

## **Year Two - The DeFINE Program: A Clinical and Technology Transfer Immersion Program for Biomedical Needs Identification and Valuation**

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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 Fellows, a program of the Epicenter and co-managed by Stanford University and Venturewell, has inspired Breanne to share her passions 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 versus 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 BMESStart 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.

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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 has been a business and educational program development consultant with the Coulter Foundation, advising NIH NIBIB SBRI awardees in technology translation.

**Ms. Carson Mackenzie Ida Brewer, Clemson University**

Carson Brewer is a second year student at Clemson University studying Bioengineering. Through many research opportunities in the department, Carson has led a team to the Limbs Summit in El Paso, Texas where they presented a functioning, 3-D printed, lower arm interface that allowed a subject with a congenital arm defect to successfully use a forearm crutch. Carson now focuses her research on designing medical devices for the developing world with an infant temperature regulation device. Having had these opportunities, Carson plans to pursue further research that enables her to reach out to others through engineering.

# **Year Two: The DeFINE Program: A Clinical and Technology Transfer Immersion Program for Biomedical Needs Identification and Valuation**

## **I. Introduction**

Universities wish to educate their students to be leaders in their fields, but the current higher education structure is often criticized for favoring education over innovation, which can limit the ability of entrepreneurial thinkers to receive the experiences needed to bring student innovations to the marketplace. In fact, the education that they are receiving at university is often not even the content that future employers are seeking. While 96% of college provosts believe their students are prepared for the job market, only 11% of business leaders agree.<sup>1</sup> An article by Johri and Olds states that “the disjuncture between school-engineering and work-engineering remains intact, and significant efforts are needed to bridge this gap”.<sup>2</sup> To begin to offset this educational gap, the bioengineering design program at the disclosed institution developed a comprehensive 6-week summer clinical and technology transfer immersion experience to close the “school-engineering” and “work-engineering” gap for bioengineering students.<sup>1</sup>

The DeFINE (Design Fundamentals in Needs-Finding Experience) program seeks to offer students a clinical and technology transfer immersion experience to enable students to practice the processes of clinical needs finding and biomedical technology valuation; two key steps in the identification and translation of clinical needs into biotechnology innovations. The purpose of this paper is to detail the structure and content of this the program and compare initial assessment results from the first two years of the program. Where possible, comparisons between year one (2014) and year two (2015) results will be discussed relative to changes that were implemented based on assessments and recommendations for improvement for the program. In this paper, it is hypothesized that the 2015 DeFINE Program will deliver a greater usefulness to participating students in comparison to the 2014 DeFINE Program with improved evaluation of the tools and techniques utilized in 2015.

## **II. Methods**

The DeFINE (Design Fundamentals in Needs-Finding Experience) Program is a six-week National Institute of Health (NIH) and VentureWell funded program with two immersive experiences: (1) a clinical immersion experience that enables rising juniors, seniors and graduate students in bioengineering to experience, empathize and observe a variety of clinical specialties with the goal to identify needs that all too often go unseen by traditional senior design experiences and (2) a technology transfer immersion experience that enables these students to evaluate the defined clinical needs from a technology valuation perspective with a goal enabling students to be able to assess the likelihood of technology commercialization for potential products designed to satisfy those needs.

The DeFINE Program was developed and first offered in summer 2014 in partnership with Clemson University and the regional healthcare system, Greenville Health System (GHS). This program PI and director (author JD) is a mechanical/biomedical engineer and associate professor who directs the university’s bioengineering design program. Additional directors included

author (BP)- a co-instructor for the university's bioengineering senior capstone design program, the program Co-PI and chief of surgery at GHS, an assistant professor that leads the graduate student biodesign program at Clemson University, and the director of licensing for technology transfer at the Clemson University's technology transfer office. The program takes place at a bioengineering clinical translation facility located on the campus of the regional healthcare system (not the university academic campus), Clemson University BioEngineering Innovation Campus (CUBEInC.).

The program focuses on bioengineering undergraduates and provides summer stipends of \$1,500 for the student participants. Participating students were selected from a pool of departmental applicants. Applications were distributed in March 2014 for the summer 2014 DeFINE Program participation (due to the award timeline of the grant), and December 2014 for the summer 2015 DeFINE Program participation. In addition to GPA and class demographics, the application required the students to answer the following 3 questions in short paragraph form: 1) Please summarize why you are interested in participating in the DeFINE Program 2) Summarize your previous experiences in design, clinical shadowing, and technology transfer activities and 3) Describe your future academic and professional goals, and how you think the experiences and tools gained through the DeFINE Program would be applied to these goals. From 31 applications in 2014 and 42 applications in 2015, 18 students were chosen to participate in each year's summer program, which took place from mid-June to the end of July.

The program started off with a one week orientation for the students. In addition to completing administrative tasks such as hospital badging and payroll, students also completed training in HIPPA, biomedical and clinical research compliance, radiation safety, and operating room procedures. Students then were introduced to design and needs-finding tools and techniques, such as team building, design-thinking, ethnography, empathy, observation, technology valuation, professional interactions, interviewing skills, videography and clinical etiquette.

