System Safety Engineering for Social and Ethical ML Risks: A Case Study

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Abstract

Governments, industry, and academia have undertaken efforts to identify and mitigate harms in ML-driven systems, with a particular focus on social and ethical risks of ML components in complex sociotechnical systems. However, existing approaches are largely disjointed, ad-hoc and of unknown effectiveness. Systems safety engineering is a well established discipline with a track record of identifying and managing risks in many complex sociotechnical domains. We adopt the natural hypothesis that tools from this domain could serve to enhance risk analyses of ML in its context of use. To test this hypothesis, we apply a "best of breed" systems safety analysis, Systems Theoretic Process Analysis (STPA), to a specific high-consequence system with an important ML-driven component, namely the Prescription Drug Monitoring Programs (PDMPs) operated by many US States, several of which rely on an ML-derived risk score. We focus in particular on how this analysis can extend to identifying social and ethical risks and developing concrete design-level controls to mitigate them.

1 Introduction

A large and growing community of researchers, practitioners, and policymakers is concerned with the social and ethical risks that attend machine learning (ML) systems. These problems extend beyond the *alignment* of the technology itself to the embodied and contextual use of ML-driven tools in entire sociotechnical systems. Systems safety engineering provides tools, techniques, and procedures that have been studied carefully in context for their ability to identify and control risks in complex sociotechnical systems [1, 2]. Although it has previously been suggested that such frameworks can perform similarly for ML systems safety risks, including social and ethical risks [3, 4], the concrete use of these techniques has not yet been validated. Nor is it known to what extent tools for managing risk in complex sociotechnical systems can be adapted to identifying social and ethical risks in particular. To test the hypothesis that systems safety engineering provides tools for assessing and mitigating social and ethical risk, we apply Leveson's System Theoretic Process Analysis (STPA)

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to a representative ML system, giving special attention to socially and ethically problematic system outcomes operationalized as safety hazards. As a case analysis, we apply STPA to a notional data-derived risk score as it would be used in the administration of the Prescription Drug Monitoring Program (PDMP) in many states. By analyzing the concrete application of STPA in a realistic ML case study, we can determine if STPA can effectively and repeatably identify and provide a path to eliminate or mitigate social and ethical risks that may result from a system.

The state of the art in ML evaluation generally relies on ad-hoc review of chosen metrics such as AUC, metrics derived from confusion matrices, or – for social and ethical risks – so-called “fairness metrics”. Metric-based evaluation is a fundamentally narrow view of model performance, especially for social and ethical risks: it frequently fails to address wider critical equities at stake [5, 6]. Fairness metrics, while a common proxy for identifying social and ethical concerns, are widely acknowledged to be imperfect operationalizations of underlying human values [7]. Additionally, it can be particularly difficult to assign responsibility for social and ethical risks in ML systems or to determine appropriate interventions to mitigate problems even once discovered [8, 4, 9, 10].

In response, several efforts aim to create concrete evaluation frameworks designed to identify harms, especially social and ethical risks, and propose mitigation. For example, the US NIST’s draft AI Risk Management Framework process [11] and the pending “AI Act” legislation in the European Union both categorize the management of social and ethical risks in ML systems as a risk management problem and envisage solutions in standardized evaluation frameworks. But even so systematized, assessments of social and ethical risks will remain ad-hoc – these frameworks are based only on best consensus expert judgement. Instead, effective risk governance must be based in experience, scientific evaluation, and process validation. Practitioners and academics alike recognize the need for valid evaluation practices and welcome standardized frameworks [12, 13, 14, 15].

A strength of system safety engineering frameworks is that they connect abstract safety policies, which are difficult to make actionable through technical means alone, to implementable requirements. Tools from this domain further have the advantage of being regularly applied in high consequence domains, well studied, and providing a strong basis on which to systematize efforts to identify social and ethical risks [16, 17]. Such tools include traditional safety-through-reliability techniques like fault-tree analysis (FTA) [18] and Failure Mode and Effects Analysis (FMEA), quantification-oriented approaches used for decades to reduce the number of failures in systems under analysis [19]. By contrast, Leveson’s Systems Theoretic Accident Model and Process (STAMP) [2] explicitly rejects the notion that reducing failures improves safety, noting that safety is a property of systems not components. STAMP instead models hazardous states that could lead to defined losses as insufficient control within an entire sociotechnical system.

