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Work-in-Progress: Teaching Responsibility for Safety in Bioengineering Design

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Abstract

Bioengineers who develop technologies for the medical and healthcare industries bear special responsibility for protecting people along the entire supply, implementation, and disposal life-cycle. Consequently, educators of future bioengineering professionals carry the responsibility for instilling the commitment and providing the knowledge needed to design for safety in the biomedical industry. This work-in-progress paper presents the concept of “Prevention through Design” as a means for designing safety into bioengineering innovations. The paper describes instructional materials that prompt consideration of possible hazards throughout a design project and discuss risk assessment methods for evaluating and systematically reducing hazards associated with different design alternatives. These educational resources enable engineering students to purposefully design safety into a technology.

Introduction

Biomedical engineers have clear obligations to design and implement technologies and practices that ensure the safety of people involved. ABET Engineering Criteria state that engineering graduates must understand professional and ethical responsibility and must be able to design a system, component, or process to meet desired needs within realistic constraints such as health and safety[1]. Further, the Biomedical Engineering Society code of ethics states that biomedical engineers “use their knowledge, skills, and abilities to enhance the safety, health, and welfare of the public.”[2] Clearly, the ability to design and utilize technologies safely and to minimize the occurrence of equipment and procedural failures that can affect the health and well-being of the public are of paramount importance to engineers in the biomedical field.

A decade-old report from the National Academies points out that medical errors may result in 98,000 human deaths each year, more than die separately from motor vehicle accidents, breast cancer, and AIDS[3]. As the number five cause of death in the United States, the safety of medical devices and practices must receive the highest attention of biomedical engineers. Engineers must be sensitized to the importance of safety issues, be prepared to recognize and evaluate safety risks, and be able to develop improved technologies and practices that reduce hazards.

The National Institute for Occupational Safety and Health (NIOSH), the research and education arm of the Centers for Disease Control and Prevention (CDC), has launched a major effort to reduce safety risks in the workplace, including biomedical and healthcare settings. The Prevention through Design (PtD) initiative seeks to prevent and control occupational injuries, illnesses, and fatalities by "designing out" or minimizing hazards and risks early in the design process.[4] More specifically, the concept of PtD is defined as: “Addressing occupational safety and health needs in the design process to prevent or minimize the work-related hazards and risks associated with the construction, manufacture, use, maintenance, and disposal of facilities, materials, and equipment”. This concept embodies a philosophy that the engineer has a responsibility to minimize health and safety risks, strategically, systematically, and comprehensively.

Curriculum Materials

Adoption of new instructional materials or methods in biomedical engineering education requires that the new instructional resources align with Diffusion of Innovations theory.[5] To be readily adoptable, new instructional materials must demonstrate relative advantage and observable improvements in student learning. They must be easily tried by faculty, fit with current instructional practices, and be usable without much training. The authors chose to develop three Prevention through Design lessons, in PowerPoint format, designed to be easily incorporated into existing biomedical engineering courses and structures—minimizing faculty investment required to adopt the resources. These lessons highlight the severity of safety issues, provide tools for assessing risk, and enable students to achieve significant risk reduction in their existing projects—empowering students to realize significant reductions in safety risks in current and future projects. Thus, these resources offer recognizable potential for improving the capability of biomedical engineering graduates for confident, safe design.

Three 50-minute lessons introduce the PtD concept, teach basic risk assessment and control methods, and apply the PtD process to reducing risk in projects in which students have a significant investment. Lessons are designed for use in collaborative learning settings where group processing increases depth of learning and retention of knowledge.[6] Stories of serious safety lapses are used to make students aware of hazards and to motivate students to find solutions to problems characteristic to biomedical devices and procedures. The framework presented for risk assessment and control gives student a basis for quantifying risks, focusing design activities on high risks, and documenting improvements to safety. Lesson materials are downloadable without cost for use by others.

Lesson 1: Why Prevention through Design?

The first lesson seeks to prepare graduates with a safety consciousness and a competence in designing for safety in a business context (i.e., beyond the classroom). In this lesson, students discuss the types of hazards that can exist in the biomedical workplace, common sources of accidents, and ways to address them. They discover that prevention through design is the best alternative for reducing workplace accidents and injuries. They also learn the roles of different federal agencies, and they hear that the National Institute for Occupational Safety and Health (NIOSH) promotes Prevention through Design as a means for reducing workplace injuries. They learn about the Hierarchy of Controls per ANSI/AIHA Z10-2005, which shows "design the hazard out" to be the approach that makes the most health and business sense.[7] The Prevention through Design concept is discussed in the context of each stage of the engineering design process to illustrate how PtD is evident throughout design activity, but best able to influence safety when applied in the earliest stages of design.

