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ARTICLE

Patient and healthcare professional acceptability of pharmacogenetic screening for *DPYD* and *UGT1A1*: A cross sectional survey

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Abstract

This study explored the acceptability of a novel pharmacist-led pharmacogenetics (PGx) screening program among patients with cancer and healthcare professionals (HCPs) taking part in a multicenter clinical trial of PGx testing (PACIFIC-PGx ANZCTR:12621000251820). Medical oncologists, oncology pharmacists, and patients with cancer from across four sites (metropolitan/regional), took part in an observational, cross-sectional survey. Participants were recruited from the multicenter trial. Two study-specific surveys were developed to inform implementation strategies for scaled and sustainable translation into routine clinical care: one consisting of 21 questions targeting HCPs and one consisting of 17 questions targeting patients. Responses were collected from 24 HCPs and 288 patients. The 5-to-7-day PGx results turnaround time was acceptable to HCP (100%) and patients (69%). Most HCPs (92%) indicated that it was appropriate for the PGx clinical pharmacist to provide results to patients. Patients reported equal preference for receiving PGx results from a doctor/pharmacist. Patients and HCPs highly rated the pharmacist-led PGx service. HCPs were overall accepting of the program, with the majority (96%) willing to offer PGx testing to their patients beyond the trial. HCPs identified that lack of financial reimbursements (62%) and lack of infrastructure (38%) were the main reasons likely to prevent/slow the implementation of PGx screening program into routine clinical care. Survey data have shown overall acceptability from patients and HCPs participating in the PGx Program. Barriers to implementation of PGx testing in routine care have been identified, providing opportunity to develop targeted implementation strategies for scaled translation into routine practice.

Marliese Alexander and Michael Michael made equal contributions to this work.

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Study Highlights

WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?

Robust evidence and international guidelines support routine pharmacogenetic (PGx) testing prior to fluoropyrimidine and irinotecan-based chemotherapy.

WHAT QUESTION DID THIS STUDY ADDRESS?

What is the acceptability and barriers to implementation of PGx screening among healthcare professionals and patients with cancer in the Australian setting?

WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?

PGx testing/dosing is infrequently performed in routine clinical practice. Translation into practice is challenging for some prescribers, particularly in curative treatment settings. Lack of financial reimbursement and resource infrastructure are key barriers to implementation in routine practice.

HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?

Acceptability of PGx testing as a component of routine cancer care requires attention to financial reimbursement and investment in clinical services. Further research is needed to develop and test strategies to enhance acceptability (implementation science methodologies) of PGx testing at patient and healthcare system levels.

INTRODUCTION

Pharmacogenetics (PGx) is an emerging discipline and promising tool increasingly used to tailor medicine selection and dosing according to individual patient gene(s) profiles and their inherent capabilities to metabolize and clear medicines.[1,2] Particularly in cancer care with frequent use of high risk and multiple medicines, PGx can thus reduce the potential for serious/life-threatening side effects, that result in reduced quality of life, hospitalization, or death. As well as the associated increased healthcare costs and poor treatment compliance.[1]

There are international guidelines for a wide range of medicines, including those utilized for the treatment and supportive care of cancer, such as Clinical Pharmacogenetics Implementation Consortium (CPIC) and Dutch Pharmacogenetics Working Group (DPWG). Our focus is the PGx guided dosing of fluoropyrimidines (FPs) and irinotecan chemotherapies, agents commonly used for the treatment of a wide range of solid cancers.[3,4] Despite evidence for these agents existing for many decades, translation of PGx into routine clinical care remains a challenge. Understanding barriers to implementation is essential to maximize the likelihood of clinical care implementation. Known barriers include financial reimbursement for PGx testing, as there is no Medicare rebate for *DPYD* or *UGT1A1* genotyping in Australia. Hence, PGx gene testing is not routinely preformed in many hospitals. Other barriers include test turnaround times, unfounded concerns with decreasing efficacy of FPs with dose reductions based on PGx testing, and lack of clear clinical workflow within a PGx service.[5,6]

