Let's look at your favorite kitchen utensil....

Design Exercise

- What do you like about the device?
- What don’t you like about the device?

Fill in up to 5 likes & dislikes of kitchen product on sheet NOW

Assignment #6: Part I

Overview of Product Evaluation

- Who regulates?
- Why do it?
- How to do it?

Image courtesy of Dr. June Fisher

In Health Care...

Both patient safety & healthcare worker safety are critical considerations when evaluating products

Interrelationship Between Patient & Healthcare Worker Health & Safety
Who Regulates Products?

- Environmental Protection Agency (EPA) - disinfectants
- Food & Drug Administration (FDA)
  (Not regulated for healthcare worker [HCW] safety)
  - medical devices
  - hand hygiene agents

Why Evaluate Products?

- To determine potential safety problems
- To ascertain if infection risk to patient or employee
- For cost-effectiveness
- As part of regulations (e.g., Needlestick Safety & Prevention Act)
- Because you might use them

What Types of Products?

- Urinary catheters
- Needle devices
- Soaps, waterless hand hygiene agents, lotions
- Cleaners, sterilizers, disinfectants
- Gloves, gowns, masks
- Numerous other examples

How do products get purchased?

- Individual institutions
- Group purchasing organizations

How is this Influenced?

Usual Process
- What is available on group purchasing list?
- Sales representatives demonstrating device to purchasing or managers

User-based Process
- Product evaluation committees (should involve front-line users)

What is Infection Control’s Role?

- Protect patients, employees, visitors
- Have input into product selection & evaluation using these goals
- Serve on committees (Infection Control, Safety, Product Evaluation)
- Work with other departments to assure user involvement
- Provide feedback to manufacturers re: design
Design in Everyday…
Work

Device Exercise

Questions

• Is is use apparent/intuitive?
• Does it work with ease?
• Is there a learning curve?
• Would use be apparent to a stranger in your kitchen?
• Are there any potential hazards?
  – Does it need to be kept away from children?
• Are there any built-in safety features?

Pioneer in Product Design & Evaluation for HCW Safety

June Fisher, MD
San Francisco, CA
Director, TDICT Project, Trauma Foundation, San Francisco General Hospital & Associate Clinical Professor of Medicine
University of CA, SF

General Considerations

• Usability
• Intuitiveness
• Adaptability
• Universality
• Skill
• Learning curve
• Safety/cleanliness

Questions

• Is it sanitary?
• Is it better than the previous device you used for the same purpose?
• Are directions necessary? Were these clear?
• Is it multi-functional?
  – Is it apparent?
  – Is there a compromise in design because of this?

Device Exercise

Dr. Fisher’s favorite:
(A love/hate relationship)
Let’s Re-evaluate your Utensil...
List some likes & dislikes using new criteria you just learned

Needlesticks in Healthcare Workers (HCWs)

- 600-800,000 needlesticks occur annually in HCW in the U.S.
- Safer medical device use, as part of BBP risk-reduction program, can ↓ sharps injuries
- CDC estimates 62-88% of sharps injuries prevented by use of safer devices

A Brief Chronology of Changing Perspectives on Sharps Injuries as an Occupational Hazard

Chronology of Changing Perspectives on Sharps Injuries as an Occupational Hazard

MID 1980s
Wider acceptance of universal precautions
Beginning attention to the concept of engineering controls

JUNE 1988
Safety butterfly designed by Steve Schoenberg
Early manufacturing interest in protected devices

LATE 1970s
McCormick and Maki research on recapping

EARLY 1980s
HIV emerges
Concept of Universal Precautions proposed

FDA approval of Hepatitis B vaccine (derived from blood plasma): Limited availability led to identification of high risk HCWs

Steve Schoenberg - Safety Butterfly (1988)
Images courtesy of Dr. June Fisher

Chronology of Changing Perspectives on Sharps Injuries as an Occupational Hazard
Chronology of Changing Perspectives on Sharps Injuries as an Occupational Hazard

JULY 1988
Jagger et. al – classic paper on epidemiology of sharps injuries

1990
Labor petition to OSHA for a blood borne pathogens standard

1992
First generation of safety syringes marketed

OSHA BBP Standard
1) Universal Precautions
2) Hepatitis B vaccine offered
3) Review of engineering controls (no mandate for use)

Chronology of Changing Perspectives on Sharps Injuries as an Occupational Hazard

MID 1993
FDA alert (re: Needleless IV systems)

MID 1990s
2nd generation of devices introduced

Chronology of Changing Perspectives on Sharps Injuries as an Occupational Hazard

1997
MMWR report on efficacy of safer devices

1999
CalOSHA BBP standard amended mandating the use of safer devices

Chronology of Changing Perspectives on Sharps Injuries as an Occupational Hazard

2000
Passage of federal legislation mandating
1) Use of safer devices
2) HCW involvement in selection

2001
Revision of federal BBP standard

Explosion of new devices

Needlestick Safety & Prevention Act, P.L. 106-430
Let’s review this document now

Recordkeeping: 1910.1030(h)
Sharps Injury Log
– Only mandatory for those keeping records under 29 CFR 1904
– Confidentiality
– Maintained independently from OSHA 200

https://upload.wikimedia.org/wikipedia/commons/3/34/Sharps_Container.jpg
Sharps Injury Log
At a minimum, the log must contain, for each incident:
• Type & brand of device involved
• Department or area of incident
• Description of incident

Summary of Provisions
• New requirements in the Exposure Control Plan, paragraph (c)
• Non-managerial employees involved in selection of controls, paragraph (c)
• Sharps injury log, paragraph (h)

HCW Resistance to Introduction of Engineering Controls to Prevent Occupational Blood Exposure
• Increased workload/short staffing/fatigue
• Unsatisfactory experiences with 1st generation devices
• Inadequate training/long training curves
• Available device may not be appropriate for certain clinical procedures
• Devices not consistently & easily available
• Lack of confidence in competency with device
• FEAR OF COMPROMISING PATIENT CARE

Training for the Development of Innovative Control Technology (TDICT) Project

The TDICT Project is a collaborative effort of healthcare workers, product designers & industrial hygienists dedicated to preventing exposure to blood borne pathogens through the design & evaluation of control technology.
Collaborating Institutions

- San Francisco General Hospital
- Product Design Program, School of Engineering, Stanford University
- Industrial Hygiene Program, University of California, Berkeley
- Dental School, University of the Pacific
- Bay Area Visiting Nurses Homecare Agencies
- American Nurses Association
- Occupational Health Branch, California State Department of Health

Why Involve Line Healthcare Workers in All Phases of Control Technology?

- Mandated by OSHA
- Tap their expertise
- Assure that product’s are user-friendly & truly effective
- Develop systems that improve compliance
- Improve employee morale
- Improve patient care

A User-Based Systems Approach for the Evaluation, Selection, & Institutionalization of Safer Medical Devices

June M. Fisher, MD
Director, TDICT Project

A Step Further...

Involve users in the process of design & evaluation

“Design Evaluation” Course

- 10 front line HCWs
- 24-hour course spread over 3 weeks
- 250 page text developed by TDICT with intro. to fields of Industrial Hygiene & Product Design
- Lectures, creative problem solving, guided product testing, discussion, & “take to work” assignments
“Design Evaluation” Course Success

“The course is so valuable. Without it I would never have been able to explain to you what’s wrong with this piece of equipment.”

Mary McGee, RN
Labor & Delivery, SFGH