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# "Careful and Complete Observation of the Patient:" Nurses and the Sociotechnical System of Medical Research, 1930-1962

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# "Careful and Complete Observation of the Patient:" Nurses and the Sociotechnical System of Medical Research, 1930-1962

## **Abstract**

ABSTRACT

CAREFUL AND COMPLETE OBSERVATION OF THE PATIENT;" NURSES AND THE SOCIOTECHNICAL SYSTEM OF MEDICAL RESEARCH, 1930-1962

Amanda L. Mahoney, MS, RN

Julie A. Fairman, PhD, RN, FAAN

This study addresses the history of nurses working in medical research between 1930 and 1962, a time of tremendous growth in the use of experimentation to further clinical knowledge. Nurses were part of an intricate network of people, machines, knowledge and space—a socio-technical system—that made the clinical discoveries of the mid-20th century possible. Nurses were heavily involved in the day to day practices of medical research, thus this dissertation employs a microhistory approach, focusing on individual research projects conducted at the Hospital of the University of Pennsylvania (HUP) in Philadelphia, Pennsylvania. Archival sources related to clinical trials and nursing at HUP were examined as well as the historical records of funding agencies. Nurses performed important, skilled tasks including data collection and complex patient care. The requirements of research studies as well as the new technologies associated with clinical trials required nurses to develop methods and systems to accommodate an increased work load, collect data, and implement new treatments and techniques. This knowledge work was performed in the busy, understaffed world of the mid-20th century hospital. Nurses provided close observation and careful control of the patient, making metabolic research in particular feasible within hospitals. Nurses maintained the cooperation of research patients, a critical aspect to studies involving special diets. Within the hospital, nurses created a “zone of control” around the bedside of research patients, implementing research protocols, closely observing patients and gaining their compliance or cooperation. Using the work of bedside nurses as a historical lens reveals much about the world of medical research and the many factors that contributed to the growth and acceptance of experimentation as a normal part of clinical medicine. Marginalized actors have the agency and power to influence the success or failure of medical research even if they are denied official power. Nursing may hold the solutions to many of the challenges researchers face today.

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“CAREFUL AND COMPLETE OBSERVATION OF THE PATIENT;” NURSES AND  
THE SOCIOTECHNICAL SYSTEM OF MEDICAL RESEARCH, 1930-1962

**Amanda L. Mahoney, MS, RN**

A DISSERTATION

in

Nursing

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in

Partial Fulfillment of the Requirements for the

Degree of Doctor of Philosophy

2016

“Careful and complete observation of the patient.” Nurses and the Sociotechnical System  
of Medical Research, 1930-1962.

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Amanda L. Mahoney

For my family

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## ABSTRACT

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cooperation of research patients, a critical aspect to studies involving special diets.

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## Chapter 1 – “Accountable to evidence;” Uncovering the work of nurses in 20<sup>th</sup> century U.S. medical research

### Introduction

The received history of medical research is one of great discoveries and great men, miracles in the laboratory and the clinic achieved by dedicated physicians or scientists, working alone against the odds to conquer disease with modern medicine.

Farber had infuriated the authorities at Children’s Hospital with his first clinical trial. With this, the second, he pushed them over the edge. The hospital staff voted to take all pediatric interns off the leukemia chemotherapy unit (the atmosphere in the leukemia wards, it was felt, was far too desperate and experimental and thus not conducive to medical education)—in essence, leaving Farber and his assistants to perform all of the patient care themselves.

--Siddhartha Mukherjee, *The Emperor of All Maladies: A Biography of Cancer*<sup>1</sup>

This quote is drawn from a passage describing the challenges faced by Dr. Sidney Farber as he sought to treat children with acute lymphoblastic leukemia (ALL) with experimental antifolate drugs at Children’s Hospital Boston in the late 1940s. The excerpt illustrates how the narrative of clinical research is framed around lead researchers, implying that Farber and his physician colleagues are the only actors in the story that matter. Are we to understand that these men were administering medications, cleaning bedpans, collecting specimens and monitoring the patients? Did they answer phones, perform lab tests, take x-rays, change the air filters and pay the ward’s electricity bills? No.<sup>2</sup> The system of people, knowledge, technology, and other resources that kept the

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<sup>1</sup> Siddhartha Mukherjee. *The Emperor of All Maladies: A Biography of Cancer* (New York, London, Toronto, Sydney: Scribner, 2010), 34.

<sup>2</sup> It should be noted that Dr. Mukherjee interviewed medical residents, nurses, technicians, patients and family members while researching his Pulitzer Prize-winning book.

hospital running supported Dr. Farber's work, while continuing to maintain patient care and the other functions of the hospital. This socio-technical system and the nurses, lab technicians, custodians, secretaries and hospital administrators within it made medical research possible. This system was large, dynamic, and highly contingent on time and place. Not only does the socio-technical system (STS) of research not fit neatly into narratives of discovery, it is a complex and cumbersome concept, difficult to pin down and describe.

...in the leukemia ward with these children there was blood all over. There was blood on the sheets, blood on the pillows, blood on the floor; the nurses were covered with blood...Zubrod came out in the hall one day and said, 'This blood is a bloody ugly mess, Freireich. Why don't you do something about hemorrhage?' So being that I was a young guy, respectful, I said, 'Yes sir.' I went to the lab and I did simple experiments...If you just take the children's plasma and take fresh platelet in the laboratory, it is 100% corrected. So I said, gee-whiz, all we got to do is give them platelets.<sup>3</sup>

In this harrowing anecdote, cancer researcher Emil J. Freireich recalls the creation of effective platelet transfusions, one of the technologies critical to the success of cancer chemotherapy. He frames it as a "eureka" moment that occurred around 1961. Peter Keating and Alberto Cambrosio, co-authors of a recent book on the significance of post-World War II cooperative cancer chemotherapy research, remark that the "discovery" of workable platelet transfusions was much more complicated than Freireich describes.<sup>4</sup> The creation of an effective means to administer platelets, a blood component vital for clotting and hemostasis, obtain them from donors and safely store this delicate material was a long process involving many individuals. It required the use of a state of the art

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<sup>3</sup> Peter Keating and Albert Cambrosio, *Cancer on Trial: Oncology as a New Style of Practice*. (Chicago and London: University of Chicago Press, 2012), 59. Quoted from a 2006 interview with Freireich.

<sup>4</sup> *Ibid*

laboratory equipment, available to Freireich and his National Cancer Institute (NCI) colleagues at the National Institutes of Health (NIH) Clinical Center. This STS made platelet transfusions possible for VAMP trial patients and relied on the knowledge and skills of actors other than Freireich and his co-investigators.

Freireich's quote identifies one such overlooked group of actors in the VAMP trial—nurses. His longer narrative both omits nurses from the proceedings of the VAMP trial through his “gee-whiz” story of developing platelet transfusion and places them literally and viscerally—“covered with blood”—at the bedside of VAMP trial patients. Though their work is rarely explored in the historical literature, nurses were working with and within medical research studies or clinical trials during the middle of the twentieth century. Nurses' roles ranged from providing routine bedside care to patient subjects or administrative support to study physicians, to less conventional assignments such as complex specimen collection or staff education.<sup>5</sup> From their position at the bedside and within the clinic, nurses provide an excellent vantage point for the historian interested in the day-to-day activities of research and the transformation of new treatments such as

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<sup>5</sup> For example of how the work of nurses in mid-twentieth century cancer chemotherapy trials has been described in the secondary nursing literature, see J.Q. Benoliel, “The historical development of cancer nursing research in the United States,” *Cancer Nursing* 6 (1983):261-8, P. J. Haylock “Cancer Nursing: Past, Present, and Future,” *Nursing Clinics of North America*, 43 (2008): 179–203, Kathy Forte “Pediatric oncology nursing: providing care through decades of change,” *Journal of Pediatric Oncology Nursing*. 18 (2001):154-63. E.L. Smith, C. Skosey, J. Armer, D. Berg, C. Cirrincione, M. Henggeler, “The cancer and leukemia group B oncology nursing committee (1983-2006): a history of passion, commitment, challenge, and accomplishment,” *Clinical Cancer Research* 12 (2006):3638s-41s.

cancer chemotherapy from experimental compounds to effective and routine patient therapy.

According to historian and essayist Jill Lepore, “History is the art of making an argument about the past by telling a story accountable to evidence.”<sup>6</sup> Do the stories we tell about medical research fit the evidence? The scaling-up of medical research that took place in the decades surrounding World War II generated huge amounts of archival material: institutional records, published research reports, and material culture, a rich source of data for historians of healthcare. This archival record of the day-to-day work of medical research in U.S. hospitals between 1930 and 1962 does not support this “lone wolf” narrative. Rather, the historical record reveals that a complex STS of institutions, individuals and other resources was required for the success of mid-twentieth century medical research. Holding the “story accountable to the evidence” tells us that nurses at the bedside played a key role in this system, making research in U.S. hospitals possible during this groundbreaking era in the creation of new medical knowledge.<sup>7</sup> The work of nurses in medical research during the mid-twentieth century is integral to the history of clinical research, not a corollary or footnote in a narrative of discovery. Charlotte Bunch and Mary Hunt crafted the phrase “add women and stir” to describe any approach to change that fails to allow women to alter the structure of the institution in question.<sup>8</sup>

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<sup>6</sup> Jill Lepore, *The Story of America: Essays on Origins*. (Princeton, NJ: Princeton University Press, 2012), 15.

<sup>7</sup> Fairman, Julie, “Alternative Visions: The Nurse-Technology Relationship in the Context of the History of Technology,” *Nursing History Review*, 6 (1998): 129-146. 137.

<sup>8</sup> Charlotte Bunch, *Passionate Politics: Essays 1968-1986* (New York: St. Martin's Press, 1987), 140. The author wishes to thank Dr. Julie Fairman for her suggestion of this quote.

Bunch wrote: “Feminism must be more than adding women into structures as they are; it must be about transforming these institutions...”<sup>9</sup> To gain a fuller picture of what medical research looked like during the 1930s through 1960s, one cannot simply insert missing elements such as nurses into the existing historical narrative and expect new insight. Rather than applying this “add nurses and stir” approach to existing, physician-oriented narratives of medical research, the history of nurses and their work should be understood as woven into the fabric of clinical practice, a key component of the STS that makes both medical care and clinical research possible.<sup>10</sup> In this dissertation, I demonstrate the critical role nurses played in the success of medical research during the mid-twentieth century and explore the ways in which their contributions shaped the STS supporting research in U.S. hospitals.

The role of nurses in medical research between 1930 and 1962 varied over time, between institutions, and by region. How the nurse fit into a particular research project was contingent upon the unique circumstances of each hospital, principle investigator and individual nurse. Examining nurses as part of a STS for medical research in hospitals provides a fuller picture of what research work looked like at this time and particular setting. This perspective gives us insight into the reality of clinical research during these formative decades. Nurses were more than just “there too.” Uncovering the contributions of nurses shows us what they are capable of but unless we critically examine these contributions, how nurses shaped the STS and how the made research possible, important

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<sup>9</sup> *Ibid.*

<sup>10</sup> Fairman, Julie and D’Antonio, Patricia “Reimagining Nursing’s Place in the History of Clinical Practice,” *Journal of the History of Medicine and Allied Sciences* 63 (2008): 436.

lessons may be missed. What can an examination of nurses add to the history of clinical research between 1935 and 1945?

Historians have used nurses as sources, through oral history interviews, nurse-authored journal articles on experimental treatments, and photographs showing nurses when exploring the history of 20<sup>th</sup> century medical research. However, few have examined the work of nurses themselves or explored the role of nurses in translating research discoveries into practical patient therapies. In the recurring “If You Ask Me” section of the January, 1962 issue, the editors of the *American Journal of Nursing* asked three nurses, “What are nurses’ functions in a medical research project?”<sup>11</sup> Margaret M. Yuen, head nurse at The Hospital of the Rockefeller Institute, New York, NY described the role of the nurse in medical research in general terms:

The nurse assists in a variety of ways. For example, she orients the other disciplines represented on the team to nursing equipment, procedures, and the nursing care of the patient. She assists in the interpretation to patients and instructs them in the various tests and other procedures which may be used in connection with the research. She makes the necessary careful observations of the patient and records them accurately. Further, the nurse is able to assess and then report to the doctor the patient’s feelings towards his therapy.<sup>12</sup>

In the role Yuen describes, the nurse was ideally positioned to collect data, monitor the patient, and enforce research protocols. Nurses were also the best option for consistent observation of the research patient in the hospitals of the mid-20<sup>th</sup> century. Patients were monitored to ensure their safety as well as to control the experiment.

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<sup>11</sup> Margaret M. Yuen, Rochelle Schmitz and Ruth Barney Fine, “If You Ask Me...,” *American Journal of Nursing* 62 (1962): 46-47.

<sup>12</sup> *Ibid*, p46.



Physicians were unsuited for this task and unable to perform it. Rochelle Schmitz, head nurse, cardiac surgery unit, University Hospitals, Madison, WI wrote:

A primary advantage which the nurse has as a member of a medical research team is that she is able, usually, to administer therapy and make observations on a more continuing basis than can other members of the research team.<sup>13</sup>

Schmitz's quote reflects the understanding that the patient bedside was understood as the nurses' domain in the 1960s, with the environment, patient and access to the patient controlled by the bedside nurse. Other authors stake out patient observation as strictly within the nurse's purview.

No one but the nurse will ever have the time and entrée to observe and record the intimate details of the patient's condition and the progress of disease... The doctor is too busy to be present for continuous observation and the members of the patient's family are emotionally not in condition to give accurate reports on conditions present. The nurse is constantly present and emotionally calm.<sup>14</sup> [Emphasis in original]

Note that the knowledge, technical skills, and professional demeanor of nurses are all aspects that qualify the nurse to perform the vital research task of patient observation.<sup>15</sup> Physician authors shared this view of nurses as ideally prepared and positioned to collect observational research data.<sup>16</sup> These same physicians openly doubted the ability of the nursing profession to appreciate "...the real significance and

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<sup>13</sup> *Ibid*

<sup>14</sup> Edith S. Bryan. "Methods of Research and Study," *The American Journal of Nursing*, 32 (1932): 749-752, 751.

<sup>15</sup> Note also how well this quotation fits into D'Antonio's description of the aura of expert knowledge and professional detachment surrounding the nurse identify. Patricia D'Antonio *American nursing: A history of knowledge, authority, and the meaning of work*. (Baltimore: JHU Press, 2010): 43-46.

<sup>16</sup> Clement Pirquet "Should the nurse take part in the scientific work of the medical profession?," *The American Journal of Nursing* 27 (1927): 723-726.

meaning of certain medical discoveries,” and to perform scientific research work.<sup>17</sup>

Pediatrician and bacteriologist Clemens von Pirquet supported the role of educated, independent-thinking nurses at the bedside and in medical research. He remarked upon the ability of nurses to observe clinical findings in patients overlooked by physician-researchers in a 1927 address to the International Council of Nurses.<sup>18</sup> In the same speech, von Pirquet recommended that those nurses with a capacity for scientific thought should be encouraged to do research, though, von Pirquet asserted, such women would be rare; “There are many natures that can do excellent imitative work but are inadequate as soon as they try to produce original ideas. A capacity for original thought is rarer, apparently in women than in men.”<sup>19</sup>

### **Who does the work of research?**

Contributing to the absence of nurses from stories of medical research were deep-seeded gender and class-based beliefs about who can (and should) “do” research. In the medical publications of the mid-20<sup>th</sup> century, research is understood as an intellectual pursuit, performed by white, male physicians. In the traditional framework, researcher-physicians fit the definition of a “knowledge worker,” a loosely-defined term coined by management theorist Peter Drucker to “describe the man or woman who applies to productive work ideas, concepts, and information rather than manual skill or brawn.”<sup>20</sup>

The visible work of nurses tends towards the manual, patient care tasks performed at the

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<sup>17</sup> *Ibid*, quote from Frank J. Hewitt “Osteomyelitis: Development of the Use of Maggots in Treatment,” *The American Journal of Nursing* 32 (1932): 31-38, 31.

<sup>18</sup> Pirquet, 1927.

<sup>19</sup> *Ibid*.

<sup>20</sup> Peter F. Drucker, “The age of discontinuity: Guidelines to our changing economy.” (1968), 264.

bedside while “knowledge work,” such as creating new systems to collect specimens for research and “soft skills” including gaining patients’ cooperation are largely invisible. Sharon Hartmann Strom used the phrase “hidden skills of judgment” to describe the unseen yet critical aspects of clerical work performed by women during the first half of the 20<sup>th</sup> century.<sup>21</sup> Clinical research as well as patient care was dependent upon nurses’ “hidden skills of judgment” despite the fact that the STS of the hospital did little to support or recognize such skills in its nurses. As I demonstrate, the success of medical research in the mid-20<sup>th</sup> century absolutely relied upon all types of nursing work.

Drucker included both men and women in his 1968 description of a knowledge worker, however within the world of medical research, the classrooms of elite universities, the conference rooms of funding agencies and the wards and laboratories of research-oriented hospitals, research was almost exclusively the domain of white, male physicians.<sup>22</sup> Thus nursing work—exclusively performed by female nurses in the studies examined for this dissertation—was not understood as “research” in part because it was done by women. Historian of technology Jan Zimmerman noted the tendency of society to form an exclusionary definition of technology; “technology is what women don’t do,” a convention that is not reflected by the actual work of women.<sup>23</sup> In the clinical environment of the 1930s-1960s, medicine and medical research was defined by what

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<sup>21</sup> Sharon Hartman Strom, “Machines Instead of Clerks”: Technology and the Feminization of Bookkeeping.” *Computer Chips and Paper Clips: Technology and Women’s Employment*, Volume II: Case Studies and Policy Perspectives 2 (1987): 63.

<sup>22</sup> There are notable exceptions of women researchers at HUP throughout the time period included in this dissertation who will be identified in the relevant chapter.

<sup>23</sup> Zimmerman, *Technological Women, Interfacing with Tomorrow* (Praeger, New York: 1983), as cited by Nina E. Lerman, Arwen Palmer Mohun, and Ruth Oldenziel. “Versatile tools: Gender analysis and the history of technology.” *Technology and Culture* (1997): 1-8, 2.

nurses *didn't* do: create formal research questions, apply for grants, attend research conferences, and publish academic papers.

Laboratory workers, dialysis technicians and secretaries who were women also made tremendously important contributions to the research projects examined here. Like male technicians, these actors are typically overlooked by research publications and historians alike, perhaps due to the manual nature of their work.<sup>24</sup> Important exceptions where nurses and technicians were officially recognized as co-authors are discussed in the chapters that follow. Women, as a general rule did not do clinical research as it was understood by the medical community (and many nurses themselves) during the 1930s-1960s. However, nurses and other women performed scientific work critical to landmark therapeutic discoveries. Historian and sociologist of science Steven Shapin observed that the assistants who performed experiments in the 17<sup>th</sup> century laboratory of Robert Boyle “...made the machines work but could not make knowledge” according to the values of the scientific community.<sup>25</sup> Like these 17<sup>th</sup> century laboratory technicians, nurses were understood as skilled but lacked the qualifications—maleness, a medical or research degree, and status above the working classes—to create knowledge.<sup>26</sup> Nurses did in fact create new knowledge despite the reality that their gender, education and class disqualified their work from being understood as scientific. Nurses created new systems

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<sup>24</sup> For a notable exception, see Peter Twohig, *Labour in the Laboratory: Medical Laboratory Workers in the Maritimes, 1900-50*. (McGill-Queen's Press-MQUP, 2005).

<sup>25</sup> Steven Shapin, "The house of experiment in seventeenth-century England." *Isis* (1988): 373-404, 395.

<sup>26</sup> *Ibid.* Shapin also notes that technicians, as paid workers lacked credibility as one could say they were only performing a task or giving scientific testimony because they were paid to do so, unlike the aristocratic scientists who organized experiments purely to further knowledge. As hourly workers closely allied with the patient, hospital or physician paying their fees, nurses may have been similarly understood as lacking impartiality.

to organize patient care tasks, and applied their knowledge and skills to enforce protocols, gather data, and control patients.

The historical data presented in this dissertation demonstrates the disconnect between how the medical research community categorized the work of nurses, as non-scientific and auxiliary and the actual work nurses performed, which was in fact, scientific and central to the STS of medical research.<sup>27</sup> They gathered the data analyzed by researchers (and later statisticians) to prove or disprove hypotheses. Nurses enforced study protocols and kept research patients cooperative, compliant and controlled. At the bedside of cancer patients at the NIHCC, nurses kept patients alive long enough for new drugs to eradicate their disease in Freiereich's chemotherapy trial. Nurses devised systems for making new or experimental clinical tools workable at the bedside.

While the elite perspective often used by historians of medicine emphasizes the achievements of brilliant, self-sacrificing physicians such as Sidney Farber, it obscures the vital work of countless other actors and the tremendous resources that are necessary to make research projects successful. Rather than a deliberate oversight on the part of these authors, the exclusion of less eminent contributors to medical research is a result of the historical questions being asked by each author and the archival material used to explore them. In her study of the female "computers" who programmed and operated ENIAC, an early computer developed during World War II, historian Jennifer Light notes the bias in history towards "male-centered terms."<sup>28</sup> Light notes, "The result is a distorted

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<sup>27</sup> Jennifer S. Light "When computers were women." *Technology and Culture* 40 (1999): 455-483, 482.

<sup>28</sup> Light, "When computers were women," 482-3. "Male-centered terms" quote is from Gerda Lerner. "The necessity of history and the professional historian." *The Journal of American History* (1982): 19.

history of technological development that has rendered women's contributions invisible and promoted a diminished view of women's capabilities in this field.” Male voices and the records of national institutions dominate the archival record of the history of medical research, further perpetuating the fallacy that women did not participate in research work. For example, Harry M. Marks examines the history of medical research through the lens of drug evaluation and regulation.<sup>29</sup> His sources include archives from the Food and Drug Administration (FDA), the American Medical Association (AMA) and various government bodies overseeing antibiotic research during World War II.<sup>30</sup> In *The Care of Strangers*, a history of the American medical profession, Charles Rosenberg describes how a slow-growing respect for laboratory research emerged to shape medical practice during the late nineteenth and early twentieth centuries, citing editorials and personal papers from research-oriented physicians.<sup>31</sup> The contributions of historical actors involved in the day-to-day work of clinical research are unlikely to be captured in such sources.

Recent social historians of medicine have expanded the narrative of the history of cancer in the twentieth century beyond stories of great discoveries, powerful figures and national public health organizations. Scholars have used cancer research as a framing device for complicated issues in the history of medicine. These issues include race,

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<sup>29</sup> Harry M. Marks, *The progress of experiment: science and therapeutic reform in the United States, 1900-1990*. (Cambridge University Press, 2000).

<sup>30</sup> *Ibid*

<sup>31</sup> Rosenberg does however emphasize the importance of a trained nurse workforce in the expansion of hospital-based medicine in the late 19<sup>th</sup> through early 20<sup>th</sup> centuries. Charles E. Rosenberg, *The Care of Strangers: The Rise of America's Hospital System*. (New York: Basic Books, 1987).

gender, age, and the politics of the medical profession. The success of recent historians of nursing and medicine suggest that a study of the work of nurses in mid twentieth century medical research will result in a richer history of postwar healthcare.<sup>32</sup> Other recent works in the history of medicine have shifted the perspective away from elite researchers and employed the perspective of patients to study the experimental treatment of disease during the twentieth century. Historian Gretchen Krueger examines the experience of pediatric cancer patients and their families in the 1950s and 1960s, demonstrating that placing the patient at the center of cancer chemotherapy clinical trials uncovers a space where science, medicine, the health care marketplace, social and cultural attitudes about cancer collide.<sup>33</sup> In *Bittersweet*, a history of the development of insulin therapy for diabetes, Chris Feudtner explores the transformation of the illness from a deadly childhood illness to a chronic disease and the unintended consequences of insulin therapy on the lives of young patients and families.<sup>34</sup> Each of these works demonstrate the potential of doing the history of medicine from the “bottom up,” looking at the experience of patients and families as a way to provide a more nuanced history of medical advancements and explore other possible outcomes and approaches to practicing medicine. This scholarship adds to the understanding of the development of new

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<sup>32</sup> Fairman and D’Antonio, “Reimagining Nursing’s Place in the History of Clinical Practice,” 435-446.

<sup>33</sup> Gretchen Krueger, *Hope and Suffering: Children, Cancer and the Paradox of Experimental Medicine*. (Baltimore: Johns Hopkins University Press, 2008).

<sup>34</sup> Chris Feudtner, *Bittersweet: Diabetes, Insulin, and the Transformation of Illness*. (Chapel Hill: University of North Carolina Press: 2003).

therapeutics from bench to bedside, tracing the complex and difficult process of converting an idea into a successful medical treatment.

The biography of oncology nursing pioneer Renilda Hilkemeyer does suggest, however, that the successful cancer chemotherapy clinical trials conducted at large cancer hospitals owed much to the establishment of the right kind of nursing infrastructure.<sup>35</sup> Hilkemeyer, who joined M.D. Anderson Cancer Hospital in Houston, Texas as director of nursing in 1955, created educational programs, professional support networks and expanded roles for nurses working at the bedside and within clinical trials at the facility, actions which made both the research and patient care missions of M.D. Anderson Hospital a reality.<sup>36</sup> An oral history interview of Hilkemeyer is rich with information about the changes she made at M.D. Anderson and the role of nurses in the groundbreaking medical research that took place there in the 1960s. For example, the physician who spearheaded the development of “life island” isolation units to protect immune compromised chemotherapy patients gives Hilkemeyer and the M.D. Anderson nurses much credit for the success of the research and the resulting technology.<sup>37</sup>

Other authors, including nurse historian Brigid Lusk describe the actual work of nurses at the bedside of cancer patients during the second half of the twentieth century,

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<sup>35</sup> J. Hostutler, M.S. Kennedy, D. Mason, T.M. Schorr, “Nurses. Then and now. Oncology nursing,” *American Journal of Nursing* 100 (2000): 76-7.

<sup>36</sup> *Ibid*, 76. This is potential fodder for a broader project. Also MD Anderson became desegregated early in Hilkemeyer’s tenure with African American and white patients in the same trials housed together. See Renilda Hilkemeyer Oral History Interview, May 23, 2000, Research Medical Library, The University of Texas M.D. Anderson Cancer Center.

<sup>37</sup> Renilda Hilkemeyer Oral History Interview, May 23, 2000, Research Medical Library, The University of Texas M.D. Anderson Cancer Center.



bringing to light how medical advances such as chemotherapy often resulted in unexpected consequences that had major implications for cancer nurses.<sup>38</sup> The anti-cancer drug 6-MP (6-mercaptopurine), for example induced severe nausea and vomiting during early drug trials.<sup>39</sup> Nurses were tasked with managing patient comfort, nutrition and hydration of these patients without the modern day arsenal of anti-nausea drugs. Lusk in particular emphasizes that using novel therapeutics such as radium for cancer were not “new” in the 1960s, but rather part of a long history of medical treatment as experimentation. She substantiates her argument with descriptions of the role of nurses as gatekeepers, technicians and symptom management experts for the use of therapeutic radium in American hospitals as early as the 1930s.<sup>40</sup> Nurses were central to the implementation and use of cutting edge medical technology and their contributions in this area warrants further investigation. This centrality granted nurses locally powerful, direct but rarely acknowledged influence on the development of medical technologies such as cancer chemotherapy through clinical trials.

### **What is technology?**

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<sup>38</sup> Brigid Lusk, “Prelude to specialization: US cancer nursing, 1920-50,” *Nursing Inquiry* 12 (2005):269-77., Brigid Lusk, “Nursing Patients With Cancer in the 1950s: New Issues and Old Challenges,” in *Nursing Interventions Through Time: History as Evidence*, eds. Patricia D’Antonio and Sandra B. Lewenson, (New York: Springer, 2011):123-138., Kathy Forte “Pediatric oncology nursing: providing care through decades of change,” *Journal of Pediatric Oncology Nursing*. 18 (2001):154-63., P.J. Haylock, “Cancer Nursing: Past, Present, and Future,” *Nursing Clinics of North America*, 43 (2008): 179–203., and Susan Hubbard, “Reflections on the Oncology Nurse’s Role in Cancer Therapy: Future Challenges,” *Seminars in Oncology Nursing* 3 (1987): 154-158.

<sup>39</sup> Kreuger, *Hope and Suffering*, 122.

<sup>40</sup> Lusk, 2005.

Before we can define and discuss the concept of a socio-technical system (STS), we must first set parameters for the use of the term “technology.” Historian of technology Ruth Schwartz Cowan states that the word is used: “...to denote those things that people have created so that they can exploit or manipulate the natural environment in which they are living.”<sup>41</sup> A broad working definition of technology is useful when writing history from a nursing perspective as it includes activities, knowledge, objects and other context left out of the picture when technology is understood only as machines and their inventors. In order to illustrate the idea that technology is more than machines, historian of medicine Joel D. Howell summarizes the work of previous historians of technology into a three-layered definition of the term.<sup>42</sup> These levels are: first of the artifact, the object or machine, second the activities that surround that object and third the knowledge required to use or apply the object.<sup>43</sup> While it includes knowledge, activities and work, Howell’s definition of technology remains centered on the artifact. Historian of technology Judith McGaw defines technology as a “system of tools, skills, and knowledge needed to make or do things.”<sup>44</sup> Using such a broad definition, we can understand nursing and medicine, systems of people, places, objects, and know-how as technologies themselves.

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<sup>41</sup> Ruth Schwarz Cowan, *A Social History of American Technology*, New York, (Oxford: Oxford University Press, 1997), 2.

<sup>42</sup> Joel D. Howell. *Technology in the Hospital: Transforming Patient Care in the Early Twentieth Century*. (Baltimore and London: Johns Hopkins University Press, 1995), 8-9.

<sup>43</sup> *Ibid.*

<sup>44</sup> Judith McGaw “Women in the History of Technology,” *Signs* 7 (1982): 802 as quoted in Fairman, “Alternative Visions,” 131.

McGaw also observes that technologies cannot be separated from their social and historical context, the ways in which an object or practice was applied and the meanings attached to the technology are embedded within it just as the object is embedded within its socio-technical system.<sup>45</sup> The term socio-technical system (STS) is used throughout this dissertation to describe the network of machines, objects, locations, knowledge, people and interpersonal interactions that surrounded the work of medical research between 1940 and 1970. In a discussion of the Electric Bond and Share Company (EBASCO), an electric utility holding company, historian Thomas P. Hughes defines the organization's arrangement of people, places and things as a technological system, intentionally de-emphasizing the social components of the company.<sup>46</sup> Hughes acknowledges that the EBASCO system included social aspects and institutions but argues, "This privileging of the technical in a technological system is justified in part by the prominent roles played by engineers, scientists, workers and technical-minded managers in solving the problems arising during the creation and early history of a system."<sup>47</sup> The author goes on to state that older, more established technology-centered systems rely on the work of less-technical managers to proliferate and maintain them, thus becoming "more social and less technical."<sup>48</sup>

While the world of medical research during the post-World War II era was certainly centered on technology—dialysis machines, experimental drugs, statistical

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<sup>45</sup> *Ibid.*

<sup>46</sup> Thomas P Hughes, "Technological Momentum," in *Does Technology Drive History? The Dilemma of Technological Determinism*, ed. Merritt Roe Smith and Leo Marx. (Cambridge and London: The MIT Press, 1994), 105-106.

<sup>47</sup> *Ibid.*

<sup>48</sup> *Ibid.*

methods, medical knowledge, etc.—its overarching purpose was to improve the care of sick *people*. As argued in this dissertation, the social aspects of the system surrounding clinical research were vital to its function from the very beginning. For example, building strong professional relationships with physicians, nurses’ expert knowledge in navigating the complex official and unofficial hierarchy of the hospital, and the public’s trust in nursing as a profession were key factors in the ability of nurses to do their work and make clinical research projects function within the hospital. To deemphasize the social in this truly socio-technical system would be to obscure vital components, ignore major influences that shaped the developing research network, and obscure the contributions of those whose work was at times understood as “social,” namely, nurses.

### **Nurses and technology**

According to Fairman and Lynaugh, early critical care nurses, like much of society, did not understand common, everyday patient care tools such as oxygen and stethoscopes as “technology” but rather reserved the term for new, complicated machines such as heart monitors which changed their work and presented new patient data (and new patient problems).<sup>49</sup> The authors argue that the implementation of new technologies such as heart monitors and dialysis machines was made possible only through the work of nurses, “Technology came second; in fact, its full utilization was dependent on the reorganization of nursing practice.”<sup>50</sup> Though Fairman and Lynaugh do not state this explicitly in *Critical Care Nursing: A History*, both scholars would agree that the

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<sup>49</sup> Julie Fairman and Joan E. Lynaugh. *Critical care nursing: A history*. (Philadelphia: University of Pennsylvania Press, 2000), 16.

<sup>50</sup> *Ibid*, 17.

“reorganization of nursing practice” so crucial to the success of critical care during the mid to late twentieth century was in itself a “new” technology. Historian Kathleen Burke traces the establishment of the Swan-Ganz catheter in the ICUs of a major medical center during the 1960s and 70s.<sup>51</sup> The author argues that while the catheter, which was inserted into a major artery via the neck to closely monitor blood pressure and other metrics, was invented by physicians, nurses were faced with making the technology actually function in practice.

In *Devices and Desires*, the most extensive study of technology and nurses to date, Margarete Sandelowski studies the multi-faceted relationship between nurses and the medical technology, which shaped their working lives.<sup>52</sup> Sandelowski argues that this relationship is a negative one, with technology coming between nurses and their patient and thus denigrating the professional nurse to the role of operator. Fairman suggests that while the relationship between nurses and technology has certainly been complicated on the everyday level, as well as from the point of view of nursing leaders and national organizations, for many nurses the integration of diagnostic and monitoring technology into their workplace was an empowering experience.<sup>53</sup> In addition to suggesting that historians expand the dialogue on the nurse-technology relationship beyond “good vs. bad,” Fairman illustrates the possibilities of “interpretive flexibility” when thinking about

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<sup>51</sup> Kathleen G Burke, “Trial and Negotiation in a Technological System” Case Study of the Swan-Ganz Catheter,” in D’Antonio, Patricia and Lewenson, Sandra, eds. *History as Evidence: Nursing Interventions Through Time*, (New York: Springer, 2010).

<sup>52</sup> Margarete Sandelowski, *Devices and Desires: Gender, Technology, and American Nursing*. Chapel Hill and (London: The University of North Carolina Press, 2000).

