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IT-based Regulation of Personal Health: Nudging, Mobile Health Apps and Personal Health Data

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Abstract:
Mobile health applications and devices ("mobile health apps") are increasingly embedded in organizational programs to regulate the personal health behaviors of individuals and populations. In this paper, we draw on de Vaujany et al.'s (2018) framework for IT-based regulation systems to consider how regulatory outcomes can develop in such settings, in which individual actors have strong agency and regulation is indirect and voluntary. Through an instrumental case of a continuous glucose monitoring system used for self-regulation of diabetes, we examine how IT artifacts become embedded in self-regulation practices, how data generated by these apps are implicated in regulatory feedback loops, and how networks of individual, organizational and technological actors are mobilized in regulatory regimes. We examine how data about bodily states and IT features such as displays and alarms 'nudge' individuals towards compliance with expert rules materialized in the IT artifact. We then identify regulatory affordances of mobile health apps for predicting and surveilling personal health. We also theorize how multilevel networks of trifecta of rules, IT artifacts, and practices develop through regulatory episodes as a regulatory lattice, and how social regulation is realized as a result. We conclude by considering the theoretical and practical implications of this analytical approach to investigate IT-based regulation in the open, distributed, and indirect regulatory contexts.

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Introduction

Mobile personal health applications and devices ("mobile health apps") are playing increasingly important roles in the lives of consumers. These trends are evident in many contexts of personal health, where widespread consumer interest has attracted the attention of health sector

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organizations as well as large technology firms, such as Apple and Google. Examples of mobile

health apps include, among many others, sleep trackers, fitness trackers, fertility apps, continuous glucose monitors, smart thermometers, and home EKG monitors (Baldwin et al., 2017; Kao and Liebovitz, 2017). Individuals typically use these technologies for self-regulating and monitoring their personal health behaviors in the hopes of improving their health. A variety of organizational actors with an interest in regulating the health of populations also promote use of mobile health apps (Lupton, 2013a, 2013b). For instance, public health and medical professionals may advocate use of health apps to advance patient engagement and self-care behaviors (Akbar et al., 2020; Baldwin et al., 2017). Technology firms market apps and wearable devices to employers and insurers, as these organizations promote the employees' use of wellness apps through corporate wellness programs (Brown, 2016; Fleming, 2020).

While mobile health apps may appear to be simply consumer products and services, many are embedded in regulatory programs aimed at directing individuals' health-related behaviors explicitly or implicitly (Laurance et al., 2014; Lupton 2013b, 2014) and thus become apparatuses through which individuals encounter social rules, norms and expert advice intended to influence their personal health behaviors. Regulatory actors include government health agencies (Lupton 2013a), health care providers (Akbar et al., 2020; Laurance et al., 2014), health insurers and employers (Brown, 2016), health researchers (Milne-Ives et al., 2020), firms seeking to monetize health data (Bourreau et al., 2020; Yeh, 2018), and technology firms that provide the mobile apps, devices and information technology infrastructure (Deering et al., 2013). For instance, during the Covid-19 pandemic, technology firms worked with public health agencies to develop mobile apps that could track users' locations, alert them about exposure to Covid-19 and even evoke quarantine rules (Ming et al., 2020).

The use of mobile health apps is an inherently interesting and important research setting, given the societal importance of human health, the socio-economic resources dedicated to healthcare services, and the tensions between protecting individual privacy and advancing health system innovations by using the health data these devices generate (Winter and Davidson, 2022). This setting also brings to the theoretical foreground important questions about how IT artifacts become embedded in voluntary regulatory practices, how data generated and utilized by IT artifacts are implicated in regulatory feedback loops, how networks of individual, organizational and technological actors are mobilized in IT-based regulatory regimes, and whether regulatory systems may be more (or less) effective as a result and for which societal groups. Such questions are relevant in a number of settings in which effective regulation depends on individuals' voluntary actions and as IT artifacts become ever-present behavioral monitoring systems, particularly with the deployment of Internet of Things (IoT) capabilities and devices.

De Vaujany et al. (2018) refer to assemblages of rules, IT artifacts, and practices aimed at regulating behavior as *IT-based regulation systems*. In this paper, we address the above questions by examining individuals' practices using mobile health apps through the lens of de Vaujany et al.'s (2018) framework. Our research goals are to consider how personal health practices become entangled with IT artifacts and the data they generate, how these micro-level regulatory practices are interwoven with organizational regulatory processes, and the circumstances that can enhance or diminish their regulatory effectiveness. We draw on the concept of behavioral health nudging (Baldwin, 2014; Sunstein et al., 2019; Thaler and Sunstein, 2008) to consider voluntary regulation, individual action, and choice, as we analyze trifecta of mobile health apps, expertise-based rules and norms, and personal health practices. We also consider how data revealed

through these IT artifacts act as resources in individual-level self-regulation practices and in organizational-level regulatory networks.

In the next sections, we review key aspects of de Vaujany et al.'s (2018) theory of IT-based regulation and of literature on nudging strategies (Sunstein et al., 2019; Thaler and Sunstein, 2008) and digitization in public health (Lupton, 1995, 2014) that informed our study. We develop and analyze an empirically grounded vignette of mobile health app use (continuous glucose monitoring by persons with diabetes) as a series of regulatory episodes (de Vaujany et al., 2018) to examine individual-level practices and organizational-level processes in IT-based regulation surrounding use of the mobile health app. Our discussion highlights regulatory affordances of predicting and surveilling personal health actions and outcomes, and we develop the concept of a regulatory lattice of trifecta to explicate the complex, fragmented and IT-mediated nature of social regulation (de Vaujany et al. 2018). Finally, we consider the practical and theoretical implications of our study and areas for further research.

Theoretical Foundations

IT-based regulation systems

To direct research attention to how organizational regulation is increasingly mediated by and enacted through IT artifacts, de Vaujany et al. (2018) draw from actor-network theory (Latour, 1992), practice theory (Nicolini, 2009; Reckwitz, 2002), and temporal structuring (Orlikowski and Yates, 2002) to articulate a trifecta lens of IT-based regulation emerging across relationships between rules, practices, and IT artifacts. They define organizational regulation broadly as "the collective process constitutive of rulemaking, rule maintenance, rule following, and rule enforcement" (757). Rules represent expected and acceptable behaviors applicable in particular

contexts and can be described by their normative assumptions (permissions, prohibitions,

guidance), the actors targeted by or subject to the rule, the situations in which the rule is applied, and the behaviors to which the rule should apply (de Vaujany et al., 2018). Practices are routinized behavioral patterns that individuals enact in their day-to-day activities (Nicolini, 2009; Reckwitz, 2002). Rules are applied and acted on, and importantly, made sense of within practices by reflexive agents, who decide whether and how to follow rules. The IT artifact, including material computing technologies and the related software stack, "encode, store, process, and display rules and possess the power to convey and enforce rules within practices" (de Vaujany et al., 2018: 759-60). IT capabilities to encode and adjust rules dynamically while identifying, recording, and tracking regulatory events create "unparalleled means to control organizational practices" (de Vaujany et al., 2018: 759).

As depicted in Figure 1 (de Vaujany et al., 2018: 759), the IT-based regulation system arises from the relationships among rules, practices, and IT artifacts and the work and outcomes involved in these relationships. From this trifecta view, the *materialization* of rules in IT-based systems is dependent on the unique capabilities of the IT artifacts to record, maintain or expand on complex rules (758). *Elicitation* is a process which "invites" the user to find and follow the rules materialized in the technology, while also directing the user's practical behavior once rules are invoked. Through *sensemaking*, a user's awareness of the rules emerges from practical experience, "whereby the content of the rule becomes expressed, defined, negotiated, and enacted in local practices that define rules and socially enforce related rule following. " (760).

