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Achieving Warranted Acceptance of Biotechnologies

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Achieving Warranted Acceptance of Biotechnologies

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Abstract

The U.S. has faced long-standing shortages of generic drugs, causing negative health effects and spikes in drug costs. To address these shortages, investments in critical technologies and policies to support their adoption will be needed. The success of these technologies and policies depends on public acceptance. We studied public acceptance using the mental model approach, which identifies gaps in understanding that can be addressed with communications. We began with semi-structured interviews with experts in pharmaceutical manufacturing. Based on these interviews, we developed and conducted surveys of the general public, physicians, and pharmacists. Similar strategies could be applied to improve communications for other quality risk management issues, such as the adoption of novel pharmaceutical technologies and regulatory practices.

1. Introduction

In response to the United States CHIPS and Science Act, we have applied decision science methods to study the public acceptance of critical technologies and policies, with a case study of the approaches to addressing shortages of generic drugs. Public acceptance is key to technology development and deployment through the public's role in political support, consumer demand, and workforce recruitment. Research in many domains has found that such acceptance requires two-way communications between technology and policy leaders and public stakeholders. Only by listening to the public can leaders design technologies and policies that address its concerns. Only by speaking with the public can leaders explain their work and demonstrate their respect – creating trusted relationships and framing the issues before their opponents do.

2. Background

The COVID-19 pandemic and related supply chain issues have exacerbated the long-standing generic drug shortage problem with adverse effects on patient health and healthcare costs (Fox PharmD et al., 2014). At the end of 2022, there were shortages of 295 drugs identified by the American Society of Health-System Pharmacists (ASHP, 2023). The root causes of the shortages, identified by FDA's 2019 task force, include low profit margins, a lack of incentives to enter the generic market, and a race to the bottom for drug pricing that encourages fragile supply chains (U.S. Food and Drug Admin., 2019). As a result, there may be only one or two manufacturers for any generic drug. The focus on pricing can compromise quality control, leading to plant shut-downs, sometimes with no available alternatives. Manufacturers may then choose to cease manufacturing a drug, when potential profits do not justify the costs of improved quality control.

Proposals for improving the resiliency of generic drug supply chains include both technology and policy solutions (National Academies of Sciences, Engineering, 2022). Automated sensing and control processes can mitigate the likelihood of a shortage by improving quality control of manufacturing lines (Read *et al*., 2010). Continuous manufacturing can enable greater flexibility and speed in meeting fluctuations in demand (Lee *et al*., 2015). Changes in reimbursement schedules and government incentives can spur the development and adoption of new technologies and practices.

The success of any technology or policy intervention will depend on public acceptance. To study public acceptance, we have followed the four steps of decision science's mental models methodology (Bostrom et al., 2012; Fischhoff and Broomell, 2020; Morgan et al., 2002):

(i) characterize expert opinion regarding the expected impacts of policies designed to promote adoption of a critical technology;

(ii) characterize expected acceptance of the policies by diverse public stakeholders, with varying degrees of prior knowledge;

(iii) identify opportunities to improve acceptance by improved design, so that technologies and policies better meet stakeholders' needs;

(iv) develop communication content and channels that share evolving expert knowledge and public opinion.

Our approach adapts strongly grounded methods from behavioral and decision science to the unique challenges posed by the need to secure informed judgments regarding unfamiliar, evolving technologies and policies, with complex, often unintuitive effects. Thus, the research extends the basic science while taking advantage of its demonstrated ability to identify and address potential sources of biased judgments. It will enable policy makers to create more acceptable policies and communicate proactively about them, not leaving a void that misinformation can fill.

3. Mental Models Approach

Our methodology adapts the mental models approach, a flexible risk communication and consultation methodology developed by researchers at Carnegie Mellon University thirty years ago (Bostrom et al., 2012). Since then, the method has been applied to a wide range of technologies and policies. The mental models approach has been used to study and inform an individuals' decisions about his/her own lives (e.g., how much more will I pay for an assured drug supply?) (Bruine de Bruin *et al*., 2007; Byram et al., 2001; Fischhoff et al., 1998; Riley *et al*., 2001) and about public policies (e.g., how much do I support industry subsidies?) (Fischhoff *et al*., 2006; Maharik and Fischhoff, 1993). It facilitates two-way communication between experts and stakeholders. It can be used to understand what the public needs to know in order to make informed decisions and what the public already knows. It recognizes that the public includes diverse groups, with differing backgrounds, preferences, and information needs.

