Take an Aspirin (or Two) and Call (or Text or Email) Me (or Us) in the Morning (or Later)

Michael Mendoza, MD, MPH, MS
Assistant Professor, Department of Family Medicine and Department of Public Health Sciences
Medical Director, Highland Family Medicine

Public Health Grand Rounds
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Objectives

At the end of this presentation, I hope you will:

1. Understand the complexity surrounding aspirin use for primary and secondary prevention of cardiovascular disease,
2. Define evidence based practice and describe two major barriers to evidence based practice, and
3. Appreciate that eliminating these barriers can pave the way for advances in clinical care and population health.
Early History of Aspirin

- 1543 BC – Medicines made from willow and other salicylate-rich plants appear in Egyptian pharonic pharmacology papyri
- 460 BC – Hippocrates described the use of powder of the willow tree, so-called “salicylic tea” to reduce fevers
- 1763 – Edward Stone comes upon the bark of the willow tree by accident, credit with discovering aspirin
XXXII. An Account of the Success of the Bark of the Willow in the Cure of Agues. In a Letter to the Right Honourable George Earl of Macclesfield, President of R. S. from the Rev. Mr. Edmund Stone, of Chipping-Norton in Oxfordshire.

My Lord,

Among the many useful discoveries, which this age hath made, there are very few which, better deserve the attention of the public than what I am going to lay before your Lordship.

There is a bark of an English tree, which I have found by experience to be a powerful astringent, and very efficacious in curing aguish and intermittent disorders.

About six years ago, I accidentally tasted it, and was surprised at its extraordinary bitterness; which immediately raised me a suspicion of its having the properties of the Peruvian bark. As this tree delights in a moist or wet soil, where agues chiefly abound, the general maxim, that many natural maladies carry their cures along with them, or that their remedies lie not far from their causes, was so very apposite to this particular case, that I could not help applying it; and that this might be the intention of Providence here, I must own had some little weight with me.

The excessive plenty of this bark furnished me, in my speculative disquisitions upon it, with an argument...
Modern Discovery of Aspirin

- **1800s** – Lewis and Clark allegedly used willow bark tea as a remedy for fever for members of the famous expedition.
- **1838** – Salicylic acid is discovered and used by physicians throughout the mid-19th century to treat pain, fever, inflammation. Gastric irritation is well-described.
- **1853** – Charles Frederic Gerhardt isolated acetylsalicylic acid.
- **1897** – Chemists (Felix Hoffman) produced a pure (and stable) form of ASA, named Aspirin® by Bayer
  - Felix Hoffman goes on to develop diacetylmorphine which Bayer named “heroin” because it made people feel heroic.
  - Jewish chemist Arthur Eichengrun claimed ownership, records expunged by Nazis.
Aspirin in the 20th Century

- **1900s** – Bayer is committed to “ethical drugs” (those available to pharmacists, and to consumers only by prescription). So-called “patent” drugs and direct-to-consumer marketing was widely considered unethical and illegal.
  - 1903 – Bayer establishes its first American subsidiary in Rensselaer, NY and aggressively markets the drug by imprinting Bayer on a compressed tablet.

- **1920s – 1960s** – Aspirin is used worldwide:
  - Spanish Flu Pandemic
  - World War I and World War II
  - “Take two aspirin and call me in the morning.”
  - Mechanism of action unknown
Aspirin as a Heart Drug

- 1950s – Antiplatelet effects first noted by family physician Lawrence Craven who directed tonsillectomy patients to chew Aspergum for pain. Noticed increased rehospitalization of patients for bleeding.

- 1971-73 – Peter Elwood, an epidemiologist, began first study looking at secondary prevention of MI in patients with history of MI. Not statistically significant reduction in MI in treatment group

Reye’s Syndrome

- In 1979, Dr. Karen Starko and colleagues conducted a case-control study in Phoenix, AZ and found the first statistically significant link between aspirin use and Reye's syndrome.
- Documented cases rare in adults. In children, however, mild to severe permanent brain damage is possible, especially in infants.
- Mortality rate of 30% among cases reported in the United States from 1981 through 1997.
Take One (or Two)?

