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Modeling Veterans Healthcare Administration Disclosure Processes

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Modeling Veterans Healthcare Administration Disclosure Processes: CY 2012 Summary

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Abstract

As with other large healthcare organizations, medical adverse events at the Department of Veterans Affairs (VA) facilities can expose patients to unforeseen negative risks. VHA leadership recognizes that properly handled disclosure of adverse events can minimize potential harm to patients and negative consequences for the effective functioning of the organization.

The work documented here seeks to help improve the disclosure process by situating it within the broader theoretical framework of issues management, and to identify opportunities for process improvement through modeling disclosure and reactions to disclosure. The computational model will allow a variety of disclosure actions to be tested across a range of incident scenarios.

Our conceptual model will be refined in collaboration with domain experts, especially by continuing to draw on insights from VA Study of the Communication of Adverse Large-Scale Events (SCALE) project researchers.

ACKNOWLEDGEMENTS

The Sandia National Laboratories team that conducted this analysis would like to thank the Veterans Health Administration (VHA) Office of Public Health and the Study of the Communication of Adverse Large-Scale Events (SCALE) research team (funded by VA Health Services Research and Development SDR 11-440, PI: Elwy) for ongoing support of the effort.

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NOMENCLATURE

CASoS	Complex Adaptive System-of-Systems
CIPRS	Center for Implementation Practice and Research Support
HSR&D	Health Services Research and Development
LSAEs	large-scale adverse events
OIG	Office of Inspector General
Sandia	Sandia National Laboratories
SCALE	The Study of the Communication of Adverse Large-Scale Events
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
UCLA	University of California Los Angeles
US	United States

PREFACE

The Office of Public Health, US Veterans Health Administration (VHA) is engaged in a collaborative research program with the Complex Adaptive System of Systems (CASoS) group at Sandia National Laboratories (Sandia). This program continues the long-standing research partnership between the institutions aimed at applying advanced modeling and simulation methods to large-scale emerging problems in public health and healthcare management. This second year of the current research program has focused on leveraging the modeling capability developed in the first year to address policy issues of current interest to VHA leadership. This document describes current status of research efforts as of December 15, 2012.

As with other large healthcare organizations, medical adverse events at the Department of Veterans Affairs (VA) facilities can expose patients to unforeseen negative risks. The VA strives to notify potentially affected individuals rapidly for screening and follow-up care. VHA leadership recognizes that properly handled disclosure of adverse events can minimize potential harm to patients and negative consequences for the effective functioning of the organization.

This task seeks to help improve the disclosure process by situating it within the broader theoretical framework of issues management, and to identify opportunities for process improvement through modeling disclosure and reactions to disclosure. The computational model will allow a variety of disclosure actions to be tested across a range of incident scenarios. Our initial focus this fiscal year was on reconnaissance and scoping. We collected and reviewed published information on past incidents (both Office of Inspector General [OIG] reports and media accounts) and VHA policies and procedures for managing disclosure. We also had a number of enlightening conversations with VA personnel, which were helpful in understanding the current practice and its perceived limitations. Our recent work has focused on two reinforcing efforts that we believe can help lead to an improved disclosure process:

First, framing the specific problem of disclosing adverse medical events in the more general theoretical context of issues management can connect the disclosure problem to analogs in other industries. These analogs can become a source of new cases and solutions to inform policy design.

Second, quantitative modeling of the process involved in the event creation-detection-disclosure-reaction cycle can identify the specific aspects that most strongly control outcome. These aspects can then become the targets of more detailed policy design, focused on achieving the performance requirements necessary for the desired systemic results.

We have developed a conceptual model, and look forward to refining it in collaboration with domain experts, especially by continuing to draw on insights from VA Study of the Communication of Adverse Large-Scale Events (SCALE) project researchers.

1 OVERVIEW

Many processes interact to determine the outcome of an adverse medical event in the Department of Veterans Affairs (VA) healthcare system and of any ensuing public disclosure. Such events and institutional reactions to them can spread from the patients and clinicians involved in the episode or practice to affect patients and practitioners broadly. Effects can spread further to parts of the population, such as non-patient veterans and the general public, whose opinions of VA medical services influence the ability of the system to serve patients effectively. Reactions to events and their disclosure can compound over time so that the response to a succeeding event is conditioned by the way prior events were managed. Events requiring disclosure are quite diverse, capable of creating a wide spectrum of system reactions.

Considering the complexity of process interaction and the diverse character of precipitating events, the formulation of a general policy for effectively managing disclosure is extremely challenging. Policy formulation can be informed by many kinds of analyses, including case studies of prior events, characterization of media coverage, and interviews and surveys of patients. The Veterans Health Administration (VHA) conducts many such investigations in pursuit of the most effective approaches to disclosure. The purpose of this project is to examine whether and how the distinctive analytical perspective of Sandia National Laboratories' (Sandia's) Complex Adaptive Systems of Systems (CASoS) Engineering group can contribute to this pursuit, and to make those contributions that are warranted.

We discuss two reinforcing efforts that we believe can help lead to an improved disclosure process. First, framing the specific adverse medical event in the more general theoretical context of issues management whereby disclosure problems can be connected to analogs in other industries. These analogs can become a new source of examples and solutions to inform policy design. Second, quantitative modeling of the process involved in the event creation/detection/disclosure/reaction cycle can identify the specific factors that most strongly control outcome. These factors can then become the targets of more detailed policy design, focused on achieving the performance requirements necessary to reach the desired systemic results.

The theoretical background on issues management is presented in Section 2 where the problem of disclosure is shown to be related to the more general class of institutional interface management challenges. An important general finding is that any system perturbation can potentially crystalize into an "issue" when there is a gap between an organization's behavior and its stakeholders' expectations. As such, effective issues management requires attention to both the precipitating event and public perception of its management.