The final section of lesson 1 uses case studies to put faces on the consequences of safety failures. Three video cases discuss the hazards of needle sticks, hazardous materials, and surgical fires. Students see how accidents impact people's lives. They also learn about subsequent actions taken to protect people from similar hazards in the future. The emotional impact of these videos creates personal commitments to designing for safety. The lesson ends with a quiz to determine its impact on student learning.

Lesson 2: Risk Assessment for Injury Prevention in Design Projects

The second lesson seeks to prepare graduates with commitment and tools to design for safety. Students explore tools for assessing risks of failure and risks of injury from potential hazards in the bioengineering workplace. Consistent with the definition of Prevention through Design, they learn to identify potential hazards and design to prevent the occurrences of accidents and injuries for the benefit of everyone involved. Factors affecting level of risk include: (a) likelihood of the dangerous event occurring, (b) severity of the potential impact on a person, (c) number of people who might be impacted, and (d) extent to which the impacts are controllable.

Two types of risk analysis are discussed in detail. The first examines risks of failure (a system or process or device failing to perform as intended)—important in design for reliability. MIL-STD-1629A Failure Mode, Effects, and Criticality Analysis (FMECA) is used to assess reliability.[8] Students apply the FMECA method to an example student design project to see how it guides designers to a more reliable design solution. The second type of risk analysis discussed is safety risk analysis. The risk assessment and reduction process begins with embracing a Prevention through Design philosophy, identifying and assessing potential hazards, and reducing identified risks. Risk reduction design efforts seek first to design the risk out, then to erect physical safeguards, next to establish procedural safeguards, and finally to specify personal protective equipment and post warnings of hazards.[9]

Students in small groups perform a risk analysis for an example design project using ANSI B11.0.[10] They are introduced to a table of likelihood of occurrence or exposure vs. severity of illness or injury published by the American National Standards Institute (ANSI) for assessing conditions in workplaces. ANSI Z10: Risk Level and Remedial Action standard defines remedial actions based on combinations of likelihood and severity.[11] Through this exercise, students realize that risk reduction can result from reducing the likelihood of failure (more robust design), reducing frequency of exposure (separation from point of danger), or reducing severity (using protective equipment). Lesson 2 ends with a quiz to determine student learning from the lesson.

Lesson 3: Implementing "Prevention through Design" in Projects

The third lesson seeks to prepare graduates to apply Prevention through Design to engineering design projects to which students have ownership, typically team projects in a senior design class. Lesson 3 begins with a review of principles and methods used in Prevention through Design. Then students are shown a simple table of hazard probability vs. severity as published for the healthcare industry, the Healthcare HFMEA™ Hazard Scoring Matrix.[12] This matrix emphasizes that risks must be very low to be acceptable in the healthcare industry.

Student teams are guided through a process of risk assessment and reduction for their design projects. With the ANSI B11.0 scoring scales for likelihood, frequency, and severity in hand, teams identify hazards in their design that are of overt, functional, or failure types or that may occur as a result of misuse. Teams construct a table for documenting data used in risk assessment and reduction, including: deriving a risk score, defining an action plan, revising the risk score, and specifying an outcome measure. During the class time, teams perform an initial risk assessment for a few hazards in their design, determine if these risks justify redesign, propose design changes, and re-assess the risk. They then reflect on the importance of Prevention through Design and its value to themselves, their employers, and society in the future. The lesson ends with a quiz to determine how this lesson has affected individual students' attitudes and understanding of Prevention through Design.

Summary and Conclusions

Three lessons on Prevention through Design are presented as instructional resources to motivate and empower bioengineering and biomedical engineering students for designing safety into technologies. The lessons align well with principles for adoption of innovations, which suggests that safety-related innovations will be utilized readily by engineering faculty concerned about safe biomedical technologies. The first lesson, focused on the need for safe designs, is readily adaptable to introductory non-project based courses in bioengineering. The second and third lessons, focusing on principles and methods for reducing safety risks, are most applicable in senior level design project courses where students engage heavily in design. Together, this three-lesson Prevention through Design module offers tools to assist faculty in preparing bioengineering and biomedical engineering graduates for responsible design of safety into biomedical technologies.

These materials are available for download from the website of Washington State University's Voiland School of Chemical Engineering and Bioengineering:

http://voiland.wsu.edu/research/research_Prevention_through_Design.html

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