Students were trained to document observed clinical problems by way of four multi-modal tools: These included (1) Written logbook documentation, followed by reflection and compilation of these notes; (2) Clinical video interviews that further pressed the initial observations made during the shadowing and allowed the students to gain greater insight into the problems they were observing; (3) A mind-mapping process (MindMeister: mind mapping software (Munich, Germany)), through which the students organized their observations and clinical contacts as a team, and (4) The adoption of a "Four P's structure", wherein all of these observations and interactions could be structured by either a) People, b) Processes, c) Procedures, or d). Places. From this organization and documentation, the students were able to further organize and analyze the observations made with the final goal to develop need-statements for each critical problem that was identified. It is these needs assessments and mindmaps that were broadly disseminated to the bioengineering senior design program at the disclosed institution for future use.

During the first week, students were allowed to select two clinical areas of interest, and based on these identified interests, the students were grouped into teams of 2-3 people. Clinical areas for shadowing were identified in the weeks preceding the program. These contacts were usually arranged directly with clinicians and research colleagues who were familiar with the activities of

the bioengineering program and senior design activities. These clinicians were introduced to the DeFINE program goals, activities and timeline and were allowed some flexibility with regards to scheduling shadowing experiences, duration and number of students. Surgical specialties were targeted, and included areas such as vascular surgery, surgical oncology, plastic surgery, obstetrics and gynecology, otolaryngology, interventional radiology, sports medicine, colon and rectal, minimally invasive surgery and pediatrics. Usually one primary collaborator was identified within each specialty, but during the students interactions with that surgical division, numerous other clinical collaborators were identified and shadowed. This networking effect was left to the students' initiative.

Following the orientation week, the teams completed four full weeks of clinical shadowing and technology transfer activities. Typically, four days out of each week was spent shadowing clinical collaborators within two surgical disciplines (two weeks each). These shadowing experiences included both operating room and clinic observation time, and the specific schedules during these four weeks were flexible so as to accommodate both the clinical partners and hospital schedules and constraints.

The fifth day of each week was spent working directly with the university technology transfer office (Clemson University Research Foundation-CURF) to provide exposure to portfolio assessment, technology marketing, and technology licensing and commercialization. With mentorship from the technology transfer officers and interns, the students evaluated both the needs they were identifying in their own clinical shadowing experience as well as those previously designed and housed within the university intellectual property medical technology portfolio. Commercial potential was evaluated by the students themselves with the goal to gain insight into the process that their future senior design projects would eventually undergo at the conclusion of their senior design experience. Both immersions were vital to the collection of defined needs and impact on student's future goals.

The sixth week brought the students back together for reflection, documentation and assessment. It allowed for thorough final clinical documentation and needs evaluation to conclude the immersive experience and prepare the students for the senior design course to follow. Each team prepared and presented a final review of their experiences to their peers and program instructors, and a final group presentation was given to the hospital administration and leadership.

Program and student assessments took three forms. The first was an assessment of student demographics and motivations. The second was an assessment of student productivity during the program, and the third was an assessment of student perception of the program itself. For both the 2014 and 2015 programs, content and assessment were very similar. For example, each year placed equal emphasis on documentation and the use of the four-P's for translation of the students clinical shadowing experiences into defined needs. However, some changes in methodology between 2014 and 2015 were implemented, based on review and assessment results from 2014. These changes included moving up the videography skills workshop in the week-on orientation, embedding the graduate students into the undergraduate teams rather than just having them as mentors to the teams, increasing the number of hospital OR tours and orientations from 1 to 3, so as to include more facilities that the students would visit, targeting rising seniors more heavily, increasing the number of clinical collaborators so as to add some

flexibility to the students schedules and afford greater opportunity to interact with a diverse network of healthcare providers. In addition, in 2015, the graduate students were given the additional task of mapping the hospital administrative process of adoption of new procedures and biomedical technology.

