Patients were not offered a PenST if they had any of the following exclusion criteria: Stevens-Johnson syndrome, toxic epidermal necrolysis, hemolytic anemia, nephritis, hepatitis, or oral and/or skin blisters associated with or attributed to previous penicillin-class antibiotic use. Patients who had a history of anaphylaxis, respiratory problems, hives, local swelling at the site of injection, other rashes, gastrointestinal symptoms, unknown index symptoms, and other mild symptoms not specifically excluded by already-mentioned criteria were tested. Medical history data were obtained from each study subject at the time of the PenST by the nurse performing the test or the physician treating the patient. Study subjects were asked the following questions, and their medical records were reviewed to confirm or add additional information that the patient could not provide:

1. How long has it been since your last adverse reaction to a penicillin-class antibiotic? The result was recorded as the time since reaction (TSR) in years.
2. How long after the first dose of penicillin associated with the last adverse reaction did it take for the first adverse reaction symptom(s) to be noticed? The five choices given were as follows: less than 1 hour, 1 to 24 hours, 25 to 72 hours, 73 or more hours, unknown.
3. What type of adverse reaction occurred? Because this was an open-ended question, the answers were sorted into the following eight categories:
   a. Anaphylaxis— if the word anaphylaxis was offered, if shock occurred, or if more than two organ systems were involved
   b. Hives— if a pruritic rash occurred, where individual lesions making up the rash lasted <24 hours; angioedema could also occur with the hives

Medical history data were obtained from each study subject at the time of the PenST by the nurse performing the test or the physician treating the patient. Study subjects were asked the following questions, and their medical records were reviewed to confirm or add additional information that the patient could not provide:

1. How long has it been since your last adverse reaction to a penicillin-class antibiotic? The result was recorded as the time since reaction (TSR) in years.
2. How long after the first dose of penicillin associated with the last adverse reaction did it take for the first adverse reaction symptom(s) to be noticed? The five choices given were as follows: less than 1 hour, 1 to 24 hours, 25 to 72 hours, 73 or more hours, unknown.
3. What type of adverse reaction occurred? Because this was an open-ended question, the answers were sorted into the following eight categories:
   a. Anaphylaxis— if the word anaphylaxis was offered, if shock occurred, or if more than two organ systems were involved
   b. Hives— if a pruritic rash occurred, where individual lesions making up the rash lasted <24 hours; angioedema could also occur with the hives
c. Local swelling—if only an area around an injection swelled
d. Other rashes—if some other nonhive rash occurred
e. Gastrointestinal—if only abdominal pain, nausea, vomiting, and/or diarrhea occurred
f. Pulmonary—if shortness of breath occurred in isolation
g. Other—if any other mild symptoms occurred that were not in categories a through f or in the exclusion criteria noted above
h. Unknown—if the patient did not know what happened and if the reaction type could not be determined by medical-record review.

We also attempted to collect data on patients’ recollections of the index reaction-associated infection, the specific type of penicillin-class antibiotic used, and the route of penicillin administration. Health Plan demographics were obtained for 2007. Data from all Health Plan patients who had at least one outpatient visit in 2007 were reviewed. Patient-reported drug allergy and intolerance was tabulated.

Statistical Analysis
Hypothesis testing for continuous variables was by means of Student’s t-test (two groups) and analysis of variance (ANOVA) more than two groups) and for categoric variables by $\chi^2$. Relationships between year of study and rate of positive results on skin tests, and between year of study and mean patient age were determined by simple linear regression. Results were expressed as the average change per year on the basis of the regression coefficient, with the adjusted R$^2$, ANOVA, F, and p value of the models also presented. Independent predictors of positive findings for skin test reactivity were determined by means of stepwise multiple linear regression. In this model, the dependent variable was the percentage of positive penicillin skin test results, and the independent variables were mean age of skin-tested patients, mean TSR, and year tested. Because of potential colinearity, a forward stepwise algorithm was used. Nominal statistical significance was set at $p = 0.05$. All statistical analyses were performed using SAS version 9.1 statistical software (SAS Institute, Inc, Cary, NC, USA).

Results
Penicillin skin testing was performed on 3469 unique individuals between November 16, 1994, and January 21, 2008, including 3158 previously reported on.12,14–19 Study cohort demographics are reported in Table 1. Of 3469 study subjects tested, 255 had positive results on PenSTs. Of 411,543 Health Plan patients seen during 2007, 37,059 (9.0%) reported a history of penicillin allergy. More females, 11.0%, than males, 6.6%, reported a history of penicillin allergy ($p < 0.0001$). Males accounted for 33.2% of the Health Plan patients with a history of penicillin allergy in 2007 and 30.8% of the patients undergoing PenST over the course of the study (Table 1). The proportion of positive PenSTs, including the subgroup with positive results on penicillin puncture, was not significantly different between females and males (Table 1). TSR data was not available for 355 (10.2%) study subjects.

There were 36 adverse reactions, both subjective and objective, during testing, 13 (5.1%) in the group with positive PenST results and 23 (0.72%) in the group with negative PenST results ($p < 0.0001$). In the former group, there were 21 (8.2%) who had positive results on penicillin puncture. There were 4 (19.0%) adverse reactions in the PenST group with positive findings on.

<table>
<thead>
<tr>
<th>Table 1. Study subject demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
</tr>
<tr>
<td>Study subjects tested</td>
</tr>
<tr>
<td>Age (mean years ± SD)</td>
</tr>
<tr>
<td>Time since reaction (mean years ± SD)</td>
</tr>
<tr>
<td>Positive findings on penicillin skin test</td>
</tr>
<tr>
<td>Positive findings on penicillin puncture test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Penicillin skin test results by year of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time period</td>
</tr>
<tr>
<td>1994</td>
</tr>
<tr>
<td>1995</td>
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<tr>
<td>1996</td>
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<td>2004</td>
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<tr>
<td>2005</td>
</tr>
<tr>
<td>2006</td>
</tr>
<tr>
<td>2007</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>
puncture and 9 (3.9%) in the PenST ID group with positive findings (p = 0.0024). None of the testing-associated reactions were severe. Fewer than half received any treatment. Seven were treated with epinephrine and antihistamines, five were treated with antihistamines only, two received ammonia inhalant, and the rest received no treatment.

The percentage of positive findings on PenSTs by year of test, along with mean age of tested study subject, TSR, and mean age of Health Plan patients, are shown in Table 2. There was a significant decrease in the rate of positive findings on PenSTs with time (R^2 = 0.501; F = 14.069; p = 0.0032). Study subjects were progressively older at an average rate of 1.18 years per year over the 13 years studied (R^2 = 0.556; F = 13.783; p = 0.0034). The average age of Health Plan patients increased by only 0.22 years per year. After 2001, a greater emphasis was placed on testing hospitalized individuals who were older than average Health Plan patients (data not shown).

The prevalence of positive findings on PenSTs was highest in younger patients and decreased significantly (p < 0.0001 \chi^2 for trend) with advancing age, as displayed in Table 3A. Nearly 70% of patients with positive findings on PenSTs were ≤50 years old. Half of the study subjects with positive findings on PenSTs were ≤38 years old. If a patient reported an age of <38 years (median), the relative risk of a positive finding on a PenST was 2.1 (95% confidence interval [CI] = 1.6–2.7).

The relationship between the TSR and the prevalence of positive findings on PenSTs is displayed in Table 3B. Patients with positive findings on PenSTs had shorter TSRs (13.3 ± 15.4 years) than patients with negative PenSTs (21.7 ± 18.7 years; p = 0.0001). Half of the study subjects with positive findings on PenSTs had a TSR ≤6 years. One quarter of the study subjects with positive findings on PenSTs had a TSR ≤3 months. Ten percent of the study subjects with positive findings on PenSTs had a TSR ≥38.2 years. If a patient reported a TSR ≤13 years (mean) the relative risk of a positive finding on a PenST was 2.1 (95% CI = 1.6–2.8).

Given that both study subject age and TSR correlated to PenST results and the overall population studied was older as the study progressed, a stepwise linear regression was performed to see if the year of testing had an independent effect on the proportion of patients with a positive finding on a PenST in a given year. The rate of positive findings could be accounted for by the year of testing (R^2 = 0.56; p = 0.003) without any significant contribution from the patient’s age or the TSR.

The relationships among the type of index reaction to proportion of positive findings on PenSTs, patient age, and TSR are displayed in Table 4. Time to onset of the index adverse reaction to penicillin was not significantly associated with PenST outcome (n = 2279; \chi^2 = 4.05; p = 0.26). The index reaction type was related to a positive result for a PenST (Table 3; n =

### Table 3A. Relationship of subject age (by quartile) to the prevalence of positive findings on penicillin skin tests

<table>
<thead>
<tr>
<th>Study subject age quartile (years)</th>
<th>No. of study subjects tested</th>
<th>Percentage of study subjects in that quartile who had positive findings on penicillin skin test</th>
<th>Percentage of study subjects who had positive findings on penicillin skin test who are in that quartile</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30</td>
<td>866</td>
<td>11.3</td>
<td>38.4</td>
</tr>
<tr>
<td>30–50</td>
<td>884</td>
<td>9.1</td>
<td>31.4</td>
</tr>
<tr>
<td>51–65</td>
<td>844</td>
<td>5.2</td>
<td>11.5</td>
</tr>
<tr>
<td>&gt;65</td>
<td>875</td>
<td>3.8</td>
<td>12.9</td>
</tr>
</tbody>
</table>

\(p < 0.0001 \chi^2 \) for trend.

### Table 3B. Relationship of time since reaction to the prevalence of positive findings on penicillin skin tests

<table>
<thead>
<tr>
<th>Time since reaction category (years)</th>
<th>No. of study subjects tested</th>
<th>Percentage of study subjects in that category who have positive findings on penicillin skin test</th>
<th>Percentage of study subjects who have positive findings on penicillin skin tests who are in that category</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>944</td>
<td>10.4</td>
<td>38.9</td>
</tr>
<tr>
<td>1–10</td>
<td>609</td>
<td>9.5</td>
<td>33.0</td>
</tr>
<tr>
<td>11–20</td>
<td>366</td>
<td>7.9</td>
<td>11.5</td>
</tr>
<tr>
<td>&gt;21</td>
<td>1455</td>
<td>4.6</td>
<td>26.6</td>
</tr>
</tbody>
</table>

\(p < 0.0001 \chi^2 \) for trend.
There was a significant relationship between age and the index reaction type (ANOVA; F = 40.85; p < 0.0001). The most pronounced difference was noted between individuals reporting hives (mean age, 40.7 years) compared with those reporting local swelling (mean age, 60.4 years). There was also a significant relationship noted between the TSR and the index reaction type (ANOVA; F = 35.72; p < 0.0001). Again, the most pronounced differences were seen between study subjects reporting hives (mean TSR, 15.5 years) and those reporting local swelling (mean TSR, 30.7 years). Subjects reporting anaphylaxis were intermediate (mean TSR, 21.6 years).

Patient recollection of the infection associated with the index reaction and the specific penicillin-class antibiotic used were too poor to produce a meaningful analysis.

Oral challenges with amoxicillin or penicillin were given to 311 individuals with negative results on PenSTs after July 16, 2006. Data on study subjects given oral challenges before July 16, 2006, have been previously reported.12,15 There were six (1.9%) acute subjective reactions reported; five patients noted itching, but no visible rash was present; and one patient reported chest tightness but had completely normal spirometry results while symptomatic. There were also 5 (1.6%) delayed-onset reactions reported, all rashes starting from 5 to 30 hours after the oral challenge. Several were treated with oral antihistamines, and there were no severe reactions.

**Discussion**

We find in a large, well-characterized group of individuals with a history of penicillin allergy that the rate of positive results on PenSTs has decreased since 1995. The rate of positive findings on PenSTs was lower in older patients and in those with longer TSRs, but the decreasing rate of positive findings on PenSTs was independent of these variables. A partial explanation for these observations may lie in the changes over time in the route and frequency of outpatient antibiotic use. Parenteral antibiotic use has become rare in the outpatient setting, where most antibiotic use occurs. Consistent with this, patients with histories of local reactions to penicillin injections were the oldest group of patients studied. Overall outpatient oral antibiotic use has also decreased significantly in our Health Plan (data not shown). Reduced use of antibiotics over time, especially by the parenteral route, could help explain the overall decrease in positive results on PenSTs over time as well as the relationship between positive results on PenSTs and both older age and longer TSRs.

Even though the rate of positive findings on PenSTs is decreasing and is lowest in older patients, positive test results still occur. Thus, the PenST is a very useful clinical tool in older individuals who are more likely to be hospitalized and, when in the hospital, much more likely to require antibiotics.18

We did not see higher rates of positive findings on PenSTs in women, as reported recently by Park et al.6 We did see overall similar low rates of positive findings on PenSTs in adults. For patients undergoing penicillin skin testing between June 2, 2002, and June 30, 2004, Park et al reported 64 (3.7%) positives from 1722 valid test results. When they reanalyzed their data using 5 mm as the threshold for a positive finding on a PenST as we did in this study, they did not see a significant difference between males, 8/724 (1.1%) and females 19/988 (1.9%) (Miguel Park, MD personal communication, September 2008).a

Penicillin skin testing as we describe is safe.20 However, a few individuals with positive results on PenSTs, 7% to 10%, also have positive results on PenST puncture tests and are thus extremely allergic. These individuals

| Table 4. Relationship between the type of index reaction to the proportion of positive findings on penicillin skin tests, study subject age, and time since reaction |
|-----------------------------|-----------------------------|-----------------------------|
| **Type of index reaction** | **No. of subjects (%)** | **No. of positive findings on penicillin skin tests (%)** |
| Pulmonary | 59 (1.7) | 8 (13.6) |
| Anaphylaxis | 148 (4.3) | 20 (13.5) |
| Hives | 1539 (44.4) | 143 (9.3) |
| Local swelling | 242 (7.0) | 15 (6.2) |
| Gastrointestinal | 91 (2.6) | 5 (5.5) |
| Other rashes | 782 (22.5) | 36 (4.6) |
| Other | 168 (4.8) | 4 (2.4) |
| Unknown | 440 (12.7) | 24 (5.5) |
| **Total** | 3469 (100) | 255 (100) |
| **Study subject age (mean years ± SD years)** | **Time since reaction (mean years ± SD years)** |
| Pulmonary | 54.0 ± 19.3 | 20.7 ± 19.5 |
| Anaphylaxis | 51.2 ± 17.4 | 21.6 ± 18.0 |
| Hives | 40.7 ± 23.9 | 15.5 ± 16.9 |
| Local swelling | 60.4 ± 18.4 | 30.7 ± 17.8 |
| Gastrointestinal | 50.2 ± 21.9 | 19.5 ± 17.8 |
| Other rashes | 49.3 ± 23.9 | 22.9 ± 18.7 |
| Other | 55.7 ± 17.0 | 25.9 ± 18.4 |
| Unknown | 50.4 ± 20.2 | 36.6 ± 14.3 |
| **Total** | 46.9 ± 23.3 | 21.1 ± 18.6 |
The Production of Penicilloyl-poly-lysine

Penicilloyl-poly-lysine (PPL) was produced as follows: All chemicals were obtained from Sigma Chemicals (St Louis, MO; www.sigmaaldrich.com). A solution of 2 mmol of lysine (0.25 g) in the form of poly-L-lysine hydrobromide (Sigma Chemicals P0879; molecular weight, 1–5 kDa) in 50 mL of sterile deionized water was made by stirring until everything was completely dissolved in the water. An equal molar amount of potassium penicillin G (Sigma Chemicals P8721), 2 mmol (0.0746 g), was slowly added into the solution during continuous stirring. The pH was adjusted to 11.5 with 5N NaOH. The mixture was continuously stirred at room temperature for 90 minutes. A three-times molar excess of succinic anhydride (Sigma Chemicals 28-5500), 6 mmol (0.06 g), was slowly added to the solution with continued stirring. The pH was maintained at 11.0 for 1 hour while stirring continued. Another 0.6 g of succinic anhydride was added into the solution. Stirring continued as pH was maintained at 9.5 for 1 hour. The last 0.6 g of succinic anhydride was added into the solution. Stirring continued as pH was maintained at 9.5 for a final hour. The mixture was transferred into a Spectrum/Por #6 MW cutoff 1K dialysis tubing (Spectrum Laboratories, Inc; Rancho Dominguez, CA; www.spectrapor.com). The PPL was dialyzed against 4-L PBS baths at 4°C, with daily buffer changes, for 7 days. On days 1 and 2, 0.002 M Tris, at a pH of 8.5, with 5 g of BioRad 50W-X2 resin was used. On days 3 to 7, 0.15N NaCl with no resin was used. The dialyzed solution was filtered through a 0.22-µm Millipore (Billericia, MA, USA) filter. The PPL solution was placed into sterile tubes and lyophilized to obtain PPL powder. The PPL was assayed using the penamaldate (HgCl$_2$) titration method to determine the moles of penicillin bound. The molar concentration was calculated using an extinction coefficient of 22.325 for the penicilloyl moiety at 282 nm, pH 7.6. The penicilloyl-bound concentration (M) = 500/(A$^{\text{max}}$(3 + 0.02N)/3 – A$^{\text{ini}}$)/22.325 b, where A$^{\text{max}}$ is the maximum absorbance observed at 282 nm, A$^{\text{ini}}$ is the initial absorbance at 282 nm, N is the number of 20-µL portions of 0.007% HgCl$_2$ solution (3.5 mg of HgCl$_2$ in 50 mL water) added, and b = the width of the cuvette. A dilution factor of 500 was chosen on the basis of the transfer of 10 µL of the PPL test solution into 5 mL of phosphate-buffered saline (PBS) at a pH of 7.6. The assay was performed using 3 mL of the penamaldate-PPL-PBS mixture in a standard 3-mL quartz cuvette, b = 1 cm. Samples were then tested for endotoxin. Sterility was verified using blood agar plates and a BBL-enriched thioglycolate anaerobic broth (Becton, Dickinson and Company, Franklin Lakes, NJ, USA). The PPL was then diluted with sterile PBS to the desired concentration of 6 × 10$^{-4}$ molar. The PPL was stored at 4°C until ready for skin testing. The PPL solution has been found to be stable for >2 years at 4°C.

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The Falling Rate of Positive Penicillin Skin Tests from 1995 to 2007

Penicillin skin testing as we describe with oral challenge is an effective way to allow the majority of individuals with a history of penicillin allergy to are likely to have a testing-associated reaction and may benefit from an oral antihistamine given as soon as the positive puncture finding is apparent. This is also the reason we do not perform any ID tests on an individual with any positive puncture results. Our use of amoxicillin at about 2 mg/mL or 0.01 molar, compared with the 20 to 25 mg/mL used by some other investigators, helps explain two findings. First, it may explain the very high rates of false positive results on PenSTs recently noted by Goldberg and Confino-Cohen, where only 6.6% of individuals with positive results on PenSTs responded to an oral challenge, only mild rashes were seen, and no severe reactions to the oral challenges occurred. Second, it might explain the relatively high rates of systemic testing reactions reported by some European investigators. If 0.02 mL of a 25-mg/mL solution of amoxicillin is used for ID testing, it results in 0.5 mg of systemic antibiotic exposure, which may be enough to cause a reaction. Additionally concentrated amoxicillin solutions have to be very basic because the solubility of amoxicillin in water at physiologic pH is only about 4.0 mg/mL, which may contribute to a nonspecific irritant effect. The use of a mean wheal diameter of 5 mm with erythema greater than wheal as the positive test result cutoff reduced the rate of false positive results on PenSTs in our study.

The use of an oral challenge after a negative skin test result is safe. Our oral challenge reaction rates after a negative PenST result are about an order of magnitude lower than recently reported by European investigators. About 3% of individuals with a history of penicillin allergy and a negative finding on a PenST will report some sort of adverse reaction, generally mild, after a therapeutic course of a penicillin-class antibiotic. Some of these delayed-onset reactions may be T-cell mediated. In our study, only rarely did an individual report a delayed-onset reaction—one to two days later—at the site of ID tests with negative findings. Our rates of delay time-type hypersensitivity reactions after PenSTs are also about an order of magnitude lower than seen by European investigators, who used much higher amoxicillin concentrations. Their rate of positive findings on PenST puncture was higher than ours, but their overall rate of positive findings on PenSTs was very similar to ours.
subsequently take penicillin-class antibiotics. The longer an allergic individual goes without exposure to an allergen, the more likely an allergy is to become clinically insignificant. This was demonstrated well with latex allergy starting in the late 1980s through the early 2000s. The inverse relationship demonstrated in our current study between TSR and the rate of positive results on PenSTs is consistent with this paradigm as well.

In summary, our data suggest that testing would be particularly helpful for older individuals, who are more likely to benefit from the use of penicillin-class antibiotics and less likely to have positive results on a PenST.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

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References

Penicillin skin testing as we describe with oral challenge is an effective way to allow the majority of individuals with a history of penicillin allergy to subsequently take penicillin-class antibiotics.
“Thriving at 20 till 7”

photograph

By John Davenport, MD

John Davenport, MD, is a Family Medicine Physician at the Lakeview Medical Center in Anaheim, CA.
Developing Minimally Invasive Surgery Centers Within Kaiser Permanente: The Integrated Multidisciplinary Experience of Los Angeles

Gary W Chien, MD
Maher A Abbas, MD, FACS, FASCRS

Abstract
Minimally invasive surgical therapies are growing in type and volume of interventions. As one of the largest health delivery organizations in the US, Kaiser Permanente staff must be aware that the proliferation of these technologies has occurred in parallel within many surgical specialties, with a large variation in level of implementation between different regions and even within regions. In Los Angeles, we have developed the Minimally Invasive Surgery Center, encompassing a multidisciplinary, integrated approach. It unites the effort and expertise of many outstanding practitioners within the organization and consolidates the achievements of many surgical specialties. It also brings together the elements needed to provide the highest level of care to our patients in a safe, efficient, cost-effective environment, with minimal morbidity and best long-term outcome.

Introduction
Surgical procedures and interventions remain an important cornerstone of modern health care and contribute to the care of millions of individuals in the US every year. Surgery is invasive and often requires large soft-tissue incisions to gain access to diseased organs and compartments of the human body. Although the morbidity of a procedure is determined by its nature and that of its target organ (eg, bone, brain, bowel, urologic tract, gynecologic organs), the invasiveness and magnitude of the soft-tissue incision is one of the determinants of postoperative recovery, complications, length of hospital stay, pain, and eventual resumption of normal daily activities.

Since the 1980s, the surgical fields have been in a revolutionary phase with the development and implementation of new technologies and procedures that have provided surgeons across many specialties with an armamentarium of less-invasive therapies. Many conditions traditionally approached with open surgery are now treated by alternative means. Minimally invasive surgery (MIS) can address many disease processes by allowing the surgeon access to the area of interest through smaller incisions that are at lower risk of morbidity. The advantages and benefits associated with MIS have translated into fewer complications and less morbidity for the patient without compromising the principal goal of surgical therapies, which is the eradication or control of disease (eg, removal of an inflamed gallbladder, ablation of endometriosis, excision of colon cancer, repair of an aortic aneurysm, evacuation of a herniated vertebral disc, elimination of gastroesophageal acid reflux). As experience with MIS has evolved—and is still evolving—there has been rapid growth in both the types and volume of such surgeries performed, with a shift from simple procedures such as hernia repair to more complex and advanced procedures such as gastric bypass and radical prostatectomy, partial nephrectomy, and cystectomy.

Many MIS techniques have now become the standard of care (eg, cholecystectomy for cholecystitis, splenectomy for hematologic disease, adrenalectomy for adrenal tumors, transsphenoidal resection for pituitary tumors, arthroscopic shoulder surgery for rotator cuff injuries, endovascular therapy for aortic disease), but other procedures increasingly compete with open surgery for percentage volume of cases and a growing number of indications...
(eg, colectomy for diverticulitis or colon cancer, hysterectomy for fibroids or malignancy).1,3,14

Several new, advanced MIS techniques are being implemented, are under development, or are being investigated for technical feasibility and results.15–25 Research is currently underway to evaluate the results of MIS for oncologic disorders such as rectal cancer.15,16 Robotic surgery is gaining momentum in the US and other countries as more data are collected on short- and long-term outcome and its potential role in and impact on pelvic surgery for urologic, gynecologic, and colorectal conditions as well as foregut and thoracic surgery.6,18–22 Kaiser Permanente (KP) recently introduced robotic surgery in its Southern and Northern California Regions and is closely monitoring the effects of this evolving technology. Finally, active investigation is underway to assess the technical feasibility, safety, and outcome of single-port surgery (accessing the abdominal cavity and performing abdominal surgery assisted by a device through a single 2-cm umbilical incision) and of natural orifice transluminal endoscopic surgery (NOTES) accessing the abdominal cavity through a puncture in the stomach, rectum, or vagina and performing abdominal surgery through a flexible endoscopic device).17,23,24 Research in these emerging areas will yield innovations, new technologic advances, and new tools.

**Rapid Growth in Volume of Advanced Minimally Invasive Procedures**

KP embraced the MIS revolution from the beginning. Some KP hospitals got involved with the introduction and implementation of these new procedures early in their development. For example, the San Diego facility in Southern California pioneered some of the MIS procedures to advance the care of patients with intestinal and abdominal conditions.27 Since the early 1990s, surgeons at the KP San Diego Medical Center have performed numerous laparoscopic colonic resections. Their surgical skills have benefited not only KP San Diego patients but also patients across the US through their contributions as surgery educators at many symposia and conferences. More recently, the West Los Angeles Medical Center in Southern California implemented robotic surgery for radical prostatectomy. Within a short time, our group of urologists has performed one of the largest series of patients at both the national and international levels. Our collaboration has yielded comprehensive short-term outcomes and a model of efficiency for future expansion of robotic surgery within KP. Although noting all MIS advancements at a regional or national level is beyond the scope of this article, we note that KP physicians both inside and outside the Southern California region are responsible for many MIS achievements.

Across KP nationally, the growth of advanced MIS procedures was gradual in the 1990s, but there has been a rapid surge in volume in the first decade of the 21st century. This phenomenon stems from several factors: influx of a large number of fellowship-trained surgeons with advanced MIS skills, the increasing availability of surgical tools and technology to perform such operations, proliferation of outcomes data demonstrating the benefits of MIS, patients’ demands, and an institutional commitment to provide state-of-the-art care to patients.

Our own experience at the Los Angeles Medical Center (LAMC) illustrates the growth in MIS practices within KP. Our institution serves as the regional tertiary center for all hospitals within Southern California and occasionally provides extraregional care to patients from the Hawaii and Northwest regions. Since 2003, we have witnessed a swift growth in the number of MIS procedures across many specialties at LAMC: for instance, the volume of advanced laparoscopic urologic procedures has increased more than tenfold, and the percentage of colorectal excisions performed with laparoscopic or endoscopic techniques has increased from <5% in 2003 to >60% in 2008. Currently, pediatric surgeons perform 40% of their procedures in children using MIS techniques; a few years ago, none of them used MIS. Orthopedic MIS procedures for upper-extremity conditions such as rotator cuff injury, unstable joints, and contractures represent >60% of the total volume of cases. Within the field of neurologic and spine surgery, approximately 100 MIS procedures are performed at LAMC every year. Finally, there has been a major shift in the MIS training and expertise of the staff in the various surgical subspecialties at our medical center. Within the Department of Surgery (general surgery and its subspecialties), for example, the percentage of surgeons offering advanced MIS procedures (laparoscopic, endovascular, endoscopic) grew from 18% (2 of 11 surgeons) in 2003 to 71% (12 of 17 surgeons) in 2008.

**The Need for Multidisciplinary Minimally Invasive Surgery Centers**

The implementation of new technology and growth in MIS procedure volume has benefited both patients and the health care system but has also presented many chal-
... we have reached a point in the history of surgery where an infrastructure is needed that can both support existing practices and accommodate the proliferation of future technology. We must evolve from a surgeon-driven process to a team- and system-based process. Challenges. Different procedures have been established at different times and have been implemented at different rates within KP because of the gradual evolution of the technology. Furthermore, the introduction and promotion of MIS procedures within KP has been driven by individual surgeons in various specialties according to their interest level, training, and expertise. In most instances, the implementation of these new procedures has been fragmented, with large variation in practice patterns among surgeons in the different regions and even within the same region or medical center. Despite leadership support and commitment to MIS, there has not been a systemic approach to MISS implementation at a local, regional, or national level. Medical centers have not optimized the introduction of these new procedures. Furthermore, each subspecialty has its own learning curve. Often, the different surgical subspecialties do not share resources, consolidate accumulated experiences, or exchange information on best practices to make the learning curve less steep and resolve the challenges of developing and implementing new technology. Although there are unique issues for each specialty, many common issues, such as anesthetic considerations, organizing operating room teams for MIS, standardization of disposable products and electrosurgical units, testing and implementation of new equipment, postoperative care, education, simulation, training, and research, could be effectively and efficiently addressed through a multidisciplinary approach.

