

# Proceedings from the National Summit on Overuse

September 24, 2012

Organized by The Joint Commission  
and the American Medical Association-  
Convened Physician Consortium for  
Performance Improvement® (PCPI®)



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## Abstract

The National Summit on Overuse focused on overuse as a patient safety and quality concern, and endorsed the need to reduce instances of overuse in five specific areas: antibiotics for viral upper respiratory infections (URIs), over-transfusion of red blood cells (called appropriate blood management for purposes of the summit), tympanostomy tubes for middle ear effusion of brief duration, early-term non-medically indicated elective delivery, and elective percutaneous coronary intervention (PCI). The summit was held on September 24, 2012, in Chicago. The Joint Commission and the American Medical Association-Convened Physician Consortium for Performance Improvement® (PCPI®) convened five multi-disciplinary work groups that each summarized their efforts related to these issues and presented recommendations on interventions, practices, and methods aimed at reducing overuse in these clinical areas.

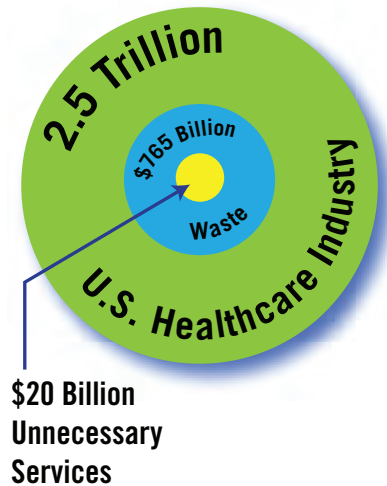
## Introduction

Sometimes overlooked or neglected as a leading contributor to problems with quality and patient safety, overuse of medical interventions affects millions of patients.<sup>1</sup> Overuse has been described as the provision of treatments that provide zero or negligible benefit to patients, potentially exposing them to the risk of harm. While many medical procedures are associated with tradeoffs between benefits and risks, the risks that are incurred in instances of overuse are not balanced by benefits to patients. Five subject areas that have triggered concerns about overuse and quality were addressed by work groups convened for the summit by The Joint Commission and the American Medical Association-Convened Physician Consortium for Performance Improvement® (PCPI®):

- Antibiotics are often prescribed to treat viral upper respiratory infections (URIs); yet, antibiotic use in these instances is ineffective, conflicts with current evidence,<sup>2,3,4</sup> may cause harm in adult and pediatric patient populations, and contribute to the public health threat of increasing antimicrobial resistance to antibiotics.

- While blood transfusions can be life-saving, they also carry risks that range from mild complications to death. Variation in clinical transfusion practices<sup>5,6,7,8</sup> results in waste of a limited resource when unnecessary transfusions are given, and contributes to public health concerns about blood product shortages.
- There is variability in the therapeutic approaches taken to address brief acute otitis media with effusion (OME),<sup>9</sup> the most common illness resulting in pediatric physician visits. Current guidelines do not explicitly address the use of tympanostomy tubes.<sup>10,11</sup> Concerns have been raised that the insertion of tympanostomy tubes may present more risk than benefit in some cases.<sup>12</sup>
- Evidence shows that the timing of many early-term elective deliveries is based on convenience and yet may result in significant short-term neonatal morbidities.<sup>13</sup> Early elective deliveries increase premature births and medical complications for mothers and babies.<sup>14,15,16</sup> Early elective deliveries also increase rates and numbers of Caesarian sections,<sup>17</sup> which are associated with higher rates of newborn respiratory distress syndrome, mechanical ventilation, sepsis, and hypoglycemia.<sup>14</sup>
- National Cardiovascular Data Registry® (NCDR) data from the first quarter of 2012 suggests that 6 percent of elective percutaneous coronary intervention (PCI) procedures were “inappropriate,”<sup>18</sup> based on application of the American College of Cardiology Foundation’s Appropriate Use Criteria. Notably, there was also evidence of improvement, with a reduction in the “inappropriate” rate from 12 percent in the fourth quarter of 2011.<sup>18</sup> An analysis of Accreditation for Cardiovascular Excellence (ACE) data estimates that 8 percent of PCI procedures are inappropriate.<sup>19</sup> The designation of an “inappropriate PCI” is applied, for example, to procedures performed in patients in whom that treatment was not necessary, or when a medical or surgical intervention would be more clinically effective.

**Overuse has been described as the provision of treatments that provide zero or negligible benefit to patients, potentially exposing them to the risk of harm. While many medical procedures are associated with tradeoffs between benefits and risks, the risks that are incurred in instances of overuse are not balanced by benefits to patients.**



– *Institute of Medicine, The Healthcare Imperative*

Plenary speakers Mark Chassin, M.D., the president of The Joint Commission, and Bernard M. Rosof, M.D., chair of the PCPI, provided a history and an overview of issues and challenges relating to overuse. After defining overuse as a test, treatment or procedure providing zero or negligible benefit that exposes a patient to the risk of harm, Dr. Chassin emphasized that overuse is **not** a high rate of use or variation in use based on geography. Overuse is a problem resulting from many decisions between doctors and patients. It may result from many factors including payment incentives, time pressures, referral patterns, malpractice fears, patient demand, a culture that has a bias toward “doing something” rather than not, and an inclination to use technology to solve clinical challenges.

