Applying System-Theoretic Accident Model Process View to Patient Safety for Treatment with Oral Chemotherapy and Anti-Cancer Drugs

by

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Abstract

Although the use of anti-neoplastic chemotherapy provides benefit to patients with both malignant and non-malignant diseases, the use of these agents can be at times associated with safety concerns for both patients and the healthcare workers that administer the medication. In order to mitigate the risks or hazards that are identified there are several potential tools to consider. The tool considered for this thesis will be applying a System Theoretic Accident Model and Processes (STAMP).

STAMP is used to investigate the safety of complex systems involving humans, organizations, computers, and other equipment. STAMP has the advantage of facilitating the understanding of highly complicated environments where traditional safety techniques become too costly and cumbersome and hence less efficient.

"In the traditional causality models, accidents are considered to be caused by chains of failure events, each failure directly causing the next one in the chain" (Leveson, Engineering a Safer World, 2011). This view is rather different from the perspective taken by STAMP. In STAMP, accidents arise from complex processes involving, not just component failures and faults, but also system design errors, unintended component interactions, human errors, management oversight inadequacies, and more (Leveson, 2011).

This thesis presents the “control structure” component of STPA as derived from inputs from healthcare workers particular to the Dana-Farber Cancer Institute. The suggested control structure will ultimately lay the groundwork for future work on a detailed Systems-Theoretic Process Analysis (STPA) and generate specific recommendations to help address the identified risks and hazards in addressing patient safety issues.

Thesis Advisor: Nancy Leveson
Title: Professor of Aeronautics and Astronautics
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<td>EHR</td>
<td>Electronic Health Records</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FMEA</td>
<td>Failure Mode and Effects Analysis</td>
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<td>IV</td>
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<td>PCA</td>
<td>Patient-Controlled Analgesia</td>
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<td>RCA</td>
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<td>RPN</td>
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<td>STAMP</td>
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We embraced the role of system design in the prevention of error and of information technology as a particularly powerful forcing function for delivering chemotherapy safely. We developed order set templates and created an electronic order-entry system for chemotherapy. We engaged interdisciplinary groups of front-line clinicians in the design and implementation of chemotherapy protocols, understanding that safe cancer care requires an extraordinarily high level of communication and coordination. To ensure ongoing information system improvements, we committed, and continue to commit, significant resources.

– James B. Conway, former COO of the Dana-Farber Cancer Institute

(Conway & Weingart, 2005)
Introduction and Motivation

1.1 Research Objective

Oral chemotherapy, or more broadly oral anti-cancer medications, denote a variety of hazardous medications that patients take at home without direct medical supervision. This stands in contrast to the more traditional intravenous chemotherapy, which is also hazardous, but administered under well-defined conditions by trained staff and healthcare providers. Mitigating the additional risks of oral chemotherapy is of particular importance to the Dana-Farber Cancer Institute, with whom this research was focused on.

With a problem like making oral chemotherapy safer, finding out where to best apply organizational resources is important. However, securing patient safety in such a fractured environment can be difficult. Individuals, especially patients, can operate with a great deal of autonomy. What tools can help organizations solve preventable issues encountered by patients and practitioners?

Current methods of investigating healthcare system hazards tend to focus on immediate hazards, which has some limitations when it comes to the most complex issues. This research will investigate using a Systems-Theoretic Accident Model and Processes (STAMP) within a hospital setting to understand patient hazards with respect to oral chemotherapy.

STAMP looks at the various decision-making units within the system, called ‘controllers.’ For automated systems, these controllers are computers. For organizational systems, like the oral chemotherapy healthcare system, these controllers are more likely to be individuals or even groups of individuals. These are arraigned into a hierarchical structure of controllers and how they act on one another with regards to safety actions, called a ‘safety control structure.’ Digging into the control structure can reveal the actions each controller/individual should take to ensure the outcomes are safe. Whereas the traditional hazard analyses tend to focus more on the specifics of immediate problems, STAMP analyzes the system’s structure itself for problematic interactions.
The complexity of healthcare makes it an excellent testbed to demonstrate the effectiveness of the systems approach for solving organizational issues in a human centered way.

1.2 Systems-Theoretic Accident Model and Processes

Developed by Nancy Leveson, the Systems-Theoretic Accident Model and Process (STAMP) is a view of accidents based in controls theory. STAMP takes into account complex organizational interactions, human error, software design, physical equipment, and change over time by viewing systems as “interrelated components that are kept in a state of dynamic equilibrium by feedback loops of information and control” (Leveson, 2004).

STAMP has been successfully used in many domains including aerospace, defense, energy, chemical, healthcare, and transportation systems. STAMP is especially adept at capturing behavior in modern complex human- and software-intensive systems where component interaction accidents have become increasingly common and traditional chain of events models have proven inadequate.

(Thomas, 2013)

As described in Engineering a Safer World, there are three primary concepts in STAMP: safety constraints, hierarchical control structures, and process models. Through the lens of STAMP, accidents arise through violations of the system’s safety constraints\(^1\), not as a linear chain of events. Constraints can be enforced through physical design, processes, and social controls. Unexpected and complex interactions between human errors, environmental influences, and mechanical failures are tolerated as long as the

---

\(^1\) Example constraint: a patient must not receive a lethal dose of medication (Leveson, 2004)
system is designed to account for these disturbances. Controllers are the adaptive decision making units that allow for such flexibility. These are typically individuals, groups of individuals, or software components within the system. Controllers are responsible for receiving feedback from other components, deciding what action(s) to take, and then issuing their chosen action. These possible actions taken by controllers are called ‘control actions.’ Controllers are connected to one another by issuing control actions to lower-level components and providing feedback to higher-level components. The resulting network is called the hierarchical control structure. STAMP also examines the controllers’ process model, which is the way by which they choose their actions.² (Leveson, 2011)

\[\text{Hierarchical Safety Control Structure}\]

\[\text{Inadequate Enforcement of Safety Constraints on Process Behavior}\]

\[\text{Inadequate Control}\]

\[\text{Hazardous Process}\]

\[\text{Hazardous System State}\]

*Figure 1 – Accidents result when safety control structure does not adequately enforce constraints (Leveson, 2011)*

² Example process model: to maintain a temperature, a thermostat could “[contain] the current temperature and the setpoint and perhaps a few control laws about how the temperature is changed” (Leveson, 2011)
STAMP can provide specific recommendations on how to address a system’s safety deficiencies. The system should be designed so that controllers, as described above, enforce and do not violate the safety constraints through their control actions (Leveson, 2011).

The safety control structure is built of controllers, all operating to not violate the safety constraints while handling external disturbances. This creates a flexible and adaptive approach in preventing accidents. Additionally, the process models by which controllers make decisions can be analyzed. For human operators, this would be the mental model used to perform a process. Controllers “act in harmony” with their mental models, therefore understanding these models in context is important to understanding their behavior (Nelson, 2008).

