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Teaching Tips - Special Issue (COVID)

Capstone During COVID-19: Medical Device Development at Home to Solve Global Health Problems

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CHALLENGE STATEMENT

Capstone is a cornerstone of undergraduate biomedical engineering (BME) programs. At the Georgia Institute of Technology, Capstone is a one-semester course covering the product development cycle. Curriculum includes clinical immersion and customer discovery, conversion of user needs to design inputs, concept ideation, patent analysis, prototyping, and engineering analysis (Fig. 1). Projects are often advised by clinical and industry experts, and topics tend to be geared towards high-tech devices to address US healthcare needs. Henceforth, the one-semester, US-focused Capstone is referred to as "traditional Capstone."

In 2018, we founded a sister program to traditional Capstone, Global Health Capstone (GHC), which focuses on addressing clinical needs in resource-limited settings. Excellent programs in global health device design exist at other universities, including Clemson University, Johns Hopkins, Rice University, and University of Michigan.[4–6,9,12] Whereas traditional Capstone focuses on development of first-generation prototypes to prove early feasibility, GHC is a multi-semester experience focused on developing high fidelity prototypes positioned for clinical studies. GHC solutions must be robust, inexpensive, and locally sustainable. Current projects aim to address high infant and maternal mortality rates in Ethiopia.[11] Since program inception, GHC has expanded to include students across majors, academic years, and universities to create a collaborative, interdisciplinary program.

COVID-19 brings several challenges to maintaining the academic requirements and rigor of traditional Capstone (Fig. 1). The traditional Capstone model requires substantial in-person interactions with clinicians, access to medical facilities, and use of specialty equipment for prototyping. Prior to COVID-19, we experienced some similar challenges in our first attempt at international collaboration through GHC. Although GHC teams had the opportunity to travel to the host country, in-person clinical immersion was limited to one week prior to the start of the academic year, not all students were able to travel, and conversations with clinical advisers became more limited after returning to the US. In-country immersion also included visits to local markets and engineering workshops within the hospital to assess available resources for device manufacture. Students observed that specialty equipment for in-country device manufacture was unavailable. Thus, a sustainable medical device solution required a low-tech design using locally-sourced materials. The situation we experienced in GHC is now akin to the current challenges faced in traditional Capstone due to COVID-19, specifically limited access to medical centers for clinical immersion and limited resources for prototyping.

NOVEL INITIATIVE

GHC has a multi-tiered, vertical structure, extending to students across different universities, majors, and academic years (Table 1). Under the overarching

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GHC program, students are divided into different sub-teams—the Senior Engineering Team, the Junior Engineering Team, and the Clinical Team. The Senior Engineering Team consists of students that are graduating at the end of the academic year. Through GHC, the Senior Engineering Team satisfies traditional Capstone requirements needed for graduation. Typically, students on the Junior Engineering Team are not graduating in the current academic year, and they participate in GHC through research for credit opportunities or as an elective. Since students on the Junior Engineering Team join the GHC program earlier in their academic career, their role is to work alongside the Senior Engineering Team to assure project continuity. The Clinical Team consists of medical students and public health students. Their role is to assist the Senior Engineering Team with clinical protocol development and to lead translational efforts.

Time commitments for each sub-team vary between multi-year or one year. Therefore, GHC uses several tools to assist with transfer of knowledge between sub-teams, to establish student expertise, and to implement vertical integration. All teams prepare written formal reports to document project progress each semester, effectively serving as a design history file. Teams also prepare detailed instructional videos to document device manufacture and operation. Part of the on-boarding process for new students is to make the device using these videos. Lastly, lab notebook documentation is critical, and grading criteria includes how useful the notebook is in communicating concepts to other team members.

