# The Evolution of Radiology through Product and Process Innovation

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## Abstract

Grounded in visual perception and observation, the tools and techniques used by radiologist are used for both screening and diagnostic purposes throughout the continuum of patient care. Despite the overwhelmingly positive impact that radiology has played in just over a century, the medical specialty is facing significant challenges such as declining reimbursements and an avalanche of new imaging data. The basic challenge to increase productivity and reduce costs is not necessarily new. In fact, scholars have long observed patterns of successful innovation that contribute to the pace, direction, and progress of many industries. This thesis explores the evolution of radiology through product and process innovation. Special attention is given to the role of labor and equipment specialization in reducing the number of steps while increasing productivity. An analysis of contemporary industry indicators such as residency program application rates and image volumes is presented in order to better understand the current climate of radiology. The goal of this study is to shed light on where the industry has come and where it stands, in order to provide clinicians, engineers, managers and entrepreneurs alike with action ideas to help bring in a new era in radiology.

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# Chapter 1 – Introduction

## Background

On November 8th, 1895, Wilhelm Conrad Roentgen of Germany observed that a platinobarium screen glowed in the presence of a shielded Crookes tube. Shortly after he used the same technique to create an image of his wife's hand. The medical community quickly realized the significance of the discovery – these "Roentgen's Rays", latter called x-rays, could pass through soft tissue in the body leaving bone and metallics visible. Fast-forward 120 years and the medical community is still realizing the full impact of this discovery. The innovation, which was awarded the Nobel Prize in physics in 1901, kickstarted an entire medical imaging industry, giving rise to new technologies in ultrasounds, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI) (Thomas and Banerjee 2013).

Perhaps the crowning achievement of medical imaging technologies is the ability to unobtrusively find disease before it's demonstrated clinically and thus while disease is still in the most curable form – it's estimated that over 40,000 lives are saved each year in the United States alone through screening for breast cancer in women and lung cancer in smokers. Radiology is also employed for diagnosis of acute medical ailments. For example, before the use of radiology in evaluating an acute abdomen there was a 20% negative exploration rate for appendicitis. Today, radiologists have reduced that rate to just 1% or 2% and eliminated over 65,000 false negative exploratory laparotomies for appendicitis in the United States each year (Allen Jr. 2015). Grounded in visual perception and observation, the tools and techniques are used for both screening and diagnostic purposes throughout the care delivery chain.

## Motivation

Despite the overwhelmingly positive role that radiology has played in improving patient care in such a short amount of time, the specialty is not without its share of challenges. Healthcare delivery in the United States is in the midst of a major transformation - the existing payment models that encouraged the healthcare system to drive volume and capacity utilization are being reformed to incentivize quality and value. While much of the discussion has focused on redefining the role of primary care in a capitated or mixed-payment environment, relatively less attention has been given to the impact on specialty care disciplines such as radiology (Seltzer and Lee 2014).

## Primary Research Objectives

Scholars have long observed patterns of successful industrial innovation that contribute to the pace, direction, and progress of an industry. Utterback expanded on these patterns by introducing a dynamic model of innovation, which forms a relationship between product and process innovations, labor specialization, and the state of an industry among others (Utterback 1996). While the role of product and process innovations as it relates to patterns in industrial progress has been demonstrated in the production of both assembled and non-assembled products, the model was primarily inspired by mechanical and analog products – not necessarily the delivery of medical care in a digital age. In fact, advances in medicine, computing, and Internet technologies were almost unimaginable at the time of Utterback's work "Mastering the Dynamics of Innovation." Given the myriad challenges to radiology as a medical specialty, an analysis of the role of product and process innovations in the development of radiology as a medical specialty is of critical importance.

The objectives of this research are twofold: First, it is to determine if the model of innovation presented by Utterback is observable in a medical specialty such as radiology. That is, is there an observable historical interrelationship between product and process innovations along with increased labor and equipment specialization in the delivery radiological services? The study will review literature on the dynamics of innovation before evaluating the historical development of medical imaging technologies and radiology through innovations in both product and process. The second objective is to reveal the current climate of radiology through an analysis of key indicators such as radiology residency application rates and study volumes. Innovation is an uncertain process that involves a number of forces and even a bit of chance. As such, the intention of this study is not necessarily to project the future of radiology. Instead, the framework used in this study is intended to shed light on where the industry has come from and where it is today, in order to provide clinicians, engineers, managers and entrepreneurs alike with action ideas for tomorrow.

## Chapter 2 – Literature Review

Healthcare systems face the challenge of providing high value and effective care to the patients whom they serve. However, global trends such as budget limitations, aging populations, and a shortage of clinical manpower threaten the industries existing care delivery models (Aslani and Naaranoja 2013). Despite policy changes and financial commitments from governments across the globe, the gap between the demand for services and the ability of the existing healthcare systems to provide such services is widening (Grimson 2001). This is also true in radiology, where there is a need for specialists with appropriate radiological interpretive skills (Hussain 2015). In order to deal with these challenges, it's important to understand the dynamics of innovations within an industry and the factors that impact the diffusion of innovations.

### The Dynamics of Innovation

Innovation is broadly viewed as the investment of resources in an idea and the implementation of the idea in the market. While this notion captures the basics, it fails to recognize the dynamic relationship that exists between product and process innovations, the organizational structure and the technology evolution at play. Professor James Utterback of the MIT Sloan School of Management and the late William Abernathy at the Harvard Business School developed the idea of a dynamic model of innovation.

It has been demonstrated through the development of a typewriter as an assembled good as well as plate glass as a non-assembled good that technological innovation tends to occur in distinct patterns, or waves, that govern the rate of innovation as well as the underlying dimensions of product, process, competition, and organization

(Utterback 1996). Three phases have been used to model this pattern of innovation: a fluid phase, a transitional phase, and a specific phase.

### The Fluid Phase

During the early stages of development, or the fluid phase, the consumer has low expectations for a product in terms of form and function. In the absence of universal standards and a clearly defined market, the entrepreneur and early firms are free to readily test new product features to determine what is desired from the marketplace. As a result, the rate of product improvement tends to increase rapidly despite the uncertainty in terms of the market and technology. However, the processes employed to create the product tend to be rather crude and inefficient during this period of rapid advances to the product (Utterback 1996).

### The Transitional Phase

If product momentum builds, the entrepreneurs who endured in the face of technology and market risks are often rewarded with an expanding customer base. The fluid period defined by rapid product innovation begins to shift into the transitional phase, characterized by the emergence of a dominant design, where product variation tends to narrow as R&D resources focus on incremental product improvements. As such, the realization of a dominant design has been demonstrated to shift the focus from product innovation to process innovation (Utterback 1996). For example, Utterback describes the manufacturing process during early stages of Thomas Edison's development of the light bulb as laborious, marked by an absence of specialized tools, machines, and dedicated craft traditions. During the transitional phase, however, the number of steps in the manufacturing process dropped from 200 to 30. As a result, the manufacturing process progressed from working with individual bulbs, to less-skilled laborers working on batches, to specialized equipment working on semi-continuous production.

### The Specific Phase

The final phase of innovation is referred to as the specific phase, where product differences across competitors in the industry tend to be far fewer than the similarities. The process used in manufacturing becomes so specialized that product changes are difficult to introduce. As a result, firms are limited to incremental product improvements, and compete on the basis of process efficiency, quality and costs. Firms that fail to reach maximum efficiency are forced out of the market. Utterback notes that only a radical departure can liberate a firm once it has entered the specific phase.

### Dynamic Model of Innovation Summary

The dynamic model of innovation involves both product and process innovations in terms of three phase patterns: fluid, translational, and specific. The model has been demonstrated through innovations of mechanical and analog products, including both assembled and non-assembled products. This dynamic model does not operate in isolation. Instead, it influences and co-evolves with increasing labor and equipment specialization. Before analyzing the historical development of radiology, this study will examine the key factors that impact the diffusion of past, present and future innovations.

## The Diffusion of Innovations

E.M. Rogers developed Diffusion of Innovation theory in the 1960s to explain how an innovation gains momentum and diffuses through a population. He describes "diffusion" within the context of innovation as the "the process in which an innovation is communicated through certain channels over time among the members of a social system." This working definition includes the spread of both spontaneous diffusion as well as planned diffusion that is arranged in advance (Rogers 2003). His research separates the definition into four distinct elements that this study will examine individually in order to develop a working definition of the diffusion of innovation within the context of radiology:

- Innovation ("An innovation")
- Communication Channels ("is communicated through certain channels"
- Time Dependence ("over time")
- Social System ("among the member of a social system")

**Innovation**

Rogers goes on to define "innovation" as "an idea, practice, or object that is perceived as new by an individual or other unit of adoption." In the context of healthcare, innovation can be described using more specific language. For example, healthcare systems are concerned with ensuring patient safety, patient outcomes, and organizational performance. In other words, healthcare innovation includes "changes that help healthcare practitioners focus on the patient by helping healthcare professionals work smarter, faster, better and more cost effectively." (Thakur, Hsu, and Fontenot 2012)

**Commutation Channels**

Communication is broadly defined as the exchange of information. The very definition implies a connection to facilitate this exchange. According to Rogers, diffusion is a certain type of communication in which the message content is concerned with a new idea. The process facilitates a mutual understanding or decision in regards to the idea. A key aspect of this communication is the extent to which the participants are similar, as ideas are most frequently exchanged between agents that are homophilous (Rogers 2003).

Broadly speaking, physicians and radiologists can be considered a relatively homophilous group – they are educated and trained with a relatively standard curriculum that is focused on clinical skills in diagnosis and treatment. They have certifying tests, are members of similar professional associations, attend conferences, pursue continued medical education, typically enjoy a similar socio-economic status (Cain and Mittman 2002). However, characteristics such as age, language, technical grasp, and radiological subspecialty can be quite heterogeneous.

**Over Time**

The third element in the definition is the dimension of time within the context of innovation adoption. That is, the time duration required for an organization to do something differently than what they had previously. Rogers describes this innovation decision-making process as "an information seeking and information processing activity in which an individual is motivated to reduce uncertainty about the advantages and disadvantages of the innovation." (Rogers 2003) Research suggests that there are five qualities that help to explain the rate of adoption:

1. **Relative Advantage** - The degree to which an innovation is perceived as better than the idea it supersedes. The degree of relative advantage may be measured in economic terms, but social prestige factors, convenience, and satisfaction are also important factors.

2. **Compatibility** - The degree to which an innovation is perceived as being consistent with the existing values, past experiences, and needs of potential adopters.
3. **Complexity** - The degree to which an innovation is perceived as difficult to understand and use.
4. **Trialability** - The degree to which an innovation may be experimented with on a limited basis.
5. **Observability** - The degree to which the result of an innovation are visible to others.

While these characteristics can help to summarize varying rates of adoption, they fail to capture the element of complexity. Decisions in healthcare can involve a vast stakeholder network that requires contributions from patients, providers, payers, and suppliers. It is therefore best to look at these factors of innovation adoption at the organizational and consider how the stakeholder network can influence the time dimension.

