Co-designing a consumer-focused digital reporting health platform to improve adverse medicine event reporting: Protocol for a multi-method research project (the ReMedi project)

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Abstract

Background: Adverse medicine events (AMEs) are unintended effects that occur following administration of medicines. Up to 70% of AMEs are not reported to, and hence remain undetected by, healthcare professionals and only 6% of AMEs are reported to regulators. Increased reporting by consumers, healthcare professionals, and pharmaceutical companies to medicine regulatory authorities is needed to increase the safety of medicines.

Objective: We describe a project that aims to co-design a digital reporting platform to improve detection and management of AMEs by consumers and healthcare professionals and improve reporting to regulators.

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Results: This project is currently underway, and we will publish findings progressively as we complete our analyses.

Conclusions: This project adopts a co-design methodology to develop a new digital reporting platform for AME detection and reporting, considering the perspectives and lived experience of stakeholders and addressing their requirements throughout the entire process. The overarching goal of the project is to leverage the potential of both consumers and technology, to address the existing challenges of under-detection and under-reporting of AMEs to healthcare professionals and regulators. The project potentially will improve individual patient safety and generate new data for regulatory purposes related to medicine safety and effectiveness.

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Keywords: Adverse drug events; drug-related side effects and adverse reactions; adverse drug reaction reporting systems; pharmacovigilance; digital health; medication safety; co-design; qualitative research, user-centred design.

Introduction

Adverse medicine events (AMEs), also known as adverse drug events, are unintended effects that occur following administration of a medicine and include adverse reactions and harm from medication errors.[1] AMEs are common and result in patient harm. In Australia, an estimated 1.2 million people reportedly experienced an AME within a six-month period.[2] While AMEs can occur in anyone, people with chronic conditions and older people are particularly vulnerable to and are most affected by AMEs. For example, one in five hospital admissions in older adults in Australia is due to AME.[2-4] According to a 2022 estimate, medicine-related hospital admissions, including instances of non-compliance, overdose, and AME incur an estimated annual cost of AUD$1.4 billion in Australia, with AME being the most prevalent contributing factor.[2,5] Early detection and management of AMEs is crucial to preventing avoidable harms such as medicine-related falls, hospitalisations and deaths. However, findings from surveys and reviews of consumer medical records conducted internationally suggest that many consumers do not disclose their AMEs unless prompted to do so. Consequently, up to 70% of AMEs are undetected by healthcare professionals,[6,7] emphasising the need for proactive interventions to identify and resolve AMEs.

AMEs are also under-reported to medicine regulatory authorities (‘regulators’), making it difficult to understand how medicines affect consumers. Spontaneous reporting of AMEs is the most common mechanism of safety surveillance worldwide after a medicine has been introduced to the market.[8] Spontaneous reporting of AMEs by consumers, healthcare professionals, and pharmaceutical companies is vital for regulators to identify potential medicine safety signals[9] and -when relevant- mandate necessary changes, such as updating product labels or withdrawing medicines from the market. A major challenge, however, is the very low AME reporting rate; as evidenced by a systematic review of 37 studies from 12 countries; only an estimated 6% of AMEs experienced by patients were reported.[10]

Consumers often detect AMEs before their healthcare professionals notice them[11], and, where patient engagement is implemented, consumer self-report of AMEs alert regulators to new and previously unknown reactions prior to health professional reports.[12,13] In Australia, however, the number of reports to regulators from consumers is disproportionately low compared to those made by healthcare professionals and pharmaceutical manufacturers[14], partly because of consumers’ limited awareness of the reporting system, and perceived absence of benefits of reporting.[15] The AME reporting system, developed by the medicine

regulatory body, the Therapeutic Goods Administration (TGA),[14] has seen limited consumer uptake in Australia. Additionally, there is currently no Australian-specific AME reporting platform co-designed with consumers. To address this gap, we developed a prototype system in a small pilot project, comprising both Android and iOS apps and a public-facing website for consumers to report any AMEs they experienced.[16] The system was shown to be user-friendly, however the development involved limited stakeholder engagement and participation (n=3 consumers).

Building on this pilot project the current project aims to co-design with stakeholders (consumers, healthcare professionals, and regulators) a digital reporting platform to improve AME detection, management and reporting. The ultimate goal of this project is to empower consumers to actively detect, manage, and report AMEs, fostering a collaborative approach with their healthcare professionals, and at the same time improve AME reporting to the TGA.

