The DeFINE Program: A Clinical Immersion for Biomedical Needs Identification

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Breanne Przestrzelski is a University Innovation Fellow at Clemson University where she is pursuing her PhD in Bioengineering with a focus on innovation of biomedical devices and translation thereof through immersion of bioengineers in design and entrepreneurship opportunities. The University Innovation Fellowship, which is a program of Epicenter and a joint-venture of VentureWell and Stanford University, has inspired Breanne to share her passion for design and entrepreneurship through a variety of initiatives she is helping to bring to Upstate South Carolina, one of which is the NIH- and VentureWell-funded DeFINE Program. Breanne obtained her B.S. in May 2012 (research focus: nanomedicine technology) and her M.S. degree in August 2013 (research focus: glenoid loading and stability of the inlay verus onlay shoulder system) both from the Clemson University bioengineering department.

Breanne was a four year varsity collegiate athlete, rowing for the Clemson University Women's Rowing Team, where she learned how to foster her team-centered leadership. Breanne moved on to lead her senior design capstone team to a 1st Place finish in the 2012 NCIIA BMEStart Undergraduate Design Competition for the team's innovation: Assurefit- a chest tube stabilization device. Breanne found her drive for innovation and fascination with design during the development of this technology and seeks to equip students with this same drive through experiential learning.

Dr. John D DesJardins, Clemson University

Dr. John DesJardins is the Robert B. and Susan B. Hambright Leadership Associate professor in Bioengineering at Clemson University and the director of the Frank H. Stelling and C. Dayton Riddle Orthopaedic Education and Research Laboratory at CUBEInC. He received his BS in Mechanical Engineering from Carnegie Mellon University, his MS in Mechanical Engineering from the University of Pittsburgh, and his Ph.D. in Bioengineering from Clemson University in December 2006. He has worked for over 25 years as a biomechanical research engineer, and has co-authored over 200 peer-reviewed conference or journal publications in the areas of biomechanics, biomaterials tribology, engineering education, biomedical design and mechanical testing. He directs the Laboratory of Orthopaedic Design and Engineering on the main campus of Clemson University, and in his 7 years since joining the bioengineering faculty, he has graduated 4 PhD students and 15 MS students, and has led or has been a co-PI on numerous multi-disciplinary research teams funded through NASA, DoT, DoD, NIH, NSF, the Gates Foundation, biomedical industry and other regional non-profit foundations. He is an active contributor to many professional societies and review panels, including the NSF, VentureWell, the American Society for Engineering Education (ASEE), the Orthopaedic Research Society (ORS), and the Biomedical Engineering Society (BMES) where he is currently the Chair of the Student Affairs Committee. He was a recent guest editor with the Annals of Biomedical Engineering, developing a special issue on Design Innovation in Biomedical Engineering, and is a business and educational program development consultant with the Coulter Foundation, advising NIH NIBIB SBRI awardees in technology translation.

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I. Introduction

There is a need for biomedical engineering students to more fully engage in the problem identification and needs-finding stages of the biomedical device design process through experiential learning and immersive experiences. Many publications have documented the importance of immersion outcomes in design, technology commercialization, and overall student learning.

Kline et al. documents eight best practices for technology commercialization projects that foster innovation education and fit a variety of innovation stages that might vary per student design.[1] Zappe et al. agrees that non-traditional education mechanisms for teaching design are critical to understanding what design truly is[2] as documented by Atman et al: "Design is situated in real contexts, involves social processes, and involves people with different perspectives… from different disciplines within and outside engineering, working together to solve complex technological problems that address societal as well as consumer needs."[3] In Atman's research, it was found that identifying the problem and its constraints, communicating, …and seeking information were among the most important design activities.[2] It is these concepts of design and technology commercialization that are often not explored enough in current semester-long design capstone classes and it was these concepts that were further explored by the students involved in the DeFINE Program.

The purpose of this paper is to describe and document student response to needs-finding training practices of Clemson University's new NIH and VentureWell funded clinical immersion program in Bioengineering: The DeFINE (Design Fundamentals In Needs-finding Experience) Program.

II. Course design

Upon receiving a program development grant from VentureWell and the National Institute of Health (NIH), a new comprehensive 6-week clinical and technology transfer immersion experience was developed and first offered in partnership with Clemson University and the Greenville Health System (GHS) in the summer of 2014. The DeFINE Program was divided into two experiences: (1) a clinical needs-finding immersion rotation to enhance student engagement with clinical mentors and to develop in-depth clinical needs assessments for future design teams in collaboration with GHS and (2) a technology transfer office internship to enable students to critically evaluate key business elements of these clinical needs and to accelerate the understanding of technology-transfer processes in the marketplace in collaboration with the Clemson University Research Foundation (CURF).

This program was directed by the author (JD), a mechanical/biomedical engineer and associate professor who directs the university's Bioengineering Senior Design Program. Additional directors included author (BP), a University Innovation Design Fellow and teaching assistant for the university's Bioengineering Senior Design Program, the chief of surgery at GHS, an assistant

professor that leads a division of the university's Bioengineering Senior Design Program, a research assistant professor that co-directs the university's Bioengineering Freshmen Design Program, and a technology commercialization officer at the university's technology transfer office.

III. Student learning outcomes for this course

1. Students will develop team and leadership skills.
2. Students will develop professional and life-long learning skills through professional interactions with clinical staff and experiences in a healthcare setting.
3. Student teams will learn the fundamentals of and practice needs-based clinical observation and device commercialization assessment.