Dr. Rosof placed the overuse initiative into the context of the Department of Health and Human Services’ National Quality Strategy of better care, healthy people and communities, and affordable care. He presented visual representations from the Institute of Medicine (IOM) illustrating an estimated \$765 billion in waste within the nation’s \$2.5 trillion health care industry.<sup>20</sup> Of that amount, approximately \$210 billion is attributable to unnecessary services, according to the IOM.<sup>20</sup> He also shared 2011 Organization for Economic Cooperation and Development health data showing that the United States currently spends about \$8,000 per capita on health care – 30 to 50 percent higher than what is spent by peer industrialized countries.<sup>21</sup>

During a lunch presentation at the summit, health care quality and patient safety expert Rosemary Gibson discussed overuse from the patient perspective. She cited a Commonwealth Fund finding that 32 percent of people surveyed said they had medical care they thought was unnecessary.<sup>22</sup> Ms. Gibson asserted the importance of urgently addressing the problem of overuse, to reduce waste within the health care system, to make more resources available to populations affected by health care disparities, and to create a sustainable American health care system. Commenting on the estimated 18 percent of the gross domestic product spent on health care – which if unchecked may spiral higher and inhibit growth in other economic sectors – she urged summit participants to remove waste within the health care system before federal and state governments are forced to make draconian cuts to health care programs.

The summit complements work being done throughout the nation to address the overuse issue. For example, the American Board of Internal Medicine Foundation’s “Choosing Wisely Campaign”<sup>23</sup> recently added more partner societies and 90 treatments to its initial list of 45 questionable tests and procedures compiled in collaboration with nine medical societies. Each medical society involved in the campaign has named five tests or procedures that are usually not indicated in particular instances, and which patients and their doctors should “Choose Wisely” when discussing that option. The campaign expects to release another list in late 2013. The PCPI has also developed performance measures to address concerns about overuse.

**Choosing Wisely  
Identified**

**45**

**Tests &  
Procedures**

**Initial  
List**

**+**

**90**

**Treatments  
Added to  
List**

**=**

**135**

**Questionable  
Tests and  
Procedures  
that may be  
unnecessary, and  
in some instances,  
can cause harm.**

The “*Choosing Wisely Campaign*” is focused on encouraging physicians, patients and other health care stakeholders to think and talk about medical tests and procedures that may be unnecessary, and in some instances, can cause harm.

## Charge of the **five** work groups

- **Validate the evidence and data on overuse of the intervention**
- **Review guidelines and quality measures**
- **Identify or develop strategies for organizations and key stakeholders to reduce overuse**

### Methods

The five multi-disciplinary work groups convened for the summit were charged with validating the evidence and data on overuse of the intervention, reviewing guidelines and quality measures, and identifying or developing strategies for organizations and key stakeholders to reduce overuse. The work groups were comprised of stakeholders from physician organizations, medical specialties, government agencies, health care associations, research institutions, and patient advocacy groups. Each work group was chaired by a physician and supported by Joint Commission and AMA-PCPI staff. Each group met three times prior to the summit, twice via conference call and at one in-person meeting.

Prior to the summit, the work groups had incorporated feedback obtained from stakeholders into presentations covering quality concerns and rationales, clinical settings, evidence, guidelines, interventions, surrounding issues, and preliminary recommendations. During the summit, work groups received additional feedback during their presentations from a broader group of stakeholders in attendance. Each group presented their learnings and recommendations during the summit's report-out sessions.

### Summary of Work Group Presentations and Recommendations

There was general agreement about the need for all stakeholders to collaborate to successfully address overuse. Common strategies identified by all work groups included:

1. Inspire physician leadership.
2. Create a culture of safety and mindfulness.
3. Align guidelines and evidence-based performance measures that span the spectrum of practitioners who care for patients with a specific clinical condition. Medical societies, health care quality organizations, providers and payers need to work together to create these guidelines and measures.



4. Leverage advances in health information technology to standardize data collection and reporting.
5. Work with payers to align payments and incentives with optimal practice and to remove incentives for overuse.
6. Educate and engage patients and consumers on the proper indications for these treatments and about the potential for harm when treatments are given that are not medically indicated.
7. Continue to study the overuse problem.
8. Encourage professional organizations to continue their efforts to address the problem of overuse.

### **Antibiotics for viral upper respiratory infections** ***Chair, Donna E. Sweet, M.D., American College of Physicians***

Antibiotics are often prescribed to treat viral upper respiratory infections (URIs). However, antibiotic use for these infections is ineffective, conflicts with current evidence,<sup>2,3,4</sup> and can cause patient harm in adult and pediatric populations. The overuse of antibiotics contributes to antibiotic resistance and cumulative overexposure<sup>24</sup> and may also cause allergic reactions, gastrointestinal distress, immune system suppression, and adverse reactions with other medications. Estimates are that \$1 billion is spent annually on unnecessary adult URI antibiotic prescriptions.<sup>25</sup>

In many cases, differentiating viral from bacterial illness is difficult and symptoms initially overlap. Providers may prescribe antibiotics out of concern for the patient and to be on the “safe side.” In addition, patients may demand antibiotics because they believe antibiotics will help them, and patient satisfaction is reduced if antibiotics are expected and yet not received. Antibiotic overuse occurs in ambulatory, emergency, urgent and long-term care settings.