There are numerous unresolved issues, at KP and elsewhere, surrounding the care of patients treated with MIS procedures: There is an ongoing debate of how to best train residents, fellows, and practicing surgeons not proficient in advanced MIS techniques. Additionally, there is no consensus as to how to best proctor or credential physicians requesting privileges for MIS procedures.28–30

Also, changes in the operating room environment are particularly stressful for surgeons and supporting nursing staff. The majority of practicing scrub and circulating nurses are skilled at assisting in open procedures. For more than 100 years, surgical nurses and technicians have received extensive training on how to best assist surgeons to perform traditional procedures. The nursing surgical heritage and knowledge of instrumentation and equipment have been transmitted from one generation to the next in nursing and technical schools and perfected in operating rooms everywhere. Therefore, many support personnel lack the skills set necessary to effectively assist surgeons with MIS techniques. Our experience has been that most operating room nurses and technicians have been acquiring the necessary experience on the job, a process that is often stressful and frustrating to the surgeon and costly to patients and institutions because of decreased efficiency, increased duration of surgery, and thus increased fees. Furthermore, labor regulations and considerations affect staffing and logistical issues. Finally, a shortage of nurses in the US has affected the operating room at several levels. However, unlike surgeons, who have increasingly taken up subspecialties, with focused expertise in, for example, shoulder, spine, or sinus surgery, the majority of nurses are expected to assist with all subspecialties of surgery. The discrepancy in level of expertise between the surgeon performing an advanced MIS procedure and supporting personnel can often affect both patient well-being and the efficiency of the operating room.

In addition to these human factors, the physical environment in which we practice can also contribute to some of the daily difficulties encountered. Our group practices in high-quality, well-equipped hospitals, but many of our facilities were designed and built before the MIS revolution. Existing operating rooms have plenty of space to allow for the conduct of traditional open procedures but not for MIS procedures, which require additional equipment (eg, monitors, electrosurgical units, fluoroscopic machines, robotic equipment) that in turn requires additional time for setup, retrieval, and troubleshooting. Clearly a system-based approach is needed to maximize the efficient and safe integration of advanced MIS technology within health care systems such as KP. Although individual surgeons can make significant contributions to the process of establishing MIS programs, we have reached a point in the history of surgery where an infrastructure is needed that can both support existing practices and accommodate the proliferation of future technology. Collaboration is needed at all levels: surgeons, anesthesiologists, nurses, technicians, administrators, and educators. A new platform needs to lay the foundation for addressing the continuing and emerging needs of MIS. We must evolve from a surgeon-driven process to a team- and system-based process. The value of an operating
room team approach has been well established and validated in several studies, but it is important to keep in mind that operating room teams are only one of the critical elements necessary to successfully support MIS practices. MIS Centers are required to serve as umbrella structures to address the needs of MIS at several levels.

**Organizing Minimally Invasive Surgery Centers Within Kaiser Permanente: The Los Angeles Experience**

The changing nature of surgical practices at our tertiary referral center at LAMC and the increasing number of practitioners offering advanced MIS procedures have led us toward a multidisciplinary approach to address challenges. To fulfill the needs of surgeons providing MIS and patients seeking it, LAMC launched an MIS Center. Originally we set up an MIS committee to address the implementation of new technology at our facility. Recognizing that this endeavor addressed only one aspect of MIS, we expanded the focus to a multidisciplinary MIS Center that would tackle all facets of MIS care at our institution and might also serve as a regional and national integrated model of MIS within KP. The mission of our Center of excellence is to support the clinical practices of MIS surgeons, to offer state-of-the-art care for our patients, to provide education opportunities through residency and fellowship training programs, and to advance the science of MIS through research and innovation. To fulfill this mission, we have assembled a team of experienced surgeons and nurses to guide the development, growth, and direction of the Center.

It is important to point out that there has been a rapid proliferation of MIS Centers of excellence within the US since the mid-1990s. Unfortunately, many of these centers are driven by marketing and financial considerations and rarely represent collaborative efforts to address the needs of MIS. Although some of these centers have clinical value, most are promoted by an individual practitioner or a small group of same-specialty surgeons as a vehicle to increase practice revenues. Whether for gastric bypass for obesity, spine surgery for disc disease, or radical prostatectomy for cancer, advertisements for such centers are ubiquitous on the Internet, on television, in newspapers and magazines, and on radio. In reality, there are few comprehensive multidisciplinary MIS Centers nationally or internationally.

KP’s “secret” for success is its complete integration. Using this platform, LAMC has developed and integrated a multidisciplinary approach to MIS. Our multispecialty group practice, collaborative nature, institutional resources, large patient population, and commitment to provide the best possible care without any financial incentive provide us with all the elements necessary to pursue this endeavor. In Los Angeles, we invested in these unique features of KP to successfully launch and grow our MIS Center at a local, regional, and national level (Figure 1).

**Clinical Practice Initiatives**

A significant contributor to the volume and quality of advanced MIS procedures is the expertise and skills of surgeons. At LAMC, the chiefs of surgery and other surgical subspecialties have actively recruited new fellowship-trained surgeons proficient in the delivery of the latest technology. As mentioned earlier, the percentage of MIS-trained surgeons has grown rapidly, paralleled by an increasing amount of collaboration and exchange between the different subspecialties to tackle issues universal to all surgical specialties. The MIS Center at LAMC has served as a forum for exchange of information on best practices and of technical skills. Interpersonal relationships among MIS surgeons have enhanced patient

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**Figure 1. Schematic diagram showing the multidisciplinary integration model of an Minimally Invasive Surgery center.**
care, especially when combined specialty procedures are necessary. Furthermore, the lack of financial incentive within our organization has fostered a collegial collaborative atmosphere.

The MIS Center has actively engaged the Anesthesiology Department to encourage an open dialogue to improve the delivery of MIS care within the institution. For instance, an anesthesia colleague serves on our general committee to represent that aspect of MIS care. Several cardiopulmonary and physiologic considerations come into play with MIS techniques such as laparoscopy. Preoperative factors such as baseline comorbidities and body habitus can have a direct impact on intraoperative events (eg, carbon dioxide metabolism, difficulty with ventilation in extreme positions such as severe Trendelenburg for low pelvic surgery). Guidelines for selective preoperative cardiopulmonary testing and evaluation are now being delineated. Surgeons often select a patient for an MIS procedure on the basis of technical feasibility and outcome, which in turn depend on surgical history (eg, presence of scars or adhesions) and disease process (ie, benign, inflammatory, or malignant). Input from anesthesia colleagues as to the fitness of a patient to withstand a prolonged MIS procedure is critical. Many of these procedures require additional considerations such as more time in the operating room, extreme positioning, and physiologic changes. We have solicited their direct feedback through personal interactions, group discussion, and educational activities such as grand rounds on MIS topics led by LAMC surgeons.

As mentioned earlier the increased volume of MIS procedures has affected support personnel as much as it has affected surgeons. With that in mind, we have approached nursing staff at several levels, from nursing administrators to frontline nurses, to raise awareness about the changing nature of our practices and to solicit their thoughts about ways to enhance operating room efficiency. Several of our MIS surgeons have conducted educational activities for our nurses. In-service training sessions have been conducted regularly with refreshers by surgeons, nurse educators, and industry representatives to review instrumentations and equipment. We have welcomed several nurses as members of our MIS Center and have encouraged their participation in all of our meetings to guide policy. This overture has been much appreciated, and the presence of nurses as partners in the process of advancing MIS at LAMC has been critical. These efforts have culminated in the realization of the importance of the team approach to MIS. Jointly we have created specialty lead positions that oversee the Center’s day-to-day clinical activities. The nursing leads are seasoned nurses who provide support to our nursing staff by guiding the setup of cases and being available during procedures should a scrub nurse or circulator need additional help. This has improved operating room efficiency and increased nursing expertise and familiarity with MIS procedures.

**Hospital and Equipment**

As already discussed, most KP facilities were designed or built before the era of MIS. The equipment needed for the conduct of most advanced procedures has outgrown the physical space needed. In the spring of 2009, LAMC was scheduled to inaugurate its new state-of-the-art tertiary hospital. The new facility was designed to accommodate current and emerging technologies. All rooms are spacious and fully equipped to support the delivery of advanced MIS. Many of the issues faced in the older generation of operating rooms, such as space constraints, the requirement of extra time to wheel in and retrieve equipment, and maximization of working space, have been addressed. The move into the new hospital will constitute a major milestone in the continuous evolution of the Center.

The delivery of MIS care has been driven by the introduction of new tools and devices that have enabled surgeons to refine and advance their techniques. There has been a steady stream of new technology, most of which has clinical merit. However, the explosion in number of products available on the market has posed many problems: escalating cost, variable efficacy and quality, the added burden of maintaining a larger inventory of products on the shelf, compliance issues with national contracts, and training issues and familiarity of supporting staff with a wide spectrum of disposable instruments. The Center’s policy is to support the needs of each individual surgeon within the framework of the organization. Members of the MIS Center are actively involved with the operating room committee and the regional and national product council. Although we encourage being at the forefront of surgical care delivery, we critically evaluate requests for new products and take into consideration available scientific data, cost, volume of use, niche specialty need, and existing approved products. All products are approached from a multidisciplinary angle. When conducting trials with
a new product, surgeons from various specialties are invited to participate and to provide feedback.

**Residency and Fellowship Training Programs**

Members of the MIS Center are active faculty at several postgraduate training programs at LAMC. MIS has played an increasing role in the education of future surgeons, urologists, and gynecologists. In addition to these three residency programs, LAMC offers an endourology fellowship and is awaiting regulatory approval for a fellowship from KP and the University of California, Los Angeles (UCLA) in pelvic floor and female genitourinary tract reconstruction. Both of these fellowship programs entail MIS training. Residents and fellows are eager to acquire MIS skills. Accreditation and licensing organizations, such as the American Council on Graduate Medical Education and American Board of Surgery, have established graduating requirements that include a minimum number of MIS cases. In 2008, the American Board of Surgery established an additional requirement for all graduating surgeons seeking board certification: certification in fundamentals of laparoscopic surgery (FLS). FLS is a training program jointly developed by the Society of American Gastrointestinal and Endoscopic Surgeons and the American College of Surgeons. FLS entails acquiring the basic knowledge and skills required to safely and effectively provide MIS care. FLS education is provided through a Web-based training program and skill practice on training boxes. Certification is obtained by passing a written examination and taking a technical skills test. The purpose of FLS certification is standardization of MIS care within the US and ensuring that surgeons offering MIS care are qualified to do so. The FLS program has been validated through numerous studies.35–42 There is ongoing discussion within several national organizations to make FLS certification a hospital credentialing requirement for surgeons seeking privileges for MIS procedures. Eight members of our LAMC MIS Center have already obtained the certification or are seeking it to provide the training needed to our residents and fellows.

**Simulation Center**

There is increasing evidence of the importance of simulation in training physicians to acquire new skills.43–47 Simulation can provide many of the necessary skills in a stress-free environment at a comfortable pace and without jeopardizing the safety of a patient. Accordingly, we have designed and developed an MIS Simulation Center at LAMC that is equipped with seven training stations, including a state-of-the-art virtual simulator that provides trainees with various tasks appropriate to their level of training and expertise. Several surgeons have set up a multidisciplinary curriculum that is task oriented (eg, suturing, dissecting, manual dexterity, visualization, trocar placement) rather than procedure oriented (eg, how to perform a hysterectomy). In addition to providing skill acquisition and refinement, the program offers a series of didactic lectures at regular intervals. Finally, performance data and testing are provided as feedback to trainees.

**Local, Regional, and National Educational Endeavors**

To foster exchange of ideas, knowledge, and expertise of MIS, the Center has launched several educational endeavors. A multidisciplinary lecture series has featured KP surgeons from throughout the Southern California region as well as academic surgeons from institutions such as the Mayo Clinic and UCLA. Diverse topics have been discussed, including instrumentation in spine surgery, operating in a liquid environment such as the knee, endovascular therapies, evolution of robotic surgery, and laparoscopic pelvic surgery. We have invited several visiting professors from prestigious academic institutions to join us for a two-day visit to share with them our work and to benefit from their expertise in MIS.

In 2009, the Center, in conjunction with surgical colleagues from other regions, held the first annual KP National Multidisciplinary Minimally Invasive Surgery Symposium. It addressed the current and future developments within the field of MIS, including those in the arenas of surgical education, simulation, natural orifice surgery, single-port surgery, and robotics. Leaders in academic surgery joined us from such institutions as the Mayo Clinic, the Cleveland Clinic, and the Lahey Clinic.

In addition, the Center is launching MIS Web-based education in 2009. The Web site will feature the range of services offered by expert surgeons, patient-education information on pre- and postoperative care, MIS publications by members of the LAMC MIS Center, active research, and a video library of MIS procedures performed by KP surgeons. The Web site will be a venue for all KP surgeons at LAMC, in Southern California, and in other regions to share their expertise. All KP physicians, regardless of geographic location, are encouraged to submit videos and write-ups of their work to the Web site. The contact person is the
Conclusion

As KP is one of the leaders in health care delivery, it strives to provide state-of-the-art care to its patients in several geographic areas of the US. Surgical interventions represent a significant portion of rendered care and contribute to the well-being of thousands of patients within the different regions every year. Within KP, MIS therapies are growing in type and volume of interventions. The proliferation of these technologies has occurred in parallel within many surgical specialties, with a large variation in level of implementation between different regions and even within regions. A multidisciplinary approach to MIS unites the efforts and expertise of many outstanding practitioners within the organization and consolidates the achievements of many surgical specialties. Organizing centers for MIS within KP will bring together the elements needed to provide the highest level of care to our patients in a safe, efficient, cost-effective environment, with minimal morbidity and best long-term outcomes. We hope that the integrated multidisciplinary model implemented in Los Angeles will guide the future development of MIS Centers within KP at the national level.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Katharine O'Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References


Developing Minimally Invasive Surgery Centers Within Kaiser Permanente: The Integrated Multidisciplinary Experience of Los Angeles


The Greater Satisfaction

As I sat by the side of this great surgeon [Lawson Tait], a question suggested itself … Which would give the most satisfaction to a thoroughly humane and unselfish being, of cultivated intelligence and lively sensibilities: to have written all the plays Shakespeare has left as an inheritance for mankind, or to have snatched from the jaws of death more than a hundred fellow-creatures … and restored them to sound and comfortable existence?

— Our Hundred Days in Europe, Oliver Wendell Holmes, Sr, 1809 – 1894, poet, physician, and essayist
Patrick Ting, MD, is a General Surgeon at the Rock Creek Medical Center in Lafayette, CO.

Here, we see four photos of two complete tea sets. In “Spherical Tea Set,” the top photograph demonstrates the tea set in exhibition mode with the teacups and the teapot forming a spherical sculpture. In service mode (bottom photograph), the teapot and cups are completely functional and the lid of the sphere forms the lid of the teapot. In “Spiral Tea Set,” the top photograph demonstrates the tea set in exhibition mode with the teacups and the teapot forming a cylindrical sculpture. In service mode (bottom photograph), the teapot and cups are completely functional. The tea sets are made of earthenware clay, initially formed through a slipcasting technique, then hand glazed.

More of Dr Ting’s work may be seen at his Web site: www.tingteas.com.
An Exploratory Case Study: Effects of a Physician Organizational Socialization (Enculturation) Program

Richard Pitts, DO, DABEM, DABPM

Abstract
This article presents compelling data supporting a comprehensive enculturation program for physicians entering a medical group practice and fills a void in the literature about improving the process whereby physicians can more effectively enter a medical group. As far back as 1999, a study noted that physicians joining the Mayo Clinic physician group took five years to be fully integrated into the medical group. Further research was called for, yet no studies on enculturation of physicians into a medical group have been reported. Unlike medical science, in which double-blind studies are the gold standard for proving a hypothesis of care, double-blind studies are essentially impossible to conduct in the social sciences. However, what can sometimes be identified are patterns of behavior that although they fail the test of a double-blind study can be helpful in decision making when it comes to individual and group behavior. It is in that spirit that I conducted a social science exploratory case study. In the midst of a challenging year of conversion to an electronic medical record, the survey had a 40% response rate with compelling comments on the effects of the program. The study suggests that the enculturation program provided those queried a clearer understanding of the complexities of a large integrated medical group, with much earlier integration into a large medical group in contradistinction to the Mayo Clinic study. This study is important because of the lack of research in the area of enculturation of physicians into large medical groups.

Introduction
Why should an organization care about what happens when a newcomer joins the organization? It seems obvious that companies invest time, energy, and money in recruiting and trying to retain workers that a company values. However, do organizations try to discern the newcomer’s perspective on what happens when a newcomer joins a company? Some newcomers set personal work goals, and these frequently are centered around job satisfaction. Yet what if these goals are not achieved or are deemed unachievable by the newcomer? The newcomer’s commitment to the organization may either falter or simply not develop at all.

Schein shook up the management world with his thoughtful article on what happens when someone joins an organization. For better or worse, a newcomer receives an informal or a formal introduction to the organization in which the newcomer learns what it means to belong to the organization. Schein coined the term organizational socialization to describe the process whereby newcomers learn how to get things done in an organization in an acceptable manner while remaining welcome there. It seems that achieving mutual expectations is what organizational socialization is all about. Yet organizational socialization that is too formal risks making the newcomer a conformist to such an extent that creativity and fresh ideas are smothered. Conversely, too little of a socialization process in an organization may result in the newcomer being disruptive. Perhaps even worse, if no formal organizational socialization occurs, informal socialization may occur, resulting in a default culture. Companies may be reluctant to invest time and money in an organization socialization program. Yet can the dollar value of a loyal and committed organization member be calculated?

“In effect, we must teach our students to become change-agents, whatever their disciplinary specialty turns out to be. We must teach them how to influence their organizations from low positions of power without sacrificing their professional values in the process. We must teach them how to remain creative individuals in the face of strong organizational pressures.”

Of all professions, medical groups may have the most difficult time socializing newcomers. After US medical students complete college, they must complete an additional 7 to 11 years of technical education (specialty dependent) to become licensed and achieve board certification. Al-
An Exploratory Case Study: Effects of a Physician Organizational Socialization (Enculturation) Program

though the technical training is intense and comprehensive, physicians in general do not receive training in group dynamics or learn how to become an effective member of a medical group. In this study, I investigated the effects of formal organizational socialization on a six-year cohort of new physicians entering a medical group.

Bender et al. found that it could take up to five years for a physician to reach the highest level of group function at the Mayo Clinic. They posited that it is common sense that whatever must be done to integrate new physicians as quickly as possible into a healthcare organization should be done. As a result of their findings, Bender and et al called for research in the area of physician socialization into health care organizations.5

Besides trying to make medical groups function more effectively, what about reducing physician attrition from medical groups? Cooper-Thomas and Anderson established that newcomer acquisition of information improves job satisfaction and commitment to the organization and decreases intention to leave an organization. Also, patient satisfaction relates directly to physician satisfaction, which in turn relates to being tightly bonded to the medical group. Hence, satisfaction for all three—medical group, physician, and patient—is highly interdependent.6,7

Purpose
This study was conducted as a preliminary attempt to understand the effects of a formal organizational socialization program for physicians who enter a large medical group practice.

Significance
Effective organizational socialization assists with at least three facets of an organization member’s life: improved job satisfaction, improved commitment to the organization, and decreased likelihood of leaving the organization.8 At the time that I conducted my study, the most recent data on health care costs in the US were from 2004. According to the Centers for Medicare and Medicaid Services, 2004 US health care costs approached $1.9 trillion. Estimates were that these costs would rise an average of 7.2% per year, resulting in an estimated cost for health care of $4.0 trillion by 2015.9 In an attempt to decrease overhead costs, physicians tend to practice in groups instead of alone.10 Yet little has been written about how to integrate physicians into a group environment. The knowledge generated by this research may have wide applicability to the medical profession as it transitions to more of a group-practice environment from solo entrepreneurial practices. Also, those medical groups that continue to add new physicians may also benefit from understanding the importance of rapid organizational socialization of newcomers. This research may help to establish recognition that rapid organizational socialization may help stem the loss of physicians from a medical group as well as help physicians reach their full potential within the group earlier than the five years suggested in the study by Bender et al.5

Background
I conducted my study at Kaiser Permanente (KP) Orange County, which had approximately 40,000 patient members at the time. The county is a mixed urban and suburban community. KP is a partnership between two entities, an insurance plan—the Kaiser Foundation Health Plan—and the Permanente Medical Groups. The KP program provides comprehensive care to almost nine million individuals and has an annual budget of more than $25 billion. One of KP’s core values is to spend as much of the premium dollar on health care as possible and as little as possible on non-direct patient care.11 (Kenneth Bell, MD, personal communication, December 2003).4

The Colorado Permanente Medical Group (CPMG) determined that the loss of a single physician from [the] CPMG resulted in approximately $300,000 in expenses not related to direct health care as well as unnecessary utilization of medical resources (Kenneth Bell, MD, personal communication, December 2003).4

Corroborating the CPMG study, Buchbinder et al.12 reported similar results. Included in the costs were the expense of recruiting a new physician to replace the one who left, training costs of integrating the new physician into the culture of the organization, increased Emergency Department visits because of lack of familiarity by the patient with substitute physicians, and an increase in the use of laboratory and radiology studies.

Literature Review
What are the dimensions of organizational socialization? In a seminal article, Chao et al.13 identified a lack of precision in terms of the dimensions of organizational socialization. In 1994, literature on the topic was focused on either the process of socialization or its content. However, Chao et al. noted that there was little if any actual research to verify the content of organizational socialization. They designed and completed a five-year longitudinal study that set out to confirm six content dimensions of organizational socialization through the use of a self-reporting questionnaire that used a Likert scale for reporting. Their research supports the idea that organizational socialization is a dynamic state depending on...
what is going on in an individual's life at the time a survey is completed. The results of their study support the idea that job performance, proficiency, company politics, language unique to the organization, organization goals and values, and organization history are six conceptual dimensions of organizational socialization.

The beginnings of organizational socialization as a science can be traced to the mid-1900s. At that time, anthropologists started to explore the commonalities found in groups of people and, more specifically, how these groups of people or collectives behaved. What evidence is there of the significance of the first year in a new organization? Chatman15 found that the socialization process of new members of an accounting firm was especially active during the first year of employment.

What about rapidity of organizational socialization? Cooper-Thomas and Anderson1 identified a gap in the literature with respect to how quickly organizational socialization takes place. They constructed a longitudinal study over eight weeks in a group of British army recruits. Although this study was admittedly in a very intense military environment, significant adjustment was found in the newcomers at the end of two months of training.

How is the idea of success measured in organizational socialization programs? Typically, researchers have adopted three items to measure that correlate with success: job satisfaction, organizational commitment, and intention to quit.16

**Research Design Methodology**

Unlike medical science, for which double-blind studies are the gold standard for proving a hypothesis of care, double-blind studies are essentially impossible to conduct in the social sciences. However, what can sometimes be identified are patterns of behavior that despite failing the test of a double-blind study can be helpful in decision making when it comes to individuals' and groups' behavior.

Currently KP offers a health care program in eight regions: Mid-Atlantic (Washington DC, Virginia, and Maryland), Ohio, Georgia, Colorado, Southern California, Northern California, Northwest (Oregon and Southwest Washington), and Hawaii. At the time that I carried out my research, these eight regions combined served approximately nine million members. In each region, a regional Permanente Medical Group (PMG) is partnered with the Health Plan to provide integrated health care. The PMGs are discrete corporations with physician shareholders. In Southern California, the PMG is organized as a partnership of approximately 4500 physicians called the Southern California Permanente Medical Group (SCPMG). There are many subdivisions of the Southern California Region of KP, one of which is KP Orange County, CA. KP Orange County has approximately 400 physician partners serving approximately 340,000 Health Plan members and is one of the fastest-growing medical service areas in the KP program.11

The population for this study was physicians new to SCPMG Orange County. These new physicians completed a formal nine-month organizational socialization program. The program was designed in accordance with the work of Chao et al.13 The program met approximately every two weeks for nine months. Each meeting was approximately 90 minutes long. Teaching methods stressed small-group interactions followed by reports to the larger groups from the small groups.

**Study Subject Selection**

Permission was sought and granted by the Walden University institutional review board and by the medical director of the KP Orange County Medical Service Area to conduct the proposed case study research. Great care was taken to avoid selection bias of study subjects. Six years of physician-participant archival logs were used to determine data for physician participants, including what year each one participated in the program. A random-number generator was used in the selection of names to take part in the study. Three candidate participants were randomly identified from each of the six-year cohorts of participants, yielding a total of 18 possible participants.

A letter of invitation approved by the institutional review board, was e-mailed to the 18 potential participants, along with the initial study questions. Seven of the 18 invitees were willing to participate in the study, and 11 formally declined, citing current intense work conditions because of the implementation of an electronic health record. Originally, the study was envisioned as using face-to-face interviews. However, with workplace conditions changing because of the implementation of an electronic health record, virtually all of the candidates preferred to answer the questions in writing at their convenience.

**Data Collection**

Participants were asked to fax the completed questionnaire to a secure fax. On arrival, the faxes were photocopied and separated into two batches, which were securely stored at two separate physical locations. As each fax arrived, the participant list was updated to reflect completion of the questionnaire.
Data Analysis
The purpose of this exploratory case study was to gain an initial understanding to serve as a platform for a more comprehensive case study of the effects on participants of a formal organizational socialization program. The initial analysis of the data began with data loaded into an Excel (Microsoft, Redmond, WA, USA) spreadsheet. Color-coded data cells were used to identify patterns of responses. Usefulness of the questions was also evaluated.

Limitations
The purpose of an exploratory study before a more in-depth study is in essence to see whether the researcher is on the right track in planning a more detailed study. Hence, inherent in an exploratory study is incompleteness. However, important information may still be obtained, as is presented here. An additional limitation is that because data collection was done through self-reporting, the data have the potential for reporting bias and/or recall bias.

Results
Of the 14 questions in this exploratory study, six questions were simply gathered data. Eight of the questions were substantive and generated a total of 84 potential response cells on the data spreadsheet. Seventy of the 84 cells could be populated with data, yielding an 83% cell-completion rate.

Color-coding of the 70 data cells suggested four major areas of confluence or themes with respect to answers. Sample responses in support of these themes are:
1. Developed a strong sense of belonging: “Having the history/philosophy of KP gave me a sense of belonging and understanding. I feel like I belong rather than just [show] up for a job.”
2. Gained improved communication skills: “It was a great venue [in which] to meet my fellow colleagues, and my interaction with them was enhanced by the program. We now usually page each other first for advice because we have such a great relationship.”
3. Gained multiple resources for success at home as well as at work: “I am more patient with others. I also see that my husband is more patient with me, and we try to understand each other’s point of view on a personal and a professional level.”
4. Gained information in the program that will produce better function within the organization: “I feel that doing the enculturation program allows me to appreciate how complex yet organized our system is and how I can work best within this system and what is expected of me.”