We undertook a multicenter PGx trial (PACIFIC-PGx, Australian New Zealand Clinical Trials Registry Number: ANZCTR12621000251820) in adults diagnosed with cancer assessing PGx guided dosing for dihydropyrimidine dehydrogenase (*DPYD*) and UDP glucuronosyltransferase 1 family, polypeptide A1 (*UGT1A1*), genes responsible for the metabolism of FP and irinotecan, respectively.[7] As part of the PACIFIC-PGx trial, fast turnaround times of 5 days for *DPYD* and 7 days for *UGT1A1*28* genotyping results was achieved. A clear clinical workflow/infrastructure was established by having a dedicated program pharmacist to coordinate PGx testing, reporting of PGx gene test results, provide clinicians with dose recommendations, and follow-up patients for acute toxicities.

As a component of the trial, we undertook a cross sectional survey, one of a few international studies, and the first in Australia. The survey was aimed to assess the acceptability of a novel pharmacist-led PGx screening program among healthcare professionals (HCPs) and patients with cancer and identify potential barriers to implementation of the technology, process, or program as a component of usual care. The primary aim was to describe acceptability of participating in PGx screening program as part of a multicenter clinical trial (PACIFIC-PGx). Key

secondary aims were to: (1) identify barriers to implementation of PGx testing beyond the trial; and (2) generate information to inform strategies for implementation of PGx testing beyond the trial.

METHODS

Pharmacogenetic screening program

The PACIFIC-PGx trial was a prospective, multicenter single arm clinical trial across four sites (metropolitan/regional), assessing the feasibility and impact of pretreatment *DPYD* and *UGT1A1* gene testing and PGx guided dose adjustments on reducing severe FP and irinotecan-related adverse events (PACIFIC-PGx ANZCTR: 12621000251820).[7] Adult patients were enrolled in the trial if newly commenced on FP and/or irinotecan with any tumor type.[7]

Patients enrolled in PACIFIC-PGx trial had PGx screening and dose adjustments prior to FP and/or irinotecan commencement. The trial was operated under the Networked Teletrial Model[8] with centralized testing and coordination by PGx pharmacists via tele-health. Gene samples were collected by cheek swab (remote/at-home testing), with option for blood sample. Real-time gene testing for five common CPIC recommended *DPYD* genetic variants (c.1905+1G>A, c.1679T>G, c.2846A>T, c.1236G>A, and c.557A>G) and *UGT1A1*28*. Eligible patients were identified by their treating clinician to the lead PGx pharmacist for patient education and consent, coordination of PGx testing, reporting of results, providing PGx guided dose recommendations, and following up post-chemotherapy cycle one (days 3–7) for acute toxicities. Dose modifications recommended to treating clinicians according to CPIC/DPWG guidelines: (1) FP: 50% dose reduction in *DPYD* intermediate metabolizers, avoid in poor metabolizers and (2) irinotecan: 30% dose reduction in homozygous *UGT1A1*28*.

Survey recruitment and consent

HCPs (medical oncologists and oncology pharmacists) and patients involved in the multicenter PACIFIC-PGx trial were invited to take part in an observational, cross-sectional survey.

HCPs who treated patients on FP/irinotecan-based therapies within the PACIFIC trial were eligible to participate in the anonymous survey. Informed consent was indicated by completion of the survey. One medical oncologist and one pharmacist who contributed to survey development, were also included as participants.

Patients treated with FP and/or irinotecan and enrolled in the PACIFIC trial were invited to complete the survey at any time after their commencement of cycle one FP and/or irinotecan and before cycle three, where PGx screening, results reporting, and dosing changes were implemented and after the pharmacist conducted post-cycle one follow-up review. Informed consent was obtained by patients prior to completing the survey (as part of PACIFIC-PGx trial consent).

