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Prescription drug monitoring program in Australia: a qualitative study of stakeholders' experiences and perceptions of a state-wide implementation

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Abstract

Background Prescription Drug Monitoring Programs (PDMPs) are increasingly implemented across the globe with aims of managing and mitigating risks relating to high-risk prescription medicines. There is limited research focused on identifying strategies or processes for large-scale PDMP implementation. This study aimed to identify strategies perceived as necessary for successful state-wide implementation of a PDMP by exploring the experiences and perceptions of stakeholders responsible for the implementation in New South Wales (NSW), Australia: to identify (1) the drivers of implementation; (2) perceived strategies that worked well; (3) barriers to implementation; and (4) the elements needed for long-term success of SafeScript NSW.

Methods This study used a qualitative descriptive design. Theoretical frameworks used to design interview questions and guide thematic analysis were the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework and Quadruple Aim framework. Participants were stakeholders responsible for PDMP implementation in NSW. Recruitment and data collection were completed between March and April 2022. Semi-structured interviews were audio-recorded and transcribed. Two researchers independently reviewed transcripts, generated codes from the data, and mapped these to each NASSS domain. They came together multiple times during data analysis to review the codes and grouped them into higher level themes via a discussion and consensus process. Themes were then organised according to the four objectives of the study.

Results Eight interviews were conducted and analysed after which thematic saturation was reached. All participants had a common understanding of the perceived benefits and drivers for PDMP implementation. Participants outlined ten key ingredients for perceived successful state-wide implementation. Strong and iterative engagement with a large number of stakeholder groups was viewed as critical, as was targeting user experience, ongoing monitoring and evaluation. These were facilitated by a phased roll-out strategy. Participants identified some barriers to implementation, particularly around poor usability and user experience of the tool.

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Conclusions This is one of the first studies focused on strategies for what was perceived to be successful state-wide implementation of PDMP. Successful implementation requires significant time and resourcing, with the design and configuration of the technology being only one component of a multi-strategy process. Knowledge and insights gained from this study may be useful for other implementations of similar digital health tools in large-scale jurisdictions.

Keywords Prescription drug monitoring programs, Prescription drugs, Digital health, Primary care, Clinical decision support, Implementation

Contributions to the literature

- Evidence on the effectiveness of prescription drug monitoring programs (PDMPs) is mixed, with poor uptake and usability issues contributing to failure to achieve desired benefits.
- This is one of the first studies focused on describing strategies necessary for successful state-wide PDMP implementation, involving a multi-strategy approach involving significant time, resourcing, and careful design and configuration of the technology and its use.
- Our study contributes to recognised gaps in the literature, in particular identifying factors that are crucial for successful digital health tool implementation on a large-scale.

Background

Prescription drug monitoring programs (PDMPs) are tools that allow clinicians and health regulators to track and monitor certain high-risk or controlled prescription medicines with intended aims of managing and mitigating risks relating to these medicines. Common medications included in PDMPs are opioids, benzodiazepines, stimulants, and gabapentinoids, as these are often associated with misuse, diversion, and adverse outcomes including dependence, overdoses, and deaths [1, 2].

A systematic review of reviews showed studies evaluating PDMPs were either outcome or process evaluation reviews [3]. Reviews summarising PDMP outcomes were focused on opioids, with the majority of the studies specifically examining PDMPs in the USA [3]. Mixed evidence with respect to the effectiveness of PDMPs in reducing opioid related use and harms was shown, likely resulting from inconsistencies in the methods and outcome measures used, varying from prescribing or dispensing events, misuse, and morbidity and mortality outcomes between studies [3]. Reviews summarising process evaluations were also variable, with most reporting barriers to PDMP use or implementation, and others including utilisation, usability, effects of knowledge and attitude on intention to use, and PDMP impact on clinical decision making [3]. Only one of seven process evaluation reviews of PDMP utilised a theoretical model or framework to inform barrier identification [3]. Evidence on PDMPs was therefore conflicting and of low overall quality [3]. This review did highlight a key factor influencing PDMP effectiveness and delivery of benefits was the uptake of the tool by intended users [3]. Underutilisation of PDMPs was often linked to barriers like poor usability and poor user satisfaction. Strategies to support PDMP implementation should therefore consider, and target identified challenges to ensure uptake and program success. There is limited research focused on identifying the strategies or processes necessary for successful PDMP implementation. Qualitative studies have shown that facilitators to implementation include integration into electronic health records [4, 5], training and awareness [6], and collaboration across agencies and stakeholders [6], but these studies explored and reported on specific implementation conditions such as sites (for example emergency departments) and features (like mandatory access or opioid prescribing laws), not implementation strategies.