A hazard analysis technique based on STAMP is the System-Theoretic Process Analysis (STPA). STPA is a systematic approach to performing a hazard analysis, which “works on a model of the system and has ‘guidewords’ to assist in the analysis,” this guidance “provide[s] some assurance of completeness” (Leveson, 2011).

1.3 Cancer

Cancer can be defined as an “inappropriate and uncontrollable cell growth within one of the specialized tissues of the body, threatening normal cell and organ function” (Hosick, Rizzo, & al., 2017). Cancer is an umbrella term describing a wide category of diseases that disrupt this careful balance of individual cells. Ignoring their cellular environment, cancerous cells “grow out of control and become invasive … [and], unlike normal cells, cancer cells continue to divide without stopping” (NIH, 2017b).

3 This “set of guidewords is based on lack of control rather than physical parameter deviations” (Leveson, 2011).
The dawn of multicellular life began approximately 3.5 billion years ago when “Cyanobacteria-like organisms” began to form filamentous mats (Grosberg & Strathmann, 2007). To function properly, multicellular organisms require careful coordination and collaboration between large numbers of individual cells. Deviation from this careful coordination can lead to catastrophic effects for the organism. Thus, there are many cellular controls and regulatory mechanisms to keep everything working together properly.

One mechanism to regulate the growth of cells as well as the overall shape of tissues is programmed cell death or apoptosis. In an adult human, billions of cells undergo apoptosis in just the bone marrow and intestines alone (Alberts, Johnson, & et al., 2002).

The human and economic costs associated with cancer are enormous. There are 1,688,780 new cancer cases and 600,920 deaths\(^4\) estimated for 2017 in the United States alone (CDC, American Cancer Society, 2017). In the US, “the estimated total annual economic cost of cancer was approximately US$ 1.16 trillion in 2010 ... even this impressively high figure is a lower bound, as it does not include the substantial longer-term costs to families and caregivers” (Stewart & Wild, 2014).

The field of Oncology is concerned with addressing cancers. Oncology is a multidisciplinary practice and involves increasing levels of specialization (Croke, 2012). The field contains three primary areas of focus: surgical oncology, radiation oncology, and medical oncology (American Society of Clinical Oncology, 2017a).

Surgical Oncology involves the physical removal of tumor masses from the patient, over the years this has evolved into subspecialties focused on “smaller anatomic sections” (Lawrence W. J., 2017). Radiation Oncology involves bombarding the diseased area with radiation to damage and shrink the tumor.

\(^4\) “Rounded to the nearest 10; estimated new cases exclude basal cell and squamous cell skin cancers and in situ carcinomas except urinary bladder. About 63,410 carcinoma cases in situ of the female breast and 74,680 cases of melanoma in situ will be newly diagnosed in 2017” (CDC, American Cancer Society, 2017).
The treatment utilizes high-energy photons, protons, and electrons from a variety of sources, including technologies such as Intensity Modulated Radiation Therapy (IMRT), High Dose Rate Brachytherapy, and Intraoperative Radiation Therapy (Massachusetts General Hospital, 2017).

Medical Oncology is often the primary specialty that the patient will interact with over their course of receiving cancer treatment. This specialty makes extensive use of drugs such as chemotherapy and hormonal therapy in collaboration with the other oncological specialists to deliver patient care (NIH, 2017a).

The focus of this thesis will be regarding patient safety within Medical Oncology – specifically, the delivery of chemotherapy to patients as the field moves to new delivery methods for these drugs.

1.4 Chemotherapy

Chemotherapy, sometimes shortened to simply ‘chemo,’ works by selectively damaging tumor cells over healthy body cells. Many tumors grow and divide much more quickly than non-cancerous cells, therefore the target of chemotherapy treatments are primarily rapidly growing and dividing cells (American Cancer Society, 2017a). Many patients experience hair loss when undergoing chemotherapy as the roots of hair follicles contain rapidly dividing cells (Chadha V, 2003). Chemotherapy drugs are toxic and damaging to all cells, but are more so to cancer cells.

There are two types of chemotherapy, Intravenous (IV) Chemotherapy and Oral Chemotherapy. With IV chemotherapy, the chemotherapeutic drugs are delivered directly into the patient’s bloodstream through an intravenous connection and can take several hours at a time (American Society of Clinical Oncology, 2017b).

However, there are some disadvantages to this approach. The application of the drug is by nature intermittent and for certain treatments, this can result in a lower efficacy than more prolonged exposures to the drug; additionally, traveling to receive the treatment at a specific location places a burden on the patients (Bhattacharyya, 2010).
In contrast, oral chemotherapy, usually shortened to ‘oral chemo,’ involves ingesting the antineoplastic chemotherapeutic drugs as a liquid or as a pill (American Cancer Society, 2017c). This solves some of the challenges highlighted above with IV chemo, such as requiring the patient to travel to the clinic, and has subsequently grown in popularity (Mahay, 2009). However, oral chemotherapy has introduced new challenges for patient safety into the care environment.

Since the patient’s role has changed from that of a more passive recipient of care in the clinic setting to an active one with responsibility to take the medication appropriately, patient behavior and adherence to the drug regimen can have a significant impact on outcomes and safety. Misunderstanding timing, forgetting to take the medicine, “[trying] to catch up on missed doses,” poor interactions with food or supplements, and vomiting after taking the drug are all major factors that can lead to reduced success and poorer outcomes (Aisner, 2007).

Due to the toxic nature of chemotherapeutic drugs, it is recommended that the patient’s caregivers (often relatives), understand the dangers of exposure to these drugs; they should wash the bedsheets regularly, double-flush the toilets, and wear gloves when handling the drugs or other items that come in close contact with the patient’s sweat, saliva, urine, or other bodily fluids (Goodin, Griffith, & al., 2011).

1.5 The Problem with Oral Chemotherapy
Since many chemotherapy drugs are inherently cytotoxic, any mismanagement can be quite dangerous. One high profile case of this is the case of the journalist Betsy Lehman. As reported by the New York Times in 1994, she was a patient at the Dana-Farber Cancer Institute in Boston, Massachusetts. Due to receiving a miscalculated dosage, she received “4 times” as much cyclophosphamide, a chemotherapeutic drug, as she should have. Sadly, she died soon after. However, the Institute was not

---

5 A broader term would be oral anti-cancer medication, to include hormonal therapy as well.
aware of the mistake until later during a routine data check. The autopsy report did not find the overdose error. (Lawrence A. K., 1995)

This prompted the extensive investigation and reorganization of the Institute. There were numerous changes made initially:

- New rules were adopted mandating close supervision of physicians in fellowship training
- Nurses were required to double-check high-dose chemotherapy orders and to complete specialized training in new treatment protocols
- Interdisciplinary clinical teams reviewed new protocols and reported adverse events and drug toxicities
- A trustee-level quality committee was reorganized and strengthened
- Discussions were begun regarding the transfer of inpatient beds to nearby Brigham and Women's Hospital

(Conway & Weingart, 2005)

Since this time, Dana-Farber has committed to continuously improve patient safety and to “focus its attention and energy on medical errors and iatrogenic injuries” (Conway & Weingart, 2005).