<sup>53</sup> Fairman, *Alternative Visions*.”

health care technology, its social context and the complex and shifting meanings that surround the socio-technical system of healthcare.<sup>54</sup> Using the process, working knowledge and apparatuses of hemodialysis during the 1960s as an example, Fairman demonstrates how considering the question of who “owned” hemodialysis at the time—patients, their home caregivers, nurses, or physicians—opens up larger issues such as how conflicting opinions about ownership influenced professional relationships, the economic and political forces that pushed dialysis out of the hospital and the contingent nature of this process.<sup>55</sup>

### **The Socio-technical system of medical research**

“Had an awful time there at first. Had diarrhea, bed would be ‘soakin’ in the morning. Was irrigating [large] bowel with 10 cans a day. One nurse up there told me “we don’t help people up here.” Said I would have to do it myself. I didn’t know where the bathroom was or what the set-up was. I didn’t irrigate for three days, and ‘it was awful.’ Then that nurse was ‘Off’ and a nice little one was on. She took me up to the room, and had a hook put up for me where I could reach it to put my own water in the can, she cut the tube off for me so it would fit better, and everything went fine. I could put the water in without standing up. Then a nurse from “Memorial” came up... She helped me most by talking. I was scared. She explained to me about the operation and ‘the healing process.’ She suggested that I take Sitz baths for the mucus. It helps some. She helped me a lot, and told me that if I ever had any questions I could call and find out the answers.”

--Colostomy Care Patient Interview, 1951<sup>56</sup>

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<sup>54</sup> *Ibid*, 139-142.

<sup>55</sup> *Ibid*, 141.

<sup>56</sup> “Colostomy Care Patient Interviews, 1951, Dericks Papers, box 1, folder11, Center for Nursing Historical Inquiry, Claude Moore Health Sciences Library, Historical Collections, University of Virginia; as quoted in Brigid Lusk., “Cancer in the 1950s: New Issues and Old Challenges,” in *Nursing Interventions Through Time: History as Evidence*, Patricia D’Antonio and Sandra B. Lewenson, editors, (New York: Springer Publishing Company, 2011), 129-30.

The anonymous patient describes her recovery and rehabilitation from an experimental surgery where the section of cancerous bowel was removed and an appliance was implanted via a surgical incision in the abdomen (colostomy) to allow solid waste to exit the body through a hole in her abdominal wall. Though the cancer was removed in the operating room, this patient was faced with adapting to the new reality of life with a colostomy appliance, first in the hospital and later—perhaps the most challenging phase—at home. The nurses who assisted this patient utilized a range of technical and social knowledge and skills to care for her immediate needs and help her move towards self-sufficiency with her new colostomy. One nurse had the technical skill and knowledge to adjust the ostomy appliance tube and set the patient up for self-irrigation as well as the social knowledge and interpersonal skills to have a hook installed in the patient's bathroom. Another nurse used her knowledge of anatomy, surgical procedures and the workings of the hospital to reassure the patient about her current condition and establish how to seek help should problems arise. She had the social skills to explain the surgery and “the healing process” in such a way that the patient both understood and felt better about the situation.

All of this nursing work, technical and social was absolutely vital to the long-term survival of this patient and the success rate for the particular surgical procedure. It is not recorded whether or not this patient was part of a clinical trial, but if this was the case, the nursing work involved would have been critical not only to the success or failure of the experimental surgery but also to the patient's willingness to participate in an ongoing research study. An object as simple as a hook and undocumented, “social” work such as

an encouraging conversation are part of the therapeutic system played a crucial part in the survival, success, and functional capability of research patients. Perhaps most importantly, the patient states that the nurse who talked to her “helped me the most,” demonstrating that sometimes, “socio” takes precedence over “technical” in this technologically-focused system.

This quote also demonstrates that experimental treatments and patient support technologies didn’t always “work,” and not all nurses were necessarily facilitating their success. The unhelpful nurse who told the patient “we don’t help people up here” was also part of the STS intended to provide patient care and ensure the success of the relatively new colostomy procedure. This nurse’s failure to even show her patient the bathroom is a peek inside the aspects of the system that were not functioning well: perhaps the nurse was overwhelmed with sick patients, had inadequate knowledge of supportive care for a new colostomy or expected the patient to already know how to irrigate. Rather than individual incompetence, understanding the hospital as a socio-technical system reveals this failure as an inadequacy in the infrastructure, a complex, multi-faceted problem of communication, education and staffing.

The work of nurses surrounding patient care and support, including invention, innovation, implementation, dissemination and adaptation were vital to the success of medical research and the proliferation of effective new therapies between 1930 and 1962. Although a hook, conversation and emotional support may seem like unconnected pieces the patient’s ability to navigate the consequences of the experimental therapy, remain part of the ongoing trial, and to survive the trial may rest on these simple therapies.



### **Nurses in the socio-technical system of research**

Envisioning the nurse as “...a person embedded in a network of social relations that limits and controls the technological choices that she or he is capable of making...” and examining the STS of medical research from the nurses’ perspective will provide an “inside the network” view of clinical trials and other research activities inside U.S. hospitals.<sup>57</sup> Thinking about nurses in this way, embedded in an STS of experimentation and healthcare will reveal much about the daily activities of research work, the complex socio-technical system necessary to complete clinical trials, and how nurses made research possible during this era.<sup>58</sup> Nurses are not the only actors missing from the history of clinical research. The role of physicians-in-training, lab technicians, research subjects, and administrative workers in the postwar research boom has rarely been explored.<sup>59</sup>

As quoted above, historian of technology Ruth Schwartz Cowan discusses the value of examining an STS from the point of view of the consumer of a technology, at the point of consumption, or selection and actual use. Nurses working within medical research during the post-war decades could arguably be understood as consumers,

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<sup>57</sup> Ruth Schwartz Cowan, “The Consumption Junction: A Proposal for Research Strategies in the Sociology of Technology” in Weibe E. Bijker, Thomas P. Hughes, and Trevor Pinch (eds) *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology*, (Cambridge: The MIT Press, 2012): 253-272, 254-255.

<sup>58</sup> *Ibid*

<sup>59</sup> Exceptions include: Twohig, *Labour in the Laboratory* and Laura Stark, *Behind closed doors: IRBs and the making of ethical research*. (Chicago: University of Chicago Press, 2011).

producers, users, innovators and inventors of research-related technologies.<sup>60</sup> Considering carefully the relationship between nurses and technology and bearing in mind the flexibility and contingency of this relationship will further illuminate the role of nurses within the system of medical research as well as the multiple meanings they attached to their work and the technology in question.

### **Why nurses?**

What exactly can we gain by understanding the work of mid-twentieth century nurses in medical research as part of a socio-technical system? Though their perspective is rarely explored in the historical literature, nurses were working with and within medical research studies or clinical trials during the middle of the twentieth century. Nurses' roles ranged from those providing routine bedside care to patient subjects or administrative support to study physicians, to less conventional assignments such as complex specimen collection or staff education.<sup>61</sup> Recent explorations into the history of nurses and technology suggest that while the nursing profession has a complex relationship with medical technology, nurses made new technology work as therapy through the application of unique nursing knowledge, tinkering, and patient education.<sup>62</sup> Most importantly, nurses at the bedside ensured the correct, precise, and controlled collection of data for research. Given that the typical hospital between 1935 and 1965

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<sup>60</sup> As could physicians, hospital administrators, and the "end user," patients.

<sup>61</sup> For an example of how the work of nurses in mid-twentieth century cancer chemotherapy trials has been described in the secondary nursing literature, see Benoliel, 1983, Haylock, 2008, Forte, 2001, Smith et al, 2006.

<sup>62</sup> Sandelowski, *Devices and Desires*, Burke, "Trial and Negotiation in a Technological System," and Fairman, "Alternative Visions."

was ill-suited to produce good-quality data, this was no small task. During this era, medical treatment was idiosyncratic rather than protocol-based, student nurses provided the bulk of patient care and communication between researchers in hospitals, medical schools and other institutions was rudimentary. Understanding the challenges of getting medical research done in hospitals during the mid-20th century requires an in-depth study of how the socio-technical system of a typical university-affiliated institution gradually adapted to accommodate clinical research.

Hospitals without a respected nursing school or with a sub-standard nursing service were less likely to receive research funding between 1940 and 1960. For example, most applications to the Office of Scientific Research and Development, Committee for Medical Research (OSRD-CMR), a World War II government funding organization were from elite, university-affiliated hospitals. Researchers applying to the OSRD-CMR were typically already part of an exclusive network of research institutions and publications. As the government invited researchers to apply for funding and pre-approved applications for the OSRD-CMR to review, applicants outside of the established network may have been screened out of the process. Elite institutions including HUP with its professional affiliations to the OSRD-CMR and NIH through prominent figures such as I.S. Ravdin and track record of research projects during the 1940s and 1950s had a significant advantage over other hospitals hoping to take advantage of the General Clinical Research Center (GCRC) program to access resources for patient research.<sup>63</sup>

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<sup>63</sup> Compare the recipients of the first 20 GCRC grants as listed in the NIH archives to the institutions granted OSRD-CMR contracts listed in Irwin Stewart, *Organizing Scientific Research for War*, 1948. RG 443 NIH Committee on Clinical Research Centers, Records of Meetings, 1959-1961 General Clinical

The Committee on Clinical Research Centers reviewed proposals for new GCRCs based on the review of paper applications, personal knowledge about the institution and associated researchers, and site visits to view current patient research projects and possible locations for research units. The existing system of nurse staffing was concerning to committee members on several occasions, usually at public hospitals or large city institutions but also at elite institutions with existing GCRCs. One application was denied despite promising research proposals from physician researchers due to poor patient care at the hospital where, it was noted nursing care was “deficient quantitatively and qualitatively” to support research.<sup>64</sup>

As NIH funding for research became increasingly important to the reputation and success of hospitals and universities after the mid-1960s securing funding through the GCRC and other programs was vital to advancing the reputation of large, expensive hospitals including HUP. Nurses and a system of patient care that could support research was necessary to secure the NIH funding that would attract students, residents and patients in an increasingly competitive marketplace.

### **The historical record**

There is ample material documenting the development of funding programs, ethical and practical guidelines for research, and the rising national profile of medical research within the institutional archives of the NIH, FDA, and research-focused

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Research Committee Records of Meetings, 1962-65. Clinical Research Facilities ad hoc Committee Memo, February 23, 1960.

<sup>64</sup> NARA II RG 443 National Institutes of Health, Committee on Clinical Research Centers, Records of Meetings, 1959-1961, General Clinical Research Centers Committee, Records of Meetings, 1962-65, Box 1. Meeting Minutes, June 8-9, 1962, October 18-19, 1962, February 13-14, 1963.

universities. The time period spanned by this dissertation was in fact determined by landmark changes in the national research scene despite its microhistory perspective. World War II launched an unprecedented boom in funding for medical research, rendering significant changes in how research was conducted in U.S. hospitals between 1930 and 1946. The 1950s saw the rise of the NIH and the growing importance of new discoveries in medicine in the public consciousness. Increased awareness about research led to more resources for clinical trials as well as more inquiry and oversight during the 1960s. This dissertation draws upon historical data through 1962, the year the FDA officially required signed consent forms from patients receiving experimental drugs, signaling the start of a slow evolution of the socio-technical system of research from a disjointed network of idiosyncratic, local methods for gathering experimental data to one dominated by the NIH's mandated system of ethical, financial, and scientific oversight. The story of how the FDA, NIH and other funding agencies shaped the national research scene during the 20<sup>th</sup> century is the subject of several excellent works in the history of public policy, science, and medicine.<sup>65</sup>

### **Microhistory**

Microhistory can be defined as either a methodology or a historical lens. According to some historical theorists, it is the study of small-scale history, an examination of non-elite historical actors and minor events in order to validate and/or refute the dominant historical narrative.<sup>66</sup> Others see microhistory as a method or

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<sup>65</sup> For example: Rasmussen, Nicolas. *Gene jockeys: life science and the rise of biotech enterprise*. JHU Press, 2014.

<sup>66</sup> Syed Muhd Khairudin Aljunied, "Micro-history and the study of minorities: working-class Sikhs in Singapore and Malaya," *Social History*, 36:1, (2011): 23.

approach to historical research where documents from everyday life, the perspective of the average person, and other aspects of the mundane provide important contrast and context for significant historical events.<sup>67</sup> Theorist and microhistorian Giovanni Levi stated:

"Microhistories need not necessarily be histories of the excluded, the little people, the far-off. They aim, rather at reconstructing moments, situations, and persons which examined with an analytic eye, in the context of their particularity, put on weight and color; not as examples, for lack of better general explanations, but as physical correlatives to the complexity of the contexts within men and women live and move."<sup>68</sup>

The microhistory approach to the history of medical research gives us access to the experience of nurses, allowing the historian to connect the daily work of bedside nurses, physicians and other actors to the development of clinical research on the national scale during the mid-20<sup>th</sup> century. Clinical research evolved into its current prominent position in healthcare at the patient bedside as well as in the conference rooms of the National Institutes of Health.

Gaining insight into the experience of patients, families and other non-elite actors such as nurses, technicians and medical residents through historical archives is no easy task. Access to patient charts from the 1930s through 1960s, which would contain a record of the day to day experience of hospitalized patients as well as the work of bedside nurses and physicians is rarely granted to historians. Because the personal papers, publications and administrative record of powerful researchers are more available, historians interested in the work of medical research have tended to focus on principal

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<sup>67</sup> Giovanni Levi, "On microhistory." *New perspectives on historical writing* 2 (1991): 97-119.

<sup>68</sup> Levi, "On microhistory," 115.

investigator physicians, the “great men” struggling to advance medical knowledge through experimentation. Evidence of less prominent (but perhaps no less important) actors can be found, however embedded in the archival records of “great men.”

Localizing this investigation into the daily activities of clinical research helps to narrow the archival field and allows the investigator to form a deep understanding of the complex, highly local circumstances—interpersonal relationships, departmental politics, patient demographics, etc.—that shaped the day to day work of patient research.

### **The Hospital of the University of Pennsylvania**

In the chapters that follow, I examine the work of several nurses active in medical research between 1930 and 1962, focusing on research projects at a single institution, the Hospital of the University of Pennsylvania (HUP) in Philadelphia, Pennsylvania. While other institutions are included in this study, focusing on a single hospital allows an up-close examination of the daily activities of clinical research during the decades when national and local systems for getting the work of medical research done were created and established. HUP was selected due to the depth of the historical record and the availability of individuals able to give first-hand accounts of research work through oral history interviews. The institution’s position within the national network of research institutions, hospitals, regulatory organizations and sources for research support also improved the quality and reach of the archival record. HUP had strong ties to funding bodies such as the Office of Scientific Research and Development (OSRD) during World War II and the National Institutes of Health (NIH) in later decades. Because of these close relationships and the prestigious reputation of the Hospital, physicians at HUP had

privileged access to new medical knowledge, experimental therapies, and most importantly, to financial support for research from public and private sources.

In the chapters that follow, I discuss how research projects at HUP both typified the research work of the time and differed from similar studies at other institutions. I also make connections between national-scale changes or reforms in research funding, regulation, and the dissemination of research findings. In order to provide context for the clinical research studies at HUP, I discuss in general the history of medical research for the relevant topic and time period using secondary sources and archival material. Transitions in nursing practice, education and administration on the local and national scale contextualize the discussion of nurses' daily work on research studies during the mid-20<sup>th</sup> century.

The work of nurses examined in each medical research study varied greatly and was highly contingent on the individual circumstances of the project. In the next chapter, I examine a research program organized at HUP during the 1930s to investigate the problem of low serum protein in abdominal surgical patients. The observational studies and clinical trials led by HUP physicians absolutely relied upon the work of nurses assigned to its wards. This work demanded much of nurses at the bedside. They carefully performed specimen collection and the administration of complex special diets while fulfilling the considerable responsibilities of nursing these very ill, unstable patients. Though the success of research hinged upon complete, precise sample collection, close observation, and expert nursing care of very ill patients, resources for hiring dedicated



research nurses and establishing long-term research facilities within HUP were scant, further limiting the size and scope of clinical research during the 1930s.

Concerned about the health of its army, the U.S. government became very interested in medical research, forming committees and advisory boards to fund and sponsor civilian medical research in the 1940s. Chapter 3 explores how the availability of funding for research allowed HUP physicians to conduct larger, more complex research studies with the support of nurses hired specifically to work with research patients. Data collection and skilled patient care by nurses continued to be critical to the success of studies during the 1940s. Assigning nurses to research rather than relying upon existing staffing to support research on HUP's wards was an important contributing factor to the success of wartime metabolic research.

The 1950s and early 1960s saw tremendous growth in clinical research at HUP and across the U.S., much of it funded by the burgeoning NIH. Researchers further expanded their research programs into large clinical trials of new drugs and investigations into physiology and pathology that required sophisticated machines, carefully controlled environments and expert staff. Nurses were especially critical in controlling the conditions of research as clinical trials became increasingly routine in the hospital. Chapter 4 investigates how two different nurse-centered systems were adapted or devised to support research projects at HUP with mixed results.

The work of nurses in medical research has been largely ignored by historians of medicine and nursing. This story needs to be told, not to simply show that nurses were also there or to prove that their work made clinical research possible, but to illustrate how

our current STS of medical research was forged during the postwar boom in funding. Nurses, patients and other actors shaped this system despite being marginalized by the principal investigators, funding bodies and administrators who created it (for themselves). Looking back at how the system for getting research done was formed reminds us that our current system is not only way to generate new medical knowledge and that marginalized actors have the power to influence the success or failure of a study even if they are denied official power. The “story accountable to the evidence” of twentieth century medical research suggests that nursing may hold the solutions to the challenges faced in clinical research today.

## Chapter 2 - "...the actual work of the study" Nurses and the burden of medical research on the surgical ward, 1930-1940.

In a 1931 *AJN* article, nursing leader Marian Rottman discussed the responsibility of a hospital's nursing service to promote the medical and administrative goals of the hospital.<sup>69</sup> Supporting medical research was one such responsibility on both the administrative and bedside nursing level, according to Rottman because of the important role nurses played in clinical research:

"In scientific studies of disease and in problems of research, it is the nursing staff, sometimes a special group of nurses, who do the actual work of the study under the direction of a physician."<sup>70</sup>

Examining the "actual work" of research studies and how nurses and physicians negotiated and accomplished this work reveals much about how the existing systems of patient care, nursing administration and medical education shaped clinical research. In this chapter, I demonstrate the critical role of nurses in the research studies of the 1930s and early 1940s through a discussion of a small but important area of inquiry, the study of low blood protein (hypoproteinemia) on the surgical wards of HUP and similar hospitals. Clinical research was a small but growing enterprise in the hospital wards of the 1930s, an endeavor that placed a considerable burden on the already heavy workload of nurses, support staff and physicians. In response, nurses developed and adapted the system of patient care to accommodate the requirements of these clinical inquiries.

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<sup>69</sup> Marian Rottman, "The Role of the Nursing Service in the Promotion of the Medical and Administrative Aims of the Hospital." *The American Journal of Nursing* (1931): 480-484.

<sup>70</sup> *Ibid*, 482.

Though hypoproteinemia research at HUP was on a small scale during the 1930s and 1940s, the findings of these investigations were important. Advances in the understanding of hypoproteinemia was based on data collected and controlled by nurses on the surgical ward.<sup>71</sup> This research program was critical to the current understanding of the role of nutrition in recovery from gastric surgery.<sup>72</sup>

I also explore how medical advancements closely associated with this research including pumps for gastric (stomach and intestinal) suction and the use of intravenous fluid required nurses to learn new skills, negotiate scope of practice, and further adapt patient care systems to make these technologies useful in the hospitals of the 1930s and 1940s. This work was pivotal to the success of both patient care and medical research. As I demonstrate, the actual use of such technologies and the success of hypoproteinemia research absolutely relied on expert bedside nursing and the functioning of nurses within the socio-technical system of the hospital. Through the work of nurses: the nursing of fragile patients, tinkering and troubleshooting equipment and procedures, and re-shaping the system of patient care on the ward, nurses made the small-scale but groundbreaking

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<sup>71</sup> While this chapter focuses on clinical research at the patient bedside in university-affiliated teaching hospitals, research was not limited to these settings. Nurses also contributed in roles outside of traditional bedside care, acting as prototypical “research nurses,” ensuring protocol compliance, recruiting and retaining patient participants and administrating studies with many moving parts. Specialized research roles for nurses did not play a role in the hypoproteinemia research studies discussed in this chapter but they were important players in specialized research hospitals and outpatient settings, such as pediatric feeding clinics. For example: Teresa Folin Rhoads, Milton Rapoport, Ruth Kennedy, and Joseph Stokes. “Studies on the growth and development of male children receiving evaporated milk: I. The effect of various vitamin supplements on growth in length and incidence of rickets during the first two years of life.” *The Journal of Pediatrics* 19 (1941): 169-189.

<sup>72</sup> After expansion with federal funding during the 1940s, the hypoproteinemia studies of the 1930s led to the development of intravenous hyperalimentation (IVH) or total parenteral nutrition (TPN) at HUP in the late 1960s. Stanley J. Dudrick, “History of parenteral nutrition.” *Journal of the American College of Nutrition* 28, (2009): 243-251.

research into hypoproteinemia possible despite the lack of financial and institutional support for clinical research during the 1930s and early 1940s. At times nurses enabled increasingly complex treatments and clinical trials through tight control of patient care, control that nurses were able to exert with the authority they held at the bedside. Nurses' ability to consistently maintain such control was impeded by the limited time, authority and autonomy allotted to nurses within the hospitals of the 1930s. Thus, ward nurses could not have supported larger, more closely controlled metabolic studies that could have answered clinical questions about hypoproteinemia more definitively. Through exploring the work of nurses at the bedside of hypoproteinemia patients studied at HUP and similar institutions, we can form a better understanding of just how important the work of nurses was to the success of the foundational research studies of the 1930s and early 1940s.

### **History of clinical research ca. 1930-1940**

During the early 20<sup>th</sup> Century, medical research or “clinical investigation” was a small but growing component of medical education, clinical teaching and patient care in most U.S. hospitals and medical schools.<sup>73</sup> The influence of French and Scottish medical scholarship during the mid-19<sup>th</sup> century shifted medical practice towards new understandings of disease based on anatomy, physiology, and pathology.<sup>74</sup> The increasingly important process of physical diagnosis required physicians to develop skills in patient observation and quantification of signs and symptoms, skills that were also

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<sup>73</sup> Charles E. Rosenberg, *The Care of Strangers*, 158.

<sup>74</sup> Richard H. Shryock, *American Medical Research Past and Present*. (London: Oxford University Press, 1947, New York: The Commonwealth Fund, 1947), 22 & 35.

important in the recently professionalized field of nursing.<sup>75</sup> German medical science played a greater role in shaping American medical education after about 1860, advancing the role of basic science (or “bench”) research in medical schools and promoting the translation of discoveries made in the laboratory into clinical treatments.<sup>76</sup>

Despite the burgeoning importance of both pre-clinical and clinical medical research in the universities of the 1930s, financial support for clinical research was scant. Hospital and university administrators were reluctant to allot precious resources—space, staff, physician time and patients—for an enterprise that had scientific potential but demonstrated few real benefits for patient care or institutional advancement. There was no system for organizing and supporting medical research in hospitals and universities at this time despite the promising scientific discoveries of the early twentieth century.<sup>77</sup> As laboratory discoveries contributed to visible advancements in medical practice, for example the utility of blood serum tests, medical schools and their associated hospitals slowly became more supportive of clinical research both at the bench and bedside. Rosenberg argues that while medical research played a limited role in patient care during this era, the work of early 20<sup>th</sup> century research pioneers laid the groundwork for the acceptance of laboratory tests as clinical tools by patients and providers and became increasingly understood as an important experience for medical students and residents.<sup>78</sup>

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<sup>75</sup> *Ibid*, 22-23.

<sup>76</sup> *Ibid*, 39-72.

<sup>77</sup> *Ibid*, 131-144. Stephen P. Strickland, *Politics, Science and Dread Disease: A Short History of United States Medical Research Policy*. (Cambridge, MA: Harvard University Press, 1972), ix-x.

<sup>78</sup> Rosenberg, *The Care of Strangers*, 158.

Until the intra-war and post-war funding boom of the 1940s-1960s, medical research in hospitals remained small-scale, conducted by individual researchers with a limited number of patients and disseminated through medical journals and professional organizations. Some physicians explored applications for new scientific ideas within their own practices, occasionally publishing their findings in the form of case studies. Physician investigators managed to get research done before the 1940s, typically in elite institutions including the Hospital of the University of Pennsylvania (HUP), Bellevue Hospital (associated with Cornell and New York University) and Massachusetts General Hospital (affiliated with Harvard University). The clinical research conducted in the 1930s and 1940s at these sites and others formed the foundation for the groundbreaking medical advancements of the post-World War II decades, particularly in the areas of metabolic or nutritional research, burn treatment and the use of antibiotics.<sup>79</sup> Nurses contributed to this foundational research both at the bedside and in expanded research roles.

While advancements in medical knowledge were made during this period, the socio-technical system of the hospital supported only small-scale research projects and limited what researchers were able to accomplish in terms of collecting sufficient quantities of good-quality experimental data.<sup>80</sup> There was no system in place to support

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<sup>79</sup> Julius H. Comroe, and Robert D. Dripps, *The Top Ten Clinical Advancements in Cardiovascular-Pulmonary Medicine and Surgery 1945-1975*. (Bethesda, Md.: U.S. Dept. of Health, Education, and Welfare, Public Health Service, National Institutes of Health, 1977).

<sup>80</sup> Clinical research at this time was limited in scale and scope in part because the socio-technical system of the hospitals could not support large-scale research grounded in scientific principles, but also because rigorous experimental design and statistical methods for analyzing data were relatively new in the field of medical research. The existing socio-technical systems of hospitals and their affiliated universities could

the transition of new medical knowledge from clinical trial to clinical practice in a practical or sustainable way, even in the most elite hospitals.<sup>81</sup> Scientific discoveries did however make their way from the bench to the bedside during this era despite the lack of a translational research support structure. In 1977, physician researchers Comroe and Dripps published a study tracing the development of ten major clinical advancements made in the fields of cardiovascular and pulmonary medicine during the between 1945 and 1975.<sup>82</sup> Many of these therapeutic developments, including the diagnostic use of x-rays, the use of electrodes to measure blood pH, and advanced surgical repair of blood vessels were based on research papers published before 1935.<sup>83</sup>

It is important to note that there were little to no protections in place to ensure patient safety while undergoing experimental treatments, nor was it considered necessary to gain patient consent or even inform them that they were part of a clinical trial during this era. Ethical concepts such as informed patient consent were not part of the clinical culture until after World War II.<sup>84</sup> Formal safeguards to protect research subjects such as internal review boards were not commonplace until the 1970s. Nurses were an important part of the research enterprise in the era before informed consent and played a significant role in maintaining the cooperation of patients in research studies.

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not ensure adequate, good-quality experimental data collection or support the meaningful analysis of experimental data. See Shryock, *American Medical Research Past and Present*, Strickland, *Politics, Science and Dread Disease*, and Rosenberg, *The Care of Strangers*.

<sup>81</sup> *Ibid.*

<sup>82</sup> Comroe and Dripps, *The Top Ten Clinical Advancements in Cardiovascular-Pulmonary Medicine and Surgery 1945-1975*.

<sup>83</sup> *Ibid.*, 46-55.

<sup>84</sup> Baker, Robert. *Before bioethics: A history of American medical ethics from the colonial period to the bioethics revolution*. Oxford University Press, 2013: 232-273. See also Halpern, Sydney A. *Lesser harms: The morality of risk in medical research*. University of Chicago Press, 2006.



Though rudimentary by current standards, the medical research work of the first half of the 20<sup>th</sup> Century advanced physicians' growing understanding of the physiology of shock, infection and metabolic imbalances such as hypoproteinemia (low serum protein), discoveries that enabled the therapeutic advancements of subsequent decades. These advancements were made despite the lack of supportive systems for clinical research prior to World War II due to the hard work, ingenuity and luck of a handful of research workers—physicians, laboratory technicians, and nurses.

### **Clinical Research in U.S. Hospitals, 1900-1940**

While some administrators recognized the potential for research and the need for dedicated laboratory space in hospital and medical school facilities, medical students and physicians were rarely given the time or professional freedom to do research work.<sup>85</sup> Making room in the socio-technical system of medical education and academic medical practice took time and occurred more rapidly in some institutions compared to others. Large, mainly East Coast medical schools including the University of Pennsylvania School of Medicine (UPSOM), Johns Hopkins University and Harvard University gradually created space within their schools and affiliated hospitals for clinical research during the early decades of the 20<sup>th</sup> Century.<sup>86</sup> Physicians interested in clinical inquiry typically had to carve out time for research while supporting themselves financially through private practice and maintaining their teaching responsibilities at their sponsoring institution. Beginning in the 1920s, some schools including UPSOM created research

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<sup>85</sup> *Ibid*, 163-165, 184-189.

<sup>86</sup> *Ibid*, 297.

appointments for physicians who had demonstrated their ability to attract patients and students to the institution, or whose works were understood as potentially profitable or advantageous in terms of advancing the school's reputation.

### **Surgical Nutrition Research at HUP before 1940**

Surgeon and clinical investigator Isidor Schwaner Ravdin became the first chair of surgical research in the Harrison Department of Surgery at HUP in 1928.<sup>87</sup> In this role he helped create a culture of clinical inquiry among junior surgeons at HUP and students from the UPSOM, where he served as a professor starting in 1935.<sup>88</sup> In addition to work on shock, Ravdin studied the multi-faceted problem of hypoproteinemia at HUP during the late 1920s and early 1930s. Hypoproteinemia is a deficiency in the amount of serum proteins available in a patient's blood. Serum proteins, including albumin, play a critical role in maintaining fluid balance and are low in malnourished individuals. Patients with gastrointestinal disease often had an insufficient diet due to lack of appetite, vomiting and abdominal discomfort.<sup>89</sup> Absorption of nutrients across the gastrointestinal tract was also a factor in the malnutrition of hypoproteinemia patients as inflammation or other damage to the intestines impairs the body's ability to digest food. A lack of protein in the diet

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<sup>87</sup> For a concise biography of I.S. Ravdin, see the University Archives, University of Pennsylvania, available at: [http://www.archives.upenn.edu/faids/upt/upt50/ravdin\\_is.html](http://www.archives.upenn.edu/faids/upt/upt50/ravdin_is.html)

<sup>88</sup> Ravdin looms large in the history of HUP and UPSOM. He began a prolific career in medical research, surgery and administration as a medical student at the University of Pennsylvania in the class of 1918 and held influential positions in research organizations such as the National Research Council, Office of Scientific Research and Development Committee on Medical Research, the National Institutes of Health and the American Cancer Society until his death in 1972. As a clinical researcher, surgeon, administrator, fund-raiser and revered medical authority, Ravdin did much to shape the socio-technical system of medical research and patient care on the local and national scale. Ravdin took nursing at HUP seriously and while his goals did not always match those of nurse leaders and educators, his influence over nursing policy, practice and education at HUP was significant throughout his long career.

<sup>89</sup> C. M. Jones and F. B. Eaton, "Postoperative Nutritional Edema," *Archives of Surgery* 27 (1933).

leads to hypoproteinemia as well as poor wound healing and a decreased ability to fight infection. Thus malnutrition in gastrointestinal patients led to complications, longer hospital stays and poor surgical outcomes.

The impetus for hypoproteinemia research stemmed from the fact that patients with low serum proteins after surgery did not respond well to fluid replacement therapy, had prolonged wound-healing times, and experienced poorer outcomes than patients with normal serum proteins.<sup>90</sup> Given the fragility and instability of patients with hypoproteinemia, the condition was a difficult one to study. Ravdin, along with other physicians from the Department of Surgery at HUP and the PSOM studied the effects of hypoproteinemia on wound healing in experimental animals during the 1930s, publishing findings in professional journals as early as 1932.<sup>91</sup> These publications list medical residents and other physician collaborators as co-authors but do not identify the laboratory technicians, administrative staff, and animal keepers who would have also contributed work to the study. As these projects did not involve human patients, Ravdin's early hypoproteinemia research most likely did not employ nurses, whose professional realm was closely linked to patient care during the 1930s.<sup>92</sup>

Hypoproteinemia was poorly understood and created challenging patient care problems for surgeons and surgical nurses. By the early 1930s, researchers had observed

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<sup>90</sup> Jones and Eaton, "Postoperative Nutritional Edema."

<sup>91</sup> For example: R. P. Barden, I. S. Ravdin, and W. D. Frazier, *American Journal of Roentgenology*. 38 (1932): 96.

<sup>92</sup> Nurses did sometimes work outside of direct patient care including as laboratory technicians, see Margaret Warwick, "The Nurse as Laboratory Technician," *American Journal of Nursing* 27 (1927): 95-97.

a relationship between poor nutrition, hypoproteinemia, and edema, swelling of the body's tissues with fluid from the blood vessels. Edema lowers blood pressure and, if unchecked leads to poor perfusion, organ failure and death.<sup>93</sup> Surgeons noted that this type of edema, referred to as nutritional edema during the 1930s and 1940s was common among patients with gastrointestinal problems, whose disease impaired eating and nutrient absorption. Gastrointestinal surgeries—in the mouth, esophagus, stomach or intestines further impeded the patient's ability to eat and the absorption of protein, electrolytes and fluids by the digestive tract.<sup>94</sup>

Nutritional edema was a medical emergency causing significant patient suffering and often death. It had major implications for the physicians and nurses caring for the patient before and after their surgery. Before the advent of diuretics such as carbonic anhydrase inhibitors in the mid-1940s and the much more effective drug hydrochlorothiazide in 1959, physicians and nurses had few tools to combat edema and shock.<sup>95</sup> Intravenous (IV) therapy, infusion of fluids into the patient bloodstream via veins was a relatively new treatment for shock by the 1930s. In cases of hypoproteinemia, the use of IV fluids could spur a patient's decline rather than reverse shock.<sup>96</sup>

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<sup>93</sup> For example: A. A. Weech, and S. M. Ling. Nutritional Edema, *Journal of Clinical Investigation*, 10 (1931): 869.

<sup>94</sup> Jones and Eaton, "Postoperative Nutritional Edema."

<sup>95</sup> Garabed Eknayan, "A history of diuretics." *Diuretic Agents: Clinical Physiology and Pharmacology* (1997): 3-28. Fairman and Lynaugh, 1998, 5-11.

<sup>96</sup> I. S. Ravdin, Alfred Stengel, and Mitchell Prushankin. "The control of hypoproteinemia in surgical patients." *Journal of the American Medical Association* 114, (1940): 112. Ravdin was experimenting with new intravenous treatments for shock including albumin. See: I. S. Ravdin and William T. Fitts. "The so-called "blood substitutes"." *The American Journal of Surgery* 80 (1950): 744-752.

Hence hypoproteinemia was a complex problem for the physician to both treat and study. According to case study reports included in several papers published during the 1930s, hypoproteinemia (or nutritional edema as it was more commonly referred to in practical nursing literature) also added considerably to the already heavy workload of nurses caring for a typical surgical patient. Most HUP patients experiencing hypoproteinemia were surgical patients admitted for gastrointestinal complaints. What did the nursing care of patients undergoing surgical interventions for gastrointestinal disease look like during the 1930s and early 1940s? How did research projects investigating hypoproteinemia change or add to that work?