Recognizing and responding to the social and ethical risks of an ML model requires viewing that tool in its context of use, as part of a broader sociotechnical system [20]. We therefore borrow from STAMP its hazard analysis technique, Systems-Theoretic Process Analysis (STPA). STPA has a successful track record in high consequence domains [1, 21]. By considering the full sociotechnical system, STPA contextualizes ML hazards with respect to social and ethical risks that result from component interactions and environmental factors in addition to component behaviors. Specifically, we apply STPA to a realistic notional case where social and ethical risks from ML have already been identified: several US state Prescription Drug Management Programs (PDMPs) use an ML-based risk score in their workflow. Our analysis seeks to answer several questions about STPA: Can STPA recover causal paths to social and ethical harms effectively? Does it suggest effective design interventions to avoid those unsafe system behaviors? What portions of the STPA process readily apply to social and ethical impact analysis and mitigation for ML systems? What aspects apply with only minor adjustments? What gaps still remain? Finally, we propose some adaptations or interpretations of STPA to bridge those identified gaps–towards a proven, systematic approach to advancing social and ethical impact analysis for complex ML-enabled sociotechnical systems.

2 Case Study: A Systems-Theoretic Process Analysis of PDMP Scoring

STPA is a top-down system safety analysis tool, part of a family of techniques belonging to Leveson’s Systems Theoretic Accident Model and Process (STAMP) paradigm [2, 22, 1]. At a high level, STPA analysis requires four steps (for more detail about the STPA technique, see Appendix A): 1) Defining the purpose of the analysis, including defining losses and hazards for the system of interest (SoI);

2) Modeling the full sociotechnical control structure for the system; and 3) Identifying unsafe control actions (UCAs) within each control loop which can cause a loss; and 4) Identifying causal loss scenarios for each UCA.

ML-based risk scores are widely used in Prescription Drug Monitoring Programs (PDMPs) throughout the United States.[1] For more detailed information on our subject ML system, refer to Appendix F. We examine this system using STPA to better understand how social and ethical harms arise from the ML components and to identify design constraints and corrective controls to mitigate them.

In step one of the STPA, the team defined the purpose of our analysis as to identify and where possible, eliminate sociotechnical harms whether manifested as various forms of inequity between social groups, such as representational, allocative, quality of service, interpersonal or societal harms [24], or more narrowly manifested as traditional safety harms such as loss of life, injury, and loss of quality of life to individuals. For more detail on the harms taxonomy we adopt for our analysis, see Appendix G. This part of the process serves to align the resulting system with desired societal values [25]. We identified our primary stakeholders as patients, followed by doctors and pharmacists. Our initial list of losses was built from the harms stated above and included approximately 30 losses (Appendix D.1), which we consolidated and further grouped into a set of five distilled losses (Appendix D.2 for the grouping). We found the PDMP risk score losses were best grouped thus: 1) Death, Injury or Disability, 2) Disparity of Benefits or Harms, 3) Social or Economic Injury, 4) Damage to Quality of Healthcare, 5) Coerced Criminality or Unsafe Treatment.

From these losses a set of 10 system-specific hazards were identified, see table 1 in Appendix D.3. For step two, the team continued to comb through documentation and research on PDMP risk score ML models, seeking to develop a useful control structure for analysis. Early on, we acknowledged a need to address both the operational control structure *context* of the ML system as well as solve how and to what level of abstraction the ML life-cycle should be modeled within the control structure. This was an iterative process and settled on the structures found in Appendix B, figure 1 for the operational context and figure 2 for the treatment of the ML life-cycle. The usefulness of this interpretation will be discussed further in section 2.2. Step two also required defining each controller and controlled process' function, the associated control actions and feedback as depicted in figures 1b and 3.[2]

For STPA step three, the team used the control structure and potential hazards to identify control actions whose misapplication can lead to a hazard. These are unsafe control actions (UCAs), and for each control loop, we considered the four standard misapplications of control: 1) Not providing control causes hazard; 2) providing control causes hazard; 3) control is too early, too late, or out of order; 4) incorrect control duration (too long, too short). This yielded the control action tables found in Appendix E. We found that when applying the four standard control misapplications to the ML development cycle control loop, whereas the temporal question (i.e., too early, too late, wrong order) was not useful, it was useful to alter the duration misapplication (too long, too short) to instead refer to concepts of quantity, i.e., too many/much, too few/little. Finally, with the UCAs outlined, the causal scenarios logically follow, manifesting system losses. The result is that logical requirements for sociotechnical system design modifications to eliminate or mitigate the risks of the identified hazards become far easier to motivate, reason about and outline.