Foundational data and information sources are outlined in Section 3. In Section 4 we describe our development of a preliminary model for the processes affecting disclosure. Model development begins with the definition of specific measures of performance against which alternative policies can be evaluated. Causal models are then proposed for the processes that influence those measures. With this framework alternative disclosure policies are represented in terms of parameters describing information flow, such as latency and accuracy. The final structure of the model, and the possible values for its parameters, will be established in collaboration with domain experts, especially drawing on insights from VA Study of the Communication of Adverse Large-Scale Events (SCALE) project researchers. Some preliminary simulation results are included for illustration. Proposed next steps are described in Section 5.

2 THEORETICAL FRAMING

Although implementation of standards and legal frameworks, in addition to the promulgation of best practices, has contributed to a consistently higher quality of care, efforts to promote transparency in the communication of medical errors to patients have not been sufficient to allay fears or meet expectations (Gallagher, 2007). Our review of VHA policies revealed many analogies between VHA's disclosure process and the challenges identified in issues management literature (also referred to as "strategic issues management"). Incorporating insights from multiple academic and practitioner disciplines, issues management provides a robust theoretical foundation for the development of new processes as well as a source of industry best practices.

The notion that "issues" can and should be managed can be traced back to the 1960s when it arose as a reaction to increasingly uncertain sociopolitical conditions. The term "issues management" emerged in the 1970s, and beginning in the 1990s, two defining characteristics of the modern practice of issues management materialized: (1) its prominence as a technique for both corporate and non-corporate entities (e.g., Dougall (2008) reminds us of Greenpeace's role in drafting the Kyoto protocol in 1997) and (2) its application proactively, rather than solely being employed as a defensive technique (Heath, 2009). Perhaps not surprisingly, there remain considerable differences in the way that scholars and practitioners define and implement issues management.

There is little consensus among academics or practitioners regarding what constitutes an "issue." Wartick and Mahon (1994) conducted an extensive review of relevant literature. They found the emphasis within definitions varies by discipline: in business strategy literature issues are defined by impact; in public policy literature issues are defined by controversy; and in business and society literature issues are defined by expectational gaps. The authors synthesized these characterizations and composed a comprehensive, albeit somewhat complex, definition (pg. 306):

> *(a) a controversial inconsistency based on one or more expectational gaps (b) involving management perceptions of changing legitimacy and other stakeholder perceptions of changing cost/benefit positions (c) that occur within or between views of what is and/or what ought to be corporate performance or stakeholder perceptions of corporate performance and (d) imply an actual or anticipated resolution that creates significant, identifiable present or future impact on the organization.*

Wartick and Mahon's findings are consistent with Heath and Palenchar's (2009) assertion that despite notional differences, many public affairs practitioners' and academics' definitions are founded in the belief that an "issue" is a gap in between an organization's behavior and its stakeholders' expectations (see also Palese & Crane, 2002).

In medical practice, the terms "adverse event" and "incident" are used similarly to the way "issue" is used in relevant management and public affairs literature (Levinson, 2012). In prior research related to healthcare disclosure, discrepancy between patients' expectations and clinicians' behavior also appears to be a central theme (e.g., Fein et al., 2007; O'Connor, Coates, Yardley, & Wu, 2010; Gallagher, Bell, Smith, Mello, & McDonald, 2009). Disclosure itself might constitute an issue when there is a discrepancy between what patients expect and what practitioners actually disclose (Fein et al., 2007).

Issues management can be most accurately understood as a process through which organizations detect, explore, and attempt to close the gap between their behavior and their stakeholders' expectations. This process varies by organization (see for example, Palese & Crane, 2002; Regester & Larkin, 2005; and Heath & Palenchar, 2009), but commonly includes identification of issues, analysis of issues, prioritization of issues, formulation of responses, implementation of responses, and evaluation, monitoring and control of results (Carroll & Buchholtz, 2008).

An essential element of the process, although sometimes not well articulated in the literature, is the importance of detecting changes in the environment which may crystalize into an issue (Dougall, 2008). It is helpful to think of an organization as a system in which any exogenous or endogenous perturbation can potentially crystalize into an issue. With this initiating potential in mind, we define issues management as the anticipatory, strategic management process through which organizations detect and respond appropriately to system perturbations. This definition builds on work by Heath and Palenchar (2009), Mahon and Waddock (1992), Palese and Crane (2002), and Carroll and Buchholtz (2008), among others, wherein issues management is identified as an inherently strategic function.

Issues are commonly described as having a "lifecycle" composed of five stages: early, emerging, current, crisis, and dormant (Dougall, 2008). The relationship between issues management and crisis management, and their respective lifecycles, is the source of some debate. For example, Heath & Palenchar (2009) argue that crisis management is a function of issues management, while Jacques (2007) suggests that issues management is a part of the "Crisis Preparedness" stage in the crisis management continuum (Crisis Preparedness, Crisis Prevention, Crisis Incident Management, and Post-Crisis Management). Extensive studies exist on crisis communications, which are informing subsequent research efforts examining actual disclosures. From a process perspective, there are many similarities between the issues and crisis management processes.

Mahon and Waddock (1992) argue that there are three dominant lenses through which the issue lifecycle can be viewed: the corporate strategist, the public policy maker, and the pressure group. These perspectives help to define key stakeholders, stakeholder actions that may accelerate or decelerate an issue through lifecycle stages, and the metrics an organization uses to measure success. Metric definition and outcome measurement are challenging undertakings, particularly because some metrics are more tangible than others. Some common metrics include: extent and tone of media coverage, legislative influence, competitive positioning, market share, and correcting allegations (Dougall, 2008).

Although it is intuitive to envision the issue lifecycle as a linear path, defined by time and issue intensity, Bigelow, Fahey, and Mahon (1993) suggest that issue paths actually reflect the "intensity and diversity" (pg. 27) of stakeholder actions, and that such paths are neither linear nor sequential. Similarly, Jaques (2007) describes the stages of crisis management as a relational model connecting clusters of actions in a nonlinear fashion.