### **Organizing nursing work on the hospital ward c. 1930-1940**

During the 1930s, the nursing workforce in a typical U.S. teaching hospital consisted of a mix of nursing students, staff nurses and private duty nurses.<sup>97</sup> Though large, urban hospitals such as HUP were shifting away from using student nurses as the primary workforce by 1939, students were still heavily relied upon to provide nursing labor on the wards.<sup>98</sup> “Specializing” patients, hiring private duty nurses to provide care for

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<sup>97</sup> For more on the nursing workforce in the 1930s and 1940s see Susan Reverby, *Ordered to Care: The dilemma of American nursing, 1850-1945*. (Cambridge and New York: Cambridge University Press, 1987): 180-198 and Whelan, Jean C. "Too Many, Too Few: The Supply and Demand of Private Duty Nurses, 1910-1960." Ph. D. dissertation, University of Pennsylvania, 2000.

<sup>98</sup> HUP did not fully shift away from students and private duty and install staff nursing until after 1957, the year the National League for Nursing (NLN) issued an unfavorable review of the HUP training school. HUP's reliance on student nurses for hospital labor at the expense of instructional time almost cost this elite school its NLN accreditation. Fairman, Lynaugh, and Campbell, *Critical Care Nursing: A History*, 59-60.

individual or small groups of private patients at a rate billed directly to the patient was another staffing practice slowly falling out of favor in the late 1930s, but still widely used to meet labor demands in the hospital. Graduate nurses in the role of head nurse, assistant head nurse and staff nurse would have been responsible for supervising the work of student nurses and trained attendants on the ward. Given the workload and scarcity of graduate nurses in the hospital, student nurses typically provided general nursing care to patients with little assistance or oversight.<sup>99</sup>

In this timeframe, nurses were not typically assigned to particular patients, rather the nursing work was accomplished through “functional nursing,” assigning a nurse or group of nurses a single task for all of the patients on the ward, such as administering patients’ medications, performing all of the enemas ordered for the day and so on.<sup>100</sup> Orchestrating the nursing work took considerable skill and effort on the part of the head nurse who in some settings may have had an assistant head nurse available to help organize staff, supervise and instruct the patients and coordinate with physicians and other members of the hospital patient care hierarchy.<sup>101</sup>

The responsibilities of nurses were not limited to direct patient care tasks. Making sure that laboratory tests were completed correctly and promptly reported to the physician, preparing patients for surgery and transporting patients to the operating room, educating patients and families for discharge, and coordinating necessary social services

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<sup>99</sup> Reverby, *Ordered to Care*.

<sup>100</sup> Fairman, and Lynaugh, *Critical Care Nursing: A History*, 50.

<sup>101</sup> Private duty nurses “specialing” a patient would have been responsible for all of the work for an individual patient or to a small cluster of patients in an arrangement called “group nursing.” Private duty nurses were typically found on private wards and while they may have coordinated their work with the head nurse, they were not under her supervision. See Whelan, *Too Many, Too Few*.

were just some of the non-clinical tasks within the nursing purview. Considerable interpersonal skills and a good understanding of the hospital's many departments, staff members and procedures were expected of nurses, especially head nurses and those in administration. Physicians heavily relied upon the social skills and knowledge of nurses to accomplish patient care and for getting the work of medical research done. How exactly nurses coordinated the many moving parts of the hospital system was highly contingent on time, institution and individuals. However, nursing literature from this era reflects a general consistency in the nursing tasks required for the care of hypoproteinemia patients.

Nurses created their own systems for getting the work of patient care done in hospital wards during the 1930s and 1940s.<sup>102</sup> New or adapted nursing systems had to be developed in order for new medical procedures, such as those associated with hypoproteinemia research to work efficiently and effectively at the bedside.<sup>103</sup> As one nurse wrote:

“...for the practical application of every new development in medical science and technic there have to be, as a rule, new varieties of nursing technic developed, new sets of terms and symbols learned, new groups of symptoms and results or reactions observed and recorded.”<sup>104</sup>

New clinical tools required users, in this case, nurses to develop new systems for their actual use.<sup>105</sup> For example, nurses devised standard sets of equipment, referred to as

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<sup>102</sup> Dorothy E. Fisher, “Administration of a Medical Ward: Functions and Activities of the Personnel,” *American Journal of Nursing*, 41 (1941): 1281-1288.

<sup>103</sup> *Ibid*, 259.

<sup>104</sup> Ann Doyle, “The Journal, the Index and the Private Duty Nurse.” *The American Journal of Nursing* (1927): 723-726.

<sup>105</sup> Ruth Schwartz Cowan, “The Consumption Junction,” 261-80.

“trays” for nursing and medical procedures. This practice simplified the procedure itself by ensuring that all necessary supplies were at hand and guided those unfamiliar with the given procedure—new medical residents or private duty nurses, for instance—through the various steps as practiced at a particular hospital. Preparing trays also saved time and money; supply orders could be predictable and excess steps and equipment eliminated from the particular process. With no plastics or disposables largely unavailable until the 1960s and 1970s, such predictability also allowed for a scheduled routine of cleaning, sterilizing, and preparing equipment, processes that required considerable time, organization and delegation among the nursing staff.<sup>106</sup>

Creating trays for a new procedure such as intravenous (IV) fluid administration was a multi-step process that relied upon nursing knowledge, experience and social skills. Nurses tinkered with existing protocols, troubleshooted prototype trays, and worked closely with other staff, including engineers to devise the best set up for a given procedure tray at their particular institution.<sup>107</sup> Inventing, implementing and maintaining procedure trays were just one aspect of the complex socio-technical system of patient care sustained by nurses in hospitals during the 1930s and 1940s. The organization of nursing labor during this era limited the amount of time nurses had available for developing such ingenious approaches to nursing problems even as it relied upon the adaptability of nurses to new

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<sup>106</sup> A. M. Rivera, K. W. Strauss, Adrien Van Zundert, and Eric Mortier. "The history of peripheral intravenous catheters: how little plastic tubes revolutionized medicine." *Acta anaesthesiologica Belgica* 56, (2005): 271.

<sup>107</sup> For an example of the tinkering necessary to develop a procedure tray, see Winifred Whitney, Merle Walker, Sally Johnson, and Irene Kelly, "Comparative Nursing Methods: Lumbar Puncture, Hypodermoclysis, and Intravenous Infusion Trays," *American Journal of Nursing* 30 (1930): 253-260.



medical procedures and equipment. Some nurses found the time to engage in knowledge work such as the development of procedure trays and creating procedures for the use of new clinical tools.<sup>108</sup> Evidence that nurses valued this work can be found in the many articles and photo essays describing new nursing methodologies and their evolution published in local and national nursing publications.

Using the nursing and medical literature of the time as well as textbooks, procedure manuals and hospital archives, it is possible to learn much about the hospital stay of the average gastrointestinal surgical patient.<sup>109</sup> We can extrapolate the nursing work that made such surgical treatment possible and understood how the socio-technical system of the hospital functioned (or did *not* function) to provide care for patients with peptic ulcers, stomach cancer and other gastrointestinal problems. We must first establish what routine nursing care looked like for the average, uncomplicated surgical patient before we can examine the ways in which hypoproteinemia research affected the work of nurses and the ways that nurses contributed to these studies because, as we shall see, the effects were subtle. The demands hypoproteinemia patients placed on ward nurses and

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<sup>108</sup> Drucker, 1968. For a discussion of the variable definition of knowledge work in organizational and labor studies literature see *Knowledge workers and knowledge work: A knowledge economy programme report*. Work Foundation, 2009, pp12-41. Available online at [http://www.theworkfoundation.com/DownloadPublication/Report/213\\_213\\_know\\_work\\_survey170309.pdf](http://www.theworkfoundation.com/DownloadPublication/Report/213_213_know_work_survey170309.pdf)

<sup>109</sup> It is usually not possible to identify what staffing systems were in place for a particular patient or on a particular ward at any given time, even in the rare cases when patient charts are available from the 1930s and 1940s. Nurses charted by exception with the routine work of nursing, bathing, feeding, toileting as well as duties understood as being part of the usual course of treatment for a patient not typically recorded. On the rare occasion that patient charts are available to the modern historian, ascribing the tasks to particular nurses and identifying the employment status, training and experience of that nurse are practically impossible. The patient chart, as Sandelowski notes should be understood "...as part and as tool..." of clinical work rather than a complete documentation of the nursing and medical tasks performed. See Sandelowski, *Devices and Desires*, 16-17.

gastric surgeons further limited the scope, scale and quality of research Ravdin and others could accomplish during the 1930s and early 1940s.

### **Nursing care for the typical gastrointestinal patient c.1935**

A 1932 article, “Nursing Care in Gastric Surgery” published in the *American Journal of Nursing (AJN)* describes the nursing protocol for an uncomplicated gastric surgery case at Bellevue Hospital in New York City.<sup>110</sup> The author, Florence Talbot, R.N. the teaching supervisor in the hospital’s surgical division, included methods used to instruct student nurses on the underlying physiological principles of the patient care tasks involved and described how nurses organized patient data for physician use via the bedside chart.<sup>111</sup> Talbot’s article gives an overview of the nursing work surrounding gastric surgery patients and gives the reader a glimpse of how nurses developed methodologies for patient care, organizing clinical information, enforcing protocols, and disseminating new clinical knowledge—work essential to the success of medical research.

### **Nursing the gastric surgery patient c. 1930-1940**

Much of the nursing work associated with surgical patients was part of the so-called invisible or hidden work of nurses that was understood as routine or expected and thus not included in the patient chart or physician’s orders.<sup>112</sup> Many surgical patients

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<sup>110</sup> Florence Talbot “Nursing Care in Gastric Surgery,” *American Journal of Nursing* 32 (1932): 281-284.

<sup>111</sup> “Our Contributors,” *American Journal of Nursing* 32 (1932): 302.

<sup>112</sup> This article was published in tandem with a paper on the surgical treatment of peptic ulcers written by Talbot’s physician colleague at Bellevue, Robert K. Felter, who co-authored a textbook on surgical nursing. Robert K. Felter, “Surgery of Peptic Ulcer,” *American Journal of Nursing* 32: 277-281. The hospitals discussed in this chapter Bellevue, Massachusetts General and HUP were all large, urban institutions with closely affiliated medical schools and their own hospital training schools for nurses. While the protocols for

were confined to bed for weeks at a time. The nursing responsibilities associated with bed-bound patients provide several examples of unseen nursing tasks left out of the historical record. Surgical patients were almost exclusively confined to bed both before and after surgery, usually until close to discharge and those few permitted to use ward bathrooms required supervision and assistance. Thus patient care required toileting patients via bedpan or urinal, bathing and dressing the patient, changing linen and administering all therapies with the patient supine in bed. In order to avoid some of the liabilities of prolonged bed rest, pressure ulcers (bed sores), discomfort and loss of mobility, nursing tasks such as repositioning, massage and in-bed exercises were also performed when possible.<sup>113</sup> Other nursing work included keeping the patient clean and dry despite incontinence, bathing and changing linens while the patient remained in bed, supporting the patient psychosocially for the operation, following the hospital's anti-pneumonia regimen for all postoperative patients, instructing junior staff or student nurses on any given number of patient-care topics, and innumerable tasks intended to improve patients' comfort during their stay, which in uncomplicated cases lasted over two weeks.<sup>114</sup>

Patient cooperation and compliance was important to the smooth running of a busy surgical ward. Nurses understood that earning a patient's trust was understood as a

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treating gastric surgery, nutritional edema and hypoproteinemia patients would have differed somewhat between hospitals (as well as between ward, surgical service, physician, nurse and patient) there would have been strong similarities in the nursing work performed at all three institutions.

<sup>113</sup> Helen Zuelzer, "An Obstinate and Sometimes Gangrenous Sore": Prevention and Nursing Care of Bedsores, 1900 to the 1940s, in *Nursing Interventions Through Time: History as Evidence*, Patricia D. and Sandra B. Lewenson eds, (New York: Springer, 2011), 43-57.

<sup>114</sup> Talbot, "Nursing Care in Gastric Surgery," 284.

critical aspect of a good nurse-patient relationship. Nursing literature featured tips on gaining a patient's trust and cooperation throughout the 1930s.<sup>115</sup> An understanding of human nature could be "...utilized in molding attitudes and moods so as to decrease distress and facilitate recovery."<sup>116</sup> Thus working to gain a patient's trust was frequently framed as work done in their best interest, rather than making a nurses' job easier. Some sources hinted at the advantages of a trusting patient, who "...will cooperate much more willingly, and the outcome of his hospitalization will be much happier for all concerned."<sup>117</sup> Nurse authors suggested maintaining a cheerful attitude, listening to their concerns, and ceding small, unimportant arguments to the patient could transfer the most recalcitrant subject into a "good"—compliant—patient.<sup>118</sup>

Patient compliance and cooperation were important as standard preoperative procedures for surgical patients were complex and often unpleasant. The relationship between patient trust in the nurse and compliance or cooperation with patient care has not been explored by historians and warrants investigation. For example, Talbot described a schedule of nursing tasks designed to prepare patients for gastric surgery and assist their recovery and discharge. Enemas and colonic irrigations were performed in series before the procedure to cleanse the bowel for surgery and repeated as needed post-operatively to

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<sup>115</sup> Bailey, Ruth, Marie Diorio, and Laura Jewett. "The application of psychology." *The American Journal of Nursing* (1934): 1013-1018., Mather, Vera G. "The Psychiatric Aspects of General Nursing." *The American Journal of Nursing* (1937): 1187-1196., Aikens, Charlotte Albina. *Studies in Ethics for Nurses*. WB Saunders Company, 1930.

<sup>116</sup> Mather, "The Psychiatric Aspects of General Nursing," 1196.

<sup>117</sup> Bailey, Diorio, and Jewett, "The application of psychology," 1014.

<sup>118</sup> *Ibid.*

relieve painful gas.<sup>119</sup> Gastric lavage, another arduous bedside procedure was also performed the night before the surgery and repeated just prior to sending the patient from the ward to the operating room to reduce the acidity of the stomach and clean the upper digestive tract for surgery.<sup>120</sup>

Providing nursing care for a ward of surgical patients required nurses to develop methodologies for each task and systems for organizing and managing the workload. Nurse-developed systems surrounding three categories of nursing work were particularly critical to the treatment and clinical study of hypoproteinemia patients: gastric lavage, fluid administration and recording of patient input and output.

### **Gastric lavage**

For nurses working in a hospital during the mid-twentieth century, the term “gastric lavage” described a constellation of procedures: the removal of excess or toxic fluid—stomach acid, blood, etc.—and material from the stomach through a tube inserted into the stomach via the nose or mouth (“stomach pumping”), bathing the stomach with fluid as part of this removal or to relieve pain due to excess acid, and the collection of stomach fluid via the tube under various conditions.<sup>121</sup> Removing excess fluid relieved tension on surgical incisions and allowed inflamed or surgically repaired digestive organs to rest and heal. Nurses were largely responsible for performing the many tasks surrounding gastric lavage; the difficult process of inserting the tube or encouraging the

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<sup>119</sup> Talbot, *Nursing Care in Gastric Surgery*,” 284.

<sup>121</sup> Laura Maria Vietor, “Simpler Methods in Gastric Lavage.” *The American Journal of Nursing* (1930): 46-48.

patient to swallow it, enforcement of dietary restrictions or regimens and preparation of that regimen, measurement of all collected fluid, withdrawal of the specimen, initial examination of the fluid, preparation of the specimens for laboratory analysis, and careful charting of the procedure and acquired data.<sup>122</sup> Organizing and preparing equipment and bathing solutions for gastric lavage was the responsibility of the nurse, as was cleaning, sterilizing and storing these materials after the procedure. Designing and implementing trays or kits for gastric lavage was one way that nurses created systems to streamline the many nursing tasks required to care for hypoproteinemia patients at HUP.

The protocol for each patient would have varied according to the individual's clinical condition, symptoms and surgical procedure with further variation between physicians, hospitals and over time. In order for the information gathered via gastric tube to be clinically useful the procedure must have been followed exactly, the diet properly enforced, the measurements precise, and the patient's cooperation absolute.<sup>123</sup> Nurses instructed patients about the gastric lavage procedure and its general purpose in order to keep the patient calm and cooperative.<sup>124</sup> Nurses worked to accommodate nervous patients with calm reassurance and careful organization, for example, hiding the lavage equipment from the patient until the physician arrived.<sup>125</sup>

Negotiating who was responsible for each aspect of gastric tube use added an additional layer of work for physicians, nurses and administrators. For example, in cases

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<sup>122</sup> *Ibid.*

<sup>123</sup> Sister Lillian, "Nursing Patients with Intestinal Obstruction and Peritonitis." *The American Journal of Nursing* 34 (1934): 975-979.

<sup>124</sup> Bailey, Diorio and Jewett, 1016.

<sup>125</sup> *Ibid.*

of severe vomiting, an unconscious patient, or if another high-risk complication was suspected, physicians may have inserted the stomach tube with the assistance of the nurse, who was then responsible for the remainder of the procedure.<sup>126</sup> How exactly gastric lavage was performed and by whom would have been highly contingent on the individual circumstances during the late 1930s through 1940s, even with very ill patients and those being observed for research purposes. Documentation from HUP in 1944 reveals that the insertion of stomach tubes was left to the “Physician’s Discretion,” indicating that the patient’s physician decided who performed the procedure.<sup>127</sup> At HUP, nurses were explicitly barred from inserting gastrointestinal tubes only in cases of small bowel obstruction, when a physician was required to pass the larger, double-bore Miller-Abbott tube necessary for treatment and the risk of complication was high.<sup>128</sup> How “physician’s discretion” translated to actual practice at HUP and other hospitals is unclear, when a physician was unavailable during the night shift, when pumps malfunctioned or when patients were in acute distress, nurses may have been expected to administer gastric lavage in risky patients without direct physician oversight.<sup>129</sup> The risks

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<sup>126</sup> For example, when the nurse’s initial study of a gastric fluid specimen revealed the tell-tale signs of serious bleeding—brown, coffee-ground material or bright red blood—the physician was responsible for all further gastric tube insertion. “...what a blessing it is...” wrote one nurse “...to have the doctors take the responsibility of passing the tube.” in cases where bleeding was strongly suspected. *Ibid.*, 47-48.

<sup>127</sup> Procedures—University Hospital, Page 1. Jonathan Evans Rhoads Collection, University of Pennsylvania Archives. Box 39, FF5. Nursing literature from this era indicates that in instances when the lavage was understood as routine or uncomplicated; for diagnostic purposes or as part of the preoperative or postoperative routine for patients on a particular surgical service, nurses performed the entire procedure alone. Physicians were more likely to perform the steps of the gastric lavage procedure understood as most risky: passing the tube and starting continuous suction in patients with surgical complications such as bleeding, perforation of the stomach wall by an ulcer, or obstruction from cancer or post-operative swelling.

<sup>128</sup> *Ibid.*

<sup>129</sup> Fairman, and Lynaugh, *Critical Care Nursing: A History*, 79-80.

associated with gastric tube placement and the use of suction, including perforation of the stomach wall and gastric contents entering the lung, were real. However, how doctors, nurses and administrators understood these risks varied across time, place and situation, rendering the assignment of gastric lavage tasks controversial and contested at times. Responsibility, authority, and oversight over medical and nursing procedures were highly contingent. The case of tube placement for gastric lavage illustrates the contingency of a nurse's responsibilities and demonstrates how the role of the nurse was a fluid, adaptable component of the socio-technical system of patient care and medical research during the 1930s and 1940s.

It is perhaps less important to know who performed gastric lavage on patients than it is to understand that in complicated cases such as post-surgical patients with hypoproteinemia, gastric lavage was a time consuming, multi-stage procedure requiring collaboration with physicians as well as considerable time, skill and planning on the part of the nursing staff. Responsibilities differed over place and time. Unstable, complicated surgical cases such as those studied by hypoproteinemia researchers made more work for everyone, adding to the tasks that needed to be negotiated between physician and nurse for each patient.

### **Administration of fluids**

Fluid administration was another range of hospital work that spanned the purview of physicians and nurses, ranging from unseen nursing work to specialized medical procedures performed exclusively by physicians. Coordinating staff, patients and equipment for these procedures required the technical, social and organizational skills of



experienced nurses. Fluid replacement therapy was an important and routine aspect of treatment for nutritional edema. As with gastric lavage, intravenous and subcutaneous fluid administration was in some instances a collaborative procedure, and in others understood as well within the scope of practice for nurses, or strictly the responsibility of physicians. Infusing fluid through the subcutaneous layer of the patient's skin, referred to as hypodermoclysis or pectoral infusion in the medical literature of the 1930s-1950s was routinely used to administer fluids as a preventative measure to avoid dehydration and fluid imbalance postoperatively and in cases where veins could not be accessed for the faster-flowing intravenous method. Procedures for administering hypodermoclysis were created, adjusted and disseminated by hospital nurses according to the staffing, supply and patient needs of their particular setting.<sup>130</sup>

Nurses usually had the authority and responsibility to administer hypodermoclyses as part of routine postsurgical protocols such as that described by Talbot in 1932.<sup>131</sup> In emergent cases with a rapidly declining patient, or in situations understood to carry a higher risk, administering a hypodermoclysis may have been collaborative or partially performed by the physician at the bedside. With full time hospital practice a rarity for physicians prior to World War II, resident physician labor was in short supply, thus requiring nurses to perform "physician only" tasks in emergent situations. Responsibility for various aspects of hypodermoclysis varies greatly within the

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<sup>130</sup> For example, see the various procedure tray set-ups described in Whitney, Walker, Johnson and Kelly, *Comparative Nursing Methods: Lumbar Puncture, Hypodermoclysis, and Intravenous Infusion Trays*."

<sup>131</sup> Talbot, "Nursing Care in Gastric Surgery," 282. Renzo Dee Bowers, "Legal Hazards for Nurses: Negligence or Incompetence May Result in Financial Penalties," *the American Journal of Nursing*, 47: 523-524.

nursing literature and hospital archives of the 1930s and 1940s.<sup>132</sup> Though less dangerous than intravenous infusions in terms of inducing shock due to the smaller amounts of slowly administered fluid, perforating a blood vessel or causing infection, hypodermoclysis was not without real risks, causing tissue damage, scarring, edema and pain if not done correctly and closely monitored.<sup>133</sup>

Proctoclyses, more commonly called rectal taps or retention enemas were a method of fluid administration decidedly within the scope of nursing practice and frequently administered as part of standard gastrointestinal surgery protocols and in the treatment of nutritional edema.<sup>134</sup> Though routine, rectal taps were not without risk, cases of severe internal and external burns and bowel perforations can be readily found in the nursing and medical literature of the mid twentieth century.<sup>135</sup>

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<sup>132</sup> A 1936 report on the procedure for giving hypodermoclyses in post-partum patients treated by a physician-led home obstetrics service framed the intervention as an emergency measure performed by a physician and nurse in close collaboration. In this example, nurses were responsible for setting up the equipment and the physician for accessing the skin with needles and setting up the flow rate, with some aspects of the set-up performed by the physician to expedite the process. Physicians bore the risk of penetrating the patient's skin with a needle in the home setting but nurses were responsible for monitoring the patient for complications during the infusion, removing the needles and observing the patient for an hour after the procedure, intervening and reporting to the physician as needed. Hope Perry, "Hypodermoclysis for the Post Partum Patient in the Home," *The American Journal of Nursing* 36: 588-590. At HUP in 1944, nurses had full authority to administer hypodermoclysis as ordered while in 1945, the medical staff at Northwestern Hospital in Minneapolis newly authorized graduate nurses to initiate subcutaneous fluid infusions in light of wartime staff shortages. See Procedures—University Hospital, Page 1. Jonathan Evans Rhoads Collection, University of Pennsylvania Archives. Box 39, FF5. Sylvia Wetzel, "Wartime Nursing Procedures," *The American Journal of Nursing*, 45: 443-444.

<sup>133</sup> Renzo, "Legal Hazards for Nurses," 524 describes a case where a nurse was found liable for damages when she failed to stop a pectoral hypodermoclysis after signs that the fluid was not being properly absorbed.

<sup>134</sup> The understanding that rectal taps were a nursing responsibility was such that it did not appear on the 1944 procedure list at HUP, see Procedures—University Hospital, Pages 1 and 2. Jonathan Evans Rhoads Collection, University of Pennsylvania Archives. Box 39, FF5.

<sup>135</sup> "Ethical Problems," *The American Journal of Nursing* 33: 600.

Unlike rectal taps, Intravenous fluid (IV) therapy was not a routine nursing procedure during the 1930s and 1940s. IV therapy was commonly used to prevent or treat shock and is described frequently in the case studies of hypoproteinemia and nutritional edema published in research journals. Typically, as in the case of the high-risk, home obstetrical patient, the physician performed the actual needle puncture with the nurse responsible for setting up the infusion apparatus and monitoring the patient for adverse effects such as fluid overload or perforation of a vein, which could be life-threatening.<sup>136</sup> While the physician was seen to bear the risk of adverse outcomes to IV therapy by performing the venipuncture, serious complications such as allergic reaction, infiltration or shock were most likely to occur after needle placement, while a nurse was observing the patient during the infusion, thus placing responsibility for recognizing and responding to complications squarely on the shoulders of the bedside nurse.<sup>137, 138</sup> This is in keeping with the belief that observation of the patient was the domain of nurses. Other institutions gave nurses the authority to start IVs during wartime staff shortages including HUP, where IV access may have changed from a “physician” task to one delegated according to

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<sup>136</sup> Sandelowski, *Devices and Desires*, 107-110.

<sup>137</sup> See Sandelowski, *Devices and Desires*, 108.

<sup>138</sup> Some hospitals had specially trained intravenous nurses during this era and in others, nurses routinely performed venipuncture for fluid administration and instructed medical students on the procedure. See Sandelowski, *Devices and Desires*, 109, Margaret F. Heyse, “Nursing for Medical Students,” *The American Journal of Nursing* 39: 1338-1339.

the “physician’s discretion” in 1944.<sup>139 140</sup> Often, organization of the tasks surrounding IV fluid administration was determined by the needs of individuals in power, physicians and administrators designing a socio-technical system to meet their needs and goals rather than dictated by actual or perceived risk to the patient.

Regardless of who accessed the patients’ vein with a needle, IV fluids required considerable time and effort on the part of nurses. The use of IV therapy can be seen in articles from the 1930s and 1940s describing the treatment of severely ill gastrointestinal surgical patients, such as those with bowel obstruction, infections or nutritional edema but was not part of the routine for patients in better states of health.<sup>141</sup> While they may not have performed every step of fluid replacement procedures, nurses were responsible for the bulk of the time and labor involved: preparing equipment, monitoring the patient and recording fluid input and output.<sup>142</sup>

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<sup>139</sup> Compare the two copies of “Procedures—University Hospital,” available in the Rhoads Collection Archives. One copy, sent with a cover letter announcing a meeting to discuss changes in the procedure manual is unmarked, the other, attached to materials handed out at the meeting was annotated by Dr. Rhoads. Intravenous is shown as changing from “Physician” to “Physician’s Discretion.” The understanding that rectal taps were a nursing responsibility was such that it did not appear on the 1944 procedure list at HUP, see Procedures—University Hospital, Pages 1 and 2 (both copies), Jonathan Evans Rhoads Collection, University of Pennsylvania Archives. Box 39, FF5.

<sup>140</sup> IV therapy may have been seen as less risky in general by the 1940s; at Northwestern Hospital, nurses, recently given the authority to start IVs and hypodermoclyses sometimes delegated the task of observation of patients receiving infusions to nurse’s aides and volunteers, See: “Both aides and Gray Ladies can sit with patients who are having intravenous injections.” Wetzel, 443.

<sup>141</sup> See Talbot, “Nursing Care in Gastric Surgery,” Lillian, “Nursing Patients with Intestinal Obstruction and Peritonitis,” Jones and Eaton, “Postoperative Nutritional Edema,” Ravdin et al, “The control of hypoproteinemia in surgical patients.”

<sup>142</sup> A variety of fluids were administered to stable gastric surgical patients in hopes of replacing fluid or replenishing electrolytes and proteins while the patient’s diet was restricted after surgery. In uncomplicated patients, low-volume rectal taps and hypodermoclyses were administered frequently after gastrointestinal surgery with the frequency and volume tapered off as the patient’s oral intake was slowly increased. Talbot, “Nursing Care in Gastric Surgery,” 282-283. Lillian, “Nursing Patients with Intestinal Obstruction and Peritonitis,” 975-979.

### **Patient diet & Recording fluid input and output**

Careful measurement and documentation of all fluid input and output (urine, feces, vomit and liquid collected via gastric lavage or other drainage) was part of routine nursing care during this era and required significant time and organizational skill to perform accurately. Nurses needed to exercise considerable control around the patient's bedside to ensure accurate fluid balance data and enforce oral fluid restrictions as several individuals, other nurses, younger students new to the unit, ward maids, nurses' aides and volunteers were attending to the patient.<sup>143</sup> Potential immeasurable loss of fluid from vomiting, diarrhea, incontinence, and rectal tap and enema procedures would have been an additional barrier to accuracy in gastric surgical cases. Nurses knew how to avoid and account for such challenges, for example weighing the bed sheets of incontinent patients to extrapolate the amount of fluid lost.<sup>144</sup> Nursing and medical journals of the era describe strict preoperative diets with carefully balanced amounts of nutrients, followed by a strict no food or fluids by mouth restriction the day before and two days after surgery.<sup>145</sup> Postoperatively, the patient was given clear fluids (water, juice or broth) in small amounts as frequently as once per hour for eight to ten hours on the second day following surgery and stopped immediately if the patient experienced nausea or vomiting.<sup>146</sup> The regimen for advancing the diet from clear fluids to solid food was

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<sup>143</sup> Dorothy E. Fisher, "Administration of a Medical Ward: Functions and Activities of the Personnel," *American Journal of Nursing*, 41 (1941): 1281-1288.

<sup>144</sup> Dorothy I. Geist, "Round the Clock Specimens," *The American Journal of Nursing*, 60 (1960): 1300-1302.

<sup>145</sup> Talbot, "Nursing Care in Gastric Surgery," 281, Ravdin et al, "The control of hypoproteinemia in surgical patients," 107.

<sup>146</sup> Talbot, "Nursing Care in Gastric Surgery," 283, Lillian "Nursing Patients with Intestinal Obstruction and Peritonitis," 978-979.

strictly enforced by nurses at the bedside as a slow, careful return to a normal diet—which required a great deal of nursing work—was understood as critical to patient recovery. Physicians ordered the advancement of a patient’s diet based on the observations of the nurse but the actual process was managed and supervised by nurses at the bedside with the patient’s response carefully recorded. This information was used by the physician to determine the course of treatment, for example, when it was safe to remove any gastric tubes in use, add solid food and allow the patient out of bed.<sup>147</sup>

Accurate fluid input and output data were of special importance in patients with fluid imbalance due to hypoproteinemia as physicians used this information to chart a course back to homeostasis and avoid damage to the internal surgical site by excess edema.

Nurses developed and negotiated systems for collecting specimens and recording input and output information including charts, color-coded specimen jars and organizing staff to coordinate non-routine specimen collections, such as the 24-hour urine sample required for hypoproteinemia research at HUP.<sup>148</sup> Nurses at the University of Iowa Hospitals in Iowa City created methods for collecting 12 and 24-hour urine specimens from pediatric patients too young to cooperate with traditional collection methods.<sup>149</sup>

These methods were published in the *American Journal of Nursing* with helpful

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<sup>147</sup> Nurses probably did not have the authority to make these decisions, though they certainly influenced the physician’s course of action and may have been responsible for the resulting work, such as removing simple stomach tubes. Removal of stomach tubes is not one of the procedures noted in the 1944 HUP document, however physicians are noted as performing the removal of surgically-placed or complicated types such as the Abbot-Rawson tube, indicating that nurses may have been responsible for removing simple varieties such as Levine tubes. See Barrett, 22 and Procedures—University Hospital, Pages 1 and 2, Jonathan Evans Rhoads Collection, University of Pennsylvania Archives. Box 39, FF5.

<sup>148</sup> Genevieve I. Anderson and Ronald E. Bales, “Nursing in Chemical Industries,” *The American Journal of Nursing*, 48 (1948): 639-642. Geist, “Round-the-Clock Specimens,” 1300-1302.

<sup>149</sup> Geist, “Round-the-Clock Specimens,” 1300-1302.

illustrations, instructions, and sewing patterns. The set-up used to collect urine in male patients was adapted from an experimental collecting apparatus developed by a physician at the same institution in the 1930s.<sup>150</sup> Nurses adjusted the urine collection set-up to work with materials readily available on the pediatric ward and improve the comfort and safety of their young patients. Two systems for collecting urine from female pediatric patients were created by University of Iowa Hospital nurses, one requiring a special mattress with a hole cut into the center and the other easily improvised with a canvas sheet and empty bed frame. In addition to a detailed description of how to construct each device, the article included vital nursing knowledge on how to make the set-ups workable. For example, the authors pointed out which components of the apparatus could be prepared ahead of time and suggested how to reposition the child without losing sample material or contaminating the specimen. Solutions to potential problems such as blankets and toys falling into the collection funnel were suggested.

According to historians of medicine Cynthia Connolly, Janet Golden, and Benjamin Schneider, nurses at Baltimore's Sydenham Hospital adapted the STS of the hospital ward to accommodate the changes in bedside care caused by the rapidly adopted use of sulfonamide for the treatment of children with meningitis in the early 1940s.<sup>151</sup> This included creating new procedures for precise measurement of urine and the collection and organization of patient input and output data.<sup>152</sup> As sulfonamide was given

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<sup>150</sup> *Ibid*, 1301.

<sup>151</sup> Cynthia Connolly, Janet Golden, and Benjamin Schneider. "'A Startling New Chemotherapeutic Agent': Pediatric Infectious Disease and the Introduction of Sulfonamides at Baltimore's Sydenham Hospital." *Bulletin of the History of Medicine* 86, no. 1 (2012): 66-93.

<sup>152</sup> *Ibid*, 80-81.

orally to pediatric patients, nurses at Sydenham were faced with the challenge of ensuring their young, very ill patients ate or drank the correct dosage.<sup>153</sup> Nurses maintaining the diets of adult hypoproteinemia also faced this difficulty.

### **Patient Diet and Feeding**

Given the many responsibilities of ward nurses, ensuring that hypoproteinemia patients were consuming as much of their prescribed diet as possible was challenging. Staff shortages, poor patient appetites, and insufficient time to prepare protein-supplemented meals made it difficult for nurses to carry out physician's orders for special diets. A 1946 source attributed the failure of prescribed diets to improve hypoproteinemia in burn patients to "a lack of nurses to encourage eating."<sup>154</sup> Ward nurses typically did not have the flexibility or autonomy to provide study patients with supplemental food based on their appetites, nor could they consistently implement experimental dietary protocols given their many responsibilities on the ward. Building a strong, trusting relationship with individual patients was challenging for nurses spread thin on the hospital ward.<sup>155</sup> Ward nursing and the high ratio of patients to nurses common at HUP limited the success of dietary interventions for hypoproteinemia patients both on the individual, patient care level and limited the size, scope and success of hypoproteinemia research.

