March 14, 2014

How High, How Low?
Shared Decision Making Amidst Shifting Hypertension Guidelines
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Madge Kaplan, IHI’s Director of Communications, is responsible for developing new and innovative means for IHI to communicate the stories, leading examples of change, and policy implications emerging from the world of quality improvement — both in the U.S. and internationally. Prior to joining IHI in July 2004, Ms. Kaplan spent 20 years as a broadcast journalist for public radio – most recently working as a health correspondent for National Public Radio. Ms. Kaplan was the creator and Senior Editor of Marketplace Radio’s Health Desk at WGBH in Boston, and was a 1989/99 Kaiser Media Fellow in Health. She has produced numerous documentaries, and her reporting has been recognized by American Women in Radio and Television, Pew Charitable Trusts, American Academy of Nursing and Massachusetts Broadcasters Association.
Don Goldmann, MD, Chief Medical and Scientific Officer, Institute for Healthcare Improvement (IHI), works both internally and externally to deepen IHI’s profile, credibility, and influence in health care and health promotion. As Chief Medical Officer, Dr. Goldmann supports IHI’s content leads in identifying innovative approaches, cutting-edge developments, and expert faculty in areas of strategic focus, using his external relationships to identify important or emerging gaps in IHI content, particularly with regard to innovations and evidence-based interventions that emerge from academia.

As Chief Scientific Officer, his primary goal is to strengthen ties between IHI and the health services research and academic communities. In this capacity, Dr. Goldmann works with IHI colleagues, especially the Results and Evaluation Team, to ensure the rigor of IHI’s results-oriented work, and to disseminate these results in presentations at national meetings and peer-reviewed publications. He also serves as senior lead for the IHI Fellowship Program, and continues to train and mentor emerging investigators at Harvard Medical School, Boston Children’s Hospital, and the Harvard School of Public Health.
Eric D. Peterson, MD, MPH, FAHA, FACC, is the Fred Cobb, Distinguished Professor of Medicine in the Division of Cardiology, a DukeMed Scholar, and the Executive Director of the Duke Clinical Research Institute (DCRI). He is a recognized leader in outcomes and quality research, with over 700 peer-reviewed publications in the field. Dr. Peterson is the Principal Investigator of the NHLBI’s Coordinating Center for its Outcome Research Network, and the AHRQ Cardiovascular Center for Education and Research on Therapeutics (CERTs). He is also the PI of the Data Coordinating Centers’ for the Society of Thoracic Surgeons (STS) National Cardiac Surgery Database, the American College of Cardiology’s National Cardiac Database (ACC-NCDR) and the American Heart Association’s Get With the Guidelines Database (AHA GWTG). Dr. Peterson recently received the American Heart Association Meritorious Achievement Award. He is also a Contributing Editor on the Journal of the American Medical Association.
Figure. 2014 Hypertension Guideline Management Algorithm

Adult aged ≥18 years with hypertension

Implement lifestyle interventions (continue throughout management).

Set blood pressure goal and initiate blood pressure lowering medication based on age, diabetes, and chronic kidney disease (CKD).

General population (no diabetes or CKD)  Diabetes or CKD present

Age ≥60 years  
Blood pressure goal  
SBP <150 mm Hg  
DBP <90 mm Hg

Age <60 years  
Blood pressure goal  
SBP <140 mm Hg  
DBP <90 mm Hg

All ages  
Diabetes present  
No CKD  
Blood pressure goal  
SBP <140 mm Hg  
DBP <90 mm Hg

All ages  
CKD present with or without diabetes  
Blood pressure goal  
SBP <140 mm Hg  
DBP <90 mm Hg

James et al JAMA December 13 2014
JATOS And VALISH Results

**JATOS**

- **Graph:** Cumulative incidence (%)
  - Strict-treatment group
  - Mild-treatment group
  - $p = 0.98$ (Log-rank test)

- **Data:**
  - Number at risk:
    - Strict-treatment group: 2212, 2055, 1964, 1883, 1815, 1755, 1482
    - Mild-treatment group: 2206, 2042, 1959, 1885, 1797, 1742, 1500