2.1 PDMP Findings

This analysis resulted in an informative contextualized control structure for a PDMP risk score algorithm and its surrounding sociotechnical system. It identified 30 specific initial losses (Appendix D.1) which were grouped and pared down to five loss types (Appendix D.2). The analysis was scoped to the two most interesting of the seven primary control loops identified and modeled, namely *Patient Care*, figure 1b and *Data Decisions*, figure 3. Analysis provided a combined 13 unsafe control actions as shown in tables 2 and 3 to inform and motivate actionable sociotechnical system requirements to eliminate or mitigate the identified harms in the system going forward.

[1] The authors performed an informal search of state public health websites and official news releases and could confirm 27 of 51 states and D.C. use an ML based scoring system as a major component of their PDMP. Additionally, five of the top seven U.S. pharmacy businesses (by 2021 prescription revenue) [23], likewise require their pharmacists to use an ML-based PDMP scoring system in their workflow. Many of these entities use the same scoring tool provided by a third-party vendor.

[2] Referenced descriptions within the control structure are treated in more detail in Appendix B.1

Many calls for action to adopt PDMP risk scores were motivated by the U.S. opioid epidemic, the tragic and increasing loss of life fueled by opioid overdoses every year. One early discovery that quickly became apparent in the STPA analysis was that, though often motivated by the desire to save lives and prevent opioid overdoses and Opioid Use Disorder (OUD), the objective function of this ML model is aimed at minimizing drug *diversion* instead, defined by the US Department of Health and Human Services as "the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber." The underlying premise is that reducing drug diversion will save lives. However, considering the hazards, control loops, and UCAs we identified in our short analysis of this system, it is rationally defensible to hold that the opposite could be true[3]. The control loops show possible mechanisms whereby actions taken by prescribers and dispensers to ostensibly protect an individual, or act in their business's best interest based on the patient's score, instead may result in more desperate and dangerous behavior by the patient as effective treatment is sought but may not be provided. This overall issue highlights a frequent problem in ML systems where the objective function may not be suitably matched to the system goal [27], here immediately raised as a possible issue in the first steps of the analysis and further questioned as the STPA is carried out.

2.2 ML Life Cycle: Data Decision Phase Example

One challenge of applying STPA to machine learning that was identified early was how to best apply control structure and follow-on analysis to the development life-cycle of ML systems. The team made progress on this challenge, coming to the conclusion that the various phases of the life-cycle should be abstracted as individual control loops with the *phase* modeled as the *controlled process* and the *development team* modeled as the *controller* (figs 2 and 3). Our effort shows this to be a promising way forward having resulted in control actions, meaningful validation questions and requirements with respect to the social and ethical impact framing. With respect to PDMP risk scores, table 3 shows our results in finding unsafe control actions in the data decision phase alone that can lead to social and ethical losses. This is an ongoing investigation with new insights, developments and applications forthcoming.

3 Discussion

Conducting an STPA for social and ethical impact forces development teams and other stakeholders to do the necessary work to fully consider the larger system context that a product or component will inhabit, the larger sociotechnical system. As stated before, recent history shows that frequently, teams are hyper focused on the SoI they are developing and thus miss the bigger picture, the larger purpose and direction. The STPA process cultivates a rich appreciation for the sociotechnical system a new system or product is entering, and provides an effective abstraction with which to reason about these harms, as well as the instruments, tools, and methods (both social and technical) that we can bring to bear to eliminate or mitigate them.

Another important contribution of STPA is the mandate to consider carefully the overall goal of the system (step 1) and in our treatment, verify that the objective function that is adopted does not itself lead to the social and ethical losses the STPA identifies. For example, applying STPA to the health benefits scoring system system studied by Obermeyer [27] could reveal the need for a check for racial and socio-economic disparities resulting from an objective function mismatch early in development and could have enabled a shift to a more appropriate governing optimization.