Questions and Sample Responses
The following key questions were used in the survey; I have included some of the compelling

<table>
<thead>
<tr>
<th>Themes</th>
<th>Benefit to organization</th>
<th>Benefit to physician</th>
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<tr>
<td>Developed a strong sense of belonging</td>
<td>Physicians’ confidence in organization improved</td>
<td>Physicians have a sense of belonging—of being part of a community</td>
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<td>Physicians have a sense of a support system</td>
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<td>Physicians are more open-minded</td>
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<td>Physicians developed cross-specialty friendships</td>
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<td>Gained improved communication skills</td>
<td>Physicians able to advocate on behalf of organization</td>
<td>Physicians developed a sense of ownership of problems</td>
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<td>Physician-to-physician communication for consults improved via direct informal personal communication channels established at program meetings</td>
<td>Less use of formal on-call schedule for advice in managing patient specialty care</td>
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<td>Gained multiple resources for success at home as well as at work</td>
<td>Physicians can function more effectively because they understand organization’s culture</td>
<td>Physicians understand organization’s culture</td>
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<td></td>
<td>Improved function inside the organization</td>
<td>Less frustration</td>
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<td></td>
<td>Physicians understand change parameters</td>
<td>Physicians understand change parameters</td>
</tr>
<tr>
<td></td>
<td>Physicians have an understanding of just how complex the organization is</td>
<td>Physicians understand that change is possible</td>
</tr>
<tr>
<td>Gained information in the program that will produce better function within the organization</td>
<td>Physicians less disruptive when frustrated with change issues</td>
<td>Physicians have a more realistic understanding of the complexities of the organization</td>
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<td></td>
<td>Physicians clearly know what is expected of them</td>
<td>Physicians confident that change can be enacted within certain parameters</td>
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An Exploratory Case Study: Effects of a Physician Organizational Socialization (Enculturation) Program

responses from the cohorts sampled:
• Engaged in workplace? (All responded yes.)
• Can you cite examples in your work at KP where you used principles that you learned in the enculturation program to help you solve your problems?
  - “Daily dealings with patients, staff, colleagues.”
  - “Learning about the process of change in a large organization. We have successfully acquired more psychiatric space at Euclid after reviewing the data, working collaboratively and problem-solving instead of making hasty decisions.”
  - “Be ‘proactive; not reactive.’ With angry patients, I try to hear what they are saying and listen to them, and they are very appreciative.”
  - “Doing group and team activities in the enculturation program has assisted me tremendously in [understanding] how our other specialties operate, and to develop friendships.”
  - “There was a situation in which a patient was belligerent to the staff and support staff. Instead of directly confronting the patient, I recruited the ombudsman (KP ombudsman presented during the enculturation program) to serve as a liaison, and everyone was happy.”
  - “With the enculturation program, I have become more open-minded, appreciative, creative, patient, efficient, and knowledgeable about our organization—which has resulted in better patient care.”
  - “The four (clinical) habits program showed me how to better interact and respond to my patients. It has definitely helped me in situations when I had to deliver bad news to my patients, [such as] a diagnosis of colon cancer.”
• Have you seen behavior in either yourself or others as a result of the enculturation program? If yes, what behavior?
  - “Being leaders/role models in the workplace.”
  - “From the way my colleagues operate, it appears that they have also completed the enculturation program, so I have not noticed that they don't demonstrate these principles.”
• Are you happy with your position at KP Orange County? (All responded yes.)
  - “I feel much satisfaction in my work.”
  - “I feel like I belong and can do what is best for my patients without worrying about the cost. Generally, there are very few egos to deal with.”
  - “I like helping my patients. I enjoy being with my coworkers … I don't enjoy the stress of too much indirect work.”
  - “Wonderful partnered and associate physicians willing to work together for the needs of our members. Good working relationships with ancillary staff.”
• What aspects of the enculturation program contributed to either your job satisfaction or dissatisfaction?
  - “Indirect work difficult at times.”
  - “I have been very satisfied and happy with my position [here]. I enjoy my job, my peers, my work environment, and the way patients are receiving good quality care.”
  - “I enjoy working with my patient population. It is gratifying. I also enjoy working with my colleagues.”
  - “Happy, strong group of colleagues.”
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  - “Happy, strong group of colleagues.”

Discussion
This preliminary study prepares for a more comprehensive study, as is often the case in both the medical sciences and social sciences. It can save valuable time and resources later by fleshing out unforeseen issues in designing a comprehensive study or by confirming preliminary assumptions regarding the more comprehensive planned study. On occasion, an exploratory case study may uncover compelling information of interest to the larger community, as in this study.

Overwhelmingly, the respondents agreed that the enculturation program provided them with valuable information and tools to better do their jobs at KP and to a certain extent in their private lives as well. Their clearer understanding of the complexities of the organization resulted in earlier integration into a large medical group, in contradistinction to the Mayo Clinic study. Substantial effort was undertaken to avoid selection bias, which suggests that the broader group may provide similar results.

As already mentioned, the four major areas of confluence or themes from physicians’ responses were as follows: 1) developed a strong sense of belonging; 2) gained improved communication skills; 3) gained multiple resources for success at home as well as at work; 4) gained information about the program that will
produce better function within the organization.

An unsolicited comment from John Davenport, MD, JD, Chief of Family Medicine for KP Orange County, supports the positive effects of the enculturation program as reported here. Dr. Davenport noted that when asking for physician volunteers for projects or committees, he received a higher percentage of positive responses to his call for help from the physicians who had completed the enculturation program than from those who had not. This observation is consistent with information on citizenship, ownership, and partnership responsibilities presented during the new-physician enculturation program.

One final observation with respect to the enculturation program at KP Orange County: The physicians who complete the program are frequently heard to say that they have formed lifelong friendships that cross geographic and specialty boundaries. Many physicians comment that when they need advice on how to manage a case, instead of using a call list to get help, they will simply call one of their friends in that particular specialty—a friend made during their participation in the enculturation program. Does this confirm the idea that first comes a relationship, then comes ease of communication? What value can be placed on ease of communication when asking for help in a large organization?

Improved understanding of the complexities of the KP organization, along with improved understanding of expectations in the areas of citizenship, ownership, and partnership, plus earlier engagement in the group role as physicians in a multidisciplinary medical group, are compelling reasons for a robust and competently administered enculturation program early in a physician’s entry in to a medical group.

* Former Medical Director, Kaiser Permanente Orange County.

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References
Abstract
Many authorities have suggested that some variant of team training is likely to reduce human error in operating rooms, Emergency Departments, resuscitation teams and other settings within health care—where human interaction is common, and where breakdowns in communication and teamwork can have critical consequences. The Kaiser Sunnyside Medical Center Regional Simulation Center achieves this end. In particular, simulation prepares people for error-prone, high-risk, or unusual situations. Here, we will cite several scenarios and two actual protocols; five principles for managing critical events; results (2006 People Pulse favorability, 2007-2008 postsimulation survey favorability); Kaiser Permanente Northwest departments trained; strategic initiatives supported including service internalization; collaboration with local and regional community programs; and process transferability.

Introduction
Many authorities have suggested that some variant of team training is likely to reduce human error in operating rooms, Emergency Departments (ED), resuscitation teams and other settings within health care—where human interaction is common, and where breakdowns in communication and teamwork can have critical consequences. These authorities cite the work done in aviation’s crew-resource management; recommendations made by the Institute of Medicine’s landmark report, To Err is Human: Building a Safer Healthcare System, released in 2000; and the Joint Commission’s comprehensive Patient Safety Plan. Because of the success of the Kaiser Permanente Northwest (KPNW) Region’s Perinatal Patient Safety Project in training teams in standard communication—how to respond in critical patient events—and the need to practice these situations in a controlled environment, Kaiser Sunnyside Medical Center (KSMC) leadership approved and created a Regional Simulation Center (RSC). Here multidisciplinary teams sharpen their clinical and communication skills and practice managing escalating scenarios such as mock codes, infant resuscitations, and malignant hyperthermia. Team communication skills are reinforced by using human factors tools such as Situation Background Assessment and Recommendation (SBAR) and Assertion and Situational Awareness. Simulation addresses individual technical performance and important elements of teamwork—listening, leadership, communication, respect, role clarity, and Crew Resource Management (CRM). In particular, simulation prepares people for error-prone, high-risk, or unusual situations.

Objectives
Preventive measures to increase patient safety are grounded in scientific literature on team training, CRM, and critical thinking. Because KPNW has specifically trained individuals and teams in Human Factors communication, reliable design, and managing escalating patient events, they reduced birth-related, potentially compensable events, claims, and lawsuits between 2002–2007. KPNW meets the key objectives of simulation training—reduce medical errors and improve patient safety—by using the RSC and by adding simulation mannequins as training tools (Table 1).
Methodology

The RSC, constructed in fall 2006 by adjoining two small conference rooms into the Sim-Lab, is coordinated by one full-time Registered Nurse (RN), (trained in simulation), one part-time RN simulation nurse educator, and one full-time trained simulation operations specialist. The RSC team work with department staff, managers, clinical experts, and educators to construct simulation scenarios relevant to individual teams. The RSC team use a four-tiered approach in reaching their objectives with staff (Figure 1).

1. Simulation Mannequins and Clinical Scenarios:
   Simulations occur on one of four simulation mannequins—SimMan, SimBaby, (Laerdal Medical, Wappinger Falls, NY; www.Laerdal.com); Birthing Mother Noelle (and fetus), wireless Newborn HAL, and wireless Adult HAL (Gaumard Scientific, Miami FL; www.gaumard.com). The simulation nurse manages the scenario from a control booth, adjusting the mannequin’s change in condition dictated by the scenario and the participant’s interventions. Sim Man can mimic most any condition; his heart can emit 2500 different sounds, he has bowel sounds, pulses, temperature, blood pressure and he can speak through a wireless microphone system. The other mannequins have similar functions. RSC also has an inventory of low-fidelity mannequins for task training listed on their Web site (http://internal.or.kp.org/simlab; password protected) including:
   * Airway management, Neonatal Resuscitation Program recertification, and ED technician training.
   * Simulation Scenarios in 2007 are listed in Table 2, and two actual simulation protocols are detailed in the Sample Simulation Scenario Sidebars: Malignant Hyperthermia (MH) in the Post-Anesthesia Care Unit (PACU) and Precipitous Delivery in the ED and the Neonatal Resuscitation Program.

<table>
<thead>
<tr>
<th>Table 2. RSC simulation scenarios in 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACLS and BLS Codes</td>
</tr>
<tr>
<td>Medical-Surgical Adult Sepsis</td>
</tr>
<tr>
<td>Malignant Hyperthermia in the PACU</td>
</tr>
<tr>
<td>MD, RN, RT Neonatal Resuscitation Team Training</td>
</tr>
<tr>
<td>OB/GYN Hemorrhage and Code</td>
</tr>
<tr>
<td>Emergency Department Neonatal and ACLS Code</td>
</tr>
<tr>
<td>Emergency Department Pediatric Code</td>
</tr>
<tr>
<td>Acute Coronary Syndrome</td>
</tr>
</tbody>
</table>

   * ACLS = Advanced Cardiac Life Support; BLS= Basic Life Support; PACU = Post Anesthesia Care Unit |

<table>
<thead>
<tr>
<th>Table 3. Advantages of simulation training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation of uncommon but critical scenarios in which a rapid response is needed, and where there are few means other than simulation to conduct systematic training to manage such critical events (eg, malignant hyperthermia, which occurs in every 40,000 anesthesia cases).</td>
</tr>
<tr>
<td>Errors are allowed and reach their conclusion so participants can see the results of their decisions and actions.</td>
</tr>
<tr>
<td>With mannequin-based simulators, clinicians can use actual medical equipment, exposing limitations in the human-machine interface.</td>
</tr>
<tr>
<td>Complete interpersonal interactions with other clinical staff can be explored in training for teamwork, leadership, and communication.</td>
</tr>
</tbody>
</table>


   In a number of fields, simulation has been used in crew resource management training where the focus is on behavioral skills such as interteam communication during critical incidents.

   The RSC provides an incredible opportunity for clinicians and staff to learn by experience. Poor critical event management often results in delayed diagnosis and ineffective treatment processes, even when clinical knowledge and skills are adequate. According to the Center for Medical Simulation, 1 effectively managing a critical event

![Figure 1. Four-tiered approach.](image-url)
Table 4. Five principles for managing critical events

| Role Clarity: | An event manager delegates responsibilities to the team members while paying attention to workflow. Other team members define their role responsibilities and do not change roles without an explicit discussion with the event manager. |
| Communication: | All communication flows through the event manager who reliably repeats all information for the benefit of the entire team. All verbal communication should be closed-looped—the teller gives information to the listener who repeats what s/he heard and understood; the teller then confirms that information. All communication is directed to an individual by name. |
| Personnel Support: | The event manager is responsible for calling for help when needed. Because task loading tends to cause one to forget to call, it is important to summon help early in the event evolution. |
| Resources: | Team members must be familiar with all of the equipment and supplies necessary to manage the event. Understanding the infrastructure of the environment and institutional systems is also important. |
| Global Assessment: | Frequent verbal status reports, reviewed by the event manager, is the best mechanism for avoiding fixation, promoting clarity of a situation, and prompting new ideas. |

requires attention to five principles (Table 4) in addition to timely diagnosis and appropriate medical treatment. These principles relate to clinicians’ individual behaviors and to the group dynamics of the clinicians and their individual behaviors.

2. Equipment and Materials: The RSC is outfitted with medical equipment, which includes a code cart with defibrillator. Cabinets and the control booth were recycled from a recent remodel of the KSMC ED. The control booth allows the simulation educator to monitor and control the patient’s vital signs in line with the scenario and in response to the actions of the clinical team. S/he may advance the scenario or recover the patient on the basis of team responses. Supporting equipment includes: a video camera, computers to preprogram and run the scenarios, and a television monitor used to immediately replay completed scenarios to the team during debriefing (Table 5).

3. Standardized Patient: The “standardized patient” is an actor who often plays a role as a family member of the patient (mannequin). The standardized patient reacts in real time to the patient’s clinical signs and to the actions of the health care team. This person will ask and answer questions, and make observations and comments to the team. There are times when the standardized patient adds tension to the simulation, increasing what could be an already stressful situation. For example, a “standardized patient” often plays the role of the distraught parent in a pediatric or newborn resuscitation simulation. The objectives of including a “parent” or “family member” is to increase awareness of family-centered care principles, to illustrate the effects of distractions on clinical care, and to use crew resource management concepts to meet the family members’ needs.

4. Debriefing: All participants of each videotaped simulation debrief directly after the simulation. Topics discussed are: communication, leadership and roles, crisis resource management, system improvements, highly reliable team characteristics, handoffs and SBAR, human factors and situational awareness, and best clinical practices and standards.

After simulation and debriefing, individuals complete an evaluation, noting its value and relevance, the value of the debriefing, and improved patient-care skills. Surveys from the first year of the RSC, were analyzed compared to baseline measurements.

Results 2006

A 2006 job satisfaction survey (People Pulse) question asked: “Do you receive the training necessary to do your current job well?” to which 71% of respondents...
responded favorably. This encouraged further development of the RSC.

2007

In November of 2006, the RSC moved into a conference room formerly used for storage and created a fully operational, high-fidelity simulation laboratory. Approximately 666 physicians, nurses, respiratory therapists (RTs), CRNAs, CNAs, students and technicians trained using simulation in 2007.

The postsimulation survey used by the RSC for the period February 2007—January 2008 evaluated four components (Table 6). Using a ranking methodology of 1-5, poor to excellent, a numerical value was substituted for analysis (poor = 1 and excellent = 5). Six hundred sixty-six participants were surveyed about the scenario in which they were involved. Overall, teams felt the most positive about the value of the debriefing session—4.6 average, in 8 of 11 scenarios (Table 7).

Many comments gathered from the KPNW RSC post-

<table>
<thead>
<tr>
<th>Table 5. Regional Simulation Center equipment list</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Human patient simulators (Mannequins—includes warranty)</strong></td>
</tr>
<tr>
<td>SimMan – 1</td>
</tr>
<tr>
<td>$42,000.00</td>
</tr>
<tr>
<td>SimBaby – 2</td>
</tr>
<tr>
<td>One in lab and one portable $46,000.00 for each</td>
</tr>
<tr>
<td>Megacode Kid Advanced</td>
</tr>
<tr>
<td>$6700.00</td>
</tr>
<tr>
<td>HAL Mobile Team Trainer</td>
</tr>
<tr>
<td>$28,000.00</td>
</tr>
<tr>
<td>Noelle</td>
</tr>
<tr>
<td>$17,000.00</td>
</tr>
<tr>
<td>Noelle S575 with newborn</td>
</tr>
<tr>
<td>$43,000.00</td>
</tr>
<tr>
<td>Baby HAL S3010</td>
</tr>
<tr>
<td>$24,000.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Task trainers</strong></th>
<th><strong>Features</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric intraosseous leg</td>
<td>Right leg of a one-year-old for intraosseous access practice. Also has a simulated femoral artery and vein in the upper thigh.</td>
</tr>
<tr>
<td>$600.00</td>
<td></td>
</tr>
<tr>
<td>Central Line Man System</td>
<td>A realistic anatomical model complete with internal landmarks, allows practice of subclavian, supraclavicular, and interjugular access techniques. The tissue responds to ultrasound imaging for needle guidance.</td>
</tr>
<tr>
<td>$4800.00</td>
<td></td>
</tr>
<tr>
<td>Trauma Man System</td>
<td>An anatomical human body form designed to practice surgical procedures including cricothyroidotomy, chest tube insertion, pericardiocentesis, diagnostic peritoneal lavage and IV cutdown.</td>
</tr>
<tr>
<td>$21,000.00</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Airway management task trainers</strong></th>
<th><strong>Features</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gaumard S312</td>
<td>One-year-old pediatric upper torso-airway trainer with anatomically accurate, intubatable airway.</td>
</tr>
<tr>
<td>$550.00</td>
<td></td>
</tr>
<tr>
<td>Gaumard S315</td>
<td>Adult upper torso-airway trainer with anatomically accurate, intubatable airway</td>
</tr>
<tr>
<td>$1600.00</td>
<td></td>
</tr>
<tr>
<td>Laerdal Deluxe Difficult Airway Trainer</td>
<td>Adult upper torso mannequin, capable of multiple difficult airway scenarios, including laryngospasm.</td>
</tr>
<tr>
<td>$2400.00</td>
<td></td>
</tr>
<tr>
<td>Laerdal Airway Management</td>
<td>Trainer mounted on a practice board, this mannequin can be used to demonstrate and practice intubations, ventilation, suction, and bronchoscopy.</td>
</tr>
<tr>
<td>$1600.00</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Other equipment</strong></th>
<th><strong>Features</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthing bed, hospital bed, infant warmer, code cart with defibrillator, wardrobes for mannequins, video cameras and television monitors, control booth.</td>
<td></td>
</tr>
</tbody>
</table>
simulation evaluation supported the personal value of simulations. Examples include: “These exercises were really helpful, I feel more comfortable handling the initial 241 scenarios,” (participant of a 241 code, which indicates a newborn in distress). Another responded, “The SimMan made things so real that I almost forgot he wasn’t a real patient.” Many others expressed more confidence in speaking up in code situations if there is unclear leadership or direction given. Participants said they valued the experience of participating in simulations, the ability to become more focused in their jobs and to relieve anxiety about certain escalating situations prior to practicing their drill. A newly graduated nurse commented, “Simulation may be the next or only time a nurse gets to practice something s/he learned in nursing school.”

2008

Approximately 864 clinicians and staff trained using simulation in 2008.

In support of the KPNW internalization efforts in Cardiovascular Services and Behavioral Health and Addiction Medicine services, teams from both disciplines used or planned to use the RSC to conduct scenario sessions to test readiness prior to “go-live” opening. Five such scenario sessions were conducted for Brookside—a free-standing residential treatment facility. These simulations included a cardiac arrest in a group therapy session, an anaphylactic reaction to a medication, a patient leaving against medical advice, admission procedures, and an escalating behavioral situation. Simulations were also conducted in the new Cardiac Catheterization Laboratory to test systems prior to opening.

Objective data was gathered during the cardiac resuscitation drill. The scenario used a patient exhibiting signs of shortness of breath and tightness of chest during a group therapy session in one of the Behavioral Health unit’s group therapy rooms. As the staff became aware of the medical emergency, and a Code 99 was announced, support staff from KSMC responded. Many opportunities for system improvements were identified during the debrief session: correcting emergency response time, staff finding their way to the emergency site, signage, locked security doors, equipment needs, and physical plant adjustments. Finding these challenges during the simulation allowed them to be addressed before the Residential Treatment Facility (RTF) opened.

In July and August 2008, KSMC completed a massive training endeavor with over 25 Mock Code 99 drills involving 100 people from the inpatient critical care units, medical-surgical units, and the entire Code 99 team. The goal was to involve as many of the staff as possible, on the various units. This endeavor facilitated the highest level of teamwork within a true Code 99 situation.

As of March 31, 2009, 403 staff have participated in simulation.

Discussion

Quality of Care and Patient Safety

An RSC serves an essential function in the creation, maintenance and improvement of quality of patient care and patient safety by providing training opportunities for staff. Comments and scores on evaluation surveys obtained during postsimulation self-assessment demonstrated that staff feel the simulation training is of definite value in improving their job performance and their confidence in performing a procedure and in providing patient care.

KSMC staff experiences confirm other reports in the scientific literature, for example in simulation-based orientation training for first-year pediatric critical-care fellows in the US, students viewed simulation training for common pediatric critical care management as effective for improving self-efficacy.

Table 7. Average survey scores

<table>
<thead>
<tr>
<th>Scenario</th>
<th>General team</th>
<th>ACLS mock code</th>
<th>Med-Surg septic mock code</th>
<th>RN, RT, MD team</th>
<th>Malignant hyperthermia</th>
<th>MD, RN, RT neonatal resuscitation</th>
<th>OB/GYN mock code</th>
<th>ED neonatal and ACLS mock code</th>
<th>ED peds code</th>
<th>Acute coronary</th>
<th>Med-Surg mock code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average of all questions in each survey</td>
<td>4.5</td>
<td>4.5</td>
<td>4.6</td>
<td>4.4</td>
<td>4.5</td>
<td>4.7</td>
<td>4.7</td>
<td>4.5</td>
<td>4.6</td>
<td>4.5</td>
<td>4.4</td>
</tr>
</tbody>
</table>

*on a scale of 1-5 (1 = poor; 5 = excellent)*

ACLS = Advanced Cardiac Life Support; ED = Emergency Department; RT = Respiratory Therapist
Regional Initiatives

The use of the RSC is connected to regional goals and supports regional and national strategic initiatives. In particular, the RSC supported the KPNW internalization efforts in Cardiovascular Services and Behavioral Health and Addiction Medicine services, and for the new RTF prior to opening. Simulations were conducted in the new Cardiac Catheterization Laboratory to test systems prior to its opening. Simulation sessions have occurred in preparation for the opening of the Cardiovascular Intensive Care Unit, planned for 2009. Finally, more simulation scenarios are being developed for use by surgical teams involved with the Highly Reliable Surgical Team project and the Reliable Emergency Departments projects.

Additional Activities

The RSC and its staff provide educational opportunities for organizations and groups throughout the greater Portland, OR and Vancouver, WA areas, such as simulation activities for local nursing programs allowing student nurses to practice what they are learning in the classroom and provide a systems approach to real-time clinical learning. KPNW also hosts a bimonthly simulation roundtable to provide opportunities for area simulation educators to network. The roundtable is supported by grants from the state of Oregon. In addition, the KSMC Coordinator for Regional Simulation Operations is a member of the governing council of the Oregon Simulation Alliance (OSA). Activities of the OSA include providing simulation training courses and apprenticeships, increasing public awareness of the value of simulation, and hosting an annual Sim Summit Conference. Participants from Oregon, Washington, and Idaho attend this conference to learn multidisciplinary approaches to simulation. Clinical teams on the KSMC campus often use the RSC as action items of Sentinel Event Root Cause Analysis work to improve team communication. Because the Sim Lab is mobile it regularly travels to KP medical and dental offices for staff emergency preparedness training. Sim Lab staff also participate in citywide disaster training, providing mannequins, and standardized patients for the drills.

Transferability

Because the RSC was built on a “shoestring” budget with the costs for furniture controlled by recycling furniture and materials from areas undergoing remodels.

Sample Simulation Scenario: Precipitous Delivery in the Emergency Department and Neonatal Resuscitation Program

Intended Audience: ED Consortium, new graduate RNs

| Brief description of scenario: G4P3, age 34 years, presents in ED in active labor, SROM clear fluid, bloody show, states strong urge to push. Spontaneous vaginal delivery occurs on ED stretcher without maternal complications. Infant requires stimulation and PPV, and recovers. |
| Scenario Objectives: Participants will demonstrate: |
| 1. Recognition of signs of impending birth |
| 2. Appropriate skill in delivering baby |
| 3. Appropriate Neonatal Resuscitation Program skills |
| 4. Appropriate care and safety for mother and baby following delivery |
| 5. Resource management, teamwork, and communication skills. |
| Description of Patient: Patient is in labor, wearing street clothes, in active labor. Patient is unaccompanied. SROM obvious, positive bloody show on towel between legs. |
| Pertinent Medical History: Normal prenatal course, no problems. Baby has been active. Labor began several hours ago, SROM within the last hour, clear fluid. UCs now every three to four minutes, getting stronger, patient has urge to push, has bloody show. |
| Progressive Outline: |
| Noelle – Initial State: Head is crowning – prior to scenario, let head deliver until “Turtle sign.” Wet towel with bloody show inside underpants. |
| Baby HAL – Initial State: Cyanotic, HR = 80, RR = 0, limp. After about 20 seconds of PPV, baby recovers: Pink, HR = 120, RR = 40, active, crying. |

ED = Emergency Department; G4P3 = Gravida 4, Para3 (gravida is number of pregnancies, para is number of live births); HR = heart rate; PPV = positive pressure ventilation; RR = respiratory rate; SROM = spontaneous rupture of membranes; UCs = uterine contractions.
Northwest Simulation Center—Sharpen's Clinical and Communication Skills for Individuals and Teams

and from the Region's surplus warehouse, it is a model for low-cost start-up. RSC also gained momentum from the Perinatal Patient Safety Reliability project and now can serve as an added demonstration of simulation value. Space, staff wages, and the mannequins are the true costs of developing such a “laboratory”; however, KP is also investing in the resource of human patient simulators. The staff of the KPNW RSC is available to consult with any KP Region or hospital looking to add their own simulation center. Their internal KP Web site is on the KP Northwest homepage: http://internal.or.kp.org/simlab (password protected).

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

References


Attend to the Details

Even a trained student should attend to every detail, if he wishes to master with assurance and speed each aspect of his profession which he has already learned by the general method.

— On the Affected Parts, Galen of Pergamum, 129-200, Roman physician and philosopher of Greek origin
Ohio Safety Action Teams

Cindy Ebner, RN, MSN, CPHRM, FASHRM

Abstract
Ambulatory care presents many challenges for implementing a risk management and patient safety program. In addressing a perceived problem about inadequate response to reports in the Kaiser Permanente Ohio Region, interdepartmental Safety Action Teams (SATs) were created and activated in 2005-6.

The Kaiser Permanente (KP) Ohio Region includes various locations widely separated through northeast Ohio. Team Lead Registered Nurses, Managers, and Directors are responsible for primary care, specialty care, and other services that are located across the Region rather than in one building. Physicians and allied health professionals practice in more than one location. Practice variations in affiliated hospitals with which the Ohio Permanente Medical Group (OPMG) contracts—only some of which have OPMG Hospitalists—add to the challenges.

To improve the process, the SATs mapped the current process and ran Plan-Do-Study-Act cycles to test the new process prior to implementation. Nineteen SATs have been implemented since inception and eleven are completed. In a post-SAT survey, participants showed they knew more about building a reliable process, their job satisfaction increased, patient safety was improved, and the gains were sustained. The plan to continue SATs is felt to have a solid future and is readily transferable to other areas and facilities.

Introduction
Ambulatory care presents many challenges for implementing a risk management and patient safety program. A random sample of employees throughout the Kaiser Permanente (KP) Ohio Region revealed that staff had become discouraged and no longer reported incidents or issues because of a perceived lack of response, either in the form of feedback or of action to address issues. In response to this and because the KP Ohio Region includes various locations widely separated throughout northeast Ohio, a Safety Action Team (SAT) program was developed. At that time, the Ohio Region did not have an active performance improvement mechanism and the Risk Management Patient Safety (RMPS) committee was composed of staff and managers without the authority to implement change. Additionally, in 2006, an annual employee satisfaction survey (People Pulse) indicated that only 71% of staff felt encouraged to speak up about errors.

Safety Action Teams: Construction and Implementation
In 2005-2006, to address these challenges, several building blocks were put into place to create the foundation for an RMPS program. The program’s goal is to do the right thing right the first time, which is consistent with the Region’s strategic plan. A strategy was created to establish a culture of safety and to build a highly reliable organization. The six most important activities were: 1) to create a just culture using David Marx’s Just Culture Model and Just Culture Algorithm in collaboration with human resources; 2) to implement an anonymous electronic incident reporting system; 3) to restructure the RMPS committee with department chiefs and managers who can review critical events and trends and drive improvement; 4) to bring safety to the forefront through education, executive walkarounds, senior leadership support, and safety fairs; 5) to implement SATs to improve systems and processes by engaging frontline staff, managers, and leadership who touch the system/process; and 6) to build relationships through fostering collaborations between departments on the SATs, Quality Resource Management Committees and RMPS committee.

Glossary of Abbreviations
SAT – Safety Action Team
RMPS – Risk Management Patient Safety
PIPS – Performance Improvement and Patient Safety
QRPS – Quality and Risk and Patient Safety
PIPPRO – Performance Improvement and Provider and Practitioner Review and Oversight
PDSA – Plan-Do-Act-Study cycle
ASC – Ambulatory Surgery Center
PAR – Preadmission Requisition

Cindy Ebner, RN, MSN, CPHRM, FASHRM, is Director of Risk Management and Population Care Management for Kaiser Foundation Health Plan in Cleveland, OH. E-mail: cindy.ebner@kp.org.
Methodology

The SATs began in the third quarter of 2006 and were designed to engage frontline staff, physicians, and leadership to improve the systems and processes. Issues are identified as noted in Table 1. The goals were to make the processes error free, to eliminate waste, to decrease steps, and to standardize where applicable, thus creating processes that are highly reliable and decrease costs and resource utilization. SATs are composed of frontline staff, managers, directors, and executives of each department the issue touches. A Performance Improvement and Patient Safety (PIPS) Department staff member leads and facilitates the team and records the team’s progress. PIPS Department includes staff from the Quality and Risk and Patient Safety Department (QRPS).