To fully appreciate an issue's position and trajectory, one must examine its stage in the lifecycle, the stance of relevant stakeholders and those stakeholders' power, legitimacy, and urgency (Mahon & Waddock, 1992; Mitchell, Agle, & Wood, 1997). As an issue progresses through the lifecycle, the number of engaged stakeholders expands and their expectations become more entrenched (Kingdon, 1984). Mahon, Heugens, and Lamertz (2004) argue that despite commonly being managed separately, issues management and stakeholder management are inexorably

intertwined. Mahon at al. argue that issues management is ad hoc while stakeholder management is continuous: stakeholders are only mobilized around issues, and issues only emerge when stakeholders advocate (Bigelow et al., 1993). Media can serve as an accelerator by publicizing the details of an issue and the reactions of stakeholders (Heath & Palenchar, 2009): "Longevity and strength of reaction are also enhanced when media reports of new issues are framed by rehearsals of similar previous issues. This is a particular concern with medical mishaps due to their inevitable recurrence."

It is generally believed that as stakeholder expectations solidify, organizations have fewer strategic choices to "close the gap," making issues less manageable as they move through the lifecycle (Heath & Palenchar, 2009). Alternately, Knight (2007) suggests problems receiving considerable public scrutiny can be transformed by an organization into an issue of common interest and concern, "amenable to negotiation and reform" (pg. 313). In this manner, the issue formation process provides an opportunity to play down the negative nature of a topic while acknowledging that it is a valid concern. Knight (2007) gives the example of Nike's successful conversion of a perceived systemic labor-exploitation problem into a common issue involving a globalized labor market fraught with cultural and regulatory inconsistencies regarding child labor.

Although issues management provides a useful foundation for understanding how organizations detect and respond appropriately to system perturbations, there are a number of organization-specific factors and types of stakeholders that add complexity to the issues management process. In the case of the VA, for example, the potential for patient harm to compound over time may be a factor, in addition to the accelerating reputational damage caused by delayed disclosure (Mahon and Waddock, 1992). Similarly, early disclosure of partial or inaccurate information may erode trust among patients, thus creating a tradeoff between time and perceived transparency. Organizational distrust can spread through affected patients' social networks to a broader population of potential patients. Because reputation can act as a linkage among communities as well as within and between organizations, the reputational risk associated with disclosure timing has the potential to spread far beyond the tenure of any given issue (Scott & Walsham, 2005).

3 INFORMATION OBTAINED

To fully appreciate VHA's specific disclosure management process, we conducted a review of relevant VHA policies and publications:

- VA Handbook 6300.4: Procedures for Processing Requests for Records Subject to the Privacy Act (1998)
- VHA Directive 2008-002: Disclosure of Adverse Events to Patients (Rescinded) (2008)
- VHA Handbook 1004.01: Informed Consent for Clinical Treatments and Procedures (2009)
- VHA Handbook 1004.08: Disclosure of Adverse Events to Patients (2012)
- VHA Handbook 1050.01: VHA National Patient Safety Improvement Handbook (2011)
- VHA Handbook 1058.01: Research Compliance Reporting Requirements (2011)
- VHA Handbook 1100.17: National Practitioner Data Bank (NPDB) Reports (2009)
- VHA Handbook 1605.1: Privacy and Release of Information (2006)
- National Ethics Committee of the Veterans Health Administration: Disclosing Adverse Events to Patients (2003)

We then engaged in discussions with VHA and affiliated personnel to better understand the current practice and its perceived limitations:

- Victoria Davey, Ph.D., M.P.H., R.N.,Chief Public Health Officer
- Richard Martinello, M.D., Chief Consultant, Clinical Public Health
- A. Rani Elwy, Ph.D., M.Sc., Health Psychologist, Center for Healthcare Organization and Implementation Research
- Elizabeth Maguire, M.S.W., Project Manager, Center for Healthcare Organization and Implementation Research
- Carter Mecher, Ph.D., Senior Medical Advisor for Public Health
- Aram Dobalian, Ph.D., M.P.H., J.D., Director, Veterans Emergency Management Evaluation Center
- Edward Chan, Ph.D., Research Health Scientist, Veterans Emergency Management Evaluation Center
- Tamar Wyte-Lake, D.P.T., M.P.H., Program Director/Investigator, VA Health Services Research and Development Center of Excellence and VA Center for Implementation Practice and Research Support
- Johanna Klohn, M.P.H., J.D., Chief Risk Officer, UCLA and Santa Monica Medical Center
- Catherin Duda, D.P.H., M.P.H., Chief Administrative Officer, Department of Anesthesiology & Emergency Medicine, UCLA Heath System
- Deborah Glik, Sc.D., Professor of Community Healthy Science and Director of the UCLA Health and Media Research Group, UCLA Fielding School of Public Health

Finally, we reviewed a number of data sources related to past incidents of concern to understand how the prescribed processes translated to action:

- VA OIG reports (e.g., “Healthcare Inspection,” 2012)
- Congressional testimony (e.g., “Veterans at Risk,” 2010)
- Related literature (e.g., “Results from a large-scale epidemiologic look-back investigation of improperly reprocessed endoscopy equipment,” 2012)

We also aggregated a number of news media accounts related to incidents of concern to better understand the prevalence and tone of media coverage compared to that of the sources provided above. This process was largely exploratory, and we look forward to future collaboration with the VA SCALE research team whose study offers a comprehensive content analysis of media coverage and notification letters for six recent VA large-scale adverse events (LSAEs).

The information obtained, coupled with the theoretical framework of issues management has given us some preliminary insights into the particular challenges faced by the VA in managing disclosure of large-scale events:

- Issues occur when perceived performance departs from expected performance. Effective management therefore involves both framing the events that degrade perceived performance and conditioning background expectations.
- Early response is important for shaping opinion, but this may be in tension with conveying accurate and complete information, which is an especially critical value for health care providers to manifest.
- Although the specifics differ greatly among disclosure events, events are recurrent, which creates the opportunity for the management process to adapt over time.

