



Health Watch USAsm The First Decade

A Report to the Community Health Watch USAsm Initiatives and Successes On improving quality

"In the gap between excellence and perfection, there is suffering, harm, tragedy, and death." -- Jim Conway

December 2015

Who We Are: Health Watch USAsm is a non-profit 501C3 organization incorporated in Aug. 25, 2005 in the State of Kentucky. It is composed primarily of both patient advocates, consumers and retired healthcare professionals who provide a wide range of expertise in epidemiology, statistics, research integrity, and medical care.

- Health Watch USA was designated a community leader for value-driven healthcare by the U.S. Dept. of Health and Human Services Secretary, Michael Leavitt, Aug. 2007.
- Health Watch USA became a member of Consumer Union's Safe Patient Project, Jan. 2009.
- Health Watch USA became a member of the NQF Consumer Council, Sept. 2010.

Our mission: "promote health care transparency, competition and patient advocacy."

Health Watch USA collaborates with patients and advocacy organizations to improve healthcare quality and public access to information (transparency). Specific objectives are:

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| #1. Promote quality healthcare. | 2 |
| <ul style="list-style-type: none">• Assurance of adequate nurse staffing.• Financial incentives and penalties to promote healthcare quality (value-based purchasing).• Assurance of a healthcare structure to promote quality; and adequate numbers of providers to promote patient choice, quality and control costs. | |
| #2. Assure accurate information is provided to the public. | 8 |
| <ul style="list-style-type: none">• Public release of hospital accreditation surveys.• Public reporting of healthcare acquired infections.• Reporting of Antibiotic Resistance Organisms.• Medical devices: Safety, Efficacy, Adverse Event Reporting. | |
| #3. Infectious Disease Research Integrity – Surveillance & Use of Chlorhexidine. | 16 |
| #4. Medical Overuse. | 18 |
| #5. Communications to the Public. | 20 |
| <ul style="list-style-type: none">• Newsletter.• Webcasts.• Radio Shows.• Annual Conference. | |
| #6. National Professional Activities, Awards and Related Activities. | 23 |

"No one makes a greater mistake than he who did nothing because he could do so little" – Edmund Burke

ConsumersUnion®
POLICY & ACTION FROM CONSUMER REPORTS

Promotion of Healthcare Quality -- Assurance of adequate nurse staffing

The initial Board members of Health Watch USA determined early on that one of the keys to healthcare quality at hospitals is having adequate numbers of trained high quality nurses. The rationale behind this position was outlined in a number of Op-Eds and in a review paper which was published in the Journal of Nursing Scholarship.



Publications in Peer-Reviewed Journals – Adequate Nurse Staffing

- Kavanagh KT, Cimiotti JP, Abusalem S and Coty MB. Moving Healthcare Quality Forward With Nursing-Sensitive Value-Based Purchasing. Journal of Nursing J Nurs Scholarsh. 2012 Dec;44(4):385-95. PMID: 23066956
<http://onlinelibrary.wiley.com/doi/10.1111/j.1547-5069.2012.01469.x/full>

Opinion Editorials (Op-Eds) – Adequate Nurse Staffing

- Hospitals reckless to leave floors short of nurses. Lexington Herald Leader. Jun. 28, 2008.
http://www.healthwatchusa.org/HWUSA-Publications/Op-Eds-Herald-Leader/20080628-Hospitals_reckless_short_of_nurses_Op-Ed.pdf
- Too much expected of too few nurses. Frontline Caregivers Get Little Support In Protecting Patients. Lexington Herald Leader. Apr 16, 2007.
<http://www.healthwatchusa.org/HWUSA-Publications/Op-Eds-Herald-Leader/20070416-Kentucky.com%20Nursing.pdf>
- UK wrong to downplay loss of nursing honor. Lexington Herald Leader. Mar 21, 2011.
<http://www.kentucky.com/opinion/op-ed/article44085474.html>

Presentations – Adequate Nurse Staffing

- Jeannie Cimiotti, PhD, RN, FAAN. Nursing Burnout and the Importance of a Culture of Safety. HW USA Conference Nov. 1, 2013.
https://www.youtube.com/watch?v=8_YbwFnATME
- Jeannie Cimiotti, PhD, RN, FAAN. Nursing Workforce and Quality of Care. HW USA Conference Nov. 19, 2010. <https://www.youtube.com/watch?v=mccaerlHkUk>

Healthcare Quality -- Financial Incentives & Penalties to Promote Healthcare Quality (Value-Based Purchasing)



Advocating for better healthcare is of utmost importance. But to produce a meaningful change, Health Watch USA advocates that performance should be tied to financial incentives both penalties and bonuses. Currently, the Centers for Medicare and Medicaid Services has undertaken several value-based purchasing initiatives which are designed to reduce medical errors and patient harm (adverse events).

