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Research and Applications

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Improving the design of California's prescription drug monitoring program

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ABSTRACT

Objective: The US CDC identified prescription drug monitoring programs (PDMPs) as a tool to address the contemporary opioid crisis, but few studies have investigated PDMP usability and effectiveness from the users' perspective. Even fewer have considered how practices differ across medical domains. In this study, we aimed to address these gaps, soliciting perspectives on PDMPs from providers contending with the opioid crisis: physicians working in emergency departments (EDs) and pain management clinics. We aimed to provide practical design recommendations to improve PDMP workflow integration, as well as controlled substance history retrieval, interpretation, and decision support.

Methods: We conducted 16 in-depth semi-structured interviews with practicing emergency and pain physicians regarding their procedures, problems, and proposed solutions surrounding their use of CURES, California's PDMP. We investigated design problems in CURES by combining users' feedback with our usability inspection, drawing upon an extensive body of design literature. Then, we generated alternatives using design methods.

Results: We found CURES's design did not accommodate the unique information needs of different medical domains. Further, clinicians had trouble accessing CURES and retrieving patients' controlled substance histories, mainly due to usability problems that could be addressed with little technical adjustment. Additionally, CURES rendered patient histories in large, cluttered tables, devoid of overview or context, making interpretation difficult and precarious. Lastly, our interviewees had rarely noticed or used advanced features, such as decision support.

Discussion and Conclusion: Usability barriers inhibited adoption and effective use. We provide practical recommendations for improving opioid control by way of improving PDMP design, based on interviewees' suggestions and research-based design principles. Our findings have implications for other disciplines, including surgery and primary care.

Key words: prescription drug monitoring programs, user-computer interface, pain management, emergency medicine, California

INTRODUCTION

In 2016, the opioid crisis claimed 91 lives in the United States every day on average.[1] The US Centers for Disease Control (CDC) advised prescribers to minimize patient harm, in part by using prescription drug monitoring programs (PDMPs).[2] As of this writing, PDMPs across the US provide physicians with access to patients' controlled substance prescription and dispensing history. PDMPs operate at the state level; each state determines which controlled substances are monitored, who may access the data, whether the data can be shared

with other states, and who must review the database at what times. Each PDMP collects, monitors, and analyzes prescribing and dispensing data, electronically submitted by pharmacies and dispensing practitioners. The data can be then used by healthcare professionals, regulatory boards, and law enforcement agencies, with the aim of improving patient care and reducing prescription drug misuse and diversion. In 2014, all states in the US (except Missouri), in addition to the District of Columbia and Guam, had enacted legislation authorizing PDMP creation and operation, and now have an operational PDMP.[3] California's PDMP has been named the Controlled Substance Utilization Review and Evaluation System (CURES), and it is maintained by the California Department of Justice. California law now mandates all pharmacists and healthcare providers who are licensed to order, administer, furnish, or dispense Schedule II–IV controlled substances to register in the system.[4] The California Department of Justice now mandates those prescribing or furnishing opioids to first consult CURES, effective October 2, 2018.[5]

Numerous reports in the literature[6–9] have written about PDMP usability barriers which impeded emergency, pain management, primary care, and surgical physicians nationwide as they attempted to retrieve, interpret, and integrate patients' controlled substance histories. According to the field's eponymous book, many in biomedical informatics recognize that usability problems can create inefficiencies, and that they can even threaten patient safety.[10]

Leichtling et al.[6] found differences in information-seeking practices between short-term (eg, ED) and long-term (eg, pain management, primary care) opioid prescribers; differing needs must be accounted for in PDMP design. Leichtling et al. restricted their study to PDMP use; they did not aim to inform design directly. Finley et al.[11] solicited design suggestions from clinicians in a military health setting. As theirs was a foundational work, many of the suggestions they gathered, such as "easy to use" and "automated to minimize provider burden," were quite vague.

We aim to provide thorough, specific critique and recommendations that PDMP developers and regulators will find useful. In this article, we describe how we conducted a qualitative study to better understand the issues that physicians encountered, and we investigated CURES, the California PDMP implementation, using both physicians' perspectives and literature-informed design principles. We analyzed the data to identify design-relevant themes. We chose to include emergency and pain management physicians as a starting point for comparison. Specifically, they allowed us to compare short- and long-term patient management, respectively. They also allowed us to compare settings where workloads fluctuate as emergencies arise with settings where workloads are scheduled in advance.

METHODS

Recruitment

We recruited physicians practicing in three academic medical centers in southern California through our professional networks. We approached them in-person, via email, and via phone call or text message. As part of our sampling strategy, we solicited the viewpoints of physicians of differing genders, diverse cultural backgrounds and various levels of experience until we reached theoretical saturation. Expert qualitative researchers have stated that theoretical saturation eludes formal definition, and instead provide working definitions such as this: *the point at which the researchers no longer find that new interviews reveal new findings*.[12]

Table 1. Participant experience levels and demographics

	Pain management	Emergency medicine
Experience, including residency and fellowship		
<5 years	0	3
5–10 years	5	1
10–20 years	2	3
20–30 years	1	1
Gender		
Men	5	6
Women	3	2
Ethnicity		
White American	4	5
Middle Eastern American	2	0
South Asian American	1	1
East Asian American	1	2

We conducted semi-structured interviews on the phone or in-person with 17 physicians. One was excluded from analysis because we later discovered this physician did not practice in an ED or pain management clinic. We collected physicians' demographic data. Table 1 details participants' experience levels and demographics.

Theoretical basis

In Strauss and Corbin's grounded theory,[13] one often starts with a set of predetermined constructs, leaving open the possibility that the empirical evidence at hand may present the need to transform the theory. We took this approach, planning our semi-structured interviews around the theoretical constructs of the Thinking Together[14] model. This model is grounded in a systematic review of the clinical decision support literature, which it takes as empirical evidence. The Thinking Together model takes the theory of distributed cognition as its own starting point, acknowledging that memory and cognition are distributed among actors and artifacts, and over time.[15]

In the CURES context, the first process of Thinking Together, *discovery and retrieval,* pertained to how prescribers retrieved or were given patients' controlled substance histories. The second, *processing,* pertained to how prescribers interpreted what they found. We refer to the last concept, *storage and sending,* as *documenting and disseminating* in this article for clarity. This process pertained to how prescribers documented, shared, and stored their interpretations and actions.

Semi-structured interviews

For each of our theoretical constructs, we asked participants how they performed each activity, and any issues they had with each activity. We asked for recommendations to address each issue they raised. Table 2 characterizes our interview structure. We noted the clinical actions that participants reported as they contextualized their responses, and asked probing questions to gain a full view of participants' experiences and perspectives. This study was approved by our IRB, which did not require signed consent forms.