The surveys were approved by Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC/66681/PMCC-2020).

Survey development

In the absence of validated measures, study-specific surveys were developed by relevant cancer researchers, oncology pharmacists, and medical oncologists. Steps involved in the survey development included: (1) primary researcher drafted survey questions based on the literature and current knowledge gaps as informed by the theoretical framework of acceptability (burden, affective attitude, experience, ethical consequences, opportunity costs, experience, and intention)[9] and (2) draft was reviewed, refined, and approved by a multidisciplinary team. At the completion of the survey development process, two surveys were designed (Supplementary materials 1 and 2 in Appendix S1).

One survey consisted of 21 questions and targeted HCPs. Twenty questions were quantitative and one open-ended question invited any additional feedback/comments focused on burden of program participation (i.e., paperwork, management, or coordination of the PGx screening program). The final eight questions were completed by medical oncologists only, to explore the potential impact of PGx testing on clinical decision making in terms of dose adjustments and the timeliness of *DPYD/UGT1A1* genotyping in different treatment settings (curative, palliative, or symptomatic). Two questions investigated medical oncologists' willingness to offer PGx testing to their patients beyond the trial and barriers to implementation of PGx service into routine care (Supplementary material 1 in Appendix S1).

The patient survey included 14 quantitative questions and three open-ended questions inviting additional feedback/comments focused on burden of participation, appropriateness of care, fear of gene test results, and practicalities of the program (Supplementary material 2 in Appendix S1).

Ethics approval

The study was approved by the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC/66681/PMCC-2020). The study was performed in accordance with the Declaration of Helsinki.

Survey distribution

The HCPs' survey was distributed electronically via REDCap between May 6, 2021, and July 20, 2021, and completed anonymously to encourage open responses. An email reminder was sent 2 weeks after the initial invitation.

Patients were invited to complete the survey electronically or in hard-copy and completed non-anonymously during their enrollment in the trial between January 7, 2021, and February 25, 2022.

Data analysis

There was no formal sample size calculation for this end-user acceptability survey within the PACIFIC-PGx trial, rather a pragmatic sample of those participating. A five-point Likert scale was used, presenting lowest to highest score for grading acceptability, tailored to the question. Data from surveys were summarized using Microsoft Excel and reported separately, using descriptive statistics. Key themes were extracted and summarized from open-ended questions with individual responses tabulated.

RESULTS

Healthcare professionals survey responses

Demographics

A total of 24 HCPs completed the survey including 21 complete and three partial responses included in the analysis from metropolitan 54% (13/24) or regional 38% (9/24) centers (Table 1).

TABLE 1 Demographics table for healthcare professional survey.

Demographics	*n*	%
HCPs		
Medical oncology consultants	15	63
Medical oncology fellows	4	17
Medical oncology registrar	1	4
Pharmacists	3	13
NR	1	4
Place of practice		
Metropolitan	13	54
Regional	9	38
Rural	0	0
Metropolitan and regional	1	4
Metropolitan and rural	1	4
Cancer patients treated at the clinicians' hospital per week		
>500	8	33
>200	10	42
51–200	6	25
Years of practicing in oncology		
≤5	7	29
≤10	5	21
≤15	4	17
≤20	4	17
≥25	4	17

Abbreviations: HCPs, healthcare professionals; NR, not reported.

Service delivery (affective attitude/burden/experience)

The majority of HCPs 92% (22/24) highly rated the pharmacist-led PGx service with regard to education, reporting results and patient follow-up post chemotherapy (Figure 1). All HCPs found the turnaround time for PGx test results "very acceptable" or "acceptable." Most HCPs 92% (22/24) indicated that it was "very appropriate" or "appropriate" for the pharmacist to communicate PGx test results and advice on medication dosing directly to patients (Figure S1). Most HCPs 79% (19/24) indicated that they perceived patients participating in the program understood the purpose/intent of PGx screening, whereas 13% (3/24) selected unsure and 8% (2/24) thought patients had little understanding.