Non-Payment of Medical Errors: In the Spring of 2008, Ken Conner, JD, presented on Medicare and Medicaid non-payment of Never Events at Health Watch USA's annual conference. During the conference, an initiative was formulated in conjunction with another presenter, Lisa McGiffert from Consumer Union. Subsequently, Consumer Union joined with Health Watch USA and other advocates to advance the policy of Medicaid Adopting Medicare regulations regarding non-payment of certain severe adverse events (Never Events). This policy was incorporated into the Affordable Care Act and adopted. [View 2008 Health Watch USA Conference Presentations](#)

This policy was found to produce small changes in quality. Some used this outcome to advocate that financial penalties do not work and should be abandoned. However, on further analysis, it was found that too few penalties have been levied for the initiative to be viable. For example: Considering Central Line Blood-Stream Infections, less than 30 events were penalized each year for all the hospitals in the United States. This is due to the methodology of hospital payments, largely as single payment based upon the admitting diagnosis. Sometimes a single bump in payment can be obtained through a variety of additional diagnoses. Health Watch USA wrote numerous letters in peer-reviewed medical journals pointing out this problem.

- Kavanagh KT. Letter to the editor regarding: The effectiveness of Medicare's non-payment of hospital-acquired conditions policy. Health Policy. Aug 27, 2014. PMID: 25201486 <http://www.healthpolicyjrnl.com/article/S0168-8510%2814%2900221-8/pdf>
- Kavanagh KT. A comment on: Lee GM, Kleinman K, Soumerai SB, Tse A, Cole D, Fridkin SK, Horan T, Platt R, Gay C, Kassler W, Goldmann DA, Jernigan J, Jha AK. Effect of

nonpayment for preventable infections in U.S. hospitals. N Engl J Med. 2012 Oct 11;367(15):1428-37. New England Journal of Medicine. 2013; Jan. 368:191-192. PMID: 23301747 <http://www.nejm.org/doi/full/10.1056/NEJMc1213732>

- Kavanagh KT. A comment on: Jha AK, Joynt KE, Orav EJ, Epstein AM. The Long-Term Effect of Premier Pay for Performance on Patient Outcomes. N Engl J Med. 2012 Apr 26;366(17):1606-15. Epub 2012 Mar 28. PMID: 22455751; N Engl J Med. July 26, 2012; 367:381-383. PMID: 22830476 <http://www.nejm.org/doi/full/10.1056/NEJMc1206170>

Healthcare Acquired Conditions: Health Watch USA has written support for the Hospital - Acquired Condition (HAC) Reduction Program's proposed rule in the Federal Register, 79 FR 27977. The letter was signed by 15 patient advocates and advocate organizations. To view letter: <http://www.healthwatchusa.org/HWUSA-Initiatives/PDF-Downloads/20140627-HAC-Comments.pdf>

Dr. Kevin Kavanagh was also appointed as a member of the CMS Technical Expert Panel (TEP) for Hospital Acquired Conditions (HAC) in 2014 and 2015.

Healthcare Quality -- Assurance of a Healthcare Structure to Promote Quality and Control Costs.

Culture of Safety: One of the most important aspects of any healthcare system is their culture of safety. Health Watch USA demonstrated the importance of a culture of safety in a study which compared the rate of Central Line Bloodstream Infections in Intensive Care Units to various questions on facility-wide patient surveys. We expected that these infections would be most related to the cleanliness of patient's rooms but the highest relationship was with nurse response time. The study concluded that this correlation to facility-wide characteristics was due to the presence or absence of a culture of safety. The paper's findings also exemplifies the importance of nursing and supports the concept of having a single star rating of facilities.

- Saman DM, Kavanagh KT, Johnson B, Lutfiyya MN. Can Inpatient Hospital Experiences Predict Central Line-associated Bloodstream Infections? Plos One. April. 5, 2013. PMID: 23577195
<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0061097>
- Saman DM, Kavanagh KT. Response to patient satisfaction as a possible indicator of quality surgical care. JAMA Surg. 2013 Oct 1;148(10):985. PMID: 24132396
<http://archsurg.jamanetwork.com/article.aspx?articleid=1756992>

Accountable Care Organizations: Paramount in the establishment of a culture of safety is the commitment of the institution's Board to patients. The Affordable Care Act created new types of provider organizations called Accountable Care Organizations (ACOs). They were intended to promote healthcare quality and lower costs. However, proposed regulations had the composition of the Board to be composed of a majority of providers and the fiduciary responsibility (loyalty) of this organization to the ACO. The regulations did not mention the patient.

In addition, the ACO board of non-profit ACO's had a board composition similar to For-Profit organizations, in that 51% of the members were not without a conflict-of-interest. They were ACO providers. In response, Health Watch USA organized a regulatory comment letter which was signed by 20 patient advocates and/or advocate organizations.

- Concerns regarding Accountable Care Organization Boards being accountable to the ACO and not the patient. 2011, Apr. 21. View Comment Letter:

<http://www.healthwatchusa.org/HWUSA-Initiatives/PDF-Downloads/ACO-Berwick-11b.pdf>

- Kavanagh KT. The Changing Role of the Physician. ACS Surgery News. Oct. 23, 2012. <http://www.acssurgerynews.com/opinions/editorials/single-article/the-changing-role-of-the-physician/9dbaf6056dcb9a966c5beef8cb438de6.html>

The final regulation provided for a waiver mechanism, but the Board structure of Accountable Care Organizations (ACOs) and their fiduciary responsibility continues to be a major concern of advocates. A golden opportunity was missed. An opportunity to have all ACO's patient centered with a non-profit board structure, instead the opposite may have taken place.

Healthcare Integration: Healthcare integration is the joining together of different types of providers into a single coordinated system of care. Although integration of healthcare is desirable to provide for better continuity of care, concerns have been raised over integration to the extent that if too extensive, will dramatically decrease patient choices and drive up healthcare costs.