PDMP implementation across the entire state of New South Wales (NSW) provided us with a unique opportunity to examine a large-scale implementation of a PDMP. The NSW PDMP, named SafeScript NSW [7], is available to all NSW and interstate prescribing and dispensing clinicians to voluntarily register and use. SafeScript NSW provides these clinicians with access to information on prescribing and dispensing history for certain high-risk or controlled medicines for patients in NSW and can provide alerts to clinicians when certain predetermined risk criteria (such as multiple providers or concurrent harmful polypharmacy) were met [7]. The system can be accessed by the relevant clinician via the web portal, with or without an alert prompt. This study aimed to identify strategies perceived as necessary for successful state-wide implementation of this digital health tool by exploring the experiences and perceptions of stakeholders responsible for the implementation of PDMP (SafeScript NSW) across NSW. We set out to identify: (1) the drivers of implementation; (2) perceived strategies that worked well; (3) barriers to implementation; and (4) the elements needed for long-term success of SafeScript NSW.

Methods

Study design

To achieve the study's four objectives, this study used a qualitative descriptive design.

Study setting

The healthcare system in Australia is both federal and state/territory based. A base platform for PDMP was supplied by the federal government, with each state/territory customising its system for local needs and use. The implementation of PDMPs varied, with the earliest implementation in jurisdictions of Tasmania, Australian Capital Territory, and Victoria. The 'go live' roll-out of SafeScript NSW (in this manuscript, used interchangeably with PDMP) took place between April 2021 and May 2022 in three phases across 10 primary health networks (PHNs) consisting of metropolitan, rural, and regional areas of NSW. Phase 1 occurred in one PHN (November 2021), Phase 2 in two PHNs (March 2022), and Phase 3 across all other PHNs and primary care services in the state (May 2022).

Study sample and recruitment

Purposive sampling was used to recruit stakeholders employed by the state health department directly responsible for all three phases of the implementation of SafeScript NSW, including those who were involved in communication, change management, partnerships, and engaging with key business representatives. These participants were chosen because they were aware of and delivered many of the strategies that support implementation. To recruit participants, email invitations, including the Participant Information Statement and Participant Consent Form, were distributed to all eligible participants by the SafeScript NSW implementation team project manager (AH) on behalf of the research team. Participants who were interested were required to contact a researcher (ET), who was independent from the program, to arrange an interview time. Written informed consent was obtained from all participants prior to commencement of their interview. Recruitment of participants ceased when saturation was reached from the data collected and no new information was gained. This was determined in one of the data analysis meetings between researchers. All interviews were completed in March and April 2022, coinciding with Phase 2 roll-out.

Data collection

Semi-structured interviews were conducted over videoconference (by ET) and were audio-recorded and transcribed. Transcripts were de-identified, and each participant was assigned a numerical code. The interview guide (Additional file 1) was developed by the research team, which was comprised of experts in human factors, digital health, health economics, community and primary health care, clinical pharmacology and addiction medicine, and was informed by two theoretical frameworks, described below.

Theoretical frameworks used to guide interview questions and analysis were the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework [8] and the Quadruple Aim framework [9]. NASSS proposes that successful implementation of a digital health technology can be explored through seven domains. The interview guide included questions to explore these seven domains: the condition (high risk medicines use and harm), technology (SafeScript NSW), value proposition (desirability, efficacy, and cost effectiveness of SafeScript NSW implementation), adopter system (healthcare providers, patients, caregivers), organisation (health system in NSW), wider context (including regulatory and societal context relating to SafeScript NSW implementation), and the embedding and adaptability of technology (SafeScript NSW) over time [8]. We used the Quadruple Aim framework [9] to further explore one NASSS domain, value proposition, and draw on participants' perceptions of the impact of the technology on four dimensions of care: patient experience, provider experience, population health, and effectiveness and cost efficiency of health care delivery.

Data synthesis and analysis

Researchers used both inductive and deductive coding to analyse the data [10]. The interview guide was structured around the NASSS, so quotes were extracted and coded into the seven domains of the NASSS framework, but categories within each NASSS domain emerged from the data. The two researchers (ET and MB) independently reviewed transcripts, generated codes from the data, and mapped these to each NASSS domain. They came together multiple times during data analysis to review the codes and grouped them into higher level themes via a discussion and consensus process. Themes were then organised according to the four objectives of the study. That is: the drivers of implementation; strategies perceived as necessary for successful implementation; barriers to implementation; and long-term success elements.

This study was approved by the University of Sydney's Human Research Ethics Committee. Standards for Reporting Qualitative Research is reported in Additional file 2.

Results

Twelve potential participants were sent the study invitation, and eight agreed to participate (67% response rate). Interviews ran for 26 to 50 min (average 42 min).

Participant demographics

Participants who took part in the study comprised a wide range of roles in the SafeScript NSW implementation team, which included management/managerial, business, change adoption, analytics, and regulatory. Their professional training background included clinical (pharmacy ($n=3$), psychology ($n=2$)) and non-clinical (information technology ($n=2$), digital health ($n=1$)). Half ($n=4$; 50%) of the participants had 1–5 years of experience in digital health, while the remainder reported more than ten years of experience.

