JUMP-STARTING BIOMEDICAL DESIGN EDUCATION IN THE SOPHOMORE YEAR:

A Human-Centered Approach

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Abstract

This paper will review the pedagogical structure of The Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory University's sophomore design class. The department as a whole has had many device industry success stories, and at their foundation is the sophomore engineering design course, BMED 2300. BMED 2300 is a required preparatory engineering design course that introduces undergraduate biomedical engineering students to the basic skills and processes required to be successful in the medical device design industry. Through the reverse engineering of an existing medical device, students gain an invaluable foundation in engineering intuition, design thinking, and collaboration strategies used in the design process. Special emphasis is placed on human-centered design (HCD) methodologies to analyze and redesign the existing medical device. Students take advantage of HCD methods to better understand the users as well as the clinical need and application for the device. Evidence of this new understanding is demonstrated throughout a semester-long redesign project.

Introduction

Preparing engineering undergraduates to be innovative problem solvers is an important goal of the Wallace H. Coulter Department of Biomedical Engineering (BME) at Georgia Tech and Emory University. As such, undergraduate students move through a rich and diverse curriculum rooted in problem-based learning (PBL) with a careful emphasis on the application of engineering design to synthesize knowledge. The foundation of our engineering design pedagogy is grounded in human-centered design (HCD) methods that are carried across several BME design courses. Students are first introduced to HCD during their sophomore engineering design course, BMED 2300. Giacomin defines HCD in "What is Human Centered Design?"

> Today's human centered design is based on the use of techniques which communicate, interact, empathize and stimulate the people involved, obtaining an understanding of their needs, desires and experiences which often transcends that which the people themselves actually realized. Human centered design is thus distinct from many traditional design practices because the natural focus of the questions, insights and activities lies with the people for whom the product, system or service is intended, rather than in the designer's personal creative process or within the material and technological substrates of the artefact (Giacomin 2014, 610).

HCD has been embraced in engineering design education due to evidence of improved quality, improved human factors, and overall user satisfaction with HCD-created products (Zoltowski, Oakes, and Cardella 2012, 29-30). As such, our design program relies on HCD methods to improve the work of our students and to distinguish our engineering students from more technical programs.

The pedagogy in the BME department at Georgia Tech and Emory has incorporated PBL as a key element since its founding in 1997. In PBL courses, students encounter open-ended, large-scale questions and work in teams with their peers in many of their major courses. Instruction in HCD is a logical and complementary addition to their PBL-based science courses, since many aspects of the instruction are similar. Both courses use a flipped classroom model of instruction, and our students are comfortable forming their own teams, scoping their own problems, and establishing their own measures for the success of their designs. We challenge student teams to apply this pedagogical model to problems and solutions centered on user needs.

Design students, however, like professional designers, tend to make false assumptions about product experiences, especially when they encounter or design for users who have experiences different from their own. These differences fall along the lines of race, socioeconomic position, health, age, ability, and lifestyle (Wilkinson 2014, 616). While it is difficult for new designers to imagine an experience that different from their own, anecdotally and in our review of the literature, user involvement is deemed as beneficial in order to challenge those assumptions. Teaching HCD in the undergraduate curriculum expands students' ideas of what an engineer does and what design is. Although this is an engineering course, pedagogical emphasis is placed on incorporating technical engineering into the analysis and design of devices. BMED 2300 students are guided away from purely technology-centered design (Krippendorff 2006)—focused only on engineering requirements rather than intangible qualities (aesthetic, experiential, material)—and are challenged to design for requirements that come from the goals of all users.

Integrating these human considerations into the design process can be daunting, particularly since most students enrolled in BMED2300 are undertaking their first comprehensive design project. The design process for medical devices requires an intimate understanding of how a device relates to both the physiology and psychology of several different users. The goal of BMED 2300 is to give students a framework that equips them to analyze complex human-related problems, which they can then use to create an environment for problem solving that will inspire innovative thinking in their eventual roles as engineers and healthcare professionals.

