The Growing Momentum for Improved Patient Safety and Protection

W41A, 30 August 2011 14:00 - 15:30

Start	End	Topic	Speakers
14:00	14:05	Introduction: Teaching Objectives	• Nancy Muller
14:05	14:20	Initiatives Across the U.S.	• Nancy Muller
14:20	14:35	Initiatives Across Europe	• Mary Lynne van Pomfret-Poelgeest
14:35	14:50	Initiatives Across Japan	• Kaoru Nishimura
14:50	15:10	Framing Issues: General Discussion	All
15:10	15:25	Patient Centeredness: What the future holds Globally for Patient Safety Concerns and Patient Advisory	All
15:25	15:30	Summary and Concluding Remarks	• Nancy Muller

Aims of course/workshop

1. To expose delegates to current initiatives on different continents aimed at addressing patient safety concerns that relate to continence care

2. To update participants in new directives for patient centered outcomes research, both in the U.S. and abroad

3. To place the patient needs and perspectives in proper balance with both scientific evidence and provider experience and judgment, using the complete definition of 'evidence based health care'

Educational Objectives

The educational value of this workshop is one of inclusiveness so that patient perspectives can be more fully considered by society members both in their daily interaction with patients and in their research objectives and activities.

The Growing Momentum for Improved Patient Safety and Protection

Speakers:

Nancy Muller, PhD (USA)
Lynne van Pomfret-Poelgeest Dr's (Netherlands)
Kaoru Nishimura, RN (Japan)

2011 Annual Meeting of the International Continence Society – Glasgow, Scotland

Workshop Agenda

- Introductions
- Initiatives Across the U.S.
- Initiatives Across Europe
- Initiatives Across Japan
- Framing the Issues (Input from Audience)
- What the Future Holds Globally for Patient Safety Concerns (Discussion)
- Summary and Concluding Remarks

Aims and Objectives

1. To expose ICS delegates to current initiatives on different continents aimed at addressing patient safety concerns that relate to continence care
2. To update participants in new directives for patient centered outcomes research, both in the U.S. and abroad
3. To place the patient needs and perspectives in proper balance with both scientific evidence and provider experience and judgment, using eh complete definition of *evidence based healthcare*

Introduction of Kaoru Nishimura, RN

•Founder and Chairperson of the Japan Continence Action Society and a director of the Japanese Society of Geriatric Urology
• Japanese Society for Dementia Care Board member
• Studied in England and returned to Japan as the country's first continence advisor in 1988
•Author of over twenty books on continence care and consultant for several continence clinics, known throughout Japan for her dedication to continence care
•Works with industrial designers to develop devices for individual patients with unique incontinence challenges
•Recognized with the 2006 AVON Award and the "Healthy Society Award" in 2007
•A member of the Continence Promotion Committee of the International Continence Society
•Member of the World Federation of Incontinent Patients Executive Committee.

Introduction of Lynne van Pomfret-Poelgeest Dr's

- **Since 1998 actively engaged in patient advocacy work promoting rights and interests of patients at both national (Dutch) and international level.**
- **Chairperson Netherlands Interstitial Cystitis Patients' Association**
- **President World Federation for Incontinent Patients - WFIP**
- **Member Continence Promotions Committee**
- **Various EU advisory functions in connection with patient advocacy work**

Introduction of Nancy Muller, PhD

- Received her Bachelor of Arts, magna cum laude, from Duke University and her Master of Business Administration from the University of Virginia
- Worked for 15 years for W. R. Grace & Co. in corporate finance, marketing, and international sales management, entering healthcare in 1992 as head of marketing for a medical products manufacturer
- Since 2000, she has been employed as executive director of the National Association For Continence in the U.S. During this time, she completed her PhD in health services research from Virginia Commonwealth University. She has published several dozen journal articles and writes a monthly column for the Journal of Ostomy Wound Management.
- She is Secretary of the World Federation of Incontinent Patients, on the Board of Directors of the Worldwide Fistula Fund, on the Visioning Board of the International Council on Active Aging, and a member of the ICS Continence Promotion Committee.