One of the drivers of massive healthcare integration is the Center's for Medicare and Medicaid's policy to pay twice as much for outpatient services provided by hospital-employed physicians or hospital-owned outpatient centers (imaging centers and surgery centers) than those provided by independent physicians or outpatient centers.

In July, 2011, Health Watch USA, raised concerns regarding this policy with MedPAC (Medicare Payment Advisory Committee). MedPAC's response to Health Watch USA stated they were analyzing this matter. In 2012, MedPAC, recommended reversal of this policy. Health Watch USA has been featured in over 10 news reports on this subject, including The Washington Post, The Denver Post, Lexington Herald Leader, Modern Healthcare, The Kansas City Star along with others. In addition, Health Watch USA has authored an article in the Bulletin of the American College of Surgeons on this subject and has published numerous op-eds.

Opinion Editorials (Op-Eds) – Healthcare Integration

- Kavanagh KT. Costs soar when doctors work for hospitals. Lexington Herald Leader. Apr. 22, 2013. <http://www.kentucky.com/2013/04/22/2610324/costs-soar-when-doctors-work-for.html>
- Kavanagh KT. Two Takes: Should Hospitals Be Allowed to Charge Facility Fees? US News & World Report. Jan 11, 2013; Hospital Facility Fees Raise Out-of-Pocket Costs for

Medicare Patients. US News & World Report. Jan 28, 2013.

<http://www.usnews.com/opinion/articles/2013/01/28/hospital-facility-fees-raise-out-of-pocket-costs-for-medicare-patients>

- Kavanagh KT, Bukulmez H. More doctors controlled by hospitals mean restricted care. Herald Leader, Lexington, Kentucky, March 1, 2012.
<http://www.kentucky.com/2012/03/01/2089879/ky-voices-more-doctors-controlled.html>

Publications in Peer-Reviewed Journals – Healthcare Integration

- Kavanagh KT. Health care integration: Will physicians lose their voice? Bulletin of the American College of Surgeons, June 2011. PMID: 22315908
<https://www.facs.org/~media/files/publications/bulletin/2011/2011%20june%20bulletin.as>

Revision of this payment discrepancy was contained in the 2015 budget bill. However, the discrepancy was only corrected for off-main-campus facilities and all existing facilities were grandfathered in.

Assure Accurate Information is Provided to the Public – Public Release of Hospital Accreditation Surveys.

Similar to accreditation reports for schools and universities, hospital accreditation survey reports should be released to the public. In Kentucky, restaurants are required to post the health department survey results for all to see. But by law, the Federal Government cannot release survey results for hospitals and nursing homes. In an attempt to correct this situation, Health Watch USA organized two large petitions regarding this problem.

- Letter to Senator Mitch McConnell calling for revision of the Social Security Act to allow the release of hospital accreditation surveys. Final Letter signed by 31 business purchasing alliances and/or affiliated organizations. Oct. 27, 2012. View Comment Letter: http://www.healthwatchusa.org/HWUSA-Initiatives/PDF-Downloads/20111118NS_Senator_Mitch_McConnell.pdf
- Letter to Senator Tom Harkin calling for revision of the Social Security Act to allow the release of hospital accreditation surveys. Letter signed by 53 patient advocate and/or advocate organizations. Sep. 2, 2012. View Comment Letter: http://www.healthwatchusa.org/HWUSA-Initiatives/PDF-Downloads/20110910-Senator_Tom_Harkin-Post-2.pdf

Despite coverage by news media, hospital accreditation surveys remain shielded from the public.

Assure Accurate Information is Provided to the Public – Accurate Quality Data and Interpretation.

Health Watch USA has been a leader in analysis of how quality is measured (quality metrics) and in the promotion of clarity in publically reporting of the data.

Two major issues have been addressed. The first is the mechanism in which performance is measured. Many systems, including the Federal Government's Hospital Compare website, compare performance to a national benchmark. But this benchmark is the starting point, an unacceptable high level. It is not the goal. Thus, some facilities have advertised that their rates for adverse events (infections) are at or below the National Benchmark when in fact their rates are well above the national average. Health Watch USA has other concerns regarding how the data is adjusted and questions the appropriateness of adjustments for facility or unit size and being a teaching institution.

- Saman DM, Kavanagh KT, Abusalem S. Redefining the Standardized Infection Ratio to Aid in Consumer Value Purchasing. *Journal of Patient Safety*. 2013 Jun;9(2):55-8. PMID: 23370222

A major metric which is used for financial penalties and the public reporting of urinary tract infections may not be providing the most accurate information. There is concern that high performing facilities that have substantially decreased catheter utilization may be penalized with the current metric.

- Calderon LE, Kavanagh KT, Rice MK. Questionable Validity of the Catheter Associated Urinary Tract Infection Metric Used for Value Based Purchasing. *American Journal of Infection Control*. Published Online Jul 1, 2015.
<http://www.ajicjournal.org/article/S0196-6553%2815%2900613-6/fulltext>

In response to this article, the Centers for Disease Control and Prevention submitted a letter outlining changes which will be tested to incorporate catheter utilization measures into the CAUTI metric. Health Watch USA compliments the Centers for Disease Control and Prevention for this change.

Assure Accurate Information is Provided to the Public – Public Reporting of Healthcare Acquired Infections (HAI).