Interview transcript analysis

We transcribed all interviews for qualitative analysis. Then we applied qualitative coding[16] to each interview. We coded the data to identify key categories of concepts (eg, "there should be a graph") and used sub-codes to provide detail (eg, "it should display MMEs per day," "it should use different colors for different prescribers"). We created categories and sub-codes in an iterative process.

Table 2. Conceptual representation of a typical interview's structure

Theoretical construct	Activity	Perceived issues	Recommendations for solutions
Discovery and retrieval	Q1. How do you discover and retrieve information from CURES?	Q2. What would you name as the top issues with how you have to go about discovering and retrieving information from CURES?	Q3. How would you fix that? (*Asked for each issue*)
Display and interpretation	Q4. How do you interpret the information that CURES displays?	Q5. What would you name as the top issues with the way CURES information is displayed for your interpretation?	Q6. How would you fix that? (*Asked for each issue*)
Clinical actions	What physicians did in which situations	Undesirable constraints on clinical work and their consequences for patients	Stated desires for what should be possible
Storing, sending, and reusing	Q7. How do you go about documenting information from CURES for later use?	Q8. What would you name as the top issues with the way you have to go about documenting?	Q9. How would you fix that? (*Asked for each issue*)

For example, if two codes were sufficiently similar, we would merge them; if we needed to track details, we would create sub-codes.

Usability inspection

We also used CURES's training documentation[17] to compare physicians' accounts with available features. Next, one of the authors (A.M.N.), a practicing physician, verified feature availability and functionality in the live system using her own login, during the course of normal clinical work, producing step-by-step descriptions of those features. She then provided those descriptions to another author with a background in design research (M.H.), who inspected them for usability.

Similar to heuristic analysis,[18] this inspection involved critiquing the existing features of a design, much as one proofreads a paper, to discover usability problems. Here, the critiquing author augmented Nielsen's original heuristics[18] with a wide variety of relevant design literature. Nielsen's original heuristics were concise, at the expense of comprehensiveness, because they were intended to enable novices to critique interactive designs. Also, since they were written in 1994, they did not include considerations based on discoveries made after 1994.

As an example, Nielsen's heuristics did not mention *inattentional blindness*. This effect is observed when one is absorbed in a task (eg, investigating a patient's controlled substance history), and they do not see visual information that is irrelevant to the task (such as a decision support table), although it may be inside one's visual field. This effect was first documented in the cognitive psychology literature in 1992,[19] and popularized in 1999.[20]

As another example, Nielsen's heuristics provide no guidance on graphic perception.[21] The critiquing author, therefore, needed to use the relevant graphic perception literature to interpret physicians' reports pertaining to how they extracted meaningful information from controlled substance history tables.

Designing alternatives

After inspecting for usability, we engaged in a rigorous design process to generate alternative user interfaces that were unlikely to exhibit the reported problems. This design process has been described in depth by Atman.[22] We started the process by gathering ideas for alternative designs from transcripts where physicians suggested solutions and brainstorming[23] more ideas ourselves. Then we sketched those alternatives, evaluated them, and narrowed them down via further usability-informed inspection. Finally, we created the figures shown throughout to communicate our recommended designs.

RESULTS

During our analysis, a fourth theoretical construct emerged to augment the Thinking Together model: *clinical actions*. This type of interplay between theory and empirical evidence is typical of Strauss and Corbin's grounded theory.[13]

In this section, we first present the results of our analysis, organized around our key themes:

Differing needs. Emergency and pain physicians had different needs, due to the nature of their domains. For example, emergency physicians faced less predictable workloads, and pain specialists took more extensive notes due to the long-term nature of their care. Medicolegal requirements for emergency and pain physicians differed, reflecting their unique needs.
Cumbersome account access. Usability issues, such as stringent password requirements, account lockouts, and an inability to access CURES from the EHR impeded information access.
Cumbersome patient report retrieval. Suboptimal design also led to information retrieval difficulties. For example, the search form led some users to create overly specific search queries, an unnecessarily time-consuming task which often yielded search results that excluded relevant records.
Visual display and interpretation. Controlled substance histories were difficult to interpret. They lacked overview and context, making interpretation both time-consuming and error-prone. This was exacerbated by systemic configurations that created missing data.
Unusable advanced features. Advanced features, such as computerized decision support, that might have been helpful, were largely unused.

Table 3 summarizes of the results by theme; it includes quotations only to illustrate the concepts in a concrete and convenient manner for the reader. We detail each theme in the following sections. Afterward, we present possible solutions for many of the documented problems. For ease of comparison, we present the alternative designs we developed alongside the illustrations of CURES's current design throughout this section.

Differing needs

The emergency and pain physicians whom we interviewed had different practices—and therefore different needs—when using CURES. In this section, we highlight the differences most relevant to the *context* of their use: their varying conservatism when prescribing

Table 3. Summarized interview results

Themes	Examples	Illustrative quotes
Differing needs	• Pain specialists sought controlled substance histories more often, due to more their more controlled workloads • Emergency physicians had more leeway with opioid prescribing due to the acute nature of their care, resulting in less need for CURES use	*I look at CURES anytime I prescribe opioids. . .and then I go ahead and use it at every single visit, although the recommendation is no more than every third or fourth visit.* *– Physician 3, Pain Specialist* *I do not feel I need access to [controlled substance histories] in a routine fashion. There is a certain threshold of suspicion that needs to occur before I care if a patient has a long history of receiving prescriptions or not, because, in the vast majority of cases, there is an acute reason why I am doing it, and I would [prescribe an opioid] regardless of [their] history with controlled substances.* *– Physician 13, Emergency Physician*
Cumbersome account access	• Exclusive login • Password expirations • Account lockouts • Sessions expired quickly	*The login changes all the time, so I am always forgetting my password.* *– Physician 4, Pain Specialist*
Cumbersome record retrieval	• Suboptimal search feature design necessitated workarounds • Difficulty locating records	*You have to have exact information, and if you are off by even one number, or if they changed address, then you have difficulty finding them.* *– Physician 10, Pain Specialist*
Visual display and interpretation	• Cluttered display • Lack of context • Incomplete information	*There is so much superfluous information that can obscure what you are trying to find.* *– Physician 2, Pain Specialist*
Unusable advanced features	• Decision support alerts for risky patient regimens • Opioid agreements intended to represent physician designated as patient's sole opioid provider • Clinician-to-clinician communication • Delegated patient record lookups (Physician could delegate patient report retrieval task to support staff)	*CURES should automatically calculate morphine milligram equivalents, and risk-stratify using MMEs per day, as per the CDC Guideline, and it should let you know if the patient is also taking benzodiazepines. (CURES already had these features at the time of the interview)* *– Physician 11, Emergency Physician*

opioids to patients with past opioid use disorder, their correspondingly varied history-seeking thoroughness, and their correspondingly varied documentation thoroughness.