IV. Goals of the course

1. To enhance student engagement with clinical mentors
2. To develop in-depth clinical needs assessments for future design teams
3. To develop a stronger engineer-clinician relationship between the Clemson University Bioengineering Department and Greenville Health System, both with the common goal of increasing the quality of healthcare
4. To give design students a more immersive needs-finding experience in the healthcare environment than what is currently offered in the senior design curriculum
5. To aid in the development of student observation, interview, and documentation skills
6. To teach and apply clinical and problem mapping processes
7. To identify and document areas of unmet medical device and system needs
8. To enable students to critically evaluate key business elements of identified clinical needs
9. To accelerate student understanding of technology transfer processes in the marketplace
10. To expose and develop skills in intellectual property assessment decisions, portfolio management, technology marketing, technology licensing, and technology commercialization
11. To prepare a sub-set of senior undergraduate students to come to the capstone series with experience in needs statement development, and medical device commercialization assessment skills

V. Course structure

The 6 week summer program was broken down as follows:
Preparatory work for the program
Orientation Week
Internship Weeks
Final Presentations

Preparatory work for student participation in the DeFINE Program included appropriate health check-ups and proper hospital certification and training (CITI). All participating students received a stipend to offset travel costs to the facility and provide base income in place of a summer job elsewhere, regardless of registering for course credit or not. Three students chose to register for the course. The course was assessed with a letter grade, and a syllabus was used to assign grades. All three students that were registered received an A. Administrative work to allow payment of stipend was also required for each student that chose the stipend option.

The internships were preceded by an orientation week that presented the following introductory information to prime the students for the 6-week clinical immersion program.

Orientation Week

1. Program Overview: a summary of the expected outcomes, structure, and goals of the 6-week DeFINE Program, led by author (JD)
2. Needs-Finding Lecture: an introductory lesson on the importance of needs-finding in the design process, led by author (JD)
3. Introduction to Observation: a tool for the exposure to the power of observation and what is missed that should not be, led by author (BP)
4. CURF (Technology Transfer Office) Internship Introduction: a summary of the expected outcomes, structure, and general information concerning the technology transfer office immersion internship, led by a university technology commercialization officer
5. Tour of Clemson University Bioengineering Clinical Facilities: a brief tour to introduce the home base facilities that the DeFINE Program would be operating from on a weekly basis, led by program directors
6. Interview Skills Workshop: a session to illustrate the importance of communication in an interview setting to prepare the DeFINE students for their clinical interviews, led by a human resources director at the major partnering hospital (GHS)
7. Industry Expert Guest Speakers- GORE Medical: a guest company web-chat to highlight the importance of the voice of the customer (VOC) when seeking to identify problems, led by product specialists and quality engineers at GORE Medical
8. What to do after you have a successful design? E-Team/VentureWell Introduction: one of the future outcomes of the NIH/VentureWell grant is to produce designs worthy of entering design competitions and becoming E-Teams, so this overview of the benefits of E-Team and VentureWell sought to inspire and motivate the DeFINE students, led by author (BP) who has worked directly with VentureWell and E-Team programs for several years as both an E-Team grant winner and a VentureWell BMEStart Undergraduate Design Competition Winner
9. Ethnographic Observation Introduction: an interactive workshop that introduced basic observation techniques for ethnographic research, led by guest lecturer and ethnographic expert
10. Bloodborne Pathogen Safety Talk: a seminar intended to prepare students for the safety regulations and protocols faced in the hospital and biological settings, led by the university safety technician

11. Design Thinkers Group Workshop: a day-long ethnographic research, needs-finding, and design-thinking workshop, led by local managing partners of Design Thinkers Group, USA, Inc.
12. Patent/Marketing Research Tools: an in-depth look at the databases accessible for DeFINE students to utilize for market research and patent research in both the clinical and technology transfer office internships, led by university reference librarian who specializes in patent searching, in-depth research consultation, and sci-tech database searching
13. Mind-mapping Introduction: a tutorial to the mind-mapping software to be utilized for documentation purposes in the DeFINE Program (MindMeister (https://www.mindmeister.com/)), led by the co-director for the Freshman BioE Design Program
14. Tour of Patewood Memorial Hospital: a brief tour of one of the facilities that the DeFINE students would be shadowing in, led by a Patewood Memorial Hospital Staff Member
15. Tour of Greenville Memorial Hospital Operating Room: an in-depth, half-day tour of the surgical facilities that some of the DeFINE students would be shadowing in with an emphasis on proper operating room etiquette, led by Greenville Memorial Hospital Surgical Staff Members
16. Video Interview Skills Session: a constructive critiquing session to present proper video interviewing skills and also evaluate current video interview skills and seek improvements for future clinical interviews, led by Visual Services and Surgical Laboratory Coordinator at one of the major partnering clinical facilities (Hawkins Clinic of the Carolinas)

For each of the topics listed above, an author, a program director, or a guest lecturer presented the information to the DeFINE student participants.

In total, 18 students, 15 rising juniors and seniors and 3 graduate student mentors participated. There were 7 females and 11 males. The course was team-based: five teams of three undergraduates were partnered with one of three graduate student mentors who rotated between teams every week. Teams were formed at the end of the orientation week following all of the introductory sessions. Teams were formed based on interest in the nine clinical areas available to the students and grouped such that 3-4 undergraduates were paired with one graduate mentor.

The 3 graduate students were selected from applications, just as the undergraduate participants were, and they also received stipends equal to the undergraduates. These graduate students had already completed a senior design experience before participating in the 2014 DeFINE Program and were asked to be mentors to the teams while also assisting in some instruction of design fundamentals.

The basic structure of the program required each team split their time between the two internships (1) clinical needs-finding internship and (2) technology transfer office internship. Each week teams would coordinate their clinical immersion schedules with their clinicians, with the remaining time spent on their tech transfer internship. Each Friday, a day of progress reports

would allow for the information to be collected and presented to the larger group on a weekly basis.