Damanpour's description helps to capture the manner in which adoption time is influenced by complexity by referring to innovation adoption as a process. That is, "the adoption of innovation is conceived as a process that includes the generation, development, and implementation of new ideas or behaviors." Perhaps most importantly, he later describes that innovation "is conceived as a means of changing an organization, either as a response to changes in the external environment or as a preemptive action to influence the environment." (Damanpour 1996) This suggests that environmental factors, such as challenges facing a medical specialty, can also be key to understanding the adoption of a product or technology.

### Social System

The diffusion of innovation typically occurs within a social system, which is the final component of our definition. Awareness and understanding of the behaviors of this social system will be essential to affecting the pace at which innovations are adopted. Rogers defines a social system as a "set of interrelated units that are engaged in joint problem solving to accomplish a common goal." (Rogers 2003) This sort of social system in the context of radiology is will have an influence in the diffusion innovations.

Research has shown that members of a social system adopt innovations at different rates, that is, adoption is not simultaneous. While radiologists around the globe are bound together with the common goal to do what is best for the patient, the decision to adopt is typically established through a structure of key option leaders and followers. This type of clinical leadership comes in many forms.

At the top are the regulatory bodies that govern the sales and marketing of healthcare products. Their job is to protect consumers by weighing the risks and benefits associated with drugs, devices, and diagnostics (World Health Organization 2012; Davis 2015). In many aspects of innovation there is not always a clear cut advantage; however, healthcare is somewhat unique in this regard as part of the responsibility of these regulatory bodies is to ensure that innovations are superior to the existing clinical option, or at a minimum the innovation must be non-inferior. Other centers such as the Department of Health and Human Services as well as academic research centers such as the National Institutes of Health (NIH) act as healthcare opinion leaders able to influence other individuals' attitudes or overt behavior by providing information, advice, and mandates regarding healthcare innovations. Within the context of radiology, The American College of Radiology is the largest group of radiologists in the U.S. Their society is dedicated to "serving patients and society by empowering radiology professionals to advance the practice, science and professions of radiological care." (Retrieved from http://www.acr.org 12/4/2014)

While the primary objective of healthcare systems is to adopt innovations that improve patient care, in reality, the heterophilous nature of the clinical social structure influences many of the decisions. Physicians often leave their clinical roles to fill administrative leadership positions, requiring them to balance financial and operational expectations with patient care decisions. The influence of regulatory bodies and opinion leaders can weigh heavenly on the rate of adoption within a social system. To this end, the diffusion of innovation is concerned with various influencers within the social system, all of whom have an impact when adopting new ideas.

**Working Definition**

For the purpose of this study, facets from each of the aforementioned definitions are extracted to form a working definition of the diffusion of innovations within the context of radiology – "The process in which innovations that help radiology professionals to focus on the patient by working smarter, faster, better and more cost effectively are adopted by healthcare organizations."

# Chapter 3 – Historical Development of Medical Imaging

Scholars have long observed patterns of successful industrial innovation and even dynamic models of innovation in the evolution of both assembled and non-assembled products; however, prior work has not necessarily been applied to the delivery of medical care in a digital age. This chapter therefore considers the case of medical imaging technologies in the diagnosis of medical conditions through waves of product and process innovations.

## Early Development of Medical Imaging

While mathematicians and physicist were busy trying to understand the basis of the mysterious rays discovered by Wilhelm Conrad Roentgen and his Crookes tube, the global medical community pushed forward with new imaging techniques to diagnose disease and related aliments. Charles Thurstan Holland noted that at that time "there were no experts, no literature, and no knowledge of the normal, to say nothing of the abnormal." (Thomas and Banerjee 2013)

Crookes tubes consisted of a cathode and an anode held within a glass tube enclosure. The glass tube apparatus contained gas held at a low pressure. When connected to high power source, the anode attracts the electrons emitted by the cathode across the length of the tube. However, some of the electrons bypass the anode and collide with the glass of the tube, producing what we now know as x-rays, as they exit the tube. After leaving the Crookes tube the x-rays lose energy as they penetrate objects, including the human anatomy. The remaining energy is then absorbed by a detection device such as film to expose an image (Sears and Grieve 1979).

While photography was well established in the late 19th century, the low power nature of the original Crookes tube apparatus made it difficult to image thick or dense regions of the body using glass plates, cellulose-nitrate films, or paper alike. Therefore, it was commonplace for pioneering radiologists to use a fluorescent screen or a cryptoscope to reveal these internal images. Unfortunately, the harmful side effects of prolonged radiation exposure were not understood until the mid 1900s. As such, the absence of protective equipment lead to a myriad of injuries to the early x-ray handlers (Thomas and Banerjee 2013).

Early radiographic images were acquired in a variety of diagnostic settings. One of the first documented cases occurred within a year of the discovery when, on April 23, 1896, Elizabeth Ann Hurley was shot four times by her husband. The bullets caused severe injuries to her jaw, ear, and neck. The town's medial practitioner, Dr. W.G. Little, enlisted the help of his colleague Professor Arthur Schuster at Owens College to help locate the bullets in Mrs. Hurley. Schuster is said to be one of the first to receive a copy of Roentgen's first publication. Unfortunately, Schuster was sick at the time so he sent two of his assistants equipped with a Crookes tube and unexposed glass plate film to help find the missing bullets. The delicate radiographic apparatus took over an hour to capture to first image on a glass plate and another 70 minutes to capture the second. The glass plates were then returned to Professor Schuster in Manchester for processing, who in turn telegraphed the results to Dr. Little (Thomas and Banerjee 2013).

The innovation gained considerable momentum through a number of military campaigns during the late 1800s and early 1900s despite its limited diagnostic capabilities and fragile nature. During the Spanish-American War, large American hospitals and three American ships were equipped with the apparatus to avoid unnecessary probing of the body. Initial preparations for the Boer War equipped hospitals with the apparatus as general equipment for the impending campaign. As the conflict stretched on longer than anticipated, vehicles were equipped with aftermarket x-ray diagnostic capabilities to help detect both fractures and foreign bodies of military personnel in the field. In what can be considered as an early form for tomography, the depth of foreign bodies in relation to the wound point were often examined using a technique that moved the apparatus around the patient. The apparatus was also powerful enough to diagnose thoracic injuries. In some respects, x-ray technology advanced military capabilities by alleviating suffering, preserving limbs and limiting the loss of life for combat soldiers (Thomas and Banerjee 2013).

Interest in basic light photography throughout the 1800s helped to fuel innovations in film detector technology. Despite both the fragile nature of glass plates and considerable costs, pioneers in the field of radiography typically employed glass plates as an x-ray detector. However, a turning point was reached during military operations of 1914 when the production of glass plates from Belgium was halted due to World War I operations. Of course, the demand for a suitable detector was increased during this same time period due to the diagnostic capabilities of x-ray technology when operating on wounded soldiers. These events helped to fuel innovations in cellulose nitrate base x-ray film. The new film, which had been invented only one year earlier in 1913, enabled better medical images that were achieved with less exposure at a decreased cost (Haus and Cullinan 1989).

## The Coolidge Tube - A Dominant Design

While the medical community was enthralled with this revolutionary view of the body, the Crookes tube was unreliable as an x-ray source due the varying pressure states of the gas in the tube. Over time, the glass wall of the tube absorbed the gas leading to inconsistencies of the energy level of the x-rays as well as the quantity. Ultimately, the tubes would stop working entirely (Hessenbruch 2002). Consequently, researchers from the global community pressed forward during the fluid period of medical imaging innovation with new x-ray emitting designs aimed at improving performance.

William David Coolidge, an American and MIT trained physicist, made famous the invention of ductile tungsten. In 1913, he applied tungsten to the Crookes tube, creating what is referred to as a "hot cathode" tube. This new "Coolidge tube" design took advantage of the thermionic effect, where thermally induced charge carriers flow from a surface or over a potentially energy barrier. He also incorporated high-vacuum tubes. This design made the continuous flow of x-rays possible in a far more controllable and consistent manner than the Crookes tube (Hessenbruch 2002).

While the design of the x-ray apparatus varied significantly during the early fluid stages of development, this breakthrough marked the end of the fluid period of innovation in x-ray medical imaging. By 1920, Coolidge tubes became enormously popular in the marketplace. They set a new standard of performance and proliferated through the global medical imaging community. To this day the essence of Coolidge tube design remains as the dominant source of x-rays (Thomas and Banerjee 2013). Following this breakthrough, patients were diagnosed through the medical imaging process identified in Figure 1. The subsequent decades were largely spent perfecting this process through a series of incremental innovations in x-ray detectors.

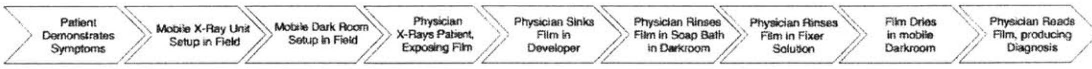


**Figure 1 - Original Radiology Process Workflow**

## Standardization and Process Innovations in Focus

The transitional phase of innovation is marked by the emergence of a dominant design and a shift to process improvements (Utterback 1996). The decades that followed the emergence of Coolidge tubes witnessed a new breed of labor professionals, gradual standardization of the medical imaging techniques and workflow enhancements through incremental improvements to imaging detector technology. For starters, Coolidge tubes necessitated the use of larger, static machines having greater electricity requirements. Field units transitioned to hospital and office settings, where the formation of radiology departments was a natural offshoot to many electrotherapy and electric departments (Thomas and Banerjee 2013).

### Labor Specialization – The Radiographic Technician

Disruptive innovations often give rise to new industries – Utterback notes that the mainstream adoption of the typewriter in the late 1880s gave rise to a whole new class of clerical worker responsible for handling the production of written documents (Utterback 1996). In the early days of x-ray adoption physicians set up the apparatus, imaged the patient, developed the glass plate or film, and interpreted the result with practically no assistance. However, increasing use during World War I coupled with the rise of screening examination required more time and expertise than the physician could feasibly manage. Physicians, anxious to probe the human body with this new technology, began to realize the value of a well-trained radiograph assistant. As a result, a whole new class of worker would be defined as physicians trained office and hospital workers in the basics of image acquisition and film development. Thus, Radiology as a medical specialty coevolved with the Radiologic Technician (Hoing, M. 1952).

**Medical Imaging Standardization**

Societies began to form across the globe as radiologic examinations entered a period of gradual standardization. In 1920, the American Association of Radiological Technicians was formed in the United States. The distinction between these budding specialties is clearly drawn through a passage in their founding creed "We believe that the standard for all plate and film work should be established by the professional man, doing the work of interpretation, and that it is our duty to qualify ourselves to produce the desired standard. We Believe that no expression of our opinion regarding treatment, diagnosis, or interpretation concerning any patient with whom we work should ever be given to other than the professional man to whom we are responsible." (Hoing, M. 1952)

During the same time period, The Society of Radiographers was setup in the UK to represent the medical radiographic workforce. One of their initial undertakings was to create an examination for radiologists entering into the workforce. The first examination was administered in 1922 to a group of 45 students, of which only 20 passed. One such student, Miss K.C. Clark, recognized the need for increased standardization in the field and went on to write a landmark book in 1930 titled "Positioning in Radiography." The book was significant for two reasons. First, the book described techniques for patient positioning and dose during common radiographic examinations. Second, the book included high quality scientific images of the body. As a result, consistent diagnosis in radiology could finally be achieved throughout the global medical community (Thomas and Banerjee 2013).

