Prime Areas for Improvement in Skin Cancer Detection and How Technology Can Help

by

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B.S. in Mechanical Engineering
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Abstract

About 5 million cases of skin cancer will be diagnosed in the United States in 2015, making skin cancer the most common cancer diagnosis in the United States. About 13,000 Americans will die from skin cancer in 2015. Often skin cancers are diagnosed at later stages, are expensive to treat, and result in fatalities. For melanoma, responsible for 75% of skin cancer deaths, the overall 5-year survival rate is 98% for skin lesions detected in their early stages, and this survival rate drops to 16% after the disease has spread to other organs. If these fatal skin cancers were detected earlier they would cost less to treat and result in better patient outcomes.

There is no single resource available that maps the full state of the skin cancer care delivery, and most current views are colored by a stakeholder’s perspective. We connected with stakeholders at different levels of the skin cancer care delivery system to create an overall picture of the system’s current state and to identify gaps in care. We interviewed 9 skin cancer patients, 8 primary care physicians, and 9 dermatologists.

Through this research, we discovered that the structure of how skin cancer care is delivered promotes opportunities to miss skin cancers and includes many barriers between initial cancer suspicion and disease diagnosis. Frequently patients do not evaluate themselves for skin cancer, primary care physicians have low accuracy in identifying skin cancers, and dermatologists manage a very small portion of the population who develop skin cancers. At a higher level, feedback between patients and physicians is frequently lost in the system, physicians are not accountable for patient outcomes, and patient health is not supported by the system until the patient identifies a health issue and acts to remedy the issue. To close these system gaps, we identified technologies, including micro-biopsies and electrical impedance spectrometry, which could be used to improve rates of skin cancer identification and promote better patient health outcomes. Additionally, we recommend physicians find a way to collaborate on cases, identify their own weaknesses in assessment, and capture patient outcomes to relay incorrect assessments to other physicians to improve future patient care.

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Title: Principle Research Scientist, MIT Department of Mechanical Engineering & Director, MIT Master of Engineering in Manufacturing Program
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Chapter 1: Introduction

Many people are diagnosed with skin cancer each year, and some discover their skin cancers early while others discover them at late stages. This section introduces the skin cancer care delivery system, justifies the case for investigating skin cancer care, and establishes the organization of this thesis.

1.1 - Background

Skin cancer is the most common form of cancer worldwide and the only one cancer of the top seven most prevalent cancers that is increasing in incidence (Howlader et al. 2015). Three types of skin cancer account for 99% of skin cancer incidence: basal cell carcinoma, squamous cell carcinoma, and melanoma (U.S. Department of Health and Human Services 2014). As most skin cancers appear visibly on the surface of the skin, three major components contribute to increased patient mortality, increased medical costs, and significant long-term cosmetic effects: delays in detection, delays in diagnosis, and delays in removal (Eriksson et al. 2014).

Melanoma is the most fatal type of skin cancer accounting for only 4% of skin cancer cases yet 75% of skin cancer deaths in the US (American Cancer Society 2015a). About 73,000 cases of melanoma will be diagnosed in the US in 2015 and about 10,000 people will die from melanoma this year (American Cancer Society 2015a). The mortality rate in the population has remained consistent over the past 10 years (Howlader et al. 2015). Emphasis in proper treatment in the medical community for specialized diseases such as skin cancer are often put to specialists, yet more primary physicians than dermatologists diagnoses melanoma each year (Koh et al. 1992, 918).

Sensor technologies and communications have significantly advanced in the past 20 years, allowing for low-cost medical diagnostics to improve objectivity in diagnosis, increase critical communication within the medical community, and empower primary physicians and patients to better manage patient health. While low-cost imaging technologies have already been identified to do simple tasks like scan high-quality images of eyes to determine prescriptions ("EyeNetra - Eye Care for 2.4 Billion People in Need" 2015), but most skin cancers are reviewed qualitatively and subjectively by a mix of family, friends, and physicians prior to biopsy and diagnosis by a pathologist. The objective of this thesis is to identify areas of improvement in skin cancer detection within the US healthcare system, understand use case restrictions of various
stakeholders, and establish available and applicable technologies that can drive improved patient outcomes through matching clinical insight with viable technologies.

Primary research included twenty-six qualitative, in-person and phone interviews with skin cancer patients, primary care physicians, dermatologists, and dermatological surgeons in California, Ohio, Utah, Texas, Alabama, Massachusetts, and Florida. The skin cancer patients interviewed ranged in age from 29 to 72 years old, and physicians interviewed ranged from medical residents to physicians with more than 30 years of experience. Patients were asked questions related to their personal experiences with skin cancer, their habits for managing their care today, how they’ve interacted with the greater medical care delivery system in the United States, and general lifestyle. Physicians were asked about how they examine and treat patients for skin cancer, how patients are processed in their office, how they interact with other physicians, and their biggest challenges with skin cancer detection and care.

All interview subjects were informed that the study was to investigate new ways to use technology to improve early detection of skin cancers. MIT’s Committee on the Use of Humans as Experimental Subjects (COUHES) approved this research. The purpose of this method of interviewing was to identify the perspectives of each stakeholder in the early detection and delivery system, identify challenges to early stage detection not previously identified through a literature search, and identify opportunities to successfully introduce technologies in the skin evaluation process- ultimately to improve early stage detection to drive better long-term patient outcomes.

1.2 - Thesis Organization
The remainder of this thesis is organized as follows:

- Chapter 1 highlights the motivation for evaluating the skin cancer detection process and the interview method selected to evaluate the overall system.
- Chapter 2 details the three most prevalent types of skin cancer and biological characteristics of each disease.
- Chapter 3 explains the current state of skin cancer delivery and sets the stage for later analysis.
- Chapter 4 extensively explores interview findings of skin cancer patients, primary care physicians, dermatologists, and oncology psychiatrists.
• Chapter 5 extensively establishes gaps in care and areas for improvement with two complimentary models to highlight control issues and dynamic challenges in skin cancer care delivery.

• Chapter 6 explores the technology side of skin cancer detection, establishing current technologies, evaluating potential technologies, and selecting feasible technologies to improve the standard of care.

• Chapter 7 connects the technology exploration with use case requirements and missing information.

• Chapter 8 establishes a model for improved prevention and detection methods based on Australia’s successes and failures.

• Chapter 9 concludes the research, proposing improvement methods to shrink gaps in care, establishing future work, and providing advice for stakeholders in the system.
Chapter 2: Skin Cancer as a Disease

There are multiple types of skin cancer, each with many different types of clinical presentations. This chapter will establish the characteristics and nuances of the most common and fatal types of skin cancer to illustrate the specifics of what is known today, how cancerous lesions are identified, and the biological factors at play in a skin cancer’s growth and development.

2.1 - General Skin Cancer

This section will provide a general overview of the most relevant characteristics of skin cancer and introduce each of the three most common types of skin cancer.

Skin Cancers: A General Biological Overview

Skin cancers range between types that grow slowly and are not likely to spread throughout the rest of the body, (e.g. basal cell carcinoma), to types that are much more likely to spread throughout the body in short periods of time, (e.g. melanoma). There are estimated to be over 5 million cases of skin cancer diagnosed in 2015, and incidence of all types of skin cancer is rising (American Cancer Society 2015a). The high incidence of this disease contributes to a major portion of US healthcare costs (Baldi, Pasquali, and Spugnini 2013, 18). From 2007 to 2011 the estimated average annual cost associated with skin cancer was $8.1 billion according to the CDC (“US Skin Cancer Costs Rise from 2002 through 2011” 2015). The incidence of skin cancer has increased at an estimated rate of 4.2% per year over the past 20 years, suggesting that incidence will continue to rise (Rogers et al. 2010).

Skin cancers affect both young and old, with melanoma cited as the most common type of skin cancer in the 25-29 age range in the US, though the disease is much more common as people age (Howlader et al. 2015). Additionally, skin cancer has increasing incidence and is diagnosed at later stages with a poorer prognosis in minority populations in the United States such as Hispanics and African Americans (Baum and Duarte 2015). Skin cancer is typically found on the surface of the skin in sun-exposed areas, such as the face, neck, arms, and legs, but can also be found in areas that are very rarely exposed, including the back, chest, palms, genitals, and toenails. All skin cancers are malignant, meaning that they can invade nearby cells, but they
may not be invasive, meaning they can take over other surrounding tissues. Skin cancers can grow in people of many different ages, ethnicities, and all different parts of the body.

Skin cancer is prevalent globally, but is especially common in the US, Australia, New Zealand, the UK, and western and northern European countries. These countries correspond to populations with lower pigmentation in their skin. Though these are areas of high incidence, skin cancer is not limited to these regions. For example, one specific type of melanoma, acral lentiginous melanoma, is most common in Asian and African populations, and frequently appears on the palms of hands, soles of feet, and underneath fingernail and toenail beds.

Skin cancers, like most cancers, increases in likelihood based on a combination of genetic factors and environmental factors. Cancer forms when DNA is damaged and cannot repair itself (Baldi, Pasquali, and Spugnini 2013, 30). Damage to DNA is a function of an individual’s genetics and external factors (Baldi, Pasquali, and Spugnini 2013, 33), and DNA must undergo multiple functional changes to actually develop into a cancer. This process will be detailed in later sections.

**Skin Cancer Types**

There are many types of skin cancer: the most common types are listed below and will be examined in detail in the rest of this chapter. These skin cancers make up over 99% of skin cancers diagnosed in the United States. This section will dive into detail for each of these types of skin cancer, what contributes to them, how they grow, and how they are diagnosed today.

- Melanoma
- Basal Cell Carcinoma
- Squamous Cell Carcinoma
2.2 - Melanoma

Melanoma is the most fatal type of skin cancer, responsible for less than 4% of skin cancer cases in the US (with an estimated 73,000 melanoma cases expected in 2015) and the vast majority, 75%, of skin cancer deaths (American Cancer Society 2015a). Melanoma has the fastest growth rate of all skin cancers (Baldi, Pasquali, and Spugnini 2013).

**Melanoma: What is it?**

Melanoma is a malignant tumor of melanocytes, which are cells located within the skin's outer layer called the epidermis (Nosé 2014, 8). The epidermis and melanocytes can be seen in Figure 2.2. These cells produce melanin, and melanin in the skin affects an individual's skin pigmentation. Because melanoma is most commonly a collection of irregular pigmented cells, it is often recognized for its color, pattern, and growth irregularities compared with other pigmented skin spots on an individual's body, but melanoma can also be detected based on itchiness, ulceration, growth speed, and other factors significant to that skin spot compared to other spots on a patient's body. This information was discovered based on interviews with primary care physicians and dermatologists for this research.
**Who is impacted?**

Melanoma may occur at any age and across ethnicities, but is much more frequently found in individuals with fairer skin, with red or blonde hair, and older individuals. Melanoma is most commonly found in adults but also can be found in children, particularly children with genetic disorders of DNA repair, like the disorder xeroderma pigmentosum (Nosé 2014, 12). Visual risk factors for developing melanoma include freckles and moles induced by solar irradiation, a history of severe blistering sunburns, and an individual’s inability to tan (Borden 2002; Hong 2010, 1459). Environmental factors contributing to the likelihood an individual will generate melanoma include living closer to the equator, living in a tropical area (Nosé 2014, 8), intermittent heavy exposure resulting in sunburns (Borden 2002, 4), immunosuppression, and artificial light such as light generated by tanning beds (Borden 2002, 4). One genetic factor known to contribute to the likelihood of a melanoma diagnosis is a mutation in tumor suppressor genes (Nosé 2014, 8), and there are many others.
Melanoma: Clinical Diagnosis

Melanoma may appear anywhere on the skin, and is more common on legs in women and on the back in men (Nosé 2014, 8). Up to 33% of melanomas start from a preexisting mole, but many do not (Nosé 2014, 9). Melanomas are demarcated by a few different characteristics most commonly visually detected: A melanoma is often pigmented and has variegated colors with shades of tan, brown, black, blue-black, red, gray, or white. It can have irregular jagged borders, an irregular raised surface, be asymmetric, show ulceration, or change size or color quickly (Nosé 2014, 9–10). Pigmentation is often distinctly different from other moles, but in rare cases a melanoma is not pigmented and determined to be amelanotic, around 2-8% of cases (Ungureanu et al. 2015).

Currently melanoma is evaluated through visual and tactile characteristics on the surface of the skin during a physician’s visit: pigmentation size and pattern, feel, elevation, comparison to skin type, comparison to other moles on the patient, and information asked of the patient about the skin lesion, such as how quickly the mole has grown. This information was gathered through patient and physician interviews. Physicians also take into account other factors in selecting moles to send to the pathologist for evaluation, such as the patient’s personal and family history. Patients most frequently discover melanoma, but physicians, family members, and friends often play a role in initial identification or concern (Koh et al. 1992).

Patient Identification

The standard of identifying melanoma has been the ABCD method since the 1970s (Rigel, Russak, and Friedman 2010), with an “E” added fairly recently in 2004 (Tsao et al. 2015). These features are taught to patients to aid in at-home identification and are the backbone for public health campaigns targeting early stage melanoma detection.

A – Asymmetry – The shape of one half does not match the other half
B – Border irregularity – The edges of the mole are ragged, notched, or blurred
C – Color that is uneven – Shades of black, brown, or tan, are common, but areas of white, gray, red, pink, and blue are also possible
D – Diameter greater than 6mm (the size of a pencil eraser)
E – Evolving – The mole has changed in the last few weeks or months

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MIT SDM Thesis
Additionally there are free booklets and online resources to assist patients with at-home identification of suspicious lesions (National Cancer Institute 2010). Typically these instructions include guidance on identifying suspicious moles by applying the ABCDEs, noting other irregular features common in melanomas, and providing guidance and steps for at-home full body exams.

**Melanoma: What's going on in the body**

Like many cancers, an individual’s likelihood for developing skin cancer depends on biological and environmental factors, and each cancer is different. A malignancy forms when DNA has been damaged and the DNA cannot repair itself. A cell mutates to generate the characteristics required for a cancerous cell to grow and multiply at a faster rate than other cells (Baldi, Pasquali, and Spugnini 2013, 33). Two characteristics exhibited are behaviors by proteins: cell reproduction is uncontrolled and cells override their built-in self-destruct mechanisms to never undergo cell “death” (Crowson, Magro, and Mihm 2006, 373). Normal melanocytes have controlled growth, as keratinocytes control the melanocyte growth activity. In the case of melanoma, the cells do not require external growth factors in order to promote continuous growth and consume more and more of the body’s resources (Crowson, Magro, and Mihm 2006, 378).

Additionally, melanin is one of the main contributors to a skin’s pigmentation, and can play a significant role in the development of melanoma. There are two types of melanin: one type, eumelanin, is a black-brown pigment. Normally UV exposure increases the creation of eumelanin in the skin to protect against future free-radical damage for future UV exposure. The other type of melanin, pheomelanin, is a red-brown pigment in the skin, and pheomelanin when exposed to UV radiation, generates a potentially carcinogenic compound, increasing the likelihood of melanoma development (Panzella et al. 2014). Redheads have higher amounts of pheomelanin in their skin and hair, predisposing them to increased production of pheomelanin and ultimately increased risk of developing melanoma (Panzella et al. 2014).

As most melanocytes in the skin are located in the epidermis, close to the epidermal-dermal junction, most melanomas evolve in this level of the skin as well (Hong 2010, 1460). This can be
seen in Figure 2.2. On a cellular and cross-sectional level, melanomas exhibit different patterns than normal skin, including higher mitotic rates (the number of cells multiplying in a given volume), vertical directional growth, irregularity in growth, patterns of “nests” of melanocytes, and bands of fibrous tissue (Nosé 2014; Hong 2010; Borden 2002). These are the visible characteristics that pathologists evaluate when examining biopsied skin lesions under a microscope.

Types of Melanoma
There are many types of melanomas, often distinguished based on their growth patterns, visual characteristics, and places they appear on the body. The most common types are lentigo maligna melanoma, superficial spreading melanoma, nodular melanoma, desmoplastic melanoma, acral lentiginous melanoma, and nevoid melanoma (Nosé 2014, 9). Superficial spreading melanomas account for approximately 70% of melanomas and exhibit typical ABCD (asymmetry, border irregularity, color variegation, and a diameter larger than 6 millimeters) characteristics (Shaikh 2012). Nodular melanomas account for 10-15% of melanomas but do not show typical ABCD characteristics. These are the fastest growing melanomas, growing vertically from the start, and are frequently not identified at early stages. Nodular melanomas account for 37% of skin cancer deaths (Shaikh 2012).

Melanoma Growth
Melanoma is staged based on how deep the tumor has grown into the body, as this metric, known as Breslow thickness, is the strongest indication of advancement of the disease and long-term health outcomes (Liu et al. 2006). Melanoma growth rates significantly vary, as some lesions can metastasize in less than one month while others take over 5 years (Tejera-Vaquerizo et al. 2012; Borden 2002, 6). Almost all melanomas grow radially first then vertically (Borden 2002, 6). One or more darker, raised nodules in the lesion indicates vertical growth (Borden 2002, 6). Evaluating melanoma growth speed is difficult, as lesions are frequently biopsied or removed once they are suspected to be melanoma. The primary method to evaluate growth speed is patient recollection of the lesion growing. Lieu and Dowling evaluated growth speed by asking patients to recollect when the lesion started changing, and they established that one-third of melanomas grew 0.5 mm per month or faster (2006). The pathogenic mechanism of quick vertical growth in melanomas is not well known at this time (Baldi, Pasquali, and Spugnini 2013, 19).
<table>
<thead>
<tr>
<th>Melanoma Type</th>
<th>% of US Melanomas</th>
<th>Growth Pattern</th>
<th>Visible Characteristics</th>
<th>Location on Body</th>
<th>Median Age</th>
<th>Ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial spreading melanoma</td>
<td>70%¹</td>
<td>Radially then vertically</td>
<td>ABCDEs</td>
<td>Trunk, legs, feet, many others</td>
<td>40s²</td>
<td>Primarily non-Hispanic whites²</td>
</tr>
<tr>
<td>Nodular melanoma</td>
<td>15%¹</td>
<td>Vertically</td>
<td>“E” – Evolving, dark pigmentation, outward growth, can be amelanotic</td>
<td>Chest, head, and neck in normal skin</td>
<td>53³</td>
<td>White, black, Pacific Islander²</td>
</tr>
<tr>
<td>Lentigo maligna melanoma</td>
<td>13%¹</td>
<td>Radially, over several years</td>
<td>ABCDEs</td>
<td>Face and neck</td>
<td>Elderly²</td>
<td>Non-Hispanic whites and American Indian²</td>
</tr>
<tr>
<td>Acral lentiginous melanoma</td>
<td>2-3%¹</td>
<td>Radially then vertically</td>
<td>ABCDEs, stripe on fingernail, can lack color¹</td>
<td>Feet (soles, nails), Hands (palms, nails)¹</td>
<td>63¹</td>
<td>Dark-skinned (black, Asian, Hispanic)¹</td>
</tr>
<tr>
<td>Desmoplastic melanoma</td>
<td>1-4%³</td>
<td>Slowly growing lump³</td>
<td>Hard scaly area or nodule, no varied pigmentation, resembles scar</td>
<td>Commonly head and neck</td>
<td>60s⁴</td>
<td>Non-Hispanic whites⁴</td>
</tr>
<tr>
<td>Amelanotic melanoma</td>
<td>2-8%⁵</td>
<td>Radial or vertical initial growth⁵</td>
<td>Little or no color in lesion, appears to be nodular basal cell⁵</td>
<td>Trunk of men, limbs of women⁵</td>
<td>Older⁵</td>
<td>Whites²</td>
</tr>
</tbody>
</table>

Table 2.1: Different types of cutaneous (skin) melanoma and specific characteristics. ¹ (Bradford et al. 2009), ² (Wu et al. 2011), ³ (Javabal and Subramanian 2015), ⁴ (Feng et al. 2011), ⁵ (Ungureanu et al. 2015).
Nodular melanomas pose the greatest risk to patients due to their speedy growth rates and minimal visual cues. In Lieu and Dowling’s study, the median growth of nodular melanomas was 0.49mm per month while the median growth rates of superficial spreading melanoma and lentigo maligna melanomas were 0.12mm and 0.13mm per month, respectively (2006). Nodular melanomas grow vertically from the beginning, leading to faster metastasis, or the melanoma spreading to lymph nodes and distant organs, and worse patient outcomes (Borden 2002, 6).

**Melanoma Staging**

The American Joint Committee on Cancer determines the overall staging methods used in the United States. The standard for staging is driven by identifying physical metrics of skin cancers at their time of diagnosis that indicate the patient’s long-term likelihood of survival. This drives which treatments the patient undergoes after diagnosis, ranging from how wide or deep the skin removal should be to further biopsies and radiation treatments. In 2009 the standard for skin cancer staging changed from the anatomic Clark level of invasion, which categorized invasion based on the deepest skin layer containing the cancer (Nosé 2014), to the TNM system, which evaluates the primary tumor, presence of cancer in regional lymph nodes, and distant metastases. The TNM system combines these three values to determine overall cancer staging from Stage 1 to Stage 4 (Balch et al. 2009).

**Melanoma Causal Factors**

Environmental and genetic factors combined contribute to the development of melanoma. A skin cancer tumor develops because of the body’s inability to repair DNA damage (Baldi, Pasquali, and Spugnini 2013, 30). Environmental contributors include UV exposure, both UVA and UVB ranges of exposure, and other exposures such as arsenic (Nosé 2014, 8). Melanoma incidence increases with increasing proximity to the equator. Intermittent heavy exposure to sunlight resulting in sunburns is believed to increase the likelihood of an individual developing malignant melanoma (Borden 2002, 4). Genetic factors contributing include mutations to specific genes that have been linked with cancer proliferation, such as mutations in tumor suppressor genes (Baldi, Pasquali, and Spugnini 2013, 76).
Melanoma: What are the challenges today?

Melanoma has a few factors that contribute to its high mortality rate. This list details the main contributors of high mortality rates caused by melanoma.

1. **Growth speed.** Most melanomas grow much more quickly than other skin cancers (Liu et al. 2006).

2. **Age at occurrence.** This is about a decade younger than other major cancers (breast, colon, lung, prostate) and other skin cancers (Baldi, Pasquali, and Spugnini 2013, 19). The median age for diagnosing superficial spreading melanomas, responsible for 70% of incidences, is mid-40s. Melanoma is the most common form of cancer in young adults from 25-29 and the second most common form of cancer in adolescents and young adults 15-24 (L. B. Campbell et al. 2015).

3. **Disease Presentation: Amelanotic.** Amelanotic melanomas make up 2-8% of melanomas and have little or no pigmentation. These have very similar visual characteristics seen in basal cell carcinomas, a disease that develops much more slowly and very rarely becomes spread to other parts of the body. This reduces the ability of clinicians and patients to identify the criticality of a lesion.

4. **Disease Presentation: Nodular.** Nodular melanomas, about 15% of melanomas, but have quick growth rates and do not show the typical ABCDs. These melanomas skip the radial growth stage that displays common visual identifiers of melanoma such as multiple colors and irregular borders. Beyond this, the disease primarily grows vertically, permeating lower layers of skin quickly. As vertical permeation is one of the biggest indicators of quick metastasis and worse patient outcomes, nodular melanomas are particularly deleterious.

5. **Disease Presentation: Desmoplastic and Spitzoid.** These types of melanoma have long been difficult for clinicians to identify, worsening patient outcomes for those with unrecognizable melanomas (Feng et al. 2011).

6. **Late Identification.** Likelihood for survival significantly decreases once the disease has metastasized and spread to distant organs. The likelihood of patient survival five years after diagnosis drops from 98% when locally diagnosed and 16% (American Cancer Society 2015a).

7. **Difficulty in Diagnosis.** Unlike basal and squamous cell carcinomas, melanomas are not straightforward to diagnose by a pathologist. Interpretation of the disease requires weighing cellular characteristics with qualitative characteristics, such as the asymmetry...
of the overall skin lesion. This makes differentiation between severe atypical and early melanoma difficult for pathologists. This information was discovered based on a discussion with a pathologist in addition to interviews with dermatologists.