Patient Centeredness in the Pursuit of Safe and Cost Effective Healthcare: Today's U.S. Initiatives

Nancy Muller, PhD
Executive Director
National Association For Continence (USA)
World Federation of Incontinent Patients

U.S. Healthcare Challenge: High Cost + Shortfalls in Quality = Poor Value for Patients and the General Public

- To Err is Human: Building a Safer Health System (1999)
- Crossing the Quality Chasm: A New Health System for the 21st Century (2001)

The Leapfrog Group: Volume as the Solution

- Patients to be directed to hospitals and doctors who have performed the greatest volume of identical procedures
- Premise that high volumes are correlated with high expertise and thus high quality
- Assumption that costs will be lower by forcing concentration of specialized care, particularly on high risk procedures
- Payer-driven initiative, without patient input

Indeed there is evidence of specialization by community hospitals, in labor & deliver in particular

- Where should we be willing to make the tradeoff to provide access to experts? Is there evidence that costs are truly minimized by reducing access? What about rural areas?
- In highly prevalent conditions such as loss of bladder and bowel control, should the focus for optimizing care and cost not be one of maximizing access?
- When payers restrict access to care and access to advanced technology, is it because they don't value quality of life?

Patient Safety: Intertwined with Provider Fear of Litigation

- Providers calling for tort reform and ceilings on awards
- The re-writing of consent documents
- Patient advocates calling for a more narrowly defined consent, whereas providers are pushing for a wider consent: A central complaint by TRUTH IN MEDICINE regarding use of surgical mesh in pelvic repairs

Guiding Principles of Ethics in Health Care

- Autonomy
- Beneficence
- Non-malfeasance
- Justice

The Process of Informed Consent:

Necessity of recognizing that informed consent is shared decision-making involving the patient, physician, nurse, family, and all those with an ethical interest in the patient

Elements of Informed Consent

- Patient's capacity to understand and participate
- Disclosure of information (need to know) and the provider's recommendation of a plan
  - 1) Transparency by the provider(s)
  - 2) Comprehension of the patient – use of lay language
- Consent: 1) In favor of a plan 2) Authorization
- Exceptions: 1) Emergency 2) Incapacity 3) Patient waiver 4) Threat to self or others 5) National waivers (e.g., vaccination programs)
- Related issues: 1) Culture 2) Under age or mentally challenged

Disclosure: Informational Elements

- The nature of the therapy
- The purpose
- The risks and consequences
- The benefits
- The probability that the therapy will be successful (and a discussion of how "success" is defined)
- The feasible alternatives
- The prognosis if the therapy is not undertaken

The Incontinent Patient's Bill of Rights

1. Receive treatment
2. Have unrestricted access to services
3. Be given a correct and timely diagnosis
4. Obtain up-to-date information
5. Be given treatment options with freedom of choice
6. Participate in the decision process
7. Have access to quality therapy and medical care
8. Have access to public toilets
9. Have access to interdisciplinary care

Criteria Necessary for the Conduct of Ethical Medical Research

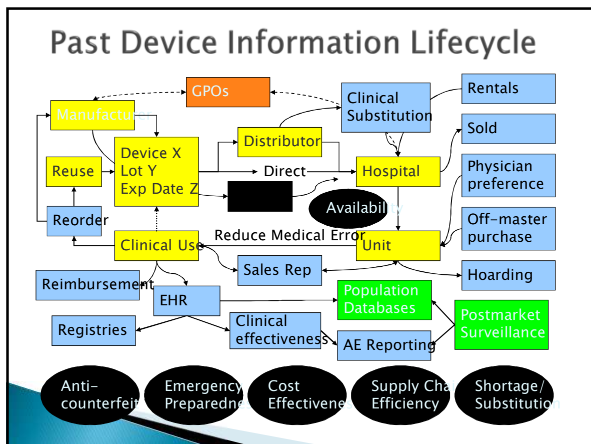
- Societal value
- Scientific validity
- Fair selection of subjects
- Favorable risk-benefit ratio
- Independent review
- Informed consent
- Respect for the subjects

