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Design and Biomedical Engineering*

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This paper provides an overview of the status of design (upper level courses and related industrial and governmental support) in the undergraduate biomedical engineering curriculum in the United States. A brief history and overview of the biomedical engineering curricula at Vanderbilt is given as an example of the genesis of such a program. The content and structure of the design course at Vanderbilt is then covered, with mention of the structure and topics covered by other representative universities. Several recent phenomena that will impact all such programs, but largely the design courses, are then discussed. These include internships, the new accreditation criteria, and private and governmental support of research and design activities in biomedical engineering programs.

INTRODUCTION

IT IS THE GOAL of this paper to present a general discussion of the topic of design and biomedical engineering oriented to the interests of manufacturers of biomedical devices as well as to the interests of educators in the field [1]. This will be accomplished through a review of the history and structure of an undergraduate curriculum in biomedical engineering, by a discussion of undergraduate design in this curriculum, and by a discussion of some of the major current trends in support of biomedical engineering throughout the United States. It is anticipated that this information will be of special value to potential employers who might be considering collaborating with university biomedical engineering departments and/or hiring their graduates. This will be accomplished by covering the following items in sequence:

- Enrollments and composition of BME programs (US).
- Academic thrusts of BME.
- Design in BME—overviews.
- Internships in BME.
- ABET 2000 and BME.
- NSF, Whitaker, NIH.
- Future directions.
- Conclusions.

The majority of the discussion to follow is aimed at the undergraduate thrusts of various programs throughout the US, as it is felt that this contingent is of greatest import to industry.

ENROLLMENTS AND COMPOSITION OF BME PROGRAMS (US)

The undergraduate program at Vanderbilt is typical of some of the early undergraduate programs in Biomedical Engineering. The department was first granted permission to offer a degree-granting program in 1969 when two students graduated. For many of its early years, it graduated about 10% of all BME undergraduates in the USA; this figure is now about 6% of all BME undergraduates in the USA. Sixty students graduated in 1998. Figure 1 gives data for our program in five-year averages since 1970. It is apparent that the program has grown rapidly, and shows no apparent sign of leveling off. Our University does have a cap on the various schools' enrollments, our 320 BME undergraduates out of an 1100 maximum engineering undergraduate college population is likely close to what we will see as our maximum.

Another item of importance, also to be seen in this figure, is that the placement data for our students has changed dramatically. Our initial students overwhelmingly went to Medical School upon graduation; our curriculum initially was slanted toward this as a career goal. Our placement data currently shows that about 70% of our students go directly into engineering work (BME, EE, ChE, etc.), with 20% going to Medicine and 10% going to other fields (teaching, physical therapy, business) Our curriculum has changed to support this change in placements; the standard 'professional track' curriculum may be modified to allow attainment of premedical requirements as desired, or may be used to achieve a dual major program with another department, such as Electrical Engineering.

These trends have been mirrored nationwide. Table 1 lists sixty nine academic programs in BME (data mixed, as of ~1995.) Of these, at least 21 are currently accredited by ABET, which implies that at least those curricula have a significant design thrust to their undergraduate program. In most cases, this is accomplished with a senior year design course. (In fact, there are at least 26 design courses on the web, as may be seen at: http://

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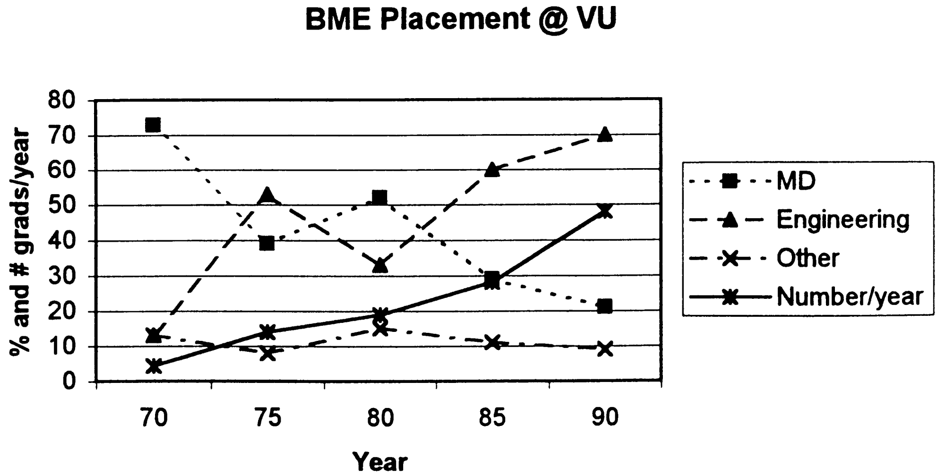