**Evolution of the Film Development Process**

A central point in story of the development of medical imaging is the interplay between innovations in imaging modalities, the standardization of patient diagnosis, and process innovations to imaging workflow. Early x-ray film was made of cellulose nitrate, a highly flammable substance. In 1923, Kodak introduced a film base consisting of cellulose acetate. This new product was marketed as "Safety Film." Despite the marketing effort, the cellulose nitrate film wasn't fully phased out until 1929 when an explosion at the Cleveland Clinic Hospital left 126 people dead (Haus and Cullinan 1989).

Despite the benefits of safety films, the process for film development remained entirely manual. Hass and Cullinan described the intricate and time-consuming process as a series of five steps: First, the exposed radiographic film had to be immersed successively in individual containers of developer. Next the film was rinsed in a stop bath followed by a fixer solution before being washed in running water. Finally, the washed radiographs were hung to drip and air dry. Of course, this entire process had to be completed in a dark room. The intricate process made it difficult to achieve consistent results – "Image quality, reproducibility of results and patient exposure were dependent on the user's control of processing time, solution temperatures, solution freshness, agitation, and general housekeeping." (Haus and Cullinan 1989) During a period with limited information on the risks of human exposure to radiation, the exposure time was often increased in order to reduce the amount of time spent in film development.

The process of manually processing radiologic film changed in 1942 when Pako introduced the first automatic film processor. This design essentially used a series of special hangers to replicate the process of manually developing the films. The model could process 120 films per hour with a total cycle time of approximately 40 minutes per film. Despite the remarkable improvement, the innovation was still limited to darkrooms as film development had to be completed in the absence of light. Following Pako's innovation, patients were diagnosed through the medical imaging process identified in Figure 2.

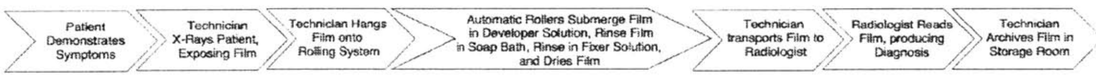


**Figure 2 - 1942 Radiology Process Workflow**

Medical imaging experienced a major process improvement when Kodak introduced the first roller transport film processor in 1956. The device bares a striking resemblance to the modern copy machine, albeit roughly 10 feet long. The automatic film processor allowed technicians to insert a film into a feed tray. The film was then developed internally before being ejected into a receiving tray (Haus and Cullinan 1989).

In addition to being fully automatic, the automatic processor did not require a specialized film. This feature allowed hospitals that purchased the new processor to continue working with their existing film inventories. Kodak's innovation was a boon to radiology departments busy with an increasing volume of x-ray films. While the previous film development process required upwards of 40 minutes to process a film, the new automatic processor could develop film in six minutes. Not only did the new automatic process improve the workflow and departmental efficiency, it took a major step in standardization by removing the human element from film processing, allowing for consistent diagnosis of the patient (Haus and Cullinan 1989).

The advent of the automatic film processor was the last major process improvement and marked the end of the transitional phase of medical imaging. Coolidge tube technology remained the dominant design as a source of X-rays. Enormous progress in labor specialization and the film development process led to increased standardization. At this time patients were diagnosed through the medical imaging process identified in Figure 3. Medical imaging and the associated diagnosis became a result of a systematic process, reducing the number of steps and amount of time to acquire an image from multiple hours to only a few minutes.

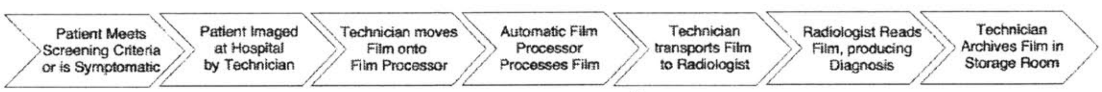


**Figure 3 - Radiology Process Workflow Following Automatic Film Processor**

## Stalled Progress in Medical Imaging

Innovations in the x-ray source and detector technology began to reach a ceiling by the late 1950's. Minor improvements to film handling and stability continued into the early 1960s, but the profession had reached the limits of diagnostic capability through x-ray visualization of the skeletal structure and the detection of tumors. While the profession was still its infancy relative to other medical specialties, innovation gradually stalled resulting in an environment that was ripe for change. A radical departure was necessary in order advance the practice of disease diagnosis. Fortunately this period of dormancy would not last long – parallel advances to computing capabilities created new possibilities to traditional x-ray radiography while opening the door for new imaging modalities altogether.

## A Wave of New Product Innovations in Medical Imaging

### Ultrasound

Heart surgery began to gain momentum in Lund, Sweden during the late 40s and early 50s, when physicians operated on adults to correct mitral stenosis. In some cases, however, blood leaked backwards due to mitral insufficiency, leaving patients worse off than had they not had the procedure at all. While Roentgen rays proved to be a valuable tool for imaging the skeletal system and tumors, they were of no use for imaging of soft tissue due to the penetrating nature of the x-rays. Inge Elder was a young internist at that time responsible for preoperative heart evaluations who quickly recognized this diagnostic problem. Partnering with Hellmuth Hertz, a physicist and former prisoner of war who had found his way to Copenhagen, the two managed to borrow an ultrasound system from a local shipyard. Ironically enough, the ultrasound device was used at the shipyard to examine weld seams in ships for faults. Together with Elder, the two began to recognize an echo that moved with the pace of the heart when the device was used to probe the chest (Eklof, Lindström, and Persson 2012).

The shipyard's ultrasound system was not suitable for recording measurements and lacked a key feature – the film camera. The pair formed a partnership with Siemens in Germany and the first moving pictures were recorded of the heart in late 1953. As the technology developed, recording movements from the anterior mitral valve became the cornerstone of preoperative candidate evaluation for mitral valve surgery (Eklof, Lindström, and Persson 2012).

Ultrasound developed dramatically in the years that followed. Although the images were difficult to interpret, it soon became possible to obtain two-dimensional pictures as well as to visualize the detailed movements of valve patterns and the heart wall. Later in the 1960s, it became possible to read ultrasound in real time – producing an image every 15 seconds on a screen (Thomas and Banerjee 2013). Ultrasound technology had a profound effect on clinical practice as the scope of ultrasound increased gradually, spreading as a diagnostic tool to many specialty areas including neurology, obstetrics, and gynecology (Eklof, Lindström, and Persson 2012). Today, ultrasound is the most commonly used medical imaging technology, primarily due to its compact nature, portability, and price. In fact, in addition to the bedside machines used throughout the medical care delivery chain, pocket sized probes are now available as an accessory to the modern mobile phone.

**Computed Tomography (CT)**

Some might say that tomography actually originated on the battlefields of World War I, where physicians would rotate the Crookes tube apparatus around wounded soldiers in an attempt to determine the depth of lodged bullets. In 1917, Austrian mathematician named Johann Radon developed the mathematical proof that indicated if the line integrals for a particular object could be known for all the lines intersecting a slice of an object, then the object could be reconstructed exactly. This principle formed the basis of tomography; however, there would be roughly 70 years of evolution in computing technology before physicians could rely on a dedicated scanner to generate a three-dimensional visualization of the body (Thomas and Banerjee 2013).

The problem with traditional x-ray technology is that a two-dimensional image is used to represent a three-dimensional structure. Hence, the physician lacks depth information when interpreting the image. This all changed when Godfrey Hounsfield and colleagues at EMI invented the first CT scanner, which debuted at Atkinson Morley's Hospital in October of 1971. The neuro-radiologist in charge of the unit, James Ambros, had worked in the 60s to develop a cranial ultrasound technique to determine the position of the midline of the brain. Unfortunately, the technique was prone to artifacts and thus very difficult for radiologists to interpret. Ambros' new CT scanner presented the opportunity to complete his early work using a new imaging modality (Thomas and Banerjee 2013).

Early CT scanners required approximately five minutes of scanning to acquire a single 80x80 image and did not even include a computer attached to the machine. Instead, the data was stored onto magnetic tapes and sent off-site for processing. While EMI enjoyed a brief monopoly as the only manufacturing of CT equipment, they were quickly joined by eight manufactures that brought along new techniques for imaging the many other organs of the body.

As with the shift experienced in traditional x-ray technology from product innovation to process innovation, CT technology witnessed a plethora of improvements in the 1980s aimed at improving image quality and reducing acquisition time through innovations to acquisition technique and workflow. In the early days of CT, the examination table was stationary while the gantry rotated 360 degrees. After one 360-degree rotation, the patient table, the patient table was manually adjusted with respect to the gantry before another 360-degree rotation was performed. This technique had its obvious shortcomings as it was time consuming and prone to artifacts created by patient movements during the table rotation.

A significant process improvement came to fruition in 1990 with the introduction of continuous gantry rotation. This new design included a completely fixed patient examination table while the gantry rotated continuously on a slip ring, allowing for the acquisition of an entire cross-section of the chest of abdomen in a single breath. While this new technique allowed for significant clinical advances, it offered no solution for imaging organs that exhibit involuntary movements, such as the beating of the heart. Fortunately, process innovations continued through the 1990s that would increase the spatial resolution and decrease acquisition time.

In 1998, a four-detector CT scanner was introduced that decreased acquisition time considerably and expanded the capabilities of computed tomography during an angiography. Of course, only four short years later the four-detector CT gave way to a sixteen-detector CT by 2002. Unsurprisingly, by 2004 the witnessed sixteen-detector CT lost its battle to a sixty-four-detector CT. After years of continuous advances in the computing industry, the modern CT scanner is capable of acquiring twelve hundred 512x512 transverse image sections in only one second, which represents an efficiency increase of 1.5 billion percent (Rubin 2014).

### Magnetic Resonance Imaging (MRI)

While the introduction of CT helped to revolutionize traditional x-ray imaging, the technology is not without its drawbacks. Chief among them is that longitudinal studies cannot be completed due to the hazards associated with prolonged exposure to ionized radiation, such as cancer. Additionally, CT scans provide little soft tissue differentiation, rendering the diagnostic largely unsuitable for imaging of the brain, spine, joints, and other soft tissue body parts.

Magnetic resonance images (MRI) are obtained by placing the person or object of interesting into the presence of a strong magnetic field. The phenomenon relies on the hydrogen nuclei within the cells, which align their polarity with the magnetic field. Next, radiofrequency pulses create an oscillating field that causes the nuclei to move out of their alignment. As the nuclei relax from a state of excitation back to their equilibrium state, electromagnetic waves are emitted by the nuclei that can be measured by the receiving coil and translated into an image. This signal is then transformed by a series of algorithms into an image. While x-ray images are created through the different absorption rates of the body, MRI takes advantage of varying proton density and proton relaxation times through out the different tissue regions of the body. Thus, images are obtained that demonstrate diverse tissue characteristics by varying the pulse sequence (National Institutes of Health (U.S.) 1988).