4 MODEL DEVELOPMENT

Modeling the system's reaction to adverse events and their disclosure can provide significant support for the design and testing of policy. A model can help identify undesired consequences arising from unanticipated interactions through the systematic testing of the performance of prospective policies against a large range of cases. Model analysis can also uncover those processes and interactions that have the greatest influence on overall performance, helping policy-makers to focus on improving those critical processes.

We employ an approach that has been used to model a variety of complex socio-technical systems for the purpose of informing policy design (Glass, Davey, Min, Beyeler, & Glass, 2008; Moore et al., 2012; Bech, Beyeler, Glass, & Soramäki, 2007; Conrad, Beyeler, & Brown, 2012). The distinctive features of this approach include: explicit identification of the important metrics of system performance (e.g. number of patients mishandled) and the kinds of policy interventions anticipated; development of an initial model of the processes that interconnect system metrics and policy decisions; comparative evaluation of alternative policies using the model; iterative refinement of the model and its parameters.

Bringing model uncertainty into the foreground is an essential part of this process. The conceptual formulation of entity relationships and assignment of parameter values for any model, however sophisticated, are uncertain. The underlying processes may be stochastic and, thus, unpredictable in principle. Any judgments about the possible consequences of implementing a policy must consider this uncertainty. In addition to reflecting our current state of knowledge about system response to policy, uncertainty analysis helps identify the areas in which new information has the greatest power to clarify differences among policies (by reducing uncertainty in model structure or parameter values). Using the requirements of the decision-making context to guide model refinement creates a clear criterion for model accuracy, helping insure that model development is focused on areas where it is most useful.

A model is a representation of a specific hypothesis about how a system functions which can be used to test policy performance. It need not be computational however the number of interacting elements and processes necessary to represent most systems typically mandates solution by computer simulation. Simulations take different forms depending on the features of the model. As an example, agent-based simulations are useful when representing a large population of similar *elements* that interact in ways such that an aggregate outcome cannot be anticipated. System dynamics models (Sterman, 2000) are useful when the system consists of interactions among distinct kinds of *processes*, each of which may be modeled using a few dynamical equations. Some problems are better approached through the use of multiple models, each reflecting a different possible hypothesis about system behavior for example. Model implementation may change over time as increased detail in some aspects of the system is discovered to be useful for resolving policy effects.

When the object of analysis involves communication among people with differing backgrounds, an initial qualitative definition of the model is often extremely valuable. A qualitative definition specifies the entities the model represents, their properties, and the processes that influence the entities and properties. Graphical specification can be especially effective. We frequently use causal loop diagrams to portray model structure because of their simplicity and clarity. We use these diagrams below to present our current proposal for the disclosure model.

4.1 Performance Measures

Disclosure is initiated by adverse events: an effective disclosure policy will necessarily seek to minimize negative consequences. These consequences would include any health impacts to treated patients, secondary health impacts (for example psychological stress to patients and their friends and family), psychological stress to clinicians and others involved in treatment, and loss of reputation of VHA medical personnel and institutions among prospective patients, the general public and political entities.

Clearly, direct and induced health effects are measures of interest; they are also relatively easy to quantify. The preservation of reputation is more difficult to formulate as a clear objective of policy design. A good reputation is an essential component of providing medical services: it strongly influences veterans' decisions to seek treatment and the public's willingness to support the VHA. It also influences the effort and cost of acquiring staff, and the ability to retain them. These considerations underscore the importance of utilizing the flow of patients seeking treatment as a quantitative performance measure. An effective disclosure process will tend to maximize this flow relative to inferior processes, reducing health problems that would otherwise arise in veterans deterred from treatment. A positive reputation is especially important for communicating an adverse event affecting a small group of patients to the entire population of prospective patients while minimizing its potential for escalating negative exposure.

Disclosure of an adverse event necessarily has a negative impact on reputation. This effect can be short-lived, however, if the event is seen to have been handled "well." If events are regularly seen to be well-handled, this characteristic can enhance the reputation of the disclosing institution.

Our initial hypothesis about the processes that connect disclosure to the primary system performance measures (health impacts to patients and size of the untreated population) is illustrated in causal diagram below (Figure 1).