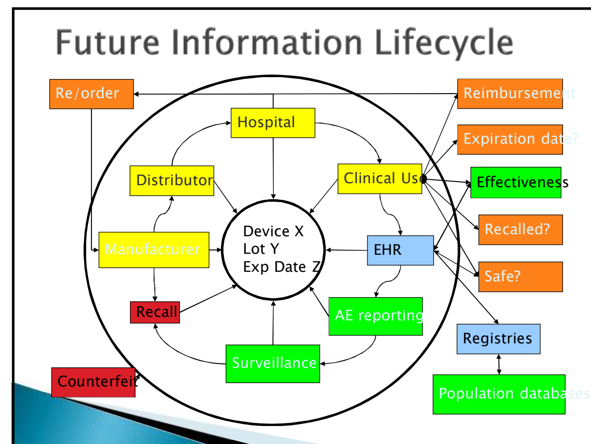
2007 FDA Initiative for Improved Medical Device Identification

Developed a system to identify medical devices, which is:

- Consistent
- Unambiguous
- Standardized
- Differentiated along all identification dimensions
- Unique at all levels of packaging
- Harmonized internationally

18





Cost Containment by Payers: Evoking Patient Safety as an Objective

- The estimated total cost of measurable medical errors in the U.S. was $17.1 billion in 2008, which was 1% of the $2.4 trillion spent on healthcare that year.
- In 2008, the Center for Medicare and Medicaid Services (CMS) began denying coverage for "never events" including hospital acquired UTIs, injuries from falls sustained while self-toileting during hospitalization, and hospital acquired pressure ulcers. Private payers are following the federal government.

Frequency and Costs of Medicare "Never Events" (2008)

MEDICAL ERROR	# of Injuries	Cost per Error	Total Cost (MM)
Pressure Ulcer	394,699	$ 8,730	$3,273
Catheter UTI	13,515	$24,901	$ 320
Object left in body	12,305	$ 8,031	$ 94
Blood type incompatibility	6,685	$ 5,911	$ 38
Air embolism	335	$26,100	$ 8

U.S. Hospitals Face New Pressure to Cut Infection Rates

- Under laws enacted in 2011 in half of all 50 states, hospitals are now required to report infections, risking their reputations as sterile sanctuaries, or pay a penalty to the government.
- About 90,000 patients still die each year from preventable infections resulting from routine surgeries and hospital care.
- Among the hospital acquired UTIs are infections following mesh sling surgery for SUI (approximately 9% of all cases)

The issues in summary:

- Access to expertise (and identifying who the experts really are) vs. local access to services
- Achieving transparency by the provider, with shared decision-making by the patient in a fully informed consent process
- Safeguarding ethics in research to minimize bias while including all parties in evidence-based input (published research, providers, patient)
- Mandating heightened post-market surveillance and tracking of adverse events
- The payer's role in reducing costs: priorities on reducing medical errors rather than cutting access to care and proven technology

Can Patient Partnerships Make Healthcare Safer?

Lynne van Pomfret-Poelgeest Dr's (Netherlands)

WORKSHOP – ICS 2011
World Federation of Incontinent Patients (WFIP)

If not a crisis, certainly a loss of public confidence

- Patients are the only constant in the continuum of care

Patient Safety System

- The system by which the governing body, senior leaders, managers and staff members share **responsibility** and are held **accountable** for the safety of patient care.
- From ***Boardroom*** to ***Bedside!***

Comparisons of Mortality

20000
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
MVA
SUICIDE
HAI

- Deaths per year in the UK

Why is patient safety important?