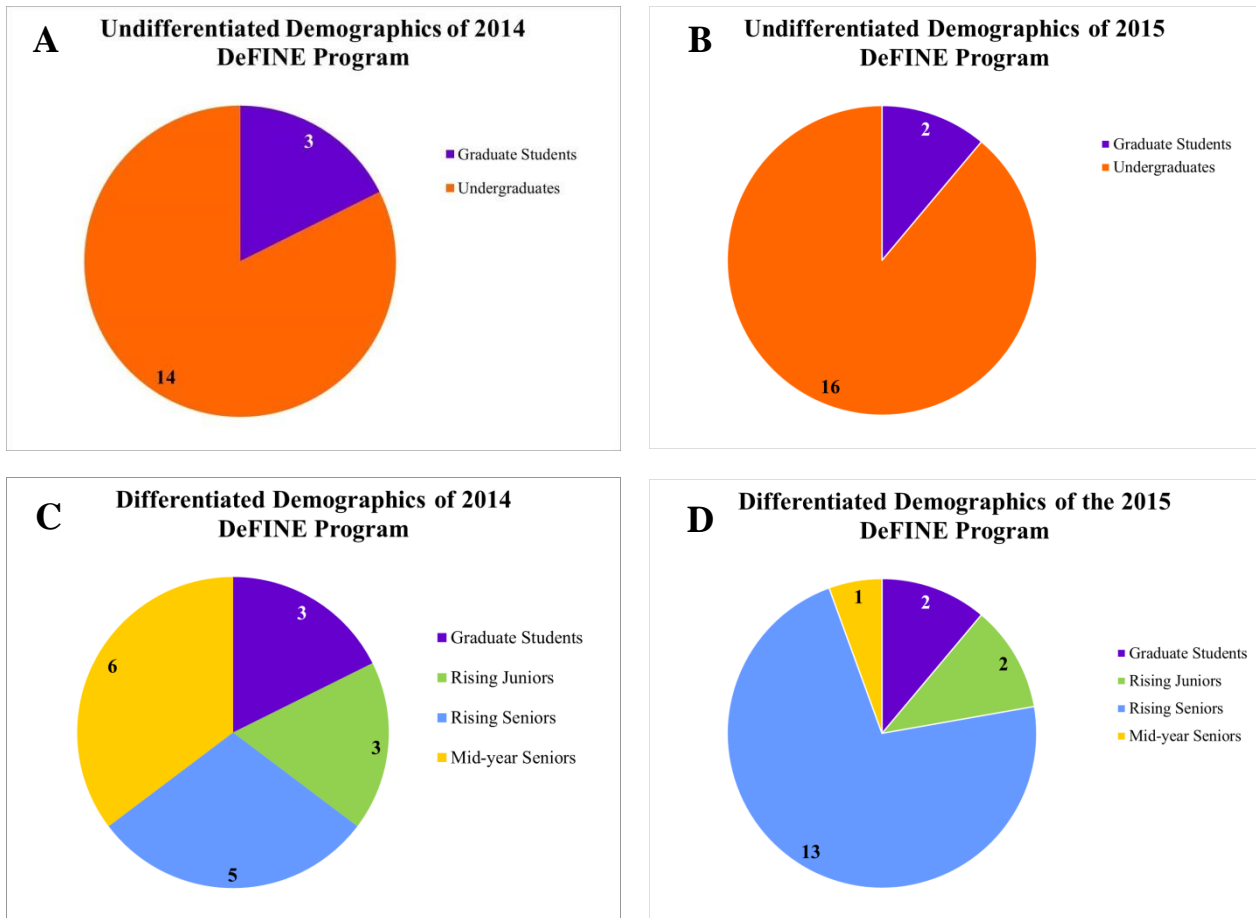
One of the new metrics that was introduced in 2015 was the assessment of translatability of learned skills to the senior design class for fall 2015 and spring 2016. The tools to be utilized to evaluate this transferability of skills from the DeFINE Program to the Senior Design Class will focus on measuring the readiness of the student for the workplace (by way of student perception) as well as the readiness of the developed design for the marketplace (by way of technology transfer office perception). The senior design project evaluations will heavily involve the university technology transfer officers and their technology assessments while an internal evaluation of student's perception of their readiness for their plans post-graduation will be separately evaluated. The summer 2015 DeFINE Program prepares students for the Fall 2015-Spring 2016 academic senior design program and as the Spring 2016 semester is still underway, this design process is still in progress. Therefore, one of the purposes of this paper is to provide an overview of the summer 2015 program results with expected results of the student leadership and designs produced in the year-long Senior Design course that concludes in May 2016.

### III. Results and Discussion

#### DeFINE Demographic Distribution

Results of student demographics from 2014 and 2015 can be seen in Figure 1.

The demographic distribution between 2014 and 2015 is similarly distributed between the graduate and undergraduate students. However, as can be seen in Figure 1, 2015 possesses a much larger group of rising seniors (n=13) as opposed to the nearly equal distributions with rising juniors and mid-year seniors in 2014. This extra emphasis placed on the rising senior group was conceived due to 2014 results showing that the rising senior group found the DeFINE Program to have the greatest usefulness for future senior design experiences as well as the greatest influence on their future goals (shown in Figure 4 and Figure 5).<sup>3</sup> This group was therefore sought out in greater number for the 2015 DeFINE Program. It should be noted that all of the undergraduates will undergo the full senior design course following the DeFINE Program except for the mid-year seniors, who will only undergo the second semester of the senior design course (the product development semester). It should be noted that this study did not assess the influence of industry experience- undergraduate students who had previously participated in an industry co-op or internship was not recorded, but could be in future years. Both of the graduate students participating in the DeFINE Program were graduates of the senior design program at the disclosed university, and therefore possessed prior knowledge of and experience in the full design process, which was critical to the mentorship of the undergraduates progressing through the program. It was noted that the responses of the two graduate students in the following research did not represent a large sample size and therefore, were evaluated with that consideration in mind.