The vertical program structure of GHC can be applied to traditional Capstone or team-based design courses to assist with adapting to remote learning. By implementing the vertical approach, previous students and instructors have familiarity with the problem space to alleviate some dependence on extensive in-person clinical immersion and access to medical facilities. Another difficulty of remote learning is instructor ac-

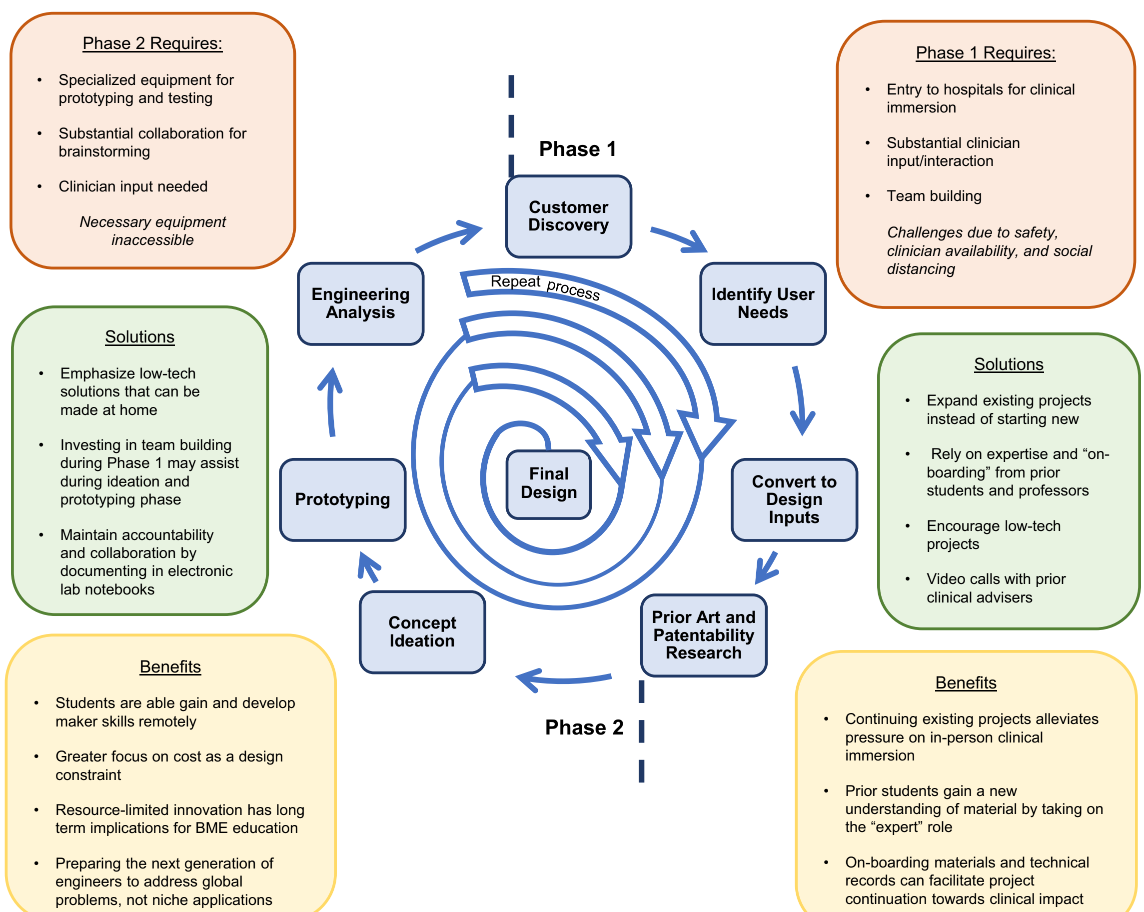

FIGURE 1. Diagram of the workflow of traditional Capstone. Potential challenges during research-focused Phase 1 and prototype development-focused Phase 2 are described. Solutions come from applying concepts from our sister program, Global Health Capstone, which focuses on low-tech device development for resource-limited environments. Traditional Capstone, which tends to be US focused, may benefit from a global mindset by targeting devices that can be produced at home or in remote learning scenarios, where specialized materials and equipment are unavailable.

TABLE 1. Summary of Global Health Capstone (GHC) program.