- Health care systems are missing opportunities to add additional safeguards if they fail to include patients and their families in their efforts to improve safety.
- Until the patient participates in their care, health systems reinforce the separatist care-giver vs. care- recipient notion of healthcare.
- Patients want a safe health care experience and want to help to make sure that happens.

Research in hospitals

Evidence-based report

Ineffective handovers can lead to:

- Wrong treatment, delay in treatment, severe adverse events, patient complaints
- Increase H/C costs, length of stay (and more)

System Culture Individual

Australian Council for Safety and Quality in Health Care. Clinical hand-over and Patient Safety Literature Review Report; March 2005. Available http://www.safetyandquality.org/clinhovrlitrev.pdf

30

Recent Research

12 Simulated Patients

5 consecutive handover cycles – 3 different styles

- Verbal handover resulted in loss of *all* data
- Note taking style resulted in loss of 31%
- Form with verbal handover resulted in minimal loss

Pothier, D. Monteiro, P, Mooktiar, M, Shaw, A "Pilot study to show the loss of important data in nursing handover". British Journal of Nursing, 2005, vol14, No. 20.

31

Another Pair of Eyes in the System

- Patients / family / carers can help prevent some mishaps if *actively* invited and given *consumer-friendly* tools
- Environmental safety
- Clinical safety

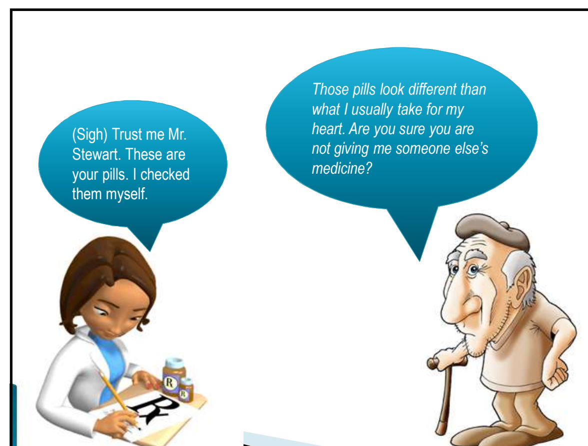
Does Consumer Involvement Improve Satisfaction?

- Hospital units that were more patient centered were associated with higher patient satisfaction

Bechel DL, Myers WA, Smith DG. Does Patient-Centered Care Pay Off? *The Joint Commission Journal on Quality Improvement* 2000; 26(7): 400-409

- Teamwork culture found to be positively associated with inpatient satisfaction

Meterko M, Mohr DC, Young GJ. Teamwork culture and patient satisfaction in hospitals. *Medical Care* 2004; 42(5): 492-498.

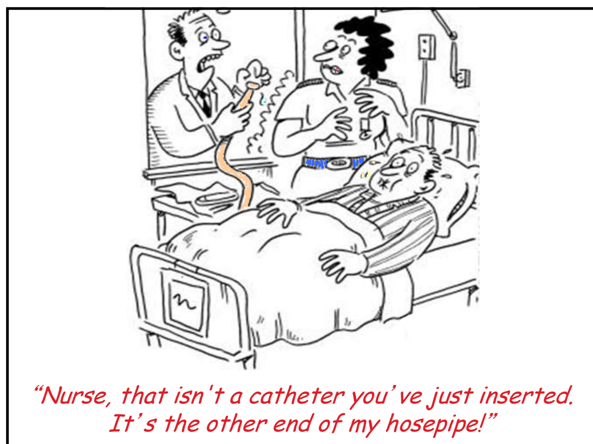


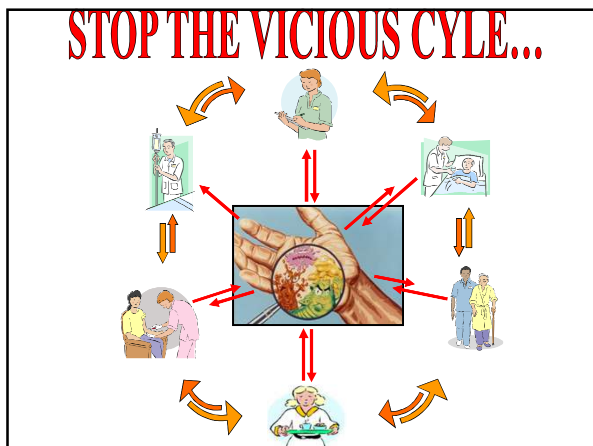
Barriers can inhibit patient / family / carer involvement