Prescribing for patients with histories of opioid misuse

Emergency physicians were far more willing to negotiate opioid prescriptions with patients who had recovered from opioid use disorder than pain specialists. Because emergency physicians faced more acute pain cases, they encountered fewer situations where information from CURES would have changed their prescribing. Therefore, they needed to access CURES less often. As of this writing, these differing needs were reflected by differing medicolegal requirements.[24]

CURES did not allow physicians to access records past a 12-month horizon, so they often relied on their patients to reveal a long-past history of opioid use disorder. If a patient presenting acute, verifiable pain made such a revelation, emergency physicians generally negotiated with the patient:

> *Some patients will say, "Do not give me opioids, because I have had problems before," because they don't want to fall back into it. It's a discussion to have with the patient.*
>
> *– Physician 17, Emergency Physician*

Pain specialists reported more reluctance with these patients. One recounted a troubling case:

> *He has been clean for five years, and he has a true pain complaint. It's so bad that he can't go to work. Nobody will prescribe for him because he's being honest—he's being punished for his honesty.*
>
> *– Physician 2, Pain Specialist*

Seeking stories

Pain specialists not only prescribed more conservatively; they also sought patients' histories more thoroughly. They reported performing a CURES search prior to *any* opioid prescription—including for those patients already taking opioids. In contrast, most emergency physicians *consistently* accessed CURES as time permitted (a previous study[6] described this as "inconsistent").

Emergency and physicians alike cited *red flag* patient behaviors that would trigger a CURES lookup, such as claiming to have misplaced opioids, claiming allergies to lower-risk analgesics, changing their story, or requesting an opioid by name. When there were red flags, emergency physicians made an effort to use CURES. If they could not use CURES due to time constraints, they made a "judgment call." Pain specialists, by contrast, had more time to integrate a variety of sources, such as peer notes, family and police reports, urine toxicology results, and opioid risk calculators.

Documentation practices

Pain specialists documented more thoroughly than emergency physicians. Emergency physicians tended to communicate in-person rather than through notes, and they tended to document their CURES review only when it caused them to reconsider opioids. One

commented that, since ED physicians often encounter emergencies, they had more leeway in opioid prescribing (and in general). Since documentation is—among other things—a space for justification, theirs was less elaborate. In contrast, pain specialists, who conducted longer-term care, took more comprehensive notes, used EHR notes to conduct some communication, and documented every CURES review.

Although pain specialists had more time than emergency physicians, time still constrained how much information a pain specialist could legitimately review prior to a patient visit, so actionable information needed to be easy to retrieve. For example, pain specialists required patients taking opioids to periodically sign *exclusivity agreements*, colloquially known as "contracts," to represent that the patient agreed to only accept opioids from one physician. These agreements outlined the *aberrancies* or *breaches* which would be cause for the prescriber to restrict or terminate care of the patient (eg, a "two strikes" rule). Pain specialists needed an aberrancy record, but CURES did not provide this. So, they used EHR notes to track aberrancies. They did this by "copying forward" past aberrancies from previous notes, ensuring that this actionable information did not get "lost" in the archives.

Emergency and pain physicians alike documented the evidence they considered, including the patient's story and any justificatory symptoms or diagnoses, followed by the decision to prescribe opioids or not. If not, they might have documented that they explained the rationale to the patient. If they chose to prescribe opioids, the medical board required them to educate the patient about the risks involved[24]; they documented their educational efforts.

Epic, the EHR that our participants used, supported "smart phrases," intended to speed up documentation. For example, if one typed ".labs24," the EHR automatically imported lab values from the past 24 h. Although these were customizable, only one pain specialist reported that they had built their own smart phrases to speed up their controlled substance history documentation. No emergency physicians reported having done so.

Cumbersome account access

Physicians often accessed CURES with difficulty. As of this writing, physicians had to leave the EHR to access CURES, and they had to memorize a separate set of login credentials. Interviews suggested that this extra login effort sometimes prevented physicians from using CURES in time, increasing the likelihood of an inappropriate prescription.

This situation was further exacerbated by account lockouts, which users experienced upon password expiration, or when logging into CURES from more than one workstation. During a lockout, participants reported that it was frequently impossible to contact California's centralized technical support in time to see the patient. Additionally, sessions expired after a short period of inactivity, an estimated 5 min.

Cumbersome record retrieval

Physicians reported difficulties retrieving patients' records due to typos, name changes, and names that did not conform to CURES's expectations. As of this writing, CURES did not have unique identifiers for patients; physicians retrieved patient records using names and birthdates. This resulted in situations where submitting a search form produced no records; in these cases, physicians used workaround strategies, such as trying alternate spellings. A patient could be hard to find if their name had changed recently (eg, upon marriage). Although the latest US Census recorded that 2 in 5 Californians were Latin American,[25] records for Latin American patients were often difficult to find because CURES assumed that patients had two given names ("first" and "middle") and a single family ("last") name; many Latin American patients instead had two given names and two family names. It was common to find two names "stuck together" in one field. Although the search system used the Metaphone algorithm,[17,26] it was reportedly sensitive to slight misspellings.

Some physicians believed that both the first and last name fields were required, while others believed that some overall *number* of search fields, two or three, were required. We verified that two factors were required: (1) date of birth and (2) either first or last name. This confusion likely stemmed from an "and/or" construction on the search form, as shown in Figure 1. The search form also did not indicate that it permitted partial names (eg, "Kath" instead of "Katherine" or "Kathryn"). The overall effect was that some users provided too much information, resulting in overly specific search queries that yielded no results, requiring extra time to resolve.

Further, our results revealed that some physicians were unaware of a feature in CURES that allowed one to save searches, and those who did use it sometimes found that a search they thought they had saved had not, in fact, been saved. We found that, after running a search, one could save a search by clicking the Save Search button, typing a title into the resulting dialog window, and clicking a confirmation button. Then, the dialog would disappear, and the text "Saved search: <title>" simultaneously appeared in black—a color that hardly stands out—as feedback. We had trouble noticing this feedback ourselves, and hypothesized that it was masked because it appeared at the same time that the dialog box disappeared, an example of the *change blindness* effect, which was well-known in perceptual psychology.[20] This was problematic because system feedback is important; it allows users to know that they have completed a task successfully.[27]

Visual display and interpretation

Before interpreting a patient's controlled substance prescription history, physicians needed to convert it into a readable form. Although CURES presented a Web table with sortable and filterable columns, it displayed this in a 1.5 inch-tall frame, as shown in Figure 2. Since the table was far larger than its frame, it required extensive scrolling. So, physicians generally downloaded a PDF for on-screen viewing by clicking the "Print" button. The PDF required no scrolling, and its table had fewer (but still too many) unnecessary columns, but it lacked the ability to filter by column.

