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Pharmacogenomics Screening for Chemotherapy & Supportive Care:
Gaps & Barriers to Overcome

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MASCC™ MULTINATIONAL ASSOCIATION OF SUPPORTIVE CARE IN CANCER

Conflicts of Disclosure

- Nil to declare

Acknowledgments

- This presentation is in collaboration with ***Multinational Association of Supportive Care in Cancer (MASCC)***
- The **PRECISION-ITS Trial** was supported by funding from the Medical Research Future Fund Preventive and Public Health Initiative (2022 Quality, Safety and Effectiveness of Medicine Use and Medicine Intervention by Pharmacists opportunity) - *MRFMMIP000011, CIA Alexander*

Presentation Contents

1. Background

- Pharmacogenomics
- Clinical applications in cancer care (chemotherapy, supportive care)
- References & guidelines

2. Real-world applications

- Clinical Pharmacogenomics Service at Peter Mac
- PRECISION-ITS trial network tele-trial model

3. Implementation Challenges

- Heterogeneity factors
- System/Infrastructure factors
- Patient factors
- Healthcare professional factors

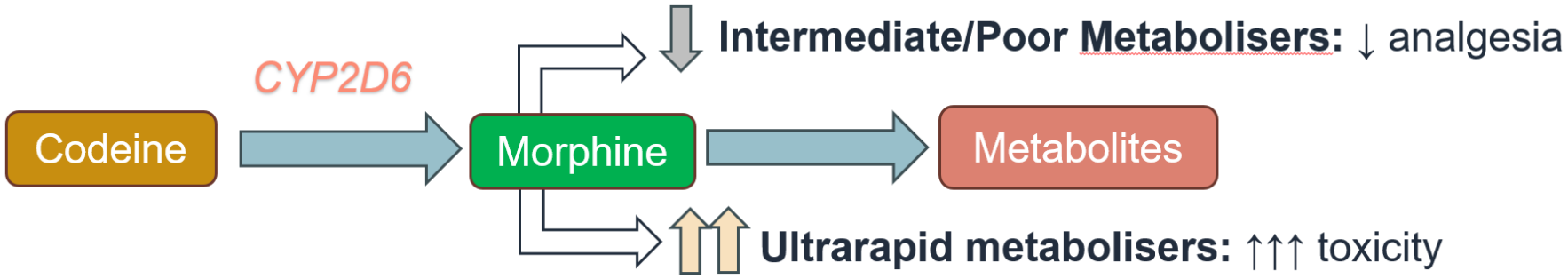
4. MASCC

- Conference Program
- Membership

5. Discussion activity

Pharmacogenomics (PGx)

- The study of how variations in a patient's genome influences medication response