The mental models approach has four interdependent steps. The first asks what factors are most important to address the problem at hand, based on the research literature and expert elicitation. The next step involves semi-structured interviews with members of the general public, paralleling those with the experts, so that their mental models can be compared to the expert model. In the third step, those interviews inform the development of structured surveys suited to large sample administration, identifying critical topics and appropriate language. The fourth step develops and deploys communications to address gaps in understanding between experts

and the public, as identified in the third step. The second step may be skipped in situations, like generic drug shortages, where there has been little public discussion. In that case, the structured survey must offer enough background information to elicit meaningful responses. As will all research elements, that information is extensively pretested for comprehensibility and balance.

4. Mental Models Frameworks

The mental models approach uses an influence diagram to summarize knowledge about the factors determining the critical outcomes of policy decisions. In this application, the decisions are the national and industrial policies affecting the success of innovative technologies. The outcomes are national objectives, as identified by the CHIPS and Science Act: national security, social equity, environmental sustainability, manufacturing productivity, and workforce development (*H.R.4346 - Chips and Science Act*, 2022). The draft model is based on the research literature, which is refined through the expert interviews. We have created two general models, suited for diverse applications (see Figures 1 and 2 below).

Each model is read, roughly speaking, from left to right, going from driving factors to strategic outcomes, with moderating and mediating factors in between. Analyses of these processes can reveal opportunities for technology policy leaders in (a) policy and technology creation; (b) implementation, through the intermediary organizational processes; and (c) priority setting, among the outcomes.

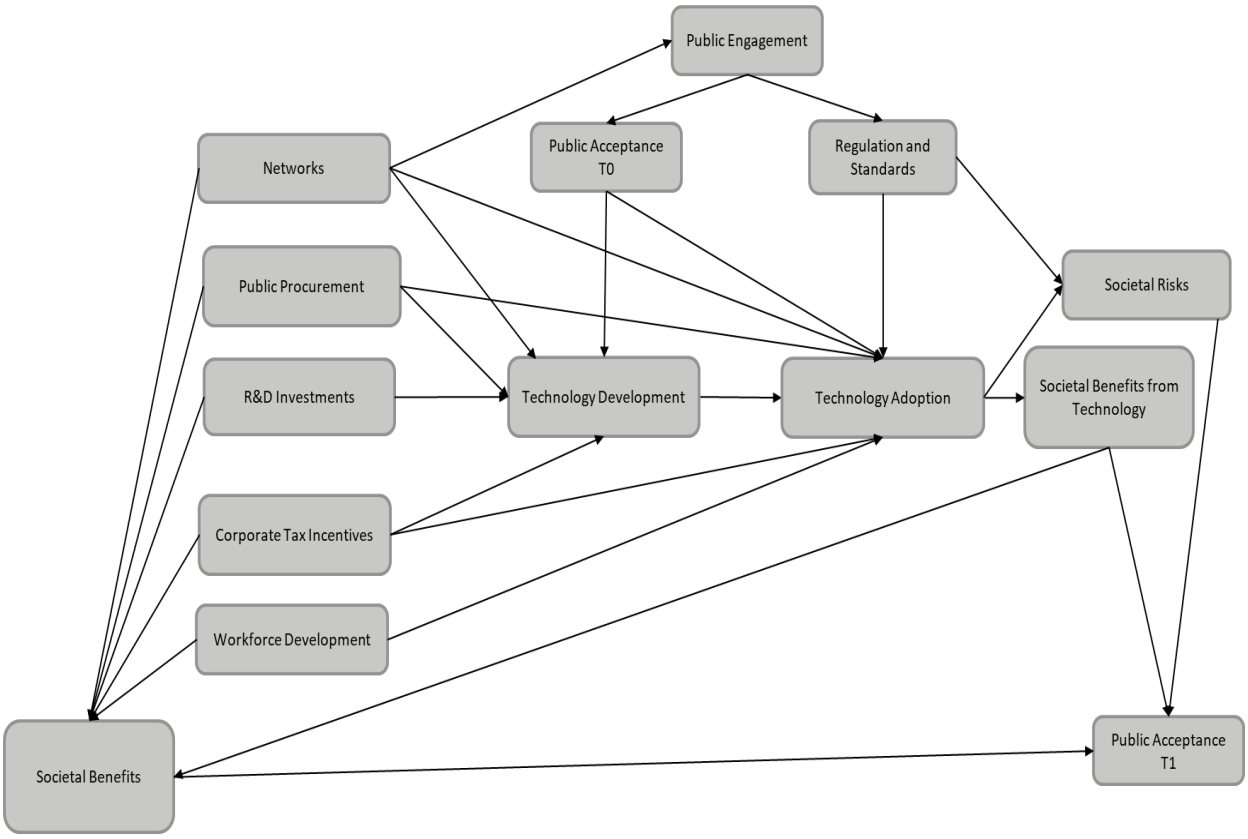

Figure 1. Expert model for predicting public acceptance of a technology and its supporting policies

