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ORIGINAL RESEARCH & CONTRIBUTIONS

4. Identifying Opportunities for a Medical Group to Improve Outcomes for Patients with Coronary Artery Disease and Heart Failure: An Exploratory Study.

Courtney Jordan Baechler, MD, MScE; Thomas E Kottke, MD, MSPH

The potential impact of optimizing care for patients age 60-75 years treated for coronary artery disease and heart failure, by a multispecialty group between August 2007 and July 2008, was calculated using deaths that might be prevented or postponed if optimal care was achieved. The greatest opportunity to prevent or postpone deaths—70% of the total opportunity—lies with optimizing care for ambulatory patients. Optimizing care for patients hospitalized for acute myocardial infarction with or without ST-segment elevation on ECG would prevent or postpone only 2% of deaths.

15 A New Model of Well-Child Care: Implications for Resource Costs and Dissemination. Disha P Kusnetz, PhD; Anna Sadkowska, MA; Anna L Beck, PhD; David Bergman, MD

Demographic and health care utilization data associated with 14,510 pediatric enrollees, ages newborn to 5 years, enrolled at Kaiser Permanente Colorado were used to simulate the change in costs attributable to an innovative high-performance model of Well-Child Care. Simulation models and sensitivity analyses suggest it is likely to be relatively resource cost neutral in a managed care system, allowing for efficient reallocation of resources to higher-risk children.

22 When Rapport Building Extends Beyond Affiliation: Communication Overaccommodation Toward Patients with Disabilities. Ashley P Duggan, PhD; Visalath S Brubaker, DO; MS; Natalie Swigal, Wayne Alman, MD, FAAP

Physician rapport with patients is described as a vital component of relationship-centered care, but rapport-building communication behaviors may exceed boundaries and instead indicate patronizing behavior toward patients with disabilities. Videotaped interactions between third- and fourth-year medical students (N = 142) and standardized patient educators with physical disabilities were qualitatively analyzed. Results suggest six primary themes: baby talk, kinesic movement, vocables, relationship assumptions, emotional divergence from patient disclosure, and inconsistency with patient emotional cues.

31 Adverse Reactions Associated with Therapeutic Antibiotic Use after Penicillin Skin Testing. Eric Macy, MD, MS, Ngoc | Ho, PhD

This study presents electronic medical record data from a large cohort on the incidence of new antibiotic “allergy” after all outpatient therapeutic antibiotic use in all the individuals who had penicillin skin testing at a medical center from January 1, 2000 through December 31, 2004. This gives a real-world picture of the incidence and severity of new antibiotic “allergy” in patients with a history of penicillin “allergy.”

39 Birth Outcomes Among Low-Income Women—Documented and Undocumented. Rich Ngoc Dang, MD, Louise Van-Duyl, BS, MBA; Jane Hanke, RN, MD; MPH; Mago A Hilliard, MD, MPH

In January 2007, Texas expanded the Children’s Health Insurance Program (CHIP) to include prenatal care for the unborn children of undocumented low-income women. In a retrospective cohort study of 10,763 pregnant women (CHIP) and 4,014 (Medicaid) delivered between January 1 and August 31, 2008. Hispanic women had the lowest preterm and low-birth-weight rates (18.5% and 5.8%) and non-Hispanic black women had the highest (14.3% and 12.4%).

44 Can Patient Factors Predict Early Discharge After Pyelonephrectomy? Shawn L Liu, MD, FACS, FAAP; Rebecca Mark, MD

The authors conducted a retrospective review of pyelonephr- ecтомy performed within a six-year period to determine whether patient factors could predict length of hospitalization in patients with pyelonephritis. Of 230 patients, 58% were discharged within 24 hours, 33% between 24 and 48 hours, and 11% after 48 hours. Patients with lower weight and a longer preoperative duration period had an increased risk of prolonged hospitalization.

93 LETTERS TO THE EDITOR

95 CME EVALUATION FORM
Implementation Study

52 Reducing Antipsychotic Polypharmacy Among Psychogeriatric and Adult Patients with Chronic Schizophrenia. Yen-Li Goh, MD; Kok Han Seng, MD; Alex Su Hsin Chuan, MD; Hon Choon Chua, MD

In phase 1 of a project conducted with inpatients with chronic schizophrenia, the average chlorpromazine-equivalent dose per day in psychogeriatric patients was reduced from 375 mg to 170 mg. In phase 2 with adult patients, there was a reduction in both the average number of antipsychotics from 2.9 to 2.27, and an average chlorpromazine-equivalent dose per day from 1523 mg to 1246 mg, with no documented relapse within six months of implementation of both the projects.

Implementation Study

57 Improving Patient-Centered Care—Reducing the Use of Seclusion and Restraint in Psychiatric Emergency and Adult Inpatient Services. Joyce B Wale, LCSW; Gary S Belkin, MD; Robert Moon, LMSW

Seclusion and restraint (S/R) use is associated with high rates of patient and staff injuries and is a coercive and potentially traumatizing intervention. The New York City Health and Hospitals Corporation, operating 1117 adult inpatient psychiatric beds with 36,000 psychiatric emergency services visits, conducted a sequenced, intensive series of interventions (2007 to 2009) resulting in a substantial decline in the overall time spent in S/R, a reduced use frequency, and reduced patient injury.

SPECIAL REPORTS

63 Is Patient-Centered Care the Same As Person-Focused Care? Barbara Starfield, MD, MPH

Person-focused care, based on accumulated knowledge of people, specifically focuses on the whole person. It refers to inter-relationships over time, considers episodes as part of life-course experiences with health, views diseases as interrelated phenomena, often considers morbidity as combinations of types of illnesses (multimorbidity), and views body systems as interrelated. Tools to assess person-focused care are available and deserve more widespread use in primary care.

CASE STUDY

80 Acute Hypersensitivity Syndrome Caused by Valproic Acid: A Review of the Literature and a Case Report. Robert G Bota, MD, MSG; Allein P Ligasan, RN; Tom G Najdowski, LCSW; Andrei Novac, MD

Valproic acid is an antiepileptic medication used in the treatment of bipolar disorder. This literature review focuses on aromatic anticonvulsants (AA) and non-AA medications causing acute hypersensitivity syndrome, a less well-known complication. A case is presented of a woman, age 25 years, with a generalized rash, fever, liver and kidney involvement, and eosinophilia.

CLINICAL MEDICINE

Corridor Consult

85 Calcific Uremic Arteriolopathy: An Underrecognized Entity. Victoria Ann Kumar, MD

This condition often occurs with chronic kidney disease or end-stage renal disease. Diagnosis is based on clinical judgment and recognition of lesions, secondary to small-vessel calcification, that appear as painful necrotic eschars, ulcerations, indurated nodules, and treated with rigorous wound care, strict control of mineral metabolism with avoidance of calcium and vitamin D analogs, and pain control.

90 ECG Diagnosis: Complete Heart Block. Joel T Levis, MD, PhD, FACEP, FAAEM

Third-degree atrioventricular block, when more P waves than QRS complexes exist with no relationship between them, and the ventricular rate varies from 30-40 beats/minute, complicates 10% of acute myocardial infarctions, the most frequent unstable bradycardia. Permanent pacing (not atropine) is usually required as vagal stimulation is not the cause.

EDITORIAL

91 The Patient’s Question—Unanswered. Mikel Aickin, PhD

Faced with a treatment choice for a newly diagnosed condition, the patient’s question is “Which treatment will give me more benefit?” Although unanswerable, a question that may be is “What is the probability that I will do better on treatment A or B?” This article explores this philosophical question offering a method to recover real clinical research: the “almost perfect experiment,” using a group of highly, closely matched pairs, each given treatment A or B.
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Identifying Opportunities for a Medical Group to Improve Outcomes for Patients with Coronary Artery Disease and Heart Failure: An Exploratory Study

Courtney Jordan Baechler, MD, MSCE
Thomas E Kottke, MD, MSPH

Abstract

Context: A decision-support tool was created to identify opportunities to improve outcomes for patients with coronary artery disease and heart failure by delivering all efficacious interventions; that is, “optimizing” care. When national data were applied, nearly 75% of the deaths that could be prevented or postponed by optimizing care for patients with heart disease would occur among ambulatory patients.

Objective: The purpose of this analysis is two-fold: 1) to determine whether medical group data are adequate to use in the decision-support tool, and 2) to determine whether the conclusions generated from the medical group data are similar to the conclusions generated from US data.

Design/Main Outcome Measure: The potential impact of optimizing care for patients age 40 to 75 years treated for coronary artery disease and heart failure by a multispecialty group between August 2007 and July 2008 was calculated using deaths that might be prevented or postponed if optimal care was achieved.

Results: The greatest opportunity to prevent or postpone deaths—70% of the total opportunity—lies with optimizing care for ambulatory patients. Optimizing care for patients hospitalized for acute myocardial infarction with or without ST-segment elevation on electrocardiography would prevent or postpone only 2% of deaths.

Conclusions: This study demonstrates that 1) it is feasible to use the decision-support tool to analyze opportunities for improvement in a medical group, and 2) as concluded from national data analysis, optimizing ambulatory care presents the greatest opportunity to improve outcomes for patients with heart disease.

Introduction

Epidemiologic observations, clinical trials, and sophisticated analytic techniques have all led to an understanding that a significant portion of heart disease might be prevented for those who do not yet have the disease and recurrent events could be prevented for patients who have already suffered a cardiac event. To help policymakers and clinicians identify opportunities to improve outcomes for patients who have or are at risk for heart disease, we created a decision-support tool that estimates the number of deaths that could be prevented or postponed (DPP) if all efficacious services were delivered for the prevention and treatment of coronary artery disease (CAD) and heart failure (HF); that is, if care were optimized. Despite the fact that heart disease is a leading killer of Americans, no transparent, unbiased method has been available to calculate the comparative effectiveness of heart disease prevention and treatment interventions. The ability to compare the effectiveness of different strategies has the potential to increase the effectiveness and value of public health campaigns and clinical care improvement initiatives.

When an individual has an event that leads to the diagnosis of CAD or HF, it occurs in one of three scenarios: 1) an out-of-hospital cardiac arrest; 2) hospitalization for an acute event characterized by symptoms such as chest pain, dyspnea, or syncope; or 3) initial diagnosis made in the ambulatory setting because of symptoms or a routine examination. The decision-support tool divides the ambulatory population into three prevalence pools of individuals with: 1) no apparent heart disease, 2) symptomatic heart disease with a left ventricular ejection fraction (LVEF) >35%, and 3) symptomatic heart disease and a LVEF ≤35% (Figure 1).
This analysis focuses on the scenarios in which patients with CAD and/or HF are treated by clinicians in the hospital and in the ambulatory setting. We chose not to include out-of-hospital cardiac arrest because treatment relies on the organization of emergency medical services rather than hospital or ambulatory services. We also chose not to address primary prevention because we did not have robust data on levels of physical activity and nutrition for our population.

The analysis addresses two questions: 1) are sufficient data available in a “real” medical group to use the decision-support tool?, and 2) are the results obtained from the analysis of medical group data similar to those generated from US data?

Methods

The target population for this study was the HealthPartners Medical Group in Minneapolis, MN. All data related to clinical care were abstracted from the HealthPartners electronic medical record. Data related to acute events (hospitalizations) was based on Regions Hospital data. Regions Hospital is the main hospital affiliated with HealthPartners, however it is important to note that not all HealthPartners patients were hospitalized at Regions Hospital. Mortality rates were based on analysis of the HealthPartners insured population. This study was approved by the HealthPartners institutional review board as protocol 08-093.

Case Definitions

Cases were defined as those meeting at least one of six scenarios with at least one International Statistical Classification of Diseases and Related Health Problems, 9th Revision Clinical Modification (ICD-9-CM) diagnostic code in the range of 410 to 414 or 420 to 429. Diagnoses were assigned using the following hierarchy: hospitalized for ST-segment elevation myocardial infarction (STEMI) on electrocardiogram (ECG); hospitalized with acute HF and an LVEF ≤35%; hospitalized for non-ST-segment elevation myocardial infarction (nSTEMI) on ECG; hospitalized for unstable angina pectoris (UA); initial diagnosis of CAD and/or HF in the ambulatory setting without hospitalization; and chronic, prevalent heart disease. The period of observation was August 8, 2007 (the date that HealthPartners’ inpatient and outpatient ECG files were merged into a single file) to July 31, 2008. Records for patients who had not been hospitalized during this period were also examined for ICD-9-CM diagnostic codes 410 to 414 or 420 to 429 for August 8, 2005 to August 7, 2007 to determine whether they had been diagnosed with heart disease before August 8, 2007 and thus would be considered to have chronic prevalent disease rather than heart disease newly diagnosed in the ambulatory setting.

Confirming the Cases

To characterize the medical care received by patients in each of the six categories, randomly selected candidate patients were reviewed until at least 30 confirmed patients in each category were identified. The medical record of each candidate patient was reviewed to confirm the diagnosis. Demographic and treatment data were abstracted on confirmation. Hospitalized patients with an ICD-9-CM diagnostic code of 410.0 to 410.9 or an elevated troponin level plus text in the medical record consistent with acute myocardial infarction (MI) were classified as STEMI or nSTEMI, depending on the ECG patterns. Hospitalized patients with an ICD-9-CM diagnostic code of 425 or 428 with an LVEF ≤35% and a clinical history consistent with acute HF were categorized as HF. Patients with ICD-9-CM discharge codes of 410 to 414, 420 to 424, 426, 427, or 429 and normal troponin values (or no troponin measurements) were categorized as UA if their clinical presentation was consistent with the diagnosis.

Any patient having a clinical visit between August 8, 2007 and July 31, 2008 with ICD-9-CM codes 410 to 414 or 420 to 429 but no record of hospitalization for heart disease during that period and no clinic visits with heart disease codes between August 8, 2005 and August 7, 2007 were considered to have heart disease newly diagnosed in the ambulatory setting. **Figure 1.** Conceptual model of heart disease used in the analysis. Members of the population reside in one of three prevalence pools. All clinical events are classified as one of three types. The analysis focuses on the treatment of patients who have been diagnosed with heart disease, hospitalized with acute and/or emergent syndromes, or newly diagnosed in the ambulatory setting. Reprinted with permission from Kottke TE, Faith DA, Jordan CO, Pronk NP, Thomas RJ, Capewell S. The comparative effectiveness of heart disease prevention and treatment strategies. American Journal of Preventive Medicine 2009;36(1):82-8,88.e1-88.e5.
Identifying Opportunities for a Medical Group to Improve Outcomes for Patients with Coronary Artery Disease and Heart Failure: An Exploratory Study

Calculating Event, Case-Fatality, and Mortality Rates

Not all patients treated at Regions Hospital are members of HealthPartners, and only a minority of members of HealthPartners treated for an acute cardiac event are hospitalized at Regions Hospital. That is because when a patient has an acute event, they often go to the nearest hospital regardless of affiliation with the insurance company. To overcome this limitation, we used the experiences of all HealthPartners members (the Medical Group of interest) between August 8, 2007 to July 31, 2008 to estimate event rates and help overcome this limitation.

At the time of data abstraction, the most recently available death certificate data were from 2007. Therefore, the case-fatality rate for each type of acute event and for the entire population with CAD and/or HF was calculated from HealthPartners membership for August 8, 2005 to December 31, 2007. The data from all HealthPartners members during this period were used to minimize the error of the estimate and generate rates from a defined population.

Ascertaining of Left Ventricular Ejection Fraction in the Cohort with Chronic Prevalent Disease

To estimate the prevalence of chronic heart disease associated with an LVEF ≤35%, the records of all patients who met the criteria for chronic prevalent disease were reviewed for August 8, 2007 to July 31, 2008. This period was selected because the LVEF was automatically entered into a data field in the medical record starting in August 2007. The analysis is based on 565 ambulatory patients.

Estimating the Ratio of STEMI to nSTEMI Cases

The ICD-9-CM diagnostic codes for MI in the medical records did not accurately distinguish between STEMI and nSTEMI cases. Therefore, the ratio of STEMI to nSTEMI cases was estimated from the validated cases of acute MI. Thirty-two of the randomly selected cases with an ICD-9-CM 410.x discharge code were STEMI cases; 26 were nSTEMI. Six additional nSTEMI cases were identified because of elevated troponin values and a history consistent with acute MI without an ICD-9-CM 410.x discharge code. The ratio of STEMI to nSTEMI cases was considered 1:1.

Estimating Physical Activity Levels

We did not have adequate data in the Medical Group to estimate physical activity levels. Because these data were lacking, we assumed that the average physical activity level for patients in our analysis was the same as the US average for patients with heart disease. The US average physical activity level for patients with heart disease was based on the American Heart Association Heart and Stroke Statistics from 2007.2 Regular leisure-time physical activity was defined as ≥ 30 minutes ≥ 5 days a week or vigorous activity ≥ 20 minutes ≥ 3 times a week.3 Adequate levels of physical activity varied from 19% to 33% depending on the age, sex, and ethnicity. 33% was used for this analysis, as it results in the least overestimation of impact if physical activity levels were to be optimized.

The analysis used the cumulative relative-benefit approach of Mant and Hicks to calculate the joint effect of simultaneous interventions.4 The results were not discounted because discounting biases against future generations.
Sensitivity Analysis

To test the sensitivity of the conclusions, upper-bound estimates and lower-bound estimates were created as ±20% of the observed values (plausible ranges). This range was selected to allow for a lower confidence in the accuracy of the observed data and estimates.

Results

During the period of observation, 13,805 patients of HealthPartners Medical Group or Regions Hospital ages 40 to 75 years had either prevalent CAD and/or HF or experienced an acute CAD and/or HF event. The average age was just over 60 years, and just less than 60% were men (Table 1). More than half of those with CAD and/or HF also had hypertension and hyperlipidemia. More than two-thirds of the group was overweight or obese. More than 90% of the members with CAD and/or HF had an LVEF >35%.

The prevalence of CAD and/or HF in the HealthPartners population ages 40 to 75 years was 9646/100,000; the number of deaths from any cause among members with a diagnosis of CAD and/or HF was 104/100,000 (plausible range, 67 to 150). Despite the death rate for the members with an LVEF >35% of about four times greater than the death rate for members with an LVEF >35%, most deaths occurred among members who had an LVEF >35% (Table 2).

The rate of acute CAD and/or HF events was 3226 per 100,000 adults ages 40 to 75 years (Table 3). About 3% of the events were STEMIs; about 4% were because of HF with an LVEF ≤35%; 3% were nSTEMIs; and more than 20% were because of UA. Nearly 70% of acute events were CAD and/or HF newly diagnosed in the ambulatory setting. One-year fatality rates differed by a factor of 10 from 0.013 for patients with heart disease newly diagnosed in the ambulatory setting to 0.137 for patients hospitalized for HF with an LVEF ≤35%.

Acute events were followed by 72 deaths per year per 100,000 adults ages 40 to 75 years. The largest number of deaths followed a new diagnosis of heart disease in the ambulatory setting. The second largest number of deaths followed hospitalization for HF with an LVEF ≤35%. Less than 10% of the deaths followed hospitalization for STEMI. The same was true for hospitalization for nSTEMI.

Potential Impact of Increasing Specific Interventions

The outcome of interest used in this analysis, DPP, is an accepted outcome that has been used to estimate the source of the change in deaths from heart disease

<table>
<thead>
<tr>
<th>Population pool</th>
<th>Pool size (plausible range)a</th>
<th>All-cause death rate (plausible range)*</th>
<th>Annuals deaths per 100,000 adult members ages 40 to 75 years (plausible range)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease with LVEF &gt;35%</td>
<td>8874 (7099 – 10,649)</td>
<td>0.0088 (0.0070 – 0.0106)</td>
<td>78 (50 – 112)</td>
</tr>
<tr>
<td>Heart disease with LVEF ≤35%</td>
<td>772 (618 – 926)</td>
<td>0.341 (0.0273 – 0.0410)</td>
<td>26 (17 – 38)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical event</th>
<th>No. of events (plausible range)*</th>
<th>One-year fatality rate (plausible range)*</th>
<th>Annual number of deaths per 100,000 members ages 40 to 75 (plausible range)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI</td>
<td>112 (90 – 134)</td>
<td>0.042 (0.034 – 0.050)</td>
<td>5 (3 – 7)</td>
</tr>
<tr>
<td>Acute heart failure with LVEF ≤35%</td>
<td>130 (104 – 156)</td>
<td>0.137 (0.110 – 0.164)</td>
<td>18 (11 – 26)</td>
</tr>
<tr>
<td>nSTEMI</td>
<td>112 (90 – 134)</td>
<td>0.042 (0.034 – 0.050)</td>
<td>5 (3 – 7)</td>
</tr>
<tr>
<td>Unstable angina/other heart disease</td>
<td>690 (552 – 828)</td>
<td>0.024 (0.019 – 0.029)</td>
<td>16 (11 – 24)</td>
</tr>
<tr>
<td>Heart disease newly diagnosed in the ambulatory setting</td>
<td>2182 (1746 – 2618)</td>
<td>0.013 (0.010 – 0.016)</td>
<td>28 (18 – 41)</td>
</tr>
</tbody>
</table>

a Ranges are “plausible” estimates defined as ±20% of the observed value.

b One-year fatality rates for STEMI and nSTEMI are assumed to be the same. Electrocardiograms were not available for review, and ICD-9-CM coding did not adequately discriminate between STEMI and nSTEMI.

LVEF = left ventricular ejection fraction; nSTEMI = myocardial infarction without ST-segment elevation; STEMI – ST-segment elevation myocardial infarction
in the US and several other countries. The number of DPP with optimal care was calculated as follows:

\[
\text{DPP_{optimal care}} = \frac{X \times (1 - \text{current implementation rate})}{X \times \text{mortality}}
\]

where \(X\) is the number in the population.

**Prevalence pools**: The potential to increase the DPP by optimizing care for patients with prevalent CAD and/or HF and an LVEF >35% would be 31.9 deaths (plausible range, 8.1 to 82.3) (Table 4). Nearly 90% of these patients were taking aspirin and beta-blockers, and three-quarters or more were taking statins and angiotensin-converting enzyme (ACE) inhibitors and were tobacco-free. However, only one-third of patients were physically active. Among the interventions, keeping patients physically active would contribute the largest DPP. The impact of optimizing physical activity was followed by abstaining from tobacco, and increasing use of ACE inhibitors, aspirin, beta-blockers, and statins.

The potential to increase DPP by optimizing care for patients with prevalent CAD and/or HF and an LVEF ≤35% would be 20.1 (plausible range, 6.20 to 35.7). Nearly 80% of these patients were taking aspirin, beta-blockers, and ACE inhibitors; two-thirds or more were taking statins and were tobacco-free. However, only one-third were physically active. Implantable cardioverter-defibrillators (ICDs) or biventricular pacemakers were implanted in only about 40%, and only 20% were taking spironolactone. As with patients with an LVEF >35%, the largest increase in DPP would be achieved by keeping patients physically active. Optimizing the use of ICDs or biventricular pacemakers would contribute a DPP of 6.50. The impact of increasing spironolactone use would be nearly the same, with abstaining from tobacco and using statins having less impact.

**Acute events**: For patients hospitalized with STEMI, the DPP achieved by optimizing care would be 0.70 (Table 5). Nearly 100% of patients presenting with STEMI were given aspirin, beta-blockers, statins, rescue angioplasty, and a prescription to participate in cardiac rehabilitation. Two-thirds of patients had quit smoking at the time of the STEMI, and 80% were given ACE inhibitors. The largest increase in DPP would accrue from increasing abstinence from tobacco, followed by increasing participation in cardiac rehabilitation, 26 and prescribing IIb/IIIa inhibitors, clopidogrel, and ACE inhibitors.

The combined potential to increase DPP for patients hospitalized with an nSTEMI could be as large as 2.8 (plausible range, 0.1 to 11.3). Nearly 100% of these patients were given aspirin and beta-blockers, and roughly 80% were given statins and ACE inhibitors. However, only 60% participated in cardiac rehabilitation, and nearly 10% continued to smoke. The largest increase in DPP would come from increasing participation in cardiac rehabilitation, followed by increasing abstinence from tobacco, and increasing the use of statins.

The combined potential increase in DPP for patients in CAD and/or HF newly diagnosed in the ambulatory setting was 9.7 (plausible range, 1.9 to 24.8). More than 90% of these patients were given a prescription for aspirin, and three-fourths were given beta-blockers and statins. However, only about 15% of the patients participated in cardiac rehabilitation, one-fourth continued to smoke, and one-third were not given a prescription for ACE inhibitors. The largest increase in DPP would come from increasing participation in cardiac rehabilitation, followed by increasing abstinence from tobacco and increasing the use of beta-blockers, ACE inhibitors, statins, and aspirin.
Identifying Opportunities for a Medical Group to Improve Outcomes for Patients with Coronary Artery Disease and Heart Failure: An Exploratory Study

<table>
<thead>
<tr>
<th>Intervention goal</th>
<th>Expected mortality reduction in the candidate population (plausible range)*</th>
<th>Current level of implementation (plausible range)*</th>
<th>Additional DPPs by optimizing care (plausible range)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic heart disease with an LVEF &gt;35%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>0.20 (0.16 – 0.24)</td>
<td>0.85 (0.68 – 1.00)</td>
<td>2.30 (0.00 – 8.60)</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>0.23 (0.15 – 0.31)</td>
<td>0.88 (0.70 – 1.00)</td>
<td>2.20 (0.00 – 10.3)</td>
</tr>
<tr>
<td>Statin</td>
<td>0.12 (0.09 – 0.16)</td>
<td>0.79 (0.63 – 0.95)</td>
<td>2.00 (0.20 – 6.60)</td>
</tr>
<tr>
<td>Abstain from tobacco</td>
<td>0.36 (0.29 – 0.42)</td>
<td>0.84 (0.67 – 1.00)</td>
<td>4.50 (0.00 – 15.5)</td>
</tr>
<tr>
<td>Eliminate ETS</td>
<td>0.01 (0.01 – 0.01)</td>
<td>0.35 (0.28 – 0.42)</td>
<td>0.60 (0.20 – 1.20)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>0.16 (0.05 – 0.25)</td>
<td>0.73 (0.58 – 0.88)</td>
<td>3.40 (0.30 – 11.7)</td>
</tr>
<tr>
<td>Remain physically active</td>
<td>0.42 (0.25 – 0.71)</td>
<td>0.33 (0.26 – 0.40)</td>
<td>22.00 (7.50 – 58.8)</td>
</tr>
<tr>
<td>Combined potential</td>
<td></td>
<td></td>
<td>31.90 (8.10 – 82.3)</td>
</tr>
<tr>
<td>Symptomatic heart disease with an LVEF ≤35%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>0.20 (0.16 – 0.24)</td>
<td>0.77 (0.62 – 0.92)</td>
<td>1.20 (0.20 – 3.50)</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>0.37 (0.28 – 0.45)</td>
<td>0.77 (0.62 – 0.92)</td>
<td>2.30 (0.40 – 6.60)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>0.24 (0.17 – 0.34)</td>
<td>0.80 (0.64 – 0.96)</td>
<td>1.30 (0.10 – 4.60)</td>
</tr>
<tr>
<td>Abstain from tobacco</td>
<td>0.36 (0.29 – 0.42)</td>
<td>0.70 (0.56 – 0.84)</td>
<td>2.80 (0.80 – 7.00)</td>
</tr>
<tr>
<td>Eliminate ETS</td>
<td>0.00 (0.00 – 0.00)</td>
<td>0.35 (0.28 – 0.42)</td>
<td>0.00 (0.00 – 0.10)</td>
</tr>
<tr>
<td>Statin</td>
<td>0.12 (0.09 – 0.16)</td>
<td>0.70 (0.56 – 0.84)</td>
<td>1.00 (0.20 – 2.70)</td>
</tr>
<tr>
<td>Spironolactone</td>
<td>0.30 (0.18 – 0.40)</td>
<td>0.20 (0.16 – 0.24)</td>
<td>6.30 (2.30 – 12.8)</td>
</tr>
<tr>
<td>Remain physically active</td>
<td>0.63 (0.16 – 0.83)</td>
<td>0.33 (0.26 – 0.40)</td>
<td>11.10 (1.60 – 23.2)</td>
</tr>
<tr>
<td>ICD or biventricular pacemaker</td>
<td>0.43 (0.20 – 0.60)</td>
<td>0.43 (0.34 – 0.52)</td>
<td>6.50 (1.60 – 14.9)</td>
</tr>
<tr>
<td>Combined potential</td>
<td></td>
<td></td>
<td>20.10 (6.20 – 35.7)</td>
</tr>
</tbody>
</table>

* The plausible range is defined as ±20% of the observed value.