- **Fear**
  - Care may be compromised or they may be labeled a "problem"
- **Not "Invited"**
  - Speaking up not *actively* encouraged by caregivers
- **Speak-up expectations too overwhelming**
  - Consumers inundated with information

Overcome Barriers

- An organization-wide commitment with top leadership support is needed to overcome barriers
- Physicians and staff dislike being challenged or not trusted
- Physicians and staff fear that involving patients will take more time than is available
- Physicians and staff often don't recognize the safety value of involving patients/families

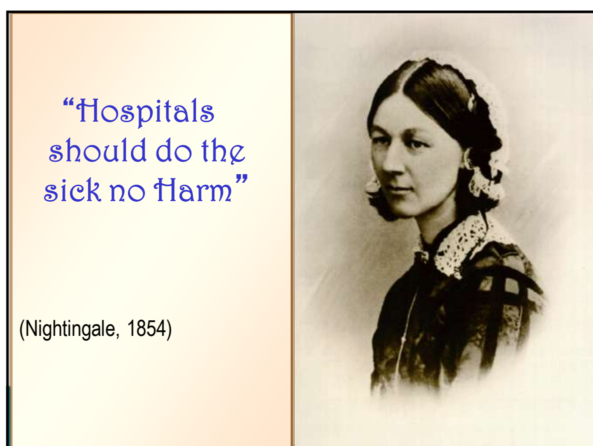




My mother was a smart woman and to witness the sharp decline in her physical and mental health was extremely distressing for all the family. We struggled to cope but it came clear that my mum required 24 hour nursing care.
Soon after she was admitted to a care home, my mum became incontinent as she was not able to find the toilet and was often uncooperative when attempts were made to take her. She started suffering from other conditions such as recurrent anaemia, for which she had to be admitted to hospital.

At the hospital she was catheterised, I asked why and they answered, 'to monitor her output'. Well I noticed that the bag was not emptied all day and she didn't have a record sheet. I expressed my concern and requested that the catheter be removed. It was removed after 24 hours.

The next morning, my mum seemed flushed. I asked a nurse to check her temperature and discovered to have low grade pyrexia. I again expressed my concern about UTI, and she was described antibiotics. Soon afterwards, she was discharged but in a few days, her condition deteriorated and she died peacefully a week later. The cause of death, Septicaemia secondary to UTI.



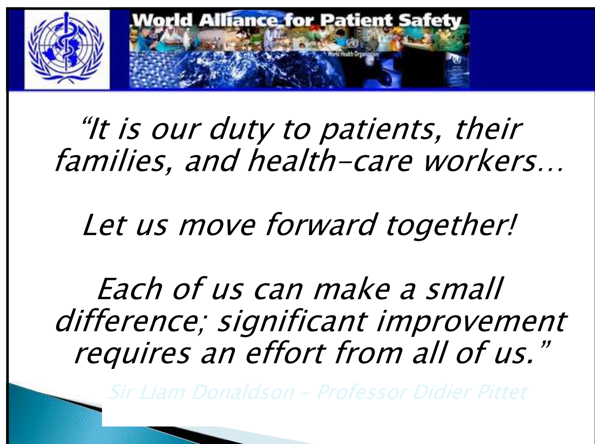
- "So far today,

I've changed 24 beds, dressed 25 wounds, emptied 10 urinebags, washed and dressed 16 patients, given 25 injections, bandaged 3 sores, removed 48 stitches and helped 10 people in a loo..