The goal of this thesis research was to highlight areas of improvement in oral chemotherapy patient safety. However, given that the scope of the thesis is mainly to create a “control structure” that can begin to focus improvement efforts as well as provide the foundation for a more complete hazard analysis in the form of System-Theoretic Process Analysis (STPA)

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6 Please see section 1.2 on Systems-Theoretic Accident Model and Processes for more details.
Thus, the problem to be taken on is patient safety in context of administration of oral chemotherapeutic agents. In trying to identify and eliminate sources of preventable patient hazards, this thesis will use STAMP to tackle the problem from a holistic systems perspective. In particular, the focus will be on the creation of one the key components of STAMP. The control structure. This can later be utilized as a building block for future system level recommendations.
Chapter 2: Literature Review

2.1 Safety in Chemotherapy

2.1.1 Chemotherapy Risks

Chemotherapy drugs require careful management to achieve a therapeutic dose without reaching a toxic dose. Subsequently, underdosing and overdosing with chemotherapeutic drugs are two errors that can be particularly detrimental to the patient.

The danger of underdosing is that the tumor may not be fully treated. In one breast cancer study, low dosage patients had a five-year survival rate of 72% vs. 79%\(^7\) for the higher dosed patients (Budman, Berry, & et al., 1998).

Overdosing on these drugs can be very harmful and, in some cases, fatal. For many chemotherapy drugs, increasing the dose does increase toxicity, but with often little additional therapeutic benefit (Gurney, Dodwell, Thatcher, & Tattersall, 1993).

Another risk is the unintentional exposure to active agents during handling. Simply handling the medicine can expose the patient’s personal caregivers to harm. “Accidental exposure to oral chemotherapeutic agents can occur at various stages,” so there is a need for proper development and dissemination of safety and handling instructions during the entire lifecycle of the drug (Goodin, Griffith, & et al., 2011).

There are also health concerns stemming from chemotherapy that extend beyond just the treatment window. Depending on the specific chemotherapeutic agent, there are a multitude of potential complications that include: congestive heart failure, coronary artery disease, arrhythmia, hypertension, lung damage, early and severe menopause, infertility, hearing loss, increased stroke risk, memory loss, attention

\(^7\) Both the 72% and 79% survival rates have a standard error of ± 2% (Budman, Berry, & et al., 1998)
difficulties, emotional difficulties, secondary cancers, fatigue, hormonal issues, digestion issues, oral health problems, and other complications (American Society of Clinical Oncology, 2017c).

2.1.2 Importance of Patient Education

Patients and their personal caregivers are central to compliance with specific and complex instructions when taking oral chemotherapy drugs at home. Patient education is one of the most critical aspects to promoting adherence.

*At treatment onset, oncology nurses can engage patients directly in a collaborative dialogue ... by providing individually tailored educational material. A practical approach to patient education, along with building strong health care provider-patient relationships, can help patients overcome nonadherence to new oral anticancer therapies and treatment paradigms.*  

(Wood, 2012)

According to Elizabeth Bettencourt of the Association of Community Cancer Centers, patient education is an essential component for oral chemotherapy drug compliance. A nurse should not only provide a single bout of initial training but should also follow-up with the patients and provide them with continuing education. Patients should be taught about the drug’s storage and handling requirements, drug-food interactions, and how to manage missed doses and concurrent treatments. Each drug differs in its specific storage requirements and can be very sensitive to temperature excursions, frequently compounded by already short shelf lives. Some drugs require room temperature storage (without spikes in temperature), others require refrigeration and many need dry and dark conditions. Another critical safety-related function is the physical handling of the pills. Contact with the medication or its residue can expose caregivers to the active agents. Unfortunately, the risks of accidental exposure are not yet well understood. Caregivers should wear gloves if patients cannot take the medicine without help. It is important to be assiduous in avoiding contact, such as using the pill bottle cap to dispense the capsules. Both caregivers and patients should wash their hands afterwards. Pills should be kept in their original containers or in pill boxes separate
from other medications. Any clothing or bedding soiled with bodily fluids should be washed separately from other laundry. The chemotherapeutic drugs can also interact in numerous significant ways with other drugs and food. Anticoagulants, antibiotics, antacids, and proton pump inhibitors are some of the drug classes that can cause significant complexity for the treatment regimen. Some foods can lower the absorption of the active agent. Certain fruits, like grapefruit, should be avoided all together due to the effects they may have on the metabolism of certain chemotherapeutic agents. If the patient misses a dose, it is often possible to make it up within six hours. However, after that time period, the missed dose should be skipped altogether. (Bettencourt, 2014)

2.1.3 The Role of the Oncologist

The oncologist is the primary healthcare provider for patients during their cancer diagnosis and treatment (NIH, 2017a). Key responsibilities of the oncologist include the following:

- Explaining the cancer diagnosis and stage to the patient
- Discussing all relevant treatment options and the oncologist’s recommendations
- Delivering high-quality, compassionate care
- Helping the patient manage cancer-related pain and other symptoms or treatment side effects

(American Society of Clinical Oncology, 2017a)

2.2 Current Safety Analysis Methods in Medicine

Two common methods to analyze safety in healthcare and medicine are Root Cause Analysis and Failure Modes and Effects Analysis. Root cause analysis is a retrospective method that looks at accidents and near misses that already happened. Failure Modes and Effects Analysis examines a system for where safety hazards are most likely to occur. However, despite their popularity, there are some limitations to these approaches.
2.2.1 Root Cause Analysis

According to The Joint Commission, Root Cause Analysis (RCA) is a technique to retroactively understand and find the root cause to problems experienced by organizations and systems. A root cause is defined as the fundamental reason or reasons that led to a failure. In the context of patient safety, these failures would be any event that causes severe harm or death not related to the natural course of a patient’s illness or treatment. (Joint Commission, 2015)

A simplified method for getting to the root cause is a technique called the ‘5 Whys’. Developed by Sakichi Toyoda for use at the Toyota Industries Corporation, this technique asks why a problem occurred in order to connect the preceding problem that directly caused it; this process is performed five times before the root cause is identified (Serrat, 2009).

![Diagram of 5 Whys process]

Figure 2 – Typical example of a 5 Whys worksheet (Minnesota Department of Health, 2017)
A more involved method to perform a root cause analysis is provided by the United States Veterans Affairs Center for Patient Safety. When performing the RCA, the investigator must answer four key questions: what happened, why it happened, what can be done to prevent it, and how to insure the responses taken will be effective. Beginning the analysis, the investigator looks at the organization’s rules, safeguards, environment, equipment, information technology systems, staffing resources, training and communication. After collecting all this information, there is a “critical step” where the cause and effect are “clearly linked.” Once these causes have been determined, investigators brainstorm recommendations to fix the problems. These recommendations are then prioritized based on “action strength.” A recommendation that removes dependence on human decision-making is considered stronger, whereas still leaving room for personal interpretation is considered weaker. (U.S. Department of Veterans Affairs, 2016)

An advantage of RCA is that it begins to get investigators thinking beyond the immediate causes and a bit deeper into the contributing factors. RCA investigators must be careful to not settle on assigning individual blame and direct their efforts towards systemic factors instead (Joint Commission, 2015).