ACE = angiotensin-converting enzyme; DPP = deaths prevented or postponed; ETS = environmental tobacco smoke; LVEF = left ventricular ejection fraction; ICD = implantable cardioverter-defibrillator

12. Lam SK, Owen A. Combined resynchronisation and implantable defibrillator therapy in left ventricular dysfunction: Bayesian network meta-analysis of randomised controlled trials. BMJ 2007 Nov 3;335(7626):923.
# Table 5. The potential impact of optimizing care with an acute coronary artery disease and/or heart failure event

<table>
<thead>
<tr>
<th>Intervention goal</th>
<th>Expected mortality reduction in the candidate population (plausible range)*</th>
<th>Current level of implementation (plausible range)*</th>
<th>Additional DPPs by optimizing care (plausible range)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>With STEMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>0.20^{+} (0.16 – 0.24)</td>
<td>1.00 (0.80 – 1.00)</td>
<td>0.00 (0.00 – 0.30)</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>0.04^{-} (-0.08 – 0.15)</td>
<td>1.00 (0.80 – 1.00)</td>
<td>0.00 (0.00 – 0.20)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>0.07^{+} (0.02 – 0.11)</td>
<td>0.80 (0.64 – 0.96)</td>
<td>0.10 (0.00 – 0.30)</td>
</tr>
<tr>
<td>Statins</td>
<td>0.12^{-} (0.09 – 0.16)</td>
<td>0.97 (0.78 – 1.00)</td>
<td>0.00 (0.00 – 0.30)</td>
</tr>
<tr>
<td>Angioplasty(b)</td>
<td>0.33^{-} (0.26 – 0.40)</td>
<td>0.66 (0.53 – 0.79)</td>
<td>0.60 (0.20 – 1.40)</td>
</tr>
<tr>
<td>Abstain from tobacco</td>
<td>0.36^{-} (0.29 – 0.42)</td>
<td>0.66 (0.53 – 0.79)</td>
<td>0.60 (0.20 – 1.40)</td>
</tr>
<tr>
<td>Eliminate ETS</td>
<td>0.00^{+} (0.00 – 0.00)</td>
<td>0.35 (0.28 – 0.42)</td>
<td>0.00 (0.00 – 0.00)</td>
</tr>
<tr>
<td>Cardiac rehabilitation</td>
<td>0.20^{-} (0.07 – 0.32)</td>
<td>0.97 (0.78 – 1.00)</td>
<td>0.00 (0.00 – 0.50)</td>
</tr>
<tr>
<td>Combined potential</td>
<td></td>
<td>0.70 (0.20 – 2.00)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute heart failure with LVEF ≤35%</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>0.26^{-} (0.23 – 0.29)</td>
<td>0.86 (0.69 – 1.00)</td>
<td>0.60 (0.00 – 2.40)</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>0.37^{-} (0.28 – 0.45)</td>
<td>0.97 (0.78 – 1.00)</td>
<td>0.20 (0.00 – 2.70)</td>
</tr>
<tr>
<td>Spironolactone</td>
<td>0.30^{-} (0.28 – 0.40)</td>
<td>0.30 (0.24 – 0.36)</td>
<td>3.70 (1.30 – 8.10)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>0.26^{-} (0.17 – 0.34)</td>
<td>1.00 (0.80 – 1.00)</td>
<td>0.00 (0.00 – 1.80)</td>
</tr>
<tr>
<td>Statins</td>
<td>0.20^{-} (0.16 – 0.24)</td>
<td>0.73 (0.58 – 0.88)</td>
<td>1.00 (0.20 – 2.70)</td>
</tr>
<tr>
<td>Abstain from tobacco</td>
<td>0.36^{-} (0.29 – 0.42)</td>
<td>0.73 (0.58 – 0.88)</td>
<td>1.70 (0.40 – 4.70)</td>
</tr>
<tr>
<td>Eliminate ETS</td>
<td>0.00^{+} (0.00 – 0.00)</td>
<td>0.35 (0.28 – 0.42)</td>
<td>0.00 (0.00 – 0.10)</td>
</tr>
<tr>
<td>Cardiac rehabilitation</td>
<td>0.35^{-} (0.08 – 0.54)</td>
<td>0.19 (0.15 – 0.23)</td>
<td>5.00 (0.70 – 12.2)</td>
</tr>
<tr>
<td>Combined potential</td>
<td></td>
<td>9.60 (2.50 – 21.6)</td>
<td></td>
</tr>
<tr>
<td><strong>With nSTEMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>0.20^{+} (0.16 – 0.24)</td>
<td>0.97 (0.78 – 1.00)</td>
<td>0.00 (0.00 – 0.40)</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>0.04^{-} (-0.08 – 0.15)</td>
<td>1.00 (0.80 – 1.00)</td>
<td>0.00 (0.00 – 0.20)</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>0.07^{-} (-0.08 – 0.21)</td>
<td>0.74 (0.59 – 0.89)</td>
<td>0.10 (0.00 – 0.60)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>0.07^{+} (0.02 – 0.11)</td>
<td>0.80 (0.64 – 0.96)</td>
<td>0.10 (0.00 – 0.30)</td>
</tr>
<tr>
<td>IIb/IIIa inhibitors</td>
<td>-0.10^{-} (-0.29 – 0.14)</td>
<td>0.60 (0.48 – 0.72)</td>
<td>0.20 (0.20 – 0.50)</td>
</tr>
<tr>
<td>Immediate revascularization</td>
<td>0.37^{-} (0.23 – 0.48)</td>
<td>0.54 (0.43 – 0.65)</td>
<td>0.80 (0.20 – 1.90)</td>
</tr>
<tr>
<td>Statins</td>
<td>0.12^{-} (0.09 – 0.16)</td>
<td>1.00 (0.80 – 1.00)</td>
<td>0.00 (0.00 – 0.20)</td>
</tr>
<tr>
<td>Abstain from tobacco</td>
<td>0.36^{-} (0.29 – 0.42)</td>
<td>0.74 (0.59 – 0.89)</td>
<td>0.40 (0.10 – 1.20)</td>
</tr>
<tr>
<td>Eliminate ETS</td>
<td>0.00^{+} (0.00 – 0.00)</td>
<td>0.35 (0.28 – 0.42)</td>
<td>0.00 (0.00 – 0.00)</td>
</tr>
<tr>
<td>Cardiac rehabilitation</td>
<td>0.20^{-} (0.07 – 0.32)</td>
<td>0.66 (0.53 – 0.79)</td>
<td>0.30 (0.00 – 1.10)</td>
</tr>
<tr>
<td>Combined potential</td>
<td></td>
<td>1.40 (0.10 – 4.50)</td>
<td></td>
</tr>
<tr>
<td><strong>With unstable angina(c)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>0.20^{+} (0.16 – 0.24)</td>
<td>0.96 (0.77 – 1.00)</td>
<td>0.10 (0.00 – 1.40)</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>0.04^{-} (-0.08 – 0.15)</td>
<td>0.96 (0.77 – 1.00)</td>
<td>0.00 (0.00 – 1.90)</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>0.07^{+} (-0.08 – 0.21)</td>
<td>0.54 (0.43 – 0.65)</td>
<td>0.00 (-0.03 – 3.00)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>0.07^{+} (0.02 – 0.11)</td>
<td>0.82 (0.66 – 0.98)</td>
<td>0.20 (0.00 – 0.90)</td>
</tr>
<tr>
<td>Statins</td>
<td>0.12^{-} (0.09 – 0.16)</td>
<td>0.79 (0.63 – 0.95)</td>
<td>0.40 (0.00 – 1.50)</td>
</tr>
<tr>
<td>Abstain from tobacco</td>
<td>0.36^{-} (0.29 – 0.42)</td>
<td>0.93 (0.74 – 1.00)</td>
<td>0.40 (0.00 – 2.70)</td>
</tr>
<tr>
<td>Eliminate ETS</td>
<td>0.00^{+} (0.00 – 0.00)</td>
<td>0.35 (0.28 – 0.42)</td>
<td>0.00 (0.00 – 0.01)</td>
</tr>
<tr>
<td>Cardiac rehabilitation</td>
<td>0.20^{-} (0.07 – 0.32)</td>
<td>0.64 (0.51 – 0.77)</td>
<td>1.20 (0.20 – 3.90)</td>
</tr>
<tr>
<td>Combined potential</td>
<td></td>
<td>2.80 (0.10 – 11.3)</td>
<td></td>
</tr>
</tbody>
</table>

*Continued on next page.*


The relative magnitude of opportunities to improve outcomes: Among the two ambulatory populations with stable CAD and/or HF and the four types of acute events, the largest opportunity to increase the DPP would accrue from optimizing care for ambulatory patients (Figure 2). Nearly 70% of the total potential increase in DPP by optimizing care would accrue from the two pools of ambulatory patients. With the exception of more aggressive treatment of acute HF with an LVEF ≤35%, very little improvement would be expected from further improvements in care for patients with acute events. Only about 2% of the potential increase in DPP is predicted to accrue from improved care for patients experiencing a STEMI or nSTEMI.

Sensitivity analysis: With the exception of eliminating environmental tobacco smoke exposure, optimizing any single intervention for patients in the two prevalence pools would have a larger impact than optimizing all interventions for STEMI and nSTEMI combined. However, the impact of improving care for patients hospitalized with HF could be as large as improving care for patients with ambulatory presentations.

Comment

In this analysis, we asked two questions: 1) are medical group data adequate to identify opportunities to prevent or postpone death among individuals with heart disease?, and 2) if the data are adequate, are the conclusions generated from medical group data similar to those we previously generated from US statistics? We found that, with the exception of physical activity data, the medical group data were adequate to identify opportunities to prevent or postpone deaths and that the conclusions for a single medical group were consistent with previous conclusions based on national data.1 We found that nearly 70% of the total opportunity to increase the DPP would accrue from optimizing care of ambulatory patients. Among hospitalized patients, the greatest DPP would accrue from optimizing care for patients with HF with an LVEF ≤35% and patients with UA. Optimizing care for hospitalized patients with either STEMI or nSTEMI would prevent or postpone only about 2% of deaths. This is in part because of the fact that presentation with STEMI or nSTEMI is infrequent relative to other presentations and to the nearly optimal care that patients with STEMI or nSTEMI already receive.

We acknowledge that limitations in the data weaken the conclusions that can be drawn. For example, fatality rates and sheer numbers of patients suggest that many of the patients we classified as having heart disease newly diagnosed in the ambulatory setting.
Identifying Opportunities for a Medical Group to Improve Outcomes for Patients with Coronary Artery Disease and Heart Failure: An Exploratory Study

Determining mortality rates should not introduce significant error using a relatively recent historical cohort to estimate mortality cohorts and populations with acute events. It is most important to analyze current clinical practice; the purposes of care-improvement initiatives, it is data always lag behind clinical data. We feel that, for use mortality as an outcome is that death certificate any medical record. There would have been no need to manually review patients’ ECGs for patterns of interest had been available, newer ECG reporting software with the capability to "acute myocardial infarction with ST elevation"). If patients’ ECGs for patterns of interest (eg, the words by the Medical Group did not permit searching for commercial software, we did need to manually review medical records of patients with acute MI to distinguish between STEMI and nSTEMI; the ICD-9-CM diagnostic codes did not reliably distinguish between STEMI and nSTEMI, a computer-based search of text in the medical record for words indicating STEMI or nSTEMI was unreliable, and the ECG analysis software used by the Medical Group did not permit searching for patients’ ECGs for patterns of interest (eg, the words "acute myocardial infarction with ST elevation").

Although it is possible to collect nearly all of the data used in this analysis with currently available commercial software, we did need to manually review medical records of patients with acute MI to distinguish between STEMI and nSTEMI; the ICD-9-CM diagnostic codes did not reliably distinguish between STEMI and nSTEMI, a computer-based search of text in the medical record for words indicating STEMI or nSTEMI was unreliable, and the ECG analysis software used by the Medical Group did not permit searching for patients’ ECGs for patterns of interest (eg, the words "acute myocardial infarction with ST elevation"). If newer ECG reporting software with the capability to search ECGs for patterns of interest had been available, there would have been no need to manually review any medical record.

A conundrum for quality-improvement efforts that use mortality as an outcome is that death certificate data always lag behind clinical data. We feel that, for the purposes of care-improvement initiatives, it is most important to analyze current clinical practice; because mortality rates are relatively stable for ambulatory cohorts and populations with acute events, using a relatively recent historical cohort to estimate mortality rates should not introduce significant error into the calculations.

Although it would be attractive to have a model that includes all heart disease, which is possible, we chose to limit our codes to CAD and HF for this pilot study. Arrhythmias and valvular heart disease could be included in the analysis as specific conditions, but doing so would add a level of complexity that we wished to avoid. It would also be possible to use the same model to analyze the opportunities to prevent and treat several chronic diseases simultaneously. For example, cerebrovascular disease, peripheral arterial disease, and chronic obstructive pulmonary disorder could be added to the analysis of heart disease opportunities.

This study raises important questions about the current focus of efforts to improve heart disease outcomes in the US. To the extent that the nearly optimal care given to hospitalized patients in this study is representative of the care received by all Americans hospitalized with heart disease, there is relatively little opportunity to improve outcomes by improving care during acute events other than HF with an LVEF <35%. The large size of the ambulatory population with CAD and/or HF magnifies the care deficiencies they experience. Although we acknowledge that it is highly unlikely that all patients with heart disease will become physically active, eat a healthy diet, and abstain from tobacco, this analysis shows that even modest improvements in the rates of these behaviors will have the largest impact on outcomes for these patients.

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

References
Identifying Opportunities for a Medical Group to Improve Outcomes for Patients with Coronary Artery Disease and Heart Failure: An Exploratory Study

17. Lam SK, Owen A. Combined resynchronisation and implantable defibrillator therapy in left ventricular dysfunction: Bayesian network meta-analysis of randomised controlled trials. BMJ 2007 Nov 3;335(7626):925.
A New Model of Well-Child Care: Implications for Resource Costs and Dissemination

Debra P Ritzwoller, PhD
Anna Sukhanova, MA
Arne L Beck, PhD
David Bergman, MD

Abstract

Objective: Current pediatric well-child care (WCC) may be inefficient and inadequate with respect to primary care physicians’ abilities to deliver prescribed preventive and developmental services. New Internet-related technologies may improve the efficiency and effectiveness of WCC. This article examines the potential resource cost implications associated with a change in the delivery model of WCC in a capitated, integrated managed care system.

Study Design: Decision analyses and Monte Carlo simulations were used to estimate the variation in resource costs between the current WCC model and a high-performance WCC model, stratifying by age, risk level, and the proportion of pediatric members that may not seek WCC.

Methods: Demographic and health care utilization data associated with 14,910 pediatric enrollees, ages newborn to 5 years, enrolled at Kaiser Permanente Colorado were used to simulate the change in costs attributable to a change in the model of WCC.

Results: Simulation models and sensitivity analyses suggest that the implementation of the high-performance WCC model is likely to be relatively resource cost neutral in a managed care system.

Conclusions: Preliminary findings suggest that implementation of innovative changes in WCC may allow for efficient reallocation of resources to higher-risk children in a relatively cost neutral manner. However, innovative changes that involve the use of unreimbursed non-face-to-face encounters and nonphysician health care professionals may present challenges with respect to implementation of a new model of WCC in a fee-for-service environment.

Introduction

Current pediatric practice, especially the provision of developmental and preventive care services, is inefficient and out of step with the expectations and needs of many families with young children.1 In our current system, well-child care (WCC) is the primary way for providing these services to children. It comprises almost 25% of pediatric visits, and over 50% of all visits in the first year of life. In spite of this considerable allocation of time and resources, many children do not receive the care they need.2

Much of this unmet need stems from a lack of time and resources on the part of the primary care physician (PCP) to deliver the prescribed preventive and developmental services during WCC visits.5-5 Some of these time constraints could be lessened if the PCP was able to collect screening information and parental concerns before the visit. This would allow for the visit to be tailored to the specific needs of the patient and family and would improve the efficiency and effectiveness of the encounter. Current research has shown that the adoption of new technologies that allow for patient transactions outside the primary care office can significantly affect the effectiveness, patient-centeredness, timeliness, and efficiency of child development and health promotion practice.6-10 The potential benefits of this type of technology for WCC are considerable. If developmental and psychosocial screening can be accomplished through non-face-to-face transactions over the Internet and communicated to the PCP before the visit, the PCP can ensure that the specific needs of the family are met during the WCC visit in an efficient and effective manner.

In spite of the potential benefits, adoption of new technologies to deliver WCC has been slow. One of the perceived barriers to more widespread adoption is the lack of perceived return on investment for Web-based transactions between families and clinicians. PCPs are
The new model ... was designed to improve the efficiency and effectiveness of well-child care by engaging families in Web-based transactions before the visit ...

reluctant to embrace a new way of delivering care if it potentially will add to time and resources needed to deliver care. However, adoption of these new technologies may lead to increased efficiencies that save money or keep costs neutral and be of greater value to the patients and their families.

The uncertainty surrounding the impact of adopting new technologies in WCC makes it difficult for health care organizations to “take risks ahead of the data” and proceed with the development of redesigned systems of care. To help reduce this uncertainty we sought to model the potential economic impact of a new system for WCC at Kaiser Permanente Colorado (KPCO) that was designed to deliver enhanced and tailored care during the WCC encounter.

The new KPCO model of WCC, high-performing WCC (HPWCC) was designed to improve the efficiency and effectiveness of WCC by engaging families in Web-based transactions before the visit and using this information to tailor the WCC visit to best meet the needs of parents. To better understand the economic impact of implementing HPWCC, we estimated the resource costs associated with current American Academy of Pediatrics-recommended WCC service schedules (www.aap.org/research/pedmedcostmodel.cfm), as modified by KPCO, as compared to HPWCC, for pediatric patients, ages newborn to 5 years.

Background

The HPWCC model was developed in collaboration with staff and parents of pediatric KPCO members in 2007. Bergman et al and Beck et al describe this model in detail.\(^{11,12}\)

In brief, this system incorporates three improvements to the WCC visit: 1) the use of a Web-based, previsit assessment completed by the family that allows the practitioner to tailor the visit to the family needs; 2) the use of different visit types, eg, brief visits or e-visits that allow the clinician to modify resources and personnel based on the needs of the child; and 3) an extended visit for children with special health care needs. A key component of the HPWCC model is the Web-based tool, the Child Health and Development Interactive System (CHADIS) (www.childhealthcare.org/chadis). This Web-based system captures parental responses to validated developmental and behavioral surveys and allows parents to articulate their child’s challenges and strengths as well as any questions they may have for the upcoming visit. The CHADIS assessment is completed before the visit and the results are presented in a one-page summary that is accessed and reviewed by the clinician before the visit. The clinician uses this information to tailor the content and length of the visit and to involve other health care staff as necessary to meet the identified needs of the family.

Methods

Several data sources were used for this analysis including the demographic and health care utilization data associated with the 2006 KPCO pediatric population, ages newborn to 5 years; American Academy of Pediatrics visit schedules; and other published research related to the proportion of the pediatric population with special needs.\(^{13}\) We estimated the age and risk stratification of the 2006 KPCO pediatric population. We then used decision analysis models and Monte Carlo simulations to estimate the variation in WCC cost stratified by age, risk level, and care approach (current WCC vs HPWCC). We also performed sensitivity analyses to adjust for the proportion of pediatric members that may not seek WCC and for the distribution of high-risk patients. This study was reviewed by KPCO’s institutional review board and was considered exempt as a quality-improvement project.

Age, Risk Stratification, and Users of Well-Child Care Services

We identified children born between January 1, 2000, and January 1, 2005, (ie, age 0 to 5 years as of January 1, 2005) who were members of KPCO continuously between January 1, 2005, and December 31, 2006. These data were used to estimate the age distribution of pediatric members by the following age categories: age <1 year, age 1 to 2 years, and age 3 to 5 years. We examined total office visits and then divided them into two different subsets: 1) WCC visits versus other and 2) primary care versus specialty or ancillary care (radiology, lab, etc.). These analyses also allowed us to identify the proportion of the KPCO pediatric population (age <5 years) who were nonusers of WCC. Colorado-specific data from the National Survey for Children with Special Health Care Needs\(^{13}\) along with a validated pharmacy-based risk adjustment system, called RxRisk,\(^{14,17}\) were used to assign the proportion of pediatric members by age category that were likely to have been “high risk” in 2006.

Allocation of Resources and Costs Based on Current Well-Child Care versus High-Performing Well-Child Care

We used WCC visit schedules described in Table 1, which note the visit schedule by age, visit description, and clinician. A description
### Table 1. Well-child care visit schedules for current practice, high-performing well-child care, and high-risk children with special health care needs

<table>
<thead>
<tr>
<th>Visit</th>
<th>Current pediatric WCC with augmented developmental and behavioral screening Description/provider</th>
<th>Visit schedule for HPWCC for high-risk children with special health care needs Description/provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perinatal</td>
<td>Home visit/PA or NP</td>
<td>Home visit/PA or NP</td>
</tr>
<tr>
<td>2 week</td>
<td>Pediatrician visit/MD</td>
<td>Pediatrician visit/MD</td>
</tr>
<tr>
<td>2 month</td>
<td>Pediatrician visit; partner violence screening/MD</td>
<td>Pediatrician visit; CHADIS partner violence screening/MD</td>
</tr>
<tr>
<td>4 month</td>
<td>Pediatrician visit; maternal depression screening/MD</td>
<td>21st century WCC visit; CHADIS maternal depression screening/MD</td>
</tr>
<tr>
<td>6 month</td>
<td>Pediatrician visit; developmental screening/MD</td>
<td>Pediatrician visit; CHADIS developmental screening/MD</td>
</tr>
<tr>
<td>9 month</td>
<td>No 9 month visit</td>
<td>e-Visit; CHADIS developmental screening/MD/RN/development specialist</td>
</tr>
<tr>
<td>12 month</td>
<td>Pediatrician visit; maternal depression screening; developmental screening/MD</td>
<td>Pediatrician visit; CHADIS, maternal depression screening/MD</td>
</tr>
<tr>
<td>18 month</td>
<td>Pediatrician visit; M-CHAT, developmental screening/MD</td>
<td>21st century WCC visit; CHADIS developmental screening; M-CHAT; partner violence screening/MD</td>
</tr>
<tr>
<td>2 years</td>
<td>Pediatrician visit; M-CHAT, developmental screening/MD</td>
<td>21st century WCC visit; M-CHAT/MD</td>
</tr>
<tr>
<td>3 years</td>
<td>Pediatrician visit; developmental screening; partner violence screening/MD</td>
<td>21st century WCC visit; CHADIS developmental screening/MD</td>
</tr>
<tr>
<td>4 years</td>
<td>Pediatrician visit; developmental screening; pediatric symptom checklist/MD</td>
<td>Pediatrician visit; CHADIS preschool check; developmental screening; pediatric symptom checklist/MD</td>
</tr>
<tr>
<td>5 years</td>
<td>Pediatrician visit; developmental screening; pediatric symptom checklist/MD</td>
<td>21st century WCC visit; developmental screening; pediatric symptom checklist/MD or care coordinator</td>
</tr>
</tbody>
</table>

An HPWCC visit will use the Internet-based CHADIS program to shift a portion of the care involved with a WCC visit to before the office visit. Specifically parents will have opportunity to assess their child’s development, articulate their concerns, and relate the good parts and the challenges of parenting. The physician will be able to respond by e-mail to parents’ questions and concerns before the visit. This will hopefully allow more efficient visits with the physicians, which should take 10 minutes instead of the usual 20 minutes per visit. If the previst assessment identifies concerns the physician can allot more time for the visit. Parents always have the option of declining the HPWCC visit for a standard visit.

An e-visit is similar to an HPWCC visit except in the case that the child's development is normal and there are no parental concerns that can't be addressed through e-mail or a phone call, there is no office visit required. Parents always have the option of declining the HPWCC e-visit for a standard office visit.

CHADIS = Child Health and Development Interactive System; HPWCC = high-performing well-child care; M-CHAT = modified checklist for autism in toddlers; MD = physician; NP = nurse practitioner; PA = physician assistant; WCC = well-child care
of the associated Common Procedure Terminology (CPT4) codes and associated WCC procedures for each visit is available online at: www.thepermanentejournal.org/images/Spring2011/WellChild-CareCPTCodes.jpg. Table 1 contains the current KPCO WCC schedule for visits and developmental and behavioral screening. It also describes the content and visit schedule associated with the HPWCC model\textsuperscript{11} that was developed at KPCO.

### Managed Care Costs

KPCO’s Decision Support System (DSS) was used to estimate 2007 resource costs for WCC, using the visit schedules noted in Table 1. The DSS allocates health care costs for all internal services provided directly by KPCO based on the personnel and other resources used in the delivery of health care services. Internal costs are allocated by CPT4-specific resource intensity weights (by service department and procedure) using KPCO’s general ledger.\textsuperscript{18,19} Specifically, the numerator in the DSS system is the total costs associated with the delivery of all health care at KPCO (excluding insurance and marketing costs), and the denominator is all activity as captured resource value units (RVU) that are derived from CPT4 and Evaluation and Management codes, etc, associated with delivery of care. This allows for estimation of cost per RVU, which can then be translated to costs per CPT4 code or type of visit. If DSS-based cost estimates were not available for a particular CPT4 code, we imputed CPT4 level costs by mapping comparable RVU estimates from other CPT4 codes that were captured in the DSS system in order to estimate a comparable cost metric.

### Simulation Models

We employed TreeAge Pro 2008 (TreeAge Software, Inc, Williamstown, MA) to develop decision models along with Monte Carlo simulations to estimate the variation in WCC costs between the two models of care. This type of analysis has frequently been used within the field of pediatric research as an analytic tool to better understand the range of predicted costs associated with implementation of an intervention, or a new model of care.\textsuperscript{20-23} This technique can be used to address variations in the inputs (in this case visit types) within the models while capturing the effects of uncertainty. This Monte Carlo simulation used cohorts of simulated pediatric patients as they pass through a year of WCC. In this analysis, our Monte Carlo simulation was based on parameters derived from the 2006 KPCO pediatric patient population (described above) including age, risk category, user status, and CPT4 level DSS cost estimates. As the subjects pass through the model, they are randomly assigned within the decision tree model to the current WCC model versus the HPWCC model.

### Sensitivity Analyses

In the sensitivity analyses, we examined the variation in risk stratification of the pediatric members, and the proportion of members that potentially would, or would not use (or come to clinic for) WCC. Monte Carlo simulations were also run separately for both high-risk and normal-risk groups and by age category. Mean, minimum, and maximum total annual costs were estimated using the entire pediatric population as well as excluding nonusers of WCC (the estimate of the proportion of children who do not come in for WCC). Values were estimated based on 500 repeated randomized samples from a normal probability distribution function. Monte Carlo is a mathematical simulation model that relies on random sampling when it is not feasible to compute results based on the deterministic algorithms. Since results for both intervention and control groups were not actual observation, but rather computer generated numbers, it is not possible to calculate statistics such as p values.

### Results

The baseline estimate for the high-risk cohort was estimated at

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### Table 2. Number of Kaiser Permanente Colorado 2006 pediatric enrollees using well-child care services, distribution by user status and risk category

<table>
<thead>
<tr>
<th>Age</th>
<th>2006 pediatric population</th>
<th>2006 pediatric population minus nonusers of WCC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal risk</td>
<td>High risk (12% age &lt;2 years, 15% age 3 to 5 years)</td>
</tr>
<tr>
<td>&lt;1</td>
<td>2454</td>
<td>335</td>
</tr>
<tr>
<td>1-2</td>
<td>2668</td>
<td>364</td>
</tr>
<tr>
<td>3-5</td>
<td>7726</td>
<td>1363</td>
</tr>
<tr>
<td>Total</td>
<td>12,848</td>
<td>2062</td>
</tr>
</tbody>
</table>

\textsuperscript{*} High-risk cohort estimated at 12% for age <2 years, and 15% age 3 to 5 years

\textsuperscript{a} Data from 2006 demonstrated that the distribution of nonusers of WCC was 17% of patients age <2 years and 12% for patients age 3 to 5 years.

WCC = well-child care
an average of 12% for age <2 years and 15% for ages 3 to 5 years. This estimate was based on evidence described in Blumberg et al. Results derived via the implementation of the RxRisk model using pharmacy dispense data associated with the 2006 KPCO pediatric population suggested that the high-risk cohort could range from 12% to 16% for age <2 years and from 14% to 18% for ages 3 to 5 years. These parameters were then used in the decision analysis.

The distribution of nonusers of WCC for pediatric enrollees age <2 years and age 3 to 5 years was 17% and 32%, respectively. Table 2 describes the distribution of the 2006 KPCO pediatric population by age category, estimated risk stratification, and user status WCC.

**Managed Care Resource Costs**

Figures 1 through 3 describe the variation in annual total cost estimates derived from the Monte Carlo models where we evaluated WCC now, relative to the HPWCC Model, employing KPCO specific resource costs based on CPT4 codes. Figure 1 includes estimated annual total costs, along with the estimates of the range total costs, for all normal-risk (not high-risk) pediatric patients, newborn through age 5 years, stratified by age categories noted above. The annual total costs for 12,848 normal-risk pediatric patients using the current WCC model are estimated to range from $4,122,335 to $7,655,766 (depending on use of services, etc) with an average annual total cost of $5,889,051. The HPWCC model average annual total cost estimate was $6,167,199 (range from $4,317,059 to $8,017,359). Little variation is noted in the range of estimated costs for normal risk pediatric patients, with the exception of infants less than age one year, where the estimated costs for the HPWCC model are higher.

Figure 2 describes the estimated annual total costs for both models of care for the 2062 high-risk pediatric patients, in total, and stratified by age category. The range of total annual costs for all high-risk pediatric patients in the current WCC model versus the HPWCC model was $1,955,169 to $3,631,029, and $2,069,726 to $3,843,776, respectively. The HPWCC models generated slightly higher ranges of cost estimates across all age categories.

Figure 3 describes the estimated ranges of KPCO annual total costs between both WCC models for...
all pediatric patients (normal and high risk combined). The range of total annual costs for pediatric patients for current WCC versus HPWCC model was $6,077,504 to $11,286,795 and $6,386,765 to $11,861,135, respectively. Little variation in costs estimates between the two models are noted for the age 1 to 2 years and age 3 to 5 years categories, with a difference in mean estimated costs for ages 1 to 2 years of $51,242, and a difference of $109,065 for ages 3 to 5 years. Consistent with normal risk estimates in Figure 1, most of the overall variation in cost estimates between the two models is driven by the estimated cost differentials for infants less than one year of age.

**Discussion**

With the exception the category of infants age <1 year, our simulation models and accompanying sensitivity analyses suggest that the implementation of the HPWCC model is likely to be relatively resource cost neutral in an integrated managed care system such as KPCO. Although the HPWCC models generated slightly higher cost estimates, the range of probable cost estimates overlapped by a large degree (Figures 1 to 3). Our results suggest that it may be possible to achieve greater efficiencies, with respect to engaging families before the initial WCC visit without adversely affecting the overall cost of WCC in a managed care environment.

Although managed care organizations may provide the infrastructure and financing that make innovation more feasible than in fee-for-service settings, these organizations face their own challenges when deciding to adopt innovative practices. Often innovations are required to have a business case that estimates a return on investment to offset implementation costs. Cost offsets are usually estimated from associated reductions in other services (eg, sick visits, Emergency Department visits, admissions to the hospital and/or Neonatal Intensive Care Unit) or from efficiencies gained by implementing the innovation. In the future this challenge will most likely not be confined to managed care organizations. Recent health care legislation suggests new models such as Accountable Care Organizations, which have a global payment to the organization for the health services of a defined population. These new models will then confront the same challenges of current managed care organizations in estimating the return on investment on new and innovative systems.

We plan to conduct additional analyses to determine whether HPWCC is associated with either decreases or increases in the use of other health services, as well as efficiencies in providing WCC. However, decisions to adopt innovations in managed care systems are not always based on cost offsets—they may also be driven by evidence of significant improvements in quality of care and/or patient satisfaction justifying investment in the innovation. This is particularly true for the development of innovative preventive services for children. Whereas these methods allow us to examine the more proximate costs related to resource use, they do not factor in the potential downstream benefits in preventing adult-onset disease and in long-term improvement in quality of life with the concomitant savings in health care costs. This is particularly true for children identified as high risk. The design of systems such as HPWCC that allow for the allocation of appropriate resources to high-risk children through the use of new technologies to accrue efficiencies in the care of normal children will be particularly important in preventing future adverse outcomes in the high-risk group of children. We feel that the ability to model resource allocation before the implementation of such services will help organizations manage the risk associated with new innovations and will facilitate implementation and evaluation of new models of care.

This study has several limitations. It is based on simulation models that were informed by the pediatric population characteristics of those enrolled in KPCO in 2006-2007. Although we ran sensitivity analyses to account for variation in the proportion of high-risk patients, the low-level Medicaid participation rate in KPCO may bias our estimates. We also did not examine or model how the HPWCC model will affect non-WCC services. It is possible that significant cost off-sets may be found for this age group for non-WCC services given the more intensive use of development screenings, etc. Our cost estimates were based on the perspective of the health plan. We also did not include other changes in societal costs, including the time costs of the parent. Although the previsit screen does require parent time to complete, anecdotal findings from our pilot study suggest that these time costs are recouped by more efficient WCC visits.