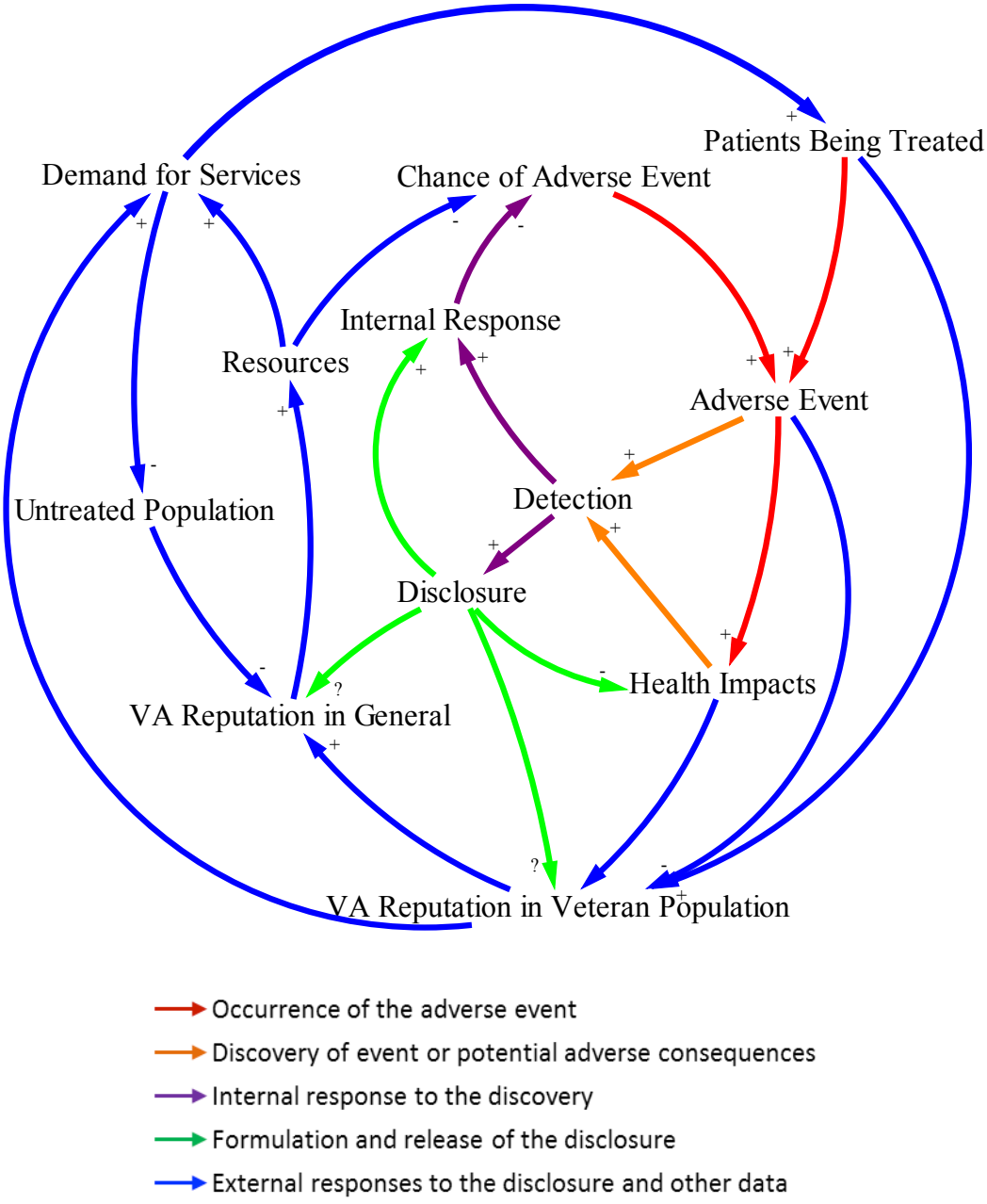

Figure 1: Causal diagram showing the hypothesized influence of disclosure on the health of treated and prospective patients

Arrows indicate assumed causal connections between state variables. The direction of influence of one variable on another is indicated by a plus or minus sign (+/-) near the arrow head. A positive sign indicates that an increase or improvement in the upstream variable tends to increase or improve the downstream variable. The diagram is color-coded to distinguish five processes influencing the need for, and effects of, disclosure.

4.2 Policy Options

An identified policy for disclosure creates categories of disclosure, specifies the kinds of events that require disclosure, and defines specific processes for creating and reviewing the information disclosed. The objective of disclosure is to convey information about the adverse event as quickly and as accurately as possible to those who need it in a manner that will encourage an appropriate response. Several components of this complex objective may create conflicting requirements: requirements for timeliness and accuracy may be in tension, for example, because a complete understanding of the scope and causes of the adverse event may require an extended period of time to assemble.

We propose to model alternative disclosure policy options via functional characteristics of the disclosure process, that is, for example, by the time required to develop a response to an adverse event and by the accuracy of the public characterization of the event. This formulation has two advantages: it provides a natural driver for the evolution of reputation and it informs the design of detailed policies by identifying the specific processes (e.g. information gathering, deliberation) that have the greatest influence over performance as well as defining functional requirements for them.

4.3 Initial Model

The primary performance measures we utilize in the initial model are health effects of adverse medical events in the patient population and the number of untreated patients afflicted with the same disease condition. Disclosure is viewed functionally as a process for characterizing the nature and scope of an adverse event and a process of formulating and communicating information to patients and the public. The effectiveness of the disclosure depends on the accuracy and latency of the proffered information relative to the current norms of veterans and the general public. To be effective a disclosure policy must be aligned with other processes occurring in the system. If a disclosure policy provides information more slowly than concurrent public dissemination, the VHA might be seen as excessively bureaucratic and unresponsive; if it responds more rapidly than the internal information-gathering processes then inaccuracies in the resulting disclosures may erode the VHA's perceived reliability.

We model the overall system as the interaction of five processes (indicated by arrow colors as shown in Figure 1):

- Patients receiving a specific kind of treatment suffer an adverse event of some kind. This might be a random occurrence among patients so treated or might be a systematic feature of a treatment which is later found to be potentially harmful. The process generating adverse events, including the propensity for adverse events to compound (through infection for example) is the fundamental driving process. (Variables related to event occurrence are shown in red).
- The fact that an adverse event has occurred is recognized by a clinician either within the VA or in some other institution. This recognition may occur through a wide variety of mechanisms with very different implications for the potential size and duration of the event. The event (or an instance of it when it is recurrent) might be detected as it occurs; recognized later as having occurred by the treating clinician; recognized on subsequent examination of the patient, either by the original clinician, another VA clinician, or by someone outside the VA (Orange arrows denote the detection process).

- Detection of the adverse event leads to information-gathering designed to determine its cause and scope. If the cause is a generally-used process or material then defining the possible scope may require a great deal of data collection and reporting at many facilities. (Purple arrows)
- Development of a disclosure response, including the content and scope of the disclosure (Green arrows).
- Assimilation of information about the event and the ensuing disclosure by the veteran population, the political system, and the general population (Blue arrows).

The major relationships among these processes are illustrated in Figure 1. In this initial causal diagram, the necessary simplification/abstraction eliminates many potentially important distinctions and, therefore, is not sufficient to define a quantitative model. For example although a single link connects the adverse event and its detection, there are several mechanisms that might lead to detection (as discussed above) with very different implications for the scope of the event and for the way it is perceived.

Figure 2 presents a more detailed picture of the system from which a quantitative model can be developed. The major interactions involved in the five basic processes (event creation, detection, information collection, disclosure, and reaction) are discussed below. Each process is controlled by a small number of parameters, summarized in Table 1.