However, some drawbacks to this approach have been recognized. RCA is fundamentally based on the concept that accidents arise from a chain of events, which has some limitations, as described in Engineering a Safer World:

Event-based models are limited in their ability to represent accidents as complex processes, particularly at representing systemic accident factors such as structural deficiencies in the organization, management deficiencies, and flaws in the safety culture of the company or industry. We need to understand how the whole system, including the organizational and social components, operating together, led to the loss.

(Leveson, 2011)
2.2.2 Failure Modes and Effects Analysis

While Root Cause Analysis looks at errors that have already transpired, Failure Mode and Effects Analysis (FMEA) is a proactive technique to understand how problems can arise in a system before they happen (Joint Commission, 2015). Developed in the 1950s, FMEA originated as a reliability method to understand “all [the] conceivable failure modes” and the “magnitude of their effects,” typically presented in a chart format (Rausand & Hoyland, 2004). A FMEA first looks at each component in the system and their expected failure modes; then potential causes, effects, severity, probability of occurrence, and criticality of each failure mode is examined in turn (American Society of Quality, 2017).

According to the Institute of Healthcare Improvement (IHI), FMEA has been adopted into the world of healthcare and used by hundreds of hospitals through their programs, including Patient Safety Summits and Collaboratives. To perform a FMEA in a healthcare setting, the IHI recommends assembling a multidisciplinary team of individuals working on different stages of the process being investigated. First, all process steps are listed along with all the possible problems the team can come up with. Each failure is then given a score from 1 to 10 each for likelihood of occurrence, likelihood of escaping detection, and severity of harm. These scores are then converted into a Risk Priority Number (RPN) by simply multiplying them together. The resultant range of the RPNs is from 1 to 1000 of least possible to greatest possible concern. For example, a failure assigned a score of ‘5’ in each category would then have a RPN of 125. The resultant ranking of RPNs for the identified failures provides an ostensible method to prioritize concerns and direct the efforts to reduce harm. (Institute for Healthcare Improvement, 2004)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Failure Mode</th>
<th>Failure Cause</th>
<th>Failure Effects</th>
<th>Occurrence Likelihood</th>
<th>Detection Likelihood</th>
<th>Severity</th>
<th>Risk Profile Number</th>
<th>Actions to Reduce Occurrence of Failure</th>
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There are other healthcare FMEA variants used as well. The U.S. Veterans Administration’s Healthcare FMEA (HFMEA) removes the detection score while adding columns for a Decision Tree Analysis and delegation of responsibility. The Decision Tree Analysis begins with the hazard score (similar to RPN), possible control measures, and a series of yes/no questions. Taking all this into account, a higher level of criticality may be triggered. (DeRosier & Stalhandske, 2002)

In some cases, the validity of FMEA has been called into question. While FMEA provides guidance on how to progress through the method itself, it “doesn’t offer guidance in the identification of failure modes or their causes” and the investigative team must correctly identify all important failures at the start of the process through “the domain expertise of the analysts” (Teikari, 2014). Boston Medical Center Health Services Research states “the concept of multiplying ordinal scales to prioritize failures is mathematically flawed” and recommends that “until FMEA’s validity is further explored, healthcare

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8 The questions asked are:
- “Does this hazard involve a sufficient likelihood of occurrence and severity to warrant it be controlled?”
- “Is this a single point weakness in the process?”
- “Does an effective control measure exist for the identified hazard?”
- “Is the hazard so obvious and readily apparent that a control measure is not warranted?”
(DeRosier & Stalhandske, 2002)

9 Four types of numerical scales: Nominal, Ordinal, Interval, and Ratio (FEMA uses an ordinal scale to rank)
- Nominal: numbers are only unique labels with no deeper mathematical meaning or ordering
- Ordinal: denotes the ordering of elements, the exact distance between each is not defined
- Interval: maintains a constant distance between each number, allowing addition and subtraction
- Ratio: constant intervals but also anchored at zero, which also allows multiplication and division
(Holtzman, 2001)

Examples
- Nominal: the switch has two states, the first is on, the second is off
- Ordinal: first/second/third place in a race denotes a known order but not how close they are
- Interval: Celsius, each degree is the same amount of heat energy as others but 0°C is not absolute zero
- Ratio: Kelvin, each degree is the same amount of heat energy and 0°C does equal absolute zero

28
organizations should not solely depend on their FMEA results to prioritize patient safety issues” (Shebl, Franklin, & Barber, 2012).

2.3 STAMP Application to Healthcare

As STAMP excels in dealing with complex socio-technical systems, healthcare systems are a promising candidate for application of this approach. Two examples are presented below with a focus on the hierarchical safety control structures.

2.3.1 Proton Therapy Machine

The PROSCAN facility located at the Paul Scherrer Institute in Switzerland contains clinical proton therapy gantries for treating tumors (Baumgarten, Rizzoglio, & Gerbershagen, 2017). In proton therapy, a cyclotron accelerates protons into a beam, which is then directed at a patient’s tumor mass where it ionizes and damages the targeted cells (The National Association for Proton Therapy, 2017).

According to the STPA performed on PROSCAN by Blandine Antoine at MIT, the objective was to identify any hazardous scenarios. This is in contrast to the safety report originally created for PROSCAN, with the goal to document protective measures to licensing authorities. The STPA was able to identify all unsafe behaviors detailed in the draft safety report, plus an additional three unsafe behaviors not previously documented. These advanced STPA results were obtained at the cost of “few resources” in comparison to traditional methods. (Antoine, 2013)

The first safety control structure created for the system was quite high-level,\(^{10}\) containing only three components:

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\(^{10}\) In systems theory, a low level of abstraction contains a great deal of information and details. However, this makes understanding the context inherently difficult. A high level of abstraction provides much clearer view of the context but at the expense of detail. (Checkland, 1999, p. 9)
Already at this level, there are numerous important interactions identified. This is significantly different from the view provided by system’s official documentation, which tended to focus on physical components and processes. Further zooming into the Treatment Delivery controller reveals significantly more detail:
Armed with this safety control hierarchy from STAMP, safety recommendations can be generated through the STPA process. Each control action shown is analyzed for its contributions to ensuring safety constraints are not violated.

### 2.3.2 Intravenous Patient-Controlled Analgesia Pump

Patient-Controlled Analgesia (PCA) pumps allow patients to self-administer analgesics for pain management without needing constant physician supervision. Despite the apparent simplicity of the system, there have been 87 recalls and tens of thousands of FDA reports about PCA pumps (Thomas & al., STPA Analysis of Intravenous Patient-Controlled Analgesia, 2017).