The roots of magnetic resonance can be traced back to Isidor Isaac Rabi, who in 1934 demonstrated perhaps the first account of nuclear resonance in his groundbreaking paper entitled "Measurement of Nuclear spin by the Method of Molecular Beams: The Spin of Sodium." (Thomas and Banerjee 2013) A number of experiments followed during the subsequent decades but researchers still couldn't determine where exactly the signal originated within the sample. This all changed in 1974, when Paul C. Lauterbur of the United States and separately Peter Mansfield of England described the use of magnetic field gradients for spatial localization. Although the pair were unaware of each other's work, they were jointly awarded the Nobel Prize in Physiology or Medicine in 2003 (Geva 2006).

The years following this discovery proved to be fruitful. In 1975, Mansfield and his colleague Andrew Maudsley proposed a line technique that led to the first in-vivo image of a cross section of finger. In 1977, Hinshaw et al. acquired an image of the wrist and Damadian et al. acquired an image of the human chest. By 1978, researchers at EMI reported the first stack of images through the human head (Thomas and Banerjee 2013). While clinical applications of MRI were starting to become readily apparent, advances to the Fourier reconstruction techniques in the early 1980s enabled three-dimensional volume imaging (Vlaardingerbroek and Boer 1999). The technology allowed researchers to produce acceptable clinical images in all three imaging planes: axial, sagittal, and coronal. However, at that time a single image could be captured in approximately five minutes (Geva 2006).

There were very few architectural changes made during the development of MRI. Perhaps this is due to the benefit of having witnessed the evolution of x-ray, ultrasound, and computed tomography technologies. Unlike early CT applications, where the patient position was adjusted with respect to the x-ray source and detector, early MRI patients remained immobilized throughout the duration of the scan. In fact, even the process of acquiring an MRI largely resembles the process that is used today. The initial design required a dedicated room for MRI imaging, coming equipped with copper walled rooms to shield the device from external radiofrequencies interference as well as to prevent metal objects from being magnetically pulled to the scanner. To this day, dedicated MRI rooms are ubiquitous (Thomas and Banerjee 2013).

The transitional period of MRI technologies was marked by refinements in acquisition technique – faster scanners, and increased magnetic fields. Denis Carr and Wolfgang

Schorner introduced intravenous contrast agents, previously used to view the urinary track in x-ray imaging, in MRI imaging in 1981. The pair completed the necessary clinical trial in 1984 (Thomas and Banerjee 2013; Carr et al. 1984). By 1986, the imaging time was reduced to approximately five seconds (Vlaardingerbroek and Boer 1999).

Although MRI has been used commercially for almost twenty-five years, innovations are helping radiologists to view soft tissue structures in a whole new way. Instead of looking at merely static macroscopic images, new techniques such as functional MRI and NMR spectroscopy allow physicians to glean clinical information ranging from real-time cellular networks down to the properties of organic molecules. Computer algorithms are used to remove patient motion, allowing real-time diagnostic capabilities during surgical procedures. Each improvement helps the interpreting radiologists and medical professionals to delineate disease at a level that Roentgen could have never realized when he acquired the first medical image of his wife's hand.

## Back in Focus - Standardization and Process Innovations

### Direct Radiography

Inspired by the success of Computed Tomography as well as other new imaging modalities, a new wave of process innovations began to take form in the early 1980s. Until the mid 1980s, conventional radiographs were still produced using a combination of film and an intensifying screen; whereby the x-ray energy passes through the patient, losing energy depending on skeletal and tissue characteristics, before being converted into light by the screen and exposing the film. In this traditional system, however, the film is compromised as it serves as both the imaging sensor and the image display medium. At the time, Sonoda et al. noted that this combination "requires high speed and wide latitude, and as the image display medium, which requires good contrast and low noise. Theoretically, however, these performance aspects are mutually conflicting." (Sonoda et al. 1983)

This method for creating an image changed in the early 1980s when H. Kato and his colleagues at Fuji Film developed Digital Radiography (DR). Earlier attempts at a conversion from analog film images to digital resulted in a technology referred to as Computed Radiography, a two-step process where the image was temporarily stored on cassettes before being converted to a digital image. In Digital Radiography, the imaging plate is coated with photostimulable phosphorus crystals that are capable of storing the energy absorbed in a quasi-stable state before being scanned by a laser beam and converted into electric signals. Next, the imaging plate is flooded with light to erase the residual energy it contains and prepare it for the subsequent image acquisition. Thus the conventional analog film radiography is replaced by a digital technology (Kato, Miyahara, and Takano 1985).

**Picture Archiving and Communication System**

It's difficult to separate the development of digital x-ray imaging sensors from the archives, transmission, and viewing technology required to display the resulting digital images. In fact, shortly after filing an initial patent on digital radiography, Minora Sonoda and her colleagues at Fujifilm noted that the digital signals could "be transmitted to a central reading room for image process and reproduction. Radiographs could be permanently stored on a digital memory disc so that radiographic film could be destroyed for silver recovery. In the future, it has the potential of developing into a total radiographic filing system employing a large scale memory on optical discs to facilitate the exchange of medical images and information between hospitals." (Sonoda et al. 1983)

Sonoda's remarks proved to be quite providential over the next thirty-five years, helping to usher in a new era of imaging modalities while enabling a digital workflow. This new digital workflow allows images to be seamlessly forwarded to a variety of workstations, including Picture Archiving and Communication System (PACS), which facilitated the storage and exchange of medical images. Moreover, the technology has given rise to a whole new profession, the PACS administrator. Whereas before the radiological technician or office assistant was tasked with managing film storage rooms, the PACS administrator is responsible for orchestrating digital workflows and managing the long term archiving of digital images.

PACS combines electronic media storage, diagnostic workstations, and network communication. It provides an archive for the long-term storage of medical imaging data including the data generated during x-ray, computed tomography, magnetic resonance imaging, and ultrasound examinations. In many cases radiologists will perform their primary review of the images using PACS, often recalling prior exams from the same patient to observe tissue changes over time.

In a clinical setting PACS workstations are typically connected to display workstations, where radiologists read the imaging data, as well as Hospital Information System (HIS) and Radiology Information System (RIS) to manage and communicate patient related imaging examinations (Huang 2014). Thus, a major component of PACS is the exchange of medical imaging information. As such, a network standard protocol referred to as Digital Imaging and Communications in Medicine (DICOM) was created to facilitate the receiving, sending, and transferring of medical imaging data across hospital networks.

### Teleradiology

Telemedicine is the practice of using telecommunication technology to connect patients to providers across a distance. The practice can be traced back to the early 1900s, where captains employed radios to verbally transmit medical information to medical professionals, who returned medical advice to the ship. In as early as 1906, the telephone was used to transmit electrocardiogram information. By the space age, telemedicine allowed medical professionals to monitor astronauts' vital signs from afar (Coates, Kvedar, and Granstein 2015).

In many respects the application of telemedicine to radiology can be viewed as the next logical process innovation aimed at improving diagnostic efficiency. Instead of sending the medical imaging data to a reading room, the data is sent offsite where radiologists are available for interpretation. What started as a means of load balancing during peak hours, a replacement for a "nighthawk" radiologist, or as an essential tool for the emergency departments has grown into a high volume service provided to many hospitals and radiology groups. While teleradiology is still in its infancy, the emergence of Internet technologies, PACS, complex imaging modalities, as well as economic pressures have all helped to pave the way for teleradiology services.

### Summary

This review demonstrates the historic relationship between product and process innovations in radiology. The early years of radiology were quite laborious – a lack of specialized equipment and specialized labor force required early adopters to work through a tedious image acquisition, film development, and interpretation process in order to diagnose an ailment. However, the century that followed was marked by a series of incremental process improvements that resulted in dramatic productivity gains. Radiology soon moved from the battlefields to hospitals and office settings, resulting in the creation of two professional specialties: the radiological technician dedicated to image acquisition and years later the PACS administrator dedicated to data management. The role of the radiologists has evolved to include numerous sub-specialties. Specialized equipment such as new imaging modalities, automatic film processors, digital sensors, and PACS have allowed radiological acquisition and interpretation to become the result of a systemic process. Refer to Figure 4 for the evolution of radiology through product and process innovation, where each row represents the image acquisition, interpretation, and storage workflow during a time period. Workflow evolution is a continuous process, however, for simplicity the workflows below have been categorized into the most appropriate period given the corresponding product and process innovations.

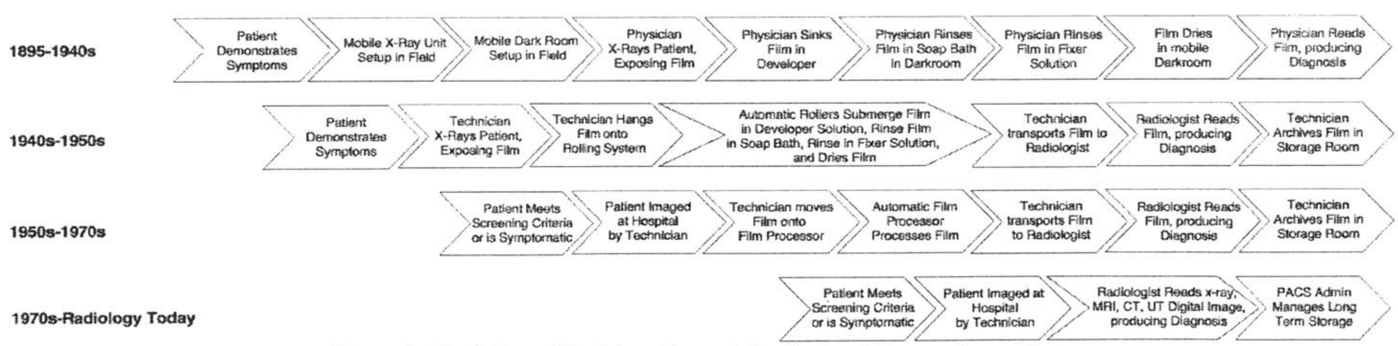


**Figure 4 – Evolution of Radiology through Product and Process Innovation**

Healthcare delivery in the United States is in the midst of a major change from fee-for-service to bundled payments. While this study has shown that there is an observable historic relationship between product and process innovations, increased labor and equipment specialization in radiology, it currently falls short of examining the unprecedented economic forces that threaten the existing care delivery workflow. Given the myriad of changes on the horizon, the next chapter will take a closer at the current climate that surrounds radiology.

# Chapter 4 – Radiology Today

Radiology is facing major challenges as it attempts to keep pace with the demand for its services. Amid a period of declining reimbursement rates, an avalanche of new image data poses interpretation challenges for the radiologists. A recent shift in residency applications may signal a declining attractiveness of the medical specialty. Therefore, this chapter dives into the current climate of radiology in order to develop an understanding of the environment in which future innovations will be met.