When asked to rate the value of pretreatment PGx testing for FP and irinotecan to assist with decision making as a component of usual care, all HCPs rated it highly or fairly (Table S1). Most HCPs 83% (20/24) reported that PGx screening program was acceptable in terms of paperwork, management, coordination, communication, or data collection requirements. A few 17% (4/24) reported that paperwork or data collection were excessive ($n=3$), difficulty to coordinate the program or causing anxiety to patients ($n=1$).

HCPs believed it was "very appropriate" or" appropriate" for patients to receive PGx test results via phone 83% (20/24) or via tele-health 96% (23/24) (Figure S2A,B).

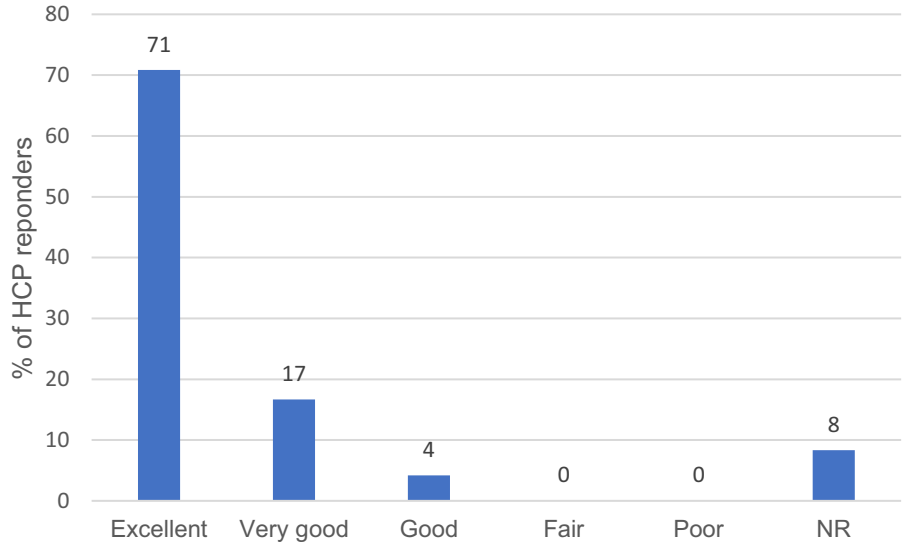

FIGURE 1 Health care professional perspective on pharmacist service with regards to education, reporting results and following up post chemotherapy. HCPs, healthcare professionals; NR, not reported.