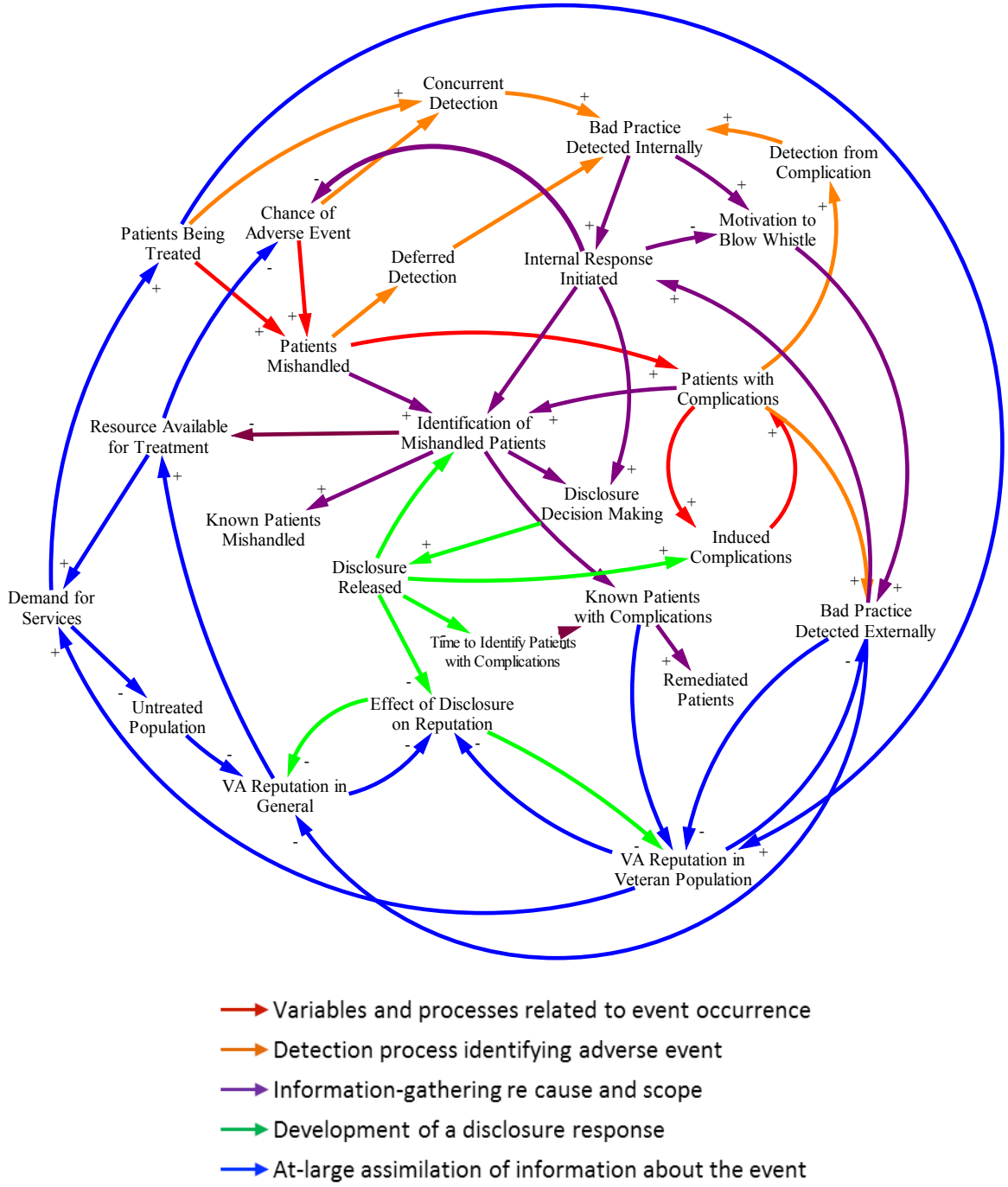

Figure 2: Causal diagram showing a more detailed representation of the processes and interactions that define the disclosure model

Table 1: Parameters of the Initial Model of Disclosure

Model Parameter	Description
Patients Needing Treatment	Pool of patients requiring VAH services
Chance of Adverse Event*	Probability that a patient's visit for treatment will result in an adverse event
Chance of Concurrent Detection	Probability that an adverse event will be detected at the time it occurs
Chance of Deferred Detection	Probability that an adverse event will be detected following its occurrence, but not due to development of complications
Chance of Complication	Probability that an individual adverse event will lead to medical complications
Chance of Detection from Complication	Probability that an adverse event will be detected due to ensuing complications
Chance of Propagation	Probability that a patient who develops complications will engender complications in their contacts
Time to Identify Mishandled Patients	Average time to identify a patient who has been subject to an adverse event once the event has been detected
Time to Identify Patients with Complications*	Average time to identify a person who has developed complications as a consequence of an adverse event once the event has been detected. Indirect consequences (due to propagation) may take longer; disclosure is expected to reduce this time
Time to Remediate Patients	Average time to treat complications created by the event
Time to Formulate Disclosure	Time to develop and review the disclosure statement once the relevant information is available
*May change from its initial value due to the influences shown on Figure 2	

An adverse event is represented as a random process that occurs with some probability for each patient receiving a particular treatment. This construct can be used to describe both stochastic processes and processes affecting all patients over a given time period. Adverse events create a population of "Mishandled" patients in the model shown in Figure 2. Some kinds of events may invariably compromise a patient's health; others can put a patient at risk of a (further) degradation. The development of complications is represented as a random process that occurs

with some probability, creating a population of "Patients with Complications" over time. Adverse events such as exposure to an infectious agent have the potential to induce cases outside of the initially mishandled population. These "Induced Complications" increase the scope of the adverse event and may significantly complicate subsequent tracking and notification.