Methods

The project is being conducted in three phases (Figure 1) from 2023 to 2026 and employs a co-design methodology that prioritises designing equitably with all stakeholders.[17] Co-design methodology focuses on generating and reflecting on data related to people's lived experiences, and engaging participants in action to enhance the quality of their lives. Co-design facilitates collaboration among stakeholders to address challenges within socio-technical systems and daily services.[18,19] It employs design-based strategies to collect qualitative data around users' experience and the interests of the stakeholders providing services to those users to foster dialogue for mutual insights. Using a range of research methods including stakeholder workshops, focus group discussions and interviews, co-design aims to describe, categorise, question, and evaluate the needs, experiences, opinions, interests, decisions, and behaviours of stakeholders, ensuring equity through structured reflection.

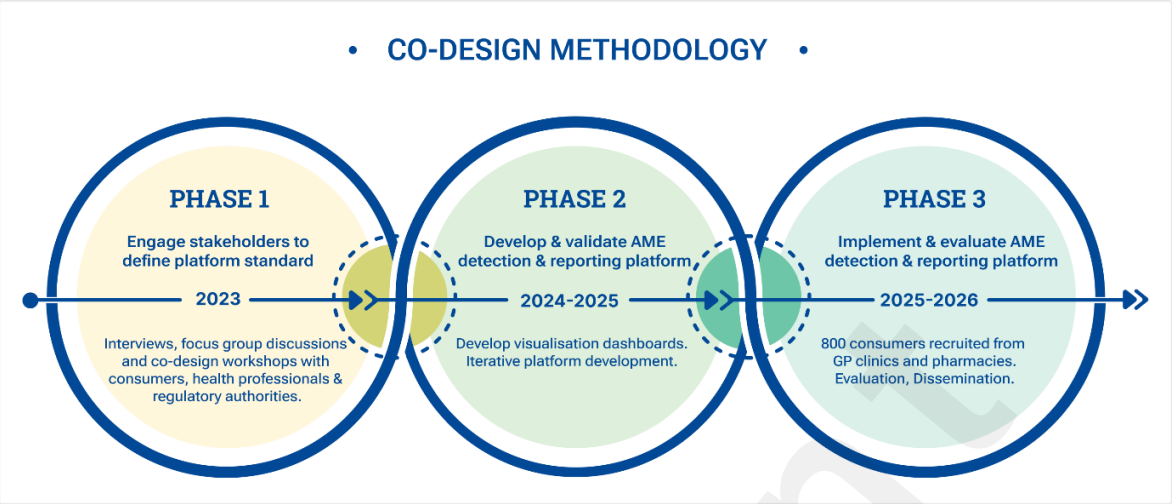

Figure 1: Key activities in each phase of the project. AME = adverse medicine event; GP = general practitioner.

Our project is guided by the Consolidated Framework for Implementation Research (CFIR), which considers five domains for effective intervention development and implementation: innovation, outer setting, inner setting, individuals, and implementation process.[20] The innovation domain includes the construct's trialability and evidence base, which we addressed in our pilot work[16] and systematic review.[21] We will consider constructs in each domain that influence use of our platform by consumers including innovation, complexity and usability, consumer needs and preferences, feedback, design and engagement.[20,22-24]

PHASE 1: Engage with stakeholders to define platform development standards

Phase 1 involves interviews, focus groups discussions and co-design workshops with three specific stakeholder groups: consumers, healthcare professionals, and regulators.

Individual semi-structured interviews across the three stakeholder groups will be conducted to understand their experience with, or perspectives toward medicine use and the current AME reporting process in Australia. Individual interviews offer the opportunity for researchers to have in-depth, one-to-one discussions with participants about their experiences and perspectives and enable participants to offer their ideas and insights in confidence and without the possible influence of bias from other participants. Each interview will run for approximately 60 minutes. Findings from the interviews will be used to develop personas (characterisations of user archetypes) that will then be discussed in focus group discussions to determine their accuracy and thoroughness as exemplar of user groups. Two separate focus group discussions will be held with each of the three stakeholder groups and participants will

be asked to consider and define the respective needs, priorities, and motivations their persona might have for reporting an AME and to define their reporting goals for the platform. Each stakeholder focus group discussion will run for two hours. Outcomes from the focus group discussions will then inform the development and delivery of three co-design workshops that will be held for the same stakeholders collectively. Workshop participants will be asked to employ the co-designed user personas to build a user journey map as a means to evaluate the processes of AME detection, management, and reporting, generate and agree on notional platform content and feature set to guide its subsequent development. Each co-design workshop will last three to four hours.