GHC sub-team	Academic major	Time commitment	Project role	Desired outcomes
Georgia Tech Junior Engineering team	Various STEM undergrad	Multi-year	• Supports Senior Team on device development and testing • Lead smaller scale independent projects related to global health device design	• Understand foundational concepts in global health device design • Gain familiarity with product development in preparation for Capstone • Develop independent research skills • Become the new engineering experts for project continuity
Georgia Tech Senior Engineering Team	Various STEM undergrad	One-year	• Lead device product development efforts • Teach the Junior Team key project concepts • Assist the instructor in identifying and managing Junior Team goals as the project technical experts • Support efforts of Clinical Team	• Create high fidelity prototypes positioned for Clinical trials and transfer to in-country collaborators • Validate device design with rigorous engineering analysis • Develop project management Skills • Transfer knowledge to Junior and Clinical Teams for project continuity
Emory University Clinical Team	3rd year medical students and masters in public health	Multi-year	• Lead preparation of clinical protocol alongside clinical collaborators • Support execution of clinical studies • Analyze resulting data from clinical studies • Assess device acceptability during clinical studies • Assist instructors in grant preparation	• Develop a set of recommendations for future device modifications for the engineers based on findings from clinical studies

The vertical integration of different sub-teams can be applied to traditional Capstone or other team-based design courses to create a wider network of resources for students to support remote learning during COVID-19.

cess. Although the instructor remains closely involved with each project and is the key resource for teaching students the product development process, communication of information is inherently different in a remote scenario. Creating an additional network of students to serve as secondary project experts can be a useful resource for new students, if carefully managed. The added responsibility of mentoring newer students may also instill a sense of project ownership for the Senior Engineering Team, which may be a valuable motivating factor in a remote-scenario where accountability can be challenging.

As opposed to encouraging students to pursue high-tech solutions, GHC focuses on development of low-tech devices. This mindset can help address challenges in prototyping during remote learning, where access to specialty equipment or materials are limited. As an example, the most recent GHC cohort developed a warming device to prevent neonatal hypothermia. The device consisted of a warming pack and a cloth swaddle to wrap the infant. The warming pack was made using a heat sealer to make a vinyl pouch that contained baking soda, vinegar, and a metal activator to start an exothermic reaction to generate heat. The cloth swaddle was made using cotton fabric and a sewing machine. Following institutional closures, the GHC team took all materials and equipment home and easily continued prototyping. On the contrary, many traditional Capstone teams that focused on high-tech solutions were not able to continue prototyping upon transitioning to remote learning. For the upcoming academic year, emphasizing low-tech solutions from the start of the semester in traditional Capstone provides a better opportunity for students to develop a working prototype while at home. Before encouraging at-home prototyping, measures to assure student safety should be taken according to institutional regulations. Although students may not be able to develop the same high-tech maker skills, developing simple maker skills can be equally as valuable, and environmental design constraints can drive innovation.[1,5]

REFLECTION

Vertical integration was already underway in the Spring 2020 term, prior to institutional closures. By the end of the semester, GHC students completed rigorous engineering analysis for their high fidelity prototypes. Based on the quality of work and extended performance and safety testing, the team prepared a clinical protocol to conduct studies in Ethiopia. Although clinical studies were postponed due to COVID-19, several members of the Junior Engineering Team continued to work on the project remotely over the Summer 2020 term. The Junior Engineering Team was able to make the device at home using previously prepared reports and recorded videos from the Senior Engineering Team. Vertical integration and emphasizing low-tech solutions were critical in maintaining project momentum and smoothly transitioning to remote learning for all students in the GHC program.

Although project outcomes were generally positive, there were some challenges in implementing vertical integration and at-home prototyping. Based on student feedback, one issue was confusion on the roles between sub-teams with vertical integration. More specifically, the Junior Engineering Team needs to be encouraged to take ownership of the project and innovate in new directions. The Senior Engineering Team needs to be encouraged to take a leadership role and delegate tasks. In addition, it is important that the Senior Engineering Team remains focused on their main goal of developing a high fidelity prototype. Although it is a valuable secondary goal for the Senior Engineering Team to develop skills in project management and teaching, these additional responsibilities can be time consuming. The instructor needs to closely monitor interactions between all sub-teams to assure a positive learning experience.