- Germline DNA
- Can impact drug efficacy & toxicity with various PK/PD impacts

PGx Testing

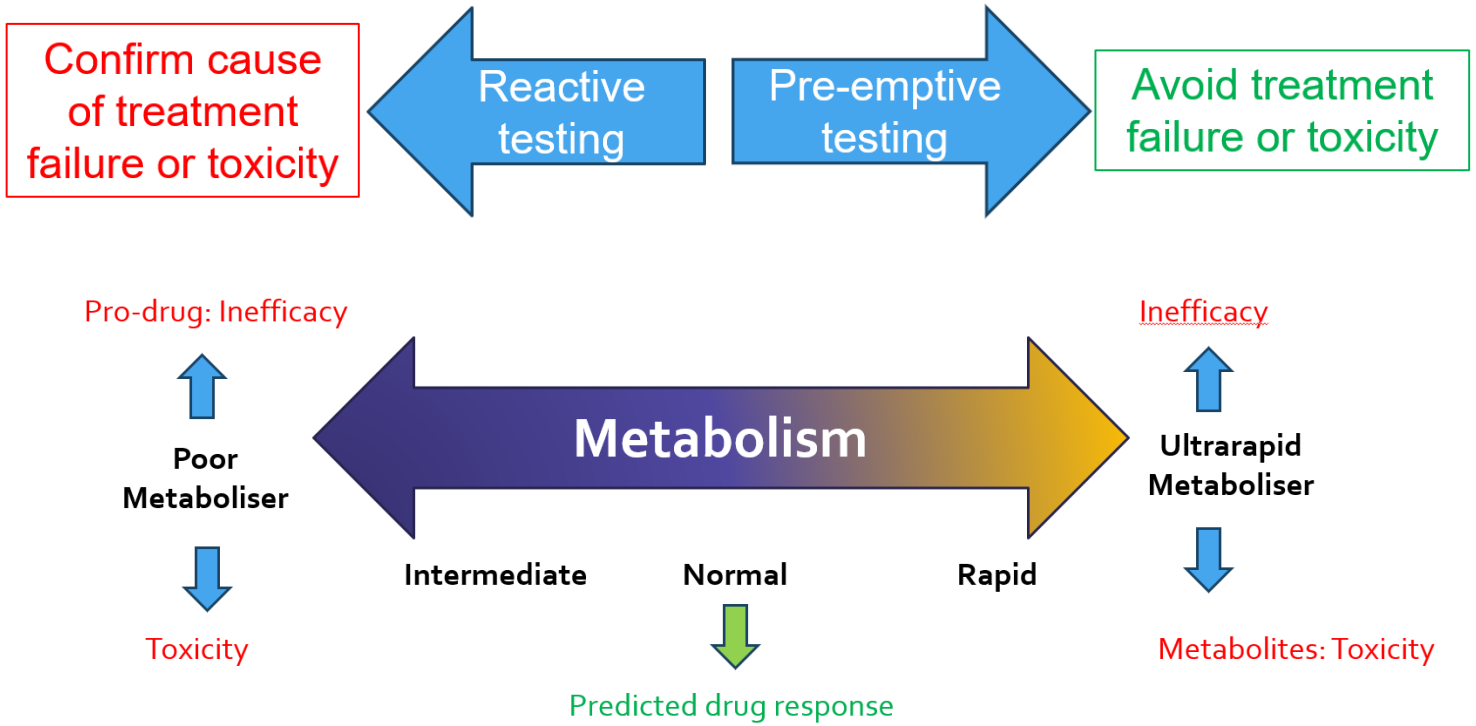
- Blood sample – 4mL purple top EDTA tube
- Buccal Sample
- Direct to consumer or clinician referral

Important Considerations

- Transplant settings – liver, alloBMT
- Predictive drug response only – actual/observed response may differ

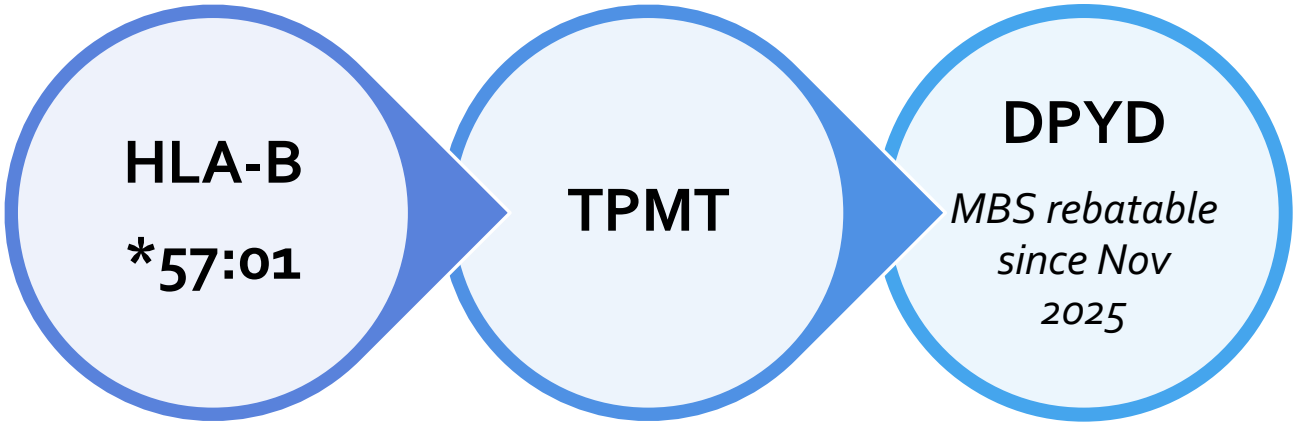
Clinical Benefits

- Pre-emptive PGx testing provides predicted medication response at time of prescribing