We will use purposeful sampling to recruit 10 to 15 consumers with broad demographic variation to ensure they represent consumers across different ages and social groups, levels of education and experience, and who have a range of health conditions and use a range of medications to ensure our platform meets the needs of diverse groups of people. In addition, ten healthcare professionals (e.g. pharmacists, medical doctors, nurse practitioners) and personnel who work for the medicine regulators will also be recruited. All participants will be asked to participate in all three activities: semi-structured interviews, focus group discussions, and co-design workshops. Attrition is natural in longitudinal projects such as this, and we will mitigate this by recruiting additional participants.

The interviews, focus group discussions and co-design workshops will be conducted face-to-face where possible and audio- or video-recorded where participants agree. If participants are located interstate from the researchers or prefer to engage remotely for convenience, interviews, focus group discussions and co-design workshops will be conducted online. All recordings will be transcribed verbatim, manually coded and analysed thematically in ATLAS.ti software (ATLAS.ti Scientific Software Development GmbH, Berlin, Berlin, Germany).[25] Research instruments that will be developed to facilitate the collection of each data set include: persona profiles (which will be used to summarise the identified needs, priorities, motivations, goals and challenges of each user archetype) and user journey maps[26] (which will be used to visualise and document participants' discussions of the likely experience personas might have during the process of reporting or reviewing AMEs as they move through the system). The findings of this phase will be used to guide subsequent phases of the project.

PHASE 2: Develop the platform and interactive data visualisation tool

The second phase of the project focuses on the development of the platform. First, we will work with a software developer and user interaction designers to develop the underlying relational structure that received data from users might have, how the data functions in terms of reporting and what principle features a front-end user experience might have for gathering it (Phase 2a - Platform development). Initial outcomes from this could take the form of a web-based platform, a mobile application or both, based on findings from Phase 1. To ensure equity across stakeholder interests, we will continue to adhere to co-design principles throughout this phase by inviting consumers, healthcare professionals and regulators to participate in this process. The platform development will undergo cycles of iteration and review where stakeholders will test, compare and contribute to decision-making on the content, form and function of the platform through each iteration. We will perform the iterative cycles with stakeholders until no new issues are identified with the platform. We anticipate the process will require up to five cycles before saturation and a deployable outcome is achieved. Stakeholders recruited in Phase 1 will be invited to participate in this process, and additional participants will be invited to compensate for any attrition.

Next, as part of our communication and engagement strategy, we will develop an interactive data visualisation tool or dashboard to translate and disseminate the data collected to the public, healthcare professionals and regulators (Phase 2b - Development of interactive data visualisation tool). The visualisation tool will be implemented with back-end integration in the digital reporting platform and developed collaboratively through two co-design workshops with eight stakeholders. The visualisation tool will be configured to allow both consumers and their healthcare professionals to access the data they provided, obtain information on the medicines they are taking and compare their experience with those reported by other consumers taking the same medicines. A separate visualisation tool will be developed for use by regulators and will include further levels of configuration necessary for them to examine data relative to their decision-making. All consumer reports will be reviewed by study investigators (clinicians) for causality assessment (i.e. likelihood that the medicine caused the observed AME) using the Naranjo probability scale.[27] The causality assessment will be done to determine whether the platform has collected all the information needed for a causality assessment.

PHASE 3: Digital platform implementation and evaluation

In the third phase of the project, we will implement the new platform in selected South

Australia general practices and pharmacies and assess its impact for, i) increasing AME detection, ii) improving AME management, and iii) increasing AME reporting and enhancing existing TGA workflows.

A quasi-experimental study will be conducted to involve consumers who have recently begun taking new medicines. This is because most AMEs tend to occur within 4 weeks of patients commencing new medications.[28] Depending on results from Phases 1 and 2, criteria for further inclusion may be specified (e.g. consumers initiating medicines with a black triangle warning). Eligible consumers will be identified initially by general practices and pharmacies applying the in-/exclusion criteria to their software (e.g. Doctors Control Panel software[29] and dispensing software used in the pharmacies). Eligible consumers will then be approached by a dedicated research assistant via phone, SMS or email to assess their eligibility, discuss the details of the project, answer any questions, and facilitate the process of obtaining informed consent from interested individuals. We will seek consent to send information reported by consumers to their healthcare professionals and regulators (i.e. the Therapeutic Goods Administration or TGA). Consumers will then be prompted to use the platform to report whether they have experienced any suspected or possible AME. Where the consumer has consented, a report will be sent electronically to their general practitioner and pharmacist to enable targeted assessment for managing the AMEs. For those who provided consent, consumer reports will also be submitted to the TGA. Subsequent prompts to use the platform will be sent to the consumers via automated text messages. The frequency of sending the text messages will be determined based on co-design workshops with stakeholder groups. Consumers will be given a summary report of their data and access to the interactive data visualisation tool (Figure 2).