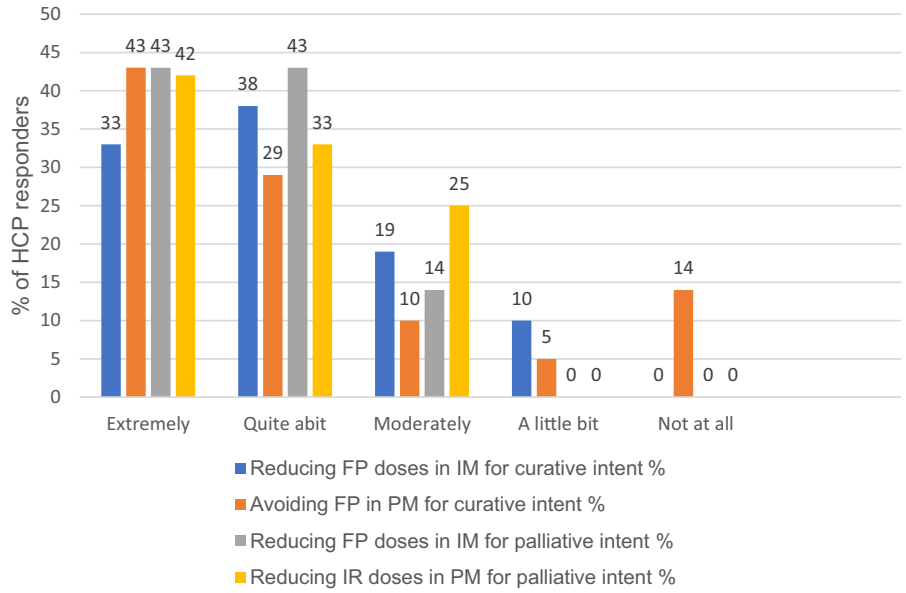

FIGURE 2 HCP perspectives on fluoropyrimidines and irinotecan dose adjustments based on treatment settings. FP, fluoropyrimidines; HCPs, healthcare professionals; IM, intermediate metabolizer; IR, irinotecan; PM, poor metabolizer.

Dose adjustment based on pharmacogenetic results (medical oncologists)

Dose adjustment based on gene test results was supported by 77% of medical oncologists for FP and 59% for irinotecan dosing (Table S2). More clinicians 86% (18/21) preferred to reduce FP for *DPYD* intermediate metabolizers in the palliative treatment setting rather than curative setting 71% (15/21), or to avoid FP for *DPYD* poor metabolizers in curative settings 71% (15/21), but the difference was not significant ($p = 0.12$). Seventy five percent of clinicians (9/12) preferred to reduce irinotecan dose in palliative treatment setting (Figure 2).

Pre-emptive pharmacogenetics screening, willingness, and implementation barriers (ethical consequences/intention/opportunity costs)

When asked about pre-emptive PGx screening beyond *DPYD* and *UGT1A1* (i.e., broad panel PGx testing), 57% (12/21) felt it would negatively impact timeliness of treatment commencement (Figure S3) or anti-cancer treatment, more so in the symptomatic patient setting 76% (16/21) than curative 57% (12/21) or palliative settings 43% (12/21) (Figure S4). The majority of HCPs 91% (19/21) reported willingness to offer PGx testing to patients beyond the trial (Figure 3) and most identified

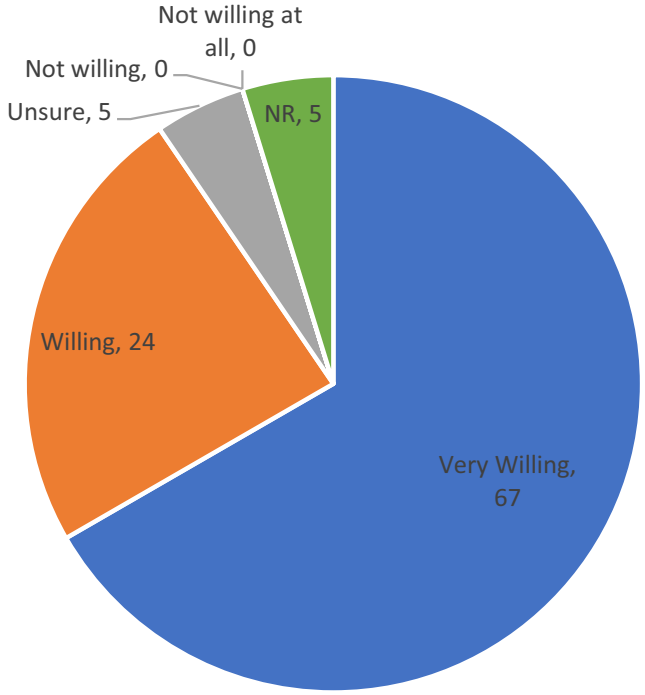

FIGURE 3 Percentage of healthcare professionals willing to offer pharmacogenetic testing to patients beyond the trial. NR, not reported.