Course Structure

BMED 2300 is the preparatory engineering design course that introduces BME undergraduate students to the skills and processes required to be successful in the medical device industry in a studio format (Little and Cardenas 2001, 309). Through the reverse engineering and redesign of an existing medical device, the students gain a foundation in engineering intuition, design thinking, iterative design development, and collaboration strategies. Evidence of the new skills learned is demonstrated through drawings, prototypes, formal presentations, and technical documentation. BMED 2300 builds upon strategies learned in the freshman year PBL course, BMED 1300. In addition, BMED 2300 satisfies several ABET performance criteria for students, who:

- Develop thoughts and interpretations of data, analysis, and engineering concepts, and expresses them clearly and convincingly in writing
- Demonstrate understanding of NSPE Code of Ethics
- Engage in self-directed learning

The semester-long, project-based course is structured in three phases and requires that students learn and use many basic technical engineering skills to progress through each phase. The three phases are "Analyze It," "Redesign It," and "Build It," which is when teams fabricate functional prototypes. The technical skills include measuring, drawing, problem scoping, concept refinement, prototyping, CAD modeling, and 3D printing. The skill-building exercises are introduced concurrently with the three-phase, semester-long medical device redesign project.

Instruction is provided via a combination of weekly hour-long lectures and two smaller lab or studio sessions. The lecture includes up to 160 students, and the smaller studio sessions are divided into sections of no more than 32 students. During the lecture period, the students are introduced to topics such as HCD, anthropometry, usability, manufacturing, ethics, regulatory affairs, intellectual property, and professional practice.

The space used for this course is an open studio with desks grouped to allow students to work in teams on individual skill-building exercises, as well as on their semester-long medical device analysis and redesign project. During the studio sessions, students work in teams of three to four on a semester-long design project, facilitated by an instructional team made up of: one design instructor who delivers skill-building knowledge through demonstrations and in-class exercises, one graduate TA who runs the project, and three to four undergraduate TAs who mentor and assist teams in the synthesis of conceptual and hands-on ideas. The instructional team is present to introduce skills, to help manage team conflicts, and to keep the course running smoothly.

Students are assessed via three formal presentations and submit regular technical reports summarizing their research understanding and design goals. There is also one comprehensive exam, which covers topics presented in lecture and lab, as well as readings from *Engineering Design: A Project-based Introduction* (Dym, Little, and Orwin 2013). Throughout the course, and specifically during the three project phases, we encourage our students to keep users needs in mind, think about the context of use, and employ empathy. Our students learn to balance HCD ideals with their new technical skills. Below, we have outlined our approach to each part of the semester-long curriculum.

Skill-Building

This accelerated semester-long engineering design course would not be possible without a firm foundation in technical engineering skills and design communication skills. Concurrent with the three phases of the device redesign project, students are introduced to and individually assessed on various design communication skills including drawing, modeling, and CAD.

Students are provided with an initial introduction to orthographic and perspective drawing. The students work through a series of drawing exercises independently, testing their familiarity with drawing tools, drawing conventions, and three-dimensional thinking. Once a basic level of drawing competency has been established, the students are asked to design a series of concepts for a "widget"—a physical geometric form conceived through adding and subtracting cubes or cylinders from an initial mass. Students are tasked with showing proficiency in measuring, geometric construction, and freehand drawing skills.

Throughout this skill-building assignment, students receive feedback from the instructional team on the feasibility of constructing their various designs. Once a design is selected, the students must devise a set of plans to build their widgets. As a test of their abilities to both conceive of an object and to read a set of specifications, the students must build their own widget design, as well as one of their teammates' designs. Widgets are then built of bristol board and are graded on craft, which encompasses overall cleanliness and aesthetics, in addition to accuracy according to their build plan and dimensional gauging. All dimensions are inspected with digital calipers with a tight tolerance range to ensure that students are planning, executing effectively, and iteratively improving their build process. Students who have planned well and done some preliminary testing of their build process can usually complete the assignment in five to ten hours (Figure 1).