2.3 - Squamous cell carcinoma

Squamous cell carcinoma (SCC) is the second-most fatal type of skin cancer. Squamous cell carcinoma is more prevalent than melanoma and results in fewer deaths: it is responsible for 20% of skin cancer cases and 25% of skin cancer deaths (Howlader et al. 2015). Squamous cell carcinoma typically presents the following characteristics: scaly red patches, a bleeding or scabbed patch, open sores, or an elevated growth with central depressions (Nosé 2014, 12). Squamous cell carcinoma is typically composed of abnormal squamous cells in the outer layer of the skin, and often evolves from actinic keratosis (AK) (Nosé 2014, 12). This can still be an invasive disease, but typically has a slower rate of progression than melanoma, progressing on a scale of months to years (Hong 2010, 1489). Squamous cell carcinoma is most commonly found on the ear, lower lip, face, balding scalp, hand, and arms, and most cases are caused by cumulative UV exposure (Baldi, Pasquali, and Spugnini 2013, 31).

Squamous cell carcinoma: what is it?

It's a proliferation of invasive atypical squamous keratinocytes, the predominant cell type in the epidermis (Nosé 2014, 13). Squamous cell carcinoma occurs in the epidermis and outer layers of skin with mucal linings (Hong 2010, 1490), and occurs in significantly damaged skin, often-sun damaged. It is usually in the head and neck regions (Nosé 2014, 12), and can also occur on skin sites with scars and burns (Baldi, Pasquali, and Spugnini 2013, 31).

Who is impacted?

Squamous cell carcinoma is usually diagnosed in elderly, but seen in wide age range (34-95 years). This disease is slightly more common in males (Nosé 2014, 12). Squamous cell carcinoma often arises in individuals with damaged skin or skin exposed to chronic irritation (Hong 2010, 1489).
Clinical Diagnosis and Patient Identification

The vast majority of cases are connected with preexisting actinic keratosis (Nosé 2014, 12). Actinic keratosis presents as a rough, dry, or scaly patch of skin, and the vast majority of AKs do not turn into squamous cell carcinoma. SCC is frequently a small, rounded mass or pattern of small rounded nodes. The skin spot may be ulcerated, bleeding, hemorrhagic, or growing outward (Nosé 2014, 12). Squamous cell carcinoma varies significantly in appearance based on region of the world, occupation, race and life habits of the patient (Hong 2010, 1489). A hallmark of the disease is firmness on palpation, and late stage lesions are often eroded, crusted, and ulcerated (Hong 2010, 1490). SCC is often slow-growing, but usually evolves faster than basal cell carcinoma (Hong 2010, 1489).

There are no commonly used rule sets (such as the ABCDEs of melanoma) to assist patients in assessing skin spots for squamous cell carcinoma, but there are general guidelines along with pictures for identifying basal and squamous cell carcinoma by the National Cancer Institute for patients (National Cancer Institute 2010):

- A lump that is small, smooth, shiny, pale, or waxy
- A lump that is firm and red
- A sore or lump that bleeds or develops a crust or scab
- A flat, red spot that is rough, dry, scaly, and may be itchy or tender
- A red or brown patch that is rough and scaly

Causal Factors

Skin cancer tumor development requires the inability for the body to repair DNA damage (Baldi, Pasquali, and Spugnini 2013, 30). Environmental and genetic factors combined contribute to the development of this disease. Some cases are likely related to chronic inflammation, and other causes include UV exposure, prior radiation therapy and HPV (Nosé 2014, 12). Immunosuppressed patients are more likely to develop SCC (Nosé 2014, 12). In fact, transplant patients have a 65-fold increased likelihood of developing SCC. Tumors in these patients tend to behave more aggressively (Hong 2010, 1489). Genetic factors also contribute to the likelihood a patient will develop SCC (Nosé 2014, 12).
Types of Squamous Cell Carcinoma

While melanoma diagnosis is frequently correlated with its clinical characteristics and location on the body, squamous cell carcinomas are typecast based on their cellular structures. Types include verrucous, spindle cell, keratocanthoma, Bowen's disease, and erythroplasia of Queyrat (Panizzon and Seegenschmiedt 2015, 105).

SCC Staging

Staging categorizes the extent of the disease. Squamous cell carcinoma follows the consistent staging system for both basal and squamous cell carcinomas most recently updated in 2009, with 3 categories, called the TNM system (Balch et al. 2009). This system characterizes the extent of the primary tumor ("T"), the extent the skin cancer has spread to regional lymph nodes ("N"), and if the cancer has metastasized beyond the lymph nodes ("M") (Balch et al. 2009).

Squamous cell carcinoma: What are the challenges today?

Squamous cell carcinoma is difficult to identify as specific types can act very quickly. Lip and ear tumors are more aggressive (Nosé 2014, 13) with a metastatic rate of 3-6% (Hong 2010, 1491), though many squamous cell carcinomas do not metastasize.

- Rate of growth. Some types of squamous cell carcinomas are much more aggressive than others (Panizzon and Seegenschmiedt 2015).
- Incidence. Approximately 700,000 cases of squamous cell carcinoma are diagnosed each year. This makes for significant costs to the healthcare system for treatment and removal, particularly with Mohs surgery, which consists of many surgeries over the course of a few hours (Karia, Han, and Schmults 2013).
- Growing Incidence. Squamous cell carcinoma incidence has increased up to 200% over the past three decades in the United States (Karia, Han, and Schmults 2013).
- Difficulty in Patient Identification. There are few patient "rules of thumb", and many patients do not know how to identify squamous cell carcinoma unless they have gotten the disease before and have learned the signs (National Cancer Institute 2010).
- Variance in Reporting. As squamous cell carcinoma infrequently metastasizes, it is not tracked nearly as closely as melanoma and other high-fatality cancers and is excluded from the national cancer registries (Karia, Han, and Schmults 2013). Because of this
reason there is significant variance in estimates of actual incidence of squamous cell carcinoma.

2.4 - Basal Cell Carcinoma

Basal cell carcinoma (BCC) grows in the epidermis and results from the abnormal growth of epithelial keratinocytes, the most common cell type in the epidermis (Schlag et al. 2002, 160:259). The layers of the skin, including keratinocytes, can be seen in Figure 2.2. This is considered a low-grade malignancy because of the low speed of growth of the vast majority of basal cell carcinomas and its very low likelihood of metastasizing (Baldi, Pasquali, and Spugnini 2013, 76). Basal cell carcinoma has many forms of presentation on the skin and is the most common form cancer worldwide, appearing much more frequently in fair-skinned, older adults (Nosé 2014, 2).

Who Develops Basal Cell Carcinoma?

Basal cell carcinoma is most commonly diagnosed in light-skinned older adults, and is more commonly found in men than women (Nosé 2014, 2). BCC is rarely diagnosed in black, oriental, and Hispanic individuals (Baldi, Pasquali, and Spugnini 2013, 76). Risk factors include red hair and tanning bed use (Nosé 2014, 2).

Clinical Diagnosis and Layman's methods

Clinical presentation is usually a single lesion and unless a rare, aggressive type, it does not metastasize (Baldi, Pasquali, and Spugnini 2013, 76). How BCCs may present on the skin varies significantly. Clinical presentation can range from very small (a few millimeters) to several centimeters (Nosé 2014, 2), and range in color from dark, to flesh colored, to light lesions, though most are not pigmented (Nosé 2014, 2). Lesions can be ulcerated, depressed or protruding, and can have spider vein patterns across them. There are five primary different presentations: a firm, pearly nodule with spider vein patterns, a scaly, flat lesion often with a raised, pearly border, a flat or depressed lesion with white or yellow scaly pattern (plaque), a hardened, unpigmented protruding sphere, or a pink or flesh-colored nodule with a constricted lower border (Baldi, Pasquali, and Spugnini 2013, 80).
BCC is most common in the head and neck region (up to 80% of cases), while others occur on the trunk and shoulders (15%) (Nosé 2014, 2). It is almost exclusively found on skin with hair follicles (Baldi, Pasquali, and Spugnini 2013, 76).

**Diagnosis under the Microscope**

Basal cell carcinoma resides in the epidermis, seen in Figure 2.2. Basal cells are the "base" cells that produce new epidermal skin cells as old ones die off. These line the intersection between the epidermis and the dermis, along with melanocytes (Baldi, Pasquali, and Spugnini 2013, 75). Six cellular features and patterns are found in almost all BCC subtypes, making BCCs fairly straightforward for pathologists to diagnose under the microscope. These features include nests of basaloid cells, "walls" of these nests along the outside areas of the lesion, high mitotic rates (the number of cells multiplying in a volume), dead keratinocytes, unusual connective tissue between cells (stroma), and a separation between cell nests and connective tissue (Baldi, Pasquali, and Spugnini 2013, 81).

**Causal Factors**

There are many factors, including environmental and genetic. The vast majority of cases are related to sun exposure, but some cases are also associated with radiation, immunosuppression, burn scars, and genetic syndromes (Nosé 2014, 2). Individual risk factors include gender, age, immunosuppression, pigment traits, and genetic dysfunctions (Baldi, Pasquali, and Spugnini 2013, 76). It has been shown that cumulative occupational sun exposure is associated with BCC development in older individuals, and acute recreational sun exposure in adolescence correlates strongly with the youngest diagnoses of BCC (Baldi, Pasquali, and Spugnini 2013, 77).

**Types of Basal Cell Carcinoma**

There are 5 primary clinical types of basal cell carcinomas (Longo et al. 2014)

1. Nodular/Ulcerative
2. Diffuse (infiltrating and morphoeic,)
3. Superficial
4. Pigmented variant

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5. Fibroepithelioma of Pinkus

BCC Staging

Staging categorizes the extent of the disease, and is rarely done with basal cell carcinomas unless is likely to become or has become invasive (Panizzon and Seegenschmiedt 2015, 103). Though many non-melanoma skin cancers are not staged, there is a consistent staging system for both basal and squamous cell carcinomas determined in 2009, with 3 categories (the TNM system). This system characterizes the extent of the primary tumor ("T"), the extent the skin cancer has spread to regional lymph nodes ("N"), and if the cancer has metastasized beyond the lymph nodes ("M") (Balch et al. 2009).

Basal cell carcinoma: What are the challenges today?

Clinical presentation varies so much that this disease can be hard to diagnose (Panizzon and Seegenschmiedt 2015, 260). BCCs are distinguished more by their cellular structure than physical presentation, challenging physicians to predict cellular behavior based on varied presentation. Additionally, some BCCs can grow and ulcerate quickly (Baldi, Pasquali, and Spugnini 2013, 80), which is concerning given physician urgency to treat is low as most BCCs grow over the course of years.

1. Difficulty in Patient Identification. BCC has varied clinical presentations, even within the same patient. This was noted based on interviews with patients for this research.
2. Incidence. There were an estimated 2.8 million cases of BCC in the United States in 2010. The sheer number of cases and healthcare costs associated with removing these skin cancers poses a huge burden on the general healthcare system.
3. Growth in Incidence. As baby boomers live longer and enter retirement the greater healthcare system will experience increased demand to treat patients with BCC.

2.5 - Other Types of Skin Cancer

Other types of skin cancer include much rarer kinds, such as Kaposi's Sarcoma and Merkel Cell Carcinoma, and Sebaceous Gland Carcinoma. These have been excluded from this analysis, but are important diseases not to be overlooked in future studies.
Chapter 3: The Current State of Skin Cancer Care Delivery

This chapter establishes how skin cancer identification is currently delivered, highlighting materials flows, information flows, current standards for processing patients, and opportunities for a skin cancer to be identified. This analysis looks at two models: a control structure model and a system dynamics model for the skin cancer care delivery system. We introduce each stakeholder and their influences on the system, setting the stage for deeper analyses of system gaps and individual stakeholders in later chapters.

3.1 - Current Skin Cancer Value Delivery

Skin lesions are currently identified either in the home or in the physician's office during an exam. The current standard of treatment is for a patient to come into the physician's office with an issue, either concerned about a skin lesion or some other health issue. The physician will assess the lesion and decide to advise the patient of one of three paths forward: leave the lesion on, take a biopsy of the lesion, or refer the patient to a dermatologist for analysis. After a referral, a dermatologist will examine the skin for irregular lesions and determine whether or not a skin lesion is suspicious enough to biopsy. Biopsies are sent to a certified pathologist for review under a microscope. The physical flows of this process can be seen in Figure 3.1.

Though many patient experiences vary, for the purposes of this analysis we will consider this the “average” case. The process to be treated involves three primary stakeholders: the patient, the patient’s primary physician, and the dermatologist. Though these stakeholders are the most central, there are often many other people involved in the process. We have identified the following stakeholders that most frequently play a role in skin cancer care delivery: the patient, the patient’s significant other, the patient’s direct family, the patient’s friends, the patient’s primary care team, other specialty physicians with which the patient interacts, the patient’s dermatologist, and surgeons after skin cancer diagnosis. For the purposes of this analysis surgeons were considered out of scope, as they are primarily involved after the skin cancer has been identified and diagnosed. The patient and medical stakeholders are illustrated in Figure 3.1.
Figure 3.1 illustrates how patients typically enter and flow through the skin cancer care system based on patient interviews. Often a specific “major” event launches the patient into the system. This can be another patient health issue or a family member’s diagnosis that can cause a patient to seek care. From here, the patient seeks treatment, visits a physician, and is assessed for cancerous lesions. The patient cycles back out of the system, either being seen again after a specific period of time or staying out of the system until another health issue arises.
3.2 - System Dynamics Model Introduction

The patient-flow diagram (Figure 3.3) illustrates how patients typically move through the medical system in another form: a system stock-and-flow diagram. This information was discovered through patient and physician interviews, and maps the dynamic nature of patients flowing through the system. This is known as a system dynamics model (Sterman 2000). Most frequently, a patient will be concerned about a skin lesion and either discuss the lesion with his or her primary care physician or the physician they’re seeing at the time as a secondary concern. For women, especially during pregnancy, this physician is their OBGYN. The primary care physician or specialist will review the lesion and either deem it innocuous, biopsy it, or refer the patient to a dermatologist.
indirectly. It also shows how information is being spread through the system. This model only includes the “stock”, or cumulative amount, of patients and their “flow” through the system which is influenced by other factors, such as the ability for a healthcare system to manage an increased flow of patients or a lab’s ability to process more lesions than the average rate of processing. This is an introduction to the system dynamics involved in care delivery and will be discussed more in later chapters.
Figure 3.3: A system dynamics model of patient movement through the skin cancer system
Another model that depicts the typical mental model for how diseases are identified in the United States healthcare system is the Swiss Cheese model (Leveson 2011, 34).

3.3 - The Swiss Cheese Model

The methodology behind this model is typically used in accident analyses, and works on the premise that many independent operators responsible for catching errors must fail in order for the entire system to fail. This is known colloquially as the perfect storm. Applied to skin cancer, a patient and the greater system supporting the patient have multiple opportunities to identify a cancerous skin lesion and remove it before it develops into a late stage cancer.

Skin cancer is a disease that is identified by either patients or physicians, and there are many opportunities to attribute failure to specific stakeholders. The general approach for skin cancer identification has been to apply more steps and opportunities for identification when a patient is high risk, particularly if that person has been diagnosed with skin cancer before, as they are much more likely than the average person to have skin cancer again. The routine is to send the patient through the system more frequently (every 3 or 6 months) to ensure they are cancer-free or closely monitored by a physician. Prior to a cancerous diagnosis, however, this is not the course of action.

The Swiss Cheese model in Figure 3.4 portrays the barriers of detection, from self-check, family or friend check, general physician check, and dermatologist check. In this model, vertical hierarchy does not illustrate control like in the STAMP model, but instead vertical organization of stakeholders in the system represents the average frequency that stakeholder can examine the patient. A patient has multiple opportunities a day to examine his or her skin condition, followed by that patient’s significant other or direct family, with physicians examining the patient least frequently. From patient to patient, the regularity and frequency of potential scans varies significantly. For example, if a patient does not have a significant other, they do not have a significant other barrier of defense. The barriers of detection illustrated represent the average patient condition. This model is useful in this analysis as it shows how many people can be involved in the identification and diagnosis process, and illustrates how frequency of evaluation can impact patient outcomes.
Barriers of Detection

Each cycle through the system requires a solution or outcome that is selected based on a complex set of information available, often gained by answering the following questions: is it itchy or bleeding? does it have irregular borders? how has it changed over the last few weeks to few months? is it in an easily-seen area of the body to monitor those characteristics? does it have its characteristics of growth? The quality of this information can vary significantly, particularly due to the memory of the patient or the availability of medical records. The information that should be factored in, such as risk factors like if the patient has a family history of skin cancer, is increasingly complex. With this burden of complexity comes a burden of
documentation, so either this information can be reviewed in the future or be passed along to another physician.

3.4 - STAMP Applied to Skin Cancer
The next model will illustrate systems thinking, applying a way in which we can identify issues in the entire system through the Systems-Theoretic Accident Model and Processes method (Leveson 2011). In this model there is no one primary issue, and each risk situation has multiple causes that contribute to it. This varies from the Swiss Cheese model as it allows for analysis of the interactions between stakeholders and the performance of the system as a whole.

STAMP Application to Skin Cancer Care Delivery
To build a snapshot of current care delivery, the skin cancer care system was analyzed by combining information from interviews of members at different points in the patient value delivery chain. The STAMP method, or Systems-Theoretic Accident Model and Processes method, was used to analyze this information (Leveson 2011), as skin cancer care delivery is ultimately about ensuring patient safety. This is a method to evaluate how information is exchanged within a system in addition to identify reliability issues in systems to provide a full-view of errors that can happen and how to improve them.

Why STAMP?
Many accidents occur when an unintended event happens, and this unintended event affects other systems around it. This is true for industrial accidents, such as Fukushima Daiichi’s nuclear disaster in 2011 leading to leakage of radioactive chemicals into the surrounding ecosystem, or the BP’s Deepwater Horizon oil spill in 2010, which leaked millions of barrels of oil into the Gulf of Mexico (“Deepwater Horizon Oil Spill Draft Phase IV Early Restoration Plan and Environmental Assessments” 2015). In the case of skin cancer, the greatest risk results from not identifying the lesion or removing it, causing the cancer to grow and become more invasive. This safety analysis method was selected as it focuses on operator actions and interactions in a services system, where many operators are acting to manage a pool of patients who have or may develop skin cancer. This method is often used in safety analyses of large complex systems, and provides a clear illustration of information transferred between stakeholders in the system to deliver patient care.

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3.5 - Defining Goals, Hazards, and Constraints in STAMP

The first step in building a map of current skin cancer care delivery is establishing system goals and hazards. The system engineering goal the skin cancer detection and care system is to:

*Provide effective early detection and swift removal of skin cancers to improve outcomes for skin cancer patients.*

In the case of medical delivery, both unnecessary action and inaction can play a role in creating a "hazard" or accident. The *hazard* in this case is the following:

*A patient develops skin cancer.*

And the accident or adverse event is:

1. *A patient develops skin cancer that is detected late*

With a secondary accident or adverse event:

2. *A patient does not develop skin cancer and is overtreated (false positive)*

A skin cancer may be detected late for many reasons: a patient may not notice a skin lesion that is cancerous, a care provider may provide assurance about a skin lesion that later becomes cancerous, or a physician may see a skin cancer in an early stage before it exhibits more characteristics common in skin cancers. A patient may not develop skin cancer but be treated excessively because they have atypical moles, or the physician may want to be more cautious and have a low threshold for deciding to biopsy. This secondary risk is still a risk to the system, but is secondary to the primary adverse event of missing skin cancers or diagnosing them late, because the risk associated with overtreatment is patient recovery from a skin excision, while missing a skin cancer may result in the cancer metastasizing. Additionally, overtreatment of non-cancers reduces the time available for physicians to treat and remove actual cancers. These examples were discovered through patient and physician interviews and synthesized into this analysis.

Some environmental conditions are required for adverse events or accidents to occur. Hazards are circumstances or events that could contribute or lead to an accident or adverse event. The
goal of a system analysis is to reduce hazards as much as possible in order to reduce or even eliminate accidents.

System Hazards

Based on our analysis and interview data we have identified the following hazards within the system. Hazards are circumstances that contribute to situations that can cause accidents.

Hazard 1: A skin cancer appears on the body and is not detected early

1. The patient does not notice the skin cancer
2. The patient notices the skin cancer but does not know how to identify the skin cancer
3. The patient notices the changing lesion but does not see a physician for review
4. The patient cannot see a physician for review quickly enough
5. The patient does not have access to a physician for review
6. A physician reviews a cancerous skin lesion but misidentifies it
7. A physician reviews a benign skin lesion and gives assurance to the patient of the lesion that later becomes cancerous
8. A physician reviews the cancerous lesion and refers the patient to another physician, and the patient does not see the follow on physician
9. A physician reviews a cancerous lesion and removes it for review by the pathologist who misdiagnoses the lesion as benign
10. The patient does not understand the cancerous diagnosis
11. The patient ignores the cancerous diagnosis

Hazard 2: A patient is treated for skin cancer who does not have skin cancer

1. A pathology lab incorrectly diagnoses a benign lesion as a cancerous lesion
2. A physician removes a skin lesion that is not cancerous and is not likely to become cancerous
3. A physician incorrectly biopsies a lesion and must do an excess biopsy after the melanoma is diagnosed
STAMP Constraints

From these identified hazards and the overall system goal we derive high-level constraints for the system. These define the most important system safety requirements and drive lower-level constraints on the system.

1. The patient must not develop skin cancer.
2. If the patient develops skin cancer, the patient or health delivery team must quickly identify and remove the cancer.
3. If a patient does not develop skin cancer, the medical system will not over treat the patient, causing damage to their overall health and take away resources from other patients.

These constraints are collectively exhaustive to address potential adverse events. From these higher-level constraints, we can derive lower-level system constraints with actions and responsibilities for stakeholders, categorized four ways:

1. Patients are informed to manage their own care
   a. Patients in the community must be educated on the causes and best practice prevention techniques to reduce their likelihood for developing skin cancer
   b. Patients in the community must be educated on the signs of cancerous skin lesions
   c. Patients must be informed of changes to their own skin
   d. Patients must be informed of their personal and family history with skin cancer
   e. Patients must seek medical help for irregular skin lesions
   f. Patients must allow physicians to review irregular skin lesions
   g. Information is available to support patient monitoring and checks

2. Physicians are available and capable of managing patients for skin cancer
   a. Physicians must be available to examine skin lesions
   b. Physicians must review irregular skin lesions regularly (screening)
c. Physicians must be informed of patient information relevant to their likelihood of developing a skin cancer
d. Physicians must be trained to identify and review skin lesions appropriately
e. Physicians must select the appropriate, affordable treatment for skin lesions
f. Physicians must follow up with referring or referred physicians
g. Physicians must accommodate patients with immediate concerns

3. Physicians must guide patients for managing their future care
   a. Physicians must be trained to advise patients on appropriate follow up procedures after a review
   b. Physicians must advise patients on monitoring skin after review
   c. Physicians must accommodate patients with immediate concerns
   d. Physicians must verify patients have been treated if handing off patient health responsibility to a referred physician
   e. Physicians must follow up with patients after critical diagnoses

4. The healthcare system must support preventative care measures
   a. There must be enough physicians to manage patient care
   b. The patient must be able to be seen by a physician within a reasonably short time
   c. Payers must provide financial support to physicians for proactive measures of managing patient care

These constraints are heavily informed by problems that have been identified in previous skin cancer cases. We will expand more on these problems in Chapter 5. These higher-level constraints include few interactions, and the following section will augment this stakeholder-centric constraint analysis as it includes a full set of stakeholder interactions, information flows, and control flows to build a static picture of the system. This will provide a basic framework for the system.
3.6 - STAMP Total System Control Structure

The next step in the process of understanding the current state in the system is to analyze the safety control structure. These include all of the stakeholders that impact a patient's care, both direct (e.g. primary physicians) and indirect (e.g. media sources). The control structure illustrates two things: information exchanged between parties and levels of control. The general model a control loop can be seen in Figure 3.5.