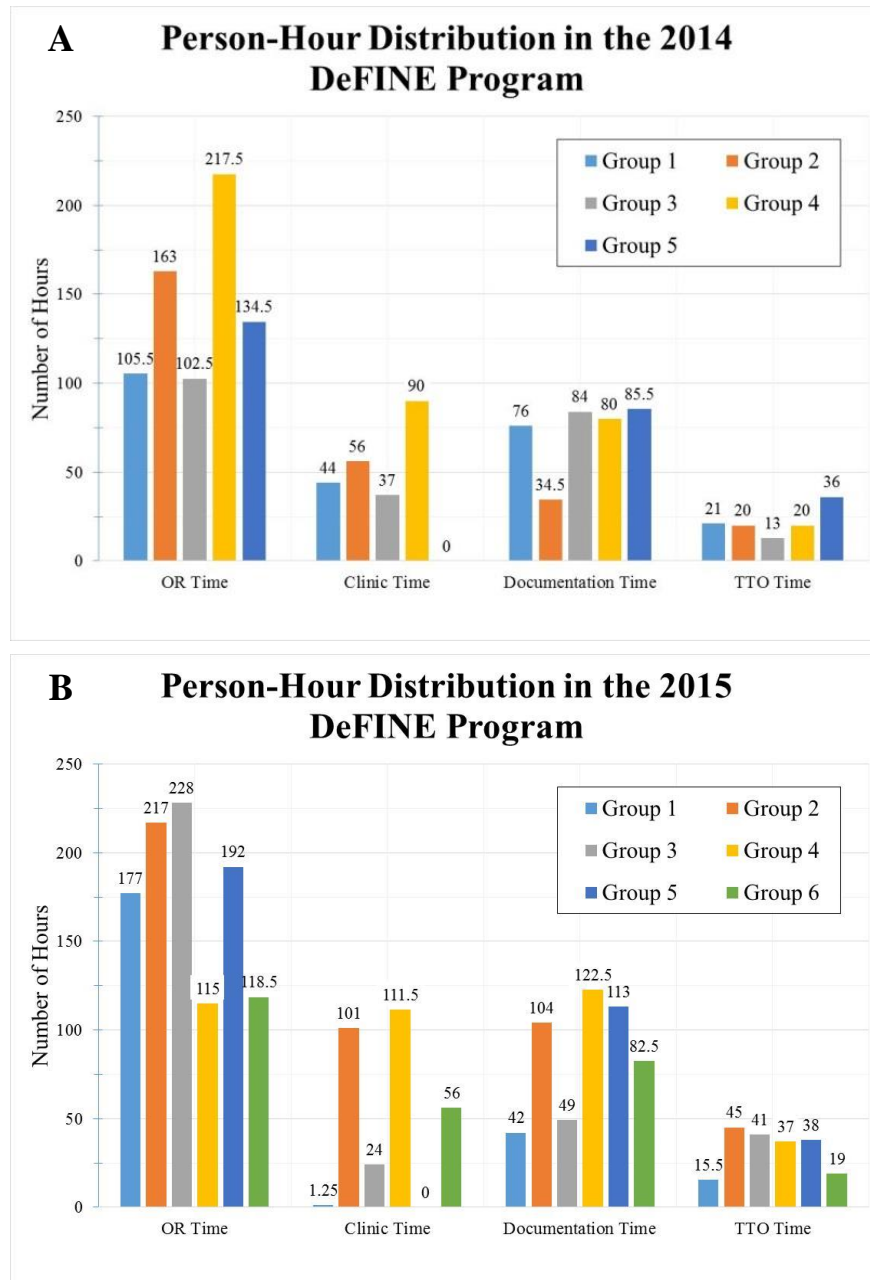
**Figure 1:** The DeFINE 2014 vs 2015 classes as shown (A) and (B) undifferentiated within the undergraduate class and (C) and (D) differentiated within undergraduate class.

Both the 2014 and 2015 students formed teams of approximately 3-4 students each. In 2014, the three graduate students rotated between the five teams, whereas in 2015, the graduate students were integrated as team members on teams. This is why there are five teams in 2014 and six teams in 2015 with the same number of participating students both years (n=18). Based on the teams' preferences and clinical collaborators schedules, each team selected two clinical areas to shadow for two weeks each. Table 1 details these clinical areas.