Various pathways for detection of the adverse event are shown in orange. "Concurrent Detection" denotes events detected as they occur during treatment with essentially no delay. "Deferred Detection" occurs when there is significant delay between the problematic treatment and recognition of the adverse event. Additional events may occur during this time and patients may develop complications depending on the nature of the event. Deferred detection might occur because the adverse character of the event is discovered during subsequent interactions between the patient and clinicians, or because a commonly-followed practice is later recognized to have been inappropriate. In the former case deferred detection can be modeled as a random process occurring with some specified frequency for each mishandled patient; in the latter case it could be modeled as a random process with no dependence on the number of mishandled patients. We regard detection from complications as a third pathway distinguished by its potential to involve further delay and the concurrent likelihood of generating a larger impact on reputation than would earlier detection. Detection along the first three pathways is assumed to happen within the VHA system. A fourth possibility involves detection at an outside practice which may have significant effects on VHA's ability to subsequently gather information as well as maintain its reputation.

Detection by any pathway generally initiates an "Internal Response" (components shown in purple on Figure 2). Response entails: 1) stopping the process that causes the adverse event; 2) identification of potentially affected patients; and 3) determination of the nature, content, and timing of the disclosure. Identification gradually builds a population of "Known Mishandled Patients" and, separately, of "Known Patients with Complications." These populations are distinguished because patients with complications might possibly take longer to identify (if the event is capable of propagating) and because additional time and resources may be required to remediate their complications. In some cases the internal detection of the event may not lead to an internal response or the response might be delayed due to disagreements about the facts or ramifications of the event(s). Delays between initial detection and initiation of a response are assumed to create some potential for "whistleblowing" by which the event may be brought to the press or some other institution outside the VHA.

Decision-making regarding the timing and content of the disclosure begins as part of the internal response. This process draws on information about the nature of the adverse event (assumed as background information in Figure 2) as well as on the current understanding about the number of patients and patient associates affected by the event. This understanding changes with time as the internal response discovers relevant information.

The disclosure may induce stress and anxiety in patients receiving related treatments or in the VA patient population generally. This potential is represented as a kind of complication induced by the disclosure itself. Other potential reaction pathways for the veteran population and the general public in response to information about adverse events are denoted by blue arrows in Figure 2, extending from both internal disclosure and other sources. Each disclosure is presumed to diminish the VHA's reputation to some extent among both veterans and the general public; however this effect would dissipate over time if the manner in which the event is handled and disclosed is seen to meet some norm/expectation. Reputation will be especially diminished if the

event is first detected outside the VHA or if it leads to complications. In many cases the character of reaction to real events turns on details that seem unrelated to objective factors, such as risks to patient health or the responsiveness and transparency of the VHA. This tendency can be captured in the model by including a random component in the influence of an event on reputation. Although such influences on reputation are not (by definition) responsive to the timing or content of disclosure, they may be useful to include in the model to establish practical objectives for the components of response that can be influenced through disclosure. The effect of disclosure on reputation may depend on the reputation prevailing at the time the disclosure occurs. This reinforcing feedback between current reputation and the reaction to disclosure is the focus of the implementation described below.

4.4 Experimental Implementation

We have developed experimental implementations of some core processes in the model in a system dynamics framework. These implementations allow us to understand the effects of alternative formulations of these basic processes, and to get a clearer understanding of parameter sensitivities than can be distilled from the results of an integrated model.

As an example, the simple system dynamics construct shown in Figure 3 models the effect of a disclosure on reputation (not distinguishing between reputation among public and patients). Reputation is indicated by a single scalar variable.

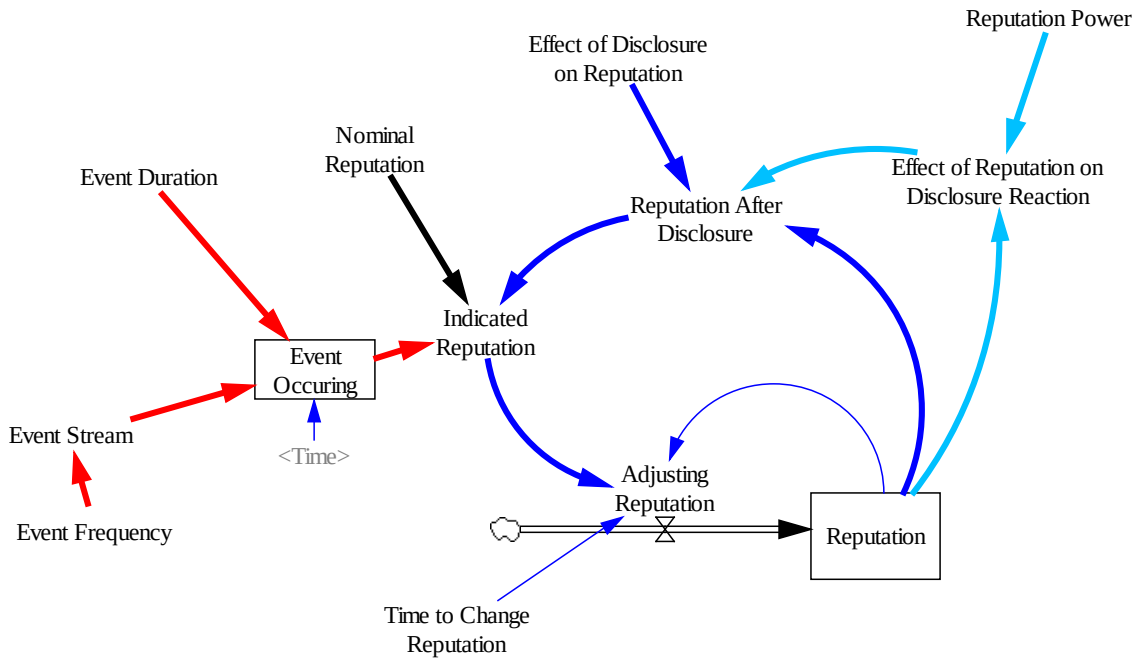

Figure 3: System dynamics construct used to represent the compounding effect of a sequence of disclosures on reputation

To focus on reputation effects, a synthetic random stream of disclosure events is directly to be fed into the model. This process enables us to focus on the reputation effects while stipulating

the event creation, detection, and formulation processes that precipitate disclosures. In the absence of disclosure, Reputation adjusts to the Nominal Reputation value, arbitrarily set at 1. During a disclosure, Reputation declines towards some fraction of its value at the time the disclosure is initiated. That fraction is itself a function of Reputation, with higher initial reputation leading to smaller relative decline, and lower initial reputation causing greater relative decline. The strength of this reputation-dependence is controlled through the Reputation Power parameter.