- **Primary prevention**: 75–162 mg once daily, continue indefinitely, provided there are no contraindications.
- **Secondary prevention**: 50–325 mg daily; some data suggest lower dosages (75–81 mg daily) may have similar benefits and possibly less bleeding risk.
- **Acute prevention**: If rapid and complete platelet inhibition is required (e.g., if a patient is having a heart attack), the first dose of aspirin should be 160 to 325 mg.
The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians discuss aspirin chemoprevention with adults who are at increased risk for coronary heart disease. Discussions with patients should address both the potential benefits and harms of aspirin therapy. This is a grade A recommendation.
Aspirin & Colorectal Cancer (2007)

- The USPSTF recommends against the routine use of aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs) to prevent colorectal cancer in individuals at average risk for colorectal cancer. This is a grade D recommendation.
  - Limited data (observational studies) suggest that aspirin or other NSAIDs may reduce the risk of various cancers (e.g., colorectal, breast, gastric cancer) but these results generally not confirmed in randomized controlled trials.
  - Regular use (e.g., daily) associated with a reduction in the risk of recurrent colorectal adenomas and colorectal cancer in some studies.

- Beneficial effects of NSAIDs in reducing colorectal cancer risk dissipate following discontinuance of such therapy.
Aspirin & Cardiovascular Disease (2009)

- United States Preventive Services Task Force (USPSTF) strongly recommends routine aspirin use if potential reduction in risk of myocardial infarction outweighs potential harm to due gastrointestinal hemorrhage for
  - men aged 45-79 (USPSTF Grade A recommendation)
  - women aged 55-79 (USPSTF Grade A recommendation)
- USPSTF recommends against routine aspirin use for men < 45 years old or women < 55 years old (USPSTF Grade D recommendation)
- USPSTF makes no recommendation for routine aspirin use in men and women ≥ 80 years old (USPSTF Grade I recommendation)
Risks of aspirin outweigh benefits in people without cardiovascular disease, shows analysis

Susan Mayor

London

Prophylactic aspirin reduces the risk of non-fatal myocardial infarction in people without cardiovascular disease but does not reduce cardiovascular or cancer mortality, and any benefit is offset by the raised risk of bleeding events, shows a large meta-analysis looking at aspirin in primary prevention.

The authors argue that guidelines currently recommending use of aspirin in primary prevention should be reviewed in the light of their findings. They say that routine use of aspirin for primary prevention is not warranted and that treatment decisions need to be considered on a case by case basis (Archives of Internal Medicine doi:10.1001/archinternmed.2011.628).

The lead author of the meta-analysis, Rao Seshasai, clinical lecturer in preventive cardiology at St George’s, University of London, said that there was no question about the evidence for aspirin in preventing cardiovascular events in people with established cardiovascular disease. “However, the benefits of aspirin in those individuals not known to have these conditions are far more modest than previously believed, and in fact aspirin treatment may potentially result in considerable harm due to major bleeding,” he said.

“Hence, it would be worthwhile to review the existing recommendations, such as the US Preventive Services Task
Use of Aspirin for Primary Prevention of Heart Attack and Stroke

[05/02/2014] Cardiovascular disease, including heart disease and stroke, affects tens of millions of people in the United States. Consumers and patients who do not suffer from cardiovascular disease sometimes consider taking aspirin to reduce the possibility of having a heart attack or stroke. Reducing the possibility of having a first heart attack or stroke is called primary prevention. The FDA has reviewed the available data and does not believe the evidence supports the general use of aspirin for primary prevention of a heart attack or stroke. In fact, there are serious risks associated with the use of aspirin, including increased risk of bleeding in the stomach and brain, in situations where the benefit of aspirin for primary prevention has not been established.

The available evidence supports the use of aspirin for preventing another heart attack or stroke in patients who have already had a heart attack or stroke, or have other evidence of coronary artery disease, such as angina or a history of a coronary bypass operation or coronary angioplasty. Reducing the risk of additional heart attacks or strokes is known as secondary prevention. In patients who have had such cardiovascular events, the known benefits of aspirin for secondary prevention outweigh the risk of bleeding.

FDA is committed to reviewing any data supporting new medicines and new uses to improve the health of the American public.
Do Clinicians Recommend Aspirin to Patients for Primary Prevention of Cardiovascular Disease?

Kevin Fiscella, M.D., M.P.H.¹,², Paul C. Winters, M.S.¹, Michael Mendoza, M.D., M.P.H.¹,², Gary J. Noronha, M.D.³, Carlos M. Swanger, M.D.³, John D. Bisognano, M.D., Ph.D.⁴, and Robert J. Fortuna, M.D., M.P.H.³

¹Department of Family Medicine, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA; ²Public Health Sciences, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA; ³Center for Primary Care and Department of Internal Medicine, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA; ⁴Department of Medicine, Division Cardiology, University of Rochester School of Medicine and Dentistry, Rochester, NY, USA.