When an issue arises, it is presented to the RMPS Committee who determines if a SAT is warranted. Members of the SAT follow the process detailed in the following example of the images-to-operating-room process. The average time to complete a SAT is five to seven months. Department managers are responsible for incorporating the new processes into department policies and procedures, communicating regularly on team progress, involving staff in Plan-Do-Study-Act (PDSA) cycles, soliciting feedback from physicians and staff, and monitoring the process after implementation.

Safety Action Team Example: The Images-to-Operating-Room Process

An example to best illustrate using a SAT was the one formed to improve transferring KP radiologic images to affiliated hospital operating rooms (ORs) in a timely fashion prior to surgery.

Identifying the Problem

A surgeon referred this issue to the RMPS Committee, insisting that scans were rarely in the OR prior to scheduled surgery, which led to cancellations, delays, repeated scans, and surgeries performed without scans. Upon investigation, it was discovered that the process had a long history of challenges, which had led to several workarounds being developed, which included patients being responsible for the delivery of their own scans, physicians bringing the films, scans being reprinted by the file room, the use of STAT courier services, and repeated scans. All of these led to increased costs and delays for the affiliated hospital, for KP, and for the patient (Table 3).

A SAT was assembled (Table 4). PIPS Department staff and the courier manager visited each department involved to map the current process. Microsoft Office Visio Professional 2003 (Redmond, WA) process mapping software was used to identify issues and sent to the SAT for review and revision.

Defining the Goals

At an initial teleconference, the findings were discussed and goals and possible metrics were outlined. The group-defined goal was to get the images to the OR 24 hours prior to each surgery. Possible metrics included monitoring the number of STAT courier deliveries.

Developing a Solution

The process map developed clearly showed how departments interact and where challenges arise. The map removed hierarchies, allowing participants to feel comfortable voicing their opinions, and created opportunities to build relationships between departments and staff. After mapping the process, one of the surgeons pointed out that surgeons were not completing the Preadmission Requisition (PAR). This set the tone for sharing and collaboration. If key decisions are made at a higher level, it avoids the trickle down effect to the lowest level of staff who is blamed when the process fails. In this case, the file room clerks were blamed by hospitals and surgeons when scans weren’t in the OR as expected. Because the surgeon identified this problem, made obvious from the process map, it removed barriers and the reluctance to be forthright.

Surgeons suggested creating templates of the scans consistently necessary for particular surgeries, which
were then developed by the ASC Medical Director and other Department Chiefs. The OR Manager and schedulers collaborated with the affiliated hospitals to obtain OR schedules and to brainstorm efficient file room notification for additional scheduled surgeries.

Implementing and Refining

One team surgeon attended a Surgery Department meeting to share the SAT goals and to explain the need to complete the PAR. The surgeon explained the importance of the project and its potential benefits. To build trust and to address concerns raised by physicians, a safety net was created in which the file room sent a text page to the physician the night before surgery verifying the scans were at the hospital. This was extremely successful and within one month was no longer necessary. Any surgeon not completing the PAR was contacted by the ASC Medical Director and persuaded to try the process. Two surgeons preferred to review their scans the day before surgery in their offices and an accommodation was developed for them.

Biweekly one-hour SAT teleconferences—to develop

Table 3. Improving the process for delivering images to the Operating Room project summary

<table>
<thead>
<tr>
<th>Safety Action Team</th>
<th>Goal</th>
<th>Improvements</th>
<th>Time to complete project</th>
<th>Metrics</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Challenge:</strong> Images were often not available at the time of surgery in our contracted facilities. There were multiple failure modes in the system that led to workarounds and an inefficient and unreliable process. This led to delayed or cancelled surgeries, repeat x-rays, additional copies of images produced, STAT courier deliveries, and dissatisfaction from everyone involved in the process.</td>
<td>Delivery of images to the hospital 24 hours prior to surgery for 100% of scheduled cases.</td>
<td>1. All surgeons must fill out the PAR delineating the films and/or reports requested 2. PARs are sent to the file room by OR schedulers with schedule 3. Template developed by surgeons for standard films needed per type of surgery 4. Blue index card with specific information required by hospital to get the film to the OR put in front of film jacket 5. Daily schedule obtained from contracted facilities to identify add-ons and sent to file room 6. Courier delivery schedule changed 7. File room calls hospitals prior day to verify films are there</td>
<td>Start Date: 11/06  Completion Date: 3/07</td>
<td>1. Number of STAT courier deliveries on scheduled surgeries. 2. Number of times films not in OR on time.</td>
<td>1. Not tracked until 3Q07. No STAT courier deliveries to date. 2. Five times since project completed (one because a physician did not fill out PAR, three because staff distraction occurred on same day with same person; one because the image was not the right one: the physician did not want the default view but another view.</td>
</tr>
</tbody>
</table>

**Team Members:** Medical Director and Manager ASC; KP file room staff and manager; three contracted hospital file room staff and managers and OR managers; courier manager and staff; three KP surgeons; KP OR schedulers; system telephone operators

**Biweekly one-hour SAT teleconferences**—to develop

**Cost Savings and Benefits**

<table>
<thead>
<tr>
<th>Cost avoidance: soft dollars</th>
<th>Capacity</th>
<th>Dollars saved: hard savings</th>
<th>Time saved</th>
<th>Patient benefits</th>
<th>Other departments affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average cost per lawsuit: $350,000</td>
<td>Increased surgeries scheduled in hospital OR because of avoidance of delays and cancellations</td>
<td>1. Processing additional films -$1.05/film(^a) 2. $25.17 per minute for delays in the OR(^a) 3. Number of additional x-rays taken at hospitals x $500(^a) 4. STAT courier delivery from contracted company -$12/ delivery(^a)</td>
<td>• Minutes to recopy x-rays • No additional courier deliveries • No delays in surgery because of missing images</td>
<td>• Surgeries take place on time • No additional radiation exposure • Surgeon has necessary information to perform surgery • Expenses involved in delays or cancellations for surgery • Potentially avoid complications because of performing surgery without images</td>
<td>Radiology does STAT films at contracted facilities OR has to delay or cancel surgeries at contracted facilities Contracted couriers doing STAT deliveries to hospitals</td>
</tr>
<tr>
<td>Surgeon turnover because of job dissatisfaction</td>
<td>Increased productivity for file room staff</td>
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<td>File room turnover because of job dissatisfaction</td>
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<td>Damage to KP’s reputation</td>
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\(^a\)Original process completed and extended to contracted referral office visits at Cleveland Clinic Foundation. Pink index card created for their specific needs. Designated delivery and pick up places and delivery times changed to improve reliability.

\(^b\)Unable to quantify volumes since it was not tracked before implementation of this project. According to the surgeons, missing films happened frequently.

ASC = Ambulatory Surgery Center; KP = Kaiser Permanente; OR = operating room; PAR = Preadmission Requisition
actions with a completion goal based on the findings from previous meetings—continued until the project was completed. For example, the electronic routing form was confusing because it listed the information to return the scan to KP. The courier manager and the PIPS staff worked with each hospital file room to determine how to best organize the information needed to get the scan to the OR on time. A surgeon suggested using an index card on the front of the file jacket with the required information—a simple and elegant solution. The PDSA cycle was completed to determine the potential success of this solution; the evaluated process was implemented.

### Transfer

The first phase of the project was completed in three months and a trial for the clinics was developed and tested in the Cleveland Clinic Foundation offices for consultations. The process was again successful and, with minor changes, was implemented.

### Results

In addition to improving the process, this project built relationships with people in affiliated hospitals and KP shared the learnings about building reliable processes and performance improvement. The staff at hospitals readily participated, excited that KP was proactively addressing failed processes. Ultimately, the project will improve KP’s reputation in the community through continued patient safety initiatives.

From a survey created and sent to all SAT participants feedback was obtained and used to identify areas for improvement. The response rate was 50% (n = 20) and of those who responded 100% agreed that they knew more about building a reliable process as a result; 97.4% agreed that it increased their job satisfaction; and 100% believed that patient safety was improved and the gains were sustained (Figure 1).

### Discussion

Ambulatory care presents many challenges. The KP Ohio Region’s Safety Action Team program has proved successful in addressing some of these. Following implementation of the program, participants agreed that patient safety was improved and they acknowledged that the gains made through the program were sustained. They also agreed that they knew more about building a reliable process and that the program increased their job satisfaction.

![Figure 1. Safety Action Team Survey—Ohio Region; January, 2009](image)
Table 5. Requirements for a Safety Action Team

<table>
<thead>
<tr>
<th>Requirement</th>
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<tr>
<td>Method to identify dysfunctional systems</td>
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<tr>
<td>Processes and referral system for process improvement</td>
</tr>
<tr>
<td>Quality, patient safety, and risk professionals trained in process improvement</td>
</tr>
<tr>
<td>One hour every two weeks for meetings</td>
</tr>
<tr>
<td>Teleconference line</td>
</tr>
<tr>
<td>Visio or other process map software</td>
</tr>
<tr>
<td>Adobe Acrobat Professional (San Jose, CA) to convert the Visio map to a readable format</td>
</tr>
<tr>
<td>Administrative assistant to set up initial meeting</td>
</tr>
<tr>
<td>Oversight committee to evaluate the progress of SATs and to assist with project barriers</td>
</tr>
<tr>
<td>Frontline staff, managers, administrators, and physicians willing to participate</td>
</tr>
<tr>
<td>Template for tracking team progress</td>
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<tr>
<td>E-mail communication system</td>
</tr>
<tr>
<td>Information Technology (IT) support for data and to assist on teams</td>
</tr>
<tr>
<td>Brainstorming tools</td>
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</table>

Program Transferability
SATs can be implemented in any region for inpatient/ambulatory care and can be customized for smaller performance improvement projects. The Ohio Region is committed to working with any region or facility interested in implementing this process. Requirements for a SAT have been developed (Table 5).

Where We Are Now
In 2008, to each new committee we added KP nonemployee patients who participate in team activities, provide feedback, and drive some changes. For instance, patients and families in Oncology were interviewed for input regarding their experience in the Infusion Center for the Oncology SAT. Patients kept a time log to identify delays and inefficiencies in their treatment process. Patients and families were enthusiastic and willing to help us. An added benefit is that staff has the opportunity to interact with patients in a different relationship.

Improvements planned for 2009 include tracking the outcomes, costs, and benefits for each new team in the Performance Improvement record; working with unit-based teams with a scaled-down version of the SAT approach; educating department staff on how to use the process algorithms; incorporating Webinars or shared desktop for meetings; and developing a one-page monthly update for all department staff not involved in the program for feedback.

Conclusion
Since the inception of SATs, 19 teams have been implemented and 11 are completed. The teams run simultaneously and are led by different members of the PIPS team (Director, regional safety lead, and/or three quality consultants). All goals were met and the gains are sustained within each team. New workflows were developed and policies and procedures were changed where applicable. Staff and leaders in the department monitor the new process for 6-12 months. Any failures are investigated by the staff in collaboration with the PIPS team leader and adjustments to the process are made as appropriate. When issues are brought to the RMPS, they are investigated with consideration to the level of risk to patients before a project is undertaken. The Senior Quality Council receives quarterly SAT reports and all staff is updated quarterly per the PIPS Department newsletter.

Future plans are being made to offer assistance in improving processes for issues identified by affiliated clinicians. This will build collaboration, increase reliability, and further develop a culture of safety. This initiative will include education, alerts, recalls, implementation of The Joint Commission National Patient Safety Goals, and creating a just culture. The overall goal will be to improve patient outcomes by making it easy for all of our clinicians to do the right thing right the first time.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

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References
Evany Zirul, MFA, DO, is a former Ear, Nose, Throat, and Facial Plastic Surgeon for the former Permanente Medical Group of Mid-America (PMGMA) in Kansas City, Missouri. She has retired from the medical profession and is now a full-time artist. She creates drawings and bronze sculptures. She states, “My art is figurative. It is realism expressing the maleness, femaleness, and emotional nuances mirrored by our bodies and our life experiences.”

“Modern Woman Torso” was created for the Pink Show in Fresno, CA.
Incidental Gallstones

Jeffrey K Wang, MD
Shannon M Foster, MD
Bruce G Wolff, MD, FACS

Abstract

Gallstones develop in approximately 10% to 15% of the US population and represent one of the most common and most costly of all digestive diseases. Studies investigating gallstones' natural history have shown that gallstone-related complications arise at a rate of approximately 1% per year in asymptomatic patients and 2% per year in patients who already have symptoms. Patients can have any of multiple presentations with gallstone-related problems along a continuum of health threats from intermittent biliary colic to septic shock from ascending infections. In most clinical situations in which the patient's gallstone symptoms are either recurrent or have caused complications, cholecystectomy remains the procedure of choice. Laparoscopic cholecystectomy, first performed in the mid-1980s, has quickly become the gold standard in the US. For clinicians who perform abdominal procedures, the literature is consistent in advocating cholecystectomy for gallstones found incidentally during other abdominal procedures.

Prevalence and Demographics of Gallstone Disease

Gallstones represent the most common and costly of all digestive diseases, with an estimated overall financial burden in the US of more that $5 billion. From a consensus statement published by the National Institutes of Health (NIH), approximately 10% to 15% of the US adult population has gallstones.1 Epidemiologic studies estimate the number of gallstone patients in the US to be approximately one million per year. Since the 1980s, we have gained insight to major risk factors for the development of gallstones, including increasing age, female sex, obesity, pregnancy, rapid weight loss, systemic illnesses such as liver disease or hematologic disorders, a long list of medications, and specific bowel surgery.

Historical Perspective on Gallbladder Surgery

The first recorded surgery performed on the biliary system was in 1867 in Indianapolis, IN, when John Stough Bobb operated on a woman with massive gallbladder hydrops. Bobb performed an open cholecystostomy, extracted the gallstones, and then sutured the gallbladder closed. Approximately 15 years later in Berlin, Carl Langebuch performed the first cholecystectomy on a patient with biliary colic. This became the standard operation for patients with symptomatic gallbladder disease for more than 100 years until Erich Mühe revolutionized the field in 1985 in Boeblingen, Germany by performing the first laparoscopic cholecystectomy.2 In less than one decade, >90% of cholecystectomies performed in the US were being performed laparoscopically.

Since the early 1990s, continual improvement has been made in both the instrumentation and optics needed to perform the laparoscopic cholecystectomy. With ongoing research on indications, methods, and outcomes, a great deal of experience with laparoscopic cholecystectomy has been amassed worldwide.

Natural History of Gallstones

Studies have shown that the vast majority of patients with gallstones will remain asymptomatic throughout life.3 The reason a subgroup of individuals will ultimately develop symptoms remains unknown; however, once symptoms arise, the recurrence rate is high and risk of progression to gallstone-related complications is significantly increased.4 An article by colleagues from the Kaiser Permanente Medical Care Program in Oakland, California,5 reported that 289 patients with documented gallstones were monitored for up to 25 years after diagnosis. Using life-table analysis, the researchers found that complications developed in approximately 1% per year of asymptomatic patients with gallstones and in about 2% per year of symptomatic patients. These figures are similar to those in...
Incidental Gallstones

Symptoms.

In approximately 90% of patients with typical biliaryproof that laparoscopic cholecystectomy eradicates symptomsof symptomatic individuals. Long-term results have shownpresent in one of three clinical stages: asymptomatic, symptomatic, and with complications. Approximately two-thirds of symptomatic patients presentwith chronic cholecystitis characterized by pain that issevere and episodic, epigastric or right upper quadrant inlocation, that lasts one to five hours, and that oftenwakes the patient at night or beginning after a fatty meal. This pain is most often caused by a gallstoneobstructing the cystic duct, the sole biliary outflow tract ofthe gallbladder. This leads to progressively increasinggallbladder wall tension and thus to pain. Nausea andvomiting are commonly associated symptoms.

The diagnosis of chronic cholecystitis or symptomaticcholelithiasis is made when the typical symptoms are present and gallstones are found using various imaging modalities. Abdominal ultrasonography remains the gold-standard diagnostic test, capable of detecting >90% of gallstones. Occasionally, gallstones are found incidentally during abdominal radiographs or computed tomography (CT) scans. In these cases, ultrasonography of the formal right upper quadrant should be performed before surgery.

After its introduction in 1987, laparoscopic cholecystectomy quickly became the standard of care for symptomatic individuals. Long-term results have shown that laparoscopic cholecystectomy eradicates symptoms in approximately 90% of patients with typical biliary symptoms.

Acute Cholecystitis

Once a gallstone has obstructed the cystic duct for an extended period of time, inflammation of the gallbladder wall causes it to become grossly thickened and edematous and may lead to the formation of pericholecystic fluid. These findings represent the cornerstones of diagnosing acute cholecystitis. If the obstruction and contamination are not relieved, inflammation can evolve into infection and abscess formation, creating a gangrenous gallbladder. Uncommonly, this may lead to free perforation of the gallbladder wall, causing development of peritonitis, development of fistulasinto adjacent organs, or formation of intra-abdominal abscesses. The symptoms of acute cholecystitis are similar to those of chronic cholecystitis, but in contrast to typical biliary colic, the pain does not regress and may last for several days if untreated. Associated symptoms are broadened to include fever, chills, and anorexia. Physical examination will often show focal tenderness with guarding. A classic characteristic of acute cholecystitis is the finding of Murphy sign, or an inspiratory arrest on deep palpation of the gallbladder in the right upper quadrant. Also in contrast to chronic cholecystitis, in which laboratory study results are generally normal, leukocytosis with white blood cell counts >12,000 cells/mm³ is commonly present. Levels of other substances for which patients are tested, such as those for liver function (alkaline phosphatase, transaminases, and bilirubin), may be elevated.

Diagnosis is most often confirmed using ultrasonography, which may show gallstones, a thickened gallbladder wall, and fluid next to the gallbladder. For atypical cases or for those in which the diagnosis is uncertain, biliary radionuclide imaging, such as hepatobiliary iminodiacetic acid scans, may be helpful. The finding consistent with acute cholecystitis is the lack of filling of the radionuclide into the gallbladder within four hours, indicating obstruction of normal biliary flow from the liver into the gallbladder.

Cholecystectomy, whether open or laparoscopic, is the treatment of choice for acute cholecystitis. One area of controversy in recent years has been the timing of cholecystectomy in acute cholecystitis. A prospective, randomized study by Lo et al. found that barring patient-related factors that would rule out surgery, early cholecystectomy (within two or three days of initial symptoms) should be recommended to patients because it offers a definite solution in one hospital admission, results in quicker recovery times, and also allows for earlier return to work. When patients present after the initial window of opportunity for cholecystectomy (after three or four days of initial symptoms), they can be treated with antibiotics and then scheduled for interval laparoscopic cholecystectomy after six to eight weeks. Of these patients, this therapy will fail in approximately 20%, who will require surgery sooner. The concern about attempting laparoscopic cholecystectomy outside of the initial or late windows is due to the increased rate of conversion to an open procedure, which is associated with increased pain, longer hospitalizations, and obvious cosmetic drawbacks. For patients unfit for surgery, drainage of the gallbladder using either a percutaneous approach through the
liver or an open approach in conjunction with a tube or drain can be performed. This tube can ultimately be removed once a contrast study through the tube shows a patent cystic duct. Laparoscopic cholecystectomy can be performed after the tube has been removed.

**Choledocholithiasis**

Stones that are found within the common bile duct arise in two ways: 1) secondary migration of gallstones formed in the gallbladder down the biliary tree or 2) primary formation within bile duct. The majority of ductal stones in the US are formed secondarily within the gallbladder.

The spectrum of clinical manifestations in choledocholithiasis is vast, from asymptomatic to complete obstruction with resulting pain, infection, and pancreatitis. Patients report similar biliary colic–type symptoms, with nausea and vomiting commonly associated. These symptoms may be more temporal, causing pain and jaundice as the gallstone temporarily obstructs the bile duct, acting like a ball-valve mechanism. Because the gallstone may completely obstruct the normal flow of bile, patients may become jaundiced and levels of liver function tests, including alkaline phosphatase, serum bilirubin, and transaminases, may be elevated.

Ultrasoundography is commonly the first test obtained to document stones in the gallbladder as well as the size of the common bile duct. A dilated common bile duct (>8 mm in diameter) in conjunction with jaundice, biliary colic, and appropriate elevations in levels of substances measured by laboratory studies is suggestive of choledocholithiasis. Other noninvasive studies, such as magnetic resonance cholangiography, may also provide further details about the biliary system. Endoscopic retrograde cholangiography (ERC) not only is the gold standard for diagnosing common bile duct stones but also is potentially therapeutic if stones are extracted from the common bile duct or sphincterotomy is performed to relieve an obstructing stone.11

Common bile duct stones can either be relieved by sphincterotomy and ductal clearance through peroperative ERC or extracted via intraoperative common bile duct exploration through the cystic duct or common bile duct. ERC may also be performed postoperatively when common bile duct stones encountered during routine laparoscopic cholecystectomy. Choledochotomy or common bile duct exploration can be performed laparoscopically or in an open fashion; in either case, a T-tube drain should be left in place to drain bile and stones to the level of the skin. In the case of an abnormally dilated bile duct secondary to impacted stones in the ampulla, anastomosing segments of bowel, such as in choledochoduodenostomy or choledochojejunostomy, may be the best option.

**Cholangitis**

Acute cholangitis occurs when a stone either partially or completely obstructing the common bile duct causes bacterial contamination and leads to an ascending infection of the biliary system. Immunoglobulins within the bile and a continuous downward flow from the liver normally keep bile sterile. The most common cause of cholangitis is gallstones, but any disease process that leads to obstruction may precipitate cholangitis, such as bile duct strictures, parasites, external compression, and blocked biliary stents. Cultures taken of the bile, of stones within the common bile duct, and of stents produce positive findings in >90% of cases. The most common microbiologic sources are Gram-positives and Gram-negatives: *Escherichia coli* (25%–50%), *Klebsiella pneumoniae* (15%–20%), *Enterococcus* (10%–20%), and *Enterobacter* (5%–10%).12

The spectrum of clinical presentation varies widely from mild, intermittent pain to life-threatening septic shock. The classic Charcot triad, consisting of fever, right upper quadrant pain, and jaundice, is present in approximately 50% to 75% of patients with cholangitis.13 This triad may progress to Reynolds pentad, which adds mental-status changes and septicemia-associated hypotension to the presentation. Physical examination findings are similar to those for patients with acute cholecystitis.

Laboratory findings will often show leukocytosis with elevation in serum bilirubin levels, transaminases, and alkaline phosphatase. Ultrasonography is useful in documenting the presence of gallstones as well as the diameter of the common bile duct. The initial treatments for acute cholangitis are intravenous broad-spectrum antibiotics, aggressive fluid resuscitation, and ultimately drainage of the infected bile, either externally through the skin or within the duodenum through the ampulla of Vater.14 Many patients will need intensive care unit monitoring and temporary vasopressors.

Endoscopic retrograde cholangiopancreatography (ERCP) is useful in both confirming the diagnosis and with sphincterotomy or stone extraction relieving the obstruction. A stent may have to be placed to allow for drainage of bile. When ERCP is not available, percutaneous transhepatic cholangiography (PTC) may have to be used. It can demonstrate the level of obstruction, allow for bile culturing, and establish a route for drainage of bile, removal of stones, and tube placement. When neither ERCP nor PTC is available, open surgery to
decompress the biliary system with T-tube placement is the treatment of choice. Cholecystectomy can be performed electively once the obstruction is relieved and infection has been controlled.

**Gallstone ileus**

Rarely, gallstones can cause a mechanical bowel obstruction in the distal segments of the small intestine, known as gallstone ileus. It occurs in <0.5% of patients with gallstones and is the cause of 1% to 4% of all cases of bowel obstruction. There is a strong female predilection, with gallstone ileus being 3 to 10 times more common in women than in men. The most common mechanism of gallstones causing ileus is a biliary-enteric fistula, which is created after local inflammation causes adhesion formation between the bile duct and intestine. Ongoing inflammation leads to necrosis between the biliary system and the small bowel, leading to communication between the two organ systems. Presenting symptoms are related to mechanical bowel obstruction that causes episodic vague abdominal pain, nausea, and vomiting. The diagnosis is confirmed through plain radiographs and computed tomography scans that demonstrate signs of mechanical bowel obstruction, air within the biliary tree (pneumobilia), or sometimes even the offending stone. Treatment of gallstone ileus remains controversial because there are various opinions regarding the management of the biliary-enteric fistula. Those who advocate a one-stage procedure, by removing the stone, managing the fistula, and cholecystectomy, agree that it is reserved for patients with low surgical risk. With regard to the small bowel, a longitudinal enterotomy is made to carefully remove the stone and is subsequently closed transversely to prevent bowel stenosis.

**Incidental Cholelithiasis**

Gallstones detected either before or at the time of another gastrointestinal procedure present a difficult and long-debated problem for surgeons. There are arguments both for and against: the possibility of adding significant morbidity and mortality to the index procedure versus the likelihood that biliary symptoms and complications will develop in the future. Of utmost importance when dealing with this issue is an understanding of the natural history of asymptomatic gallstones. As already stated, the complication rate in the US for asymptomatic patients with gallstones is approximately 1% per year. Because of this low rate of progression, prophylactic cholecystectomy as the sole procedure, meaning performing cholecystectomy for the purpose of removing the gallbladder and the associated stones, is rarely indicated.

What does one do when a patient will receive abdominal surgery and the gallbladder can be easily removed? The authors of the 1992 NIH Consensus Statement wrote: “It remains controversial whether incidental cholecystectomy during nonbiliary abdominal surgery in asymptomatic individuals is beneficial.”

Despite this statement, there are numerous reports in the literature that support performing incidental cholecystectomy in conjunction with another abdominal procedure, such as from vascular, colorectal, and thoracic surgeries. Juhasz et al reported on a single-institution retrospective review over five years that identified 305 patients who underwent colorectal surgery. Of that cohort, 195 (63.9%) had incidental cholecystectomy that was discovered before, during, or within one month after surgery. Patients were excluded if they developed biliary symptoms before surgery. Using surgical morbidity and long-term complication rates as outcomes, Juhasz et al concluded that incidental cholecystectomy was not associated with increased postoperative morbidity. Furthermore, they found that 14.6% of patients who did not receive cholecystectomy despite having gallstones went on to develop biliary symptoms after a median follow-up period of six years. Twelve of those 16 patients ultimately underwent cholecystectomy.

In a similar study examining patients who underwent incidental cholecystectomy during laparoscopic antireflux surgery, Klaus et al had a much smaller cohort (67 of 1065, or 6.3%) who underwent combined surgery. The goal of the study was to compare the outcomes for patients who underwent cholecystectomy with outcomes for those who underwent fundoplication alone. Using questionnaires to gather information about postoperative symptoms related to gallstones such as abdominal pain, nausea, and vomiting, the authors found no significant difference between groups. They concluded that concomitant laparoscopic cholecystectomy did not influence the outcome of the index surgery and is a safe procedure. The literature supports performing cholecystectomy in conjunction with another abdominal procedure. As long as the surgeon is comfortable performing it, doing so does not put the patient at significant additional risk or significantly increase the duration of the index procedure.

**Disclosure Statement**

Jeffrey K Wang, MD, and Shannon Foster, MD, have no conflicts of interest to disclose. Bruce Wolff, MD, FACS, is a consultant for Transzyme Pharma, Roche, and Cenzone Tech, Inc.
Incidental Gallstones

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References

Stones of Various Shapes and Colors
Moreover I have taken out innumerable stones with my own hands, with various colors found in the kidneys, in the lungs, in the liver, in the portal vein ... Also in the gallbladder ... I found stones of various shapes and of various colors and very many in some others.

— De re Anatomica Libri, Matteo Realdo Colombo, 1516-1559,
Italian Professor of Anatomy and Surgeon at the University of Padua, Italy
An Unusual Presentation and Etiology of Hypotension Seen in Nephrotic Syndrome

Objective and Clinical Importance
An unusual clinical case of hypotension and acute kidney injury seen in a patient with underlying nephrotic syndrome is presented with an emphasis on understanding the differential diagnosis as well as the pathophysiology of the underlying disease.