### **Laboratory Samples**

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<sup>153</sup> *Ibid*, 81.

<sup>154</sup> Stanley Levenson, Ross W. Green, Charles C. Lund, "An Outline for the Treatment of Severe Burns," *The New England Journal of Medicine*, 235, (1946): 76-79, 78.

<sup>155</sup> Mather, 1937, p1193.



When orchestrating the treatment for patients with fluid imbalance during the 1930s and 1940s, physicians relied on the precise measurement of patient input and output, as well as chemical analysis of urine and blood to determine the nature of the imbalance. Specimen collection of urine, stool and emesis was the purview of nurses, while collection of blood samples was restricted to doctors in many settings.<sup>156</sup> As I've discussed, the simple act of collecting patient urine quickly becomes much more complicated when the patient is very young or immobile or the sample collected under controlled circumstances. Ensuring precise, accurate lab results through proper specimen collection created more "hidden" work for nurses as tests often required careful timing and strict adherence to drug, fluid and dietary regimens.<sup>157</sup> The instructions needed to be followed exactly in order for a test to be accurate and there were quite a few things that could easily go wrong. Ensuring that the protocol for a lab test was adhered to amid a busy day on the ward would have required communication with the patient and other staff and careful control of the bedside to avoid losing urine voided during a designated sample period or disrupting the timing of tablets used to dye the urine sample. As with intravenous fluids, laboratory tests would have been used more frequently in the care of

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<sup>156</sup> Annette Williams, "The Nurse and Laboratory Procedures," *The American Journal of Nursing* 44: 949-952, 952. Notes from the 1944 meeting on procedures at HUP indicate that nurses drew blood for laboratory tests but Dr. Rhoads or others at the meeting were considering restricting this procedure to physicians and that the laboratory had suggested that physicians draw blood for more complicated tests. "Dr. Austin's Suggestions", Jonathan Evans Rhoads Collection, University of Pennsylvania Archives, Box 39, FF5 and Procedures—University Hospital, Pages 1 and 2 (both copies), Jonathan Evans Rhoads Collection, University of Pennsylvania Archives. Box 39, FF5.

<sup>157</sup> For example, a hippuric acid excretion test, intended to determine liver function required the following nursing procedure: "1. Light breakfast of toast and coffee. 2. One hour later give sodium benzoate 6 grams in 30 cc. of water, flavored with oil of peppermint. Follow with one-half glass water. 3. Have patient void immediately after taking the drug and discard this specimen. 4. Collect all urine voided during the next four hours and send to the laboratory as one specimen." Williams, "The Nurse and Laboratory Procedures," 952.

patients experiencing surgical complications such as hypoproteinemia or those being studied for clinical research.

Considerable skill and knowledge was necessary to accomplish a single laboratory test for a single, stable patient within the socio-technical system. Very ill patients, such as those with hypoproteinemia due to prolonged gastrointestinal illness or after abdominal surgery required additional work, especially for nurses. Clinical research with hospitalized patients required nurses to coordinate unusual or extensive laboratory tests, collect new types of data, comply with research protocols and work with new treatment technologies, all while providing advanced bedside care.<sup>158</sup> With clinical research still an unusual feature on the wards, even at institutions with rudimentary support for research projects, the existing socio-technical system of the hospital strained to accommodate projects such as Ravdin's hypoproteinemia studies. This is reflected in the small sample sizes, missing data and observational quality of the majority of research studies published during the 1930s and early 1940s. Surgical ward nurses and the investigating physicians spearheading such projects performed the extra work of research that was later designated to medical residents, specialized research nurses, secretaries and statistical workers in addition to the considerable patient care tasks associated with complex surgical patients.

### **Nursing and medical care of the unstable gastric patient**

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<sup>158</sup> For a discussion of how clinicians and hospitals adapted to the new types of data generated by clinical trials and new laboratory tests, see: Howell, *Technology in the Hospital*, 246-249.

A 1933 paper published in *JAMA* collected data on 34 gastrointestinal surgery patients drawn from the surgical services at Massachusetts General Hospital and New England Deaconess Hospital in Boston, MA.<sup>159</sup> The lead author, Chester M. Jones was a surgeon building a specialty in gastrointestinal procedures who was affiliated with Harvard University's School of Medicine. Jones' paper focused on the 26 patients from the group who showed signs of edema, and included serum protein values, electrolyte levels, urine specific gravity, fluid input and other data collected over the course of the patient's hospital stay.<sup>160</sup> This paper presented case studies for some of the more "interesting" or complicated patients, providing a narrative of the patients' clinical trajectory with details including the amount of fluids provided via oral, rectal, intravenous and subcutaneous infusions, the number and amount of blood transfusions and the progression of the patient's clinical picture as reflected in both symptoms and lab values.<sup>161</sup>

In this study, the severity of the patients' illness and treatment required a considerable amount of nursing work to manage. The typical patient in the study was middle-aged and had been suffering the consequences of cancer, ulcer or abdominal infection for weeks, months or years—anorexia, weight loss, pain, vomiting, diarrhea, and nutritional deficiencies. The case studies from Jones and Eaton showed that a wide

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<sup>159</sup> *Ibid.* With the archival record scant on hypoproteinemia research during the 1930s and 1940s, the nursing work associated with these studies can be extrapolated from the research reports published in medical journals and supported with information on nurses' work gleaned from procedure guidelines, nursing journals and instructional materials.

<sup>160</sup> The second author, Frances B. Eaton was most likely the chemist or laboratory technician who performed the many chemical analyses gathered both for the study and in hopes of managing the edema patients' often rapidly deteriorating condition. Jones and Eaton, "Postoperative Nutritional Edema," 159.

<sup>161</sup> *Ibid.*

range of nursing tasks were necessary to manage the sequelae of nutritional edema and also serve to remind the reader that at the center of the research and nursing work were desperately ill, suffering people. Case 12, a 62-year-old man who underwent gastric surgery due to a pyloric ulcer showed signs of malnutrition, weight loss and slight edema in his lower body due to three months of anorexia and occasional vomiting induced by the ulcer. Prior to the procedure, the edema dissipated, which the authors attributed to “rest in bed and a fair intake of milk and cream.”<sup>162</sup> Nurses at the bedside would have carefully controlled and recorded Case 12’s diet, even during this pre-operative period. Elevating his legs in bed, massage and exercises as demonstrated or performed by nurses would have also contributed to the pre-operative improvement noted in the case study.

Despite these promising signs, the patient did not respond well to surgery and frequently required gastric lavage to relieve pain and pressure in his stomach and provide a respite from vomiting.<sup>163</sup> Seven days after the procedure Case 12’s lower extremity edema returned and rapidly worsened. Despite administration of digitalis, believed to cause diuresis, and fluid administration, the patient developed pulmonary edema on day 13 and died the following day.<sup>164</sup> The authors attributed the patient’s death to edema of the stomach and intestinal wall, which caused failure of the surgical procedure and prevented the patient from absorbing sufficient protein and electrolytes to maintain fluid balance.<sup>165</sup>

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<sup>162</sup> *Ibid*, 162. This diet and the elevation of the lower limbs while on bedrest may have helped the excess fluid redistribute. Also, the patient was able to absorb sufficient protein from the milk and cream diet to improve hypoproteinemia to the point that edema no longer occurred.

<sup>163</sup> Jones, and Eaton, “Postoperative Nutritional Edema,” 162-163.

<sup>164</sup> *Ibid*, 162.

<sup>165</sup> *Ibid*

### **Control and Collection of Clinical Data, c. 1933**

Research methodologies we see as standard today were not conventional in 1933. For example, there was no standard treatment for nutritional edema and no research protocol for data collection. Other patients similar to Case 12 presented in the paper are noted as receiving blood transfusions and oxygen tent therapy to treat the same nutritional and pulmonary edema he experienced. These interventions are not noted in the Case 12's case study, either because he did not receive them or because the authors did not think this information relevant when presenting his case. Lab values were inconsistently reported in the case studies. Red blood cell counts, blood pressures and details about the patients' operation, physical condition and mental state appear for some patients and not others. Socio-cultural influences would have shaped patient treatment at Massachusetts General but the limited information provided by Jones and Eaton make it difficult to glean from the published report.<sup>166</sup>

The lack of data produced by the Jones and Eaton study was the product of a socio-technical system unable to support the type of large-scale, regimented and regulated clinical trial familiar to the modern reader. With little to no funding for research, even for a Harvard Medical School professor, Chester Jones collected the data available from patient charts—much of it collected and recorded by nurses—and slowly

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<sup>166</sup> With limited capability for transfusions in 1933, it is possible that only those patients with a family blood donor, or those understood as worthy of the hospital's scant blood supply were ordered transfusions. No demographic data beyond the patient's age, sex and diagnosis were given, so it is unclear how race and social status may have influenced physician's treatment decisions, the allocation of hospital resources or affected the patient's selection for clinical study.

gathered findings on patients from his busy surgical service.<sup>167</sup> Hospital rules or conventions—part of the socio-technical system—may have dictated data collection rather than science.<sup>168</sup>

Jones and Eaton relied on the data routinely gathered or coordinated by nurses—patient input and output, urine specific gravity and serum values—to explore the relationship between gastrointestinal surgery and hypoproteinemia. Observations made by nurses at the bedside such as the first signs of edema, abdominal pain and appetite were included in the case studies alongside physician observations including autopsy data and surgical findings all presented as part of the clinical story of nutritional edema. Nurses are not mentioned in the article but their work appears throughout: subpectoral and rectal infusions, gastric lavage, oxygen tent therapy, input and output measurement, encouragement of increased oral intake, specimen collection, and drug administration are all noted and were crucial to the survival of patients and the success of the study. Considerable time, skill and knowledge on the part of the nurses of Massachusetts General Hospital was necessary to make this clinical study possible.

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<sup>167</sup> The language used by Jones in the introduction to the paper suggests the study was retroactive. See Jones and Eaton, “Postoperative Nutritional Edema,” 159-160.

<sup>168</sup> *Ibid*, 159 & 170. Jones and Eaton included data on three patients from a colleague at another hospital, and it’s possible that patients in the study were under the care of different physicians, accounting for some of the discrepancies in treatment and data. Perhaps serum protein studies were limited to every other day at Massachusetts General Hospital to control cost or because of limited laboratory capabilities. Serum data were included for eight gastrointestinal surgery patients who did not present signs of edema, probably indicating that serum protein and electrolytes were measured routinely in all gastric patients at Massachusetts General. There is no evidence that lab procedures and diagnostic ranges were standardized between institutions or even within different departments of the same hospital. It is also possible that Jones had serum drawn and analyzed on thirty-four patients total for the purposes of the study, though the language used throughout the paper suggests that the data was drawn from former, rather than active cases.

How was the nursing work required for the patients in Jones and Eaton's study any different from that described for the "typical" gastric surgery patient in Talbot's *AJN* article? It seems that in this particular case, the difference was that the patients—the sicker, more unstable hypoproteinemia patients described by Jones and Eaton required more nursing work. Some of the work would have been more of the same: more infusions, more gastric lavage, frequent collection of specimens for lab studies and more steps to keep the patient comfortable. A sicker patient meant closer observation in terms of vital signs and monitoring of signs and symptoms. In the case of hemodynamically unstable patients, input and output would have been vital to determining the course of treatment, leading the nurse to put greater effort into accuracy both due to the added importance of the data to the patient's survival and closer scrutiny of this evidence of her efficiency by the physician.<sup>169</sup> The condition of the nutritional edema patients required procedures not part of the informal gastric surgery nursing protocol but well-known and routine to the staff nurse; oxygen tent therapy and blood transfusion as noted by Jones and Eaton and other interventions for shock which may have been performed by nurses but were not described in the journal article, such as rotating pressure dressings (tourniquets) to combat edema in the extremities.<sup>170</sup>

The nutritional edema patients described by Jones and Eaton were sometimes hospitalized for months. There were some patients with prolonged declines, others who died suddenly and dramatically and a few who recovered successfully from their surgery

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<sup>169</sup> It is possible too that nurses were aware that Jones was collecting data on patients with nutritional edema and put greater effort into collecting the relevant information in the patient's chart.

<sup>170</sup> Fairman, and Lynaugh, *Critical Care Nursing: A History*, 68.

and the resulting edema. The psychological toll on these patients from their illnesses is not discussed in general in the 1933 article, though one patient, an unusual case admitted for an infected hip joint was described as "...very irrational for about ten days."<sup>171</sup> How the nurses interacted with this "very irrational" patient, who later made a full recovery was not mentioned but we can imagine that the infusions, transfusions, rectal taps, specimen collection and body care this patient required was only made more difficult by his distress and confusion.

Surgical nursing in 1933 was complex and demanding. The professional knowledge and skills of the nurse as well as her ability to negotiate within the socio-technical system of the hospital to get her work done were critical to the successful treatment of both typical and complicated gastric surgery patients. Observational clinical research, such as that of Jones and Eaton at Massachusetts General Hospital did not require a new kind of nursing work, or even a reorganization of existing systems for organizing nursing tasks, but absolutely relied upon the fastidious and detailed, yet routine work of nurses; patient care, control of the bedside, data collection and observation.

Enforcing a research protocol on ward patients at HUP without minute-to-minute supervision and control of the patients was not possible during the 1930s and early 1940s. Physicians with teaching responsibilities and active private practices could not spend

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<sup>171</sup> Jones and Eaton, "Postoperative Nutritional Edema," 169.



much time at the patient bedside.<sup>172</sup> Medical residents often did have the flexibility to spend more time on the hospital wards, however patient care tasks, even those associated with medical research were well outside of their scope of practice. Even if medical residents did have ample time to tightly control data collection at the bedside, they would not have had the appropriate knowledge or authority to get the work done. Physicians doing research on surgical nutrition during this era may have had an advanced understanding of the physiology of protein deficiency, but they had limited knowledge about the tasks necessary to collect their experimental data. This work—preparing meals according to the prescribed diet, administering medications and supplements via mouth or stomach tube, collecting various types of fluid samples, and most importantly, gaining the patient’s trust and cooperation with consuming the food, complying with dietary and activity restrictions and measuring all bodily output—was the strict purview of nurses. The typical nurse staffing of a surgical ward did not allow for consistent collection of high-quality patient data outside the routine lab tests and fluid input-output measures understood as a part of routine patient care. Unfavorable nurse to patient ratios and the hospital’s reliance on student nurses as the primary source of nursing labor led to the reliance on functional nursing, assigning nurses to tasks rather than patients to ensure that the considerable amount of nursing work on the ward was accomplished.<sup>173</sup> This system

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<sup>172</sup> Attending physicians, senior physicians who oversee the treatment of patients and the training of medical residents and students were not a common fixture at HUP and other teaching hospitals until after the 1960s. Physicians maintained private practices and held admitting privileges (sometimes at more than one facility), centering their work around a clinic or office rather than the hospital. For more on the evolution of medical education and organization of physicians, see Paul Starr, *The social transformation of American medicine*, (New York: Basic Books), 1982, Rosemary Stevens, *American medicine and the public interest*. (Berkeley: University of California Press), 1998, and Rosenberg, *The Care of Strangers*.

<sup>173</sup> For a discussion of nurse to patient ratios at HUP during the 1950s, see Fairman, Lynaugh, and Campbell *Critical Care Nursing: A History*, 50-53.

maximized efficiency for “doing things” but did not allow for the close observation of patients and careful control of specimens and data collection on a significant scale. The use of private duty or “special” nurses for study patients could have solved the problem of surveillance and data quality for Jones, Eaton and other physician researchers, but it was simply not possible before funding for research became more available during World War II. Not only were there no funds available to cover the considerable cost of extra nurses for study patients, but the sporadic nature of research work would have made it especially difficult to have a private duty nurse trained on the protocol available when an appropriate patient was admitted.

The level of support offered to research projects by nurses varied and was highly contingent on the nature of the research work, the unique infrastructure of each hospital, ward and nursing shift and the individuals involved. Specialized research units and clinical studies with designated beds and nursing staff were rare in U.S. hospitals, including HUP before government funds for medical research became widely available during World War II. Thus hospital nurses rarely chose to do research work prior to the 1940s, rather they encountered clinical research through their typical ward assignments. While research patients presented more work for nurses—additional specimens to collect, tighter observation of intake and output, more data to report and collect, etc.—the extra work offered no extra pay and little recognition. Some nurses may have been interested in gaining new skills and knowledge or in forming professional partnerships with physician researchers to advance their careers. Most ward nurses, however had scant motivation to assist researchers beyond performing their usual bedside nursing tasks. In fact, the extra

work required by some research studies may have led nurses to push back against clinical research on their unit. Protests may have taken the form of official complaints to hospital administrators via the head nurse or unofficial actions such as work slowdowns and even direct sabotage. With little resources available for clinical study, researchers could not get around this problem by hiring private duty nurses to “special” research patients, an expensive approach to nursing labor where the private nurse performed all of the nursing work for an individual or small group of patients. Lack of nursing labor is one of the factors that greatly limited the size and scope of research projects prior to World War II.

Missing data and poor-quality data are recurring themes in medical research articles published in journals prior to the 1960s. Jones and Eaton’s 1933 paper on hypoproteinemia presented inconsistent and incomplete data on its 34 patients.<sup>174</sup> The authors noted “Unfortunately, all four determinations [serum values] were not made in every instance, but for the most part the chemical studies were reasonably complete.”<sup>175</sup> As medical research expanded during World War II with more resources, more coordination between investigators and more oversight by funding agencies, data that were “reasonably complete,” “for the most part” were increasingly understood as inadequate. Both the researchers attempting to definitively answer clinical questions and the government agencies who funded their projects sought ways to more definitively solve clinical problems through better quality experimental data. The existing way of conducting clinical research: using small number of research patients scattered

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<sup>174</sup> Jones and Eaton, “Postoperative Nutritional Edema.”

<sup>175</sup> *Ibid*, 160.

throughout the hospital, fitting research work into a busy teaching schedule, conducting research with little coordination outside the institution and most importantly relying on the typical nursing infrastructure of the wards would no longer work for physicians conducting research after the 1940s. In the following chapter, I examine how the expansion of hospital-based clinical research with government funding affected the role of nurses in medical research and how the socio-technical system of the hospital adapted (or did not adapt) to the challenges of larger, more complex research studies.

In Chapter 3, I discuss how the availability of wartime funding allowed physician researchers at HUP to hire special nurses to work full-time on research work, claim dedicated space within the hospital for a study ward, and increase the size and complexity of their research studies. Paid directly from government research grants, these special research nurses had the knowledge, power, authority and autonomy to control the patient bedside and enable metabolic studies on the wards of HUP and similar hospitals. Even with dedicated research nurses at the patient bedside, the support of the university and ample funding for staff and supplies, investigators still faced considerable challenges in setting up and conducting research work in U.S. teaching hospitals during World War II.

**Chapter 3—“...assigned to the care of the patients and to assure the collection of specimens:” Nurses and OSRD-CMR research, 1940-1946.**

As discussed in Chapter 2, the socio-technical system as it existed in the teaching hospitals of the 1930s and 1940s allowed for small-scale clinical inquiry, such as

investigating the problem of hypoproteinemia in gastrointestinal and surgical patients. However, the system had its limitations, especially in regard to data quality. Recording of patient data and the coordination (or direct collection) of specimens for laboratory analysis were well-established nursing tasks during this era. The unusual, very precise or complicated measurements sometimes required for research could not be consistently accommodated by the staffing system of ward nursing, an important component of the existing socio-technical system.

This chapter explores how newly available federal funding for medical research allowed for expanded nursing roles in research during World War II. Following the development of hypoproteinemia research at HUP in particular during the pre and peri-war years provides an excellent case study on nurses' role in medical research during the 1940s because the studies involved relied heavily on nursing work.<sup>176</sup>

### **Hypoproteinemia Research Continues, 1939-1942**

By 1939, hypoproteinemia researchers at HUP had shifted away from physiological studies of the condition and its causes and towards clinical trials of new, experimental therapies to prevent or correct low serum protein. How did the shift from research studies with an observational design to studies with an experimental design influence nursing work during the 1930s and 1940s? Between 1938 and 1939, HUP

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<sup>176</sup> It is also worth noting that this chapter relied upon a rare collection of archives. A cache of materials recording the OSRD-CMR contract application process and the daily work of inpatient research on the Rhoads and Starr nutrition project were saved by I.S. Ravdin's secretary, Marjorie Lucas and preserved in the personal papers of Ravdin and Rhoads. Lucas reorganized Rhoads' OSRD-CMR files after the physician missed a few reporting deadlines to Washington. University of Pennsylvania Archives, Jonathan Evans Rhoads Papers UPT50R474 Box 61, Folder 8.

surgeon Ravdin and colleague, Alfred Stengel, Jr. ran a research study designed to “...investigate the methods by which hypoproteinemia could be corrected prior to operation and controlled afterward.”<sup>177</sup> The research program studied different methods of improving serum protein levels in hypoproteinemic laboratory animals and human patients before and after surgery: changing the nutritional profile of the patient’s oral diet, intravenous amino acid solutions, jejunal (stomach) and rectal feeding of a prepared protein solution, and the intravenous administration of two types of serum preparations.<sup>178 179</sup>

Ravdin and Stengel’s hypoproteinemia project was typical of pre-World War II research studies in many ways; the research study presented was small in scale, used the patients and patient care facilities already at hand, and employed a case study approach to discuss the clinical course of notable patients. The HUP study differs from the project described by Jones and Eaton in 1933 (see Chapter 2) in that Ravdin and his collaborators were administering experimental treatments for hypoproteinemia and observing their effects on the patients’ clinical status and laboratory values. Thus they were using a simple experimental design in addition to a case study approach, closely tracking the clinical course of gastrointestinal surgical patients with low serum protein. While Ravdin, Jones and their contemporaries did not consider the presence of an experimental

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<sup>177</sup> *Ibid*, 107.

<sup>178</sup> *Ibid*, 107.

<sup>179</sup> A laboratory technician or assistant, Mitchell Prushankin is listed as co-author to Ravdin and Stengel and was probably responsible for the considerable amount of serum protein analysis and other chemical work required to track the changes in the patients and animals over the experimental period. Prushankin was co-author on a study with frequent Ravdin collaborator, Cecilia Riegel using similar Riegel, C., I. S. Ravdin, and M. Prushankin. "Effect of Sodium Dehydrocholate (Decholin) on Bile Salt, Chloride and Cholesterol of Bile in Dogs." *Experimental Biology and Medicine* 41.2 (1939): 392-395.

variable (e.g. the preoperative tube feedings administered by Ravdin et al.) as making the 1939 project fundamentally different from the observational study published by Jones and Eaton, adding a new intervention to the treatment protocol and observing its effects made quite the difference in the amount and nature of the work for the physicians and nurses involved.<sup>180</sup>

The study included the use of a gastric pump, similar to that described in Chapter 2 to slowly administer nutritional mixtures directly into the gastrointestinal tract of hypoproteinemia patients typically via a tube inserted through the nose and down the esophagus. Ravdin and Stengel were probably responsible for the initial set up of the pump, with nurses administering the continuous feeds, providing minute-to-minute observation and making adjustments based on physician's written orders. Not only was this the typical procedure according to the nursing and medical literature of the time but as the pump was a prototype developed by Ravdin and collaborator Dr. Harry Vars, this particular device would have been understood as belonging to the physicians and under their direct purview. The physicians conducting the research arranged for a steady supply of special nutritional supplements for the study, either from laboratories at the University

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<sup>180</sup> Ravdin, Stengel and Prushankin cite Jones and Eaton in the 1939 *JAMA* article and Chester M. Jones was present and provided commentary when the paper was presented at the Section on Surgery, General and Abdominal meeting at the Ninetieth Annual Session of the American Medical Association in St. Louis, May 19, 1939. In the abstract of the discussion that followed the paper presentation, Jones described the work of Ravdin et al. as a "...substantiation of the clinical and experimental observations that I made six years ago." The 1933 paper he referred to (and discussed above) was not what modern readers understand as "experimental"—no variables, controls, etc.—but fell well within the boundaries of clinical research and investigation according to the standards of the 1930s and 1940s. See I.S. Ravdin, Alfred Stengel, Jr., and Mitchell Prushankin. "The control of hypoproteinemia in surgical patients." *Journal of the American Medical Association* 114, (1940): 111-112. For more on the conceptualization of clinical research and experimentation during the 20<sup>th</sup> century see: Rosenberg, *The Care of Strangers*, 158. and Marks, *The Progress of Experiment*.

of Pennsylvania or from the manufacturer. Ravdin and Stengel would have spent significant time coordinating with the head nurse on the study patient's unit to ensure the proper administration of the different nutritional regimens, the maintenance or monitoring of the pump and the collection of specimens and data. Given that these patients were not localized to a single ward but scattered throughout the hospital, the time spent setting up a new study patient, educating staff on the pump protocol and coordinating unusual lab tests would have been significant for the physicians as well as the nurses who would perform the actual tasks for each patient.

The work of nurses at the bedside of Ravdin and Stengel's hypoproteinemia patients seems similar to the routine care of unstable post-abdominal surgery patients discussed in Chapter 2. The mixing and administration of new supplements would have been similar to the standard, carefully controlled diets prescribed to gastrointestinal surgery patients. For example the Sippy diet, which required small meals of milk, cream, eggs, cereals and vegetable purées at carefully timed intervals.<sup>181</sup> Coordinating between dieticians, the laboratory or pharmacy for the supplements was a typical nursing responsibility. Interacting successfully with the many components of the socio-technical system of the hospital to administer diet and medications as ordered by a physician was one of the ways in which nurses made the existing system work for research studies such as Ravdin and Stengel's in the 1930s and 1940s. Tinkering with the prototype pump required Ravdin and Stengel to be present at the bedside of the patients in the study more

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<sup>181</sup> Bertram W. Sippy "Gastric and duodenal ulcer: medical cure by an efficient removal of gastric juice corrosion." *Journal of the American Medical Association* 64 (1915): 1625-1630.



than was usual and allowed them to observe more closely the work of nurses on the ward.<sup>182</sup> This led to more precise administration of special diets and more careful charting of data on the part of the nurses, who adapted under scrutiny or because they understood their work as somehow different due to the research study. Research required close collaboration between physicians and nurses, even in studies such as Ravdin and Stengel's that involved small changes in the routine care of surgical patients.

Interpersonal communication skills were an advantage for both physician and nurse as they negotiated tasks and determined how best to balance the needs of the patient and the research study. Building trust and forming professional partnerships between physicians and nurses was a critical, though an undocumented component of the socio-technical system for research that developed in hospitals between the 1940s and 1960s. Such partnerships sometimes led to professional advancement for nurses and certainly helped physicians with the practical problems of conducting large, complex clinical trials.

Much of Ravdin's work was continued in his absence during the war by his protégé and hypoproteinemia research collaborator Dr. Jonathan Rhoads, a conscientious objector who was appointed interim Chair of the Harrison Department of Surgical Research.<sup>183</sup> Already a respected surgeon and investigator in his own right, Rhoads took

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<sup>182</sup> While nurses routinely handled the pumps used for gastric lavage, this particular pump was a prototype, a one of a kind machine designed and built by Dr. Vars, who would have taken partial responsibility for its maintenance and repair.

<sup>183</sup> Rhoads was a lifelong member of the Religious Society of Friends, a Christian congregation commonly referred to as "Quakers." Quakers or Friends have a long tradition of conscientious objection to war, with many performing alternative service during World War II. See Bacon, Margaret Hope. *The quiet rebels: The story of the Quakers in America*. New Society Pub, 1985. Dr. Elizabeth G. Ravdin, a pediatrician, clinical researcher and wife of I.S. Ravdin took over many of her husband's considerable administrative responsibilities during World War II and acted as a conduit for his communications with stateside

full advantage of the professional opportunities available to him in Ravdin's absence, building upon the hypoproteinemia studies of his mentor to create a program of research in surgical nutrition with OSRD-CMR funds.<sup>184</sup> This program formed the foundation for the development of intravenous hyperalimentation (IVH) or total parenteral nutrition (TPN) in the late 1960s, a major medical advancement largely credited to Rhoads.<sup>185</sup>

By 1942, I. S. Ravdin, in collaboration with Rhoads and others, had completed several studies on hypoproteinemia and nutrition in surgical patients with a recent focus on the experimental feeding methods they had designed to either treat or prevent the condition.<sup>186</sup> The group at HUP continued to test new ways to improve outcomes for patients hospitalized for abdominal surgery, focusing on nutritional supplementation and precisely balanced diets as a way to protect against surgical complications such as liver damage or to improve time to recovery.<sup>187</sup> Like his observational hypoproteinemia projects from the 1920s and 1930s discussed in the previous chapter, Ravdin's studies from the early 1940s were observational. The experimental design did not control variables such as the number of times a patient received a particular supplement.<sup>188</sup>

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colleagues after the 20<sup>th</sup> General shipped out for Assam, India in April of 1943. See Memo, August 9, 1943. NARA, RG 227, OSRD-CMR General Records, 1940-1946, Entry 165, Folder Ravdin, Dr. I. S.

<sup>184</sup> Rhoads' involvement with multiple OSRD-CMR contracts may have also permitted him to spend the war tending to his practice at HUP rather than at a conscientious objector camp. F.F. Borsell, MD to Lt. Col. E. S. Everhart, May 28, 1943. Jonathan Evans Rhoads Papers, University of Pennsylvania Archives, UPT50R474, Box 17, Folder 12.

<sup>185</sup> Dudrick SJ, Wilmore DW, Vars HM, Rhoads JE (Jul 1968). "Long-term total parenteral nutrition with growth, development, and positive nitrogen balance". *Surgery* 64 (1): 134-42.

<sup>186</sup> Ravdin, Stengel, Jr., and Prushankin, "The control of hypoproteinemia in surgical patients."

<sup>187</sup> *Ibid.*

<sup>188</sup> Though Ravdin, Cecilia Reigel, Rozanne Peters and Rhoads, who collaborated on the research were able to analyze liver composition of 127 patients at HUP admitted for surgery to the biliary tract, only 37 of those patients were administered a special diet. The composition and administration of the experimental diet varied greatly between patients. There was also no "control" protocol for the patients who did not receive the special diet. For example, the journal article does not state whether these patients received

Ravdin's work was seen as successful. For example, the 1939 hypoproteinemia study was highly praised by colleagues at an American Medical Association meeting.<sup>189</sup> However, this type of quasi-experimental, semi-controlled study design could not answer more complex questions about nutrition in surgical patients, such as the relationship between protein intake, serum nitrogen levels, and recovery from surgery. Metabolic studies, in which precise measurements of patient input and output and the chemical composition of bodily fluids could provide insight into the physiology of nutrition, the body's recovery from injury, hypoproteinemia and fluid balance were possible in 1942 using precise scales, closely controlled diets, precise specimen collection and laboratory tests. However, such research required resources unavailable at most teaching hospitals. The necessary resources included nurses, medical residents and laboratory technicians able to devote significant time to research work, dedicated beds for research patients, a steady supply of patients that fit the research study, laboratory and clinical equipment and most importantly, funding for salaries, equipment, and space.

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nutritional supplements as part of the routine treatment of surgical patients with liver damage, or the composition of their diet after surgery. In the published paper, which was presented at the 1942 meeting of the American Medical Association (AMA), Ravdin and his team concluded that the improved liver glycogen and lipid concentration seen in the experimental patients was due to the special diet. Ravdin and colleagues' liver damage study would not meet modern standards due to the relatively simple, observational design of research studies during the 1940s and the lack of the sophisticated statistical techniques used today to, for example, determine the significance of findings or determine an adequate sample size to study a hypothesis. While the study was not interpreted as providing a definitive answer as to the best diet to facilitate liver repair in surgical patients, it sparked serious questions at the AMA about the standard, carbohydrate-based diet typically prescribed for such patients in 1942. See Ravdin, Thorogood, Riegel, Peters and Rhoads. "The Prevention of Liver Damage and the Facilitation of Repair in the Liver by Diet," *Journal of the American Medical Association*, 121, (1943): 322-325, Abstract of Discussion, 324-325.

<sup>189</sup> While the study was not interpreted as providing a definitive answer as to the best diet to facilitate liver repair in surgical patients, it sparked serious questions at the AMA about the standard, carbohydrate-based diet typically prescribed for such patients in 1942. See Ravdin, Thorogood, Riegel, Peters and Rhoads. "The Prevention of Liver Damage and the Facilitation of Repair in the Liver by Diet." Same note as above

Surgeons and physicians were also studying the problems of nutrition for patients undergoing surgery at other teaching institutions including Bellevue Hospital, Massachusetts General, and Johns Hopkins University Hospital.<sup>190, 191</sup> Like Ravdin and Rhoads, these researchers also had to limit the size and scope of their clinical research to studies that could be supported by the existing infrastructure of their respective institutions. Metabolic studies required expensive equipment to precisely weigh patients and measure electrolyte values from patient specimens. Most importantly, these types of projects needed tight control of patient intake, precise, complete collection of all patient output and absolute enforcement of the research protocol. Such control was not possible in hospitals during the 1930s through the early 1940s and missing data seem to have been accepted as status quo.<sup>192</sup> With small quantities of semi-controlled data, physician researchers used the data they could acquire to support clinical observations of hypoproteinemia patients presented in case study format.

### **The OSRD-CMR**

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<sup>190</sup> Ravdin, Thorogood, Riegel, Peters and Rhoads. "The Prevention of Liver Damage and the Facilitation of Repair in the Liver by Diet."

<sup>191</sup> R. C. Bodo., F. Co Tui, and L. Farber. "Liver glycogen storage in diabetic animals." *American Journal of Physiology* 103, (1932): 18-24. Emmett L. Holt, Anthony A. Albanese, Joseph E. Brum-Back, Charlotte Kajdi, and Dorothy M. Wangerin. "Nitrogen Balance in Experimental Tryptophane Deficiency in Man." *Experimental Biology and Medicine* 48, (1941): 726-728 and Fuller Albright, William Parson, and Esther Bloomberg, "Cushing's syndrome Interpreted as Hyperadrenocorticism Leading to Hypergluconeogenesis: Results of Treatment with Testosterone Propionate I," *The Journal of Clinical Endocrinology & Metabolism* 1, (1941): 375-384.

<sup>192</sup> Hypoproteinemia studies published during this time rarely discussed the fact that much of the data presented in a given study was incomplete or inconsistently available across patients. Jones and Eaton, authors of the 1933 study of nutritional edema discussed in Chapter 2 briefly address the incomplete serum data presented in their paper: "Unfortunately, all four determinations were not made in every instance, but for the most part the chemical studies were reasonably complete." Jones and Eaton, "Postoperative Nutritional Edema," 160.

Established by the President shortly after the United States entered World War II, the Office of Scientific Research and Development, Committee on Medical Research (OSRD-CMR) was designed to support civilian clinical research projects with military application. The funding provided by the OSRD-CMR enabled physician researchers to conduct studies on a larger scale: more patients, more data and more complex clinical questions and investigative protocols.<sup>193</sup> Funding from the committee had major implications for nurses' roles in medical research during the mid-1940s.