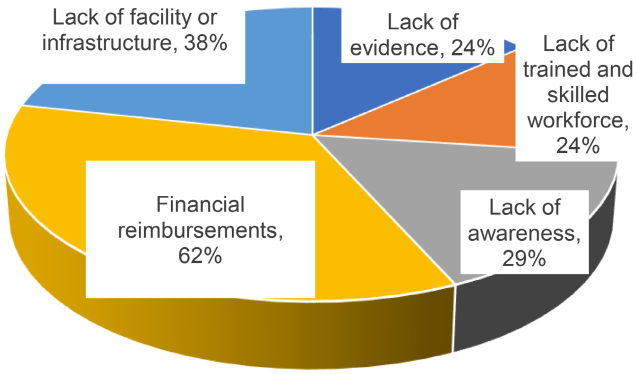

FIGURE 4 Healthcare professional perspectives on reasons for preventing/slowing the pharmacogenetic service implementation.

that lack of financial reimbursements (62%) and lack of infrastructure (38%) were the most common barriers to implementation of PGx services into routine care (Figure 4).

Patient survey responses

Demographics

A total of 288 patients were invited to take part in the survey, including 76% (219/288) complete and 3% (9/288) partial responses. Patients completed survey on their own 66% (191/288), with assistance of family/friend/other 7% (21/288), assistance from a member of the research team 4% (12/288), or unspecified 22% (64/288).

Service delivery (affective attitude and experience)

When asked to rate the pharmacist-led PGx service, 76% (220/288) rated good to excellent and 0.3% (1/288) rated poor (Figure 5). The majority of patients 71% (205/288) found the pharmacist education on serious side effects acceptable (Figure 6). Seventy-one percent (205/288) did not feel that undergoing PGx testing had caused unacceptable delays to treatment and 69% (198/288) found the turnaround time for PGx results acceptable (Table S3). Most patients 98% (162/166) reported "extremely" or "quite a bit" acceptable for pharmacist to inform of the PGx results (Table S3). The majority of patients felt that the information given about the PGx screening program has prepared them to undergo PGx testing (large extent, 52%, 151/288; Figure S5). The majority of patients found the information provided to them regarding the relevance of PGx testing in deciding their cancer treatment was clear 70% (202/288) and valuable 71% (204/288) (Figures S6 and S7).

Reporting of pharmacogenetics results (burden)

Patients were given the opportunity to comment on the level of appropriateness for different methods of communicating the PGx test results (phone, tele-health, or in person; Figure S8). Most patients reported phone, tele-health, or in person were all "very appropriate" or "appropriate" (Table S4). Patients found that the PGx screening program was appropriate 76% (220/288) i.e., not unnecessary or difficult or distressing), with 65% (187/288) reporting that participation was not impractical (i.e., too much time or paperwork or surveys or appointments; Figure S9; Table S5). Patients reported equal preference for receiving PGx results from either a doctor (59%) or a pharmacist (56%) (Figure S10).

Dose adjustment based on pharmacogenetics results (opportunity costs)

Patients were asked if they worried about the impact of their PGx test results on dosing of cancer-directed therapies; 46% (133/288) indicated "not at all." Patients were given the opportunity to expand on their answers if answered "yes, a lot" 4% (12/288), summarized in Figure S11.