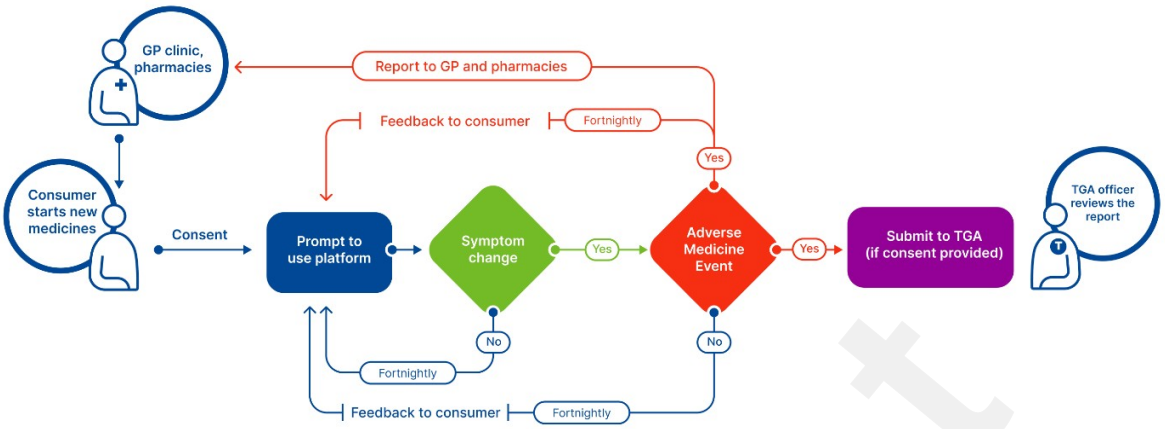

Figure 2: Flowchart for platform implementation in Australia. GP: General practitioner; TGA: Therapeutic Goods Administration

Based on interventions to improve AME reporting [30] which report a relative risk of 2.04 (57% in intervention group versus 28% in controls), α of 0.05 and power of 80%, a total of 80 consumers experiencing and reporting AME is needed. Assuming that 20% of consumers starting medicines experience an AME and half of the consumers will report their AMEs, we aim to recruit 800 people for Phase 3. The sample size was calculated based on Statistical Power Analysis using R.[31] Initial database analysis in one of our participating clinics with eight FTE (full-time equivalent) general practitioners indicated that each general practitioner prescribes a medicine that is new to the patient for about 40 people/month (320/month for the practice), supporting the feasibility of recruitment of 800 participants within 6 months.

To assess whether the platform improved AME detection, interrupted time series analysis will be used to determine the proportion of AME detected pre- and post-platform implementation in the general practices. A random sample of up to 1000 patient records in the participating general practices will be manually reviewed by nurses at the practices to determine the number of AMEs detected up to 3 months prior to platform implementation. Additionally, we will describe the number of AME reports submitted to the TGA by our study participants post-platform implementation.

Finally, we will conduct two focus group discussions with the project team and stakeholders to evaluate the implementation process (what works, where, and why),[20] the acceptability of and satisfaction with the platform. Questions related to the implementation process will be adopted from the CFIR interview guide tool.[20] The focus group discussions will be audio-recorded, transcribed and analysed using thematic analysis.[25]

Ethical considerations

Ethics approval for Phases 1 and 2 has been received from the University of South Australia Human Research Ethics Committee (Application ID 204984). Ethics approval will be sought from the same committee prior to starting Phase 3. Informed consent will be sought from all participants.

Results

This project is currently underway, and we will publish findings progressively as we complete our analyses. In addition to the traditional research outputs (journal articles and conference papers), the designers on our project team will develop a series of non-traditional research outcomes including, but not limited to, a communication platform that support consumers and healthcare practitioners to report adverse events, an icon system for nonverbal communication, and the dissemination of visual outcomes in the form of a public exhibition, either online or in person. We will organise public displays of the visual works at multiple venues in Australia to increase awareness and discussions about the importance of detecting, managing and reporting AMEs. We will promote the exhibitions and project findings through our teams' respective institutions' media platforms.