The safety control structure is as follows:
This analysis was able to capture interoperability issues, potential human errors, as well as possible accidents arising from component interactions beyond simple component failures (Thomas & al., STPA Analysis of Intravenous Patient-Controlled Analgesia, 2017).
Chapter 3: Dana–Farber Cancer Institute’s Perspective

The Dana–Farber Cancer Institute has publically recognized that providing cancer treatment is a challenging responsibility that requires constant learning and improvements:

Most important, we learned that the work of creating safe care is never finished. Cancer care is a particularly hazardous undertaking. Our patients are perilously ill, and their treatment requires the use of highly toxic therapies. The margin of cure and of harm is often razor thin; this is a fact of life for patients and clinicians alike. We recognize that mistakes will happen and that it is our responsibility to recognize them quickly, mitigate the harm, disclose any errors to our patients, and look after the staff’s psychological well-being. We have a broad responsibility to learn from each mistake and to share the results of our learning.

(Conway & Weingart, 2005)

3.1 Initiatives

As oral anti-cancer therapies continue to grow in popularity, Dana–Farber has put forth initiatives to better understand the safety of the situation. Especially when comparing the current state of safety in oral vs the more traditional IV chemotherapy processes.

A recent internal panel of experts looked at how oral chemotherapy stacks up to the quality of IV chemotherapy. The investigation revealed there are areas where care can be bolstered.

Many of the issues pertaining to the challenges around oral chemotherapy stem from its greater complexity to administer compared to IV chemotherapy. In particular, the Institute must rely heavily on the patient and their personal caregivers in adherence to the regimens provided (Dana–Farber Cancer Institute, 2017b).

Within the Dana–Farber umbrella, the healthcare systems and their relationships to one another are intricate. As presented by Dana–Farber, there are six primary drivers of patient safety and oral
Chemotherapy adherence: providers, pharmacy, information systems, financial systems, the organization itself, and the patients and their families. Providers are responsible for creating/maintaining treatment plans, adhering to clinical practices, administering patient education, and care. The pharmacy must make the correct drugs available and ensure proper packaging. Information Systems manage the Electronic Health Record system (EHR), reporting, and monitoring. Financial services are responsible for looking after insurance, co-pays, prior authorizations, and the patients’ socioeconomic situation. The organization sets the policies, culture and communication. Finally, the patients manage adherence, storage of drugs, consent to care, and communicate any issues they experience. (Dana-Farber Cancer Institute, 2017c)

Dana-Farber Cancer Institute has mapped out process flow diagrams, or process map, for different treatment types. These diagrams show the sequencing of critical decisions and authorizations needed for the patient to receive treatment. For comparison, the IV Chemotherapy process flow is divided into three primary centers of responsibility: Provider, Infusion Nurse, and Specialty Pharmacist. The patient is not featured on the process map; once they consent to the treatment, they are primarily a passive recipient of care. Based on number of the number of handoffs and number of steps, oral chemotherapy is a more complex process IV chemotherapy. (Dana-Farber Cancer Institute, 2017a)

Compiling all the information from the interviews, who gets what from whom and what each group’s responsibilities are, the control structure was built out. It was an iterative process that required verification and refinement with the subject matter experts. These discussions began to reveal certain feedbacks that were not present in all cases or had no rigorous system to enforce them, which open up avenues for advancing the safety of the system.

3.2 Interviews

In understanding Dana-Farber’s patient safety structure for oral anti-cancer medication, interviews were held with individuals from various groups within the Institute. These individuals represented physicians, program nurses, hospital administration, a clinical pharmacist, and a patient advocate. Of the interviewed physicians, one was external to Dana-Farber. This perspective helped shed light on which
factors were specific to Dana-Farber and which were more general, as the structure of hospitals around the United States and the world is not monolithic.

The purpose of these interviews was to gain an understanding of how Dana-Farber’s oral chemotherapy program works, particularly with a goal towards building a STAMP-based hierarchical safety control structure. The questions focused primarily on parsing and clarifying the relationships and responsibilities of the various participants. Also, participants were shown in-progress drafts of the control structure to highlight any inaccuracies. The administration’s perspective has been omitted below as most of the discussion focused on the control structure itself. This information is captured in Chapter 4.

What follows are summaries of these discussions.

3.2.1 Physician’s Perspective

The oncologists at Dana-Farber will first encounter a patient when they are referred from their Primary Care Physician, self-referred, or coming for a second opinion. The patient will be seen in the clinic and their history reviewed. Depending on circumstance, the patient may see other specialists and have additional tests, screenings, or biopsies requested.

Physicians will then enter the patient data into the EHR system called Pathways. There is an algorithm that provides a suggested treatment plan. The oncologist will then decide on what course of action to take for the patient.

The physician will then come up with a treatment plan for the patient. Treatment plans are often fairly standard but may require modifications to account for the special circumstances and needs of the patient.

11 Please refer to Chapter 2 for more information.
12 Interviews were conducted during April and May 2017
individual. As Dana-Farber is a research hospital, some patients may also be put on experimental plans associated with a pharmaceutical clinical trial.

Once decided upon, the treatment plan will be entered into the EHR and the prescription will be sent to the pharmacy. The ordering and delivery of medication itself is largely out of the physician’s sight. The patients are simply counseled to contact the physician’s office once the first dose is in hand and to not begin treatment until they have talked to the doctor.

Receiving the medication can take some time. The timeline for processing and insurance approvals is highly variable. This disparity is notable because with IV chemo it is possible to start treatment on the same day.

Once a patient begins treatment, the scheduling of medications can become very complex. Different medications may be taken at different times of the day with a varying number of pills taken each time. Then, there can be intermittent rest periods, sometimes lasting weeks. It can be confusing for the patient. Therefore, for every situation, the oncologists must weigh the benefits of providing a more precise drug regimen against a more cognitively manageable one.

As the progress is monitored, the physician may alter the treatment to better suit a patient’s changing situation. This modification can be a potential stumbling block for the patient, as they have to understand and remember how their drug schedule has changed. This difficulty can be compounded if the pharmacy is not notified about prescription updates. If the patient was taking three pills per day and gets switched to two pills per day, the pharmacy will continue sending the full prescription. This is not only confusing and dangerous for the patient, but potentially expensive as well. Another complicating factor is that patients may omit facts that they believe to be irrelevant to their treatment but which can still have clinically significant effects. Taking various herbs and supplements tend to fall in this category.
In the course of their work, the oncologist will work closely with a Nurse Practitioner in their office who is familiar with all the oncologist’s patients. Once treatment has begun, the physician and nurse practitioner will usually rotate who sees the patient during their appointment.

If there are any issues during treatment, patients can call the physician’s office directly. The receptionist will then direct the call to either the program nurses and/or send the oncologist and nurse practitioner an email. Between the physician and nurse practitioner, they try to respond to all their emails every day, which can be a challenge on days when the physician is in the clinic seeing patients. For more serious or urgent issues, the receptionist will forward the call directly to the doctor.

3.2.2 External Physician’s Perspective\(^{13}\)

Physicians may need to verify with the pharmacist for drug reconciliation if the patient is taking multiple, potentially interacting medications. Physicians do not have the time to look up the latest information on all the possible drug interactions.