- **Publication:** Hypertens Res. 2008;31(12):2115-2127

**VALISH**

- **Graph:** Incidence rate of events
  - Moderate control group (12.0/1000 patients-year)
  - Strict control group (10.6/1000 patients-year)
  - $p = 0.383$ (log-rank test)
  - Hazard ratio (95% CI): 0.89 (0.60-1.31)

- **Data:**
  - Number of patients followed:
    - Strict: 1545, 1482, 1408, 1336, 1306, 1295, 924, 336
    - Moderate: 1534, 1461, 1375, 1304, 1279, 1265, 902, 335

- **Publication:** Hypertension. 2010;56(2):196-202
BP Treatment Targets Have Risks Both Ways

• If one supports keeping threshold at 140/90 in all
  – Performance Measures and incentive programs may encourage over-treatment
    • More hassle, potential safety concerns (falls) in elderly

• If one supports relaxing to 150/90 in older patients
  – Risk of worsening under-treatment of BP in US
    • Despite existing goals and PM’s set at 140/90, <50% of patients reach goal!
    • Is this like the speed limit (always exceed by a little)
Recommendations for Treating Hypertension
What Are the Right Goals and Purposes?

Eric D. Peterson, MD, MPH; J. Michael Gaziano, MD; Philip Greenland, MD

Hypertension is the most common cardiovascular risk factor in the United States, affecting approximately two-thirds of adults aged 60 years or older. Observational studies have demonstrated a linear relationship between blood pressure (BP) and risk of cardiovascular events. Randomized controlled trials (RCTs) have found that lowering BP by as little as 10 mm Hg in patients with hypertension can reduce a person’s lifetime risk for cardiovascular and stroke death by 25% to 40%. Yet for such a common and treatable condition, the ideal treatment goal remains uncertain—both overall and as a function of a patient’s age. Compared with younger patients, older patients with hypertension are at increased risk for cardiovascular and stroke events yet are more vulnerable to complications related to pharmacological treatment of hypertension.

The last Joint National Committee (JNC 7) Guideline, sponsored by the National Heart, Lung, and Blood Institute (NHLBI), was released more than a decade ago. The updated recommendations for management of high blood pressure from the panel members appointed to the JNC 8 Committee was launched 5 years ago. The process used in the most recent update differed from the prior interpreted. Prior guidelines were generally based on the totality of evidence, including observational studies, RCTs, and meta-analyses, as well as expert opinion. Noting that the risks for cardiovascular events in untreated adults increased rapidly as SBP was elevated beyond 140 mm Hg, experts defined hypertension and its treatment targets at this level. Nevertheless, direct RCT evidence to support this threshold is limited. The original hypertension RCTs were selective and generally excluded elderly patients. Later trials that focused specifically on older populations found that treating isolated SBP was beneficial, yet these trials had treatment intervention targets of SBP lower than 160 mm Hg. More recently, 2 Japanese RCTs directly compared a more intensive treatment strategy (lowering SBP <140 mm Hg) vs a more conservative one (<150 mm Hg) among older patients (≥65 years). Neither trial found a significant difference in the primary outcome, yet both trials had relatively short follow-up and limited overall power to exclude a clinically meaningful difference in outcomes. The evidence gap for patients younger than 60 years is even more profound because no RCTs have specifically addressed ideal SBP targets in this age group.
Craig W. Robbins, MD, MPH, has been a family physician with the Colorado Permanente Medical Group (CPMG)/Kaiser Permanente (KP) since July 1998. In KP Colorado, he currently serves as the Medical Director, Clinical Guidelines. At the KP National level, Dr. Robbins serves as the Medical Director of the Center for Clinical Information Services in the KP Care Management Institute (CMI). In this CMI role, he is the lead physician for the KP National Guidelines Program which has been an organizational member of the Guidelines International Network (G-I-N) since 2010. He is a current member of the G-I-N Board of Trustees, the Executive Advisory Board for the Kaiser Permanente Research Associates Evidence-based Practice Center (KPRA-EPC), and the Editorial Board for the National Guideline and Quality Metric Clearinghouses (NGC/NQMC). He is a past chair of the CPMG Board of Directors (2007-8). He was the Physician Lead for Clinical Content development during KP Colorado’s implementation of the KP HealthConnect EMR (2003-5).
About Kaiser Permanente