Discussion

Medicine safety is complex and requires well-developed systems, strategies and processes to keep consumers safe. Effective systems and strategies for AME detection, management and reporting are crucial to ensure medicines are used safely and effectively. However, AME reporting by consumers remains low.[14] Instead, consumers were generally more likely to report AMEs to doctors or pharmacists[32], potentially stemming from inadequate or lacking systems that enable the proactive detection and management of AMEs. Our project will bring these two aspects together to build what we hypothesise to be a single, readily available solution that integrates AME detection and management by consumers in consultation with their general practitioners and pharmacists, and which also potentially benefits AME reporting to regulators. As such, our project aims to serve both patient-level clinical needs and population-level regulatory needs on medication safety issues.

The level of end-user involvement during the development phase of digital interventions that are implemented in practice is unclear. Despite the development of numerous digital

interventions to improve medicine management and safety, the minimal engagement of end-users in this process and a failure to meet their needs adequately, results in the low adoption of these interventions in practice.[33] For instance, the implementation of GuildCare (GuildLink), an AME surveillance system designed for Australian community pharmacists was introduced in 2014. While the initial year saw a notable increase in AME reporting rates to the TGA, the subsequent year saw a decline, hinting at challenges in maintaining sustained adoption.[34] Factors influencing the adoption and ongoing use of digital health technologies include cost, simplicity of language, ease of use, design, scientific evidence base, motivation and perceived value by end-users.[22-24] To effectively tackle the challenges related to fulfilling the requirements of stakeholders and overcoming low adoption rates, our project takes a unique approach by grounding it in a multidisciplinary ideology from its outset. This includes collaborating with experts from various disciplines including medicine safety, co-design, user-experience design, communication design, psychology, engagement, and cybersecurity to address fundamental issues that predict successful implementation of the system in practice. This partnership, grounded in a co-design methodology, also represents one of the first instances where a digital intervention for AMEs is co-produced with consumers, healthcare professionals and the regulators. The approach seeks to ensure that the digital intervention directly addresses the needs of the three stakeholder groups, thereby increasing the likelihood of adoption in practice and ensuring its long-term sustainability.

AME reporting by consumers has the potential to improve the safety of medicines. In a previous study conducted in Australia, despite acknowledging limited awareness, consumers expressed a positive attitude towards AME reporting.[15] The perceived lack of benefits for the reporting consumer, however, was recognised as a barrier to the reporting process.[15] The significance of our proposed platform lies in its potential to incorporate consumers' voices into their medicine and healthcare journey, enabling consumers to report AMEs to their healthcare professionals and to the regulators. If successfully implemented, the proposed platform has the potential to result in an increase in the proportion of consumer AME reports submitted to the TGA, which currently accounts for only 3.4% of the total reports submitted to the TGA.[35]

There has been a decline in the percentage of AME reports from doctors in Australia, decreasing from 28% in 2003 to 4% in 2016.[32] The potential increase in participation by consumers through use of our proposed platform may contribute to increased identification of safety signals. By streamlining the AME reporting process to the TGA, our platform has the

potential to contribute to more timely detection and verification of potential medicine safety signals. This initiative addresses a national[36] and global health priority,[37] and addresses two components of the Australia's National Strategy for Quality Use of Medicines: monitoring outcomes and improving people's ability to solve problems related to medicines, such as negative effects.

The introduction of a visualisation tool as part of the platform has the potential to enhance end-user interaction and participation in research, and may facilitate early and effective communication of safety issues to relevant stakeholders. The development of interactive data visualisation tools marks a creative initiative to enhance communication and transparency between consumers and regulators. While visualisation tools for conveying important public health issues have become common, especially during the COVID-19 pandemic, they frequently lack transparency in describing the development process, fail to engage end-users in design and development, and leave uncertainty about whether they adequately meet the needs of those end-users.[38] Our user-centric co-design methodology for this project has the potential to ensure that the visualisation tools effectively meet the diverse needs of consumers, healthcare professionals, and regulators alike.