OBJECTIVE: Our aim was to examine clinician aspirin recommendation among eligible persons based on cardiovascular risk scores and USPSTF cutoffs.
DESIGN: We used cross-sectional analysis of a current nationally representative sample.
PARTICIPANTS: Participants were aged 40 years and older, and in the National Health and Nutrition Examination Survey (NHANES) (2011-2012).
MAIN MEASURES: We determined aspirin eligibility for cardiovascular disease (CVD) prevention for each participant based on reported and assessed cardiovascular risk factors. We assessed men's risk using a published coronary heart disease risk calculator based on Framingham equations, and used a similar calculator for stroke to assess risk for women. We applied the USPSTF risk cutoffs for sex and age that account for offsetting risk for gastrointestinal hemorrhage.

KEY WORDS: aspirin; primary CVD prevention; USPSTF guidelines.
J Gen Intern Med
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The United States Preventive Services Task Force (USPSTF) released updated guidelines in 2009 regarding aspirin prophylaxis to prevent myocardial infarction among at-risk men and stroke among at-risk women.¹ This followed a 2002 USPSTF recommendation regarding myocardial infarction prevention in adults.² However, determination of aspirin eligibility for primary prevention involves weighing 10-year cardiovascular disease (CVD) risk calculations against gastrointestinal bleeding risks. The USPSTF suggested separate risk
Low Recommendation Rates for Aspirin

- 3,439 patients aged 40 and older
- Primary Prevention
  - Men
    - 87% eligible, 34% recommendation rate
    - 13% ineligible, 24% recommendation rate
  - Women
    - 16% eligible, 42% recommendation rate
    - 84% ineligible, 28% recommendation rate
- Secondary Prevention
  - 76% recommendation rate
- Diabetes
  - 63% recommendation rate
Diffusion of Innovation Curve

Penetration of Target Market

Time

- Innovators
- Early adopters
- Early majority
- Laggards
# Health Care Innovations Diffuse Slowly

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Practice</th>
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<tbody>
<tr>
<td>1601 – English sea captain James Lancaster discovered that lemon juice supplements were a cure for scurvy in sailors</td>
<td>1795 – British navy routinely stocks ships with citrus fruits and supplements</td>
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<td>1847 – Ignas Semmelweiss, a house officer in one of the two obstetric clinics at the University of Vienna observes that maternal mortality rates, mostly attributable to puerperal fever, were substantially higher in one clinic compared with the other (16% vs. 7%)</td>
<td>2014 – Hand washing rates at Strong and Highland remain &lt;100%</td>
</tr>
</tbody>
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"Landmark Findings" Also Slow to Diffuse

<table>
<thead>
<tr>
<th>Clinical Procedure</th>
<th>Landmark Trial</th>
<th>Rate of Use (2000)</th>
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<tbody>
<tr>
<td>Flu vaccine</td>
<td>1968</td>
<td>64%</td>
</tr>
<tr>
<td>Thrombolytic therapy</td>
<td>1971</td>
<td>20%</td>
</tr>
<tr>
<td>Pneumococcal vaccine</td>
<td>1977</td>
<td>53%</td>
</tr>
<tr>
<td>Diabetic eye exam</td>
<td>1981</td>
<td>48.1%</td>
</tr>
<tr>
<td>Beta blockers after MI</td>
<td>1982</td>
<td>92.5%</td>
</tr>
<tr>
<td>Mammography</td>
<td>1982</td>
<td>75.5%</td>
</tr>
<tr>
<td>Cholesterol screening</td>
<td>1984</td>
<td>69.1%</td>
</tr>
<tr>
<td>Fecal occult blood test</td>
<td>1986</td>
<td>20.6%</td>
</tr>
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We all own this...

- We shouldn’t continue to expect, browbeat, hope, or pray for any one health care or public health professional to fix this
- We need a *system* that makes quality health care possible, desirable, affordable
  - Safe, effective, patient-centered, timely, efficient, equitable
Evidence Based Practice & Public Health

Applying the best available research results (evidence) when making decisions about health/population care. Health care professionals who perform evidence-based practice use research evidence along with clinical, program-planning, policy expertise and patient/population preferences.