- Largest nonprofit health plan in the U.S.
- Integrated health care delivery system
- 9.1 million members
- 16,000+ physicians
- 48,000+ nurses
- 174,000+ employees
- Serving 8 states and the District of Columbia
- 37 hospitals
- Almost 600 medical offices/outpatient facilities
- $50.6 billion operating revenue*

Scope includes ambulatory, inpatient, ACS, behavioral health, SNF, home health, hospice, pharmacy, imaging, laboratory, optical, dental, and insurance

*Source: 2012 Kaiser Permanente Annual Report
KP National Guideline Program (NGP)

- Provides evidence-based clinical recommendations on core clinical topics to support care delivery and optimize the health of KP members.
- Supports KP broadly in its quest to provide the highest quality of care through the consistent delivery of effective clinical practices.
- Implemented guideline recommendations help to reduce unwarranted variation in care and improve clinical outcomes.
KP NGP Portfolio 2014

- Asthma (NHLBI EPR3)
- Breast Cancer Screening
- Colorectal Cancer Screening
- Depression
- HIV/STD Screening & Prevention
- Lung Cancer Screening
- Osteoporosis
- ADHD
- Cervical Cancer Screening (USPSTF)
- CVD Risk Reduction
  - CAD
  - Diabetes
  - Dyslipidemia (ACC/AHA?)
  - Hypertension (JNC8?)
- Prostate Cancer Screening
# GRADE: Quality of Evidence

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting grade based on study design</td>
<td>Reduce grade</td>
<td>Raise grade</td>
<td>Final grade</td>
</tr>
<tr>
<td>RCT - High</td>
<td></td>
<td>High-quality observational studies</td>
<td></td>
</tr>
<tr>
<td>Observational – Low</td>
<td>Study quality (risk of bias)</td>
<td>Serious (-1) or very serious (-2) limitations</td>
<td></td>
</tr>
<tr>
<td>Quasi-RCT</td>
<td>Inconsistency</td>
<td>Inconsistency (-1)</td>
<td>High</td>
</tr>
<tr>
<td>Cohort</td>
<td></td>
<td>Important inconsistency (-1)</td>
<td>Further research unlikely to change confidence in the estimate of effect</td>
</tr>
<tr>
<td>Case-control</td>
<td>Indirectness</td>
<td>Some (-1) or major (-2) uncertainty about directness</td>
<td>Moderate</td>
</tr>
<tr>
<td>All others – Very Low</td>
<td>Imprecision</td>
<td>Imprecise or sparse data (-1)</td>
<td></td>
</tr>
<tr>
<td>Case reports</td>
<td></td>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Case series</td>
<td>Publication bias</td>
<td></td>
<td>Very Low</td>
</tr>
</tbody>
</table>

- **RCT - High**
  - **Large magnitude of effect**
    - Large effect (+1)
    - RR > 2 or < 0.5, based on consistent evidence from two or more observational studies with no plausible confounders
  - Very large effect (+2)
    - RR > 5 or < 0.2, based on direct evidence with no major threats to validity
  - Dose response gradient (+1)
  - All plausible confounders would have reduced the effect (+1)

- **Observational – Low**
  - **Inconsistency**
    - Important inconsistency (-1)
  - **Indirectness**
    - Some (-1) or major (-2) uncertainty about directness
  - **Imprecision**
    - Imprecise or sparse data (-1)
  - **Publication bias**
    - High suspicion (-1)

- **All others – Very Low**
  - Case reports
  - Case series

- **Low**
  - Further research very likely to have an important impact on confidence in the estimate and may change the estimate

- **Very Low**
  - Any estimate of effect is very uncertain
<table>
<thead>
<tr>
<th>Factor</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>Balance between desirable and undesirable effects</td>
<td>The larger the difference, the higher the likelihood that a strong recommendation is warranted.</td>
</tr>
<tr>
<td>Quality of evidence</td>
<td>The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted</td>
</tr>
<tr>
<td>Values and preferences</td>
<td>The more they vary, or the greater the uncertainty, the higher the likelihood that a weak recommendation is warranted</td>
</tr>
<tr>
<td>Resource use (Costs)</td>
<td>The higher the costs of an intervention, the lower the likelihood that a strong recommendation is warranted</td>
</tr>
</tbody>
</table>
IOM CPG Standards (2011)