In addition, findings from this study may not translate to the fee-for-service, noncapitated or integrated environment including Medicaid. We measured costs using KPCO’s cost allocation system, not Medicaid or other fee-for-
service-based estimates. How one defines the measures and the key outcome variables such as costs versus reimbursements (Medicaid or other) may be critical to the study outcome or findings.\textsuperscript{27,28} Too often redesigned care calls for new types of health care professionals and the use of non-face-to-face encounters that are not reimbursed in existing fee-for-service systems.\textsuperscript{29,30} Although work is underway to develop criteria for reimbursement of e-visits, to date there has not been widespread reimbursement for these services.\textsuperscript{31}

Given the issues noted above, the policy implications from this study may depend heavily on where the program is implemented. In an integrated care system like KP, where a large majority of the enrollees have access to the Internet, HPWCC may allow greater flexibility for patients and clinicians and for a more efficient allocation of resources for high-risk pediatric patients. However, alternate models of HPWCC that do not rely on the Internet (e.g., use of promotoras [a community outreach worker who is responsible for raising awareness of health and educational issues], kiosks in clinic waiting rooms with developmental assessments, etc) may be more likely to achieve such efficiencies in underserved populations.

The strength of this study is that it incorporates actual health services utilization data (and data for nonusers) into simulation models, thereby increasing the accuracy of the cost models. Ultimately these findings need to be confirmed through a study of the implementation and evaluation of the HPWCC model in clinical settings. We are evaluating HPWCC in three intervention clinics at KP to validate the cost predictions presented in this study.

### Disclosure Statement

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### Acknowledgments

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### References

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ORIGINAL RESEARCH & CONTRIBUTIONS

A New Model of Well-Child Care: Implications for Resource Costs and Dissemination


Civilization

The level of civilization attained by any society will be determined by the attention it has paid to the welfare of its children.

— The Children’s Bill of Rights, 1968, Billy F Andrews, MD, pediatrician and lecturer
When Rapport Building Extends Beyond Affiliation: Communication Overaccommodation Toward Patients with Disabilities

Abstract

Introduction: Physician rapport with patients is described as a vital component of relationship-centered care,1 where rapport consists of trust and understanding, harmony, and affinity. Overall, rapport-building through open and symmetrical posture, more direct body orientation, closer interpersonal distance, more smiling, head nodding, eye contact, facial expressiveness, and vocal concern are described as beneficial.2 In the clinical context, physician nonverbal rapport-building behaviors are associated with positive outcomes including increased disclosure about psychosocial components of illness,3 patient satisfaction,4 and communication patterns that are reciprocated between physician and patient.5 Similarly, rapport-building behaviors may indicate nurturing and acknowledging relational/emotional qualities unique to the person rather than the person’s group identity.6 However, in interactions with patients with disabilities, physician communication otherwise associated with rapport may instead indicate an overly nurturing inclination to care for the “afflicted” individual.7 The disability may be the un-named “elephant in the room,” shifting the meaning of communication behaviors in readily apparent to subtle ways.8 Language implying familiarity and relationship beyond biomedical knowledge may be perceived as biased.9 As observed in communication toward elderly individuals, high-pitch, exaggerated intonation, simplified vocabulary, and repetition, or non-verbal kinesic/body movement cues—including extended

Introduction

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dismissive gestures, dismissive facial expressions, or avoidance—may indicate patronizing communication.\textsuperscript{10}

Rapport-building behaviors may indicate familiarity beyond what is appropriate in the particular physician-patient interaction. In addition, physicians are vulnerable to exceeding their judgment and capacity regarding group affiliation and its significance and may rely on cultural bias and stereotyping. In the disability domain, negative stereotypes include dependence and incompetence. Exaggerated intonation, simplified vocabulary, or exaggerated nonverbal cues may indicate negative attitudes by the physician. The elicitation of negative stereotypes is associated with withdrawal, reduced sense of control, and lower self-esteem.\textsuperscript{10,11} Similarly, secondary baby-talk as observed in interactions with elderly individuals through high pitch, exaggerated intonation, “we” language to refer to one individual, redundancy, simple vocabulary, pet names, and exaggerated praise\textsuperscript{12-13} is also considered patronizing.

This article provides a comprehensive analysis of medical students’ communication toward patients with disabilities. We examined medical students’ verbal and nonverbal behaviors associated with rapport and suggest that quantity or context of these behaviors may restrict patient disclosure and may infantilize patients. Behaviors are interpreted through the theoretical framework of Communication Accommodation Theory (CAT), which describes the ways people adjust their speech styles, or “accommodate” as a means of expressing values, attitudes, and intentions.\textsuperscript{14-16} CAT provides a means to interpret communication behaviors in intergroup encounters and proposes that the extent to which individuals shift their communication styles communicates social approval or disapproval.\textsuperscript{17} CAT posits that communication behaviors are fueled by social stereotypes of groups, which translate into individual attitudes. For patients with disabilities, stereotypes are abundant and can be exceedingly negative. Attitudes toward people with disabilities are the learned, emotionally toned predispositions representing values and beliefs.\textsuperscript{18} Attitudes toward people with physical disabilities include perceptions of sickness, dependency, bitterness, sinfulness, incompetence, asexuality, accident proneness, and nonproductivity.\textsuperscript{19} Medical students’ negative attitudes toward patients with disabilities may affect the patients’ self-concept and general health.\textsuperscript{20}

Adapting communication to patients with disabilities can be seen as a tension between dominant group discourse to keep disabled “others” in place,\textsuperscript{21,22} or in contrast, empowering exchanges by emphasizing “person first” language and discourse about the person as a whole.\textsuperscript{23} CAT frames the degree of accommodation (modified communication) in terms of convergence, divergence, and maintenance as the result of perceiving group membership (in this case disability) as salient. Convergence is a change in speech pattern, so as to better fit that of the person to whom one is speaking, and indicates approval, solidarity, personal affiliation, liking or acceptance.\textsuperscript{24,25} The desire to meet the expectations of others is described as the driving force in convergence. Physicians who reciprocate language preferences used by patients with disabilities would be converging. Divergence emphasizes differentiation between communication of the physician and patient\textsuperscript{25} and is described as demonstrating differences from the “other.” As observed in Duggan et al.,\textsuperscript{26} medical students who use different language than patients with disabilities, particularly by using “sickness” after the patient uses “disability,” would be diverging. Maintenance occurs when individuals resist change in communication. Physicians who believe that there is “nothing to be done” if a cure is not possible\textsuperscript{27} may underaccommodate to patients with disabilities by indicating uneasiness, avoidance, and low rapport. However, physicians may display positive behaviors through “faking good” in attempts to be socially appropriate,\textsuperscript{28} which may be observed in overaccommodation through excessive rapport-building behaviors. Expressions of pity or “cute” language\textsuperscript{29} would be interpreted as overaccommodation.

To examine the type and context of rapport-building communication toward patients with disabilities and the ways rapport building was identified as exceeding appropriate degree or frequency, or diverging in responding to patient communication behaviors, we asked:

**Research Question 1:** What communication messages and communication contexts suggest that rapport-building behaviors have extended beyond expectations of indicating affiliation towards patients with disabilities?

If communication behaviors exceeding rapport are indeed related to the ways medical students respond to disability, then these behaviors should not be observed in comparable interactions toward patients without a disability. Thus, we compared interactions for the same participating medical students to interactions of comparable complexity but not involving disability.

**Research Question 2:** Will behaviors extending beyond rapport boundaries also be observed toward patients without disabilities?
Methods
Participants and Procedures
Interactions between third- and fourth-year medical students (N = 142), and Standardized Patient Educators (SPEs), were videotaped. To compare whether the identified behaviors were targeted only toward patients with disabilities, the same medical students were videotaped in other similar educational interactions not involving disability (a nutrition counseling interaction). All interactions were recorded with digital videorecorder with a wide-angle lens set on a tripod primarily focusing on the student physician, while also recording the SPE. Institutional review board approval was obtained before beginning videotaping, and every step of the protocol guaranteed medical student confidentiality. Participating medical students received a copy of their DVDs and received initial analyzed descriptions of their own behaviors. Interactions occurred as part of the students' family medicine clerkship and included a 12- to 15-minute simulated medical interview followed by nonevaluative, formative feedback from a peer observer, the SPE, and a faculty observer; Duggan et al describe the interaction formative feedback from a peer observer, the SPE, and a faculty observer; Duggan et al describe the interaction.

Interaction Descriptions
During disability interactions, SPEs role-played a shoulder pain complaint, while incorporating their own disability. SPEs were recruited with the criterion of a visually apparent disability and then selected for their backgrounds and perspectives as nonjudgmental educators, articulate communicators, and positive to their backgrounds and perspectives as nonjudgmental educators. Individuals’ disabilities included multiple sclerosis, juvenile rheumatoid arthritis, traumatic spinal cord injury, neurodegenerative disorders, cerebral palsy, muscular dystrophy, blindness, paraplegia, quadriplegia, respiratory failure, and mobility constraints. SPEs initial training included two weekend-long training sessions (12 to 24 hours) and a series of videotaped practice interviews. SPEs received financial compensation for their training and work. Medical students focused on history taking and negotiated a treatment plan (without a physical exam) in a case designed to elicit questions about psychosocial and biomedical components of illness.

Medical students participated in a nutrition counseling interaction used to compare their behavior, where SPEs were prompted to seek counseling by the sudden death of a friend of the same height and body type. The nutrition counseling case was designed in consultation with the nutrition faculty of the participating medical school. The disability case was designed in detailed consultation with an advisory committee composed of people with disabilities, family members of people with disabilities, state disability agency representatives, and medical educators; the case was pilot-tested and refined prior to the current recording project.

Qualitative Analysis
The first author (AD), whose expertise includes nonverbal communication, reviewed recordings of all disability interactions to identify examples of medical students responding to an SPE in a manner that appeared inconsistent with other interactions. A research assistant (NS), trained in communication accommodation, then watched this subset of disability interactions and transcribed these portions of the interaction. Blinded to the research question, the same research assistant then watched the nutrition interactions looking for similar behaviors or behaviors that appeared inconsistent with other interactions. The first author and research assistant sorted transcriptions qualitatively and independently into primary and secondary themes, without preconceived categories, using Glaser & Strauss’ constant comparative method. In other words, both coders read and categorized all of the interactions separately using an inductive approach to allow categories to emerge from the data. The coders then reviewed identified categorizations together. Where there was disagreement (6% of interactions), coders shifted and reorganized independently and then re-reviewed together until consensus was reached. As an additional guard against arbitrary decision making, coders analyzed the data together after the categories were developed to minimize force fitting the data. Once themes were confirmed by the two independent assessments, transcriptions were quantified within each identified theme. A third communication specialist (YB) reviewed results and videotapes after initial results were presented.

Results
Medical students’ communication behavior was initially flagged based on excessive quantity or duration of the behavior, inconsistency with the verbal message, and nonresponsiveness to patient expressions. In the sample of 142 participating medical student interactions, 57 disability interactions (40%) were identified as crossing the boundaries of rapport through “positive” behaviors that indicate unexpected intensity, duration,
or out-of-context messages. Twenty-nine of the identified 57 of these interactions had more than one example, resulting in a total of 86 occurrences of communication behaviors identified as exceeding expected boundaries of rapport. Within nutrition interactions, only 9 instances of communication inconsistent with the verbal message were identified. Analysis by both initial coders and another communication specialist (AD) revealed that themes identified in the disability interactions were distinct and did not overlap those in the nutrition interactions. Thus, identified behaviors were unique to the disability interactions, indicating that medical students used different communication behaviors toward patients with disabilities.

Primary themes are categorized by types of communication behavior. Secondary themes within each of these six primary themes are related to finer distinctions in language or nonverbal behavior.

**Primary and Secondary Themes for Crossing Rapport Boundaries**

Within the interactions where the medical students demonstrated aspects of crossing the boundaries of rapport (n = 86), six primary themes were identified: 1) baby talk; 2) kinesics and posture overaccommodation; 3) vocalic overaccommodation; 4) relationship assumptions; 5) divergence or underaccommodation; and 6) inconsistency with patient’s emotional cues.

**Baby Talk**

Nineteen medical students demonstrated secondary baby talk through behaviors common for parents to use in talking to a toddler that communicate paternalistic assumptions when used with adult patients with disabilities. Identified behaviors include exaggerated nonverbal gestures or vocal pitch, “we” language to indicate “you,” trivializing language, and using oversimplified language for technical terms.

Exaggerated nonverbal gestures or vocal pitch. Four medical students exhibited nonverbal forms of baby talk, including exaggerated pitch range, particularly within the high pitches, or exaggerated gestures to illustrate spoken terms that would seemingly not require visual clarification. Examples include making a large lifting motion with his hands while the medical student asked “How much more stressful workload stuff do you have to do” and nodding “no” while increasing forward lean (as sometimes observed in talking to an infant) while asking “Did anything you were doing bring on the pain?”

“We” to indicate “you.” Six medical students used “we” to indicate “you.” For example, they asked, “How are we doing today?” or “Why are we here today?”

**Trivializing language.** Four medical students used trivializing language or slightly flippant speech or tone of voice, or “cute” language toward the SPE. Examples include asking with a “cute” tone of voice, “Can you point to the pain in just one little spot?” or, holding up one finger and demonstrating pointing, “Are you able to point to the pain with just one finger?”

Oversimplifying technical terms. Five medical students exhibited baby talk by oversimplifying technical and medical terms. One example includes explaining that “Some of the muscles in your shoulder, they attach to bones, right? When they get inflamed, they get angry. That’s called tendonitis. The –itis means inflammation.” Similarly, another student suggested: “To help in your work you should go and get some ergonomics stuff. You know like at Staples, any place that sells computer stuff. You just go to Staples or Best Buy and tell them ‘I have problems using the computer and I need a different keyboard.’ The padding that can be placed on keyboards will feel like a teddy bear.”

**Kinesics and Posture**

Eight students exhibited overaccommodation in kinesic behavior or posture in ways that indicated attempts at rapport but translated into awkward communication. Identified behaviors included chair shifting, stiff or closed posture, and awkward handshakes. Although these behaviors may be indicative of general nervousness or inexperience, the same medical students did not use these awkward behaviors in the nutrition counseling interaction.

**Chair shifting.** Three medical students shifted in their chairs in a continuous manner over the course of the interaction, spinning from side to side in a restless manner, while conducting the medical interaction.

**Stiff or closed posture.** Three medical students displayed stiff or closed posture, including sitting with hunched shoulders and a rounded back, minimizing the amount of space of their bodies by sliding their hands between their knees or under their legs.

**Awkward handshake.** Two medical students attempted to shake the hand of an SPE whose range of motion would not allow for reciprocating the gesture. Uncertainty in addressing the handshake was communicated by verbally announcing “I am going to shake your hand” or by reaching to shake hands with a smile that is too big for the context of the initial medical interaction.

**Vocalics**

Thirteen medical students showed signs of overaccommodation in the form of modified vocalics, where the volume, pitch, annunciation, or fluency seemed to interfere with the flow of conversation.
Volume. Three medical students overaccommodated their speech volume; two students who used quiet, hushed tones, and one student was extremely loud. 

Pitch. Five medical students indicated overaccommodation through a high-pitched voice, ridden with multiple inflections. Their speech took on a singsong quality where consecutive sentences followed the same, exaggerated pattern of pitch variation.

Annunciation. Two medical students overaccommodated by excessively annunciating their words during the interaction, speaking overly slowly and deliberately. Their sentences were noticeably drawn out and slow in tempo.

Vocal nonfluencies. Three medical students overaccommodated with vocal nonfluencies: two students used repeated stuttering, and one student giggled when they discussed mobility restrictions.

Relationship Assumptions
Ten medical students overaccommodated by showing surprise to learn that the SPE carried on healthy relationships and communicated negatively framed assumptions about relationships, or about friends or romantic partners, or about general expectations of relationships being defined by receiving care.

Who takes care of you? Three medical students indicated that a patient with a disability would require daily assistance and would not likely live alone. These students showed surprise to learn that a person with a disability lived alone, asking: “Who takes care of you?” when the SPE said s/he lived alone.

Friends. Two students complimented the SPE for having relationships with friends, responding to disclosure about getting together with friends with comments like, “That’s wonderful! Do they remind you to do your exercises?”

Significant other: Three students responded in an overly positive manner when they learned the SPE was married or lived with a relational partner, indicating, “Yeah? That’s wonderful!” or “It’s so good you have a boyfriend.”

Mother. Two medical students misinterpreted disclosure communication by the SPE’s about taking care of his/her ailing mother as assuming they lived with the mother in order to receive ongoing care.

Divergence or underaccommodation. Twenty-one medical students exhibited communication inconsistent with SPE emotional disclosure, responding with positive comments to negative or to neutral disclosure. The same medical students were more likely to match SPE emotional disclosure in the comparison/nutrition counseling interaction.

Positive response to negative disclosure. Six students responded with positive comments to negative or painful SPE disclosure, particularly about disability. For example, when the SPE says, “My disability is muscular dystrophy. I was diagnosed when I was 13 and I sat in a wheelchair when I went to college at 17,” the medical student responds, “That’s great you went to college to study graphic design.” Another student, upon hearing the SPE could not lift her hand to shake hands, says, “Oh, great! How are things otherwise?”
Positive response to neutral disclosure. Nine medical students responded with positive comments to neutral disclosure, responding to disclosure about everyday life as if getting through work and maintaining a relationship is an accomplishment. For example, students learned that the SPE was a computer programmer and responded, “Wonderful. That’s really wonderful. Do you work every day?” Similar examples include overly positive responses to learning the SPE was married (responding with “That’s really very good.”) or took a daily multivitamin (responding with “Wow. That is great.”) These overly positive responses were absent in the nutrition counseling interactions used for comparison.

Discussion

This study suggests that communication behaviors generally described as positive, rapport-building behaviors can pose negative implications when they exceed the expected quantity or duration, or when they are inconsistent with patient verbal disclosure or nonverbal expressions. Such overly positive behaviors were observed toward patients with physical disabilities, suggesting overaccommodation to the disability, and highlighting group differences toward people with disabilities rather than interpersonal similarities. This project adds light to group differences toward people with disabilities. The sometimes subtle distinctions between rapport building and crossing boundaries may indicate general discomfort with people with disabilities. Additionally, behaviors extending beyond rapport included stilted or closed posture and the tendency to spin from side to side in the chair while conducting the medical interactions. This closed-off body language could indicate discomfort or insecurity, as such forms of posture often coincide with feelings of uncertainty and self-doubt. The awkward kinesics or postures of medical students may reflect students’ discomfort with the disability. Interestingly, more than half of the students exhibiting stiff or closed posture simultaneously leaned forward from the waist. Out of context of the disability interaction and the other indicators of awkwardness or avoidance, leaning forward may indicate interest and attentiveness. The awkward kinesics and posture combined with the forward lean provide a mixed message. It may increase the likelihood that the patient with disability might be “forgiving” of the attitudes implied, but decrease the likelihood the patient would feel comfortable labeling the medical student as awkward overall.

Vocalic indications of exceeding boundaries of rapport included more pronounced announcement. This overarticulation perhaps intended to decrease ambiguity may instead suggest potential misinterpreted signs of physical disability as mental challenges. Overly deliberate speech through high volume was often accompanied by noticeably high vocal “singsong” pitch. The melodic inflections occur out of context with patients’ seeking reassurance. Giggling and stuttering may indicate general discomfort with people with disabilities.

When the discussion shifted from chief complaint to the way in which the pain affected their relationships, behaviors extending beyond rapport included messages indicating assumptions of daily need for care. Half of the students who indicated surprise about relationships appeared surprised to learn someone with a disability might be married. Similarly, these students’ complimentary remarks about a strong network of friends communicated attitudes that implied that this was remarkable and unexpected for people with disabilities.

Communication behaviors may subtly transmit such cultural biases and negative stereotypes and may inhibit the potential for building patient-relationships through these very behaviors generally considered positive.
Medical students who exhibited divergence emphasized distinction from patient cues by minimizing disclosure, or in contrast by embellishing disclosure. Furthermore, students who diverged by sitting on the examining table to conduct the interaction or spoke with a lack of formality may have attempted to restore a sense of normalcy to a situation that felt foreign to them. Although perhaps intended to build comfort, these informal cues may blur professional boundaries.

A subset of medical students responded to SPE emotional disclosure with noticeable inconsistency, where positive or encouraging responses were out of context. A positive response in reply to a painful or negative disclosure may indicate uncertainty in addressing patients' emotional cues and treat behaviors expected from able-bodied individuals as “accomplishments” from people with disabilities.

Limitations and Future Directions

Although the current study extends the literature in both communication and medical education, limitations can be identified. First, interactions were conducted with SPEs, which may limit generalizability compared to the larger patient population. SPEs cannot represent exactly the same style of interaction with each of the medical students, and their own varying degrees of communicative behaviors may have ultimately influenced the ways medical students responded. The current research does not yet account for the ways in which overaccommodation may be gender-specific. For example, females may be more likely to exhibit overaccommodation in the kinesic or vocalic involvement, while males may do so in their questioning patterns. Future research should examine sex differences in identified behaviors.

Notwithstanding these limitations, the current study provides extensive, systematic analysis of communication behaviors in a large, representative data set. Future analysis should examine the mutual influence process between medical students and patients in order to describe the extent to which patients influence changes over time in medical students' behaviors. Future research should also examine a comprehensive analysis of the ways communication behaviors are predictive of process outcomes, such as the ways the interactions are conducted, as well as short- and long-term health outcomes for both physicians and patients. Future research should also examine whether behaviors observed in medical students continue to manifest in interactions with patients with disabilities.

Conclusions

Identified behaviors that may otherwise be interpreted as rapport building can shift the interaction in ways that pose negative implications for behaviors that on the surface are interpreted positively. This work suggests that subtleties in quantity or duration, or behaviors that are out of context or inconsistent with the verbal content, can imply attitudes and assumptions toward members of stigmatized groups such as persons with disability. Communication behaviors may subtly transmit such cultural biases and negative stereotypes and may inhibit the potential for building patient-relationships through these very behaviors generally considered positive. Interpreting communication behaviors within the context of patient disclosure and comparing medical student communication across multiple patients would be an important step in developing the capacity to distinguish attitudes and biases limiting communication by addressing the communication behaviors that transmit them interpersonally. A significant first step for medical students would be to begin to recognize when their communication behaviors actually build rapport, and when otherwise positive behaviors actually inhibit the interaction.

Acknowledgments

The authors acknowledge the interaction team behind the project, especially Paula Minihan, PhD, MPH, MSW, from Tufts University School of Medicine and Linda Long-Bellil, PhD, JD, from University of Massachusetts Medical Center who are crucial to the success of the ongoing project, as well as the dedicated Tufts University School of Medicine faculty members, clinical and academic, who regularly share time to provide formative feedback for medical students. The authors also acknowledge the commitment, talent, and professionalism of the Standardized Patient Educators: Liz Casey, Jeanette Ector, Karen Foran Dempsey, Charlie Gamer, Lillian Johnson, Paul Kahn (1945-2010), Betsy Laitinen (1965-2007), Kia Scott (1970-2007), Robert Sneirson, and MacArthur Williams (1968-2010). In addition, Family Medicine Coordinators, Rachel Fouché, Katina Keftas and Vanessa Rios are greatly appreciated.

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When Rapport Building Extends Beyond Affiliation: Communication Overaccommodation Toward Patients with Disabilities

References


Original Research & Contributions

Adverse Reactions Associated with Therapeutic Antibiotic Use after Penicillin Skin Testing

Abstract

Background: There is little prospective data on the antibiotics prescribed and the adverse reactions associated with their use after penicillin skin testing.

Objective: Provide data on antibiotic use and new antibiotic “allergy” incidence after penicillin skin testing.

Methods: All patients who had penicillin skin testing at our Medical Center between 1-1-2000 and 12-31-2004 were followed through 12-31-2009. All therapeutic antibiotic use and all new “allergies” listed in their electronic medical records were reviewed.

Results: There were 1684 study subjects of whom 1191 (70.7%) were female. There were 118 (7.0%) positive to at least one penicillin skin test reagent and 3 (0.2%) were positive only to amoxicillin. The mean follow-up period was 4.5 ± 2.9 years. Subjects were exposed to a mean of 8.2 ± 10.5 therapeutic antibiotic courses during follow-up. The highest new antibiotic “allergy” incidence rates in skin test-negative subjects were noted for penicillins, 2.9%, and sulfonamides, 2.7%, p = 0.9097. Females had higher overall incidences of new antibiotic “allergy,” independent of skin test result. Penicillin skin test-negative females treated with penicillin had a nonsignificantly higher new penicillin “allergy” incidence, 3.3% per course versus 1.9% for males, p = 0.0644. Cephalosporins had new antibiotic “allergy” incidence rates not significantly different from tetracyclines, quinolones, macrolides, clindamycin, metronidazole, nitrofurantoin, and other antibiotics.

Conclusions: Females had higher new antibiotic “allergy” incidence rates. New “allergy” to cephalosporins occurred no more frequently than with non-beta-lactam-antibiotics, independent of skin test result. Sulfonamide antibiotics were associated with the higher rates of new antibiotic “allergy” than cephalosporins.

Introduction

Recent reviews on adverse drug reactions note that only a small minority of the adverse reactions associated with antibiotic use are either IgE or T-cell mediated.1,2 The vast majority of antibiotic-associated adverse drug reactions, and, thus, drug “allergy” reports in the medical record, do not have an immunologic cause and their recurrence is not reliably predicted by immediate type hypersensitivity skin tests or oral challenges. Clinically, it is important to know both the incidence and expected severity of new adverse reactions associated with therapeutic antibiotic use in patients with a history of penicillin “allergy.” It is important to have data on reactions associated with the use of both penicillins and nonpenicillin antibiotics, after both positive and negative penicillin skin testing, to make rational prescribing decisions.

Decay of true IgE-mediated allergy over time does completely explain why historically less than 20%, and recently for our group less than 5%, of penicillin skin tests are positive.3 There may be less IgE sensitization to penicillin because of less parenteral penicillin use. Testing individuals who are not Allergy Department patients may also identify more individuals with non-IgE-mediated reactions. Resensitization, documented by a history of penicillin “allergy,” an initial negative penicillin skin test, a reaction associated with a therapeutic penicillin use or challenge, and then a positive penicillin skin test, has been shown to be a rare event by our group and other investigators.4-7

Previously we reported on therapeutic antibiotic-associated adverse reactions after penicillin skin testing in a relatively small, 249 patient, case-control study.8 We noted adverse reaction rates of 3.2% to 5.4% per antibiotic course, comparing penicillin, cephalosporin, and other non-beta-lactam antibiotic use during three years of mean follow-up. Penicillin skin testing was only able to predict penicillin-associated adverse drug
Adverse Reactions Associated with Therapeutic Antibiotic Use after Penicillin Skin Testing

Excluding accidental penicillin exposure in penicillin skin test-positive individuals, non-beta-lactams were associated with adverse drug reactions more often than penicillins or cephalosporins, independent of the penicillin skin test result. Cephalosporins were used as or more safely than non-beta-lactams in both penicillin skin test-positive and negative individuals. However, not all of these reports resulted in a new antibiotic “allergy” being entered in the medical record, as there was no uniform place that the drug “allergy” history was kept in the paper medical record at that time.

We now present electronic medical record (EMR) data from a larger cohort with longer follow-up. We provide data on the incidence of new antibiotic “allergy” after all outpatient therapeutic antibiotic use in all the individuals who had penicillin skin testing at our medical center from January 1, 2000 through December 31, 2004. We stratify the results with respect to gender and penicillin skin test result. The data we present here gives a real world picture of the incidence and severity of new antibiotic “allergy” in patients with a history of penicillin “allergy.”

Methods

This study was reviewed by the Southern California Kaiser Permanente (KP) institutional review board. Written informed consent was obtained from all study subjects prior to penicillin skin testing and medical record review. The majority of the subjects included in this article were also subjects in a previous publication.3

Data on demographics, total years of active Health Plan coverage after penicillin skin testing, diagnoses, drug “allergy” history, outpatient antibiotic courses used, and new drug “allergy” entries were extracted from the KP EMR, HealthConnect, and from other legacy electronic databases. Significant electronic data on drug “allergy” were maintained by KP pharmacies and were downloaded into HealthConnect before it became clinically active in 2006. The data were not available electronically to clinicians using primarily paper charts before 2006.

Drug “allergy” was defined as what was listed in the drug allergy field of the EMR. Oral and parenteral antibacterial antibiotic use was determined. Topical and ophthalmic antibiotics were excluded because the systemic exposure from these routes is typically low and often quite variable compared to oral or parenteral exposure. Antiviral, antiprotozoan, and antihelminth “antibiotics” were excluded. Inhaled antibiotics were considered as oral. If there was a break of fewer than three days in the use of any single antibiotic, it was considered a single course. Antibacteria antibiotics were divided into ten classes: penicillins, cephalosporins, tetracyclines, quinolones, macrolides, sulfonamides, clindamycin, metronidazole, nitrofurantoin, and others, for the purpose of determining antibiotic class allergy. The clindamycin class also included lincomycin. The other antibiotics category included amikacin, aztreonam, capreomycin, colistimethate, cycloserine, dapsone, erythromycin, ethambutol, ethionamide, fosfomycin, gentamicin, imipenem, isoniazid, linezolid, methenamine, neomycin, paromomycin, pyrazinamide, rifabutin, rifampin, tobramycin, and vancomycin. All other medications were divided into 13 classes: narcotics, nonsteroidal anti-inflammatory drugs, ACE inhibitors, other antihypertensives, anticholesterol, antiseizures, antidepressants, stimulants, contrast materials, local anesthetics, intact proteins, corticosteroids, and other medications. Thus, for the purposes of this analysis, the maximum number of drug class “allergies” one individual could have was 23. If more than one new

<table>
<thead>
<tr>
<th>Table 1. Patient demographics</th>
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<tbody>
<tr>
<td>Attribute</td>
</tr>
<tr>
<td>Females (%)</td>
</tr>
<tr>
<td>Age in years (mean ± sd)</td>
</tr>
<tr>
<td>Time since index reaction in years (mean ± sd)</td>
</tr>
<tr>
<td>Length of follow-up in years (mean ± sd)</td>
</tr>
<tr>
<td>Total antibiotic courses per year of follow-up (mean ± sd)</td>
</tr>
<tr>
<td>Total antibiotic class allergies noted on 12-31-2009 (mean ± sd)</td>
</tr>
<tr>
<td>Total nonantibiotic class allergies noted on 12-31-2009 (mean ± sd)</td>
</tr>
</tbody>
</table>

\(\text{dna} = \text{data not available}; \text{ns} = \text{non-significant}; \text{sd} = \text{Standard Deviation}\)
antibiotic “allergy” in a single class was reported after only one antibiotic use in that class in any one year, then only the first entry was noted. A common example would be a single oral use of amoxicillin resulting in an amoxicillin “allergy” report followed two weeks later by a penicillin class antibiotic “allergy” report.