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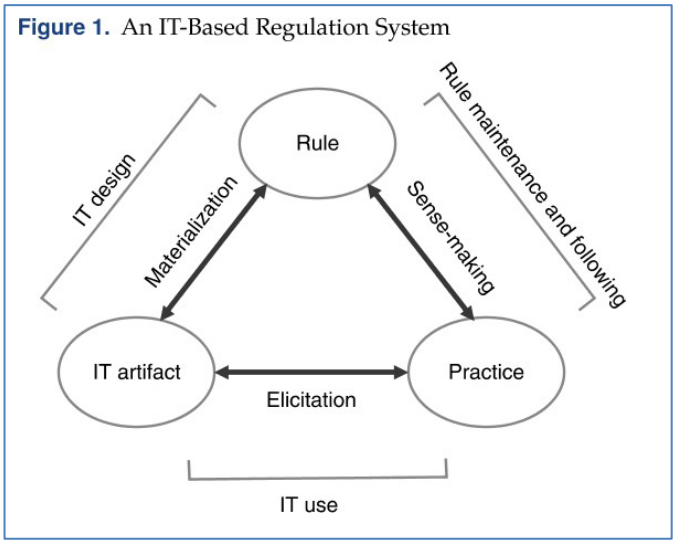

Figure 1: An IT-based regulation system (de Vaujany et al., 2018: 759)

Data about regulatory events are resources for and outcomes of the relationships depicted in Figure 1, as de Vaujany et al. (2018) argue: "IT artifacts can infer new facts (conditions) based on the ways in which actor's rule following unfolds as to determine whether new rules are needed, or which rules to apply to a given situation (creation of new rules)" (758). Data make aspects of actors' compliance to rules available to the IT artifact, allowing artifacts to adjust with greater precision to actor behaviors; data generated and presented to the user can better inform an actor's elicitation of applicable rules and their sensemaking about the practical relevance of rules. Moreover, data can activate regulatory processes that are temporally and spatially distant from specific regulatory events and organizational boundaries. For instance, AI algorithms can utilize data aggregated across a range of practices, contexts, and time to refine emergent rules, to recommend or enforce rules in new settings and to influence immediate as well as future practices (Yeung, 2018). The regulatory feedback loops that data engender across trifecta thus suggest how regulatory networks are instantiated and evolve (Zuboff, 2015).

IT-based regulation and behavioral nudging

Regulation is typically thought of in terms of administrative rules that require or prescribe conduct, but regulation can also facilitate or direct activities by improving the ability of individuals to make choices with few or no restrictions, and thus can influence the conduct of individuals or organizations indirectly (Orbach, 2012). These regulatory strategies direct and encourage voluntary compliance with normative practices (self-regulation) rather than relying on coercion or restrictions to enforce rules. Thaler and Sunstein (2008) describe a *nudge* as a specific choice architecture that seeks "to alter people's behavior in a predictable way, without forbidding any options or significantly changing their economic incentives" (Thaler and Sunstein, 2008: 6). Based on studies of human information processing and decision making, nudge theory has developed to identify how choice architectures–realized through environmental cues, artifacts, information, and so on — can influence individuals towards actions and decisions intended to benefit themselves, or society more broadly, without completely constraining a user from alternative choices (Dolan et al., 2012; Ewert et al., 2020). For example, a government may incentivize grocers to display fruits and vegetables prominently to encourage shoppers to adopt healthier food choices (Broers et al., 2017).

Informational nudges delivered through IT can be an effective means of prompting self-regulated behaviors (Baldwin, 2014; Lorini and Moroni, 2020; Sunstein et al., 2019). Nudges can range from simple displays of alternatives to highly persuasive suggestions, and to de facto normative rules designed into an information system to prompt targeted users to adopt specified practices (Quigley, 2013; Sunstein et al., 2019). For instance, nudges delivered as notifications through an IT-interface can influence how individuals respond to information security policies (Renaud and Zimmermann, 2018). Choice architectures encoded into information system interfaces can direct users towards accepting default values such as an opt-in to a privacy policy,

or alternatively, to provide users easier choices for adjusting default settings to their personal preferences (Sunstein et al., 2019, 17). When powered by big data, nudges have the potential to greatly influence individuals' behavior by making behavioral patterns visible to regulatory actors (including IT artifacts) to fine-tune intervention strategies to be more effective (Sætra, 2020).

Personal health and IT-based regulation

Much government regulation aimed at regulating population health relies on indirect, self-regulatory approaches, such as health promotion programs that encourage individuals to adopt recommended behavioral guidelines. Expert prescriptions for personal health practices are not explicitly enforced—we will not be fined for avoiding exercise or vegetables—and instead influence personal conduct through social norms that are accepted as good and necessary edicts (Lupton, 1995) and individuals' willing compliance with these rules (Lorini and Moroni, 2020). Lupton (1995) argues that health promotion activities nonetheless have strongly coercive elements that shape and normalize human behavior, as they "invite individuals voluntarily to conform to their objectives, to discipline themselves, to turn the gaze upon themselves in the interest of their health" (11). From this perspective, self-regulation of personal health can be understood as distributed and disciplinary forms of knowledge that "reaches into the very grain of individuals, touches their bodies and inserts itself into their actions and attitudes, their discourses, learning processes and everyday lives" (Foucault, 1980: 30).

Such indirect, voluntary forms of regulating personal health practices are evident in the growth of digital health initiatives and the blurring of regulatory boundaries between individuals' voluntary compliance to social norms for health practices, government and corporate strategies directed at the health of populations, and the growing presence of information technology firms in the healthcare sector (Lupton, 2014: 174). Employees, patients, consumers are all encouraged

to adopt mobile health apps to self-monitor and "quantify" their bodies to better manage their health (Lupton, 2013a, 2013b). Enthusiasts view the data generated by these technologies as an improvement on (or substitute for) an individual's haptic awareness of their bodies that can empower self-care practices, while critics argue that self-monitoring can be overwhelming and disempowering for some people (Lupton, 2013a, 2013b; Milne-Ives et al., 2020; Mol 2009). The voluminous health data generated by these apps are then expected to contribute to enhanced regulation of population health through health care research and mass-personalization of health care services (Laurance et al., 2014; Lupton, 2013a, 2014; Rowland et al., 2020).

Personal health regulation, nudging, and mobile health apps

Nudging interventions are a widely accepted strategy to influence and direct, and thus to regulate, the health behaviors of patients (Harrison and Patel, 2020; Möllenkamp et al., 2019; Patel et al., 2018). Nudges are also used as public health policy instruments–so-called "behavioral public policy" to influence population health (Ewert et al., 2020; Quigley, 2013). Mobile health apps/devices arguably are effective mechanisms to deliver nudges, because they are highly personal IT artifacts, nearly always close-at-hand, and capable of collecting and making visible detailed behavioral data. Nudges embedded into mobile health applications and monitoring devices attached to the human body (e.g., activity trackers or medical biometric devices) target health behaviors such as diet, exercise, sleep, stress reduction, chronic disease management, and so on (Lupton, 2013a, 2014). Nudges are typically based on the guidance of health experts and are materialized in a mobile health app as information displays, auditory alerts, visualizations, gamification rewards, recommended actions, and so on.

Nudges can be customized to user preference through the app interface or adjusted based on collected biometric and behavioral data, so that guidance is more personalized for specific

behaviors and situations (Mills, 2022). This is important for users' sensemaking and action-taking, because if a nudge is not personally relevant, is not delivered at the right time, or is too frequent, it may become an irritant, be ignored, or cause the user to reject the mobile app (Villalobos-Zúñiga and Cherubini, 2020). Apps make visible a variety of biometric data (e.g., heart rate, pulse), self-reported health measures or symptoms, and health-related activity data (e.g., exercise, diet, sleep). The user retains limited control over the visibility of the data, for instance whether to share health data with others (Deering et al., 2013). Nonetheless, mobile health apps and the health data they generate may be available to networks of organizations with societal interests in regulating individuals' health practices of individuals or in exploiting the economic potential of this intimate health data (Winter and Davidson, 2022; Yeh, 2018).