Limitations

First, the success of our digital reporting platform will ultimately rely on the level of user engagement and participation. Robust stakeholder engagement strategies, including co-design workshops and ongoing collaboration, does not guarantee user uptake and continued use. Factors beyond our control, such as accessibility to devices, individual motivation and preferences, previous negative experiences with reporting may influence the level to which consumers actively engage in this new digital platform. The introduction of any new system, service, or technology is frequently considered an additional burden or challenge when implemented in practice. However, our early engagement strategy with stakeholders, from Phase 1, is designed to potentially mitigate some of this resistance and to increase the chances of adoption. Second, the reliance on interrupted time series analysis for outcome evaluation introduces potential confounding factors that may not be fully accounted. Thirdly, the small number of consumers recruited in Phase 3 means that we will not be able to determine whether the platform had an overall effect on the number of consumer reports to the TGA, or whether the reports from our platform helped generate new or different medicine safety signals. Finally, certain processes in our project rely on interim review or support from members of the research team. These workflows and processes will require revision and

adaptation when implemented in clinical practice.

Conclusions

This paper describes our co-design project that will actively involve key stakeholders in the development and evaluation of a new digital platform for AME detection, management, and reporting, with a central focus on consumers. The use of a co-design methodology ensures the incorporation of the perspectives and requirements from consumers, healthcare professionals, and regulators—a crucial element for fostering the adoption and sustainability of the intervention. The project harnesses the potential of both consumers and technology to address the existing challenges in under-detection and reporting of AMEs to healthcare professionals and regulators. The overarching goal is to enable consumers to actively participate in medication safety-related matters; thus, enhancing the quality of their lives, influencing clinical decisions related to their health, and contributing to overall medicine safety.

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Authors' contributions

EAG, CT, MT, STdeV, AA, LKE, OF, PYC, KRC, TLL, and RL contributed to the conception and design of the project. EAG and RL drafted the manuscript. All authors revised the manuscript critically for important intellectual content and provided final approval to the manuscript.

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Conflicts of interest

None declared.

Abbreviations

ADE: Adverse Drug Event

AUD: Australian Dollar

CFIR: Consolidated Framework for Implementation Research

FTE: Full-Time Equivalent

GP: General Practitioner

NHMRC: National Health and Medical Research Council

SMS: Short Message Service

TGA: Therapeutic Goods Administration

References

1. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *The Lancet*. 2000/10/07/ 2000;356(9237):1255-1259. doi:https://doi.org/10.1016/S0140-6736(00)02799-9

2. Lim R, Semple S, Ellett LK, Roughead EE. Pharmaceutical Society of Australia. Medicine Safety: Take Care. PSA; 2019. 19 May, 2019. https://www.psa.org.au/wp-content/uploads/2019/01/PSA-Medicine-Safety-Report.pdf

3. Lim R, Semple S, Ellett LK, Roughead EE. Pharmaceutical Society of Australia. Medicine Safety: Aged Care. 2020. https://www.psa.org.au/wp-content/uploads/2020/02/Medicine-Safety-Aged-Care-WEB-RES1.pdf

4. Parameswaran Nair N, Chalmers L, Bereznicki BJ, et al. Adverse Drug Reaction-Related Hospitalizations in Elderly Australians: A Prospective Cross-Sectional Study in Two Tasmanian Hospitals. *Drug safety*. Jul 2017;40(7):597-606. doi:10.1007/s40264-017-0528-z

5. Lim R, Ellett LMK, Semple S, Roughead EE. The Extent of Medication-Related Hospital Admissions in Australia: A Review from 1988 to 2021. *Drug safety*. Mar 2022;45(3):249-257. doi:10.1007/s40264-021-01144-1

6. Habib B, Tamblyn R, Girard N, Eguale T, Huang A. Detection of adverse drug events in e-prescribing and administrative health data: a validation study. *BMC Health Services Research*. 2021/04/23 2021;21(1):376. doi:10.1186/s12913-021-06346-y

7. Cahir C, Wallace E, Cummins A, et al. Identifying Adverse Drug Events in Older Community-Dwelling Patients. *The Annals of Family Medicine*. March 1, 2019 2019;17(2):133-140. doi:10.1370/afm.2359

8. Segal ES, Valette C, Oster L, et al. Risk management strategies in the postmarketing period : safety experience with the US and European bosentan surveillance programmes. *Drug safety*. 2005;28(11):971-80. doi:10.2165/00002018-200528110-00001

9. King CE, Pratt NL, Craig N, et al. Detecting Medicine Safety Signals Using

Prescription Sequence Symmetry Analysis of a National Prescribing Data Set. *Drug safety*. Aug 2020;43(8):787-795. doi:10.1007/s40264-020-00940-5

10. Hazell L, Shakir SA. Under-reporting of adverse drug reactions : a systematic review. *Drug safety*. 2006;29(5):385-96. doi:10.2165/00002018-200629050-00003