Another potential source of difficulties is when the correct medication is prescribed but interpreted incorrectly by the pharmacy. This can be particularly problematic if the physician uses acronyms or abbreviations different from those his or her peers use. Although this is potentially more of an issue for primary care physicians, who may deal with a wider set of medications and drug interactions than oncologists.

A problem inherent to the healthcare system is that physicians have difficulty knowing exactly what the patient is taking outside of their view. This is especially true with narcotics which patients may be loath to admit. Physicians have access to “in system” patient medical history and will therefore only have knowledge of the drugs that were prescribed and dispensed within their internal hospital network.

\(^{13}\) This physician was not affiliated with Dana-Farber
For patients without financial means or personal support networks, there is usually a social worker who helps manage their case. This person checks in on the patient, makes sure they are complying with the medication instructions, managing their side effects, and are able to afford the drugs.

3.2.3 Program Nurse’s Perspective

The Program Nurses’ primary responsibility is dealing with patient issues between appointments. The physicians are unable to take every call from the patient, thus the program nurses handle all the non-immediate issues for the physicians.

When they have issues or questions, the patient is usually directed to the call center first. The call center ensures that even during off hours or at a busy time, the caller will reach a live person to talk to about their concerns. From there, the program nurse will either take the call or receive an email for them and follow-up later.

When talking to the patient, the nurses will follow one of their approved standard procedures to deal with common issues, such as nausea or vomiting. For more worrying issues, the nurse will loop in either the primary oncologist or other supportive groups. However, it is difficult to help patients if their information was entered incorrectly in the system or something material has changed since that information was entered. Common problems include treatment plan changes which the physician has not updated in the system, or if the patient has changed insurance providers without alerting Dana-Farber.

Program nurses also make many routine calls to patients, beyond the initial medical teaching call performed by the clinical pharmacist. To teach properly requires building a great deal of trust. If there are language issues, the program nurses have access to translators on the line.

The program nurses receive the upcoming teaching calls and current issues come to them in a shared email inbox. Patients can also reach out for information through the online system Patient Gateway. The staff can receive and send email through this system, but patients are cautioned not use the online tools for
reporting symptoms. It is too difficult to reach the patients in a timely manner, so calling is emphasized as the best option.

3.2.4 Clinical Pharmacist

Prescriptions are initially sent to the Dana-Farber pharmacy. This occurs once the physician initiates a treatment plan or writes a prescription in the EHR. If necessary, Dana-Farber will wait until receiving prior authorization from the patient’s insurance. If Dana-Farber cannot fill the prescription in house, the prescription will be sent to an external pharmacy.

The pharmacists wait until the patient has their medication in hand and can confirm the label by phone. Pharmacists then instruct the patient on the medication, dosing schedule, how to manage typical side effects, and warning signs. The teaching is done primarily with the standardized teaching tool MOATT.\textsuperscript{14} The oncologist will approve of any modifications that need to be made before the teaching commences. This is more difficult without a treatment plan entered into the EHR, as sometimes happens when the physician just writes the prescription without submitting the plan.

If the prescription is sent to an external pharmacy, the patient may also receive teaching in accordance to that pharmacy’s procedures. Dana-Farber will always perform teaching for oral chemotherapy patients, which can potentially introduce a source of conflicting information.

Some drug regimens are especially complicated. It is common to take two drugs with widely different usage patterns simultaneously. Follow-up calls tend to be the responsibility of the program nurses whereas the pharmacy usually focuses on initial teaching.

\textsuperscript{14} Developed by the Multinational Association for Supportive Care in Cancer (MASCC), this is the MASCC Oral Agent Teaching Tool (MOATT).
Neuro-Oncology cases, cancers of the brain and nervous system, patients are handled separately. Nurses with specialized training perform the teaching, instead of the clinical pharmacists, due to the increased risk of patient mental impairment.

The pharmacy team is made up of a number of individual groups – primarily Clinical Pharmacists, Staff Pharmacists, Benefits Coordinators, Resource Specialists, and the technicians who perform the physical mixing of drugs.

The clinical pharmacists will often go on rounds with the physicians, where they will meet the patients and answer any questions about the medication. It is not possible for the clinical pharmacists to meet with all patients in the clinic, so new patients are prioritized.

Staff pharmacists will review all the incoming cases. Benefits coordinators do much of the work with insurance authorization and other administrative tasks. If there is an issue, such as insurance requesting more information or denying payment, the case gets elevated to the Resource Specialists. Resource Specialists will request additional information from the physician. Sometimes the pharmaceutical companies will provide extra funding and support for patients who are not covered. The pharmacy will be in contact with the social workers employed by Dana-Farber for patients without personal support networks.

3.2.5 Patient

For patients and families, the emotional aspect of entering the system is extremely stressful. Patients are overwhelmed emotionally as they are being deluged with information. There is a lot to learn: which drugs to take, how long each phase will last, which team is assigned to them for what purposes, and what are the possible outcomes. Being able to prioritize, being emotionally resilient, and just taking each day one at a time are critical survival skills in a situation where even missing some paperwork for the proper reimbursements could cost hundreds of thousands of dollars.

In the world of oral chemo, outcomes can be heavily dependent on the linguistic and technical skill of the caregiver and strength of the family support network. The medication is taken at home and there are
simply things the physician does not see. Communicating symptoms, side-effects, adverse events, and other relevant information back to the providers is critical to success. From the patient’s perspective, outcomes are better when the caregivers are strong advocates for their loved ones and are not shy about calling the providers, explaining clearly the effects being seen and escalating to the oncologist if necessary. However, when communicating with different healthcare professionals throughout the system, there is a risk of getting slightly different explanations. Compound this with all the information publically available on the internet, not all of which is accurate. The information dispersal is significant and families must be able to navigate this sea of information.

Every patient’s personal situation is different and their relationship to their personal caregiver varies widely. With adults, it is often the patient who manages their own care with the support of a spouse or other family members. In some cases, the caregiver may be hired by the family to help. It could be a social worker, or house call nurse. With minor patients, it is usually the parent who is the primary caregiver and completely manages their medication and interactions with the healthcare system. Still, in other cases, it is not unheard of for young children to act as a partial caregiver for a parent, especially when the parent is relying on the child as a translator.

The patient’s broader support network is extremely important. What is the rest of the family doing? How to get time off of work? If the child is the patient, the parent also continues parenting. Explaining what is going on to the child, still getting them to school if they can get out of bed, providing alternate methods of nutrition when they do not wish to eat, and looking after their siblings. Parents and other caregivers must be sure to communicate between themselves to avoid double dosing the patient on any given day.

