

# Health Watch USA 2015 Patient Safety Conference Nov. 13, 2015, Lexington Kentucky

Theme: Setting Standards for Ebola & Infections; Oversight and Safety of Medical Devices

## Conference Objectives

- To understand the importance of full disclosure and its importance to both the patient and in quality assurance.
- To become familiar with the reported safety problems of medical devices and how lax oversight and post marketing reporting has exacerbated medical quality problems.
- To understand the importance of having strong standards in the prevention of infectious disease.
- To develop insight into some of the healthcare policy problems which came to light during the Ebola Outbreak in the United States.
- To understand problems in and areas of deficiency in healthcare quality assurance.

## Keynote Speakers:

- 1) **Peter Eisler** Investigative Reporter for USA Today, presenting on the newspapers role in the assurance of medical quality.
- 2) **Kaci Hickox, MPH, RN**, Nurse and Healthcare Quality Advocate who treated patients with Ebola in Africa. She underwent mandatory quarantine upon her return to the United States, despite being asymptomatic and not having any history of a break in contact precaution protocols.

There will also be presentations by Dr. Richard Wild, Chief Medical Officer Atlanta Regional Office Centers for Medicare and Medicaid Services, Dr. Joycelyn Elders, past U.S. Surgeon General, Rice Leach Commissioner of Health for Lexington and Fayette County, Dr. Stephen Tower, Dr. Daniel Saman, Patient Advocate David Antoon, Patient Advocate Kathy Day, RN and Dr. Kraig Humbaugh, Deputy Commissure, Kentucky Department for Public Health.

## Agenda: Health Watch USA – Nov. 13, 2015 Conference

Introduction	Kevin Kavanagh, MD, MS	8:30 am - 8:45 am
Patient Advocacy and Personnel Stories	Daniella Nunez, David Antoon, Joyleen Chambers	8:45 am - 10:15 am
	Break	10:15 am - 10:30 am
Healthcare Standards and Ebola Preparation	Kevin Kavanagh, MD	10:30 am – 10:40 am
Safety of Nurses Treating Infectious Disease	Cokie Giles, MD	10:40 am – 11:02 am
Failures in Risk Communication to the Public with Ebola.	Kaci Hickox, RN, MPH	11:02 am - 11:25 am
The Lexington Ebola Experience	Rice Leach, MD, MSHSA	11:20 am – 11:45 am
<i>Panel Discussion on Healthcare Worker Safety and Ebola</i>	Steve Kraman MD, Rice Leach, MD, MSHSA Kaci Hickox, RN, MPH, Cokie Giles, RN.	11:45 am – 12:15 pm
	Lunch	12:15 pm – 1:00 pm
Assurance of Medical Device Quality	Peter Eisler	1:00 pm - 1:45 pm
Update on CMS Quality Assurance	Richard Wild, MD, JD	1:45 pm - 2:30 pm
Kentucky's Regulation for Reporting of Dangerous Infections	Kraig Humbaugh, MD, MPH	2:30 pm - 3:15 pm
	Break	3:15 pm - 3:30 pm
Medical Device Safety & <i>The 21<sup>st</sup> Century Cures Act</i>	Stephan Tower,	3:30 pm - 4:00 pm
How We Measure Urinary Catheter Infections	Mara Rice, RN	4:00 pm - 4:25 pm
The Importance of the Microbiome (Good Bacteria) in Maintaining Health.	Daniel Saman, DrPH, MPH, CPH	4:25 pm - 4:50 pm
Conference Summary	Marvin Feit, PhD	4:50 pm - 5:00 pm

## Presentation Titles and Objectives

### David Antoon

Title: Do we know if our hospitals are safe?

Objectives:

#1. Participants will be able to describe the responsibility and mission of major agencies in the oversight of our healthcare system. These include: Medical Boards, State Departments of Health, Insurance Companies, State Insurance Commission, CMS, HHS/Office of Civil Rights, Joint Commission and Courts.

#2. Participants will be able to identify lapses in effective oversight either related to industrial conflicts-of-interest or in lack of statutory authority in the above agencies.

CLE Objective #3: The attendee will understand concerns regarding implementation of the Social Security Act (CFR 42 Section 489.53) which requires concurrent notice to the public of facilities placed on payment termination tract.

### Peter Eisler

Title: Assurance of Quality and Safety of Medical Devices

Objectives:

#1. The participants will understand problems with exist in the United States Medical Device Reporting System, which has led to questionable reliability regarding device-related safety problems. These problems include:

- Poor compliance with FDA's Medical Device Report (MDR) requirements
- Lack of FDA/DoJ enforcement against device manufacturers who fail to disclose safety problems
- Poor tracking of MDRs, lack of oversight

#2. The participant will learn about the 510K approval process and associated problems of validation of medical device safety.

- Poor compliance with pre-market device certification requirements

- Lack of pre-market validation testing/data for new and/or modified devices
- Lack of oversight for companies that violate 510K clearance rules

#3. The participants will be able to discuss the problems in oversight associated with adulterated devices

- Weak government recall authorities
- Inadequate public outreach/notification mechanisms
- Spotty federal enforcement vs. bad actors

#4. The participants will be able to present a case study example regarding medical devices: The public health threat posed by contaminated endoscopes

- Devices allowed on market without 510 clearance or validated safety data
- Emerging safety problems unrecognized due to poor reporting
- Poor communication in notifying patients and medical community on public health risks

### **Cockie Giles, RN**

CLE Objective: CLE Objective #6. The attendee will develop an understanding how in the case of infectious disease and Ebola the “standard of care” was set to low, causing both patient and staff harm.