The following International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) codes were used to determine possible significant life-threatening antibiotic-associated adverse reactions: 695.1 (Stevens Johnson syndrome), 695.10 (toxic epidermal necrolysis), 695.13 (Stevens Johnson syndrome), 695.14 (Stevens Johnson Syndrome and toxic epidermal necrolysis overlap including erythema multiforme), 695.15 (toxic epidermal necrolysis), and 995.0 (anaphylaxis). If one of these diagnoses was made within ±30 days of a new antibiotic “allergy” entry, it was considered related.

All statistical analyses were performed using SAS Enterprise Guide version 4.1 software (Carey, North Carolina). Descriptive statistics were summarized using frequency and percentage. Hypothesis testing for continuous variables was by means of student t-test. Chi-square was used for categorical variables. Alpha level of 0.05 was used for statistical significance.

Results

Patient demographics are reported in Table 1. These patients have all been previously reported on in part.8

The mean follow-up was 4.5 ± 2.9 years for the entire cohort. The mean follow-up times were longer for the penicillin skin test-positive cohort because of the fall-off rate of positive penicillin skin tests that we have previously documented.9 There were 787 (46.7%) individuals exposed to an average of 8.2 ± 10.5 courses of penicillin-class antibiotics. Amoxicillin alone accounted for 1648 (67.1%) and amoxicillin/clavulanate accounted for 435 (17.7%) of the penicillins used. There were 873 (51.8%) individuals exposed to at least one course of a cephalosporin class antibiotic. There were 469 (27.9%) individuals exposed to at least one course of a sulfonamide antibiotic. There were 770 (45.7%) individuals exposed to at least one course of a quinolone antibiotic.

There were 646 (38.3%) individuals exposed to at least one course of a tetracycline antibiotic. There were 480 (28.5%) individuals exposed to at least one course of a macrolide antibiotic.

Therapeutic antibiotic use and any associated new entry in the drug “allergy” field of the EMR during follow-up after penicillin skin testing are reported in Table 2. Females overall had higher new antibiotic “allergy” incidence rates, 1.9% per course versus 1.1% for males (p = 0.002). The highest overall new antibiotic “allergy” incidence rates in penicillin skin test-negative subjects were noted for penicillins, 2.9%, and sulfonamides, 2.7%, (p = 0.9097). In both sexes and in both skin test-positive and negative cohorts, cephalosporins had new “allergy” rates not significantly different from tetracyclines, quinolones, macrolides, clindamycin, metronidazole, nitrofurantoin, and other antibiotics. There was no significant difference in the overall new antibiotic “allergy” rate between the genders in the penicillin skin test-positive cohort, 1.2% for females versus 1.7% for males, (p = 0.5113).

Among the 70 penicillin skin test-negative patients noting a new penicillin “allergy,” 37 reacted during the first reuse, 16 during the second reuse, and 17 during the third or greater reuse. The mean time to the new penicillin “allergy” report was 2.9 ± 2.3 years. Among the new penicillin “allergies” 52 were associated with amoxicillin, 8 with amoxicillin/clavulanate use, 6 with penicillin, and 2 each with ampicillin and dicloxacin. There was 1 penicillin skin test-positive female, age 74 years when she was intradermal skin test-positive to penilloate only in 2000. She received oral amoxicillin in 2005 and intravenous ampicillin in 2007, with no desensitization prior to either episode and no reactions noted.

There were a total of 54 penicillin skin test-positive individuals exposed to a total of 169 courses of cephalosporins with only 1 (0.6%, 95% confidence interval (CI) = -0.56, 1.75) new cephalosporin “allergy” noted. This reaction occurred 4 years after penicillin skin testing during the first course of intravenous cefazolin that individual was exposed to, 1.5 years after tolerating oral cephalaxin. There were a total of 819 penicillin skin test-negative individuals exposed to 2485 courses of cephalosporins with 29 (1.2%, 95% CI = 0.78, 1.64) new cephalosporin “allergies” reported, 9 with the first course, 9 with the second course, and 11 with the third or greater course. One individual had a reaction associated with the tenth course used.
Table 2. Antibiotic use and new antibiotic “allergy” reported in penicillin skin test

<table>
<thead>
<tr>
<th>Antibiotic class</th>
<th>Patients exposed (%)</th>
<th>Total courses (mean, range)</th>
<th>New drug allergy reports (% per course)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative females (N = 1106)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penicillins</td>
<td>528 (47.7%)</td>
<td>1704 (1,25)</td>
<td>56 (3.3%)</td>
<td>(2.45, 4.15)</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>578 (52.2%)</td>
<td>1741 (1,35)</td>
<td>25 (1.4%)</td>
<td>(0.93, 2.07)</td>
</tr>
<tr>
<td>Sulfonamides</td>
<td>308 (27.8%)</td>
<td>645 (1,15)</td>
<td>17 (2.6%)</td>
<td>(1.37, 3.83)</td>
</tr>
<tr>
<td>Quinolones</td>
<td>525 (47.4%)</td>
<td>1713 (1,26)</td>
<td>20 (1.2%)</td>
<td>(0.68, 1.72)</td>
</tr>
<tr>
<td>Macrolides</td>
<td>305 (27.5%)</td>
<td>596 (1,14)</td>
<td>11 (1.8%)</td>
<td>(0.73, 2.87)</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>420 (37.8%)</td>
<td>1072 (1,26)</td>
<td>16 (1.5%)</td>
<td>(0.77, 2.23)</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>280 (25.3%)</td>
<td>639 (1,29)</td>
<td>11 (1.7%)</td>
<td>(0.7, 2.7)</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>221 (19.9%)</td>
<td>368 (1,11)</td>
<td>4 (1.1%)</td>
<td>(0.03, 2.17)</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>326 (29.4%)</td>
<td>749 (1,22)</td>
<td>11 (1.5%)</td>
<td>(0.63, 2.37)</td>
</tr>
<tr>
<td>Others</td>
<td>37 (3.3%)</td>
<td>56 (1,6)</td>
<td>1 (1.8%)</td>
<td>(-0.68, 5.28)</td>
</tr>
<tr>
<td><strong>Negative males (N = 460)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penicillins</td>
<td>225 (48.8%)</td>
<td>750 (1,26)</td>
<td>14 (1.9%)</td>
<td>(0.92, 2.88)</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>241 (52.3%)</td>
<td>744 (1,24)</td>
<td>4 (0.5%)</td>
<td>(-0.01, 1.01)</td>
</tr>
<tr>
<td>Sulfonamides</td>
<td>124 (26.9%)</td>
<td>360 (1,69)</td>
<td>10 (2.8%)</td>
<td>(1.1, 4.5)</td>
</tr>
<tr>
<td>Quinolones</td>
<td>193 (41.9%)</td>
<td>610 (1,51)</td>
<td>5 (0.8%)</td>
<td>(0.09, 1.51)</td>
</tr>
<tr>
<td>Macrolides</td>
<td>122 (26.5%)</td>
<td>264 (1,53)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>171 (37.1%)</td>
<td>428 (1,21)</td>
<td>1 (0.2%)</td>
<td>(-0.22, 0.62)</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>92 (20.0%)</td>
<td>171 (1,8)</td>
<td>1 (0.6%)</td>
<td>(-0.56, 1.76)</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>63 (13.7%)</td>
<td>93 (1,7)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>25 (5.4%)</td>
<td>41 (1,7)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Others</td>
<td>18 (3.9%)</td>
<td>72 (1,35)</td>
<td>2 (2.8%)</td>
<td>(-1.01, 6.61)</td>
</tr>
<tr>
<td><strong>Positive females (N = 85)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penicillins</td>
<td>1 (1.2%)</td>
<td>2 (2)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>37 (43.5%)</td>
<td>132 (1,16)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Sulfonamides</td>
<td>30 (35.3%)</td>
<td>65 (1,6)</td>
<td>4 (6.2%)</td>
<td>(0.34, 12.06)</td>
</tr>
<tr>
<td>Quinolones</td>
<td>39 (45.9%)</td>
<td>181 (1,21)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Macrolides</td>
<td>35 (41.2%)</td>
<td>71 (1,7)</td>
<td>3 (4.2%)</td>
<td>(-0.47, 8.87)</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>42 (49.4%)</td>
<td>160 (1,30)</td>
<td>1 (0.6%)</td>
<td>(-0.6, 1.8)</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>25 (29.4%)</td>
<td>68 (1,8)</td>
<td>1 (1.5%)</td>
<td>(-1.39, 4.39)</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>16 (18.8%)</td>
<td>20 (1,3)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>21 (24.7%)</td>
<td>70 (1,13)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Others</td>
<td>2 (2.4%)</td>
<td>7 (1,4)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td><strong>Positive males (N = 33)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penicillins</td>
<td>none</td>
<td>none</td>
<td>none</td>
<td>-----</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>17 (53.1%)</td>
<td>37 (1,6)</td>
<td>1 (2.7%)</td>
<td>(-2.52, 7.92)</td>
</tr>
<tr>
<td>Sulfonamides</td>
<td>13 (21.9%)</td>
<td>16 (1,7)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Quinolones</td>
<td>13 (40.6%)</td>
<td>43 (1,11)</td>
<td>1 (2.3%)</td>
<td>(-2.18, 6.78)</td>
</tr>
<tr>
<td>Macrolides</td>
<td>18 (56.3%)</td>
<td>52 (1,10)</td>
<td>1 (1.9%)</td>
<td>(-1.81, 5.61)</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>12 (37.5%)</td>
<td>53 (1,16)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>10 (31.3%)</td>
<td>18 (1,3)</td>
<td>1 (5.6%)</td>
<td>(-5.02, 16.22)</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>6 (18.8%)</td>
<td>12 (1,3)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>1 (3.1%)</td>
<td>1 (1)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
<tr>
<td>Others</td>
<td>1 (3.1%)</td>
<td>1 (1)</td>
<td>0 (0%)</td>
<td>-----</td>
</tr>
</tbody>
</table>

CI = confidence interval
Adverse Reactions Associated with Therapeutic Antibiotic Use after Penicillin Skin Testing

There were no episodes of life-threatening antibiotic-associated adverse drug reactions such as toxic epidermal necrolysis, Stevens Johnson syndrome, toxic epidermal necrolysis/Stevens Johnson syndrome overlap, or anaphylaxis in the entire cohort during the follow-up period.

Discussion

Penicillin skin testing, followed by an oral challenge if negative, is now considered to be the gold standard test to reliably determine the presence of clinically significant IgE-mediated penicillin allergy and most clinically significant, thus reproducible, T-cell-mediated reactions. Oral challenges were not routinely done in all penicillin skin test-negative individuals when the current study subjects were evaluated for penicillin allergy prior to 2005. Since 2009, oral challenges are routinely done in all penicillin skin test-negative individuals at our medical center. We administer oral challenges in response to the relatively high rate of new “allergy” associated with the initial penicillin-class antibiotic reuse in penicillin skin test-negative individuals, particularly females, as we document in this report. Because the challenge is part of the testing protocol, the primary care, or other treating physician does not have to deal with these reactions. The oral challenge also helps the patient, and the referring physician understand that the penicillin skin testing only predicts rapid onset IgE-mediated reactions.

If a therapeutic use is functionally the same as a post-skin-test oral challenge, it may have been possible to identify some of the 37 individuals who had reactions with their first post-skin-test therapeutic penicillin use at the time of the testing. However, there may be higher rates of new “allergy” noted with therapeutic antibiotic use because of other factors, including concomitant viral infections. Even though all of these patients were evaluated with a complete set of penicillin skin test reagents, the oral challenge should help identify patients at risk for clinically significant delayed onset T-cell-mediated reactions, and thus should reduce the rate of new penicillin “allergy” reports. We are in the process of collecting prospective data to determine this.

We noted 1684 individuals in this report, compared to 1638 in a previous publication, as having a penicillin skin test between January 1, 2000 and December 31, 2004. This was because some of the individuals in the previous report had their initial penicillin skin test before January 1, 2000 and thus were not noted during the current study interval in the previous publication. Our current cohort used a mean of 1.82 antibiotic courses per year of follow-up compared to the 2.32 antibiotic courses per year of follow-up noted in our previous report. This may reflect our Health Care Plan’s efforts to reduce unnecessary antibiotic use.

Previously, in a large study that examined all of the antibiotic use and new antibiotic “allergy” in a population of 411,543 unselected Health Plan patients cared for in San Diego County in 2007, we have shown that females used more antibiotics than males. Females had higher rates of antibiotic “allergy” prevalence for all classes of antibiotics. There was a steady increase in antibiotic “allergy” prevalence with aging for both sexes. Females had higher incidence rates of antibiotic “allergy” for all classes of antibiotics. The antibiotic “allergy” incidence rates in females were highest with sulfonamides, 3.4% per course, compared with 1.5% per course for penicillins, and 1 to 1.3% per course for all other classes of antibiotics. Antibiotic “allergy” incidence in males was also highest for sulfonamides, 2.2% per course, compared with 1.1% per course for penicillins, and 0.5 to 0.6% per course for all other classes of antibiotics. We did not see a statistically significant difference between new antibiotic “allergy” between the male and female penicillin skin test-positive cohorts in our current study because of the relatively small sample.

We did not note an increased rate of positive penicillin skin tests in females as reported by Park and coworkers. This appears to be due to our using 5 mm or greater wheal, with flare greater than wheal, as the definition of a positive penicillin skin test result as opposed to the 3 mm or greater threshold used by the Park group at the Mayo Clinic. Also, we saw a much lower overall rate of positive penicillin skin tests compared with the recent report by Lin and co-workers at the University of California Los Angeles. They only tested hospitalized patients between 1995 and 2007. Though they used exactly the same penicillin skin test reagents as we used, they used a 4 mm wheal, instead of 5 mm, as the threshold for a positive test. They noted more individuals who were uniquely skin test-positive to amoxicillin, 5.8% versus 0.2%, (p = 0.28), but this difference was not significant. They did not provide a breakdown of positive skin tests by year of testing to see if they also had a falling rate of positive penicillin skin tests.

We did not note any significant difference in the rate of adverse reactions associated with future cephalosporin use in penicillin skin test-positive individuals compared with penicillin skin test-negative individuals, unlike a recent report by Park and coworkers. They selected 85 penicillin skin test-positive cases exposed
We did not note any significant difference in the rate of adverse reactions associated with future cephalosporin use in penicillin skin test-positive individuals compared with penicillin skin test-negative individuals...


---

**Playing About**

When I asked Sir Alexander Fleming about his views on research his reply was that he was not doing research when he discovered penicillin, he was just playing.

---

*The Art of Scientific Investigation, Chapter XI, Sir WIB Beveridge, 1908-2006, Australian animal pathologist*
Pacific White-Sided Dolphins bow riding in the inside passage just north of Vancouver Island.

Dr Henry is retired from The Permanente Medical Group. He was Chief of Urology at the San Jose Medical Center. He has been a photographer for over 30 years, with his work in local galleries and published in various venues. More images may be found at www.henryimages.net and at www.photo.net/photos/SteveH.
Birth Outcomes Among Low-Income Women—Documented and Undocumented

Abstract

Background: In January 2007, Texas expanded the Children's Health Insurance Program (CHIP) to include perinatal care for the unborn children of undocumented low-income women and certain documented women ineligible for Medicaid or CHIP because of income or residency status. CHIP Perinatal includes coverage for undocumented women and provides a glimpse into the birth outcomes of this difficult-to-reach population.

Objective: Community Health Choice (CHC) is the largest health maintenance organization provider of CHIP Perinatal in Texas, and we sought to determine preterm and low-birth-weight rates among women enrolled in CHC CHIP Perinatal and compare them with women of similar low-income status enrolled in Medicaid.

Methods: We conducted a retrospective cohort study of women enrolled in the CHC CHIP Perinatal and Medicaid plans and who delivered between January 1 and August 31, 2008. Logistic regression was used to determine odds of poor birth outcome, and analyses were adjusted for maternal age.

Results: The CHC cohort included 10,763 pregnant women enrolled in CHIP Perinatal and 4614 pregnant women enrolled in Medicaid. Those in the Medicaid group are significantly more likely to have preterm (adjusted odds ratio [aOR] = 2.1; 95% confidence interval [CI], 1.8–2.4) and low-birth-weight infants (aOR = 2.2; 95% CI, 1.9–2.6) than those in the CHIP Perinatal group. Within the Medicaid population, Hispanic women have the lowest preterm and low-birth-weight rates (6.6% and 5.8%, respectively), and non-Hispanic black women have the highest preterm and low-birth-weight rates (11.3% and 12.4%, respectively). However, Hispanic women enrolled in Medicaid are more likely to have preterm (aOR = 1.7; 95% CI, 1.4–2.1) and low-birth-weight infants (aOR = 1.6; 95% CI, 1.3–2.0) than their mostly Hispanic CHIP Perinatal counterparts.

Conclusion: Women enrolled in CHC CHIP Perinatal have significantly lower prematurity rates than women of similar economic status enrolled in Medicaid, despite receiving less comprehensive medical benefits. Favorable birth outcomes for the mostly Hispanic CHIP Perinatal population persist even when restricting the comparison Medicaid group to Hispanics. Further analysis controlling for factors such as social and behavioral characteristics is needed to better understand differences between the CHIP Perinatal and Medicaid populations.

Introduction

Preterm birth and low birth weight constitute leading causes of infant morbidity and mortality in the US. In 2007, preterm infants accounted for 11.0% and low-birth-weight infants accounted for 6.5% of live singleton births. In 2006, preterm-related complications accounted for 36.1% of infant deaths. In addition to high infant mortality, premature infants incur more health complications than full-term infants. According to a 2007 report from the Institute of Medicine, preterm infants resulted in an average medical expenditure of $33,200 in the first year of life, compared with $3325 for full-term infants. The high rate and cost of preterm and low-birth-weight infants are growing public health concerns, and addressing issues of prematurity is essential to improving birth outcomes.

Texas has high preterm and low-birth-weight rates. In 2007, preterm infants accounted for 12.1% and low-birth-weight infants accounted for 6.7% of live singleton births (Center for Health Statistics, personal communication, 29 Nov 2010). Two public insurance programs provide coverage for the majority of low-income pregnant women in Texas: the State of Texas Access...
Reform (STAR) Medicaid plan and the Children’s Health Insurance Program (CHIP) Perinatal plan. For simplicity, we refer to STAR Medicaid as Texas Medicaid. Texas Medicaid provides comprehensive medical coverage and unlimited prescriptions for pregnancy and non-pregnancy-related conditions. Eligibility requires an income ≤185% of the federal poverty guideline and a minimum of five years as a permanent resident. CHIP Perinatal is an extension of CHIP and provides coverage for the unborn children of undocumented women, documented women with less than five years’ permanent residency status, and some higher-income women not eligible for Medicaid or CHIP. Eligibility requires an income ≤200% of the federal poverty guideline, and there is no stipulation on residency status. The CHIP Perinatal program only covers medical care related to the unborn child. Benefits include up to 20 prenatal visits, prescription coverage for pregnancy-related conditions, labor and delivery, and two postpartum visits.

In 2008, women comprised 39% of the adult undocumented immigrant population in the US, and infants born to an undocumented parent comprised 8% (340,000) of US births. Texas has the second largest population of undocumented immigrants, estimated at 1.45 million (of 11.9 million in the US). CHIP Perinatal serves as the safety-net public insurance for the unborn children of undocumented women. Launched in January 2007, Texas CHIP Perinatal has enrolled 182,549 unborn children (Center for Strategic Decision Support, personal communication, 2010 Nov 30).

However, the program’s impact on birth outcomes is not known. Although it provides perinatal care for the unborn child, it does not cover non-pregnancy-related conditions for the pregnant woman. We conducted a retrospective cohort study to determine the preterm and low-birth-weight rates of women enrolled in CHIP Perinatal and compare them with women of similar low-income status enrolled in Texas Medicaid.

Methods

Data Source

Community Health Choice (CHC) is the largest health maintenance organization (HMO) provider of CHIP Perinatal in Texas and sole provider in the 20 counties of the Texas Gulf Coast region. It also administers the Texas Medicaid program in 6 of the 20 Texas Gulf Coast counties. The CHC database contains members’ date of birth, ZIP code of residence, information on other primary insurance, and data on the newborn’s gestational age and birth weight. Claims data identify pregnant women and live infants with a diagnosis code from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) for preterm birth. CHC also encourages facilities to submit delivery notifications with data on gestational age. These identified additional preterm births. Self-reported maternal race and/or ethnicity data was abstracted for Texas Medicaid members only. CHIP Perinatal does not collect race and/or ethnicity data for pregnant women or the infants they deliver.

Definitions of Variables

Pregnancy outcomes of interest included preterm birth and low birth weight. Preterm birth was defined as birth before 37 completed weeks of gestation. Low birth weight was defined as a weight <2500g at birth.

Statistical Analysis

Statistical analysis was carried out with Stata software (version 9.2; StataCorp, College Station, TX, USA). Logistic regression was used to determine odds of poor birth outcome for babies delivered by women in the CHC CHIP Perinatal and Medicaid plans. Analyses were adjusted for maternal age. Odds ratios (OR) with 95% confidence intervals (CIs) were calculated. ORs were considered statistically significant if the 95% CIs excluded one.

Results

Women enrolled in CHC CHIP Perinatal delivered 10,966 babies between January 1 and August 31, 2008. Analysis excluded 96 sets of twins, 2 sets of triplets, 4 singletons with birth weights <500g, and 1 fetus that died. The final CHIP Perinatal study population included 10,763 singletons.

Women enrolled in CHC Texas Medicaid delivered 5015 babies between January 1 and August 31, 2008. Analysis excluded 68 sets of twins, 1 baby whose twin sibling died, 1 baby whose twin sibling’s member number could not be locat-
ed, 6 singletons with birth weights <500 g, 3 fetuses that died, and 254 babies delivered to women with other primary insurance. The final CHC Texas Medicaid study population included 4614 singletons.

Maternal demographics are summarized in Table 1. Women enrolled in CHC CHIP Perinatal were older than women enrolled in Texas Medicaid. Both groups had similar incomes. Only 2.4% of women with CHIP Perinatal did not meet eligibility criteria for Texas Medicaid because of income status alone (income >185% but ≤200% of the federal poverty guideline). Although the CHIP Perinatal database does not contain race or ethnicity data, surname analysis suggests that the overwhelming majority of women enrolled in CHIP Perinatal are Hispanic.

Infants born to CHIP Perinatal-enrolled women had significantly lower preterm and low-birth-weight rates than infants born to women receiving Texas Medicaid. Singleton infants born to women with CHC Texas Medicaid were more likely to be preterm (adjusted odds ratio [aOR] = 2.1; CI, 1.8–2.4) and have low birth weight (aOR = 2.2; CI, 1.9–2.6) than infants born to women with CHIP Perinatal (Table 2). Among infants born to women receiving care through Texas Medicaid, Hispanic infants had the lowest preterm and low-birth-weight rates (6.6% and 5.8%, respectively), and non-Hispanic black infants had the highest preterm and low-birth-weight rates (11.3% and 12.4%, respectively) (Table 3). Although infants born to Hispanic women enrolled in Medicaid had lower preterm and low-birth-weight rates compared with other infants born to non-Hispanic women enrolled in Medicaid, these rates were higher than their mostly Hispanic CHIP Perinatal counterparts. Infants born to Hispanic women enrolled in Medicaid were more likely to be preterm (aOR, 1.7; CI, 1.4–2.1) and have low birth weight (aOR, 1.6; CI, 1.3–2.0) than CHIP Perinatal infants.

Discussion

In our study, women enrolled in CHIP Perinatal unexpectedly had significantly better birth outcomes than women enrolled in Texas Medicaid, despite more limited medical coverage. The CHIP Perinatal program provides a glimpse into the birth outcomes of undocumented women. Only 2.4% of the women with CHIP Perinatal did not meet eligibility requirements for Medicaid because of income status. The remaining 97.6% presumably did not meet eligibility requirements for Medicaid because of inadequate residency status. It is unclear why this population of mostly undocumented Hispanic women had significantly better

Table 1. Demographic characteristics of women enrolled in CHC CHIP Perinatal and Medicaid

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CHIP Perinatal (N = 10,763)</th>
<th>Medicaid (N = 4614)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, years ± SD</td>
<td>28 ± 5.9</td>
<td>25 ± 5.4</td>
</tr>
<tr>
<td>≤14</td>
<td>0.1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>15–19</td>
<td>10.0%</td>
<td>18.9%</td>
</tr>
<tr>
<td>20–34</td>
<td>78.0%</td>
<td>75.0%</td>
</tr>
<tr>
<td>≥35</td>
<td>11.9%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Maternal race or ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>—</td>
<td>43.9%</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>—</td>
<td>31.1%</td>
</tr>
<tr>
<td>Non-Hispanic black</td>
<td>—</td>
<td>23.3%</td>
</tr>
<tr>
<td>Asian</td>
<td>—</td>
<td>1.5%</td>
</tr>
<tr>
<td>American Indian</td>
<td>—</td>
<td>0.3%</td>
</tr>
<tr>
<td>Other</td>
<td>—</td>
<td>0.1%</td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;185% FPG</td>
<td>97.6%</td>
<td>100%</td>
</tr>
<tr>
<td>≥185% and ≤200% FPG</td>
<td>2.4%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

* At delivery.

CHIP Perinatal does not collect race or ethnicity data for pregnant women or the infants they give birth to.

CHC = Community Health Choice health maintenance organization; CHIP = Children’s Health Insurance Program; FPG = federal poverty guideline.

Table 2. Birth outcomes among women enrolled in CHC CHIP Perinatal and Medicaid

<table>
<thead>
<tr>
<th>Health care insurance</th>
<th>N</th>
<th>Preterm</th>
<th>aOR (95% CI)</th>
<th>N</th>
<th>LBW</th>
<th>aOR (95% CI)</th>
<th>N</th>
<th>Preterm or LBW</th>
<th>aOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No. (%)</td>
<td></td>
<td></td>
<td>No. (%)</td>
<td></td>
<td></td>
<td>No. (%)</td>
<td></td>
</tr>
<tr>
<td>CHIP Perinatal</td>
<td>10,763</td>
<td>472 (4.4)</td>
<td>Ref</td>
<td>7470</td>
<td>368 (4.9)</td>
<td>Ref</td>
<td>10,763</td>
<td>671 (6.2)</td>
<td>Ref</td>
</tr>
<tr>
<td>Medicaid</td>
<td>4614</td>
<td>382 (8.3)</td>
<td>2.1 (1.8–2.4)</td>
<td>4164</td>
<td>334 (8.0)</td>
<td>2.2 (1.9–2.6)</td>
<td>4614</td>
<td>503 (10.9)</td>
<td>1.9 (1.7–2.2)</td>
</tr>
</tbody>
</table>

* Odds ratios are adjusted for age.

* Missing birth-weight data for CHC CHIP Perinatal: 3293/10,763 = 31%; for CHC Medicaid infants: 450/4614 = 10%.

aOR = adjusted odds ratio; CHC = Community Health Choice health maintenance organization; CHIP = Children’s Health Insurance Program; LBW = low birth weight; Ref = Reference group.
Decreased adverse health behaviors, increased social support, and selective migration represent possible explanations for the healthy migrant phenomenon.\textsuperscript{13,14}

<table>
<thead>
<tr>
<th>Maternal race or ethnicity</th>
<th>Number of participants</th>
<th>Preterm births</th>
<th>Number of participants</th>
<th>Low birth weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic white</td>
<td>1434</td>
<td>125</td>
<td>8.72</td>
<td>1293</td>
</tr>
<tr>
<td>Non-Hispanic black</td>
<td>1073</td>
<td>121</td>
<td>11.28</td>
<td>968</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2025</td>
<td>134</td>
<td>6.62</td>
<td>1829</td>
</tr>
<tr>
<td>Total\textsuperscript{a}</td>
<td>4614</td>
<td>382</td>
<td>8.28</td>
<td>4164\textsuperscript{b}</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Includes Asians, American Indians, and those of unknown race.

\textsuperscript{b}Missing birth-weight data for infants receiving care through CHC Medicaid: 450/4614 = 10%.

CHIP = Community Health Choice health maintenance organization

Birth outcomes compared with their low-income Medicaid counterparts. Ethnicity may play a role. National and regional data consistently show that Hispanics have birth outcomes comparable to those of non-Hispanic whites and significantly better than those of non-Hispanic blacks.\textsuperscript{2,10} Interestingly, favorable birth outcomes for this mostly Hispanic CHIP Perinatal population persisted even when we restricted the comparison Texas Medicaid population to Hispanic women. Various studies show better birth outcomes and overall health among certain immigrant populations compared with their US-native ethnic-racial counterparts.\textsuperscript{11,12}

Decreased adverse health behaviors, increased social support, and selective migration represent possible explanations for the healthy migrant phenomenon.\textsuperscript{13,14} Our study results showing differences in birth outcomes by maternal residency status are consistent with outcomes of prior studies showing better health outcomes among certain immigrant populations. However, it is uncertain how factors such as maternal behavior (eg, cigarette smoking, alcohol use, and drug use), level of social support, time of entry into prenatal care, service use, appointment adherence, and self-efficacy compare between women with CHIP Perinatal and Medicaid.

The Department of Health and Human Services \textit{Healthy People 2020} report\textsuperscript{15} and the Institute of Medicine \textit{Unequal Treatment}\textsuperscript{16} report highlight the importance of eliminating disparities in health and health care. These reports recommend improved collection of data on race, ethnicity, and primary language by public and private health plans for comparative measurements and disparities reduction. Before the establishment of the National Health Plan Collaborative in 2004, most health plans including Medicare and Medicaid had virtually no race or ethnicity data.\textsuperscript{17} The systematic collection of data on race and ethnicity proves vital for comparative measurements of health outcomes by race and ethnicity. Understanding the determinants of favorable health outcomes in certain populations is as important as understanding the determinants of poor health outcomes. At the organizational level, the Texas Health and Human Services CHIP Perinatal program should consider exploring means for collecting data on race and ethnicity. This may shed light as to why the CHIP Perinatal population has better birth outcomes.

\textbf{Limitations}

Our study had certain limitations. First, the ideal study evaluating CHIP Perinatal’s impact on birth outcomes would entail a comparison of birth outcomes among undocumented low-income women before and after CHIP Perinatal. However, a database of undocumented low-income pregnant women before the advent of CHIP Perinatal does not exist. Second, our study is limited by the use of administrative claims data for epidemiologic analysis. CHIP obtains preterm birth ICD-9-CM codes for administrative purposes and pays individual clinicians set professional fees irrespective of whether a birth is coded as preterm. Thus, the preterm birth rates in our study may represent conservative estimates. Nevertheless, it is not expected that the coding behavior of clinicians would differ between the two health plans. Third, 31% of infants born to CHIP Perinatal-enrolled women and 10% of infants born to women receiving Texas Medicaid had missing birth weight data, and it is not clear if there were any differences in the infants who did have documented birth weights and those who did not. Fourth, the lack of complementary social, behavioral, and clinical data limited our ability to control for such variables. In addition, the lack of race and ethnicity data for CHIP Perinatal members precludes adjustments for those characteristics.

\textbf{Conclusion}

Certain characteristics inherent in the CHIP Perinatal population are associated with lower preterm and low-birth-weight rates compared to the Hispanic Medicaid and overall Medicaid populations. These lower rates exist in spite of limited medical benefits and similar economic

\textsuperscript{13} Includes Asians, American Indians, and those of unknown race.