Clinical Needs-Finding Internship

These students were paired with established clinical design collaborators to conduct needs-based assessments of biomedical devices with the goal being to map clinical care processes and identify areas of unmet medical device and system needs. These needs assessments and outcomes were then, upon conclusion of the 6-week summer program, broadly disseminated for future use by other biomedical engineering senior design students to increase the impact of the program beyond the 18 students that participated.

Ten clinicians were initially identified, but with dynamic interactions during the rotations, over 44 clinicians ultimately participated as clinical design collaborators in the areas of plastic surgery, sports medicine, pediatric surgery, minimal access and bariatric surgery, thoracic and oncology surgery, interventional radiology, otolaryngology surgery, OBGYN, and vascular surgery. Students had the opportunity to shadow clinicians in these areas within the operating room, in the clinic and throughout the hospital environment.

Technology Transfer Office Internship

To provide entrepreneurial relevance to this clinical immersion, the DeFINE Program featured an internship in technology management with the university technology transfer office, CURF, during which time the students were exposed to: (1) intellectual property assessment decisions and portfolio management, (2) technology marketing, and (3) technology licensing and commercialization. The students were challenged to assess the needs discovered in their clinical immersion experiences as well as existing bioengineering technologies within CURF's intellectual property portfolio for their potential as commercial products. Specific outcomes of the technology management internship included enhanced analytical skills in technology assessment, identification of viable commercialization technologies, and patent landscape assessments.

The technology evaluation was conducted by each team for one technology that was present in the university technology transfer office's portfolio. This internship was conducted under the supervision and with the mentorship of the technology commercialization officers of the university technology transfer office. Commercial potential for each technology was evaluated but for confidentiality purposes, the information and technologies evaluated will not be discussed in this paper.

Instructor Programming

The two grants that support the DeFINE program did not support instructor significant salary, these grants being a NIH 1R25EB016589-01A1 Grant and 2014 VentureWell Faculty Program Grant. The DeFINE program was structured to qualify as a 3 credit course, so the instructional and organizational load were approximately that of such a course. The collaborations and organization of facilities and clinician interactions were the most intense, and required a few

months of communication during the previous spring semester to organize. The clinical mentors were asked to be available for a minimum of 2 hours per week for interviews and one-on-one interaction with the students, but otherwise the students simply observed the clinicians during their normal clinical work activities. Following program initiation, the faculty and coordinator roles involved oversight, guidance, and mentoring of the participating students.

Documentation Tools and Techniques

Students were tasked with observing, interviewing, and documenting all that was experienced during their 6-week clinical immersion. Appropriate documentation of the student activities was collected in multi-modal forms including logbooks, mind-mapping software, and clinician video interviews. Initial documentation of observations was recorded in each student logbook. This initial clinical documentation was limited to logbook documentation as no pictures or video footage was obtained in the operating room or clinical environment that compromised patient privacy. At some point during the clinical shadowing period, clinical partners would participate in video interviews in which they further detailed problems often encountered in the working environment and demonstrated proper techniques for procedures. Teams would compare logbook notes and interview video footage to create a comprehensive mind-map detailing the observations from each clinical experience. These observations were recorded in one of four simplified areas: People, Processes, Procedures, and Places (The Four P's). This technique was used to simply all of the information that was being observed and documented by the students. These four areas and the information thereof were organized for analysis and future review in a mind-map. It is this documentation mode that will be most commonly accessed by future senior design students seeking additional insight into the people, processes, procedures, and places that make up the need they are seeking to solve. An example mind-map can be seen in the Appendices.

The collection of observations into a mind-map and interview video was the foundation on which the student teams defined the problems present in the clinical area from which needs statements were formulated. Appropriate instruction of needs statement construction was articulated by the program directors and aided in their definition of what was needed to be solved for future BioE senior design students.

Following the conclusion of the 6-week clinical and technology transfer immersion internships, the students were asked to present their findings in presentation form and then complete an end-of-program survey to discuss their satisfaction with the content and their opinion of the tools, techniques, and influence of the program.

VI. Results-and Discussion

The following results were gathered upon the conclusion of the 6-week DeFINE Program. The demographics by class standing of the DeFINE participants can be seen in Figure 1.

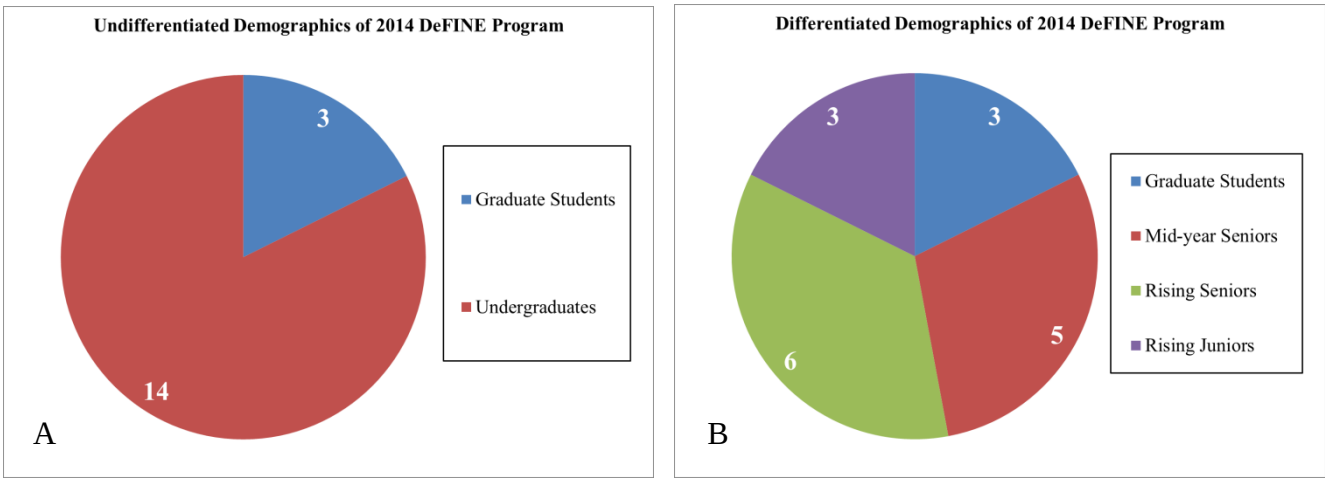

Figure 1: The class standing distribution of the 2014 DeFINE student end-of-program survey respondents as (A) undifferentiated within undergraduate class and (B) differentiated within undergraduate class.