**Table 1:** Comparison of demographic distribution and clinical area by team from 2014 to 2015

	2014 DeFINE Program			2015 DeFINE Program		
	Demographics	Clinical Areas		Demographics	Clinical Areas	
Team 1	2 Rising Seniors, Mid-year senior, Rotating Grad	Plastic Surgery	Vascular	Mid-year senior, Rising Senior, Grad	Plastic Surgery	Vascular Surgery
Team 2	Rising Junior, Rising Senior, Mid-year senior, Rotating Grad	Sports Medicine	Minimally Invasive Surgery	3 Rising Seniors	Oncology	Obstetrics/Gynecology
Team 3	Rising Junior, Rising Senior, Mid-year senior, Rotating Grad	Pediatrics	Ear, Nose, and Throat (ENT)	3 Rising Seniors	Otolaryngology	Interventional Radiology
Team 4	Rising Junior, Rising Senior, Mid-year senior, Rotating Grad	Minimally Invasive Surgery	Sports Medicine	2 Rising Juniors, Rising Senior	COIS/Pediatrics	Sport Medicine
Team 5	2 Rising Seniors, Mid-year senior, Rotating Grad	Thoracic Surgery	Obstetrics/Gynecology	2 Rising Seniors, Grad	Minimally Invasive Surgery	Vascular Surgery
Team 6	-	-	-	2 Rising Seniors, Rising Junior	Sports Medicine	Colon/Rectal Surgery

## DeFINE Program Outcomes



**Figure 2:** The distribution of time spent during the six-week summer (A) 2014 DeFINE Program and (B) 2015 DeFINE Program both show a heavy emphasis on OR time and documentation time.

during their 4 weeks, and shadowed them to identify over 600 problems, from which over 200 needs were defined. These distributions of time-spent between OR, clinics, technology transfer

The teams were asked to document how their time was spent across the week rotations. The data shown in Figure 2 shows the distribution of work hours in both the 2014 and 2015 DeFINE Program iterations.

For the 2014 DeFINE Program, it should be noted that only five teams participated and therefore direct comparison between the two groups was limited in this analysis, but further analysis of average hours completed per student will be later evaluated.

With a more specific focus on the 2015 DeFINE Program, it can be seen that over 1000 person-hours (defined as one person conducting one hour of activity) were spent defining needs in the operating room, nearly 300 person-hours in the clinic, and nearly 200 person-hours working with the technology transfer office. Although less than 20 clinical collaborators were initially identified by name at the beginning of the program, the DeFINE students interacted with over 110 clinical partners



office (TTO) and documenting their observations and learnings during the six-week DeFINE Program can be seen in Figure 2.

When parsed out in the manner displayed in Figure 2, it is shown that the majority of the DeFINE students' time was spent in the OR (average of 120 hours per team for 2014 and 175 hours per team for 2015), while the least amount of time was spent in the technology transfer office immersion (average of 18 hours per team for 2014 and 33 hours per team for 2015). This distribution is expected with the course schedule with four of the weekdays allotted for clinical immersion and only one weekday allotted for technology transfer office immersion. The average time spent in the clinic was nearly 38 hours for 2014 and 50 hours for 2015 and was highly dependent on the type of clinical area shadowed.

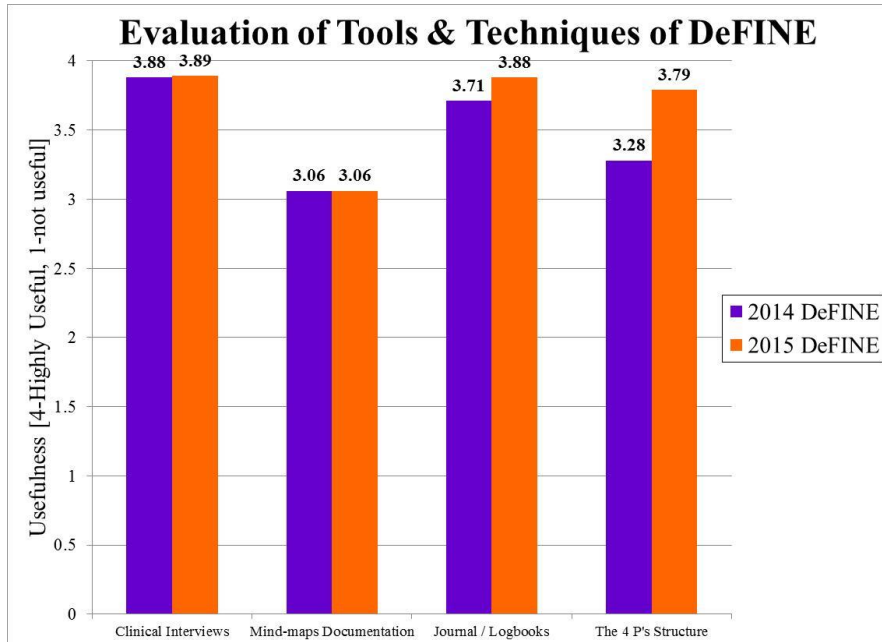
When further parsed out by the average time spent per-student for the whole program in the four respective regions, a distinct change in average hours per-student can be seen. Both the 2014 and 2015 Programs engaged n=18 students, with 2014 having five groups and 2015 having six groups of students. It can be noted that the average time per-student increased in each of the four areas between the 2014 and 2015 DeFINE Programs (40 to 58 hours in OR Time, 13 to 16 hours in Clinical Time, 20 to 29 hours in Documentation Time, and 5 to 11 hours in TTO Time).