PGx Funding in Australia

- Medicare funding is limited to specific genes
- Evidence for pre-emptive testing and cost effectiveness is limited



Abacavir

Thiopurines
(6-MP, 6-TG, azathioprine)

5-FU & Capecitabine

The Royal College of Pathologists of Australia. Accessed 14/6/26:
https://www.rcpa.edu.au/Library/Practising-Pathology/Pharmacogenomic-Indications-in-Australia

PREPARE trial: pre-emptive PGx testing

Design

- 3-year, multi-centre, prospective, open-label, cluster-randomised crossover implementation study

Population

- Patients from 7 European countries across multiple health care settings (n=6944)

Intervention

- Pre-emptive PGx multi-gene panel testing/prescribing vs SOC medication prescribing

Outcomes

- Grade 2+ adverse medicines events related to PGx index drug within 12 week f/up period
- Feasibility of pre-emptive testing across multiple healthcare settings in Europe

Swen et al. Lancet 2023; 401: 347-56

PREPARE: Key Findings

- Intervention group had a **30% reduction in clinically relevant grade 2+ adverse medicine events**

	All patients				Patients with an actionable variant*			
	Study group (n=2923)	Control group (n=3270)	OR (95% CI)	p value	Study group (n=725)	Control group (n=833)	OR (95% CI)	p value
Clinically relevant adverse drug reactions	628 (21·5%)	934 (29·0%)	0·70 (0·61–0·79)	<0·0001	152 (21·0%)	231 (27·7%)	0·70 (0·54–0·91)	0·0075

- **Pre-emptive PGx testing is feasible** across real-world settings in Europe
- Median testing turnaround time = 7 days
- **Rate of actionable med-gene interactions = 25.2%**

Swen et al. Lancet 2023; 401: 347-56

S14 Proportion of actionability per drug

Drug	Frequency (n)	Actionable (n)	Percentage	Percentage from literature (DPWG)
Atorvastatin	716	204	28.5%	15.1-36%
Clopidrogel	619	172	27.8%	28.4%
Tacrolimus	472	56	11.9%	14.5%
Simvastatin	435	132	30.3%	15.1-36%
Capecitabine	410	14	3.4%	6.4%
Sertraline	403	122	30.3%	26-28.4%
Tramadol	379	183	48.3%	47.5%
Codeine	351	145	41.3%	47.5%
Fluorouracil	311	13	4.2%	6.4%
Flucloxacillin	308	10	3.2%	0-11.2%
Escitalopram	268	63	23.5%	28.4-33.7%
Citalopram	254	64	25.2%	28.4%
Venlafaxine	241	113	46.9%	47.5%
Tamoxifen	228	98	43.0%	44.4%
Aripiprazole	224	21	9.4%	6.8%
Warfarin	221	80	36.2%	26.7%
Haloperidol	220	15	6.8%	9.9%
Metoprolol	209	100	47.8%	47.5%
Irinotecan	129	12	9.3%	5-15%
Acenocoumarol	105	15	14.3%	14%
Amitriptyline	101	40	39.6%	47.5%
Paroxetine	79	3	3.8%	3.1%
Oxycodone	67	26	38.8%	47.5%
Clomipramine	33	11	33.3%	47.5%
Nortriptyline	32	8	25.0%	47.5%
Zuclopenthixol	26	14	53.8%	47.5%
Flecainide	23	12	52.2%	47.5%
Fluorouracil cutaneous	23	0	0.0%	0.004%
Azathioprine	16	2	12.5%	6.2-11.6%

Limitations

- Low portion of patients receiving anti-cancer drugs
- 97.7% self-reported European descent
- PGx prescribing interventions as per DPWG guidelines

…PRECISION-ITS trial will provide real-world data for patients with cancer in Australian healthcare setting