As we detail in this section, interpretation was no easy task, even in the preferred format. As an interviewee explained, interpretation was complex enough that they were often asked to explain why particular controlled substance histories constituted evidence of patient misconduct during judicial proceedings. Physicians interpreted their reports by verifying patients' self-reported histories against CURES's records.

The interpretation process was problematic for two main reasons. The first was clutter. For example, we observed columns that simply repeated the patient's name, date of birth, and address on every row; these superfluous elements detracted from more important elements.

The second problem was a lack of context. For example, if one found that a patient received opioids from multiple prescribers, one would initially find this suspicious, but would need to engage in inferential work to determine if the past prescribers followed the same

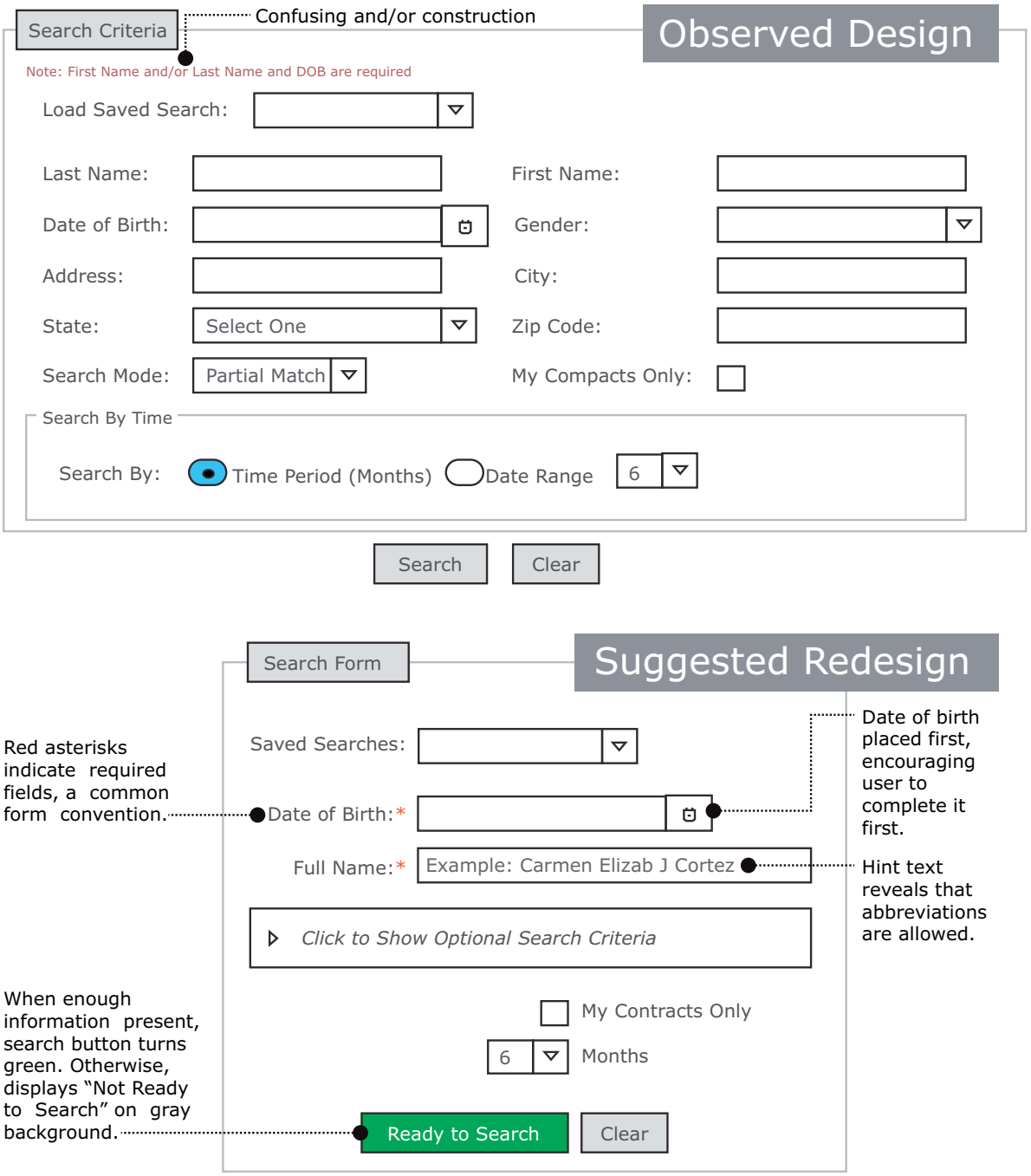

Figure 1. Observed CURES search form (above), and our suggested redesign (below). All data are fictitious.

plan of care; such a patient may have been receiving consistent care from multiple prescribers within the same health system or medical group. Interpretation was so rife with inferential reasoning that an interviewee characterized it as *detective work*.

Lack of overview: extracting decision-swaying cues from a cluttered display

When reading a controlled substance prescription history report, physicians first recovered *where*, *how*, *when*, and *by whom* controlled substances had been prescribed and dispensed. Starting with *elementary features* (eg, dates, tablet amounts), physicians extracted *information*. Some common tasks, such as counting unique prescribers, or calculating fill frequencies, took a long time, and could have been extracted computationally, but CURES provided no such conveniences. The process of extracting information from tables was further slowed by clutter; research-based design principles have recommended keeping tables as clear as possible.[28,29] Physicians found it problematic that CURES displayed controlled substance histories, whether in Web or PDF format, as an enormous, cluttered table. As one stated:

> *There is so much superfluous information that can obscure what you are trying to find.*
> *– Physician 2, Pain Specialist*