The results for the demographic distribution were obtained from the surveys completed by the DeFINE students following their 6-week clinical and technology transfer immersion experience. One undergraduate student did not complete the survey and therefore the total number of DeFINE participants represented in Figure 1 does not match that which was previously presented. Overall, 18 students participated in the DeFINE Program, and it can be seen in Figure 1A that the ratio of graduate student to undergraduate was approximately 1:3, when accounting for the one undergraduate that did not complete the end-of-program survey. This ratio allowed for the five groups of three students to have sufficient graduate student mentorship from one of the three graduate students. As is seen in Figure 1B, the distribution across upperclassmen can be divided out by the following definitions: Mid-year seniors were classified as those who had already taken the first semester of the two-semester senior design class; Rising seniors were classified as those who had completed their junior year curriculum but had not yet taken then first semester of the two-semester senior design class and would do so in the following semester; Rising juniors were classified as those who had not yet completed their junior year curriculum but would complete the first semester of the two-semester senior design class within three semesters of completion of the DeFINE Program. With this being the first offering of the DeFINE Program, the distribution was more heavily weighted with rising seniors (6 participants) and mid-year seniors (5 participants) in comparison to the 3 rising juniors. Specific outcomes were further analyzed by this demographic class standing distribution and will be discussed later.

Each of the participants documented the time distribution of all activities performed during their DeFINE experience with the distribution being: 106 weekly procedure hours, 227 clinic hours, 723 operating room hours, 360 hours of documentation, and 110 technology transfer office hours. These reported hours can be further valued by the number of clear needs that were identified by the students. In the 2014 DeFINE Program, 550 needs were clearly defined by finalized need statements with even more problems identified in each of the clinical areas.

As can be seen in Figure 2, the documentation tools and techniques were evaluated by each student for their usefulness. Clinician interviews were thought to be most useful on average with a rating of 3.88 on the usefulness scale (1- not useful, 2- somewhat useful, 3- moderately useful, and 4-highly useful) while the journal/logbooks were ranked second in these tools and techniques with an average usefulness ranking of 3.71. The Four P's Structure was seen as above moderately useful with an average ranking of 3.29 while the mind-maps documentation ranked last with 3.06 on the usefulness scale. Overall, it is meaningful to see that each of the tools and techniques were ranked moderately useful, the variation between such tools/techniques most likely stemming from the level of difficulty associated with each and time required for each. The clinician interviews did not require much more time than was set aside to discuss problems encountered in the clinical environment and the journals/logbooks were utilized in the same environment. However, it was the 4 P's structure and the mind-maps documentation that required slightly more attention and time to deliver the appropriate content. A tendency might exist for students to find tasks completed individually more time consuming and potentially less useful to the process. However, each tool/technique was completed first as individuals and then as a team to avoid this tendency. Both of these concepts might be an area to further assess in future DeFINE Programs. Additionally, future programs will ask students how each of these tools might be improved to accompany their ratings from Figure 2. This will provide commentary similar to that of the author hypotheses discussed in relation to Figure 2.

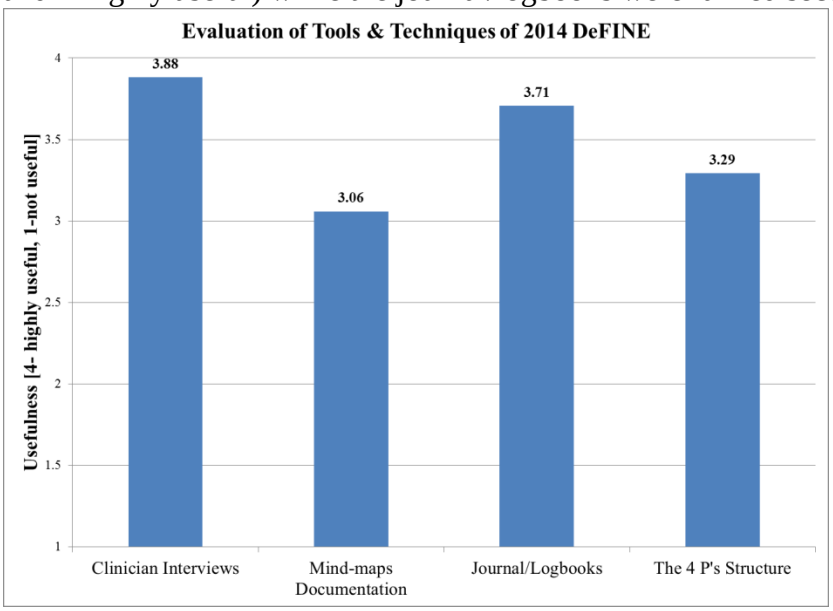

Figure 2: DeFINE participants evaluated the tools and techniques presented according to their usefulness with 4 being "highly useful" and 1 being "not useful". The results show that all methods were seen as at least moderately useful (3) to the 2014 DeFINE students.