Finding a way to abstract and model STPA in the ML life-cycle was a challenging aspect of applying STPA to S&E impact in ML systems. One benefit of the ML life-cycle treatment the team developed (see section 2.2 and figures 2 and 3) is that it breaks the STPA modeling into manageable pieces where each phase or stage has a reasonable number of control actions which can be decomposed into measurable and verifiable considerations and checks.

A particular nuance of a thorough social and ethical impact STPA should also consider whether the resulting product algorithm could be used by the funding or owning company (or sold as a service to another) in a manner not overtly intended in the stated purpose of the system but (regardless of

[3] A possibility at least not refuted by nationwide statistics showing a marked reduction in drug diversion and opioid prescribing coinciding with the adoption of PDMPs in every state, mandated risk score use in over half, and an overall overdose death rate that is nevertheless increasing [26]

legality) presents a potential negative social or ethical impact on society. Part of these analyses should also be to consider these types of uses or outputs to other interests and suggest mitigations or scope statements that warn of these potential issues and the need for separate STPA analysis for those uses.

In the case study system, a number of the controllers or controlled processes involved humans who are free agents, such as doctors, pharmacists and their staffs. Considering Goodhart's law "...when a measure becomes a target, it ceases to be a good measure," it is to be expected that an entity modeled as a controlled process may alter their behavior or feedback paths to exert influence on the modeled controller. One potential approach would be to also examine these relationships in the opposite direction and ask the same control, hazards, and scenario questions. This practice can reveal potential for, in the case of PDMP score systems, such behaviors as abandonment by doctors and service refusal by pharmacists, and the attendant losses which may result. Identification of these types of potential behaviors only serve to expand the analytical potential for discovering hazards and thus identifying controls to prevent those hazards.

One final benefit of the STPA process is that it necessarily provides a traceable path from every derived requirement to its causal scenarios, contributing unsafe control actions, control loops of origin and orginating hazards and losses. This property enables the complete retracing of the logic and reasoning behind every decision in design and operations.

3.1 Conclusion

In this paper we record the results of a two week sprint where we applied STPA, a traditional system safety engineering analysis methodology to the challenge of assessing the social and ethical impact of a machine learning system, a Prescription Drug Monitoring Program risk score. We found that STPA's rigorous approach when coupled with a thorough harms taxonomy produced a trove of hazards and unsafe control actions against which new system requirements for sociotechnical control mechanisms could subsequently be applied to prevent social and ethical losses. Additionally, we adapted a useful abstraction of the machine learning life cycle for STPA which recovered potential unsafe control actions in a manner similar to those captured by their analogous operational control loops. Future work will examine the applicability and generalizability of STPA for social and ethical impact by investigating case studies across different applications of ML systems. In so doing we seek to introduce a tool to provide an organized, proven systematic approach to social and ethical analysis for complex ML-enabled sociotechnical systems.

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A System Theoretic Process Analysis (STPA)

STPA is a top-down system safety analysis tool, part of a family of techniques belonging to Leveson's Systems Theoretic Accident Model and Process (STAMP) paradigm [2]. STPA is a proven and systematic hazard analysis process that frames accidents not in terms of component failures but instead as a control structure which prevents the subject system from entering hazardous states which could lead to unacceptable losses. Typically, losses are defined by key stakeholders such as system owners or operators and often include: death, injury, damage to property, financial loss, or loss of mission. Hazards are typically described as a system state that when coupled with a specific set of worst-case conditions results in a loss(es). In STPA, hazards and their resulting losses follow from inadequate system control, i.e., unsafe control actions (UCA)s. [2].

Notably, STPA expands on the scope of traditional reliability-driven safety analysis to include unforeseen behavioral interactions across the entire sociotechnical system. For example, STPA analysis includes consideration of human-machine interfaces, supporting governance hierarchies, and even organizational culture. Rejecting the idea of a "root-cause", STPA proceeds from the thinking that accidents are, as Perrow puts it, "normal behaviors" of complex systems. Far from unlikely, accidents are inevitable emergent system behaviors, arising from system structure and function that must be identified and subsequently controlled [28, 2].