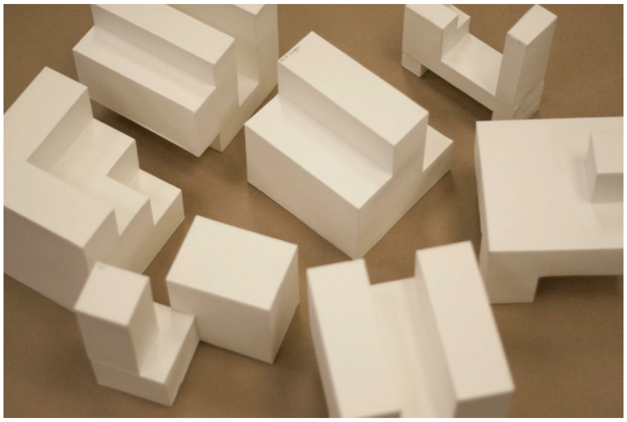


Figure 1. Widget Models

3D modeling and a basic of understanding of Computer Aided Design (CAD) is also part of an engineer's skillset. Without it, students wouldn't be able to take advantage of the campus's machining and rapid-prototyping capabilities. CAD is taught as a continuation of the manual drawing and modeling skills that were taught earlier in the course, rather than as a separate phase of the course. CAD modeling is taught using SolidWorks, but the concepts are taught in order to maximize transfer of skills to other solid modeling platforms. Emphasis is put on the fact that learning the mechanics of the software is only part of the learning process. The truly important part of the process is the development of analytical thinking, which allows the student to understand the form and construction of 3D objects.

In order to get the students up to speed in such a compressed curriculum, CAD is introduced during the fourth week of the semester. Early on, students are assigned a series of six online tutorials and weekly homework exercises. The tutorial videos were created by a design instructor and include a step-by-step video as well as a written transcript. Students must create and submit a model representing the object that has been modeled in the tutorial, along with another object of similar complexity from their own imagination. Explicit connections are made to orthographic drawing conventions and perspective drawing construction, as well as datums, geometric relationships, measuring, and tolerances. These are not trivial skills for students to learn, and several dozen hours are typically required for them to attain a level of proficiency warranting top marks (Figure 2).

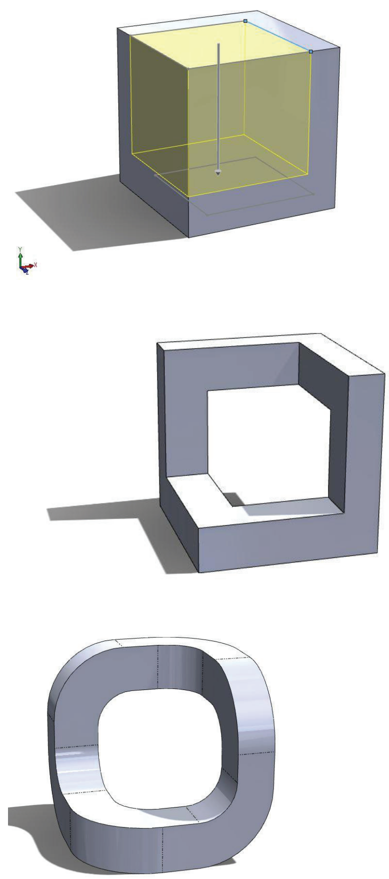


Figure 2. Construction of a seemingly-complex shape using primitive solids

The students are supported during the six weeks of self-paced tutorials with in-person help sessions provided by a team of undergraduate teaching assistants. The students are assessed on their CAD skills individually through graded homework assignments, a quiz of low weight, and a higher-stakes CAD exam. There are some students for whom the projected-3D environment is so foreign that they cannot become proficient in the time allotted, even if they put forth reasonable effort. These students fare much better with the current method of instruction, which spreads out the SolidWorks tutorials over several weeks, than in the previous model, which compressed all the CAD instruction into an unbroken "SolidWorks Boot Camp" toward the end of the semester. There are problems with the self-paced tutorial model as currently implemented, but significantly higher rates of success have been observed with a mix of self-paced tutorials and live, in-person help sessions than were observed with in-person instruction alone.

Phase One: Analyze It—Reverse Engineering

In this initial phase of the project, teams are asked to identify an existing medical device to redesign. Teams of three to four students are formed based on shared interest in one of the following device categories: Personal Health Administration, Personal Health Monitoring, Environmental Health and Safety, Personal Protective Equipment, Mobility and Ambulatory Assistive Devices, Orthopedic Health and Prosthetics, Physical Therapy Devices, Handheld Surgical Devices, Health Care Environments, Aging in Place, and Pediatric Care. After forming, teams must obtain existing medical devices, contact users and stakeholders, and then work together to identify problems and opportunities that can be addressed later in the redesign of the device.