Fig. 1. Biomedical engineering student placement at Vanderbilt, 5-year averages.

vubme.vuse.vanderbilt.edu/King/BME_design_links.htm There were at least 5000 undergraduate students listed in this chart, ranging from 753 at University of California at San Diego to a low of 55 at Catholic University. Extrapolating, this translates into approximately 1000 Biomedical Engineering graduates per year from accredited programs in this country, all of whom have had some design experience.

Having advised BME students for many years, I have had to tell the students that they must educate their prospective employers as to their skill set. This was during the years when 45,000 electrical engineers graduated per year, and only hundreds of BMEs graduated, most of whom went on to Medical School. Many of these current graduates are candidates for employment in the medical design and manufacturing industry; it is one of the goals of this paper to cover this possibility.

ACADEMIC THRUSTS—BME

Our Biomedical Engineering curriculum at Vanderbilt is typical of many such programs and requires the following:

- math: 17 semester credits (calculus, differential equations, statistics)
- chemistry/physics/biological science: 24 credits
- electrical engineering basics: 11 credits (minimum)
- biomedical engineering core: 28 credits

Table 1. Academic programs in biomedical engineering

Ala. at Birmingham+	Illinois at U-C	Southern California
Allegheny	Iowa*	Stanford
Arizona State*+	Kentucky	Syracuse*
Boston*	Louisiana Tech*+	Tennessee, Memphis+
California State	Marquette*+	Texas A&M*
California, Davis	Memphis	Texas at Arlington+
California, San Diego*+	Mercer	Texas at Austin
California, San Francisco & Berkeley	Miami*	Toledo
Carnegie Mellon	Michigan	Trinity College
Case Western*	Milwaukee Sch. of Eng*	Tulane*
Catholic U.*+	Minnesota	Utah
Cincinnati	North Carolina	Va. Commonwealth
Clemson	North Dakota State	Vanderbilt*
Columbia	Northwestern*+	Vermont
Connecticut	Ohio State+	Virginia
Drexel	Pennsylvania State	Washington
Duke*+	Pennsylvania*	Washington, St. Louis
Florida	Pittsburgh	Wayne State
Georgia Tech+	Purdue - Indiana	Western New England
Hartford	Rensselaer Polytechnic*	Wisconsin
Hofstra	Rice	Worcester Polytechnic+
Johns Hopkins*	Rochester	Wright State*
Illinois at Chicago*+	Rutgers	Wyoming

* Undergraduate biomedical engineering/bioengineering program accredited by the Accreditation Board for Engineering and Technology. Source: http://fairway.ecn.purdue.edu/v1/bme/academic/grand.html
+ Indicates programs with a Whitaker supported internship program. (MIT not included above also has an internship program.) Source: Whitaker Foundation.

- approved electives (premed, engineering, other): 11 credits
- program electives: 7 credits
- humanities and social sciences: 18 credits
- open electives: 6; introductory engineering and computing: 7 credits.

With a minimum of additional hours, a student may pursue both the Biomedical Engineering degree and Electrical or Chemical Engineering. Alternatively, a student may meet medical school requirements with a simple selection of the required coursework, which may be accomplished with no additional hours of coursework. A second major with Math has been a favorite path for many students in the past, students pursuing a second degree with Mechanical Engineering or Computer Science have been rare. About 20 to 30% of our current graduates pursue the option of a second degree major.

DESIGN IN BIOMEDICAL ENGINEERING, OVERVIEWS

Recently, the Whitaker Foundation announced a competition to develop new and profession specific textbooks for Biomedical Engineering. One of the requests for proposals included a request for textbooks in the area of design. A brief listing of the design components required in the text proposal follows [2]:

- device design from need recognition through marketing
- team formation & management
- specification
- conceptualization
- prototyping
- testing,
- safety considerations
- animal and human clinical trials
- optimization
- materials selection
- manufacturing and quality control
- economic issues
- marketing
- legal issues
- ethic considerations
- government regulations
- other related issues at a minimum.