One of the first initiatives of Health Watch USA was the submission in 2008 of state legislation to require screening and isolation of MRSA carriers (Kentucky SB 118). The bill did not pass and several attempts were made over the following years.

Finally in 2014, the Governor of Kentucky enacted a regulation to require all healthcare facilities, not just hospitals, to report infection of multi-resistant drug organisms to the State Health Department.

The regulation would require reporting of CRE (carbapenem resistant enterobacteriaceae) along with other virtually untreatable organisms. In addition, it would require laboratory reporting of MRSA and C. Difficile. The MRSA requirement would be for all infections not just for blood-stream as is required by the Federal Government. In addition, the definition of an outbreak was clarified and quantified.

Most importantly, the regulation recognizes this epidemic as a health system problem which cannot be controlled by any single facility. All facilities are required to report and the KY Public Health Department would be in charge of coordinating the effort to eradicate these organisms. The Centers for Disease Control and Prevention has since adopted a similar plan of action.



Although this bill did not require screening, Health Watch USA believes it will encourage screening for these organisms since screening is a requirement for effective control. Health Watch USA was the only advocacy group that provided written comments in favor of this regulation and the only group to testify before Kentucky Senate and House Committees advocating its adoption.

Through the six year period of this initiative, Dr. Kavanagh testified 10 times before the KY State House and Senate Committees on this subject (see <http://www.healthwatchusa.org/>

Opinion Editorials (Op-Eds) on Public Reporting and Multi-Drug Resistant Organisms

- Kavanagh KT. Needed: Greater Surveillance, New Norms in the Fight Against Antibiotic Resistance Center for Disease Dynamics, Economics and Policy. Oct. 8, 2015. http://cddep.org/blog/posts/needed_new_norms_antibiotic_resistance_surveillance_stewardship
- Kavanagh KT. Legislative panel must support more hospital reporting of infection outbreaks Lexington Herald Leader. Jan. 13, 2015. <http://www.kentucky.com/2015/01/12/3638563/legislative-panel-must-support.html>
- Kavanagh KT. How Ebola reveals scary gaps in U.S. health care. Lexington Herald Leader. Oct 12, 2014. <http://www.kentucky.com/2014/10/12/3476736/ky-voices-dr-kevin-kavanagh-on.html>
- Kavanagh KT. Mandate reporting of Ky. health-care related infections. Lexington Herald Leader. Mar. 13, 2014. <http://www.kentucky.com/2014/03/13/3136695/mandate-reporting-of-ky-health.htm>
- Kavanagh KT, Saman DM. Better monitoring needed in a post-antibiotic era. Lexington Herald Leader. July 11, 2013. <http://www.kentucky.com/2013/07/11/2710637/ky-voices-better-monitoring-needed.html>
- Kavanagh KT, Saman DM. Hospital Infections are Under Reported. Courier Journal, Louisville, Kentucky, January 31, 2012. <http://www.courier-journal.com/apps/pbcs.dll/article?AID=2012302010056>
- Saman DM, Kavanagh KT. Public, patients have right to know hospitals' infection rates – Herald Leader, Lexington Kentucky, July 11, 2011.
- Kavanagh KT. Tracking of Hospital Acquired Infections – Courier Journal, Louisville, Kentucky, Apr. 20, 2011 .
- Kavanagh KT. State Reporting on Hospital Infections, Lax Dangerous - Lexington Herald Leader, Lexington, Kentucky, Jan. 21, 2011.
- Hawpe D, You should learn the ABCs of HAI and MRSA. Courier Journal Editorial. Jul. 28, 2009. This editorial endorsed Health Watch USA's position on HAI reporting. <http://www.healthwatchusa.org/downloads/20090727-CJ-MRSA.pdf>

Radio Presentations on Public Reporting and Multi-Drug Resistant Organisms

- Dr. Arjun Srinivasan, Associate Director for Healthcare Associated Infection Prevention Programs, Division of Healthcare Quality Promotion, Centers for Disease Control and Promotion and Dr. Kevin Kavanagh, Chairman of the Board Health Watch USA, present on healthcare associated infections. Jack Pattie Show (Radio). Apr. 9, 2014. <http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20130423-CDC-HAI/HWUSA-Radio-Srinivasan-Kavanagh.htm>

Assure Accurate Information is Provided to the Public – Medical Devices

Safety oversight for medical devices not only mirror the problems found with healthcare associated infections (HAIs) but also have added quality assurance problems associated with their approval process. The vast majority of devices implanted into patients are untested and based on “predicate devices” which have to be “substantially similar” to the new device. But what is substantially similar is vague and ill-defined. Even if a new device is based upon a device which has been withdrawn from the market, it can still be approved.

Medical devices which have been approved and are now known to have quality problems include: Hip implants, retrograde duodenal endoscopes, morcellators, pelvic mesh, birth control devices, along with a long list of other implanted devices.

Health Watch USA has disseminated information regarding these devices and encouraging the public to make informed risk versus benefit decisions before an implant is performed.



Presentations Regarding Medical Endoscopes (Retrograde Duodenal Scopes)

The problems with retrograde medical endoscopes has gone undetected by the United States for years. Not until media began reporting the spread of the deadly virtually untreatable bacteria carbapenem resistant enterobacteriaceae (CRE) did the government learn of the problem and take action. The problems were known to European oversight agencies two years prior to being reported to the U.S. Food and Drug Administration.