Thematic saturation was achieved. Themes that were generated during coding process are presented in Fig. 1 as the overall study outcomes on stakeholders' views of successful PDMP implementation.

Drivers for PDMP implementation – value and impact to stakeholders

Participants were consistent in describing SafeScript NSW as a system implemented to monitor medications known to be inadvertently or deliberately misused, diverted, and involved in overdoses, emergency presentations, hospitalisations, and deaths. SafeScript NSW was identified to be both a clinical decision support and a regulatory tool. Participants were also consistent in describing benefits expected from the implementation of SafeScript NSW, with only a small number of potential negative outcomes reported.

Healthcare practitioners or clinicians

Most participants described SafeScript NSW as a clinical tool to support healthcare practitioners (prescribing and dispensing clinicians) make informed decisions about prescribing and dispensing monitored medicines.

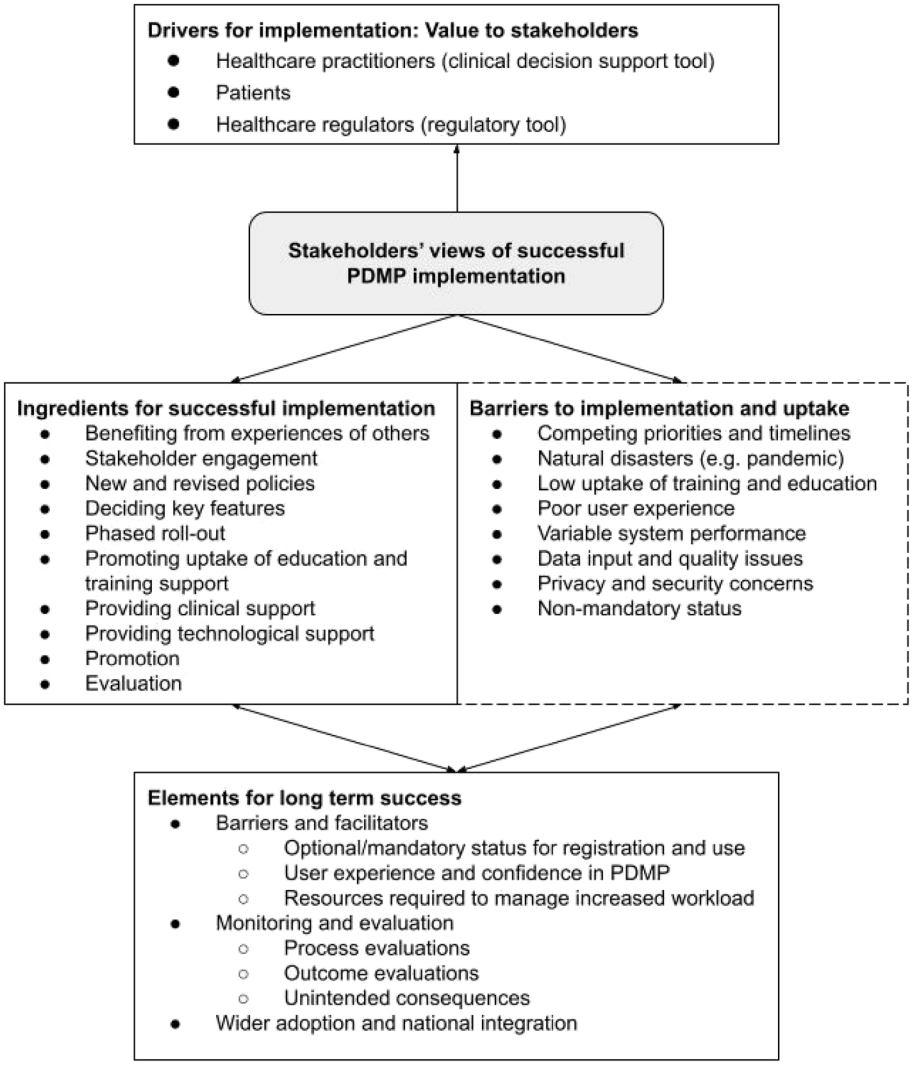

Fig. 1 Overall study outcomes on stakeholders' views of successful PDMP implementation. Note. PDMP = Prescription Drug Monitoring Program

…the practitioners of NSW can use the system and the information stored within it to supplement their existing clinical workflow and their clinical decision making. – Participant 4.