11. Egberts TC, Smulders M, de Koning FH, Meyboom RH, Leufkens HG. Can adverse drug reactions be detected earlier? A comparison of reports by patients and professionals. *BMJ*. 1996;313(7056):530-531. doi:10.1136/bmj.313.7056.530

12. Avery AJ, Anderson C, Bond CM, et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technol Assess*. May 2011;15(20):1-234, iii-iv. doi:10.3310/hta15200

13. Hasford J, Bruchmann F, Lutz M, Thürmann P, Schmiedl S. A patient-centred web-based adverse drug reaction reporting system identifies not yet labelled potential safety issues. *European Journal of Clinical Pharmacology*. 2021/06/18 2021;doi:10.1007/s00228-021-03134-9

14. Therapeutic Goods Administration. Annual performance statistics report 2019-20. Accessed 18 October, 2021. https://www.tga.gov.au/sites/default/files/annual-performance-statistics-report-july-2019-june-2020.pdf

15. Aslani P, Hamrosi K, Tong V, et al. Consumer opinions on adverse events associated with medicines and vaccines. *Patient Prefer Adherence*. 2018;12:1383-1392. doi:10.2147/ppa.S167396

16. Lim R, Thornton C, Stanek J, Ellett LK, Thiessen M. Development of a web-based system to report medication-related adverse effects: a design and usability study. *JMIR Preprints*. 2022;http://doi.org/10.2196/preprints.37605

17. Glenn R, Donetto S, Williams O. Co-designing Healthcare Services with Patients. The Palgrave Handbook of Co-Production of Public Services and Outcomes. In: Loeffler E, Eds TB, eds. Springer International Publishing AG; 2020.

18. Steen M, Manschot M, Koning ND. *Benefits of Co-design in Service Design Projects*. 2011. 2011.

19. Sanders EBN, Stappers PJ. Co-creation and the new landscapes of design. *CoDesign*. 2008/03/01 2008;4(1):5-18. doi:10.1080/15710880701875068

20. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*. 2009/08/07 2009;4(1):50.

doi:10.1186/1748-5908-4-50

21. Lim R, Ellett LK, Roughead EE, Cheah PY, Masnoon N. Patient-Reported Questionnaires to Identify Adverse Drug Reactions: A Systematic Review. *International Journal of Environmental Research and Public Health*. 2021;18(22):11877.

22. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). *Implementation Science*. 2016/10/26 2016;11(1):146. doi:10.1186/s13012-016-0510-7

23. Andrade AQ, Roughead EE. Consumer-directed technologies to improve medication management and safety. *Medical Journal of Australia*. 2019;210(S6):S24-S27. doi:https://doi.org/10.5694/mja2.50029

24. de Vries ST, Wong L, Sutcliffe A, et al. Factors Influencing the Use of a Mobile App for Reporting Adverse Drug Reactions and Receiving Safety Information: A Qualitative Study. *Drug safety*. 2017;40(5):443-455. doi:10.1007/s40264-016-0494-x

25. Bergman MM. Hermeneutic Content Analysis: Textual and Audiovisual Analyses within a Mixed Methods Framework. In: Tashakkori A, Teddlie C, eds. *SAGE Handbook of Mixed Methods in Social & Behavioral Research*. 2nd ed. SAGE Publications, Inc.; 379-96.

26. Martin B, Hanington B. *Universal Methods of Design : 100 Ways to Explore Complex Problems, Develop Innovative Strategies, and Deliver Effective Design Solutions.* Rockport Publishers; 2012.

27. Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther*. Aug 1981;30(2):239-45. doi:10.1038/clpt.1981.154

28. Kalisch Ellett L, Caughey G, Roughead E, Gilbert A. The prescribing cascade. *Aust Prescr*. 2011;34:162-6.

29. Doctors Control Panel. https://www.doctorscontrolpanel.com.au/

30. Zhou TT, Wang R, Gu SJ, et al. Effectiveness of Mobile Medical Apps in Ensuring Medication Safety Among Patients With Chronic Diseases: Systematic Review and Meta-analysis. *JMIR Mhealth Uhealth*. Nov 22 2022;10(11):e39819. doi:10.2196/39819

31. Zhang Z, Yuan K. *Practical Statistical Power Analysis using WebPower and R.* ISDSA Press; 2018.

32. Fossouo Tagne J, Yakob RA, Dang TH, McDonald R, Wickramasinghe N. Reporting, Monitoring, and Handling of Adverse Drug Reactions in Australia: Scoping Review. *JMIR Public Health Surveill*. 2023/1/16 2023;9:e40080. doi:10.2196/40080