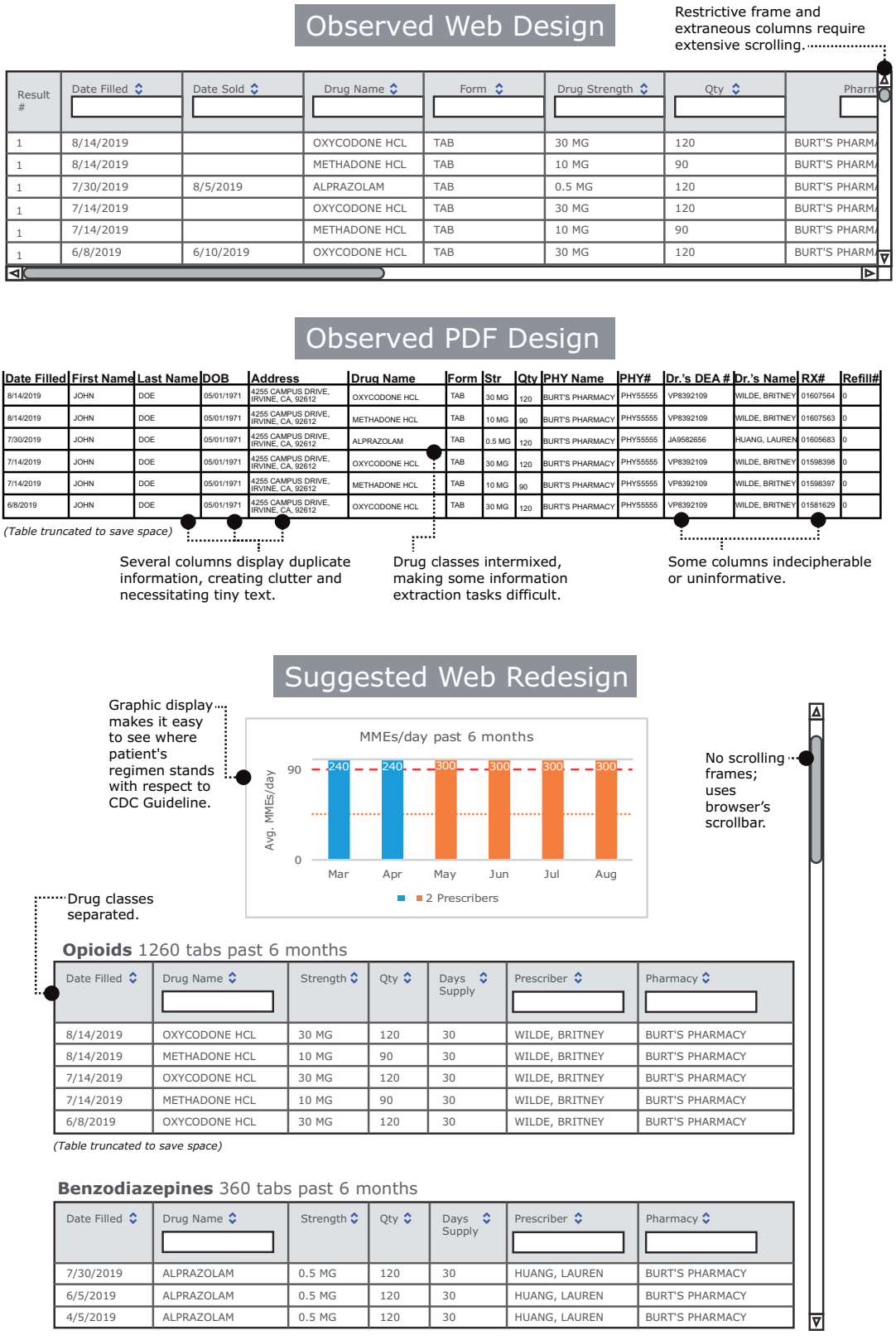

Figure 2. CURES's designs for report tables on Web and PDF (above), and our suggested Web redesign (below). All data are fictitious.

After extracting information, physicians searched for decision-swaying evidence, which we refer to as *cues*. They used the term *red flags* to refer to cues that may indicate aberrant behavior. For example, a burst of activity over the course of 3 days might indicate a drug-seeking behavior that exploits delays between a fill and its appearance in CURES. This behavior was colloquially known as

"doctor shopping," though physicians avoided the value-laden term. CURES's table displayed records at equal spatial intervals, obscuring temporality and slowing activity burst extraction.

Lack of context

The digital traces of past prescriptions that CURES presented in its controlled substance history tables, as shown in Figure 2, allowed physicians to extract many cues. However, physicians often had to infer the answer to their most important question: "*Why* did this patient receive these medications?"

The best place to look—others' EHR notes—might not have had the answer; physicians reported that EHR notes and prescriptions were generally only available to peers inside the same health system, and to those using the same EHR (Epic)[30]; this reality remained despite the goals of the HITECH Act.[31] Moreover, notes were tedious to search:

> *I wish I didn't have to search through everybody's chart to find out why a patient is abusing. If I could just find the reason, it would be easier to fix.*
>
> *– Physician 7, Pain Specialist*

As a result, physicians relied on inference, resulting in both false positives and negatives.

False positives. Here, we note four examples of situations in which clinically permissible actions would have incorrectly appeared suspicious, due to the way CURES presented controlled substance histories.

First, it would be easy to mistakenly conclude that a patient who was adhering to a single plan of care administered by multiple prescribers within the same health system or physician group was instead seeking opioids by visiting multiple healthcare entities. This was because CURES's historical reports did not display information about past prescribers' institutions; physicians had to look for overarching prescription patterns when reading reports to make this critical distinction.

Second, patients with low socioeconomic status (SES) would often visit EDs instead of primary care,[32] but CURES did not record SES. Emergency physicians would sometimes provide patients with low SES and legitimate chronic pain with short-term opioid prescriptions, an admittedly suboptimal but pragmatic and humanitarian course of action. The resulting effect was that controlled substance histories representing such patients would show multiple emergency prescribers—a pattern that generally aroused suspicion. Our results suggested that some ED physicians might have avoided treating these patients for this reason.

Third, in pain management, what initially *appeared* to be an exclusivity agreement breach may have represented a genuine emergency (eg, a broken bone). Our impression was that this was typically unproblematic; pain specialists reported discounting these suspicions if the patient could explain them with a convincing, consistent story. We only include this case to preemptively dispel any notions that "breaches" are the type of clear-cut objects that can be detected computationally.

Finally, opioid overconsumption sometimes indicated a misdiagnosis, rather than opioid use disorder. For example, a patient may have appeared in the ED with ankle pain, received "sprained ankle" as an initial diagnosis, and received a small supply of opioids upon discharge. If they reappeared in the ED after consuming these opioids more quickly than expected, emergency physicians might have suspected that the "sprained ankle" was, in fact, a broken bone.