\textsuperscript{14} Missing birth-weight data for infants receiving care through CHC Medicaid: 450/4614 = 10%.

\textsuperscript{15} CHIP = Community Health Choice health maintenance organization.

\textsuperscript{16} Includes Asians, American Indians, and those of unknown race.

\textsuperscript{17} Missing birth-weight data for infants receiving care through CHC Medicaid: 450/4614 = 10%.
status. In contrast, non-Hispanic black women with Medicaid have the highest preterm and low-birth-weight rates. Further studies controlling for factors such as social and behavioral characteristics are needed to better understand the differences between the CHIP Perinatal and Texas Medicaid populations that may account for differences in birth outcomes.

**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**


**Object of Care**

The woman about to become a mother, or with her new-born infant upon her bosom, should be the object of trembling care and sympathy wherever she bears her tender burden, or stretches her aching limbs.

— Oliver Wendell Holmes, 1809-1894, American jurist and Associate Justice of the Supreme Court of the United States
Can Patient Factors Predict Early Discharge After Pyloromyotomy?

Steven L Lee, MD, FACS, FAAP
Rebecca Stark, MD

Abstract

Background: Because of increased pressure to shorten hospital stays, some advocate discharging patients with pyloric stenosis within four hours of pyloromyotomy. Because some patients have persistent emesis after pyloromyotomy and thus require prolonged hospitalization to prevent dehydration, it would be helpful to be able to predict in which patients this will occur.

Methods: We conducted a retrospective review of pyloromyotomies performed within a six-year period to determine whether patient factors could predict length of hospitalization in patients with pyloric stenosis. The study outcome was time to discharge after pyloromyotomy, and the independent variables were patient's age, patient's weight, symptom duration, duration of preoperative hydration, and pyloric length and thickness. Patients were grouped on the basis of time of discharge after pyloromyotomy: <24, 24 to 48, and >48 hours.

Results: Of 230 patients, 58% were discharged within 24 hours, 31% between 24 and 48 hours, and 11% after 48 hours. Patients' weight was inversely proportional to the postoperative length of hospitalization. Conversely, length of time required for preoperative hydration was directly proportional to the duration of postoperative hospitalization.

Conclusions: Patients with lower weight and a longer preoperative hydration period had an increased risk of prolonged hospitalization after pyloromyotomy.

Introduction

Hypertrophic pyloric stenosis is a common condition treated by pediatricians, family-medicine specialists, and pediatric surgeons. In general, within 24 hours after pyloromyotomy, most patients tolerate full feedings and are discharged. Despite different feeding regimens and the recent adoption of a minimally invasive approach, this duration for postoperative stay remains relatively unchanged. In the current environment of rising health care costs and shorter hospitalizations, some advocate discharging patients three or four hours after pyloromyotomy, with resumption of feeding at home. However, some patients have persistent emesis after the procedure and thus require a prolonged hospital stay to prevent dehydration. Currently, there is no way to predict which patients can tolerate early discharge and which will require a longer hospital stay. Thus, we conducted a study to determine whether patient factors could predict length of hospitalization in this population.

Methods

After obtaining the approval of our institutional review board, we conducted a retrospective review of all cases involving patients who underwent pyloromyotomy for hypertrophic pyloric stenosis during a six-year period. The study outcome was time to discharge after pyloromyotomy, and the independent variables were patient's age, patient's weight, symptom duration, duration of preoperative hydration, and pyloric length and thickness. Patients were grouped on the basis of time of discharge after pyloromyotomy: <24, 24 to 48, and >48 hours. Statistical analysis was performed using analysis of variance, with post hoc Bonferroni adjustment for pairwise comparisons.

Results

Of the total of 230 patients (21% of whom were girls) identified for this study, 51 underwent laparoscopic pyloromyotomy and 179 underwent open pyloromyotomy. Results are detailed in Table 1. Fifty-eight percent of patients were discharged within 24 hours, 31% at a point between 24 and 48 hours, and 11% after 48 hours.

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Can Patient Factors Predict Early Discharge After Pyloromyotomy?

<table>
<thead>
<tr>
<th>Variable</th>
<th>&lt;24 hours (n = 133)</th>
<th>24–48 hours (n = 71)</th>
<th>&gt;48 hours (n = 26)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (weeks)</td>
<td>5.3 ± 2.7</td>
<td>5.0 ± 2.4</td>
<td>5.7 ± 5.6</td>
<td>0.74</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>4.2 ± 0.8</td>
<td>4.0 ± 0.8</td>
<td>3.6 ± 1.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Duration of symptoms (days)</td>
<td>8.1 ± 7.0</td>
<td>8.0 ± 7.5</td>
<td>7.9 ± 7.5</td>
<td>0.92</td>
</tr>
<tr>
<td>Duration of preoperative hydration (days)</td>
<td>0.7 ± 0.8</td>
<td>0.8 ± 1.0</td>
<td>1.1 ± 1.0</td>
<td>0.03</td>
</tr>
<tr>
<td>Pyloric length (mm)</td>
<td>19.8 ± 3.1</td>
<td>19.5 ± 3.1</td>
<td>19.6 ± 2.6</td>
<td>0.97</td>
</tr>
<tr>
<td>Pyloric width (mm)</td>
<td>4.9 ± 0.8</td>
<td>4.8 ± 0.8</td>
<td>4.6 ± 0.7</td>
<td>0.07</td>
</tr>
</tbody>
</table>

Discussion

It would be useful to predict which patients can tolerate feedings and discharge early after pyloromyotomy and which patients cannot, so as to benefit from the significant cost savings and improved use of hospital beds that result from early discharge and yet prevent Emergency Department visits and readmission for some patients and anxiety for their parents. Previous studies have shown little change in the time to discharge on the basis of feeding regimen. Early feeding (less than four hours) after pyloromyotomy did not decrease the time to full feedings or the duration of postoperative hospitalization. Furthermore, ad libitum feedings also had little effect on time to full feedings and to discharge.

The most recent change in the treatment of pyloromyotomy has been the adoption of laparoscopic pyloromyotomy. A recent multi-institution, prospective, randomized trial by Hall et al showed that the time to both full feedings and discharge was reduced by 10 hours with the laparoscopic technique. However, in that study, the time to full feedings was still 18.5 hours and the duration of hospitalization after surgery was 33.6 hours. Furthermore, two other prospective studies showed that the time to full feedings and the time to discharge were similar between the laparoscopic and open techniques. Predicting early discharge on the basis of the pyloromyotomy technique is thus not feasible.

Because those earlier studies found no effect from factors not associated with the patients themselves, we sought correlations between patient-specific factors and length of hospital stay. We found that the patient’s age had no effect but that the patient’s weight was inversely proportional to the duration of postoperative hospitalization. This finding confirms our anecdotal observation that smaller children tend to require a longer recovery period. However, the mean weight of the patients with a short postoperative course (<24 hours) was 4.2 kg versus 3.6 kg for patients requiring a prolonged hospital stay (>48 hours). Thus, the weight difference between these two groups was only 0.6 kg, making the clinical significance of this finding questionable. Furthermore, we do not currently support the use of a threshold weight of 4 kg to determine whether patients should be discharged after a four-hour observation period. However, in view of these data, this aspect may be a good starting point for designing a prospective study.

Unlike our anecdotal observation that smaller infants required a prolonged recovery, this was not true for symptom duration. We had also believed that patients with a delayed diagnosis also required a longer postoperative course. Yet in our study, we found that symptom duration and pylorus size had no affect on postoperative length of stay. However, we did find that the duration of preoperative hydration was directly correlated to duration of postoperative hospitalization. This finding suggests that the severity of dehydration is a more important factor than symptom duration with respect to the postoperative recovery period. Again, we are not advocating early discharge in patients with a short rehydration period, but we believe that this information is helpful in planning a prospective study to validate or refute this finding.

Our study had multiple limitations. First, it was a retrospective study. Several different surgeons performed the pyloromyotomies, and the specific technique used was based on each surgeon’s preference. During the study period, the minimally invasive approach had just begun to be implemented, accounting for the low number of laparoscopic pyloromyotomies. However, we do not believe that the use of different techniques had a major affect on recovery, as shown by multiple previous studies. Another limitation of our study was...
that the postoperative feeding regimen was not standard-ized. Again, we do not believe that this had a major impact on postoperative length of stay, as shown by previous studies.1–3 Furthermore, the discharge criterion was fairly standard: Patients had to be tolerating full feedings before discharge. Finally, only slightly more than half of the patients in our study were discharged within 24 hours. This group of patients would most likely be the best candidates for early discharge (after a four-hour observation period), with resumption of feedings at home. We found that this group of patients had a higher weight and shorter length of preoperative hydration than the other groups. Because these differences were small, at this time we believe that until a prospective study confirms these findings, patients should remain hospitalized until they tolerate full feedings after pyloromyotomy. We are now designing just such a prospective study.

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

Acknowledgment
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References

Attending to the Nature and Constitution
Medicine is an art, and attends to the nature and constitution of the patient, and has principles of action and reason in each case.
— Gorgias, Plato, c427-347 BCE, Greek philosopher and educator
This photograph was taken in the summer of 2009. Oneonta Falls is only a few hundred yards from the road, but an adventure to get to nonetheless, requiring traverse of a huge slippery log jam and waist-deep wading in icy-cold water through the gorge. Oneonta is a narrow offshoot of the Columbia Gorge. Landscape photography is classically best in early morning and late afternoon light. In this case the best light was midday, filtered through the mist in the narrow canyon. I feel lucky to have such an amazing visual resource as the Columbia Gorge within an hour of Portland.

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Inpatient Palliative Care Consults and the Probability of Hospital Readmission

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Abstract

Context: Many patients and their families have difficulty making decisions when confronted with complex medical problems. Often their expectations and hopes are beyond what medical science can deliver, and at times their desires seem to conflict with their treatment plans. Additionally, costly tests and treatments with little or no benefit are often explored. Inpatient palliative care consultation services for end-of-life-care planning can help patients navigate this complexity, arrive at a care plan consistent with their personal values, and be good stewards of precious medical resources.

Objective: We conducted a study to assess the effect that one function of our organization’s Inpatient Palliative Care Service—consultation regarding end-of-life-care planning—has on readmission rates. We believed that our study would show that interdisciplinary end-of-life-care planning improves resource use by reducing the probability and rate of hospital readmission.

Methods: We retrospectively reviewed electronic records for Kaiser Permanente HealthConnect at Kaiser Permanente South Bay Medical Center in Harbor City, CA, for 200 consecutive patients referred to our Inpatient Palliative Care Service between November 2006 and February 2010, comparing hospital readmissions between two groups of patients. Members of both groups (100 patients in each) all had an Inpatient Palliative Care consult ordered for end-of-life-care planning—has on readmission rates. We believed that our study would show that interdisciplinary end-of-life-care planning improves resource use by reducing the probability and rate of hospital readmission.

Results: We found that with the post-team consultation, readmissions to the hospital per patient per six months after consultation decreased from 1.15 to 0.7 admissions per patient.

Introduction

End-of-life-care planning offers important opportunities for improving patient care and the overall care experience at Kaiser Permanente (KP). These consults provide the opportunity to discuss the patient’s underlying treatment values and any nonmedical concerns. They also provide an interdisciplinary environment for discussing detailed information about the patient’s illness and prognosis.

Patients were deemed appropriate candidates for consultation when their attending physician indicated that there was a need for exploration, discussion, and clarification of goals of treatment, including interpretation of advance directives and Physician Orders for Life-Sustaining Treatment. These were patients and families who faced values conflicts when dealing with complex medical problems. We postulated that our Inpatient Palliative Care end-of-life-care planning team consultations would reduce hospital readmissions.

Team participants included a palliative care physician, an inpatient palliative care register nurse (RN) specializing in both end-of-life conversations and in care planning after hospital discharge, a social worker, a bioethicist, a hospital chaplain. To provide meaningful consults, the team would prepare for the meeting by discussing the case before the consult. Once the meeting commenced, all participants were introduced and explained their roles. The palliative care physician presented medical information clearly and discussed
the big picture, reviewing the patient’s current medical condition. The inpatient palliative care RN helped explain the patient’s medical picture within her scope of practice and assisted the patient and family in discovering their goals and plans for continued care beyond the hospital setting. The social worker reviewed the general plan and goals for the meeting with the patient, family, and team members. The social worker also assessed psychosocial issues, intervening as appropriate. The bioethicist facilitated resolution of values conflicts and provided guidance if the family experienced a conflict when discussing treatment choice. The chaplain addressed any spiritual concerns that the patient and family presented. All team participants provided assistance with interpreting advance health care directives and Physician Orders for Life-Sustaining Treatment when necessary.

The interdisciplinary consult team focused on strengthening patient autonomy by providing in-depth information from multiple professional perspectives. An important goal was better-informed decisions for the patient and family. They were better equipped to consent to beneficial treatment because shared decision making was emphasized and the discussion environment remained patient centered.⁴

Viewed more closely, the interdisciplinary consult addressed many additional issues, including discussing untreated pain and related symptoms of distress; discussing patient and family needs; reviewing prior communication; providing ample time to resolve conflict among clinicians, patients, and families; addressing the divergence of treatment goals from patient and family preferences; reviewing concerns about implied or real delays in implementation of appropriate care plans; and identifying treatments that offer benefits that outweigh burden.⁵ Our study, approved by our institutional review board, addressed the question of whether an interdisciplinary end-of-life-care planning team plays an important role in reducing hospital readmission.

**Methods**

All consults were conducted while patients were hospitalized and included family members and power-of-attorney decision makers. The intervention followed the format outlined in the introduction of this article. Data collection included retrospectively reviewing 200 continuous inpatient cases in which an Inpatient Palliative Care consult for end-of-life-care planning was ordered by an attending physician. All patients were hospitalized at the KP South Bay Medical Center in Harbor City, California, between November 2006 and February 2010. Our data included a 6-month follow-up assessment for all 200 patients to determine the hospital readmission rate for the 6 months after consultation.

The 200 patients represented two distinct groups. For the first 100 cases, comprising group A, a palliative care RN conducted the consult before the advent of an interdisciplinary team. For the second 100 cases, comprising group B, consults were conducted by an interdisciplinary team consisting of a continuing care physician, a bioethicist, a social worker, a palliative care RN, and a chaplain. The same nurse (coauthor GR) served in both groups. The rest of the team had and have full-time responsibilities apart from the consult team and took on the extra task without adding any part-time staff or FTEs. About the same amount of time was spent with patients and families in both groups. The RN coordinator made sure all of the same relevant material (ie, the domains) was covered in both settings. The costs associated with each model were roughly equivalent.

All cases were reviewed retrospectively, and data were examined from the patients’ electronic charts. We measured readmission rates collected for both arms of the study and compared group A with group B statistically for both probability and frequency of readmission. We were looking for a decrease in readmission probability of at least 30% per patient consulted for group B and likelihood of a 20% drop in hospital readmission for group B of at least 95%. Sample size was determined by the total number of patients consulted by the palliative care RN for end-of-life planning.

**Results**

Figures 1 and 2 show our findings. The patients in the two groups were matched by virtue of having a consultation with Inpatient Palliative Care for end-of-life-care planning formally ordered by their attending physician. Group A was the control group. The patients in group A did not have a consultation with an interdisciplinary team for end-of-life-care planning; instead a palliative care RN conducted the consult. Group B was the test group. The patients in group B did have a consultation with an interdisciplinary team for end-of-life-care planning.

Some of our patients died during the six-month period, yet for our study, we focused on readmission. When our patients died
after consultation and during the six-month review period, it was only important for this study to note whether they were readmitted before they died in the hospital during that readmission. None of our patients were counted twice if their admissions were eight months apart and received two consultations or had a consultation in both group A and group B. Readmissions per patient per six months were recorded, and the probability for readmission was calculated. Probability analysis, using Bayes’ theorem, gave us an estimate for hospital readmission for each patient who had a consultation, six months after that consultation. Probability analysis also estimated the probability of a hypothesis, in our case “readmission,” using a formula for calculating odds and likelihood ratios.6,7

Group A yielded 1.15 readmissions per patient per six months after consult, generating a Bayesian probability of readmission for each patient consulted of 73%. Group B consultations yielded 0.70 readmissions per patient per six months after consult, generating a Bayesian probability of readmission for each patient consulted of 33% (Figures 1 and 2). Group B results were statistically evaluated using a one-sample, one-tailed t-test. Using an interdisciplinary consult team, we calculated the mean decrease in hospital readmissions, with \( t = 2.056 \) (critical value for \( t_{0.025, 100} \) was 1.984). Thus, we estimated a >95% likelihood (\( p = 0.025 \)) that the mean reduction of hospital readmissions is 20%, and the likelihood of this occurring by chance alone is <5%. No confounders were identified for this study.7-10

Discussion
Creating moral space for discussion within the health care delivery system is progressively becoming an integral part of the medical enterprise.11 As Gawande wrote, the conversations that occur within the moral space of modern medicine present “… a clear understanding of the limits and possibilities of medicine and realize this understanding to be more of a process and not an epiphany.”12 The patients for whom this process works best are those who need to clarify treatment goals and often need to focus on end-of-life issues. Interdisciplinary consultations help the patient and family understand the possibilities of medicine, discuss treatment values, discuss nonmedical concerns, repair conflicts in the decision-making process, and decide about intensity of treatment, in addition to providing guidance in those contexts when treatments provide little quantitative benefit to the dying patient.13 Interdisciplinary-team consultation can help define a patient-centered goal that helps the patient understand the benefit of an intervention and diminishes the possibility that medical interventions become isolated from the larger clinical picture.14

Our study compared two consultation methods. Data for group B showed that the consultation we offered provided the depth and thoroughness of interdisciplinary consultation and also played an important role in reducing number of days of hospital use by reducing hospital readmission.15

Greatly significant in our study was when an interdisciplinary consultation team was used, readmissions to the hospital per patient per 6 months after consultation decreased from 1.15 to 0.7 admissions per patient; the probability of readmission for each patient consulted decreased from 73% to 33% for each patient consulted. In addition to the probability of readmission, our \( t \)-test results indicated that the mean reduction of hospital readmissions is 20% and that the likelihood of this occurring by chance alone is <5% (\( p = 0.025 \)). Therefore, on the basis of Zhang et al,16 we concluded that the consultations drove the difference.
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The cost savings produced by reduced hospital readmission, calculated by using the average hospital adjusted expense per inpatient day for California patients, comes to $49,226 per 100 patients consulted. A retrospective analysis of 155,474 hospitalizations between 2002 and 2005 at 17 Northern California KP hospitals yielded a median length of stay for all hospitalizations of 2.8 days, with an interquartile range of 1.3 to 5.1 days. Applying this KP data to the average hospital adjusted expense per inpatient day for California patients a potential savings is possible between $63,994 and $251,053 per 100 patients who had a consultation with an interdisciplinary team.

Future investigations might include a prospective trial in which the study design could rely on a logistic-regression model examining wider categories of data. Patient characteristics such as age, sex, diagnoses, palliative care, and hospice care could potentially allow a refinement of where the benefit of end-of-life-care planning would yield the greatest benefit. It would also be helpful for future studies to directly correlate the effect of early consultation intervention on patient survival and the connection between early introduction of end-of-life care planning and the mitigation of unnecessary and burdensome personal and societal costs.

In addition, much work is still needed to find ways of using objective metrics to measure worth and value for qualitative services provided by inpatient palliative care end-of-life-care planning consultation services. Care must be exercised, though, as quantitative metrics can never completely characterize the essence of a positive health care experience. We must continue to look for practical opportunities that help us provide the benefit that comes from interdisciplinary consultation. Interdisciplinary end-of-life-care planning consultation is an important way for KP to enhance the care experience, help with patients’ decision making, and to improve relationships between clinicians and patients.

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

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References
Implementation Study

Reducing Antipsychotic Polypharmacy Among Psychogeriatric and Adult Patients with Chronic Schizophrenia

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**Abstract**

**Introduction:** At the Institute of Mental Health/Woodbridge Hospital, 55% of the long-stay patients are on more than two antipsychotics for treatment of chronic schizophrenia. Our aim was to reduce antipsychotic polypharmacy (APP) among chronic schizophrenia inpatients at the long-term wards at the Institute of Mental Health, Singapore from 2006 to 2008.

**Methodology:** Using Clinical Practice Improvement Program (CPIP) methodology and using a Plan, Do, Study, Act approach, we surveyed patients, physicians, and nurses for responses regarding reducing the amount of APP for psychiatric patients. The first CPIP (CPIP1) was conducted from August 2006 to January 2007, and focused on psychogeriatric chronic schizophrenia inpatients. This methodology was spread to a second CPIP (CPIP2) from April 2008 to October 2008, which focused on adult chronic schizophrenia inpatients.

**Results:** Both CPIPs were successful in the reduction of APP within the geriatric and adult long-term patients. For CPIP1, eight patients had their antipsychotics reduced. There was a reduction of an average chlorpromazine-equivalent dose per day from 375 mg per patient to 170 mg. For CPIP2, the average number of antipsychotics was reduced from 2.9 to 2.27 from July 2008 to October 2008. There was a reduction of an average chlorpromazine-equivalent dose per day from 1523 mg per patient to 1246 mg. There was no documented relapse within six months of implementation of both the projects.

**Conclusion:** APP in long-term patients suffering from chronic schizophrenia can be safely reduced with proper clinical titration, aided by guidelines and protocols.

**Introduction**

Singapore is a small country in Southeast Asia with a land area of 710.3 square kilometers in 2009. As of June 2010, Singapore’s total population was 5.08 million. The Institute of Mental Health/Woodbridge Hospital is the only state tertiary mental hospital in Singapore providing multidisciplinary psychiatric services. Our hospital serves approximately 2000 inpatients and has a comprehensive network of outpatient clinics and day centers islandwide outside its main campus at Buangkok Green Medical Park.

Antipsychotic polypharmacy (APP) refers to the concurrent use of two or more antipsychotic medications in a single patient. It is recommended that minimum effective doses of antipsychotics should be prescribed, specifically in the range of 300-1000 mg of chlorpromazine equivalents per day, APP and excessive dosing is common in clinical practice. In 2000, Chong et al published a study at the Singapore Institute of Mental Health/Woodbridge Hospital.
Health showing that the rate of APP was 59% of 534 patients with chronic schizophrenia with a median daily dose of 400 mg chlorpromazine equivalents (range 50-2875 mg). In 2004, in a multicentered Asian study, Sim et al found that APP was 45.7% (n = 1097) of the patients with wide intercountry variations. In this study, the most commonly prescribed antipsychotics in Singapore were chlorpromazine, haloperidol, and trifluoperazine. Hung and Cheung in a Hong Kong study showed that APP was the main determinant of high-dose antipsychotic prescribing.

APP is a significant problem among long-term inpatients at the Institute of Mental Health in Singapore. In December 2008, hospital audit findings showed that 55% of the long-term inpatients were on more than two antipsychotic medications for treatment of chronic schizophrenia.

**Methodology**

**Part 1**

A multidisciplinary team comprised of psychiatrists, nurses, and a pharmacist embarked on a Clinical Practice Improvement Project (CPIP1) from August 2006 to January 2007. The target population was all eligible psychogeriatric long-term inpatients on three wards, with a time period of six months, and a desired outcome that no patient would experience symptom relapse.

The three aims were: 1) reduce the number of patients on more than two antipsychotic medications (including depot medications); 2) reduce the average chlorpromazine (mg) dose equivalence per patient; and 3) reduce the average number of antipsychotic medications per patient. The team used the Plan, Do, Study, Act (PDSA) methodology.

Through a brainstorming session, the main contributors to the problem were identified as: lack of guidelines; lack of continuity of care; fear in physicians and nurses that patients would relapse; insufficient time for review; and physician inexperience (Figure 1).

The team surveyed patients, physicians, and nurses, to gauge their response to reducing the amount of antipsychotic medication for patients (CPIP1 survey). Then the team developed simple guidelines/protocols including a dose-reduction table for physicians to use during their two-monthly reviews (Figure 2).

Finally, all ward staff were briefed and trained on the project and the guidelines.

**Part 2**

This CPIP1 methodology was spread to another project (CPIP2), from April 2008 to October 2008, directed at adult long-term inpatients with schizophrenia on

Figure 2. Medication reduction algorithm 1.

NB: 1) Patients are to be reviewed for medication adjustment any time they develop relapse symptoms; 2) for patients on both depot and oral antipsychotics, the depot form should be reduced first unless the patient has swallowing difficulties or is noncompliant with oral medications.

Figure 3. Causes of antipsychotic polypharmacy in long-stay psychogeriatric wards (CPIP1). CPIP1 = Clinical Practice Improvement Project 1.

Figure 4. Causes of antipsychotic polypharmacy in adult long-stay wards (CPIP2). CPIP2 = Clinical Practice Improvement Project 2.
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The objective was to reduce the use of APP within six months without acute symptom relapses. The team also used the PDSA methodology.

**Results**

**Part 1**

The preliminary survey of the perceptions and beliefs of APP among patients (n = 14), nurses (n = 13), and physicians (n = 17) was conducted in 2006. The results indicated that 57% of patients preferred to have antipsychotic medications reduced, 29% preferred to maintain their current status, and 14% had no preference, also 86% had no strong objection to a proposed change. The results for nurses indicated 60% of nurses felt it beneficial to reduce antipsychotic medications, to reduce side effects, and 40% preferred to maintain current recommendations. The results for physicians indicated that: 82% feared relapse of the condition; 71% respected nurses' fear of relapse; 70% felt that there was a lack of supervision/guidelines; 59% felt they had insufficient time; and 35% did not see the benefit. In 2008, a second survey would follow.

Causes of APP in the long-term psychogeriatric wards include: 1) lack of guidelines; 2) lack continuity of reduction plans; 3) nurses' fear of patients' relapse; 4) physicians' fear of patients' relapse; and 5) insufficient time for review (Figure 3).

In CPIP1 the team developed a clinical protocol for the reduction of APP in long-term psychogeriatric patients. This protocol was spread to CPIP2 (Figure 4). The aim of the clinical protocol was to develop simple guidelines for physicians to follow during their two-monthly reviews.

**CPIP1:** For the geriatric population, 8 patients had their antipsychotic medications reduced, 4 patients had their antipsychotic medication injections stopped, 3 patients had improvement in their blood pressure readings, 3 patients had significant improvements in reduction of their drug side effect symptoms, no patients experienced falls or urinary tract infections, 2 patients showed improvement in mental alertness and in their physical activity, and there was a reduction of an average chlorpromazine equivalent dose per day from 375 mg per patient to 170 mg (Figures 5-7).

**Part 2**

In 2008, CPIP2, a survey of the perceptions and beliefs among nurses (n = 14) and physicians (n = 17) of antipsychotic medication use was conducted. The survey showed that all (100%) of the nurses wanted to reduce APP; 90% of the nurses saw the benefits and were eager to reduce APP; 79% of
nurses expressed that reducing APP would reduce side-effects; and more than 50% expressed that it would reduce medication error and drug-drug interactions. For physicians, 88% feared that reducing APP would cause a relapse; 65% saw the benefit of reducing APP; and 59% expressed concern that they would encounter patients’ and nurses’ resistance. About 50% of physicians indicated that they were not familiar with the patients and that there was a lack of guidelines; 29% did not see the benefits to APP reduction and reported that there was a lack of clinical supervision.

Causes of APP in the long-term adult wards include: 1) nurses’ resistance and fear of reducing antipsychotic medications, and 2) physicians’ fear of patients’ relapse in the event of reduction of APP (Figure 4).

CPIP2: For the adult long-stay patients, there was a reduction of the average number of antipsychotics from 2.9 to 2.27, a reduction of an average chlorpromazine equivalent dose from 1523 mg per patient to 1246 mg, and there was no documented relapse within six months of implementation of both the projects. Both CPIPs were successful in the reduction of APP within geriatric and adult long-term patients (Figures 8-10).

Discussion

APP is described by Stahl8 as a “dirty little secret,” and is a frequent and unrecognized phenomenon among clinicians. Although it is common in clinical practice, APP is not evidence-based.9

These significant results demonstrate that APP in long-term patients suffering from chronic schizophrenia can be safely reduced with proper clinical titration and monitoring. The protocols and flow charts can be applied to all the long-term wards at the Institute of Mental Health/Woodbridge Hospital. A Japanese study by Suzuki and Uchida et al.,10 involving chronic schizophrenia patients in which antipsychotic combination regimen (polypharmacy) was switched to a treatment with the single main antipsychotic (monotherapy) in cross-tapered fashion, showed that 55% of 44 patients remained stable at 24 weeks of evaluation. Similarly, Ito11 showed that quality and performance improvement were emerging to reduce APP prescriptions in Japan. With adequate guidance, supervision, and support, junior physicians can be empowered to make decisions on drug reduction for patients. APP reduction can be safely accomplished for long-term stable psychiatric patients with a well-supervised review aided by guidelines and protocols.
Reducing Antipsychotic Polypharmacy Among Psychogeriatric and Adult Patients with Chronic Schizophrenia

In another Japanese study by Ito et al., APP and excessive dosing were influenced by the psychiatrist’s skepticism towards the use of algorithms and nurses’ requests for more drugs. Hence, constant education and evidence-based results are essential to change the staff’s mind-set about drug reduction for patients.

The benefits of reduction of APP affects patients, physicians, nurses and hospitals. A naturalistic systematic study by Glick et al. showed that for most stabilized, chronic patients with schizophrenia, tapering adjunctive medications did not change outcome.

APP adversely affects quality of life among patients, resulting in higher total doses of multiple neuroleptics, higher use of concomitant anticholinergic medications, underutilization of atypical neuroleptics, drug side effects, drug interactions and compliance issues. Increasing an antipsychotic medication’s daily dose was associated with decreased cognitive performance.

APP adds substantial cost burden to the treatment of patients suffering from chronic schizophrenia. A study of five US Medicaid programs showed that cost savings from limiting APP could be significant. A study of 116,114 patients within the California Medicaid Program showed that 4.1% received a combination regimen, and that APP was the most expensive form of second-generation use.

In conclusion, APP in long-stay patients suffering from chronic schizophrenia can be safely reduced with proper clinical titration and monitoring. Physicians can increase their confidence in reducing the number of antipsychotic medications for patients using the guided protocols. All staff and patients expressed satisfaction with project interventions. There were also significant cost savings for the reduction of APP.