Participants reflected on the improved transparency and visibility of information relating to the use of monitored medicines with SafeScript NSW. A key reported benefit was a reduction in morbidity and mortality associated with reduced hospital presentations due to misuse, overdoses, and deaths. Participants perceived improved clinical decision-making related to prescribing and dispensing monitored medicines to be a benefit. Some participants noted SafeScript NSW could assist healthcare practitioners in identifying patients who may benefit from earlier redirection to other appropriate treatment such as pain management, mental health, or addiction services. Some participants also noted the potential added value to community prescribers (primarily general practitioners) by increasing their confidence in managing certain patients within the primary care setting.

…making it easier for doctors and pharmacists to identify people who are at risk, intervene earlier, and reduce harm and death associated with prescription meds and overdose and toxicity. – Participant 1.

However, some participants felt that SafeScript NSW may result in unintended consequences, including increasing demands on certain health or specialist services and encouraging a shift to increasing use of illicit drugs or other non-monitored medicines.

…there might be some system impacts in the sense that if there's GPs that are identifying more patients that require specialist advice or support, it might increase referrals into pain and drug and alcohol services. So that might be an event, unintended impact of this program. And that will create kind of a system issues. – Participant 7.

Patients

Some participants discussed the value of SafeScript NSW to patients (or consumers), including improved continuity of care and relationships with healthcare practitioners, and subsequent confidence in the appropriateness of care received.

So it's important that people have, feel confident in it, that patients feel that it's the right thing for them that it's actually there to help them and not hinder them. – Participant 6.

The other thing we're hoping is that consumers will see the benefit of having a key kind of doctor, like key prescriber, but also like a key pharmacists that they go to, so that they're going to the same health professionals and getting to know that health professionals, they're getting that kind of continuity of care, whilst they're being treated for you know, whether it's pain management or, you know, or for their addiction. – Participant 7.

A participant added however a potential risk of patients denied necessary care or treatment by clinicians in response to data accessible on SafeScript NSW.

Healthcare regulators

Some participants described SafeScript NSW as a tool used by the state's health regulatory unit to assist in monitoring prescribing and dispensing activities.

From a regulators point of view, the benefit for us of having access to SafeScript is that we really can get a pretty complete picture of what's being prescribed and what's being dispensed out there. – Participant 2.

Participants described SafeScript NSW data being utilised by the regulators to target investigations and perceived the tool and data as enabling proactive regulation and surveillance through improved visibility of trends in medicine use.

So the regulator can use the information inside SafeScript NSW to target their investigation and enforcement activity … it's a really important part of the medicines regulatory framework in NSW and SafeScript NSW means that that team can be more targeted and more efficient and more effective in their activities. – Participant 1.
…the long term aim is to have capability doing some proactive surveillance, rather than purely reactive… – Participant 3.

SafeScript NSW implementation – key ingredients for successful state-wide roll-out

Participants described ten strategies that contributed to what was perceived to be successful implementation of SafeScript NSW. These are listed with illustrative quotes in Table 1 and described below.

Benefiting from experiences of others

Many participants described benefiting from the experiences and learnings of other jurisdictions that had already implemented PDMPs.

Table 1 Illustrative quotes on perceived key ingredients for successful PDMP roll-out

