

CLINICAL OBSERVATIONAL DESIGN EXPERIENCE: A Large Design Oriented Clinical Immersion Course Based In Emergency Departments

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Abstract

In this paper we describe a unique program offering an extended clinical immersion experience to a large number of students. This program makes use of emergency departments where students can be exposed to a wide range of medical procedures, diagnostic testing, clinical conditions, and healthcare providers. The program offers students 4 to 8 hours per week of clinical immersion throughout the semester. Students use the available staff as their clinical preceptors rather than having students paired with a single clinician who modifies their normal routine to work with them. Over the past seven years, roughly 360 students have had extended clinical experiences in five emergency departments in four different healthcare systems.

Introduction

It is well established that exposure to clinical settings is important for development of medical devices (Zenios, Makower, et al. 2010; Yazdi and Acharya 2013; Broadhead, et al. 2012-2014; Privitera 2015). While many biomedical engineering programs offer opportunities for shadowing and clinical observation, these are usually of limited duration and already focused on a specific device or clinical problem (Mittal, Thompson, et al. 2013; Sienko, Kaufmann, et al. 2014) (Heller, Michelassi, et al. 2008). We have developed a clinical immersion program aimed at arranging an extended observation experience that will provide a basis for future clinical exposure. Students participating in this program do so before or concurrently with their capstone/senior design experience. This course is supplemental to clinical experiences they may have with their capstone advisor.

Over the past seven years we have provided extended immersion experiences for over 360 students in active emergency departments. Our program has made use of five different emergency departments. While most clinical immersion programs provide a ratio of one clinician to up to four students, our program makes use of a single clinician who regularly meets with the class of 20 to 60 students and also meets with the student groups when needed. The course has been offered using Atlanta area Emergency Departments (EDs), including Grady Memorial Hospital Emergency Care Center, Emory University Hospital, Emory University Hospital at Midtown, Children's Healthcare of Atlanta at Egelston, and the Kaiser Permanente Advanced Care Center at Town Park – a “freestanding” ED. These sites include academic centers as well as true community practice settings.



Emergency departments offer many unique advantages for learning how to understand and work within clinical environments. These advantages include the prominence of emergency care within medicine, the nature of emergency care, and the structural components of the ED. Emergency Medicine (EM) is a board-certified specialty in stabilization and treatment of acute injury and illness. An emergency physician (EP) can manage a wide range of injuries including major trauma, severe sepsis, and cardiac and neurologic emergencies, and is equally at ease providing routine health care (American College of Emergency Physicians 2015).

EDs, whether in an academic or in a community setting, contain a wide variety of personnel who assist with patient care. These staff members include physicians and nurses, as well as a variety of other healthcare professionals, including respiratory therapists, radiology technologists, and phlebotomists. Non-clinical staff, including maintenance, biomedical engineering, registration, and environmental services personnel, are also present, providing a broader understanding of what it takes to deliver care. The large number and diversity of staff in the ED creates good “cover” for students to blend in with while observing.

Emergency care is uniquely episodic: students are often able to observe complete care of patients during an observation period. While emergency departments care for all manner of patients and clinical conditions, most students enter the immersion program with at least some firsthand experience, either having been patients themselves or accompanied friends or family to an ED. Multiple television shows and movies may provide a useful, if somewhat inaccurate, point of reference for students. Emergency medicine makes a broad use of procedures and diagnostic tests, which provides students with broad exposure to opportunities for improvement. Due to the wide range of clinical problems,

including those that the emergency physician is not trained to definitively manage, the ED offers a location to meet providers from other specialties. This significantly broadens the range of clinical problems that can be identified by students for the purposes of both this course and future design courses.

Despite these characteristics, EDs are not frequently used for clinical immersion. This may be in part because all care and procedures done in the ED are also performed by other medical or surgical specialties. Observing care with specialists is advantageous because procedures and patient visits occur on a scheduled basis, which allows clinicians to show their advisees the procedure or the scenario that they want the student to see. In contrast to observation in the ED, this unfortunately means that students have limited opportunities to understand the larger context within healthcare.

History

“Clinical Observational Design Experience” (CODE) was started seven years ago. This course was built from a previously offered course, “Clinical Research Practicum” which placed undergraduate biomedical engineering students in a single ED where they served as research assistants. The didactic portion of the course taught clinical research methodology. This course followed the model developed at the University of Pennsylvania, which has been adopted in multiple academic EDs associated with universities with undergraduate programs.