The Whitaker request left open the possibility that the text could be electronic in nature (web-based), the likelihood is that it will be paper-based. One will also note that, from the outline, the textbook proposal is very similar to the text by Fries [3], it would of necessity be written on a more student-tutorial basis. It is noteworthy that this work by Whitaker is a first professional attempt to clearly define the required structure for design in the profession.

How is design currently being taught at the University level? Vanderbilt's catalog description is fairly representative:

Design of biomedical engineering devices and systems
This is an integration of the engineering and life science backgrounds of senior biomedical engineering students through the presentation of design principles and case studies of medical devices and systems. A semester (plus) design project is required, with oral, written and tangible communication of work performed.

A look at various courses around the nation (see earlier design link) will indicate that many of the courses are two semesters in length, with a small percentage only one semester. The method of instruction will also vary from institution to institution; our process is outlined below.

- Web-enhanced—most communication and documentation is web-based (v. paper only).
- Lectures by instructor: safety, consulting, professionalism, brainstorming, reverse engineering, forensics, informatics.
- Short project (3 week, team based).
- Homework assignments (~ 8).
- Guest lectures—safety, patents, clinical trials, jobs, QA/QI, databases, internships, projects.
- Semester plus project (proposed by faculty, industry, physicians, etc.), reporting—oral, web, proposal, progress reports, poster, final paper, prototype if feasible.

To support the design course, we supply the followingdesign facility items:

- *Software:* Microsoft *Office Professional*, Microsoft *Visual Studio, Designsafe*, Microsoft *FrontPage 98*, Microsoft *NT 4.0,* copies of ABC *Flowcharter*, Microsoft *Project 98, Electronics Workbench,* and *Working Model* 2D and 3D. We plan to add *SolidWorks* and *TechOptimizer* as soon as we can get a site license (*SolidWorks*) and educational price (*TechOptimizer.)* A computer design facility is proposed in a new building.
- *Hardware:* facility and network (backbone, Internet 2) for 11 computers, model shops, machine shop, design lab (workbench, hood), digital video cameras (ViCAM), personal labs of project proposers Access to a stereolithography unit will be solicited in the future.

At Vanderbilt, projects are solicited by sending a request letter to past sponsors and likely sponsors, on campus and off, academic and industrial. One or two projects each year are student-proposed, due to personal interest in some project that has not been proposed by others. A requirement is that a mentor must be found, even for these projects. *No* 'canned' projects are listed or allowed, all projects must fulfill a real need. (This varies at other schools.) Most projects are single device or process driven, but some projects are strictly single assistive technology or rehabilitation projects. In these cases, at Vanderbilt, the assistive projects generally involve multiple small projects relating to one or more patients or students. For the 1998–1999 academic year at Vanderbilt, our current statistics are: 53 students enrolled; there were 36 people proposing projects.

The projects fall in the following categories: Device development—20; System/process development or Improvement—12; Database and related—18; Rehabilitation/special—23, for a total of 73 projects. Without the support of the community with real projects, the use of canned projects might become a necessity.

Representative projects this year include [4]:

1. Fetal stabilizer design: a surgical clamp is under development to allow access for spinal bifida surgery.
2. Development implanted glucose sensor: two students are working with an electrical engineering professor to develop a diamond-coated glucose sensor.
3. Ossicular prosthesis design: three students are working with a surgeon in otolaryngology to develop an ossicular prosthesis.
4. Steerable catheter design: two groups of two students are working with a cardiologist to develop a steerable catheter for treatment of cerebrovascular aneurysms.
5. FEL guidance system for orthopedic applications: two students are developing a guidance/control system for our free electron laser system to enable accurate bone cutting in surgery.
6. Voice controlled wheelchair: three students are working with a parent who has a need to develop a system for voice control of a wheelchair by a child with cerebral palsy.

Other universities have their own particular slant on their list of design projects, for example the web site at Tulane lists the following projects for 1998:

- rocking chair assist device development;
- foot-assisted toothbrush device development;
- office ergonomics study to assist a specific individual;
- car egress assist device;
- light switch assist device.