BARRIERS TO EVIDENCE BASED PRACTICE
Barriers to Evidence Based Practice

- Evidence
- Workforce
- Information Technology
- Reimbursement, Regulatory and Compliance Factors
- Practitioner, Patient and Community Factors
Reimbursement and Regulatory Barriers

- Reimbursement and quality are not well aligned
  - Cochlear Implants (1978)
  - Group Visits
  - Fee-for-service medicine

- Regulation and compliance can impede application of best practice
  - Scope of Practice
  - Pain Scores, Universal IPV Screening, Depression Screening
  - Documentation
    - “>50% of visit devoted to counseling...”
Information Technology

- Electronic health records are disjointed, within and among health care systems
- Data entry (and therefore data retrieval) is inconsistent
CONSISTENCY

It's only a virtue if you're not a screwup.
Evidence Wars

- Prostate cancer screening
  - The USPSTF recommends against prostate-specific antigen (PSA)-based screening for prostate cancer.
    - The USPSTF recommends a discussion between patient and physician about benefits and risks of prostate cancer screening if a patient requests screening.
  - American Cancer Society states that men at average risk over age 55 (AUA) or age 50 (ACS) who expect to live at least 10 more years should decide, in partnership with their physician, whether to be screened for prostate cancer.
  - Only 17 percent of top-ranked consumer health websites advise against screening for prostate cancer.
Evidence Explosion

Pubmed: "aspirin [ti]"

Medical Articles Catalogued Each Year

Total Articles

Year

0 100,000
100,000 200,000
200,000 300,000
300,000 400,000
400,000 500,000
500,000 600,000
600,000 700,000
700,000

Year


References

Medicine of the Highest Order

UR Medicine
Evidence Noise Pollution

- Thousands of articles a month
- PURLs
  - Relevant
  - Valid
  - Change in Practice
  - Applicable to Medical Care
  - Immediately Applicable
  - Clinically Meaningful
- 1 per 100,000
Barrier to EBP: Rising Demands on Workforce

- Average primary care panel in US is **2300**
- PCP with panel of average patients will spend
  - **7.4 hours** per day doing recommended *preventive care*
  - **10.6 hours** per day doing recommended *chronic care*

Residency Match, 2010 – 2012
% of graduating US medical students choosing specialties

2010 NRMP Main Residency Match data

2014: Adult primary care = 12%
Workforce: Generalist Supply vs. Population

Colwill et al., Health Affairs, 2008:w232-241
NPs and PAs to the rescue?

- New graduates each year
  - Nurse Practitioners: 8,000
  - Physician Assistants: 4,500
- % going into primary care
  - NPs: 65%
  - PAs: 32%
- Adding new GIM, FM, NPs and PAs entering primary care each year, the primary care clinician to population ratio will fall by 9% from 2005 to 2020.

Colwill et al, Health Affairs Web Exclusive, April 29, 2008; Bodenheimer et al, Health Affairs 2009;28:64.
Workforce Shortage in Public Health

- Public health nurses, epidemiologists, county health departments
- Public health workers per 100,000 Americans fell from 220 (1980) to 158 (2000)
- The average age of a public health worker in state government is 47 (and rising).
  - The average age of new hires in state health agencies is 40.
- In 2007, estimated that 20% of the average state health agency’s workforce will retire by 2010.
  - Over 50% eligible to retire in 2012.
If it wasn't for the Pirin tablets...
I don't think I could go on.
TOWARD A NEW ERA OF POPULATION HEALTH
Translate Evidence into Practice

- Medical Education
- Information mastery
  - Interdisciplinary Education – Librarians
  - PURLs
  - Decision Support at the Point of Care (Health IT)
- Interprofessional Education
  - Learn in teams in order to practice in teams
- Practice Support, emphasis on point of care solutions
- Ongoing feedback on evidence based practice
  - Peer Review
  - Interdisciplinary Review
Expand public health infrastructure

- State and federal funding to support public health workforce (which is largely publicly funded)
- Promote public health careers
  - Support increased competitiveness of careers in public health
- Partnerships with hospital systems and primary care
  - Lay health educators
  - Community health workers
  - Health promotion programs that target areas of highest cost in system
    - Avoidable Hospital Readmissions
    - Avoidable ED Visits
Expand primary care capacity

- Short (and long) term
  - Interprofessional Teams
    - Medical Assistants engage with patients in motivational interviewing, population management
    - Lay health educators partner with patients
    - No longer just a doctor’s job to recommend one (or two) aspirin
    - No longer expect a call from patients (MyChart, Email, Telemedicine)
    - Nurses and MAs field questions, and answer questions
    - From visit-based to asynchronous care (not in the morning, maybe later)
  - Long-term
    - Develop pipeline for primary care
    - New payment models that incentivize value, quality and outcomes
KEYNOTE SPEAKER

Barbara Brandt, PhD  Director of the National Center for Interprofessional Practice and Education  Associate Vice President for Education, Academic Health Center  University of Minnesota  Registration is required • Lunch will be provided
Medicine of the Highest Order
Acknowledgements