![Figure 3.5: The basic model for a control loop (Leveson 2011, 88)](image)

In Figure 3.5 control is represented graphically by placing a controller above the process being controlled. Modifications to that control are sent from the controller to the controlled process, and signals are sent from the controlled process to the controller above. Figure 3.6 depicts in more detail each of the components of this structure.
Figure 3.6: A detailed view of the basic control structure loop (Leveson 2011, 93)

Figure 3.6 more specifically represents the interactions between the controller and the controlled process. This also shows how controllers can influence the same controlled process, causing interference and overlap. Figure 3.7 illustrates this control loop applied to the skin cancer patient’s own control over his or her skin condition.
Basic Control Loop

Figure 3.7: The primary control loop of the patient monitoring the patient's skin condition

The primary control algorithm is the patient's awareness of his or her skin condition, and all other stakeholders in the system support this patient and the patient's base control algorithm of managing the patient's skin condition. This basic control loop can be seen in Figure 3.7. The patient has an underlying genotype that drives the patient's phenotype, contributing to the patient's baseline skin condition. The patient behaves in certain ways, changing his or her skin condition. One example of this is the patient deciding to go to the beach on a hot summer day. This "mental model" of the patient's skin is updated when the patient becomes aware of changes to their skin condition through the feeling of a sunburn or a visual scan of their skin. The patient can modify behavior to change his or her skin condition or can seek help from an outside source like the healthcare system.

This model structure applied to the overall skin cancer value delivery chain can be seen in Figure 3.8. This includes stakeholders beyond those discussed and interviewed thus far, such as insurance companies, regulators, and research institutions which all impact how care is delivered and how "front-line" workers like dermatologists and primary care physicians operate.

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Figure 3.8: The full safety control structure for skin cancer care delivery
Figure 3.8 is a different type of control structure than found in typical engineering safety control analyses, as this control structure is stakeholder-centric rather than component and process-centric. Another differentiating factor in this control structure compared to typical safety control structures is that the end beneficiary (the patient) ultimately drives care. The patient must choose to be part of the healthcare delivery system, and must initiate connections by doing activities such as making appointments, selecting health insurance policies, or choosing a primary physician. At any point the patient can choose to ignore feedback from any level of the loop. Additionally, the patient can skip levels within the control structure, though patients may have to deal with consequences like paying out-of-pocket rather than having insurance coverage after visiting a physician. The control structure in this case is not concrete, but illustrates the increased likelihood of compliance based on these levels. For example, a patient is more likely to listen to advice from a physician than comply with medical advice they read online. As you can interpret from Figure 3.8, the structure is initiated at the highest levels of US healthcare authority, and the government plays a key role in establishing mandates for regulators. From here, regulators, such as a state’s medical board, licenses physicians to practice in that state. This license allows physicians to directly give advice and treatment to patients.

**Stakeholders in the Greater System**

Figure 3.8 illustrates a set of feedback and control relationships in the greater skin cancer detection system. In this model, unacceptable losses are driven by failures to complete control and feedback loops. Stakeholders in blue in Figure 3.8 show stakeholders who directly impact the care of the patient. Many of the stakeholders and the functional role they play have been abstracted and consolidated for clarity. For example, regulators are made up of both federal and state organizations, including state medical boards who license physicians and the Federation of State Medical Boards (FSMB), a non-profit representing the state medical boards in in Washington D.C.

The skin cancer safety control structure is constructed with a myriad of influencers. Patients are the center of this control structure. This stakeholder plays an active role in all of the critical loops of the system. The patient drives his or her social interactions, selects media exposure, selects health insurance, and enters the medical system.
Educational institutions train physicians and further research. Physicians are trained in undergraduate academic institutions, medical school, and medical residencies. These define the practice standards they use later, and they must comply with school demands and examinations.

Research institutions are often connected with educational institutions and build future knowledge for the industry. Public research in the field of medicine is often funded by government sources with the right to approve or not approve research. Research institutions are often combined or closely associated with educational institutions. Research findings are published by medical association journals and other publications that filter this information for physicians and other researchers.

Regulators control a physician’s ability to practice medicine. Official regulators license and enforce continuing education for physicians once they are practicing. This is regulated at the state level.

Medical associations represent large groups of physicians and independently define practice standards. These associations enforce non-mandated certifications and provide information for the medical community. For example, The American Board of Medical Specialties oversees independent associations of medical specialties, such as the American Board of Dermatology. The American Board of Dermatology provides a voluntary certification of dermatologists to be “board-certified.” Other medical associations, such as the American Academy of Dermatology, produce journal articles that provide references to improve the standard of practice by dermatologists.

Physicians advise and treat patients. Physicians are primarily funded by patient insurance, which is often determined by patient’s employer and pre-agreed contracts with health insurance companies. These companies, with some influence of regulators, define which tests and services physicians can provide to patients that are reimbursable. Physicians are officially certified by regulators and medical institutions and can achieve further certifications through medical associations.
Family and friends regularly interact with the patient. These people often have the least amount of expertise, and set standard social behaviors that can increase an individual's likelihood of developing skin cancer. They can look at an individual's skin and provide advice, relaying stories of other acquaintances and their health experiences.

News and media sources regularly expose the patient to news and warnings. Online information, news, or fundraising campaigns can influence a patient's awareness of skin cancer, and can be resources after a patient becomes aware or concerned about having or developing skin cancer.

The purpose of this research is to understand how to deliver better care concerning early stage detection, so we will deep dive into the primary stakeholders that directly impact patient care, and address higher-level controllers (like payers and regulators) as they arise in directly influencing patient care.

3.7 - STAMP Patient Facing Control Structure

Figure 3.9 further illustrates the three primary stakeholder groups directly involved in patient care delivery. The green box and green arrows illustrate follow-on care that is outside of the system boundary of detecting and diagnosing skin cancer. Once a patient is diagnosed with skin cancer often physicians will refer the patient to other physicians to collaboratively establish follow-on care. This map is intended to provide a framework of influencers of value delivery for patients who may have skin cancer: improvements will be discussed later.
Figure 3.9: The safety control structure of directly impacting stakeholders
Interactions involved in processing and diagnosing of patients include material flows (patients, skin biopsies), information flows (referrals, requests for reimbursement, advice), control flows (reimbursement, mandates), and financial flows (fees, tuition). For simplicity these have been reduced to control flows and information flows. If the stakeholder granting the flow to a later stakeholder could influence that stakeholder in their decision-making, this was considered a control flow. Two examples of this control are through funding: the National Institutes of Health, or the NIH, is part of the government and can select research projects to fund. Another example is payers: health insurance companies can define how much they will reimburse for a physician’s service. These control methods impact future research projects that academics pursue and the willingness of a physician to perform a service.

Pure information flows were defined as a general exchange of information with little influence on behavior after this information is communicated. Two examples of information flows are the patient’s skin condition interpreted by family and friends and payments from future physicians to educational institutions. The patient can ignore advice from family and friends, and future physicians have very little influence on the medical education they receive by paying tuition. An important consideration is that this control structure illustrates the processing of all patients who may have skin cancer, whether or not they have had a prior skin cancer diagnosis. The patient must either rely on self-assessment, social influences, or physician detection to start the skin cancer care delivery process.

Stakeholders in the Direct System

Stakeholders that directly influence the patient can have the largest effect on how the patient perceives his or her own health risk. This section details each patient-influencer and their role in impacting patient care. Figure 3.10 illustrates the stakeholders most likely to impact the decision-making process of the patient.
Primary Beneficiary

Patient. This individual is ultimately responsible for his or her own health. The patient synthesizes advice and feedback from other stakeholders, and patient action is required to seek evaluation of skin lesions and later treatment. This model is patient-centric.

- **Who they control:** The patient is responsible for his or her own health, behaviors, exposures, and general livelihood. They control their influences, such as interactions with family and friends, and how much they interact with the medical system. The patient has ultimate control over his or her own health.

- **Who controls them:** The patient has many influencers, but is more likely to comply with advice and recommendations from physicians than social influences. This is shown through vertical control hierarchy in Figure 3.9.

- **Responsibilities:** The patient is ultimately responsible for his or her own health. For assistance with this, the patient can turn to support from social and medical influences.

Social Influences

Significant Other. This stakeholder has the most influence on patient behavior, the most frequent interaction with the patient, and the more access to reviewing the patient’s skin.
condition than all other stakeholders. Many prior skin cancer patients enlist help from their significant other to monitor hard-to-see skin areas such as the patient's back, a frequent site for melanoma.

- **Who they control:** This stakeholder has strong influence, but does not control the patient.
- **Who controls them:** This stakeholder is influenced by his or her own experiences with the medical system and social interactions.
- **Responsibilities:** This stakeholder supports the general health of the patient.

**Family.** This stakeholder group has the greatest influence on patient behavior after the significant other. Patients interviewed for this research regularly mentioned that they sought parental influence and review of irregular skin lesions prior to seeking treatment from physicians. This stakeholder group also sets childhood standards for patient exposure and seeking medical advice.

- **Who they control:** This stakeholder also has strong influence on the patient, particularly setting the tone of patient and medical system interactions in the patient's youth, but no actual control on the patient's health.
- **Who controls them:** This stakeholder group is influenced by its greater family network and social influences.
- **Responsibilities:** This stakeholder is involved in the health of the patient, but not responsible for the health of the patient.

**Friends.** This stakeholder group regularly interacts with the patient and helps to set patient behavior standards for sun exposure in addition to family members. Friends frequently see less surface area of skin that could develop cancerous lesions. Friends have a peer-effect that is very strong in setting standard patient behaviors, particularly after puberty.

- **Who they control:** This stakeholder has influence on the patient's behavior standards and leisure activities, but does not have control over the patient's behaviors.
- **Who controls them:** This stakeholder group is more influenced by their own family and social interactions than the patient's stakeholder network.
- **Responsibilities:** This stakeholder group has little responsibility for the patient's health.
Medical Influences

Primary Care Physician (PCP). This stakeholder is commonly the first stakeholder with whom a patient interacts in the medical system. PCPs are responsible for assisting patients with many health issues, including skin lesion evaluation. This stakeholder frequently connects the patient with other physicians in the medical system. Patients interact with this physician typically once every few years to a few times a year.

- **Who they control:** PCPs can prescribe medications, authorize tests, and give advice and recommendations to patients. They influence patient behavior and can modify the patient's skin condition, particularly by taking biopsies or allowing the patient to access skin-modifying medications. The PCPs controls which physicians the patient is referred to and which lab reviews skin biopsies.

- **Who controls them:** PCPs are licensed by state regulators, given degrees by medical institutions, influenced by medical publications and peers, and required to undergo continuing education. The pathologist evaluates the disease state of a skin lesion and recommends a course of action for the patient, so pathologists very strongly influence a primary care physician's suggestions to the patient.

- **Responsibilities:** The primary care physician is responsible for delivering quality care to the patient and giving advice to the patient going forward. The PCP is not directly responsible for the health of the patient.

Dermatologist. This stakeholder specializes in skin diseases, and is frequently more expensive and requires a primary physician's referral. This specialist manages one-off and recurring skin diseases that are deemed more advanced or complex than can be managed at the primary care level. This stakeholder can have long wait times, and frequently sees patients on a regular basis for maintenance of their skin issues after initial appointment for diseases. These repeat visits include after-diagnosis full body scans or monitoring of recurrent issues such as psoriasis.

- **Who they control:** The dermatologist collaborates with other physicians and can influence the behavior of the patient or modify the patient's skin condition. Dermatologists control which surgeons they refer patients to after a critical diagnosis and which labs they send biopsies to.

- **Who controls them:** Dermatologists are licensed by state regulators, given degrees by medical institutions, and are required to undergo continuing education. They can
voluntarily seek re-certifications for other medical institutions like board certification by the American Board of Dermatology. Publications and peers also influence how they practice.

- **Responsibilities:** The dermatologist is responsible for evaluating and treating the patient and providing advice for the patient going forward. The dermatologist is not directly responsible for the health of the patient.

*Other Physician.* This stakeholder is also a specialist, but not in dermatology. Many other specialists have patients referred to them and identify skin issues, which they either manage directly or refer the patient to a dermatologist or their primary physician. "Other" physicians include OB/GYNs, allergists, rheumatologists, chiropractors, and many other specialists. As skin is considered the "window" to the human body, many diseases have present in some form at the skin level, and can be identified in many different parts of the medical system.

- **Who they control:** The other physician is in charge of delivering a specific type of care to the patient. This stakeholder can strongly influence the behavior of the patient, and select other physicians to refer the patient to if another health issue arises.

- **Who controls them:** This physician is licensed by state regulators, given degrees by medical institutions, and required to undergo continuing education and regular certifications by their own medical institutions related to their specialty. Publications and peers also influence how they practice.

- **Responsibilities:** This physician is primarily responsible for the specific service they are delivering to the patient, but has a general knowledge of healthcare and can provide consultation and review for other issues. They are not directly responsible for the health of the patient.

*Pathologist.* This stakeholder views skin samples that have been stained and prepared for cross-sectional viewing under a microscope. This stakeholder owns the official diagnosis of skin lesions and factors in information outside of what is seen on the slide, such as patient history. This is considered by physicians to be an additional physician consult.
• **Who they control:** Pathologists determine the disease state for skin lesions, so they strongly influence the front-line physician's procedures for treating the patient and make recommendations on the type of care the patient needs based on the disease diagnosis.

• **Who controls them:** Pathologists are regulated similarly to other physicians, receiving degrees from medical institutions, requiring continual training, acquiring state licenses to evaluate the disease state of lesions, and being influenced by peers and publications. Physicians taking the biopsy select which pathologists they want to review the lesion.

• **Responsibilities:** The pathologist is responsible for evaluating lesions and providing an accurate diagnosis with appropriate follow-on treatment recommendations to physicians.

### 3.8 - Modeling Patient Care as a System

In skin cancer care delivery each patient is decoupled from the greater system, meaning patients do not pass along skin cancer from one patient to another, but other characteristics, such as methods of treatment and behavioral norms, are passed along culturally from patient to patient and physician to physician. This system is similar to that of a network of aircraft: each plane is independent from the greater system, so a major error in one plane will not reverberate throughout the rest of the system, but the planes are linked by a larger network managing their routes and ensuring their safety.

The current US system acts as an open loop system, meaning there is no feedback, and patients are examined for skin issues when concerned or otherwise prompted to have their skin checked. Only active controls (rather than passive controls) are in place to identify skin cancer. Skin cancer identification is further complicated as skin cancer forms from a combination of inherent biological factors as well as environmental factors. While we can use STAMP to examine errors within the treatment system and environmental factors, inherent biological factors are not very well known today nor easily modeled.

Another important factor in modeling the healthcare system is that the system works the opposite way that most safety systems work. When a skin cancer forms the skin cancer must be identified, and inaction can result in greater consequences than action. In most systems, errors occur because of an inappropriate action, not inaction. Additionally, patients can be over
treated, causing unnecessary harm to a patient who would not be subjected to this otherwise. A balancing act must occur, where all patients with a disease must be treated with the appropriate amount of medical care.
Chapter 4: Interview Findings

This chapter establishes the bulk of information acquired through interviews with various stakeholders. This includes an in-depth review of who was interviewed, consolidated stakeholder perspectives on how early stage identification is done today, how they think it can improve, and their perspective on how technology can be better utilized to improve care. Following this, interactions between stakeholders are evaluated. Finally, the findings from interviewing psychologists who regularly treat cancer patients are discussed, and characteristics of patients who are very good at managing their own care are shared.

4.1 - Background on Interview Findings

This research began with the premise of identifying ways to improve early detection. Often, technologies are built with no end user in mind. A method of gathering data was selected to encourage open communication about the challenges each stakeholder faces and to identify needs. Qualitative interviews were devised for three stakeholder categories: skin cancer patients, practicing primary care physicians, and practicing dermatologists in the United States with a combination of in-person, Skype, and phone interviews. Questions asked included topics about physician workflow, physician and patient decision-making, current methods for identification, challenges in skin cancer identification, technologies with which they regularly interact, how they “hand off” work to other stakeholders, and how they view other problems in the greater skin cancer care delivery system. Questions were framed to be open-ended and not suggestive of answers the interviewee could give. This method was used to identify challenges in skin cancer care delivery and to identify how technologies could successfully integrate into their lives.

Methodology

Over the course of 3 months, 9 skin cancer patients, 9 dermatologists, and 8 primary care physicians were interviewed, with prior support of question framing from dermatologists, primary care physicians, skin cancer patients, and others with significant experience in the greater healthcare delivery system. Additionally, two psychiatrists were interviewed, based on information that surfaced over the course of the interviews that skin cancer patients would frequently forego treatment to remove their skin cancers, and the underlying psychological reasons were of interest. The dermatologists interviewed ranged from third year dermatology residents to dermatologists with over 30 years of experience, practicing in Massachusetts,
Texas, Utah, California, and Ohio. Three of these board-certified dermatologists primarily performed surgeries on skin cancer patients. The experience range of primary care physicians interviewed was from 9 years of experience to over 30 years of experience; they were based in Massachusetts, Texas, and California, in both large hospitals and smaller private practices. One nurse practitioner interviewed directly provided care for the homeless population of Boston, a group with frequent skin cancer issues and limited access to care. The skin cancer patients that were interviewed lived in Texas, Alabama, Massachusetts, California, and Florida, ranged in age from 29 to 78. The skin cancer patient interviewees included patients from both non-Hispanic and Hispanic origin. All of the interviews were between 20 minutes to two hours long, with most interviews lasting about 45-minutes.

4.2 - Skin Cancer Patient Findings

The 9 skin cancer patient interviewees lived in the greater Boston area, Alabama, Texas, southern California, and Florida, and ranged in age from 29 to 78 years old. Five of the skin cancer patients interviewed were older than 60. Interview skin types included types I and II on the Fitzpatrick scale (C. A. Sinclair et al. 2014), and included individuals of both non-Hispanic and Hispanic origin. Four of the interviewees were women and five were men. Interviewees worked in a range of careers and were in many different stages in their lives. To meet the interview requirements the interviewees needed to have been diagnosed with at least one type of skin cancer. Six had been diagnosed with melanoma, six with basal cell carcinoma, and two with squamous cell carcinoma. It should be noted that only skin cancer survivors were interviewed, which is not fully representative of all skin cancer cases.

What Drives the Patient?

What do patients think is most important?

From interviews conducted with skin cancer patients, we concluded that patient’s number one priority is maintaining his or her lifestyle. If they have skin cancer, they would like to find out quickly and accurately. If they have a clear health risk, they would like to be treated immediately. Otherwise, the priority the patient cares most about is continuing to pursue their normal activities when not visiting the physician. This includes raising a family, pursuing a career, and generally enjoying themselves and participating in social activities with family and friends.
**What are the patient's challenges?**

We concluded that one of the biggest challenges these patients faced in their diagnosis and treatment was fear that their diagnosis would impact their family, friends, and general lives. Patients stated that the meaning of a “cancer” diagnosis was more difficult to manage mentally than physically: many made small changes to their lives such as seeking shade, wearing hats, and doing regular skin checks. The more fundamental challenges these patients faced were psychological fear knowing whether the cancer was fully removed, knowing whether they could trust their physicians to spot a skin cancer in the future, waiting to either hear a biopsy result or remove the cancer after diagnosis, and worrying how surgery recovery would affect their ability to support their family. Another challenge patients faced was the ability to ask follow up questions to their physicians after they had left the physician’s office.

**What motivated patients to be seen?**

Patients mentioned multiple reasons for not visiting a physician until many indicators and comments inspired them to have a lesion professionally reviewed. Some of the factors at play were other activities in their lives, such as parenting young children or working at their place of employment. For example, one patient sought professional help only after multiple reminders from a patient’s direct family to have skin spots reviewed that the patient made an appointment. In another case the patient’s mom made the appointment for him. In yet another case a primary physician’s wife insisted multiple times for him to have spots on his back examined. For patients already seeing a physician for other reasons, the barrier for identifying the skin cancer was much lower, and they were more likely to have skin spots evaluated by a physician.

**Patient decision-making**

There are many factors that go into a patient’s decision to seek treatment. In these interviews a few factors played a large role in how patients described their decision to seek care. Primary reasons were related to family, whether that was appeasing a spouse, fear of not being there for their family in the future, or reminders of the importance of health after a family member experienced failing health. Many patients consulted their direct family before visiting a physician about an issue. This direct family contact included the patient’s significant other, mother, father, daughter, or siblings. Patients were more likely to discuss their own issues with members of the family who worked in healthcare or members of the family who had already had skin cancer. Other factors that impacted whether a patient sought medical care included if the patient had an emergent pressing problem (such as a skin rash) or had a previous diagnosis of skin cancer.
Older interviewees showed a preference for wanting his or her physician to identify any skin cancers, while younger interviewees showed a preference for identifying lesions on themselves to ensure they could seek timely treatment. The type of care they sought often depended on their prior experience with the medical care system.

Who impacts the patient?
Patients were most strongly influenced by significant others, physician advice, and social standards, such as golfing and going to the beach, set by close family and friends. If the patient changed behavior to maintain his or her health, it was most likely to be immediately after their cancer diagnosis. If a physician made an error in assessing the skin lesion, and the patient discovered later that the lesion evaluated as benign was malignant, the patient took particular care to ensure a different, more highly qualified physician managed his or her long-term care going forward.

What annoys patients?
Patients are annoyed when they try to contact physicians and they cannot reach them to ask a question, and the length of time they must wait to be seen by the specialist of their choice. Patients are also annoyed with the paperwork and information they must fill in every time they see a physician, as they perceive that physicians do not communicate with one another. Patients who had been previously misdiagnosed were frustrated with their care, as they needed to contradict their physician’s advice and seek a second opinion or demand a biopsy to be diagnosed for their skin cancer.

Patient Diagnosis Story

Who found it?
Of the patients interviewed, dermatologists discovered three cancerous skin lesions, patients discovered three cancerous lesions, patients’ spouses discovered two cancerous lesions, and a patient’s mother discovered one cancerous lesion. “Discovered” in this case is defined as the first person who mentioned that the skin lesion was concerning enough to warrant a medical visit or medical procedure. This only applies to the first skin cancer the patient had.

Who biopsied it?
When a skin cancer was first diagnosed, seven were biopsied by dermatologists, one was biopsied by a surgeon, and one was biopsied by the patient’s OBGYN.
Who was part of the routing process?
Once an irregular skin lesion was discovered, three primary care physicians were involved in routing the patient to a follow-on physician to treat the lesion, one patient’s mom facilitated the patient’s appointment with a dermatologist, and one allergist pointed the patient to a dermatologist for examination of the irregular skin lesion.

Who switched physicians after diagnosis?
Two of the nine patients interviewed switched to other physicians for their continuing care after diagnosis. One patient was misdiagnosed multiple times by her OBGYN and told her skin lesion was not cancerous. She later changed OBGYNs after another physician biopsied her lesion and it was later diagnosed as melanoma. Another patient’s dermatologist applied liquid nitrogen to burn off an irregular pigmented skin lesion. The irregular lesion returned and the patient insisted the dermatologist biopsy the spot, later discovering it was melanoma. After discovery, this patient underwent three surgeries in a seven-day period, with the skin lesion excessively bleeding after surgery each time. The patient switched dermatologists to a skin cancer specialist and a different surgeon after this experience.

Why did the patients take action and seek treatment?
Each patient interviewed mentioned a specific circumstance that caused him or her to take action and see a physician. For example, one patient’s mom died from breast cancer, and she learned that individuals with a family history of breast cancer are at higher risk of developing skin cancer. Another patient was already seeing a dermatologist for psoriasis issues, and two other patients were strongly encouraged to visit a physician by their spouses who were concerned about skin lesions.

After Diagnosis
How did patients understand their diagnosis?
Patients were asked about which sources they turned to in order to understand their diagnosis. Five patients cited their primary resource for understanding their diagnosis was information from their physician, while the other four patients cited their primary resource was searching on the Internet to learn about the disease. Younger patients were more likely to review information on the Internet as a primary resource than older patients.
Do previously diagnosed patients screen at home?
Patients interviewed varied significantly in how they screen at home. Some patients only regularly reviewed their faces in the mirror and relied on physicians to do skin screenings, while others had regular times of the year they schedule for self-screening, often with the help of a significant other. Frequency varied as well: some checked at a specific time in the month, others impromptu checked just prior to getting into the shower, and others never checked. Method varied as well: some patients mentioned no pattern for skin review while others mentioned where they started and ended in reviewing their skin. All patients relied on memory only to determine whether their skin lesions had changed.

What characteristics concerned patients the most?
The following are characteristics of skin lesions that would call alarm to patients and were mentioned at least twice by different patients: a lesion changing or growing, a lesion that is easily irritated, an elevated lesion, a lesion with irregular borders, a dark spot on the lesion, and a lesion that is obviously strange-looking.

How did family and friends respond to the patient’s diagnosis?
Family and friend responses significantly varied, as many showed active concern, but impact of a family member or friend’s skin cancer diagnosis on their own behavior was minimal or non-existent. Some patients did not discuss the diagnosis with those outside of very close family. This information was gathered by asking patients about how family and friends responded, not by asking the family and friends themselves.

