Teaching Safety Through Design In Biomedical Engineering Design

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Abstract: The importance of safety in design of biomedical engineering devices and processes in health and the environment can be covered in a variety of ways in a senior design course. Students can be initially sensitized to the necessity via a discussion of current literature (recent newsprint of accidents), via a discussion of the National Academy of Science publication "To Err Is Human: Building a Safer Health System", through a discussion of case studies from texts such as "Set Phasers on Stun" or "Medical Device Accidents", and/or through a discussion of clinical consulting cases. A review of methods for hazard analyses and fault tree analysis for hazard identification is useful if time permits, otherwise a more limited discussion and use of one or two techniques is recommended. The use of a structured safety analysis software package to provide student experience with safety analyses on both homework and on student design projects will be discussed in this paper.

Introduction: ABET requirements for design state that "Students must be prepared for engineering practice through the curriculum culminating in a major design experience based upon the knowledge and skills acquired in earlier coursework and incorporating engineering standards and realistic constraints that include most of the following considerations: economic; environmental; sustainability; manufacturability; ethical; health and safety; social; and political." That biomedical engineering design work would involve health aspects is obvious, to include the several aspects involving safety and the potential for liability requires some planned activities in terms of lecture content and student exercises. These activities, as performed in the senior design course at Vanderbilt University[1,2] are outlined in this paper.

Some of the methods employed include more traditional statistics, case studies and special topic lectures. An innovative approach that has proved successful has been to require that students complete a safety analysis using hazard analysis and risk assessment software under a grant from the Institute for Safety Through Design (ISTD).

Methods for Teaching Safety: The senior design course at Vanderbilt is a two semester three-credit hour per semester course. The initial portion of the Fall term consists of lectures by the instructor and guests on design topics and on proposed design projects. There are typically ten to fifteen homework assignments to provide practice in the lectured material. A final exam is given in early November; students are then expected to devote full class time for the remainder of the school year to their single or group design projects. The exam counts about 33% of the final

grade, proposals and progress reports about 10%, homework exercises count the remainder. Discussions of safety and exercises involving safety are interspersed throughout the year. Specific examples of this coverage include the following:

1. Medical Error Statistics

The recently published National Academy Press publication **"To Err is Human: Building a Safer Health System"**[3] has provided several notable statistics that are useful for introductory comments made at the beginning of the course, specifically regarding the number of deaths attributed to medical errors. This statistic permits comparing medical error deaths to the number of deaths due to other accidental causes, such as may be found from the National Safety Council website, and to the number of deaths due to specific diseases. The magnitude of the numbers serves to impress on the class the need for safety and good protocols. (Similar, but older statistics may be obtained from Bogner.[4])

2. Medical Case Studies

Specific references are made to incidents that cause patient injury or death. The class is invited to "solve" the problem after an initial presentation. In one scenario, based upon a medical accident, the students are presented with the particulars of the case: a young down's syndrome patient with multiple heart defects died from an air embolism during a preoperative cardiac flow/oxygenation catheterization study. The class is presented with the catheterization assembly and enough of the preoperative data to determine "fault" in the death. Class discussion not only is guided toward understanding how the air entered the patient, but also toward ways to prevent such an event in the future both specific to this incident and more generally in the design of medical devices. During the term, at least two to three other medical errors are discussed.

3. Drug Interactions and Materials

Major design problems in some devices and drugs have resulted from drug interactions and materials failures. The need for both animal and human testing for drug interactions and possible materials testing for implanted materials serves as a beginning point for discussions of these topics. Specifically, the drug thalidomide and some of the early experiences with heart valves deserve mention in discussions on historical problems.[5,6,7]

4. Quality Improvements

At least one lecture each year is given by personnel from the quality improvement department of the University Health Center. The lectures given cover process improvement work underway in the hospital, projects are proposed that will decrease risks to patients in the hospital. (Some of these become design projects.) Fault tree analysis was used in one lecture this year to illustrate the many potential contributors to a "bad infusion" process in certain patients.

5. Selected Topic Lectures

Selected lectures cover such topics as human factors and problems that result from bad designs, with illustrative examples.[8] Other lectures address the reasons for the development of the FDA, from discussion of patent medicines to discussions of quack medical devices, with their inherent risks to human safety.[9,10]

6. *designsafe* risk assessment software

A major emphasis on safety begins with the introduction of the class to a risk assessment software program named *designsafe*.[11] This program is introduced early in the first semester and is used by the students at least twice – once in a homework assignment and once to validate their own design projects. *designsafe* is a computer program that guides a user conducting a task based risk assessment by virtue of the structure of the prompts and menus presented during use of the program. The program is very systematic; users can do useful documentation and risk analysis after a minimal introduction to the technique.

The software package *designsafe* was made available to this course through a grant from the Institute for Safety through Design[12], which is part of the National Safety Council.[13] As part of its mission, the ISTD is actively working to integrate safety into engineering design curricula so that safety can be truly 'designed in' rather than remain a retrofit activity only after a design is complete. Sponsoring grants of the designsafe software is one of the ISTD's initiatives. The software grants remain available. Further information can be obtained at http://www.nsc.org/news/Nristd01.htm.