The first model addresses the impacts of a technology and its supporting policies. The model starts with a linear model of technology development, where technology development leads to adoption, and adoption leads to societal benefits and risks. We chose this simplified model so that it could apply to many technological areas, recognizing that many complexities are not captured (Tang and Martin, 2007). Because we are interested in how policies can affect technology development and adoption, we include six common policy levers (Edler and Fagerberg, 2017).

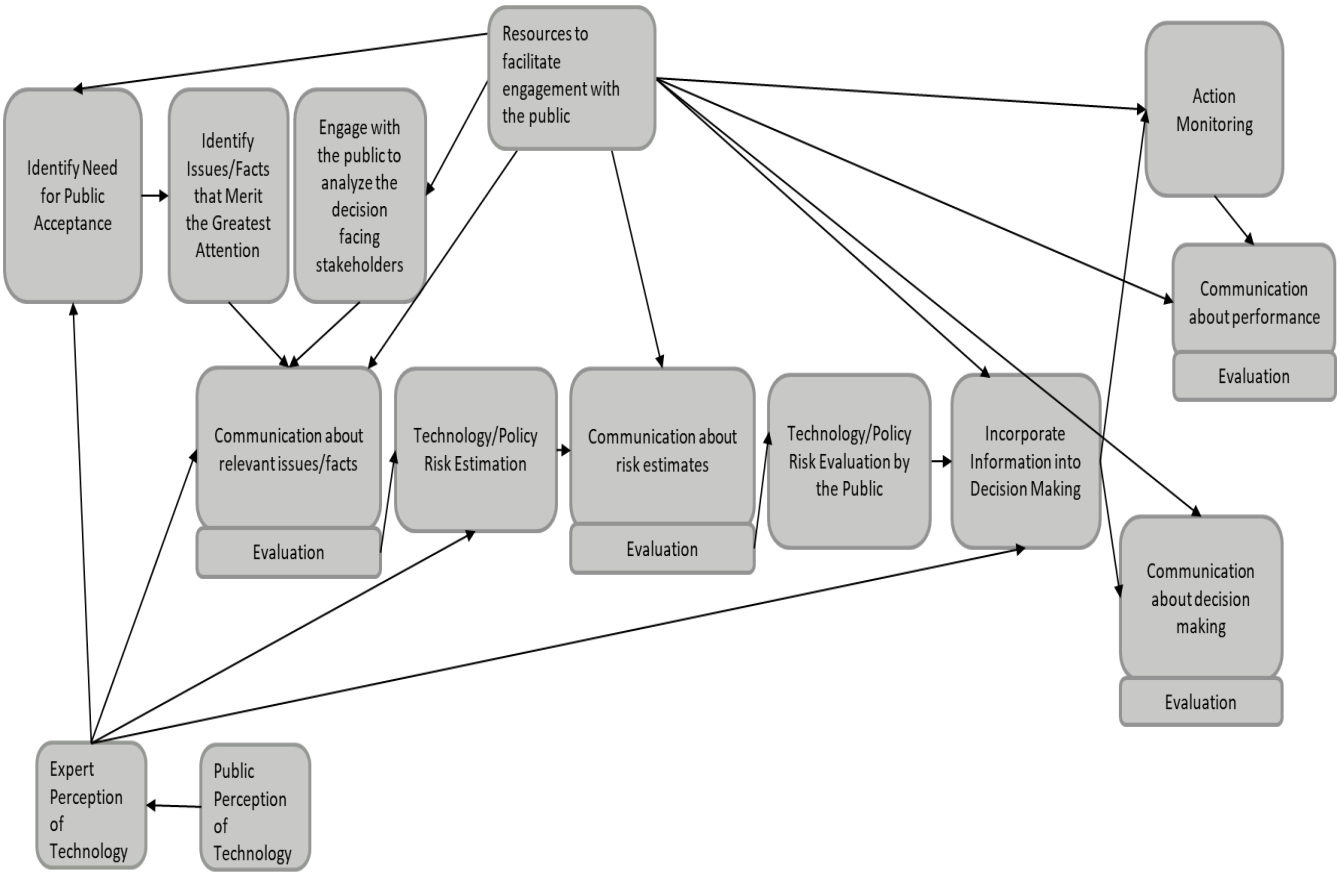

Figure 2. Expert model for communication processes affecting public acceptance

The second model addresses interactions with the public that affect its trust and acceptance of the technologies and policies. This model shows the range of issues where technology and policy leaders may seize opportunities to communicate with the public. It summarizes research on effective risk communication (Fischhoff, 2013), reflecting the need for two-way communication and evaluation at each stage of adopting a new technology or policy. It follows the convention of using "risk communication" to include all potential consequences, and not just risk estimates. Early pilot interviews identified additional issues which completed the model used to structure further work. These included the influences of expert and public perceptions on communication strategies.