What can patients do better?
When patients were asked if there were additional proactive measures which would help them better manage their own skin cancer care, seven of nine stated that there was nothing they thought they could do better. One patient stated he/she could see the physician regularly (as he had not visited the dermatologist since his melanoma diagnosis a year prior) and one patient cited that he/she could take pictures and compare them.

What do patients identify as the biggest issues in the skin cancer value chain? These thoughts were aggregated and interpreted from our perspective based on patient responses throughout the interview. These are not ranked in any particular order.

- Making sure they have a high-quality evaluation
• Waiting for biopsy results or surgery
• Making lifestyle changes that conflict with social norms
• Determining if a skin lesion is irregular enough to involve their dermatologist
• Taking time to visit the physician about skin lesions
• Not knowing if they are going to develop skin cancer again

4.3 - Practicing Primary Care Physician Findings
Practicing primary care physicians (PCPs) interviewed were based in Massachusetts, Texas, and California, with four primary care physicians in the Cambridge and Boston area, and two in suburban areas of Massachusetts, one in suburban Texas, and one in San Francisco. In terms of certification, six are Doctors of Medicine (MD), one is a Doctor of Osteopathic Medicine (DO), and one is a nurse practitioner (NP). PCPs interviewed ranged in experience from nine years to over 30 years and worked with a multitude of patient demographics from treating homeless and indigent populations to treating highly educated healthy populations. They also practiced in different settings, from practicing as physicians at Massachusetts General Hospital with a large community of subspecialties to practicing in suburban private-practices without strong university affiliations. Most primary care physicians interviewed had strong ties to education and research communities.

What drives the primary care physician?
What do primary care physicians think is most important?
Our interpretation of the PCPs primary goal based on physician interviews was to help many patients treat their issues and to help patients become healthier in the future. Whether this means identifying the causal issue, prescribing the right medication, connecting with the patient with a specialist, or providing advice. To achieve this goal, the physician must run a profitable practice to stay in business and continue treating that population.
What are the primary care physician’s challenges?
The primary care physician’s challenges span from treating all of the issues a patient has within a certain time period that has been scheduled to managing all of the paperwork required to bill the patient’s health insurance and record patient information. Primary care physicians are also responsible for providing advice for patients and helping them identify healthier habits going forward, though preventative care has little reimbursement support. Primary care physicians are the “front line” workers of the healthcare system, responsible for treating most patient issues and funneling higher risk patients with more difficult diseases to the correct specialist.

How do primary care physicians make decisions?
PCPs make decisions based on information they can see on the patient, such as a rash, the patient’s memory of the evolution of the issue, the patient’s history with the issue, and the resources they have available. If the issue is not clear they will run tests to provide clarity. They also consider waiting to see how the issue evolves, whether it goes away or presents more clear symptoms. There is no clear algorithm physicians use to make evaluations, but each uses a tailored synthesis of information and personal experience. The risks associated with a procedure and the available resources can largely impact the physician’s decision on how to treat. For example, a primary physician in a large hospital in an urban area is much more likely to refer a patient to dermatology for issues while a primary physician in a rural area with fewer dermatologists available is more likely to biopsy the lesion or refer the patient to a plastic surgeon.

Who impacts the primary care physician?
The patient, the physician’s peers, other specialists, the physician’s prior teachers, and thought leaders in the industry impact a primary care physician’s practice method and follow-on procedures. Often this information is communicated in publications, from primary care journals to UpToDate, an online medical textbook that is frequently updated with information on diseases and procedures ("UpToDate" 2015).

What annoys primary care physicians?
Most primary care physicians expressed annoyance about the amount of time they must spend documenting and billing healthcare companies for patient treatment. They are also not pleased that they are responsible for synthesizing all of the information available and treating all of a patient’s needs, but do not get paid as well to do this work that requires a wide breadth of
knowledge as specialists are. They often feel they have too little time with the patient to develop a trusting relationship and to handle all of the back-end work required to provide care to patients. One of the PCP’s bigger annoyances is when the physician’s priorities are different from the patient, and the patient does not take physician advice that will improve the patient’s health outcome.

PCPs Examining Patients

What information do primary care physicians factor in to making decisions about skin cancer?
Primary care physicians visually examine the lesion, compare it to other lesions they've studied, ask the patient about the lesion's history, ask the patient about their personal or family history with skin cancer, and evaluate the patient’s complexion. They will also sometimes palpate the lesion with fingers, ask if the lesion feels irregular to the patient, or refer to images from medical textbooks, dermatology atlases, and UpToDate to compare the lesion with other documented and diagnosed lesions (“UpToDate” 2015). They also consider if the patient is willing to see a specialist about the issue, as some patients do not like to pay additional copays or book additional appointments.

What questions do PCPs ask?
Frequently asked questions include if the lesion has changed, how much it has changed, how fast it has changed, how long it has been there, if the patient has a personal history of skin cancer, if the patient has a family history of skin cancer, and how much sun exposure the patient has had in their lifetime. Less frequently asked questions include if the lesion feels itchy, if it is easily irritated, if the patient has seen a dermatologist before, and if they use sunblock and other protective measures.

What materials and resources do PCPs refer to in order to assess skin cancers?
Primary care physicians interviewed mentioned reading primary care journals, UpToDate, medical school textbooks, dermatology atlases, and tailored reference materials created by the healthcare company for which they work (“UpToDate” 2015).
How do PCPs feel about full-body screening?

Primary care physicians mentioned that while full-body screenings may catch more skin cancers, full-body screenings are not reimbursed, take a significant amount of time (approximately 10 minutes) including patient disrobing, frequently do not reveal skin cancers, and do not allow the PCP to take as much time as they would like to treat the issues the patient was concerned about. PCPs also expressed reservations about screening for skin cancers as they thought that many non-cancerous lesions would be falsely identified as skin cancers as many more people would be evaluated and primary care physicians are not as skilled at skin screenings as dermatologists are.

Do primary care physicians biopsy?

Primary care physicians interviewed either biopsy frequently or do not biopsy at all. Reasons PCPs stated they did not biopsy were because they did not want to be responsible for missed skin cancers so they would immediately refer, the ease and speed of referring to a dermatologist within their practice, the area on the body (such as a cosmetically sensitive area like the face), the number of dermatology issues the patient has, and the high level of hassle and time required to prepare equipment to take the biopsy. PCPs in suburban and rural areas and PCPs who self identified as family physicians more frequently stated that they conduct biopsies.

Primary Care Physicians: Looking Forward

What opportunities do PCPs see for technology to improve their work?

Primary care physicians mentioned many different areas for technology to improve their work; one suggestion was creating physician decision-making tools, such as computer algorithms that can generate suggested follow on procedures based on input information about the patient’s case. This would help primary care physicians synthesize the information available along with known information about patient risk to help the physician make better recommendations. Another suggestion was a communication tool, such as a cell phone app, for primary physicians to send high quality pictures of lesions to dermatologists so the dermatologist could suggest a follow-on procedure. One physician interviewed was adamant about new technologies being free or reimbursable to encourage primary physician adoption. Many physicians mentioned that technology that would help them write up clinical notes or more effectively organize EMR information. One physician mentioned that she does not have enough IT support to utilize all of
the technology available to her effectively, as it regularly does not work correctly and she must find other ways to assess the patient.

What do PCPs wish patients did better?
Primary physicians liked this question and had many ideas on ways to improve patient behaviors. Many answers centered around improving patient lifestyles for general health, such as smoking less, sleeping more, and exercising more. Other physicians wanted patients to take more responsibility for their own health and to be empowered to care for themselves for very simple issues. A physician with a primarily highly educated, high income population wished that patients would communicate with her before going straight to the dermatologist for simple rashes and other simple dermatology issues. Other PCPs wished that patients were better able to identify major general health issues and actually visit the physician. The nurse practitioner closely working with homeless populations wished his patients would be safely housed, so they would have fewer health issues and be able to manage the other parts of their lives better.

What do PCPs view as the biggest problems in the skin cancer value chain? The following points were synthesized based on primary care physician interviews and interpreted as the biggest problems in the skin cancer value chain. These are not ranked in any particular order.

- Patients are not good at identifying if lesions are cancerous.
- Patients often do not take much responsibility for their own health in general (denial, delay, unawareness).
- PCPs have little time to manage lesions and do full body screenings (time spent doing follow up paperwork, treating other issues, seeing other patients).
- PCPs are not confident in their ability to identify borderline pigmented lesions.
- PCPs examine many dermatology issues with patients but very few cancerous lesions.
- PCPs find it difficult to identify how lesions have changed.
- Dermatologists are a limited and expensive resource.

PCPs on Medical Equipment

What were primary care physicians’ reservations about a technology to detect skin cancer?
Primary care physicians mentioned the following follow up questions as important when considering whether or not to adopt a device:
• What is the device accuracy (sensitivity/specificity)?
• How much can they actually trust the device to work?
• How much would it cost?
• How portable and durable is it?
• What certification is required for the physician to operate?
• Will patient clothing have to be removed?
• Would there be assistance in interpreting the lesion? Would the reading be sent to a dermatologist?
• Could it be used on people with many different skin colors?
• Why would the primary physician want another tool? There are already so many.

One characteristic identified throughout these interviews is that currently used medical equipment takes about a minute to operate and output a measurement. Otoscopes, stethoscopes, scales, height measurements, pulse oximeters, and blood pressure cuffs take less than a minute to generate a measurement. Other tests can take much longer, from minutes to weeks, but these tests run while the primary physician is attending to other work. This one-minutes estimate was verified with one primary care physician interviewed.

**What advantage did they see a technology to detect skin cancer could provide?**

Physicians could see many benefits, as it could provide speedy results to the patient, make a non-specialist an expert, reduce unnecessary biopsies, decrease referrals, and ultimately provide higher quality patient care.

**How do PCP practices make decisions on new equipment to buy?**

Often this is a group decision made by the physicians in the practice. This involves weighing how frequently the device will be used, how much money they can make on the equipment, and how profitable the equipment will be to the practice. There is often a procedure for the practice or hospital to go through to make purchase decisions above a certain amount.
4.4 - Practicing Dermatologist Findings

Nine dermatologists were interviewed, practicing in Massachusetts, California, Utah, Ohio, and Texas. Three of these dermatologists primarily performed dermatologic surgery, and three of these dermatologists were based in the greater Boston area. Most dermatologists had close ties with the dermatology research and academic community. Dermatologists treated a mix of rural, suburban, and urban populations for a variety of dermatology issues. These dermatologists ranged in practice experience, from third year dermatology residents to one dermatologist practicing for over 30 years.

What drives the dermatologist?
What do dermatologists think is most important?
Dermatologists want to give high quality care to patients. Dermatologists do not like missing melanomas, even ones that are very difficult to visually identify, such as amelanotic melanomas. Dermatologists want to evaluate patients but also enable them to have better health in the future. They are familiar with large scale issues patients face, such as the lack of care in rural areas, increasing dermatology wait times, and the skyrocketing costs of healthcare, but these are not the most present issues in their day-to-day operations.

What are dermatologist's challenges?
Dermatologists have difficulty identifying skin cancers that have atypical presentations, such as desmoplastic, amelanotic, or spitzoid melanomas, which are frequently flesh colored. Dermatologists are also challenged by the amount of care each patient needs and the amount of time allotted, as some patients need much more care and review. One challenge dermatologists regularly face is when patients have recurrent skin issue that cannot be cured, such as eczema. Other challenges dermatologists face include the amount of time required to document patient visits for insurance companies, having patients to pay on time, running a profitable business, and adapting to new technology like a new EMR system.

How do dermatologists make decisions?
Dermatologists take into account a lot of information when seeing patients. They ask extensive questions about patient personal history, prior tests, prior cancer diagnoses, phenotype, and family history prior to the patient entering the exam room. During the exam the dermatologist will frequently do a full body check to identify suspicious lesions and compare lesions with other
lesions. The dermatologist will also ask the patient lesion-specific questions such as how long a lesion has been there and if it has grown and changed recently. Dermatologists primarily depend on their visual and tactile senses to make decisions on whether or not to biopsy a lesion, combined with their prior experiences in identifying cancerous lesions, but also take into account the patient's responses and patient risk factors. There is variance in how dermatologists document: some take far away and close-up pictures of lesions while others do not take any pictures. Location of the lesion on the body is commonly noted by a marking on a front-and-back schematic of the body. Some dermatologists describe the lesion's characteristics while others note the disease they believe the patient has.

Who impacts dermatologists?
Dermatologists are impacted by patients, support staff, colleagues, medical teachers, mentors, and thought leaders.

What annoys dermatologists?
Dermatologists are annoyed when PCPs or other referring physicians biopsy skin lesions inappropriately, biopsy too much or too little, or do not understand their own limits in identifying skin cancers. Dermatologists are also annoyed when PCPs do not document the location of a skin lesion by either taking a zoomed-out picture or describing the location specifically. When it comes to patients, dermatologists are annoyed when patients lie to them and when patients make excuses as to why they are not reducing their sun exposure. Dermatologists are also bothered that teledermatology reduces the quality of dermatology evaluations as skin lesion images do not have a high-resolution, and dermatologists do not have enough information about the lesion or patient to make a highly accurate evaluation of the lesion's cancerous state.

Dermatologists Examining Patients
What information do dermatologists factor in to making decisions about skin cancer?
Dermatologists factor in a range of information, from personal and family history, lesion history, lesions characteristics, patient skin type, and patient concern.

What questions do dermatologists ask?
Dermatologists ask a range of questions, starting off in the waiting room asking about patient and family history of cancer. They ask questions about the lesion, how it feels, and its history. They also ask questions about why the patient is concerned and the patient's past radiation
Dermatologists also ask about how the patient burns and tans to pinpoint the patient’s skin type and his or her likelihood of developing skin cancer.

**Which labs do dermatologists send biopsies to?**

All dermatologists interviewed sent skin biopsies only to a board-certified dermatopathologists. They were insistent that lesions suspected to be melanoma be biopsied with the deepest layer, either with a punch biopsy or a deep shave biopsy, as melanoma depth of invasion is the biggest indicator of the cancer’s stage and determines how the surgeon must proceed to ensure full excision (Pickett 2011). A shave biopsy removes a superficial thin disk of tissue with a slightly curved blade, while a punch biopsy is cut with a circular blade that extends through the subcutaneous fat (Pickett 2011).

**How do dermatologists feel about full-body screening?**

This varies, as dermatologists ranged from offering all patients full skin screenings to only offering patients full skin screenings that were at moderate to high risk of developing a skin cancer. The number of patients who rejected a full body skin exam ranged from 15% to 50%. This was for a myriad of reasons, from a patient only wanting a specific problem treated to patients not wanting to disrobe in front of a physician. Patients visiting the dermatologist frequently, such as patients who visit for recurrent issues like acne or psoriasis, were more likely to not be offered a full body check every time.

**Dermatologists: Looking Forward**

**What do dermatologists wish patients did better?**

This question was popular with dermatologists and they had a lot to say on how to improve patient behavior. Dermatologists generally wished that patients took their advice in using better sun protection, learned how to better identify melanoma, generally were more aware of their skin, and would visit a physician to have problems checked out when they were first identified. After a cancer diagnosis, dermatologists wished that patients would listen better to the physician and their advice, not just find support of their opinion on the Internet, and trust US healthcare system. One dermatologist interestingly mentioned that he wished men took a melanoma diagnosis more seriously while women did not overreact to a melanoma diagnosis.
What are characteristics of patients that are very good at managing their cancer diagnoses?

There were many characteristics mentioned by dermatologists of patients who are very good at managing their cancer care after diagnosis. These patients sought the dermatologist’s advice and approval of skin protective products, wore sunscreen into the appointment, did not tan, had a good social network, exercised, listened carefully to instructions, called the physician if they had medical issues, kept track of skin changes, regularly followed up, were organized, had access to transportation, were bright, changed their lifestyle to allow for sun prevention, took ownership of their own care, had a positive outlook on life, had coping mechanisms such as sharing their story with others in a similar situation, were appreciative, were motivated to follow up, and had support from a significant other at home. Multiple dermatologists stated that the majority of their patients were good at managing their own cancer care.

How do you feel technology can help you do your job?

There were many suggestions for how technology could help improve dermatology practices. One dermatologist mentioned that a mobile phone application could tell a patient if a lesion really needed medical attention. Another mentioned that he could use help converting information known by his medical team into the computer, as this takes a lot of time. Another mentioned that a technology that could reduce the number of biopsies would be very helpful. Another wished she had better resources for capturing high quality medical images to refer back to later, but for now taking pictures takes too much time and that time is better spent doing other activities.

What do dermatologists view as the biggest problems in the skin cancer value chain?

The following are the top seven noted problems dermatologists identified in the skin cancer value chain. These were synthesized based on interviews, and are not in any specific order.

- Patients not noticing changes in their own bodies
- Patients not taking skin lesions seriously and seeking treatment
- Patients not improving their own prevention methods
- Some skin cancers have irregular presentations and are difficult to identify
- PCPs and non-specialists do not realize their own limits and misidentify some lesions
- PCPs do not take appropriate biopsy action in case a lesion is cancerous
- Dermatologists are in limited supply and high demand
- Many patients who need care cannot access dermatologists or cannot afford them
- Not enough money is spent on preventative care
Dermatologists on Medical Equipment

What were dermatologists’ reservations about a device to detect skin cancer?

The questions raised by dermatologists to this question are listed below. Dermatologists asked the following questions about a potential device the most frequently.

• What would the sensitivity and specificity of the device be?
• If the dermatologist was worried, why would they not biopsy the lesion?
• How much time would the device take to operate?
• How portable and durable is it?
• How much would it cost?

The following questions were asked by dermatologists but less frequently.

• Can a device really identify information a dermatologist can gather in an in-person visit?
• How would it help a dermatologist?
• Would I have a job after that?
• If patients could use it at home, what if they did not evaluate their whole body and missed a lesion?
• Who evaluated it and how did they evaluate it? Was it evidence-based and independently funded?
• At what point in a lesion’s evolution can it detect irregularity?

The most common, immediate question raised by dermatologists was the accuracy (sensitivity and specificity) of the device. The questions listed first were the most frequently asked questions.

What advantage did dermatologists see a device to detect skin cancer could provide?

Some of the advantages mentioned included not having to wait for the biopsy results, allowing the patient to use the device at home and be more informed of their own care, allowing PCPs to improve their screening, and improving overall diagnostic accuracy of dermatologists.
4.5 - Interactions between Interviewed Stakeholders
The following section details two-way relationships between each of the interviewed stakeholders in order to show their perception of the other stakeholder and opportunities for improvement in the system.

Patient and Primary Care Physician Relationship
Primary care physicians thought patients were often concerned about innocuous lesions, resulting in many physician requests for evaluation of evidently benign lesions. They also thought patients did not correctly remember the history of their skin lesions, resulting in missing information during the exam that could inform the skin lesion’s disease state. Some patients wanted to be able to better manage their own care, such as removing prior skin damage and assessing lesions with technology at home. Additionally, some patients did not trust the evaluation skills of primary physicians because of prior experiences with non-experts.

Primary Care Physician and Dermatologist Relationship
Primary care physicians did not want to refer patients to dermatologists if they did not need to, and wanted to be able to manage most patient dermatology care. This was because they knew patients would be less likely to follow up with the dermatologist and that dermatologists are busy and deal with many more complex skin issues. PCPs liked to be able to call and pull strings at dermatology offices to have patients seen quickly, as they could ensure patients do not have to wait. PCPs mentioned they only learned about 50% of the outcomes of patients who had been referred. Dermatologist thought PCPs did not realize their own limits in identifying lesions that may be cancerous. They thought that regularly PCPs biopsy inappropriately, as they managed the patient’s care after diagnosis and the difficulties a pathologist faced in selecting appropriate follow-on care without enough information about the invasion level of the cancer. Dermatologists also mentioned that they sometimes did not follow up with primary care physicians about a patient’s visit unless there was a significant finding such as a cancerous diagnosis, as they did not think it was necessary because the patient did not need further treatment.

Dermatologist and Patient Relationship
Patients looked to dermatologists for help managing their long-term monitoring. They thought it was fairly difficult to contact dermatologists, and patients generally did not like having scars from biopsies and excisions. Dermatologists thought that patients regularly refused full skin exams because they were embarrassed to disrobe or just wanted to be seen for the issue for which
they booked an appointment. Dermatologists also thought that patients lie about their activities, such as how frequently they visit tanning beds or their prior sexual activity. One dermatologist mentioned that one type of squamous cell carcinoma is more prevalent in patients with HPV, and an understanding of prior sexual activity helps inform dermatologists of the patient’s risk for developing this type of skin cancer. Dermatologists also mentioned that patients forget where cancerous lesions are. Dermatologists generally thought that developing trust with patients was very important to deliver quality care.

4.6 - Oncology Psychiatrist Interview Findings

One of the most unexpected findings from interviewing patients and physicians was the emotional psychological impact a cancer diagnosis can have on a patient. This can vary significantly: most patients take the diagnosis seriously, treat the cancer, and change their behavior to prevent recurrence, such as avoiding direct sunlight and using sunblock. Some patients, however, either do not acknowledge the cancer or over-respond. One dermatological surgeon mentioned that about 5-7% of patients diagnosed with skin cancer decide not to treat their cancer. Two psychiatrists who provide support for cancer patients at Harvard Medical School were interviewed to discuss this topic, as these initial decisions can have detrimental consequences to patient’s health.

Cancer: Psychological Impact

Many factors can play into a patient’s decision to go forward with treatment, and these include cultural factors, such as how the culture has dealt with prior cancer diagnoses, family support, the patient’s stage in life, the patient’s prior experience with family and friends diagnosed with cancer, the patient’s anxiety level about the disease, the responses of peers, the patient’s trust in physicians and the general healthcare system, the patient’s understanding about treatment options and the disease, and the patient’s perception of the consequences of treatment compared with benefits.

The interviewed psychiatrists mentioned a few issues that were most common in patients who struggle after a cancer diagnosis: anxiety and depression. Immediately after finding out a diagnosis, one of the biggest factors that weighs into patients deciding whether or not to treat is the cost-benefit analysis: do the benefits really outweigh the toll the treatment can take, whether cosmetic, painful, or difficult for family and friends?
After a patient has recovered from cancer treatment, two factors primarily impact the mental health of the patient: fear or recurrence and lack of social support. One psychiatrist mentioned that fear of recurrence is present in almost every patient he treats. For metastatic cancers it can be difficult to identify if the cancer has returned, as there are no obvious symptoms. Addressing the social support challenges, after patients finish their treatment regimen often patients visit their medical support team much less frequently, interact with their family and friends much less, and feel pressure to resume their lives as they were before the diagnosis. That can be mentally challenging for many patients.

From the physician interviews, almost all primary care physicians and dermatologists mentioned that their process for informing a patient of a cancerous diagnosis included either inviting the patient back into their office, or, in some cases, having a the physician or seasoned nurse call the patient and walk through treatment options and the significance of the diagnosis. It was clear that care was taken to make sure patients felt supported through the process and informed of the options. Patients often interpret cancer diagnoses based on their prior experiences with the disease or information they have access to, whether that is from a physician, online, or from social influences. Much research has been done in the field of oncology psychology and how patients process information, but there is room for improvement for managing the information available so that the 5-7% of patients who decide not to treat can have higher quality evidence-based information available and more support from their medical and social communities to make more informed long-term decisions.

4.7 - Interview Finding Conclusions

Overall, the interviews showed a difference in perspectives from each stakeholder on the challenges they faced and the challenges other stakeholders were concerned about in the healthcare detection system. Dermatologists were concerned that they were not reviewing most of the lesions they should, as the primary care physician did not refer all of the cancerous skin lesions to dermatology. Primary care physicians were concerned about the extra cost, hassle, and delays the patient would undergo if the patient were referred to a dermatologist. Patients considered the cost of dealing with the healthcare system as an inconvenience, and generally visited a physician when they were faced with an obvious health issue. Physicians expressed an understanding of patient challenges, but these were not the same challenges the physicians faced on a day-to-day basis.
Overall, we identified that patients need assistance in managing their diagnoses from a psychological perspective. This is true both in non-melanoma and melanoma skin cancer patients. Additionally, primary care physicians ask similar questions of patients concerned about skin cancer, but do not always know how to interpret this information, and do not always have a full picture of relevant information. We also established that care delivery significantly depends on how a physician is trained and his or her care delivery environment. Primary care physicians must deliver more care to rural patients without ready access to specialists.