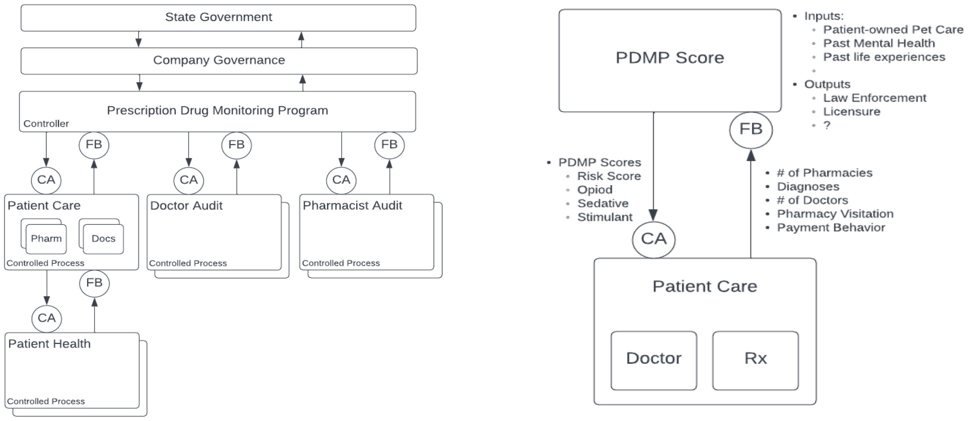
A.1 STPA Process

Applying STPA consists of the following core steps which are intended to be applied while studying the system of interest across the system's lifecycle. The STPA process should be repeated at higher levels of detail until the purpose of the analysis can be satisfactorily addressed.

1. Define the purpose of the analysis: Identify stakeholders, define what constitutes a loss and surface system-specific hazards to be eliminated or mitigated to prevent losses from occuring.
2. Model the full sociotechnical control structure for the system. This involves mapping the feedback control loops of the sociotechnical system to the level of abstraction necessary to meaningfully reason about them.
3. Considering the control structure and potential hazards, identify unsafe control actions (UCAs) for each control loop, (i.e., what controller action, inaction, or misapplied action (too early, too late), or applied for the wrong duration, etc. - can go wrong and cause a loss?)
4. Identify and consider potential loss scenarios (i.e. causal scenarios) for each UCA. A tangible benefit of this final step is the development of a set of requirements that need to be enforced to ensure a safe sociotechnical system results, these may include but are not limited to new design decisions, requirements, procedures, operator training, test cases or even periodic audits [22].

B Control Structure

Figure 1a situates our identified operational control loops for the PDMP scoring algorithm within the health system. Figure 1b shows more detail for the particular Patient Care control loop for the PDMP score. Figures 2a, 2 and 3 show the machine learning lifecycle, how this study proposes to model that cycle as a set of control loops and the specific control loop addressing the Problem Conception and Data Decisions portions of the cycle, respectively.



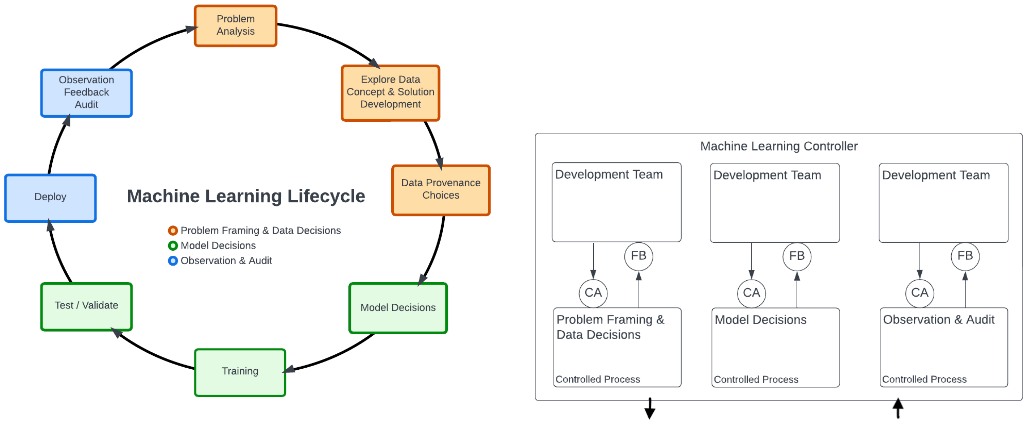
(a) High Level Control Structure

(b) Patient Care Control Loop

Figure 1: PDMP Score Control Structure and Inset Patient Care Loop

B.1 Control Loop Component Descriptions

PDMP Score Algorithm: Feedback and Control Actions *Patient* - Given patient data, provide risk score for propensity for opioid abuse, overdose, diversion to inform healthcare clinical decisions regarding treatment and prescriptions.