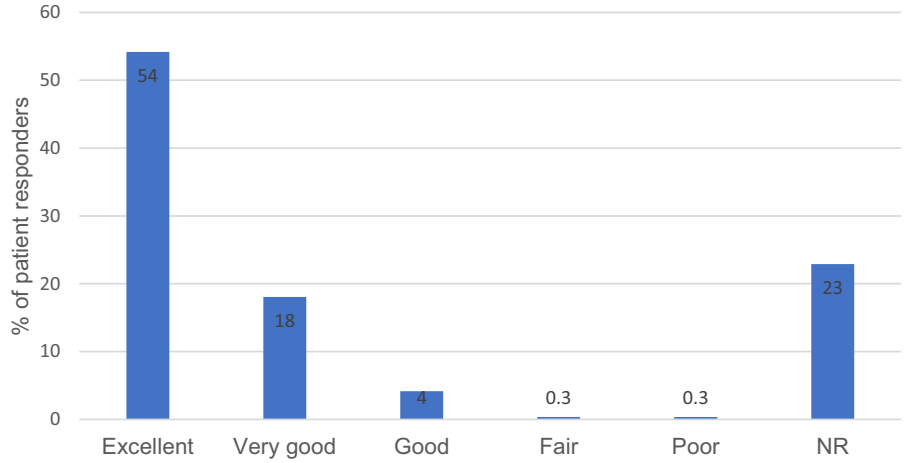

FIGURE 5 Patients' perspective on pharmacogenetic service provided by program pharmacist. NR, not reported.

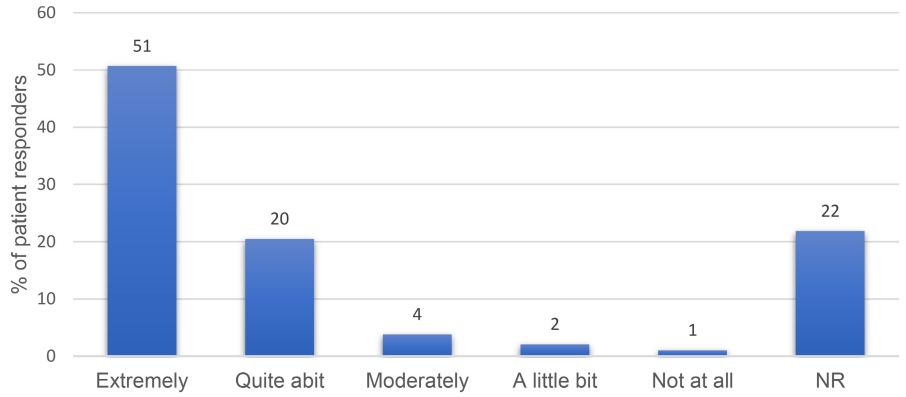

FIGURE 6 Patients' acceptability for program pharmacist education on serious side effects. NR, not reported.

DISCUSSION

This study describes the end-user experience of a PGx screening program among HCPs and patients with cancer. It is important due to divergence of implementation settings and viewpoints, including from metropolitan and regional locations, within speciality and general hospitals, and through virtual and face-to-face clinics. Findings demonstrated that the PGx screening program was acceptable to both patients and HCPs, but with implementation issues that could be addressed to optimize scaled translation into routine practice.

Lengthy PGx test turnaround times and/or clinician inexperience with PGx test interpretation have been highlighted as main barriers to implementation in the United States and European data surveys.[6,10] However, our data demonstrated that HCPs and patients found the turnaround time of five to seven days for PGx results acceptable and that it was appropriate for pharmacists to provide results to patients. HCPs and patients were also accepting of receiving results via tele-health, phone, or in-person, supporting the concept of a flexible clinic structure to meet individual needs. Acceptance of "virtual clinics" has been reported widely in the literature,[8,11] particularly during the coronavirus disease 2019 (COVID-19) pandemic where service model changes were rapidly implemented.[12] An Australian/European study reflecting on practices over the course of the pandemic found clinicians main concerns of "virtual clinics" related to inability to physically examine the patient, being more likely to miss a diagnosis, and reduced clinical assessment.[13] None of these factors were relevant in the context of PGx screening, and no additional concerns/barriers were identified through our surveys.