Case History
A woman, age 58 years, reported having experienced presyncopal dizziness for two weeks. During her physical examination, her systolic blood pressure was found to be approximately 70 mm Hg. She reported that for two weeks, she had taken 20 mg of furosemide daily for lower-extremity edema. She said that she had not had any chest pain, palpitations, shortness of breath, fever, or hypothermia and did not have any history of bleeding, diarrhea, polydipsia, dysuria, seizures, or abdominal pain. She did exhibit gastrointestinal symptoms of nausea and early satiety as well as urinary symptoms of polyuria and nocturia. Her medical history included hyperlipidemia and rheumatoid arthritis. She had no history of diabetes, liver disease, or cardiac disease. She had at one time undergone a hysterectomy and an appendectomy. She reported that she did not use tobacco, alcohol, or street drugs. Her prescribed daily dosages of oral medications included 20 mg of furosemide; 20 mg of simvastatin; 20 mg of omeprazole; 40 mg of benazepril; 200 mg of Oysco 500; and hydrocodone-acetaminophen, which she had been taking for several months. She was not taking any disease-modifying agents for her rheumatoid arthritis. Her vital signs were as follows: blood pressure, 70/30 mmHg; temperature, 98.6°F (37°C); pulse rate, 96 beats per minute; respiration rate, 18 breaths per minute; oxygen saturation, 99%; weight, 75 kg. The physical examination demonstrated bilateral 2+ pedal edema, several bruises on her back and legs, and right-eye subconjunctival hemorrhage. Jugular venous pressure was not elevated, and there were no rales. The patient did not have any joint deformities. The patient had negative results on guaiac testing.

Case Workup
Initial investigative workup produced normal echocardiography findings, negative findings on tests for cardiac enzymes, negative findings on blood cultures, a finding of a low level of thyroid-stimulating hormone, and a finding of a normal level of free T₄, the latter three of which ruled out cardiac dysfunction, septicemia, and hypothyroidism, respectively. Her laboratory testing also revealed acute kidney injury, with a creatine level of 7.3 mg/dL (compared with a baseline of 1.1 mg/dL). Dipstick urinalysis revealed 2+ protein, no blood, and 1+ glucose, although her serum glucose was 100 mg/dL with no history of diabetes mellitus. A 24-hour urine quantititation revealed 19 g of protein and a urine albumin level of 10 g in a collection of 2.4 L. Her proteinuria, together with her clinical presentation of peripheral edema and later laboratory findings of hyperalbuminemia and hyperlipidemia, indicated that she had nephrotic syndrome. The differential diagnosis included primary glomerular diseases, such as minimal-change disease, focal segmental glomerulosclerosis, membranous nephropathy, and membranoproliferative glomerulonephritis, as well as secondary causes such as systemic diseases, including diabetes, human immunodeficiency virus, hepatitis B or C, myeloma, and amyloidosis.

The discrepancy between the total urine albumin and total urine protein quantitation suggested a paraproteinemiac process. The chemistry panel also revealed a nonanion-gap metabolic acidosis with a serum bicarbonate of 14 mEq/L.
An Unusual Presentation and Etiology of Hypotension Seen in Nephrotic Syndrome

The urinalysis also demonstrated glucosuria despite a normal serum glucose level, further suggesting renal tubular dysfunction. A renal infiltrative process was suspected. The decrease in blood pressure after the patient began taking a low dose of furosemide also suggested possible vascular rigidity and involvement. Renal ultrasonography demonstrated normal kidney size and echogenicity bilaterally. Urine and serum protein electrophoresis produced negative findings for any light chains (LCs) or monoclonal spikes by immunofixation, respectively.

Diagnosis

A renal biopsy was performed and revealed both renal and vascular amorphous material deposition in the mesangium, capillary walls, interstitium, arteries, and arterioles (Figure 1). Congo red staining produced positive results, and apple-green birefringence was present on polar spectroscopy. Immunofluorescence demonstrated immunoglobulin A (IgA 4+), IgM (1–2+), and λ LCs (3+) in the capillary walls and mesangial regions of all the glomeruli in a diffuse pattern, in the interstitium, and in tubular casts. Electron microscopy revealed fibrillary deposition in the mesangial regions of the glomeruli, interstitium, and walls of the arteries and arterioles. The abnormal material consisted of haphazardly arranged fine fibrils, approximately 12 nm in diameter and of indefinite length. The definitive diagnosis was primary systemic (AL) amyloidosis.

Discussion

Amyloidosis, a multisystem disease, can manifest in different ways with varying severity. Its major classifications are AL amyloidosis, composed of Ig LCs and arising from a clonal B-cell disorder, familial (AF) amyloidosis, most commonly due to transthyretin; and secondary (AA) amyloidosis, which is composed of the acute-phase reactant serum amyloid A protein that occurs in the setting of chronic inflammatory or infectious diseases. Clinically relevant renal involvement mainly occurs in AL or AA amyloidosis.

AL amyloidosis is the most common type of systemic amyloidosis in North America. It is estimated to affect 5 to 12 people per million each year, although autopsy studies suggest that the incidence might be higher. More than 90% of patients have a serum or urine monoclonal Ig protein that can be detected by immunofixation electrophoresis or free-LC assay. The standard serum protein electrophoresis and urine protein electrophoresis are not useful screening tests because the clonal Ig in AL amyloidosis, unlike in multiple myeloma, is often not present in sufficient quantity in the serum to produce a monoclonal “M spike” on these tests. This phenomenon was illustrated in the patient discussed here whose urine and serum protein electrophoresis produced negative findings for any LCs or monoclonal spikes by immunofixation, respectively. The clonal Ig was detected in the patient, however, by immunofluorescence on the renal biopsy, revealing IgA (4+), IgM (1–2+), and λ LCs (3+) in the capillary walls and mesangial regions of all the glomeruli in a diffuse pattern, in the interstitium, and in tubular casts.

AL amyloidosis is usually a rapidly progressive disease that presents with characteristic clinical syndromes, recognition of which is key to making the diagnosis. The kidneys are the most frequently affected organs in approximately 80% of patients with the disease. The paraproteinemia, proteinuria,
An Unusual Presentation and Etiology of Hypotension Seen in Nephrotic Syndrome

Hypoalbuminemia, and edema seen in the patient discussed here were the result of amyloidosis having caused nephrotic syndrome with tubular dysfunction and glomerular injury. Cardiac dysfunction, which the patient did not exhibit, is the second most common presentation. Involvement of the nervous system can include peripheral sensory neuropathy, carpal tunnel syndrome, and autonomic dysfunction with gastrointestinal motility disturbances (early satiety, diarrhea, constipation) and orthostatic hypotension. Our patient did exhibit certain clinical features suggesting the presence of autonomic dysfunction, such as dizziness, nausea, early satiety, and polyuria; however, her hypotension and dizziness quickly resolved after minimal fluid resuscitation.

Occasional patients have a different renal presentation because the amyloid deposits are primarily limited to the vessels, leading to narrowing of the vascular lumens. These patients usually present with slowly progressive chronic kidney disease with little or no proteinuria. Along with both glomerular and tubular involvement, the patient discussed here had vascular involvement, illustrated by deteriorated renal function, with low-dose diuresis causing further worsening of renal function, which was aggravated by the presence of angiotensin-converting inhibitor in the setting of low blood pressure. As mentioned earlier, the patient also had several areas of ecchymosis on her back and legs as well as subconjunctival hemorrhage, further suggesting the presence of peripheral capillary vascular compromise due to amyloid infiltration. Vasculature with amyloid infiltration cannot respond normally with appropriate vasoconstriction when presented with slight hypovolemia due to mild diuresis. As expected, the patient’s hypotension quickly resolved after minimal fluid resuscitation, given the increased vascular rigidity caused by the amyloid infiltration. This allowed for adequate perfusion to the kidneys, resulting in the rapid correction of the patient’s acute kidney injury.

Conclusion

Amyloidosis is a multisystem disease that can manifest in different ways with varying severity. The case discussed here illustrates an unusual presentation of hypotension due to amyloid infiltration of the vasculature, leaving the patient susceptible to acute kidney injury even from what is generally considered mild diuresis. Paraproteinemia and proteinuria were due to the amyloidosis having caused nephrotic syndrome with tubular dysfunction and glomerular injury. The patient’s hypotension and acute kidney injury, which likely occurred because of the increased vascular rigidity caused by amyloid infiltration, did eventually resolve with volume resuscitation. It was planned for the patient to be evaluated by a hematologist for a more specific workup and therapy, but she left and did not return.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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References


Urine

All we know for certain about the kidney is that it makes urine.

— Homer William Smith, ScD, 1895 – 1962, American physiologist and advocate for science
An Unusual Cause of Elevated Values on Liver Function Tests in a Liver Transplant Patient

Ankur Jain, MD
Amandeep Sahota, MD
Najeeb S Alshak, MD
Jim K Tung, MD

Introduction
Biliary obstruction and rejection are two of the most common causes of abnormal findings on liver function tests (LFTs) in patients who have already undergone liver transplantation. Here we present a post-transplant patient with jaundice. Tests showed that he had no hepatitis B surface antigen before transplantation; he received a core antibody-negative liver. He was not previously vaccinated against hepatitis B, however, and acute hepatitis B was found to be the cause of his increased values on LFTs. His case demonstrates the need to keep a broad differential during laboratory workup of such patients and to vaccinate those patients at risk for acquiring hepatitis B or developing complications.

Case Presentation
A man, age 25 years, taking immunosuppressive medications after orthotopic liver transplantation (OLT) presented to our clinic and reported having had jaundice for four days. The patient’s medical history was notable for primary sclerosing cholangitis, diagnosed three years earlier, and for which he underwent OLT a year later at a transplantation center outside the Kaiser Permanente system. He had no prior history of rejection, cytomegalovirus hepatitis, biliary strictures, or hepatic artery ischemia. He was admitted to the hospital for further evaluation.

His post-transplant course was complicated by pulmonary coccidiomycosis, which was treated with oral fluconazole, resulting in symptomatic improvement and partial clearing, as seen on chest radiographs. Several weeks before admission, the patient developed tacrolimus toxicity while taking fluconazole, as manifested by an elevated tacrolimus level. His dosage of tacrolimus was reduced, which ameliorated the toxicity, but his dosage of mycophenolate mofetil was maintained. All liver enzymes remained normal during this period.

The patient did well until admission, when he reported developing icterus and jaundice over the preceding four days. He said that he had not had fever, abdominal pain, or pruritus, but he did report fatigue and nausea over the last several weeks. He reported no cough or shortness of breath, which he had previously reported having with pneumonia. He said that he had not recently traveled, eaten unusual foods, or had contact with anyone who was ill. He reported taking his transplant medications as prescribed, except for discontinuing fluconazole one month earlier because he had been feeling better. His physical examination findings were normal other than for jaundice.

Admission laboratory results were as follows: aspartate aminotransferase (AST), 1369 U/L; alanine aminotransferase (ALT), 921 U/L; alkaline phosphatase, 402 U/L; total bilirubin, 5.1 mg/dL. His international normalized ratio (INR) was 1.1, and his tacrolimus level was slightly low. Epstein-Barr virus testing and cytomegalovirus polymerase chain reaction were negative. A Coccidioides immitis complement fixation antibody titer also produced negative findings. Ultrasonography with Doppler showed no definite stones or strictures. A chest computed tomography scan showed nearly complete resolution of the previous infiltrate.

Because of concern about acute organ rejection, the patient’s tacrolimus and mycophenolate doses were increased, but no steroids were given. The patient’s total bilirubin and INR began to rise (to a peak of 12.1 mg/dL and 1.3, respectively) and a percutaneous liver biopsy was performed (Figures 1A and 1B). Biopsy showed severe lobular inflammation with occasional ground-glass hepatocytes. There was no evidence of rejection or biliary obstruction. Stains for hepatitis B sAg and cAg were positive (Figures 1C and 1D). The patient also tested positive for hepatitis B sAg and hepatitis B cAb immunoglobulin M (IgM) in the se-
rum, with a viral load of >20 million IU/mL. Serology for hepatitis B eAg was positive; serology for hepatitis B eAb and hepatitis D IgM Ab were negative. The diagnosis was thus acute hepatitis B.

The patient had negative serologies for hepatitis B sAg and hepatitis B cAb before transplantation, and review of the patient’s transplantation records revealed that the donor liver was hepatitis B cAb negative. The patient had not been vaccinated before transplantation. On further questioning, the patient reported no recent unprotected sexual activity other than with his wife, whose test results were negative for hepatitis B. He also reported no intravenous drug use, recent tattoos, or blood transfusions. HIV and syphilis test results were negative. The patient was promptly given entecavir for acute hepatitis B. AST, ALT, alkaline phosphatase, and total bilirubin were monitored throughout hospitalization and began to trend downward. The INR remained stable. Before being discharged from the hospital, the patient was given fluconazole again and his tacrolimus was again decreased to maintain appropriate levels. Prednisone was not continued.

The patient was examined again in our clinic two weeks after hospital discharge and reported feeling much better, with decreased jaundice. He was no longer fatigued or nauseated. After three months of entecavir, his AST and ALT levels were 59 U/L and 73 U/L, respectively, with an alkaline phosphatase and total bilirubin levels of 183 U/L and 1.8 mg/dL, respectively. His INR was 1.1. He remains positive for hepatitis B sAg, but his viral load has decreased to 2079 IU/mL.

**Discussion**

An estimated 350 million people worldwide are chronically infected with hepatitis B. In the US, approximately 1.25 million people have chronic hepatitis B, of whom 20% to 30% acquired their infection in childhood. The implementation of effective vaccination programs in many countries such as the US has resulted in a significant decrease in the incidence of acute hepatitis B.

The most common risk factors for hepatitis B in adults include sexual exposure (sexual contact with a person with hepatitis B, multiple sex partners, or men having sex with men) and use of injectable drugs. In addition to vaccinating these high-risk populations, the Centers for Disease Control and Prevention also recommends vaccinating all patients with chronic liver disease against hepatitis B. Immunity should then be confirmed with a hepatitis B surface antibody. Our patient was not vaccinated before transplantation and, despite denying having any risk factors, he developed acute hepatitis B, which could have resulted in serious consequences, given his post-transplantation immunosuppression.

Hepatitis B may present with constitutional symptoms, including anorexia, nausea, jaundice, and right upper quadrant discomfort, but is often subclinical. AST and ALT values of 1000 to 2000 U/L are typically seen during the acute phase, with ALT values being much higher than AST values. The INR is the best indicator of prognosis.

Treatment of acute hepatitis B in otherwise healthy individuals is mainly supportive, with close monitoring of the INR. Treatment of such patients with nucleoside/nucleotide
therapy is controversial because the likelihood of fulminant hepatitis B is <1%, and in immunocompetent adults, the likelihood of progression to chronic hepatitis B virus infection is <5%. A recent study of 71 patients with acute hepatitis B randomized to either lamivudine or placebo showed no biochemical or clinical benefit with lamivudine.

Treating certain patients with acute hepatitis B has been advocated, including those with a severe or protracted course (coagulopathy with an INR >5), symptoms that persist for more than four weeks, or marked jaundice with total bilirubin >10 mg/dL. Patients with fulminant hepatic failure undergoing transplantation evaluation and those who are immunocompromised, have coinfection or preexisting liver disease, or are elderly should also be considered for treatment. Chronicity from hepatitis B is known to develop more frequently in immunocompromised patients and in up to 60% of patients receiving dialysis. In most cases, treatment can be stopped after confirmation that the patient has cleared hepatitis B sAg.

Liver transplant recipients who develop acute hepatitis B represent a special population of immunocompromised patients. They may undergo reactivation of a previously acquired infection. Alternatively, those who were seronegative may develop hepatitis B after transplantation (de novo) by acquiring it through traditional risk factors or as a result of receiving a liver testing positive for hepatitis B cAb, which is the most common means of acquisition. Rate of transmission from the donor liver has been reported to be between 43% and 78%. Combination therapy with lamivudine and hepatitis B immunoglobulin has been shown to prevent hepatitis B infection in seronegative recipients of hepatic allografts from donors positive for hepatitis B cAb.

Patients with de novo hepatitis B after transplant have primarily been treated with lamivudine alone or in combination with adefovir. Long-term use of lamivudine is limited by its high rate of resistance, however, and adefovir should probably be avoided as well because of its slow onset of action and potential for nephrotoxicity. Newer antivirals such as entecavir and tenofovir are being evaluated for their role in these patients. Our patient’s hepatitis responded well to entecavir. He will likely require lifelong treatment because of his immunosuppression and the risk of reactivation of hepatitis B.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

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References
Corridor Consult

Early and Accurate Diagnosis of Sudden Sensorineural Hearing Loss

Barry Rasgon, MD
Luke James Schloegel, MD

Case 1
An obese man, age 57 years, with a medical history of depression presented to his primary care physician with three days of sudden left-sided hearing loss. He did not report pain, tinnitus, vertigo, or external auditory canal discharge. He said that he had not experienced any recent trauma, upper respiratory infection, or loud noise exposure or taken any ototoxic medications.

His physical examination revealed normal-appearing external auditory canals and tympanic membranes. The membranes exhibited good mobility with insufflation. Findings on the Rinne test with a 512-Hz tuning fork were consistent with air conduction greater than bone conduction on the right side; the left side could not be tested because of profound hearing loss. Findings on the Weber test with a 512-Hz tuning fork were lateralized to the right side. On the basis of the patient’s medical history and physical examination findings, the primary care physician suspected sudden sensorineural hearing loss, prescribed oral prednisone, and referred the patient for urgent audiologic and otolaryngologic examinations. At the four-week follow-up examination, an audiogram showed return of hearing to near baseline on the left side.

Case 2
A woman, age 54 years, with hypertension, presented to the urgent care clinic with two days of right-sided hearing loss and right ear fullness. She reported that she had recently had an upper respiratory infection. Physical examination revealed a normal tympanic membrane appearance and mobility, so a tuning-fork examination was not done. The physician diagnosed eustachian tube dysfunction (ETD) and gave the woman oral decongestants.

She was referred to the Head and Neck Surgery Department when there was no change in her symptoms two weeks after onset. After a thorough medical history was obtained and a physical examination, tuning fork tests were performed showing lateralization to the left ear on Weber test. An audiogram was obtained that showed severe right-sided sensorineural hearing loss, and a diagnosis of sudden sensorineural hearing loss was made. The patient was given oral prednisone and acyclovir. Later, magnetic resonance imaging (MRI) with gadolinium enhancement of the internal auditory canals revealed no retrocochlear lesion. A follow-up audiogram obtained two months after initial presentation showed no improvement in the patient’s hearing.

Discussion
These case presentations illustrate the difficulty of accurate diagnosis of idiopathic sudden sensorineural hearing loss (SSNHL), treatment of patients who present with it in the primary care setting, and the variable prognosis for the disorder. Briefly, SSNHL is defined as a 30-dB hearing loss in three consecutive frequencies whose onset is less than three days. Its incidence in the US has been reported at 5 to 20 cases per 100,000 persons annually. Although numerous etiologies and treatments have been considered, most researchers agree that SSNHL is likely to be of vascular, immunologic, or viral origin.

SSNHL is regarded as an otologic emergency, and the time between symptom onset and treatment initiation is one of the most important prognostic factors. Most studies report the greatest recovery of hearing when corticosteroids are initiated within the first one to two weeks after symptom onset and little if any benefit when initiated four weeks or more after the onset of symptoms. Ideally, corticosteroid therapy should be started as soon as possible, with an audio-
gram performed within 24 to 48 hours to document the hearing loss. The severity of the hearing loss at presentation is directly proportional to the likelihood of recovery. Those with mild losses usually obtain full recovery, and those with profound loss rarely do so.\textsuperscript{1,2} Other poor prognostic indicators are the presence of vertigo and age <15 years or >60 years.

Primary care physicians, in the Emergency Department, Urgent Care Clinic, or Outpatient Clinic, are often the first clinicians consulted for sudden hearing loss, making accurate diagnosis and treatment critical because delay can have serious consequences for prognosis. A recent study that we conducted revealed that 33 of 53 (63%) patients whose hearing loss was eventually diagnosed as SSNHL were initially given an incorrect diagnosis by the primary care physician. Most often, that diagnosis was ETD. This led to an average delay in referral for audiologic and otolaryngologic examination of 20.8 days.\textsuperscript{3}

As seen in the illustrative cases, the hearing loss is incorrectly attributed to ETD and other diagnoses such as otitis media with effusion, because many patients with SSNHL have had a recent upper respiratory infection, and this acts as a red herring. Ear fullness is also a common presenting symptom and often attributed by patients and clinicians to impaction of cerumen or congestion from allergies.\textsuperscript{2} Furthermore, monocular otoscopy is the only option for otologic examination by the primary care physician. Although it remains a very important diagnostic tool, it decreases the ability to accurately assess a normal tympanic membrane, adequately clear the external auditory canal of cerumen, and insufflate to assess mobility as compared with binocular otoscopy. Simple Weber and Rinne tuning-fork tests are available yet are not routinely performed by most primary care physicians.

Although there are a multitude of potential causes of SSNHL, most cases are idiopathic; therefore, focused history, physical, and ancillary testing are essential. The first goal of evaluation is to rule out conductive loss by a thorough examination of the tympanic membrane and assessment of its mobility. The most critical step may be the use of a tuning fork to conduct the Weber and Rinne examinations. In the Weber test, a 512- or 1024-cycle tuning fork is placed on the forehead, on the premaxilla, or between the incisor teeth. If the sound is localized by the patient to the contralateral side of the involved ear, then the hearing loss is sensorineural. In unilateral conductive loss, the sound is localized to the involved side. The Rinne test, which compares loudness of sound when a tuning fork is placed on the skull versus near the external auditory canal, may supplement the diagnostic information obtained from the Weber test.

Although they are not good independent tools for screening for hearing loss, the Weber and Rinne tests should be used primarily to differentiate sensorineural from conductive hearing loss to accurately distinguish SSNHL from other causes of sudden hearing loss such as ETD and otitis media with effusion, which will not cause the sound to be localized in the contralateral ear. In our study, there was evidence for the efficacy of Weber and Rinne tests for patients with suspected SSNHL: Nine of the ten patients who underwent a documented tuning-fork examination performed by a primary care physician were initially given an accurate diagnosis of SSNHL, but of the 43 for whom no documentation of a tuning-fork examination was found in the chart, only 11 were given accurate diagnoses.

The goal of the initial evaluation of patients with suspected SSNHL is urgent referral to an audiologist and head and neck surgeon so that further workup can be conducted as necessary (see Figure 1). In patients who do not have contraindications to systemic

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![Figure 1](image)

**Figure 1.** Clinical algorithm for evaluation of patients with suspected sudden sensorineural hearing loss (SSNHL).

HNS = Head and Neck Surgery
Early and Accurate Diagnosis of Sudden Sensorineural Hearing Loss

Steroid treatment, medical treatment with oral steroids for 10 to 14 days should be carried out. There is no agreed-on dose or duration of treatment; many clinicians recommend starting with 60 mg of prednisone for five days, followed by a taper by 10 mg every two days. Medical therapy remains controversial because spontaneous recovery of hearing has been reported in 45% to 65% of patients with SSNHL and because good clinical studies are lacking. Wilson and colleagues5 performed a double-blind clinical study and found that steroids were effective in achieving at least partial recovery of hearing in 61% of patients, compared with only 32% who achieved recovery with the use of placebos. Intratympanic application of steroids to the middle ear has proven to be effective in some patients in whom SSNHL had been refractory to oral steroids. New research is examining the efficacy of intratympanic dexamethasone as first-line therapy. In a recent study, Battaglia and colleagues showed that intratympanic dexamethasone and high-dose prednisone taper (HDPT) used in combination resulted in higher rates of hearing recovery and better quality of hearing recovery than HDPT alone. In the future, initial treatment with intratympanic steroids may be indicated. At the conclusion of their study, Battaglia and colleagues recommended that treatment be initiated as quickly as possible, ideally within ten or fewer days of onset of hearing loss and that referral be made to an otolaryngologist who is comfortable with transtympanic injection. This reinforces the algorithm of accurately identifying SSNHL by using a tuning fork, starting oral steroids when not contraindicated, and providing urgent referrals to audiology and Head and Neck Surgery Departments for further treatment.

There is no evidence that antiviral medications make any difference in hearing outcomes. Two prospective, randomized, double-blind, placebo-controlled, multicenter clinical trials showed that antiviral medication was no better than corticosteroid alone in the treatment of SSNHL.

A thorough discussion of all possible etiologies and diagnostic tests for sudden sensorineural hearing loss is beyond the scope of this article, but there are some basics to be aware of: Gadolinium-enhanced MRI examinations are routinely obtained in all patients with asymmetric sudden hearing loss from which the patient does not recover after four weeks, because vestibular schwannoma rarely presents as sudden hearing loss. Obtaining a thorough medical history investigating possible causes, including autoimmune diseases, inner ear trauma, ototoxic medications, vasculopathies, and viral exposures, can eliminate the need for exhaustive diagnostic testing. Some advocate administering the fluorescent treponemal antibody absorption test or the microhemagglutination test for Treponema pallidum because syphilis is a potentially treatable cause of SSNHL. Furthermore, Ménière disease can initially present with sudden hearing loss, but the natural course usually defines these distinct entities. In rare cases, sudden hearing loss can be the initial presentation of multiple sclerosis, and MRI is frequently diagnostic.

Conclusion

Because most times SSNHL is idiopathic despite extensive diagnostic testing, the focus of initial evaluation of patients with sudden hearing loss is to distinguish a sensorineural from a conductive loss. If this cannot be reliably done with otoscopic examination, the use of the Weber and Rinne tuning-fork tests can help differentiate between the two. Once a sensorineural hearing loss is confirmed or suspected, urgent referral for audiologic and head and neck surgery evaluation should be made. In patients who can tolerate systemic steroids and are aware of the potential side effects, medical treatment with oral steroids should be initiated. Accurate diagnosis and early treatment has been shown to lead to better hearing outcomes in SSNHL.

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References

Josh Schechtel, MD, is a hospital-based Pediatrician and Chief of Professional Staff Education at the Oakland Medical Center in Oakland, CA. He has been drawing, designing gardens, and fabricating tile mosaics for many years and started painting about two years ago. Dr Schechtel says that his streetscapes attempt to address the interaction between the geological forces that have created the topography of San Francisco: the plants and other natural elements of the environment, and the roads and buildings that humans have constructed on it. Although none of these elements are unique to San Francisco, the whole is greater than the sum of its parts, creating a unique sense of place, and it is this synergy that fascinates him. These relationships are not always comfortable or easy. They contain many compromises and awkward situations, which make it a more interesting, vibrant place to work.

More of Dr Schechtel’s work may be seen at: www.joshschechtel.com.
Statement on behalf of the Kaiser Permanente Medical Care Program before the Committee on Health, Education, Labor, and Pensions; United States Senate on January 15, 2009

Investing in Health IT: A Stimulus for a Healthier America

Senator Mikulski (D – MD) and Senator Enzi (R – WY) and other distinguished members of the committee, thank you for the invitation to be here today. I am Dr Jack Cochran, the Executive Director of The Permanente Federation—the national umbrella organization for the regional Permanente Medical Groups. The Permanente Medical Groups employ more than 14,000 physicians, who care for approximately 8.7 million Kaiser Permanente (KP) members. I appear today on behalf of the national KP Medical Care Program, the nation’s largest integrated health care delivery system.

The Promise of Health Information Technology

As Congress considers ways to stimulate the economy, it should explore investing in the nation’s health care delivery system. I am delighted to be here to discuss how promoting the effective use of health information technologies can improve health care quality, efficiency, and literally save lives.

Medicine is far behind other industries in adopting and leveraging information technologies. While other industries have been quick to automate, the health care industry has often been slow to adopt.

Individual medical records, medication lists, along with the latest medical research and up-to-date information on applicable clinical trials must be available for clinicians and patients at the click of a mouse. Under appropriate patient confidentiality safeguards, secure electronic health records (EHRs) should allow various health care providers across vast geographic spans to collaborate and coordinate care for their patients based on current, comprehensive clinical information. The economic stimulus package should promote the development of effective, interoperable clinical information systems and the skills to use them.

But it is important to link these improvements in processes with systemic changes in financial incentives to continually advance the effectiveness and reliability of health care delivery. As you know, our nation’s health care delivery system is fragmented, disorganized, and hampered by ineffective and perverse incentives for quality and efficiency. Health information technology (HIT) is one critical tool that can help move our system toward a highly functioning, organized, patient-centered one. However, it is important that these investments be strategic and worthwhile. As one wise policymaker quipped, “Making the wrong investments in HIT could simply result in doing the wrong things faster.”

Kaiser Permanente

When she invited me to speak today, Senator Mikulski asked me to share some of the lessons we’ve learned in developing what we believe is the world’s largest civilian deployment of an EHR. As Senator Mikulski knows, we are proud to serve members in the state of Maryland. We also provide health care to nearly nine million individuals in eight other states, including California, Oregon, Colorado, Georgia, Hawaii, Ohio, Virginia, Washington, and the District of Columbia.