**Disclosure Statement**

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

**References**

Implementation Study

Reducing the Use of Seclusion and Restraint in Psychiatric Emergency and Adult Inpatient Services—Improving Patient-Centered Care

Abstract
The reduction of seclusion and restraint (S/R) use has been given national priority by the US government, The Joint Commission, and patient advocacy groups. It is associated with high rates of patient and staff injuries and is a coercive and potentially traumatizing intervention. The New York City Health and Hospitals Corporation (HHC) is the largest municipal health care system in the country, with 11 HHC facilities operating psychiatric emergency services and inpatient psychiatric services. HHC operates 1117 adult inpatient psychiatric beds with an average length of stay of 22.2 days that generated over 19,000 discharges in 2009. In 2009, there were over 36,000 psychiatric emergency services visits. HHC’s Office of Behavioral Health provides strategic leadership, planning, and support for the operations and quality objectives of these services. In January 2007, the corporate office initiated the Seclusion and Restraint Reduction Initiative with a sequenced, intensive series of interventions and strategies to help focus the behavioral health leadership and staff on the need for continued culture change toward a more patient-centered and safe system of psychiatric emergency and adult inpatient care. From 2007 to 2009, there was a substantial decline in HHC’s overall rate of S/R incidents in inpatient units. The more substantial impact was in the reduced overall time spent in S/R; the reduced frequency of use of S/R; and the reduced likelihood of patient injury from S/R use.

Introduction
Context
Regulators and advocates have called for the reduction of seclusion and restraint (S/R) use in inpatient psychiatric settings. S/R is viewed as a treatment failure rather than a treatment intervention. S/R is associated with high rates of patient and staff injuries and is considered a coercive and potentially traumatizing intervention with no established therapeutic value. New York City Health and Hospitals Corporation (HHC) has a long history of S/R-reduction efforts with successes in both psychiatric inpatient and emergency services. In 2007, to build on these gains and to continue the culture change from a medical model to a patient-centered rehabilitation and recovery-oriented service system, HHC launched the Seclusion and Restraint Reduction Initiative. Since 2000, HHC has sought to change the attitudes and beliefs of clinical professionals about mental illness and recovery by providing education about rehabilitation and recovery in a discussion and dialogue format presented by paid part-time consumer advocates. As part of this effort, HHC established a Peer Counselor program to offer jobs to mental health consumers who want to enter or re-enter the workforce as advisors, mentors, and/or advocates for those seeking psychiatric treatment at HHC hospitals. They were included in the interdisciplinary teams on the inpatient, emergency service and outpatient services.

Kick-off
On January 20, 2007, a large corporatewide kick-off event was held, led by the Corporate Executive Vice President and his management team. The goals of the initiative included further reductions in S/R use and continued culture change to make the psychiatric inpatient and emergency services more patient centered and trauma informed. Interdisciplinary change teams that would be in charge of the initiative at each
Reducing Seclusion and Restraint in Psychiatric Emergency and Adult Inpatient Services—Improving Patient-Centered Care

The Mandt System teaches the use of a graded system of alternatives, which uses the least amount of external management necessary in all situations.

The Mandt System teaches the use of a graded system of alternatives, which uses the least amount of external management necessary in all situations.

Materials and Methods

Phased Interventions/Strategies

Using the corporate Office of Behavioral Health as Seclusion/Restraint Reduction Initiative Project Manager (planning phase): In late 2006, HHC asked the Commissioner of the New York State Office of Mental Health to request for HHH-wide implementation “Creating Violence Free and Coercion Free Mental Health Treatment Environments for the Reduction of Seclusion and Restraint” training from the National Association of State Mental Health Program Directors’ Office of Technical Assistance (OTA). This nationally recognized training module was reserved for state-run facilities. HHC was awarded an external two-year grant for staff retraining. This enabled HHC to have the necessary resources to manage and implement the training and other implementation strategies of the initiative.

Corporate culture change training (planning and implementation phases): Three two-day training sessions were held in early March 2007 and July 2007, with a total attendance of nearly 760 leadership and direct care staff. On the basis of the National State Mental Health Program Directors’ OTA training model, participants were introduced to six core strategies that have been proven to reduce S/R use including concepts of primary and secondary prevention, leadership roles and responsibilities, key characteristics of trauma-informed care systems, using data to inform practice, environmental factors that can be modified to create a safer or calmer environment, rigorous post-event debriefing, and consumer and family roles in the inpatient setting. At the end of the second day, staff gathered by facility to develop a facility-specific work plan to implement the six core change strategies.

Eleven facility-specific consultations (planning and implementation phases): As a next step in assisting the facilities to develop their work plans and to identify opportunities and strategies for improvement, HHC contracted with OTA faculty to provide consultation consistent with the OTA training. The visits occurred between July 9 and September 11, 2007, and focused primarily on the adult inpatient units of each hospital.

Several hospitals included their child and/or adolescent units as part of the site-visit consultation. Several of the hospital-visit consultations also addressed issues specific to Emergency Department programs and/or forensic programs. The consultants used a review protocol for the HHC consultation and site reviews that is an adaptation of the formal review instrument developed for a Substance Abuse and Mental Health Services Administration-funded eight-state OTA evaluation project. At each site, the consultants met with the facility’s behavioral health leadership team, quality-improvement staff, nursing leadership, and frontline staff to get a thorough picture of the facility’s efforts to reduce the use of S/R. The consultants also reviewed S/R documentation in a random sample of facility records. After each site visit, they prepared summary reports of their findings, and their analysis of hospital strengths and priority areas recommended for improvement. Over 100 HHC behavioral health leaders participated in these leadership sessions. Consultants also met with numerous staff and consumers.

Crisis de-escalation training (implementation phase): Train-the-trainer models for crisis prevention and management were developed and provided in August-September 2007 and in May 2009. Sixteen highly interactive Mandt training sessions were provided for groups of 35 behavioral health staff to help them develop crisis de-escalation skills. The Mandt System teaches the use of a graded system of alternatives, which uses the least amount of external management necessary in all situations.

Sensory modulation tools and approaches (implementation phase): Sensory modulation approaches and tools on inpatient psychiatric service are an emerging best practice. The use of sensory modulation approaches means that the need for more coercive measures such as S/R is reduced. HHC hired sensory modulation experts to train HHC staff at the end of November 2007 and again in May 2009 with a total of 334 staff trained. The corporation also used grant dollars to purchase sensory modulation equipment for each inpatient psychiatric unit operated by the corporation. Each of the 58 units received a variety of sensory tools (including a rocker, weighted blankets, and vests) and a rolling cabinet in which to store them. As part of the training, staff were able to view and rehearse use of equipment. HHC has recently published a guideline on the use of sensory modulation tools and techniques on inpatient psychiatric services that has been distributed along with a staff training module to reinforce effective and safe use of this emerging best practice.
Data transparency (planning and implementation phases): HHC facilities were asked to submit S/R data to the corporate office before the project was officially announced so that a baseline could be analyzed and shared. Since the kick-off, facilities have been submitting data on S/R restraint use and patient and staff injuries associated with the use of S/R. This data was reviewed monthly by the HHC Council of Directors of Psychiatry of the Departments of Psychiatry at each of the 11 acute care hospitals and lessons learned were discussed. The data is also shared quarterly in a comprehensive data book with corporate and individual facility S/R trend charts. This project was the first time that individual facility data was shared. In addition, in July 2007, HHC included individual facility S/R on its quarterly dashboard/corporate performance report.

Managing agitated patients workgroup (implementation phase): In November 2007, 11 months after the start of the initiative, HHC established a workgroup to focus on how to better manage agitated patients. The workgroup resulted in several initiatives that had an impact on the HHC Seclusion and Restraint Reduction Initiative: 1) various models of psychiatric emergency response teams were explored and shared with HHC facilities; 2) training modules for hospital police were created to clarify their role when asked by the clinical staff to respond to a patient who is agitated or in crisis; and 3) the corporation created a new job title called a Behavioral Health Associate. Behavioral Health Associates receive extensive crisis prevention and de-escalation training and perform some of the duties that had been assumed by hospital police.

Corporate guidelines for developing facility-specific restraint and seclusion policies and procedures (implementation phase): In December 2007, HHC issued corporate guidelines to assist HHC facilities with the revisions that would need to be made to their facility-specific policies and procedures to bring them in line with changes in The Joint Commission and, more importantly, in Centers for Medicaid and Medicare Services regulations. The guideline addresses both behavioral and medical-surgical restraints and went further than federal or state requirements by imposing a two-hour maximum limit on an S/R order for adults, two hours less than what is allowed by Centers for Medicaid and Medicare Services and New York State Office of Mental Health.

A corporate psychiatric emergency services assessment (implementation phase): On January 6, 2008, HHC implemented a psychiatric emergency assessment form developed by the HHC Office of Behavioral Health through a corporatewide workgroup that is used in all the Psychiatric Emergency Services (PES) that includes a trauma assessment, which explores the impact of past trauma on current functioning, patient preferences regarding effective calming measures, triggers for agitation, and preferences regarding S/R use.

Results
The total number of S/R incidents by calendar year is summarized in Table 1. Please note that we were

<table>
<thead>
<tr>
<th>Year</th>
<th>Adult inpatient Restraints</th>
<th>Adult inpatient Seclusions</th>
<th>Adult inpatient PES Restraints</th>
<th>Adult inpatient PES Seclusions</th>
<th>Adult inpatient PES</th>
<th>No. of staff injuries</th>
<th>No. of patient injuries</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>No. of episodes</td>
<td>No. of episodes</td>
<td>No. of episodes</td>
<td>No. of episodes</td>
<td>No. of episodes</td>
<td>No. of episodes</td>
<td>No. of episodes</td>
</tr>
<tr>
<td>2007</td>
<td>940</td>
<td>1399</td>
<td>1047</td>
<td>39</td>
<td>1</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>2008</td>
<td>782</td>
<td>203</td>
<td>849</td>
<td>32</td>
<td>10</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>2009</td>
<td>643</td>
<td>235</td>
<td>737</td>
<td>25</td>
<td>3</td>
<td>23</td>
<td>2</td>
</tr>
</tbody>
</table>

PES = psychiatric emergency services
Reducing the Use of Seclusion and Restraint in Psychiatric Emergency and Adult Inpatient Services—Improving Patient-Centered Care

Also, the duration per episode of restraint (Figure 4) went from a mean of 246.81 minutes to 57.62 minutes between 2007 to June 30, 2009, a 77% reduction and the mean duration per episode of seclusion (Figure 5) decreased from 88.78 minutes to 50.50 minutes, a 43% reduction.

A one-way analysis of variance (ANOVA) of the mean differences between 2007, 2008, and 2009 was conducted (Tables 2 and 3). The overall change in inpatient restraint rate did not achieve statistical significance. However, the patterns of use of these methods did change significantly reflecting more targeted and safer use, and significant reduction in the most acute treatment areas. For the adult inpatient service, reductions in frequency of seclusion, mean duration per restraint and mean duration per seclusion were significant at 0.04. Patient injury (restraint) reduction was significant at 0.05. In the PES settings, frequency of restraints was significant at 0.02 and patient injury was significant at 0.03.

Given that at the outset of the Seclusion and Restraint Reduction Initiative some facility leadership and staff were concerned that further reductions in S/R use would be difficult especially with the advent of including counts of manual restraints in the S/R data, these declines strongly speak to the success of the initiative. Unfortunately, staff injuries have remained generally level, which could reflect that despite fewer restraints, those patients that are restrained represent a core of significantly violent or agitated patients that contribute to injury.

Discussion

What Worked and How Well

In our view, the success of the initiative derives from the sequencing of the implementation strategies/interventions; each building upon lessons learned with the aim of sustainability. Among the most critical individual strategies were:

Involvement of the leadership: The express interest of the HHC President in this initiative and the decision to manage it centrally gave it a focus that had not existed in prior efforts to reduce and/or eliminate S/R use. Leadership committed to organizational change is the first of the six National State Mental Health Program Directors OTA core strategies to reduce S/R use. Furthermore, part of the project’s charter was the understanding that the Director of Psychiatry would be in charge of the change effort, not his/her designee. Progress on the initiative was routinely shared with the HHC Directors of Psychiatry, Administrators of Psychiatry, and Psychiatric Nursing Directors and...
Table 2. Analysis of variance—adult inpatient

<table>
<thead>
<tr>
<th>Labels</th>
<th>Type</th>
<th>F-test</th>
<th>Significance</th>
</tr>
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<tbody>
<tr>
<td>Frequency of seclusion episodes per 1000 patients hours</td>
<td>Between groups</td>
<td>4.788</td>
<td>0.04</td>
</tr>
<tr>
<td>Mean duration per restraint episode</td>
<td>Between groups</td>
<td>4.819</td>
<td>0.04</td>
</tr>
<tr>
<td>Mean duration per seclusion episode</td>
<td>Between groups</td>
<td>4.932</td>
<td>0.04</td>
</tr>
<tr>
<td>Patient injury (restraints) per 1000 patient hours</td>
<td>Between groups</td>
<td>4.411</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Table 3. Analysis of variance—psychiatric emergency services

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<tr>
<th>Labels</th>
<th>Type</th>
<th>F-Test</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of restraint episodes per 100 patients registered</td>
<td>Between groups</td>
<td>6.128</td>
<td>0.02</td>
</tr>
<tr>
<td>Patient injury per 100 patients registered</td>
<td>Between groups</td>
<td>5.192</td>
<td>0.03</td>
</tr>
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provided by the HHC President to the Corporation to Hospital executives and the HHC Board of Directors.

Corporate culture change training: It was critical to the project’s success that HHC facilities embrace the culture shift involved in moving toward a less coercive, more recovery-oriented system of services. Use of S/R could no longer be considered as a treatment option, but as a treatment failure. The National State Mental Health Program Director OTA training was chosen as it focuses on why mental health services need to change and how they can better support mental health consumers in their recovery.

Data analysis and transparency: As the project progressed, we changed data collection from a quarterly to a monthly basis to make it more actionable. Each of the Directors were given a data analysis of three indicators of S/R use: a) total duration of S/R per 1000 patient hours; b) frequency of S/R per 1000 patient hours, and c) corporate mean duration of S/R per 1000 patient hours. For the PES, “100 patients registered” was used as the denominator. Each of these indicators was analyzed at the corporate and facility levels. When the total duration of S/R indicator was added to a corporate quality indicator dashboard, key stakeholders beyond the Departments of Psychiatry also became interested and involved in the project’s success.

Facility-specific consultations: Facility-specific consultations were extremely useful because they gave an opportunity for immediate feedback from the experts on each facility’s specific issues related to S/R reduction. The consultants’ reports offered a clear future roadmap with suggestions and resources for areas needing improvement.

Limitations—Barriers Encountered and Methods Used to Address Them

Corporate culture change to a rehabilitation and recovery-oriented service system: Some HHC leadership and direct care staff were fully committed to maximum reductions and the associated culture change; others were not as focused on the goal. Culture change is always extremely difficult. As stated earlier, HHC has used a number of strategies to promote the shift to a more patient-centered, rehabilitation and recovery-oriented behavioral health services including the development of “Work from the Heart: Improving Patient-Centered Care,” a toolkit disseminated to all the HHC Departments of Psychiatry. The hiring of Peer Counselors for psychiatric inpatient and emergency services and the consumer-led staff dialogues have been very successful with leaders and direct care staff. Another strategy that seemed especially effective in engaging facility leaders was the data transparency and the competition that it created.

Summary

The HHC Seclusion and Restraint Reduction Initiative incorporated sequenced implementation strategies and interventions, each building upon lessons learned, with the aim of sustainability of practice change in this area across a very large and diverse system of care. Among the most critical individual strategies were leadership involvement, facility culture change, the learning of concrete de-escalation skills, and the use of data to drive system change. These resulted in reduced, but significantly more targeted and safer use of these methods. These lessons learned can be shared with other hospitals addressing similar issues at very little or no cost.

Use of seclusion/restraint could no longer be considered as a treatment option, but as a treatment failure.

New York State’s Office of Mental Health is one of eight state grantees in the Alternatives to Restraint and Seclusion State Infrastructure Grant Project (S/R-SIG), an initiative of the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Center for Mental Health Services (CMHS), designed to promote the implementation and evaluation of best practice approaches to preventing and reducing the use of seclusion and restraint in mental health settings.
Disclosure Statement
The author(s) have no conflicts of interest to disclose.

References

Misery
Of all the miseries that afflict human life and relate principally to the body, in this valley of tears I think nervous disorders in their extreme and last degrees are the most deplorable and beyond all comparison the worst.

—The English Malady, George Cheyne, 1671-1743, British physician, medical writer, proto-psychologist, philosopher, and mathematician
SPECIAL REPORT

Is Patient-Centered Care the Same As Person-Focused Care?

Barbara Starfield, MD, MPH

Abstract
Both patient-centered and person-focused care are important, but they are different. In contrast to patient-centered care (at least as described in the current literature with assessments that are visit-based), person-focused care is based on accumulated knowledge of people, which provides the basis for better recognition of health problems and needs over time and facilitates appropriate care for these needs in the context of other needs. That is, it specifically focuses on the whole person. Proposed enhancements and innovations to primary care do not appear to address person-focused care. Tools to assess person-focused care are available and deserve more widespread use in primary care.

Introduction
The benefits to health from advances in medicine in the 20th century have led to a shift away from patients’ problems to disease processes, without consideration of the changing contexts in which people live and work and with a demonstrated decline in focus on the person.¹ This article explains why the concept of patient-centered care must be supplemented with the concept of person-focused care.

Patient-centered is a term in widespread use; in the US, for example, the recent movement toward reforming primary care is known as the patient-centered medical home. The preponderance of the literature assesses patient-centered care by focusing on visits involving care of (generally chronic) diseases, whereas person-focused care is provided to patients over time independent of care for particular diseases² (Table 1).

The Importance of Recognizing Patients’ Health Problems as They See Them
Both patient-centered care and person-focused care require adequate recognition of health problems experienced by people. Care is better when it recognizes what patients’ problems are rather than what the diagnosis is.³ The challenge is to do better at recognizing and documenting their problems. Assessing quality of problem recognition requires documenting the problems and how they change in response to what clinicians do.

Diagnoses are professional interpretations of observations and, increasingly, of laboratory values. A few primary care researchers in various countries have been trying at least since the late 1980s to understand the relationship between presenting problems and eventual diagnoses.⁴ There is still poor understanding of this relationship, and the more it is neglected, the less attention can be focused on problem reduction over time as a legitimate goal of treatment.

<table>
<thead>
<tr>
<th>Table 1. Differences between patient-centered care and person-focused care</th>
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<tbody>
<tr>
<td><strong>Patient-centered care</strong></td>
</tr>
<tr>
<td>Generally refers to interactions in visits</td>
</tr>
<tr>
<td>May be episode oriented</td>
</tr>
<tr>
<td>Generally centers around the management of diseases</td>
</tr>
<tr>
<td>Generally views comorbidity as number of chronic diseases</td>
</tr>
<tr>
<td>Generally views body systems as distinct</td>
</tr>
<tr>
<td>Uses coding systems that reflect professionally defined conditions</td>
</tr>
<tr>
<td>Is concerned primarily with the evolution of patients’ diseases</td>
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Barbara Starfield, MD, MPH, is a University Distinguished Professor in the Department of Health Policy and Management at Johns Hopkins University in Baltimore, MD. E-mail: bstarfie@jhsph.edu.
Patient-Centered Care

Most studies of patient-centeredness are carried out in settings involving visits. Sixteen of the 57 references in a recent review have the words communication or interaction in their titles. Prompted by a perceived poor understanding of the term, the authors asserted that patient-centeredness is “determined by the quality of interactions between patients and clinicians” and indicated that they equate patient-centeredness with communication skills, which “are a fundamental component of the approach to care that is characterized by continuous healing relationships, shared understanding, emotional support, trust, patient enabling and activation, and informed choices.” In their discussion of physician training, they make it clear that all physicians (not only primary care physicians [PCPs]) need such training. Visit-based studies of communication and/or interaction between patients and professionals provide most of the evidence for the utility of patient-centeredness. The literature is replete with evidence that communication patterns, both verbal and nonverbal, make a difference, as measured by whether patients are more knowledgeable, more willing to adhere to recommendations, or more “satisfied” with their care. There is no doubt that patterns of communication make a difference, but the extent to which good communication in individual visits is a sufficient strategy to provide the person focus and “continuous healing” that good primary care requires is unknown. It may be that other skills, such as the accumulation of knowledge about people’s resilience and vulnerability to threats to their health, are critical as patients move from one health problem to others.

Person-Focused Care

Studies that focus on the prevention and management of patients’ problems over time provide a different and complementary approach to a visit-oriented approach. The literature on primary care-oriented health systems postulates that one of the mechanisms for benefit results from a greater focus on patients as they transition from one health problem to another. Primary care is person-focused, not disease-focused, care over time. To be person-focused, it must be accessible, comprehensive (dealing with all problems except those too uncommon to maintain competence), continuous over time, and coordinating when patients have to receive care elsewhere. The essence of person focus implies a time focus rather than a visit focus. It extends beyond communication because much of it relies on knowledge of the patient (and of the patient population) that accrues over time and is not specific to disease-oriented episodes. Physicians and patients working together to reach mutual decisions often require a long-standing relationship. Patients are more likely to follow medication regimens if they share their physicians’ belief about causes of health outcomes. This is unlikely to be the case when visits are with practitioners not well known to patients (and vice versa).

Family physicians’ views concerning genetic conditions support the notion that care over time is critical to understanding patients’ needs and problems. In contrast to judging possible genetic predispositions to rare genetic problems, genetic influences on common illnesses cannot be determined in individual encounters with patients. A major failure of primary care, particularly in countries such as the US (where specialty care, including major teaching hospitals, is so dominant), is the great underestimation of the importance of long-term relationships with patients independent of care for specific disease episodes. A specialty dominance dictates that interest is mainly in individual diseases, chosen because they are costly or because they are thought to cause considerable premature mortality. Contrary to conventional wisdom, the main determinant of high costs of care is not the presence of chronic illnesses. Rather, it is the combination of various types of illnesses—that is, multimorbidity—over a period of time (Efrat Shadmi, PhD; Ran Balicer, MD, MPH, PhD; Karen Kinder, MBA, PhD; Chad Abrams, MA; Barbara Starfield, MD, MPH; Jonathan Weiner, DrPH, personal communication 2010). 

The importance of a person focus (a nondisease focus) in primary care is highlighted by primary care clinicians’ views of their roles. They appreciate the importance of costs and severity of condition (which is difficult to judge in clinical settings, except in the case of acute conditions), but they identify three additional issues: patients’ viewpoint of the problem’s relative importance, the duration of time over which priorities are set (short or long term), and the level of evidence of benefit in primary care practice. Inherent in a person focus is the notion that attention to patients’ problems in the context of their multimorbidity (multiple coexisting diseases) is at least as important as appropriate care for their individual diagnoses. Good primary care is not the sum of care for individual diseases.

Will Innovations and Enhancements to Primary Care Improve Problem Recognition and Person Focus?

Although most PCPs (and some specialists) think of their work as person-focused, reimbursement policies
and the thrust of medical education toward professionally specified diagnoses do not reward or facilitate attention to patient-defined problems. Whether current enhancements to and innovations in primary care will change the current reality is an open question. Several of these approaches are currently in vogue: guidelines, payment for performance, chronic care management, and, in the US, the patient-centered medical home.

Guidelines

Adhering to guidelines, although often very helpful to physicians, predisposes them to emphasize the management of specific diseases because clinical guidelines focus on diseases. Many common diseases are syndromes—that is, common manifestations of diverse processes set in motion by interacting influences on health. The challenges in medical care today are vastly different and much more complex than they were in the mid-20th century because of the marked increase in early diagnoses of diseases and a resulting increase in the simultaneous presence of different diseases. Despite this reality, guideline supporters continue to develop algorithms for management in primary care that are based on an outmoded concept of health problems in populations: single, discrete diseases.

Furthermore, most guidelines that are “evidence-based” have been justified on the basis of evidence on “outcomes” that are almost always proxy outcomes measured by laboratory tests. Clinical trials do not identify the nature and extent of the health problems experienced by people participating in them or the extent to which problems experienced by the participants are resolved by the intervention being tested. As a result, “outcomes” do not involve determinations of whether the intervention caused unintended adverse effects, despite the evidence that adverse events are common. Knowledge of these adverse effects is left to voluntary reporting by astute clinicians who look for them. Person focus is not realized when likely adverse events are not systematically recorded and studied.

Guidelines, although generally applied only in primary care (not specialty practice) are not developed with consideration of the nature of primary care settings. In primary care, presenting problems are often not diagnoses but rather symptoms and signs (Jean Karl Soler, MD, MSc, MMCFD; Inge Okkes, MD; Henk Lambert, MD; personal communication 2010). Furthermore, the basis for guidelines is evidence from clinical trials, which exclude people with multiple morbidities. Problems related to the presence of multimorbidity are difficult to define, describe, and understand. PCPs are in the best position to know what types of problems should receive priority for guideline development, but they are rarely either consulted or in control over the selection of problems for guideline development, the interpretation of the results of trials, or the applicability of their results to their practice.

Many patients are prone to ignore interventions based on guidelines. For example, discontinuation of prescribed lipid-lowering therapy approaches 50% after one year and 85% after two years. Adoption of guidelines, particularly those touted as preventive, fails to be consistent with the overwhelming purpose of medicine, which is the relief of suffering.

Payment for Performance

Largely spurred by studies that suggest that only about 50% of widely accepted criteria for care of particular diseases are met in actual practice in the US, some health plans in the US and, particularly, the National Health System in the United Kingdom (under the Quality and Outcomes Framework) have introduced payment systems that reward physicians or health plans for adhering to guidelines in the care of their patients. Although payment for performance is, in theory, a laudable approach to encourage adherence to justified processes of care, several aspects of its application are problematic in terms of attention to people’s problems.

The limited range of quality indicators (mostly to a few common chronic diseases) is not conducive to recognizing the vast range of health problems that confront people. The fact that these are more likely in deprived populations makes most payment-for-performance schemes antithetical to fostering equity in delivering health services. Concomitantly, the effect is to place clinicians caring for these populations at risk of lower earnings.

Performance measurement is increasingly being extended to interventions that have only a small clinical benefit at the same time that many important aspects of care are being neglected. Most quality indicators, which increasingly focus on earlier detection of disease, are not based on priorities regarding effectiveness and, especially, equity, and they have the effect of encouraging physicians to focus on compliance (both in terms of their own actions and in terms of patients’ behaviors) rather than on problem resolution. Moreover, the assumption that it is justified to pay for performance in the care of people with selected diagnoses is highly questionable as an ethical strategy in the situation where the quality of diagnosis and clinical reasoning are suspect. Diagnostic errors are prevalent. In primary
care especially, many if not most presented problems are not well defined, and the diagnosis remains uncertain. Physicians are not rewarded for recognizing and adequately responding to patients’ problems.

The ethical aspects of pay for performance have been addressed by a major US primary care medical society, which proposed an ethics manifesto. It states: *Quality measures should identify excellent comprehensive care. They must recognize successful management of multiple complex chronic conditions, meeting the counseling and communication needs of patients, and providing continuity of care and other attributes of comprehensive care. All measures must sustain and enhance appropriate patient care and the physician-patient relationship.*

Although stopping short of acknowledging the critical importance of recognizing and dealing with people’s health problems over time, both in and outside of formal consultations, the wording of this statement makes it clear that high-quality care includes person-focused goals.

**Chronic Care Management**

The chronic care model is theoretically consistent with the primary care focus on care over time. It deviates from primary care in its application. *Chronic* has been interpreted as if it referred to chronic disease. This makes it inherently incompatible with primary care, which is person-focused. All of the implementations of chronic care management are disease-oriented, and they have all of the problems of disease-oriented care.

The literature is replete with evaluations purporting to show benefit, but the vast majority have focused only on one condition (mostly diabetes), and none have evaluated the effectiveness of the intervention on improvement in person-focused morbidity or mortality. Of 944 reviewed articles, only 82 were in primary care settings. Most were from the US. Greaves and Campbell concluded that the only demonstrably effective component of these new strategies could be attributed to better follow-up monitoring of patients.

A review in New Zealand concluded that if anything, a focus on specific chronic illnesses is unlikely to lead to improved health, particularly in populations that have high morbidity burdens overall.

The US Institute of Medicine report *Crossing the Quality Chasm* urges selecting priority conditions for attention to the quality of care. The list includes cancer, diabetes, emphysema, high cholesterol, HIV and AIDS, hypertension, ischemic heart disease, stroke, and “perhaps” also arthritis, asthma, gallbladder disease, stomach ulcers, back problems, Alzheimer disease, depression, and anxiety disorders. However, it does not include major and common problems such as inadequate nutrition, occupational diseases, osteoporosis, low birth weight and prematurity, repeated acute illnesses, or virtually any childhood disorder (except asthma), and a myriad of other conditions (such as chronic renal failure) that persist over time. Moreover, there is nothing inherently more chronic about “chronic diseases” than is the case for many acute but recurrent conditions such as sinusitis, urinary tract infection, and anemia of unknown origin. The public-health community is notably absent in defining the problems of populations.

**The Patient-Centered Medical Home**

The patient-centered medical home, at least as reflected in the requirements for qualification, is heavily focused on care in the context of disease management or communication within specific encounters. There are notable exceptions. Reid and colleagues and Gilfillan and colleagues evaluated interventions consisting of elements such as secure e-mail interactions between patients and health care professionals, disease registries, care planning, self-management strategies, increased outreach to patients, team discussions, performance evaluation, practice teams, population profiling, home health, and designated specialists in settings where there was excellent primary care and included all patients (not just those with selected chronic diseases). Costs were reduced primarily by reducing hospitalizations and Emergency Department visits. In the studies by Reid et al, specialist visits unexpectedly increased, more so in the first year than in the second, suggesting that more patients’ problems were recognized at the onset of the program, which then adapted to the increase in diagnosed multimorbidity over time.
of care and is used in the Netherlands, Malta, Belgium, and Australia to characterize presenting problems. Its potential as a measure of resolution of patients’ problems, or to document unexpected adverse events from interventions, is still to be fully realized.

Mushlin and Appel used a conceptually simple method to ascertain the resolution of patients’ problems by sending them a postcard after visits. Their work does not appear to have received the attention it deserves as a method of determining patient-reported outcomes of care.

Researchers in Quebec explored the conceptual basis of instruments to assess the adequacy of primary care, including orientation to people instead of to specific diseases. On the basis of previous work, they looked for existing instruments that measured “interpersonal continuity” (communications in interactions) and relational continuity (accumulated knowledge of the person) as two distinct aspects of care. As already noted, communication and effective interactions are characteristic of all care; they are not unique to primary care. In contrast, relationship continuity is the essence of primary care; accumulated knowledge is critical to the person-focused interventions over time that are unique to primary care.

Mercer and Howie proposed adoption of a tool (the Consultation Quality Index, version 2) for incorporation into quality improvement, assessment, and payment for performance. Although this measure was intended to assess the quality of the consultation, it could be adapted to assess the quality of ongoing care.

Zulman and colleagues constructed a patient-clinician concordance score based on surveys in which patients were asked to rank their most important concerns, and clinicians were asked to rank the most important concerns likely to affect the patient’s outcomes. Although this study was conducted in conjunction with patient visits, it could be adapted for use as a measure of ongoing relationships.

The Patient Activation Measure is based on the notion that the patient’s role in problem definition is important and that people should be empowered to intervene proactively in their care. Studies using this tool have shown that more empowered people are less passive in interactions with clinicians, are more likely to be aware of potential adverse effects of treatment, have greater success in navigating health-services systems, have fewer unmet health needs and less delay in initiating care, and are less likely to lack a regular source of care, even after controlling for low socioeconomic status and poor perceived health status. They are also likely to have more responsive physicians—a major goal in achieving person-focused care.