Swen et al. Lancet 2023; 401: 347-56

PRECISION-ITS Trial Overview

Design

Multi-centre, prospective, interrupted time series tele-trial (ACTRN12624000079549)

Population

Patients commencing anticancer therapy at 6 AUS hospitals

Intervention

Pre-emptive, multi-gene panel testing with PGx-guided prescribing

Outcomes

- PRO-CTCAE & Grade ≥ 2 CTCAE
- Hospitalisations
- Prevalence of actionable med-gene interactions

Time Series 1 (Standard Care)

Accrual complete (2023-2025)

PGx prescribing limited to selected chemotherapy genes (DPYD & UGT1A1)

Time Series 2 (Expanded PGx)

Accrual ongoing (2025 – Q4 2026)

Additional PGx prescribing with multi-gene panel for supportive care (e.g. CYP2D6)

PRECISION-ITS Trial Sites

- Network tele-trial model
- PGx pharmacists at Peter Mac coordinate testing and clinical follow up for all sites

Tele-trial Site	Site Name	Status
Primary Site	Peter MacCallum Cancer Centre, Melbourne	**Active**
Satellite Sites (Regional VIC)	Bendigo Health	**Active**
	Border Medical Oncology	**Active**
	Goulburn Valley Health	**Active**
	South West Healthcare	**Active**
	Mildura Base Public Hospital	**Active**

Anti-emetics
- Ondansetron
- Haloperidol

Analgesia
- Opioids
  - e.g. Codeine, Tramadol
- NSAIDs
  - e.g. Ibuprofen, Celecoxib
- TCAs
  - e.g. Amitriptyline, Nortriptyline

Anti-infectives
- Voriconazole
- Aminoglycosides (e.g. Gentamicin)
- Dapsone
- Primaquine

Other
- Methylene blue

Is there a role of pre-emptive PGx testing for supportive cancer care drugs?

Anti-depressants
- SSRIs
  - e.g. Sertraline, Escitalopram
- Venlafaxine

Antipsychotics
- Haloperidol

TLS prophylaxis
- Allopurinol
- Rasburicase

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JUNE 25-27 | #MASCC26

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ISOO INTERNATIONAL SOCIETY of ORAL ONCOLOGY

MASCC/ISOO ANNUAL MEETING | JUNE 25-27
MELBOURNE 2026

Profiling the utility of broad-panel pharmacogenomic screening against symptom burden and toxicity in cancer care: insights from the PRECISION trial

Vivian Shen, Sarah Glewis, May Darwish, Safeera Y Hussainy, Michael Michael, Sam Harris, Javier Torres, Theresa Hayes, Krishna Rachakonda, Leslie Sheffield, Andrew Somogyi, Sherene Loi, John Seymour, Richard De Abreu Lourenco, Rachel Conyers, Paul James, Laura Forrest, Peter Galettis, Jennifer Martin, Carl Kirkpatrick, Ian Campbell, Craig Underhill, Jenny Philip, Tim Spelman, Chiao Xin Lim, Jenny Devine, Marliese Alexander* & Senthil Lingaratnam* *equal contributions