- Eisler P. (Investigative Reporter Reuters News Agency). FDA Resources for Reporting on Medical Devices. An extended discussion on the history of oversight lapses which set the stage for the spread of the virtually untreatable bacteria, CRE, with certain complex medical endoscopes. Health Watch USA Conference. Nov. 13, 2015. YouTube Video: https://youtu.be/NB3VVaO_GPs
- Eisler P. Deadly infections from medical scopes go unreported, raising health risks. USA Today. Aug. 21, 2015. <http://www.usatoday.com/story/news/2015/08/05/duodenoscope-infections-not-reported/29988165/>

Presentations Regarding Hip Implants

Metal-on-metal hip implants were associated with one of the largest recalls of an implantable device. The newer technology was largely untested and entered the market by the 510(k) approval process. However, these implants may over time cause a multitude of life threatening problems and have been implanted in 100,000's, even millions of patients. The United States healthcare system was slow to detect the problem, which was first detected in Europe. Even today, an effective post-market monitoring system is lacking and screening for cobalt poisoning is not being performed on high-risk patients. Hip implant revision rates for some devices have ranged from 15% to 44%, a far cry from the 2 to 3% revision rates of the original device. Ironically, the new hip devices are more than twice as expensive and less safe than the original implant (Charnley THA) introduced in the 1970s.

2015 Taper Corrosion of CrCo Components about 2 million Americans at risk



Osteolysis, Pseudotumor, Sciatica
56 YO active male, 6 years post THA.
Popular non-recalled Stryker 32 mm MoP 510K hip.
Osteolysis detected with surveillance XR.
Minimal Metallosis and Hypercobaltemia (0.9)

- Dr. Steven Tower, Corrosion & Cobalt poisoning associated with Hip Implants. HW USA Conference. Nov. 13, 2015 YouTube Video <https://youtu.be/q9LvvaqM6rY>
- Dr. Steven Tower, Adverse Events from Hip Implants Including Cobalt Poisoning. HW USA Conference. Nov. 11, 2014. YouTube Video https://youtu.be/j0t_Kv3k70Y
- Dr. Steven Tower, Lexington, KY. Patient Safety Problems with the Metal on Metal Hip Implants. HW USA Meeting. Apr. 2, 2014 YouTube Video <https://www.youtube.com/watch?v=mw6iDg0A6Ys>

Presentations Regarding Power Morcellators

A power morcellator is a surgical tool which is inserted into the abdomen through a very small incision in order to grind up tissue. This tissue can then be suctioned out of the abdomen via the small incision. The procedure was, until recently, widely used in hysterectomies. However, in a percentage of patients, one in a few hundred, a cancer is present and the morcellator spreads it throughout the abdominal cavity.

This often has a fatal outcome, despite aggressive therapy. The picture to the right shows a collage of patients who developed advanced stage cancer from uterine morcellation. Those with a ribbon have died. (Picture provided by Dr. Hooman Noorchasm.)



Presentations on the Dangers of Power Morcellators:

- Dr. Hooman Norchashm & Dr. Amy Reed on Uterine Morcellation and The Spreading of Cancer: Jack Pattie Radio Show / Webcast. May 12, 2015. You Tube Video <http://youtu.be/IY4sFn5hybg>
- Dr. Hooman Noorchasm and Dr. Amy Reed on the dangers of Uterine Morcellation: Health Watch USA Meeting. June 25, 2014.
 - Segment 1: Hooman Noorchashm MD, PhD on the morcellation disaster: A root cause analysis and perspective. You Tube Video: <http://youtu.be/n6226ic0Mpk>
 - Segment 2: Amy J. Reed MD, PhD on the morcellation disaster: A physician, patient, and mother of six, gives her personal perspective. You Tube Video: <http://youtu.be/glwxfkXGekw>
 - Segment 3: Dr Noorchashm presents his research and perspective leading to a plan of action to ban the procedure of morcellation and revising the 510(k) medical device approval process. You Tube Video: <http://youtu.be/Qvg5OXaiEiM>

Opinion Editorials (Op-Eds) -- Overview Medical Devices

- Kevin Kavanagh, MD. Without more monitoring, medical devices will keep harming patients We all need to encourage Congress to amend the 21st Century Cures Act to assure effective pre-market testing and post-market monitoring of medical devices. *Lexington Herald Leader*. Aug. 14, 2015 <http://www.kentucky.com/opinion/op-ed/article44615532.html>

Medical Device Presentation – Overview

- Kevin Kavanagh, MD. Short Video Clip on HW USA 2015 Conference and Medical Devices. Channel 18 News. Nov. 3, 2015. <https://youtu.be/-jXdw053hyw>
- Joleen Chambers from FIDA on the Safety of Medical Devices Failed Implant Device Alliance. HW USA Conference. Nov. 1, 2013 <http://www.healthwatchusa.org/conference2013/chambers/20131101-chambers.htm>
- Lisa McGiffert from Consumer Union on the Safety of Medical Devices. Webcast/Radio. Oct. 22, 2013 Listen to Webcast of Radio Show (Jack Pattie) Presentation. <http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20131022-CU-Medical-Devices/HWUSA-Radio-Giffert-Kavanagh.htm>

Research Integrity – Infectious Disease – MRSA Surveillance & Daily Bathing with Chlorhexidine

Health Watch USA has published numerous papers in peer reviewed journals on problems with research integrity influencing the recommendations regarding the effectiveness of surveillance. In the opinion of Health Watch USA, there has been a downplaying of valid evidence and the creation of false uncertainty regarding the use of surveillance and isolation to control Methicillin-resistant *staphylococcus aureus* (MRSA).