False negatives. As the adage goes, "absence of evidence is not evidence of absence." A pain specialist recounted a story of a new patient who asked them to take over another physician's high-dose opioid regimen. In their words:

> *I told him it was not appropriate. He said, "You are the last doctor on my list, and I've seen thirty." I had no other way of knowing that the patient had been to so many doctors! Maybe CURES should show that others have been looking at his history. Then I would know there is something going on.*
>
> *– Physician 3, Pain Specialist*

Other sources of false negatives included the delay between a prescription's fill and its appearance in CURES, and the fact that some healthcare institutions, such as methadone clinics, were not required to report to CURES.

Unusable advanced features

CURES had potentially useful advanced features that were unfortunately quite difficult to use. By closely examining user guides,[17] we discovered four neglected features:

1. Decision support alerts
2. Exclusivity agreements
3. Clinician-to-clinician communication
4. Delegated patient report lookups

Some physicians suggested decision support, which CURES already featured. Although no interviewees mentioned using the inbuilt exclusivity agreements or communication features, an ED physician mentioned it would have been nice to be able to find patients' primary care doctors. A pain specialist noted that they were aware of a communication feature, which they did not use. Only one pain specialist reported delegating patient record lookups. The documentation's descriptions of these features varied widely in their level of detail, and they were scattered between the "Publications and Training Videos" and "Frequently Asked Questions" pages of the CURES website. The former page intermixed grant and donation reports with training materials. The training videos described some advanced features; we retrieved them on January 9, 2018. Several useful videos describing how to use exclusivity agreements, communicate with other clinicians, and delegate patient report lookups (in addition to some hints about how to use the search feature) had vanished when we returned on February 12, 2018. We checked for their reappearance periodically, until August 13, 2018, to no avail.

Decision support

CURES attempted to alert physicians about patients with risky regimens; this feature is illustrated in Figure 3. The documentation[33] explained that this feature displayed alerts when any patient to whom a physician formerly prescribed controlled substances:

1. Had been prescribed over 100 MMEs/day at that time (the software actually said 90 MMEs/day),
2. Had received prescriptions from more than 5 prescribers or pharmacies in the past 6 months,
3. Had been prescribed over 40 MMEs/day of methadone at that time,
4. Had received opioid prescriptions for 90 consecutive days at that time, or
5. Had active prescriptions for both a benzodiazepine and an opioid at that time.

The alerting table showed alerts for all their past patients; it was apparently intended for population management. CURES provided

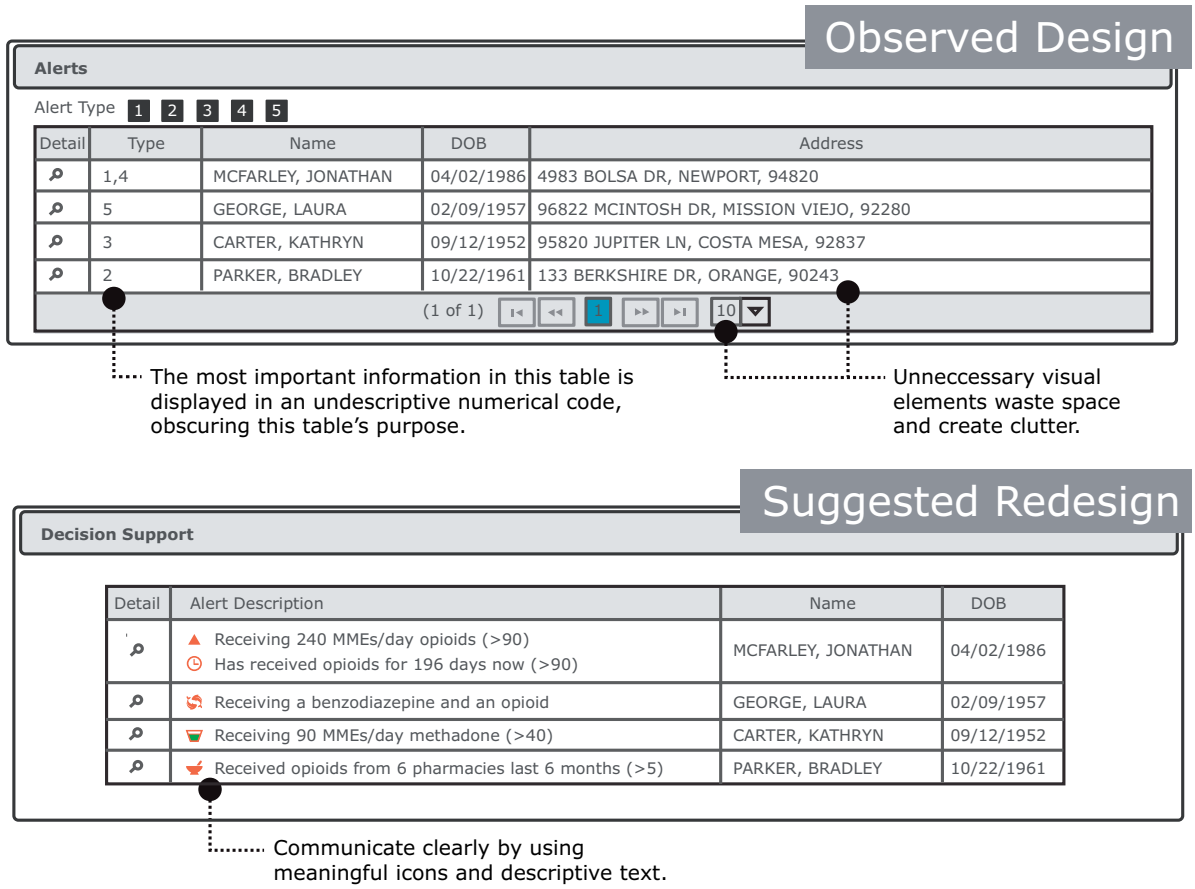

Figure 3. CURES's design for decision support (above), and our design (below). All data are fictitious.

no alerts on controlled substance history reports, so these alerts were not useful when encountering prospective patients. We hypothesized that the existing alerting table went unnoticed so often because it tended to be irrelevant to the task at hand (seeking a specific patient's controlled substance history); this is known as *inattentional blindness*.[20]

The Alerts table might also have gone unnoticed because its design did not readily reveal its purpose. Although it was displayed upon login, it displayed arbitrary numeral codes (eg, "1, 4") in a column non-descriptively labeled "Type." One needed to hover their cursor over boxes labeled "1, 2, 3, 4, 5" that were placed over the table, in a tedious mechanical maneuver, to discover what these numeral codes signified. Inexplicably, the extra space left over by this tightly regimented design displayed patient addresses, which prescribers did not find useful.