The work group developed phase I recommendations to be implemented first and to establish the foundation necessary for implementation of phase II recommendations.

**\$1 billion -**

**Estimated annual spending on unnecessary adult URI antibiotic prescriptions**

### *Phase I Recommendations*

1. Develop clinically relevant definitions of viral and bacterial URIs. A definition must be agreed upon to move recommendations forward.
  - Convene a scientific task force to resolve the following issues:
    - o Determine if acute otitis media (AOM) should be included in the viral URI definition, and differentiate between AOM and acute otitis media with effusion (OME). AOM is sometimes diagnosed when OME is the actual diagnosis. An AOM diagnosis is the most frequent reason pediatric patients receive antibiotics. OME is a mechanical process that does not involve infection.
    - o Determine if acute bronchitis should be included in the viral URI definition.
2. Align current national guidelines for viral URIs. There are several sets of guidelines produced by government agencies and professional organizations. These guidelines can be contradictory and are not consistently harmonized.
  - Identify and evaluate all current, relevant guidelines according to the evidence.
  - Develop an aligned and endorsed set of guidelines for treating viral URIs for use by prescribers, whether they are primary care providers, emergency physicians, pediatricians, nurse practitioners, or physician assistants.
  - Differentiate treatment for pediatric and adult patients in the aligned guidelines. Interdisciplinary input about both populations is absolutely necessary to producing evidence-based guidelines.
  - Publish the aligned guidelines in multiple professional journals and professional/government websites as applicable. Develop and implement a communication plan.
  - Develop a monograph that includes the aligned guidelines and best implementation practices from the field.
  - To promote practice change, develop performance measures related to antibiotic use for viral URIs.

3. Partner with the Centers for Disease Control and Prevention (CDC).  
The CDC has more than 10 years of experience addressing antibiotic overuse for viral URIs, with many educational materials and tools available online. A partnership between The Joint Commission, AMA-PCPI and CDC will provide a powerful voice of support to aligned guidelines.
4. Investigate how behavioral change concepts may be applied to improve antibiotic prescribing behavior and be integrated eventually into phase II recommendations. Information on viral URI has been directed toward physicians (and other prescribers) for over 10 years but improvement has been modest in certain patient populations. Also consider applying behavioral change concepts to patients.
5. Investigate how health information technology and clinical decision support may be used in the phase II recommendations, especially to effectively implement a “watchful waiting” process (see #2 of phase II recommendations).
6. Initiate a comprehensive national education campaign on antibiotic overuse for viral URI.
  - Establish a campaign goal of changing behavior at a local level that includes collaboration with community groups.
  - Simultaneously focus the campaign on the prescriber, the patient and the public.
  - Integrate the work of the CDC’s Get Smart Program<sup>26</sup> in the campaign.
  - Emphasize antibiotic benefit vs. harm.
7. Develop a comprehensive monograph focused on overuse of antibiotics for viral URIs.
  - Include best practices from organizations that have successfully decreased antibiotic use for viral URIs.
  - Use The Joint Commission’s hand hygiene monograph as an example of a format to follow.
  - Include “tool kit” information.

### *Phase II Recommendations*

Phase II recommendations are to be implemented after completion of the phase I recommendations. Some phase II recommendations may be incorporated into the national education campaign (#6 in phase I). For all phase II recommendations, the use of electronic medical records, clinical decision support and behavioral change concepts can be investigated.

1. Start an antibiotic stewardship program to provide a structured mechanism for organizations to address antibiotic prescribing for URIs. Work group members acknowledged that measuring individual prescribing practices over time is more difficult in the outpatient setting vs. inpatient setting. The inpatient setting allows for real-time monitoring and intervention while monitoring the outpatient setting often requires a retrospective analysis approach. Innovative methods for use in the outpatient setting should be developed and tested.
  - Focus on incentive programs for stewardship rather than penalties for prescribing.
  - Secure funding to support this initiative.
2. Implement watchful waiting/watchful observation, a process during which antibiotics are withheld unless a patient fails to respond to symptomatic management while meeting specified criteria such as CDC guidelines. Watchful waiting/watchful observation avoids harm from antibiotics that are not clinically indicated.
  - To successfully communicate the message that watchful waiting is the recommended treatment, a variety of tactics can be used, including follow-up calls or electronic reminders to patients on watchful waiting status, standardized formats for work place and day care communication letters, written “prescriptions” and downloadable instructions for watchful waiting, provider education, and school and community outreach.

3. Provide targeted education to prescribers.
  - Emergency medicine physicians and family practitioners prescribe antibiotics more frequently than pediatricians. Education to prescribers should be tailored to specific settings and include all prescribers that evaluate viral URIs.
  
4. Provide targeted education on bronchitis and pharyngitis to prescribers and patients.
  - Antibiotics are prescribed more frequently for bronchitis and pharyngitis than for the common cold. The educational effort should include targeted education about bronchitis and pharyngitis, including a safety-net antibiotic prescription process.
  - Consumer education should include how to manage symptoms and be made available in multiple languages.