Research Design and Methods

Together, these literatures provide a theoretical foundation to investigate IT-based regulation systems in the voluntary regulatory context of personal health practices and mobile health apps. With this foundation we examined of the role of IT artifacts in individual-level self-regulation practices while also considering organizational actor networks that participate in these systems. Our first step was to identify a mobile health app that would support theorizing of IT-based regulation as a multilevel phenomenon. We considered a variety of apps from simple consumer apps, such as activity tracking or weight loss apps, to medical devices with associated mobile smartphone applications. We chose to study how individuals with Type 1 diabetes use a relatively new technology (continuous glucose monitors or CGMs) as a type of instrumental case (Slake, 1995). Relationships among practices, rules, and IT artifacts are strongly evident in this case, as CGMs provide vital information to support user practices for controlling glucose levels,

which is essential for immediate survival and managing long-term health outcomes (Klein and

Klein, 1998). CGMs are embedded in socio-technical networks of technology standards, cloud data storage, Internet connectivity, and mobile smartphones. The financing and authorization for CGMs involve networks of healthcare providers, insurers and government regulators, which are just now developing around other types of mobile health apps. Thus, CGMs serve as an instrumental case to examine an IT-based regulation system empirically and to explore the relevance and boundaries of extant theory in this context (Johns, 2017).

Data sources and collection

We engaged in a series of in-depth discussions with two CGM users who had recently adopted this technology. They related their experiences acquiring and adjusting to the CGM and reflected on the challenges of integrating the CGM to their self-regulation practices, including issues such as insurance reauthorization and obtaining replacements for faulty sensors. Their reported experiences flowed from initial adoption of the technology through routinized use over time. To supplement their experiential reports, we reviewed documentation related to the CGM devices on the vendor's website along with the privacy policies and insurance company policy documents related to CGM funding. An online discussion board in which posters seek advice or share experiences with acquiring and using the CGM provided additional insights on CGM user experiences. We reviewed 450 discussion threads with 4950 replies that were posted over three months for evidence of users' sensemaking and practices, some of which were consistent with those reported by our informants as well as some experiences our informants had not discussed.

Data analysis and presentation

To synthesize and analyze data, we chose the vignette method (Ely et al., 1997; Spalding and Phillips, 2007) to depict how CGM users encounter and respond to the CGM in their day-to-day glucose control practices. Vignettes have been used in experimental and survey studies,

particularly in health behavioral research, to engage research subjects and to elicit their responses (Jackson et al., 2015; Mah et al., 2014). Here, we developed the vignette as a descriptive analytical outcome (Blodgett et al., 2011; Langer, 2016). Vignette compiled across data sources can effectively present users' experiences in their own voices, while also highlighting researchers' analytical interests (cf. Oborn et al., 2011; Wessel et al., 2019).

We drew on de Vaujany et al.'s (2018) theoretical framework and the analytical device of regulatory episodes in an abductive process, iterating between the conceptual framework and data sources, including follow-up discussions with the CGM users, to develop the vignette narrative through five regulatory episodes. (See Table 1.) De Vaujany et al. (2018) define *regulatory episodes* as temporal and spatial contexts in which "involved actors reflect upon and discuss what they should do in terms of rules and the status of their compliance" (764). Episodes develop when the "plausibility and fidelity" of the three elements of the IT-based regulatory system (IT artifact, rules, practice) are called into question as "the flow of everyday activity is in some way broken and problematic for actors" (765).

Regulatory episodes present a flexible analytic device to examine the dynamic relationships among elements of the trifecta as a system's state shifts over time (de Vaujany et al., 2018: 765). Identifying and selecting regulatory episodes to study depends on the research goals and boundaries of the case or phenomena and on the range of actors to be included in the analysis. Here, we focused on the perspective of a prototypical user of a CGM system in their day-to-day practices and included their interactions with organizational actors involved in health regulation in the U.S. healthcare system, with its many complexities, and with aspects of the technology infrastructure and CGM data that underlie and support regulatory processes. Episodes followed a progression from users' initial encounters with the CGM system to its tentative

routinization. "Zooming in" to micro-level practices (Nicolini, 2009) highlighted how users elicit, make sense of, and respond in their practices to expert prescriptions (rules) materialized in the CGM system (IT artifact), whereas "zooming out" to organizational levels exposed regulatory processes that support or hinder effective self-regulation with the CGM system. We refined the episodes iteratively with critique from the informants to articulate clearly the emergent relationships between rules, IT artifacts, and practices across the episodes.

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Table 1: Regulatory episodes in the CGM system vignette

Key Practices	Key IT Artifacts	Key Rules	Examples from online discussion forum
Regulatory Episode 1: Acquiring the CGM system			
· Securing eligibility and funding for the CGM system · Securing CGM supplies	· CGM sensor and transmitter · CGM smartphone app · Smartphone · Glucose testing devices	· Government medical device regulations · Health system / insurer policies · Vendor warranty and support rules	· "I was just diagnosed with T1D at the age of 40 and everything is a fight. I have really good insurance but the amount of time and effort it has taken to get the meds and supplies I need is just too much." · "Insurance only approves every 30 days so how do I fill the gap?"
Regulatory Episode 2: Introducing the CGM into practices			
· Initiating CGM · Setting and adjusting alarms · Calibrating a CGM sensor · Assessing and responding to CGM nudges	· CGM sensor and transmitter · CGM app · Smartphone · Alarm features (sounds, buzzes) · Informational alerts/ displays features	· Expertise-based guidelines for glucose levels · Technical operation standards	· "I'd suggest not calibrating in the first 24 hours. Let it do its thing and get settled." · "I went through two months of getting [alarms] every night … waking me and my son and my wife … I'd apologize to them and walk downstairs so the second foghorn didn't bother them, and I'd watch my BG magically jump back up into range a few minutes later."
Regulatory Episode 3: Negotiating CGM system rules			
· Adapting or disabling CGM system alerts · Responding to CGM breakdowns	· CGM sensor and transmitter · CGM app · Smartphone · Glucose testing devices	· Alerts for unsafe glucose levels · CGM vendor tech support rules and regulations	· "Is there any other way to keep [CGM] from sending me an alert every 5-minutes that I'm over the threshold?" · "The [CGM] changed my life, but it still doesn't deserve the right to override/ignore our phone settings with information we might already know."
Regulatory Episode 4: Networking the CGM system			
· Integrating CGM system with other IT devices and apps	· CGM app · Health and wellness mobile apps · Smartphone	· Inter-operability standards · Health data protection rules and regulations	· "Since you're Android, you can only access the web app, which is probably pointless." · "On iOS, it allows users to add [CGM sensor] data to your calendar, so it shows up nicely on your Apple Watch."
Regulatory Episode 5: Living with the CGM system			

· Evaluating longitudinal data and adjusting behaviors · Integrating CGM system into daily life activities	· CGM system · Analytic algorithms utilizing CGM and other health data	· Workplace rules and regulations · Diabetes expertise and guidance	· "I got a new job and the beeps are very distracting, especially when it's telling me some BS like … 'replace sensor in 6 hours'." · "I can't use the [phone app]. I can't have my phone during work … I don't like being an exception because of diabetes." · "[Vendor] recently informed me that they won't be filling my orders directly anymore, and I'll have to switch to a distributor ."

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Practicing Diabetes Self-Management with CGM Systems

The following vignette is a compilation of experiences of adults with Type 1 diabetes using a CGM system, that is, the sensor device, its software and the associated smartphone mobile app. The five regulatory episodes are conveyed through the voice of a prototypical protagonist (Camille), as she makes sense of and navigates a variety of rules, some materialized in the CGM system as nudges to manage her glucose levels and some manifest in regulatory processes of organizations that control her access to the CGM system. As a guide to the reader, Figure 2 depicts key actors and highlights relevant data flows and regulatory relationships among relevant organizations and regulatory actors.