### **Kaci Hickox, MPH, MSN, RN**

Title: What is the biggest failure in the Ebola outbreak response - communication.

Abstract: You may be surprised when I say the biggest failure of the Ebola response worldwide and specifically in the United States is communication, but let's review the evidence. Previous experience and research tells us that the general population responds to public health threats based on leadership, clear communication of risks and activities to protect the public, and media sensation. This is no less true for the Ebola outbreak, and I remain concerned that if we do not begin to lead, we will never be able to win a battle against an infectious disease. The stigma, discrimination, and fear in the U.S. population has created a culture where the people most at-risk, in our case returning health care workers (and U.S. health care workers caring for Ebola patients), are not supported. I know that we can learn from these mistakes and thus be prepared as a nation to address the next public health threat in a comprehensive, strategic, and supportive manner. Communication is the key along with an intolerance of stigma.

Goals: Attendees will be able to describe how risk communication affects a population's ability to effectively respond to outbreaks of infectious disease.

Objectives:

#1. Describe the different persons or organizations that play a role in risk communication.

#2. Using the recent Ebola outbreak in West Africa as a case study, list three examples of failure to successfully communicate risk of the disease in the United States.

#3. List at least two negative consequences of stigmatization of those most at risk of developing an infectious disease during an outbreak.



**Rice Leach, MD, MSHSA**

Title: Lexington Health Department Response to Possible Ebola-2014

Goal: Describe the course of events when a person returned to Lexington from Liberia with signs and symptoms suggestive of Ebola infection. The need for this presentation is because many places have not had to implement a local response to a person with signs and symptoms of Ebola infection and meet the multiple requirements of different providers, agencies, and health authorities. The presentation will be approximately 15 minutes with a description of the event and a brief discussion of how previous experience contributed to a positive outcome

Objectives:

- #1. Appreciate/understand the benefits of long standing cooperation among essential players (local physician, large clinic senior management, local EMS, local health department, state health department, CDC, various consultants)
- #2. Appreciate/understand the benefits of a systematic response mounted by well trained and experienced participants
- #3. Appreciate/understand the benefits of open candid communication and discussion among the key players
- #4. Appreciate/understand the patient's concerns

**Richard Wild, MD, JD, MBA, FACEP**

Title: CMS Initiatives in Health Care Transformation: from Fee for service to Value Based Payment, Better care, Smarter spending, and Healthier people.

The professional practice gaps of the learners are: that many health providers are not fully aware of current and future changes in CMS quality and payment requirements for physician and hospital value based payment and how these policies may impact their practices. GOAL is to fill in those gaps of knowledge.

Objectives:

- #1. Provide health providers information about current and future reimbursement policies of CMS. Providers will obtain a better understanding of these policies.
- #2. Explain the rationale for these policies, so that providers will better understand how, why, and when these changes will/may be implemented.

#3. Provide providers with better understanding of how these policies may serve to transform and improve health care delivery and patient outcomes and thus equip providers to better prepare their practices to successfully embrace these changes. This is designed to change learners' competence, performance, and patient outcomes.

CLE Objective #1 Affordable Care Act: The attendee will understand federal regulations and policies regarding value purchase and facility incentives and penalties. (Presenter is Richard Wild, MD, JD (Member of the Federal US District court of RI and Massachusetts Supreme Judicial Court in good standing)

CLE Objective #2. Affordable Care Act: The attendee will understand concern over the implementation of ACA regulations regarding financial incentives for hospital acquired conditions and how this implementation may be suboptimal due to a flawed measuring system for catheter associated urinary tract infections.

**Kraig Humbaugh, MD, MPH**

Title: Prevention and Reporting of Healthcare Associated Infections (HAIs) and Multidrug Resistant Organisms (MRDOs) in Kentucky

Objectives

- #1. The attendees will be able to describe the characteristics of HAI outbreaks reported in Kentucky.
- #2. The attendees will be able understand the changes in Kentucky regulations regarding reporting of MRDOs and HAIs and why these changes were made.
- #3. The attendees will learn about the CDC's "Get Smart: Know When Antibiotics Work" initiative and how antibiotic stewardship is a key component in the fight against antibiotic resistance.

CLE Objective #5. 902 KAR 2:020: The attendee will understand the new Kentucky regulatory requirements for reporting of multi-drug resistant organisms

**Mara Rice, RN**

Title: Are We Measuring Urinary Catheter Infections Correctly?

Objectives

- #1. The participant will be able to discuss the importance of urinary catheter infections and the size and magnitude of the problem.
- #2. The participant will understand the important factors in preventing urinary catheter infections.
- #3. The participant will be able to explain how current measurement systems of CAUTIs may record higher infection rates in facilities which have dramatically cut their overall facility infections.

**Daniel Saman, DrPH, MPH, CPH**

Title: The importance of the guts microbiome in the prevention of disease.

Goal: To educate participants on fecal microbiome transplantation and its role in curing patients with Clostridium difficile infection

Objectives:

- #1. The participant will be able to describe how overprescribing antibiotics leads to C. diff infection.
- #2. The participant will understand the role of hospitals in reducing C. diff infections.
- #3. The participant will understand the importance of fecal microbiome transplantation and its role in curing patients of C. diff.

**Steven Tower, MD**

CLE Objective #4. The attendee will understand concerns regarding the 510k approval process and how this may be even further weakened with the *The 21st Century Cures Act* that has passed the House of Representatives and is going before the U.S. Senate.