Notes: A recommendation to use narrow spectrum, instead of broad spectrum, antibiotics was not adopted by the work group. Also, it remains to be determined whether or not there should be recommendations that address the requirement that a child with a presumed viral URI not return to daycare until after an antibiotic has been prescribed.

## 2008 transfusion volume →

- 15 million red blood cell (RBC) units
- 2 million apheresis platelet equivalent units
- 4.5 million plasma units

## 2008 reported adverse reactions

↓  
60,000

– *National Blood Collection and Utilization Survey*

## Appropriate Blood Management

### *Chair, Aryeh Shander, M.D., Society for the Advancement of Blood Management*

While blood transfusions can be life-saving, they can also be associated with risks ranging from worse patient outcomes to death. The evidence of significant variation in clinical practice<sup>5,6,7,8</sup> suggests that inappropriate blood management interventions are contributing to unnecessary transfusions. The evidence strongly suggests overuse in many settings. Although the quality of evidence varies among settings, there is growing support of conservative transfusion practices in most subgroups of hospitalized patients.

According to the National Blood Collection and Utilization Survey, transfusion volume in 2008 was 15 million red blood cell (RBC) units (unchanged from 2006), 2 million apheresis platelet equivalent units (16.7 percent increase from 2006), and 4.5 million plasma units (11.8 percent increase from 2006).<sup>27</sup> Adverse reactions reported in 2008 totaled 60,000.<sup>27</sup> According to the Agency for Healthcare Research and Quality, blood transfusions occurred in 10 percent of all hospital stays that included a procedure.<sup>28</sup>

The work group reached consensus on the need to identify and remediate the drivers of the variability in transfusion practice to further optimize practice in line with available clinical trial data. The gaps in medical school and continuing professional education were highlighted; there are very short exposures to transfusion medicine in crowded medical school and residency curricula, and most ordering physicians do not receive additional education on transfusion medicine. In addition, there is a growing array of alternatives to transfusion and for managing anemia that need to be understood by practitioners. The use of electronic health records was seen as a critical area for development, most particularly for real-time clinical decision support and audits.

The relative lack of transfusion medicine expertise in many hospitals was also identified as a contributor to overuse; therefore, the importance of having subject matter experts within institutions was emphasized. Benchmarking and reporting physician metrics relative to their peers were seen as critical interventions. There was extended discussion of regular competency assessment of providers who prescribe blood or blood components.

Since physicians want to practice evidence-based medicine and do what's right during their interactions with individual patients, the work group emphasized the importance of having the infrastructure and support tools that help physicians make the best decisions and to document why they were made. Participants in the work group included pathologists and laboratorians, adult and pediatric hematologists, surgeons, anesthesiologists, intensivists, administrative and quality personnel from health care facilities, and representatives from the Department of Health and Human Services and National Heart, Lung and Blood Institute.

## Recommendations

1. Develop a tool kit of clinical educational materials for M.D.s throughout the learning continuum, including the risks and benefits of transfusion and the dissemination of best practices and guidelines supported by evidence.
2. Expand education on transfusion avoidance and appropriate alternatives to transfusion. Identify subject matter experts within organizations to provide guidance.
3. Advocate for scheduled periodic assessment of prescriber competency and for accountability to organizational standards.
4. Standardize performance metrics, data collection and vocabulary to allow valid benchmarking within organizations. Measure individual physician transfusion practice as part of ongoing professional practice evaluation (OPPE).

5. Develop a separate informed consent process for transfusion that communicates the risks and benefits consistent with current evidence.
6. Identify research priorities to close evidence gaps in what constitutes optimal transfusion practice.

The work group pointed out that more guidelines are not the answer, since there are many excellent trials and guidelines available that are not being followed. To make sustainable progress in the use of blood and blood components, changing behaviors when supporting data are available is the best solution.



## Tympanostomy Tubes for Middle Ear Effusion of Brief Duration

*Chair, David W. Roberson, M.D., American Academy of Otolaryngology–Head and Neck Surgery*

There is variability in the approach taken to manage brief acute otitis media with effusion (OME),<sup>9</sup> the most common illness causing pediatric physician visits. Current guidelines are not explicit on the use of tympanostomy tubes.<sup>10,11</sup> There is concern that insertion of tympanostomy tubes may be associated with more risk than benefit in some cases. Potential complications of tympanostomy tube surgery include prolonged otorrhea, persistent perforation, and scarring of the tympanic membrane, which may be associated with low-grade, long-term hearing loss.

The work group studied the available data, which show tympanostomy tube surgeries increasing from almost 500,000 in 1996 to more than 650,000 in 2006, according to the National Center for Health Statistics.<sup>29</sup> Also, 2.5 percent of all children 2 years old and older had tympanostomy tubes inserted in 2010, according to a sample of continually enrolled children from Truven Health MarketScan<sup>®</sup> Treatment Pathways and Truven Health MarketScan<sup>®</sup> Medicaid databases. The work group also noted a dearth of direct evidence of overuse.

The work group noted the current guidelines for otitis media with effusion<sup>10,11</sup> need to be updated with more specific information on the use of tympanostomy tubes. As a result, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) has convened a multidisciplinary guideline panel whose work is expected to be completed later in 2013.