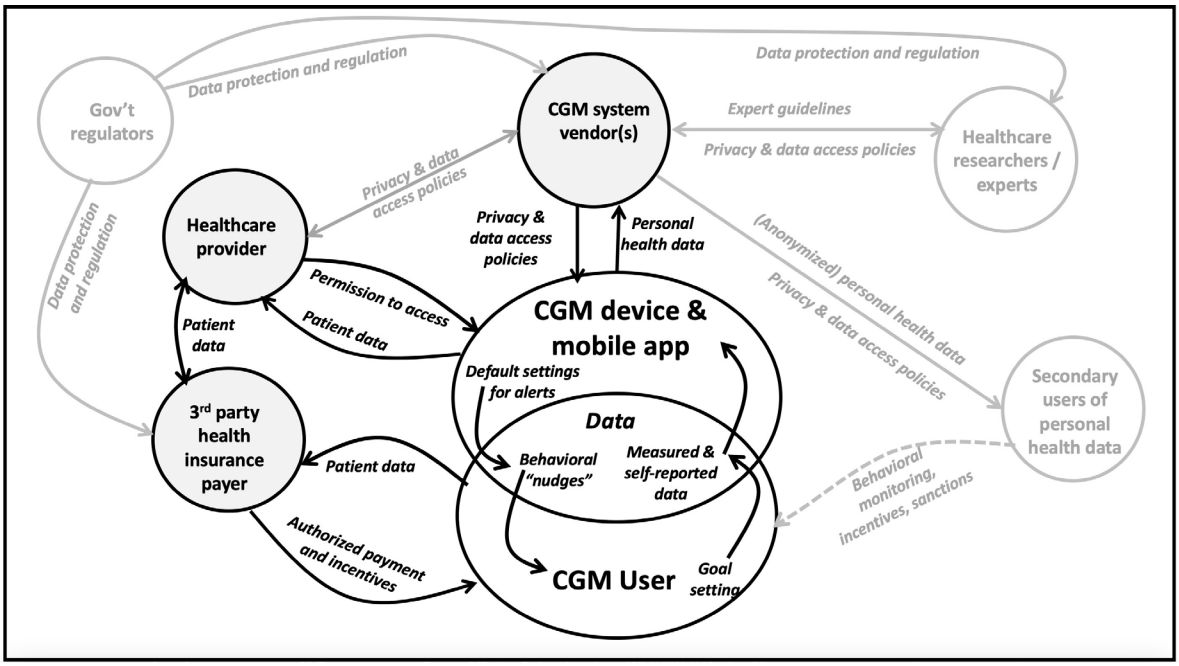

Figure 2. Actor network surrounding the CGM system in the U.S. healthcare sector

Background and setting

Camille has had type 1 diabetes–an autoimmune disorder that leaves her completely reliant on daily insulin injections to survive–since childhood. Without the insulin, she would effectively

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starve to death. Managing diabetes is a cybernetic process of acting to maintain glucose levels

within specified boundaries. Getting and keeping her glucose levels in control (within boundaries) with the correct amount of food and insulin is a constant and life-threatening challenge. Camille must always be attuned to bodily sensations that indicate a potentially life-threatening episode of low glucose (hypoglycemia) is pending or that her glucose is rising above the standard numbers for well-regulated diabetes, which over time can result in severe health complications. She also monitors her glucose level ("blood sugar") via self-administered blood tests and takes action if needed, such as consuming sugar to overcome a glucose low or injecting insulin to overcome a glucose high. She applies a small amount of blood to a test strip read by a digital meter. The meter provides a discrete number and keeps a log of her glucose levels. This sampling is limited to up to ten times per day, the maximum number of costly test strips her insurance company funds, and thus it fails to provide her a full picture of her glucose levels throughout a day.

Over the years, Camille has integrated glucose control practices into her life, for instance, discretely testing glucose levels when eating out, bringing a source of sugar with her to meetings, having a snack before exercising, and so on. Innovations with glucose monitoring systems have revolutionized diabetes control (Galindo and Aleppo, 2020). In particular, advanced CGM systems with real-time monitoring allow patients to see both their current glucose level and the rate of change over time via trend arrows, so they can be better informed about what actions to take to regulate glucose levels. The constant sampling data can also be analyzed to look for activities that may improve glucose control and diabetes regulation over time.

Regulatory Episode 1: Acquiring the CGM system

Before her regular appointments with her endocrinologist, Camille goes to a lab to test her

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HbA1c, a measure of glucose control over the past three months. This test informs her

endocrinologist about her glucose control over several months, so that he can determine whether she is within the ideal range to avoid severe health complications that accrue over time. Medical researchers establish what this ideal range is, though Camile is aware that guidelines change and there is not always consensus about target ranges. Undergoing the HbA1c test regularly and having an HbA1c within guidelines demonstrates to her physician and her health insurer (which helps funds diabetes health care costs) that Camille is complying with diabetes self-management best practices (Shrivastava, Shrivastava, and Ramasamy, 2013).

At a recent appointment, Camille's endocrinologist examines her health history and current HbA1c value and notes that she could improve the regulation of her disease. He thinks she is a "good candidate" who would benefit from CGM and asks her specific questions from a checklist to determine whether she meets her insurance plan's criteria for coverage of this costly device. Her answers indicate that she does, and Camille expresses interest in adopting the CGM system. The doctor then shares her relevant personal health data with her insurer to confirm her eligibility. This data exchange is regulated by a health data protection law, including the requirement for her written consent to share her health information with the insurer[1]. The CGM vender has recently been approved by the U.S. federal agency that monitors the safety of medical devices and must comply with this law as well. These data protection regulations, intended to safeguard individual privacy, give Camille some assurances that her sensitive health data will be handled appropriately by the CGM vendor.

Camille realizes that, due to the high initial and ongoing costs of a CGM system, she will have to navigate a network of health care providers, health insurers, and vendors that regulate

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[1] In the U.S., the Health Information Portability and Accountably Act (HIPAA) regulates privacy of clinical health data exchange. Other nations have similar laws that protect personal health information specifically or through comprehensive personal privacy regulations such as the European Union's General Data Protection Regulation (GDPR).

patient access to these useful devices. Her endocrinologist mentions that the CGM firm will contact Camille and her insurer will lower the allocated number of finger test strips from 10 to three per day when she gets the CGM. Six weeks later, Camille receives a phone call from a representative at a medical supplier firm. The representative explains that her insurance company will need to authorize coverage for the CGM system. The representative asks Camille for a log of the last month of her glucose readings. Fortunately, she has these data available, and she imports readings from her glucose testing device into a spreadsheet. Once Camille sends this personal health data to the representative, she waits for confirmation while he works with her insurance company to verify that her self-reported data along with her physician's assessment meets the insurer's policies for CGM system coverage[2].

After approval by the insurance company, Camille finally receives a three-month supply of the CGM's adhesive sensors and transmitters directly from the CGM vendor. Under her insurance plan, she learns she will have to share her personal health and usage data with the insurer periodically to continue payment authorization. The data generated by the CGM system will make visible to the insurer Camille's detailed blood glucose readings. The insurer can use this data to assess whether she is benefiting from the system by using it frequently and by complying with expert guidance for glucose control, and thus to decide whether it is cost-effective for the firm to continuing subsidizing her CGM system costs.

Camille initially navigates the insurer's rules successfully to receive her first shipment of sensors, but she continues to be challenged to elicit and make sense of the insurance firm's arcane rules that allow (or could inhibit) her continued access to the CGM system. Her second

[2] Although the cost of diabetes supplies accounts for only 1.1% of the $327 billion annual healthcare costs associated with

diabetes care in the U.S. annually, many 3rd party payers (Medicare, Medicaid, large private insurers) focus on cutting supply cost, e.g., by limiting payments for test strips to three per day. These 3rd party payers typically limit eligibility for CGM coverage to patients with type 1 diabetes and a history of using over 4 strips a day for testing (Anderson, Gavin, and Kruger, 2020).

three-month shipment of sensors is delayed for several weeks while her insurance company appears to deliberate whether to re-authorize coverage for the device. After several phone calls to the CGM system vendor, her doctor, and her insurance company, Camille is finally directed to generate a report based on the granular data from the CGM companion app and send this to her health insurer. This report shows all data collected by the sensor, including glucose levels and the percentage of time each month she has worn the device, which she suspects is linked to her insurer's invisible (to her) criteria for continued coverage. Weeks later, just after initiating her last sensor, she is relieved to receive approval for more sensors.

