

Teaching Safety Through Design In Biomedical Engineering Design

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Outline

- **ABET & Safety**
- **Methods for teaching safety**
- **New material**
- **Conclusions**

Senior Design at Vanderbilt

- **Two terms, 3 credits each**
- **Lecture 'till November**
- **Project work November->April**
- **Safety a major component via lectures, homework, final project report, ...**

ABET & Safety

ABET requirements: “Students must be prepared for engineering practice through the curriculum culminating in a major design experience ... that include most of the following considerations: economic; environmental; sustainability; manufacturability; ethical; health and safety; social; and political.”

Safety in BME Design - Lecture

- Safety in BME ...
 - “The human cost of medical errors is high. Based on the findings of one major study, medical errors kill some 44,000 people in U.S. hospitals each year. Another study puts the number much higher, at 98,000. Even using the lower estimate, more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS.”
- Nat'l Academy Press Catalog: To Err Is Human:

Safety in BME Design - Lecture

- Preventable hospital adverse outcomes cost \$25 Billion
 - medical treatments, deaths, lost wages, ...

FOR MORE INFO...

Bogner, MS Human Error in Medicine, 1994

Safety in BME Design - Lecture

- “The use of medical devices differs from the use of equipment in other industries in the range of characteristics of users”

FOR MORE INFO...

– Bogner, MS, BIT 33 No 2 April/March 1999, 105-108

Safety in BME Design - Lecture

- **Examples of adverse events**
 - blood glucose reagent strips - Denver CO
 - misloaded infusion pumps
 - walkers with hand brakes & wheels
 - air in infusion bags \Rightarrow air embolus
 - enteral pump misloaded
 - Geddes: Medical Device Accidents
 - Casey: Set Phasers on Stun

Safety in BME Design - Lecture

- **Iron law - if equipment is designed appropriately for human use in the first place, the cost may be high, but the cost is paid only once. If inappropriate designs must be compensated for in training...the cost is paid everyday. With inappropriate design ... no assurances**

FOR MORE INFO...

**Weiner, E, Congressional Testimony... Report 109, U.S.House
1988:65-71**

Safety in BME Design – Case Studies

- **Bring in to class apparatus implicated in the death of a young child due to air embolism, inform the class of the procedures used, ask for solution.**
- **Discuss the injuries received when a pressure limited respirator failed to alarm during a disconnect episode. Discuss the solution of this case.**

Safety in BME Design – Drugs/Materials

- **Discuss past drug problems, such as thalidomide & the need for testing. (Cover animal testing procedures.)**
- **Discuss the problems related to improper materials selections, such as in the early heart valve implants. (Cover introductory biomaterials.)**

Safety in BME Design – Quality Improvements

- **Guest lectures from hospital QA team, discuss the need for better blood/patient matching. (Introduce flowcharting.)**
- **Discuss the problems related to patient clinic flow patterns. (More flowcharting.)**

Safety in BME Design – Misc. Topics

- Discuss bad designs (www.baddesigns.com) (Introduce human factors.)
- Discuss the reasons for the FDA (The Jungle, Upton Sinclair)
- Discuss the reasons the FDA got into medical devices (www.mtn.org/quack).

Safety in BME ...

- 1998 competition announced for *designsafe* software, grant written & approved (V.U., U.MI, MI.T.U, Clemson)
- Grants sponsored by ISTD through the National Safety Council
- Obtain funding for one copy, several will be awarded. Must document use.

FOR MORE INFO...

<http://vubme.vuse.vanderbilt.edu/King/bme272.htm>

<http://www.designsafe.com/>

<http://www.nsc.org>

designsafe

- *dse has developed a fast, easy-to-use tool for engineers and safety professionals to incorporate safety through design by:*
 - identifying hazards
 - prompting engineers to think about hazards which they otherwise might overlook
 - conducting a risk assessment for identified hazards
 - reducing risks in a structured method
 - preventing accidents and reducing liability

designsafe

- **what it is...**

- an engineering tool for improving product designs and processes – fill in the blank (Excel Spreadsheet)
- a systematic method for conducting a task-based safety analysis – estimate risk and rate
- a technique for eliminating and controlling hazards – documentation of who is in charge of design corrections

designsafe

- Name: Laser surgery
- Description: Excision of tumors
- Analyst Name(s): Casper
- Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

designsafe - design mode

- **User** surgeon
- **Task** invasive surgery
- **Hazard** shock
- **Failure Mode** fault
- **Severity** Serious
- **Probability** Possible
- **Risk Level** High
- **Remedy** Eliminate by design
- **Status/Comments** to be done

designsafe - risk mode

- **Risk Level** High
- **User** maintenance personnel
- **Task** post operation
- **Hazard** hazardous waste handling
- **Failure Mode** varies
- **Severity** Serious
- **Probability** Possible
- **Remedy** Train user - other
- **Status/Comments**

designsafe Homework

- laser safety
- hip prosthesis
- surgical suit
- hip implant
- lithotripter
- needle stick
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designsafe in Final Report

- Final project paper: If applicable the results section must include a discussion of any safety issues regarding your project. Proper use of *designsafe* will ensure this (document).
- Generally good documentation and results...

Safety in BME Design – New Material

- 2002 AAMI Meeting – VA Lectures on Patient Safety and work done by National Center for Patient Safety (NCPS).
- Healthcare FMEA available free (www.patientsafety.gov/HFMEA.html)
- Root cause analysis (www.patientsafety.gov/tools.html)
- Will use next year...

Conclusions:

- **Safety is mandated by ABET, thus needs to be covered in BME design.**
- **Safety can be the key to tie much BME Design material together.**
- **Adequate resources exist to inexpensively give students the right tools for safe design.**