## Google Trends

It has been demonstrated that Google search engine query data can help to inform forecasts and predictions made about the future by providing insights into real-time trends or movements. For example, in 2009 researchers were able to detect influenza epidemics in areas with a large population of web searches related to topics such as flu symptoms or flu remedies. The study found that notable increases in specific web searches could estimate surveillance data a full one to two weeks ahead of publications generated by the CDC's US Influences Sentinel Provider Surveillance Network (Ginsberg et al. 2009). Of course, Google search engine query data is anonymized such that specific demographic indicators, such as age and sex, could not be deciphered. Similar methodologies have been utilized to detect volatility in the financial markets and also to describe health related information seeking behaviors in response legislation activities (Hamid and Heiden 2015; Fazeli Dehkordy et al. 2014). The essence of this growing body of research suggests that the aggregated demand for specific pieces of information is both revealing of local sentiments and can be used as an indicator of future tendencies. Therefore, this study will use Google search data to better understand the sentiments towards the radiology profession. These data can be predictive of future workforce trends, such as a shortage or abundance of radiology professions, while also helping us to better understand the pace at which innovations can diffuse (Haney, Kinsella, and Morey 2014).

The publically available Google search trends tool was used to understand the volume of queries that were made in the U.S. related to radiology workforce. The search terms of "radiologist salary" and "radiology salary " were examined and aggregated to determine the interest in salary inquiries. Similarly, the search terms "radiology residency" and "radiology programs" were examined and aggregated to understand the interest of residency programs. Refer to Figure 5 (See Appendix Table 1 for raw data). This Search Volume Index (SVI) data was obtained from Google on September 4th, 2015 and represents the interest over time. Data have been normalized between 0 and 1. There is no demographic information available for the Google search data, meaning that the queries can arise from those who are not considering radiology as a profession.

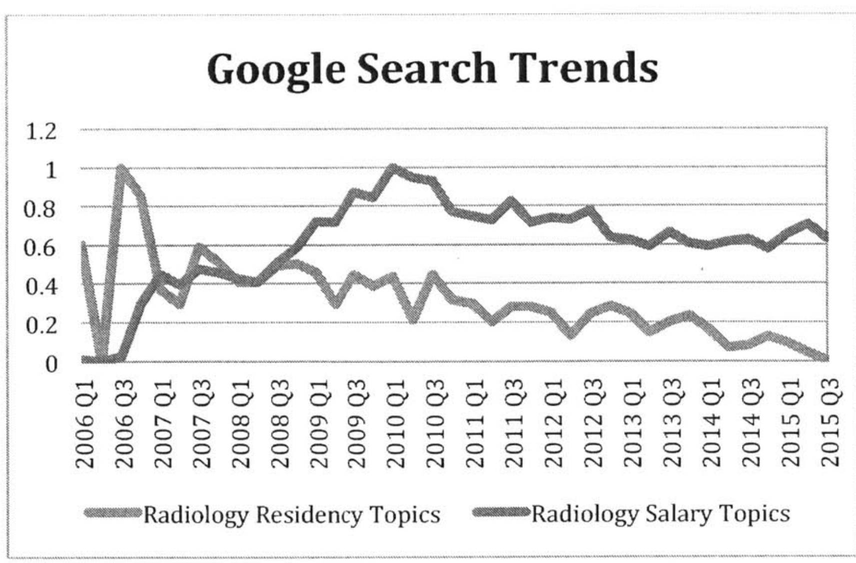


**Figure 5 - Radiology Residency & Salary Search Trends ("Data Source: Google Trends Sept. 4th, 2015," n.d.)**

Aggregating the historical online web search queries between 2006 and 2015 Q3 helps to gauge the collective mindshare and relative awareness of issues related to radiology workforce. This data indicates that online web searches for radiology salary topics have increased considerably since 2006, peaking in 2010. During the same time period, online web searches for radiology residency programs have steadily decreased since 2006. This data offers serious clues as to the challenges facing the radiology workforce – during the past decade, online web search data suggests a concern over the radiologists' salary and that the interest in radiology residency programs has been dwindling.

### National Residency Matching

Each year the National Resident Matching Program (NRMP) publishes a detailed report that summarizes residency match data, such as the number of residency positions offered, positions filed, and the number of applicants. This information is available to the public online. This study has aggregated data points related to diagnostic radiology from the annual reports for years 2006 – 2015 to determine if the warning signals characterized in the Google search trend data are also demonstrated in the residency matching data.

In 2006, the residency matching program saw a total of 26,715 active applicants apply for a total of 24,805 total residency positions. By 2014, those numbers had steadily increased to 58,443 and 30,212 respectively. Judging from the number of positions available and the overall volume of applications, this data suggests that the attractiveness of medical specialties on the whole has gone up over the last decade.

However, a troubling trend in radiology residency data begins to emerge during this same time period. Figure 6 below represents the combined radiology residency data for all applicant types (PGY-1, PGY-2, and Physician-R applicants). Refer to Table 2, Table 3, and **Table 4** in the Appendix for raw data.

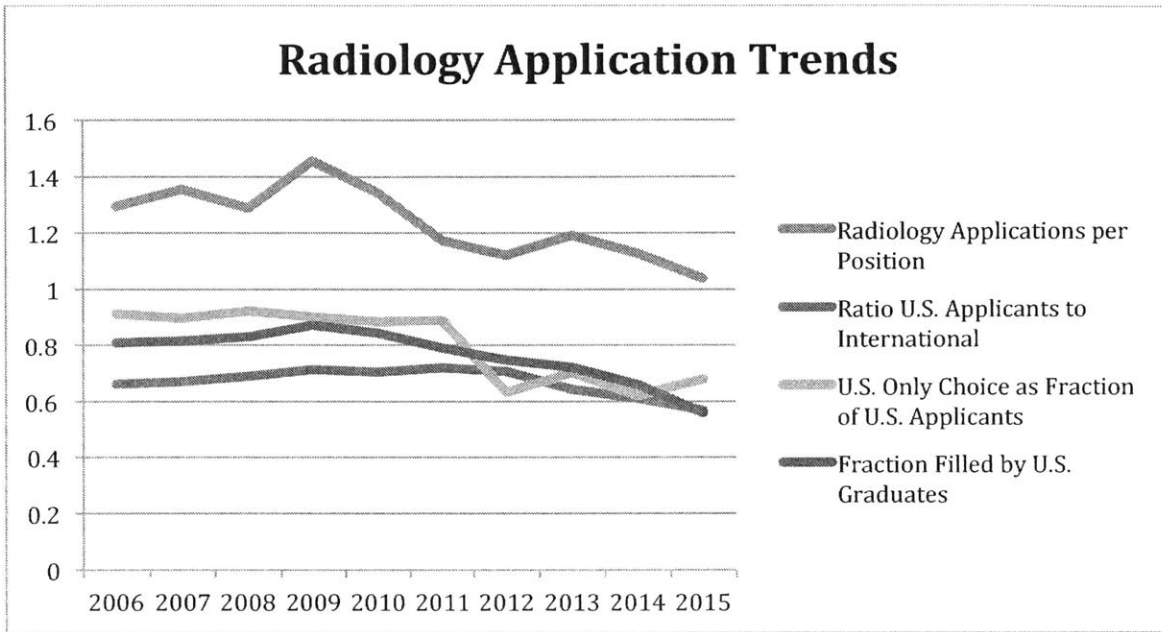


**Figure 6 – Radiology Application Trends**

The number of radiology applicants per available position peaked in 2009 with 1.45 applicants per position. However, by 2015 this number dropped to a striking 1.03 applicants per position. The NRMP reports allow us to draw a distinction between U.S. seniors and non-U.S. seniors. From 2009 to 2012 the ratio of U.S. senior medical students to non-U.S. senior medical students held steady at around .72. However, since 2012 this ratio has steadily decreased to a decade low of .55 in 2015, meaning that considerably fewer U.S. senior medical student applicants are interested in radiology. Of the cohort that is still interested in radiology, fewer are listing the profession as their only choice. In 2008 the number of radiology residency applications listing the profession as their only choice peaked at 92%. However, by 2015 the percentage of applicants listed radiology as their only choice has dropped to 68%.

Given these data it is not a surprise that radiology residency positions are left unfilled. Figure 7 shows the number of unfilled radiology residency positions over the last decade. From 2006 to 2010 we witnessed a steady decline in radiology residency positions unfilled, bottoming out at six in 2010. However, in the latest 2015 NRMP report the number of positions unfilled as increased to an astounding one hundred and fifty-one.

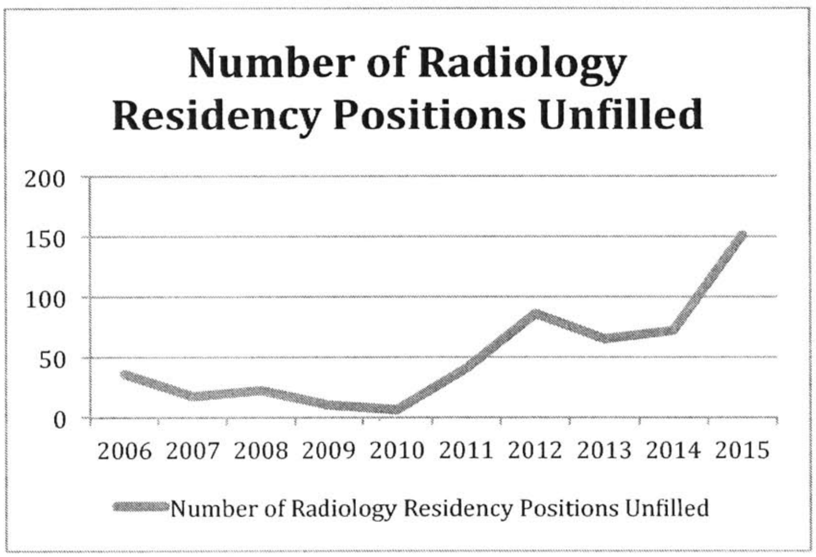


**Figure 7 – Radiology Residency Positions Unfilled**

The Google search data and National Resident Matching Program is revealing of the sentiments regarding the radiology profession and suggest the possibility of a future workforce shortage. The amount of time required to complete medical school with a specialization in radiology creates a lag effect, meaning that the decreased attractiveness of the medical specialty may take up to eight years to manifest as a workforce shortage.

## Growth of Medical Imaging Data

Healthcare reform in the U.S. is an ongoing process where reimbursements rates are continuously scrutinized to ensure maximum value for the healthcare system. Under the traditional fee-for service model, generous diagnostic radiology repayment rates led to substantial growth in the revenues tied to radiological services. However, the reimbursement rates began to stall between 2008-2013. During the same time period the volume of search query for radiology salary increased considerably and the interest in residency programs began to decline (refer to Figure 5 and to Figure 6). In this new ACO and mixed payer environment, radiology services that have traditionally been important contributors to the financial vitality of hospital institutions are at risk of shifting from profit centers to a cost centers (Seltzer and Lee 2014).