The earlier course established the presence of a significant number (up to 30) undergraduate students in the ED at Grady Memorial Hospital. Grady is the Atlanta area’s largest Level 1 Trauma Center and is a safety net hospital for underserved communities in Atlanta. These students wore light blue lab coats so that they could be easily identified while in the ED and assisted in recruitment of

study subjects and data collection for both funded and unfunded research projects. The course was initially taught by a single physician and was later supplemented by the primary author. Funding to reduce the clinical responsibilities of the faculty was provided through a budget item in the endowment from the Wallace H. Coulter Foundation.

When the lead author assumed responsibility for the course, the Department of Biomedical Engineering asked that the course be revised to have a greater engineering focus, as specified by the gift from the Coulter Foundation. Ethnography and human-centered design were introduced as the focus of the course and it was renamed “Clinical Observational Design Experience.” Due to the acceptance and visibility of the blue lab coats in the initial ED, students participating in the course continue to wear blue lab coats while observing and are referred to by the clinical staff as the “bluecoats.” While clinical research is not the major focus of the course, students continue to assist with data collection for research projects and now have also been used for quality improvement projects.

Curriculum

The course is composed of two components, the didactic component and the observation component.

Didactic Component Preparation for Immersion

Students are expected to meet all badging requirements of the healthcare institution, which are expressed in more detail in the credentialing section. Beyond these requirements, several steps are needed to prepare students for their immersion experience. While many of the educational components are required by the clinical sites for credentialing, it is important to cover several topics in class to make sure that all students have heard the content. These elements include ED basics, OSHA requirements, personal health, HIPAA, and

clinical research. While many of the students have previously been in an ED, many have a very limited understanding of what actually happens there. Students receive an overview of emergency medicine, as well as the differences between reality and what is seen on television or in movies.

OSHA requirements, specifically training in handwashing and universal precautions, is essential even though the students are not supposed to make direct contact with patients or contaminated items. While students receive instruction on use of personal protective equipment (PPE) and are encouraged to wear PPE when observing procedures and major resuscitations, they are not supposed to be doing anything that requires its use. In the ED, students will come in contact with ill patients; proper hand hygiene is reviewed. As some patients they encounter will have compromised immune systems, proper technique for coughing and sneezing are reviewed. Students are told to not come to their clinical shift when ill, as this may place patients at risk. Finally, students are taught recognition and proper response to feeling lightheaded or ill while observing.

Students learn basic clinical research technique and ethics. Some clinical sites classify student observation as “research,” while others do not. Some clinical sites ask students to gather research or quality improvement data. Students therefore complete the Collaborative Institutional Training Initiative program course (CITI, www.citiprogram.org) and this material is reviewed in class.

Human-Centered Design and Observation

One component of the course’s offerings, human-centered design (HCD) methodology, is taught primarily to students by “doing” rather than by lecturing (Schaar, Rains, and Jacobson 2015). Students learn about observation skills and ethnographic methods through a lecture and readings (Diefenthaler

and Geremia, et al. 2011) followed by an in-class design exercise. An additional lecture focuses on defining and articulating a problem. Depending on the needs of the class, additional lectures can be added partway through the semester. Students in the class have previously completed basic design courses using HCD methodology, so a more robust treatment is not needed here.

Emergency Care

In preparation for observing, students receive several lectures covering major medical and trauma resuscitation, as well as major invasive procedures. In these lectures, students become familiar with the major concepts of Basic Cardiac Life Support (BCLS/CPR), Advanced Cardiac Life Support (ACLS), and Advanced Trauma Life Support (ATLS). In addition to the lectures, patient simulators are brought to class from the Emory Medical School's simulation center so students can see and "use" the devices they have heard about. In addition, students attend a series of lectures on emergency medical procedures. The goal of these lectures and the hands-on access to equipment is to give students a better understanding of what they will be seeing in the ED before they get there.

Observation Component Clinical Shifts

Each week, students are scheduled for two shifts lasting three to four hours. When multiple clinical sites are available, students are assigned to two sites in order to broaden their experiences. We have found that having approximately twenty students per clinical site seems to be manageable for most EDs. In general, students are assigned to shifts in pairs. Our experience has been that more students distract each other from observing, and students working alone often have more difficulty developing connections with clinical staff. Students are provided with the clinical schedule for physicians, but they are not assigned to a specific clinician. They are encouraged to simply observe in different

parts of the ED, as well as shadow clinicians. Many students find shadowing ancillary staff (such as housekeeping) to be just as valuable as shadowing physicians and nurses.