The importance of person focus is also recognized in the Primary Care Assessment Tool (www.jhsph.edu/pcpc/pca_tools.html) a suite of comparable instruments for use in population health surveys, patient surveys of their experiences with primary care, clinician surveys of reports of primary care functions, and surveys of managers of health facilities. Examples of person-oriented questions asked in the population and patient surveys include the following:

- If you have a question, can you call and talk to the doctor or nurse who knows you best?
- Does your PCP know you very well as a person, rather than as someone with a medical problem?
- Does your PCP know what problems are most important to you?

Interactions between patients and clinicians are changing. “Patient portals,” “virtual visits,” “asynchronous consulting,” and “remote monitoring” are becoming increasingly common. They will be useful only to the extent that people are confident in their clinicians’ accumulated knowledge of their problems.

Yee argued that the functioning of new primary care organizations must “include innovative forms of interactions that do not depend on traditional office visits.” Klinkman and van Weel urged thinking “far beyond the encounter as the unit of health care delivery” by means of standards and robust technology to move information. A World Health Organization report proposed a vast expansion of telemedicine to bridge the distance between people and health care. Internet-based technologies provide a new way of responding to patients, as experience in Kaiser Permanente is showing. Visit-based communications and the opportunity for conventional communication strategies will decline. Person-focused care over time, not just patient-centered interactions, requires a new strategy to ensure responsiveness to patient’s problems as they experience them, not only as professionals define them.

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* Soler, Executive Director, Research Mediterranean Institute of Primary Care, Malta; Okkes, Professor, University of Amsterdam; Lamberts, Professor, University of Amsterdam
33. Raphael D. Shaping public policy and population health in the United States: why is the public health community miss-
Is Patient-Centered Care the Same As Person-Focused Care?


To Attend To

The feelings and emotions of the patients, under critical circumstances, require to be known and to be attended to, no less than the symptoms of their diseases.

— Medical Ethics, Thomas Percival, 1740-1804, English physician and author
soul of the healer

"Wendy"
bronze sculpture
Avron Daniller, MD, FACS, FRCS

The model, Wendy, is Dr Daniller’s muse: a physiotherapist at the Woodland Hills Medical Center in California. Dr Daniller is a former Chief of Plastic Surgery at the Woodland Hills Medical Center and is a Clinical Professor of Plastic Surgery at the University of Southern California. Sculpture is one of Dr Daniller’s hobbies.

While it is in our DNA as Americans to have well-documented scientific principles guide our medical and surgical practice, reconstruction plastic surgeons have for long known the importance of the guiding hand and touch of the therapist such as Wendy, in helping to achieve good results.
Unconscious (Implicit) Bias and Health Disparities: Where Do We Go from Here?

Abstract
Disparities in health care are of great concern, with much attention focused on the potential for unconscious (implicit) bias to play a role in this problem. Some initial studies have been conducted, but the empirical research has lagged. This article provides a research roadmap that spans investigations of the presence of implicit bias in health care settings, identification of mechanisms through which implicit bias operates, and interventions that may prevent or ameliorate its effects. The goal of the roadmap is to expand and revitalize efforts to understand implicit bias and, ultimately, eliminate health disparities. Concrete suggestions are offered for individuals in different roles, including clinicians, researchers, policymakers, patients, and community members.

Substantial attention has been paid in recent years to the possibility that unconscious (implicit) bias among health care professionals contributes to health disparities. In its 2003 report, Unequal Treatment, the Institute of Medicine concluded that unrecognized bias against members of a social group, such as racial or ethnic minorities, may affect communication or the care offered to those individuals.

There exists a gap, however, between reasonable inferences and what is known. To what extent does implicit bias exist in health care? How does it affect different social groups? Is implicit bias more likely in some domains than in others? Does implicit bias affect clinical outcomes? Is intervention possible and if so, what strategies are most likely to be successful?

This article provides a roadmap for research in implicit bias in health care, spanning investigations of the presence of implicit bias in health care settings, identification of mechanisms through which implicit bias operates, and interventions that may prevent or ameliorate its effects. The goal of the roadmap is to expand and revitalize efforts to eliminate health disparities. Its intended audience is researchers, clinicians, and policymakers. For reasons of clarity, this analysis is limited to the potential effects of implicit bias on the patient-clinician relationship and associated care processes, leaving aside the important issue of the potential for implicit bias to affect the working environment of the health care workforce and other ways in which implicit bias might affect health.

Definitions and Measures
In the present context, bias is the negative evaluation of one group and its members relative to another. Such bias can be expressed directly (eg, “I like whites more than Latinos.”) or more indirectly (eg, sitting further away from a Latino than a white individual). In addition to their different expressions, direct or explicit bias differs from implicit bias in terms of underlying process. Explicit bias requires that a person is aware of his/her evaluation of a group, believes that evaluation to be correct in some manner, and has the time and motivation to act on it in the current situation. Congruent with everyday experience, research suggests that explicit bias toward ethnic/racial groups has declined significantly over the past 50 years and is now considered unacceptable in general society. In contrast, implicit bias appears to be common and persistent.

Implicit bias operates in an unintentional, even unconscious manner. This type of bias does not require the perceiver to endorse it or devote attention to its expression. Instead implicit bias can be activated quickly and unknowingly by situational cues (eg, a person’s skin color or accent), silently exerting its influence on perception, memory, and behavior. Because implicit bias can operate without a person’s intent or awareness, controlling it is not a straightforward matter. Implicit bias cannot be measured with standard (self-report) survey questions. Instead, sophisticated...
Instruments have been developed for this purpose, the most commonly used being the Implicit Association Test (IAT).\textsuperscript{11,12} The IAT is a computer-based measure that relies on differences in response latency to reveal implicit bias. The IAT has been used in hundreds of studies across a wide array of disciplines, including psychology, health, political science, and market research.\textsuperscript{8,9,12} The IAT operates on the principle that it is easier to make the same response (eg, a key press) to concepts that are more strongly associated, compared to concepts less strongly associated. Respondents are thus asked to sort words or pictures into one of four superordinate groups, representing two concept dimensions (eg, race: black vs white; and evaluation: good vs bad). The strength of association between concepts is determined by the respondents’ speed in sorting the items under two different conditions, with faster responses in one condition indicating a stronger association. Most white respondents, for example, are significantly faster when the “black” and “bad” items require the same response and the “white” and “good” items require another response, compared to when “black” and “good” responses are the same and “white” and “bad” responses are the same.\textsuperscript{8,9,12} The larger the performance difference, the stronger the implicit association or bias for a particular person. Demonstrations of this test can be found at https://implicit.harvard.edu.

Background: What We Know So Far

The theoretical framework for the role of implicit bias in health care is based on well-established empirical findings in social psychology and research on health care processes. We refer interested readers to existing reviews of that work,\textsuperscript{13,14} confining ourselves to broad strokes for the present purposes. Figure 1 provides an illustration of the pathways through which implicit bias may affect the patient-clinician relationship and related processes. Consider a white male clinician whose implicit bias has been activated by a clinic visit with an elderly African-American patient who is receiving antihypertensive medications but whose blood pressure is uncontrolled. Without realizing that he is being unduly influenced, the clinician perceives the patient as uncooperative and unlikely to adhere to a more intensive drug regimen. The clinician may even erroneously “remember” that this patient can’t afford the pharmacy copay. Consequently, although the patient’s hypertension is not under control, the clinician decides not to intensify the treatment regimen. This clinician believes that he made the best decision given the situation, unaware that his perceptions were distorted by implicit bias.

Also shown in the figure is the possibility that in addition to affecting clinical decisions directly, implicit bias may also affect treatment through its effects on interpersonal communication. A number of studies have shown that people with more implicit ethnic/racial bias have poorer interpersonal interactions with minority individuals, often in very subtle ways.\textsuperscript{6,9,10} Such interactions, in turn, may contribute to a lack of trust and commitment on the part of the patient, leading to poor adherence. The figure also notes that patients bring their own implicit biases to the clinical encounter (eg, against a white physician), further complicating communication, treatment, and achievement of mutual clinical goals.

Research to Date on Implicit Bias in Health Care

Presence of implicit bias in health care. A handful of studies have measured implicit bias among clinicians\textsuperscript{15-21} (Table 1), all using the IAT. Five of these studies examined racial/ethnic bias, specifically against African Americans as compared to whites. Four of the five studies found evidence for implicit race bias among clinicians (Table 1), with the average level of bias ranging across the studies from “small” (Cohen’s $d = 0.41$) to “large” ($d = 0.90$). The one study that did not find bias against African Americans\textsuperscript{17} is notable in its reliance on a small and primarily minority clinician sample.

Although the magnitude of the reported bias varies, the presence of implicit bias is generally consistent across the studies and suggests that clinicians have similar implicit biases to others in society. The presence
Unconscious (Implicit) Bias and Health Disparities: Where Do We Go from Here?

Disparities have also been shown for other racial and ethnic groups that may be more prevalent in certain geographic regions. Disparities have also been found in many other social domains including gender, age, sexual orientation, and socioeconomic status (SES). Implicit bias against individuals with specific clinical conditions such as disability, obesity, or mental illnesses may also be present as suggested by the two studies in Table 1 on implicit bias toward injecting drug users.

Consequences of implicit bias in health care. Of even greater need is research on the correlates and consequences of implicit bias in health care. Even if one were to accept the findings shown in Table 1 as sufficient evidence of implicit bias against African Americans among clinicians, one must still ask to what degree this bias affects health care and outcomes. There is even less evidence to answer these questions. Of the five published studies already discussed, two also investigated the degree to which the clinicians’ implicit bias related to their clinical judgments in hypothetical scenarios, with one study showing that implicit race bias was related to treatment recommendations for an African-American patient and the other study showing that implicit race bias was not related to clinical judgment. One additional study examined implicit race bias in relation to interpersonal

<table>
<thead>
<tr>
<th>Citation</th>
<th>Participants</th>
<th>Focus of Implicit Bias</th>
<th>IAT Score</th>
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<tbody>
<tr>
<td>Green et al (2007)²⁵</td>
<td>220 (28%)</td>
<td>Residents in internal medicine and emergency medicine</td>
<td>African Americans</td>
</tr>
<tr>
<td>Sabin et al (2008)²⁶</td>
<td>43 (26%)</td>
<td>Residents and faculty in pediatrics</td>
<td>African Americans</td>
</tr>
<tr>
<td>Sabin et al (2009)²⁷</td>
<td>2535 (NA)</td>
<td>Physicians self-selected to Internet site, unknown specialties</td>
<td>African Americans</td>
</tr>
<tr>
<td>White-Means et al (2009)²⁸</td>
<td>331 (38%)</td>
<td>Students in pharmacy, medicine, and nursing</td>
<td>African Americans</td>
</tr>
<tr>
<td>Penner et al (2010)²⁹</td>
<td>15 (83%)</td>
<td>Residents in family medicine</td>
<td>African Americans</td>
</tr>
<tr>
<td>Brener et al (2007)²⁰</td>
<td>60 (NA)</td>
<td>Nurses and doctors in drug and alcohol</td>
<td>Injecting drug users</td>
</tr>
<tr>
<td>Von Hippel et al (2008)³¹</td>
<td>44 (NA)</td>
<td>Nurses in drug and alcohol</td>
<td>Injecting drug users</td>
</tr>
</tbody>
</table>

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The presence of implicit bias among clinicians further suggests that it could play a role in health care disparities just as it plays a role in differential outcomes elsewhere in society.
behavior, showing that more biased clinicians were rated by their African-American patients as lower in warmth and friendliness. No published study yet has examined the relation between implicit bias and actual medical treatment or outcomes.

**A Roadmap for Future Research on Implicit Bias in Health Care**

The next generation of research on implicit bias in health care must accomplish three goals: 1) determine the degree of different implicit biases for different groups; 2) assess the associations among implicit bias and processes and outcomes of care; 3) test interventions to reduce implicit bias in health care and outcomes, if bias is found to be important in health care. In this section we expand on these three goals and highlight potential approaches to accomplish them.

**Goal 1: Determine the degree of implicit bias with regard to the full range of social groups for which disparities exist**

Health disparities have been shown along multiple social dimensions (eg, race/ethnicity, gender, age, and SES) and local circumstances may bring additional dimensions to the forefront (eg, military or religious groups). Research is needed to determine whether implicit bias exists toward each of these groups. In some cases, the approach used in existing research can be easily adapted. For example, an IAT has already been developed to assess bias against elderly vs young individuals. In other cases, additional research is needed to determine what types of bias might be operating. This is likely to be particularly important with regard to gender. Research shows that people are more often implicitly biased in favor of women over men, so why does it appear that in some situations women are less likely to receive high-quality care? An even greater challenge will be the consideration of overlapping group biases. Patients are not simply members of a racial/ethnic group, a gender group, or an age group; they are simultaneously members of all these groups. The interaction among biases for or against these groups is relatively unexplored. In our earlier example, the care provided to an elderly African American by a clinician with biases against both social groups may be of lower quality, whereas implicit bias in favor of the elderly may offset some of the effects of implicit bias against African Americans. As millions of newly insured individuals prepare to enter the health care system under health care reform legislation during the next few years, the interaction of socioeconomic bias and other forms of bias (eg, SES by race) will require particular attention.

The extent to which implicit bias exists among different groups of health care professionals (eg, physicians, nurses, front-office staff), with regard to patients from different social groups must also be more fully understood. As shown in Table 1, the few studies of implicit bias in health care have focused primarily on physicians. In an environment in which care is increasingly provided by multidisciplinary teams, it is important to assess the biases of the entire range of health care professionals. A bad health care experience may come from poor service in the pharmacy or on a phone call with front-desk staff. Furthermore, little research has addressed the implicit biases that patients themselves bring to clinical encounters (eg, bias against a clinician of different race/ethnicity or with a foreign accent). Given evidence that racial, ethnic, or gender concordance between clinician and patient can affect communication and treatment, the implicit biases of patients, particularly in combination with those of their clinicians, need further study. Finally, research on implicit bias ought to be broadened to include health care beyond the US and in different cultures.

**Goal 2: Understanding the relations between implicit bias and clinical outcomes**

The second step is to test and refine the conceptual model presented earlier that describes how implicit bias might be related to the processes and outcomes of clinical care. As shown in Figure 1, the relevant processes of care necessary to achieve clinical goals also require assessment if we are to understand the mechanisms through which implicit bias affects those goals. Decisions or behaviors by either clinician or patient may suggest that implicit biases are at work. In our earlier example, both clinician-determined processes, such as the decision to prescribe an additional antihypertensive medication, and patient processes, such as the decision to adhere to that new drug, need to be assessed. The quality of communication between clinician and patient is also important to assess. If implicit bias is found to be expressed through simple aspects of communication such as speed of speech or body positioning, specific training for clinicians may be suggested. Insight may also be gained by stratifying analyses of current measures of patient satisfaction with clinicians by patient characteristics such as race and ethnicity. There are also sophisticated analytic systems for coding audio-taped or videotaped encounters, that consider both the content and style of communication.
Assessing the relation between implicit bias and outcomes is critical. In statistical terms, one needs to go beyond the demonstration of a main effect such as a health disparity between Latinos and whites, and determine whether differences in the levels of disparity found from one clinician to another co-vary with differences in levels of the clinicians’ bias.

To refine the simplistic causal model shown in Figure 1, both laboratory and clinical studies are needed. In laboratory studies, implicit bias is most likely to have an effect in situations with substantial ambiguity, room for “judgment calls,” and constraints on time and attention. Translated to the clinical setting, implicit bias may be more influential when treatment algorithms are less developed than in situations that have clearly defined algorithms for treatment. Likewise, implicit bias may have more of an effect on decisions made during a one-time visit than on decisions made in the context of an ongoing clinical relationship in which one presumes more accurate patient data has accumulated. On the other hand, laboratory research has not examined implicit bias in long-term relationships, and the possibility exists that such bias may have a cumulative effect with early instances of miscommunication building into larger problems later on.

**Goal 3: Interventions to reduce effects of implicit bias on processes of care and clinical outcomes**

If implicit biases are found to be important in health care, the third step is to adapt and test theory-based interventions at all levels, including the individual practitioner, the care team, and the delivery system. Such interventions could attempt to reduce implicit bias directly, could bolster patients’ defenses against bias, or could alter care delivery systems to mitigate the effects of bias.

The most obvious point of intervention is with the individual. If health care professionals’ implicit biases are contributing to disparities, reducing those biases seems an obvious solution. Basic research on implicit bias supports the plausibility of this approach by showing that implicit bias is potentially malleable, changing in response to situational cues and norms. Despite its intuitive appeal, a direct approach of confronting an individual with evidence of bias may actually have little effect on that bias. Although people can be rationally convinced that they ought to feel or think differently and they are motivated to do so, the operation of implicit bias is not open to easy identification and effortless control. Indeed, research shows that intentionally trying to suppress bias may actually make it “rebound” at a later time. Instead a less direct approach can be more effective.

If one thinks of implicit bias in psychological terms as an automatic cue-response association, then one might see that changing the cue is likely to be more effective than trying to will the response to change—at least in the short term. The challenge then, becomes identifying cues or situational variables that matter. Laboratory research suggests that implicit bias can be diminished by cues that bring to mind associations that run counter to the bias. To illustrate, one study found that white individuals who had been exposed to many admired African Americans, subsequently showed reduced implicit bias. Such methods need to be adapted and tested in clinical settings, but they nonetheless suggest the real possibility of change.

In addition to direct intervention on health care professionals’ implicit bias, the conceptual model shown in Figure 1 makes it clear that there are many pathways between implicit bias and health outcomes, with the possibility of intervention at each one. Patients play a role in the quality of the clinical interaction and successful treatment is often reliant on their own efforts. Patients may respond to bias in a variety of ways, some of which can worsen the situation and some of which can help to deflect a negative outcome.

Recent research on stereotype threat and, importantly, the positive effects of a self-affirmation intervention hold great promise. Stereotype threat is a stressful psychological state that occurs when a person fears being judged by others on the basis of negative stereotypes. In health care settings, stereotype threat may impair patient-physician communication, reduce self-efficacy, and increase mistrust. Because stereotype threat can impair communication between patient and physician, interventions that reduce patients’ perception of threat might lead to more functional behavior for both patients and physicians. Self-affirmation, a process in which people affirm their self-integrity (eg, important values) in the face of a threat, has been shown in educational settings to reduce racial differences in performance over time periods of up to two years. Self-affirmation thus represents a possible component of a theory-driven intervention to reduce the impact of implicit bias in health care. Studies to assess this are in progress.

Of course, interventions at the team, clinic, or delivery system level can also reduce health care disparities. Such interventions are primarily organizational in nature, and, despite their great potential, are beyond the scope of this discussion.
Table 2. Suggestions for action to understand and address implicit bias in health care

<table>
<thead>
<tr>
<th>Clinicians</th>
<th></th>
<th>Researchers</th>
</tr>
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<tr>
<td>• Consciously affirm egalitarian goals and consider specific ways to implement them.</td>
<td>• Consider the situation from the patient’s perspective.</td>
<td>• Design and test theory-based interventions in laboratory and field settings, working with clinicians to identify interventions that could be translated into actual practice.</td>
</tr>
<tr>
<td>• Consider “gut” reactions to specific individuals or groups as potential indicators of implicit bias, and consider how these reactions might affect your work.</td>
<td>• Consider changing situations that increase negative or stereotypical responses.</td>
<td>• Consider interventions at multiple levels (eg, patients, clinicians, and health care teams), acknowledging the interdependent nature of health care and the social networks that are involved.</td>
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<tr>
<td>• Acknowledge and reappraise rather than suppress uncomfortable feelings and thoughts.</td>
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<tr>
<th>Policymakers</th>
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<th>Patients and Community Members</th>
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<tr>
<td>• Affirm equity of care and diversity as core organizational and institutional values, and consider ways to improve detection of disparities, and reconsider policies that may (unintentionally) worsen disparities.</td>
<td>• Support clinicians’ efforts to implement change to address disparities directly.</td>
<td>• Realize that your clinicians are people too. To the degree that bias exists in health care, it is not unique to that arena and must be addressed as a community. Patience and honest communication can help solve many problems.</td>
</tr>
<tr>
<td>• Support research that seeks to better understand bias and develop interventions to improve communication and lessen disparities.</td>
<td>• Invite dialogue with community leaders to better identity services in need of improvement and unrecognized biases in the health care system and workforce.</td>
<td>• Provide feedback to help your clinicians improve services, especially in areas that appear to be inequitable.</td>
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</table>

Conclusions: What can the Reader do?

Eliminating health disparities is of national importance, as highlighted in reviews, such as Healthy People 2000 and Healthy People 2010. The National Institute of Health ranks this issue third among its top five priorities. As part of this effort, health care professionals have been encouraged to consider how biases (ie, stereotypes, prejudice or discrimination) may contribute to disparities, and to “dig deeper” because such effects may often be unintentional and not obvious from standard assessments.

Despite much discussion about the potential role of bias in health disparities, little research has directly investigated bias among health care professionals. The existing evidence does, however, suggest that implicit bias may affect clinical judgment and decision-making. The conceptual model in Figure 1 suggests further that implicit bias may also affect treatment outcomes by affecting clinical interactions and patients’ adherence with their treatment.

This review and suggested roadmap may have already prompted readers to consider whether bias affects their own professional domains. If the readers’ interest has been piqued but the next steps are still unclear, Table 2 offers a few concrete suggestions for individuals in different roles, including clinicians, researchers, policymakers, patients, and community members. These suggestions include prompts for conducting research as well as practical advice on combating implicit bias in health care. The latter is based on scientific theory and research on the factors that moderate implicit bias. However, it is important to note that specific interventions have yet to be tested in health care settings.

To some degree, readers will see in Table 2 much common sense advice, “be thoughtful, consider others’ perspectives and work together to achieve common goals.” This sounds simple. We think it is not simple. The many, unrelenting demands of modern life (to say nothing of a busy medical practice) leave little time for reflection and the fulfillment of even the best of intentions. It is precisely for this reason that implicit bias may go unchecked in the pressured environment of health care, and why systematic investigation is needed to better understand and address this problem. For progress to be made, these biases must be rendered less implicit and unconscious to foster real reflection, analysis and change.

Disclosure Statement
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“Tulips”

16x20

oil on canvas

Samir Johna, MD, FACS

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CASE STUDY

Acute Hypersensitivity Syndrome Caused by Valproic Acid: A Review of the Literature and a Case Report

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Allein P Ligasan, RN
Tom G Najdowski, LCSW
Andrei Novac, MD

Abstract

Valproic acid (VPA) is an antiepileptic medication used in the treatment of bipolar disorder. Its toxicity profile is characterized by a very rare but well-documented complication—hepatotoxicity. The risk of acute hypersensitivity syndrome (AHS) caused by VPA is less well known. In the vast majority of reported cases of AHS, the syndrome is the result of aromatic anticonvulsants (AAs), such as carbamazepine or phenytoin. These compounds also have in-class cross-reactivity. We present the case of a 25-year-old woman with bipolar disorder who was unable to tolerate aripiprazole, ziprasidone, and lamotrigine. She was given extended-release VPA as a trial and developed AHS with a generalized rash, fever, liver and kidney involvement, and eosinophilia one week after the initiation of treatment. She recovered after one month of treatment, which included ten days of hospitalization. Our review of the literature focuses on AA and non-AA medications causing AHS.

Introduction

Hepatotoxicity is a rare adverse effect of valproic acid (VPA). The severity of hepatotoxicity can range from reversible hepatic dysfunction to irreversible liver failure. In an earlier review, Binek and colleagues reported a risk of 1:5000 to 1:10,000 of liver failure with VPA. Most of the reported cases involved boys younger than 10 years and with mental retardation. Major risk factors were being younger than 2 years and concomitant use of other anticonvulsant medication. Furthermore, 90% of patients developing hepatotoxicity were younger than 20 years. De Wolff et al reported that in 32 children with epilepsy, VPA did not affect γ-glutamyltranspeptidase activity, but it selectively enhanced α-glucaric acid excretion. Demircioğlu and colleagues looked at 38 children with epilepsy, 31 of whom were treated with carbamazepine and 7 of whom were treated with VPA. They reported that although there were no differences between the groups in serum lipid levels and liver-function test results, the total cholesterol levels, low-density lipoprotein levels, and total cholesterol/high-density lipoprotein levels were higher in the carbamazepine group during treatment.

Aromatic anticonvulsants (AAs) such as carbamazepine and phenytoin can induce hypersensitivity syndrome (HS) at a rate of 1:10,000 in new patients and 1:1000 in patients already taking the treatment. Seitz et al suggested that there is a cross-reactivity between AAs and tricyclic antidepressants. Because cross-reactivity can be as high as 75%, they recommended that physicians be taught not to use these agents in such situations, but to instead use VPA, benzodiazepine, lamotrigine, and gabapentin. Alldredge et al reported that before the onset of symptoms, physicians for 3 of 4 patients with acute hypersensitivity syndrome (AHS) switched their medications to an anticonvulsant with an aromatic ring in the structure. They also reported that the symptoms subsided after the interruption of the medication and that all patients recovered. Three of these patients required continuation of antiepileptic drugs, and they tolerated VPA well. In an important study, Baba et al described 32 patients with AHS caused by AAs; 22 of them required continuation of anticonvulsive treatment, and they tolerated VPA well.

AHS is a potentially life-threatening condition characterized by the triad of fever, rash (most of the body surface, ranging from mild exanthem to epidermal necrolysis), and multiorgan involvement (50% liver and 11% kidney), usually occurring in the first few weeks after the initiation of anticonvul-
Acute Hypersensitivity Syndrome Caused by Valproic Acid: A Review of the Literature and a Case Report

Another patient treated with a combination of carbamazepine alone and diazepam, clomethiazole, promethazine, biperiden, and vitamins B1, B6, B12 to long-acting VPA, lithium, amisulpride, and vitamins B1 and B6. Three weeks later, the patient developed lymphadenopathy, generalized maculopapular rash, and a fever (39.1°C), and his transaminase and creatinine levels were slightly elevated. VPA and vitamins B1, B6, and B12 were discontinued, and the patient was instead given olanzapine and prednisolone (initially 80 mg/d). With this treatment, the patient recovered in one week. Another case report described a patient who, after resolution of symptoms caused by carbamazepine-induced AHS, was given VPA and immediately developed life-threatening AHS. In addition,Cogrel and colleagues reported an AHS-like condition with VPA treatment. The patient recovered after the VPA was discontinued. In a unique case involving a patient, age 48 years, with schizoaffective disorder and bipolar disorder who was treated with lamotrigine and VPA and then developed AHS because of the lamotrigine. The patient recovered after discontinuation of the anticonvulsant medication and initiation of supportive treatment. Karande et al discussed the case of a boy, age 2 years, treated with VPA and lamotrigine for epilepsy. The child developed AHS because of the lamotrigine, but went on to recover and was given VPA and discharged from the hospital. In addition, Rahman and Haider reported AHS in a patient treated with VPA after the addition of lamotrigine. Conilleau and colleagues described AHS secondary to both VPA and ethosuximide (patch test results were positive with both medications) in a Tunisian, age 6 years. After both medications were stopped and corticosteroid treatment was administered, the patient recovered.

Fatal AHS has also been attributed to VPA. For example, Huang et al discussed a case of fatal AHS caused by VPA. The patient presented to the hospital with nonspecific polymorphous eruptions, fulminant hepatitis, and jaundice. Plantin et al and Picart and colleagues reported a case of AHS caused exclusively by VPA treatment.

**Case Report**

Ms A was 25 years old when we treated her. Three years earlier, her bipolar II disorder was diagnosed. Initial treatment with quetiapine helped control her symptoms. However, she grew concerned about the significant weight gain (>7% of her initial weight) and increase in total cholesterol level (299 mg/dL), triglyceride level (257 mg/dL), and low-density lipoprotein level (192 mg/dL) that she experienced. As a result, she was willing to explore other options. An initial trial of aripiprazole, at 5 mg/d, caused extrapyramidal symptoms (EPS), and thus the medication was stopped. Lamotrigine was then started at 25 mg/d and increased by 25 mg/wk. She bipolar disorder responded well to this medication. However, after one month, the medication was discontinued because the patient developed a nonspecific rash and had concerns about severe adverse effects. The third medication tried was ziprasidone, which was stopped because of EPS that were very similar to the adverse effects of aripiprazole. While taking ziprasidone, the patient also experienced nausea and vomiting. A few weeks later, Ms A agreed to a trial of extended-release divalproex. The results of liver-function tests at the start of her treatment were normal. The initial dose of divalproex was 500 mg orally at bedtime, which was increased after one week to 500 mg orally twice a day. The plan was to obtain results from new set of laboratory tests on day 10 of therapy. Unfortunately, 6 days later, she reported gastrointestinal symptoms and a low-grade fever. She went to the Emergency Department for evaluation, where her symptoms resulted in a diagnosis of gastroenteritis and she was given 2 antibiotics. Several days later, however, her symptoms had not subsided. Thus, we ordered the laboratory tests earlier than planned. The results were as follows: VPA level, was 60.4 μ/mL;
alanine transaminase, 767 U/L; alkaline phosphatase, 681 U/L; bilirubin total, 10.2 mg/dL. The patient's primary care physician was contacted, and she was admitted to the hospital. During her stay there, she was found to have VPA HS, with generalized rash, fever, liver and kidney involvement, and marked eosinophilia.

Because of the involvement of multiple organs and the multiple possible causes for this clinical presentation, we obtained specialist consults. Possible etiologies for the syndrome at the time of admission included infection (viral or bacterial), medication (lamotrigine or VPA), and autoimmunity. A laboratory work-up for infectious diseases produced negative findings on blood and urine cultures, negative findings on chest radiographs, and negative results for acute hepatitis, Epstein-Barr virus, and human immunodeficiency virus tests. The patient had a monospot test, which produced positive findings for mononucleosis. Results of testing for autoimmune hepatitis, antinuclear antibodies, and antimitochondrial antibody were negative. Test results for serum antitrypsin and ceruloplasmin were also negative, as were tests for alcohol, acetaminophen, and salicylate levels. The gastroenterology consultant provided supportive treatment. The patient was given acetylcysteine (Mucomyst) for its antioxidant property and vitamin K for the coagulopathy that she presented with. The patient's laboratory results improved during her hospital stay.

Ms A also developed an erythematous rash on the body, which initially started on her lower legs and rapidly migrated to her trunk, chest, back, arms, and ultimately to the face and interfered with her ability to open her eyes. The rash did not involve palmar or plantar surfaces or the mucous membranes. Initially the rash was erythematous and slightly raised and patchy but confluent, but over the next few days, it became continuous with significant edema. A dermatologist treated the rash with topical corticosteroids and oral prednisone (Deltasone), starting with 80 mg/d for 10 days and then decreasing the dose by 20 mg every week. After taking 60 mg of prednisone for a week, the patient noticed a gradual exacerbation of her rash, this time including her palms, requiring an increase of the dose to the previous level and then a slower tapering off.