Analytic summary: This episode zooms out to the organizational regulatory network surrounding Camille's access to the CGM system. Her physician, her health insurance company, government agencies that approve heath technologies and provide evidence-based guidelines, the vendor that provides the CGM system all have roles in regulating the personal health behaviors of persons with diabetes, as well as in managing healthcare system costs. Camille must elicit their rules through organizational representatives or online information sources and determine how to comply with them. Detailed personal health data collected and stored in the CGM system serve as indicators of her glucose control practices that activate organizational practices and rules for authorizing her access to the CGM system. Health data protection regulations become salient to Camille through consent agreements she must accept so that data flows can take place.

Regulatory Episode 2: Introducing the CGM system into practices

Camille has been managing her blood glucose level for many years by constantly monitoring her body, her cognitive clarity (which is affected by low and high sugar), whether she has eaten or exercised recently (or plans to), and by taking measures to correct a "low" or a "high." A "finger

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prick" blood test reveals her glucose level at a particular moment, which she makes sense of

along with her self-awareness of her body's state to decide what actions to take to maintain her glucose level within the expert-prescribed range. With greater visibility into her body and her glucose levels via the CGM, Camille hopes to enhance her practices to forecast and to maintain glucose levels for better diabetes control.

After receiving her first shipment, Camille carefully reads the instructions for installing and using the CGM system. Every 10 days she must apply a small sensor with a subcutaneous cannula (a thin tube inserted under the skin) to her abdomen. When installed correctly an attached transmitter will send data from the CGM sensor to an app on her smartphone via Bluetooth technology, so that she can view real-time data about her glucose levels. As she sets up the CGM app, she is guided through a privacy policy that she must accept to use the device and basic instructions for connecting the sensor to her body and the transmitter to her smartphone. Unless she removes the monitor, it will measure her glucose levels every minute and transmit this data to the mobile app on her smartphone whenever it is in proximity. The mobile app stores the data on her phone and also transmits data to the CGM system vendor's IT cloud infrastructure. Camille is not entirely comfortable that these data give the vendor detailed visibility into her body, but she has no choice if she wants to fully benefit from the device's capabilities. She takes some comfort in knowing that health data protection regulations hold the vendor accountable to protect her personal health data.

After she applies the first sensor and waits through a warm-up period, Camille is excited to see her glucose values in real time. (See Figure 3). Later, she is also able to view several hours of recent readings in the app display. The CGM app interprets the data transmitted from the device attached to her body to determine whether the readings are within the recommended range. Auditory notifications (alerts) sound when her glucose level is too low or high compared

to the expert-specified range, or when it is rapidly rising or falling. Directional arrows displayed on the smartphone app indicate whether her glucose is stable, rising, or dropping. These informational nudges transmit expert guidelines to Camille based on her body's real time data and supplement her awareness of her body's state, making it easier to take the right action, such as adjusting her insulin injections or exercise to stay within the expert-prescribed range.

Camille, who understands the rules for glucose control well after years of self-regulating diabetes, soon realizes the CGM system's nudges do not always align with her own self-awareness of her body's state, for instance signaling a "low" when she is not feeling "low". This triggers her sensemaking about how to respond to rules manifest in the CGM system. For instance, she consultis with other users in an online CGM discussion forum. She learns that others also experience inaccurate readings on occasion, that faulty sensors are not uncommon, and that the sensor's placement on her abdomen and the position of her body during sleep can affect readings. Reflecting on their experiences and her own, Camille realizes that she will need to continually assess the CGM system's data and alerts in combination with her haptic awareness to decide whether and how to comply with the device's nudges. Nonetheless, with this new visibility into her body's functioning, Camille expects to modify her day-to-day practices to manage glucose levels more closely and continuously. She also hopes that the CGM system will shift some of the cognitive burden of monitoring glucose levels to the mobile health app and its analytic systems by providing her with accurate, timely nudges.

Analytic summary: This regulatory episode zooms in to the micro-level relationships among the trifecta of rules, IT artifact, and user practices, while the regulatory processes evident in Episode 1 become less salient to Camille, for a time. The CGM system assesses when expert prescriptions and guidelines (rules) apply based on the data it collects continuously from

Camille's body, and then brings rules to Camille's attention as informational nudges in displays, notifications, and auditory alerts. As she explores the CGM system's capabilities, the continuous, detailed data about her body enhances, but also challenges, Camille's sensemaking about whether and how to comply with the system's informational nudges by taking an action.

Regulatory Episode 3: Negotiating CGM system rules

Like other users on the CGM forum, Camille finds the auditory alarms can be irritating and disruptive, particularly when they are triggered by misleading readings or device maintenance issues like low battery warnings. Alarms are intended to warn her when her glucose level deviates from the prescribed range (Figure 4), but she would like to reset ranges to those she knows from experience work for her. Camille tries customizing alarms in the CGM app interface, and after tinkering with it, she can adjust some alarms to her preferences but is constrained to stay within specified ranges for others. For instance, the alarm for very low glucose levels cannot be adjusted or turned off, even if her phone is on mute or "do not disturb." She speculates this is due to the CGM vendor's concerns about product liability.

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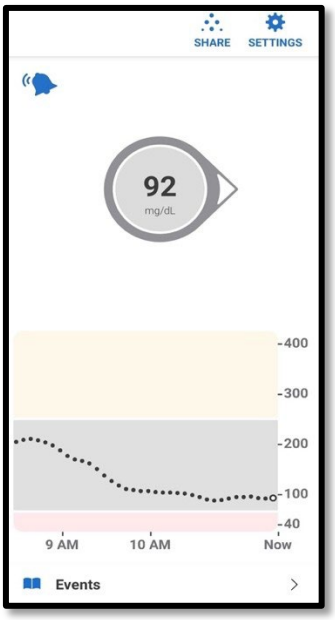

Figure 3: Real-time glucose readings over time

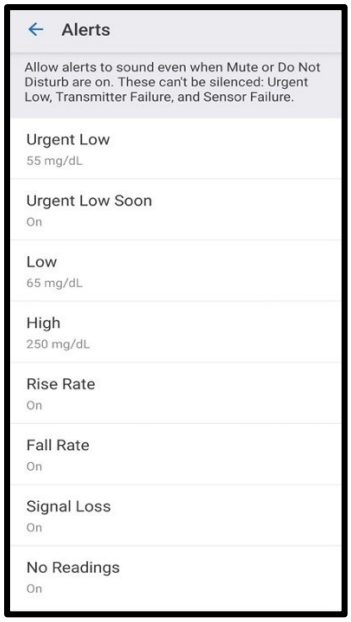

Figure 4. CGM alarm settings

While Camille can negotiate to a degree with the CGM system about what alerts and alarms she receives, she cannot influence what data the CGM sensor takes from her once it is affixed to her body. This means she must accept some intrusive auditory alerts unless she removes the sensor or shuts off her smartphone entirely. Camille has been kept awake all night when the app repeatedly sounds a shrill alarm indicating that she is heading towards a dangerously low glucose episode. Before responding to this alert, she determines this is not the case through a finger-prick blood test using her manual glucose reader, but the CGM system continues to sound disruptive alarms that cannot be muted. She is concerned about disturbing family members and spends several hours in the living room trying to troubleshoot the device. Camille decides her only option is to take off the sensor and begin the two-hour process of attaching and starting up a new one. The sensor is wasted and will need to be replaced.

Camille realizes she will have to convince the CGM vendor that the sensor was defective

to get a cost-free replacement. She begins this process early the next morning when she calls the

manufacturer's technical support line. She is asked a series of questions about where she placed the sensor, what position she sleeps in, and what over the counter medications she is taking. Camille is unhappy to learn that the technician in a remote call center can view data collected by her CGM system at its most granular level. After agreeing the sensor was malfunctioning, the technician tells Camille a replacement will be sent to her, but to get a replacement sensor in future, she must adhere to the vendor's warrantee replacement rules: She must report specific details about the sensor online or via a phone call, calibrate the device if she feels that it is not accurately measuring her glucose values, and call technical support before removing a malfunctioning sensor. The requirement to calibrate multiple times concerns her, as this would deplete her limited supply of the costly finger test strips for her older glucose monitor.