Health Watch USA is also concerned about the abundant research being published regarding effectiveness and risks of universal daily bathing of patients with the antiseptic chlorhexidine to prevent infections. Health Watch USA believes the research is riddled with conflicts-of-interest. In addition, the indications for daily bathing is primarily based on a single study which appears to have problems with spinning of the results, incomplete reporting of data and changing of metrics after study initiation.

Publications in Peer-Reviewed Journals – Infectious Disease Research Integrity

- Kavanagh K, Abusalem S. Mounting evidence supports universal surveillance for MRSA in preoperative patients. J Am Col Surg. 2011 Aug;213(2):335-6. PMID: 21787990
- Kavanagh K, Abusalem S, Saman DM. A Perspective on the Evidence Regarding Methicillin-resistant Staphylococcus aureus Surveillance. J Patient Saf. 2012 Sep;8(3):140-3. doi: 10.1097/PTS.0b013e3182627b89. PMID 22874134
http://journals.lww.com/journalpatientsafety/Fulltext/2012/09000/A_Perspective_on_the_Evidence_Regarding.6.aspx
- Kavanagh KT, Saman DM, Yu Y. A Perspective on How the United States Fell behind Northern Europe in the Battle against Methicillin-Resistant Staphylococcus aureus. Antimicrob Agents Chemother. 2013 Dec;57(12):5789-91. doi: 10.1128/AAC.01839-13. Epub 2013 Oct 7. PMID: 24100502 <http://aac.asm.org/content/57/12/5789.long>
- Kavanagh KT, Saman DM, Yu Y. Reply to "Planned Analyses of the REDUCE MRSA Trial". Antimicrob Agents Chemother. 2014 Apr;58(4):2486-7. doi: 10.1128/AAC.02821-13. PMID: 24643844 http://www.healthwatchusa.org/HWUSA-Publications/PDF-Downloads/20140318-Antimicrob_Agents_Chemother-2014-Kavanagh-2486-7.pdf
- Kavanagh KT, Calderon LE, Saman DM, Abusalem SK. The use of surveillance and preventative measures for methicillin-resistant staphylococcus aureus infections in

surgical patients. Antimicrob Resist Infect Control. 2014 May 14;3:18. eCollection 2014. PMID: 24847437 <http://www.aricjournal.com/content/3/1/18>

- Kavanagh KT, Calderon LE and Saman DM Viewpoint: a response to “Screening and isolation to control methicillin-resistant Staphylococcus aureus: sense, nonsense, and evidence” Antimicrobial Resistance and Infection Control 2015, 4:4 (5 February 2015) <http://www.aricjournal.com/content/4/1/4>
- Wu AW, Kavanagh KT, Pronovost PJ, Bates DW. Conflict of interest, dr charles denham and the journal of patient safety. J Patient Saf. 2014 Dec;10(4):181-5. PMID: 25408235 http://journals.lww.com/journalpatientsafety/Fulltext/2014/12000/Conflict_of_Interest,_Dr_Charles_Denham_and_the.1.aspx

Health Watch USA has also sent comments to the Agency for Healthcare Research and Quality (AHRQ) regarding its draft position paper on MRSA Surveillance. Health Watch USA believes the AHRQ paper was flawed and that surveillance and isolation should be among the highest level of recommendations for the control of MRSA.

- Comment on AHRQ position paper on MRSA Surveillance. Letter signed by 19 patient advocates and/or advocate organizations. Mar. 26, 2012. To view letter: <http://www.healthwatchusa.org/HWUSA-Initiatives/PDF-Downloads/20120325-4L-MRSA-CommentLetter-Final.pdf>

Presentations on Research Integrity.

- Kavanagh KT. The Status of MRSA Surveillance and Isolation. Health Watch USA 2014 Conference. YouTube Video: <https://www.youtube.com/watch?v=dgsQatT4f8I>

In addition, Health Watch USA has sent comments on a draft regulation to the FDA. The comments called for more research and data on the antiseptic chlorhexidine.

- Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record. Letter signed by 14 patient advocates and/or advocate organizations. May 1, 2015. To view letter: <http://www.healthwatchusa.org/HWUSA-Initiatives/PDF-Downloads/20150610-CommentToFDA.pdf>

Medical Overuse

Health Watch USA has been an advocate for curbing medical overuse. Kentucky has the highest rate of antibiotic consumption in the United States. This overuse is believed to be fueling the emerging epidemic of antibiotic resistant organisms. However, overuse permeates our healthcare system tests, medications and surgery. For some tests and treatments, estimates of overuse approach almost 50%. A common excuse for this overuse is defensive medicine or the fear of being sued. Health Watch USA analyzed Medicare billing data to determine if overuse was related to malpractice reform. The premise was that if a state has undergone significant malpractice reform, there should be less fear of being sued and lower medical utilization. However, this was not observed, and there was evidence that the reverse may even be true.