## Tympanostomy tube surgeries

**1996:** Almost 500,000

**2006:** More than 650,000

– *National Center for Health Statistics*

**2010:** 2.5 % of all children 2 years old and older

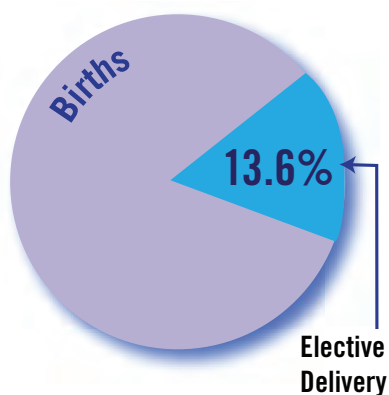
– *Truven Health MarketScan<sup>®</sup> Treatment Pathways and Truven Health MarketScan<sup>®</sup> Medicaid databases*

## Position Statements

1. Direct evidence of the overuse of tympanostomy tubes is lacking and needs further study once updated performance measures are in place (see recommendation #1 below).
2. There is indirect evidence in the literature that tympanostomy tubes may be overused for isolated brief otitis media with effusion (OME) and infrequent acute otitis media (AOM) in otherwise healthy children.
3. There is a continued need for rigorous investigation into the appropriateness of tympanostomy tube use which should consider comparative effectiveness, quality of life, functional health status, patient-centered outcomes and cost-effectiveness.
4. Tympanostomy tubes are not typically indicated for OME of brief duration (less than 3 months) in otherwise healthy children. In these cases, the relevant history must be fully documented to justify tympanostomy tube insertion.
5. There is a need for a current trusted guideline specifically addressing the use of tympanostomy tubes. Issuance of guidelines by the multidisciplinary panel convened by American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) is expected to be a significant step forward in providing evidence-based recommendations for the management of OME.
6. There is a need to update primary care clinicians, parents, and surgeons about appropriate indications for tympanostomy tubes, and to reduce variation in practices amongst the different providers.
7. There is a need for high quality evidence-based performance measures in order to prospectively assess appropriateness of tube placement.

## Recommendations

1. AMA-PCPI should make appropriate use of tympanostomy tubes a priority topic for performance measure development.
2. Hospitals, other surgical facilities, and physician governance groups should determine the frequency with which tympanostomy tubes are performed for inappropriate indications in otherwise healthy children without an additional rationale in order to validate or lessen current concerns, as appropriate, about possible overuse.
3. Hospitals, surgical facilities or physician governance groups should take corrective action if they become aware of a pattern of overuse of tympanostomy tubes. This might include incorporation into clinicians' ongoing professional practice evaluation (OPPE), institutional quality improvement projects, or other actions.
4. Documentation in the medical record prior to tube insertion in children should include effusion duration, an assessment of hearing difficulties, the number of episodes of AOM in the prior 12 months, physical exam findings, and patient co-morbidities that influenced the recommendation for tube insertion (e.g., syndromes, craniofacial anomalies, underlying permanent hearing loss, speech/language problems, or developmental delays/disorders). Socio-economic factors and concerns about access to health care should also be documented if deemed relevant to the decision-making process.
5. National research priorities should focus on standards for research studies, studies of the effectiveness of medical treatments for otitis media, the appropriate role for tube placement, and the role of shared decision making with parents and other caregivers.
6. Specialty societies should specifically incorporate trustworthy guidelines and evidence-based performance measures into CME, MOC, and other educational materials about otitis media treatment and appropriate indications for placement of tympanostomy tubes.



– *The Joint Commission Annual Report on Quality and Safety, 2012 (2011 data)*

### Early Term Non-Medically Indicated Elective Delivery Chair, Bryan T. Oshiro, M.D., Loma Linda University Medical Center and Children's Hospital

Evidence shows that many early elective deliveries are for convenience and may result in significant short-term neonatal morbidities.<sup>13</sup> Work group members agreed that early elective deliveries increase premature births and medical complications for mothers and babies.<sup>13,14,15</sup> Early elective deliveries also increase Caesarian section rates,<sup>17</sup> which are associated with higher rates of newborn respiratory distress syndrome, mechanical ventilation, sepsis, and hypoglycemia.<sup>14</sup>

The Joint Commission 2011 quality and safety report data showed that elective deliveries account for 13.6 percent of all births.<sup>31</sup>

American Congress of Obstetricians and Gynecologists and the American Academy of Pediatrics recommend 39 completed weeks of gestation before considering an elective delivery.<sup>32</sup> The group noted some potential unintended negative consequences of the 39-week standard, with providers either delaying an already indicated induction until week 39 or increasing the number of elective deliveries at 39 weeks.

To reduce the number of early non-medically indicated elective deliveries, work group participants identified the need for multidisciplinary involvement of certifying bodies, physicians, certified nurse midwives, nurses, patients, payers, and consumer groups to promote a change in practice culture. The group also noted that an inability to code certain medical indications may erroneously contribute to higher numbers of deliveries that are considered not medically indicated. Making the list of indications and exclusions as comprehensive as possible will contribute to a better understanding of the factors leading to early elective deliveries, help educate providers about acceptable medical indications, and reduce the number of early deliveries.