Students are asked to thoroughly research and map out all the design decisions that shaped the original device in its current state. The students begin their analysis through inquiry into the following aspects of a device:

- The underlying physiological need for the device
- Identifying all stakeholders and users and assessing their needs
- A detailed market segment analysis and product benchmarking
- Review of the prior art and historical context
- Manufacturing and engineering analysis

While it is important for the students to gain a technical understanding of their device, particular emphasis is placed on understanding how the device is used in context and the user's experience. As stated in Zoltowski, Oakes, and Cardella (2012), "A critical part of design thinking and human-centered design is understanding the people affected by the design." In BMED 2300, we begin by introducing ergonomics, and in particular anthropometry (Nickpour and Dong 2011, 94), as one of the core concepts of designing for others. The strategy is to review anthropometry with students through lectures and body measurement demonstrations. The students are informed of available anthropometric data resources including the Dreyfuss Human Scale cards (Dreyfuss 1973) and body measurement databases. As the most quantitative of the HCD techniques, anthropometry is also fairly scientific, and engineering students are comfortable dealing with known or measurable variables as they engage in engineering and form analysis. Through this endeavor, teams gain a greater appreciation of how the diversity of the human body informs design decisions.

Once teams have identified and recorded the user needs, they begin to prioritize them. Students are given examples of various ranking systems through which they may organize their project metrics. Hierarchies may be used, such as functions-means trees, FPSCO charts, pairwise comparison charts, or any other logical method for organizing the overwhelming mass of data that the students have collected to this point. Upon completing their analysis, the teams create storyboards and usability flow charts to document their initial research, which includes literature reviews, user observations, expert interviews, and role-playing.

Next, students create orthographic drawings of the device by hand (Figure 3). The purpose is to practice skills in design communication as detailed in the skill-building section later in this paper. These drawings are expected to show a high level of craft and thoughtfulness.

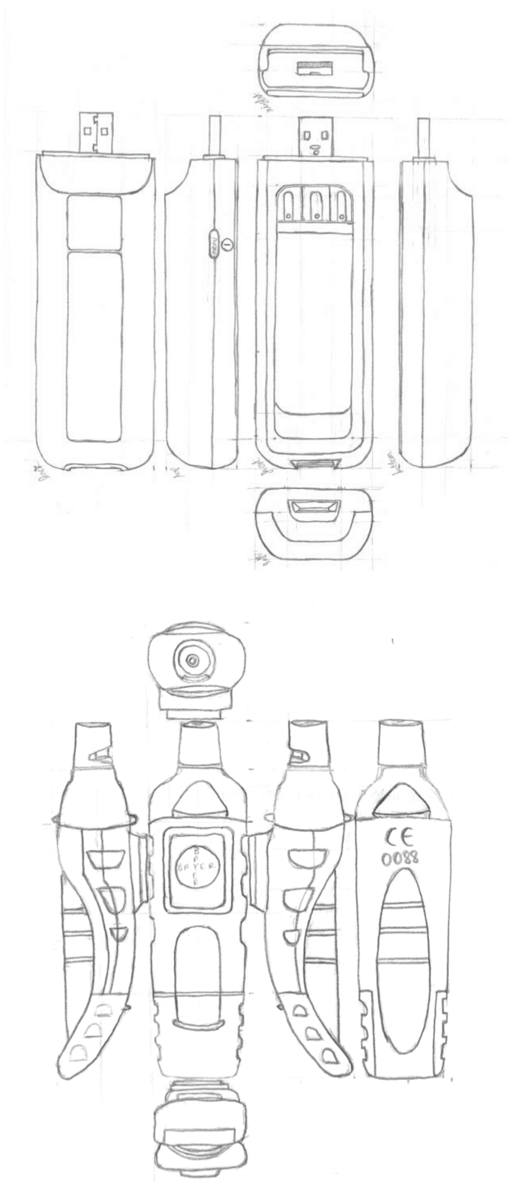
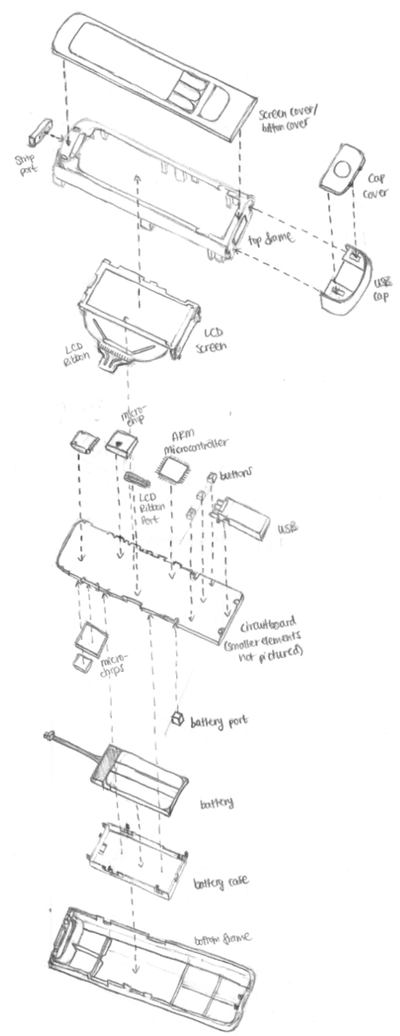