The effect of this reinforcing feedback can be dramatic. When presented with the succession of disclosure events shown in Figure 4, the response of Reputation strongly depends on the strength of the non-linear effect of Reputation on the reaction to disclosure.

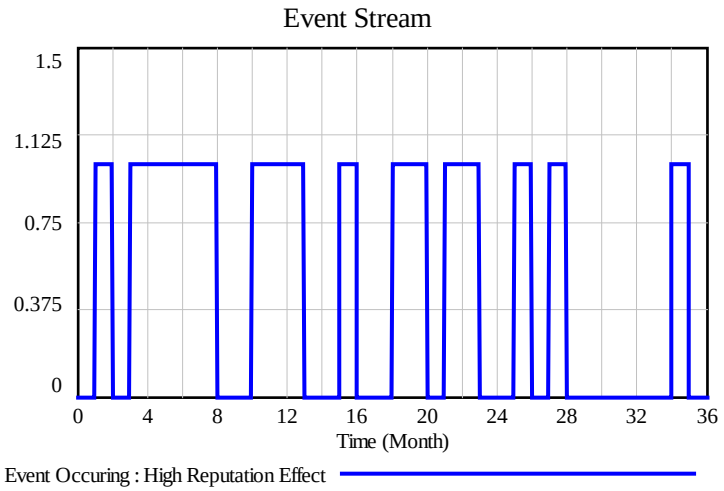

Figure 4: Stream of modeled disclosure episodes affecting reputation

The effects of two alternative settings for the Reputation Power parameter in response to the series of disclosures above are illustrated in Figure 5.

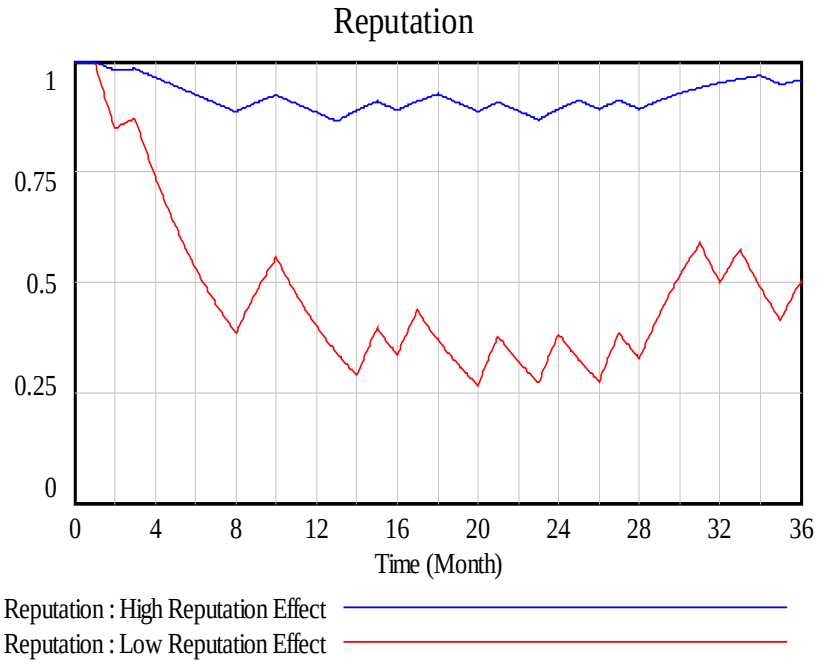

Figure 5: Reputation response to the sequence of disclosure events shown in Figure 4 for two contrasting values of Reputation Power

Reputation begins at its nominal value of 1 in both cases. Disclosure events depress reputation in both cases, however in the High Reputation Effect case the decline is moderated by the high initial reputation. This moderation allows the reputation to recover following the disclosure, which sustains the buffer when the next disclosure occurs. In the Low Reputation Effect case the initial disclosure produces a larger initial decrease in reputation. This decrease compounds the response to the second disclosure, which depresses reputation to a level from which it is unable to recover. The outcome of the non-linear buffering effect is not simply to amplify the effect of disclosures, but evidently to create distinct equilibrium levels of reputation, with the potential for sharp transitions between them. The purpose of examining simple models such as that shown in Figure 3 is not to predict reputation effects in specific cases, but to understand basic behavioral characteristics of the system, such as the propensity to undergo abrupt transitions of this kind.

5 NEXT STEPS

The entities, variables and relationships that constitute the model need to be reviewed and discussed with subject-matter experts. Continued engagement with the SCALE team will be indispensable. Developing and sharing prototype implementations such as the model described in Section 4 will be an important mechanism for exchanging information. We need to verify that the represented processes are reasonable and reasonably complete. As an example, the effects of events and their disclosure on practitioner efficiency and morale are not currently included. Should they be? Or should the extra workload created by remediation be represented as increasing the chance of a subsequent event because of the added demands on staff and administration?

One important avenue for verifying model structure is through examination of its ability to describe past disclosure events in terms of available model parameters (e.g. chance of detection at various stages, propensity to propagate). Factors that are regularly used to describe real events but which don't appear in our model indicate missing processes. Parameters that are never found applicable, or whose values are difficult to assign, suggest superfluous or poorly conceived model elements.

Once the model scope and the surrounding processes have been vetted, some processes (e.g. disclosure decision-making) may be found to benefit from further refinement. For example, the time to formulate the disclosure might be made to depend on the parameters of the initiating event (e.g. chance of complication, chance of propagation).

A system dynamics implementation of core parts of the model has been developed for experimentation and testing. This kind of implementation is well suited for prototyping because it can be easily changed to track changes in the model. When this initial conceptual model stabilizes, we expect to transition to an agent-based implementation that will allow systematic and quantitative exploration of the space of events and policies.

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