As can be seen in Figure 2, 2015's Group 1 and 2015's Group 5 had relatively little clinical time whereas 2015's Group 2 and 2015's Group 4 spent nearly half or equal time in the clinic as compared to the OR. This is due to the OR-heavy areas that were shadowed by 2014's Groups 1 and 5 as compared to the clinic-heavy areas shadowed by 2015's Groups 2 and 4. These hours are also highly dependent on flexibility of clinician and availability of the clinical schedule for the students- some clinician's staff have confirmed schedules weeks in advance whereas others must operate on a more spontaneous schedule that does not allow the DeFINE students, who live between 0.5-1 hours from the clinical site, to always participate. What is promising to see is the high average time spent on documentation of needs with an average of over 60 hours per team for 2014 and 85 hours per team for 2015. This highlights the importance that DeFINE students and DeFINE program coordinators placed on the documentation of the needs observed in the clinical environment. Without this documentation, the information cannot be measured or passed on to future design students.

### Program Tools and Techniques Evaluation

At the conclusion of the DeFINE Program, each of the four multi-modal tools was evaluated by the students for their usefulness both in 2014 and 2015 as shown in Figure 3. The students ranked their usefulness value on (1) clinical interviews, (2) mind-mapping documentation (Mindmeister), (3) clinical journaling/logbooks, and (4) the 4 P's structure: People, Processes, Procedures, and Places. The results displayed in Figure 3 suggest that the findings from 2014 were met or exceeded in 2015, with all of the tools being evaluated as at least moderately useful for both the 2014 and 2015 DeFINE students. However, 2015 DeFINE students saw a significant increase in usefulness for both the journal/logbooks as well as the 4 P's structure in comparison to the 2014 DeFINE students. The 2015 program saw three out of the four tools evaluated as highly useful tools, with mind-mapping still being seen as moderately useful. Again, the level of difficulty associated with utilization of each tool should be noted when evaluating the results.

The consistency in lowest ranking of the mind-mapping documentation might be due to the increased required attention to detail associated with this tool as compared to the others. However, these results should be noted and taken into account when preparing DeFINE tools in the future.



**Figure 3:** A usefulness scale from 1-4, where 1 represents "not useful", 2 represents "somewhat useful", 3 represents "moderately useful", and 4 represents "highly useful" was utilized to evaluate the four multi-modal tools (clinical interviews, mind-map documentation, journals/logbooks, and the 4 P's structure). Findings suggest that all tools were seen as at least moderately useful to the 2014 (n=17) and 2015 DeFINE (n=18) students, with slight increases in usefulness for all tools in the 2015 DeFINE class.

This increase in usefulness for nearly each of the tools and techniques proves the hypothesis for improved tools and techniques evaluation from 2014 to 2015. These results also point to a possible improvement from 2014 to 2015 in instructor experience with the tools and techniques of the program: the instructors' experience with these tools between 2014 and 2015 and their ability to communicate the importance of these tools to the students might have transferred to the students' ability to use them and thus eventual higher ranking in usefulness. Additionally, the maturity of the students as mostly

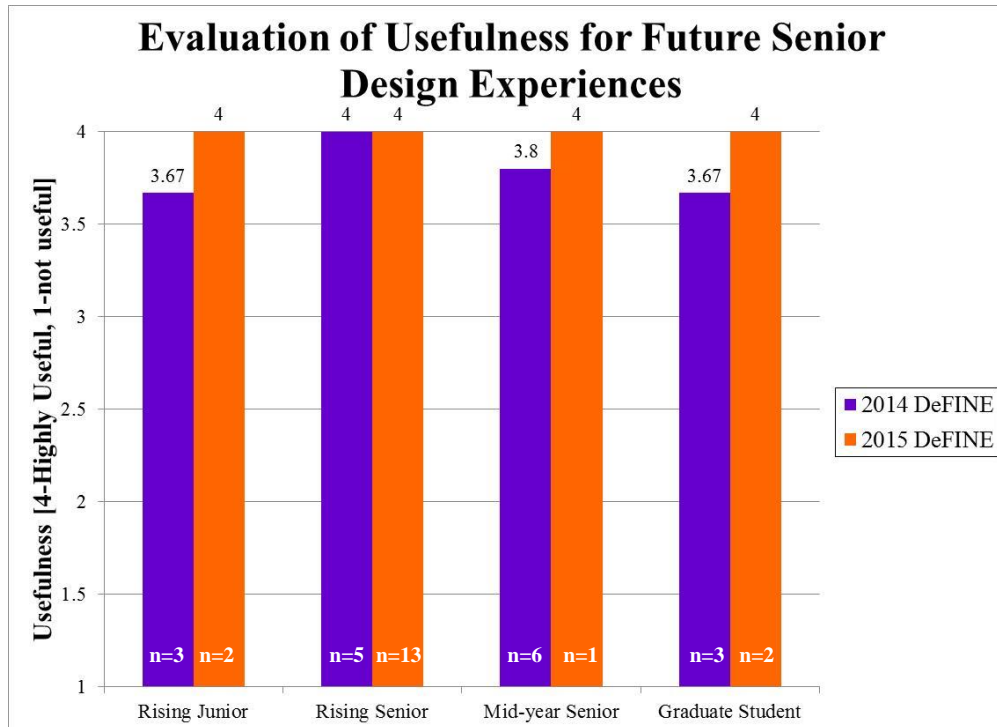
seniors in 2015 as compared to 2014 might have enabled the students to see the relevance of these tools towards their senior year more clearly and thus they considered them more useful. These insights might be applicable to future results as well.