The content for the DeFINE Orientation Week was similarly evaluated for its usefulness by the DeFINE participants following their 6-week program. The results for each topic can be seen in Figure 3.

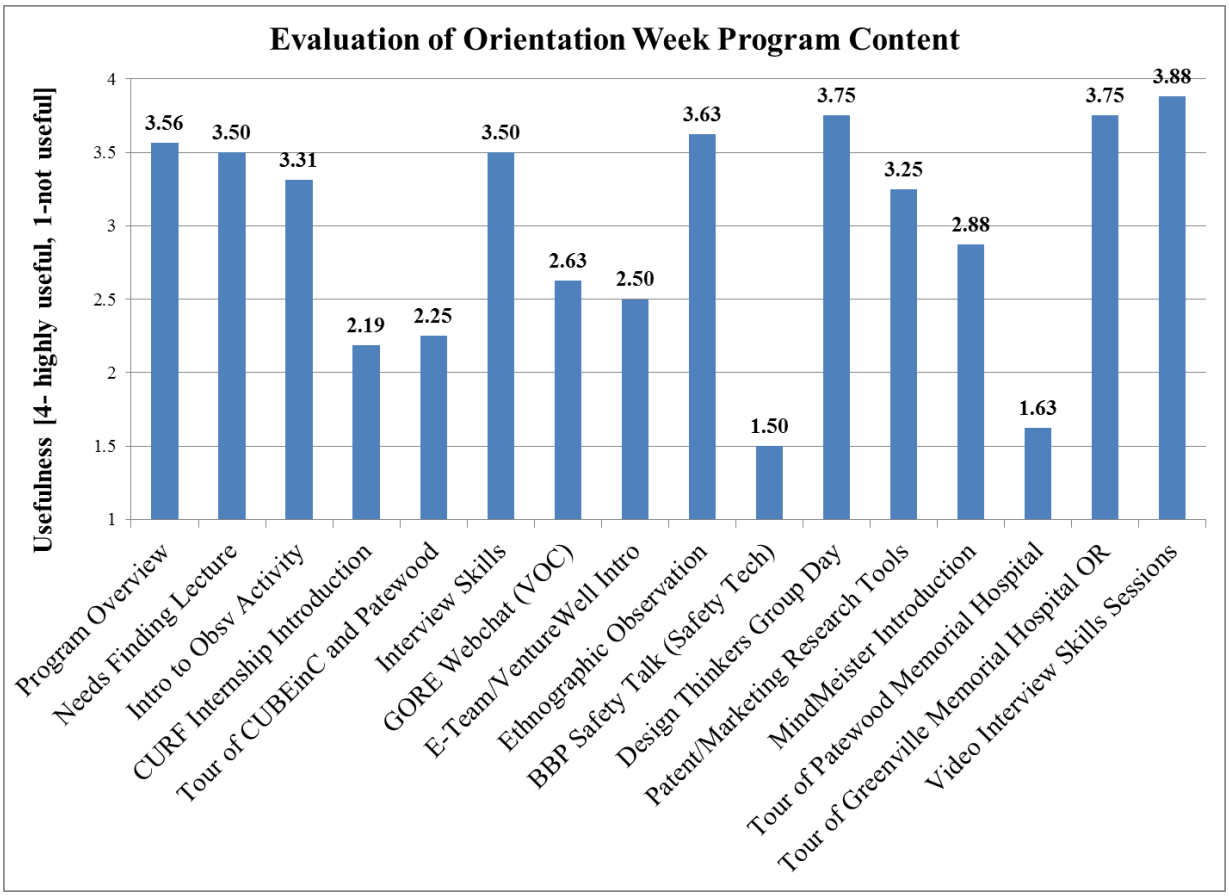

Figure 3: The usefulness of each topic presented over the DeFINE Orientation Week was evaluated on a 1-4 scale with 1 being not useful, 2 being somewhat useful, 3 being moderately useful, and 4 being highly useful. The topics are displayed in chronological order such that the Program Overview opened the week and the Video Interview Skills Sessions closed the Orientation Week.

It is shown by the response of the DeFINE participants that the usefulness of the Orientation Week activities spanned the range of being "not useful" such as the blood-born-pathogen (BBP) safety talk with an average rank of 1.50 and the Tour of Patewood Memorial Hospital with an average rank of 1.63 activities to those almost "highly useful" such as the video interview skills sessions with an average rank of 3.88. A closer look at the topics that fell short of "being somewhat useful" with an average rank of 2 should be further examined during future DeFINE Programs to see if this ranking improves. It should be mentioned that the Tour of Patewood Memorial Hospital most likely fell short of the usefulness reached by the Tour of CUBEInC. and Patewood (2.25) and the Tour of Greenville Memorial Hospital OR (3.75) because that specific time of day was not conducive to clearance of a large group of students and the tour guide did not have clearance to the majority of the spaces that would have been open for a larger group. Overall, the content intended to introduce major topics such as needs-finding, observation, interview skills, ethnographic observation, and patent/marketing research tools all received at least a "moderately useful" ranking with the lowest being 3.25 (patent/marketing research tools). This shows that the content that was most relevant to the productivity of the students in the DeFINE program was well-received and considered to be helpful throughout the process of the

6-week program. Future programs will consider other methods by which to hopefully improve these usefulness rankings.

As was discussed earlier, the DeFINE participant class standing was evaluated alongside other parameters of interest. The first was that which can be seen in Figure 4 which involves the student post-program assessment of the DeFINE program's usefulness for future senior design experiences.