Key ingredients for successful state-wide roll-out	
Benefiting from experiences of others	"For example, I did go to Melbourne, I need to speak to our colleagues in Melbourne about the rollout of SafeScript in Victoria. And it seems to me that what we're actually doing is a lot more advanced…" – Participant 3 "When we looked at SafeScript, we talked to all the different states to see what they've done, and some gone big bang, and you know, some have gone one pilot, and then all of the rest of the state. So we look at quite a few options." – Participant 5
Stakeholder engagement	"Although at every stage we've also consulted with all the peak bodies, so the professional councils as well as the professional bodies…" – Participant 2 "And there's also a lot of communications, a lot of webinars, presentations to a massive range of stakeholders, which includes not only the prescribers and pharmacists in the areas which are phase one, phase two, phase three areas, but also other major stakeholder groups such as professional organizations (…), consumer groups, hospital pharmacists, and so on." – Participant 3 "We consulted really widely, and we spoke to lots of stakeholders. So having a really good kind of stakeholder engagement plan was also quite effective." – Participant 7 "So there's, in consumer health advocacy, … and there's quite a few general health advocacy groups, … we knew that the patient cohort that we would be impacting, are likely to be from the addiction and the pain space. So we really wanted those leading advocacy groups in those two areas. And I think having them on board and making sure that they were consulted throughout really helped." – Participant 8
New and revised policies	"…how many policies and procedure documents were impacted, it was, I don't know, almost 200 for the whole program." – Participant 6
Deciding the key features of SafeScript NSW	"So we have a committee set up, which is ongoing, a monitored medicines committee, and they will look at all the evidence which is available and make recommendations, but the decision makers eventually will come back to the Ministry on what goes into the monitored medicines list." – Participant 3 "There's also an expert panel on monitored medicines, which meant to determine, and meets again regularly to determine which medicines would be included in our NSW monitored medicines list." – Participant 4 "So the view of the regulator in NSW is that for a system, you shouldn't regulate a system unless you have evidence to suggest that it needs to be regulated. So we really need to gather the evidence that actually we need to regulate this system, or we need to make this mandatory because we've now got evidence saying that if we don't, nobody uses it. … So you don't have to mandate every single clinical tool to make sure people use it if it's good clinical practice." – Participant 8
Phased roll-out	"And then the team looked at, if that was the case, which region should go first, second, third. So looking at the some of the characteristics within those geographical areas, including the number of allied health services … and would the support services be in place for go live? Perhaps not immediately. So those sorts of regions were, you know, move towards one of the later levels of implementation." – Participant 4 "I think the phased implementation was a really good idea because it gave us an opportunity to find if you've got teething problems, or if something doesn't quite work in the first phase, so you can learn about that. And apply those learnings." – Participant 8
Promoting uptake of education and training support	"…so I guess a strategy that we implemented was to use existing training agencies, so agencies or organizations that already train our target audience and already deliver education and training. … so definitely using those partners and not trying to introduce a new teacher, if you like, but leveraging those existing channels because they're trusted sources. It's what prescribers and pharmacists know where they go to get further education. So that was really important." – Participant 8
Providing clinical support	"So these were three modules to help support health practitioners in understanding what system is, how to use the system and kind of how it supports clinical practice, and also a communications module to support them in having conversations with their patients about prescribing monitored medicines." – Participant 7 "It's (Clinical Advisory Line) not meant to be a telehealth service. It doesn't take over the management of the patient. So that was really put in place for that, to provide that kind of high-level management advice rather than clogging up the system." – Participant 2
Providing technological support	"And then we developed a webpage, which also has a whole range of information on there, including Help pages, if clinicians have issues from a technical perspective using the system." – Participant 7
Promotion	"We also did a lot of partnering with health professional organizations, consumer organizations… to send communication material and information out to their members about SafeScript NSW… So our principle has been to use existing channels that exist within health organizations and other professional organizations already…" – Participant 1 "So even though this system isn't consumer facing, so consumers don't have access to the system, we thought it was really important that they were aware of this system and what it means to them as a patient and any potential impacts that might have on the way that they are treated…" – Participant 7
Evaluation	"So we did a diary study with a small number of clinicians very early on in the process… And we got some feedback from them about things that kind of were frustrating for them and things that worked well. And we also did a health practitioner survey more recently… And looking at sort of bigger picture health practitioner experience." – Participant 1 "And then I think we'll also be doing evaluation in phase three. And if the numbers are not, if the adoption rate, so I think we were looking at tail strategy … Once we've done the phase two and phase three evaluation to see how do we bring all those … people who are slow on the uptake, bring them on board." – Participant 5 "You know, how many sort of things are done, how many people register, how many actively using the system, and that will be monitored on an ongoing basis." – Participant 6 "We also did a consumer survey to, again, understand the experiences of consumers in the first couple of months of SafeScript and what they see as any potential impacts that they might have as a consumer." – Participant 7

Stakeholder engagement

Good stakeholder engagement throughout all stages, which included engagement with governance, clinicians, and consumer stakeholders, were also described as crucial for successful implementation.

New and revised policies

Participants highlighted the importance of development of new policies and changes to current policies, procedures and guidelines to facilitate the implementation of PDMP. Some described amendments to the Poisons and Therapeutic Goods Act to enable the collection of information into the monitored medicines database, and others described the development of a new privacy policy that restricts access to data on SafeScript NSW to certain people and conditions.

Deciding the key features of SafeScript NSW

A critical implementation process reported was the customisation of features for the state, including medicines selected for monitoring within the tool ("monitored medicines list"), rules relating to the types of data collected, the user interface, and rules relating to alert triggers. Participants said a new monitored medicines committee was set up that looked at available evidence and made recommendations for medicines to be included in SafeScript NSW.

Determining whether use of SafeScript NSW was to be made mandatory was described by participants as an important decision, with the state opting against mandated use. Participants held the view that evidence is required prior to implementing mandated use of the tool and explained that the current non-mandated access is in keeping with many other existing clinical tools.

Phased roll-out

An important implementation approach mentioned by most participants was the phased roll-out strategy. This iterative process was perceived to help the team obtain feedback, identify issues and revise strategies to support implementation of later phases. Some participants explained that the order of roll-out to PHNs was guided by the availability of resources and the capacity of networks to manage potential increased workload for certain specialist services such as addiction and pain management services.

Promoting uptake of education and training support

Participants frequently mentioned partnerships with existing trusted professional bodies responsible for education as being key to successful implementation. These organisations delivered information and educational content relating to SafeScript NSW via subscribed channels to members. Participants perceived helpful elements of education and training for the program to be its availability online, and the incentive of them being accreditable Continued Professional Development activities for healthcare practitioners.