### Program Impact on Future Senior Design Experiences

A purpose of the DeFINE Program is to better prepare students for their senior design experience. Therefore, DeFINE students were differentiated by class standing (rising junior, rising senior, mid-year senior, and graduate student) to examine the differences in perceived usefulness following their involvement in the DeFINE Program as seen in Figure 4.

The overwhelming consistency in the 2015 DeFINE students' perception of the "high usefulness" for future senior design experiences is highlighted. In 2014, only the rising seniors valued the DeFINE Program's future applicability to their senior design experiences as highly

useful so this dramatic increase in all four classes of students is very promising. The increase in usefulness perception of the graduate students might be the most surprising of the results. This is thought to be such due to the particular graduate students involved in the 2015 DeFINE Program,



**Figure 4:** The usefulness of the 2014 and 2015 DeFINE Programs was evaluated and compared on a usefulness scale from 1-4, where 1 represents "not useful", 2 represents "somewhat useful", 3 represents "moderately useful", and 4 represents "highly useful".

timed such that an immediate interpretation of the future effects on design could be captured. It is also intended to capture the students' responses following their full participation in the associated senior design course.

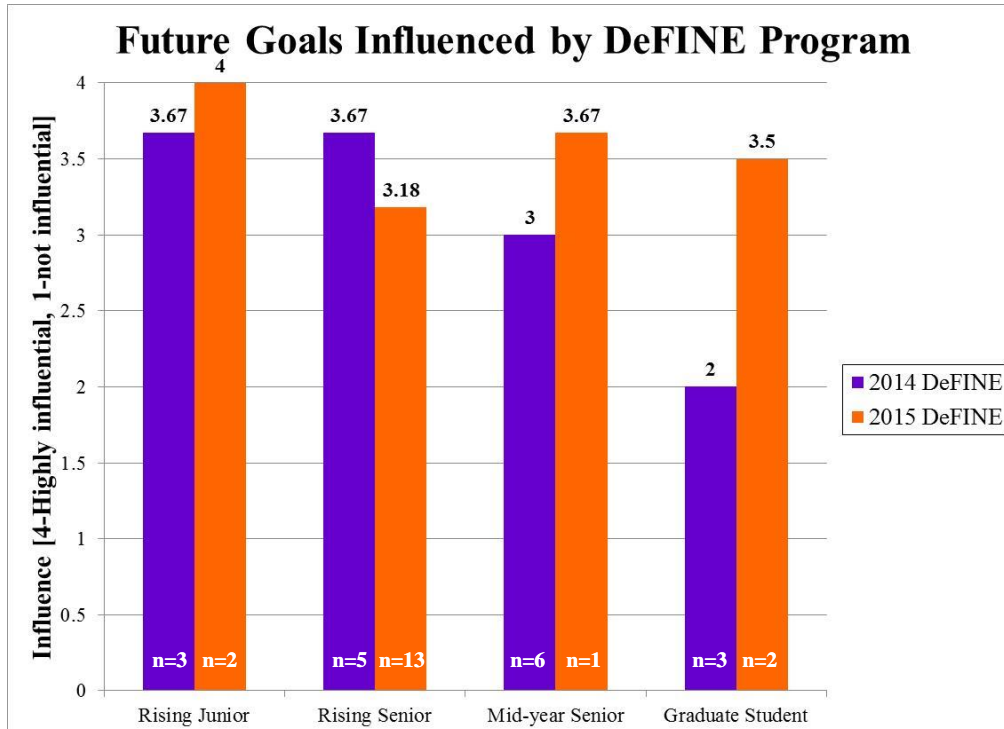
This increase in usefulness for future senior design experiences for all but one of the student groups (rising senior remained the same) proves the hypothesis for improved student response to the program from 2014 to 2015.

### Program Impact on Student Goals

The final area of interest that was examined with class standing of the DeFINE Program in 2014 vs 2015 is that of the students' perception of how the DeFINE Program influenced their future goals. This evaluation can be seen in Figure 5.

both of whom are often involved as senior design mentors during the academic year, and both of whom are pursuing heavy design-based graduate student research projects, from which their passion and mentorship for senior design can continue to thrive.

The student evaluation of their perceived usefulness of the program directly after the program's conclusion was



**Figure 5:** The level of influence of the DeFINE Program on the students' future professional objectives or educational goals was ranked on a scale from 1-4, 1 representing "not influence", 2 representing "somewhat influenced", 3 representing "moderately influenced", and 4 representing "highly influenced".