Analytic summary: This episode zooms in to the micro-level as Camille must make sense of how rules (expert guidance) are materialized in the IT artifact (the CGM system) and elicited as informational nudges (alerts) in response to data (glucose readings), in order to make sense of the relevance of the nudge to her self-regulation practices. She can alter how some rules are materialized, but other adjustments (e.g., removing a faulty sensor) trigger the trifecta of vendor warranty practices, rules, and information systems that she must also navigate. Data flows between her CGM system and the vendor's information systems link her practices to the CGM vendor's user support practices.

Regulatory episode 4: Networking the CGM system

Camille knows that the CGM sensor and its mobile app must be compatible with her smartphone to be effective for her. Compatibility depends on the CGM vendor keeping up with technical standards and rules, which are invisible to her (and most users) until something "breaks". This

happens when she upgrades her smartphone's operating system, and again when she upgrades

the phone. The CGM app is no longer compatible with her smart phone. She finds a technical workaround on the CGM user forum – a modified app that will work with her phone. However, she worries that if she shifts the configuration of her smartphone again, the CGM system may again no longer sync through the phone's application programming interface (API).

Camille considers how she could integrate the CGM system with other mobile health apps to more effectively support her glucose control practices. For instance, she knows she could integrate data automatically with other health mobile apps (e.g., the Apple or Samsung health apps and monitors) via the CGM system's API. This would allow its algorithms to assess her health behavior patterns more accurately and give her more nuanced, personalized nudges on how to improve diabetes self-regulation practices such as exercise or weight management. On reflection, she decides against mixing protected health data like glucose readings with data from consumer devices at this time, as she knows these apps do not share the same levels of data protection regulation. While this is an important concern for her, she observes that most users on the CGM user forum seem to be unaware of, or unconcerned about health data privacy tradeoffs.

Analytic summary: This episode zooms out to the fragile technological network of app developers, technology firms and government regulators that Camille must rely on for effective CGM use. Key technology protocols (rules) are invisible to Camile unless she unknowingly violates a rule by altering her own technical artifacts. Data integration that could enhance the CGM system's effectiveness for her would also allow personal health data to flow across borders for protected health data regulation with uncertain consequences for her privacy. (See Figure 2.)

Regulatory episode 5: Sustaining the CGM system effectiveness

After several months of her using the CGM system, Camille's doctor notes that her HbA1c has

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improved, indicating improved self-regulation of glucose levels. Camille reflects on how the

CGM system has helped reduce the constant cognitive overhead of keeping track of her glucose level and forecasting how her actions will affect it, but she sometimes worries that her practices for assessing body states and moods might diminish as she increasingly relies on the CGM system to tell her how her body is responding and what actions to take.

As day-to-day use of the CGM system becomes more routine, Camille considers how to make more progress by using the detailed, longitudinal data the system collects and analyzes. The CGM phone app provides Camille with charts of her glucose levels over time (daily, weekly, monthly) (Figure 5) and estimates her HbA1c from these data. The app uses these data in conjunction with expert guidelines to nudge her with customized recommendations for further improving her glucose control practices. For example, the companion app sends her an update about her "best day" of compliance each week to learn from. She also receives suggestions if the companion app detects a pattern, such as frequently elevated glucose at a particular time of day. These informational nudges direct Camille's sensemaking towards how she might adjust her current glucose control practices to better conform with expert guidance and then to assess effectiveness of these adjustments over time. She is motivated to be compliant, because the long-term health benefits are compelling to her.

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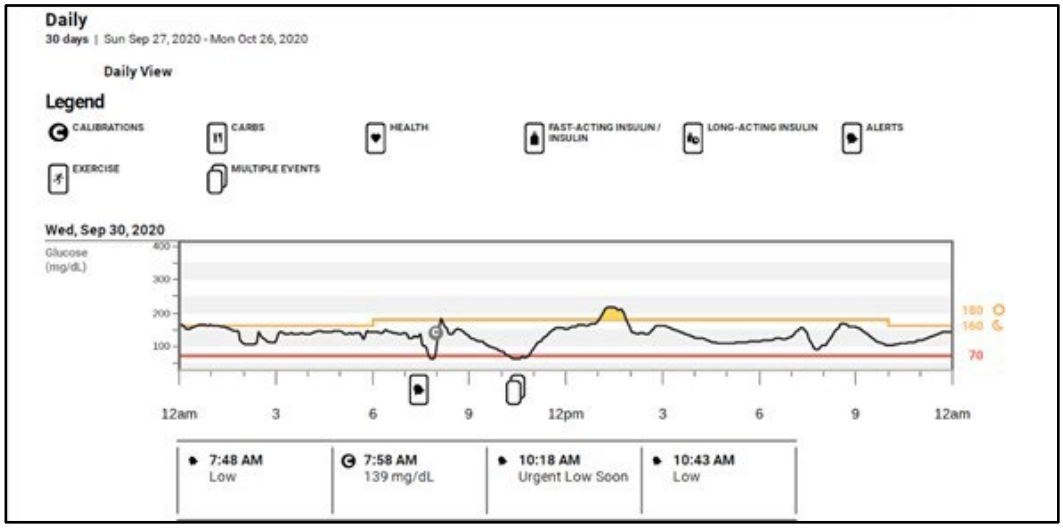

Figure 5. CGM companion app daily chart of glucose levels

Camille is also learning how to balance her reliance on the CGM system's nudges with social and workplace constraints on her uses of it. She sometimes must deal with its disruptive alarms while she is at work. On several occasions she has disclosed details about her health to colleagues while in meetings to explain the loud alarm. She has a job that allows her to keep her smartphone with her, but she knows from the online CGM user forum that some users must deal with workplace rules that restrict smartphone use on the job. In her social life, for instance at the movies, she worries that an auditory alarm would disrupt others, so she sometimes turns her smartphone off to prevent this from happening.

Camille has also read on the CGM user forum about ongoing problems with health insurers, the CGM vendor, and distributors of sensors. She negotiated organizational rules successfully to gain access to the CGM system, but she realizes that she must be prepared to deal with changes in their rules and practices to maintain her self-regulation practices for diabetes, now centered around her use of the CGM system. She worries, for instance, if her personal health data, which she periodically provides to the insurer for reauthorization, might somehow disqualify her in the future, if the insurer determines her self-care practices, imputed from the detailed glucose level data, do not merit renewal of her financial coverage.

Analytic summary: This regulatory episode highlights the ongoing interplay of micro-level and macro-level processes in IT-based regulation. The CGM system becomes an increasingly effective regulatory system in Camille's individual-level practices, but she then depends increasingly on her ability to adjust to macro-level regulatory processes within networks of organizational actors to support and maintain her efforts.

Discussion

In this paper we examine user experiences with a mobile health app to manage their personal health as an instrumental case of voluntary IT-based regulation. Following de Vaujany et al.'s (2018) lead to systematically probe recursive relationships among rules, IT artifacts, and practices, our exploration of five regulatory episodes of CGM-enabled diabetes self-regulation illustrates how IT-based regulation emerges through these relationships. Regulatory Episode 2 (Introducing the CGM system into practices) and Episode 3 (Negotiating CGM system rules) highlight at the micro-level the recursive relationships between how glucose control guidelines (expert rules) are materialized in the CGM system (IT artifact), how these are elicited and communicated to the vignette protagonist as informational nudges via alerts and displays, and how nudges influence her sensemaking about what actions to take to control glucose level (practices). At the same time, nudges stimulate the protagonist's sensemaking about how rules are materialized in the IT artifact and her altering how and when rules are elicited (via settings in the CGM app interface), so that the rules elicited become more relevance to her practices.