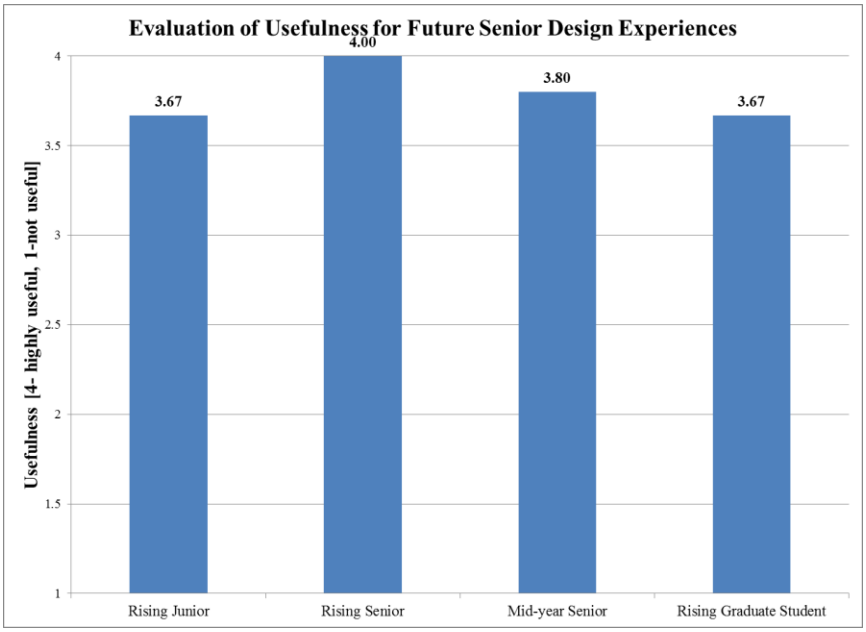

Figure 4: The usefulness of the 2014 DeFINE Program to future senior design experiences was evaluated on a scale from 1-4 with 1 being not useful, 2 being somewhat useful, 3 being moderately useful, and 4 being highly useful. Each average evaluation was classified by class ranking, chronologically ordered.

As is shown in Figure 4, no matter the class ranking of the student participant, each group held the opinion that the DeFINE Program would be highly useful for future senior design experiences. This is mostly evident in the rising senior classification ranking of 4.00 (highly useful) as it is this group that is making the preparations for the upcoming two semesters of senior design. The second highest ranking of usefulness is that of the mid-year senior group, who on average ranked the DeFINE Program's usefulness for future senior design experiences to be 3.80. The results of the rising senior and mid-year senior class standing is not surprising when considering that the rising senior is most concerned with their next two semesters of senior design, whereas the mid-year senior is concerned with the second semester of design, but having passed the first semester of senior design, does not have the same high value of usefulness as the rising senior. The rising junior does in fact have both senior design semesters ahead but it is thought to be distant enough in the future so as not to be quite as useful as those rising seniors and mid-year seniors. It is somewhat surprising to see a similarly high ranking of usefulness in the graduate student classification as compared to the rising junior. It is believed that this high ranking is influenced by these graduate student mentors' future involvement and mentorship in senior design teams.

A second parameter of interest was compared directly with the class standing of the DeFINE student participants. The final area of interest to be examined in this paper is the level of influence the DeFINE Program provided on the student's future goals. This relationship by class standing can be seen in Figure 5.

Results showed that with increased time in the Bioengineering program, the less the DeFINE students' future professional objectives or educational goals are influenced. As shown in Figure 5, with increased class standing, there persists a decrease in the level of influence of the DeFINE Program on goals and objectives. This may be in part due to the student's priorities at the time of taking the DeFINE Program. Both rising juniors and rising seniors, those furthest from potentially already having a professional objective or education goal set, ranked highest among their goals being influenced by the DeFINE Program. Those closest to the potential for already having a professional objective achieved or an educational goal set, the graduate students, ranked lowest with an average influence of only 2.00 (somewhat influenced). The mid-year seniors, many of whom were only one semester away from graduation, ranked their level of influence just below the rising juniors and rising seniors (both with an average of 3.67) and just above the graduate student ranking. These mid-year seniors averaged a 3.00 influence rating which corresponds to a moderately influenced opinion of how the DeFINE Program influenced their goals and objectives. It is interesting to observe this trend that has some clear distinction based on the class standing of the participating students. This and other parameters will be evaluated in future DeFINE Programs to achieve a potentially more definitive result with a higher sample size.

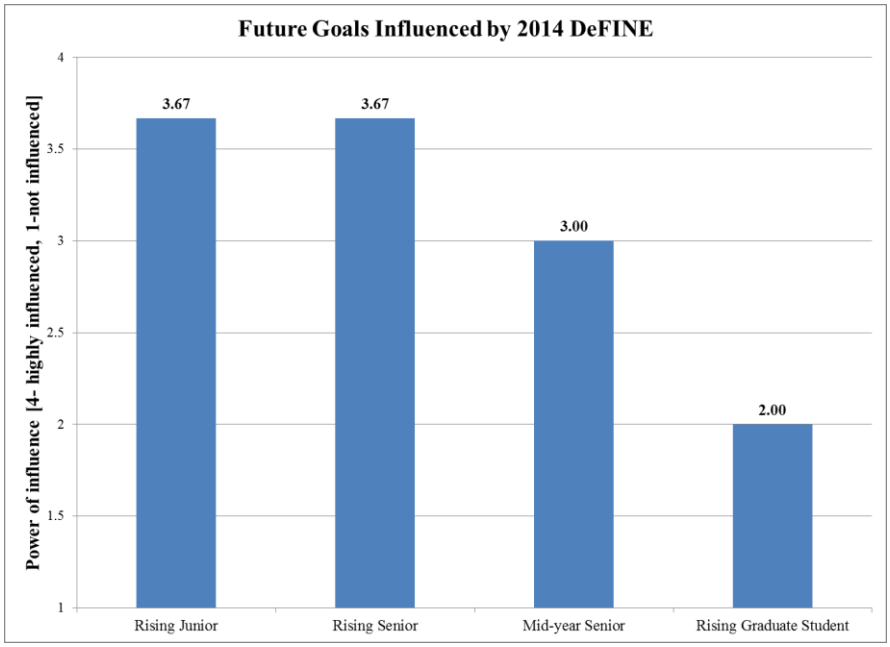

Figure 5: The level of influence of the 2014 DeFINE Program on the student future professional objectives or educational goals was ranked on a scale from 1-4, with 1 being not influenced, 2 being somewhat influenced, 3 being moderately influenced, and 4 being highly influenced.