Medicare Part B is federally funded medical insurance that covers services and supplies considered medically necessary to treat health conditions. Each year, the Medicare spending and procedural volume data is made available to the public for analysis. This data becomes the basis for research conducted by the Harvey L. Neiman Health Policy Institute (HPI), who has aggregated Medicare part B data for analysis.

In this analysis, procedures identified using Berenson-Eggers Type of Service Code (BETOS) was applied to Medicare Part B Physician/Supplier Procedure Summary Master Files to determine the radiology imaging procedure volume and spending levels between 2003 and 2013. Data is provided by HPI and represents the U.S. national records, including data from US territories.

Between 2003 and 2008, the number of imaging examinations interpreted by diagnostic radiologists almost doubled, increasing from 171 million to 303 million. 2008 through 2011 represents a period of declining procedural volume, dropping to 260 million. The data suggest the decline is beginning to stabilize at around 250 million (refer to Figure 8).

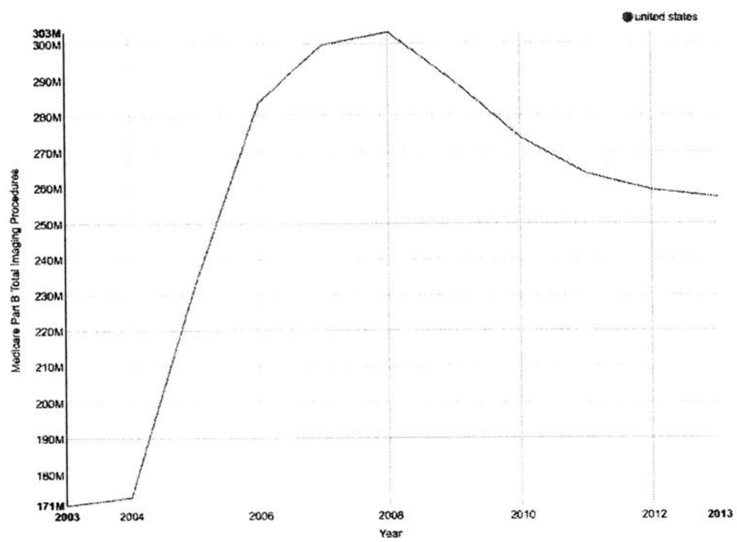


**Figure 8 - Medical Part B Total Imaging Volume (*Harvey L. Neiman Institute - CMS Physician/Supplier Procedure Summary* 2015)**

While the national Medicare part B imaging procedure data reflects a sharp increase and moderate decline before stabilizing, not all healthcare institutions have a large Medicare payer mix. In the following analysis, the Massachusetts General Hospital (MGH) Picture Archiving and Communication System (PACS) was queried to display the number of imaging studies for each calendar year from 2004 through 2014. These results include both inpatient and outpatient imaging exams and are plotted in Figure 9 below.

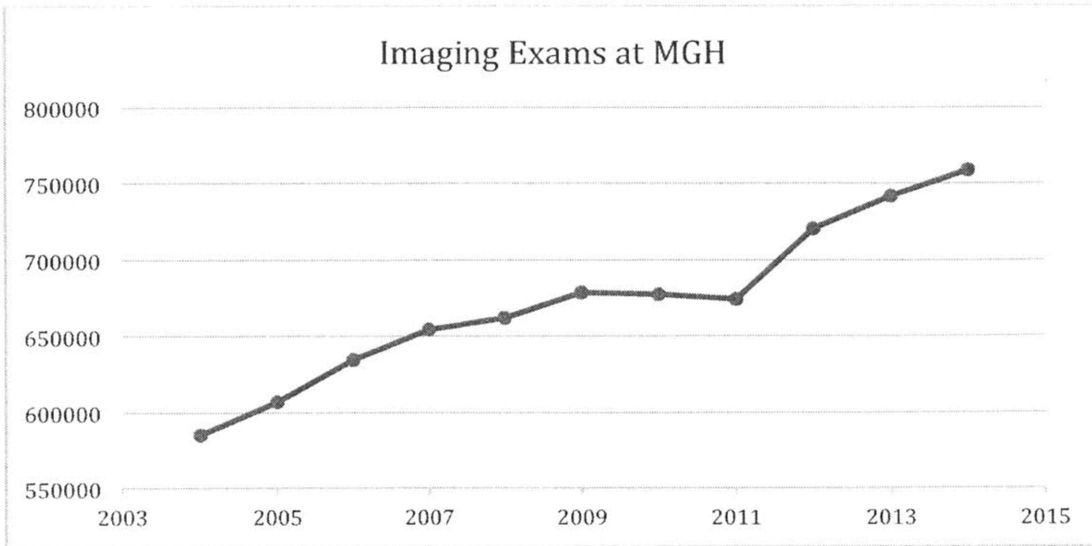


**Figure 9 - Study Volume at Massachusetts General Hospital**

The interpretation techniques used by radiologist are utilized for both screening and diagnostic purposes throughout the care delivery chain, becoming a standard of care for many major medical conditions including cancer. Cancer is a major health problem in the U.S. and around the globe. In 2015 alone, 231,840 women in the U.S. were diagnosed with breast cancer and 40,290 died from the disease (Siegel, Miller, and Jemal 2015). However, it is well documented that early detection is a key defense to combat cancer. In many cases an imaging exam is the first step in identifying the disease. Mammograms, or breast imaging examinations, are commonly used to check for breast cancer in women who may have no signs or symptoms. According to the data published by HRI, between 2004 and 2013, the number of mammography examinations interpreted by diagnostic radiologists, increased from 10.4 million to 13.8 million (refer to Figure 10).

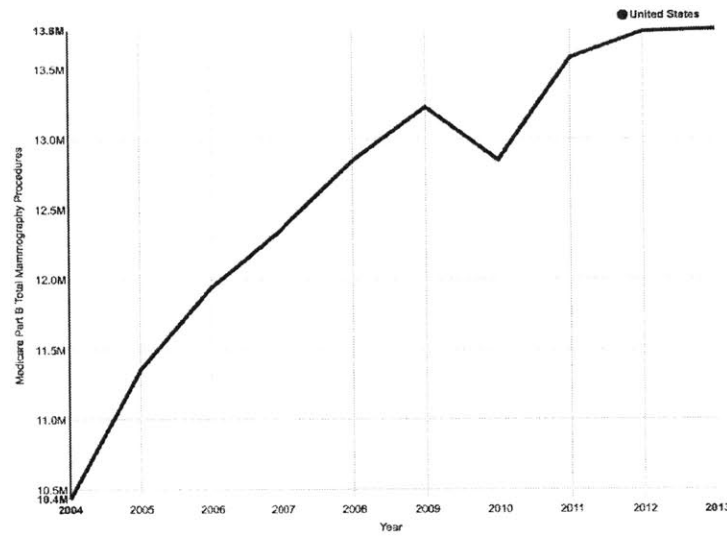


**Figure 10 - Medical Part B Total Mammography Procedures (*Harvey L. Neiman Institute - CMS Physician/Supplier Procedure Summary* 2015)**

Screening mammograms help to lower mortality rates and are widely viewed as a gold standard for breast care. During these examination, the radiology technician will typically acquire an image of each breast from the top view, referred to as cranial caudal, as well as a side profile view of each breast referred to as mediolateral oblique. Thus, radiologists are tasked with reviewing 4 total images per patient mammogram for the presence of breast cancer. Unfortunately there are limitations that can prevent proper diagnosis during these mammography screenings. Research suggests that dense breast tissue lowers detection rates by is obstructing radiologists' view of regions that would otherwise be flagged as suspicious.

Recent R&D efforts have led to advances to medical imaging technology that are poised to improve the visualization and characterization of abnormalities. 3D mammography, or Digital Breast Tomosynthesis (DBT), was developed to aid in the detection of lesions in dense breasts. Similar to standard 2D mammography, a DBT image is formed using x-rays. However, during DBT imaging the x-ray tube is moved in an arc during the exposure period. A reconstruction algorithm is used to remove tissues surrounding the plane to construct a 3D stack, or volumetric, set of the breast images (Destounis and Gruttadauria 2015).

The clinical studies used for regulatory approval can be characterized as comparing radiologists' performance when reading traditional 2D imaging with their performance reading 3D DBT images (either as a compliment or alone). By adding the 3D imaging as a compliment to the 2D imaging, the studies have found that there was a 30% reduction in recall rates in the examinations that were free of cancer. On the other hand, DBT alone was able to reduce recall rates by 10% (Gur et al. 2009). These innovations are fueled by the demand for better evaluation and characterization of suspicious lesions in the breast. However, these studies fail to evaluate the impact on the radiologists in terms of the amount of time spent reading each case as well as the reading complexity.

Digital breast tomosynthesis can involve either one or two imaging series per breast depending on the manufacturer. For General Electric's (GE) new SenoClair breast tomosynthesis product, an average of 65 radiological images are acquired per DBT volume of the breast. Thus, instead of reading 4 images per patient mammogram, radiologists will now be tasked with reading 130 images per patient mammogram (65 x 2).

3D mammography facilitates better patient outcomes by improving reader sensitivity and specificity; however, the avalanche of new of imaging data increases overall interpretation burden. In fact, a recent study set out to examine the logistical impact of 3D mammography screening by comparing the acquisition time and reading time of 2D and 3D mammography. The study found that 3D mammography prolongs the screen-reading time. The average reading time for a 2D mammography study was 33 seconds, compared with 77 seconds for 3D mammography (Bernardi et al. 2012).

This 133% increase in reading time is indicative of a larger problem – new modalities that improve patient care have the effect of increasing the reading burden for the radiologists who are responsible for interpreting the exam. These incremental jumps in image volume become unsustainable over the long run. New imaging modalities and viewing techniques also give rise to findings that are secondary to the original reason that the test was ordered, otherwise known as an "incidental finding". For example, a radiologist might identify unexpected pulmonary nodules during a chest exam. The frequency of incidental findings can vary by imaging modality, clinical, and reporting guidelines; however, studies have found that the average rate of reported incidental findings is around 24% (Radhiana et al. 2014).

## Inattentional Blindness

Despite the increased prevalence of incidental findings discovered using new imaging techniques, publications have highlighted a phenomenon known as "inattentional blindness", where people miss the occurrence of an unexpected but obvious event when they are engaged in a different task. While most of the inattentional blindness demonstrations have focused on naive observers involved in an unfamiliar tasks, a study conducted by the Visual Attention Lab at Boston Brigham and Women's hospital set out to see how expert radiologists with years of training would respond to a significant abnormality artificially burnt into medical images.