Existing interventions include hospital policies, peer review, and weekly review before and after inductions. Resources are available from the Maternity Care Shared Decision Making Initiative,<sup>33</sup> Hospital Engagement Networks (HENs),<sup>34</sup> the AHRQ Partnership for Patients,<sup>35</sup> the California Maternal Quality Care Collaborative/March of Dimes 39 Weeks Toolkit,<sup>36</sup> March of Dimes: Healthy Babies Are Worth the Wait,<sup>37</sup> and AWHONN: “Don’t Rush Me...Go the Full 40.”<sup>38</sup>

### New Requirements

For 2013, the Centers for Medicare and Medicaid Services (CMS) adopted the perinatal care (PC) core measure on elective delivery. Acute care hospitals are now required to report on this measure or receive reduced payment. Beginning on January 1, 2014, Joint Commission-accredited hospitals with more than 1,100 births annually will be required to report on the PC measure set. Elective delivery (PC-01) is a component of this measure set. The PCPI has also developed a physician level performance measure specific to early delivery.

### Recommendations

- Standardize how gestational age is calculated, as well as the data source within the medical record.
- Make the early elective deliveries indications and exclusion list as comprehensive as possible to improve clinical practice, address coding gaps, and improve the data available to decision-makers.
- Standardize the process for collecting data.
- Support hospitals in achieving the first three recommendations.
- Enlist consumers and clinicians by educating them on the risks of non-medically indicated early elective deliveries.

- Encourage shared decision making between the clinician and parents, including a discussion of potential risks and benefits.
- Recommend American Congress of Obstetricians and Gynecologists (ACOG) continue its work on guidelines on the best method to establish gestational age.
- Involve additional organizations, such as the American Hospital Association, American Academy of Family Physicians, and public health organizations.
- Identify research gaps.
- Develop a white paper on this topic.

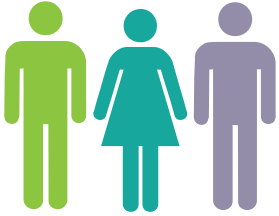
## **Elective Percutaneous Coronary Intervention (PCI)** **Chair, Carl L. Tommaso, M.D., NorthShore University** **Health System**

Elective PCI is one of multiple therapies available to manage stable ischemic heart disease (SIHD). Medication therapy and surgical revascularization, or coronary artery bypass grafting (CABG), are also important interventions to consider for patients with coronary artery disease who are stable but symptomatic. The work group focused on the appropriateness of elective percutaneous coronary intervention (PCI) on patients with SIHD.

For the purposes of the overuse summit, the work group determined that elective PCI is defined as a “scheduled outpatient or observational stay procedure for a patient not requiring pre-hospitalization for treatment of coronary disease.” ST-segment elevation myocardial infarction (STEMI), non-STEMI, and unstable angina are not included in this definition. The work group was comprised of a broad group of stakeholders, including cardiac interventionalists, cardiologists, a cardiac surgeon, a general practitioner, a radiologist, and a patient advocate.

Concern was expressed by some representative societies at the summit that the scope of the work group should have been broadened to address the overuse of PCI in patients with severe, extensive coronary artery disease, particularly in diabetic individuals who comprise one-third of all SIHD patients in the U.S., and in patients with impaired left ventricular systolic function. PCI overuse may result in premature mortality for patients with severe coronary artery disease. These patients receive about 25 percent of all diagnostic cardiac catheterization procedures in the U.S.<sup>40</sup> Clinical evidence demonstrates that patients with multi-vessel coronary artery disease who receive CABG have a survival advantage over those with this disease who are treated with PCI.<sup>41,42,43,44,45,46,47</sup>

**16,838 – or 11.6% –  
of non-acute  
PCIs were  
inappropriate,  
performed  
in patients with:**



- **No angina = 53.8%**
- **Low risk ischemia = 71.6%**
- **Suboptimal (<1) anti-anginal medication = 95.8%**

– *National Cardiovascular Data Registry®*

According to a presentation prepared by the work group, 325,000 PCI procedures were performed on Medicare recipients in 2011, of which approximately 50 percent were elective. National Cardiovascular Data Registry® (NCDR) data from the first quarter of 2012 suggested that 6 percent of elective PCI procedures were done “inappropriately,” applying the American College of Cardiology Foundation’s Appropriate Use Criteria, a reduction from 12 percent in the fourth quarter of 2011.<sup>18</sup> Accreditation for Cardiovascular Excellence (ACE) data estimates that 8 percent of PCI procedures are inappropriate.<sup>19</sup> Inappropriate PCI has deemed to have been provided when, based on the evidence from clinical trials, a treatment was not necessary, or when a medical or surgical intervention would have been expected to be more clinically effective.

Work group members reviewed the results of an analysis from the NCDR of indications for non-acute PCIs. In that study, 72,911 PCIs (50.4 percent) were classified as appropriate, 54,988 (38 percent) as uncertain, and 16,838 (11.6 percent) as inappropriate. The majority of inappropriate non-acute PCIs were performed in patients with no angina (53.8 percent), low-risk ischemia on non-invasive stress testing (71.6 percent), or suboptimal (< 1) anti-anginal medication (95.8 percent).<sup>48</sup> Further exploration of PCI applications classified as uncertain is needed in clinical situations where CABG is considered appropriate and medical therapy may be preferred.