The *designsafe* software was first used in this course in 1998 and it has continued to be a mandatory part of the course since. The software has been introduced through at least two minor examples. A favorite example involves discussing the background of crush injuries and deaths caused by the shaking of drink vending machines by irate customers. The discussion and student comments lead very naturally to constructive use of the *designsafe* program to identify hazards, assess risks and develop risk reduction methods.

The software must also be used at least once in a homework exercise, one of which reads:

"Pick a biomedical device or process of your choice and do a complete safety analysis using designsafe.… . (Projects are permitted from those presented to the class and from exhibits from the FDA medical accident reporting site[14].)

Some of you may wish to generate a preliminary safety analysis involving your own design project. If you have not yet decided on a project, a medical device of your choice will suffice. Please be as thorough as possible (to include all users and tasks—hazard analysis & risk assessment.) If you choose a device or process with many extensive components focus on the most important part of the device/process. Please limit your analysis to about one page (this time.)"

Finally, student term projects and papers must include a safety analysis per the stated course requirement which is posted as: "If applicable the results section **must** include a discussion of any safety issues regarding your project, the proper use of *designsafe* will ensure this (document)." Although stated as an option, most student final reports must include this section; these may be seen in the archives section off of the course main web site, http://vubme.vuse.vanderbilt.edu/King/bme272.htm. Some sites are, however, password protected due to intellectual property issues.

Results of using *designsafe*:

Students generally have had little difficulty with the lectures and minor exercises involved with the use of *designsafe*. In the use of the program for their term projects, they generally adequately analyzed their problems correctly, but tended to be overly comprehensive in their inclusion of hazards. One group, for example, worked on a device for otological surgery in the school year 2000-2001. A portion of their *designsafe* final report may be seen below (original site is password protected):

designsafe Report

Application: Easy Fingers Otologic Surgery Tool

Description: Comprehensive End-User Analysis

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

		Initial Assessment Severity			Final Assessment Severity		
User / Task	**Hazard / Failure Mode**	**Exposure Probability**	**Risk Level**	**Risk Reduction Methods**	**Exposure Probability**	**Risk Level**	**Status / Responsible**
skilled user normal use	mechanical : cutting / severing When doing the normal use of the instrument, the surgeon could be injured by [cutting] himself while handling the instrument.	Slight Frequent Negligible	Moderate	gloves	Slight Frequent Negligible	Moderate	Complete [4/1/2001] Brian and Joy
skilled user normal use	ergonomics / human factors : repetition When doing the normal use of the instrument, the surgeon could be injured by repititious movements used in using the instrument.	Serious Frequent Unlikely	High	warning label(s), standard procedures	Serious Frequent Negligible	Moderate	On-going [Daily] Brian and Joy
skilled user normal use	health : blood borne diseases When doing the normal use of the instrument, the surgeon could be injured by blood borne diseases on the instrument	Serious Occasional Unlikely	Moderate	gloves	Serious Occasional Negligible	Moderate	Complete [4/1/2001] Brian and Joy
skilled user disposal	health : blood borne diseases When doing the disposal of the instrument, the nurse/tech could be injured by blood borne diseases on the instrument.	Serious Remote Unlikely	Moderate	gloves	Serious Remote Negligible	Low	Complete [4/1/2001] Brian and Joy

The students are rightfully concerned with such problems as blood borne diseases, ergonomics, and accidental injury to the surgeon, etc. The main problem from a teaching perspective and which is not shown here – is that they were so comprehensive that their final analysis ran 19 pages! Although extensive in length, their confidence in the results and understanding of the potential hazards is necessarily high. This type of breadth and depth in the analysis of a design is unusual and perhaps more than is required for a student project. Yet without the *designsafe* software, this level of analysis and understanding would not have been practical.

Students generally had no problem using this program and did do an adequate job of coverage of required topics. On a few occasions, they forgot the most important user – the patient! This was definitely called to their attention during the grading process.

Conclusion: Adequate resources exist to cover the necessary inclusion of safety topics in a senior biomedical engineering design course. These methods have been well received by students and have been effective in integrating safety into the design course. The above-discussed level of coverage is strongly recommended as a minimum, it has worked well at Vanderbilt University.

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BIBLIOGRAPHIC INFORMATION

[1] See http://vubme.vuse.vanderbilt.edu/King/bme272.htm for Fall term information
[2] See http://vubme.vuse.vanderbilt.edu/King/bme273.htm for Spring term information
[3] "To Err is Human; Building a Safer Health System", National Academy Press, 2000.
[4] Bogenr, M.S., Human Error in Medicine, Lawrence, Erlbaum Associates, Hillsdale, N.J., 1994.
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[7] Geddes, Leslie, 1998, Medical Device Accidents With Illustrative Cases, New York, CRC Press.
[8] See www.baddesigns.com for example.
[9] http://www.cyberus.ca/~sjordan/pmmain.htm
[10] http://www.mtn.org/quack/
[11] see www.designsafe.com
[12] see http://www.nsc.org/istd.htm
[13] see www.nsc.org
[14] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm

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