At KP, we have found strength and opportunity through the fundamental and often unique partnerships within our organization: the physician and patient relationship; the collaboration between labor and management; the linkage of clinical research to improved care delivery; our investments and involvement in the communities we serve; and the shared coordination of care across inpatient, outpatient, ancillary services, and all the settings of care delivery.

In 2003, KP began the KP HealthConnect™ project. KP HealthConnect is a comprehensive health information system that includes one of the most advanced

John H Cochran, MD, FACS, is the Executive Director of The Permanente Federation in Oakland, CA. E-mail: jack.h.cochran@kp.org.
COMMENTARY

The EHR has allowed our physicians to be more productive in patient care. We have seen a 20% reduction in productivity in the first three to six months, and you should not expect immediate cost savings. You have to go slow to go fast. Initial stages of implementation must be well planned and tested. Patience is key, and physician leadership is critical.

Physician Adoption and Acceptance of HIT

In April 2008, we completed implementation of KP HealthConnect in every one of our 421 medical office buildings, ensuring that our 14,000 physicians and all other ambulatory caregivers have appropriate electronic access to their patient’s clinical information. In addition, we have completed the deployment of inpatient billing; admission, discharge, and transfer; and scheduling and pharmacy applications in each of our 32 hospitals. Now, we are in the midst of aggressive installation schedule for bedside documentation and computerized physician order entry (CPOE). As of the end of 2008, we had 25 of our 32 hospitals fully deployed. (An interesting anecdote: the new hospitals we are building in California as a response to the seismic upgrade requirements are being built without medical record rooms.)

Now, you may ask, did this all happen easily? Did our physicians and nursing staff immediately embrace our EHR? The simple answer is, no. Any major transition like this requires fundamental change in workflows. We had to build in time for testing, training, and some belly aching too. But if we tried to take KP HealthConnect away from any of our doctors and nurses now, a riot would ensue.

Implementing HIT in a clinical setting is tremendously disruptive. You have to expect about a 20% reduction in productivity in the first three to six months, and you should not expect immediate cost savings. You have to go slow to go fast. Initial stages of implementation must be well planned and tested. Patience is key, and physician leadership is critical.

Change can cause apprehension and concern. If not handled properly, it can also interfere with the quality of care that is delivered. In an outpatient setting, you can build in time for training by scheduling patients differently or making sure you do not implement a new IT system during flu season, for example. In an inpatient setting, you simply do not have the same flexibility, so the challenges are different.

At first, Permanente physicians were reluctant to complete after-visit summaries as a written acknowledgment of everything that was discussed during the visit. These after-visit summaries are stored in each patient’s EHR. Because patients can access them later, the summaries can help remind them about what they and their doctors discussed regarding medications, follow-up treatment, etc. Primary care providers who give their patients an after-visit summary typically score an average of 14 points higher on satisfaction surveys.

Since the deployment of our integrated medical record, we have begun to see major advances in using health information systems as a diagnostic tool (for identifying and understanding patients with certain risk factors) as well as for appropriate therapeutic intervention (for encouraging adherence and for intensification or moderation of therapy when needed).

The EHR has allowed our physicians to be more efficient by giving them better practice management and communication tools that help them reduce unnecessary visits and phone calls. Today, our doctors don’t ask, “How many patients can I see?” but rather, “How many problems can I solve?” Data gathered in three of our regions (Colorado, Hawaii, and the Northwest) demonstrate how implementing an EHR lowers both primary and specialty care office visit rates by enabling the clinician to resolve certain issues for patients with fewer face-to-face contacts. For example, a simple response to an e-mail may be all that a patient needs from his or her doctor. Because our system allows our physicians to view appropriate medical information online, patients and physicians can interact with each other when it’s most convenient for both of them.

Patient Acceptance and Adoption of HIT

One of our greatest lessons has been how much KP members value the ability to use online tools to manage their health. Launched in 2005, our personal health record, My Health Manager, now has more than two

One of our greatest lessons has been how much KP members value the ability to use online tools to manage their health.
Investing in Health IT: A Stimulus for a Healthier America

What could be better coordinated. Our early results demonstrate 1) there will be no duplication of effort to collect data that already exists; 2) the insights of one physician’s office, an EHR can be shared among all physicians caring for a patient. For example, when a physician’s visit takes three hours out of an individual’s day, so members value the ability to use My Health Manager on kp.org to handle routine health care needs, including refilling their prescriptions, which can be delivered directly to their home or a pharmacy. Results from a study published in the American Journal of Managed Care showed an 8% reduction in office visits and a 14% reduction in phone calls among My Health Manager users. The study also confirmed that secure messaging is used primarily for nonurgent issues; nearly two-thirds were coded as “brief” or lower.

Transforming Health Care Delivery

While we have documented some specific dollar savings, our greatest benefits are improvements in clinical and service quality. With 24/7 access to comprehensive health information, our care teams are able to coordinate care at every point of service—physician’s office, laboratory, pharmacy, hospital, on the phone, and even online. Unlike the paper chart locked in a physician’s office, an EHR can be shared among all physicians caring for a patient. For example, when a patient comes into the Emergency Department at 2 am: 1) there will be no duplication of effort to collect data that already exists; 2) the insights of one physician are more easily available to others; and 3) care can be better coordinated. Our early results demonstrate what Crossing the Quality Chasm predicted: HIT helps to make care safer, more effective, patient-centered, timely, efficient, and equitable.

Through our experience with KP HealthConnect, we have found that implementing the technology was just the first step. A far more crucial endeavor is determining how to translate the data collected within the system into useful information that will deliver value. It’s not just about digitizing the visit—it’s about using the data from that visit and other sources to inform and ultimately to transform care delivery.

For example, our use of HIT and our comprehensive approach (partnership of primary care providers, cardiologists, nurses, and pharmacists with accountability across the continuum of care—preventive, chronic, and acute) have significantly reduced Emergency Department visits and mortality. In Colorado, we have seen a 76% reduction in cardiac mortality for those who participated in our Collaborative Cardiac Care Service compared with those who received regular treatment. Based on NCQA data, as compared to the national HMO average, we prevent more than 280 cardiac events annually in Colorado. This improvement saves $2 million in annual hospital costs. In Northern California, if you are a member of KP, you have a 30% less chance of dying of heart failure compared to a member of the general population. In Oregon and Washington, by using KP HealthConnect in a new Regional Telephonic Medicine Center staffed with emergency room physicians and advice nurses, we have achieved an 11% reduction in the number of members who need to visit the emergency room between the hours of 12 noon and 10 pm. In Southern California, from 2004 to 2007, combining the power of our IT systems and our integrated delivery model, we were able to increase mammography screening rates for women aged 50-69 from 80% to nearly 90%.

This last example was highlighted for me by a recent letter that puts a human face on these statistics:

Early last year, I came to your facility to have a foreign body removed from my eye. I visited your Ophthalmology Department, and your competent staff dealt with this minor emergency.

What made this visit so meaningful was my interaction with your nurse after my visit with the doctor. In addition to giving me some after-visit instructions, she noticed in the computer that I needed a mammography exam. I had been reminded before, but I tend to be too busy to take care of my own health. This time the nurse was very insistent. She even made me an appointment so I could walk in and get an exam within the hour. Since I did not have to wait too long, I had an exam done that day. Well, they found a mass in my right breast, and it was cancer. I have gone through chemotherapy and radiotherapy, and today I am cancer free.

I am convinced that I am alive today because
of your organization’s focus on my total health. My interaction with your entire health care system has been nothing but positive. I am especially appreciative to the young nurse who took the time to convince a stubborn old lady to take responsibility for my health.

Thank you for giving me many more years to thrive.

This letter describes a simple act by one of our nurses that was possible only because the nurse had access to that patient’s information, acted on it, and was part of an integrated health care system that encourages this series of events.

KP HealthConnect also allows us to share content across all regional facilities, providing the best technical platform to disseminate drug formulary changes, best-practice alerts, and automated clinical guidelines to the entire enterprise. Our members can move through any facility within a given region, and their clinical and administrative information will follow them.

As an example, during the 2007 wildfires in San Diego, when KP facilities within the fire lines closed, we contacted members and directed them to open facilities. When our members arrived at these new facilities, their new care teams had appropriate access to their records via KP HealthConnect, ensuring continuity of care in a time of crisis.

When we started down this path, KP faced many of the same barriers that other health care organizations and providers face today when they start to utilize HIT to improve care delivery. These barriers involve both process (eg, complexity of health care is increasing, workflows will be disrupted, end-to-end patient-centered view is not well known) and technology (eg, data is “locked away” in various paper files, applications, and databases; data standards, interoperability standards, usability standards must be integrated). I am here to tell you that these issues can be overcome.

KP and other multispecialty groups like Group Health Cooperative, Intermountain Healthcare, and Geisinger can set the gold standard with a sophisticated EHR and integrated care delivery systems. Harder to overcome are the misaligned incentives in systems that are not vertically integrated, because these do not encourage providers to redesign care delivery to incorporate evidence-based care processes for improving quality and effectiveness. As a nation, we can decide to create payment incentives that reward health professionals who share information, who learn from each other, and who hold themselves and one another accountable to generate the best health outcome at the most reasonable cost for each patient.

An Interoperable HIT System

Congress has the ability to create a system that is truly interoperable. Today, far too often, our systems speak different languages. Even when electronic information exists for patients, critical clinical information can be lost during an emergency or when patients transfer from one system to another because the different systems simply cannot communicate with one another.

After discussing interoperability of medical records for years, KP recently demonstrated successful data exchange of health records involving our shared patient population with the Veterans’ Administration. This demonstration project uses test data for fictitious patients, but it also shows that privacy and security requirements will work to protect real patient data. The demonstration uses the national interoperability standards recognized by the Department of Health and Human Services (HHS), proving they work in the real world.

Sound HIT policy should stress the critical importance of standards-based interoperability to achieve coordinated patient-centered health care. The ability of separate HIT systems to interconnect with each other depends on uniform adherence to strictly defined standards. Most of these standards exist today. KP supports the HHS-adopted interoperability standards selected by the Healthcare Information Technology Standards (HITSP) and used in the National Health Information Network (NHIN).

Only when these existing technical standards are used consistently across the delivery system will HIT be able to achieve its promise for both direct care of individual patients and for population-based care.

Connected HIT will not be adopted by most clinicians and institutional providers without mandates or a system of incentives and penalties that are materially more advantageous or costly to providers than those outlined in current and previous proposals. For instance, one approach could use Medicare conditions of participation as a means to promote adoption, with metrics for adoption of HIT, determined by the Secretary and used by HHS as benchmarks. Achieving benchmark measures for HIT could trigger loan forgiveness or incentive payments.

Above all, dollars should be attached to outcomes. For example, organizations that receive HIT incentives...
could be required to adhere to certain clinical care pathways or demonstrate that they have “functional EHRs.” This may mean that their EHR must show it is capable of sending and receiving lab, pharmaceutical, and other clinical information—not just payment claims information.

HIT system functions and interoperability are essential cornerstones for policies such as primary care-centered medical homes, coordination of care for chronic conditions, value-based care, comparative effectiveness research, and pay-for-performance/pay-for-quality initiatives. Some EHR-systems come as “blank slates,” with functionality, but without built-in clinical content or knowledge; these systems demand tremendous amounts of time, skill, and energy to harness the tools to the purpose of actually improving quality. Linking the implementation of HIT to health system reforms is essential. To promote appropriate and clinically effective uses of HIT over the mere acquisition of technology, the Secretary of HHS should develop and implement measures for HIT connectivity and data exchange as well as measures for EHR-based quality reporting.

Privacy

All consumers should be able to rely on appropriate and consistent minimum levels for privacy and security protections among all entities—both public and private—that access or use individual health information. A high level of trust in these protections is crucial for HIT to succeed. It will be important for Congress to strike an appropriate balance between the competing interests of protecting privacy concerns versus advancing HIT, EHRs, and public health initiatives. Both can be achieved. Today, many state laws risk slowing down the rate of progress by allowing consumers to opt out of disease registries and other community health initiatives due to privacy concerns.

We believe that HIPAA should remain the basis of new privacy rules. However, privacy policy also must cover personal health data consistently, regardless of what entity holds the records. Privacy requirements can achieve better protection for consumers without adding to the cost of HIT, changing the practice of medicine, or creating medical liability issues.

There are good models in state law for guarding against security breaches in ways that do not impede access to health information by clinicians; it is important to remember that the lack of appropriate and complete health information for clinicians who are treating a patient can also endanger that patient’s life.

In our experience, California law provides a model for breach notification that is clear and consistent across all types of entities, events, and circumstances. We believe HIPAA disclosure accounting for treatment, payment, or health care operations purposes would add a significant amount to the total cost of HIT implementation and could harm the practice of medicine by disrupting clinical workflows. HIT innovators should not be penalized by regulations that force unnecessary or disproportionate system overhauls to achieve compliance, especially when such modifications will consume resources that could be spent to deliver high-quality care. Efficiency should be a goal of new investments and rules.

Improving Safety, Quality, and Efficiency

The real objective of HIT in the economic stimulus package should not be technology, but rather to improve safety, quality, and efficiency.

At KP, we believe the keys to the solution will be health care led by clinicians, integrated with functional IT systems, and staffed with innovative, enthusiastic, computer-enabled health care professionals.

Having HIT and the means to exchange information will do us little good if we do not foster and support better information about the effectiveness of care, including the relative benefits, risks, and costs of treatments and services. We need a robust federal commitment to comparative effectiveness research so that health professionals can ensure each individual patient gets the care that is right for him or her. Reforms must also ensure that patient information can be used not only to optimize care for one specific patient but also to improve care for all patients through, for example, the development of clinical care guidelines and disease management protocols. These goals require the use of patient information and appropriate access to patient records, with privacy safeguards as currently required under HIPAA rules.

Ultimately, however, to effect real change, provider payment systems should be based on value rather than the number of procedures, drugs, tests one orders—regardless of whether the best evidence calls for such action. To keep coverage affordable and to really fix our broken health care system, we must change the way we deliver and pay for health care. Financial incentives must be changed so that plans compete on quality and efficiency, providers are rewarded for quality and keeping their patients healthy rather than for the volume of services delivered, and individuals are encouraged to
seek high-quality care and to be more actively involved in maintaining their own health.

We believe a computerized care support system that is well designed and implemented appropriately can help restore and enhance the physician’s healing mission. Maximizing information available to the clinician means optimizing care for the patient. The right systems will yield more time with patients, better information about care, and less time with traditional paperwork. The right systems also must focus on the patient’s need for affordable, well-informed, customized, and compassionate care. We believe a new HIT system will support our nation’s health care reform agenda and can help our nation fulfill its ethical responsibility to improve health care access, reduce costs, and ensure quality care for all.

We look forward to working with you to achieve these goals.

References

A Quantum Leap

America needs to move much faster to adopt information technology in our health care system …. Electronic health information will provide a quantum leap in patient power, doctor power, and effective health care. We can’t wait any longer …. Health information technology can improve quality of care and reduce medical errors, even as it lowers administrative costs. It has the potential to produce savings of 10% of our total annual spending on health care, even as it improves care for patients and provides new support for health care professionals …. This plan sorts out the myriad of issues involved in achieving the benefits of health information technology, and it lays out a coherent direction for reaching our goals.

— Health and Human Services News Release, July 21, 2004: Thompson launches “Decade of Health Information Technology,” Tommy Thompson, b 1941, US Department of Health and Human Services Secretary
In 1991, Nelene Fox, a 38-year-old mother of three, was diagnosed with breast cancer. She underwent bilateral mastectomies and chemotherapy but nonetheless developed bony metastases. Her physicians said her only chance for survival was high-dose chemotherapy and autologous bone marrow transplantation. Her Health Maintenance Organization (HMO) refused to cover the procedure (around $140,000) on the basis that it was experimental.

Her husband launched a successful fundraising effort, and Mrs Fox received the procedure, but died eight months later. Her brother, an attorney, sued the HMO for the delay in her therapy, and won $89 million in damages. Similar lawsuits played out across the country with similar awards.

For the media, this was an irresistible David and Goliath story: relatively powerless individual patients were bringing insurance companies and HMOs to their knees. Reporting focused on access to the new technology, not questioning whether it was effective. With the media frenzy and lobbying, lawmakers began requiring insurance coverage for the new procedure. Insurers, facing lawsuits, bad publicity, and new legal requirements, began to routinely cover the new procedure.

Doctors and hospitals were generally enthusiastic, optimistic, and sincere in supporting the new regimen for late-stage breast cancer, and the new approach was a financial windfall for physicians and hospitals. Clinicians became vocal advocates for the procedure, and frequently were witnesses in court. Many joined complaints against insurers. Some hospitals built new wings to accommodate patients having the procedure.

However, as clinical trial results rolled in, the story began to unravel. An early positive report from researchers in South Africa proved to be fraudulent. National Institutes of Health (NIH)-sponsored trials, long delayed, finally showed the new treatment to be no more effective than standard chemotherapy, but more toxic. The trials were delayed because women were convinced the procedure was effective, and few were willing to submit to randomization with a chance of receiving standard therapy. By the time the negative results became available, 42,000 women in the US had been treated at a cost of $3.4 billion.

The approach was rapidly abandoned, but, in retrospect, medical theories, professional egos, wishful thinking, financial incentives, and the media helped disseminate a new technology that decreased quality of care and increased costs. Clinicians sincerely believed the treatment was effective, but theoretical advantages and financial incentives may have obscured the lack of sound evidence. When access to care is a problem for millions of Americans, one may reasonably ask if there were better ways to deploy $3.4 billion.

Other Technologies that Increased Cost, but not Quality

Other “advances” that increased costs without improving quality are easy to find. Rofecoxib (Vioxx) was recalled after its association with myocardial infarction became apparent, but only after, by one estimate, 140,000 avoidable heart attacks. Most who took it would have done as well with ibuprofen because they had a low risk of gastrointestinal bleeding. Nonetheless, rofecoxib resulted in expenditures of nearly $2.5 billion per year while it was on the market.

Arthroscopic debridement and lavage for knee osteoarthritis has been a popular treatment. However, randomized trials suggest it is no more effective than sham surgery or rehabilitation. Nonetheless, costs of the procedure were estimated at $3 billion per year.3

The Antihypertensive and Lipid-Lowering treatment to prevent Heart Attack Trial (ALLHAT) suggested that old-fashioned thiazides were at least as effective as several newer...
drugs in preventing complications of hypertension. Nonetheless, their use had declined over several decades in favor of newer, more expensive drugs. Some estimated that greater use of diuretics might have prevented 70,000 myocardial infarctions and strokes per year— and saved $1.2 billion per year.6

These expensive, marginal treatments became widely used without adequate scientific evaluation or comparison to competing treatments. They demonstrate that new treatments are sometimes less effective or less safe than alternatives, yet we often learn this only after avoidable harm and expenditure.

These examples suggest that marketing, politics, media, and advocacy sometimes trump scientific considerations. Furthermore, physicians are often eager to adopt new technologies, hoping they will overcome the limitations of current approaches. However, “jumping the gun” before rigorous evaluation makes it hard for all of us to practice evidence-based medicine. And the resulting waste of resources occurs at a time when health costs are soaring and fewer Americans can afford insurance each year. Only recently have policy makers begun to address the need for better assessment of new technology and studies of comparative effectiveness.

Although many stakeholders share responsibility for disseminating marginal technology, an important factor has been the growth of industry-sponsored research.10 Sometimes focused on getting the “right” results or masking the “wrong” results.11 Sometimes professional organizations align with industry to suppress unwelcome results.12 How do these events happen and how might we improve the trustworthiness of our scientific base?

**Industry Sponsorship of Research: Getting the “Right” Results?**

A growing literature documents that industry-sponsored research produces results favorable to its own products more often than independent research.13-15 For example, 90% of industry-sponsored trials of antipsychotic drugs favored the sponsor’s drug, sometimes producing contradictory results.16 Among trials comparing olanzapine with risperidone, those sponsored by Lilly favored olanzapine five times out of five. In contrast, trials sponsored by Janssen favored risperidone three times out of four.17

How can seemingly well-designed studies reach conflicting conclusions? There are several strategies for making research results as favorable as possible.

In designing a comparison group, one might choose a high dose of a competitor’s drug that produces more side-effects than the sponsor’s drug, or a less-effective low dose of the competing drug.18,19 In some studies, oral antifungals were compared to competitor drugs that were poorly absorbed by the oral route.20

Selective reporting of subgroups, side-effects, or outcome measures is another strategy. If just one subgroup shows an advantage for the sponsor’s drug, it may be reported without results for other groups. Similarly, if one outcome measure among several shows a favorable result, it may be reported to the exclusion of others.21

Another strategy is to publish favorable results multiple times. Authors of a systematic review on risperidone found the literature to be “vexing,” “bewildering,” and “intolerably time consuming” because of overlapping reports.22 They discovered that 20 articles and several unpublished reports actually represented only seven small studies and two large ones. One larger study was reported in six publications with different authors and no reference to the others. Similar redundant reports have been identified for ondansetron, fluconazole, and nonsteroidal anti-inflammatory drugs. In each case, the duplicate data inflate apparent drug efficacy.23-25

Ghost writing and guest authorship comprise another important strategy for favorable publications. In this situation, research reports, editorials, or reviews are written by a professional writer hired by a drug company or a public relations firm. A medical authority is invited to be named as the author, and gives final approval to the article. The ghost writer’s name does not appear, but s/he has already framed the arguments in the most favorable light. In “Whose article is it anyway?” by Marilyne Larkin, writer Ronni Sandroff described her experience in writing two cancer pain articles “for MD signatures” intended for peer-review journals. She was told exactly what the drug company expected and given explicit instructions about what to play up and what to play down.26 Recent revelations regarding rofecoxib demonstrate that dozens of articles were prepared in this way.27

**Suppressing Unfavorable Results**

Finally, unfavorable trial results can be buried. Companies argue that their data are proprietary and there is no requirement that all results be published. A recent examination of FDA-registered studies for antidepressant drugs illustrated the problem. Of 74 registered studies, only 51% had a positive result for the sponsor’s drug according to FDA
review. However, 94% of published trials favored the sponsors’ drugs. Among 36 studies that the FDA judged as negative or questionable, 22 were never published; 11 were published with a positive spin to the discussion; and only three were published as negative trials.27

Company-sponsored research conducted by university investigators may seem less susceptible to manipulation. However, a recent survey of university-industry agreements suggested that academic institutions routinely participate in clinical research that does not adhere to recommended standards (from medical editors) for accountability, access to data, and control over publication.27

A striking example of suppressing results occurred at the University of California, San Francisco. In 1987, Betty Dong, MD, was approached by the predecessor to Boots pharmaceuticals, maker of Synthroid (generic: levothyroxine), to compare its product with generic competitors. Synthroid had dominated the market, thanks to concerns that other thyroid preparations had less consistent bioavailability. However, Synthroid’s market share was eroding, so Dr Dong was approached to compare Synthroid with three competitor drugs.28

Dr Dong’s study, completed in 1990, unexpectedly found that the four preparations of thyroid hormone were equivalent. Although Boots had handpicked Dr Dong, specified the study design, and made frequent quality assurance visits, executives suddenly objected to nearly all aspects of the study, and complained to university officials. Two investigations found only minor and easily correctible problems. One outside expert said, “The Boots people were deceptive and self-serving.”29

These events were a prelude to legal threats that blocked publication of the results. The company cited a clause in Dr Dong’s contract, even though restrictions on publication were contrary to university policy. This occurred in 1994, when Dong’s paper was accepted at the Journal of the American Medical Association (JAMA). Two weeks before scheduled publication, in the face of legal threats, the authors withdrew the manuscript.

While these events were unfolding, Boots was selling its drug division to a German company for $1.4 billion. Boots became part of Knoll Pharmaceuticals, and analysts suggested that publication of Dr Dong’s results would have been disastrous for Boots and its sale value.29

Eventually, in the face of negative publicity and pressure from the Food and Drug Administration for possibly misleading claims, the company relented. In April 1997, JAMA published the article along with Knoll’s cautious apology and continued objections.28,30

Knoll subsequently faced a class action lawsuit by consumers, alleging they were overcharged for medication because data on bioequivalence were unavailable. Knoll denied efforts to suppress publication but offered $135 million to settle the suit. Knoll later paid 37 states another $41.8 million to settle charges that it made deceptive statements about Synthroid.

Although this episode may seem extraordinary, attempts to suppress unwelcome news may be business as usual. Herb Needleman, MD, of Yale was attacked by the lead paint industry for many years, after demonstrating the neurotoxicity of lead in children. In 2007, the makers of OxyContin, the brand name for the time-released oxycodone, pled guilty to fraudulent marketing claims and agreed to $634 million in fines, after hiding data on addictive properties of the drug.31 Similar claims of suppressing bad news and intimidating investigators appear with alarming frequency.

**Attacks on Funding Agencies**

Another strategy for minimizing bad news is to attack research agencies that fund unwelcome research. Examples included efforts to eliminate the Injury Prevention Branch at the Centers for Disease Control after it funded studies demonstrating a higher risk of gun violence in the homes of gun owners. Attacks came from the National Rifle Association and a group called “Doctors for Integrity in Research and Public Policy,” with views similar to those of the NRA.32 The National Center for Health Care Technology was a government agency with a brief lifespan in the 1970s, eliminated after lobbying by the drug and medical device industries.33 The Agency for Health Care Policy and Research (AHCPR) was almost eliminated after lobbying by a physician organization upset with research and guidelines the agency sponsored.12

In this last example, our research team demonstrated in the 1990s that spinal fusion surgery was the fastest growing type of back surgery in the US. At the time, pedicle screws were a relatively new technology for this type of surgery, and were growing in popularity. Our work challenged the effectiveness and safety of fusion surgery for some common indications, and recommended that it be subjected to randomized controlled trials.

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At the same time, a multidisciplinary panel sponsored by the same agency was producing clinical guidelines for acute low back pain. On the basis of extensive evidence, the panel recommended nonsurgical therapy for most acute back problems, noting there were no trials of fusion surgery for patients with acute back pain.

These findings elicited a backlash from the North American Spine Society, a multidisciplinary group dominated by orthopedic surgeons. The Society organized a letter-writing campaign to Congress, arguing for elimination of the AHCPR. A member of the Society’s board founded an advocacy organization dedicated to this aim. Finally, a manufacturer of pedicle screws sought a court injunction to block release of the back pain guidelines.12

These events unfolded during Congressional controversy over the Clinton health plan and leadership of the AHCPR. The combination resulted in a House bill in 1996 that eliminated the AHCPR. The agency was restored by the Senate after strong support from other professional societies, including the American Medical Association and the American College of Physicians. Nonetheless, the AHCPR ended its guideline work altogether and sustained a 25% budget cut, eliminating new research for several years and reducing existing grant budgets.

The story continues today. Several spinal device manufacturers are currently under investigation for alleged kickbacks to surgeons. In 2006, one company paid $40 million to the US government to settle accusations of “sham consulting agreements, sham royalty agreements, and lavish trips,” without acknowledging any wrongdoing.31

**Consequences of Inadequate Research and Suppressing Data**

Several important consequences may arise from suppressing research results, influencing scientific reports, or inadequately evaluating medical innovations. First, patients may be exposed to unnecessary risks. Second, harassment discourages research in controversial areas, exactly those most needing good scientific study. In effect, vested interests may determine the acceptable research questions and results. Eliminating public peer-reviewed scientific research funding may slow the emergence of new knowledge and push investigators to seek funding associated with conflicts of interests.32 Ultimately, disseminating marginal or ineffective technology increases costs of care without increasing quality, complicating health care reform.

**Improving the Evaluation and Value of New Technology**

What are some potential solutions to these problems? First, for physicians, a renewed sense of professionalism may be essential. While we value the professional attributes of altruism, service, self-governance, and deep knowledge, the business ethos is quite different. Here, the primary responsibility is not to patients but to shareholders. The drug, device, and supply industries create many jobs, and the main focus of attention is return on investment. This contrast between professional and business priorities led the Association of American Medical Colleges to argue recently that doctors, staff, and students in medical schools should avoid certain entanglements with industry. It recommended that individuals not accept free food, gifts, or travel from drug and device companies and not accept ghost-writing services. The report strongly discouraged participation in company-sponsored speakers bureaus.35

Practicing physicians should become familiar with the rules of evidence-based medicine, as a safeguard against misleading claims. A simple-minded definition of evidence-based medicine would argue that it is not enough to know if a treatment ought to work; if it makes physiologic sense; if it is common practice; if we learned it in medical school; if we’ve always done it that way; if an expert vouches for it; or if it works in mice.34 Instead, we need to ask what is the best evidence that a new treatment extends lives or improves quality of life, and what are the risks?