Patients with SIHD deserve optimal, individualized care including surgical consultation when necessary.<sup>49</sup> The indications classified by the Appropriate Use Criteria can form the basis of what is considered inappropriate elective PCI.<sup>40</sup> The criteria incorporate five clinical elements:

- Clinical presentation
- Symptom severity
- Ischemia severity
- Extent of medical therapy
- Extent of coronary anatomical findings on angiography



Existing strategies to increase appropriate use and reduce overuse include participation in the NCDR,<sup>18</sup> regional or state databases; Accreditation for Cardiac Excellence (ACE); additional accreditation/certification; the Society for Cardiovascular Angiography (SCAI) Quality Improve Toolkit (QIT),<sup>50</sup> which will soon have the Appropriate Use Criteria tool on-line; and the Blue Cross Blue Shield of Michigan Cardiovascular Consortium PCI Quality Improvement Initiative.<sup>51</sup>

### ***Proposed interventions***

1. Encourage standardized reporting in the catheterization and interventional procedures report.
2. Encourage standardized analysis/interpretation of non-invasive testing for ischemia.
3. Focus on informed consent and promote patient knowledge/ understanding of the benefits/risks of PCI.
4. Provide public/professional education.

### ***Proposal #1: Encourage standardized reporting in the catheterization/interventional report.***

- Develop a standardized template based on the five Appropriate Use Criteria:
  - o Clinical presentation.
  - o Symptom severity.
  - o Ischemia severity.
  - o Extent of medical therapy.
  - o Extent of coronary anatomical findings on angiography.
- Use a second “time-out” during the catheterization procedure to ensure that appropriate documentation regarding the indications for the elective PCI are addressed.
- Do a formal external or internal case review periodically.
- Establish a practical and reasonable database or repository for objective and independent film review of random cases.

***Proposal #2: Encourage standardized analysis/interpretation of non-invasive testing for ischemia.***

- Develop a standardized report for non-invasive testing including the following:
  - o Radiation safety (cumulative radiation).
  - o Appropriate Use Criteria.
  - o Standardized reporting including the extent of the severity of ischemia.
- Develop criteria for stress testing; both for the referral process and the interpretation of the test.

**Comments:** Summit participants attending the elective PCI break-out session commented that incentives and standardization were needed for quantifying and qualifying ischemia. For example, a standardized form would help document information on the extent of the ischemia for analysis and interpretation. Participants also recommended making stress testing imaging more objective.

***Proposal #3: Focus on informed consent and promote patient knowledge/understanding of the benefits/risks of PCI.***

- Document on the informed consent (in standardized plain language) that the patient may need dual anti-platelet therapy for a specified length of time.
- Propose that every facility providing elective PCI have the ability to obtain surgical consultation when the need arises; for example, when patients have high SYNTAX scores.

**Comments:** Some members of representative societies participating in the elective PCI work group and breakout session advocated for a requirement that ad hoc PCI (PCI performed in the same setting as diagnostic cardiac catheterization) not be performed in patients with stable ischemic heart disease (SIHD) when indications are uncertain or inappropriate.

This requirement would only apply to coronary artery disease without evidence of ischemia, ischemia with inadequate medical therapy, and multi-vessel coronary artery disease involving the left anterior descending (LAD) coronary artery.

Rather than performing PCI in these situations, a multidisciplinary heart team including the interventional cardiologist, a cardiac surgeon and ideally a general cardiologist would review the relevant evidence with the patient after diagnostic cardiac catheterization and then participate in an informed consent process with the patient. Specific information from the relevant appropriateness criteria and CABG/PCI guidelines would be included in the informed consent document.\*

If the indications for PCI are found to be uncertain or inappropriate by the heart team, criteria and/or guidelines, the rationale for the team's recommendation and a follow-up plan would be provided in a way that the patient can read and attest to understanding. Most importantly, there needs to be a full disclosure of the anticipated risks and benefits of all complementary treatment strategies so that patients and families are fully apprised of the outcomes that can be reasonably expected with a given treatment.

Comments provided by members of representative societies included the recommendation that the SYNTAX score and the Society of Thoracic Surgeons' predicted risk of mortality be calculated for similar patients, and be included in the informed consent document.

\* In February 2012 (after the National Summit on Overuse), the American College of Cardiology Foundation's Appropriate Use Criteria for Coronary Revascularization divided scores (from 1-9) into three levels of appropriateness: appropriate procedure for specific indication; uncertain for specific indication; and inappropriate procedure for that indication.<sup>52</sup>

Others attending the break-out session commented on the need for surgical input on patients with high SYNTAX scores even in hospitals with on-site surgery facilities. For facilities without cardiovascular surgical capability, provision of surgical input (via teleconferencing or other means) needs to be made available for patients who may be candidates for revascularization.

#### **Proposal #4: Public/professional education**

- Increase awareness through education that an elective PCI may not be the appropriate treatment in certain circumstances.
- Disseminate information on inappropriate use to organizations with an interest in this area, with an emphasis on the use of standardized templates for PCI and non-invasive testing reports.