The purpose of the OSRD-CMR was to support and accelerate civilian clinical research projects whose findings could directly improve military medicine, rather than to fund medical research in hospitals through federal sources..<sup>194</sup> Its purpose echoed the mission of the Medical Department of the Navy in 1942: "To keep as many men at as many guns as many days as possible."<sup>195</sup> Projects funded by the OSRD-CMR focused on problems of battle medicine; wounds, infection, fractures, gas injury and both physical and psychological recovery from injury. Similar government and military organizations existed to support research in other Allied and Axis nations including the British Medical Research Council which collaborated with the OSRD-CMR.<sup>196</sup>

HUP and the University of Pennsylvania had strong ties to the National Research Council (NRC), which advised the OSRD-CMR from its inception. A. N. Richards, chair of the Pharmacology Department at the University of Pennsylvania School of Medicine

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<sup>193</sup> Geiger, 4-14. Strickland, 15-21, Shyrock, 287-296.

<sup>194</sup> Irvin Stewart, *Organizing Scientific Research for War: The Administrative History of the Office of Scientific Research and Development*. (Boston: Little, Brown and Company, 1948).

<sup>195</sup> Front Matter, United States Naval Medical Bulletin, No. 1 Vol. XL January 1942.

<sup>196</sup> Research Guide: *Records created or inherited by the Medical Research Council*, British National Archives, Kew, available at <http://discovery.nationalarchives.gov.uk/details/record?catid=121&catln=1>

(UPSOM) and Vice President for Medical Affairs of the University served both on the NRC and as the Chairman of the OSRD-CMR. Other HUP physicians were associated with planning for the medical needs of the U.S. military as war approached between 1939 and 1941. For example, NRC member Ravdin was asked by the Secretary of the Navy to observe the treatment of the wounded after the attack on Pearl Harbor, December 7, 1941.<sup>197</sup>

Through his involvement with the NRC, Ravdin played a key role in organizing and recruiting civilian researchers to investigate medical problems of concern to the military and served on early advisory committees for the OSRD-CMR.<sup>198</sup> Ravdin supported the OSRD-CMR applications of physician colleagues at HUP including Jonathan Rhoads, Isaac Starr, a cardiac specialist and physiologist, and John Lockwood, a general surgeon and wound infection expert, using his considerable influence with the hospital administration and the University of Pennsylvania to gain institutional support for wartime research. With Lockwood, a physician at HUP and noted expert on wound infections, Ravdin designed a plan for a large, multi-site study on the prevention and treatment of infected wounds, a scheme that had tremendous potential to improve military wound care procedures.<sup>199</sup> Despite the request of OSRD-CMR chairman

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<sup>197</sup> I. S. Ravdin, and P. H. Long. "Some Observations on the Casualties at Pearl Harbor." *US Nav. M. Bull* 40 (1942): 353-358.

<sup>198</sup> During 1941, chairman Richards consulted Ravdin frequently for his advice on organizing researchers, finding sites for studies and ways to account for the overhead costs of research in civilian hospitals. By August of that year, Ravdin was at work developing projects on the three areas of medical research; shock, burns and wound infections. I.S. Ravdin to A.N. Richards, August 18, 1941. NARA, RG 227, OSRD-CMR General Records, 1940-1946, Entry 165, Folder Ravdin, Dr. I. S.

<sup>199</sup> Lockwood, John "Wound report," October 14, 1941, p1-10. NARA, RG 227, OSRD-CMR Contract Records, 1941-1946, Entry 163, OEM-cmr 56, Folder "Pennsylvania University."

Richards to army officials that his colleague be given a stateside, research-oriented assignment, Ravdin was appointed head surgeon of the U.S. Army 20<sup>th</sup> General Hospital in early 1942.<sup>200</sup> Nurses and physicians from HUP signed up for the unit and when the group left Philadelphia for basic training in May 1942, the running of the hospital, the medical school and ongoing research projects was left to the skeleton crew of nurses, physicians and staff who remained at HUP. The relationship Ravdin cultivated between HUP and the OSRD-CMR created opportunities for his research partners who remained in Philadelphia.

### **HUP During World War II (1942-1945)**

World War II brought about big changes at HUP, with rationing of supplies, and staff shortages at all levels. The war also created tremendous opportunities for professional advancement for the physicians and nurses in the military as well as those who remained stateside. Medical researchers who remained home during World War II seized the opportunity to advance their careers in the absence of deployed colleagues and the availability of research funding from the OSRD-CMR. Recent nurse training school graduates as well as those who did not qualify for military service or opted out were presented with new opportunities for leadership positions in hospitals, schools of nursing and professional organizations. Nurses outside of the military and relief organizations

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<sup>200</sup> A.N. Richards to Rear Admiral Ross T. McIntire, January 24, 1942. NARA, RG 227, OSRD-CMR General Records, 1940-1946, Entry 165, Folder Ravdin, Dr. I. S.. Ravdin continued to consult on OSRD-CMR projects even after the 20<sup>th</sup> General Hospital was deployed to Assam, India in April of 1943. Through his OSRD-CMR connection, Ravdin was able to secure research-oriented physicians to the unit and support their research while in Assam. For example, Ravdin was able to secure a supply of gelatin to study as a replacement for serum in transfusions for Chinese army patients treated at the 20<sup>th</sup> General Hospital. See I.S. Ravdin to A.N. Richards, March 3, 1942. NARA II, RG 227, OSRD-CMR General Records, 1940-1946, Entry 165, Folder Ravdin, Dr. I. S..

such as the Red Cross may have also benefitted from the stateside nursing shortage caused by World War II with more choices for employment and better pay.<sup>201</sup> Clinical research projects funded by the OSRD-CMR created a range of opportunities for nurses, including those at HUP

Existing research projects that fit into the broad mandate of the OSRD-CMR were able to continue and expand during World War II provided that there were skilled personnel available. The hypoproteinemia research project at HUP was one such enterprise able to broaden and expand during the war with OSRD-CMR contracts.

### **Surgical Convalescence Research at HUP, 1943-1946**

Rhoads and heart physiologist Isaac Starr organized a contract application for OSRD-CMR funds for a two-pronged convalescence project as early as December 1943.<sup>202</sup> Despite being part of the exclusive researcher network and the interim director of Ravdin's surgical service, Rhoads still needed to lobby for support for his OSRD-CMR contract with numerous authorities at Penn. Though he had participated in research at HUP, Graduate Hospital and the Pennsylvania Hospital during his surgical residency, Rhoads had limited experience with the administrative and organizational aspects of research work such as hiring staff and thus consulted with senior physicians on the contract application.

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<sup>201</sup> Staff nurse wages at HUP did not increase significantly during the 1940s. Minutes of the Medical Board Meeting, May 18, 1942. Jonathan Evans Rhoads Papers, University of Pennsylvania Archives, UPT50R474, Box 40, Folder 40.

<sup>202</sup> There are no archives extant which explicitly explain how Jonathan Rhoads and Starr came to know about the availability of research funding from the OSRD-CMR, but it is likely that as part of the small, elite network of recognized medical researchers they were either invited to submit a contract application by the NRC or were recommended by Ravdin, Richards or another well-connected Penn colleague.



The project Rhoads and Starr proposed was ambitious in size and scope, involving metabolic or nutrition studies expanding upon Ravdin's hypoproteinemia work, as well as continuing Starr's use of the ballistocardiograph to study circulation in surgical patients.<sup>203</sup> Rhoads and Starr hoped to study the same patients and correlate nutritional and circulatory data in as many cases as possible, an undertaking that would require a level of organization and coordination well beyond studies conducted in the early 1940s. Based on correspondence from the planning phase of the enterprise, Rhoads, who seems to have spearheaded the project, may not have understood just how complicated it would be to organize an application for the OSRD-CMR and gain the endorsement of university and hospital officials.<sup>204</sup>

Eldridge L. Eliason, Chairman of the Department of Surgery had serious doubts that the studies—referred to by Rhoads and Starr as the “convalescent project” or “nutrition project”—were in the hospital's best interest.<sup>205</sup> Rhoads and Starr needed surgical residents from Eliason's service to put in significant time on the project and

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<sup>203</sup> A ballistocardiogram assesses heart function through measurement of the force of ejection of blood into the major blood vessels with each heartbeat. With each pump of the heart, blood ejected into the vessels around the heart causes a small vibration in the body. The ballistocardiogram, which c.1943 was a metal table picks up these minute vibrations, which are then extrapolated into a graph similar to an ECG. Ballistocardiograms required the patient to lay absolutely still while the measurement was being made. Isaac Starr, A. J. Rawson, H. A. Schroeder, and N. R. Joseph. "Studies on the estimation of cardiac output in man, and of abnormalities in cardiac function, from the heart's recoil and the blood's impacts; the ballistocardiogram." *American Journal of Physiology* 127 (1939): 1-28.

<sup>204</sup> The application consisted of a brief description of the project, the materials and staff available at the facility and a budget proposal for staff and supplied. As the OSRD-CMR infrastructure grew larger, applications and research updates became more involved, describing the underlying scientific principles of the research, previous work and collaboration with other contractors. See NARA II, RG 227, OSRD-CMR General Records, 1940-1946, Entry 165, Contracts and Contract Ledgers. For example, the support of Robin C. Buerki, Dean of the University of Pennsylvania Graduate School of Medicine and Director of Hospitals of the University of Pennsylvania was needed for all stages of the project, from submitting the application to the NRC to hiring staff and obtaining the cooperation of the hospital staff.

wanted to use beds on a surgical ward as a dedicated space for the metabolic and ballistocardiograph studies involved. Thus, his approval and cooperation were required for the contract application to move forward.<sup>206</sup> Eliason was concerned that the study as it was loosely conceived by Rhoads in December of 1943 would create extra work for the already thinly spread staff of surgical residents and surgical ward nurses and doubted the need for a dedicated area for research beds, especially given that demand for inpatient beds was steadily increasing.<sup>207</sup> Space within the hospital was scarce. HUP physicians engaged in fierce political battles in hopes of securing dedicated patient beds and clinic space for their particular service.<sup>208</sup> With patient care prioritized over research during the 1940s, researchers squabbled over laboratories and curried favor with senior physicians to gain access to patients.<sup>209</sup>

Access to dedicated patient care area and laboratory space was important to Rhoads and Starr, who cited problems with using scattered patient beds for earlier projects when appealing to Eliason for support. Rhoads wrote: “We have had so many disappointments with the collection of specimens in doing just this type of work that I doubt if either Dr. Starr, Dr. Lockwood, or I would want to assume responsibility for the

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<sup>206</sup>Eliason, whose surgical service was larger but less well funded than that of his professional rival Ravdin, may have had some personal reasons for being reluctant about the convalescence project. However, his questions and feedback regarding the proposed study were well-considered, practical critiques that ultimately helped Rhoads and Starr get the OSRD-CMR contract in April of 1944.

<sup>207</sup> J.E. Rhoads to E. Eliason, December 1, 1943, page 3. I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3.

<sup>208</sup> Minutes of the Clinical Research Advisory Committee, May 11, 1961. VPMA Papers, University Archives

<sup>209</sup> Intense battles over laboratory space and patient beds at HUP continued well into the 1960s, see Minutes of the Clinical Research Advisory Committee, May 11, 1961. Records of the Office of the Vice President for Medical Affairs, University of Pennsylvania Archives, UPC1.40001, Box 1, Folder “Clinical Research Center, 60-61.”

study without facilities for keeping it in one place.”<sup>210</sup> The precise specimen collection necessary for metabolic research was particularly difficult to accomplish on busy hospital wards. 24-hour urine samples, for example presented a considerable challenge as the loss of any urine through neglect or ignorance ruined metabolic experiments. One physician noted:

“It has been our experience that much more accurate 24 hour samples were made by cooperative patients than when collections were left to an already overworked nursing staff.”<sup>211</sup>

Training able patients, in this case healthy, pregnant women, to collect their own urine led to more complete sample collection than previous attempts to use the existing nursing system in place in the hospital. Recruiting patients to gather research data was not usually a viable option in hospitals, however as many were too ill to participate in tasks such as collecting urine. Thus researchers continued to rely on busy ward nurses to gather specimens and data.

One solution was to set aside an area of a patient ward for research patients. Localizing clinical research to a designated section of a patient ward, preferably close to laboratory space streamlined the processing of patient specimens, saved time for busy physician researchers, and lessened the risk of lost samples and missing data. Reserving lab space was not a guarantee that experiments would run smoothly within the socio-

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<sup>210</sup> J.E. Rhoads to E. Eliason, December 1, 1943, page 2. I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3.

<sup>211</sup> Davis, M. Edward, and Nicholas W. Fugo. “A Simplified Method for the Quantitative Determinations on Free Pregnanediol Excretion in Pregnancy.” *Experimental Biology and Medicine* 66 (1947): 39-42, 40.

technical system at HUP—one anecdote has an important 1940s trial ruined when a “cleaning lady” unplugged a refrigerator in the lab of a vacationing physician.<sup>212</sup>

Researchers would ideally hire private duty nurses to provide total patient care for research patients housed in these reserved beds, but small, private research grants seldom covered this expense. Dedicated research beds staffed with private duty nurses was not unprecedented at HUP during the 1940s. In the early 1940s, nephrologist Eugene M. Landis had established a small ward for renal research using private funds to hire nurses and cover the overhead cost of hospitalizing patients.<sup>213</sup> Landis did not have sufficient resources to hire additional research staff or to keep nurses on when appropriate patients were not available to study. Thus the ward operated sporadically based on his schedule and patient load.<sup>214</sup> OSRD-CMR contracts offered researchers the opportunity to establish research wards with dedicated nurses, laboratories, and technical staff that could be maintained for months or years despite ebbs and flows in the availability of research patients.

In response to Eliason’s concerns, Rhoads noted that as the study provided salary funds for “professional workers,” the intern staff would not be overloaded, and additional nurses could be hired.<sup>215</sup> The overhead allowance of the study (totaling 50% of the

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<sup>212</sup> Cardiologist and renal researcher Dr. Calvin Kay was the unfortunate party. Derek Davis, *Renal Grand Rounds...from the beginning: A History of Nephrology at Penn*, (Paoli, Pennsylvania: 1998), 9.

<sup>213</sup> Davis, “*Renal Grand Rounds...from the beginning*,” 7.

<sup>214</sup> *Ibid.* Nurses on this study were reportedly paid \$80/month, which was less than the \$125 paid to staff nurses. Landis’s project, identified as funded by the Commonwealth Foundation in an anecdotal history of nephrology at HUP warrants further investigation.

<sup>215</sup> J.E. Rhoads to E. Eliason, December 1, 1943, page 2. I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3

salaries paid out on the contract) would help the hospital cover the costs of hospitalization, including routine nursing.<sup>216</sup>

Regarding the nurse staffing, Rhoads stated: “The head nurse and other graduate nurses of this ward would preferably be paid with government funds. The usual number of student nurses would work under their direction.”<sup>217</sup> Rhoads had thus far given little thought to the work of the research project getting done. Who would be collecting specimens and enforcing the study protocol? Was a surgical resident going to collect the data leaving the nurses responsible only for patient care, or was he expecting that the existing system of ward nursing would be able to absorb the work of data collection? Would the nurses be salaried by the hospital and paid per hour or task for additional research work? Regardless of Rhoads’ thinking, his explanation was insufficient for Eliason. As a more experienced administrator, the senior surgeon understood that in order for the study to function both on the ward and within the hospital, the nurse staffing and hierarchy (which one) needed to be explicit. He further pushed Rhoads to include details such as the number of beds, the names of the surgical interns he wished to hire, etc. in the application.<sup>218</sup> After reviewing the NRC contract application in January of 1944, Eliason wrote to Rhoads: “...I see no mention as to how the nursing staff will be conducted. I

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<sup>216</sup> Health insurance was not common during the 1940s and the programs that existed did not consistently cover nursing care or laboratory tests. Lab tests were not routinely covered by health insurance until the late 1950s. See Christy Ford Chapin, *Ensuring America’s Health: The Public Creation of the Corporate Health Care System*. (New York: Cambridge University Press, 2015), 61.

<sup>217</sup> J.E. Rhoads to E. Eliason, December 1, 1943, page 2. I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3

<sup>218</sup> E. Eliason to J.E. Rhoads, January 13, 1944 I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3

gather that the nurses in charge of the patients will be under the supervision of the nurses in charge of the ward.”<sup>219</sup>

Eliason raised an important issue. How would nurses work for the study? Would “routine nursing care” be separated from the nursing tasks required for Rhoads’ metabolic studies and Starr’s ballistocardiograph measurements? How would the study nurses be organized, paid and supervised? Eliason’s assumption, that the head nurse would oversee these nurses and graduate nurses on the unit reflected his understanding of the inner workings of HUP and its professional hierarchy. Physicians wrote nurses’ orders such as medication prescriptions and special diet regimens and had more authority within the hospital than nurses. However, doctors did not typically have much say in how those orders were carried out by nurses or much involvement in the day-to-day operation of hospital wards. During the 1940s the boundaries between the work of nurses and that of physicians were seldom crossed. It would have been both inappropriate and impractical for Rhoads, Starr, or one of the surgical residents assigned to the OSRD-CMR project, as physicians, to directly supervise nurses hired for the study.<sup>220</sup>

Rhoads and Starr may have initially assumed that medical residents assigned to the project would be able to enforce protocols, collect specimens, perform ballistocardiograms and coordinate other aspects of the research work on Ward F, the

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<sup>219</sup> *Ibid.*

<sup>220</sup> For more on the hospital and nursing hierarchy, see Reverby, 66-68, Fairman and Lynaugh, 70-74. Like most surgeons at the time, Ravdin and Rhoads would have formed partnerships with individual nurses who worked with them frequently in the operating room and were preferentially assigned to their cases. There is no evidence that these same nurses were involved in research work outside of the OR nor that other private duty nurses were hired by physicians to work research cases at HUP prior to the availability of wartime funding.

surgical ward they wanted to partially appropriate for the study. By selecting surgical residents with an interest in research and paying them full time with OSRD-CMR funds, the principle investigators hoped to secure men (all of the possible candidates were young, white men) who would spend most of their lengthy workday on the research project. Even with the support of Eliason, Buerki and others at HUP, the short-staffed surgical service required much of the residents' time for surgery, clinic appointments and teaching responsibilities. Residents performed the bulk of work for their medical service. The residents who worked with Rhoads and Starr on the convalescent project and other OSRD-CMR research, C. Everett Koop, Robert Mayock, John L. Drew, John Walker, and L. W. Stevens, had to balance these projects with the demanding requirements of a surgical residency.<sup>221</sup>

Within the HUP OSRD-CMR projects, the residents' responsibilities focused on directing the medical care of study patients, gaining access to eligible patients on other services, preparing reports and papers on the research, and coordinating advanced laboratory studies.<sup>222</sup> Even if the residents had been able to spend the time necessary to perform specimen collection, protocol enforcement and directly supervise nursing care, they did not have the appropriate set of skills, education and jurisdictional power on a

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<sup>221</sup> For a description of the medical resident's role and responsibilities during the 1940s, see Stevens, Rosemary. *American medicine and the public interest*. University of California Press, 1998, 258-266.

<sup>222</sup> Residents assigned to the OSRD-CMR project performed procedures typically done at the bedside but restricted to physicians at HUP such as IV placement and certain types of blood specimen collection as part of their responsibilities as resident physicians.

surgical ward in 1944. Nurses, specifically graduate nurses had the right combination of knowledge, skill and authority to get this work done.<sup>223</sup>

Because of Eliason's concern "...as to how the nursing staff would be conducted," Rhoads (and Starr) changed their approach to organizing nurses for the study. Rhoads stated; "If it is possible, I would like to arrange for the head nurse of the ward to receive a part of her salary from government funds so that she would have a direct, though of course not exclusive, interest in the patients being studied. The nurses specializing the patients would be completely on government funds."<sup>224</sup> The term "specialing," here indicates that the nurses hired for the study would be assigned to the total nursing care of research patients instead of to the ward in general, working in the mode of private duty nurses rather than that of staff nurses or nursing students.

In this letter, Rhoads took pains to demonstrate to Eliason that he both understood and respected the delicate ecosystem of nurse-physician working relationships on Ward F. The researchers made it clear that they would take steps to make sure that their project would fit into the STS of the hospital. For example, the head nurse "...would have a direct, though of course not exclusive, interest..." in the study but her primary responsibility—ensuring proper patient care for the entire ward—would remain the same. Eleanor McGinley, the head nurse of Ward F during the early 1940s would continue in this role during the study. Furthermore, Rhoads took pains to reassure Eliason that he and

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<sup>223</sup> While ward maids, trained assistants and trained volunteers such as the Red Cross "Grey Ladies" were present at HUP during World War II, they would not have had the necessary skills, experience and authority to perform research tasks at the bedside. For more on alternatives to nurses during the 1940's see Whelan "*All who nurse for hire...*"

<sup>224</sup> J.E. Rhoads to E. Eliason, January 17, 1944, I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3.



Starr would approach the hiring and organization of study nurses carefully: “It seems to be that any arrangement made about the nurses would have to be satisfactory to Miss Lynch and I am particularly anxious not to set up any arrangement which is going to result in a lot of friction.”<sup>225</sup>

Teresa Lynch was the powerful and well-respected Director of Nursing at HUP, and professional ally of Ravdin. Lynch ran both the nursing service and the school of nursing between 1942 and 1948.<sup>226</sup> Once the OSRD-CMR awarded the study contract to Rhoads and Starr in mid-April, 1944, the investigators started negotiations with Lynch to hire nurses for the study. Lynch maintained tight control over the nursing aspects of the project, providing Rhoads with a short list of candidates and approving the final appointments, arrangements and salaries. The nurses who were eventually hired for the study were a mix of staff nurses already at work on Ward F, recent graduates of the HUP training school and private duty nurses known to Lynch and routinely hired for cases at the hospital.<sup>227</sup> These nurses (with the exception of those already working on Ward F) were all familiar with the inner workings of HUP and their knowledge, skills and experience were suitable for the project according to Lynch. As they were not currently

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<sup>225</sup> *Ibid.*

<sup>226</sup> Eleanor Crowder Bjoring, *Passing the Legacy: A History of the Last Fifty Years of the School of Nursing of the Hospital of the University of Pennsylvania* (Philadelphia: Alumni Association of the School of Nursing of the Hospital of the University of Pennsylvania, 2006), 53. Lynch continued to teach at Hunter College during her time at HUP, commuting once per week from Philadelphia to New York City. She is credited with transforming the HUP training school into a top tier educational program during the 1940s. Lynch would later launch the undergraduate nursing program at the University of Pennsylvania and was a leading figure in nursing education during her long career.

<sup>227</sup> Eleanor M. Wilson to Jonathan Rhoads, April 10, 1944, I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3.

working as staff nurses they could also be hired for the study without causing staffing problems within the hospital.

By hiring study nurses through Lynch, Rhoads and Starr secured the cooperation of the nursing department for both the OSRD-CMR project and the care of their usual hospital patients. The physician researchers had particular qualities in mind for guiding their choice of nurse. In a letter confirming salary arrangements for the nurses starting work on the study in May of 1944, Rhoads asked Lynch if a particular nurse, Marian McConnell would be available in July, when the group anticipated the need for an additional nurse.<sup>228</sup> Lynch replied that McConnell was a student and thus unavailable for any position until after graduation in January, 1945.<sup>229</sup> Rhoads then requested that McConnell be assigned to the project as part of her final clinical assignment during the last six months of her “Cadet Corps Training Nurses program.”<sup>230</sup> No further correspondence regarding this request is extant, but as McConnell is not among the nurses listed as co-authors in the many journal articles published on the study data, Lynch was dedicated to improving the HUP training school and resisted attempts to trump the

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<sup>228</sup> J.E. Rhoads to T.I. Lynch, May 2, 1944, I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3.

<sup>229</sup> T. I. Lynch to J.E. Rhoads, May 9, 1944, I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3.

<sup>230</sup> J.E. Rhoads to T. I. Lynch, May 11, 1944, I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3. Rhoads is referring to the U.S. Cadet Nurse Corps, a training program established in 1943 designed to increase nursing school enrollment during the World War II nursing shortage. Tomblin, Barbara Brooks, *G.I. Nightingales: The Army Nurse Corps in World War II*, Lexington, KY: The University Press of Kentucky, 1996, p188-194.

educational needs of her students with the labor needs of the hospital as best as she could.<sup>231</sup>

The labor needs of the convalescent project itself were considerable. Rhoads' and Starr's proposal included a budget of \$23,780.00, a figure which included staff salaries and equipment but not the cost of hospitalization.<sup>232</sup> One OSRD-CMR reviewer of Rhoads' and Starr's proposal commented, "This is an elaborate, relatively costly piece of work that would undoubtedly be well done."<sup>233</sup> In response another reviewer wrote "The high cost of the project is due to the need for careful nursing supervision to assure accurate collections of specimens for the balance studies."<sup>234</sup> The cost of nursing for the contract ranged between 28% to 35% of the total budget from March of 1944 until December of 1945.<sup>235</sup> The physician researchers were under pressure to keep salaries for nurses, technicians and interns low and produce the maximum data for the lowest possible cost. Rhoads probably requested McConnell, the student nurse as a means to

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<sup>231</sup> See correspondence and interviews, School of Nursing, Division of Medical Affairs, 1944-65, Interview with Lynch, c.1970. Theresa I. Lynch Papers, MC 102, Center for the Study of the History of Nursing, School of Nursing, University of Pennsylvania, Box 3, Folder 2.

<sup>232</sup> The OSRD-CMR experimented with formulas to cover the cost of hospitalization for study patients and other institutional overhead. For example, Rhoads and Starr requested \$23,780.00 in their first proposal and a total of \$33,770.00 was awarded. See Proposal for Extension of Contract, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 34, Folder OEM-cmr 436.

<sup>233</sup> K. B. Turner to A. N. Richards, March 23, 1944, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 34, Folder OEM-cmr 436.

<sup>234</sup> J. L. Caughey to A. N. Richards March 20, 1944, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 34, Folder OEM-cmr 436.

<sup>235</sup> Nurses on the HUP project made considerably less than nurses at work on similar studies at NYU, who also earned a significant pay increase over the course of the OSRD-CMR project while the HUP nurses, whose salaries remained at \$125/month. Other metabolic nurses including those working on contracts for Harvard and New York University were also paid at a higher rate. Nurses paid through an OSRD-CMR contract for a syphilis study at the University of Pennsylvania made upwards of \$200/month, though they may have had advanced training as public health nurses. NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 34, Folder OEM-cmr 436, Folder OEM-cmr 482, Folder OEM-cmr 326.

employ a scientifically-minded, skilled worker at no cost to the study. In addition to being the correct choice politically, negotiating nurse salaries through Lynch saved the researcher's time in tracking down qualified, available nurses. Lynch kept salary costs for study nurses low—nurses on the study made the same rate as HUP staff nurses, \$125 per month or \$6 per eight-hour shift plus meals and board.<sup>236</sup> Paying research nurses at the same rate as HUP staff nurses prevented the study from poaching the best nurses away from the hospital's nursing service, already stretched thin by the war. Private duty nurses were paid at a higher rate than staff nurses at HUP—nurse Eleanor M. Wilson turned down a position on the OSRD-CMR project, informing Rhoads, "I'm quite sure the work would be most interesting and I know I would enjoy it but the pecuniary aspects are less appealing since our expenses remain the same."<sup>237</sup>

Positions on the OSRD-CMR convalescence project appealed to the four nurses hired for the study, Anne Barnhart, Janet Boger, Marie Barnes, and Erna Goulding.<sup>238</sup> This work offered a unique opportunity for nurses. The project would span at least one year, a more stable assignment than private duty nursing typically offered. Study nurses had more control over their own work schedules, avoiding split shifts (working two four hour periods in a single day with a few hours "off" in between) and unpredictable ward assignments.<sup>239</sup> Research work may have been seen as easier or lighter duty than nursing on a ward or understood as directly contributing to the war effort. Being selected to work

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<sup>236</sup> Minutes of the Medical Board Meeting, May 18, 1942. Jonathan Evans Rhoads Papers, University of Pennsylvania Archives, UPT50R474, Box 40, Folder 40.

<sup>237</sup> Eleanor M. Wilson to Jonathan Rhoads, April 10, 1944, I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 129, Folder 3.

<sup>238</sup> Draft of newsletter article, c. May 1944, University Archives. I.S. Ravdin Papers. Box 129, Folder 3.

<sup>239</sup> Fairman, and Lynaugh, *Critical Care Nursing: A History*, 44-69.

on an OSRD-CMR project increased the status or prestige of these nurses among their colleagues at HUP. Study nurses had the opportunity to learn marketable new skills or build professional relationships that could help advance their careers. “Specialing” allowed nurses more autonomy over their own work, an aspect of OSRD-CMR contract assignments appealed to some nurses.<sup>240</sup>

The role of nurses in the convalescent project grew more autonomous as Rhoads and Starr worked with HUP administrators to get the project up and running in the spring of 1944. Documents from late May demonstrate how the role of nurses was being negotiated and crafted during the early stages of research by researchers, nurses and hospital administrators. The first draft of a description of the OSRD-CMR project prepared for the internal HUP newsletter initially described the special duty nurses as “...assigned to the care of the patients and to help in the collection of specimens.”<sup>241</sup> In the final draft, the nurses are on the ward to “assure the collection of specimens” rather than “help,” indicating the surveillance and control they were expected to enforce at the bedside. The final version also more clearly identifies the nurses involved and their responsibilities “Miss McGinley will continue as head nurse of Ward F and will also supervise the work of the project nurses. Miss Goulding as staff nurse will assist her.

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<sup>240</sup> *Ibid.*

<sup>241</sup> Draft of newsletter article, c. May 1944, University Archives. I.S. Ravdin Papers. Box 129, Folder 3.

Miss Barnes, Miss Barhnart, and Miss Boger are giving full time to the project and special care to the patients.”<sup>242</sup> <sup>243</sup>

### **Nursing work on the study**

The nursing work on the convalescence project was demanding. The principal investigators applied the funds to two areas of inquiry that shared patients, equipment and nurses: the nutrition project headed by Rhoads and the circulatory project led by Starr. The nutrition project was larger and involved more direct patient care. Rhoads and his collaborators were interested in the relationship between preoperative diet, serum nitrogen balance, and recovery from extensive surgery.<sup>244</sup> This work was of interest to the military as it could provide helpful data on the nutritional requirements of soldiers recuperating from surgery and approximate recovery times for the wounded. Rhoads’ OSRD-CMR work on nutrition established him as an expert on nitrogen balance and surgical nutrition and laid the groundwork for the development of total parenteral nutrition (TPN).<sup>245</sup> Like the earlier hypoproteinemia research at HUP, the experiments performed under the nutrition project required careful administration of diet and nutritional supplements. Many of the patients were admitted for gastrointestinal surgery

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<sup>242</sup> J.E. Rhoads to F. Grant, May 24, 1944, University Archives. I.S. Ravdin Papers. Box 129, Folder 3. It does not seem like McGinley and Goulding were paid any additional salary for their work on the study, rather their HUP salary was paid from OSRD-CMR funds.

<sup>243</sup> The unit that housed the study patients, Ward F was usually a women’s ward but because it was better suited to the project than the men’s surgical floor, Ward M, the two units exchanged patients. Report of the Director, 1943-1944, Theresa I. Lynch Papers, MC 102, Center for the Study of the History of Nursing, School of Nursing, University of Pennsylvania, Box 3, Folder 2. It is unclear why McGinley remained head nurse of Ward F after the switch. The two units may have had a different number of beds and the hospital found it more convenient to keep the existing staffing in place or McGinley may have been better-suited to supervising the research work than other head nurses at HUP.

<sup>244</sup> Riegel et al, “The nutritional requirements for nitrogen balance,” 18.

<sup>245</sup> Dudrick, “History of parenteral nutrition.”

after prolonged illness and required intensive surgical nursing as described in Chapter 2: fluid administration and gastric lavage in addition to routine bedside care tasks such as bathing, toileting and repositioning.

Conducting research on these patients added a more complex layer of tasks for nurses at the bedside. Studying the nitrogen balance of a patient required the continuous, precise collection of all patient output (urine, feces, fluid obtained through suction of the stomach and vomit) under controlled conditions. For example, in order to study nitrogen levels in patient urine, all urine output needed to be collected and saved in sterile containers, using a precise ratio of the disinfectant toluene to inhibit bacterial growth.<sup>246</sup> Correct measurement of patient input and output was an absolute requirement of accurate nitrogen balance measurements. Collecting urine and recording a patient's intake may seem straightforward, but as discussed in Chapter 2 there is much room for error, for example; forgetful patients, other staff at the bedside unaware of the need to record input, spills, and samples getting lost en route to the lab.<sup>247</sup> Organizing these nurses as "specials," freed them from ward responsibilities and gave them the time to coordinate with other departments, build working relationships with study patients and ensure strict adherence to study protocols. Teaching patients about the purpose of special diets, fluid restrictions and other restrictive requirements of metabolic studies was important in gaining their cooperation.<sup>248</sup> The patients studied by Rhoads and Starr did comply with

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<sup>246</sup> Riegel et al "The Nutritional Requirements for Nitrogen Balance in Surgical Patients During the Early Postoperative Period," 19, Helen Currier, "Nursing Care in Nephritis," *The American Journal of Nursing*, Volume 41, (1941): 889-892.

<sup>247</sup> Currier, "Nursing Care in Nephritis," 889.

<sup>248</sup> *Ibid.*

the dietary limits, exercise tests, and frequent lab tests required for the study.<sup>249</sup> Study nurses effectively maintained patient compliance for the study using their technical and interpersonal skills.

The success of the study relied upon nurses' ability to maintain compliance and cooperation on the part of the patients. Starr's aspect of the project focused on examination of the patient's circulatory status using a ballistocardiograph, an instrument that recorded the electric activity of the heart as the patient lay absolutely still on a metal table. One of Starr's protocols required that ballistocardiographs be administered at precise times during the patient's treatment including immediately after postoperative recovery from anesthesia.<sup>250</sup> This necessitated considerable coordination between the patient ward and operating room or recovery room staff to time correctly, work probably performed by nurses on the study. Exercise tests performed for the convalescence project ranged from in-bed maneuvers completed under the supervision of nurses to metabolic tests that required patients to wear heavy, tightly-fitted respirators while stepping onto a riser.<sup>251</sup> Rhoads' component of the study also relied on the ability of nurses to encourage patients to cooperate with unpleasant aspects of the research. For example, nutritional supplements administered for the study were unpalatable—chalky and thick with an unpleasant taste.<sup>252</sup>

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<sup>249</sup> Contract Ledger Entry, OEMcmr-436, NARA II, RG 227 OSRD-CMR Contract Ledgers, 1941-1946. Entry 164, Box 3 Rhoads-436.

<sup>250</sup> Isaac Starr, and Robert L. Mayock. "Convalescence from Surgical Procedures I: Studies of the Circulation Lying and Standing, of Tremor, and of a Program of Bed Exercises and Early Rising." *The American journal of the medical sciences* 210, (1945): 701-713.