Figure 3. Freehand orthographic sketches of glucometer and lancing device

Once the device is documented, students will continue to analyze its usability through flowcharts (Figure 4), storyboards (Figure 5),

and user observations (Figure 6)

Following the usability assessment, the teams reverse engineer their device in order to gain an understanding of the materials selection, manufacturing processes, and the interactions between components in the system. At this point, they create an exploded view drawing (Figure 7).



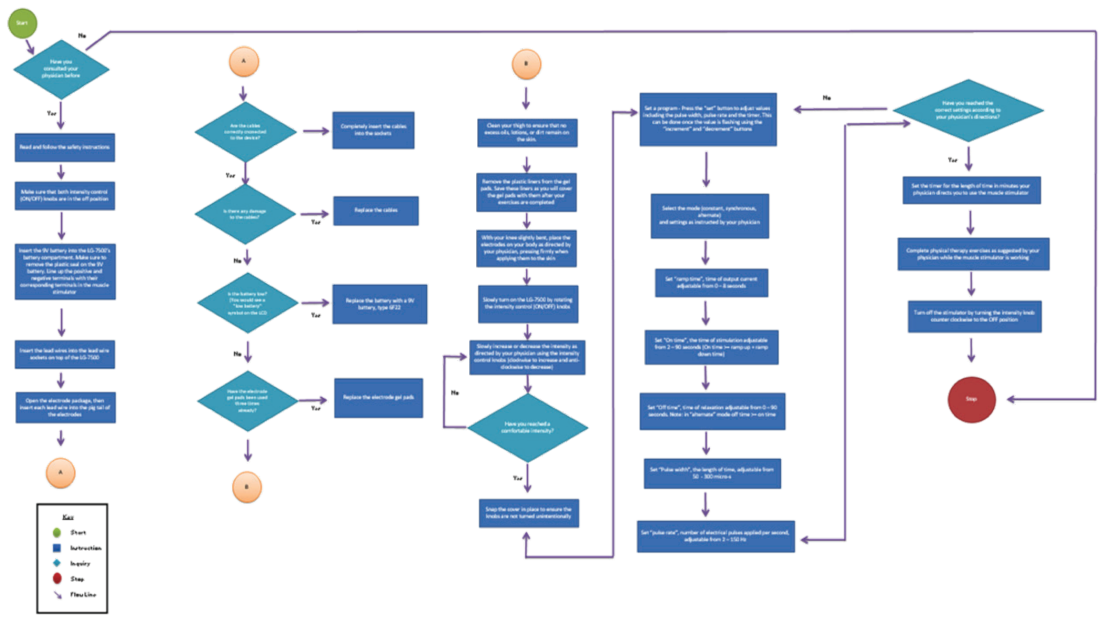


Figure 4. Usability flowchart

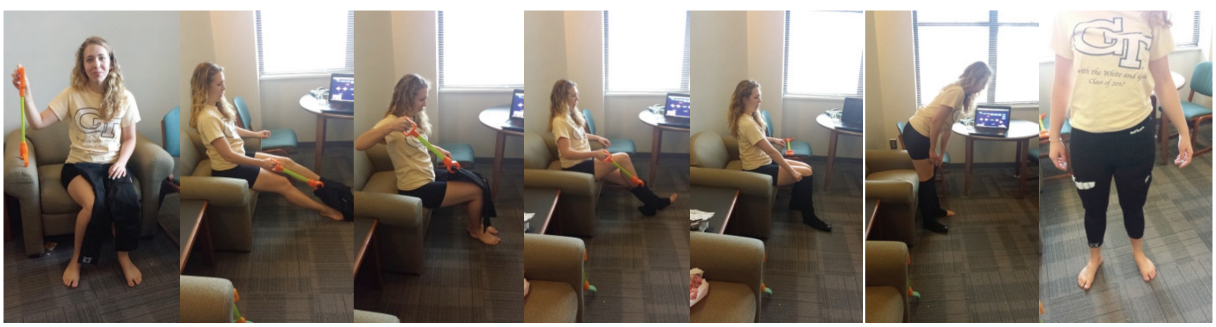


Figure 5: Student use story board

Figure 6: Students participate in PPE Training as an observation and empathy exercise