The glucose readings collected and displayed by the CGM system afford Camille detailed and continuous visibility into her body and how her actions affect glucose levels, well-beyond the visibility she had in the past. These continuous data are key to the CGM system's *effectiveness* in transforming diabetes self-regulation (Anderson et al., 2020), though control is never fully predictable or controllable with bodily functions and disease (Mol, 2009). With IT features such as auditory alerts and graphs derived from detailed data, Camille can adjust her immediate actions and longer-term practices to improve her immediate and longer-term health. We suggest that these data-enabled nudges (Thaler and Sunstein, 2008), communicated via mobile health apps/devices, present *regulatory affordances* for an individual seeking to manage personal health. Simply stated, an affordance is "the potential for action that new technologies

provide to users" (Leonardi and Vaast, 2017: 152). De Vaujany et al. (2018) posit that IT affordances span capabilities of the IT artifact, practices, and rules in IT-based regulation systems. We identified two related individual-level affordances in this case.

First, a *predictive affordance* supports Camille's goals to proactively manage glucose levels at any particular point in time, by providing her with real-time, continuous readings from the sensor and automatic, customized notifications based on her own data and settings that alert her when she is moving outside prescribed glucose levels. The heightened granularity and frequency of data and the immediacy of nudges direct her to take actions to enhance her cybernetic regulation of glucose levels *at a point in time*. Second, a *surveillance affordance* supports Camille's goal of avoiding future health problems by maintaining cybernetic control *consistently over time*. The CGM system provides Camille with informational nudges using detailed data accumulated over the past week or month (Episode 5), and she can enrich the types of data available to the CGM app's algorithms by networking it with other health apps (Episode 4). These analytic features of the CGM system enhance her ability to surveil herself and to evaluate whether she is complying with expert guidelines consistently across time and circumstances. She may then adjust practices and self-monitor to see if changes are effective at improving her diabetes self-regulation, as indicated by estimated HbA1c results.

Regulatory Episode 1 (Acquiring the CGM system) and Episode 4 (Networking the CGM system) shift analytic attention from the protagonist's phenomenological experience to the macro-level of organizational actors that enable and support, but also can hinder, effective voluntary regulation. These episodes explicate how the focal trifecta of the protagonist's self-regulation using the CGM system is entangled with organizational trifecta in an evolving network of regulatory actors and actions. In Regulatory Episode 1, Camille must elicit and then

comply with the insurer's rules that grant or limit funding, and in effect, her access to the CGM system. Episode 4 explores macro-level entanglements arising in the networks of CGM manufacturer, mobile app developers, and smartphone vendors that influence whether the CGM system can operate effectively for Camille. These macro-level trifectas are largely invisible to Camille unless regulatory processes disrupt her micro-level trifecta.

To explicate how multilevel networks of trifecta are instantiated and evolve in IT-based regulation, we develop the concept of a *regulatory lattice*. The lattice might be thought of as a type of fractal model (Zimmerman and Hurst, 1993) in that it develops, expands, or fades away in patterns of trifecta composed of practices, IT artifacts, and rules related through sensemaking, materialization and elicitation processes. (See Figure 1.) At the micro-level, trifectas are contextually situated enactments of IT-based regulation. For instance, Camille self-regulates her glucose level using the CGM system to inform her practices in conformance with expert prescriptions, whereas at the organizational level, the CGM vendor representative uses the firm's information system to apply the vendor's policies and rules to determine her eligibility for services. A *regulatory lattice* takes form as linkages develop among micro-level enactments of trifecta, functioning as a loosely assembled collective of individual and organizational IT-based regulatory systems. Thus, when Camille encounters a faulty sensor and contacts the CGM vendor for a replacement, the vendor's rules and practices for warranty services are activated. The IT artifact (CGM system) participates in both Camille's and the CGM vendor's trifecta conceptually as the object of shared interest and materially as the data from Camille's CGM system are made available to the vendor's information system to evaluate Camille's warranty claim. The lattice surrounding Camille's use of the CGM system evolves further as such linkages are activated or deactivated in ensuing regulatory episodes.

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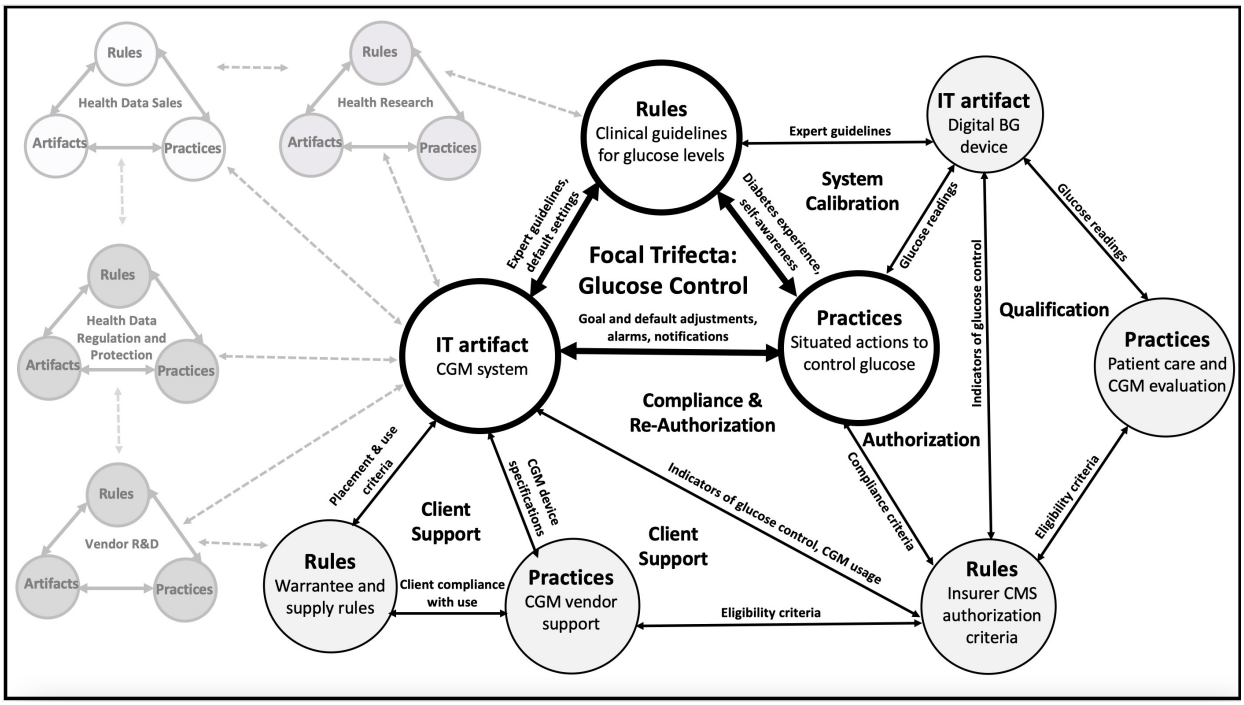

Figure 6: Lattice of key regulatory trifecta surrounding focal CGM system trifecta

Figure 6 depicts the regulatory lattice exposed in the five episodes of Camille's vignette. From the perspective of the protagonist in the focal trifecta, organizational trifecta in the lattice become visible to her when linkages are activated and then fade when linkages are no longer active or salient. Some trifectas depicted in Figure 6 may remain distant or even invisible to her, such as a firm's practices for complying with data protection regulation. (See Figure 2.) Whether visible or not, the regulatory lattice influences Camille's effective use of the CGM system in the focal trifecta. Data collected in the focal trifecta flow across trifecta as individually identifiable data for the insurer, physician, or distributor or as deidentified, aggregate data for health researchers, device manufacturers, and so on, thus serving as material resources to establish linkages among trifecta that instantiate and support the regulatory lattice. Episode 5 (Sustaining the CGM system effectiveness) suggests that a regulatory lattice surrounding the focal trifecta

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may reach a provisionally stable state but that maintaining effective IT-based regulation requires

the focal actors to continuously monitor and adjust as new linkages with organizational trifecta are instantiated or earlier linkages are reactivated due to disruptions, breakdowns, or changes.