<sup>251</sup> Starr and Mayock, "Convalescence from Surgical Procedures I."

<sup>252</sup> Nurses and dieticians were hard-tasked to disguise the taste of Amigen, described by one OSRD-CMR researcher as "objectionable." James E. McCormack to E. Cowles Andrus, August 3, 1945. NARA II, RG



Also, collection of all patient output could be inconvenient for patients, , who typically were not trusted to collect their own urine.<sup>254</sup> Small, routine components of patient care including urine collection were not considered high-status, scientific work, however they were incredibly important to the convalescence project and other OSRD-CMR studies. A single lost urine specimen could ruin an expensive, complicated metabolic study. With the need to ensure a precise account of all patient intake and output to obtain correct metabolic data, the HUP convalescence project relied upon the surveillance of patients by nurses. Patient observation was an often unseen, unrecorded aspect of nursing work that nevertheless ensured patient safety and patient compliance in the hospital. Professional standards were also upheld by the gaze of the nurse, who could not confront a physician about his actions directly but had at least some recourse to report unsafe or unethical behavior within the HUP hierarchy.

A brief survey of all OSRD-CMR contracts indicates that nurses were typically not involved in studies involving healthy volunteers, at least not until participants became ill. Nurses did not assist with a Philadelphia-based project that infected healthy conscientious objectors with hepatitis unless the volunteer became ill enough to be admitted to a special hepatitis ward.<sup>255</sup> Subjects in the Minnesota Starvation Study, also sponsored by the OSRD-CMR also did not encounter nurses unless they fell sick, at

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227, Entry 163, Records of the OSRD-CMR, Contract Records, 1941-1943, Folder OEMcmr-326. There is no data from the HUP convalescence nurses themselves on how they felt about their work or whether they questioned the efficacy of the experimental diets or the utility of ballistocardiographs on patients with no expected cardiac deficiencies.

<sup>254</sup> Edward M. Davis, and Nicholas W. Fugo, "Pregnanediol Excretion in Pregnancy," *Experimental Biology and Medicine* 66, (1947): 39-42.

<sup>255</sup> "Detour-- main highway:" *our CPS stories: College Mennonite Church in Civilian Public Service / Seniors for Peace, College Mennonite Church*, (Goshen, IN: College Mennonite Church, 1995), 64-5.

which point they were cared for by nurses at the University of Minnesota student health clinic.<sup>256</sup> The U.S. military does not seem to have employed nurses on their own research projects including the testing of mustard gas on active duty soldiers. Nurses in medical research tended to work with sick patients within hospitals and other clinical settings. Funding agencies relied upon the physician's moral responsibility and judgment to protect patients from harm rather than peer review or external guidelines on best research practices.<sup>257</sup>

### **The Worth of Nurses on OSRD-CMR Contracts**

The OSRD-CMR was concerned about tracking government dollars, and so required monthly official updates on findings from contract holders. Correspondence between contract holders and OSRD-CMR officials frequently emphasize the goal of maximizing output of new medical knowledge with contract funds. Infectious disease researcher and University of Pennsylvania professor John H. Stokes wrote the following in a letter to an OSRD official: "...we will see that every dollar expended from this amount available earns a dollar and a quarter in scientific dividends, or bust."<sup>258</sup> Researchers and OSRD-CMR officials described the importance of nurses in metabolic research in particular in correspondence related to research budgets, budget amendments and site reports. Rather than describing the role of nurses in data collection and protocol

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<sup>256</sup> Ancel Keys, Josef Brožek, Austin Henschel, Olaf Mickelsen, and Henry Longstreet Taylor. *The biology of human starvation, Volume 1*, (Minneapolis: University of Minnesota Press, 1950), 1-80.

<sup>257</sup> Baker, Robert. *Before bioethics: A history of American medical ethics from the colonial period to the bioethics revolution*. Oxford University Press, 2013.

<sup>258</sup> John H. Stokes to E. Cowles Andrus, June 5, 1945. NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 34, Folder OEM-cmr 482.

enforcement, physician researchers tended to emphasize the need for special nurses to provide patient care for very ill, unstable research patients.<sup>259</sup>

Nurses were in fact essential the success of OSRD-CMR research for reasons beyond their ability to enforce protocols and ensure proper specimen collection. The availability of nurses for bedside care was vital to the survival of the very ill, medically unstable patients being studied and followed by OSRD-CMR researchers. The study of burn treatment—which spanned problems of first aid for burns, burn-induced shock, psychiatric response to trauma, wound infection, and the effects of penicillin on infected burns—was an area of OSRD-CMR research that led to major medical advancements and absolutely relied upon the work of expert nurses at the bedside.<sup>260</sup> The most well-known burn treatment studies during World War II were those conducted at Boston City Hospital (BCH) and Massachusetts General Hospital (MGH) in the wake of the tragic Cocoanut Grove nightclub fire.<sup>261</sup> Researchers who published findings on burn treatment, shock and psychological response to trauma including surgeons Oliver Cope and Stanley Levenson and psychiatrists Erich Lindemann and Alexandra Adler extended existing OSRD-CMR research contracts or were awarded new contracts to study victims of the disaster.<sup>262</sup>

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<sup>259</sup> Stanley M. Levenson, Ross W. Green, Charles C. Lund, “An Outline for the Treatment of Severe Burns,” *The New England Journal of Medicine*, 235, (1946): 79.

<sup>260</sup> Stanley M. Levenson, Ross W. Green, Charles C. Lund, “An Outline for the Treatment of Severe Burns,” *The New England Journal of Medicine*, 235, (1946): 79.

<sup>261</sup> Oliver Cope, “Care of the Victims of the Cocoanut Grove Fire at the Massachusetts General Hospital,” *England Journal of Medicine*, 229 (1943). 138-147. Maxwell Finland, Charles S. Davidson, and Stanley M. Levenson, “Clinical and Therapeutic Aspects of the Conflagration Injuries to the Respiratory Tract Sustained by Victims of the Cocoanut Grove Disaster,” *Medicine* 25, (1946): 215-284.

<sup>262</sup> A. Alder, “Neuropsychiatric complications in victims of Boston’s Cocoanut Grove Disaster, *JAMA* 123, (1943): 1098-1101. E. Lindemann, “Symptomatology and management of acute grief,” *American Journal of Psychiatry*, 101 (1946): 141-148.

On Saturday, November 28, 1943 a fire broke out in the popular, overcrowded Cocoanut Grove nightclub killing 491 and flooding local hospitals with the dead, the dying, and badly burned survivors. Most of the victims were taken to Boston City Hospital (BCH) and Massachusetts General (MGH) with a few taken elsewhere. With so many burn patients who were otherwise young and healthy, researchers at MGH and BCH had a rare chance to study the efficacy of burn treatments and observe the effects of burns on human physiology and psychology. While the language used by Boston researchers in OSRD-CMR correspondence is sympathetic and appropriate given the scope of the tragedy, they openly recognized a need to “seize the opportunity” of the fire to advance medical knowledge through clinical research.<sup>263</sup>

Nurses, including staff nurses, students nurses and private duty nurses on hand the night of the fire played an important role in the immediate response to the Cocoanut Grove Fire at both MGH and BCH—initiating treatment for shock, setting up triage systems, applying short term dressings, and proving pain management—nurses assisting with the later stages of burn treatment as part of research studies best demonstrate just how critical bedside nursing was to the success of clinical research studies based on the fire victims.<sup>264</sup>

In a description of best practices for severe burn treatment based on two years of studies on Cocoanut Grove Fire victims at BCH, Harvard researcher Stanley M.

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<sup>263</sup> Proposal for Extension of Contract, September 1, 1943, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 18, Folder OEM-cmr 263.

<sup>264</sup> Grace Parker Follett, “The Boston Fire: A Challenge to Our Disaster Service,” *The American Journal of Nursing*, 43, (1943), 4-8. This article describes the initial response of the nursing service at MCH to the Cocoanut Grove fire in detail but does not discuss the ongoing nursing care of burn study patients. Other publications by nurses regarding their experiences with the fire have not been identified.

Levenson noted that the treatment advancements made in the wake of the fire were useless without the availability of semi-autonomous, “special” nurses for burn patients:

“Even in spite of carrying out every item in this outline, the fact remains that a patient with a deep burn of 5 per cent or more can be saved only if special nursing care is given. This is not at present provided on the wards of many hospitals unless special nurses are available. Any patient with an unhealed deep burn of 20 per cent or more needs three nurses a day; with one of 10 to 19 per cent, two periods of special nursing a day are needed; and with one of 5 to 9 percent, one period of special nursing a day is needed.”<sup>265</sup>

Levenson and his co-authors particularly emphasized the need for “special,” as in semi-autonomous nurses assigned to patients rather than the ward in general as necessary to ensure the special caloric needs of burn patients were met during the recovery period. It was not sufficient for a physician to order a high-protein, high-calorie, high-vitamin diet for burn patients and expect that the existing system of the ward could accommodate the request. Without nurses knowledgeable in the composition of such a diet, the means to arrange its preparation and the time and autonomy to work with the patient to maximize intake, the diet protocol was ineffective.<sup>266</sup>

Researchers at both MGH and BCH specifically requested additional funds for nurses from the OSRD-CMR starting in 1944, indicating that the amount previously awarded to cover hospitalization, which included routine nursing, was not enough to pay for special nurses.<sup>267</sup> Oliver Cope, a Harvard researcher working at MGH specifically

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<sup>265</sup> Stanley M. Levenson, Ross W. Green, Charles C. Lund, “An Outline for the Treatment of Severe Burns,” *The New England Journal of Medicine*, 235, (1946): 79.

<sup>266</sup> *Ibid*, 78.

<sup>267</sup> Proposal for Extension of Contract, January 26, 1945, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 17, Folder OEM-cmr 102, Proposal for Extension of Contract, September 1, 1943, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 18, Folder OEM-cmr 263.

requested funding for three “metabolic ward nurses” or “metabolic nurses” to allow for the study of nitrogen balance in burn patients in an OSRD-CMR supplemental application from January of 1945.<sup>268</sup> Charles Lund, another Harvard researcher who studied Cocoanut Grove burn victims at BCH requested additional funds for a “head” or “chief nurse” as well as for full-time nurses.<sup>269</sup>

Lund noted that even with OSRD-CMR funds, what the burn team could do for the Cocoanut Grove survivors was limited by the hospital’s resources, notably the availability of special nurses.

“In 6 seriously burned patients who, by special nursing care and careful attention to nutrition, had been protected against wasting, an abrupt deterioration in condition occurred when they were transferred from the Burns Project to routine ward care. At this time there was a drop of 50% in the amount of food actually consumed.”<sup>270</sup>

Levenson, working under Lund at BCH further lamented the lack of special nurses for his burn patients in a later publication, which presented a case study from an OSRD-CMR project on Addison’s disease in thermal burn patients.<sup>271</sup> Addison’s disease is an endocrine disorder in which the adrenal glands, located atop the kidneys, fail to produce sufficient steroid hormones, limiting the kidney’s ability to assist in the

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<sup>268</sup> Proposal for Extension of Contract, January 26, 1945, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 17, Folder OEM-cmr 102, O. Cope to J.C. Wearn, January 26, 1945, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 17, Folder OEM-cmr 102.

<sup>269</sup> Proposal for Extension of Contract, September 1, 1943, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 18, Folder OEM-cmr 263.

<sup>270</sup> Contract Ledger Entry, OEMcmr-263, NARA II, RG 227 OSRD-CMR Contract Ledgers, 1941-1946. Entry 164, Box 3 Lund-263, 2.

<sup>271</sup> S. M. Levenson, H.J. Tagnon, W.L. Goodpastor, R.W. Green, F.H.L. Taylor, C.C. Lund, “Addison’s Disease Associated with Amyloidosis Following Thermal Burns: Report of a Case,” *The New England Journal of Medicine* 237, (1947): 152-156.

regulation of electrolytes, blood glucose, and blood pressure, resulting in life-threatening imbalances.<sup>272</sup> Levenson and his collaborators were hoping to learn more about the poorly understood link between burn survivors and the disorder while testing new treatments. For the first six months of her treatment at BCH, the patient received intense medical and nursing care: IV fluids, surgical debridement of burns, skin graft placement, administration of penicillin, a wide range of blood tests, and a carefully controlled high protein diet, supplemented with tube feeding. The patient was greatly improved at the six-month mark, her lab values stabilized, the skin graft sites were healing and the patient was able to get out of bed. Levenson then notes “From the seventh month on, it was not possible to keep the patient on special nursing care. The food intake and general condition gradually deteriorated.”<sup>273</sup> The patient died five months later, approximately one year after being admitted for thermal burns. While the study authors did not entirely attribute the patient’s death to the lack of special nurses, they did feel it was an important contributing factor:

“This patient suffered from long periods of malnutrition during the course of her illness owing to the fact that it was possible to feed her adequately only when special nurses were available. At other times the amount of nursing care available was insufficient, largely because of the universal wartime shortage of nurses. The importance of special nursing care in inducing burned patients to take adequate diets and supplements has previously been emphasized.”<sup>274</sup>

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<sup>272</sup> Elizabeth Martin, "Addison's disease." In *Concise Medical Dictionary*. : (Oxford University Press, 2015). <http://www.oxfordreference.com/view/10.1093/acref/9780199687817.001.0001/acref-9780199687817-e-12118>.

<sup>273</sup> Levenson et al, "Addison's Disease Associated with Amyloidosis Following Thermal Burns," 153.

<sup>274</sup> *Ibid*, 156. While Levenson attributes the inadequate nursing as “largely” due to wartime staff shortages, other factors would have contributed to the lack of special nurses for this patient. OSRD-CMR funding for special nurses may have run out seven months into her stay. The patient is identified as an African American woman in the case study, nurses may have refused to be assigned to this patient for racist reasons or nursing administration felt she was low priority due to her race. The patient and her family may not have

In this particular case, the patient could not be kept alive long enough to see if the experimental interventions for Addison's disease were successful or to determine if the condition was caused by her burn injury. In large part, according to the study's authors, the failure to keep the patient alive was due to the absence of consistent special nurse staffing to ensure sufficient dietary intake. Switching this patient and the 6 other burn victims described by Lund from special nursing assignments on the Burn Unit to a ward care setting contributed to their decline. Not only was a ward system unable to accommodate the special diets required for these burn patients, the absence of special nurses with the time, skills, knowledge and autonomy from ward duties to keep these patients stable, comfortable and cooperative contributed to their decline.<sup>275</sup>

The significance of nurses in OSRD-CMR projects was also demonstrated in published research reports. HUP nurses Barnes, Barnhart, Boger, Goulding and McGinley were listed as secondary authors in the first paper published on nutrition project data.<sup>276</sup> Other OSRD-CMR projects that involved metabolic studies also gave

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had adequate funds to pay for special duty nurses at the high rates such nurses could demand given the wartime nursing shortage.

<sup>275</sup> Stanley M. Levenson, Ross W. Green, Charles C. Lund, "An Outline for the Treatment of Severe Burns," *The New England Journal of Medicine*, 235, (1946): 79.

<sup>276</sup> In this first article, the Nurses and technicians who worked on the study (all women) were credited under the heading "with the technical assistance of..." Additional publications based on the data collected under the auspices of Rhoads and Starr's OSRD-CMR contract did not credit nurses but did include chemical technicians Marjorie G. Battles and Rozanne P. Grigger as co-authors. These later publications can be typified as secondary data analysis of the information and specimens collected during the 1944-1946 contract and did not require additional clinical research. J. H. Drew, C.E. Koop, and R.P. Grigger, "A Nutritional Study of Neurosurgical Patients with Special Reference to Nitrogen Balance and Convalescence in the Postoperative Period," *Journal of neurosurgery* 4, (1947): 7-15. Isaac Starr, Robert L. Mayock, and Marjorie G. Battles, "Convalescence from Surgical Procedures II. Studies of Various Physiological Responses to a Mild Exercise Test," *The American journal of the medical sciences* 210, (1945): 713-725. Other Further analysis of publishing conventions during the 1940s is needed to understand why nurses and



nurses co-authorship and acknowledged their contributions within the text of the article.<sup>277</sup> Researchers from Wayne State University and the Detroit Receiving Hospital noted that the nurses supporting metabolic research on burn patients “gave faithful and careful nursing care...”<sup>278</sup> NYU researcher Frank Co Tui was so concerned by rumors that the experienced research nurses running the metabolic ward at Bellevue Hospital would be drafted into the military that he personally sent a telegram seeking advice from the Chief of the Division of Medicine of the OSRD.<sup>279</sup> Nurses with expert skills and experience were understood as a necessity for metabolic research in particular by researchers and officials as evidenced by contract amendments approving more funding for “metabolic nurses” and special nurses for metabolic studies.<sup>280</sup>

### **Administrative challenges in other OSRD-CMR projects**

The role of nurses was seldom expanded beyond bedside or clinically-centered work in wartime research, due in part to the nursing shortage and beliefs about who should conduct research work. Coordination between study sites, a common

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technicians were given credit in some instances and not others. The work of female scientific technicians was credited in engineering and physics up until the 1950s. Light, "When computers were women," 455-483.

<sup>277</sup> Publications based on OSRD-CMR funded research sometimes credited nurse workers under the heading under the heading “with the nursing assistance of...” For example, see Co Tui, Arthur M. Wright, J. H. Mulholland, V. Carabba, I. Barcham, I., and V.J. Vinci, “Studies on Surgical Convalescence I. Sources of Nitrogen Loss Postgastrectomy and Effect of High Amino-Acid and High Caloric Intake on Convalescence,” *Annals of Surgery* 120, (1944): 99-122.

<sup>278</sup> J.W. Hirshfeld, W.E. Abbott, M.A. Pilling, C.G. Heller, F. Meyer, H.H. Williams, A.J. Richards, R. Obi, “Metabolic Alterations Following Thermal Burns III. Effect of Variations in Food Intake on Nitrogen Balance of Burned Patients,” *Archives of Surgery* 50, (1945): 200. Note the paternalistic language.

<sup>279</sup> Frank Co Tui to E. Cowles Andrus, February, 1945. RG 227 OSRD-CMR Entry 165, General Records, 1940-1946, Box 28, Folder Co Tui, Dr. F. V.

<sup>280</sup> NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 18, Folder OEM-cmr 263, February, 1945. NARA II, RG 227 OSRD-CMR Entry 165, General Records, 1940-1946, Box 28, Folder Cope, Dr. Oliver.

responsibility of research nurses in the 21<sup>st</sup> century was one area in which studies struggled in the 1940s. In a separate OSRD-CMR project on burn treatment led by Rhoads, a medical resident was responsible for recruiting study patients from Philadelphia area hospitals via their physicians. The resident, John Walker was tasked with collecting timed blood samples and guiding patient treatment at several hospitals scattered across the city.<sup>281</sup> Plans to transfer burn patients to a specialized ward set up at Pennsylvania Hospital proved impractical; patients preferred to stay close to their families, physicians were concerned about losing control over treatment, and physicians, patients and hospitals raised concerns about the expense of an extended hospital stay. Due to the gasoline restrictions in place during World War II, this resident spent much of his time visiting patients via streetcar while the nurses hired specifically for the study waited to treat the few burn patients admitted to Pennsylvania Hospital.<sup>282</sup> Overloaded and untrained in bedside care, using medical residents to perform the work later accomplished by nurses—specimen collection, protocol enforcement, surveillance, observation, coordinating and patient care—was an expensive, impractical and typically unsuccessful solution. The burn study floundered, eventually folding after Walker was drafted to the Army and it resulted in no publications. Using nurses for the administrative aspects of the Pennsylvania Hospital burn study may have increased patient recruitment, improved the amount, consistency and quality of data collected, and allowed the

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<sup>281</sup> “Burns Project, 1943,” Jonathan Evans Rhoads Papers, University of Pennsylvania Archives, UPT50R474, Box 61, Folder 20, Contract Ledger Entry, OEMcmr-16, NARA II, RG 227 OSRD-CMR Contract Ledgers, 1941-1946. Entry 164, Box 1A, Lee-56.

<sup>282</sup> *Ibid.*

researchers to generate new medical knowledge. With the exception of syphilis studies employing public health nurses as follow-up workers, OSRD-CMR research studies kept nurses close to their traditional role at the bedside.<sup>283</sup>

HUP researchers designing studies during the late 1940s and 1950s tended to limit the responsibilities of research nurses to the traditional purview of patient care: administering medication, preparing special diets, ensuring special diets and coordinating data collection. This limited what nurses could do in supporting medical research projects. Investigators also relied upon the existing system of patient care already in place in the hospital for their research, which in many cases limited what they could accomplish.

### **End of OSRD-CMR funding**

In anticipation of the end of World War II, the OSRD-CMR began winding down its activities in the spring of 1945. There was some discussion on the best approach for the government to continue to support and coordinate civilian scientific research between the committee, the National Research Council and Congress during 1944 and 1945 but by war's end, there was no consensus for a national policy for medical research.<sup>284</sup> The U.S. Public Health Service (USPHS), which oversaw the fledgling NIH seemed a logical successor to the OSRD-CMR, but the Congressional Budget Bureau blocked the agency from funding extramural grants.<sup>285</sup>

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<sup>283</sup> Contract Applications, OEMcmr-482, NARA II, RG 227 OSRD-CMR Contract Files, 1941-1946. Entry 163, Box 34, Folder OEMcmr-482.

<sup>284</sup> Strickland, *Politics, Science and Dread Disease*, 18-25. Any other secondary sources?

<sup>285</sup> The USPHS would be given the power to fund external grants by Congress in 1949. Geiger, *Research and relevant knowledge*, 29.

OSRD-CMR and USPHS officials were faced with discontinuing research projects they felt were vital to public health, including ongoing clinical trials of penicillin.<sup>286</sup> During January of 1946, a coalition of committee members, USPHS and NIH researchers and sympathetic congressmen developed a work-around, transferring about fifty ongoing OSRD-CMR contracts and with their remaining funding to the USPHS.<sup>287</sup> The OSRD-CMR funded projects that remained came to an end by early 1946, including the HUP convalescence project.<sup>288</sup>

Without funding for special duty nurses, hospital overhead and laboratory tests, the convalescence project at HUP drew to a close. However, many of the investigators involved continued to publish journal articles based on the data collected with OSRD-CMR funding. Research into questions of nitrogen balance and nutrition for surgical patients continued on a small scale, typically using a small-scale or case study approach at HUP during the late 1940s and 1950s.<sup>289</sup> Institutional politics also altered the course of research within the Harrison Department of Surgery at HUP. Hospital administrators appointed I.S. Ravdin as the new head of Surgery upon his return from military service in 1946, replacing Ralph Eliason. Jonathan Rhoads became a full partner in Ravdin's surgical practice and aided in his mentor's mission to update the infrastructure of the

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<sup>286</sup> J. H. Stokes to A.N. Richards, October 3, 1945, NARA II, RG 227 OSRD-CMR Contract Files, 1941-1946. Entry 163, Box 34, Folder OEMcmr482.

<sup>287</sup> Geiger, *Research and relevant knowledge*, 25.

<sup>288</sup> Contract correspondence, OEM-cmr 263, NARA II, RG 227, OSRD-CMR Contract Records 1941-1946, Entry 163, Box 18, Folder OEM-cmr 263, Contract Ledger Entry, OEMcmr-263, NARA II, RG 227 OSRD-CMR Contract Ledgers, 1941-1946. Entry 164, Box 1A, Rhoads-263.

<sup>289</sup> For example, Jonathan E. Rhoads, and Charles E. Alexander. "Nutritional problems of surgical patients." *Annals of the New York Academy of Sciences* 63, (1955): 268-275. Herndon B. Lehr, Jonathan E. Rhoads, Otto Rosenthal, and William S. Blakemore. "The use of intravenous fat emulsions in surgical patients." *JAMA* 181, (1962): 745-749.

hospital and formalize the surgical residency program. Ravdin formed powerful partnerships with other administrators, most notably Theresa Lynch, to improve nursing and medical education at HUP, advance and expand patient care and raise the national profile of the hospital and university during the late 1940s through 1950s. While research continued to rise in importance as an aspect of academic medicine at HUP, government funding for building and educational projects through the 1946 Hill Burton Act made infrastructure growth the top priority.<sup>290</sup>

The success of the OSRD in advancing scientific discovery suggested that a coordinated effort between government, military and civilian researchers could continue to be fruitful. During the immediate postwar years, the U.S. government and the scientific community were at odds regarding how best to organize and fund research in the absence of a national emergency. Many scientists supported Vannevar Bush's proposal for an "autonomous national science foundation" that would fund and support research with indirect oversight from the federal government.<sup>291</sup> Impressed with the achievements of the OSRD-CMR, members of Congress pushed the idea for a larger, more powerful NIH to continue the committee's wartime achievements.<sup>292</sup> Physicians actively opposed the idea of a centralized government agency with the power to oversee and regulate research. Some argued that while better funding and organization of research would be a good thing, a federal agency would be too unwieldy to effectively run clinical trials.<sup>293</sup> Other

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<sup>290</sup> Bjoring, *Passing the Legacy*, 52-60. Joan Lynaugh and Barbara L. Brush, *American Nursing: From Hospitals to Health Systems*, (Malden, MA and Oxford: Blackwell Publishers, 1996), 3-4.

<sup>291</sup> Geiger, *Research and Relevant Knowledge*, 26.

<sup>292</sup> Strickland, *Politics, science, and dread disease*, 30

<sup>293</sup> Geiger, *Research and Relevant Knowledge*, 26

physicians and many medical organizations opposed the very idea of government regulation, regardless of the opportunity to better fund and coordinate research.<sup>294</sup> These opposing positions created a lull in the availability of resources for medical research during the late 1940s and early 1950s and shaped the emerging prominence of the NIH as the de facto national medical science foundation.

Physician researchers, hospital administrators and national research figures learned important lessons from the success and failures of OSRD-CMR funded projects. The employment of special nurses to provide “careful and complete control of the patient,” dedicated space for bedside research and the implementation of better-defined, better-controlled research protocols all contributed to higher quantities of good quality data in comparison to prewar research projects. With the rise of funding for medical research through the NIH in the 1950s and 1960s, these lessons would be remembered and played out in a slightly different fashion as research once again rose to prominence in U.S. hospitals during the late 1950s through mid-1960s.

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<sup>294</sup> Strickland, *Politics, science, and dread disease*, 30

**Chapter 4 – “...careful and complete observation of the patient is  
necessary...” Nurses and control in research, 1957-1962**

The availability of funding for medical research grew exponentially between the late 1940s and the early 1960s. In 1947 Congress awarded the NIH a budget of \$7.5 million, which grew to \$26.5 million the following year. One third of the NIH budget in 1948 was allocated to external research. By 1951 the allocation soared to \$60 million.<sup>295</sup> Academic researchers had access to resources like never before. Between 1947 and 1951, total grants for medical research \$10.3 to \$32.9 million.<sup>296</sup>

Hospitals, medical schools and universities lacked the clinical, scientific and organizational resources to adequately support more research studies during the 1940s and 1950s. For example, most universities did not have sufficient accounting and secretarial staff to accommodate the paperwork required by the NIH in a timely fashion and were forced to create new departments to administer external grants.<sup>297</sup> By the mid-1950s, NIH officials had realized that in order to meet its goal of expanding and improving clinical research across the nation, it needed to fund the growth of an STS or infrastructure to support research.<sup>298</sup> By 1956 the NIH was matching capital costs for health research facilities and in 1959 began a program of institutional grants to aid

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<sup>295</sup> Geiger, “*Research and Relevant Knowledge*,” 27.

<sup>296</sup> *Ibid.* The NIH provided almost 2/3 of this increase.

<sup>297</sup> *Ibid.*, 58-59.

<sup>298</sup> *Ibid.*, 180-182.

universities in developing infrastructure for research.<sup>299</sup> In 1965, NIH institutional grants totaled \$44 million.<sup>300</sup>

The result was a network of elite medical schools and affiliated hospitals dominated by clinical research, with HUP and the University of Pennsylvania ranked high among them. Oversight of how researchers applied NIH funds and conducted their research was nominal during this time. Researchers negotiated with their university for space, staff, and other resources, often with no set rules for accounting, payment of overhead, and cooperation with other medical departments.

Regulation of the practical and ethical aspects of clinical research was similarly informal. With no strict requirements for recruitment practices until the FDA required informed consent for the administration of experimental drugs in 1962, clinical researchers were largely left to their own devices in making ethical decisions about experimenting on their own patients. In the absence of a formal relationship between research subject and researcher, research studies continued to rely on the authority of nurses at the bedside and the trust placed in nurses by patients to ensure cooperation in clinical research during the 1950s and 1960s.

The presence of nurses at the bedside of research patients during these decades served to legitimize clinical research as an acceptable aspect of patient care and helped make clinical experimentation visible and legitimate at HUP and other U.S. hospitals. Nurses created a “zone of control” around research patients that made increasingly

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<sup>299</sup> *Ibid.*

<sup>300</sup> *Ibid.*



complex clinical research and experimental treatments viable during the 1950s and early 1960s. Nurses were employed by researchers at HUP in a variety of capacities, some more successfully than others. There are two main examples where nurses were employed to create a “zone of control” around research patients: the first, an unsuccessful cancer chemotherapy trial attempted with outpatients and secondly the HUP Clinical Research Center (HUPCRC), a highly successful, NIH-sponsored unit within the hospital run by nurses.

### **Growth of the NIH and competition for research dollars, 1946-1962**

Private universities, including Penn, needed NIH funding after World War II. The NIH sponsored research studies but offered little funding towards infrastructure development. Thus universities found themselves in need of research funding but lacking the resources to develop the laboratories, specialized clinical research spaces, and training programs necessary to attract both NIH grants and new researchers. Overhead costs, such as hospitalization for clinical research patients—a considerable expense for hospitals that included nursing salaries—were inconsistently and poorly reimbursed by the NIH until the late 1950s. Also, health insurance plans did not comprehensively cover the cost of routine laboratory tests, a critical component of many clinical trials until the 1950s.<sup>301</sup> University hospitals with a proven track record of running research studies under the OSRD-CMR including HUP were at a distinct advantage over less-established institutions in obtaining NIH dollars. However, obtaining funds was not a given. The reputation of a hospital’s nursing department and any affiliated nursing schools were

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<sup>301</sup> Chapin, *Ensuring America’s Health: The Public Creation of the Corporate Health Care System*, 61.

considered important aspects of infrastructure by NIH grant committees and nurses continued to contribute significantly to research studies.

The success of some wartime research, especially the development and production of penicillin under the OSRD-CMR set the public's expectations for medical research high in the years following World War II. During the immediate postwar years, Congress, government-based research institutions including the USPHS and NIH, physician groups, pharmaceutical companies and leading figures in medical research negotiated to create a national system for funding, organizing, and overseeing medical research.

Oversight and regulation of NIH funded research studies was informal and ad hoc. Universities gradually developed administrative departments to handle the rapidly expanding work of coordinating grant applications and obtaining reimbursement from the NIH for research costs. Accounting for reimbursement was a complicated job that required many Universities to overhaul their bookkeeping practices and keep careful track of research costs for the first time.

### **Nurses and the Zone of Control at the Bedside**

Fairman and Lynaugh describe the zones of security, authority and safety cooperatively constructed by nurses and physicians around the bedside of intensive care unit patients during the 1950s and 1960s.<sup>302</sup> Nurses expert in the care of fragile patients and experienced with new and complex intensive care therapies created a “zone of security” for physicians unable to remain at the patient bedside. In partnership with

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<sup>302</sup> Fairman and Lynaugh, *Critical Care Nursing: A History*, 78-79.

physicians, intensive care unit nurses gained expert knowledge in the management of unstable patients and earned a “zone of authority” around the critical care patient. The professional collaboration, proximity of expert clinicians and establishment of treatment protocols fostered by the socio-technical system of the intensive care unit created a “zone of safety” for patients. Survival rates and health outcomes improved for the critically ill as hospitals organized intensive care units and critical care nurses perpetuated the zones of security, authority and safety with their bedside expertise.<sup>303</sup>

Medical research during the mid-twentieth century required a similar construction of professional space around the patient bedside, a concept I call the “zone of control.” Like the zones of security, authority and safety surrounding the critical care patient, this “zone of control” relied upon the presence of nurses at the bedside, the recognition of their knowledge and authority by physicians and hospital administrators, and the skills of the nurses themselves. Skilled observation of the patient by nurses was a critical aspect of early intensive care units and a crucial component of the zones of security, authority and safety. The zone of control maintained by nurses at the bedside of research patients heavily relied on these same skills of observation. However, I argue that the purpose of close observation of research patients was fundamentally different than the routine watchfulness over hospital ward patients expected of nurses and the close monitoring of critically ill patients in the newly developed intensive care units of the 1950s. Rather than observing patients for strictly therapeutic purposes, making sure that a patient was safe and stable, nurses at the bedside of research patients needed to watch patients to ensure

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<sup>303</sup> *Ibid*, 28-29.

that the needs of the research study were being met. Thus the research patient required another zone or layer of nursing responsibility and power, the “zone of control” to enforce study protocols, ensure the collection of patient specimens, and collect data as needed for the study. Clinical trials required a confluence of safety, stability, and control at the patient bedside.

Nurse educators recognized the importance of good observation skills for nurses working in medical research and emphasized patient observation as an important aspect of nursing work. Mildred Montag, a nurse educator who researched education programs for auxiliary nurses (“nurse technicians”) was clear that the responsibility of nursing care and surveillance for research patients belonged to the graduate nurse.

Montag noted, “As new treatments are added careful and complete observation of the patient is necessary as well as the actual administration of the treatment.”<sup>304</sup> While routine bedside tasks could be safely and effectively performed by trained assistants, skilled nursing including the administration of experimental treatments and the monitoring of research patients required a more educated professional nurse. In the case of HUP and similar research-oriented hospitals, “nurse technicians” and other auxiliaries did not appear on the hospital wards during late 1950s through 1960s. Students from the HUP nurse training school continued to provide the bulk of nursing labor within the hospital. Researchers at HUP, however hired graduate nurses for research work during this period when funding allowed.

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<sup>304</sup> Mildred I. Montag, *"The education of nurse technicians."* (New York: Putnam, 1951), 19.

The nursing tasks within the “zone of control” and the “zone of safety” in many cases were not much different. For example, closely monitoring and recording the fluid intake for a hospital patient was a routine nursing responsibility throughout the mid-twentieth century. The general tasks for this responsibility included providing the prescribed fluids to the patient, observing the amount of fluid infused into the patient or drank by the patient, collecting and measuring all patient output (urine, feces, vomit and any fluid collected via drains or suction), and recording and tallying this input and output on the patient chart. A patient prescribed a strict fluid intake limit, such as one experiencing kidney failure, required closer observation and control by the nurse to make sure that the limit was not exceeded. Research patients undergoing electrolyte balance studies were issued strict fluid and dietary restrictions in order for the analysis of their electrolyte balance to be accurate. Enforcing these restrictions was the responsibility of the nurse. The patient surveillance by bedside nurses is required in both instances, however the motivation behind the observation is fundamentally different. Nurses employed for research were asked to exert their authority for the good of the research study, as well as for the health of the patient. Research work in hospitals created overlapping loyalties for nurses—closely watching a patient undergoing a kidney transplant, for example was in the best interest of the patient, researchers studying organ rejection, and the hospital as well as the nurses’ themselves. Further investigation is needed to understand how nurses responded, or if they responded when research and patient safety were at cross-purposes. Nurses today conceptualize themselves as an advocate for their patients, a role that was not necessarily part of the nursing identity

during the 1930s-1970s.<sup>305</sup> As a profession, nurses were well liked and trusted by the public during this era as they are today.<sup>306</sup> Nurses took advantage of the trust placed in them by patients to accomplish their many tasks—feeding, bathing, administering medications to patients, dressing changes, specimen collection, etc.—in the busy and thinly-staffed hospital wards of the mid-twentieth century.