(a) ML Life-Cycle

(b) PDMP Cycle: Control Structure

Figure 2: Modeling Life-Cycle Control

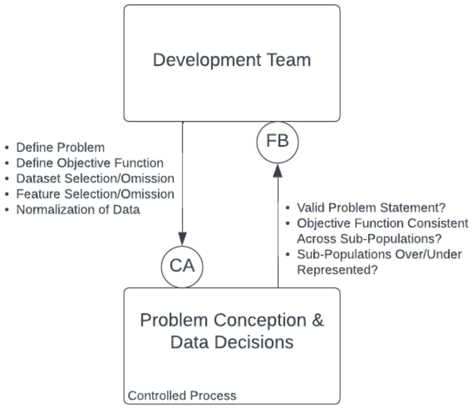

Development Team
• Define Problem
• Define Objective Function
• Dataset Selection/Omission
• Feature Selection/Omission
• Normalization of Data
FB
• Valid Problem Statement?
• Objective Function Consistent Across Sub-Populations?
• Sub-Populations Over/Under Represented?
CA
Problem Conception & Data Decisions
Controlled Process

Figure 3: Data Decisions

- *PDMP CA*: Individual risk score and component scores for narcotics, stimulants and benzodiazepines.
- *Data Feedback*: prescriptions, diagnoses, medical history, doctor selection, pharmacy selection, arrest history, prescription payment behavior, pet prescriptions, ?

Doctor - Track milligram morphine equivalents (MME)s prescribed per patient and other stats in order to flag ’aberrant’ behavior associated with risk for enabling or participating in drug diversion–deliver letters warning practitioners when thresholds crossed and later flag to law enforcement if and when mandated by state law.

- *PDMP CA*: Average PDMP risk score of Patients, average MME prescribed, stats as defined by state and DEA tracking.
- *Doctor Feedback*: prescriptions, retained patients, prescribing amounts compared to standards (not tailored to patient health)

Pharmacist - require consideration of score before filling prescription, consult prescribing doctor, reserve right to refuse patient prescription if deemed too risky.

- *PDMP CA*: avg PDMP risk score?. Average MMEs/ prescription? How are Pharmacists audited for their part in the system?
- *Pharm Feedback*: Prescriptions filled, workflow executed, reports.

Development Team: This team is responsible for executing the initial phases of the ML Lifecycle. Thus it defines the problem whose solution is sought, the conceptualization and initial decision making in forming a solution, from Operationalization of the unobservable theoretical construct to the data provenance decisions and model decisions. Requirements set. Why system is needed. Problem to solve.

C Team Composition and Study Limitations

Our analysis team is composed of five ML researchers, one sociologist, and one STPA subject matter expert. In addition to working with an experienced STPA expert, each member of the team worked to become thoroughly familiar with STPA by reading core STPA expositions – Leveson's *Engineering a Safer World* textbook [2], an associated *STPA Handbook* [22], and training videos from the group that developed the framework [29] – and studying the STPA evaluation literature. We did not have direct access to PDMP scoring systems or their datasets, however we were able to derive necessary details from from state-issued systems operating manuals, pharmacy work-flows, legal requirements, training documents as well as recent research involving the re-creation and testing of ML models based on the datasets and features stated by proprietors to be used and most "predictive of unintentional overdose death" [30, 31, 32, 33]. Given the top-down framing of the STPA approach, these documents proved sufficient to provide ample operating and development context to model control structures and for an effective exploration of STPA analysis for social and ethical impact.

D Losses and Hazards

In our initial analysis we identified over thirty potential social, ethical and safety losses that could result both from the PDMP score system proper or downstream and yet a result of the PDMP score system's interactions within the broader healthcare system, these are fully outlined in Appendix D.1. To simplify analysis going forward it was then necessary to reduce this loss list to five general categories as defined in Appendix D.2.