33. Baines R, Bradwell H, Edwards K, et al. Meaningful patient and public involvement

in digital health innovation, implementation and evaluation: A systematic review. *Health Expect*. Aug 2022;25(4):1232-1245. doi:10.1111/hex.13506

34. Fossouo Tagne J, Yakob RA, McDonald R, Wickramasinghe N. Linking Activity Theory Within User-Centered Design: Novel Framework to Inform Design and Evaluation of Adverse Drug Reaction Reporting Systems in Pharmacy. *JMIR Hum Factors*. Feb 24 2023;10:e43529. doi:10.2196/43529

35. Martin JH, Lucas C. Reporting adverse drug events to the Therapeutic Goods Administration. *Australian prescriber*. 2021;44(1):2-3. doi:10.18773/austprescr.2020.077

36. Australian Commission on Safety and Quality in Health Care. Quality Use of Medicines. 20 March, 2023. https://www.safetyandquality.gov.au/our-work/medication-safety/quality-use-medicines

37. World Health Organization. Medication Without Harm. Accessed 5 January, 2022. https://www.who.int/initiatives/medication-without-harm

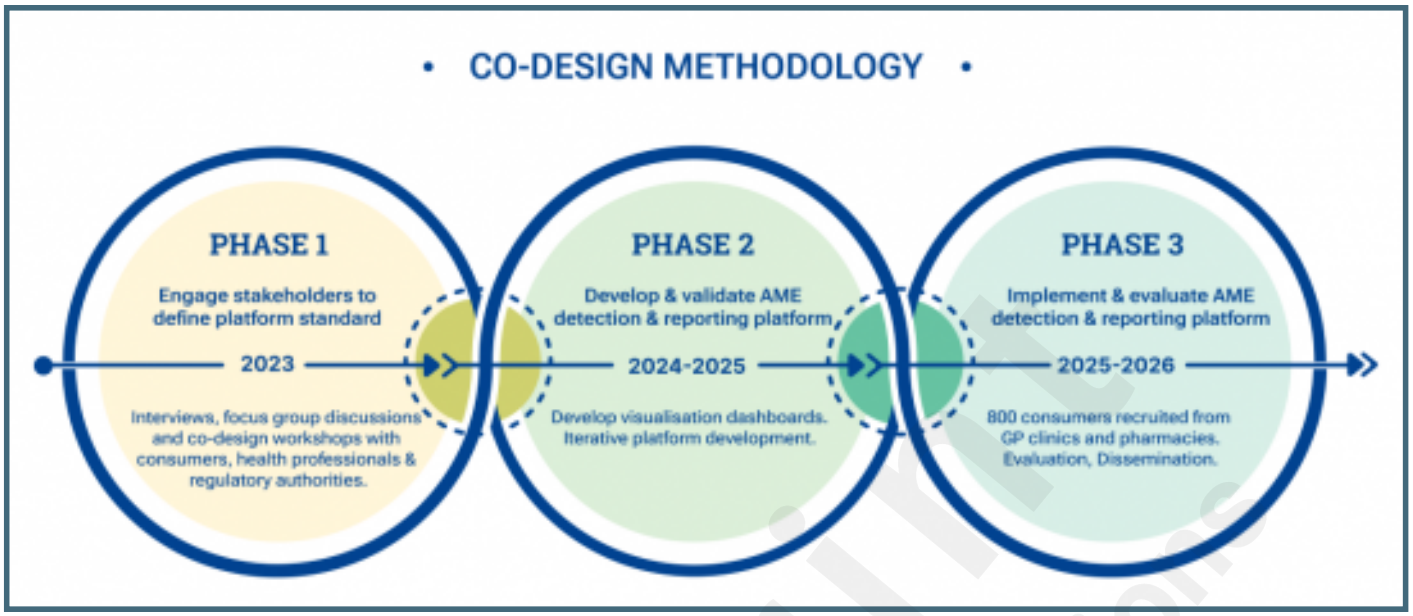
38. Schulze A, Brand F, Geppert J, Böl GF. Digital dashboards visualizing public health data: a systematic review. *Front Public Health*. 2023;11:999958. doi:10.3389/fpubh.2023.999958

Supplementary Files

Untitled.
URL: http://asset.jmir.pub/assets/396d1c74770f019bdf60de61090384b6.docx

Figures

Key activities in each phase of the project.



Flowchart for platform implementation in Australia.