Use Cases Considerations for Technology
Technologies must meet stringent requirements to be widely adopted. In a physician’s office, a technology must provide significant diagnostic accuracy improvement over current methods, be able to be dropped, be handheld and easy to move, be readily available, be affordable, operate quickly, provide an advantage over a regular biopsy, be able to be fixed quickly, and potentially allow the physician to connect with another physician or other external evaluator. A technology would be more likely to be adopted if it could interface with an electronic medical record system, be reimbursed, and have specialty thought leader support. In the patient’s home, a technology would need to chart the location of a lesion, allow for capturing of evolution or point-of-use, generate an evaluation of the lesion, be quick to use, remind the patient to reevaluate, and be affordable for patients. A technology would be more likely to be adopted if the technology allowed the patient to interface with the medical system.

Advice for Patients: Best Practices
After asking dermatologists to name frequent characteristics in patients who manage their cancer diagnoses effectively, we compiled a short list of factors mentioned frequently and less frequently. Factors frequently mentioned included having a good social network of support, adhering to physician instructions, seeking advice from physicians, playing an active role in their own medical care, using preventive measures like sunblock, and calling the physician if they have any medical issues. Factors that were less frequently mentioned were having a positive attitude, sharing their experience with others, listening carefully, engaging in physical activity regularly, having access to transportation, staying organized, being college-educated, and being married.
Chapter 5: Gaps in Care and Areas for Improvement

After setting the stage for how skin cancer care is delivered in Chapter 3 and collecting stakeholder perspectives of patients, primary care physicians, dermatologists, dermatological surgeons, and oncology psychiatrists through interviews in Chapter 4, this chapter will build a picture of gaps in care in the current system and the primed opportunities for improvement.

5.1 - Defining Gaps

Based on the STAMP model of accident evaluation and system improvement methods, the following establishes how actions or inactions can contributed to a delayed skin cancer diagnosis. This type of analysis is useful as it uses a systemic approach to monitor continuous interaction issues between stakeholders and stakeholders themselves.

Unsafe Control Actions

Unsafe control actions happen when one of the following occurs (Leveson 2011, 213). Skin cancer involved all these unsafe control actions.

1. A control action is not provided or is inadequately executed (e.g. a patient notices a strange lesion but does not have it examined)
2. An unsafe action is executed (e.g. a patient self-treats the skin cancer with a home-remedy such as bleach)
3. A control action is taken too late or at the wrong time (e.g. a patient delays visiting the physician for months)
4. A control action is stopped too soon or continued too long (e.g. a patient concerned about a benign lesion is assured the lesion is not cancerous and it later becomes cancerous without the patient noticing)

5.2 - Jennifer’s Story: A Case Study

The following is a Causal Analysis using System Theory (CAST) analysis of a young patient’s experience with melanoma and going through the healthcare system. CAST is a method of evaluating prior accidents or adverse events based on components in the control structure and
interactions between components (Leveson 2011). This example is not representative of all skin cancer patients, but does highlight key structural components in the system and illustrate where problems regularly arise. The patient’s name has been changed to protect her privacy.

Jennifer's Story

Jennifer, a 29-year-old mom, currently lives with her two kids and her husband in Massachusetts. When she was pregnant with her first child, she noticed a freckle on her stomach that became darker and grew in size, rising above the surface of her skin. She was 26 at the time and talked to her OBGYN about the issue. Her dad had previously been diagnosed with squamous cell carcinoma, and she had been to the dermatologist for full body scans a couple of times as a teen and once in her 20s. Her OBGYN reviewed Jennifer's mole, saying not to worry about it, and that pigment changes are very normal during pregnancy. She mentioned the issue again two more times to her OBGYN who continually advised that the spot was benign.

About a year after her daughter was born, she visited a nurse practitioner in her primary care office, still concerned about the lesion. She had never had a mole rise above the surface or change color in the same way. As the nurse herself had been diagnosed with a similar-looking melanoma before, she referred Jennifer to a surgeon for a shave biopsy. She did not want Jennifer to have to wait to see a dermatologist. The pathologist reviewed the biopsy and sent it to a second lab for review. About two weeks later Jennifer found out it was melanoma, and was booked for a wide incision and lymph node biopsy to see if the cancer had metastasized. Luckily, her melanoma was Stage 1, still restricted to the primary cutaneous layer, and had not spread to her lymph nodes.

After this experience Jennifer changed OBGYNs, as she did not trust her prior physician's medical judgment. She’s regretful of her diagnosis, as she spent a lot of her childhood outside on family summer vacations to the beach and went tanning a few times in her teens and 20s prior to weddings and other events in her life. She worries that she may find another melanoma, reviewing her body for changes to skin lesions every month, and enlisting her husband to help with these checks every month. She stated that her biggest challenge was that she did not know how the cancer diagnosis would impact her family. She still remembers not being able to lift up her daughter around her 1st birthday. She now visits the dermatologist once every 6 months, SUSAN CONOVER
shifting from regular visits to her surgeon who did her shave biopsy and excision to regular dermatology exams.

Jennifer's Story: Proximate Events
The following steps break down each event in Jennifer's process of being diagnosed and treated for melanoma.

1. Jennifer developed a mole on her stomach.
2. Jennifer identified the lesion was irregular and changing on her stomach, noting a color change, size change, and the lesion was raised, unlike other lesions on her body.
3. Jennifer visited her OBGYN for a regular visit during her pregnancy, mentioning the mole as a concern.
4. Her OBGYN evaluated the lesion and deemed it non-cancerous.
5. Jennifer again visited her OBGYN, raising concern for the mole again.
6. Her OBGYN again looked at the lesion, deeming it non-cancerous.
7. For the third time Jennifer brought up the lesion to her OBGYN.
8. Her OBGYN for the third time told Jennifer the lesion was not cancerous.
9. Jennifer did not bring up concern for the lesion to a physician for over a year.
10. About a year after her daughter was born Jennifer brought up the concern about the lesion to a nurse practitioner at her primary care physician’s office.
11. The nurse practitioner recalled her personal experience with a melanoma diagnosis.
12. The nurse practitioner referred Jennifer to a plastic surgeon to biopsy the lesion.
13. Jennifer made an appointment and visited the plastic surgeon.
14. The plastic surgeon took a biopsy of the lesion.
15. The pathologist examined the lesion and sent the lesion to another pathologist for a second opinion.
16. About two weeks later the pathologist report came back with a melanoma diagnosis.
17. Jennifer booked an appointment for the rest of the lesion to be removed in addition to a lymph node biopsy to see if the cancer had spread.
18. Jennifer underwent surgery to remove the rest of the melanoma in a wide excision.
19. Jennifer learned of the results a couple weeks later that the melanoma was fully removed, had not metastasized, and the melanoma was Stage 1.

20. Jennifer changed OBGYNs after this experience, not citing a purpose for changing physicians.

21. Jennifer now does regular monthly checks for skin cancer, enlisting her husband for help for areas of her body she cannot see.

Jennifer's Story: Control Structure

Figure 5.1 highlights breakdowns in the control structure of Jennifer’s diagnosis, including exceptions to protocol that functioned as corrective actions, such as the nurse practitioner sending Jennifer straight to the surgeon for a biopsy instead of to dermatology. As you may notice, this is Figure 3.9 in Chapter 3 with Jennifer’s interruptions overlayed. Figure 5.1 shows the events that both contributed to the hazard and deviated from the standard practice of processing patients. These actions are more detailed in the proximate events and contributing factors mentioned below. Many stakeholders, previous conditions, mental models, and misinformation contributed to Jennifer’s delayed diagnosis and treatment.
Figure 5.1: Issues that arose in Jennifer's delayed melanoma diagnosis
5.3 - Jennifer’s Story: Contributing Factors

As many interactions and behaviors contributed to Jennifer’s delayed diagnosis, this section will detail contributing interactions, stakeholder decisions, hazard violations established in Chapter 3, and various higher-level issues caused by non-direct stakeholders as shown in Figure 3.8. Beyond this, we will extrapolate the potential dynamic consequences of these factors.

**Contributing Interactions**

The following section details failures in the interactions between stakeholders in the system that contributed to Jennifer’s delayed diagnosis.

- **Jennifer and Direct Family** - Jennifer experienced sun exposure on vacations as a child, norms set by her family.
- **Jennifer and Friends** - Jennifer tanned prior to major events in her teens and 20s, norms set by her peers and other social influences.
- **Jennifer and OBGYN** - Jennifer’s OBGYN did not find a way to address the patient’s concerns medically after the issue was mentioned multiple times.
- **Nurse Practitioner and Dermatologist** - Jennifer’s nurse practitioner circumvented the dermatologist as the physician was thought to take a long time to see Jennifer, and directly sent her to see a surgeon.

**Contributing Stakeholders**

The following section details failures in the actions of stakeholders in the system that contributed to Jennifer’s delayed diagnosis.

- **Jennifer** - Jennifer waited a year before she visited another physician for the skin issue after consulting her OBGYN.
- **OBGYN** - Jennifer’s OBGYN was not trained to appropriately identify cancerous skin lesions. Additionally, Jennifer’s OBGYN was not trained to appropriately identify her limitations in identifying cancerous skin lesions.
- **Pathologist** - The pathologist needed a second opinion of the biopsied skin lesion, further delaying diagnosis.
- **Surgeon** - The surgeon did not perform a deep enough skin biopsy to include the lower margin of the melanoma. Additionally, the surgeon had to do an excessive lymph node
biopsy to determine the invasion of the melanoma because the surgeon did not perform a deep enough skin biopsy.

**Hazard Violations**

The skin cancer detection hazards present in Jennifer’s case were the following.

*Hazard 1.6: A physician reviews a cancerous skin lesion but misidentifies it*

*Hazard 2.3: A physician incorrectly biopsies a lesion and must do an excess biopsy after the melanoma is diagnosed*

Violating Hazard 1.6 led to a delayed diagnosis, luckily still caught at Stage 1 over one and a half years after it was first reviewed. Violating Hazard 2.3 required an excess sentinel lymph node biopsy that would not have been necessary if the surgeon had taken an appropriate biopsy of the melanotic lesion. Hazard 2.3 is not as important as Hazard 1.6, as previously discussed, but is still an error in how patients should be processed. There may have been other hazards involved in this case that are not known, as this analysis was built on from only Jennifer’s perspective.

Additionally, temporary fixes to the system, such as Jennifer’s nurse practitioner referring her directly to a surgeon, helped in her case, but the information Jennifer and her nurse practitioner learned from this expedited process was most likely not captured and spread throughout the medical community to people it could help. If more physicians made exceptions like this, appropriate procedures for how to handle patients would be much more unclear and could lead to additional procedural exceptions, further confounding communication in the system. Exceptions to protocol might not directly violate hazards but should be deeply considered in system redesigns and ensuring stakeholders in a system can share their learned experiences to prevent similar situations in the future and can acquire the care they need at the appropriate time. Beyond this, if the nurse practitioner had not been previously diagnosed with melanoma this exception may not have happened, and the skin cancer may have reached a later stage. This should also be considered in system reconfigurations.
Higher Level Issues
The following details higher-level problems that contributed to this hazard. The relationship between each stakeholder group can be seen in Figure 3.8 in Chapter 3 of this document. These are organized based on failures in training methods, failures in process methods, and failures in review methods that contributed to the delay in Jennifer's diagnosis.

Training
Two training failures were the responsibility of both education institutions and regulators (as seen in Figure 3.8). The OBGYN did not have sufficient training and practice on general skin care, and the OBGYN was not trained to identify her own capability of identifying cancerous skin lesions. Additionally, two training failures were the responsibility of both regulators and medical associations. Information spreading was (and currently is) siloed within specialties and not spread between specialties. For example, primary physicians frequently read primary physician journals while dermatologists read dermatology-related journals. Beyond this, the plastic surgeon did not have sufficient training on how to appropriately biopsy potential melanomas.

Process
One process failure was the responsibility of regulators. Only one physician examined the patient's lesion to evaluate it as non-cancerous. There was no backup safety plan for catching cancerous lesions, particularly those misdiagnosed. Additionally there were two process failures that were the responsibility of regulators and medical associations. Medical associations and regulators do not enforce physician procedures or investigate patient complaints unless there is a major issue. Also, fundamentally, patients must choose to be concerned about a lesion or another skin issue before the lesion is reviewed. After this, the patient must seek continual medical support to be professionally evaluated.

Review
Review errors directly deal with feedback issues within the system. Two review errors were the responsibility of regulators. Physicians were not evaluated based on their prior successes and failures in treating patients. Additionally, patients did not communicate back to physicians if there were issues after the patient had left the physician's office. Regulators are responsible for ensuring physicians are effectively treating patients, and the clearest method of evaluating their effectiveness, patient outcomes, is not captured.
Specialists were not evaluated on their abilities to deliver general care after becoming specialists. This review issue is the responsibility of both regulators and medical associations. The last review issue revolves around if the system is able to utilize failures and improve the system in the long term, and is the responsibility of regulators, medical associations, and education institutions: information about medical errors and corrective measures to fix these errors is not spread throughout the medical community to improve care delivery.

**Dynamic Consequences**
The following list details potential long-term consequences of how the current skin cancer care system is structured.

1. Information about physician errors becomes taboo to spread in the industry.
2. Physicians hide errors from colleagues.
4. Specialists do not maintain their ability to know general practice information and treat patient issues to the best of their ability outside of issues in their specialty.
5. Physicians become unaware of common issues if they do not have personal experience with these issues.
6. Physicians do not collaborate effectively with other physicians on diagnostic cases.
7. Physicians do not “close the loop” and find out about the outcome of their patient recommendations.

5.4 – The Challenge of Identifying Lesions

This section explores the nuances involved in identifying cancerous skin lesions and the challenges patients, primary care physicians, and dermatologists face.

**Who Discovers Lesions?**

Who finds lesions? As there is some information captured on melanoma identification, Figure 5.2 illustrates percentage estimates of who identifies melanomas.
Figure 5.2: Map of melanoma discovery in the “front line” skin cancer detection system
The blue hexagons in Figure 5.2 next to each stakeholder reveal the estimated percentage of melanomas each stakeholder identifies in the system. These numbers were derived from a combination of questions answered by dermatologists and dermatological surgeons for this research and two papers based on patient surveys sent to Massachusetts skin cancer survivors (Koh et al. 1992; Geller et al. 1992). Additionally, patients reported they had difficulty seeing 31% of lesions (Koh et al. 1992). These hard-to-see lesions are frequently on the patient's back or back of their legs. How the system is today, an informed patient or informed patient social influencers make up about 70% of a patient's support system for identifying melanoma.

**How Good Are Physicians at Detection?**

One important factor in evaluating the current state of the system is the effectiveness of patients and physicians at detecting skin cancers. We did a literature review to understand how effective physicians are at detecting malignant melanoma. The sensitivity, or “false negative” rate is considered by many to be the most important metric when evaluating potentially cancerous lesions, as it determines the number of cancerous lesions that are missed. Primary care physicians are about 52 to 72% sensitive to identifying melanomas, while dermatologists are 74% to 91% sensitive to identifying melanomas (Corbo and Wismer 2012). The values can be seen in the control structure diagram in Figure 5.3. This is a significant difference. These studies were done in a controlled setting and were executed by administrators showing images of skin lesions to physicians. It is estimated that these percentage estimates are actually higher than when primary physicians and dermatologists identify lesions in everyday practice outside of controlled lab settings with pictures.
Figure 5.3: Sensitivity and specificity ranges for physicians in melanoma detection (Corbo and Wismer 2012)
Physician Training and Practice

One major consideration in evaluating how effective physicians are at detecting skin cancers is how much training the physician has in identifying skin lesions, including original medical school training, continuing education, day-to-day exposure to the disease, and how frequently the physician learns how effective he or she is in detecting a skin cancer. These factors are a synthesis of the factors discovered in our physician interviews. Running the numbers, with 209,000 practicing primary care physicians in the United States ("The Number of Practicing Primary Care Physicians in the United States" 2011) and with around 74,000 melanomas expected to diagnosed in 2015 (Howlader et al. 2015), primary care physicians in 2015 will treat a set of patients that will contract less than half a melanoma per year, while they will treat a set of patients who contract just over 3 squamous cell carcinomas and just over 13 basal cell carcinomas per year. These numbers are averages but provide one view on how frequently primary care physicians encounter these diseases in everyday practice.

5.5 - System Dynamics in Skin Cancer Care Delivery

Figure 5.4 illustrates many of the ways a patient receives skin cancer care, and represents the average patient experience for patient with skin cancer. This system dynamics model was created to show how a patient flows through the system, emphasizing the dynamics of the process. The more patients who would like to be reviewed, the more work a primary care physician and dermatologist must do to support that patient, and the more work these stakeholders must do to identify the patients who have skin cancer.

At first, a patient is part of the "general patient population." Once the patient's concern level exceeds his or her perceived effort to see a physician for a health issue, the patient will book an appointment. The patient's concern level must generally be much higher for just a skin lesion concern than an acute issue with immediately pressing symptoms, such as a fever. Once the patient books an appointment, they can see a PCP. Primary physicians interviewed mentioned they were much more likely to review a skin lesion when the patient was visiting the primary physician for another reason, as the patients would add the skin lesion to the list of concerns they wanted assessed while in the office.
Once in the office, a primary physician decides how to treat the patient, whether that includes advising the patient they believe the skin lesion is innocuous or if they believe it is suspicious and would either like to take a biopsy or refer the patient to see a dermatologist. Primary care physicians are 52 to 72% sensitive to detecting melanomas (Corbo and Wismer 2012). If the primary physician refers the patient, the patient will need to book another appointment with a dermatologist. Often this is on a different day, as dermatologists frequently have months-long wait times for new patients. In some hospital systems the patient can be seen by a dermatologist the same day or within a week if their primary care physician starts the process. The PCP can also make recommendations to the patient at this time, requesting the patient take pictures of suspicious moles and recheck the pictures in 3 months.

Once in the dermatology office, a patient will often be reviewed for the lesion they are concerned about in addition to other lesions on their body. The dermatologist can either decide to biopsy or tell the patient they do not believe any lesions are concerning. Dermatologists are 74% to 91% sensitive to detecting melanomas (Corbo and Wismer 2012). Dermatologists frequently treat patients with many or recurring skin issues. If a patient has been previously diagnosed with skin cancer, the patient more likely to see a dermatologist regularly.

If a patient was biopsied, the patient must wait 3 days to 2 weeks to learn about the results of the biopsy from their physician. If the lesion is cancerous, the patient will gain treatment for the skin cancer. This shifts the patient from the “general patient population” to the “frequent derm issue population”. Each time the patient interacts with the medical system that experience factors into the patient’s prior medical experience, affecting their future interactions with the medical system.

The system dynamics model in Figure 5.4 can be used to illustrate many interactions, delays, bottlenecks, and feedback systems within the system. Many interacting components were left out of this model for simplicity, as the model would be too complicated and difficult for the reader to understand. For example, if the primary care physician knew his or her own rate of identification of melanocytic lesions, the primary care physician may decide to become better trained, refer more patients, or perform more biopsies. Adding new feedback loops, such as the one just stated, can change the dynamics of the entire system.

Susan Conover

MIT SDM Thesis
Figure 5.4: A system dynamics model of the patient management process
5.6 - Primary Gaps in Care

In analyzing Jennifer’s diagnosis, gaps in the control structure, and dynamics of the skin cancer care delivery system, there are many opportunities for improvement. The following points illustrate structural, accountability, disease-related, and discovery, and other gaps in how skin cancer care is delivered today.

High Level Structural Issues

*Cancer care assessment is an as-needed service.* A patient must enter the system either concerned about a lesion or some other health issue to be evaluated for skin cancer. The only way physicians help to screen is when the patient is being seen regularly for another issue or visiting the physician for a physical. This means a lot of lesions are identified late, as the individuals with the lowest skill level in skin cancer identification are responsible for reviewing their own skin cancers.

*Patients who are already part of the healthcare system receive the best care,* as they have significantly increased opportunities for a physician to identify a skin cancer. This is known as “closed-loop”, as they are regularly examined in the medical system. Patients become part of a closely monitored group after their first skin cancer diagnosis, not before. This means that many melanomas that affect young and middle-aged adults are not caught, as they are not closely monitored by the healthcare system. Many younger individuals do not visit the physician for an annual physical as advised, as they do not see the need to.

*The patient only needs to hear one physician evaluate the lesion as fine to stop the process of diagnosis.* This means that there are no standardized safety nets in place to catch skin cancers that are missed or misdiagnosed. The safety nets for patients are themselves and their social influences.

*When a skin cancer is suspected, frequently only one physician evaluates the lesion.* This dynamic is encouraged, because if each physician works independently to deliver care, then the healthcare system can process more patients and more issues more quickly. Skin evaluations are frequently not verified, and these are almost always not tracked and reviewed later at the
primary care level. Responsibility falls on the patient to bring up health issues such as skin lesions that were identified before to readdress and reevaluate these at later appointments.

Patients cannot take action to improve their own health after diagnosed with skin cancer. Patients often have to trust physicians enough to allow them to change their health after a diagnosis. Options that allow patients to have more choices and feel part of their own care include homeopathic remedies and at-home solutions, which can negatively interact with Western treatments. After a skin cancer diagnosis, patients often feel helpless to improve their own conditions, whether that includes treating their own issues or removing skin damage preemptively.

Accountability Issues

One of the fundamental accountability issues in the system is that patients are ultimately responsible for their own health and seeking care, not physicians. On top of this, physicians are not held accountable and evaluated for their prior misevaluations, and often do not find out about them. Because they often do not find out if they made a mistake, physicians cannot learn from their mistakes or talk about their mistakes to the greater medical community, missing opportunities to improve how others deliver healthcare by advising of mistakes. One of the other accountability factors is between physicians: primary care physicians do not centrally manage patient care, but “hand off” patient care to specialists after referring them. These specialists respond with notes on treatment about 50% of the time. This information was learned from patient and physician interviews and an analysis of the greater system.

Issues that Arise from the Disease

Some skin cancer evaluation issues arise from a physician’s inability to identify a skin cancer with the technologies available. These include desmoplastic, amelanotic, and early melanomas, which make up around 8% of melanomas (Ungureanu et al. 2015). This is assuming they see the issue before it has progressed, as around 31% of melanomas are in hard-to-see areas (Koh et al. 1992). Nodular melanomas (15% of melanomas) are particularly pernicious as they do not have four out of the five ABCDE characteristics, and they only show evolution (Shaikh 2012). Even if these nodular melanomas are spotted, they can metastasize in under a month (Shaikh 2012), and around 15% of melanomas grow very quickly (Shaikh 2012; Liu et al. 2006).
pernicious characteristics sometimes combine and sometimes are separate, but can lead to later stage melanomas fairly quickly (Howlader et al. 2015). An additional component of melanoma, is often melanomas do not indicate disease to the patient, as the lesions are not itchy or ulcerated (Koh et al. 1992). Outside of melanoma, squamous cell carcinomas can be diagnosed at later stages because they are frequently not pigmented, do not raise patient suspicion, and can be in sensitive areas, particularly if caused by HPV. Patients do not show as much concern about non-pigmented lesions as about pigmented lesions. This information about squamous cell carcinomas was discovered in interviews with dermatologists.

**Skin Cancer Discovery Issues**

PCPs evaluate at least twice as many melanomas as dermatologists (Koh et al. 1992) but are about 20% less sensitive to at detecting melanomas when compared to dermatologists (Corbo and Wismer 2012). Other physicians, such as specialists, identify substantially more melanomas than dermatologists (Koh et al. 1992), and their ability to detect melanomas is unknown. This means that non-specialists identify the majority of physician-identified melanomas and they have lower rates of detection in the range of 52% to 72% (Corbo and Wismer 2012).

Additionally, as we learned from Jennifer’s case, patients who are assured about lesions by physicians often delay re-evaluation, even if they are still concerned. Today patients and their family and friends are much more likely to identify a melanoma. This means that the healthcare system is largely not involved in the melanoma identification process, and melanoma identification a patient’s responsibility (Edlich et al. 2004, 222), unless this patient is seen regularly by a dermatologist.