D.1 Initial Losses

1. Patient Death
2. Inequity between social groups
   (a) Allocative - Disparity in PDMP risk score can result in a disparity in:
      - Health Treatment: affecting subsequent opportunity as well if resulting treatment disparity is debilitating reducing ability to hold a job or care for children or adult dependents.
      - Job Opportunity: Is PDMP risk score specifically prohibited from being considered when seeking a drug-dispensing or other related health care job? Can the score or some subset be an input to other products such as background checking systems, credit or hiring algorithms?

   (b) Representational - A grouping with an inappropriately high score may have the effect of categorizing a patient inappropriately as more likely drug-seeking.

   (c) Quality of Service - More difficult interactions, extra intrusive questions, when interacting with Doctors, health staff and pharmacies.
      i. Alienation:
         - Turned away at Pharmacies: Resulting in adverse emotions, distrust and exclusion from the benefits offered others for health treatment.
         - Turned away as a new patient: same as above
         - Dismissed as a patient: same as above

      ii. Increased Labor: Above reasons in Alienation repeated here as all result in additional labor for the patient to overcome to get appropriate treatment.

        iii. Service or Benefit Loss: for same reasons in alienation, benefit of treatment is lost when it cannot be overcome or cost/effort required is too high to fight.

3. Patient has untreated pain - Physical, mental anguish, social damage,
    (a) Mental Health
    (b) Physical debilitation
    (c) Social Damage
    (d) Occupation Damage
    (e) Family Care Damage
4. Loss of Safe access to Treatment/Care (Abandonment):
5. Behavior Herding: Desperate, deeply affected individuals may be herded to get the care they need from illegal means, thereby increasing risk of incarceration, addiction, abuse and death as the illegal treatment has no protections from overdose or doctor and pharmacist oversight.
6. Loss of patient care (narcotic, benzodiazepines, stimulants; overall)
7. Degraded Quality of Life: Loss of ability to work, care for children, enjoy normal life, care for adult dependents.
8. Law enforcement action - See CA state review – "law enforcement surveillance and its attendant threat of criminal investigation and prosecution incentivize patient abandonment, forced taper, and involuntary medication discontinuation.
9. Reputation loss
10. Privacy Violations
11. Licensure (Doc/Pharm)
12. Increased Liability Insurance (Docs and Pharm)
    (a) Social Control
    (b) Financial
13. Loss of Autonomy, clinical judgment
14. Inequity with social groups (poor people may have higher scores given method of payment is a factor)
    (a) Sexual assault survivor
    (b) Prior arrest history
    (c) Age, socioeconomic, regional, race, gender, sexuality
15. Reduced accessibility to Doctors

D.2 Reduced Loss List

1. Death, Injury or Disability:
    - Patient Death
    - Untreated Medical Conditions (Pain)
    - Additional Physical or Mental Injury
2. Disparity of Benefit/Harm
    - Allocative Disparity
    - Representational Disparity
    - Quality of Service Disparity
3. Social/Economic Injury
    - Damage to Reputation
    - Occupational Damage
    - Family Damage
    - Privacy Violations
4. Damage to Quality of Healthcare
    - Abandonment

- Loss of Autonomy in Clinical Judgement
- Loss of Opportunity for Care, i.e., reduced accessibility to Doctors

5. Coerced Criminality or Unsafe Treatment
    - Herding to Unsafe/Illicit Behavior
    - Increase in Law Enforcement Scrutiny

D.3 PDMP Score Hazards

This table lists all of the identified PDMP Scoring system hazards cross-referenced with the potential losses which may result from those hazards.

PDMP Risk Score Hazards						
	Hazards	L1	L2	L3	L4	L5
1	Over-prescribe	X			X	
2	Under-prescribe	X		X	X	
3A	Inappropriately Scored - High	X		X	X	X
3B	Inappropriately Scored - Low	X			X	
4	Score Leaked	X	X	X	X	X
5	Problematic/Biased Data		X		X	
6	Abandonment	X		X	X	X
7	Not provided most effective treatment.	X		X	X	X
8	Patient gives up on medical system.	X		X		X
9	Excessive false positives.	X	X	X	X	
10	Excessive false negatives.	X			X	