In this study, 24 radiologists were asked to find nodules within the lung while reviewing a computed tomography (CT) acquisition of the chest. What they didn't know is that a gorilla that was 48 times larger than the size of an average nodule was burnt into five consecutive slices of the last case that they reviewed. Surprisingly, an astounding 20 of the 24 radiologists, or eighty-three percent, missed the presence of the gorilla. The study finds that radiologists program his or her brain to search for specific patterns that are indicative of a particular disease, thus their attention is focused on a specific goal. Eye-tracking software was used in conjunction with the study in an attempt to shed some light on the nature of the missed finding, which found that the majority of those who missed the gorilla actually looked directly at its location for an average of 329 milliseconds, spending an average of 5.8 seconds viewing the five slices (Drew, Võ, and Wolfe 2013). While radiologists performed better than non-radiologists, the study indicates that even expert visual observes in their domain of expertise are not immune to inattentional blindness. The authors also suggests that a phenomenon known as "satisfaction of search", where the detection of one stimulus interferes with the detection of subsequent stimuli, could have played a role in the study as the gorilla was placed on a slice that contained a lung nodule.

The phenomenon highlighted in the invisible gorilla paper has significant clinical implications – it suggests that radiologists' ability to detect incidental findings is severely compromised after reviewing the imaging test referral information and viewing the patient's medical history. This inherent human limitation coupled with the explosion of imaging data present a troubling conundrum for radiological patient care.

**An Aging Population**

As demographics change and life spans increase so does the demand for healthcare services. Radiology plays a particularly important role in the care of elderly patients, in whom complex medical conditions and the high prevalence of disease necessitates diagnostic imaging exams.

The elderly demographic is the fastest growing segment of the population. The population age 65 and over has increased 24.7% to 44.7 million since 2003. The number of Americans aged 45-64 who will reach 65 in the next two decades increased by 20.7% between 2003 and 2013 (Administration on Aging 2014). The growth of the elderly population is not only attributed to new comers who are reaching the age of 65, but also to people who are living longer. Those born in the USA 1970 could expect an average life expectancy of 70.8 years. By comparison, those born in the USA in 2010 can expect an average life expectancy of 78.7 years, an increase of 11% (Kochanek et al. 2013).

Family physicians and primary care practitioners often refer geriatric patients to radiologists to test for a number of disorders that are more prevalent in an elderly cohort. Common referrals may include image-based tests for cardiovascular disease, cerebrovascular disease, respiratory disease, musculoskeletal disease, and gastrointestinal disease, to name a few (O'Brien et al. 2009). This shifting demographic and longevity revolution is poised to increase the utilization of radiologic tests and procedures. Based on the demographic changes and expanding medical coverage, studies predict that the overall demand for radiology services will increase 18% between 2013 and 2025 (Dall et al. 2013). Failure to grow the radiology workforce sufficiently or to adopt technology that enable radiologists to work smarter, faster, and more effectively could reduce access to care for the nation's most vulnerable patient populations.

### Clinical Turf Wars

Clinical leadership makes decisions that are in the best interest of the patient. However, some innovations are desirable for patients and some members of the clinical community while being detrimental to other. Innovations can lower revenues or shift care responsibility from one specialty to another. This kind of paradox is often referred to as a "turf war".

Many healthcare innovations have a desirable, direct, and anticipated consequence to the patient. While a priority of healthcare professionals is to accept innovations that lower cost, improve quality, and increase patient satisfaction, the reduction of uncertainty in a healthcare context is an inherent element of the mission. The following examples represent a few current and prospective clinical turf wars:

- **Non-Radiologist Performing Tests** - Innovations and cost reductions in ultrasound technology make it an attractive diagnostic tool for the primary care physician looking to better serve the patients. Adoption of ultrasounds in primary care facilities threatens a reduction in referral volume to the radiologist, who would traditionally perform such a test.
- **Radiologists Performing Non-Radiology Tests** - Radiology is considered a provisional diagnosis, whereas pathology is an actionable diagnosis resulting in therapy selection. However, computer algorithms designed by pairing medical imaging data with pathological results could one day provide an actionable

diagnosis, eliminating the need for many pathological services (Foran, Chen, and Yang 2011).

- **Blurred Specialty Boundaries** - Innovations in optical endomicroscopy allow pathologies to be imaged in situ and in real time without the need to extract and process specimens as a conventional biopsy and histopathology (Carignan and Yagi 2012). This paradigm shift could fuse radiology and pathologies medical specialties, which have historically been discrete medical specialties.
- **Commoditization through Teleradiology** - Teleradiology is the application of telemedicine in the radiology domain, that is, providing radiological services from afar. After image acquisition the image is sent electronically to radiologists practicing outside of the healthcare network that reviews the image on their computer monitor or mobile device. Adoption of telemedicine technology provides healthcare systems with access to subspecialists from around the globe.

The diffusion of innovation is concerned with the influences on each stakeholder within the healthcare system, each of who has an impact on the adoption of new ideas. Often the adoption of an innovation is advantageous for one member within the social system while being detrimental to the others.

**Summary**

Radiology is facing major challenges as it attempts to keep pace with the demand for its services. During the past decade, online web search information is indicative of a concern over radiologists' salary and the interest in radiology residency programs is dwindling. New imaging modalities are contributing to an explosion of new imaging data. An aging population and expanded medical coverage suggests that radiological exam volumes will continue to rise despite the workforce shortage. While the adoption of innovative technologies is never easy, this perfect storm of professional and patient care challenges will undoubtedly impact the pace of adoption for many radiological innovations.

# Chapter 5 – Conclusion

## Summary and Discussion

Scholars have observed patterns of product and process innovations as it relates to industrial progress in both assembled and non-assembled products (Utterback 1996). Prior work, however, was inspired by mechanical and analog products and not necessarily the delivery of medical care in a digital age. This study demonstrates the historical interrelationship between product and process innovation, specialized equipment and increased labor specialization in the delivery radiological medical services. While this historical relationship is telling, innovation remains a highly uncertain process that involves a number of forces. As such, this study has demonstrated a number of factors that exist within the current climate of radiology that may impact the pace and direction of future innovations.

Innovations in radiology can broadly be placed into one of two categories: new imaging modalities that improve radiologists' view of the body, or process improvements to better manage the view of the body. Each of several innovations to image acquisition, interpretation and storage in radiology involved a combination or elimination of steps. These changes in process architecture, from the battlefields during the late 1800s to today's advanced hospital workflow, have resulted in dramatic productivity gains.

A central point in evolution of this industry is the role of specialized equipment and labor specialization. While pioneering physicians were responsible for all aspects of radiology (image acquisition, film development, film interpretation, and storage), increased demand for their services helped them to realize the need for a trained hand, hence the rise of the radiological technician profession. During the same time period, advances to the x-ray source required increased power consumption, which had the effect of moving radiology from the battlefields and into the hospital or office setting. Fast forward almost a century and digital workflows enabled through specialized equipment such as networking technology, digital sensors and PACS have given rise to a third discrete profession, the PACS administrator. Today, each of these professions has continued to evolve to include a number of sub-specialties.

Despite the many successes over the last century, radiology today faces many major challenges and uncertainties. Interest in U.S. radiology residency programs is dwindling and the concern over salary is on the rise. An aging population and expanded medical coverage suggests that radiological exam volumes will continue to rise despite the workforce shortage. Moreover, new imaging modalities aimed at improving the view of the human body are contributing to an explosion of new and complex imaging data. This perfect storm of professional and patient care challenges will undoubtedly impact the direction of many future innovations. While not comprehensive, the ideas herein are intended to provide clinicians, engineers, managers, and entrepreneurs with insight and action ideas for future innovations in radiology.

Today's clinical workflow is represented in Figure 11 below. Patients are imaged within a hospital or office setting before the resulting image data is sent to PACS for long-term storage as well as to review workstations for interpretation. At the review workstation, radiologists are provided with the patient's medical history through the EHR before reviewing the image data and creating the report. The report is sent to EHR for long-term record keeping, as well as to the referring physician.

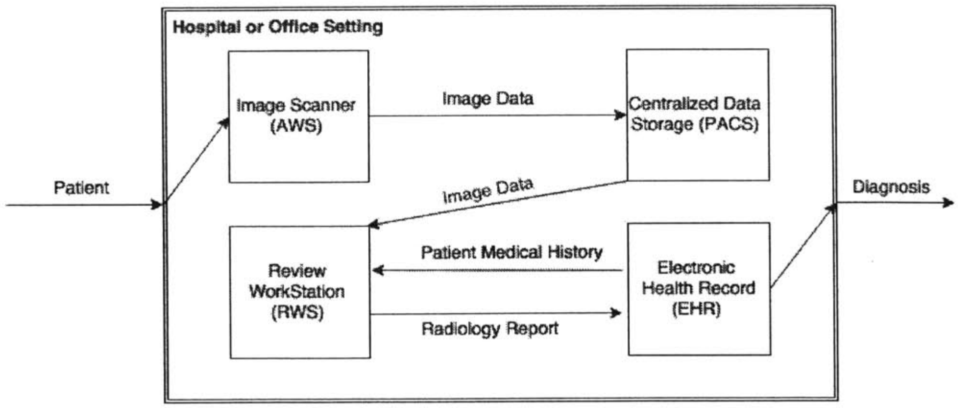


**Figure 11 - Today's Radiology Process Workflow**

Figure 12 below plants the seed for future innovations to the clinical workflow by removing the boundaries as we know them today. In this imagined environment, image acquisition, interpretation, and storage are decoupled from the hospital setting. New imaging modalities may image patients at home or on the go, potentially even before symptoms are demonstrated. PACS and EHR technology that have traditionally been confined to hospital networks may move entirely to the cloud. Similarly, review workstations and the radiologists who operate them may increasingly have the ability to interpret patient data from anywhere on the globe.

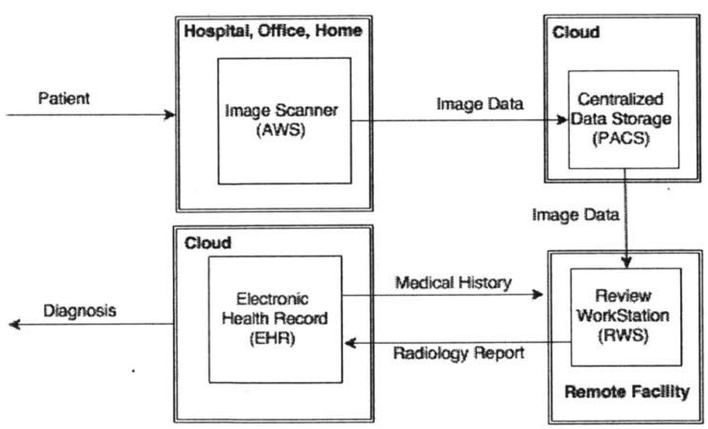


**Figure 12 – Imagined Clinical Workflow**

The field of radiology has largely evolved through incremental changes in process architecture that either combined steps or eliminated steps altogether. Throughout this evolution, diagnostic interpretation has transitioned from directly reading individual patients in the battlefields to reading patient images in batches in a hospital or office setting. Continuing on this path of innovation, tomorrow's clinical workflow may further evolve to continuous review by highly specialized radiologists. This notion supports the idea of high-volume teleradiologists who are responsible for the continuous interpretation of patient cases of a specific nature. Additionally, new computer algorithms, referred to as machine learning or deep learning algorithms, are beginning to demonstrate the ability to outperform humans in certain image analysis tasks. This rise in the performance of image algorithms may one day facilitate the elimination of human driven radiological interpretation all together. However, the precipitous elimination of Radiology as a medical specialty is unlikely as human interpretation will not be replaced over-night. Instead, we're likely to first transition into a period where image algorithms play an increasing role in radiological interpretation, working hand-in-hand with the radiologists. In the end, radiologists will continue to evolve along with the technologies – perhaps gaining an increasing role in patient care decisions through the upstream interpretation of medical or genetic information or the downstream pairing of radiological data with pathological data.