Many primary care physicians ask the same questions to patients when they come in concerned about a skin lesion, around their family history of skin cancer, personal history of skin cancer, history of sun exposure, how the lesion changed, and over what time period the lesion has changed. 90-95% of patients are diagnosed melanoma do not have a family history of melanoma (Bataille and de Vries 2008), and many do not notice lesions changing. Patients mentioned that they did not notice lesions changing in interviews we conducted. This means
that asking patients about a prior family history or lesion changes will not help catch most melanomas.

Another issue discovered from interviews with physicians is patients often do not know how to identify skin cancers. A few primary care physicians mentioned patients frequently asked if lesions that were very clearly benign were malignant. This poses a challenge to primary care physicians as they must assess so many skin lesions, and so few are actually concerning, that when patients are concerned about a lesion it is most likely innocuous and most primary care physicians have very limited exposure to actually cancerous lesions.

Other Contributing Issues

Other external issues appear to have a significant impact on skin cancer early identification. One factor is high and rising incidence. 5 million cases of skin cancer are expected in the United States in 2015 (American Cancer Society 2015a), and this is rising a rate of 4.2% per year (Rogers et al. 2010). Rising incidence increases the pressure on the healthcare system for identification, treatment, and follow-on support after diagnosis.

Another factor is the high demand for services and limited population of dermatologists in the United States. This poses an issue as dermatologists are highly paid and can select the population they would like to treat. Many patients with dermatology issues have barriers between them and acquiring care, from needing to travel a significant distance to the dermatologist, or the patient needing to take time off of work to visit, to physicians not accepting the patient’s health insurance. Much of this information was acquired from interviews with primary care physicians and dermatologists.

Another issue is that dermatologists treat patients for many different types of health issues outside of skin cancer that have increasing incidence and are often chronic skin issues. Regular dermatology visits allow these patients to receive high-quality care but limit the number of patients a dermatologist can manage. A limited population of dermatologists, combined with increasing services, poses a challenge to care delivery for patients who need to be seen quickly for a potentially fatal issue. Many dermatologists have multi-month waitlists for new patients according to interviewed dermatologists. Dermatologists often have avenues for patients to be
seen more quickly, but these often require some sort of medical validation or know-how of the system. For example, if a physician calls to have a patient seen more quickly by a dermatologist, the patient is much more likely to be seen quickly than if the patient calls the dermatologist concerned about a skin lesion.

Another confounding issue is the demand of primary care physicians. They must handle many patient issues within a short time period, and want to handle most of the patient’s issues without sending them to a specialist. This limits the likelihood that a patient is fully screened for skin cancer during the visit and limits the amount of time a primary care physician can spend on each patient’s issue, reducing the likelihood the primary care physician will compare the lesion to other reference materials and the likelihood the physician will perform biopsies.

Building on the challenges faced by primary care physicians, there are generally many steps involved in diagnosing skin lesions. Patients must decide if a lesion is concerning enough to book an appointment and take time to go to the physician’s office or mention the lesion in another visit. Beyond this, the primary care physician must decide the lesion is concerning enough, and either refer the patient to another physician to biopsy or take the biopsy themselves. After this, the lesion is physically sent to a pathologist for expert diagnosis under a microscope. Many people are involved at various stages of identification, the identification process takes multiple weeks, and the physical movement requires the patient to come in to see the doctor and physician to physically send the skin lesion to the pathologist for diagnosis. This information was synthesized from patients, primary care physicians, and dermatologists.

5.8 - Conclusions of Gaps in Care

There are a few factors that indicate that skin cancer care delivery could be improved. Currently there is a 13.5% fatality rate for individuals diagnosed with melanoma (American Cancer Society 2015a). Almost all of these could have been treated if discovered earlier. Skin cancers are identified primarily by patients and their greater social support system, not by physicians, who have more education on skin cancer, exposure to skin cancer, and connections within the medical system to help patients gain the treatment they need.
Additionally cancerous skin lesions, for one reason or another, do not indicate their cancerous nature to patients for one reason or another. They are often in hard-to-see places, are hard to identify, or the patient is not aware they could have skin cancer and does not know how to recognize the signs or is not looking. Even after the patient or their social influences identify irregularities in the lesion, the patient will not seek treatment for the lesion until later. These factors confound and contribute to late-stage diagnoses. We need to improve the ability for patients to identify their own skin lesions with fewer symptoms, improve awareness of the symptoms, improve opportunities to identify cancerous lesions in hard-to-monitor areas, and reduce the barriers between patients and seeking care, whether convenience or otherwise.

Dermatologists, specialists at identifying skin cancers, treat a very small portion of the population who might develop skin cancer. Rates of detection for melanoma are low, ranging from 52% to 91% for primary care physicians and dermatologists. Additionally, physicians vary significantly in their abilities to identify and diagnose skin cancers, indicating that technology could help augment detection rates at all levels of the skin cancer care delivery system.

On a system-wide level, physicians are not accountable for patient health, and frequently only treat patients when they mention a specific concern such as concern about a skin lesion. Additionally, as the system works today, physicians are paid for care delivery without being evaluated by the effectiveness of their work. The healthcare system should be able to improve itself based on prior experiences in clinical work, and physicians should have transparency in how accurate their assessments are so they can understand their own limits and improve based on prior experiences. Currently this information is not captured in the healthcare system. In skin cancer evaluation, the information that is captured is when a physician decides to biopsy a skin lesion, and the only information captured is the physician’s specificity, not sensitivity in detection of skin lesions.
Chapter 6: Technology Application

As discussed in prior chapters there are many opportunities to 'close the loop' and identify and diagnose skin cancers earlier. Given the opportunities identified in Chapter 5, one obvious way is by developing technologies that can augment information capture, information transmission between stakeholders, and improve lesion evaluation accuracy at all stakeholder levels. This chapter will address current technologies used, explore potential technologies to improve lesion evaluation accuracy, and then provide a recommendation based on device accuracy and use case considerations to propose the most promising technologies.

6.1 - Current Technologies Used in Skin Cancer Detection

As with most examinations, the successful identification of a disease involves combining the information available to a physician or patient with their prior experience with that disease. This section will provide a background into how skin cancer care is delivered today from a more granular level than has been previously discussed.

Lesion examination
The current standard for skin cancer detection is visual evaluation of a specific skin lesion at a single point in time. Visual evaluation is sometimes complemented by:

- a patient's memory of how the lesion has changed over time
- a patient's recollection on how the skin lesion feels (e.g. itchiness, sensitivity to touch, ulceration)
- a patient's concern of the skin lesion
- a physician palpating (or touching) the skin lesion
- a physician's examination using a dermatoscope, which uses a cross-polarized, evenly-distributed illumination and magnification of the lesion (Massone et al. 2009). Dermatologists much more commonly dermatoscopes than other physicians.

Medical Record and Environment Examination
Other information that can be factored into the assessment includes the following prior medical history and exposure history:

- a patient's personal and family history of cancerous skin lesions
• a patient’s environmental exposure to various cancer-causing agents (such as exposure to sunlight)
• a patient’s vulnerability to developing skin cancer (e.g. predisposition due to a genetic disorder)
• a patient’s general phenotype (such as the patient’s Fitzpatrick skin type evaluated based on a patient’s propensity to burn over tanning)

Current Variance in Evaluation
Technologies used by physicians and their prior experience with skin cancer varies significantly. Factors that significantly impact the ability for a physician to detect a cancerous lesion include their prior training level and their regular training through practice and continuing education. They are also impacted by their confidence in lesion evaluation and if they use resources for comparison.

The most common methods employed to identify skin lesions are visual pattern recognition based on prior identification experience and training along with questions about the lesion and questions about personal history and exposure. This method is subjective and a physician’s ability to discern skin lesions varies significantly from physician to physician.

Current Tools and Reference Sources
The following is an incomplete list of technologies and resources employed by patients and physicians to make skin evaluations:
• Dermatoscope (e.g. Dermlite (“3Gen - DermLite Dermatoscopes” 2015))
• Dermatology atlases
• Medical textbooks
• Online medical textbooks (e.g. UpToDate (“UpToDate” 2015))
• Close up pictures
• Distance pictures
• Medical Journals
• Conferences and other meetings
• Skin biopsy equipment
• Pathologist evaluation of skin sample
• Mentor and colleague evaluation
As we have established that current methods for identifying cancerous skin lesions involve mainly optical human pattern recognition based on prior experience potentially complemented with patient and information history and various reference sources, we will evaluate many different types of technologies to identify technologies that fit with use case requirements established in Chapter 4.

6.2 - Potential Technologies to Improve Evaluations

The following is an organized summary of technologies that can be used to provide more information to patients and physicians to better inform diagnoses. Table 6.1 compares each technology, its current development stage based on its technology readiness level (TRL) (Mai 2015), and other notable characteristics of the technology. Technologies were explored that can provide physicians and patients with information not currently available or only available in difficult-to-access forms. These technologies were selected based on prior evaluations of their application to skin cancer and information patients and physicians stated would be helpful in assessing skin lesions.

**Optical**

Optical methods have always been the standard evaluation method for skin cancers, and optical pattern recognition is the underlying technology of how skin cancers are identified today when patients and physicians evaluate the appearance of skin cancers. Because of the rich history of optical information about skin lesions currently available and the accessibility of gathering optical information about skin, optical solutions of surface recognition crowd the domain of technology exploration in objectively diagnosing skin lesions *in vivo*, or while still in the body. Research in optical solutions has expanded outside of the visual spectrum into other wavelengths, but primarily analyzes information available at the surface or slightly subsurface level of the skin.

*Naked eye and in-office or at home pictures.* Effective detection of melanoma with the naked eye is about 60% (Kittler et al. 2002). Much of the information that can be seen on the skin cancer can be captured with a high-resolution camera image.
**Total body photography (TBP) over time.** This method uses multiple high-definition images to monitor lesions of time. This can identify new moles and track changes to moles more effectively than other technologies. This can also verify moles that may appear irregular but are not changing, reducing some need for skin biopsies (March et al. 2015, 930). This is conventionally done in an office or hospital and requires the patient to go in for an examination outside of their typical exam with their dermatologist.

**Dermoscopy.** This method provides a different lens for analyzing melanomas and other skin cancers. Dermoscopy is non-invasive, removes surface reflectance, and allows the examiner to view deeper subsurface structures in the skin. Dermoscopy is only effective at improving sensitivity and specificity in skin cancer lesions when used by an expert with extensive training in dermoscopy, and is estimated to improve both sensitivity and specificity in melanoma detection by around 9% (Vestergaard et al. 2008). This has been the most successful technology to date in terms of adoption, and can easily be linked with a cell phone to upload pictures to the patient’s electronic health record or be sent to a specialist.

![Figure 6.1 Dermoscopy compared with a regular camera image of the same lesion (Kittler et al. 2002)](image)

**3D lesion imaging.** This method of capturing lesion information is relatively new and not yet commercialized. Three-dimensional images can capture the elevation and topology of skin lesions, features that are difficult to capture with just two-dimensional images, but are commonly distinctive in malignant melanoma.

**Raman microscopy.** This method uses inelastic scattering of monochromatic light to analyze vibrational modes of molecules, molecularly identifying chemical skin characteristics. Tests of Raman spectroscopy on skin have shown evidence of very high sensitivities (>90%) and specificities (>70%) for skin cancer, as the method can identify very specific chemical bonds.
both on the body and on tissue samples. Spectral bands have been able to identify multiple factors that differentiate different types of benign and malignant lesions, including lipids, tyrosine, polysaccharides, collagen, elastin III, and melanin (Calin et al. 2013, 1097). The cost estimate for this technology is $15,000-$50,000 (Markert et al. 2011).

Confocal microscopy. This method captures an image of skin cells from a pinhole of light of a single plane, allowing only in-focus light to reach the detector. This method allows for higher contrast and resolution in images and provides similar information as that seen through typical microscopy of lesions examined by pathologists. This method requires expertise of the technician or practitioner to identify characteristics of the cells to determine whether or not to biopsy (Calin et al. 2013). Cost estimate is $50,000 to $60,000 for the device (Borchers 2013).

Figure 6.2: A confocal microscopic image of epidermis disarray, common in melanomas (Pellacani et al. 2007)

Optical Coherence Tomography. This method is a new way of using advanced optics and backscattered or back-reflected light from tissue to generate 2D and 3D images. This was first demonstrated in the eye, and has since moved to new domains requiring high-resolution and depth (Calin et al. 2013). Costs estimate is tens of thousands of dollars (“Skin Cancer Connection Blog | Page 3” 2015).

Figure 6.3: An optical coherence tomography image of in vivo skin (Sattler, Kästle, and Welzel 2013)
**UV Fluorescence Spectrometry.** A fluorescence emission happens when a molecule initially absorbs a proton but then the molecule loses energy gained by the absorption of the proton, emitting fluorescence at a wavelength higher than that which the proton was absorbed. Human skin contains many native fluorophores, such as collagen, tyrosine, tryptophan, and porphyrins (Calin et al. 2013). This is effective in basal and squamous cell skin cancers, with lower sensitivities in detecting melanoma (Chwirot et al. 2001; Brancaleon et al. 2001). Price estimate between $1000 and $3000 (“Price List | StellarNet.us” 2015).

**Infrared Spectrometry.** This method captures chromophores that reflect various amounts and distribution of proteins in the skin. The distribution of an amount of these proteins indicates the disease state of the skin (March et al. 2015).

**Ultrasound**
Ultrasound technology uses acoustic waves to develop images based on how the waves reflect in tissue. These characteristics allow ultrasound to show borders and interfaces between different tissue types (Kleinerman et al. 2012). This adds a depth dimension assessment of skin cancers that optical and other surface technologies cannot capture.

**High Frequency Ultrasound.** The sound wave reflections off of tissues vary based on vascularity and density, driven by differences in keratin, collagen, and water content (Kleinerman et al. 2012, 478) 13.5 to 100MHz allow for viewing in the dermis and epidermis (Kleinerman et al. 2012). Evidence is still insufficient to support ultrasound at clinical trial (Bagatin, de Vasconcelos Nasser Caetano, and Soares 2013).

**Compression-based Elastography.** This method creates an image of strain on tissue imposed by a force. This method helps to calculate the degree of elasticity of the material. Malignant lesions have significantly lower elasticity than benign lesions (Kleinerman et al. 2012, 479). Elastography can provide depth information about all types of cancerous lesions that is not captured from optical views. (“Ultrasound-Based Elastogram Spots Skin Cancers | Cancer Network” 2010).
Chemical
Chemical solutions utilize bodily processes to highlight specific characteristics that are found more frequently or in higher concentrations in cancerous tissue.

*Positron Emission Tomography (PET).* This method uses a radioactive glucose (FDG) to highlight areas of the body with higher glucose metabolism, a common characteristic in malignant cells. The body is scanned while the patient’s body is processing this glucose, and the areas of the body with the highest rates of glucose metabolism emit more positrons than healthy tissue. These positrons are constructed in in a three-dimensional image of the body to find metastatic cancerous lesions (Delbeke 1999). The estimated cost for a PET/CT scan is between $3,000 and $20,000 (Saha 2010).

*Tumor Painting.* This method causes cancerous cells to fluoresce in the near IR spectrum after injection of the bioconjugate (CTX) into the patient. Tumor painting is a molecular bioconjugate that adheres to malignant tumors and was specifically tested to improve surgical accuracy, as detection of cancerous margins is currently arbitrary, and is based on visual color, texture, and vascularity differences (Veiseh et al. 2007).

*Canine Olfactory.* This method uses detection of volatile organic compounds (VOCs) commonly sensed in dogs, inspired by anecdotal evidence of canines detecting malignancies and indicating these malignancies to owners, including melanoma. These are in very early stages of development to establish technologies that can provide an objective chemical sensing (Pomerantz et al. 2015; L. F. Campbell et al. 2013).

Mechanical
Mechanical methods take advantage of physical characteristics of the skin lesion, such as how it deforms with applied pressure or how it protrudes from the body to assess its cancerous stage.

*Mechanical Stiffness.* Physicians frequently manually touch and apply pressure to skin lesions to determine how the skin deforms and gather evidence on the skin lesion’s disease state. This method applies a compression force to skin and captures images before and after the force is applied to determine deformation and underlying cellular activity in the skin (Es’haghian et al. 2015).
Microtopography. This method involves evaluating surface roughness of skin lesions compared with healthy skin. One study showed that melanoma and basal cell carcinomas were rougher than their healthy skin benchmark (Calin et al. 2013; Pacheco et al. 2005).

Electrical
Electrical methods take advantage of how electrical signals interact with the body either through transmission or reflection. Water concentration and cell density significantly impact how a body interacts with applied electricity and electric fields.

Electrical Impedance Spectroscopy. When the electrical impedance of a skin lesion is evaluated, the measurement highlights differences in the structure of the skin lesion. Electrical impedance varies based on cell shape, cell membrane structures, and water content of the cell. These characteristics vary based on the healthiness of the cell (Åberg et al. 2011; Aberg et al. 2004; March et al. 2015).

Millimeter-wave. This method uses a waveguide probe to apply millimeter waves at around 100 GHz to detect malignancy in primary skin tumors at a depth of up to 0.4 millimeters. This method takes advantage of differences in permittivity between healthy and diseased skin, as diseased skin often has higher water content levels. This was successfully demonstrated on phantom skin of similar permittivities to healthy and cancerous tissue (Topfer, Dudorov, and Oberhammer 2015). This technology has potential but is currently at a very early technology readiness level.

Terahertz (THz) Radiation. This imaging method detects differences in water content for diseased and healthy tissues. Most research in using T-rays to detect skin cancer has been on nonmelanoma skin cancers, primarily basal cell carcinoma. The technology holds promise to indicate histology of the underlying cancerous lesion and potentially reveal tumor margins (Truong et al. 2014). This technology does not appear to be effective in evaluating melanomas.
Cell Removal
The current method of diagnosis of cancerous lesions involves removing a skin lesion and examining cellular and structural characteristics under a microscope. This section explores this standards and variants of this standard.

*Micro-biopsy.* The "gold standard" for melanoma and other skin cancer diagnosis is a pathological analysis of a major portion of the skin lesion. Multiple characteristics of these biopsied lesions are evaluated, including cell type and shape and architectural features of skin lesions. This method captures a small part of the lesion to allow for cellular evaluation with some inter-cellular characteristics, either in the form of a solid biopsy (Banan et al. 2013) or a fine needle aspiration (Wolz et al. 2014).

*Tape-stripping.* This method uses simple technologies (e.g. tape) to remove cells in the epidermal layer of the skin lesion and analyze them for specific melanoma mRNA markers (Wachsman et al. 2011). This is very minimally invasive and fast, shifting complexity of the skin analysis to labs for DNA processing and comparison.

*Skin Biopsy (Punch or Shave).* This is the current "gold standard" for diagnosing skin lesions. This method involves removing all or part of the skin lesion with a bowed razor or punch, and sending this lesion to the lab with some characteristics of the patient and lesion. The lesion is stained and cross-sectionally viewed under a microscope by a pathologist who determines the disease state of the lesion based on cellular and architectural characteristics (Pickett 2011). Estimated costs of $100-$150 based on dermatologist's comments during the interview.
<table>
<thead>
<tr>
<th>Technology</th>
<th>Type</th>
<th>How It Works</th>
<th>Disease (Basal, Squamous, Melanoma)</th>
<th>TRL</th>
<th>Estimated Cost</th>
<th>Use case requirements / Portability</th>
<th>Added Potential</th>
<th>Accuracy (Sensitivity, Specificity)</th>
<th>Product Examples</th>
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<tbody>
<tr>
<td>Total body photography (TBP)</td>
<td>Optical</td>
<td>High definition images are compared over time to monitor lesion changes</td>
<td>B, S, M, primarily for M</td>
<td>9</td>
<td>$350-$500 per</td>
<td>Cart with camera, computer, and printer.</td>
<td>Can track all</td>
<td>Sens: Unknown Spec: Unknown</td>
<td>FotoFinder bodystudios¹</td>
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<td></td>
<td>(Visual)</td>
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<td></td>
<td>exam out-of-pocket</td>
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<td>changes to skin, reducing biopsies for moles that are not changing.</td>
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<td></td>
<td>(estimated based on dermatologist interviews)</td>
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</tr>
<tr>
<td>Epiluminoscopy</td>
<td>Optical</td>
<td>Magnifies the lesion and allows viewing of subsurface skin structures</td>
<td>B, S, M</td>
<td>9</td>
<td>$400-$1,300 per device (based on dermatologist interviews)</td>
<td>Extends complete skin examination by an average of 72 seconds, portable device, handheld device</td>
<td>Allows for sight of subsurface structures not visible. Can increase diagnostic accuracy of a physician &gt;10% with sufficient training.</td>
<td>M Sens: 90% M Spec: 90%²</td>
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<td></td>
<td>(Visual)</td>
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<td></td>
<td>Improves accuracy of dermatologists by about 18% over the naked eye²</td>
<td>DermLite² (<a href="http://www.dermlite.com">www.dermlite.com</a>)</td>
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<tr>
<td>3D lesion imaging</td>
<td>Optical</td>
<td>A 3D image of a skin lesion is captured</td>
<td>B, S, M, primarily M</td>
<td>6</td>
<td>“low-cost”³</td>
<td>Operator probe grabs a picture uploaded to a laptop</td>
<td>Can capture elevation and topology of the lesion from third dimension.</td>
<td>Sens: Unknown Spec: Unknown</td>
<td>3Derm camera³</td>
</tr>
<tr>
<td></td>
<td>(Visual)</td>
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</table>

*¹  FotoFinder bodystudios: Identifies time to monitor (estimated biopsies for evolving and new lesions²

²  DermLite: Improves diagnosis of skin cancers by about 20% over the naked eye²

³  3Derm camera: Improves diagnostic accuracy of dermatologists by about 18% over the naked eye²
<table>
<thead>
<tr>
<th>Method</th>
<th>Field</th>
<th>Example</th>
<th>Cost</th>
<th>Cart Description</th>
<th>Sensitivity/Specificity</th>
<th>Manufacturer/Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raman Spectroscopy</td>
<td>Optical</td>
<td>Inelastic scattering of monochromatic light shows vibrational modes of molecules</td>
<td>B,S,M $45,000-50,000$</td>
<td>Cart with probe to be operated by a general practitioner.</td>
<td>99% for cancerous and precancerous lesions (with low specificity)</td>
<td>Verisante Aura$^b$</td>
</tr>
<tr>
<td>Confocal Microscopy</td>
<td>Optical</td>
<td>A pinhole source of light is detected, eliminating out-of-focus light to represent one focal plane</td>
<td>Primarily M $50,000-$60,000, patient cost is $150 per exam$^6$</td>
<td>Cart with handheld microscope with image to be interpreted by an expert.</td>
<td>Higher resolution and contrast than traditional microscopy on a cellular level, &gt;80% sensitivity</td>
<td>M Sens: 88% M Spec:71%</td>
</tr>
<tr>
<td>Optical Coherence Tomography</td>
<td>Optical</td>
<td>Generates cross-sectional 2D and 3D images of backscattered and back-reflected light</td>
<td>Primarily B, also M, S, and other diseases $8$ Estimated tens of thousands$^8$</td>
<td>Desktop imager with connected probe to be used in clinical setting.</td>
<td>Deep skin penetration and high-resolution (3-15 micrometers deep)</td>
<td>B Sens: 79-94% B Spec:85-96%$^{31}$</td>
</tr>
<tr>
<td>UV Fluorescence Spectrometry</td>
<td>Optical</td>
<td>Molecules release lower energy photons after being excited by a light source</td>
<td>B,S,M $250-$10,000$^{11}$</td>
<td>Portable and handheld or desktop</td>
<td>Inexpensive, portable</td>
<td>Hamamatsu UV mini-spectrometer$^{12}$</td>
</tr>
</tbody>
</table>

$^a$ Estimated Cart with probe to 99% sensitivity M Sens: 100% M Spec: 70-78% B Sens: >90% B Spec: 54-95%$^{29}$

$^b$ Vivascope 3000$'$

$^c$ Livescope 9

$^d$ VivoSight 9

$^e$ Michaelson Diagnostics's

$^f$ SDM Thesis

$^{10}$ MIT SDM Thesis

$^{12}$ UV

$^{32}$ Visual, near light shows $50,000$ general and 78% IR) vibrational modes practitioner. precancerous B Sens: >90% of molecules lesions (with low specificity)