Table 1: PDMP Risk Score System Hazards

E PDMP Score Unsafe Control Actions

UCAs: Patient Care Control Loop					
Control Action	Not Provided	Provided	TE TL	Too Low	Too High
Risk Score	Score defaults to zero. Hazard if patient susceptible to addiction - H1	H6, H7, H8	N/A	H1, H3, H10	H2, H3A, H6, H7, H8, H9

Table 2: Patient Care: Unsafe Control Actions

UCAs: Problem Conception and Data Decision Control Loop					
Control Action	Not Prov	Provided	TE TL	Too Few/Little	Too Many/Much
Define Problem	N/A	H5, H3	N/A	N/A	N/A
Define Obj. Function	N/A	H1-3, H5-10	N/A	N/A	N/A
Dataset Selection or Omission	N/A	H1-3, H5-10	N/A	N/A	N/A
Feature Selection or Omission	N/A	H1-3, H5-10	N/A	H1-3,H6-10	H1-3,H6-10
Data Normalization	N/A	H3, H5, H9, H10	N/A	H3, H5, H9, H10	H3, H5, H9, H10

Table 3: Problem Conception and Data Decisions

F Subject ML System: Prescription Drug Monitoring Program (PDMP) Score

Prescription Drug Monitoring Programs are mandated in all 50 states and are intended to prevent or curtail widespread healthcare issues such as drug addiction, misuse and overdose deaths [34]. A majority of these programs employ a risk scoring system as a clinical tool, requiring physicians, pharmacists and their staffs to review a patient's risk scores prior to writing or filling prescriptions for certain schedules of drugs [35, 31]. These risk scores are calculated by machine learning systems trained on a variety of data sources [32, 36]. Thus, these ML-based PDMP tools assist in governing the health care of hundreds of millions of people across the United States. In systems like this one, which affect large numbers of people in highly consequential ways, impacting life, health and livelihood, it is incumbent on developers, company management and government officials to demonstrate due diligence by showing evidence that an ML-enabled system not only improves the performance of the sociotechnical system which it is augmenting, but that it does not also introduce unacceptable negative social and ethical impacts down stream of the system [37, 38, 5, 39]. Often, this type of analysis is not done, is attempted ad-hoc, or is treated as if it were impossible due to its complexity [20].

G ML Harms

A steadily growing number of incidents and calls to action demonstrate the necessity to include social and ethical impact analysis as a key component of the ML system development life cycle [37, 40, 41, 42]. However, in order to enable such an assessment of social and ethical impacts, we must first begin with a firm understanding of the various harms that can result from sociotechnical algorithmic systems. Additionally, special attention must be given to the deployment environment as sociotechnical systems often have far reaching social and technological connections and impacts for humans which can result in losses, hazards, and negative outcomes for entities far removed from the system–in the case of PDMP scoring systems these will no doubt include patients, doctors, and pharmacists, but also patient families and the functionality of and trust in the health system at large.

This paper adopts Shelby *et al.*'s recent work which successfully taxonomized the myriad manifestations of algorithmic harms [24]. This taxonomy provides an initial yet robust foundation to proceed from, and we use it as a basis for developing our subject system's social and ethical losses and hazards, a key part of the first step of STPA.

H STPA for Social and Ethical Impact

Although researchers suggest existing safety frameworks can address concerns of social and ethical impact in ML [3, 43], it is not known whether they are effective. Moreover, studying social and ethical risks is particularly difficult because they are often substantially decoupled from the individual components which are typically the objects of analysis [10, 20]. Thus, this research investigates whether such frameworks, STPA in particular, cause the identification of the social and ethical risks to surface as a natural consequence of their process, and further if they likewise necessarily offer a valid path (assuming one exists) to sufficiently correct and control for the discovered hazardous states.

This research will perform STPA on a machine learning sociotechnical system to determine STPA's effectiveness in social and ethical impact analysis and correction. It accomplishes this by treating social and ethical harms as losses to determine if STPA recovers a useful set of hazard scenarios. Moreover, it is the focus of the case study to determine how effective STPA is at identifying corrective actions to prevent (or mitigate) the discovered negative social and ethical impacts of the ML system. As we continue our research we will take these steps and apply them to additional subject systems from other ML system domains, such as those leveraging large language models or machine vision classification systems. In so doing we hope to introduce a tool to provide an organized, proven systematic approach to improved social and ethical analysis for complex ML-enabled sociotechnical systems.