Results show that with the exception of rising seniors, all 2015 groups felt the DeFINE Program had an increased influence on their goals as compared to the 2014 groups. The graduate student population, which was previously discounted as a group that might have already had their professional and educational goals set, was the group with

the largest rise between 2014 and 2015 (difference of 1.5). Again, this might be in part due to the particular graduate students who participated in the 2015 DeFINE Program- both of whom are younger graduate students and might have been more greatly influenced by the DeFINE Program than those in 2014 because their professional and educational goals have not yet been so strictly defined. The increase in goals influence between the 2014 and 2015 program for both rising juniors and mid-year seniors is seen as a positive result- hopefully due in part to the content revision and increase in perceived usefulness for future senior design experiences (as seen in Figure 4). The decrease in influence for the rising senior group should be further evaluated. The professional goals of many of the rising seniors of the 2015 DeFINE Program had been previously communicated to DeFINE directors in the profession of a medical doctor, a path that requires great preparation during the undergraduate years. Therefore, the results might suggest that these rising seniors, for whom the medical doctor profession was their goal prior to the DeFINE Program, did not necessarily change their professional goals, but might have simply been positively influenced for future design endeavors in their future professional area (as was seen in Figure 4). The increased number of participating rising seniors (n=5 to n=13 from 2014 to 2015) might also have had an effect on the results.

For all 18 of the 2015 DeFINE students, the positive influence on both future senior design work and professional/educational goals was evident. This suggests that the students participating in

the DeFINE Program are developing skillsets that better prepare them for their post-graduation plans.

The student evaluation of their perceived effect of the program directly after the program's conclusion was timed such that an immediate interpretation of the future effects on career goals could be captured. It is also intended to capture the students' responses following their full participation in the associated senior design course.

#### IV. Expected Results Discussion

We hypothesize that the students that participated in the DeFINE program will possess a greater readiness for the workplace if their intention post-graduation is to move into the clinical or industry environment. All are expected to graduate with a greater understanding of how to observe needs and then further evaluate the prospective solutions for licensing potential. This expectation will be evaluated by the individual student at the conclusion of the senior design experience (May 2016). Future programs might survey clinical employers to help determine how prepared the DeFINE students are for the clinical environment they are entering post-graduation. It is also expected that the designs that are developed from the DeFINE-identified needs will be more market-ready than those that were not. This is expected because the needs that were identified during the DeFINE Program were identified during actual clinical procedures; not simply chosen by a clinical stakeholder and voiced to the students, as is often the case with bioengineering senior design groups. Instead, the DeFINE-identified needs were visualized by the students themselves in the clinical environment and also clinically confirmed by the stakeholders being shadowed. These clinically-vetted needs should present greater potential for development in the design process. The extensive clinical shadowing and immersive experience that the DeFINE students engaged in should have afforded them a greater understanding and realization of observing needs in the clinical workplace. Additionally because of their technology transfer immersion experience, the DeFINE students should have engaged in their senior design process while keeping in mind the requirements for a more market-ready device, such as appropriate market size, low ease of commercialization, novelty, etc.

To evaluate how market-ready the DeFINE students' design projects are in comparison to those who did not engage in the DeFINE Program, the university technology transfer office will aid in conducting a thorough clinical market evaluation for each of the senior designs in Summer 2016 following the conclusion of the 2015-2016 senior design course. Although the 2014 DeFINE Program was completed in its entirety before the 2015 DeFINE Program analysis began, no one-year follow-up assessment for the rising seniors and juniors in the 2014 Program was completed. The program was improved in 2015 by implementing a one-year follow-up assessment and a two-year follow-up assessment for both the 2014 and 2015 students. This should capture the post-senior design experiences from the 214 DeFINE students that were juniors, the 2015 DeFINE students that were rising seniors, and the +1-year post-graduation experiences from the 2014 DeFINE students that were rising and mid-year seniors.

All of these expected results should contribute to increasing student readiness for the workforce and improved product marketability to bridge the "school-engineering" and "work-engineering" gap.<sup>1</sup>

## V. Conclusion

The 2015 DeFINE Program identified over 200 needs in ten clinical areas- many of which will be re-visited during the senior design process. These needs have since been passed on to current senior design capstone students-several of which are returning DeFINE students (the rising seniors and mid-year seniors). These students will either select a need identified through the DeFINE Program or select a need identified with their own clinical team to move forward with in their senior design process. All needs (both those that are selected and those that are not selected to develop a senior design around) will be returned to the database of clinical needs for the next rotation of senior design. It should be noted that the DeFINE students may or may not be on the same senior design team because the seniors have the opportunity to select their own teams for the senior design course without influence from the research team. It will be the DeFINE students whose success in senior design will be tracked and whose data will be compiled at a later date with close examination of how the DeFINE Program affected their technology maturity level at the conclusion of the senior design two-semester class with assistance from the university technology transfer office. It is the DeFINE Program that is enabling bioengineering students to think more critically of their environment to make biodesign changes in every area they find themselves immersed in- readying these students with skillsets that future employers are expecting.

## VI. Acknowledgements

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