Providing clinical support

All participants described a key strategy to support implementation to be the development of new web-based information portals and educational material to support the upskilling of clinicians. Participants explained that a goal of education and training was to enhance primary care led interventions. Participants reported that a new telephone advice line was set up, which provides 24-hour clinical support to clinicians, however, a small number of participants alluded to low uptake of the advice line after Phase 1 implementation.

Providing technological support

Participants described information technology support being available to users of the tool via educational resources on technical usage of the system, telephone support, and online troubleshooting resources.

Promotion

In addition to partnering with existing health professionals' organisations for education, participants explained that these partnerships were also essential for communicating with healthcare practitioners about PDMP. Partnering with consumer organisations was also frequently raised by participants as valuable, utilising existing consumer channels to distribute material and information about SafeScript NSW to increase awareness and engagement.

Evaluation

Many participants described evaluation as a key ingredient to ensuring PDMP implementation was a success. Feedback was obtained from both clinicians and consumers following the first phase of roll-out. Participants described two methods for obtaining clinician feedback – a diary study and a survey. Feedback from consumers was obtained via a consumer survey.

Barriers to PDMP implementation

In addition to the strategies above, participants outlined a number of barriers to implementation of SafeScript NSW. Table 2 further describes these with illustrative quotes.

Competing priorities and timelines between the implementation team, PDMP vendor, and other vendors or providers of community practices operating systems was identified as an issue as these were required to build an integrated workflow for SafeScript NSW.

Table 2 Illustrative quotes on perceived barriers to PDMP implementation

Barriers to PDMP implementation	
Competing priorities and timelines	"When you're talking about integration with primary care, we've got the desktop providers, we've got Medicare, we've got lots of different systems trying to talk together to get an integrated workflow. And that can be really challenging because you've got competing priorities…" – Participant 8
Delay and changes to strategies to support implementation	"And it's been a very challenging time to break through the barriers to get those messages through particularly given the pressure in the primary care sector, brought on by COVID-19, in the last 18 to 24 months…" – Participant 1 "But in lieu of doing site visits and because of COVID, we couldn't really go out and talk to lots of people. This was kind of a secondary strategy that we implemented to try and get some local kind of visibility of the program." – Participant 7
Low uptake of training resources	"There was also a reasonably low uptake of the training material, even though it's available." – Participant 2
Poor user experience	"…so in on the bad side, we've had some system issues. Well, as I said before, performance was an issue. And some of the functionality around the PIN code to log into the system hasn't been working exactly as we expected, they're probably the two most common pieces of negative feedback that we've received, we've taken active action on and finding solutions to those problems." – Participant 1
System slow and glitching	"So I think there were just a couple of issues around performance early on, which we've sort of addressing or addressed bulk of it." – Participant 5 "From a technical perspective, I'd say that, and just that systems are glitchy and slow, that always presents a challenge." – Participant 8
Login too long	"And so we needed to prioritize a solution or a fix to reduce the amount of time that it took to login and improve the system performance, which we've now done and implemented." – Participant 1 "The other issue that came up quite a bit was around the login process. So for health practitioners to log in, they need to create a password. But there's also a multifactorial kind of code that they need to enter in. …But having to do that, when you first log into SafeScript every day can be a barrier, because it's quite time consuming." – Participant 7
Data quality	"Yeah, so there have been a few data quality issues that have come up through our evaluation. Some of them are related to how the clinician enters the information into the system. So for example, if they put the wrong address in for the person or they spell the name wrong, then that creates issues… And we are working with health practitioners to encourage them to make sure that they're entering in information correctly, because that has an impact on trying to then find those patients again…." – Participant 7
Legal risks: privacy and security concerns	"So there's an additional adoption barrier, I guess. If we don't get it right with the privacy and security, I think that would put a dent in confidence, particularly from the consumer side." – Participant 4
Medicolegal challenges with non-mandatory access	"…because it's not mandatory. What does that mean? Do I have to use it? Am I going to be punished or you know, judged for not using it, if I come before a board or before a council? For a situation and I haven't registered and I haven't accessed and used, will I be found negligent? Where's that duty? Where's the standard of practice? And that will evolve as with all new tools…" – Participant 8

Participants also discussed the delay and changes to strategies to support implementation that were required because of natural disasters, including the COVID-19 pandemic and major flooding that occurred during the implementation of SafeScript NSW. A small number of participants described challenges experienced with low uptake of training resources, with feedback indicating the training and educational modules were too long for time-poor clinicians.

Another frequently reported barrier was poor user experience, which negatively impacted adoption. This included issues with variable system performance, login problems, and poor data quality. Participants explained that they had received feedback from users about the system being slow or glitching, and further work was completed to improve and enhance the system performance with the vendor of SafeScript NSW. With respect to login, participants said that users had provided feedback about the time required for multifactor login requirements. Some participants also raised concerns about data quality, with data input by clinicians affecting data output, such as the inability to access data on the system because incorrect patient details were entered.