In addition, regulatory reforms are needed. Direct comparisons of competing drugs and devices are rarely mandated by the FDA but would be enormously valuable to physicians and patients. Legislative proposals for studying comparative effectiveness deserve support. Most agree that the FDA needs more resources and better methods for post-marketing surveillance of drug and device safety. I favor a requirement for randomized trials for devices that are surgically implanted in the body. The current threshold for approval is far less rigorous than for drugs, yet the need for evidence of clinical efficacy and safety is equally great. Both private and government insurers could help produce better evidence by supporting clinical trials as a condition of coverage when the evidence for new technology is weak.37

For the research enterprise, the peer review system must resist external influences in grant review and publication.
external influences in grant review and publication. This requires eliminating efforts to block publication, reviewers with conflicts of interests, and threats to editors from their advertisers. In some cases, new university policies may be necessary to support faculty who come under attack from vested interests. Public funding agencies should be vigorously defended.

For investigators themselves, it is essential to strive for impeccable science, and to have thick skin. Research on product effectiveness is a contact sport, and investigators should anticipate a backlash, including character attacks and intimidation, to unfavorable results.

Finally, we should foster more realistic public expectations of new medical technology. Americans, more than Canadians or Europeans, believe new technology can solve all our serious medical problems. We sometimes foster such expectations with our own wishful thinking, and because it is financially convenient to generate more procedures and more care. However, the public must understand now more than ever that “newly approved” does not necessarily mean new and improved. This understanding may be critical to freeing resources that facilitate better access to care.

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References
22. Huston P, Moher D. Redundancy,

That Which Shrinks

It is error only, and not truth, that shrinks from inquiry.

— Thomas Paine, 1737-1809, philosopher and writer
The drip-drip-drip method of torture mistakenly attributed to the Chinese but more accurately Italian in origin has proven pervasive and persuasive over the past year as more and more reports of prominent and preeminent physicians failing to report substantial amounts of money from pharmaceutical and medical equipment companies hit the media.

The raison d’être of drug companies is to maximize profits for their shareholders. This has led to an ongoing ethical conflict between marketing departments whose sole purpose is to increase sales versus the pharmaceutical companies’ educational departments where distinct separation of provided commercial support from the intent and content of educational interventions is considered paramount.

Most highly paid speaking engagements offered to internationally and nationally renowned physician researchers at top universities appear, unfortunately, to be paid from the marketing departments of pharmaceutical companies. It is becoming depressingly obvious that large and substantial payments are conveniently not reported to universities as policy requires. This has, predictably, not only tainted their reputations but also raised questions about the quality of the research activities.

Consider the case of Charles Nemeroff, MD, Chair of the Psychiatry Department at Emory University as reported in the New York Review of Books. He failed to disclose, per university policy, that for over 250 educational presentations to physician audiences he had received more than $1.2 million between 2000 and 2006 from several pharmaceutical companies, primarily GlaxoSmithKline. Dr Nemeroff was simultaneously the principal investigator of a five-year $4 million grant from the National Institute of Mental Health to study several GlaxoSmithKline drugs. Federal rules call upon him to report any amounts over $10,000 to the National Institute, a regulation conveniently overlooked.

Particularly egregious was the fact that Dr Nemeroff was investigated by Emory University in 2004 and was cited for multiple policy violations as a result of which he promised to report any remuneration in excess of $10,000 from any one company. He reported $9999 from GlaxoSmithKline that year while, apparently, actually receiving $171,031. In late December 2008, Dr Nemeroff was permanently relieved of his position as Chair of Psychiatry at Emory. However, the damage is done, raising questions about his research activities, his multiple educational presentations, and his influence worldwide as co-editor of the Textbook of Psychopharmacology (Arlington, VA: American Psychiatric Press; 1998).

Dr Nemeroff’s case is not a study in isolation. Reported in The New York Times is another world-renowned psychiatrist, Joseph Biederman, MD, of Harvard University, whose research has resulted in an exponential increase in the use of powerful antipsychotic medications for children as young as two years of age. He also failed to report more than $1.6 million in consulting fees from pharmaceutical companies from 2000 to 2007. Two other colleagues in the same department failed to report similar substantial income as well.

That such preeminent and sophisticated scientists apparently chose to cover up their conflicts of interest is a sad commentary on the state of ethics in our medical profession.

Awareness of these episodes is a result of a congressional inquiry through the efforts of Senator Charles Grassley (R-IA) of the Senate Finance Committee who is now turning his investigation from psychiatrists to cardiologists. There are already multiple examples of questionable ethical behaviors involving cardiologists and orthopedic surgeons where surgical device makers appear to have a cozy relationship with physicians.
Isn’t it Time to Stop Accepting Handouts for our Educational Efforts?

promoting their products. I would venture no medical specialty would be off limits.

Continuing education for physicians is a multibillion-dollar enterprise generously supported by pharmaceutical and medical device companies historically, amounting to approximately 60% of a total outlay of $2.7 billion in 2007. Increasing fears that the firewalls promulgated by the Accreditation Council on Continuing Medical Education (ACCME) are proving porous are buttressed by the stories related above and have led to an increasing consensus for the complete separation of commercial support from educational interventions.

In November 2007, the Josiah Macy, Jr Foundation released a report on continuing education in the health professions reflecting the conclusions of a group of preeminent medical educators that commercial support for continuing education risks distorting educational content and invites bias, raises concerns about the vows of health professionals to place patient interests uppermost, endangers professional commitment to evidence-based decision making, validates and reinforces an entitlement mindset among health professionals that continuing education should be paid for by others and impedes the adoption of more effective modes of learning. The report calls for a ban on commercial support for accredited organizations that provide continuing education and recommends that faculty of academic centers should not serve on speakers’ bureaus or as paid spokespersons for pharmaceutical or device manufacturers. In addition, the report decries the common practice of publishing articles, reviews, and editorials under the names of prominent academics that have been ghost written by industry employees and recommends its prohibition.

In April of 2008, a task force on industry funding of medical education from the American Association of Medical Colleges called on all medical schools to ban drug company food and gifts and to strongly discourage faculty from serving on speakers’ bureaus. Finally, the Council on Ethical and Judicial Affairs of the American Medical Association recommended the discontinuance of commercial support for medical education, a heroic stand soundly defeated by the June 2008 House of Delegates, perhaps a reflection of the entitlement mindset mentioned in the Macy report.

Stanford University, one of the leading providers of radiology CME, has historically held elaborate vendor-supported receptions linked to large meetings, including International Symposia on multidetector row CT, PET/CT and molecular imaging, neuroradiology, etc. These receptions have been noted for “full-sized CT ice sculptures, ‘mad-scientist’-inspired hors d’oeuvres, and dancers/acrobats in colorful costumes, futuristic helmets, and roller skates.” A new policy (http://cme.stanford.edu/documents/cme_commercial_support_policy.pdf), effective September 1 2008, changes everything. Under this new policy, no exhibits are allowed. According to Philip Pizzo, MD, “If company support has been linked either directly or indirectly to marketing goals, I expect that the funding support will decline.” Stanford University has been a leader in reforming interactions between industry and the medical profession, in research, in education, and in clinical care, and has restricted commercial funding since 2006 with its Industry Interactions Policy (available at: http://med.stanford.edu/coi/siip/), which addresses the issues raised here. (Philip Pizzo, MD, personal communication, 2009 Apr 30).

Cleveland Clinic has also started publicly reporting the business relationships that any of its 1800 staff physicians and scientists have with pharmaceutical companies and device makers. This is an understandable reaction to the increasing and ongoing furor on conflicts of interest that occur when physicians work closely with pharmaceutical companies and device companies in research and development, yet artfully neglect to have appropriate financial disclosures available to all and sundry.

The Permanente Medical Group (TPMG) adopted a strong revised conflict of interest policy for its physicians effective January 2005, whereby physicians are prohibited from receiving anything from commercial vendors; this includes funding for CME programs directed at TPMG physicians. The medical group has allocated sufficient funds to cover the shortfall resulting from the loss of commercial support. Sharon Levine, MD, Associate Executive Director, TPMG, faults the assumption that if you cap the amount of money you receive as a gift or a gratuity that somehow caps the level of influence. Rather, she points out, the social science literature is replete with research that supports the premise that it is not the size of the gift, but the gifting itself that creates the desire to reciprocate.

Because of the increasing scrutiny and with multiple examples of questionable practices and given the risk of eroding the trust of our patients, perhaps it is time to consider whether all physicians and employees in Kaiser Permanente will need to build on the foundation that TPMG and other medical groups, notably...
Isn’t it Time to Stop Accepting Handouts for our Educational Efforts?

The Northwest Permanente Medical Group and the Colorado Permanente Medical Group have started: the separation of commercial support from our educational endeavors nationwide would be a great start.

* Memo from Phillip A Pizzo, MD, Dean, Stanford University School of Medicine.

References

Nothing to be Ashamed Of

Among those who call themselves pure scientists, whatever their particular field, there are many who feel that they would demean themselves and lose caste among their fellows should they engage in researches which obviously point to some utilitarian purpose. This I have always regarded as an academic pose; for in the disinterested pursuit of knowledge, to stumble, as did Roentgen or the Curies or Banting, on something not only of great scientific importance but which at the same time was immediately applicable to human welfare, is certainly nothing to be ashamed of.

— Harvey Cushing, MD, 1869-1939, American neurosurgeon and pioneer of brain surgery
Dealing With Change: Using the Conditional Change Model for Clinical Research

Mikel Aickin, PhD

Introduction

Virtually all clinical medicine is about change. The criteria for deciding whether a therapy has been successful nearly always include consideration of the degree to which the patient’s initial condition has improved or to which a deteriorating condition has been stabilized. Both criteria depend on change. In the first case it is a rise in some measurement of benefit or drop in some measurement of burden, whereas in the second it is that a downward change has been prevented.

In clinical research, therefore, one of the most frequently used approaches is to compare changes in a treated group with corresponding changes in a control group. Perhaps the most notable pedagogic failing of statistics courses and textbooks is that they do not present the appropriate way to analyze data coming from this design, which explains why published analyses are so often suboptimal, if not actually incorrect. The purposes of this article are to explain what should be the default method of analyzing change data and to indicate how to compute and display the results graphically.

Regression to the Mean

One of the earliest observations, by Sir Frances Galton (1822-1922), was the tendency of change scores to be negatively related to baseline values. In fact, the regression procedure got its name from this phenomenon, which Galton called “regression to the mean.” The notion that regression to the mean was a real biologic phenomenon supported the early 20th-century eugenics movement, especially in Great Britain. The great statistician RA Fisher (1890-1962) was an ardent participant in that movement. Although it is possible for there to be true regression to the mean, in most cases the phenomenon is artifactual. It arises from the fact that if, over time, a biologic quantity must remain in a certain range, to ensure survival of the organism, then it is automatic that high values at one time will tend to be followed by smaller values a little later on, and conversely low values at one time will tend to be followed by larger values a little later on. Thus, regression to the mean is an inevitable consequence of a time sequence of measurements needing to stay in some viable range. The fact that it is not a biologic effect but only a statistical one does not diminish its influence when one is looking at change.

The Conditional Change Model

The simple change design can be described as follows (Table 1): Each patient yields a measurement, \( y_0 \), at the start of the study, the so-called baseline measurement. At the end of the study, each produces another measurement on the same scale, \( y_1 \), the endpoint measurement. There is a further treatment variable \( x \) (such as a drug) that takes the value 0 for each patient in the control group and the value 1 for each patient in the treated group. It is called an indicator because it points to the treated patients. The purpose of the study is to compare pre-post changes \( y_1 - y_0 \) between the treated \((x = 1)\) and control \((x = 0)\) groups.

The most common advice in statistics texts is that this comparison should be made by applying a two-
sample t-test to the change scores. The null hypothesis is that the mean changes in the two groups are equal. Although it is not particularly well-known, one can carry out the two-sample t-test with a linear regression program. Figure 1 shows the mathematical model for a single patient.

$$y_1 - y_0 = \beta_0 + \beta_1 x + e$$

<table>
<thead>
<tr>
<th>Change (endpoint minus baseline)</th>
<th>Parameters (control and treated groups)</th>
<th>Baseline (measured value)</th>
<th>Residual (patient-specific)</th>
</tr>
</thead>
</table>

Figure 1. Mathematical model for a single patient.

I do not intend to go into the computation or theory behind this model—only to use it as a convenient language for thinking about the analysis. The $y$ and $x$ variables I have already defined. The $\beta$’s are “parameters,” which just means that they are imagined to be constant throughout any given study. The whole point of the model is to provide a way of interpreting and estimating these parameters. The $e$ term represents a patient-specific variable, which accounts for the fact that change (the left side of the equation) is more than just a simple linear function of the treatment indicator. The left side of a regression equation is always thought of as the outcome, the result of some process, whereas the right side provides a mathematical explanation for the result. In textbooks the result is always written as just $y$, but here we want to think of change as the outcome, so the result is a difference: endpoint ($y_1$) minus baseline ($y_0$).

The model equation says that there is one mean change in the control group ($\beta_0$) and another in the treated group ($\beta_0 + \beta_1 x$). These can be deduced by the simple but universal technique of substituting the possible values of $x$ on the right side of the equation. Thus, $\beta_1$ acquires its interpretation as the difference between the two mean changes, which is the whole point of the study.

In a remarkably useful but almost completely unknown book, Ian Plewis¹ argued strongly that in studies of change, one should include the baseline value in the analysis. The way to do this is to extend the above analytic model (Figure 2). The only difference between the two analyses is that $y_0$ appears on the right side of the equation in Figure 2. The model above thus says that changes (left side) are influenced by treatment ($x$) and baseline value ($y_0$).

Analysis Steps

As a practical matter, the dataset for such a study looks like Table 2. The steps involved in the analysis are as follows:

- Compute the change as a new variable
- Subtract the mean baseline from the baseline values (centering)
- Regress the change on the treatment indicator and the centered baseline to produce Table 3.

Table 3 is a simplified version of what most statistical programs provide. The names of the right-side variables appear first, followed by effect estimates of their corresponding $\beta$’s (under the “coefficient” column). The other two commonly displayed values are the standard deviation of the sampling distribution of the coefficient estimate (under the “SDE” column; most programs erroneously use SE, for “standard error,” for what I call SDE, for “standard deviation of the estimate”), and a p-value for testing the null hypothesis that the coefficient is in reality zero (so that the named variable would not appear in the true model equation).

Table 2. Example form of a dataset for studying change

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Endpoint</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>140</td>
<td>138</td>
<td>0</td>
</tr>
<tr>
<td>141</td>
<td>123</td>
<td>0</td>
</tr>
<tr>
<td>157</td>
<td>140</td>
<td>1</td>
</tr>
<tr>
<td>138</td>
<td>136</td>
<td>1</td>
</tr>
</tbody>
</table>

Baseline is the value measured at the start of the study, and endpoint is measured at the end. The treatment variable is 0 for a control and 1 for a treated patient.

Table 3. Example regression computer output

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>SDE</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>-4.122</td>
<td>2.178</td>
<td>0.058</td>
</tr>
<tr>
<td>Baseline</td>
<td>-0.801</td>
<td>0.213</td>
<td>0.000</td>
</tr>
<tr>
<td>Intercept</td>
<td>1.531</td>
<td>1.260</td>
<td>0.224</td>
</tr>
</tbody>
</table>

Variables are the explanatory (right-side) variables in the regression equation. Coefficients are their estimated effects ($\beta$’s), SDEs are their sampling standard deviations, and p are the p-values for the corresponding null hypothesis tests. The intercept term corresponds to $\beta_0$. 
Baseline Differences

We can interpret the coefficient estimates by referring back to the model equation. To interpret $\beta_0$, plug the values $x = 0$ and $y_0 = 0$ into the right side. Of course $x = 0$ means “in the control group.” Because we centered the baseline values, $y_0 = 0$ means “at the mean on baseline.” Thus, $\beta_0$ stands for the mean change in a control patient who was exactly average at baseline. By substituting $x = 1$ and leaving $y_0 = 0$, we interpret $\beta_0 + \beta_1$ to be the mean change among treated patients who are exactly average at baseline. The $\beta_2$ parameter captures how much the mean changes differ, if we compare two patients in the same group but who differ by 1 unit at baseline. Usually $\beta_2$ is not of interest, so it is included in Table 3 only for completeness.

Single Regression Line

Because it will play a role in the following discussion, we can note that to interpret $\beta_1$, we could have substituted any fixed value for $y_0$. That is, $\beta_1$ represents the effect of treatment on mean change when we compare any two patients in different groups but who had exactly the same baseline value. It is in this sense that we say the analysis has been “adjusted for baseline.” This is connected to the fact that if we were to graph the fitted regression equations in the two groups, like this

$$y_1 - y_0 = \begin{cases} 
\beta_0 + \beta_2 y_0 & \text{(controls)} \\
(\beta_0 + \beta_1) + \beta_2 y_0 & \text{(treated)}
\end{cases}$$

then they would appear as parallel lines. The vertical distance between the two lines is always the same and is equal to the estimated $\beta_1$. Thus, $\beta_1$ captures the effect of treatment for any group of patients who have the same baseline values.

Three Advantages: Smaller Error, Similar Groups, Less Artifact

There are three primary reasons for preferring the conditional change model over the $t$-test (Table 4). The first is purely statistical: that the SDE of the effect of interest (\(\beta_1\)) is nearly always smaller under the conditional change model. This means that the estimate of treatment effect is more precise, and it has implications for the chance of detecting a real effect using null hypothesis testing.

The second reason is that if there is an imbalance between the control and treatment groups with respect to baseline values, this undermines the whole logic of the study, in that the comparison of treatment versus control is not made across two “similar” groups. Statisticians frequently claim that randomization removes this concern, but this is an argument based on large-sample theory, which does not apply to small studies and may apply inadequately to most studies. Thus the conditional change model is seen as an attempt to lessen, if not remove, baseline differences.

The third reason is related to both of the first two. Although it is possible for there to be true regression to the mean, in most cases the phenomenon is artifactual. Thus, the final argument for the conditional change model is that it tends to reduce the artifactual effect of regression to the mean.

The Unavoidable Warnings

Outliers

Although the conditional change model should probably become the default for analyzing change, it is not without its difficulties. First, badly outlying values on the baseline measurement can cause serious damage to the estimate of the treatment effect because regression is sensitive to outliers. This is not, incidentally, an argument in favor of the $t$-test, because it is also unduly affected by outliers. Thus, it is always wise to view the baseline distributions graphically and perhaps to take some evasive action. One method, formerly widely used and now nearly abandoned, is Winsorization. One picks the largest and smallest reasonable values, and then those above the largest value are rounded down to it and those below the smallest value are rounded up to it.

Differing Regression Lines

The second potential problem is that if one separately fitted regression lines (of change, on baseline) within the two treatment groups, one might get quite different lines. In this case, the rationale for fitting a single line to both groups, which is part of the conditional change model, might seem unjustified. There is actually a deeper issue here than just model fitting. If the relationship between baseline and change is different in the two groups, then does it not follow that this might be a consequence of treatment? For example, suppose that in the control group there is the usual negative relationship between change and baseline that is predicted by regression to the mean, but there is no relationship in the treated group. Part of the effect of treatment may then have been to detach changes from baseline values.

Regardless of the source, differing regression lines...
Dealing With Change: Using the Conditional Change Model for Clinical Research

pose a real conceptual problem, which can be seen in terms of the model:

\[ y_1 - y_0 = \beta_0 + \beta_1 x + (\beta_2 + \beta_3 x)y_0 + e \]

Here the effect of baseline explicitly depends on which group the patient is in. This is accomplished in the analysis by adding an interaction term, \( xy_0 \), to the list of explanatory variables. Now if we consider two patients, one treated and one control with identical values of \( y_0 \), the difference between their mean changes is \( \beta_1 + \beta_3 y_0 \). (This is again deduced by substituting trial values on the right side of the equation.) This says that the treatment effect depends on the baseline value, so that there is no single well-defined treatment effect. The statistical way around this is to center the baseline, as I have recommended, so that the nominal treatment effect on the computer output (\( \beta_1 \)) is the effect of treatment at the mean of the baseline. This is a reasonable convention, but it does not solve the conceptual problem. Although one might be annoyed at the conditional change model for raising such an issue, if there are differential treatment effects then it would seem important to report them, which would never happen with the t-test approach.

**Three Measurement Points**

The third difficulty only arises if one extends the conditional change model beyond the comparison of baseline and endpoint values. For example, imagine a design in which the outcome variable is measured three times on each patient: baseline, midstudy, and endstudy. To measure the early effect, the change from baseline to midstudy might be subjected to conditional change analysis. One might then go on to investigate late changes by applying the same model to midstudy and endstudy values, with midstudy values now playing the role of baseline. The reason this can go awry can be seen in terms of regression to the mean. If the treatment produces an early beneficial effect, then midstudy values will be higher in the treated patients than in the control patients. The midstudy values will not be com-

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**Adjusting Data: Graphical Display of Conditional Change Results**

After having presented a statistical analysis, researchers may want to show the data graphically, to give a richer impression of the results. The danger here is that the conditional change analysis adjusts for baseline but the graphed data are unadjusted. The alert reader may see from the graphs that the asserted treatment effects are implausible, undermining the credibility of the presentation.

The solution to this problem is to adjust the data before graphing. The procedure involves two steps, adjusting the baseline and adjusting the changes. To adjust the baseline:

- Fit the regression model \( y_0 = \alpha_0 + \alpha_1 x + e \)
- Compute the fitted values (\( \alpha_0 + \alpha_1 x \) where the parameters (\( \alpha \)'s) are estimated)
- Compute the regression residuals (observed minus fitted). All programs will do this
- Subtract \( \alpha_1 x \) from each fitted value, and add \( \alpha_1 x_0 \) (parameters are estimated, \( x_0 \) determined as below)
- Add the residuals to the values just computed. These are the adjusted baselines.

Although it may have gotten lost in the recipe, the values computed are \( \alpha_0 + \alpha_1 x_0 + e \), where the parameters are estimated and \( e \) is the computed residual. These represent values that would have been observed if each patient had had \( x_0 \) in place of his or her treatment indicator. Often \( x_0 = \frac{1}{2} \) will be sensible, but one can sometimes argue for other values, such as the mean of \( x \) (that is, the treated fraction).

The process is similar for the adjusted changes:

- Fit the regression model \( y_1 - y_0 = \beta_0 + \beta_1 x + e \)
- Compute the fitted values \( \beta_0 + \beta_1 x \)
- Compute the regression residuals
- Subtract \( \beta_1 x_0 \) from each fitted value, and then add \( \beta_1 y_0 \)
- Add the residuals to the values just computed. These are the adjusted changes.

If the baseline values were centered, then their mean \( y_0 \) will be zero. However, one can choose some other value for this constant (such as the median, for example).

These two procedures will give baseline data adjusted for treatment, as if everyone had treatment value \( x_0 \) and changes adjusted for baseline, as if everyone had baseline value \( y_0 \) (or whatever baseline constant was chosen). Thus, for the adjusted data, baseline will have the same mean in the two treatment groups, and change will correspond to the effects obtained from the conditional change model.

Adjusted endstudy values are computed by adding adjusted changes to adjusted baselines, and are adjusted both for baseline treatment group imbalance and the consequences of this imbalance on change.

It must be emphasized that the adjusted data are not to be used for statistical inference. Their only purpose is to make it possible to show tables of summary statistics or graphics, with the above effects adjusted for. The reason is that in general, adjusted data have less variability than the original data (this is an inevitable consequence of removing variability due to the adjustment variable), and so effect estimates based on adjusted data will be artificially precise. It may be worth mentioning that the conditional change analysis easily lends itself to adjustment for other variables that might be thought to influence the outcome. Gender, age, and comorbidities are logical contenders. Data can be adjusted for these as well. The only part that becomes more complex is that the fourth step (as given earlier) must be done for each adjustment variable. One must then be careful to report the constant value substituted for each variable, to avoid misinterpretation of the adjusted tables or graphics.
Dealing With Change: Using the Conditional Change Model for Clinical Research

parable between the groups, and for an understandable reason. The second (midstudy → endstudy) analysis will thus try to remove real effects, some of which are just regression to the mean (the high values in the treated group tending to drop) and could actually result in the treatment appearing to do worse in this second analysis, even though continued treatment is continuing to benefit the patients. The conclusion is that for the analysis of change, one should do the baseline → midstudy and baseline → endstudy analyses, because the conditional change approach is equally valid in these cases and questionable in the midstudy → endstudy analysis.

**Conclusion**

There is an ethical principle in biostatistics, which says that the most powerful appropriate analysis should be used in evaluating the results of biomedical studies. This emerges not just from general scientific principles but also out of respect for the human participants who allowed themselves to be used in a medical experiment. For a rather long time now, this ethical principle has not been followed as well as one would like, in studies where the issue is to compare mean changes between two treatment groups, one of the most common of all clinical trial designs.

The benefits of the conditional change approach were clearly put forward by Plewis more than twenty years ago. The failure to heed Plewis’s advice may stem from the virtual absence of supportive articles, even in the statistics literature. Indeed, an otherwise excellent statistical article on the topic made misstatements about the conditional change model that were rectified two years later, but only in a letter to the editor. It is understandable that a vacuum in the literature would open the way to statistics textbooks’ continuing to promote a weak analysis. The purpose of this article has been to try to change the situation.

**Disclosure Statement**

The author(s) have no conflicts of interest to disclose.

**Acknowledgment**

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**References**


**Table 4. Differences between Conditional Change model and t-test**

<table>
<thead>
<tr>
<th>Conditional Change model</th>
<th>t-Test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary reasons:</strong></td>
<td></td>
</tr>
<tr>
<td>1. Less artifact of regression to the mean</td>
<td>1. Artifact of regression to the mean</td>
</tr>
<tr>
<td>2. Lessen baseline differences of two groups</td>
<td>2. Subject to baseline differences between two groups</td>
</tr>
<tr>
<td>3. Lower SDE (more precise)</td>
<td>3. Higher SDE</td>
</tr>
<tr>
<td><strong>Cautions:</strong></td>
<td></td>
</tr>
<tr>
<td>1. Baseline outliers producing bias</td>
<td>1. Baseline outliers producing variability</td>
</tr>
<tr>
<td>2. Assumes single regression line for both groups (should be investigated)</td>
<td>2. Assumes no regression line in either group</td>
</tr>
<tr>
<td>3. Dangerous to use mid-study value as baseline for late change</td>
<td>3. Same issue</td>
</tr>
</tbody>
</table>

SDE = standard deviation of the estimate.

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A Peculiar and Perpetual Error

It is the peculiar and perpetual error of the human understanding to be more moved and excited by affirmatives than by negatives, whereas it ought duly and regularly to be impartial; nay, in establishing any true axiom, the negative instance is the most powerful.

— Aphorisms, Sir Francis Bacon, 1561-1626, English philosopher, statesman, scientist, lawyer, jurist, and author
The Merging of the Work of Two Pioneers: Dr Weed & Dr Berwick

Attaining Comprehensive Health Care Improvement is Imperative

Lee Jacobs, MD

How about sitting with Lawrence Weed, MD, and Donald Berwick, MD, in the same week? Granted my time with Dr Weed was one-on-one for three hours in his living room in Vermont and my time “with” Dr Berwick was as part of an audience of 6000 attendees at his National Forum on Quality Improvement in Health Care in Nashville, TN (December, 2008). I felt privileged to listen to the journeys of these two men who have had such a dramatic effect on how medicine is practiced today.

Dr Weed and Dr Berwick have much in common. Both have a passion for and a vision of how to improve health care. Both have played major roles in improving health care over the past few decades. Both are pioneers and as such have for years endured the criticism of their skeptics and the accolades of their followers. Both are leaders of significant movements that have and will continue to affect health care in the US and around the world. Both provide real solutions to waste in health care. And, most importantly, both want to increase the likelihood of a positive outcome for each individual patient encountering the health care system while at the same time lessening the chances of being harmed.

During my time with these two physicians, I heard both describe with similar language the state of disrepair of our present health care system; however, I found neither was pessimistic about the future. I was struck by the can-do attitude voiced by both— the problem is huge but there is a solution and they optimistically believe it can be attained.

In leaving their mark on how health care is practiced, however, these two physicians have taken two very distinct paths on their journey.

Lawrence Weed, MD

Dr Weed is an innovator in health information management and is best known as the champion for the problem-oriented medical record. Dr Weed described for me how his journey started, when, after years as a disciplined researcher, he was asked to lead rounds on a medical ward. [Full interview in the Summer, 2009 issue.] He was astonished that the residents and students were functioning in a most unscientific manner making decisions on the basis of fragments of information from patients each of whom had a complex array of problems. To arrive at a diagnosis, the physicians put this sparse information through a diagnostic filter that was totally dependent on their recall of possibly related facts. It was from such encounters that Dr Weed saw the need to link the medical record with the care of the patient and so in the late 1950s he developed the problem-oriented record now used worldwide.