## Summit Conclusion

Overuse is a serious and sometimes overlooked quality and patient safety issue, as interventions of zero or negligible benefit expose patients to the risk of harm and increase health care costs. Collaborative strategies among all stakeholders are needed to address this problem. Steps can be taken to implement interventions and practices that reduce overuse in health care.

The summit brought together key stakeholders for an in-depth conversation about what needs to be done to address overuse in each of the five focus areas. It is evident that more research is needed. The pathways leading to improvement identified by each work group signal the need for additional professional organizations to engage in this important work. The Joint Commission and the AMA-convened PCPI encourage professional organizations to continue the dialogue and mobilize their membership to act to effect meaningful change in the areas addressed during the Overuse Summit.

**Summit Attendees**

AABB\*  
 ABIM Foundation  
 Access Community Health Network  
 AFL-CIO  
 AIM Specialty Health  
 Albany Stratton VA Medical Center  
 Alliance for the Prudent Use of Antibiotics\*  
 AMA-Physician Consortium for Performance Improvement  
 American Academy of Ambulatory Care Nursing\*  
 American Academy of Family Physicians\*  
 American Academy of Nurse Practitioners\*  
 American Academy of Otolaryngic Allergy\*  
 American Academy of Otolaryngology-Head and Neck Surgery\*  
 American Academy of Pediatrics\*  
 American Academy of Physician Assistants\*  
 American Board of Medical Specialties  
 American Board of Radiology Foundation  
 American Cancer Society  
 American College of Cardiology\*  
 American College of Cardiology, Illinois Chapter  
 American College of Emergency Physicians  
 American College of Nurse-Midwives\*  
 American College of Physicians\*  
 American College of Surgeons\*  
 American Congress of Obstetricians and Gynecologists\*  
 American Council for Pharmacy Education  
 American Dental Association  
 American Heart Association\*  
 American Hospital Association  
 American Medical Association  
 American Osteopathic Association  
 American Society for Clinical Pathology\*  
 American Society of Health-System Pharmacists\*  
 American Society of Hematology\*  
 American Society of Nuclear Cardiology  
 American Speech-Language-Hearing Association\*  
 America's Blood Centers  
 Association of Women's Health, Obstetric & Neonatal Nurses\*  
 Baylor Health Care System  
 Beth Israel Deaconess Medical Center  
 Boston Children's Hospital  
 California Maternal Quality Care Collaborative\*  
 Centers for Disease Control and Prevention\*  
 Chicago Medical School/Rosalind Franklin University  
 Childbirth Connection\*  
 Children's Hospital Association\*  
 Children's National Medical Center\*  
 Cleveland Clinic  
 College of American Pathologists\*  
 Community Blood Center/Community Tissue Services  
 Department of Defense  
 Department of Defense U.S. Army Medical Command-Western Region Medical Command\*

\* An organization representative served on at least one work group.

**Summit Attendees**

Department of Health and Human Services\*  
 Emergency Medical Services for Children National Resource Center  
 Emory Healthcare  
 Emory University School of Medicine\*  
 Englewood Hospital & Medical Center  
 HCA Clinical Services Group  
 Huntington Hospital-North Shore Long Island Jewish Health System  
 Illinois Hospital Association  
 Infectious Diseases Society of America\*  
 Institute for Healthcare Improvement  
 Institute for Safe Medication Practices\*  
 Joint Commission Resources  
 Loma Linda University Medical Center and Children's Hospital\*  
 Lown Institute  
 Loyola University Health System, Department of Pathology  
 Madigan Army Medical Center  
 March of Dimes  
 March of Dimes-Illinois Chapter  
 Mercy Hospital, St. Louis  
 Mount Sinai School of Medicine\*  
 National Association of Pediatric Nurse Practitioners\*  
 National Institutes of Health  
 New America Foundation  
 North Shore Long Island Jewish Health System  
 Northern New England Cardiovascular Angiography and Interventions\*  
 NorthShore University HealthSystem\*  
 Northwestern Memorial Prentice Women's Hospital  
 Northwestern University\*  
 Norwegian American Hospital Midwife Associates  
 Quality in Healthcare Advisory Group  
 Society for Cardiovascular Angiography and Interventions\*  
 Society for Healthcare Epidemiology of America\*  
 Society for Maternal-Fetal Medicine\*  
 Society for the Advancement of Blood Management\*  
 Society of Cardiovascular Anesthesiologists\*  
 Society of Critical Care Medicine\*  
 Society of Interventional Radiology\*  
 Tennessee Medical Association\*  
 Texas Medical Association\*  
 The Joint Commission  
 The Mended Hearts, Inc.\*  
 The Society of Infectious Disease Pharmacists\*  
 The Society of Thoracic Surgeons\*  
 The University of Toledo  
 Trust for America's Health\*  
 University of California Los Angeles  
 University of Colorado-Anschutz Medical Campus\*  
 University of Illinois at Chicago  
 University of Kansas School of Medicine-Wichita Campus  
 University of Michigan\*  
 University of Minnesota  
 University of Oklahoma, Health Sciences Center  
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\* An organization representative served on at least one work group.

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