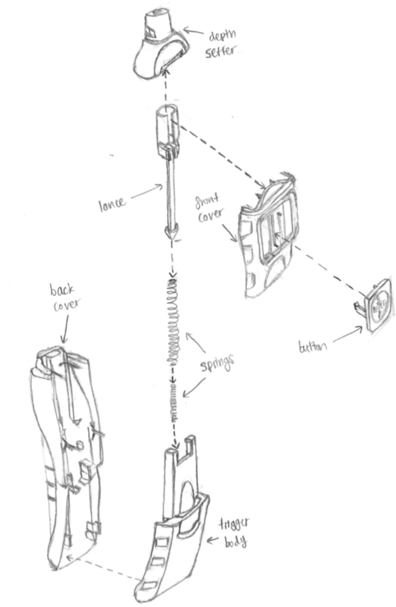


Figure 7. Freehand exploded view sketches

Teams then create an engineering flow chart to further guide the engineering analysis. Each step in the engineering flow chart should show mathematical continuity with the steps preceding it. Students then perform an engineering analysis of each step in the process, which might be as simple as a basic statics problem, or could be an analysis of a chemical reaction or processing algorithm (Figure 8). Utilizing the system of equations they have derived, students can do some simple experiments in order to better understand the analysis.

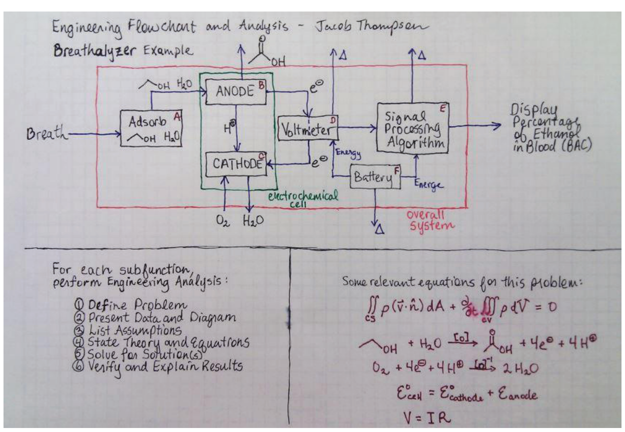


Figure 8. Engineering analysis of a breathalyzer

The work completed thus far is presented as both a group oral presentation of about six minutes in length, and a five page technical report. This work creates a strong foundation on which teams can build their redesign.

Phase Two: Design It—User Definition and Concept Generation

After the analysis phase, the teams are ready to formalize a problem statement and begin generating new concepts for the device redesign. In this second phase (P2), teams have now fully analyzed the selected a medical device; now they must begin to identify the user needs. To achieve this, students will need to go through various exercises to enable them to gain empathy for the various users. Some techniques for better understanding users are creating personas, doing usability assessments, and studying anthropometrics and human factors (Wilkinson 2014, 618, 626). During user analysis, students are asked to examine the product's use over time and to visualize these variations through storyboards and usage flow-charts.

Some groups effectively use role-play to produce storyboards as analysis and evaluation tools of existing products and their own prototypes. During P2, role-playing and scenarios also play an important role in problem scoping and user definition. Teams create descriptive user profiles and/or personas to frame the user and context and to evaluate ideas, gaining holistic understanding of their problem statement and user needs. When possible, students engage in empathy exercises by creating scenarios and using the device in context.

In *The Persona Lifecycle*, Pruitt and Adlin (2006) have several definitions of personas that are useful for our students:

- Fictitious, specific, concrete representations of target users
- An aggregate of target users who share common behavioral characteristics (i.e., a

hypothetical archetype of real users)
- Abstractions of groups of real consumers who share common characteristics and needs

These abstracted characters allow students to explore real-world design issues as well as synthesize their user research through the framing of real human experiences, contextual conditions, and emotions through the use of fictitious aggregate users. Students use storytelling techniques via the user competitions that each team holds to help them with problem scoping. Personas, and their connection to the real world, are one of the most powerful ways to get students to think critically about the experiences of others.