Clinical researchers capitalized on the position of nurses in society and within the socio-technical system of the hospital to ensure the cooperation and compliance of research patients and enforce research protocols. With the trust placed in them by patients and the authority granted to nurses by physicians and hospital administrators and earned by nurses through their clinical knowledge and expertise in getting things done, nurses were able to control research patients and collect the research data that made the clinical advancements of the mid-twentieth century possible.

### **The HUP Neoplastic Chemotherapy Clinic, 1955-1958**

Researchers at HUP sought organizational solutions to the problem of conducting well-controlled clinical trials within the hospital. Physicians at HUP conducted cancer research using funding from the U.S. Public Health Service (USPHS) and the National

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<sup>305</sup> Leah L. Curtin, "The nurse as advocate: a philosophical foundation for nursing." *Advances in Nursing Science* 1, (1979): 1-10. Janice M. Morse, "Negotiating commitment and involvement in the nurse-patient relationship." *Journal of advanced nursing* 16, (1991): 455-468.

<sup>306</sup> Karen Donelan, Peter Buerhaus, Catherine DesRoches, Robert Dittus, and David Dutwin. "Public perceptions of nursing careers: the influence of the media and nursing shortages." *NURSING* 26, (2008): 144. Robert P. Bullock, "Position, function, and job satisfaction of nurses in the social system of a modern hospital." *Nursing Research* 2, (1953): 4-14.

Cancer Institute (NCI) of the National Institutes of Health (NIH) throughout the 1950s.<sup>307</sup>

With the support of I.S. Ravdin, the School of Medicine and the HUP Department of Surgery, physicians Sylvan Eisman and Robert Ravdin (son of I.S. Ravdin, identified as R.G. Ravdin) joined forces to study the possibilities of adjuvant cancer chemotherapy during the mid-1950s. In the adjuvant approach, experimental anti-cancer drugs were given to patients after surgery to remove or reduce cancerous tumors.<sup>308</sup> Surgery was understood as the most effective approach to treating cancer during this era. Adjuvant chemotherapy was seen as augmenting surgery, a pharmaceutical extension of the surgeon's scalpel.<sup>309</sup> To further coordinate resources, R.G. Ravdin and Eisman formed the Neoplastic Chemotherapy Clinic (NCC) around 1957 and began small-scale clinical trials of anti-cancer drugs on patients drawn from the hospital's many surgical practices.<sup>310</sup>

Nurses supported the cancer chemotherapy research of this group in a number of ways. Only one nurse, Carol Salt, R.N. is known to have been employed directly by the Unit ca. 1957-1959.<sup>311</sup> Salt's documented responsibilities included coordinating patient

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<sup>307</sup> Cancer Research Grants, National Cancer Institute, Research Grants Branch, November 1, 1957, 105-108. I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 142, Folder 24.

<sup>308</sup> Bernard Fisher, Robert G. Ravdin, Robert K. Ausman, Nelson H. Slack, George E. Moore, and Rudolf J. Noer. "Surgical adjuvant chemotherapy in cancer of the breast: results of a decade of cooperative investigation." *Annals of surgery* 168, (1968): 337. John V. Pickstone "Contested Cumulations: Configurations of Cancer Treatments through the Twentieth Century." *Bulletin of the History of Medicine* 81 (2007): 183-190.

<sup>309</sup> *Ibid.*

<sup>310</sup> See correspondence and customs forms, "HUP—Coggins Report," I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 142, Folder 26.

<sup>311</sup> Sylvan H. Eisman to I. S. Ravdin, October 20, 1957. , I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 142, Folder 28.

follow-up and maintaining the group's supply of experimental anti-cancer drugs.<sup>312</sup> Managing these difficult-to-acquire and rare compounds was a major responsibility requiring considerable organizational, clerical, interpersonal and mathematical skills. Safety was paramount when working with drugs in the early phases of clinical trials such as 3-methylcholanthrene. Salt worked with customs officials, industrial chemists, foreign physicians and hospital administrators to acquire and maintain the supply of the drugs R.G. Ravdin, Eisman and their research associates wished to study.<sup>313</sup> If, like the radium nurses described by historian of nursing Brigid Lusk, Salt was responsible for controlling access to the Unit's experimental drugs, she would have held a powerful position as use of the anti-cancer drugs was tightly controlled by the NCC and the Surgical Department.<sup>314</sup> With so little known about the effects of 3-methylcholanthrene and other experimental anti-cancer compounds, the NCC was careful to limit access to its own physicians. Even these experts in the field had little understanding of how the drug would affect patients, its potential to do harm, and what symptoms in the patient signaled effectiveness or toxicity.

There is no documentation available that clearly states who administered 3-methylcholanthrene and other experimental anti-cancer drugs given to inpatients by the NCC during recovery from cancer surgery. As the individual in charge of the experimental drug supply, Salt may have administered the drug to patients, supplying the

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<sup>312</sup> *Ibid.*

<sup>313</sup> *Ibid.*

<sup>314</sup> Lusk, "Nursing Patients with Cancer in the 1950s: New Issues and Old Challenges," 123-138.



drug to other nurses or physicians, and educated staff on the proper procedure for handling the compounds.<sup>315</sup> A 1959 *American Journal of Nursing* article describes a radioisotope clinic nurse as "...the liaison between the clinic and the ward in all therapeutic procedures."<sup>316</sup> When patients receiving radioisotope therapy were housed on a hospital ward, the clinic nurse informed the head nurse on the details of the treatment, therapeutic procedures such as dressing changes and safety protocols.<sup>317</sup> Accurate urine collection was crucial for patients undergoing radioisotope studies for two reasons, the tests itself required urine samples collected over up to 96 hours and the patient's urine was radioactive. The radioisotope clinic nurse was responsible for ensuring complete specimen collection and maintaining the safe storage of radioactive urine in the clinic, away from ward patients and staff.<sup>318</sup> In this example, a clinic nurse was responsible for patient and staff safety around harmful therapeutic materials in addition to patient care and research responsibilities.

There is no evidence that Salt or any other nurse received special training on handling anti-cancer drugs or on the possible adverse effects for patients or themselves. R.G. Ravdin, Eisman or one of the rota of surgical residents working on their service may have also given the drug at HUP, as the materials were understood as dangerous, precious and expensive. Like the administration of IV fluids during the 1930s and 1940s discussed in Chapters 2 and 3, the task of giving experimental or dangerous drugs was probably

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<sup>315</sup> This is in keeping with Lusk's radium nurses, but there is no data on who administered drugs for the Neoplastic Chemotherapy Clinic.

<sup>316</sup> Stapleton, Emma W. "A radioisotope clinic." *AJN The American Journal of Nursing* 59, no. 2 (1959): 224-229, 225.

<sup>317</sup> *Ibid.*

<sup>318</sup> *Ibid.*

contingent and contested at HUP during the late 1950s and early 1960s. Who gave the drug often depended on who was present at the necessary moment and given that nurses were typically to be found at the bedside and administering medications well within their purview, ward nurses were the most likely staff member to give patients 3-methylcholanthrene and other drugs being trialed at HUP. Given the potential toxicity of the drug to its handlers and its unknown effects on patients, knowing the details of who gave 3-methylcholanthrene and other experimental drugs under what circumstances would tell us much about how researchers, nurses and patients understood and managed the risks surrounding medical research.

At the National Institutes of Health Clinical Center (NIHCC), nurses provided the day-to-day treatment of cancer chemotherapy patients during the early 1960s, including children participating in the landmark clinical trial of the VAMP regimen.<sup>319</sup> Historians of these early chemotherapy trials do not discuss the actual administration of experimental drugs and therapies or other aspects of routine patient care at the NIHCC, however photographs of nurses attending trial patients or working with bedside equipment are frequently used as illustrations.<sup>320</sup> The Children's Cancer Research Foundation's Jimmy Fund Clinic in Boston, built around Sidney Farber's "total care" philosophy integrated nursing expertise into every stage of patient treatment for pediatric leukemia during the 1950s.<sup>321</sup> Articles by nurses working with Farber emphasize the importance of other nursing skills such as skin care, diet management, and emotional

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<sup>319</sup> Keating and Cambrosio, *Cancer on Trial*, 55-83.

<sup>320</sup> For example, Keating and Cambrosio, *Cancer on Trial*, 55-83, Krueger, *Hope and Suffering*, 97.

<sup>321</sup> *Ibid*, 82-91.

support of the patient's family.<sup>322</sup> Nurses at the Jimmy Clinic also performed blood transfusions and sternal punctures to collect bone marrow samples among other traditionally medical procedures, indicating that the role of nurses at the clinic had adapted and expanded to accommodate the new demands of patient care created by clinical trials.<sup>323</sup>

The records are silent about the nurses at HUP receiving any instruction on the drug, its adverse effects on the patient, and perhaps even the actual name of the experimental compound.<sup>324</sup> HUP nursing procedure manuals and other documentation of nursing policy from the 1950s contain no mention of experimental drugs or equipment.<sup>325</sup> Training on new drugs, even those understood as experimental or dangerous was probably informal at best. The outpatient component of the 3-methylcholanthrene study, however expected home health nurses to administer the drug without instruction and outside the safety and supervision of the hospital.

### **The Neoplastic Chemotherapy Clinic and the Visiting Nurse Society of Philadelphia**

The NCC group was also conducting cancer chemotherapy research administering 3-methylcholanthrene to outpatients. In a preliminary trial led by Dr. Charles Huggins at the University of Chicago, 3-methylcholanthrene had demonstrated tremendous anti-

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<sup>322</sup> Mary Stone Brodish, "The Nurse's Role in the Care of Children with Acute Leukemia," *American Journal of Nursing*, 58 (1958): 1572-1574.

<sup>323</sup> Kreuger, *Hope and Suffering*, 89.

<sup>324</sup> Stine to Miss Shand, November 15, 1957. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3

<sup>325</sup> "Nursing Technique Book - Nursing Office," ca. 1963, Hospital of the University of Pennsylvania, School of Nursing Records, MC 94, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 6.

cancer effects in a small group of patients.<sup>326</sup> The experimental dosing regimen used in Huggins' study required daily intramuscular injections of the drug. The NCC did not have adequate staff, space or patients to justify a daily outpatient clinic, and holding appointments a few days per week throughout 1959.<sup>327</sup> The options for keeping post-surgical patients on the 3-methylcholanthrene regimen once they were well enough to be discharged was therefore limited by the lack of daily clinic appointments as well as the practical challenges for getting fairly ill patients to HUP every day for an injection. Giving patients the drug at home was the only practical choice for R.G. Ravdin and Eisman if they wished to study the anti-cancer effects of 3-methylcholanthrene. A local home health agency, the Visiting Nurse Society of Philadelphia (VNS) often contracted with HUP physicians to provide post-operative follow up to surgical patients during the 1950s. By November 15, 1957, VNS nurses were administering injections of 3-methylcholanthrene to NCC patients within their homes.<sup>328</sup>

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<sup>326</sup> The effects of the drug were probably due to hormone/adrenal suppression in patients with hormone-sensitive breast cancer. Charles Huggins and Jack D. McCarthy, "Regression of Human Metastatic Mammary Cancer Induced by 3-Methylcholanthrene", *Cancer Research* 17, (1957): 1028-1032. Huggins would later use 3-methylcholanthrene to induce breast cancer in laboratory animals, see: Charles Huggins, Giuliano Briziarelli, and Harold Sutton. "Rapid induction of mammary carcinoma in the rat and the influence of hormones on the tumors." *The Journal of experimental medicine* 109, (1959): 25-42.

<sup>327</sup> There is no data demonstrating that patients received anti-cancer drugs during clinic visits, and these appointments may have served to identify good candidates for drug trials and follow up on patients who had received experimental drugs after cancer surgery.

<sup>328</sup> In 1957, the VNS was contracted to provide home care to patients discharged from HUP as the hospital deemed necessary, though the process for assigning patients, paying for nursing services, etc. is not extant in the VNS archives. Though founded in 1886 as a charity to provide nursing care and social support to Philadelphia's poor, by 1957 the Visiting Nurse Society (VNS) had developed into a professional nursing organization providing nursing care in the homes of patients at all levels of the city's socioeconomic strata under contract from local government, other non-profits, hospitals and private paying patients to administer to the ill within their homes. Divided into regional branches and run by influential members of Philadelphia society and the medical and nursing community, the governing bodies of the VNS such as the Medical Advisory Committee included many important figures. See: Finding Aid, Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania.

What was it exactly that the VNS nurses were asked to do in the 3-methylcholanthrene trial? The archival record indicates that the NCC did not create an explicit protocol until several months into the trial, when the VNS medical board requested a detailed set of instructions.<sup>329</sup> According to this ad hoc protocol, created in March of 1958 and adapted from Huggins' earlier study, the nursing procedure for the 3-methylcholanthrene trial was arduous. The drug was in the form of crystals suspended in sesame oil, which required lengthy heating in a water bath in order to render the drug injectable via syringe.<sup>330</sup> R.G. Ravdin, who outlined the administration protocol in a letter to Dr. Charles Hubbard, chair of the VNS medical board suggested that with instruction, patients could prepare the water bath and heat the drug so that it would be ready upon the VNS nurses' arrival.<sup>331</sup> Given the severity of many of the study patient's cancer symptoms and the variability in a visiting nurse's schedule, having patients prepare the drug was not a viable time saving solution. A lidded receptacle for the syringe and needle was to be provided by the patient (the protocol stipulated that the container should never be used for cooking.)<sup>332</sup> Nurses were responsible for cleaning and maintaining the equipment.

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<sup>329</sup> R.G. Ravdin to J. P. Hubbard, March 20, 1958. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3.

<sup>330</sup> R.G. Ravdin to John B. Hubbard, March 20, 1958. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3.

<sup>331</sup> *Ibid.* John P. Hubbard was a professor in the Department of Public Health and Preventative Medicine at the University of Pennsylvania School of Medicine. See John P. Hubbard to Marian E. Shand, January 13, 1958. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3.

<sup>332</sup> R.G. Ravdin to John B. Hubbard, March 20, 1958. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3.

VNS nurses administered 3-methylcholanthrene via an intramuscular injection, typically in one of the large muscles of the patient's buttocks. Injury such as nerve damage was possible if the injection was improperly placed. The high viscosity of a drug suspended in sesame oil required a slow injection and patients from a previous 3-methylcholanthrene study identified the shot as painful.<sup>333</sup> The adverse effects of the drug included nausea, low hemoglobin, low serum protein and painful induration (tissue death) around the injection site. One patient from the Huggins' study had an injection wound that was still "slowly healing" four months after the drug had been discontinued.<sup>334</sup> Though it was standard nursing practice to observe for signs of injury and infection at injection sites and record patient symptoms including nausea during in home visits, the VNS nurses had no guidance on how to ameliorate these adverse effects or parameters on when to contact the NCC for guidance.<sup>335</sup> Not only did this put the patient at risk for ill-effects from the drug trial, it also may have made it more difficult for the nurse to maintain the patient's cooperation with the study.

A 1959 study funded by the American Nurses' Foundation Nurse-Patient Relationship Project found that the safe administration of drugs was a critical aspect of the nurse-patient relationship for both patient and nurse.<sup>336</sup> Patients surveyed for the study strongly emphasized the importance of trusting that a nurse would give them

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<sup>333</sup> Charles Huggins and Jack D. McCarthy, "Regression of Human Metastatic Mammary Cancer Induced by 3-Methylcholanthrene" *Cancer Research* 17, (1957): 1028-1032.

<sup>334</sup> Huggins and McCarthy, "Regression of Human Metastatic Mammary Cancer Induced by 3-Methylcholanthrene", 1028-1032.

<sup>335</sup> Grace Shallowhorn, "Intramuscular injections." *The American journal of nursing* 54, (1954): 438-441.

<sup>336</sup> Whiting, 663.

medication correctly and appropriately.<sup>337</sup> The Nurse-Patient Relationship study highlights the difference between what patients want regarding their care and nurses' goals in providing patient care.<sup>338</sup> For example, patients focused on the need for prompt and appropriate medication for pain while nurses were primarily concerned with safety, reporting their top concern as monitoring patients for drug toxicity or reactions.<sup>339</sup> Patients indicated that nurses' attention to their comfort was the most important aspect of nurses gaining their trust which conflicted with the nurses' focus on providing effective and safe patient care. Administering an unknown, pain-inducing drug such as 3-methylcholanthrene tested the boundaries of trust and cooperation between patient and nurse.

The safety of the patient and nurse during the 3-methylcholanthrene study was also questionable. In a letter to Hubbard describing the procedure, R. G. Ravdin reassures the VNS board chairman of the drug's safety. He goes on, however to list precautions the nurses should take to avoid contact with the 3-methylcholanthrene, such as wearing rubber gloves and disposing of the water bath contents in the toilet.<sup>340</sup> This reflects the newness of anti-cancer drugs such as 3-methylcholanthrene and the uncertainty that surrounded these drugs—were they safe? Were they effective? Did they present undue risks to the patient? Were nurses and other professionals who handled the drug at risk from exposure? The effectiveness and danger of 3-methylcholanthrene and other anti-cancer drugs were suspected but unknown in the late 1950s.

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<sup>337</sup> Whiting, 664.

<sup>338</sup> *Ibid.*

<sup>339</sup> *Ibid.*

<sup>340</sup> *Ibid.*

VNS nurses sought more information on the mysterious drug ordered by the NCC. In a memo to VNS General Director Marion E. Shand, Miss Stine, the nurse superintendent of the West Branch of the VNS presented the concerns raised by the West Branch nurses assigned to NCC patients. Miss Stine writes: “About drugs: we would like more information and direction about Agent M.J. or M.G. 30.”<sup>341</sup> Risk to themselves from the drug as well as to the patient was a top concern of VNS nurses administering the codenamed drug. VNS nurses did not receive information on the expected effects of 3-methylcholanthrene or the adverse reactions or signs of toxicity they should observe for closely during their daily visits. In the same memo requesting information on “MG 30,” Miss Stine relates the concerns of the VNS West Branch nurses regarding codenamed drugs from another clinic, noting “Medication is given to the patient unmarked or marked in code numbers. We have no idea what it is or what reactions to look for.”<sup>342</sup> Despite repeated phone calls from the nurses to the clinic in question requesting more information and more detailed dosage instructions, Stine noted that the VNS nurse would eventually “...wind up giving a medication you do not know.”<sup>343</sup>

Using the VNS to administer 3-methylcholanthrene capitalized on the trust and authority society granted to nurses and relied on the individual nurse’s ability to maintain the patients’ cooperation with the NCC study. Considering the toxic side effects of the drug—nausea, vomiting, fatigue from low hemoglobin, and pain at the injection site, this was no easy task. Receiving the injections also necessitated that the patients be home for

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<sup>341</sup> Stine to Miss Shand, November 15, 1957. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3

<sup>342</sup> *Ibid.*

<sup>343</sup> *Ibid.*



the VNS nurses' visit, a requirement that would have ranged from an inconvenience to a near impossibility depending on the patient's employment status, family responsibilities and physical health. The lack of communication between physician researchers, the nurses actually administering experimental drugs and the patients receiving the medication made the nurses' task of giving the drug and maintaining the patients' cooperation all the more difficult. The nurses' critical role in controlling the experimental protocol, assuring patient participation or compliance and closely observing and recording patient data necessary for good-quality experimental data was taken for granted in the design of the outpatient 3-methylcholanthrene trial. Physicians relied upon the VNS nurses to gain patient's trust, maintain their cooperation and follow the research protocol but gave them little support—information, training, or consultation from the NCC—in accomplishing these research tasks.

The range of the medical board's responses to the idea of VNS nurses administering 3-methylcholanthrene in the home illustrates shifting attitudes about clinical research among physicians during the late 1950s. The medical board was comprised mainly of well-respected physicians in general practice with admitting privileges at major Philadelphia hospitals including HUP.<sup>344</sup> Though some held faculty positions at local medical schools, few of these physicians were personally involved in clinical research.<sup>345</sup> Though patient-oriented research was becoming a more

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<sup>344</sup> Annual Meeting Minutes, November 1, 1957, Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 13, Folder 114.

<sup>345</sup> Paul György, a well-known researcher and discoverer of three vitamins is a notable exception. György was a professor of pediatrics at the University of Pennsylvania School of Medicine and also held

commonplace aspect of clinical practice, many questions remained as trials grew larger and more complex. What defined research? Who should do research work and where should it take place? While the VNS board physicians did consider the role of the nurse in experimentation as they debated the 3-methylcholanthrene procedure, the location of experimentation seemed much more important in their decision to halt the VNS's participation in the study. The lack of direct or indirect supervision by the physicians organizing the research and the physical distance between the patient getting 3-methylcholanthrene and the safety of the clinic seemed to be the key factors in the majority of board member's disapproval of the protocol. Most of the VNS medical board physicians did not question whether or not nurses should be giving experimental or dangerous drugs. They expressed serious doubts whether anyone should be administering investigational drugs without the direct supervision of a physician or outside of the perceived safety of the hospital or clinic. The response cards preserved in the VNS archives indicate that it was not the lack of skill or knowledge on the part of the home care nurses that made the 3-methylcholanthrene study seem inappropriate to the medical advisory board, but rather the physical distance between the patient and the NCC at the moment of drug injection.<sup>346</sup>

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appointments at Children's Hospital of Philadelphia and Philadelphia General Hospital. For the record, voted against the VNS's participation in the 3-methylcholanthrene study, adding an emphatic exclamation point on one of his response cards. Survey Response Cards, 1957-1958, Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3. See also: Paul György, "A hitherto unrecognized biochemical difference between human milk and cow's milk." *Pediatrics* 11, (1953): 98-108.

<sup>346</sup> Survey Response Cards, 1957-1958, Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3.

This is in part a story of risk and liability but also significant is the conceptualization of cancer chemotherapy experimentation as an activity that required all of the resources of HUP to be conducted properly. Those resources included the presence of physicians, nurses, operating rooms, and diagnostic equipment helpful in the case of an adverse drug reaction or other negative outcome to an injection of 3-methylcholanthrene. The VNS medical advisory board members who voted against participating in the 3-methylcholanthrene trial understood the hospital (and perhaps its outpatient clinics) as the only appropriate site for chemotherapy experimentation. Most of the physicians who voted for the VNS's participation, although in the minority, believed that with some specialized education regarding the nature of the drug and its adverse effects, the nurses and the VNS as an organization could safely and effectively administer potentially dangerous, experimental cancer chemotherapy drugs in the home.

The archives related to the 3-methylcholanthrene study record the opinions on research of physicians and administrators involved in the review process but give little insight into the response of VNS nurses to the project. VNS nurses were ordered to administer an unknown drug, labeled Agent M.J. or M.G. 30 without explicit instructions for its use or any information on its possible dangers from the NCC.<sup>347</sup> While there is no record of the specific concerns VNS nurses had about the mysterious drug, some of the nurses expected to perform research work within the 3-methylcholanthrene study were critical of that work, whether it was out of concern for themselves, their cancer patients, or their professional standing. The single memo that records the VNS nurses' request for

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<sup>347</sup> Stine to Miss Shand, November 15, 1957. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3

more information on 3-methylcholanthrene stands as evidence that nurses were not strictly ignorant bystanders or unquestioning underlings following orders when participating in the at times ethically questionable clinical trials of the mid-twentieth century. Nurses had agency and power in their professional lives. The amount of power a nurse could wield was contingent upon the circumstances at hand and typically limited—though not eliminated—by the patriarchal hierarchy of the clinical environment during the 1950s.<sup>348</sup> The VNS nurses' concerns about 3-methylcholanthrene led to the group severing its ties with the NCC study, but the decision to discontinue participation was made by the physicians on the medical board. The nurses' request for more information about the drug was taken seriously by both the board and the NCC physicians. However, the process took months. Superintendent Stine was notified of the problem by memo on November 15, 1957 and R.G. Ravdin provided the requested information on March 20, 1958. The medical advisory board was more concerned about deciding whether or not the VNS should participate in clinical trials than in getting its nurses access to the information they needed to perform safe and effective care. VNS nurses continued to administer 3-methylcholanthrene for four months without the protocol and support from the NCC they requested while the board debated the propriety of hiring its nurses out for research work.<sup>349</sup>

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<sup>348</sup> For more on nurses' negotiating the gender politics of the clinical environment during the 1950s-1960s, see Fairman and Lynaugh, *Critical Care Nursing*, p70-78.

<sup>349</sup> P. Coggins to I.S. Ravdin, August 6, 1958, and "Coggins Report," I.S. Ravdin Papers, University of Pennsylvania Archives, UPT 50 R252, Box 142, Folder 26.

VNS nurses were thinking about their role in medical experimentation and the research enterprise. Nurses did not hold a homogenous set of beliefs or attitudes about research or any other aspect of clinical care, nor did physicians. Other visiting nurse services may have supported research studies during the 1950s. The VNS itself paid nurses through grants from the American Cancer Society to cover the cost of in-home care for cancer patients during the late 1950s through 1960s, some of whom were treated by the R.G. Ravdin and Eisman at HUP.<sup>350</sup> As clinical research became a normative part of medical treatment, especially in the field of cancer, the VNS softened its policy on experimental drugs.<sup>351</sup>

### **Limitations of the zone of control**

In 1957, NCC physicians felt that employing VNS nurses to administer 3-methylcholanthrene to patients in their home created a sufficient level of safety and control both for the purposes of the clinical trial and the requirements of patient safety. Hiring the VNS, which routinely contracted with HUP surgical services to provide post-operative home care was a convenient solution for R.G. Ravdin and Eisman. Using VNS nurses and discharging cancer patients home while still receiving the experimental drug allowed the NCC to outsource the dangers of prescribing 3-methylcholanthrene, sharing the liability of adverse outcomes with the VNS.

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<sup>350</sup> Cashbooks, 1957-1960, Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 28, Folder 22.

<sup>351</sup> The experiment was led by board member Paul György and by January, 1962 only one patient had enrolled. The VNS also altered its policy on experimental or investigational drugs to reflect new FDA requirements implemented that year. Madelyn N. Hall, "District-Branch Memorandum #142, Supplement B-Addendum #1," January 5, 1962. Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 9.

The VNS board physicians, whose interest lay in protecting the reputation of its organization were far more concerned with the safety of the patient and nurses than the success of the NCC's clinical trial. The mission of the VNS, providing free or low-cost nursing care to the poor was financed through private donations and the profits from nursing contracts with insurance companies, hospitals and private patients. Maintaining the reputation of the VNS as a reliable and safe source of nursing care was critical to all aspects of this mission. Even those medical board members who sympathized with the goals of the NCC felt that the reputation of the VNS trumped the need for research into cancer treatment.

According to many of the VNS medical board members, the presence of nurses at the site of experimentation (e.g. the moment the patient received the experimental drug) was not sufficient to ensure the safety of the patient and protect the liability of the VNS. The NCC physicians believed that the VNS nurses, armed with a basic protocol and their knowledge, skills, and authority as nurses were sufficient to impose the necessary level of control for research. The VNS board, whose members were unconcerned with the quality of the research study, instead feared for the safety of the patient (and the liability of the organization). One board member commented, "The value is uncertain and the hazards might prove embarrassing."<sup>352</sup> Many who objected cited the need for such experimentation to take place within the walls of HUP where the physicians leading the research study could take full responsibility for the patient's safety. Another possibility

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<sup>352</sup> Burgess Gordon, Response Card, March-April, 1958, Visiting Nurse Society of Philadelphia Records, MC 5B, The Barbara Bates Center for the Study of the History of Nursing, University of Pennsylvania, Box 15, Folder 3.

was that given the scarcity of 3-methylcholanthrene, the few patients medically eligible to participate in the study, and the general informality of research design in the late 1950s, R.G. Ravdin and Eisman had not given much thought to the possible risks of the drug and the need for tight experimental controls. Cancer patients given the drug faced certain, and typically painful death from their disease despite access to cutting edge treatment at HUP. Giving cancer patients experimental drugs including 3-methylcholanthrene was seen as a last-ditch effort to prolong life or ameliorate their symptoms while gathering data that could help patients in the future rather than an effort to cure the patient's disease.<sup>353</sup> This desperation or fatalism focused early cancer chemotherapy trials on observing the effects of potential drugs rather than treating the patient at hand, a focus that shifted dramatically once drug regimens started to prove effective against cancer.<sup>354</sup> In the meantime, the physicians who treated and studied cancer patients during the 1950s had few tools with which to combat the disease. Excellent nursing care to manage pain, protect skin integrity, and promote adequate rest, diet and fluids was critical to maintaining the comfort of cancer patients both before and after the advent of effective chemotherapy.

With the oncology specialty in its infancy and little infrastructure available to support the treatment of cancer patients, practical problems also impeded cancer chemotherapy trials. One such challenge for the NCC researchers was the “well-ness” of the 3-methylcholanthrene trial patients—while they had been diagnosed with cancer and were undergoing treatment, they were not ill enough to require hospitalization. With

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<sup>353</sup> Pickstone "Contested Cumulations," 183-190.

<sup>354</sup> Keating and Cambrosio, "Cancer on Trial," 55-83.

hospital beds at a premium during the late 1950s, there was no space within HUP for patients well enough to stay home.<sup>355</sup> How then could researchers work with ambulatory or well patients and normal controls? Controlled, dedicated space within hospitals was needed to enable larger research studies with complex methodologies including healthy (or healthier) subjects. Nurses were also needed to control these spaces and the patients (or subjects) within them.

### **Accounting for the real cost of research**

The federal government, NIH, research institutions and private funding bodies sought ways to improve patient-oriented research after the success of the OSRD-CMR. Several solutions were attempted, including the construction of the NIH Clinical Center (NIHCC), opened in 1951 with the sole purpose of providing beds and resources for patient research. The NIHCC could host only a limited number of patients and projects at a time, and thus could not completely solve the problem of space for medical research. Expanding and improving clinical trials in research-oriented hospitals through NIH funding and oversight became a priority in the quest to ramp up medical research across the country in the late 1950s. Increasing the quality and scale of clinical trials was a major concern as the use of normal controls, advanced statistical methods, and exacting study protocols became the norm for legitimate research during the 1960s.<sup>356</sup>

As part of a national push to get medical research to live up to the potential of the World War II burst of new medical knowledge, Congress approved a massive increase in

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<sup>355</sup> Health insurance, though increasingly common at this time would also not have covered the cost of hospitalization for experimental drug testing. See Chapin, *“Ensuring America’s Health.”*

<sup>356</sup> Geiger, “Research and Relevant Knowledge,” 180-182.



funding for the NIH and sweeping legislation to expand and improve clinical research programs across the country. One piece of legislation passed in 1959 authorized funds for the General Clinical Research Center (GCRC) Program, an NIH project that would sponsor and loosely supervise small patient research units in U.S. hospitals.<sup>357</sup> The idea of a specialized research unit was not new or unique. For example, a metabolic ward opened at Bellevue Hospital in New York City in 1913. Similar units with dedicated research beds existed at a select number of elite, research-oriented hospitals including Johns Hopkins and Massachusetts General Hospital.<sup>358</sup> However, funding and space for such units was very difficult to secure. Physician researchers, even in elite hospitals such as HUP had difficulty running research projects given the limited resources available to them, as demonstrated by the failure of the 3-methylcholanthrene trial in 1958. The idea of GCRCs was to replicate the NIHCC on a smaller scale. The program provided funding for staff, hospitalization overhead, administrative support, and scientific and medical oversight. Hospitals could construct or renovate physical lab and patient care space to create NIHCC satellites across the country. The overarching goal of the program was to solve the problems researchers outside of the NIHCC faced when attempting clinical trials—money for hospitalization and patient care overhead, support (and supervision) through an advisory committee of researchers at their institution, supplies, equipment and staff—most notably a permanent staff of nurses to enforce protocols, provide excellent

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<sup>357</sup> National Advisory Health Council, Committee on Clinical Research Centers, Minutes of Meeting, November 18, 1959. NARA II, RG 443, National Institutes of Health Committee on Clinical Research Centers, Records of Meetings, 1959-1931, General Clinical Research Centers Committee, Records of Meetings, 1959-1961, Box 1.

<sup>358</sup> Edward H. Ahrens Jr., *The Crisis in Clinical Research: Overcoming Institutional Obstacles*. New York, (Oxford: Oxford University Press, 1992), 130.

patient care, and ensure the collection of good data. Nurses' skill in enforcing research protocols and assuring patient compliance were built into the GCRCs, where researchers capitalized on the authority of nurses to accomplish their research studies during the 1960s.

### **Development of the HUP Clinical Research Center 1959-1962**

Institutions awarded GCRC grants used them to create a variety of small research centers within their hospitals including pediatric, adult, and maternal-infant centers, some organized to broadly support patient research, like that at HUP, and others designed around a specific disease or program of research. HUP was one of the first eight sites awarded a GCRC grant. I.S. Ravdin, Samuel Guerin, Dean of the School of Medicine and Robert Dripps, a prominent anesthesiologist who was the original director of the HUP Clinical Research Center (HUPCRC) organized the grant application.<sup>359</sup> Approval and funding arrived quickly, and the HUPCRC Advisory Committee, which included Ravdin and Jonathan Rhoads, worked to define a purpose for the center as they sought out space within the hospital, designed laboratories and hired staff.<sup>360</sup> Though the committee determined that the HUPCRC should support a wide range of clinical research projects, the center was largely designed around the hospital's growing kidney dialysis program.<sup>361</sup>

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<sup>359</sup> Grant Application, General Clinical Research Center Program, OG-16, Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 1, Folder "Clinical Research Center, 60-61."

<sup>360</sup> Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder "Clinical Research Center, 60-61."

<sup>361</sup> Minutes of the Clinical Research Advisory Committee, February 24, 1961. Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder "Clinical Research Center, 60-61."