For curative treatments instead of palliative, the exit point can also be traumatic, though not nearly as traumatic as the entry point. During treatment, Dana-Farber’s systems provide a significant support structure around the patient. But once exited, the individuals go back to a primary care physician who may not have specialized knowledge to detect residual complications.
As a research hospital, Dana-Farber also has the most cutting-edge protocols. Many of the latest advancements aim to reduce side effects during treatment. Unfortunately, individuals going to non-research hospitals might have protocols that are outdated. In some cases, this can produce a significant difference in outcomes and without the reduction in side effects. Although the culture at Dana-Farber is just as critical as the latest procedures. Dana-Farber does work to holistically support the caregiver network around the patient and provide the psychical factors for support, helping the patient retain the will to keep going.
Chapter 4: Building the Safety Control Structure

In this chapter, the hierarchical safety control structure for oral chemo at Dana-Farber is developed. It was built iteratively with assistance from numerous subject matter experts. The following information derives from interviews with Dana-Farber members as well as close collaboration with other healthcare professionals.

Getting multiple perspectives was fundamental, especially as each profession has a different perspective on the whole system based on the groups they interact with. Through numerous iterations, the control structure became increasingly aligned with the experiences of the individuals within the oral chemotherapy system.

4.1 Control Structure Legend

The control structures in this chapter use the following color key

![Group](image1) ![Individual](image2) ![Patient](image3)

*Figure 7 – Control Structure Legend*
4.2 Basic Structure

To build the hierarchical safety control structure from STAMP, the first step is to understand the basic components of the system. In Dana-Farber’s oral chemotherapy healthcare system, there are five high-level components that make up the patient safety structure: recipients, providers, consultation, pharmacy, and the hospital administration.\(^{15}\)

![Figure 8 - Basic Control Structure](image-url)

At the base of this control structure, the recipients of care connect to the pharmacy and providers in all oral chemo cases. In more complex cases, the recipients may also need to provide information to other physicians as visualized by the consultation element. In this context, consultation is simply a collective term for any other specialties or advisory groups that the primary oncologist may call on if necessary.

\(^{15}\) There are a number of other components not included here but which still affect patient safety – for example, financial services, insurance, regulatory oversight, and the Electronic Health Records system. Please see Chapter 5 for further elaboration.
Within the healthcare system itself, providers are the central element responsible for the patient. Providers send treatment information and patient data throughout the system. The hospital administration sits further away from the patient but allocates resources and institutes policies. The pharmacy is in contact with the provider and receives prescriptions, which are then supplied to the patient.

With the basic structure built out, the control actions are added in. Note that this is not an exhaustive list of every function performed. The focus here is on patient safety. Groups may have other attendant responsibilities that are not shown. Nor does this control structure demonstrate internal functions, but rather what is passed to and received by other groups.

To the provider, the recipient of care provides their history, physical presentation, and symptoms. This information is also passed to any consultation the provider requests. The provider then renders care to the patient and supplies a treatment plan (or prescription) to the pharmacy.

*Figure 9 - Basic Structure with Control Actions*
The hospital administration receives general information about the patients being treated and produces guidelines and policies for the overall organization.

4.3 Expanding the Safety Control Structure

Each component in the basic control structure hides greater complexity under its surface. Therefore, the high-level control structure can be broken out to reveal some of the greater complexities within the chemotherapy system.

4.3.1 Recipient of Care

Starting with the perspective of the recipient, the view looks as follows:

![Diagram of Recipient's View]

*Figure 10 – Recipient's View*

The recipient element contains two internal components, the patient and their personal caregiver.\(^{16}\)

\(^{16}\) The broader family support structure and personal network is important for care but is not distinguished from the personal caregiver. Please see chapter 5 for further explanation.
As noted in the Chapter 3 patient interview, this relationship is complex and varied. Sometimes the caregiver dominates the care the patient receives. This is especially true in the case of a minor patient. Other times, the caregiver may have only a slight influence on the patient or may not exist altogether. To capture this dynamic, there are connections attaching to the recipient element as an aggregate. These connections can be performed by either party, depending on the particular circumstance. Other connections reach into the recipient element and directly connect to the patient, as only the patient can provide these.

The actions and feedback the recipients perform on one another are as follows. The patient communicates needs to the personal caregiver and receives support as well as help with drug compliance. The incentives the patient provides could be implicit (in the case of a family connection) or financial (in the case of a hired professional).
4.3.2 Provider of Care

The provider of care is a critical component that can be disaggregated, just like the recipient. In the oral chemotherapy system, the two main components under the provider designation are: the Oncologist and the Nurse Practitioner. The oncologist and nurse practitioner work closely together to care for the patient. Some of the provider functions can be conducted by either oncologist or nurse practitioner, so these are attached to the provider component as a whole. Other actions must come specifically from the oncologist, such as the treatment plan and prescriptions. Another key responsibility of the oncologist is deciding whether or not the patient is a good candidate for oral chemo at all. If the patient will have serious issues in complying with treatment, IV chemo or some other treatment may be a better fit.

Between the two, if the nurse practitioner encounters a patient issue that the physician is unaware of, they will then escalate the information.

![Figure 13 - Provider Disaggregated](image-url)
4.3.3 Program Nurses

The next important group to add is the Program Nurses. They are a critical point of contact for the recipients, conducting many tasks that would be impractical for the provider. Patients call the program nurses with any concerns they may have and the nurses call the patients with follow-ups and information.¹⁷

Figure 14 - Program Nurses Added

4.3.4 Pharmacy

The Pharmacy component was not broken out and disaggregated in this analysis. It would have been possible to show the relationships between the clinical pharmacists, staff pharmacists, benefits coordinators, resource specialists, and the technicians. But that would complicate the control structure, as clinical pharmacists would partially share the role of the ancillary specialists, without significant increase in clarity.

¹⁷ Not shown are the call center and physician's receptionists. These groups often intercept patient calls first which are then triaged to either the program nurses or provider.
4.3.5 Consultation

Consultation is an informal label for a wide range of functions. With complex cases, the oncologist may request additional specialists to examine the patient. When the primary oncologist has a particularly complex case, he or she may wish to confer with colleagues and request input from other subspecialists. These ancillary specialists can typically include Geneticists, Pathologists, Pharmacists, and Radiologists. Also at Dana-Farber, there is the Tumor Board, which reviews challenging cases and provides recommendations to the oncologist to take under consideration.

*Figure 15 – Consultation Disaggregated*
4.3.6 Administration

The administration component is an aggregate of numerous roles and responsibilities. The administration leadership itself sets the priorities and policies for the Institute. The Quality and Patient Safety department receives information from the pharmacy and providers. In turn, these groups provide reports to various Institute committees. These committees include groups such as the Executive Patient Safety Oversight and the Quality Improvement and Risk Management (QIRM) groups. They decide on recommendations for how the Institute should set its policies and priorities in the future.

![Management Diagram]

*Figure 16 – Management Disaggregated*
4.4 Complete Safety Control Structure

The following is the full safety control structure of the Dana-Farber oral chemotherapy program. It contains all the connections detailed in the preceding sections.

![Diagram of the complete safety control structure](image-url)
Chapter 5: Conclusions

5.1 Overview

The primary outcome of the research presented here is the hierarchical safety control structure. The subject of the control structure is Dana-Farber's Oral Chemotherapy and Anti-Cancer treatment program, with a focus on patient safety. This result is shown in Figure 17.