In our study, HCPs preferred to adjust FP dosing in palliative treatment settings rather than curative (86% vs. 71%, $p = 0.12$): implying hesitancy regarding the impact of dose reduction(s) on treatment response and outcomes to anticancer treatment. On pharmacokinetic first principles, a dose reduction in patients with reduced drug clearance (i.e., *DPYD* intermediate metabolizers) would not impact on drug exposure (i.e., area

under the curve).[14] This is supported by the literature, whereby Henricks et al.,[15] has demonstrated that genotype-guided dosing (*DPYD*2A*) appears to have no negative effect on effectiveness of FP-based chemotherapy, whereas resulting in significantly improved patient safety. Although a minority, there remains a notable proportion of HCPs (up to 24%), who did not prefer PGx informed dose reductions, which would likely impact implementation within routine care. Targeted education programs may be appropriate to address knowledge gaps, however, it is not clear from our study if concerns were founded on lack of knowledge, or hesitancy with the existing evidence base.

Other barriers to PGx screening have been explored in the literature, including consideration of the multidisciplinary nature of PGx, which likely includes doctors, nurses, laboratory specialists, and/or pharmacists. A European study interviewed different specialties participating in a PGx screening program reported varied perceptions of roles and responsibilities, including lack of awareness of specific roles of other craft groups.[6] These findings highlighted potential implementation challenges related to program structure, reporting lines, and coordination. We attempted to overcome this in our program by having clearly defined program structure with defined roles and responsibilities of all craft groups and exploring acceptability according to the theoretical framework of acceptability. Importantly, we implemented a central coordinator who acted as the main point of contact across all parties. In our program, this role was undertaken by a pharmacist based on their established role in guiding medication dose optimizations and interventions.[7]

Our survey data show that both HCPs and patients have highly rated the pharmacist-led PGx service. This was consistent with a US survey study in which 88% of patients understood PGx testing and had knowledge around genetics.[16] In our survey, the majority of HCPs (79%) felt that patients participating in the PGx screening program understood the purpose/intent of PGx screening. Overall HCPs were satisfied with the program with the majority (96%) willing to offer PGx testing to their patients beyond the trial. However, financial reimbursements (62%) and lack of infrastructure (38%), as major barriers to implementation, is consistent with a European study.[6] Further, the effect on clinical efficacy when dose was reduced was not evaluated. These could be addressed to optimize scaled translation into routine practice. The strengths of our study included (1) being the first survey in an Australian healthcare setting to assess acceptability of a novel pharmacist-led PGx screening program among HCPs and patients with cancer, and (2) distribution of the surveys to HCPs and patients across metropolitan and reginal centers with various practice settings and oncology specialities has enabled us to identify key barriers and enablers in order to incorporate PGx screening program as part of routine care. Limitations include the small number of HCP respondents ($n=24$), which may reflect their strong beliefs or understanding about *DPYD/UGT1A1* testing. Importantly, the low number reflected specialized prescribing within the trial, not a low response rate. Interpretation of results must also consider that the HCP participating in the trial were likely more familiar with PGx testing and guidelines and may have interests in PGx testing than the wider HCP population in Australia. They provide a perspective and reflection of experience having implemented PGx testing/dosing within their clinical service.

CONCLUSION

PGx testing in cancer care is not routinely practiced, especially in Australia. Our survey data has shown overall acceptability from both HCPs and patients participating in the PGx screening program. The consumer voice in our program may support future regulatory applications for subsided testing. Clear guidelines and procedures outlining the roles/responsibilities, central coordination, flexible clinic model, and acceptable PGx turnaround times were identified as strengths of the program structure likely to overcome barriers to clinical translation. Conversely, test costs and lack of infrastructure beyond the trial, and clinician reluctance to implement dose reductions particularly in the curative setting, remain barriers to implementing PGx screening into routine clinical care.

AUTHOR CONTRIBUTIONS

All authors wrote the manuscript. S.G., M.M., M.A., and M.K. designed the research. S.G., M.M., and M.A. performed the research. S.G., M.M., and M.A. analyzed the data.

FUNDING INFORMATION

No funding was received for this work.

CONFLICT OF INTEREST STATEMENT

The authors declared no competing interests for this work.

INFORMED CONSENT

A decision to click on the survey link by the participants and to complete/submit the survey was taken as informed consent.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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