In fact, the young researcher leading the dialysis program, physician Lewis “Bill” Bluemle was selected to replace Dripps as director of the HUPCRC during the planning stages of the project, when Dripps decided to focus on his own research and the growing anesthesia program at HUP.<sup>362</sup> While much of the designated lab space within the HUPCRC housed researchers and technicians building and maintaining dialysis machines, the 10 private and semi-private patient beds, state of the art kitchen and other available spaces allowed the unit to host research from across the hospital. Patients enrolled in cancer chemotherapy trials through the NCC were treated in the center during the early 1960s as were pediatric patients with urinary disorders, schizophrenic patients receiving new psychiatric drugs, and a pregnant woman undergoing immunotherapy to prevent early labor.<sup>363</sup> Physician researchers were able to apply new therapies such as kidney dialysis and perform diagnostic tests on patients housed at the HUPCRC much more quickly and efficiently due to the proximity of the center’s labs to the bedside and the lack of red tape to order and execute tests. The NIH grant covered the cost of these laboratory tests and other aspects of patient hospitalization, considerably lessening the financial burden clinical research placed on the hospital. The patient care available at the HUPCRC was also excellent, allowing very sick research patients to survive experimental treatments. The center was staffed by its own nurses. These women

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<sup>362</sup> Robert D. Dripps to I. S. Ravdin, November 17, 1960, Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder “Clinical Research Center, 60-61.”

<sup>363</sup> See Minutes of the Clinical Research Advisory Committee, 1960-1961. Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder “Clinical Research Center, 60-61.” Lewis “Bill” Bluemle, Interviewed by Amanda L. Mahoney, September 16, 2013.

developed and ran a complex system of patient care and clinical research at the HUPCRC, creating an ideal socio-technical system for research within HUP's walls.

### **HUPCRC Head Nurse Cordelia Shute**

The nursing staff of the HUPCRC was led by head nurse Cordelia Shute, a 1940 HUP graduate who was noted as “the only choice” for the position by Bluemle.<sup>364</sup> Shute was smart, well-organized and detail-oriented, an experienced manager with an excellent reputation among nurses, physicians and administrators at the hospital.<sup>365</sup> As a veteran of both HUP and World War II, she had the respect and trust of the powerful physician leadership at the hospital.

Shute received a Bronze Star for her work as head nurse of the Scrub Typhus Ward at the 20th General Hospital, a U.S. Army unit stationed in Assam, India during World War II. The 20<sup>th</sup> was staffed largely by HUP nurses and physicians and commanded by Ravdin. Scrub typhus, an infectious disease which can cause cerebral complications, high fevers and death led to many lost man hours in the China Burma India (CBI) and Pacific theaters of World War II. Patients with scrub typhus needed skilled nursing care to survive as they were highly unstable, requiring close monitoring of

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<sup>364</sup> Lewis “Bill” Bluemle, Interviewed by Amanda L. Mahoney, October 10, 2013. Lee Henderson, Interviewed by Amanda L. Mahoney, October 11, 2013. Clyde Barker, Interviewed by Amanda L. Mahoney, November 26, 2013.

<sup>365</sup> Lewis “Bill” Bluemle, Interviewed by Amanda L. Mahoney, October 10, 2013. Lee Henderson, Interviewed by Amanda L. Mahoney, September 16, 2013. Lee Henderson, Interviewed by Amanda L. Mahoney, October 11, 2013. Clyde Barker, Interviewed by Amanda L. Mahoney, November 26, 2013.

temperature and fluid status, frequent IV fluid administration, blood draws for serum tests and quick intervention for mental distress. Physicians on the ward, led by Thomas Magella conducted research on scrub typhus as the disease had few established treatments and was causing serious manpower problems in the under-deployed CBI theater. Shute and the nurses under her supervision not only provided the complex nursing care necessary to treat scrub typhus, they also enforced drug protocols, performed specimen collection and collected observational data with inadequate medical supplies and scant staffing.<sup>366</sup>

After the hospital disbanded in 1945, Shute served out the remainder of her military service at the Valley Forge General Hospital, a U.S. Army hospital in Valley Forge, Pennsylvania. Shute was head nurse of the neurological-dermatological unit.<sup>367</sup> Significant research into plastic surgery and adaptation to blindness and disability by wounded servicemen was conducted on this ward in the closing months of World War II and into the early 1950s. Though Shute is not acknowledged in any research publications based on research from the Valley Forge General Hospital, she further forged her reputation as a nurse who understood the needs of clinical research project and was experienced in balancing complex patient care with the requirements of clinical trials during this time. Shute's professional experience and interpersonal relationships with

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<sup>366</sup> Shute, Magella and the staff of the Scrub Typhus Ward at the 20th General Hospital were recognized for their work by Ravdin, the unit commander, the U.S. Army, and many official visitors to the hospital. See: I.S. Ravdin to The Surgeon General, Report of the 20<sup>th</sup> General Hospital, 3 April 1943-1 August 1945, U.S. Army 20th General Hospital Records, 1932-1952, University of Pennsylvania Archives, UPC 15.

<sup>367</sup> Grant Application, General Clinical Research Center Program, OG-16, Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 1, Folder "Clinical Research Center, 60-61."

administrators including Ravdin, Bluemle and Guerin made her the ideal candidate for head nurse of the HUPCRC.

As head nurse of the HUPCRC, Shute was in a powerful position over patients, nurses, technicians, and in some instances physicians. Shute was not an official member of the HUPCRC Advisory Committee, though she was present for all meetings. She routinely advised committee members on practical matters of patient care and bedside research as they considered applications from physicians wishing to house research patients on the unit.<sup>368</sup> Once a project was approved by the committee, Shute served as the gatekeeper for admitting new patients into the unit—researchers were required to telephone the head nurse when a patient for their study became available. Shute had the power to refuse the admission if she felt the HUPCRC could not meet their patient care needs.<sup>369</sup> Noted transplant surgeon Clyde Barker recalled that he was not able to admit a new kidney transplant patient without Shute’s approval, though he noted that she worked hard to accommodate admission requests when the HUPCRC was at high capacity.<sup>370</sup>

Between 1960 and 1962 the HUPCRC operated as a pilot unit in temporary quarters while its permanent location was being renovated with NIH funds. Nurses on the unit maintained a “mistake book,” described as a “running record of errors made in

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<sup>368</sup> Minutes of the Clinical Research Advisory Committee, 1960-1961. Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder “Clinical Research Center, 60-61, and See Minutes of the Clinical Research Advisory Committee, 1960-1961. Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 4, Folder “Clinical Research Center, 61-62.

<sup>369</sup> Ground Rules, General Clinical Research Center, Hospital of the University of Pennsylvania, ca. December, 1960. Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder “Clinical Research Center, 60-61

<sup>370</sup> Clyde Barker, Interviewed by Amanda L. Mahoney, November 26, 2013.

research and administration on the temporary unit.”<sup>371</sup> Such a record aided Shute and HUPCRC administrators as they tinkered with the STS of the evolving unit. Director Bill Bluemle noted that the HUP staff nurses who rotated from other wards to work on the temporary clinical research unit did not have the experience or scientific inclination to guarantee proper specimen collection and enforce and follow protocols despite being good clinicians.<sup>372</sup>

And we could never feel reliant on the collection of urine, particularly. Something would always go wrong. And we would get information that did not hold together in terms of balance. And we realize that we could not do it unless we had nurses who were particularly trained in that sort of care. Because it was not just a matter of preventing infection with a catheter, particularly. It was a matter of paying a great deal of attention to the intake and the output.<sup>373</sup>

The collection of accurate urine samples, a seemingly simple, routine nursing task became critically important in the context of clinical research. Given the mundane, unscientific value the medical world placed on nursing work, little attention was paid to tasks within the nursing purview despite their importance to successful clinical trials. Nurses were trusted with developing systems to ensure accurate collection of specimens and other data. Research, especially metabolic studies required a different type of nursing. Shute created a place where researchers could feel “reliant” on the data collected

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<sup>371</sup> Minutes of the Clinical Research Advisory Committee, February 29, 1961, Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder “Clinical Research Center, 60-61.

<sup>372</sup> Lewis “Bill” Bluemle, Interviewed by Amanda L. Mahoney, October 10, 2013. It is worth noting that most of these problems occurred on the temporary research unit piloted before the brick and mortar HUPCRC opened on the 6<sup>th</sup> floor of the Maloney Building in 1962 so the logistics of performing lab tests—collection, sending the sample to the lab and analysis may have been more complicated.

<sup>373</sup> Lewis “Bill” Bluemle, Interviewed by Amanda L. Mahoney, October 10, 2013.

by the dedicated staff nurses of the unit.<sup>374</sup> Bluemle, who considered Shute a partner in research, described her as "...a flywheel on the machine of care, keeping the whole thing going in the right direction."<sup>375</sup> The HUPCRC solved many of the problems earlier researchers at HUP faced when attempting patient research with inpatients: lost specimens, missing data, gaps in the protocol, and insufficient observation. In fact, for decades, Shute was able to solve problems that baffled physician researchers. For example, when a patient admitted to the HUPCRC showed no signs of progesterone or other pregnancy hormones in repeated urine samples despite other signs of a viable fetus, her obstetrician attributed the unusual result to an abnormal pregnancy while other physicians treating the patient searched for another explanation.<sup>376</sup> Shute determined that the disinfectant used to sterilize glassware in the lab caused progesterone and other hormones to break down into other compounds, rendering them undetectable using standard tests.

Shute, Bluemle and the HUPCRC Advisory Committee also secured additional power and autonomy for the center's staff nurses, removing them from the hierarchy of the hospital and putting them solely under Shute's authority.<sup>377</sup> This freed HUPCRC

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<sup>374</sup> Though Shute may have attended a training session with Donald Whedon at the NIHCC metabolic lab, there is no evidence that she or any other HUPCRC nurse employed during the early 1960s received any specialized research education. Shute's experience with medical research during her military service, her professional reputation at HUP and her capacity to understand the scientific principles behind research were her qualifications. Minutes of the Clinical Research Advisory Committee, January 27 1961, Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder "Clinical Research Center, 60-61.

<sup>375</sup> Lewis "Bill" Bluemle, Interviewed by Amanda L. Mahoney, October 10, 2013.

<sup>376</sup> Lewis "Bill" Bluemle, Interviewed by Amanda L. Mahoney, September 16, 2013

<sup>377</sup> Minutes of the Clinical Research Advisory Committee, February 14, 1961, Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder "Clinical Research Center, 60-61.



nurses from having to report to nursing shift supervisors and getting “floated” to work on understaffed units according to the hospital’s financial interests. Steps were taken to keep the HUPCRC’s autonomy from upsetting HUP’s ecosystem, however. While it’s unclear how nursing salaries and scheduling in the center compared to those at HUP in general, center nurses received the same number of sick days and vacations days as other staff nurses. Shute approved, raises, promotions, and vacation time instead of HUP nursing administrators, who made all personnel decisions within the HUP nursing service.<sup>378</sup> The hiring of new nurses was differentially negotiated with the hospital superintendent and the director of nursing. By 1962, all seven HUPCRC nurses were paid out of the NIH grant.<sup>379</sup> Their semi-autonomous position within the HUP system encouraged HUPCRC nurses to maintain the priorities of the center and the research project at hand rather than serve the interests of the hospital or the department of nursing. With nurses at its organizational and operational core, the physical space of the HUPCRC was designed around nurses’ critical role in research. The central role of nurses at the HUPCRC is reflected in its floor plan (see figure).

### **The Built Environment of the Zone of Control**

The HUPCRC was arranged to bring research laboratories closer to the bedside, locating labs and space for experimental machines, such as Bluemle’s dialyzer near patient beds. The clinical care area was designed to maximize the visibility of patients

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<sup>378</sup> *Ibid.*

<sup>379</sup> Lewis W. Bluemle, Jr. to Sam Silbergeld, December 11, 1961, Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder “Clinical Research Center, 60-61.

and their activities. The nurses' station was positioned to allow a view of all rooms. All visitors, including physicians, must pass by the station in order to enter the clinical care area.<sup>380</sup> Nurses could both literally block physicians from admitting patients to the unit and impede anyone from entering patient rooms. Notably, the physician and technician run laboratories, located on the east side of the floor were not visible from the patient care areas. Patient surveillance was important to the physicians running studies on the unit as well as those administering the center. When a member of the advisory board suggested that a portion of the east section be converted into space for more patient beds, the director and board members protested, stating that this area was out of view of the nurses' station.<sup>381</sup>

The nurses' station within the HUPCRC was positioned to maximize the ability of nurses to observe patient rooms and monitor activities in the clinical section of the unit (see figure). Nurses seated at the station were almost entirely obscured by a tall desk, but could easily see the doorways of patient rooms and view anyone entering the clinical corridor from the labs or central elevator.<sup>382</sup> The administrative area of the clinical wing, the nurses' station, doctors' alcove, drug room and staff restrooms were designed to obscure the activities of the clinical staff from patients and visitors. The doctors' desk is placed to keep the physicians' work out of view but also prevents the physician from

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<sup>380</sup> The HUPCRC arguably fit into Foucault's concept of the panopticon, where prisoners were controlled by the gaze of an unseen, central watchman. Michel Foucault, *Discipline and Punish: The Birth of the Prison*. (New York: Vintage Books, 1995): 261.

<sup>381</sup> Stephen Timmons, "A failed panopticon: surveillance of nursing practice via new technology." *New Technology, Work and Employment* 18, (2003): 143-153.

<sup>382</sup> Brochure, Hospital of the University of Pennsylvania Clinical Research Center, c. 1962. Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 4, Folder "Clinical Research Center, 61-62.

seeing out into the unit. Surveillance of the clinical corridor was the responsibility of the nurse.

Note also the division of space between the patient care area, the realm of the nurses and the laboratories, the physician researcher domain on the south side of the floor plan. Double doors marked the entry to the clinical area but the other hallways were open. The rooms on the west end of the building were transitional spaces between laboratory and patient room, bench research and clinical experimentation, doctor and nurse. Study rooms A and B served sometimes as treatment areas for patients (such as those on dialysis) and other times housed researchers and laboratory equipment. The specially designed diet kitchen, dietician workroom and specimen room, more directly related to patient care and treatment were placed close to the patient care wing. The director's office was located at the intersection between the laboratory hallway and that leading to the patient care area. The clinical wing was built around the nurses' gaze, maximizing the ability of nurses to control patients through monitoring. The HUPCRC laboratories were outside of the nurses' panoptic vision—the laboratory work of physicians and technicians was not part of their domain.<sup>383</sup>

Patients also had spaces under the observation of nurses but not consistently monitored, such as a recreational lounge. Access to the lounge and hallway patient bathroom probably varied between patients and the research study at hand. Was the lounge locked? Was the East stairwell unlocked, allowing patients access to the rest of

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<sup>383</sup> How exactly the built environment of the HUPCRC influenced the patient experience, the success of research studies, and the ability of nurses to maintain study protocols would be enriched by oral histories from nurses and patients, unavailable at the time of this writing.

the hospital?<sup>384</sup> The presence of the watchful nurse would have been a level of control of its own, influencing patients to behave as though they were constantly being observed.

The presence of the nurse also added an element of legitimacy, safety and the clinical to the activities of the HUPCRC.<sup>385</sup> Promotional materials created for the center's opening ceremony use nurses as a selling point for the safety and legitimacy of studies conducted on the unit. The aura of safety and legitimacy created by the presence of nurses at the HUPCRC would reassure both ill patients and healthy, volunteer control cases. There is no record of any studies involving healthy volunteers at the center during the early 1960s, but anecdotal evidence suggests the presence of "normal" patients around 1970.<sup>386</sup>

Further study of trials involving normal subjects at the HUPCRC will answer important questions about the role of nursing in medical research and the ethical challenges of clinical trials. Is surveillance of a healthy volunteer in fact different from sick patients being observed for stability and safety? Nurses enforcing protocols make the setting seem clinical rather than disciplinary. What role did gender (female nurse, male patient) play in the power dynamic between protocol enforcer (nurse) and subject? How did this dynamic shift with female patients, and pediatric patients? Female physicians became prominent in HUPCRC research during the 1970s—how did this change the dynamic between nurse, researcher and subject?

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<sup>384</sup> Nurses controlled day passes for normal volunteers who participated in inpatient studies at NIHCC. Stark, *Behind closed doors*, 127.

<sup>385</sup> The image of nurses has been used by advertisers to add a sense of safety, legitimacy, and clinical-ness to consumer products since at least the 19<sup>th</sup> century. See Beatrice J. Kalisch, Suzanne Begeny, and Sue Neumann. "The image of the nurse on the internet." *Nursing Outlook* 55, no. 4 (2007): 182-188.

<sup>386</sup> Dudrick, "History of parenteral nutrition."

The changes brought about by FDA and NIH regulations in the mid-1960s and the research scandals of the 1970s and 1980s played out in the conference rooms and laboratories of the HUPCRC, which continued to play a significant role in research at HUP through the 1990s. The rise of insurance coverage for lab tests and a gradual shift towards standardized medical and nursing practices in elite hospitals rendered the HUPCRC and similar units unnecessary for most medical research, which became widely accepted as a routine part of hospital practice. The unit is still active today as part of the Institute for Translational Medicine and Therapeutics (ITMAT). Formal structures for the regulation of research such as the 1962 FDA requirement for signed consent for experimental drugs and the surgeon general's 1966 requirement for informed consent for NIH funded research also exerted external controls over medical research that created IRBs and eliminated the need for the CRC advisory committee etc.

## **Conclusion**

The two examples discussed in this chapter illustrate the important role socio-technical systems to support medical research played in the success and failure of clinical research during the 1950s and early 1960s. Also demonstrated was the integral role nurses played in both systems. The 1957 NCC trial of the promising anti-cancer drug 3-methylcholanthrene failed because the VNS would not take on the risk of administering an experimental drug to patients in the home. The refusal of the VNS medical board to adapt the organization's policies to the needs of the study illustrates the need for controlled research space within the hospitals of the late 1950s and early 1960s.

The hospital or clinic was the only acceptable place for clinical research in the minds of many physicians and administrators despite the increasingly routine presence of clinical research. The NIH sought to meet the need for clinical research space through the GCRC program, launched in the late 1950s. The development of the HUPCRC, funded through the GCRC program required the creation of a new STS within HUP, a nurse-run unit with the power and autonomy to serve the interests of NIH-funded research without the limitations of ward nursing and the rigid hierarchy of the hospital.

## **Chapter 5—“...a flywheel on the machine of care, keeping the whole thing going in the right direction,” The evolving role of nurses in medical research**

The success of U.S. medical research between the 1930s and the 1960s required the development of an intricate socio-technical system within hospitals in order to support the growing complexity of clinical experimentation. Examining the history of clinical research using the framework of the socio-technical system highlights important factors in the success and failure of research projects overlooked when scholars focus on principle investigators. The preceding microhistories of several clinical research projects at HUP demonstrate how nurses were a particularly important factor in the success (and sometimes failure) of such endeavors. Their ability to gain patient trust and cooperation, run the technology necessary for research and patient care, collect data, and enforce research controls were crucial to the day to day activities of research. Nurses and their many functions were just one component of the complex STS necessary for medical research projects to function. As I've demonstrated, success also depended upon funding, infrastructure, and other personnel such as laboratory technicians.

Furthermore, broadening the definition of research work to include actors beyond principle investigators reveals the complex challenges of getting clinical research done in U.S. hospitals during the mid-20<sup>th</sup> century. The success of clinical trials relied not just on the validity of a scientific hypothesis but also on the quality of the data collected—the ability of workers to implement research protocols and precisely collect patient specimens and data. As researchers, hospital administrators and funding agencies developed systems to organize medical research, the ability of nurses to both provide expert patient care and implement research controls was incorporated into the design of

research projects and specialized clinical research units. Nurses at the bedside played an especially important role in data collection and control of the patient and clinical environment. In order to get high quality data, the architects of clinical trials, the NIH, hospitals and universities needed to invest in the STS, ensuring the presence of knowledgeable, skilled nurses and technicians, good patient care and laboratory facilities and a controllable research environment. This shifts our priorities away from ideas in research, though sound hypotheses are vitally important towards the mundane; how studies were staffed and organized, how data was collected, and how well-controlled was the environment. Such seemingly simple decisions such as how nurses will be paid for work on a research study were critical factors in the success and failure of research during the mid-20<sup>th</sup> century. Even with our current sophisticated STS for clinical research, the mundane can make or break a clinical trial; for example in March of 2015 the FDA forced the pharmaceutical company Orexigen to halt its study of its anti-obesity drug Contrave after learning the company had accidentally released preliminary findings to over 100 people.<sup>387</sup> Orexigen was forced to launch a completely new trial not because the drug was ineffective or harmful, but because the company's STS could not keep a patent application confidential.<sup>388</sup> Even today the development of a promising drug can be derailed by a clerical error.

The clinical environment of HUP was a limiting factor in the research studies of the 1930s. The existing system of ward nursing, where nursing students provided the bulk

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<sup>387</sup> Lisa Beilfuss, "Orexigen Terminates Required Study for Diet Drug Contrave," *Wall Street Journal*, May 12, 2015. Accessed December 23, 2015: <http://www.wsj.com/articles/orexigen-terminates-required-study-for-diet-drug-contrave-1431443914>

<sup>388</sup> *Ibid.*



of nursing labor under the often loose supervision of a graduate nurse was not ideal for clinical research. The hypoproteinemia research patients discussed in Chapter 2 were typically very ill and hemodynamically unstable, requiring extra nursing care and close observation. Patient care, including the collection of patient data such as heart rate and specimens including urine were organized by task rather than patient, leading to missing data and lost samples on the busy wards. Physician researchers focused on the complexity of their research questions and experimental design rather than simple, every day but critical practices such as urine collection. In situations where nurses had the autonomy to create or adapt systems to accommodate the work of research such as the HUPCRC, problems including lost urine samples were less common and easier to solve.

Administrators such as Bill Bluemle did not have to worry about the day to day issues of running research studies with Cordelia Shute at the unit's helm. The ward system of nursing care could not consistently absorb the extra work created by research studies, especially those involving very sick patients during the 1940s.

As the cases show, despite the limitations of ward nursing, nurses at HUP and other academic hospitals performed the bulk of research work—data collection, patient management, and enforcement of controls—during the mid-twentieth century. This kind of work, though critical, was not recognized as research work for a few reasons. First, many research tasks—collecting urine samples, administering carefully measured diets and medications, and closely observing patients—fell well into the purview of typical nursing work. Physicians and research administrators, who did not perform such tasks often considered nursing work simple and unskilled. Second, nursing work was

understood as task-oriented, not knowledge work such as developing scientific hypotheses and designing research protocols. Beliefs about who can and should perform research or scientific work were deeply gendered during the 1930s. As women working in a traditionally female profession, nurses were not considered knowledge workers according to the values of most physician colleagues and administrators.

While much of the nursing work surrounding hypoproteinemia research patients at HUP during the 1930s did not fit the definition of knowledge work as understood by scientists at the time, some nurses did engage in work that fits into this category. One example is the development of trays for bedside nursing what did it replace and medical procedures that standardized and streamlined both the procedure itself and the preparation of necessary equipment. Developing procedure trays required nurses to engage in knowledge work: brainstorming, analyzing data to understand relationships, create a new strategy for accomplishing a task, evaluate the conflicting priorities of patient care, etc. Nurses used their social skills, technical knowledge and organizational talents to integrate research into the STS of the hospital. Given the limited autonomy afforded to nurses and their heavy workload on the ward, time and professional space to perform such knowledge work was limited even for graduate nurses and supervisors. Nurses developed systems to organize data collection, gain patient trust and maintain patient cooperation with little support from researchers.

When World War II made funding for clinical research available via the OSRD-CMR, researchers were able to hire dedicated nurses to “special” research patients, assigning nurses to the complete care of one or a few subjects. Research nurses at work

on metabolic studies at HUP during the 1940s had more autonomy than the typical ward nurse. Paid directly through research funds, the nurses described in Chapter 3 were able to organize their own work and prioritize their tasks in the interest of the research study rather than the hospital's interest.<sup>389</sup> This method allowed nurses to collect patient specimens, study data and enforce research controls without the demands of ward nursing. Thus more ambitious, experimentally and clinically complex experiments were attempted with great success under the OSRD-CMR.

Patient care also became more consistent, an important factor in OSRD-CMR projects involving very sick patients. For example, when special nurses were temporarily not available to maintain an experimental, high-protein diet in burn victims from Boston's Coconut Grove fire, the result was a clinical decline for patients as well as missing experimental data for OSRD-CMR researchers. The ability of nurses to gain patient cooperation with research protocols, special diets, metabolic tests, and close observation became more significant as clinical research became more complicated and less therapeutic. Nurses at work on metabolic studies in HUP convinced patients to participate in exercise tests, requiring the patients to exert themselves while wearing a heavy, tight-fitting rubber mask. Nurses at HUP, Massachusetts General, and Bellevue Hospitals coaxed patients into consuming experimental diets, which were often unappealing and limited in calories and nutrients.

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<sup>389</sup> The reputation of the hospital was important to nurses however especially those who graduated from the affiliated training school. Future research may uncover how HUP nurses responded when faced with research activities they felt would besmirch the institution.

Research had become an integrated aspect of patient care, medical practice and medical education in teaching hospitals by the 1950s and 1960s. Universities needed to attract funding from the NIH in order to expand their educational and clinical facilities and remain competitive. The nursing reputation of research hospitals including HUP was a factor in attracting research funding during this important era of growth in clinical research.<sup>390</sup>

Researchers capitalized on the ability of nurses to control patients and enforce research controls as clinical trials became larger and more intricate. Nurses at times served as a proxy for the clinic, adding an aura of safety, legitimacy and clinical-ness to research projects. Opinion on where and how research should take place differed amongst physicians. The propriety of using nurses in research and their ability to promote safe patient care and maintain research protocols, however, was seldom questioned. The case of a Neoplastic Chemotherapy Clinic (NCC) drug study based at HUP exemplifies these trends. HUP researchers designed the study to use visiting nurses to administer an experimental anti-cancer drug daily to patients at home, believing that the presence of the nurse, armed with a research protocol was sufficient to ensure the safety of the patient and the validity of the experimental data. Nurses from the Visiting Nurses' Association of Philadelphia (VNA) were hired for the study using NIH funds. When VNA nurses requested more information about the experimental drug, the organization's medical board reviewed the study. Most of the physicians on the VNA board were of the opinion

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<sup>390</sup> For example, see NARA II RG 443 National Institutes of Health, Committee on Clinical Research Centers, Records of Meetings, 1959-1961, General Clinical Research Centers Committee, Records of Meetings, 1962-65, Box 1. Meeting Minutes, June 8-9, 1962, October 18-19, 1962, February 13-14, 1963.

that experimentation with new drugs should take place within the hospital and voted to discontinue the project. Few board members were concerned with the safety of the nurses themselves and none questioned their competence to adhere to the protocol.

The NIH developed funding programs to encourage hospitals to host research studies, changing their policy to better cover the overhead costs of clinical research, creating training grants for new researchers, and initiating institutional grants for universities. The overhead costs of clinical research, especially hospitalization was a significant burden to hospitals. In 1959 the NIH initiated the general clinical research program, which provided funds to create dedicated research units within hospitals. Not only did this program help offset the cost of research for individual institutions, centers including that at HUP (the HUPCRC) created a controlled space for inpatient studies. The HUPCRC was designed to maximize the ability of the nurse to control patient behavior through near-constant observation. Researchers during the 1960s, including those who used the HUPCRC banked on the trust placed in nurses by society to maintain the compliance and cooperation of research patients. Nurses added an element of legitimacy, propriety, clinical-ness and safety to the HUPCRC and other research-based sites.

### **Remaining Questions**

The data presented in this dissertation poses additional questions about the history of nurses and medical research. For example, what was the role of nurses in clinical trials that employed normal volunteers? Were the elements of surveillance and control somehow different when the patients were well rather than critically ill? A study of the

NIHCC, which hosted an extensive normal volunteer research program as well as many landmark clinical trials using ill patients would illuminate any such differences.

The HUPCRC was one of eight units created with the first round of NIH general clinical research center grant. Was its panoptic design unique or typical for research units? How were other CRCs staffed and structured? Were there differences between the design and operation of adult and pediatric units? Did nurses play a central role in other research centers? Continuing the study of the HUPCRC into the 1960s and 1970s could also illuminate how the rise of female physician researchers during these decades shaded the formerly bright line between male researcher and female nurse. The arrival of advanced practice nurses during this time period further blurred the role of researcher, clinician, and nurse.

As my data shows, nurses had power and agency in their professional lives. Recasting nurses as significant actors rather than powerless underlings in the history of medical research places scrutiny on the actions of nurses working in medical research between 1930 and 1962. Though history has overlooked the complicity of nurses in the darker aspects of clinical research, nurses actively participated in ethically deplorable research projects including the various USPS syphilis studies.<sup>391</sup> As modern nurses conceptualize themselves as patient advocates, there is work to do in reconciling the actual history of nurses in medical research with a narrative of nurses as innocent,

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<sup>391</sup> David J. Rothman "Were Tuskegee & Willowbrook' studies in nature'?" *Hastings Center Report* (1982): 5-7. Nurse Eunice Rivers, who was employed by the USPHS as a recruiter and healthcare provider in the Tuskegee, Alabama syphilis study is an exception. Susan Reverby. "Rethinking the Tuskegee syphilis study: Nurse Rivers, silence, and the meaning of treatment." *Tuskegee's truths: Rethinking the Tuskegee syphilis study* (University of North Carolina Press, 2000): 365-85.

unthinking or ignorant bystanders to the crimes of physicians. If we are to share credit for the groundbreaking clinical trials of the mid-20<sup>th</sup> century, so too must we share the blame for the harm they caused.

Finally, nurses at work in the clinical research projects of the mid-twentieth century had some agency over their own work and at times wielded considerable power over research subjects. Why then, have historians not held nurses accountable for the many unethical medical experiments that took place between the 1930s and 1980s?<sup>392</sup> It's possible that in some controversial studies, such as those held within prisons, nurses were left out of the study by design. I've established that nurses played an active and critical role in medical research during the mid-20<sup>th</sup> century. In some cases, including the 3-methylcholanthrene trial, nurses questioned the tasks they were asked to perform under the aegis of research. What was their motivation? How did nurses during this era understand their relationship with research patients and their responsibility to protect them from harm? Armed with the knowledge that nurses were more than unthinking automatons working in the background of clinical trials, historians can explore how nurses faced the ethical challenges and moral quandaries presented by clinical trials.

### **Concluding Thoughts**

This dissertation presents the history of nurses in medical research between 1930 and 1962 in the form of a microhistory of several research projects at a single institution, the Hospital of the University of Pennsylvania (HUP). The path from small-scale research on busy wards to large, complex clinical trials held in the controlled

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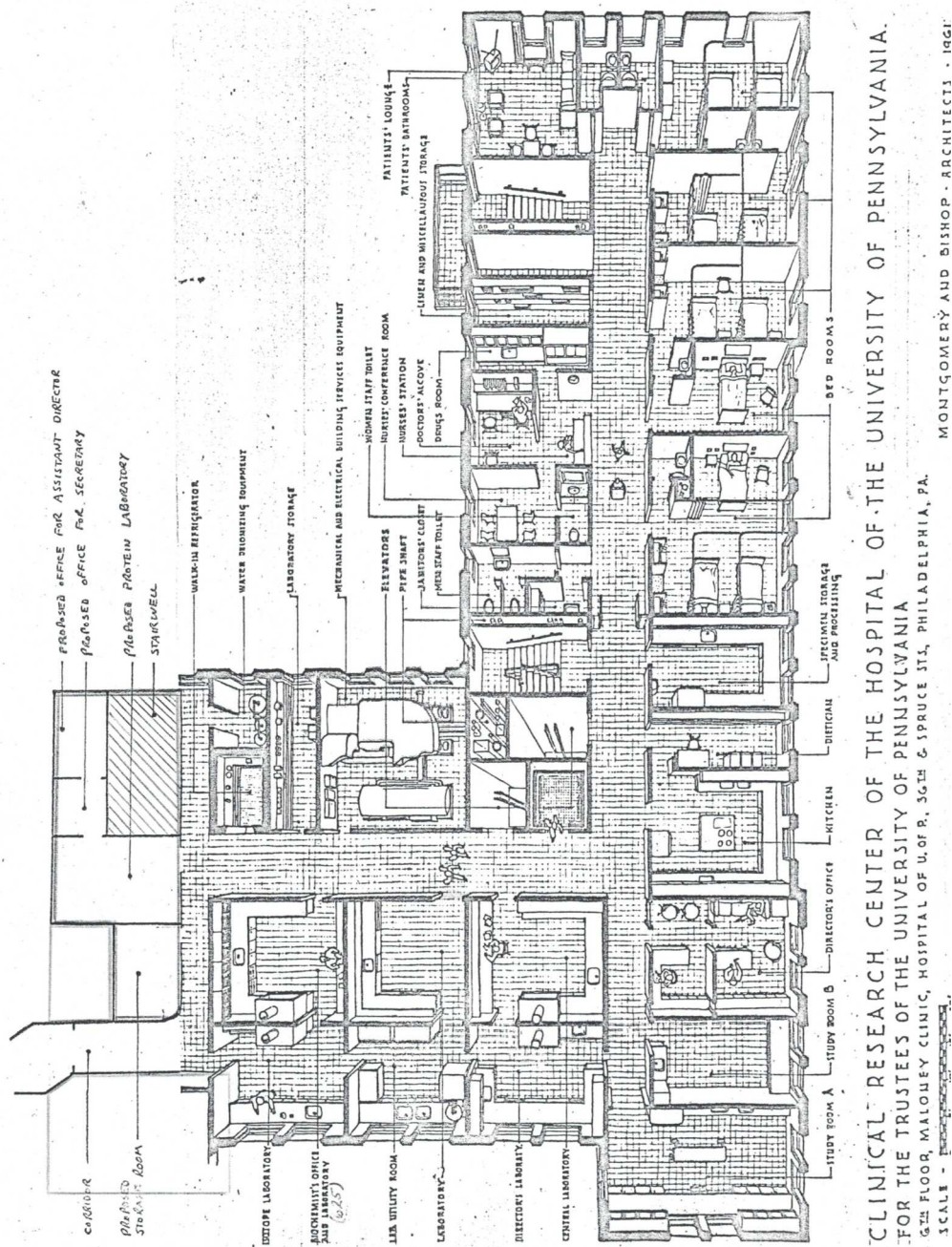
<sup>392</sup> Eunice Rivers, a nurse employed by the USPHS Syphilis Study (commonly known as the Tuskegee Study) is one notable exception.

environment of the HUPCRC was idiosyncratic. Nurses through their work at the bedside and their control patients made medical research possible during the mid-20<sup>th</sup> century and shaped the existing socio-technical system of medical research so prevalent in our healthcare system today.

This study creates a paradigm shift in the history of medical research: it required far more than good ideas. Clinical research relied upon the day to day work of professionals who are rarely acknowledged by historians. The discussion presented here broadens our understanding of how research was conducted and identifies many essential, though mundane elements necessary for success. Clinical trials require a well-functioning, organized group of collaborators to function and acquire the carefully-controlled data that advances medical science. During the mid-twentieth century nurses were key members of the research community at HUP and similar institutions. Nurses continue to play a pivotal role in the team-oriented clinical and research environments of the present.



# Floorplan of the Clinical Research Center, Hospital of the University of Pennsylvania c.1962



Medical Affairs, Vice President for Medical Affairs Records, University of Pennsylvania Archives, UPC 1, Box 2, Folder "Clinical Research Center, 60-61."

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