Legal risks relating to privacy and security concerns were also reported as additional adoption barriers. These were in relation to potential consumer concerns regarding the security and privacy of their data now available on SafeScript NSW. Additionally, participants raised the prospect of medicolegal challenges and perceived clinical liability faced by clinicians where no standard of practice is in place regarding the use of SafeScript NSW, given its non-mandatory status.

Elements required for long-term successful adoption of PDMP

Participants noted that, although all NSW-registered prescribers and pharmacists on the Australian Health Practitioner Regulation Agency are invited to register and use SafeScript NSW, full uptake was not expected, as not all will prescribe or dispense the medicines monitored on SafeScript NSW.

Barriers and facilitators to long-term adoption

Of those expected to use SafeScript NSW, a barrier to adoption was reported to be the fact that registration and use of the tool in NSW was optional.

> *I think the obvious thing is regulatory levers to compel the use of SafeScript under certain circumstances. I think that's probably the most logical thing that would increase the adoption rate. … we're really hopeful that health practitioners will self-select and use the system on their own behalf and won't be required to compel the use. – Participant 1.*

A small number of participants mentioned the potential to review the optional access status to SafeScript NSW if uptake was deemed suboptimal. Although some participants also explained that mandating use of SafeScript NSW may not change behaviours of clinicians.

> *And also, what does mandatory use look like? …I've complied with the law, because I've looked at it. But it hasn't actually affected my behaviour. So I don't know that that is, in and of itself is the answer, forcing somebody to look at something is part of the success because at least you made them look at it… – Participant 2.*

Participants discussed how poor user experience, particularly on first use, may deter people from using the tool again. For healthcare regulators, some participants noted a potential barrier to be the resources required to manage the increased traffic and workload introduced by SafeScript NSW's increased data availability.

> *I think we always knew that there would be millions of events. … And with such a huge volume of data, you can get delays in systems. – Participant 2.*

These problems were described to potentially result in negative publicity, which could negatively impact the success of implementation and limit adoption.

> *I think those things would undermine it and would you know, once it gets a bad name, and it loses its sort of shine, there's a potential that they'll just, people will just switch off and ignore it. – Participant 6.*

Participants suggested positive user experience and confidence in the accuracy, robustness, and usefulness of SafeScript NSW information would be facilitators to successful ongoing implementation and uptake. Therefore, having champions within user groups and positive testimonials were identified as important strategies to aid promotion and long-term adoption of the tool.

> *The positive user experience, I think, and the way that they're using the system, and that it's, that they feel that it's achieving something. – Participant 2.*

Monitoring and evaluation

Participants described ongoing monitoring, such as reviewing rates of registration, active use, alerts generated by the system along with rates of clinicians' viewing of alerts, would be useful for ensuring long term success. Some participants reported that evaluation of outcomes was also important, including prescription rates and patterns, and referral rates to specialists. Participants highlighted the importance of monitoring unintended consequences such as increased use of non-monitored or illicit drugs. A small number of participants described measuring system speed and effectiveness, and the impact to regulatory unit workload, such as increases in prescription authority requests.

Some participants noted that evaluation of successful implementation is complex, with most benefits not achieved immediately, but over time. The longer-term measures of success were viewed to be reductions in mortality and emergency department presentations.

Wider adoption and national integration

The majority of the participants described an indicator of success of SafeScript NSW implementation long-term being the tool becoming part of a nationally integrated information sharing system, although some participants described challenges associated with implementing a nationally integrated approach with no current plans or procedures in place. Some participants also discussed an annual review of emerging trends of other drugs that may contribute to the monitored medicines list. Having broader reach and collecting and integrating data from hospital systems were raised by participants as being part of the longer-term plans of PDMP, although some raised concerns about feasibility.

Discussion

Stakeholders responsible for PDMP implementation in NSW shared a common understanding of the perceived benefits and drivers for PDMP implementation. A reduction in harms from certain high-risk prescription medications was expected, an outcome which impacts healthcare regulators, practitioners, and patients. Participants outlined ten key ingredients for successful state-wide implementation, and identified a number of barriers, particularly around poor usability and user experience of the tool. Phased roll-out, extensive and iterative consultation with stakeholders throughout implementation, and efforts targeting user experience and perceptions were important highlights.