Subsequently, Dr Weed saw the need for computer assistance to support a more systematic collection of patient data so physicians could be certain they had all the pertinent historical facts. I recall as a medical student in the early 1970s at the University of Vermont seeing patients inputting their own history on computer systems developed by Dr Weed— years ahead of any consideration of an automated medical record.

However, the pioneering work of Dr Weed did not end there. He saw the need for major changes in how medicine is practiced even beyond the medical record. Over the past 30 years he has eloquently challenged how medicine is taught (“Students are recruited and advanced on how well they memorize and regurgitate” [Lawrence Weed, MD, personal communication, 2008]); how practitioners are licensed; and very importantly, how physicians make decisions based on recall (“The unaided human mind is not a reliable...
EDITORIAL

Attaining Comprehensive Health Care Improvement is Imperative

instrument for processing of information in the solution of patients’ problems.” [Lawrence Weed, MD, personal communication, 2008].

The recognition of the fact that the mind is not capable of managing complex data consistently is not unique to Dr Weed. A recent Harvard Business Review article discussed just this in an analysis of flawed decisions executives made on the basis of two characteristics of “brain hard wiring”—relying on “pattern recognition” and “emotional tagging.”

To address this need, Dr Weed has led a team in developing “knowledge couplers,” computerized tools to assist decision making that link patient history and findings to the complexities of possible diagnostic and management possibilities. “These powerful tools embedded in a well-defined system of care can lead to a better science of medical practice.” [Lawrence Weed, MD, personal communication, 2008]. Using computer tools such as these enables practitioners to make decisions on the basis of quality data input rather than on recall.

In summary, Dr Weed is leading a movement that addresses how practitioners process and apply information thereby challenging how medical students are taught, how practitioners are licensed and how they make decisions.

Donald M Berwick, MD

Dr Berwick is the President, CEO, and visionary leader of the Institute for Healthcare Improvement (IHI)—a quality improvement movement that has had a significant impact on care systems in the US and throughout the world. The recent 2008 IHI meeting in Nashville, TN, was a celebration of the 20 years of the National Forum gatherings of “health care leaders and learners who are passionate about improving care.”

In Summary, Dr Berwick is leading a movement that addresses the broken work-flow processes in health care systems to improve the care to the patient.

Imperative: Merge These Two Movements!

Yes, these two movements are going the same direction—both with the goal of improving the care each patient receives. Although the swathes that they are cutting are broad, they are two very distinct paths. I do not believe that significant transformation in the health care system will be realized unless and until health care professionals intentionally incorporate both improvement approaches in their quality improvement change map.

Specifically, dramatic quality improvement will only result if:

1. The culture of medical education is changed to diminish the role of memorization and increase the understanding and use of information technology
2. All practitioners have access to these tools to assist in the diagnosis and the management of patients
3. The care flow processes of health care are well understood and improved

Although these two pioneers are cutting separate paths on their journeys, it is my opinion that in the future their paths must intersect if, in fact, they are to comprehensively change the health care system. It will take a “Weedian” revolution of practitioner training and decision making PLUS dramatic “Berkwickian” refinement of the care processes for every patient to receive state-of-the-art care.

Even if the multitude of care flow processes were improved by the approach that Dr Berwick and
his followers advocate, true improvement in health care will not be realized if the initial input (practitioner decision making) into these processes is flawed. For example, if new operating room guidelines that are proven to lessen preventable injury and death are implemented but the patient didn’t need the surgery in the first place, it would be difficult to say from a patient-centered viewpoint that we have achieved quality improvement.

Conversely, if medical education and practitioner decision making was overhauled to integrate an entirely new approach as advocated by Dr Weed, but the patient then enters into a flawed care process, then again—the vision of improved health care will not be attained.

**Closing**

After sitting in the living room of one pioneer, and then the same week sitting among thousands listening to another pioneer, it was clear to me that both movements must be successful if in fact significant health care improvement is to be attained. When considering the movements of these two amazing men, it is not a question of *which one*—we need both!

In future articles, we will highlight some of the work presented at the 2008 IHI meeting in Nashville as well as articles from frontline physicians using Dr Weed’s approach to decision making. We want to hear from you. Let the dialogue begin! 🌟

* Interview with Lawrence Weed, MD, Underhill, VT. December 4, 2008.

**References**


**Achievements Never Imagined**

Significant performance improvement will only be accomplished by tracking dramatic, system-level changes. The courageous among us will get there first, achieving performance levels never imagined by previous generations.

— 2004 Progress Report, Donald M Berwick, MD, MPP, b 1947, President and CEO Institute for Healthcare Improvement

**Radical Change**

The time has come to abandon the wrong premises and inadequate tools that underlie the current systems of medical education and care. If we are willing to adopt radical change, we may find that productivity can improve by an order of magnitude.

— Lawrence L Weed, MD, President and Founder of PKC Foundation, developer of Problem-Knowledge Couplers
A Fatal Form of Contentment

Catherine Hickie, MBBS

The medical humanities can be relevant to clinical practice in unexpected ways. While researching an essay on mass tourism in Victorian England, I read about the Grand Tour of Europe, a travel experience for the select few, mostly upper class young men who travelled from England officially to complete their education with exposure to the great cultural experiences of Europe, but unofficially to let loose away from home. I identified with those young men and their freedom away from scrutiny. Studying medical humanities was supposed to broaden a narrow scientific education and reinvigorate my work as a psychiatrist but it was tempting to take courses as far removed from medicine as possible. The history of travel seemed remote from 21st-century medicine but as a virtual tourist to the study of history, I found some surprising links.

In 19th century England with the Industrial Revolution and the subsequent rise of the middle class, travel opened up. People flooded to Italy, France, Switzerland, and further afield to Egypt and other exotic destinations. In contrast to the Grand Tour, where ample money and time allowed a young man to spend months in Florence or Venice, many of the Victorian middle-class travellers were on brief vacations from work. They came to Europe on package tours that had been organized for them and travelled in groups along a beaten tourist track. There were criticisms of these new tourists who flooded the art galleries of Italy and trekked the mountains of Switzerland clutching newly printed guidebooks. One name was singled out for praise and blame in regard to mass travel, Thomas Cook.

Thomas Cook—Mass Travel

On the Internet there are thousands of references to Mr Cook and his tours, but one stands out because of its medical linkage: an obituary in The Lancet, published in July 1892. Every issue of The Lancet from 1823 till the present day is now available online. The early issues are fascinating with their mix of London medical politics and medical progress. But why would a man who pioneered mass travel be eulogized in a prominent medical journal? The obituary of Thomas Cook reads, in part: “The death of Mr Thomas Cook of Leicester, … the originator of excursions by land and sea over the world, calls for a word of deep respect and regret. We sometimes complain of the restlessness of the age and its locomotive tendencies. … His [Thomas Cook’s] is the credit of having reduced the evils and the discomfort of travel and of having enormously contributed to the width of men’s ideas of the world and of their fellow creatures.”

Thomas Cook came from a working class background. His father died before he was ten and he was apprenticed to a gardener and later to a wood turner, both men were alcoholics. Mr Cook became a committed member of the temperance movement. He was a Baptist minister and preached against alcohol. A medical journal might eulogize a man who had crusaded against the harms of alcohol, but there is no mention of this in The Lancet obituary. Cook is remembered as “the originator of excursions by land and sea over the world ….”

The first excursion Cook organized was to a temperance rally in 1841. He made a deal with the railway company for cheap tickets; he had meals provided and a pamphlet printed. Five hundred and seventy temperance campaigners travelled by train to a rally eleven miles away. He organized a similar event the next year and the year after that. The railways made it possible for large groups to travel but Mr Cook saw the greater potential. In 1845, he took a group from Leicester to Liverpool and made a small profit. The next year he took a group from Leicester for a tour around Scotland. Within ten years he was arranging trips to France, Switzerland, and further afield. What is the connection between The Lancet (and the Victorian medical fraternity) and the rise of mass travel?

Thomas Wakely—The Lancet

The Lancet is one of the world’s most respected scientific medical journals. The founder and first editor, Thomas Wakely, was a London-based physician with...
A Fatal Form of Contentment

The word “evils” is striking. Although credit of having reduced the evils and the discomfort between Mr Cook and the medical fraternity: “His is the interest should be excluded from the gaze of common defending against elitist attitudes that “places of rare travel accessible to large numbers and was vocal in learning and education: Mr Cook saw a way to make were pioneers in loosening the upper-class grip on knowledge. Whatever their personal agendas both men of travel and Dr Wakely’s dissemination of medical professions. He also wanted medical information to be in plain language so that anyone could keep up with changes in medical knowledge. In the preface of the first edition he set out the target audience for the journal: London specialists, country practitioners colonial practitioners and “every individual in these realms.”

To make The Lancet as accessible as possible, Dr Wakely determined that his journal would not use the “semibarbarous phraseology of the schools … [but] we will adopt … plain English diction.”

I see parallels between Mr Cook’s opening up of travel and Dr Wakely’s dissemination of medical knowledge. Whatever their personal agendas both men were pioneers in loosening the upper-class grip on learning and education: Mr Cook saw a way to make travel accessible to large numbers and was vocal in defending against elitist attitudes that “places of rare interest should be excluded from the gaze of common people.” The Lancet made medical science more accessible but Dr Wakely also used the journal to air his strong political views. He argued against the status and power of the London Corporations who charged licensing fees of the small practitioners for the benefit of their own cliques.

The Evils of Travel

One sentence in the obituary holds a clue to the link between Mr Cook and the medical fraternity: “His is the credit of having reduced the evils and the discomfort of travel.” The word “evils” is striking. Although The Lancet evolved as a scientific medical journal, science cannot be separated from the prevailing experiences, fears, and beliefs of its practitioners. Train travel was new in the 18th century; there were concerns about safety. Early trains had frequent accidents and poor suspension. With the introduction of signals and improvements in vehicle technology accidents became progressively less frequent. But it was not just the accidents that were a focus of concern. Comforts were minimal in the third class carriages where people sat on wooden benches, initially in carriages that had no roofs. Physicians were concerned about the effects of this rough travel especially for vulnerable people who were already sick or weak.

In 1861, The Lancet commissioned its own inquiry into train travel, “Editors note: Influence of Railway Travelling upon Public Health.” Submissions were sought from “interested parties” from individual specialists, often London based, reporting on observations they had made of their patients. In general, they reflected concerns about the body as a fragile machine: the motion of the train being seen as a source of harm. For example, on February 15th 1862, a London obstetrician wrote: “I would wish to draw attention to one very important point … the danger of excessive railway travelling to newly married women,” attributing miscarriages to the new habit of train travel. And further, “But I should expect, from the impressionable state of the nervous system in women, that whatever is found to affect this system in man, will do so to a higher degree [in women] …” And this submission from a surgeon, Samuel Solly, MD: “I was visited by a patient, aged 62, who had been suffering from congestion of the brain, which had been completely relieved by medicine and 24 leeches to the temples …. He told me he had felt perfectly well … until he travelled up this morning by rail. … a brain disturbed by congestion is injuriously affected by motion on the rail.”

Not all the observations concerned injuries, some wrote of protective factors: “… the stout, easy-going, lethargic traveller, I notice, bears continuous locomotion far better than the spare, nervous, irritable man.” This author postulated a connection between temperament and vulnerability to the effects of physical motion.

Many of the submissions viewed the motion of the train, the shaking and the vibrations, as a source of harm. And some parts of the body, such as the uterus and the brain, were seen as more sensitive than others. Pregnant women and sick people were thought to be at greatest risk. Submissions made to The Lancet can be read as an attempt to make sense of these anxieties. What beliefs and anxieties cloud our current scientific vision? One example from my own clinical practice seems relevant.

A Train Ride

During the last four years I have worked in the psychiatric service of a rural district hospital in a town on the main railway line between Sydney and Melbourne. More than once a man has alighted from the train (or been put off because of odd behaviour), found...
An editorial in *The Lancet*, in a report on an inquiry into vagrancy, called this “a fatal form of contentment.”

The police station or the hospital Emergency Department and announced that he has a mental illness and wishes to be admitted to the psychiatry unit. He gives a sketchy account of recent travels, he has just come from the outback or the coast where he has been for several months. If pressed he will give a slim account of a long psychotic history with bursts of treatment and long gaps with no medical care. He has been in other country psychiatric units. He may name a friend or a family member, but probably not. The impression is of persistent psychotic symptoms and a desire to keep moving.

I recall one of these men in particular—he had many years of psychotic symptoms and had been in the ward for a week or more when he slipped out the door of the hospital, got himself to the railway station and rode the train to Sydney. At the Sydney terminus, he approached a station guard, announced that he was a “mental patient” and asked to be taken to the hospital. When the overstretched inner-city Emergency Department discovered he had a hospital bed waiting for him in the country, transport was quickly arranged. The round trip was complete within 12 hours and the man was very pleased with his day. When I asked him why he had gone to all that trouble to end up where he started he said he just wanted to ride the train.

Patients who prefer to be itinerant present a problem to physicians. When we treat patients who have chronic conditions we emphasize the benefits of wholistic care. For patients with enduring mental illness we want to do more than prescribe medications; we aim for improvements in social function and work, establishing accommodation and building social networks. We can’t do our best work when people are itinerant. Concerns about illness and itinerants have a long history: a particular concern at the turn of the 20th century was the rapid spread of infectious diseases. Unemployed people could travel widely on foot and by catching free rides on the trains; it was feared that these people spread diseases like smallpox; concerns were also for a perceived moral problem: enjoying the pleasure of travel without having earned it through work. *The Lancet* ran a number of articles on vagrancy at the beginning of the 20th century. There was particular interest in those who chose to move freely from town to town and refused to engage in the work schemes that were established. *The Lancet* was critical of the charitable organizations that made this not only possible “but pleasant and attractive. They enabled the idle to live either by mendicancy or by crime or by both without any need to work and the example of men and women leading indolent, self-indulgent lives without responsibility or restraint is a constant temptation to others to adopt the same course.” An editorial in *The Lancet*, in a report on an inquiry into vagrancy, called this “a fatal form of contentment.”

I wonder if contentment is the motivation to leave town soon after hospital discharge, opting to ride the train rather than to accept accommodation and community treatment. Or is it to be in control, coming for treatment, then slipping away. Do the trains symbolize freedom? Adventure? Or is it something about the movement of the train itself? Were the Victorians right about the rocking and the vibrations but wrong in their conclusions? Could it be soothing or even therapeutic?

Or perhaps it is the anonymity of the train, where a traveller can be in company without pressure to communicate. Where a person who lives with schizophrenia can step out of the persona of patient and become a traveller like everybody else. Trains can offer a social mixing that is both exciting and threatening.

In the 21st century, we have our own new technology that takes us on anonymous rides, mixes up the social order, and challenges the establishment. The Internet has come with anxieties and fears just as the trains did a century and a half ago. We are all familiar with the concerns: the speed at which a child can be on a pornography site; the anonymous chat rooms as a place of social intercourse; ciber bullying and stalking. And, like *The Lancet* of the 19th century, the Internet presents an information revolution for health. Knowledge is no longer the exclusive domain of the expert, up-to-the-minute medical facts can be found on the Internet in plain language for all to read. Any amateur can set up a Web site. In some ways we are back in the unregulated age, where quacks are flourishing. This makes us nervous. We warn of the dangers of unregulated Web sites, false information, and global cons. The Internet is changing our relationships as health professionals. We may have a looser hold on knowledge but there are benefits. There are good Web sites hosted by reliable providers; and Web-based therapies may offer some solutions to unmet needs in mental health care.

In the university library, a virtual tourist to the study of history, I wondered if our hopes for new technology were so different from the hopes of the Victorians. Perhaps *The Lancet* eulogized Thomas Cook for the same reason that people set aside their fears and
embraced the train, the opening up of possibilities (risks and all) to people who were previously shut out. This, after all, was one of The Lancet’s original aims. As our anxieties subside we are embracing information technology to improve health care as well as for pleasure and private exploration. An essay on mass travel in the 19th century proved far from irrelevant to a 21st century psychiatrist.

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References

An Intellectual Challenge
The history of medicine can teach students about the structure of medical discovery and how it [affects] the way we think and the way we behave. It explores the fundamental values underlying medical practice and how they evolved. It examines both the experience of being a physician and a patient and brings understanding to the dimensions of suffering and healing. Finally, the history of medicine offers an intellectual challenge for the student.

— Norman Gevitz, PhD, medical historian
La Clinica: A Doctor’s Journey Across Borders  
by David P Sklar

The older a physician becomes, especially these days, the harder it is to find time to read a good book. If we are lucky, we find a Moby Dick with good plot, development of character, and implications for our life goals. Such a book is La Clinica: A Doctor’s Journey Across Borders, an autobiographical work by David P Sklar, MD, Associate Dean of Graduate Medical Education at the University of New Mexico (UNM) School of Medicine in Albuquerque, NM.

Like many physicians, Dr Sklar chose medicine as a career because he wanted to help people. His initiation into medicine began six months prior to starting medical school. He had volunteered at La Clinica, a small, free clinic in a Mexican village where, interestingly, the patients’ needs had multiplied with modernization. The book juxtaposes Dr Sklar’s time at the clinic in Mexico with his life, 24 years later, as Chairman of the Emergency Medicine Department at UNM Health Sciences Center. Implicitly, it questions how we train physicians.

Physicians recognize that becoming a medical doctor is a long and demanding journey and entails many sacrifices. Initially, the practice of medicine deprives us of sleep and much of our youth, but most of us are eager and proud to give these up in exchange for the knowledge and opportunity that we anticipate will become more meaningful over time. But many of us will discover that this medical education exacts a significant cost upon our lives.

Unlike many physicians who train and practice in the US, Dr Sklar wasn’t seduced by the money and power that being a physician can bring. He did what many physicians only hope to do—he created a community of caring where people helped and taught one another at an academic medical center in the US. However, like many physicians, Dr Sklar paid a steep price. The personal costs were significant, and included his decision when he suspected that his idolized mentor might be sexually abusing an adolescent child. Another occurred when his spouse contemplated divorce in response to the loneliness she experienced from his excessive dedication to his work.

Physicians begin their medical careers learning to elicit a description of symptoms from patients, learning to think in terms of differential diagnoses, and developing the skill of prescribing medications. But how do they learn to take care of their patients or, for that matter, even of themselves?

In comparison to medical school, Dr Sklar describes his volunteer stint in Mexico as the place where he actually discovered how to be a physician. La Clinica suggests that the traditional medical knowledge for which one sacrifices so much may often be lacking in certain insights and experiences. Like Dr Sklar and many others, I (SN) became a physician to help people. But, in many ways, my years of training in medical school and residency did not prepare me to take care of the true needs of my patients.

Most of my patients present with simple medical problems but complex social issues. The medical problems are easy to fix and don’t require years of training to memorize their solutions. It is the social issues that motivate most of my patients to keep coming back to my clinic. My colleagues and I sometimes feel that we are just treading water to stay afloat. We seem to make little progress on our patients’ biggest health issues—obesity, teen pregnancy, and asthma to name a few.

Sara M Nelson, MD, is a Clinical Instructor in Pediatrics at the Harvard Medical School in Boston, MA, an Assistant in Pediatrics at Massachusetts General Hospital, and a Pediatrician at the Massachusetts General Hospital-Chelsea HealthCare Center, Adolescent and Pediatric Unit in Chelsea, MA. E-mail: snelson_us@yahoo.com.

Howard King, MD, MPH, FAAP, is a Clinical Instructor in Pediatrics at Harvard Medical School, in Boston, MA; Founder of Children’s Emotional Healthlink (CEHL), Co-leader of Pediatrician-Parent Communication Training Program, and the Continuing Education Committee, Harvard School of Public Health in Boston, MA. E-mail: howieking@aol.com.
These are medical issues that are difficult to fix without identifying and improving the underlying issues; skills that I was not taught in medical school.

For instance, a major study out of Kaiser Permanente (KP) discovered that 22% of KP patients have been sexually abused as children. How does that affect such a person later in life? How does it show up in the physician's office? What does it mean that such sexual abuse is usually never recognized or acknowledged? Have physicians limited themselves to the smallest part of the problem, that part where we are comfortable merely prescribing medication and making diagnostic decisions?

In medical training, we are taught specific rules that guide our interactions with patients. We are advised to wear certain clothes. We learn to think in paternalistic ways about our patients. These actions set us apart from our patients and serve to protect us from their pain so we can seem to maintain our objectivity when determining their treatment. They also set us above our patients and allow us the authority to advise them how they should proceed with their lives.

But setting these boundaries may have detrimental effects as well. The gap may become too wide between us and our patients with the result that we may not ask uncomfortable questions. As a result, we may fail to acquire the necessary information to help them gain mastery over their lives. These rules may also end up distancing us emotionally from our family and friends.

One conclusion we might derive from La Clinica is that we need to alter these boundaries by placing physicians closer to their patients. In the course of describing the many relationships in his book, Dr Sklar challenges us to reconsider the traditional physician/patient boundaries and the usual ideas of what it means to be a physician. He presents several typically taboo relationships in such a way that one has to reconsider whether they are truly unacceptable.

These relationships remind us that no matter how evidence-based the medical profession wishes to be, the practice of medicine is only as pure as the humanity that drives the mission. Even the free clinic in Mexico that Dr Sklar measures his life work against has a dark dimension that runs counter to conventional altruism. Medicine is mystical to the uneducated and a powerful tool for those schooled in its ways, but human relationships are equally complex and influential.

Perhaps as physicians we need to revisit the boundaries that we have collectively agreed to as a profession. Are we too focused on maintaining our distance from patients instead of finding ways to ask them difficult questions? Do our rules prevent us from finding the time to genuinely care for our patients? If we modified the boundaries with our patients, would we more likely be able to unearth the true illnesses that plague our patients?

We may need to approach our patients differently in order to help them improve their lives and find ways to interrupt those cycles, which often lead to chronic poor health. Can we find another medical model, which might demand fewer personal sacrifices of a physician but might also provide more appropriate care for our patients?

Reading Dr Sklar’s book forced me (SN) to reconsider the experiences that had drawn me into medicine and to re-assess my own idealistic goals in becoming a physician. I found myself compelled to evaluate the distance I had traveled in my career and where I now find myself, twelve years later. Reading La Clinica I was obliged to ask myself, “Where do I want to go now and which path should I travel to get there?” Other physicians may find this question familiar.

Finally, the book left one of us (HK) pondering, how can my fellow educators and I teach young physicians and nurse practitioners to improve their ability to assess the emotional health of families without encouraging them to consider their own personal and professional history? Can we be successful only by teaching the use of psychotropic medications?

Isn’t it equally important to be willing to trust trainees and ourselves to reflect upon the impact of our own historical and family experiences? As was asked centuries ago, “If not now, when?”

Reference
**BOOK REVIEW**

**Medical Readers’ Theater: A Guide and Scripts**  
Todd L Savitt, Editor

The Permanente Journal is dedicated both to biomedicine and to humanism in medicine. Thus, Medical Readers’ Theater is a singularly appropriate book to review in these pages. Of the medical books that are truly helpful, most have their value in their content; rarely does a book come along where equal value lies in the concept. This is such a book.

This book consists of 14 medically oriented stories, many written by physicians with recognized literary skills: William Carlos Williams, MD; Richard Selzer, MD; and Sir Arthur Conan Doyle, MD. The short stories are divided into three categories: Physicians and Patients, Being a Physician, and Ethical and Social Issues. An imaginative faculty group at East Carolina University’s School of Medicine adapted the stories into plays for informal enactment, the goal of which is to help the audience think and talk about those interpersonal aspects of everyday medical practice that are critically important to success, but sometimes carried out clumsily, thus not given consideration in our occasional analyses of why a case went well or poorly. A memorable story by the surgeon Richard Selzer deals with the emotions of the widow of a man whose organs she agreed to have transplanted into several other people. The stories are adapted for a small cast, often with a narrator whose role is somewhat like that of a Greek Chorus.

The stories by themselves are interesting to read. Their adaptations for informal enactment by small groups are imaginatively done. And the Questions for Discussion at the end of each enactment are wonderfully probing, helpfully expanding our discussion and our understanding of what is going on and why. Those readers of this book who have seen any of the productions by Kaiser Permanente’s (KP’s) Educational Theater Program will be struck by the recognition that theater can have a major role in the education of physicians as well as of Health Plan members, even children. Advances often more readily occur at the interface of different fields. This book, as well as an understanding of the role of KP’s Educational Theater Program, will provide meaningful benefit to those of us trying better to understand the remarkably wide range of implications of our contacts with patients, and why sometimes things go poorly when we did everything in a medically appropriate manner.

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**The Delivery Room**

A library, to modify the famous metaphor of Socrates, should be the delivery room for the birth of ideas  
—a place where history comes to life.

— Norman Cousins, 1915-1990, political journalist, author, professor, and world peace advocate
CME Evaluation Program

Physicians may earn up to 4 AMA PRA Category 1 credits™ for reading and analyzing the four designated articles. Other clinicians for whom CME is acceptable in meeting educational requirements may report up to four hours of attendance.

You may earn CME credit for reading the four qualifying articles from this issue of The Permanente Journal that are listed below and then taking the online quiz. To participate, go to www.kp.org/permanentejournal. Select the most appropriate answer to the questions and complete the online evaluation form. You must complete all sections to receive credit.

Section A.

Article 1. (page 4)

Short- and Long-Term Antireflux and Asthma Medication Use in Children After Nissen Fundoplication

Regarding Pediatric Nissen fundoplication for GERD: Which of the following is true?

a. neurologically healthy and impaired children have similar outcomes
b. results in decreased use of antireflux medications
c. results in decreased use of asthma medications
d. is often performed for Barrett’s esophagus or esophageal stricture
e. decreases hospitalizations for pneumonia or respiratory distress

Which of the following is NOT true:

a. objective long-term data following Nissen fundoplication in children are not available
b. Nissen fundoplication improves symptoms in the majority of children
c. Nissen fundoplication may be safely performed in infants weighing less than 3 kg
d. the complication rate following Nissen fundoplication is similar in neurologically impaired and healthy children
e. GERD and GERD-related complications may be different based on age and associated neurologic status

Article 2. (page 31)

An Exploratory Case Study: Effects of a Physician Organizational Socialization (Enculturation) Program

Regarding an effective organizational socialization (enculturation), which one of the following is NOT true:

a. decreased salary requirements
b. increased job satisfaction
c. increased organizational commitment
d. decreased intention to leave

Regarding the Kaiser Permanente Orange County enculturation program, which one is not true:

a. the participants improved communication skills
b. the participants’ intention to leave increased
c. the participants developed a sense of belonging
d. the participants learned skills to be more effective at work and at home

The Kaiser Permanente National Continuing Medical Education Program (KPNCMEP) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The KPNCMEP designates this educational activity for 4 AMA PRA Category 1 credits. Each physician should claim only those hours of credit that s/he actually spent in the educational activity. All editors, reviewers, and authors have no conflicts of interest to disclose; where any possible conflict is indicated, it has been reviewed and found not to have any impact on the article content.

The Permanente Journal has been reviewed and is acceptable for up to 8 Prescribed credits by the American Academy of Family Physicians. AAFP accreditation begins 01/01/09. Term of approval is for one year from this date. This issue is approved for 2 Prescribed credits. Credit may be claimed for one year from the date of this issue.
Incidental Gallstones

Which of the following differentiates choledocholithiasis from cholecystitis?

a. biliary colic
b. laboratory abnormalities
c. a dilated common bile duct
d. the need for cholecystectomy

Recent data has demonstrated that performing concurrent cholecystectomy with which of the following types of abdominal operations has been shown to be safe:

a. colorectal
b. thoracic
c. vascular
d. all of the above

An Unusual Presentation and Etiology of Hypotension Seen in Nephrotic Syndrome

The most common type of amyloidosis is:

a. secondary amyloidosis (AA)
b. light chain amyloidosis (AL)
c. familial amyloidosis (AF)
d. heavy chain amyloidosis (AH)

Hypotension occurs in amyloidosis due to all of the following etiologies EXCEPT:

a. anuric acute renal failure
b. vascular infiltration of amyloid
c. autonomic dysfunction
d. cardiomyopathy

Objectives

1. to inculcate the use of evidence-based medicine as part of the science of medicine
2. to stress the art of medicine via enhanced patient-physician communication, improved care experience for patients, and more satisfying caregiving experience for physicians and staff through better teamwork
3. to review appropriate updates on the diagnosis and treatment of clinical conditions
4. to describe infrastructure and systems improvements that lead to improvements in outcomes and patient care experiences

Section B. Referring to the CME articles and the stated objectives, please choose your level of agreement next to each statement as appropriate.

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<td>The article covered the stated objectives.</td>
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Section C. What change(s) (if any) do you plan to make in your practice as a result of reading these articles?

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