- Establishing transparency
- Management of conflict of interest
- Guideline development group composition
- Clinical practice guideline-systematic review intersection
- Establishing evidence foundations for & rating strength of recommendations
- Articulation of recommendations
- External review
- Updating

IOM CPG Standards (2011)
Peter Basch, MD, FACP, is a practicing general internist in Washington, DC, and the Medical Director for Ambulatory EHR and Health IT Policy for MedStar Health. He is the current chair of the Medical Informatics Committee for the American College of Physicians, and represents the ACP at the Physicians’ EHR Coalition, a group he helped cofound in 2004. Dr. Basch is a Senior Fellow in Health IT Policy at the Center for American Progress and a Visiting Scholar in Health IT Policy at the Engelberg Center for Healthcare Reform at the Brookings Institution. He has been recognized as one of the Top 25 Clinical Informaticists by Modern Healthcare, and is a recipient of the Physician Informatics Leadership Award by HIMSS.
In 2012 MedStar Health Became the First Health System to Partner with Million Hearts®

- Aspirin consistently recommended for those where benefits outweigh risks
- Blood pressure screening and treatment to goal
- Cholesterol screening and treatment to goal
- Smoking: Determine status for current smokers, aggressively counsel/treat towards quitting

- Of the ~2M heart attacks and strokes occur each year, achieving the 2017 goals would reduce the number of new heart attacks / strokes by 10% per year
- Over 5 years – prevent 1M new heart attacks / strokes
### Million Hearts® Premise
Improving Performance Makes a Difference

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Baseline – 2012</th>
<th>Goal – 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin for those at high risk</td>
<td>47%</td>
<td>70%</td>
</tr>
<tr>
<td>Blood Pressure – screening and control</td>
<td>46%</td>
<td>70%</td>
</tr>
<tr>
<td>Cholesterol – screening and control</td>
<td>33%</td>
<td>70%</td>
</tr>
<tr>
<td>Smoking Cessation</td>
<td>21%</td>
<td>19%</td>
</tr>
</tbody>
</table>

- ~ 1/3 of adults in US have HBP (~ 67M)
- Of these – 46% (~31M) were under control
- What do we know about the ~36M with uncontrolled HBP?

CDC. MMR. 2012;61(35):703-9

March 13, 2014
Most People with Uncontrolled Hypertension Were **Aware** of their Condition

Awareness and treatment among adults with uncontrolled hypertension (millions)

- **16 M** Aware and treated
- **14 M** Aware and untreated
- **6 M** Unaware

CDC. MWR. 2012;61(35):703–9

Knowledge and Compassion **Focused on You**

MedStar Health
Most People with Uncontrolled Hypertension Are Insured and Are Receiving Regular Care

CDC. MMR. 2012;61(35):703-9
My Conclusions

Not Problems

• A new blood pressure guideline was published – and it differed from the previous one
• There are too many new guidelines – too much to keep track of…
  – JNC 7 – 2003
  – JNC 8 – 2013
• New blood pressure guidelines are too complicated
• HBP is hard to diagnose, and there are not enough good medications available to bring most patients “to goal”

Problems

• Lack of patient / family awareness
• Lack of provider focus
• Lack of a trusted test that is more than a point in time
  – Leads to providers discounting elevated BP readings
• Existing national quality measure for HBP is based on a single reading
  – May contribute to lack of provider focus AND appropriately aggressive follow-up

March 13, 2014
If you could launch an audacious goal for health, what would it be?

- Think about any of our vulnerable populations – our children, our elders, and the very sick ….if you could launch an audacious goal for their health, what would it be?
- Think about a bold aspirational goal, like “making Scotland the best place to grow up in the world.”
- Think about a goal that embodies the Triple Aim: significant improvement in health for a population, improved care for the individual, at a lower cost.
- Think about a goal that can only be achieved by engaging the whole community.

#IHILearnEscapeVelocity
Continue the Discussion over at IHI’s Facebook Page

Pop over to IHI’s Facebook page and share your thoughts from today’s program!
Thanks to everyone who makes WIHI possible!
Next up on WIHI:

March 27, 2014
• Bright Spots for Patients with Complex Needs

April 10, 2014
• Empathy and Emotions: Best Practices for Engaging with Patients

For more information & episodes, visit IHI.org/WIHI