Individuals within the system have extensive training and a deep understanding of their responsibilities but a view of the overall system is less common. The holistic view opens the door to a comprehensive systematic analysis, where gaps can be proactively identified. As medicine continues to advance, proactive analyses will become increasingly necessary as evolving systems will continue to create new vulnerabilities.

5.2 Missing Feedback

As described in Chapter 2, one benefit of using STAMP that the control loops and their feedbacks can be examined for deficiencies. The control structure can provide new insights for where to direct future improvement efforts.

When the interviewees had the control structure shown and described to them, incorrectness in presented structure became immediately obvious to these experts. This allowed for numerous refinements and improvements in the final control structure over the course of the research. More importantly, much of it conformed strongly with their experience despite having not seeing the system through this particular lens before. A strong positive as it demonstrates that many of the systems are working with the proper feedbacks according to STAMP. However, some insufficiencies in the system (as it stands) also became much more obvious to the individuals as well. This is how the control structure can become a tool to have the correct conversations about what to modify. As one physician interviewed said about the control structure, "I like this setup, it shows the relationships in an interesting way, normally I just think about the various groups I interact with regularly and not really the other groups the patient interacts with."
One such important item is the treatment plan created by the physician. The oncologist will always have a treatment plan for their patient decided on before progressing with treatment actions. However, it is not a requirement to have the treatment plan entered into the EHR. It is possible for a physician to write an oral chemotherapeutic prescription without a formal treatment plan. This can complicate the process as a prescription does not trigger decision support in the same way that a treatment plan does.

The treatment plan provides a nexus of potential improvements as different oncologists may handle it differently. A very similar issue, is around updates to the treatment plan. An oncologist may change and adapt the treatment as they become aware of the patient’s response to the treatment. However, they may not properly update the treatment plan in the EHR so all team members are aware of the dose change. For example, the pharmacy could continue sending the patient a larger amount of pills even after the oncologist told the patient to reduce their dose. These changes are often verbal discussions with the patient and are not always explicitly tracked. This potential source of patient confusion was highlighted through the creation of the control structure.

This leads to further improvements, which could be enabled through advanced oncologist-pharmacist feedbacks. For example, if the treatment plan changes and the pharmacy is updated, the pharmacy could connect that with when the patient requests a refill. In the case the oncologist reduces the dose due to side effects, the pharmacy should see a corresponding increase of time between refills. In the case of increasing the does due to lack of response, the pharmacy should see a corresponding decrease of time for the refill. Anything else would be an indication that the patient has not properly adjusted the dose according to the oncologist directed treatment plan update.

A related effect is seen by the program nurses. As the first line of defense for patient questions, having accurate information to communicate to the patient is crucial, especially in the case of complex dosing and dosing changes. Without a formal in-system treatment plan and treatment plan update, these nurses will have a more difficult time providing the most up to date information to the patient and any personal caregiver. Coordination throughout the different groups becomes more challenging.
Another insight is adverse events, who reports it and how it is reported. In examining the control structure with subject matter experts, it became immediately obvious to them that the management receives much more data on each patient from the pharmacy than they do from the oncologists. The oncologists do provide extensive documentation on each patient but it is not as organized by adverse events and critical patient safety information as the pharmacy reports are. Therefore, any issue that does not rise to the level of a safety event may not get the same visibility.

The management could potentially be missing some key insights if the patient information they record from the physicians during treatment (after initial teaching by the pharmacists) does not have as much clarity from the oncologist perspective. All the data may be there, but if it is difficult to access the relevant information to decide the policies, the policies may not be completely optimal.

Other problem hotspots are recipients of care not adequately updating their provider about their status and response to treatment and the personal caregiver’s coordination and assistance for medication compliance. The program nurses perform any check-ins with the patients, ensure continued compliance, and that issues are not going unreported. But the patients and caregivers can easily be overwhelmed with information, especially in the early stages of care. Using STAMP, this is a very visible interaction. Currently, these check-ins and follow-ups are managed through email and sometimes a shared inbox. This works much of the time but there are not controls built into the system ensure that every case is handled to the fullest extent and no call is missed.
An updated safety control structure will reveal these links where future improvement efforts can be directed:

Figure 18 – Safety Control Structure with control actions highlighted for future improvements
5.3 Future Work

5.3.1 Developing Requirements for a Safe System

Systems-Theoretic Process Analysis (STPA) is an analysis method based on STAMP. With STPA, a control structure is analyzed in a systematic and thorough manner. Each component and control action is examined for its contribution to overall patient safety. STPA also looks into the context in which individuals are making their decisions. (Leveson, 2011)

An STPA would identify requirements needed to avoid preventable harm to the patient. Further analysis would then compare these requirements to the oral chemotherapy system as it stands, revealing any existing gaps.

5.3.2 Expanding the Control Structure

When creating this control structure, many choices were made about which components to include and which to omit. As it currently exists, there is a great deal of material to conduct an STPA and make recommendations.

Once that analysis complete, it is possible to expand the control structure to capture even more aspects than currently shown.

5.3.2.1 IV Chemotherapy and Other Oncology Domains

This research focused on patients in the oral chemotherapy treatment track. However, not all patients are suitable for oral chemotherapy and may be treated in other ways. Even oral chemo patients can receive additional treatments. Capturing these other structures and decision points could be meaningful for patient safety.
5.3.2.2 Pharmacy

The pharmacy is a component represented in the control structure. Unlike some of the other components, it was not disaggregated despite containing individuals performing rather different functions. It was not readily apparent which interactions and handoffs internal to the pharmacy were as critical to patient safety as its externally facing functions. This component is a good target for future expansion.

5.3.2.3 Financial Services and Insurance

With a possible expansion of the pharmacy’s subcomponents, healthcare payers could be a natural addition as well. The patient being covered for treatment and able to navigate the financial paperwork for chemotherapy is a very important dynamic. Patient finances are tightly coupled with overall wellbeing and are likely the second most significant issue many patients face while undergoing chemotherapy. Nonetheless, this analysis was focused more specifically on patient safety and preventable harm as the most significant hazard.

5.3.2.4 Electronic Health Records (EHR) system

The EHR is an especially important component of communication in the healthcare environment. Some of the connections shown in the control structure are conducted using the EHR system. However, it was not included here as the specific methods of communication are not necessary at this point to conduct a preliminary STPA.

5.3.2.5 Receptionists and Call Center

Patients will call their physician’s receptionist or the call center with any issues or questions they may have. The call will then be routed to a nurse or physician. This interaction has potential to affect patient safety, but a call center’s accurate triage is a different issue than oral chemotherapy safety and is not as central to the patient as the groups shown.
5.3.2.6 Broader Social Support Network

Patient success can be significantly impacted by a robust social and family support network, or the lack thereof. This analysis aggregates all of those relationships under the personal caregiver. It is possible that more detail is required here. Further analysis is needed to determine if the single caregiver component can sufficiently capture these relationships. With widely varying personal situations, a generalized form will likely not capture every possible dynamic but it can still provide a useful starting point for analysis.
References


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