As may be noted, most projects are in the general area of rehabilitative or assistive technology.

In contrast some example projects from the University of Connecticut in 1998:

- talk aid
- remote environmental control
- motorized mobility device
- digital hearing aid development
- education station
- improved automated mailer for postage.

These indicate the mixture of topics available in their design course.

INTERNSHIPS IN BIOMEDICAL ENGINEERING

This paper and presentation is not meant to review some of the classical methods of support for Design in Biomedical Engineering, such as:

- SBIR (Small Business Innovation Research Program) support;
- the several years' old NSF Senior Design Projects to Aid the Disabled;
- the recent, but generic NSF GOALI (grant opportunities for academic liaison with industry) program;
- general NIH support;
- industrial support of BME design projects on an ad-hoc basis.

Instead, it is meant to cover some of the most recent events and trends that will impact on design, industry, and the universities. The sponsorship of internship programs is very high on the list of recent developments.

A formal structure for this endeavor has been developed by the Whitaker Foundation. The program, just now three years old, is titled the Whitaker Industrial Internship Program. The Foundation states in its proposal:

> Biomedical engineers who work in industry are playing an increasingly important role in the conception, design and manufacturing of healthcare products. To assist biomedical engineering students who plan careers in industry, and to familiarize companies with the capabilities of biomedical engineering students. The Whitaker Foundation invites applications for its industrial internships program [5].

Funding for this effort is allowed up to about $60,000 per year. This funding is aimed at developing and supporting an infrastructure at a university that will assist in the development of a meaningful internship program for biomedical engineering students in industry. About fifteen program development grants have been given to date. The general criteria require that the requesting program is accredited (or nearly so), that the program be well thought out with industrial support in place, and that there is a means of evaluating the process. Programs with multiyear support (such as the Arizona State University) report a phenomenal success in student placement and satisfaction, and a high (70% or better) student placement rate. Support of these programs is scheduled for a three-year period; continuation after this is expected to be self-sustaining.

We feel that this trend is professionally the correct approach to take with respect to the education and guidance of our students, and are supportive of it. It will surely benefit both our students and industry.

ABET 2000 ACCREDITATION

Also of importance to the field of design in Biomedical Engineering is the new 'Engineering Criteria 2000' as promulgated by the Accreditation Board for Engineering and Technology (ABET). Its stated vision is: 'ABET will provide world leadership to assure quality and stimulate innovation in engineering, technology and applied science education.' In short, there is a new accreditation process that must be adhered to in all accreditation visits to engineering departments throughout the country, effective on or before the year 2001. The new accreditation procedure not only replicates the past measures of 'adequate instruction time in various areas of endeavor', but overlays a quality improvement process designed to involve constituent feedback, which includes industrial feedback. Feedback processes likely will involve alumni surveys, graduate school placement data, job placement data, industry surveys, and internship information. Properly done, the internship experience might be of major importance, as the faculty and (generally) seniors who have had substantial experience should be in a good position to make useful curricular suggestions and changes.

Some expected outcomes of the new ABET procedures are:

- formalized university/industry links as appropriate;
- increased emphasis on design applied to industrial problems;
- increased applied research in universities;
- potential innovations in BME education;
- increased continuing education by universities.

NSF, WHITAKER, NIH—NEW DIRECTIONS

Several recent developments will also impact on the area of design in Biomedical Engineering. The first of these is a recently announced Engineering Resource Center in Biomedical Engineering. This NSF ERC in BME program will 'establish one ERC for bioengineering educational technology. This new type of ERC utilizes the time-proven ERC concept and focuses it on the goal of integrating research and education to advance next-generation educational technology for bioengineering education spanning undergraduate to graduate education.' This ERC will '. . . require cross-disciplinary collaborations from the fields of biology, bioengineering, cognitive science, computer and information science, curriculum development, education, engineering, instructional design, neuroscience, psychology, sociology, and other life, physical, behavioral, and social sciences. It is envisioned that these collaborations will actively involve industry and practitioner partners from educational technology, applied bioengineering, and other areas, not only in the context of research, but also for identifying the skills necessary for bioengineering practice.'