Clinical sites are provided with a photo montage of all the students, as well as a poster briefly describing the course. This signage is usually posted in break rooms. The signs also have contact information for the course faculty as well as the site coordinators, clinicians who troubleshoot site-specific problems and assist with the introductory tours for students.

Observation Notebooks

Students are required to keep and maintain an observation notebook. They are expected to record their observations, including intuitions and insights. Students are strongly encouraged to draw pictures (particularly since photography is not permitted at any of the clinical sites), maps, and diagrams to enhance their ability to communicate their observations with group members. An example of a typical page is shown in Figure 1. Notebooks are checked by teaching assistants, who provide feedback on the content.

Storytelling

Students complete two assignments for which they are required to tell a story based on their observations and experiences in the ED. Storytelling enhances communication (Olson, Barton, and Palermo 2013). Telling a good story often requires description of details so elements of the story fit together. The process of creating a story encourages the teller to develop an understanding of the thought processes and feelings of their characters—a challenging aspect of both human-centered design and ethnography (Privitera 2015). Students are encouraged to make use of the "and-but-therefore" style of storytelling both in the story assignments and in their design assignments.

Design/Discovery Assignments

During the semester, students complete four design exercises. In these assignments, students are expected to identify a “problem” based on their ED observations and shadowing. Students work in small teams, which allows them to pool information and leverage observations from multiple clinical sites.

They are expected to provide a brief and concise problem statement supported by a list of observations that led them to believe that they have found a significant problem, as well as the observations that allowed them to better understand the problem. A great many problems in healthcare are already well known, and the students are expected to locate relevant existing literature about their problem. If students identify a problem for which there is no prior literature, they are expected to look to published literature on related problems (even outside of healthcare) to better understand their problem.

Students are asked to propose a solution to their problem. While this portion of the assignment often is most important to the students, it is not the primary focus of the assignment and is not heavily emphasized in the grading. Students are expected to provide a discussion as to how they believe their solution will work. They are asked to provide a discussion of impacts of their solution beyond solving the single problem they have identified. Finally, they are asked to begin to identify reasons why their solution will not work.

Approximately one week before handing in their written assignments, students present their work to the class. Presentations are done in a modified PechaKucha (n.d.) style —only ten slides and twenty seconds per slide. This allows a large number of students to present in a single eighty-minute class period with sufficient time to

get feedback from other students, teaching assistants, visiting clinicians, and faculty.

In-class Interviews

Interviewing is a key aspect of ethnographic research and design methodologies based on ethnography. Over the course of the semester, students learn to do brief interviews with clinical staff while they are working. While they may have some opportunities for more extended interviews during their clinical time, many students have questions that either they are uncomfortable asking during their clinical time or which require a longer answer than can practically be provided. During many lecture periods, clinical faculty—who include the primary course instructor and guest clinicians—will take questions from the class.

Students are asked “What did you see that you did not understand? What did you see that you would have liked your classmates to have seen?” Students then describe the scenario that they witnessed and the clinicians can provide a brief description of how a clinician sees that situation. Clinicians can then describe the anatomy, physiology, pathology, and management of the medical condition. The goal of these in-depth answers is to allow students in the class to recognize similar situations when they see them. Hopefully they will also remember the technical language and background to enable them to record better observations and ask more intelligent questions. This also exposes them to clinical and technical jargon, enabling them to better record observations and phrase questions using more appropriate clinical language as the academic year progresses.

Patient Write-up

During the semester, students are expected to develop their clinical observation skills, and they demonstrate these new abilities in a final patient write-up. This assignment has three parts: a clinical write-up, a narrative, and a discussion of how

34

10 Nov 2015 Kaiser Shift G
 Kaiser Townpark ACC/CDU
 4:00pm - 7:00pm
 Drs. Kant, Vorack, Bharara; Kyle Dymov

Observations:

Things in hallway: at 4:10pm

LEGEND

- bed
- wheelchair
- desk chair
- urinal bag
- ┆ pressure cuff
- △ cleaning supplies cart
- ▽ ECG

Other wheelchairs stored in waiting room

Screen covers used: "Kensington"

Sometimes the glare from the sun causes her to need to reinsert

See-through when you look straight through; protect screen when you look from an angle (so patient doesn't see you typing report/quotes)

Idea: New way to check blood sugar that does not involve pricking finger

Total Computer Screens	# w/o	# w/s.p.	# w/out not in use
at 4:40pm 			
			extra s.p.
			total s.p.

Figure 1. A typical page from an observation notebook. Students are encouraged to take notes, draw pictures, include design ideas, and create tables to best capture what they have seen. Notebook page courtesy of Samantha Kiblinger.