Exclusivity agreements

As described in the Documentation Practices section, pain specialists used patient-provider opioid exclusivity agreements during the course of opioid control. We discovered that CURES had a feature to represent these agreements. No participants reported being aware of this feature, but when we pointed it out, they expressed excitement. We investigated why this feature had gone unnoticed, and found that one had to record an agreement as follows:

1. Retrieve a patient's record
2. Click the "View Prescriber Contact" button
3. Click the "Set Compact" checkbox

Using "Contact" and "Compact" to mean the same thing violated one of Nielsen's heuristics[18]: *Express the same things the same way.* Moreover, pain specialists found the term "Compact" confusing; this word choice violated another one of Nielsen's heuristics: *Speak the user's language.*

Clinician-to-clinician communication

CURES provided a way to send messages to those who had prescribed controlled substances to a patient in the past year. Those who received these messages had to retrieve them via the CURES website. Physicians did not describe this as a useful feature. The only way to communicate with potential *future* physicians was to set an exclusivity agreement. This contributed to the contextual scarcity that we described in the Lack of Context section.

Delegated patient report lookups

Some physicians wished to delegate controlled substance reviews to nurses or clerical staff, whom they would direct to retrieve, interpret, and summarize patients' controlled substance histories in a convenient chart note. To their dismay, CURES only allowed Delegates to compose search queries. Delegates could not run or review reports.

Alternative designs

In the Designing Alternatives section, we described the process we undertook to generate alternate designs. For ease of comparison, we combined the designs we observed with our suggested redesigns in

the figures throughout the preceding sections. In the following sections, we describe them in more detail. We also provide additional design guidance, and we show how the suggestions relate to the aforementioned problems.

Improving the search feature

As shown in Figure 1, we suggest redesigning the Search form to guide users through the process of composing more sensitive search queries. Our proposed design encourages users to complete the required Date of Birth field first, and then to start typing in the Name field, by placing them in this order vertically. As soon as a system-permissible search query has been typed, the form's submission button changes from gray to green, and displays the text "Ready to Search." We believe this will allow users to *discover* that they can use partial names.

Improving report usability

To make reports easier to navigate and interpret, we suggest unwrapping the Web table from its frame and hiding less-informative columns, as shown in Figure 2, to reduce its visual angle and clutter. Additionally, a graphical display would take advantage of rapid visual processing[21]:

> *I want to see milligram morphine equivalents on a graph, so I can see the running average.*
>
> *– Physician 6, Emergency Physician*

Figure 2 illustrates the main problems and suggested design improvements. We provide a more comprehensive account of the interpretation process and design recommendations in Supplementary Material available online. Several physicians suggested allowing free-text annotations within CURES. Supplementing reports with contextual information, such as by including messages sent through the existing messaging system, is likely to reduce both false positives and false negatives.

Easing documentation

Physicians suggested two ways to alleviate the documentation burden that we described in the Documentation Practices section. Some proposed the ability to import the CURES report into their EHR notes. Others suggested stock phrases. Emergency physicians, who preferred more concise notes, tended to stress that information should be condensed to avoid clutter. We synthesized phrasal suggestions for ED physicians and pain specialists separately, since they reported different documentation practices. For the ED, a dot phrase like ".pdmp" might expand to:

> *CURES checked; patient at <Risk Level> risk; obtained <X pills in last Y days> <drop-down menu: due to substance use disorder, due to psychiatric illness, due to socioeconomic status)>. Prescription <not given/given> today.*

When pain specialists feel reassured by their evidence, they might like to use a dot-phrase (eg, ".consistent") that expands to:

> *CURES consistent with patient history and absent of red flags. UDS on file and consistent with prescribed medication regimen. Prescription given today.*

UDS stands for "urine drug screen." When pain specialists do not find the evidence reassuring, they might like a dot-phrase (eg, ".aberrant") for:

> *CURES checked <consistent/not consistent>. Patient is high risk for opioid prescription due to <drop-down menu: multiple prescribers, high MMEs, substance use disorder history>. Opioids not prescribed. Patient offered Rx of naloxone and substance use disorder resources.*

Realizing the potential of advanced features

As we discussed in the Decision Support section, some physicians suggested adding a decision support feature that already existed, but which they did not seem to have noticed. Their vision for decision support involved meaningful phrases and icons, as opposed to the arbitrary numeral codes that we observed. We present our suggested redesign in Figure 3. Additionally, since physicians actively retrieved controlled substance histories for specific patients, we suggest adding patient-specific alerts near the tops of these reports. We list our proposed design changes to other advanced features in Table 4.

DISCUSSION

In the Results section, we elucidated the differing needs of ED and pain physicians, which stemmed from the predictability of their workloads and the duration of their care. We also found that usability problems hindered the effectiveness of CURES. Namely, accounts were difficult to access, and patient reports were difficult to retrieve and interpret. We also found that CURES had advanced features that might have been useful if they better conformed to user expectations. We finished by providing guidance for those looking to improve CURES or similar PDMPs.

We begin our discussion with some practical ideas for developers and regulators who may be interested in improving PDMP usability while working within existing organizational and legal constraints. Next, we discuss the deeper interplay that we found between CURES's design and medicolegal concerns, whose emergent effects have, in some instances, changed the very decisions that physicians ultimately made. Finally, since CURES is certainly not the only software used in healthcare that presents usability problems, we finish by briefly addressing the origins of these usability issues: software development processes.

Improving usability pragmatically

Despite its potential, CURES's usability, as of this writing, leaves a great deal of room for improvement, undermining its utility. We recognize that some of its usability problems may be attributable in part to medicolegal barriers.[6,7] Certain changes, such as using consistent terminology throughout, reducing clutter and excessive scrolling, and improving the clarity and availability of training materials, are unlikely to be hindered by legal constraints.

We are optimistic that the design changes that now face legal constraints will soon become viable, since the legal landscape is shifting due to the opioid crisis. For example, the US Office of the National Coordinator for Health Information Technology documented some recent pilot programs for PDMP-EHR integration, such as Wishard Hospital in Indiana, and Anderson Hospital in Illinois.[35]

For regulators and developers interested in improving CURES's usability, we would suggest starting by making it easier for users to log in, then making it easier for users to locate relevant patient records, next refining visual display, afterward improving advanced features such as decision support and opioid contracts, and finally working on issues related to data infrastructure, such as name repre-