**Limitations and Future Works**

The model of innovation presented by Professor James Utterback developed a relationship between product and process innovations, labor specialization, and the state of an industry among others. This dynamic model of innovations has been demonstrated in the production of both assembled and non-assembled mechanical and analog products, and following this study in the delivery of radiological medical care in a digital age. Related future studies could build on this work through an analysis of other medical specialties, services, and products. Innovation is an uncertain process that involves a number of forces and even a bit of chance. As such, the identification of patterns of innovation in medical imaging technologies and radiology does not suggest that future innovation is necessarily predicable. Related future studies could also build on these findings by taking a closer look at individuals, firms, and emerging technologies that may help to drive the next generation of innovation and progress to the radiology industry.

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# Appendix

**Table 1 - Google Search Data**

| Year-Quarter | Total Radiology Residency Topics Search Data | Normalized Residency Topics Search | Total Radiology Salary Topics Search Data | Normalized Salary Topics Search |
|---|---|---|---|---|
| 2006 Q1 | 1023 | 0.602941176 | 190 | 0.01159047 |
| 2006 Q2 | 449 | 0 | 172 | 0 |
| 2006 Q3 | 1401 | 1 | 214 | 0.02704443 |
| 2006 Q4 | 1263 | 0.855042017 | 631 | 0.295556986 |
| 2007 Q1 | 803 | 0.371848739 | 867 | 0.447520927 |
| 2007 Q2 | 727 | 0.292016807 | 786 | 0.395363812 |
| 2007 Q3 | 1012 | 0.591386555 | 912 | 0.476497102 |
| 2007 Q4 | 933 | 0.508403361 | 880 | 0.455891822 |
| 2008 Q1 | 838 | 0.408613445 | 835 | 0.426915647 |
| 2008 Q2 | 838 | 0.408613445 | 805 | 0.407598197 |
| 2008 Q3 | 916 | 0.490546218 | 960 | 0.507405023 |
| 2008 Q4 | 929 | 0.504201681 | 1086 | 0.588538313 |
| 2009 Q1 | 884 | 0.456932773 | 1291 | 0.720540889 |
| 2009 Q2 | 729 | 0.294117647 | 1286 | 0.717321314 |
| 2009 Q3 | 871 | 0.443277311 | 1524 | 0.870573084 |
| 2009 Q4 | 817 | 0.386554622 | 1483 | 0.844172569 |
| 2010 Q1 | 863 | 0.43487395 | 1725 | 1 |
| 2010 Q2 | 650 | 0.211134454 | 1640 | 0.945267225 |
| 2010 Q3 | 873 | 0.445378151 | 1618 | 0.931101095 |
| 2010 Q4 | 749 | 0.31512605 | 1369 | 0.770766259 |
| 2011 Q1 | 731 | 0.296218487 | 1335 | 0.748873149 |
| 2011 Q2 | 642 | 0.202731092 | 1299 | 0.725692209 |
| 2011 Q3 | 716 | 0.280462185 | 1452 | 0.824211204 |
| 2011 Q4 | 717 | 0.281512605 | 1282 | 0.714745654 |
| 2012 Q1 | 686 | 0.24894958 | 1318 | 0.737926594 |
| 2012 Q2 | 574 | 0.131302521 | 1303 | 0.728267869 |
| 2012 Q3 | 682 | 0.244747899 | 1378 | 0.776561494 |
| 2012 Q4 | 719 | 0.283613445 | 1163 | 0.638119768 |
| 2013 Q1 | 685 | 0.24789916 | 1143 | 0.625241468 |
| 2013 Q2 | 590 | 0.148109244 | 1091 | 0.591757888 |
| 2013 Q3 | 643 | 0.203781513 | 1205 | 0.665164198 |
| 2013 Q4 | 671 | 0.233193277 | 1114 | 0.606567933 |
| 2014 Q1 | 604 | 0.162815126 | 1088 | 0.589826143 |
| 2014 Q2 | 515 | 0.069327731 | 1129 | 0.616226658 |

| Year-Quarter | Total Radiology Residency Topics Search Data | Normalized Residency Topics Search | Total Radiology Salary Topics Search Data | Normalized Salary Topics Search |
|---|---|---|---|---|
| 2014 Q3 | 528 | 0.082983193 | 1146 | 0.627173213 |
| 2014 Q4 | 571 | 0.128151261 | 1068 | 0.576947843 |
| 2015 Q1 | 538 | 0.093487395 | 1191 | 0.656149388 |
| 2015 Q2 | 492 | 0.045168067 | 1268 | 0.705730844 |
| 2015 Q3 | 450 | 0.00105042 | 1150 | 0.629748873 |

Results for search terms of “radiologist salary” and “radiology salary” aggregated in column 2 and normalized in column 3. Results for search terms radiology residency” and “radiology programs” are aggregated in column 4 and normalized in column 5 (“Data Source: Google Trends Sept. 4th, 2015,” n.d.).

**Table 2 – NRMP Radiology Diagnostic PGY-1 Data**

Data source: ("NRMP Main Match Results & Data 2006-2014," n.d.)

| Year | Number of Programs | Number of Rad positions Offered | Unfilled Programs | US Applicants | Total Applicants | Total Number of U.S. Matches | Total Number of Matches | Number unfilled | Non-US Applicants | Percent Filled |
|---|---|---|---|---|---|---|---|---|---|---|
| 2006 | 33 | 129 | 3 | n/a | n/a | 105 | 123 | 6 | n/a | n/a |
| 2007 | 36 | 141 | 0 | n/a | n/a | 125 | 141 | 0 | n/a | n/a |
| 2008 | 39 | 157 | 3 | 648 | 757 | 135 | 154 | 3 | 109 | 98.089172 |
| 2009 | 38 | 151 | 2 | 730 | 850 | 132 | 148 | 3 | 120 | 98.013245 |
| 2010 | 34 | 141 | 1 | 663 | 779 | 120 | 139 | 2 | 116 | 98.58156 |
| 2011 | 37 | 144 | 7 | 635 | 737 | 115 | 136 | 8 | 102 | 94.444444 |
| 2012 | 35 | 135 | 3 | 567 | 691 | 90 | 124 | 11 | 124 | 91.851852 |
| 2013 | 55 | 164 | 9 | 595 | 820 | 101 | 150 | 14 | 225 | 91.463415 |
| 2014 | 36 | 137 | 8 | 548 | 780 | 81 | 121 | 16 | 232 | 88.321168 |
| 2015 | 36 | 133 | 9 | 457 | 721 | 67 | 120 | 13 | 264 | 90.225564 |

**Table 3 – NRMP Radiology Diagnostic PGY-2 Data**

Data source: ("NRMP Main Match Results & Data 2006-2014," n.d.)

| Year | Number of Programs | Number of Rad positions Offered | Unfilled Programs | US Applicants | Total Applicants | Total Number of U.S. Matches | Total Number of Matches | Number unfilled | Non-US Applicants | Percent Filled | Total Number of Applicants |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2006 | 170 | 882 | 16 | 862 | 1220 | 708 | 852 | 30 | 358 | 0.965986395 | 26715 |
| 2007 | 170 | 902 | 7 | 941 | 1402 | 719 | 885 | 17 | 222 | 0.981152993 | 27944 |
| 2008 | 167 | 928 | 12 | 954 | 1364 | 758 | 909 | 19 | 410 | 0.979525862 | 49945 |
| 2009 | 166 | 944 | 3 | 1117 | 1543 | 816 | 937 | 7 | 426 | 0.992584746 | 51882 |
| 2010 | 163 | 949 | 2 | 1027 | 1431 | 799 | 945 | 4 | 404 | 0.995785037 | 52565 |
| 2011 | 164 | 980 | 17 | 940 | 1299 | 773 | 947 | 33 | 359 | 0.966326531 | 52040 |
| 2012 | 164 | 976 | 39 | 875 | 1219 | 741 | 901 | 75 | 344 | 0.923155738 | 53612 |
| 2013 | 158 | 979 | 30 | 865 | 1307 | 724 | 928 | 51 | 442 | 0.947906027 | 57,960 |
| 2014 | 188 | 1039 | 41 | 803 | 1408 | 695 | 983 | 56 | 605 | 0.946102021 | 58,525 |
| 2015 | 190 | 1023 | 56 | 680 | 1233 | 579 | 885 | 138 | 553 | 0.865102639 | 58,443 |

**Table 4 – NRMP Radiology Choice Data**

Data source: ("NRMP Main Match Results & Data 2006-2014," n.d.)

| Year | Total Number of Positions Offered | Radiology - Total Number of Positions Offered | U.S. Only Choice | U.S. First Choice | U.S. Not First Choice | Independent Only Choice | Independent First Choice | Independent Not First Choice | U.S. Only Choice as Fraction of U.S. Applicants | US only Choice Selections as Percent of Total Number of Positions Offered | Number of Radiology Residency Positions Unfilled |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2006 | 19805 | 1005 | 787 | 56 | 19 | 315 | 89 | 35 | 0.912993039 | 78.31% | 36 |
| 2007 | 20429 | 1035 | 844 | 73 | 24 | 305 | 113 | 43 | 0.896918172 | 81.55% | 17 |
| 2008 | 20836 | 1076 | 882 | 57 | 17 | 290 | 96 | 44 | 0.922594142 | 81.97% | 22 |
| 2009 | 21093 | 1087 | 1016 | 70 | 42 | 282 | 110 | 62 | 0.90070922 | 93.47% | 10 |
| 2010 | 21462 | 1090 | 914 | 89 | 30 | 269 | 117 | 45 | 0.884801549 | 83.85% | 6 |
| 2011 | 22067 | 1124 | 842 | 78 | 28 | 254 | 84 | 33 | 0.888185654 | 74.91% | 41 |
| 2012 | 25710 | 1111 | 557 | 300 | 24 | 182 | 134 | 49 | 0.632236095 | 50.14% | 86 |
| 2013 | 29171 | 1143 | 614 | 231 | 29 | 241 | 168 | 79 | 0.702517162 | 53.72% | 65 |
| 2014 | 29671 | 1176 | 502 | 278 | 29 | 255 | 192 | 70 | 0.620519159 | 42.69% | 72 |
| 2015 | 30212 | 1156 | 463 | 189 | 30 | 251 | 192 | 76 | 0.67888563 | 40.05% | 151 |