**MEMORANDUM OF UNDERSTANDING BETWEEN
BOARD OF REGENTS OF THE UNIVERSITY SYSTEM OF GEORGIA BY AND ON
BEHALF OF THE GEORGIA INSTITUTE OF TECHNOLOGY
AND
GRADY MEMORIAL HOSPITAL CORPORATION
d/b/a GRADY HEALTH SYSTEM®**

This is a Memorandum of Understanding on the part of Grady Memorial Hospital Corporation d/b/a Grady Health System® (“Facility”), and the Board of Regents of the University System of Georgia by and on behalf of the Georgia Institute of Technology (“Institution”) (each a “Party” and collectively the “Parties”).

A. PURPOSE

1. The purpose of this Memorandum of Understanding is to guide and direct the Parties respecting their affiliation and working relationship, inclusive of anticipated future arrangements and agreements, to provide a high quality educational learning experience (a “Program”) for the Institution’s students.
2. Neither Party intends for this Memorandum to alter in any way their respective legal rights or their legal obligations to one another, to the students and faculty assigned to the Facility, or as to any third Party. However, the understandings contained herein may be incorporated into and made a part of a subsequent agreement executed between the Institution and Facility in a form substantially similar to that which is attached hereto and incorporated by reference as “Exhibit A” (the “Agreement”).

B. GENERAL UNDERSTANDING

1. A Program to be provided will be of such content and cover such periods of time as may from time to time be mutually agreed upon by the Parties. The starting and ending date for each Program shall be agreed upon at least one month before the Program commences. Program planning shall be subject to final approval by the Facility.
2. The number of students designated for participation in a Program will be mutually determined by agreement of the Parties, and may at any time be altered by mutual agreement. All student participants must be mutually acceptable to both Parties and either Party may withdraw any student from a Program based upon perceived lack of competency on the part of the student, the student’s failure to comply with the rules and policies of the Facility or the Institution, or for any other reason if either Party reasonably believes that it is not in the best interest of the program for the student to continue. Such Party shall provide the other Party and the student with immediate notice of the withdrawal and with written reasons for the withdrawal. Any student may withdraw from a Program upon written notification

1 of 22

Figure 2. The first page of the affiliation agreement between Grady Health System and the Georgia Institute of Technology. This agreement originally took a year to negotiate and get approved. Renewals (completed three times) have taken between three weeks and five months to complete. The entire document, including exhibits and documents which students and faculty sign, is twenty-two pages.



their patient was impacted by a problem that had been identified by the class.

Students are tasked with collecting clinical data about a single patient (stripped of identifiers to avoid HIPAA concerns) and provide a clinical patient write-up similar to what a medical student would perform. Since the students are not permitted nor trained to do any examination of the patient, they must complete this exercise using what they can see and the information they can acquire from the patient and staff. Students are expected to report these elements using appropriate medical and technical descriptions.

The students demonstrate their broader observational skills by providing a narrative of the patient's care. The challenge here is to tell a story, not simply report the series of events that happened. In doing this, students demonstrate empathy with the patient or providers involved in the patient's care. The final discussion is intended to have students demonstrate their ability to analyze the experience of one patient in the context of their other observations and their conclusions from other assignments.

Nuts and Bolts **Clinical Sites**

Finding and engaging clinical sites is challenging. Having a clinician as part of the instructional team can expedite the process of gaining access to their clinical site. Unfortunately, most clinicians are not familiar with their institution's policies and requirements regarding student observers; higher-level administrative involvement may be needed. Most healthcare systems and universities will require an affiliation agreement, which establishes the procedure for offering an observer program. Educational affiliation agreements may take a year or more to be approved.

Credentialing

Most hospitals will have an extensive list of requirements that must be completed by students. These usually include documentation of vaccinations and immunizations, recent tuberculosis screening, a seasonal flu vaccine, and clearance by a physician. Many hospitals now require criminal background checks as well as drug screening. This is usually an expense paid by the students. If this will be required, students should be informed before they register for the course, particularly since course faculty usually have no role in interpreting these reports.

Most hospitals require site-specific training. This ranges from student signatures attesting that they have read several documents to the completion of online courses or several hours of in-person employee/student orientation. A variety of other items may be required, including signed waivers of liability and HIPAA compliance attestation. One particular challenge for running courses like this is the requirement of additional insurance for the students. Depending on the university and the healthcare facility, additional liability and/or malpractice coverage may be requested, which may prohibitively increase the cost of the course.