Current plans are to fund one ERC in the United States. The decision as to which consortium will be awarded the grant, totaling about two million dollars per year for four years, should be announced by early 1999. If properly done, it is evident that design in BME will be amongst the areas impacted positively by this grant process.

The Whitaker Foundation is a major supporter of the entire field of Biomedical Engineering. One of the ways it does so is through a program called Whitaker Major Grants, where 'applicants must demonstrate substantial strength in biomedical engineering research. The emphasis should be on developing or enhancing an educational program in biomedical engineering [6] The foundation has made its first two Leadership Awards totaling more than $30 million to The Johns Hopkins University and the University of California, San Diego. They are the largest individual grants the foundation has ever made and affirm the quality of existing programs at both institutions and the visions that both have for the future of biomedical engineering.'

Two recently announced NIH programs will also positively impact the field. The first of these is titled 'NIH Bioengineering Research Grants' designed to 'support basic bioengineering research whose outcomes are likely to advance health or health-related research within the mission of the NIH. A BRG application should propose to apply basic bioengineering design-directed or hypothesis-driven research to an important medical or biological research area' [7]. The potential impact on design-driven work between Universities and Industry is obvious here.

A second major recent announcement covers a new program titled 'NIH Bioengineering Research Partnerships' which 'may propose design-directed or hypotheses-driven research in universities, national laboratories, medical schools, private industry and other public and private entities' [8]. The 'design directed' term again implies an improved support for design-driven research in the country.

In a related announcement, the Whitaker Foundation has indicated interest in supporting an undergraduate summer internship program in biomedical engineering at NIH, for students currently enrolled in a bioengineering program. The foundation has indicated support for at least three years; ten undergraduate bioengineering students will likely be sponsored per year for two months each summer.

FUTURE DIRECTIONS

The Biomedical Engineering Society met in 1998 in Cleveland Ohio, with the theme 'relating biomedical engineering research to clinical and commercial applications'. A theme-oriented industrial panel was oversubscribed, with persons having to stand in a hallway due to room crowding. A job interview fair was very well attended by both students and industry. The 1999 meeting of this society and the IEEE-EMBS will be held jointly for the first time in several years, in Atlanta Georgia, it is anticipated that this emphasis will continue.

Vanderbilt is one of several Universities intent on improving their Technology Transfer Offices, both in terms of staff and funding. In addition, funding is being developed for the provision of start-up office space and other facilities, replicating the efforts of other universities in this area. A recent interest from our School of Education has developed an Entrepreneurship Conference, inviting personnel in with many medical interests.

SUMMARY AND CONCLUSIONS

This is a time when the financial and social stages are set for a rapid increase in the direct involvement of biomedical engineering students and faculty in the growth of the medical device and design industry. Let us take advantage of this!

ENDNOTES

1. Originally presented as an oral presentation at the Medical Design and Manufacturing 1999 Conference in Anaheim CA, Jan 25–28, 1999.
2. from the Whitaker web site http://www.whitaker.org
3. Fries, Richard. 'Reliable Design of Medical Devices', Marcell Dekker, 1997
4. http://vubme.vuse.vanderbilt.edu/King/student_project_listing_1998_99.htm
5. http://www.whitaker.org/grants/indanc.html
6. http://www.whitaker.org/grants/dev.html
7. http://www.nih.gov/grants/guide/pa-files/PAR-99-009.html
8. http://www.nih.gov/grants/guide/pa-files/PAS-99-010.html

Paul H. King received the BS and MS degrees from Case Institute of Technology in 1963 and 1965, and his Ph.D. at Vanderbilt University in 1968. He is a founding member of the Department of Biomedical Engineering at Vanderbilt, which granted its first BS degree in 1969. He was the second of three chairmen to lead the department. His teaching, research, and design work has also included several years work in nuclear medicine, cardiology, orthopedics and anesthesiology. His current work involves use of the Loral Human Patient Simulator in anesthesiology, and electrocardiogram analysis in clinical pharmacology. His teaching responsibilities involve instrumentation and design; he is primarily responsible for the two-semester senior design sequence at Vanderbilt. He holds memberships in ASEE, IEEE, AAMI, Sigma Xi, and BMES. He also consults occasionally on safety issues relating to medical devices.