Table 4. List of proposed design changes

Problems	Suggested Changes
• Locked out of account when: ○ Password expires ○ Logged into more than one workstation	• Passwords that sync with the EHR • Single sign-on that activates upon EHR login • Logging into one session should log out other sessions rather than locking account • Easier password reset process for account restoration (eg, send a special link via email)
• Incorrect assumption that all have "first, middle, last" names • No ability to search by "middle" name • Search sensitive to the misspellings that pervade both queries and database records • "Note: First Name and/or Last Name and DOB are required" contains confusing and/or construction • Physicians unaware of Partial Match functionality	• Use web conventions (eg, asterisks and field hints) to guide rather than instruct, as shown in Figure 1 • Allow searching with all initials, birthdate, zip code • Instruct to "Specify at least the Date of Birth and either the First or Last name. Partial names permitted (eg, 'Kath' for 'Kathryn')" • Use only "given, family" names • Use Levenshtein distance[34] in search to forgive misspellings • Develop algorithms to search full names
• Clutter	• Always use Partial Match; remove drop-down (see Figure 1) • Remove unused columns from history report or hide by default (see Figure 2) • Remove address column from decision support (see Figure 3)
• Save Search feature: ○ Placed in an unexpected location ○ Requires unnecessary user input ○ Provides insufficient feedback	• Add Save Search checkbox to search form • Automatically assign search's title to the patient's name and birthdate; the dialog box is unnecessary • For salient feedback, fade in a green checkmark • Automatically save successful searches, suggest past searches when filling out new search query ○ Physicians should be able to clear search history and remove searches one at a time
• Disjoint records must be merged together manually • Interactive table requires excessive scrolling • User documentation difficult to: ○ Locate ○ Understand	• Preserve prior merges and support de-merging • Unwrap interactive table from frame (see Figure 2) • Provide user guides on a single, separate page • Describe features with screenshots and videos; minimize prose
• Decision support feature obscured	• Remove Address column or hide by default • Display meaningful icons, phrases in Alerts table ○ eg, "▲ 93 MMEs/day (>90)" • Display decision support in historical reports
• Agreements feature obscured • Variably referred to as "Compact," "Contact"	• Use the term "Agreements" consistently throughout • Display agreements in historical reports • Provide "Create Agreement" button on Web Report
• Lack of overview and context	• Display consumption data graphically • Automate calculations • Enable contextual preservation • See Supplementary Material Appendix A for numerous recommendations
• Aberrancies can get lost in EHR notes • Note-taking too time-consuming	• Support report annotation and notes EHR Integration: • Track aberrancies in History tab (pain management) • Provide *option* to import report into notes • Provide stock smart phrases

sentation. We believe making changes in this order will relieve the most pressing problems the most quickly; if a user is confronted by a barrier in an early step of the patient report retrieval process, they are unable to progress to all subsequent steps.

We discovered specific and important differences in opioid management practices between emergency and pain physicians; these carry implications for PDMP redesign and possible EHR integration. Other medical disciplines, like surgery, primary care, and urgent care, likely also require tailored design; further research is needed to investigate their specific needs.

Some of the usability problems are surprising. For example, one might expect the Metaphone algorithm,[26] which the CURES search form uses,[17] to return too many results, rather than too few. It seems that complex interplays between user behavior, interface design, and algorithms have rendered such speculations precarious. So, we have recommended design changes grounded in users' accounts and corroborated by the human–computer interaction and design literature. Certain recommendations, such as those proposed to reduce account lockouts, are likely to benefit all users. We believe that our suggested redesigns will improve the speed and ease of opioid control in both emergency and pain care. Further investigation is needed to validate this possibility. Next, we discuss emergent effects that are not entirely attributable to design alone.

Interplay between design and medicolegal concerns

Some of the issues we found were not best characterized as usability issues, but rather as a deeper interplay between CURES's design and medicolegal concerns. In the False Positives section, we stated that, due to contextual scarcity, physicians might turn away some patients with low SES and plausible pain, in fear of criminal penalty. Further, as we recounted in the section on Prescribing for Patients with Histories of Opioid Misuse, some longtime-sober patients might have found themselves in the position of deciding whether or not to lie about their past to pain specialists in order to escape their pain. This perverse incentive problem is unlikely to be resolved through design alone. One might, for example, suggest providing pain physicians with additional years of history. This might reduce, but could not rule out, the chance that pain specialists would depend on patient honesty from time to time.

Together, these fear-of-liability cases seemed to lend validity to the concerns raised in Whalen v. Roe, the 1976 US Supreme Court case[36] in which physicians alleged that patients would be deprived of needed medications due to law enforcement practices enabled by computerized oversight. These concerns may have been easy to dismiss in years past, but it seems the physicians' speculations have, in some sense, been realized.

Integrating usability into healthcare software development processes

Still, there is clearly much that can be done in the way of usability. In this paper, we drew upon an abundant body of usability literature, which is rich with knowledge that can be applied to other areas in healthcare. For example, as early as 1987, Erlich[37] emphasized the importance of *speed, completeness,* and *context* in office information system design. We found that these concepts were important to the users of CURES, another office information system, and one imagines these concepts are also important in—for example—EHR use. Abundant, approachable guidance on graphical display was available in 1990 (eg, Tufte[38]); through experience, we are aware that CURES is not the only software used in healthcare whose users suffer from excessive clutter. Nielsen[18] promoted heuristic evaluation as a cost-effective method for improving usability as early as 1994. CURES was first released in 1997, and its physician-searchable component was introduced in 2009.[39]

Rather than pointing fingers, we wish to move beyond the case of CURES to address a broader question: *Why* are so many healthcare IT systems so difficult to use, when usability knowledge is so readily available? We feel the subject of how to integrate usability knowledge into healthcare software development processes would benefit from concerted research. This would not only benefit those who directly use healthcare IT; poorly-designed healthcare technology can put patient safety at risk.[10]

CONCLUSION

The patients put at risk by the opioid crisis are in need of support from the healthcare community, whose response has been hindered by PDMP usability issues. In this article, we have attempted to provide practical guidance for improving PDMP usability based on user feedback from an empirical study. More broadly, we have positioned CURES as an emblematic case of a healthcare software system whose effectiveness could be improved through design. In the short term, if PDMPs are to address the opioid crisis, they must be well-suited to the task.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

CONTRIBUTORS

All authors listed meet the recommended ICJME criteria for authorship. Mustafa I. Hussain contributed substantially to the conception and design of this work, as well as the acquisition, analysis, and interpretation of data. He also drafted the work. Ariana M. Nelson provided substantial contributions to the design of the work, as well as the recruitment of participants and acquisition of data for the work. She also revised it critically for important intellectual content. Gregory Polston provided substantial contributions to the conception of the work, and revised it critically for important intellectual content. Kai Zheng provided substantial contributions to the conception and design of the work, as well as the analysis and interpretation of data. He also provided substantial editing for clarity and for important intellectual content. Final approval prior to publication was achieved by unanimous consensus among all authors, who are accountable for all the accuracy and integrity of all aspects of this work.

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