After clear problem and user definitions are agreed upon, the next step is to hold several brainstorming sessions in order to generate a wide variety of potential solutions. As this is a first exercise in concept development, each student on the team individually produces 25 concepts (Figure 9). Though initially daunting, this is not difficult, as the students find that an intimate involvement with users and stakeholders increases the number of concepts and ideas. HCD methods help the students generate a wide variety of ideas by opening them up to the experiences and motivations of others (Steen 2011, 77). The sketches are then pinned up in the studio lab (Figure 10), along with the concept drawings from other teams, and are evaluated by all peers in that studio lab section. After receiving critiques, suggestions, and endorsements from the entire section, as well as the instructional team, the teams review the feedback and decide whether to incorporate the suggestions in their next design iteration.

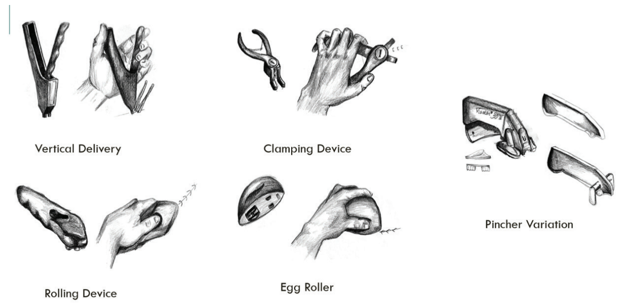


Figure 9. Concept sketches (Courtesy of Nikki Jackson)

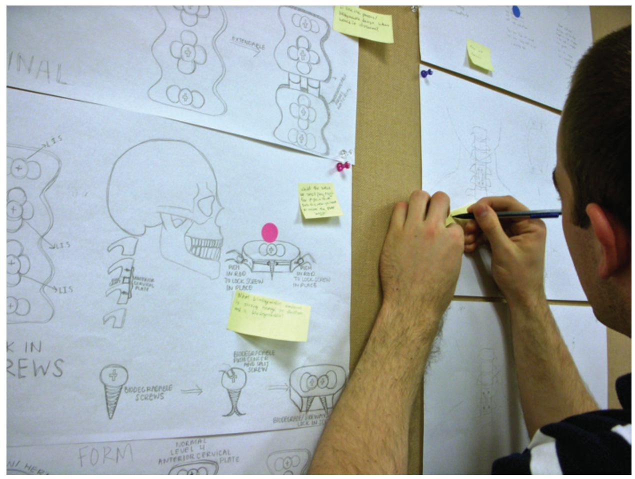


Figure 10. Concept pin-up and feedback session

Once their most promising ideas have reached a certain level of coherence, the teams are encouraged to create models or prototypes. Initially they may be lower fidelity, but eventually they will be of a higher quality in order to better demonstrate their idea. The teams must share their ideas and prototypes with expert users and health care professionals for feedback. This step is seen as critical to the project's success and thus is evaluated as part of the P2 rubric. Students will then present their model or prototype to the class and instructors, along with description of any failed designs or learning experiences they had throughout the process (Figure 11). The teams incorporate feedback from all groups and formalize a final concept direction, which is detailed in the third phase below.

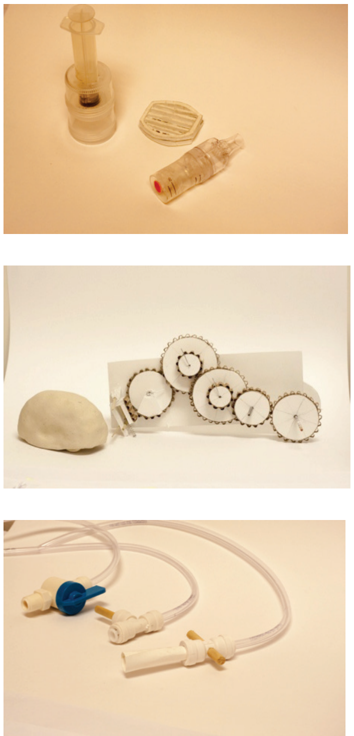


Figure 11. Phase two models showing various levels of resolution and detail

Phase Three: Build It—Prototyping, Testing, and Final Documentation

In the final phase of the course, the teams incorporate the feedback collected during Phase 2 and work to build high-fidelity and testable prototypes of their intended solutions. During Phase 3, teams further develop and refine their concepts and prototypes. During this phase, teams also have to demonstrate proficiency with the CAD program SolidWorks, the same software that they have practiced using through individual assignments throughout the semester.