Publications in Peer-Reviewed Journals – Medical Overuse

- How I Was Prescribed an Unnecessary Antibiotic While Traveling to a Conference on Antibiotic Resistance JAMA Internal Medicine, Aug 4, 2014. Published Ahead of Print. <http://archinte.jamanetwork.com/article.aspx?articleid=1892183>
- Kavanagh KT, Calderon LE, Saman DM. The Relationship Between Tort Reform and Medical Utilization. J Patient Saf. 2014 Dec;10(4):222-30. [Epub ahead of print, 2013 Oct 7] PMID: 24104483
http://journals.lww.com/journalpatientsafety/Abstract/2014/12000/The_Relationship_Between_Tort_Reform_and_Medical.7.aspx

Opinion Editorials (Op-Eds) on Medical Overuse

- Kavanagh KT. Dr. Kevin Kavanagh: Overuse of antibiotics aids attacks of deadly bacteria. Lexington Herald Leader. May 9, 2014.
<http://www.kentucky.com/2014/05/09/3234330/dr-kevin-kavanagh-overuse-of-antibiotics.html>
- Kavanagh KT, Saman DM. Patients dissatisfied with unnecessary, expensive care. Herald Leader, Lexington, Kentucky, Jun. 25, 2012.
<http://www.kentucky.com/2012/06/25/2236895/patients-dissatisfied-with-unnecessary.html>
- Saman D, Kavanagh KT. Outpatient Antibiotic Utilization Highest in West Virginia and Kentucky. The Center for Disease Dynamics, Economics & Policy. Washington, DC, Nov.

17, 2011. [http://www.cddep.org/blog/posts/outpatient antibiotic utilization highest west virginia and kentucky](http://www.cddep.org/blog/posts/outpatient_antibiotic_utilization_highest_west_virginia_and_kentucky)

Presentations on Medical Overuse

- Peter Eisler, Medical Reporter from USA Today, Dan Smoot from Operation Unite and Dr. Kevin Kavanagh from HW USA discuss the epidemic of Drug Overdose in the Elderly. Jack Pattie Show (Radio) Jun. 10, 2014. <https://www.youtube.com/watch?v=ATAgjzAalGc>
- Dr. Arjun Srinivasan, Associate Director for Healthcare Associated Infection Prevention Programs, Division of Healthcare Quality Promotion, Centers for Disease Control and Promotion and Dr. Kevin Kavanagh, Chairman of the Board Health Watch USA, present on Middle East Respiratory Syndrome (MERS), Multidrug Resistant Bacteria and Antibiotic Overutilization. Jack Pattie Show (Radio). 2014 May 13th. <http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20140513-Arjun-Srinivasan/20140513-Srinivasan-Kavanagh.htm>
- Rosemary Gibson and Dr. Kevin Kavanagh from Health Watch USA discuss medical overtreatment. Jack Pattie Show (Radio) Mar. 11, 2014. <http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20140311-Gibson-TreatmentTrap/20140311-Gibson-Kavanagh.htm>
- Dr. John Santa from Consumer Union and Dr. Kevin Kavanagh from Health Watch USA discuss the ABIM initiative of Choosing Wisely. Jack Pattie Show (Radio) Feb. 11, 2014. https://www.youtube.com/watch?v=b8MON_8ZRRQ
- Rosemary Gibson. Overuse of Medical Care. Health Watch USA Conference. Nov. 1, 2012. <https://www.youtube.com/watch?v=6pRMII-vOGE>

Communications to the Public.

Health Watch USA has actively engaged the public with communications on health care issues. This has been accomplished through various modalities including: Newsletters, radio shows, webcasts and annual healthcare policy conferences. Coverage of Health Watch USA in the news media has included USA Today, NPR and Kaiser Healthcare News along with major Kentucky Newspapers. News articles can be viewed at: <http://www.healthwatchusa.org/HWUSA-Publications/HWUSA-In-The-News.htm>



Newsletter

Health Watch USA's newsletter has been published online since Sep. 2008. The purpose of the newsletter is to distribute links to resources and documents which have a major influence on healthcare policy. Common themes are healthcare transparency, healthcare finance, value-based purchasing, healthcare associated infections, hospital acquired conditions, medical devices, and healthcare acquired conditions. Currently, the newsletter is being distributed via email using PHP list. To view newsletters go to: <http://www.healthwatchusa.org/HWUSA-Publications/newsletters.htm>

Patient Safety Conferences

Over the last nine years, Health Watch USA has conducted a yearly patient advocacy conference in Lexington, Kentucky. Presentations have covered a wide variety of health policy issues dealing with patient safety, healthcare quality and finance. Many of the presentations have been recorded and videos posted on the internet for public viewing. www.healthconference.org



Speakers have included:

- USA Today Investigative Reporter Peter Eisler. Nov. 13, 2015; https://www.youtube.com/watch?v=NB3VVaO_GPs