$^{29}$ Confocal Optical A pinhole source of Primarily M $9$ $50,000-$ Cart with Higher M Sens: 88% Vivascope 3000'$ $60,000, patient cost is $150 per exam$^6$ Cart with handheld microscope with image to be interpreted by an expert. Higher resolution and contrast than traditional microscopy on a cellular level, >80% sensitivity M Sens: 88% M Spec:71% B Sens: 100% B Spec:89%$^{30}$

$^{30}$ Vivascope 3000'$

$^{31}$ Livescope 9

$^{32}$ VivoSight 9

$^{33}$ Michaelson Diagnostics's

$^{34}$ SDM Thesis

$^{35}$ UV

$^{36}$ Visual, near light shows $50,000$ general and 78% IR) vibrational modes practitioner. precancerous B Sens: >90% of molecules lesions (with low specificity)

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$^{36}$ Visual, near light shows $50,000$ general and 78% IR) vibrational modes practitioner. precancerous B Sens: >90% of molecules lesions (with low specificity)
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test Type</th>
<th>Description</th>
<th>B,S,M</th>
<th>Cost</th>
<th>Sensitivity</th>
<th>Spec.</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infrared Spectrometry</strong></td>
<td>Optical</td>
<td>Images map the scatter and quantity of various chromophores that reflect the content on the skin surface.</td>
<td>B,S,M</td>
<td>$10,000 physician lease and $2,000 annual fee</td>
<td>95%</td>
<td>49%</td>
<td>MelaFind¹³</td>
</tr>
<tr>
<td><strong>High Frequency Ultrasound</strong></td>
<td>Ultrasound</td>
<td>Sound waves reflect on tissue based on its structure (works for skin in 13.5-100MHz range)</td>
<td>B,S,M</td>
<td>$15,000-$25,000 for device (cost estimated)</td>
<td>97%</td>
<td>Unknown</td>
<td>Dermascan C¹⁵</td>
</tr>
<tr>
<td><strong>Compression-based Elastography</strong></td>
<td>Ultrasound</td>
<td>Comparison of precompression and postcompression echos indicating skin elasticity for malignant lesions</td>
<td>B,S,M</td>
<td>$15,000-$25,000 for device (cost estimated)</td>
<td>97%</td>
<td>100%</td>
<td>Philips Epiq 5¹⁶</td>
</tr>
<tr>
<td><strong>Positron Emission Tomography (PET)</strong></td>
<td>Chemical</td>
<td>Radioactive glucose (FDG) is injected into the patient, scan monitors glucose metabolism higher in tumor cells</td>
<td>M</td>
<td>$3,000 – $20,000 per scan</td>
<td>94%–100%</td>
<td>83%-94%</td>
<td>Biograph TruePoint PET/CT (Siemens)¹⁸</td>
</tr>
<tr>
<td>Tumor Painting</td>
<td>Chemical</td>
<td>CTX is injected into the patient and areas of the body are imaged</td>
<td>M</td>
<td>3</td>
<td>Unknown</td>
<td>Chemical injection in patient and near-IR imaging modality (portable and handheld)</td>
<td>Full body analysis with inexpensive imaging.</td>
</tr>
<tr>
<td>---------------</td>
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<td>-------------------------------------------------------------</td>
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<td>---------</td>
<td>---------------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Canine Olfactory</td>
<td>Chemical</td>
<td>Dogs have been able to indicate irregularity in skin malignancies through smell of VOCs</td>
<td>M</td>
<td>1</td>
<td>Unknown</td>
<td>Currently not developed into an objective technology</td>
<td>A novel method of detection based on VOCs</td>
</tr>
<tr>
<td>Skin Stiffness (&quot;Optical Palpation&quot;)</td>
<td>Mechanical</td>
<td>Optical coherence tomography (OCT) images are taken before and after compressive loading to evaluate stress on the skin</td>
<td>M, B, S</td>
<td>3</td>
<td>Tens of thousands (Cost estimate for OCT device)⁹</td>
<td>Handheld probe with larger tabletop or cart imaging system</td>
<td>Handheld probe allowing for a novel, non-invasive evaluation of skin mechanical properties</td>
</tr>
<tr>
<td>Skin Microtopography</td>
<td>Mechanical</td>
<td>Surface roughness was evaluated in skin lesions compared with healthy skin</td>
<td>M, B</td>
<td>2</td>
<td>Unknown</td>
<td>Analysis done with latex impressions</td>
<td>Topographical evaluation of skin lesions</td>
</tr>
<tr>
<td>Electric Impedance Spectroscopy</td>
<td>Electrical Detects differences in electrical resistance within tissues</td>
<td>M, B, S</td>
<td>9</td>
<td>Not found</td>
<td>Handheld probe with desktop device and rolling station. Requires skin prep and comparison between lesion and healthy skin</td>
<td>Very high sensitivity and high specificity</td>
<td>M Sens: 95% M Spec: 49%</td>
</tr>
<tr>
<td>--------------------------------</td>
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<td>-----------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Millimeter-Wave Near-Field Electrical Detects varying permittivity in diseased and healthy skin to detected increases in water content of diseased skin</td>
<td>M, B, S</td>
<td>2</td>
<td>Unknown</td>
<td>Noninvasive, small external probe, commercial device not developed</td>
<td>High lateral resolution and non-invasive</td>
<td>Sens: Unknown M Spec: Unknown</td>
<td>Experimental probe with phantom</td>
</tr>
<tr>
<td>Terahertz Dielectric Electric Detects reflection geometry differences in water content of diseased tumors and healthy tissue</td>
<td>B</td>
<td>6</td>
<td>Unknown</td>
<td>Large probe, requires imaging interpretation expertise</td>
<td>Safe and provides high sensitivity of waves</td>
<td>Sens: Unknown M Spec: Unknown</td>
<td>TeraView Probe</td>
</tr>
<tr>
<td>Fine Needle Aspiration Cell Removal Captures a mixture of cells in a hollow-needle aspiration for analysis</td>
<td>M, B, S</td>
<td>9</td>
<td>$200-$300 per sample</td>
<td>Invasive but easily procured by a trained technician plus expert review by a pathologist</td>
<td>Minimally-invasive to skin and a known technology applied in a different way</td>
<td>M Sens: 92% M Spec: 99%</td>
<td>Argon Medical FNA biopsy needles</td>
</tr>
<tr>
<td>Method</td>
<td>Cell Removal</td>
<td>Description</td>
<td>Cells %</td>
<td>Cost/Per Cell</td>
<td>Analysis</td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>---------------------</td>
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</tr>
</tbody>
</table>
| Micro-biopsy        |                              | Captures small set of hundreds of cells in a group for analysis             | M, B, S | $200-$300 per sample (rough estimate) | Group of cells capture (mini-punch) plus expert review by a pathologist | Minimally-invasive to skin that can eliminate cancer as a concern. | M Sens: 92%  
M Spec: 99% | Microbiopsy punch²⁵ |
| Tape-stripping      |                              | Epidermal genetic information is removed from suspicious skin lesions via tape stripping on the mole’s surface and reviewed for biomarkers | M       | Unknown (high cost associated with DNA analysis) | Requires DNA analysis and a search for biomarkers (slow turnaround, intensive processing) | Simple, fast, and minimally invasive specimen gathering | M Sens: 98%  
M Spec: 73%³⁶ | Early technology readiness |
| Full Skin Biopsy    |                              | A physician removes part or all of the skin lesion with a shave or punch biopsy that is later evaluated and diagnosed by a pathologist | M, B, S | $100-$150 per lesion (based on interviews with dermatologists) | Requires physical removal, transportation and prep by pathology lab, and pathologist diagnosis | Examines physical cells to determine disease state | Gold Standard: There is no benchmark to evaluate accuracy | Nicon Ci Pathology Microscope²⁶ |


Susan Conover

MIT SDM Thesis
6.3 - Selected Technologies to Augment Detection

The technologies in Table 6.1 will be compared and contrasted based on use case requirements in three settings: the primary care physician’s office, the dermatologist’s office, and the patient’s home, and then evaluated based on technological promise and how complementary the technologies can be compared to the current initial standard: optical visual spectrum pattern recognition.

Technology Evaluation

Each technology evaluated holds promise in identifying a specific characteristic within skin cancer compared to other tissue characteristics. Total body photography can augment detection through evaluating the evolution of skin cancers. This captures information not currently effectively captured in evaluations, but requires significant setup, patient embarrassment, and is currently cost prohibitive over a long period of time for patients. Epiluminoscopy holds tremendous promise in improving diagnostic evaluations of skin lesions, and has been the most successfully adopted technology of those analyzed outside of industry standards. Epiluminoscopy can be captured easily in a high-resolution digital photograph, but requires significant training to improve diagnostic accuracy beyond naked eye screening. 3D lesion imaging holds promise, but much is not currently known about how specific or sensitive the technology can be.

Outside of the visual spectrum, Raman spectroscopy is incredibly promising in terms of sensitivity and specificity. Raman spectroscopy’s biggest hindrance to wide adoption is the large cart setup and cost associated with the device. Confocal microscopy shows significant promise for non-melanoma skin cancers, but shows limited adoption potential with high costs and a large setup. Optical coherence tomography (OCT) can achieve deep skin penetration, showing edges between lesions and healthy skin. OCT still needs to improve in terms of sensitivity and specificity to be adopted. UV fluorescence shows huge promise, as spectrometers are small, portable and cheap. This technology is as high as 93% sensitive to melanoma and has higher sensitivities for non-melanoma skin cancers. Infrared spectrometry is on the market today in a few products such as MelaFind (March, Hand, and Grossman 2015). This technology can have high sensitivities to melanoma with lower specificities. This device requires a large handheld probe and cart to be used in the office.
Moving from primarily optical solutions, high frequency ultrasound has potential in adding a new dimension to clinical lesion analysis: lesion depth. This is the primary indicator of later patient outcomes in melanoma diagnosis (Liu et al. 2006). The biggest hindrance to high frequency ultrasound is the cost and desktop or cart setup of the technology. Compression-based elastography, another ultrasound-based technology, has significant promise as an active way of evaluating skin lesion responses to applied forces. The effectiveness of this technology is unclear, and other obstacles preventing wide adoption are associated costs and the large setup of the device.

Chemical solutions include positron emission tomography (PET). This is a widely adopted technology for assessing the malignant spread of cancers. PET is cost-prohibitive and unnecessary in early stages of assessing skin lesions. PET is included in this analysis as it is the current standard for chemical assessment of skin cancer for higher-staged diagnoses. Tumor painting is a new technology with promise in visually showing skin cancers. Tumor painting’s biggest barriers to widespread adoption are its early technology readiness and lack of testing to show efficacy in identifying skin cancer. The last chemical solution considered is canine olfactory. This technology holds promise but is in its earliest stages of assessment.

Skin stiffness is a promising potential technology, but its effectiveness is not currently known. Microtopography also holds promise but is also in an early technology evaluation stage. Electrical impedance is one of the most promising technologies identified, with high sensitivity, moderate specificity, and detection accuracy of all types of skin cancer. The biggest barrier to adoption is the setup of the device and the device taking time to administer, as lesions must be cleaned and benchmarked against healthy skin (“The Nevisense Product” 2015). Millimeter-wave near-field has promise but is in its earliest stages of development. Terahertz dielectric is more advanced in terms of technology development than millimeter-wave, but has barriers to adoption including the lack of clarity in how effective the technology is in assessing skin lesions and the large setup.

New methods for physical sampling are promising as they can provide less invasive assessments of skin cancers than the current gold standard of full skin biopsies. Fine needle aspirations (FNAs) are currently widely accepted as assessment methods for other cancers but not primary tumor skin cancer. The biggest barrier of adoption for fine needle biopsies is that a pathologist would still have to assess the fine needle aspiration, but with lower accuracy than
full skin biopsies. Micro-biopsies have the same promises and barriers as FNAs. Tape-stripping is a new method of assessing molecular characteristics of skin lesions. This requires DNA analysis, and is in an early stage of technological development and is very cost-prohibitive to process a single sample. The full skin biopsy is the current standard. Barriers to more use include the costs associated with taking and processing biopsies.

**Technology Selection**

After assessing all of the technologies for accuracy, use case requirements, and their ability to complement current standards of identification, the technologies to aid in identification that are worth further commercializing today include high-resolution photography, epiluminoscopy, electrical impedance spectroscopy, micro-biopsy, fine needle aspiration, infrared spectrometry, and UV fluorescence spectrometry. These technologies are manageable in the physician’s office, add a significant advantage or one sort or another over the current gold standard of full skin biopsies, and can improve the processing of patients. Some of these technologies, high-resolution photography, epiluminoscopy, electrical impedance spectroscopy, infrared spectrometry, and UV fluorescence spectrometry, could even be used in the home if augmented with physician expertise and software analysis.

The technologies that are worth evaluating at a later development stage include all of these technologies, but the most promising appear to be Raman spectroscopy, high frequency ultrasound, and compression-based elastography in the next 10 years. These technologies still have barriers between their current state and wide adoption, primarily driven by high costs and use case hindrances such as requiring a cart or separate desktop setup, but as the technology advances these associated hindrances may reduce.
Chapter 7: Technology + Opportunity Mapping

In Chapter 5 we assessed where system improvements are most needed and how relevant technologies can be used to detect skin cancer. This chapter combines systemic opportunities and tools to propose solutions. We first address information that would assist each stakeholder in making better decisions. After this we evaluate technology locations and use cases, a variety of technological and non-technological solutions, and technology reimbursement considerations.

7.1 - Information to Assist Smarter Choices

After interviewing patients and physicians it became clear that patients have difficulty identifying if lesions are cancerous and physicians have variability in their assessments. The following lists information that if each stakeholder had better access to, they could make better decisions regarding skin cancer identification.

Selected Information That Would Help Each Stakeholder

Patients

The following information would increase the patient’s likelihood of identifying the disease earlier and understanding when to involve a physician in evaluation.

- A patient’s likelihood for developing a specific disease
- How to monitor their bodies quickly and effectively
- Tips from other patients on self-monitoring
- When they should be seen by a physician
- The importance of treating the disease quickly
- Advice for dealing with physician offices
- Different diseases a lesion could be given lesion characteristics
- Specific questions they should ask their physicians

If a patient were more informed their own skin’s state and their likelihood for developing skin cancer, they would better understand when to consult a physician and the importance of monitoring.
Primary Care Physicians

The following information would assist primary care physicians in evaluating patient skin lesions and increase the physician’s likelihood in identifying lesions that are cancerous. This would inform primary care physicians of how effective they are at assessing skin lesions and understand when to involve other physicians in future cases. This would also help primary care physicians interpret the significance of this other information.

General Information

- How effective they and their peers are at detecting cancerous skin lesions
- A clear understanding of their sensitivity in detecting skin lesions (currently never captured)
- A clear understanding of who is likely to develop a cancer and who should have regular full body screenings
- Clear suggestions on when to refer to a surgeon or dermatologist
- Clear suggestions on when to biopsy
- A clear understanding of information referred physicians need
- Feedback from referred physicians

Patient Information

- Full information on patient history, patient’s family history, genetics, and prior exposure and how to interpret this information in assessing patients
- A clear understanding of who does not seek care after a referral is given to a patient
- A clear understanding of the later outcomes of patients after they are referred
- A clear understanding on the challenges patients face when seeking medical care (wait times, taking time off of work, family obligations)

Dermatologists

The following information would assist dermatologists in better discovering cancerous skin lesions and providing high quality care to patients who need their expertise. This information would help a dermatologist be better informed of the relevant risk factors a patient has in developing a skin cancer and allow them to better assess cases remotely.

- Transparency in the patient’s predisposition to develop specific diseases
• A clear understanding of their sensitivity at detecting cancerous skin lesions (currently never captured)
• A clear understanding of all relevant patient history, including prior tests, examinations, and treatments
• A clear understanding as to why a patient was referred
• A high-quality image of a lesion prior to biopsy if it has been biopsied
• A clear understanding of where suspicious lesions are located on the body from referring physicians
• More information on patient history, lesion pattern, and lesion history when practicing at a distance (teledermatology)
• More information about a skin lesion than what is captured in a 2D high-resolution image when practicing at a distance (teledermatology)
• Reliable information on how lesions have evolved

7.2 - Technology Locations and Use Cases
A core goal of this research was to address the types of challenges patients and physicians faced to inform early and late stage technology development. The following section addresses the restrictions each of these stakeholder faces and opportunities for technology use in the home, primary care physician's office, and dermatologist's office, in addition to other opportunities for improved screening.

Location Opportunities for Technology
There are many locations where technologies can be deployed to assist in skin cancer identification. The more obvious locations include in the home, in the primary care office, in the dermatology office, and in other specialty physician offices. Less obvious areas include tanning parlors, security lines at airports, in the shower, in the bathroom mirror, locations with high-quality security cameras, nursing homes, community pools, and beach boardwalks. Generally, locations that pose opportunities to improve skin cancer screening include locations where there are higher concentrations of people likely to develop skin cancer, locations where people are showing more skin than on a typical day-to-day basis, and locations where there is more likely to be high-quality scanning for other purposes.
Use Case Conditions for Technology in the Home

Currently patients who have previously been diagnosed with skin cancer significantly vary in how they monitor their skin. Some only look at their faces in the mirror while others have specific times of the month where they examine their whole body for changes to skin lesions and enlist the assistance of a family member. Patients were more likely to check before or after a shower than at other times. Many did not check regularly, but did checks when they remembered and it was convenient. There was significant variability in the number of people living in the patient's home. Some patients lived with their kids and significant others while others lived alone. Many people mentioned they had morning and evening routines. Patients mentioned that they did not employ technologies to self-monitor other than using mirrors, and they noticed skin lesion changes based on memory alone. Patients were generally interested in being reassured regularly that they did not have skin cancer, and some patients were very interested in technologies outside of visual scanning to assist in self-monitoring.

Technologies that patients mentioned they regularly interacted with included personal computers, cell phones, cars, laptops, televisions, radios, and iPads. Technologies that are advanced enough and fit the patient's use case requirements include cell-phone enabled technologies, technologies that allow for continuous monitoring, and technologies that can augment information already available to patients. Technologies that would be helpful for patients include those that can provide skin-check reminder, take short amounts of time to operate, and generally fit into their lives. Of the technologies assessed in Chapter 6, the most relevant technologies for in-home use are high-resolution photography, epiluminoscopy, electrical impedance spectroscopy, infrared spectrometry, and UV fluorescence spectrometry, as they are significantly developed, can be portable and handheld, can be operated quickly, have high sensitivities and specificities, and complement current methods of skin cancer assessment. From a hardware perspective, technologies could assist patients in checking their whole bodies independently (e.g. selfie stick-like technology) or allow them to apply software algorithms to add assessment, such as comparing skin lesions on themselves to find "ugly ducklings" or lesions that are growing quickly. Any technology would be assisted by physician-endorsement, healthcare system integration, and reimbursement.
Use Case Conditions for Technology Opportunities in the Primary Care Office

Primary care physicians use many technologies in their day-to-day work, such as stethoscopes, pulse oximeters, and otoscopes. These are used on many patients, take about a minute to operate, and provide an immediate reading to the physician. Other tests require lab work, and these often take multiple days to process. Many younger primary care physicians use their cell phones for work related purposes, such as looking up appropriate prescriptions for specific drugs, using features in their phones such as the calculator feature, and taking pictures of remarkable lesions. One primary care physician mentioned that he would use his phone to take a picture of a lesion and send it to a specialist to have the patient treated quickly. Physicians mentioned they are accustomed to either buying or renting equipment.

Some of the technological challenges PCP faces include support when technology fails or malfunctions and device sharing between physicians. Shared technologies such as cameras may be in in different places than the PCP expects and the physician may decide finding the technology is too much hassle. Primary care physicians have short time periods with patients, often between 10 and 15 minutes, but sometimes much shorter. They have to treat the patient for all of the issues they are concerned about, and skin lesions are often assessed very quickly based on the physician’s prior experience in examining skin lesions and knowing the ABCDEs of melanoma identification.

The most immediate technology to improve skin lesion assessment and dermatology triaging is sending a high-quality image along with relevant patient information from a primary care physician to a dermatologist for patient assessment and triaging. Other technologies that are portable enough, operate quickly enough, and are advanced enough in their technology development include electrical impedance, UV fluorescence, IR spectroscopy, micro-biopsy, and dermatoscopy. Each of these technologies requires interpretation of new information, so either the physician would need to be trained to interpret the results of these technologies or software algorithms could provide a secondary interpretation of the lesion’s properties and assist the primary physician in deciding whether to take a standard biopsy, refer the patient, or advise the patient to continue monitoring the lesion for changes. Any technology adoption would be assisted by physician thought leader endorsement, reimbursement, EMR system integration, and evidence-based trials.
Use Case Conditions for Technology Opportunities in the Dermatologist Office

The most successful technology that has been recently adopted by many physicians is the dermatoscope, a technology that extends the amount of time a dermatologist spends examining a patient by an average of 72 seconds (Zalaudek et al. 2008). This device can be used to understand multiple diseases, is handheld and portable, and costs $500-$1300 to buy. Generally dermatologists have a very short amount of time they spend with patients. Additionally, if they are concerned a skin lesion may be cancerous, they biopsy the skin lesion and send it to be examined by a dermatopathologist for diagnosis. As dermatologists have a very limited amount of time, already have a gold standard for determining the cancerous nature of the lesion, and are very concerned about missing one melanoma, a technology must be fast, improve diagnostic accuracy, be durable, and be affordable to be adopted. Additionally, dermatologists would need to trust the device, and integrate with other components of the dermatologist’s workflow, such as their EMR system to be adopted. Any technology would be assisted by dermatologist thought leader endorsement, reimbursement, EMR system integration, and evidence-based trials.

7.3 - Technological Solutions

The following are proposed technological solutions to closing the gaps in skin cancer care, in specific settings and for the greater system. These were generated based on the gaps in care identified in Chapter 5 and physician and patient interviews.

Selected Technologies and Use Case Application

From Chapter 6, the most useful technologies that can be deployed quickly to improve care include high-resolution photography, epiluminoscopy, electrical impedance spectroscopy, micro-biopsy, fine needle aspiration, infrared spectrometry, and UV fluorescence spectrometry.

Small-Scale Technology Solutions in the Physician’s Office

The following are potential ways that a physician could use technology in the office to better assess skin lesions and advise patients on how to continue monitoring after the visit.
• **Advanced Technology.** Identifying skin cancers that even a dermatologist has difficulty identifying.

• **Borderline Helper.** Helping primary care physicians decide which lesions should be referred to a dermatologist or biopsied.

• **Quick evaluation.** Developing a less-invasive skin sampler or non-invasive tool that allows physicians to test multiple lesions without many full biopsies.

• **Trust Improvement.** Allowing physicians to track personal information about patients to better develop trust with the patient. This can remind a physician to follow up about personal information and recheck skin lesions later.

• **Vetted Patient Resources.** Advising patients toward specific, clear, helpful, vetted online and print resources to help them self-monitor lesions. There is significant variation in resources patients turn to before and after visiting a physician.

**Small-Scale Technology Solutions Interfacing between Physician’s Offices**

The following are potential technological ways physicians could communicate between offices to provide fast, higher quality care.

• **Image & Information Assessment.** Helping a physician send both a high-resolution image plus patient information including risk factors to dermatologists to evaluate whether they should be seen.

• **Collective Care.** Allowing physicians to communicate with each other to holistically manage a patient’s care.

• **Excess Capacity Utilization.** Allowing consultations between physicians. Some physicians are in constant demand while others are building their practice. A system could be created where physicians could consult remotely on cases in the same state, taking a portion of the consultation reimbursement and utilizing their excess capacity to provide other physicians a second opinion quickly and efficiently.
Small-Scale Technology Solutions in the Patient’s Home

The following solutions could be used in the patient’s home to assist in self-monitoring and alerting the patient of suspicious lesions. These technologies are complementary to physician evaluations in the office.

- **Online Lesion Check.** Allowing patients to determine if a skin lesion needs to be assessed by a member of the medical community. This would only advise patients if a lesion showed indicators of malignancy, but not advise patients if the lesion is benign.

- **Selfie Stick Solution.** Allowing patients to take high quality images of hard-to-reach and hard-to-see areas of their body with a cell phone extension tool, such as a selfie stick ("Selfie On a Stick" 2015).

- **Passive Monitor.** Allowing patients to passively monitor changing areas of their skin.

- **Online Risk Test.** Accessing an extensive, evaluated online test to help a patient evaluate his or her risk level for developing skin cancer.