5. Expert Interviews

We conducted interviews with seven experts from industry, academia, and government to refine each general model (Figures 1 and 2) for the specific issue of generic drug shortages. Participants were recruited at a March 2023 workshop on potential technology solutions to shortages of generic pharmaceuticals. We used an open-ended interview protocol, structured around the draft expert models. The protocol begins by asking experts to identify technologies that could be used to address those shortages. We then ask about the benefits and risks that the public might experience were they adopted. Next, we ask about the policies, investments, and regulations that might influence technology development and adoption. Finally, we elicited experts' perceptions of the stakeholders who could affect the acceptance of the technologies and policies, as well as engagement strategies that could influence public response. We transcribed each interview and coded the transcripts into Figures 1 and 2. The initial expert models were updated with emergent nodes from the expert interviews.

6. Public Perception and Acceptance Surveys

Because these technologies and policies are unfamiliar to most members of the public, we developed a survey that explains several options identified as having particular potential in the expert interviews and a recent Homeland Security report (HSGAC, 2023). These explanations were subject to iterative user testing for clarity and balance, as were the survey questions. The survey requests open-ended explanations of key responses to provide insight into respondents' mental models and to inform revisions of the survey. We administered the surveys to a diverse, but not representative sample of US respondents, recruited through the Prolific platform.

A distinctive feature of biopharma technologies and policies is that their success depends on acceptance not just from the general public, but also from critical intermediaries, including physicians and pharmacists. As a result, we adapted the public survey for administration to these critical stakeholders.

Both surveys begin by asking about experiences with drug shortages. The general public survey then describes one shortage and asks what could have been done to prevent it; the professional survey begins by asking respondents to identify shortages that would be critical to their practice and propose ways to prevent them. Both surveys then introduce three policy alternatives and ask about their acceptability and effectiveness. The policy alternatives included one option that required relatively little direct government financial support: improved supply chain reporting. A second option focused on onshoring, and described economic and national security benefits that could come from domestic manufacturing. The third option focused on a more direct method of supporting technology adoption, advanced manufacturing hubs. Finally, the surveys ask who should be included in making these policy decisions and what communication strategies are appropriate.

The open-ended responses were coded by a single reviewer looking for generalizable themes for each open-ended response. Public opinions on policy solutions and public engagement strategies were then compared to the expert models, as refined with expert interviews. The surveys are currently being analyzed. The robustness of their results will need to be tested in additional, more representative samples of the general public, physicians, and pharmacists.

7. Applications for Quality Risk Management

The contrast between our expert interviews, as summarized in the models, and the surveys identified gaps in knowledge and understanding between groups. These gaps suggest opportunities for improved communication between the groups, so that experts develop more acceptable options and communicate their expected benefits, risks, and rationales to the public. For example, our ongoing analyses suggest widespread concern for high pharmaceutical prices and a distrust of the pharmaceutical industry, leading to suspicion that new technologies and policies will mean additional costs for consumers.

The mental models methodology integrates research knowledge (in the draft expert models),

expert elicitation (in the interviews), and survey research (with members of the public and front-line professionals). Although the present application focuses on generic drug shortages, the issues that appear in Figures 1-2 recur, in some form, with all technologies and polices. Thus, the present methodology provides a common analytical framework for addressing public acceptance of the technologies and policies related to pharmaceutical quality risk management.

With respect to pharmaceutical manufacturing, a mental models approach could be applied to specific technologies with unknown public acceptance. For instance, as synthetic biology and artificial intelligence technologies advance, the public could perceive these technologies as risky compared to batch manufacturing processes. Targeted communication and regulatory approaches could be developed based on mental models studies to achieve public acceptance for specific technologies. Regulatory approaches could require public acceptance studies to ensure warranted trust of the quality of regulated pharmaceuticals. Through a mental models approach, perceived risk can be incorporated into quality risk management, improving acceptability across the pharmaceutical industry.

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