The iterative involvement of all stakeholders, including regulatory and governance groups, healthcare practitioners, professional organisations, and consumer groups, throughout all stages of planning, roll-out, and evaluation emerged as a critical factor for successful implementation of SafeScript NSW. This involved utilising existing trusted professional bodies to consult with, disseminate information, and provide platforms for training, education, and feedback. This reflected the importance of involving clinician users and consumers, as those impacted by the implementation of the tool on successful implementation [11]. Interagency and stakeholder collaborations have been identified as important facilitators to PDMP implementation in previous research [6]. Our study adds to this by highlighting the criticality of repetitive engagement with stakeholder groups for a large-scale roll-out, and importantly, throughout stages rather than in a singular consultative occasion.

Another valuable strategy emphasised was the phased roll-out of SafeScript NSW. This provided opportunities to review stakeholder feedback, manage risks or challenges encountered, and to revise and adapt system design, usability, and implementation plans to improve roll-out and ensure success. There have been no reports or evaluations of this approach in previous PDMP-related studies, although phased roll-out has been used in previous implementations of other digital tools [12, 13]. Our study highlights the perceived benefit of this approach for PDMP, particularly for state-wide implementations. Often facilitated by the phased roll-out, participants frequently mentioned the importance of continuous monitoring and evaluation of the implementation, in order to optimise the intervention, as has been done with other digital health tools [14–17]. Digital systems are not 'set and forget' interventions, with ongoing review and modifications needed to ensure they remain useful and appropriate as the digital landscape and skills and knowledge of users continually change.

Poor or negative user experience was perceived to be a barrier to the adoption and, therefore, user experience and associated uptake are key factors impacting PDMPs effectiveness and ability to achieve desired benefits—a finding consistent with a recent systematic review [3]. Ensuring user confidence in the PDMP data and tool contributing positively to clinical decision making was perceived as an important element to its long-term success and uptake. One concrete way of doing this as reported by participants, is to evaluate and obtain feedback from users in early phases and modify the tool to improve usability and trust in the tool, an approach used for other digital health tools, as described in literature [18].

When discussing the decision for non-mandated use of SafeScript NSW, participants reported that more evidence was required to demonstrate the benefits of mandatory access. This is in contrast to research showing that evidence plays a limited role in driving decisions to implement 'non-mandatory' clinical decision support tools, and likely reflects a desire to ensure benefits will be achieved, before enforcing adoption [19]. Existing literature has shown that, although mandated use of PDMPs may increase user uptake, it is associated with negative user experiences and perceptions [3], in addition to the emergence of unintended consequences such as underprescribing for patients in need [20], and increased use of other non-monitored drugs such as pregabalin and tricyclic antidepressants [21]. Thus, the decision to make a system like PDMP mandatory is complex, and requires careful consideration regarding the impact on healthcare provision from the perspective of patients and healthcare practitioners, in addition to the interrelated regulatory and medicolegal concerns that may emerge. These considerations and decisions must be accompanied by meaningful monitoring and regulation of a mandate.

Limitations

The study was conducted during the Phase 2 roll-out of SafeScript NSW, prior to the completion of full implementation. Study participants were self-selected individuals who were likely more keen to express their views than those who did not volunteer, and so may not be representative of the entire sample. This research was conducted in a high-resourced country and may not be generalisable to other settings, although many of the lessons learnt (such as phased roll-out, wide iterative stakeholder engagement and evaluation) could still be applicable and scaled appropriately. Finally, use of the NASSS framework to guide data analysis proved challenging and time consuming, with researchers often interpreting NASSS components differently. Extensive discussion between coders was needed to ensure consistency in understandings of categories and in analysis.

Conclusions

Overall, this is one of the first studies focused on identifying important strategies for perceived successful large-scale state-wide implementation of PDMP. Successful implementation requires significant time and resourcing, with the design and configuration of the technology only one component of a multi-strategy process. Iterative engagement with a large number of stakeholder groups was viewed as key, as was ongoing monitoring and evaluation, facilitated by a phased roll-out. Effective and well-considered strategies to support implementation are crucial for maximising the potential for the successful uptake of such tools and the subsequent realisation of intended benefits or outcomes. The knowledge and insights gained from this study may be applied to other implementations of similar digital health tools and/or large-scale jurisdictions.

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

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Authors' contributions
ET and MB conceived of the study, and all authors (ET, MB, MM, TLL, AH) contributed to the design of the study. ET conducted the data collection, ET and MB conducted data analysis, and all authors contributed to interpretation of data. AH assisted with obtaining approval from NSW Department of Health to enable the conduct of the study and led the distribution of recruitment emails to potential participants. ET wrote the initial draft manuscript and all authors (ET, MB, MM, TLL, AH) read and approved the final manuscript.

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Availability of data and materials
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Ethics approval was obtained from The University of Sydney Human Research Ethics Committee. All participants provided written informed consent before participating in the study.

Consent for publication
Not applicable.

Competing interests
ET, TLL, MM, and MB have no conflict of interest to declare. AH is an employee of NSW Department of Health and was program manager of the SafeScript NSW implementation team at the time of the undertaking of this study.

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