Students are encouraged to bias building and physical experimentation over extensive discussions. They are expected to experiment with multiple functional representations of their device in various forms, which may include computer-based interface mockups, basic circuit prototyping, assisted CNC machining, mechanical testing, casting, molding, 3D printing, and vacuum forming. These prototypes and models are an excellent communication tool to share with users and stakeholders for a final round of feedback.

During this phase, teams continue to research and provide more explicit information related to the following topics:

- Human factors and usability
- Materials specifications
- Manufacturing processes
- Appropriate technologies
- Intellectual property
- Ethics
- FDA and regulatory considerations

Teams are finally able to fully synthesize the course content in their final project deliverables, which include a formal presentation, physical prototypes and scale models (Figure 12), exploratory models and mockups, a detailed technical report substantiating their design process, and a six-page visual-rich process book.

Figure 12. Model of wrist-worn rescue inhaler

Conclusion

Over the past few decades, engineering design has primarily emphasized the identification and collection of engineering specifications (Zoltowski, Oakes, and Cardella 2012, 29-30). While the process of specifying metrics and constraints while satisfying objectives is still central to the engineering design process, many of the critical requirements are driven by human-centered goals rather than solely technology-centered objectives. HCD methods are excellent for encouraging creativity; as they are both divergent and convergent (Zoltowski, Oakes, and Cardella 2012, 29-30), they pull from an empathetic understanding of stakeholder and user needs while involving prototyping and testing ideas. The physical, cognitive, and emotional intuition from practicing HCD results in an accelerated design synthesis for students. The semester-long project and assessments outlined in this paper hold the BMED 2300 teams responsible for involving stakeholders throughout the design process.

While most agree that HCD techniques are valuable in driving innovation, the actual application in an undergraduate setting poses challenges (Zoltowski, Oakes, and Cardella 2012, 28). Involving users during the course of the class is difficult due to the aggressive pace of the course and because each team works on a different design problem that they cannot adequately prepare for until the class begins and the teams are formed. Despite this, BMED 2300 students have found success in their design endeavors. Teams from the Department of Biomedical Engineering program consistently take top honors in design competitions against their peers from other engineering departments at Georgia Tech (Figure 13). Some teams have even gone on to create their own start-up business (Figure 14).

Applying HCD has been a valuable methodology for BME student teams to learn for application in an industry or research setting and beyond. It is introduced in the second year of the curriculum as a foundation for design thinking and is built upon in subsequent courses. The impact of applying HCD to design projects is evident in the success of student projects. This course provides students the tools necessary to apply HCD successfully in future coursework and professional endeavors.

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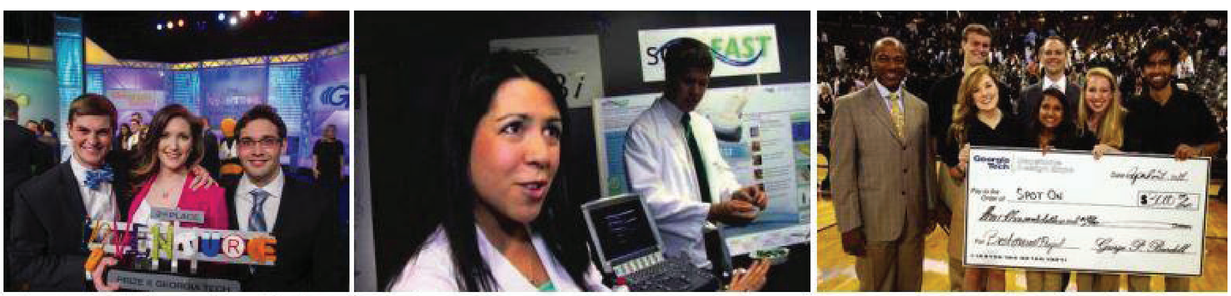

Sucette, 2014 InVenture Prize, 2nd place   Sonofast, 2014 Capstone Expo, 1st Prize   Spot On, 2014 Capstone Expo, Best Overall

Figure 13. Teams of BME students regularly take top honors in Institute-wide design competitions

Figure 14. Teams that have successfully applied human-centered design and translated their class project into a start-up

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