- Steve Kraman, MD, Founder of the Full Disclosure of Medical Error Initiative. Nov. 1, 2013. <http://www.healthwatchusa.org/conference2013/kraman/20131101-Kraman.htm>
- Leana Wen, MD, MS (Current Health Commissioner, City of Baltimore). Nov. 9, 2012. <http://www.healthwatchusa.org/conference2012/videos-wen/20121107-wen-2.htm>
- Investigative reporter, Maryn McKenna. Nov. 11, 2011. <http://www.healthwatchusa.org/conference2011/mckenna.htm>
- John Santa, MD, Director of the Health Ratings Center for Consumer Reports. Nov. 11, 2011. <http://www.healthwatchusa.org/conference2011/santa.htm>
- Jim Battles, MD, Policy Advisor for AHRQ. Nov. 19, 2010. <http://www.healthwatchusa.org/conference2010/battles/2010-Battles1-2.htm>
- Past U.S. Surgeon General Joycelyn Elders, MD. Nov. 13, 2009. <http://www.healthwatchusa.org/conference2009/elders/2009-Elders-2.htm>
- Lisa McGiffert, Director of the Consumer Union's Safe Patient Project, <http://www.healthwatchusa.org/conference2008/2008-McGriffert-2.htm>
- Nancy Wilson, MD, Senior Policy Advisor for AHRQ. Nov. 20, 2008. <http://www.healthwatchusa.org/conference2008/2008-Wilson-2.htm>
- Helen Haskell, Founder of Mothers Against Medical Error; Nov. 1, 2013.
- Regina Herzlinger, Nancy R. McPherson Professor of Business Administration at Harvard Business School. Nov. 13, 2009.

More information regarding Health Watch USA's healthcare policy conferences can be found at www.healthconference.org



Radio Shows and Webcast

Health Watch USA's Board Chairman, Dr. Kavanagh, co-hosted a monthly radio show for just under six years on healthcare transparency, quality and finance. The show provided consumers information on how to purchase and obtain high quality healthcare. Guests have included:

- Leah Binder, President and CEO of The Leapfrog Group, a business purchasing alliance:
<http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20140708-Leah-Binder/20140708-Binder-Kavanagh.htm>
- Alicia Budd, MPH, CIC. CMS's Hospital Acquired Condition Reduction Program:
<http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20140820-Budd-Alicia/HealthWatch%20082014.pdf>
- Clifford McDonald, MD. Centers for Disease Control and Prevention. Presenting on C. Difficile: <https://www.youtube.com/watch?v=7geB8FQXXtQ>
- Conway P, MD, Chief Medical Officer of CMS & Shari Ling, MD. Deputy Chief Medical Officer of CMS: http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/PDF-Download/20130731-Conway_HealthWatch%20USA%20Meeting_073113.pdf
- Lisa McGiffert, Director of the Consumer Union's Safe Patient Project:
<http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20131022-CU-Medical-Devices/HWUSA-Radio-Giffert-Kavanagh.htm>
- Peter Pronovost, MD, PhD, Sr. Vice President for Patient Safety and Quality, Director of the Armstrong Institute for Patient Safety and Quality Johns Hopkins Medicine; Prevention of adverse events, hospital acquired conditions, checklists and quality Improvement in Healthcare:
<http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20140909-PeterPronovost/20140909-Pronovost-Kavanagh.htm>
- Rosemary Gibson, bestselling author of the Treatment Trap and Wall of Silence:
<https://www.youtube.com/watch?v=6MkNeEbtmOM&feature=youtu.be>
- John Santa, MD, Director of the Health Ratings Center for Consumer Reports:
<http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20140211-Santa-Choosing-Wisely/20140210-Santa-ABIM-Choosing-Wisely.htm>
- Arjun Srinivasan, MD (Associate Director for Healthcare Associated Infection Prevention Programs, Centers for Disease Control and Prevention - CDC):
<http://www.healthwatchusa.org/HWUSA-Presentations-Meeting/20140513-Arjun-Srinivasan/20140513-Srinivasan-Kavanagh.htm>
- Leana Wen, MD (Baltimore City Health Commissioner):
<https://www.youtube.com/watch?v=G2u-M1-UX-Y&feature=youtu.be>

Opinion Editorials (Op-Eds)

Health Watch USA has published numerous Op-Eds in statewide newspapers dealing with a range of national and local healthcare policy and patient safety issues. Many of these Op-Eds have been already mentioned in this report. For a complete list of Op-Eds, please go to <http://www.healthwatchusa.org/HWUSA-Publications/HW-USA-editorials.htm>

The picture on the right is of Dr. Leana Wen, current Baltimore City Health Commissioner, Dr. Joycelyn Elders, past U.S. Surgeon General and Patty Skolnick, Founder and CEO of Citizens for Patient Safety.



National Professional Activities, Awards and Related Activities

- Kevin Kavanagh, MD, MS, Health Watch USA Board Chairman, was appointed Associated Editor for the Journal of Patient Safety on July, 2014 and currently serves in this position.
- Kevin Kavanagh, MD, MS, Health Watch USA Board Chairman, has served on the Centers for Medicare and Medicaid Services, 2014 and 2015 Hospital-Acquired Condition (HAC) Reduction Program Technical Expert Panel (TEP).
- Kevin Kavanagh, MD, MS, Health Watch USA Board Chairman, for his activities with Health Watch USA was awarded the following from the Centers of Disease Control and Prevention:
 - CDC & ATSDR Honor Award Nominee. “For forging a novel partnership aimed at elimination of infections in healthcare settings and protecting patients.” Aug. 20, 2014.
 - Honor Award Certificate. National Center for Emerging and Zoonotic Infectious Disease. “For forging a novel partnership aimed at elimination infections in healthcare settings and protecting patients.” Jun. 28, 2014.