After being discharged from the hospital, Ms A was monitored by the hospital's ambulatory internal medicine service. The results of her liver-function tests improved to normal within the following three weeks. The generalized rash resolved after one month, and corticosteroid treatment was stopped. At the next few psychiatry visits, Ms A expressed concern at the idea of starting any new medications for her bipolar illness but expressed interest in and commitment to accepting any other interventions.

**Discussion**

Ms A was treated with lamotrigine one month before the initiation of treatment with VPA. Lamotrigine was stopped because of a rash that developed while she was taking the medication. Thus, we suggest that in patients in whom treatment with lamotrigine is discontinued because of the development of a rash, a more comprehensive review of symptoms should be performed to aid in the diagnosis of AHS. This is particularly important because of the future risk of AHS after initiation of a new antiepileptic medication. Specifically, as one case report described, a patient developed the AHS after the addition of lamotrigine, thus suggesting a possible cross-reactivity between lamotrigine and other antiepileptic medications. However, Krivoy et al suggested that there is no evidence of cross-reactivity between VPA and lamotrigine.

In a recent retrospective study, carbamazepine was identified as the first cause of AHS, with phenytoin as the second cause and lamotrigine as the third. The authors concluded that VPA and benzodiazepine are safe alternatives to use in patients who present with AHS while taking the other medications. However, we identified four published reports of cases in which AHS was caused by VPA and lamotrigine.

In addition, most of reported AHS cases have involved patients treated for epilepsy, especially young boys. Apparently, being female and older than 20 years are protective factors against AHS. Cross-reactivity is a serious concern, especially in the AA class of medications.

Our patient, Ms A, expressed serious concerns regarding starting a new medication to treat her bipolar disorder. In addition, AA medications, such as carbamazepine, are associated with a higher risk of AHS than non-AAs are. We could not identify any reports regarding patients who developed AHS in response to lamotrigine or VPA who subsequently were able to tolerate antiepileptic medications with an AA ring. Thus, it is logical to question whether this is a potential consideration. Our patient was unable to tolerate aripiprazole and ziprasidone because of EPS despite...
Acute Hypersensitivity Syndrome Caused by Valproic Acid: A Review of the Literature and a Case Report

Conclusions
Since the 1980s, it has been known that VPA can cause hepatotoxicity and liver failure, but only three cases of AHS had been reported before our report here. Overall, the previous reports showed that AAs induce AHS and that there is cross-reactivity between compounds of that class. Non-AA antiepileptic medications were presumed safe. Our case suggested that even though AA medications have a much lower likelihood of producing AHS, they do still pose a real, palpable risk for patients. In addition, medical professionals must remain alert regarding the potential of cross-reactivity between AA and non-AA medications. Additional studies and pharmacologic insight are needed to shed more light on this subject.

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

Acknowledgments
We thank Daniela Alexandru, MD, and Bonita Jaros, PhD, for scientific review and critical suggestions. Dr Bota also thanks Carla Hix, PsyD, Linda DeSoucy, RN, and Soncerie Villegas, RN, for support. Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

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17. Bin-Nakhi HA, Sadeq S, Pinto RG, Habeeb Y. Anticonvulsant hypersen-
The Effect of Drugs on the Body

Following chlorpromazine, a veritable cornucopia of antipsychotic, antimanic, and antidepressant drugs poured forth, changing psychiatry from a branch of social work to a field that called for the most precise knowledge of pharmacology, the effect of drugs on the body.

— A History of Psychiatry: From the Era of the Asylum to the Age of Prozac, Edward Shorter, social historian of medicine, Hannah Professor in the history of medicine and Professor of Psychiatry at the University of Toronto
CLINICAL MEDICINE

Corridor Consult

Calcific Uremic Arteriolopathy: An Underrecognized Entity

Abstract
Calcific uremic arteriolopathy (CUA), or calciphylaxis, is an uncommon and underrecognized disease that often occurs in the setting of chronic kidney disease or end-stage renal disease. It is characterized by small-vessel calcification, although many times it is associated with normal serum levels of calcium, phosphorus, and parathyroid hormone. The lesions appear as necrotic eschars, ulcerations, indurated nodules, and dry gangrene and are usually very painful. Diagnosis is based on clinical judgment and recognition of characteristic skin lesions. Biopsy can be performed but may be complicated by poor wound healing. Treatment of CUA involves rigorous wound care, strict control of mineral metabolism with avoidance of calcium and vitamin D analogs, and pain control. Other treatment options include sodium thiosulfate, hyperbaric oxygen therapy, daily hemodialysis using low-calcium dialysate, and bisphosphonates. Even with treatment, CUA is associated with significant morbidity and mortality.

Case Presentation
A Vietnamese woman, age 67 years, with end-stage renal disease (ESRD) due to systemic lupus erythematosus currently receives short daily home hemodialysis (SDHD), using the NxStage system one machine (NxStage Medical, Inc, Lawrence, MA, USA) with the assistance of her husband. She uses a right internal jugular (RIJ) tunneled catheter because of a previous rupture of an arteriovenous fistula, complicated by a three-week stay in an intensive care unit. Her other medical problems include hypertension, pancytopenia (related to systemic lupus erythematosus), secondary hyperparathyroidism, hyperlipidemia, and asthma.

Even though the patient took calcitriol (1,25-dihydroxyvitamin D3) and phosphate binders, her parathyroid hormone level had continued to rise during the preceding year (>1000 pg/mL). She has followed instructions regarding the use of sevelamer carbonate as a phosphate binder, and her serum phosphorus level was generally controlled. After she developed hypercalcemia, she was given cinacalcet (an oral calcimimetic agent used to suppress the parathyroid gland). She developed severe nausea and vomiting, so the cinacalcet was discontinued. The patient was subsequently referred to general surgery for parathyroidectomy; however, surgery was not performed, owing to the patient’s overall condition and because she lacked symptoms such as bone pain or pruritus.

The patient later experienced poor blood flow in her RIJ catheter and was referred to interventional radiology for catheter change via a guidewire. She received a platelet transfusion just before the procedure (2 units), as recommended by her hematologist. The catheter exchange was successful, but she experienced persistent bleeding from the tunnel track and developed a hematoma after the procedure. Bleeding was controlled with lidocaine 1% and epinephrine (1:100,000, 10 mL) and Gelfoam packing. She continued to have persistent bleeding as well as elevated blood pressure, so she was admitted to the hospital for overnight observation. Her blood pressure was controlled, and she received DDAVP (1-deamino-8-d-arginine vasopressin, or desmopressin) for the bleeding.

She was discharged to her home, but on the following day, she developed swelling at the catheter site during SDHD treatment, and her husband called paramedics. The patient was admitted to a hospital not affiliated with Kaiser Permanente, where she was evaluated by a vascular surgeon. Two units of packed red blood cells and several units of fresh-frozen plasma were administered, and then her chest hematoma was evacuated. A nontunneled femoral catheter was placed for hemodialysis, though the patient’s RIJ catheter remained in position. The patient’s condition was eventually stabilized, and she was transferred to the Los Angeles County Medical Center after approximately one week.

At the time of transfer, the patient’s chest wall had a large area of eschar over the right side, with surrounding erythema and purulent drainage. Because of severe pain, the patient could not move her right arm. She was treated with intravenous clindamycin and

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Recent evidence suggests that vascular calcification is not a passive process of mineral deposition but rather an active cell-mediated process resembling osteogenesis.

**Background**

CUA is a rare condition characterized by small-vessel calcification, thrombosis, and skin and soft-tissue necrosis. The condition occurs primarily in patients with ESRD but has also been described in patients without chronic kidney disease. Reported risk factors for CUA are listed in Table 1. The pathogenesis of CUA is complex, however, and many times CUA is associated with normal serum levels of calcium, phosphorus, and parathyroid hormone. Recent evidence suggests that vascular calcification is not a passive process of mineral deposition but rather an active cell-mediated process resembling osteogenesis. Much of the current knowledge regarding CUA is based on small retrospective case series and reports. Conflicting reports, especially regarding risk factors for CUA, are common. CUA remains poorly understood and is associated with high morbidity and mortality.

**Diagnosis**

CUA should be considered when at-risk patients (especially those with ESRD) develop characteristic skin lesions. The lesions appear as necrotic eschars, ulcerations, indurated nodules, and dry gangrene and are usually very painful. Lesions occur frequently in the lower extremities, particularly the distal portion, but have also been described on the abdomen, the penis, the breast, and the upper extremities. Lesions may occur after skin trauma.

Diagnosis can be confirmed by biopsy of a suspicious area; however, poor wound healing and infection may occur after the procedure. A bone scan can aid in the diagnosis of CUA and can be used to assess response to treatment during follow-up care.

**Treatment**

Treatment of CUA involves rigorous wound care, strict control of mineral metabolism with avoidance of calcium and vitamin D analogs, adequate dialysis using low-calcium dialysate, and pain control. Sodium thiosulfate, an antioxidant and cation chelator, has been successfully used, according to several reports. Parathyroidectomy has been advocated by some researchers for wound healing, but others suggest that surgery is ineffective and does not prolong survival. Newer agents, such as cinacalcet, have been used to suppress parathyroid hormone, either alone or in combination with paracalcitol. Bisphosphonates have also been used to suppress osteogenesis in CUA. Though not widely available, hyperbaric oxygen chambers have been used with some success to treat CUA.

**Case Outcome**

When CUA was suspected in our patient, calcitriol was immediately discontinued, and she was given low-calcium dialysate (2.0 mEq/L). Even after these measures, her serum calcium level became elevated during hospitalization, probably due to immobilization. Sodium thiosulfate 25% (25 g) was administered daily as an intravenous infusion. A culture obtained from the patient’s chest wound grew *Pseudomonas aeruginosa*, which was treated with oral ciprofloxacin for a total of three weeks.

The patient was eventually discharged to her home and resumed SDHD using her RIJ catheter, despite the surrounding wound. Her husband administered sodium thiosulfate after each dialysis treatment using a peripherally inserted central catheter. She was seen in the home dialysis clinic approximately two weeks after hospital discharge, and her wound demonstrated growth of granulation tissue (Figure 1). At a follow-up examination, she reported nausea and anorexia, and her dose of sodium thiosulfate was decreased to 18 g. Her symptoms continued to decrease, and her wound continued to heal; the patient discontinued sodium thiosulfate and was maintained on oral ciprofloxacin for a total of three weeks.

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**Table 1. Potential risk factors for calcific uremic arteriolopathy**

<table>
<thead>
<tr>
<th>Risk Factor</th>
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<tbody>
<tr>
<td>Elevated calcium phosphorus product level</td>
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<tr>
<td>Calcium ingestion (especially in the form of phosphate binders)</td>
</tr>
<tr>
<td>Hyperphosphatemia</td>
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<tr>
<td>Vitamin D ingestion</td>
</tr>
<tr>
<td>Elevated serum levels of alkaline phosphatase</td>
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<tr>
<td>Elevated serum levels of aluminum</td>
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<tr>
<td>Corticosteroid use</td>
</tr>
<tr>
<td>Warfarin use</td>
</tr>
<tr>
<td>Protein C or S deficiency</td>
</tr>
<tr>
<td>Obesity</td>
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<tr>
<td>Malnutrition or hypoalbuminemia</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Liver disease</td>
</tr>
<tr>
<td>Caucasian race</td>
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<tr>
<td>Female sex</td>
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</tbody>
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Calcific Uremic Arteriolopathy: An Underrecognized Entity

Figure 1. A chest wound characteristic of calcific uremic arteriolopathy with (subsequent) growth of granulation tissue.

thiosulfate after approximately two months. The wound was fully healed by the time of manuscript preparation for this report. The patient will again be referred back to the General Surgery Department for parathyroidectomy when her general health and nutritional status improve.

Conclusion

Our case underscores the need to consider the diagnosis of CUA in patients at high risk. CUA was not initially considered in our patient, probably because the inciting event was bleeding after catheter replacement, and thus the wound was assumed to be a complication of bleeding. The diagnosis of CUA should always be considered when characteristic skin lesions present in a patient who receives dialysis. Diagnosis may be more difficult in the patient without evidence of chronic kidney disease, but if other risk factors are present in conjunction with painful skin lesions, the clinician should always consider the diagnosis of CUA. Although CUA is associated with high morbidity and mortality, early recognition of the disease and a multifaceted approach to treatment may aid in recovery.

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

Image Diagnosis: Thoracic Aortic Dissection and Thoracic Aortic Aneurysm

Sundeep R Bhat, MD
Gus M Garmel, MD, FACEP, FAAEM

Figure 1. Thoracic Aortic Dissection

Although plain film chest radiograph may be used to screen for a widened mediastinum (Image A) which suggests thoracic aortic dissection, computed tomography (CT) angiography or traditional angiography are gold-standard tests and should be obtained in any stable patient for whom dissection is suspected. Thoracic aortic dissection is generally classified using the Stanford scheme, although some texts and cardiothoracic surgeons still use the DeBakey classification (types I-III). Image B demonstrates dissection flaps seen in both the ascending and descending aorta (Stanford Type A—any involvement of the ascending aorta irrespective of site of intimal tear or distal extension). Complications of Type A dissections include aortic valve insufficiency, dissection into coronary vessels causing acute myocardial infarction, and dissection into the pericardial sac (Image C) causing hemopericardium and possible tamponade physiology. Type A dissection requires immediate surgical intervention. Image D shows an intimal flap in the descending aorta only (Stanford Type B). Patients with uncomplicated Type B dissections are typically managed medically, with blood pressure control by pharmacologic intervention.

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Aneurysmal dilatation of the descending thoracic aorta can be seen in patients with atherosclerotic disease, as well as in patients with collagen vascular disorders like Marfan’s syndrome. These images (Image A and B) demonstrate thoracic aortic aneurysm rupture with extravasation of blood into the adjacent pleural space. Risk of rupture increases with size; growth may be 0.1 - 0.4 centimeters (cm) per year; risk of rupture becomes high after reaching 6 cm in diameter. For stable patients without symptoms, computed tomography or magnetic resonance imaging at regular intervals is recommended, as is beta-blocker therapy for blood pressure control.

References
ECG Diagnosis: Complete Heart Block

Joel T Levis, MD, PhD, FACEP, FAAEM

Figure 1. 12-lead ECG from a woman, age 77 years, following a syncopal episode

Demonstrates complete atrioventricular (AV) dissociation with a ventricular rate of 32 beats/minute and a right bundle branch block.

Figure 2. 12-lead ECG from same patient following insertion of a transvenous pacemaker

Demonstrates ventricular-paced complexes (pacer spikes before every QRS complex) with a ventricular rate of 78 beats/minute.

Third-degree atrioventricular (AV) block (also referred to as complete heart block) is the complete dissociation of the atria and the ventricles.\(^1\) Third-degree AV block exists when more P waves than QRS complexes exist and no relationship (no conduction) exists between them.\(^2\) The escape rhythm may arise within the AV node (resulting in a narrow QRS complex), or lower in the conduction system (producing a wide QRS complex). The ventricular rate (pulse) varies from 30-40 beats/minute.\(^2\) Characteristically in third-degree AV block, the atrial rate is faster than the ventricular rate (60-100 beats/minute) presumably in response to the hemodynamic consequences of the block. Complete heart block complicates 10% of acute myocardial infarctions (AMI) and represents the most frequent unstable bradydysrhythmia encountered in the patient with AMI.\(^3\) In most cases of persistent third-degree AV block, permanent pacing is required.\(^1,2\) Treatment with atropine often fails to improve the ventricular rate, as vagal stimulation of the AV node is not thought to be the cause of this finding.\(^1\)

References

Because you are reading this, the chances are that you are a health professional, probably a physician. Whatever your relationship to health care, I want you to take off your professional hat for a moment, and imagine that you are a patient who has just received a diagnosis. Your condition is potentially serious in the future, but not automatically so. Your immediate issue is to decide between therapy A and therapy B. Whichever you choose, you will have to commit to it for a considerable time without knowing any direct benefit, in the hope of future benefit. As you start to discuss this choice with your physician, you have one main question in mind. Now stop reading—and before going on figure out what that question is.

The Patient’s Question. My answer is “which treatment should I choose?,” but obviously the real question behind that is “which treatment will give me more benefit?” Until doctors become seers, this is not an answerable question. But a very closely related question that could be answered is “what is the probability that I will do better on A than on B?” My purpose here is to argue that we could be answering this kind of question with existing knowledge, and that it provides a far richer and more useful way to understand medical research results than the ways that we customarily use now.

I call this The Patient’s Question (TPQ): what is the probability I will do better on A than on B? My purpose here is to argue that we could be answering this kind of question with existing knowledge, and that it provides a far richer and more useful way to understand medical research results than the ways that we customarily use now.

The Perfect Experiment. There is a methodological reason why we don’t answer TPQ, and considering that reason can lead us to some potential strategies for finding answers. The basic idea is somewhat philosophical, but for those who don’t want to go down that path, they should recognize that philosophical beliefs can have considerable impact on real events. Think about what a perfect medical experiment would be. We would give the patient A and then record what happens. We then turn back the clock to the pretreatment time, and now give the patient B without changing anything else in the world, and record what happens. Surely the difference between what happened in these two cases is the causal effect of one treatment relative to the other. No doubt the causal effect is what we are looking for, and it completely answers TPQ. And even more surely, the perfect experiment is impossible.

The critical point about the perfect experiment is that the causal effect is measured within an individual patient. This explains why randomized clinical trials (RCTs) as they are now analyzed cannot, even in principle, answer TPQ. Half of the participants are given A, but never get B, and the other half are given B, but never get A. Each person in the study provides only half the information of the perfect experiment. When we compare A-responses with B-responses we are comparing across patients, not within patients. It is a mathematical fact that from the marginal distributions of two random variables you cannot in general compute the probability that one is greater than the other. The RCT provides the marginal probabilities of A-successes and B-successes in the patient population, but it cannot compute the within-patient probability of doing better on one than the other. The answer to TPQ is beyond the RCT.

The Almost-Perfect Experiment. My solution to this problem would be to carry out the almost-perfect experiment. I would match two patients on as many factors as I could, trying to include all of those that are important for eventual success or failure on any given therapy. Even though there would inevitably be residual differences between them, therapeutically they would be as alike as I can achieve. I would then take the position that these highly matched patients shared an A-response and a B-response to see any publication in the biomedical research literature that presented an answer to TPQ.

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(or nearly so). Measuring an A-response on one of them is the same as measuring it on both, and the same for the B-response. By giving one A and the other B, I obtain (an estimate of) the within-patient causal effect of treatment. If I do this over enough pairs, then I can compute the fraction of times in which the A-response was better than the B-response, the fraction where the B-response was better than the A-response, and the fraction where they were for all intents and purposes equivalent. I can then answer TPQ, and even better, I can give the probability that it won’t make any essential difference whether they take A or B. By way of contrast, in the standard cohort-based approach differences between the two partners are computed and then summarized over the entire sample, thus discarding the (admittedly approximate) within-person information.

There are no statistical difficulties with my solution, and in fact the statistical analysis is even easier than it is in most biomedical research, because it only involves observed fractions (of times when A is better than B, and so on). I don’t believe I would spend too much time testing statistical hypotheses about the benefit probabilities, because the real issue is whether there is enough research behind them to be accurate, and that is a fairly simple statistical question.

Ambiguous Probabilities. There is, however, another large and lurking question about probabilities. Again I apologize to those who think that philosophy is irrelevant, because I think it is critical to understanding probability. When we apply a probability to a person (there is a 60% chance you will do better on A than B) we are always implicitly placing that person in the context of a population, in which the probability is as stated (60% in this case). In common parlance, probabilities are used as if they were personal characteristics, like height and weight, which do not need any external reference to be valid. But clearly this is untrue. For any given person, there may well be multiple populations I can consider them to be from, and each might (usually does) have a different probability for the event in question. Thus, if I know your age, I may say that you have an 80% chance of doing better on A, but if I then in addition learn that you are a smoker, I would say that you have a 50% chance of doing better on A, and so on with other health-related characteristics. There are profound ambiguities in the way we ordinarily talk about probabilities.

For this reason, the research program I want to encourage would provide the patient with benefit probabilities based on samples of other patients that are as much like him/her as possible. I want to be able to say that your probability of doing better on A is 60%, to mean that it really pertains in a specific way to you, and it is not simply a mass-statistic computed from a general and poorly characterized population, that you are in some vague sense a part of. I believe that making benefit probabilities patient-specific is a critical component of patient-centered biomedical research, and if we could put it into place we would be practicing much better medicine. Patient-centered analysis is novel ground, and therefore difficult to contemplate, but it is a needed counterbalance to the emphasis in biomedical science on patient populations instead of patients as individuals.

“Better” is in the Eye of the Beholder. Another lurking issue has to do with what “better” means. Here again I have been puzzled by the responses of health professionals to this issue. Some seem to believe that I must make one single definition of “better” and then stick to it throughout my analysis (by analogy with RCTs, presumably). Others believe that “better” cannot include issues like patient-preferences, costs, attitudes toward risk, evaluation of disability or side-effects, and so on. The reason I am mystified is because it seems obvious that we can use multiple definitions of “better” in a single study. In fact, it would be highly interesting to know if the benefit probabilities shift wildly, or remain essentially constant, as we vary the definition of “better.” And it is even clearer that some of our definitions of “better” can encompass harms in addition to benefits. In pain syndromes, for example, we could include both pain reduction and reduced drug taking as parts of the definition, thus accommodating patients who value the latter as much as the former. Indeed, from my perspective the false forced-choice of a single definitive endpoint in RCTs is one of the several reasons why they do not serve the interests of clinical medicine.

Real Clinical Research. Because TPQ seems to me to be so obviously important, I have thought about why we did not use this concept in coming to our current conceptualization of biomedical research. I have two theories. One is that we humans seem to be attracted by “binary thinking.” Things are either right or wrong, up or down, black or white—or if not, we are still better off thinking that way. Thus therapies should either work or not, be effective or not, be recommended or not. The second theory is that the manufacturers of therapies (mostly pharmaceuticals) need some kind of yes/no decision with regard to their products, both for regulatory approval as well as marketing leverage. The RCT is admirably fashioned for both binary thinking and promoting drugs, and that is why it has become dominant in biomedical research. Somewhere along the way the patients and their question got lost. In my opinion, it would be a good thing if we tried to recover real clinical research by putting all of our focus on answering TPQ.
Dear Editors,

This letter is in regard to the article, “Gastric antral vascular ectasia (watermelon stomach)—an enigmatic and often-overlooked cause of gastrointestinal bleeding in the elderly” published in The Permanente Journal by Nguyen et al. We share our experience managing a patient who mimicked as gastric antral vascular ectasia (GAVE).

A Caucasian male, age 83 years, was referred to our gastrointestinal clinic for iron deficiency anemia. On his six-month routine follow-up, his primary care physician incidentally noticed that his hemoglobin dropped from 14.1g/dL to 12.4g/dL. He denied any complaints of epigastric or abdominal pain, hematemesis, rectal bleeding, melena, or weight loss. He had no history of nonsteroidal anti-inflammatory drug use. His iron studies showed iron level of 43μg/dL, total iron binding capacity 462μg/dL; iron saturation 9% and serum ferritin 13.2ng/mL. His mean corpuscular volume (MCV), vitamin B-12, renal functions, and liver functions were within the normal range. His colonoscopy, performed in June of 2003, was negative. His past medical history was positive for hypertension and hyperlipidemia. There was no liver or spleen enlargement on his physical examination.

Because of his anemia, esophagogastroduodenoscopy was done. This revealed mucosal inflammation with erosion in the gastric antrum, suggesting GAVE (Figure 1). However, the biopsy indicated, Helicobacter pylori gastritis with Warthin-Starry stain showing Helicobacter pylori. He was treated with antibiotics for Helicobacter pylori and given iron supplements. On six-month follow-up, the patient was doing fine with hemoglobin level of 13.8g/dL.

The majority of GAVE patients present with iron-deficiency anemia secondary to occult blood loss. GAVE has an appearance similar to the dark stripes on the surface of a watermelon, thus the name “watermelon stomach” is commonly used. GAVE is diagnosed by the classic endoscopic appearance and may also be confirmed with endoscopic biopsy, endoscopic ultrasound, tagged red blood cell scan, or computed tomography scan.

We agree with Nguyen et al that GAVE is an often-overlooked cause of gastrointestinal bleeding in the elderly. Our case is unique in the sense that apparently it looked like GAVE on esophagogastroduodenoscopy, but pathology was different. It is interesting to note that our patient had no history of cirrhosis of liver, autoimmune diseases, atrophic gastritis, CREST syndrome and/or bone marrow transplant. As we do not know the exact pathogenesis of GAVE, if more cases like this are reported, one ponders if Helicobacter pylori also has some role in GAVE syndrome.

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References
Dear Editors and Readers,

The article by Eichbaum, et al (An Alternate Model for Medical Education: Longitudinal Medical Education Within an Integrated Health Care Organization—A Vision of a Model for the Future? In: The Permanente Journal 2010 Fall;14(3):44-9) outlines an innovative proposal of a medical school program housed within Kaiser Permanente (KP). The authors suggest that the program be modular and longitudinal, with self-paced learning. The model proposed envisions a “lifetime medical school,” where students could progress through both undergraduate and graduate medical education within the same health care organization, allowing for streamlined and less-costly application processes for medical school and residency, student-centered learning, possible reduced tuition and debt for students, and possibly enhanced patient care due to continuity experiences with physicians-in-training over time.

We write to inform you of what may be the first step in such a medical school program, or a hybrid that allows students training in university medical schools while experiencing the benefits of working in a progressive, integrated health system such as KP. Beginning in April of 2011, eight third-year medical students from the University of California, San Francisco will embark on a year-long longitudinal integrated clerkship (LIC) housed at KP East Bay (including Oakland and Richmond campuses) called KLIC (Kaiser Longitudinal Integrated Clerkship).

The current experience of clinical medical students may not be an optimal way to structure a basic clinical education. Patients have shortened inpatient stays and care has shifted more to the ambulatory setting. Additionally, inpatient attendings switch with increasing frequency and residents battle duty hours, leading to less longitudinal oversight of students’ competencies and reduced opportunity for meaningful feedback. In response to such a fragmented experience, LICs have been implemented, both nationally and internationally.¹

LICs are based upon principles of continuity with faculty, patients, populations, and a health care system. The students experience their clinical education as patient-centered and student-centered, as they progress through all seven of their core clerkships simultaneously with one faculty preceptor in each discipline, primarily based in the outpatient setting. They also experience a developmentally progressive curriculum, created to help organize their learning tasks with sequentially increasing complexity and a focus on individual pace and learning styles.¹

As recommended in the recent Carnegie Foundation report,² medical education’s key challenges include individualization, integration and insistence on excellence. We believe that by incorporating an LIC at KP we will expose clerkship students not only to the fundamental principles of continuity within an LIC, but also to improve habits of inquiry and improvement, engaging learners in a system dedicated to patient-centered care, population health and health promotion. Moving clinical learning to a health care system where quality patient care is delivered may allow students to “participate authentically in inquiry, innovation, and improvement of care” as the Carnegie report authors suggest.

It is our hope that students trained in this model will obtain not only outstanding clinical experiences, but a glimpse of a progressive health care management organization. The lessons and experiences they obtain at KP may pave the way for them to become future KP leaders, or leaders in the changing landscape of health care and health care reform. The KLIC model may be adapted to other KP sites, or into the model of a KP School of Medicine that the Eichbaum, et al article suggests. ✤

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Reference
CME Evaluation Program

Kaiser Permanente physicians (NUID required) may earn up to 4 AMA PRA Category 1 credits for reading and analyzing the four designated CME articles, by selecting the most appropriate answer to the questions below, and by successfully completing the evaluation form. Other clinicians for whom CME is acceptable in meeting educational requirements may report up to four hours of attendance. Please return (fax or mail to the address listed on the back of this form) to The Permanente Journal by September 30, 2011. Forms may also be completed and submitted online at: www.thepermanentejournal.org. You must complete all sections to receive credit. (Completed forms will be accepted until September 2012. Acknowledgment will be mailed within two months after receipt of form.)

Section A.

Article 1. (page 4)
Identifying Opportunities for a Medical Group to Improve Outcomes for Patients with Coronary Artery Disease and Heart Failure: An Exploratory Study

For patients with symptomatic heart disease and LVEF <35%, the largest potential impact would come from which of the following interventions:
- increasing beta-blocker use
- abstaining from tobacco
- remaining physically active
- increasing ace inhibitor use

The largest potential impact to prevent or postpone deaths would come from:
- patients with ST-segment elevation myocardial infarction
- patients with symptomatic heart disease with an LVEF >35%
- acute heart failure exacerbations
- patients with myocardial infarction without ST-segment elevation

Article 2. (page 23)
When Rapport Building Extends Beyond Affiliation: Communication Overaccommodation Toward Patients with Disabilities

Which of the following represents overaccommodation toward patients with disabilities?
- mirroring patient language to label “disability”
- exaggerated pitch range using “we” to indicate “you”
- responding to the subtleties of patient emotional cues
- carefully treating patients with disabilities as “normal”

What does this article indicate medical students and physicians should understand about rapport-building behaviors?
- rapport-building behaviors are generally associated with patient disclosure and sometimes with more positive outcomes
- physicians and medical students should be encouraged to use rapport-building behaviors regardless of the situation
- medical students and physicians should ask patients to rate rapport expectations
- rapport depends on physician and medical student characteristics and thus cannot be taught or modified

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**Article 3. (page 31)**

**Adverse Reactions Associated with Therapeutic Antibiotic Use after Penicillin Skin Testing**

Patients with a history of penicillin allergy, who are penicillin skin test-positive, and have no other drug allergy history:

a. will have anaphylaxis with the next course of oral penicillin they are given
b. are more likely to have an adverse drug reaction associated with a future sulfonamide antibiotic use than a cephalosporin
c. are more likely to have an adverse drug reaction associated with a future quinolone antibiotic use than a cephalosporin
d. are more likely to be male

In patients with a history of penicillin allergy and negative penicillin skin test results:

a. resensitization is common with an oral penicillin challenge after the negative penicillin skin test
b. there is less likelihood of a reaction to a cephalosporin compared to a penicillin skin test-positive individual
c. there is a greater possibility of a future antibiotic allergy if they are male
d. penicillins can be safely used

**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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The article covered the stated objectives.
I learned something new that was important.
I plan to use this information as appropriate.
I plan to seek more information on this topic.
I understood what the author was trying to say.

**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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**Article 4. (page 63)**

**Is Patient-Centered Care the Same As Person-Focused Care?**

Which of the following statements is incorrect?

a. patient-focused care provides for better recognition of health problems and needs over time
b. current medical practice appears concentrated on management of disease
c. patient-centered care focuses on the whole person
   d. patient-centered care is often linked to episodic visits

**Patient-centered care:**

a. stresses the importance of long-term relationships with patients over care for specific diseases
b. reflects the need for more than increased communication skills in continuous healing
c. reflects an understanding of morbidity as combinations of types of illnesses
d. reflects adherence to guidelines that emphasize management of specific diseases