- **Easy pics.** Allowing patients to capture high-quality pictures of skin lesions, tag their location on the skin, and recapture every 6 months.

- **Quick Tips.** Cheap solutions and tips for patients to easily and quickly track lesions.

- **Informed Evaluators.** Educational resources to identify common characteristics of melanomas, melanomas that quickly grow, and uncommon characteristics in skin lesions that can still be cancerous.

Large Scale Technology Solutions

The following are solutions to augment information flow in the entire system to improve skin evaluation quality and provide feedback to physicians for future skin evaluations.

- **Physician Evaluation.** Accountability for physicians to know when their evaluations are incorrect.

- **Circle Back Safely.** Opportunities for patients to provide feedback to physicians effectively without the threat of a lawsuit.

- **Physician Forum.** Building a forum for physicians to collaborate on cases and a reimbursement method to support this information sharing.
• **Fully Informed Teledermatology.** More opportunities for dermatologists to evaluate patient history, lesion history, patient risk, and the concerning lesion to decide whether the patient should be seen quickly and reduce misevaluations.

• **Risk Factor Evaluation.** Many primary physicians don’t take into account all of the information dermatologists do in evaluating skin lesions. There could be an electronic “risk calculator” for all diseases that a patient extensively fills out and indicates to the physician the diseases the patient is likely to get to make sure to address those issues.

• **Medical Consumer Review.** Patients can fill out evaluations, positive feedback, or complaints about their experience with physicians. Information is collected and revised before being sent to physicians regularly to provide supportive feedback and show physicians on how to improve their practice methods and service quality. Select information is available for patients to access.

• **Peer Evaluation Testing.** Often physicians do not have transparency in how effective they and their peers are at assessing specific diseases. A system of testing how effective physicians are at evaluating specific diseases could be published and accessible for physicians so they have transparency in their own abilities and know how much to trust their own skills and when referrals are most appropriate.

7.4 - Non-Technological Solutions

The following solutions are not technological and could be implemented right away to improve skin cancer identification and care.

**Small-Scale Technological Solutions**

The following section details solutions that can be applied at the patient and physician level to improve skin cancer care today.

• **Easy Second Opinion.** The patient can request more than one physician to give their opinion of a skin lesion when visiting the physician.

• **Easy Options.** The physician can give their assessment of the lesion, but offer to the patient different ways to follow up, such as referrals, teledermatology consults, or biopsies in the office.
Large-Scale Non-Technological Solutions

The following section details solutions that can be applied at a higher level to improve patient and physician awareness and identification capability and improve incentive structures for improved care.

- **School Buy-in.** A widely-accepted accreditation program for schools, summer camps, and areas with high-levels of sun exposure to make the environment sun protective-friendly and encourage reduced exposure behaviors of patrons and students.

- **Identification Expertise.** Specialists in skin cancer care whom are excellent at identifying skin lesions but do not have the skill level and varied training of dermatologists.

- **Homeopathic Curriculum.** Required learning of homeopathic and at-home remedies available to skin cancer patients so physicians can understand all of the patient’s options and help them make informed decisions about their care.

- **Revamp Continuing Education.** Changing continuing education requirements to span across a wide spectrum of patient care with examinations and tests to verify completion (e.g. OBGYNs are required to take continuing education studies on areas outside of their specialty and be tested on it).

7.5 - Reimbursement Considerations

Reimbursement strategy is essential for new medical devices to be adopted rapidly (Zenios et al, p.503). For a technology or service to be reimbursed by health insurance companies, clinical data is required to prove the efficacy of the device compared with other methods for evaluation and treatment. It is easier for a technology or service to be approved by a regulatory agency than to gain approval by payers for reimbursement. FDA approval hinges upon effectiveness and safety, while payers push beyond this and additionally emphasize requirements for medical necessity and other favorable outcomes. Payers require the device to be effective outside of controlled clinical trials and in regular use. Achieving health insurance reimbursement is faster, cheaper, less risky, and simpler if a company can utilize existing reimbursement codes (Zenios, Makower, and Yock 2010, 507). Any technology is much more likely to be adopted if it is reimbursable by insurance companies, so technology development should factor these financial considerations from the start of development.
7.6 - Technology and Opportunity Mapping Conclusions

This chapter helped to connect problems with potential solutions. From Chapter 6 we identified that many technologies could assist in skin cancer detection, but most do not fit home or clinical stakeholder conditions and are not advanced enough to be marketed today. We also identified that the technology most commonly employed today is human pattern recognition: patients noticing irregularities on their skin and clinicians relying on prior educational experiences and experienced pattern recognition in identifying lesions. We identified specific technologies that can improve the quality of skin lesion review, including modalities to monitor lesion evolution, evaluate cell shape and structure, evaluate lesion characteristics in the IR, Visual, and UV wavelength ranges, and evaluate electrical impedance. We also identified many areas within the healthcare system where simple improved information flows can improve care. We learned from interviews with patients and physicians that a successful technology must make financial sense to the stakeholder, improve accuracy of identification, operate quickly, operate easily, and provide clear analysis to indicate to the physician the appropriate follow on action.
Chapter 8: Australia - A Model for Improved Outcomes

Australia has the highest rates of skin cancer in the world, as it is estimated that 2 in 3 Australians will get skin cancer by the age of 70 (Staples et al. 2006). Because of this high incidence, the Australian government has implemented many initiatives to reduce incidence of skin cancer through encouraging prevention methods and promoting early detection of skin cancers. This section explores key findings from Australia's proactive improvement efforts including initiatives that have worked well and not to identify ways the United States can improve early skin cancer detection and prevention.

8.1 - Skin Cancer in Australia

Incidence in Australia, though continuing to rise in older populations, has declined in younger people since the late 1980s (Bevona and Sober 2002, 590). Between 1983 and 1996 there was a significant decrease in melanoma incidence in women ages 15 to 49 and a downward trend in men 15 to 34 (Bevona and Sober 2002, 590). Many have suggested that this decline in incidence was caused by primary prevention education campaigns across Australia for these younger generations. Additionally, it is estimated that SunSmart, an Australian sun awareness program, has resulted in behavior changes equivalent to 22,000 life-years saved and $2.30 Australian dollars of economic value returned for every $1 Australian dollar spent on the program (Shih et al. 2009).

The following details both compelling information from Australia's success at increasing awareness, prevention, and early detection and other studies that have proven successful at improving patient behavior and early identification of cancerous skin lesions.

8.2 - Prevention of Skin Cancer in Australia

There are three primary factors that contribute to an patient's compliance: knowledge, attitude, and behavior. Most efforts to increase prevention have focused around education of the dangers of sun exposure (A. Baum and Cohen 1998). Australia has a SunSmart program ongoing since 1982, formerly called “Slip! Slop! Slap!” This program helped to increase
awareness, behavior, decrease costs of gear, and increase societal acceptance of protective attire. This program has shown that active prevention efforts can be effective at improving behaviors (Colditz, Wolin, and Gehlert 2012).

Advice from the Cancer Council of Australia for reducing the likelihood of developing skin cancer includes reducing cumulative and intermittent sun exposure by ("Preventing Skin Cancer - Cancer Council Australia" 2015):

* Staying out of the sun during peak hours (10am-3pm)
* Wearing a wide-brimmed hat
* Wearing long-sleeves and sun-protective clothing
* Wearing sunscreen appropriately
* Wearing sunglasses
* Seeking shade when possible, and
* Avoiding tanning booths

Most Australians are familiar with these suggestions because of their exposure to media campaigns and other resources (Stanton 2004), but some attempts to improve sun-protective behaviors have not been as successful as others. Mass media campaigns have increased the amount of education Australians have on skin cancer but some of these campaigns had limited impact on Australian sun behaviors (Smith et al. 2002). Prevention programs that may work, but haven't been reliably evaluated include: campaigns in high-risk settings, such as swimming pools (A. Baum and Cohen 1998), alerting populations of risk levels of UVB (A. Baum and Cohen 1998), and social media campaigns (C. Sinclair and Foley 2009).

Prevention strategies that have been successful and reliably evaluated include primary and secondary school accreditation programs (Turner et al. 2014), a 4-week intensive prevention program incorporated into curriculum for children ages 9-11 (A. Baum and Cohen 1998), parents setting a clear precedent for children of sun-exposure prevention behaviors through their own behavior (Gefeller et al. 2014), and activating the public's fear of photoaging (Mahler et al. 2005).

One of the prevention strategies mentioned involved SunSmart's accreditation program. Minimum requirements for accreditation require schools to create a written sun protection policy meeting minimum curriculum, behavior, and environmental requirements, update this policy...
regularly, work to increase campus shade, reduce outdoor activities during peak UV periods during the year, and teach and reinforce positive sun protection behavior ("SunSmart Schools and Early Childhood Programs - Cancer Council Australia" 2015). Some schools even require children to arrive at school with a wide-brimmed hat, SPF 30+ sunscreen, and long-sleeved shirt according. This information was gathered from physician interviews. A picture of students at an Australian SunSmart-accredited school can be seen in Figure 8.1.

Figure 8.1: A photo of children at a SunSmart-accredited school in Australia ("SunSmart Schools and Early Childhood Programs - Cancer Council Australia" 2015)

Additionally, Australia sets policy standards for sun protective products (sun glasses, apparel, sunscreen) and occupational standards (Edlich et al. 2004). By the end of 2013 all Australian states had banned commercial tanning beds (Sinclair et al. 2014). In many ways skin cancer in Australia transferred from a personal responsibility to a social responsibility over the last 40 years (Edlich et al. 2004).

8.3 - Early Detection of Skin Cancer in Australia

Early detection is a challenge for Australia, as this also drives the ability for a skin cancer patient to seek treatment in time. Early detection strategies that might work and be cost effective include increasing primary care physician training of lesion identification and increased
screening, as only around 17% of patients have their skin checked by their primary physician (A. Baum and Cohen 1998).

Early detection strategies that have proved effective include increasing skin screening publicity (A. Baum and Cohen 1998), increasing skin screening availability such as in health fairs and pop-up free clinics (A. Baum and Cohen 1998), showcasing the disease on television (A. Baum and Cohen 1998), and increasing the number of patients doing monthly skin reviews (Berwick et al. 1996).

Most funding for skin cancer management in the United States goes toward cancer treatment, cancer biology, and the causes of cancer, not early detection and prevention (Colditz, Wolin, and Gehlert 2012). There seem to be key opportunities to improve social behaviors on a local and federal level, as identified with Australia’s progress over the past 40 years that could reduce incidence and increase early detection cost-effectively.

8.4 - Australia Key Learning Points
Australia has extensive experience in managing a population with a high incidence of skin cancer (Montague, Borland, and Sinclair 2001). Through many different initiatives, the Australian government and various Australian organizations have experimented with various education and identification initiatives. Increasing education about skin cancer has resulted in a population more aware of the consequences of sun exposure and the importance of early identification. Education initiatives that were effective included intensive learning modules in primary schools, continuous sun exposure policies at schools requiring child compliance, parents practicing safe exposure habits, and messaging about photoaging and the consequences of sun exposure on beauty. Early detecting initiatives that were effective included pop-up free detection clinics, advertising these free detection clinics, advertising the consequences of sun exposure on television shows, and increased self-screening patients. Australian trial-and-error can inform initiatives that may be successful in the United States in the future.
Chapter 9: Concluding Remarks

This research began as a way of understanding the challenges that patients, dermatologists, and primary care physicians face, with the ultimate goal of finding ways to improve patient outcomes through technology. This thesis turned into a mission to identify how to better utilize technologies but also help stakeholders communicate and access the information they need to make smart choices. After interviewing many patients and physicians, we identified that there are large differences in how patients view their own health issues and their lives and how physicians view patient actions that lead them to their office. There is a fundamental power imbalance at play, as patients are ultimately responsible for their own health, yet physicians hold the keys to providing them with care to treat their health issues in the US.

The skin cancer delivery system in the US, as it operates today, requires many alarm bells going off at the right time and in the right order for patients with quickly evolving skin cancers to gain treatment before the cancer metastasizes. Much of this burden is put on patients themselves, though many cancers are in hard to see areas and have varied forms of presentation. Additionally, there was a surprising amount of information that was not communicated within the system. If a patient had a negative experience with a physician, the patient changed physicians in the future, and their prior physician never found out why.

Though vast improvements in the performance of the system will require fundamental incentive structure, social, and cultural changes, these are very possible and doable, as physicians are at their core some of the most hardworking and people that are incredibly passionate about helping others. We can use simple methods of information sharing to help patients and physicians learn the information they need to make smarter decisions, and we can provide tools for patients and physicians to tap into the research and knowledge that has been established in the skin cancer care delivery system to help patients have better outcomes in the future.
9.1 - Further Research

To continue this research, follow on work would include further developing the technology analysis to find tools that can help physicians better assess skin lesions today, delivering a survey to physicians to quantify the issues discovered in the qualitative findings, investigating new incentive structures for physicians such as Accountable Care Organization (ACO) structures, investigating how physicians are liable for care to understand the potential for introducing new technologies, investigating how to change behavior in medical systems in physicians and patients, and evaluating the proposed solutions in terms of improvement potential and expected cost. Evaluation of this last point is particularly important, as many researchers have suggested entire population screening or high risk patient screening to improve the healthcare system's ability to detect melanoma (Wickenheiser MR, Bordeaux JS, and Robinson JK 2014; Zalaudek et al. 2011; Oliveria et al. 2011), yet this method is considered cost prohibitive, so we need to find new solutions to aid in the healthcare system supporting early identification.

9.2 - Final Thoughts

My suggestions for all potential skin cancer patients are to make sure to put sunblock on your ears, check your body for skin lesions regularly even if it is difficult to do, and make sure you have a supportive social system to help you manage your care when you need it. My suggestions for physicians are to make sure you find out about the negative experiences your patients have in addition to the positive, to make sure you understand your own limitations in providing care to patients, and you point all of your patients to appropriate resources and advice to help them better manage their own care.
Appendix

A.1 - Skin Cancer Patient Interview Questions

Section 1
1. Where are you from?
2. Where do you live now?
3. How old are you?

Section 2
4. Tell me about the time when you were first or most recently diagnosed.
5. How old were you? How long ago?
6. What type and stage of skin cancer have you had?
7. How did you originally find out about your condition?
8. What first caused you to be concerned?
9. Who did you first consult?
10. How soon were you treated?
11. Walk me through the steps in your treatment process.
12. What resources did you turn to in order to understand what was happening?
13. Who did you talk to about what you were going through?
14. Have you faced any challenges while getting treatment? If so, what were they?
15. What was the hardest part of your diagnosis to deal with?
16. How are you now? What results did you get back most recently?

Section 3
17. How do you manage your situation now?
18. How frequently do you visit the physician for this? Which type of physician?
19. How long do you typically wait to meet with a PCP or dermatologist?
20. How regularly do you check yourself? Do you ask help from others?
21. Walk me through the process of a recent time you examined yourself for changes.
22. What do you look for when monitoring yourself? Which are most concerning?
23. What situation would cause you to book an appointment immediately?
24. Do you keep track skin changes? If so, how?

Section 4
25. Can you walk me through your morning routine and your evening routine?
26. What electronics do you use in the course of a day?
27. What do you think you could do to better manage your care on your own?
28. What do you wish you knew more about?
29. How do you manage your health and wellness now? Do you keep track of any aspects of your health?
30. What are your living conditions? Do you live with anyone? In an apartment or a house? Do they help you with any parts of your care or managing your condition?
31. What products do you use on your skin regularly?
32. Do you have any informal communication with physicians? How can you contact your physicians?
33. How has this impacted your life?
34. How did your family and friends respond to your medical situation?
35. How do you wish your condition were easier to manage?
36. Have you been exposed to any known carcinogens that you’re aware of?
37. Have you had any other major medical diagnoses or chronic conditions?

Section 5
38. Do you have anything else to add that has not yet been said in the interview?
39. What do you think I should have asked you?
40. Who else would you recommend for an interview? Can I use your name in contacting them?

A.2 - Primary Care Physician Interview Questions

Section 1
1. How long have you been a physician at this practice?
2. What is the size of your practice, and mix of physicians?
3. Is your practice affiliated with anyone?
4. Typically how many patients do you see a day?
5. What are the most common conditions you see them for?
6. What is the typical workflow for when a patient comes in?
7. How long do patients wait in your office before seeing a physician?
8. How often do you see patients with skin issues in general? What types of skin issues?
9. How often do you see patients worried about a mole or skin cancer?
10. Is concern about a skin spot usually a primary or secondary reason for a patient visit?

Section 2
11. Tell me about how you process patients who are worried about skin issues.
12. Can you describe to me a specific situation with a patient who came in with this issue? Can you walk me through it? What did you do first? What did you do next?
13. Do you refer to any materials for cases like this?
14. What questions do you ask patients when they come in with this issue?
15. What are the characteristics you look for in a skin lesion? What are the characteristics you consider most significant?
16. What information from patients do you factor into making decisions about skin lesions?

Section 3
17. Around what percentage of patients do you refer to dermatologists who are concerned about skin lesions?
18. How often do you have patients concerned with seemingly innocuous skin lesions?
19. Who do you refer them to? What is the procedure for referring patients?
20. How many times a year do you see patients with a skin lesion they're worried may be cancerous?
21. Do you use any equipment for exams? What do you use?
22. What advice do you give patients worried about skin lesions?
23. Do you biopsy for skin cancer? If so, how often? Under what conditions?
24. When was the last time you biopsied a patient?
25. When you choose to not refer or biopsy, what do you recommend patients do?
26. How do you follow up with patients? How long is it before the follow up? Please cite an example.

Section 4
27. Who in your office makes purchase decisions for buying new equipment for your office?
28. What are your primary considerations in making these decisions?
29. What are technologies that you use in your office? Which do you use the most frequently? Give an example of operation.
30. How long does equipment take to operate? Who usually operates the equipment? Be specific.
31. Is there equipment you wish you had?
32. What business model makes technology adoption easiest for you?
33. Where do you think technology is lacking?
34. Do you follow up with the physicians you refer to? How do you typically correspond with these physicians?

Section 5
35. What are some of the biggest challenges you face in treating patients who may have skin cancer?
36. What are some of the biggest challenges you face in your job in general when treating patients?
37. What do you consider your number one goal as a physician?
38. What kind of information do you not currently have but you think would be helpful in treating patients who may have skin cancer?
39. If you could change or improve one behavior in your patients related to skin cancer, what would it be?
40. What are problems you see in the greater healthcare system in regard to skin cancer treatment? What hampers you?
41. What is better regarding the new regulations? What is worse?

Section 6
42. What are technologies you bring to work?
43. Do you use them for work purposes? What kind? What are some of the most recent instances of using this for your job?
44. How do you contact patients? How do they contact you?
45. Do you have any informal channels of communication with patients? What about other physicians?
46. What material do you consume that impacts how you examine or treat patients? How regularly do you consume this material?
47. What other sources influence how you examine or treat patients? What discussions do you have that would or could influence how you examine or treat patients?
48. Where is your current office? City, State
49. How much time do you typically spend with each patient?
50. If you had a handheld device that could detect skin cancer, what would be your primary concerns? What would make you excited?

Section 7
51. Do you have anything else to add that has not yet been said in the interview? What do you think I should have asked you?
52. Who else would you recommend for an interview? Can I use your name in contacting them? What about patients?

A.3 - Dermatologist Interview Questions

Section 1
1. What is the size of your practice? What types of physicians?
2. Does your practice have any affiliations?
3. How long have you been at this practice?
4. How many patients do you see a day? How many do you examine for skin cancer?
5. What other conditions do you see patients for?
6. How much time do you spend with each patient?
7. Is it easy or hard to get an appointment with a dermatologist at your practice?

Section 2
8. How do you examine patients for skin cancer? Walk me through the process.
9. What are the differences in examining a patient for different types of skin cancer?
10. Who else does a patient usually interact with in your office?
11. How many patients do you see a day who get a full skin check?
12. What questions do you ask patients? Cite specific instances.
13. What questions do you wish you could ask patients?
14. What things that patients mention do you pay the most attention to?

Section 3
15. What is your ‘threshold’ for deciding to biopsy for melanoma?
16. What specific characteristics do you pay the most attention to?
17. What percentage of lesions do you biopsy? Which types of skin cancer do you biopsy for?
18. After biopsying a lesion, how do you follow up?
19. What do you use pictures that you take of lesions for?
20. Which labs do you send biopsies to? Can you tell me more about why you selected them? Did you have a role in selecting them?
21. What is your correspondence with the lab?
22. Do you monitor changes to lesions? If so, how?
23. What technology do you use to monitor lesions? How frequently per patient?
24. How do you monitor patients with no skin cancer diagnosis?
25. When seeing skin cancer patients, what parts of the visit do you handle? What work is done by nurses and staff?
26. How do you keep track of pictures and other information about the lesion and patient?
27. How do you track mole position on the body when monitoring?
28. How do you refer to later specialists? (e.g. surgeons, oncologists)
29. How do you select these specialists? How do you communicate with these specialists?
30. Where do you feel technology is lacking and can help you do your job?

Section 4
31. What information do you wish you could know when seeing patients for skin cancer?
32. What information do you wish patients knew?
33. If you could change or improve one behavior in your patients, what would it be?
34. How do you follow up with patients after a critical diagnosis?
35. How many patients do not seek treatment after a critical diagnosis? What do you think drives this?
36. What characteristics or behaviors do you see in patients that are very good at managing their skin cancer conditions after being diagnosed?
37. Do you have informal communication with patients? How do you contact patients? How can they contact you?
38. Do you see any patients that do not go to a PCP before seeing you?
39. What do you wish PCPs did differently when treating patients for skin cancer?
40. How long is your patient waitlist for booking an appointment?
41. Are there any conditions under which you would agree to see a patient earlier than this wait time? What are these?
42. What material do you consume that impacts how you examine or treat patients? How regularly do you consume this material?
43. What other sources influence how you examine or treat patients?

Section 5
44. What types of information do you hear from referring physicians?
45. How do you communicate with primary physicians?
46. Some cancers are not detected or diagnosed until they reach later stages. Why do you think these are detected later?
47. What are the biggest challenges you face in your job? How do you deal with these?
48. What do you consider your number one goal as a physician?
49. What are problems you see in the greater healthcare system in regard to skin cancer treatment? What hampers you?
50. What is better regarding the new regulations? What is worse?
51. If you had a handheld device that could detect skin cancer, what would be your primary concerns? What would make you excited?
52. What do you think of teledermatology used today? What are you concerned about?
53. What business model makes technology adoption easiest for you?

**Section 6**
54. Do you have anything else to add that has not yet been said in the interview? What do you think I should have asked you?
55. Who else would you recommend for an interview? Can I use your name in contacting them? What about patients?

A.4 - COUHES-approved Consent Form (next page)
CONSENT TO PARTICIPATE IN INTERVIEW

Skin Cancer Technology Use Case Evaluation

You have been asked to participate in a research study conducted by Susan Conover from Engineering Systems Division (ESD) at the Massachusetts Institute of Technology (M.I.T.). The purpose of the study is to understand how technology can be used to help detect and diagnose skin cancers early. The results of this study will be included in Susan Conover’s Masters thesis. You were selected as a possible participant in this study because you are a skin cancer patient, practicing primary care physician or practicing dermatologist. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

- This interview is voluntary. You have the right not to answer any question, and to stop the interview at any time or for any reason. I expect that the interview will take about 45 minutes.

- You will not be compensated for this interview.

- Unless you give us permission to use your name, title, and/or quote you in any publications that may result from this research, the information you tell us will be confidential.

- I would like to record this interview so that I can use it for reference while proceeding with this study. I will not record this interview without your permission. If you do grant permission for this conversation to be recorded, you have the right to revoke recording permission and/or end the interview at any time.

This project will be completed by August 30, 2015. All interview recordings will be stored in a secure work space until 2 years after that date. The recordings will then be destroyed.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

(Please check all that apply)

[ ] I give permission for this interview to be recorded.

[ ] I give permission for the following information to be included in publications resulting from this study:

[ ] my name   [ ] my title   [ ] direct quotes from this interview

Name of Subject

Signature of Subject _______________________________ Date ____________

Signature of Investigator __________________ Date ________

Please contact Susan Conover (940-594-4337 or sconover@mit.edu) with any questions or concerns.

If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143b, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253-6787.

Susan Conover

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Bibliographic References


Observer-Blinded Evaluation by Dermatologists and Pathologists."


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