Of all the 18 DeFINE student participants, the compilation of work completed was extensive over the course of only 6 weeks. Observation hours were logged by person-hours (i.e., 5 person hours would be equivalent to one person observing 5 hours of activity or 5 people observing 1 hour of activity). In summary, the opportunities afforded to the 18 students included 106 observed surgical procedures, 227 person-hours observed in the clinic, and 723 person-hours observed in the operating room. By way of 470+ person-hours devoted to needs documentation and formal video log with the clinical design collaborators, the 18 DeFINE students identified 1000+ clinical needs. This database of clinical needs has since been distributed to the current Bioengineering Senior Design students, many of which have adopted one of these 1000+ DeFINE-identified clinical unmet needs as their primary design project of the year. The DeFINE Program will continue for four additional summers, seeking to further engage bioengineering

students in the experiential learning and immersive experiences associated with the clinical biomedical design process.

VII. Future directions

This compilation and documentation of the processes, techniques, and tools utilized in the 2014 DeFINE Program can be improved upon and revisited over the next four summer immersion internships. The results presented in this paper are the initial evaluations, many more of which are to come with future directions for this clinical and technology transfer office immersion program. One such future direction involves documenting the productivity and usefulness of the needs identified in The DeFINE Program (How many students go on to lead their senior design teams? How many students go on to Senior Design and use a need identified in DeFINE? How many students continue on in Senior Design and alter their previously agreed upon need to one identified in DeFINE?). There is also a need to quantify the resulting projects for their commercialization potential (How many needs identified in DeFINE are utilized to create IP-based solutions? How many needs identified in DeFINE are utilized to create solutions that are licensed? How many needs identified in DeFINE are utilized to create solutions that are used to start an entrepreneurial venture?). A future paper will begin to assess the long term outcomes of the uncovered needs and of solutions developed by the senior design students that address the uncovered needs. It is also important to note that in the 2014 DeFINE Program, the technology transfer office experience was not explicitly compared to the clinical experience because they each focus on unique learning outcomes (knowledge of technology transfer versus knowledge of needs-finding practices). It is possible that some metrics for parallel evaluation could be determined and will be considered for the 2015 DeFINE Program.

It also should be noted that initial evaluations were focused on the participating students, of whom the opinions and suggestions for tool improvement should be utilized in future programs. However, evaluations will be expanded to include the clinical and technology transfer mentors for subsequent years of the program.

These future directions will build on the extension of the results that were represented in this paper for a more complete understanding of the power that clinical immersion can have on the productivity of a Bioengineering senior design student.

VIII. Acknowledgements

Development of this program was supported by the faculty, clinical mentors and staff of Clemson Bioengineering and Greenville Health System (GHS). Ethnographic research workshop during DeFINE Orientation Week was conducted by Design Thinkers Group USA, Inc. Funding for the DeFINE Program was provided by NIH 1R25EB016589-01A1, VentureWell Faculty Program Grant 2014, and Clemson University Creative Inquiry.

IX. References

1. Kline, W.A., Mason, T.W., and Dougherty, B.C. “Being Innovative- Lessons Learned from the Practice of Technology Commercialization.” Journal of Engineering Entrepreneurship. 4(1). 2013.
2. Zappe, S.E., Hochstedt, K.S., and Kisenwether, E.C. “Faculty Beliefs of Entrepreneurship and Design Education: An Exploratory Study Comparing Entrepreneurship and Design Faculty.” Journal of Engineering Entreprenuership. 4(1). 2013
3. Atman, C.J., Kilgore, D., and McKenna, A. “Characterizing design learning: A mixed-methods study of engineering designers’ use of language.” Journal of Engineering Education, 97(3): 309-326. 2008.

X. Appendices

Appendix A

An overview of the 2014 DeFINE Program can be viewed at this video link: https://www.youtube.com/watch?v=EvtsjW23k6c.

Appendix B

An example Mindmeister Mind-Map documenting the 4 P’s tool utilized during the Summer 2014 DeFINE Program can be seen below:

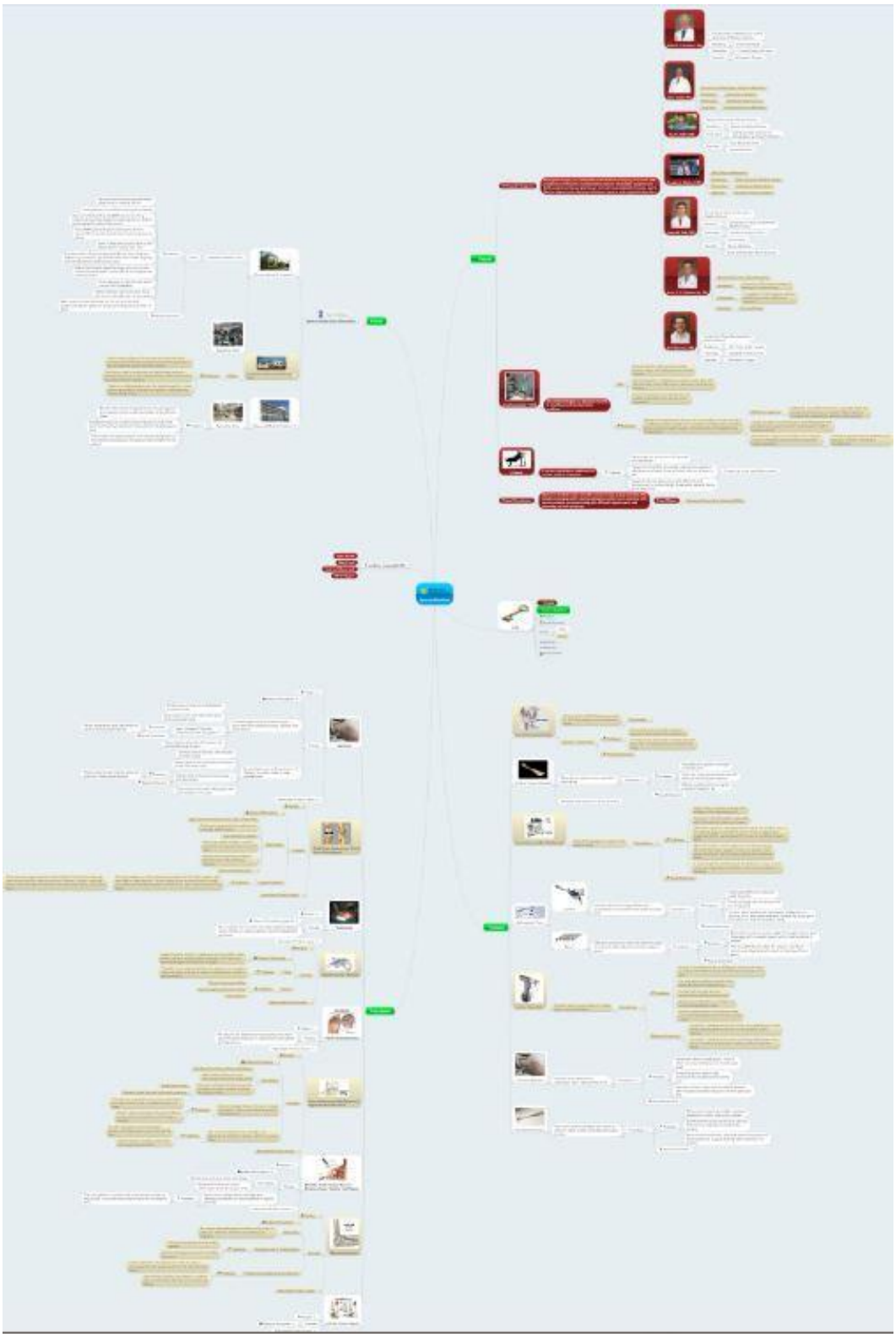

Figure B-1: A fully expanded view of an example mind-map documenting the 4 P's tool.

Figure B-2: A closer look at the People and Places P's in the Mindeister mind map

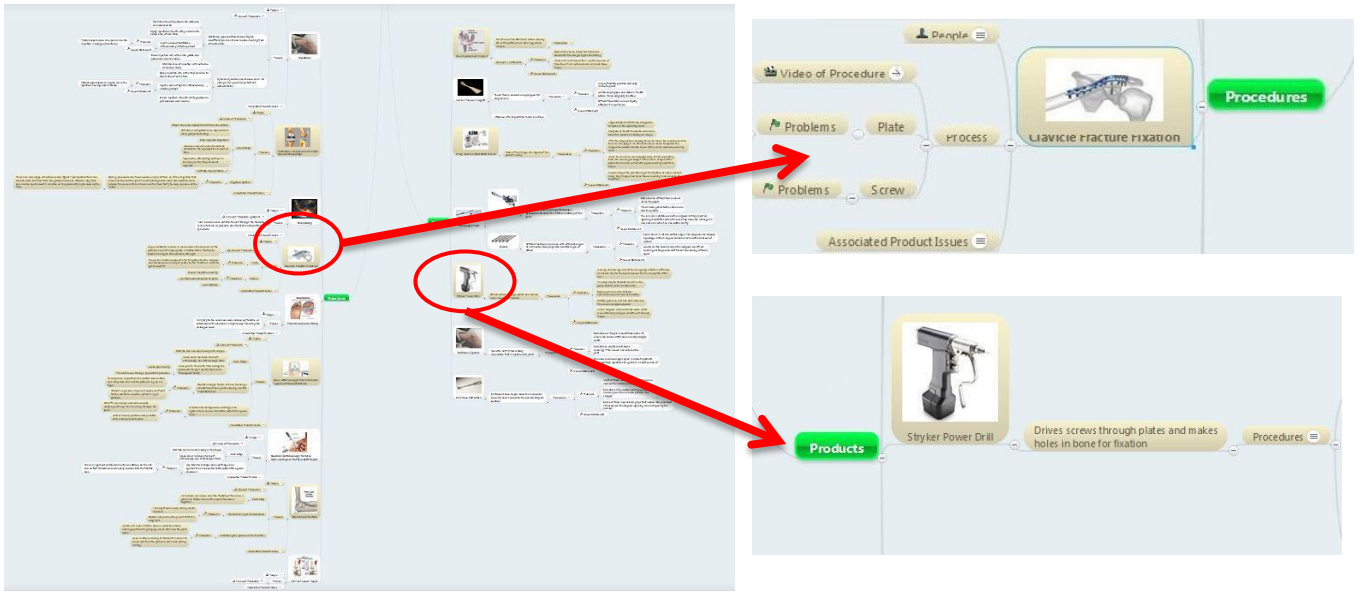

Figure B-3: A closer look at the Procedures and Products P's in the Mindmesiter mind map