......You're Next!"

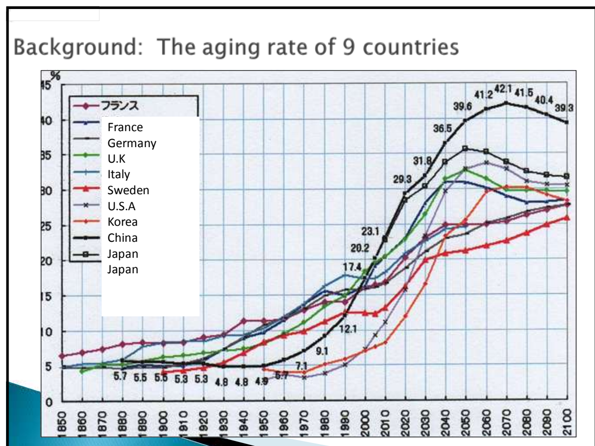
ASK YOUR NURSE OR DOCTOR:

"Have you washed your hands?"



Priorities in Japan: Concerns with Medical Errors and Lagged Access to Technology

Japan Continence Action Society
Kaoru Nishimura, RN



Background: Psychology of the Older Japanese Citizen

1. Patient
2. Restrained
3. Very respectful and accepting of authority
4. Not likely to resort to a legal action to settle a medical error

Statistics of Medical Errors Concerning Medication and Devices and Technology in Japan and the US

County (Investigation) (Report)	USA (1984) (1991)	Japan (1999-2000) 2000	Normal distribution (Z)	X2 (Yates)
Total Number	1.133	140		
Medicaちn	19.4% (220)	20.8% (28)	0.173	
Devices $ Technology	13.0% (147)	13.6% (19)Z	0.199	

T. Shibata 2003

Steps Being Taken to Reduce Medical Errors in Japan

Steps Being Taken to Reduce Medical Errors in Japan
A bill for the protection of the patient was introduced in 2006.
a. Right to be a party to his treatment.
b. Right to know and learn his disease
c. Right to receive the best treatment
d. Right to receive a safe treatment
e. Right to receive an equal treatment
f. Right to decide his own treatment
g. Right to be free from discrimination against his disease

Items being implemented by Medical Institutions

1. Enforcement of informed consent.
2. Acceptance of the patient to obtain a second opinion
3. Acceptance of the patient to review and copy his medical record
4. Protection of the patient's private information
5. Prohibition of improper restrant of the patient
6. Quick investigation and response to a medical complaint

Hotline service by JCAS During the World Continence Week, Between June 6 and 30, 2010

- 142 consultations were received. 66% of them had already received treatments by;
- urologist........70%
- gynecologist....10%
- gastroenterologist.......5%
- other..............25%
- Most of consultations were about explanation of treatments and relations with doctors

Drug Device Lag

- Fesoterodine not approved.
- Vaginal Ring Pessary- only one type of Ring Pessary is approved.
- TOT Operation Kit not approved yet.
- Artificial urethral sphincter not approved.
- Sacral nerve stimulation not approved by Ministry of Health, Labor and Welfare

Why Drugs and Devices Lag Other Countries

1.Japanese Ministry of Health , Labor and Welfare takes a long time to approve new treatment.
(Now I`m asking the reasons it takes such a long time for Japanese Pharmaceutical Manufacturers Association)

2.Japanese are very cautious about using new medical treatments.

Steps being taken to improve Drug and Device Lag

1.Lobbying activity by medical societies to the Ministry of H.L&W to speed up the approval
2.Collection of evidence data from clinical sites
3.Enlightenment of general public of the importance of continence care
4.Transmission of information by Mass Media

Framing the Issues Globally

What the Future Holds for the Patient

Workshop Summary

Our voices cannot be silent. We must work together and in unison. Despite the uniqueness of our separate nations, there is strength in collaborating as one, with the patients' interests at the center of our universe.