The transition to at-home prototyping did cause some project delays. Students should be directed to obtain materials early. For the Junior Engineering Team, students needed simple items to prototype, but were hesitant to make purchases out of concern of ordering the wrong supplies. For the Fall 2020 semester, we will encourage students to connect with instructors to give them assurance that the proper materials are being ordered. However, we will also communicate that different materials will inevitably be needed as students identify better options after gaining hands-on prototyping experience.

Vertical integration and emphasis on low-tech device development in GHC can be applied to traditional Capstone or other team-based design courses to accommodate other learning styles.[2,3] The vertical program approach encourages collaboration and social learning.[10] Although learning is still guided by the instructor to communicate product development concepts, delegating veteran team members as experts to teach newer students about technical aspects of the project improves understanding and engagement through interactions with peers.

Low-tech device development encourages active learning through cognitive constructivism.[7,8] Unlike high-tech solutions, low-tech solutions can be built at home or in small groups with minimal equipment. Although students will not have the experience of using specialty equipment, hands-on building is critical to developing intuition for what is a good device design. Students need to experience the differences between a theoretical device designed using modeling software vs. the practical implications of conversion to a physical prototype. This skill must be developed from first-hand experience, not interactions with instructors or peers.

Several assessment measures will be taken to evaluate the benefits of vertical integration and the emphasis on low-tech devices from a student perspective. Student feedback will be obtained using reflection assignments, course surveys, and individual meetings with students. The goal of the written reflections is for students to self-assess their performance while also providing feedback for course improvement using open-ended questions. Written reflection assignments will be followed by opportunities for optional individual meetings with instructors. To gain quantitative student feedback, blinded surveys using Likert scale questions will be administered at the end of the course.

For the 2020–2021 academic year, many student teams still opted to work on US-focused traditional Capstone projects. Performance on course deliverables can be compared for GHC students and traditional Capstone students to provide tangible evidence on benefits of vertical integration or the focus on low-tech solutions. Prior to analyzing student performance data, all necessary permissions will be obtained at the end of the term. All teams prepare several technical reports throughout the semester. Vertical integration may specifically impact performance on the User Needs and Design Inputs Reports. These deliverables typically require substantial independent research and clinician input to understand the problem space and design constraints. We hypothesize that vertical integration in the GHC program will provide an additional knowledge base to improve student understanding of the problem space during COVID-19, where access to outside resources is more limited. As a result, GHC students may earn higher scores on the User Needs and Design Inputs Reports than traditional Capstone students.

To assess benefits of emphasizing low-tech solutions in GHC vs. high-tech solutions in traditional Capstone, quality of final prototypes can be compared by considering physical form, function, usability, and utility. In addition to instructor assessment, final prototypes are also evaluated at a university-wide design competition, where GHC and traditional Capstone team performance is scored by outside experts. Judging criteria includes solution creativity, utility, quality of analysis, proof of function, and effective communication. Students are assigned a numerical score at the design competition, which can provide an excellent blinded dataset for analyzing differences in performance of GHC teams and traditional Capstone teams.

Although the GHC program is relatively new and opportunities for improvement remain, we have initially observed positive outcomes from implementing the vertical approach and emphasizing low-tech medical device solutions during COVID-19. Projects have reached stages beyond proof-of-concept prototyping, and GHC teams smoothly transitioned to remote learning. The principles of vertical integration and emphasis on low-tech device solutions can be adapted to traditional Capstone or other team-based design courses to benefit student learning during COVID-19.

AUTHOR CONTRIBUTIONS

All authors conceived the idea. KPK prepared the manuscript. All authors reviewed and edited the manuscript.

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The authors have no conflicts of interest relevant to this manuscript.

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There are no studies involving human participants in this work.

CONSENT TO PARTICIPATE

There are no studies involving human participants in this work.

CONSENT FOR PUBLICATION

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