Implications for Theory

In this study, we draw on de Vaujany et al.'s (2018) theoretical framework for organizational IT-based regulation systems to consider how regulatory systems operate in open and distributed contexts in which actors that are subject to regulation have strong agency (choices). In these settings, regulatory processes are for the most part indirect and putatively voluntary, so that regulatory effectiveness depends on individuals' willing compliance with rules rather than enforcement or coercion. This setting allowed us to explore the contextual boundaries of de Vaujany et al.'s organizational-level theory (Johns, 2017), to demonstrate the analytic power of the framework to investigate multilevel regulatory systems, and to motivate use of the trifecta model (Figure 1) to investigate voluntary IT-based regulation systems in a variety of contexts.

Our study highlights areas for theoretic extensions and for further research. To begin, we suggest that integrating components of nudging theory related to human information processing, decision making and choice architectures could complement the sensemaking perspective articulated in the de Vaujany et al. (2018) framework. Rules materialized in IT artifacts can be elicited as customized, targeted informational nudges to direct user actions to comply with regulations (Baldwin, 2014; Lorini and Moroni, 2020; Quigley, 2013; Renaud and Zimmermann, 2018; Sunstein et al., 2019). We identified two regulatory affordances relevant for self-regulation (*predicting* and *surveilling*) and noted that specificity of the data and timing of informational nudges were critical to the user's sensemaking and compliance with guidelines. Nudging strategies can also be viewed as manipulative or as prioritizing the interests of actors doing the

nudging over those actors being nudged (Schmidt and Engelen, 2020). In our case, nudging is

effective because the protagonist willingly complies with the discipline of diabetes self-management to enhance her prospects for a longer, healthier life. However, episodes 1 and 5 hint at conflicts in interests, such as the insurer's interests in healthcare cost containment versus Camille's goals for accessing the CGM system regardless of costs. Accounting theoretically and empirically for the goals that motivate voluntarily compliance with regulatory nudges and the potential for conflicts in actors' goals and interests within and across trifectas (Figures 1 and 6) could enhance the explanatory power to this approach to explore regulatory effectiveness.

We develop the concept of a regulatory lattice of trifecta to more fully articulate Vaujany et al.'s (2018) view that regulation has "shifted from institutionally enforced social forms of regulation to complex technologically mediated operations, which have rendered regulatory processes fragmented and complex and changed their spatial and temporal dynamics" (756). The lattice concept depicts IT-based regulation as evolving fractal patterns of trifecta of practices, rules, and IT artifacts and aligns with de Vaujany et al. (2018)'s arguments that IT-based regulation develops through regulatory episodes. The lattice concept thus serves as an analytic device to ground the empirical study of multilevel regulatory systems. The lattice concept should not be construed as a structure to be uncovered but rather as shifting relationships that extend around a focal trifecta. The relationships revealed through empirical study will depend on the regulatory episodes examined, the perspectives of key actors, and the challenges to the plausibility and fidelity of regulatory processes that these actors encounter. The lattice exposed through our vignette (Figure 6) centers on the focal trifecta of glucose regulation using the CGM system and grows with the protagonist's experiences in the complex regulatory environment of the U.S. healthcare system. Selecting a different focal trifecta or focusing on different regulatory actors would reveal a different lattice.

"Following the data flows" that activate linkages between trifecta, particularly linkages that are temporally and spatially distant from the focal trifecta, could reveal evolving patterns in how IT-based regulation systems function and how regulatory effectiveness develops, is maintained, or diminishes. Building on de Vaujany et al.'s (2018) articulation of IT capabilities and regulatory feedback loops, we argue that data have an analytically distinctive role in IT-based regulation systems. The predictive and surveillance affordances Camille experiences depend on the specificity, timeliness, and granularity of the data that the IT artifact collects, processes, shares, and analyzes. For organizational actors that are temporally and spatially distant from the focal trifecta, such as diabetes researchers, the visibility that CGM data affords into the daily experiences of persons with diabetes could contribute to new expert prescriptions and norms for self-care practices. Such regulatory effects can rebound to the micro-level as revised rules and guidelines, derived from data generated and extracted from enactments of trifecta, and materialized in the IT artifacts (Mol, 2009).

Implications for policy and practice

Our empirical study of continuous glucose monitoring is situated in the context of health promotion and public health regulation. In our analysis, the timeliness and depth of personal health data and the specificity of nudging advice delivered via the mobile app contribute to its effectiveness in this voluntary regulatory setting. These factors are present, to some degree, in other contexts involving mobile health apps, suggesting that informational nudges that present predictive and surveillance affordances to users could be effective in other personal health practices. Data-informed nudging strategies are widely endorsed in healthcare and public policy domains although their effectiveness at altering personal health behaviors has not been

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demonstrated conclusively (Prainsack, 2020; Quigley, 2013, Rowland et al., 2020). Thus,

additional study will be needed to assess when and how informational nudging delivered via mobile health apps can be effective in achieving public health regulatory goals.

The vignette of Camille's experiences with the mobile health technology (CGM system) depicts a generally positive outcome for an engaged, competent technology user. However, the experiences of persons with diabetes who use self-monitoring technologies vary widely. Some struggle or are overwhelmed trying to live up to normative expectations about self-care and self-monitoring practices; the need to also make sense of a complex IT artifact like the CGM system could heighten cognitive and emotional burdens for these individuals (Lupton, 2013a, 2013b; Mol 2009). Mobile health technologies alone, and the informational nudges encoded in them, will not provide sufficient support for all patients. CGM users who are not as knowledgeable about expert-prescriptions as our protagonist, such as persons recently diagnosed with diabetes, need significant support and education to adopt self-regulation practices and to effectively utilize IT tools that support these practices (Higa et al., 2021; Kelley et al. 2011).

An increasingly important policy question is how personal health data generated by mobile health apps and accessible in a vendor's information systems should be regulated so as to promote their use in health care research and for health system innovation, while also protecting individuals' privacy rights (Brown, 2016; Price and Cohen, 2019; Winter and Davidson, 2022; Yeh, 2018). Drawing on the concepts of regulatory trifecta (Figure 1) and of regulatory lattices that evolve around mobile health apps (Figure 6), could help identify gaps in how personal health data are regulated across trifecta as well as point out burdensome regulatory bottlenecks in data flows that inhibit desirable healthcare innovation.

Conclusions

In this paper we consider the growing use of mobile health apps for self-regulation of personal health behaviors from the theoretical perspective of IT-based regulation systems. We draw from de Vaujany et al.'s (2018) organizational-level theory to study how IT artifacts can become embedded in a user's voluntary regulatory practices and how multilevel networks of rules, IT artifacts, and practices (trifecta) can influence regulatory effectiveness. We selected the study context (CGM system use by persons with diabetes) as an instrumental case to advance theorizing about IT-based regulation. Self-management of diabetes is more demanding than many personal health practices, but the phenomena we address are not limited to this setting, and mobile health apps targeting a wide variety of personal health practices abound. The theoretical and practical implications developed from this instrumental case can provide a useful analytic lens in studies of other contexts of mobile health apps and personal health regulation.

Our study suggests that de Vaujany et al.'s (2018) theoretical framework for IT-based regulation systems and the analytic insights we develop here will be useful in research into a wide range of regulatory regimes (Orbach, 2012). In addition to mobile smartphone applications that collect data on individuals' actions, IoT networks deployed throughout homes, businesses, and public spaces are accumulating vast volumes of data on individuals' and organizations' activities. These data can (and will) be used to assess how individuals and organizations respond to regulatory policies and to develop regulatory strategies, based in part on informational nudges embedded in IT artifacts. The potential of such data-enriched IT-based regulation to promote compliance across a population of users to beneficial regulations (such as energy conservation) is compelling, as is the darker vision of IT-based regulation that "reaches into the very grain of individuals, touches their bodies and inserts itself into their actions and attitudes, their discourses, learning processes and everyday lives" (Foucault, 1980: 30). The theoretical and

methodological approaches we articulate in this paper will, we hope, contribute further insights as the IS field investigates these contrasting visions of IT-based regulation in settings in which behavioral monitoring is pervasive (Zuboff, 2015) and individuals are increasingly subjected to oversight and monitoring of voluntary regulatory actions by a host of organizational actors.

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