Because of the complexity of these issues, administrative assistance will likely be needed while working to get students credentialed. Because the credentialing requirements can change, or worse, affiliation agreements can be voided by policy changes at the clinical site or at the university, alternative clinical sites are important and students need to be informed of the fragile nature of these agreements

Clinician Engagement

Unlike most other clinical immersion programs, this course has not required regular recruitment of new clinical preceptors. While many clinical immersion programs find clinician recruitment to be an ongoing challenge, it has been our experience that

clinicians exposed to these students become a rich pool of volunteers for other courses needing clinician input. That being said, roughly half of the didactic content—medical lectures and the in-class interviews—depends on the participation of one or a small pool of clinicians. Getting administrative approval for students also frequently requires engagement from a clinician or two.

Through their ongoing engagement, clinicians become better at guiding and mentoring students. Given the large demands on clinician time, sustained commitment to this course can be challenging. An important funding consideration for a course like this is to compensate clinicians adequately for their time so that they will continue to participate in the future. Funding to support this course has come from funds designated to support clinical experiences within the department's endowment from the Wallace H. Coulter Foundation.

Conclusion

The Clinical Observational Design Experience course uniquely leverages the wide range of medical conditions managed in an emergency department, as well as the diverse personnel who staff the department. Through extended observation experiences, students gain comfort working in this environment and begin to understand the broader complexity of healthcare delivery beyond performing a single procedure or managing a single condition. This course structure also allows a large number of students to get valuable clinical experience without recruiting clinicians for each student or small group of students.

While our program has evolved under a unique confluence of circumstances, our experience with this course in five different emergency departments suggests that our program could be reproduced in other healthcare facilities. There are several challenges that we have faced which would

be encountered in attempting to replicate this program. These are as follows:

- Establishing hospital affiliation agreements
- Hospital credentialing and badging
- Recruitment of clinician participants
- Maintaining long-term clinician involvement

In the face of these and other challenges, the CODE course continues to grow and evolve. As we plan for future semesters, we have identified several directions for improvement. These include continuing to expand the number of students, making the course an interdisciplinary offering, and better integrating the course into other design courses on our campus.

References

- American College of Emergency Physicians. 2015. "Policy Statement: Definition of Emergency Medicine."
- Broadhead, K.W., R. Hitchcock, James Agutter, et al. 2012-2014. "Using Clinical Immersion as an Empathetic Training Tool in Medical Device Innovation." NIH Project #5R25EB013122-04.
- Cornell University. n.d. "BME 716, Clinical Summer Immersion." Accessed January 26, 2015. <http://weill.cornell.edu/mri/immersion/>.
- Diefenthaler, A., A. Geremia, et al. 2011. *Design Thinking for Educators*. <http://www.designthinkingforeducators.com/>.
- Heller, C. A., F. Michelassi, et al. 2008. "Accelerating Innovation Between Surgeons and Biomedical Engineers in the Academic Setting." *Surgery* 143(2): 171-175.
- Mittal, V., M. Thompson, et al. 2013. "Clinical Needs Finding: Developing the Virtual Experience—A Case Study." *Annals of Biomedical Engineering* 41(9): 1899-1912.
- Olson, R., D. Barton, and Brian Palermo. 2013. *Connection: Hollywood Storytelling Meets Critical Thinking*. Hollywood, CA: Prairie Starfish Productions.

- PechaKucha. n.d. "PechaKucha 20x20."
Accessed November 15, 2015.
<http://www.pechakucha.org/>.
- Privitera, M. B. 2015. "Chapter 1: Introduction to Contextual Inquiry." In *Contextual Inquiry for Medical Device Design*, 1-22. Cambridge, MA: Academic Press.
- Schaar, R. Y., J. K. Rains, and Martin C. Jacobson. 2015. "Jump-Starting Biomedical Design Education in the Sophomore Year: A Human-Centered Approach." VentureWell Open Conference. National Collegiate Inventors and Innovators Alliance.
- Sienko, K. H., E. E. Kaufmann, et al. 2014. "Obstetrics-based Clinical Immersion of a Multinational Team of Biomedical Engineering Students in Ghana." *International Journal of Gynecology & Obstetrics* 127(2): 218-220.
- University of California, Berkely. 2015. "Summer Biodesign Immersion Experience." <http://bioeng.berkeley.edu/biodesign>.
- Yazdi, Y., and S. Acharya. 2013. "A New Model for Graduate Education and Innovation in Medical Technology." *Annals of Biomedical Engineering* 41(9): 1822-1833.
- Zenios, S., J. Makower, et al. 2010. *Biodesign: The Process of Innovating Medical Technologies*. Cambridge: Cambridge University Press.