Principal Investigators: Marliese Alexander & Senthil Lingaratnam

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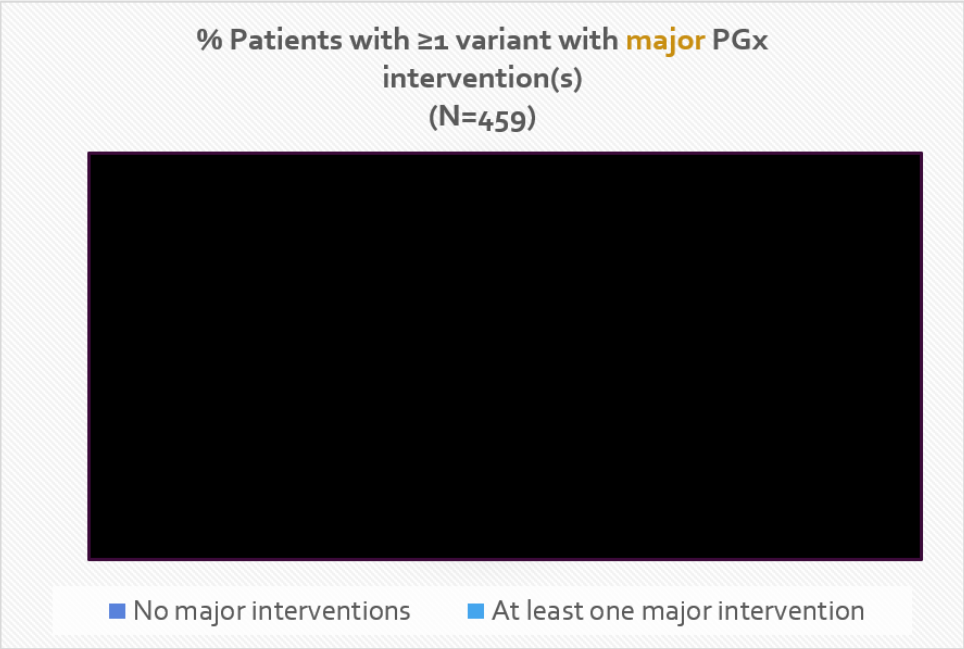
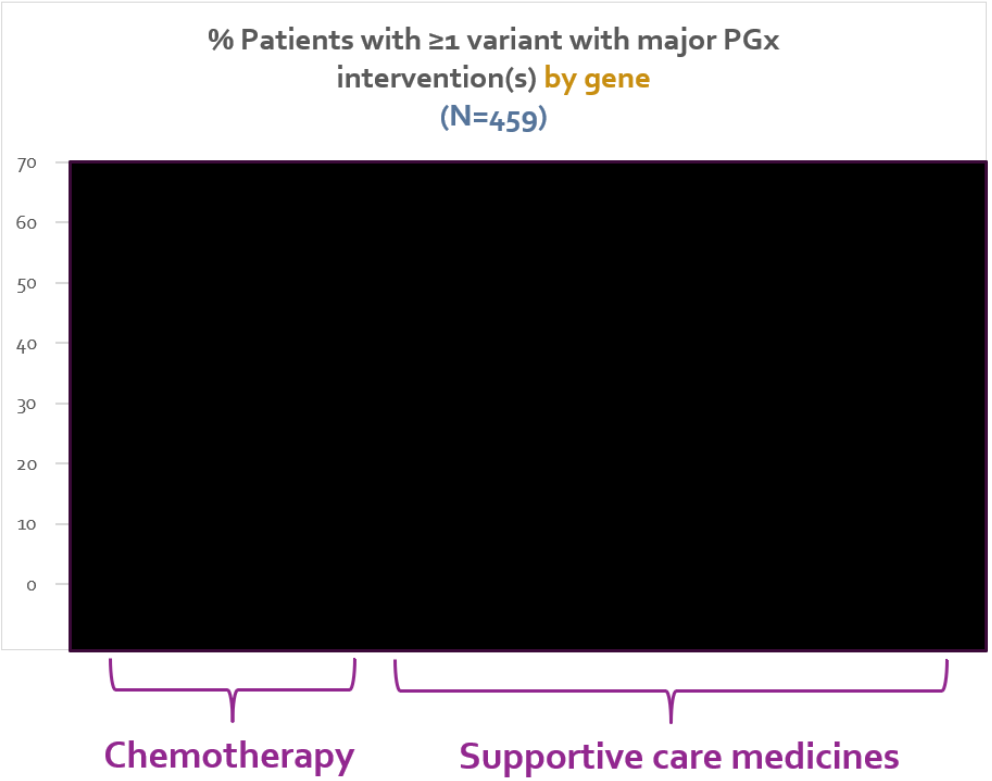
Time Series 1 Interim Report

Outcomes reported in interim data (13 Jan 2026):

- Grade ≥ 2 CTCAE
- All-cause hospitalisations in 12-week primary follow up
- Adverse medicine event (AME) = composite of medicines toxicity and symptom burden due to medication inefficacy

Potential PGx improvement opportunities





Actionable med-gene interactions

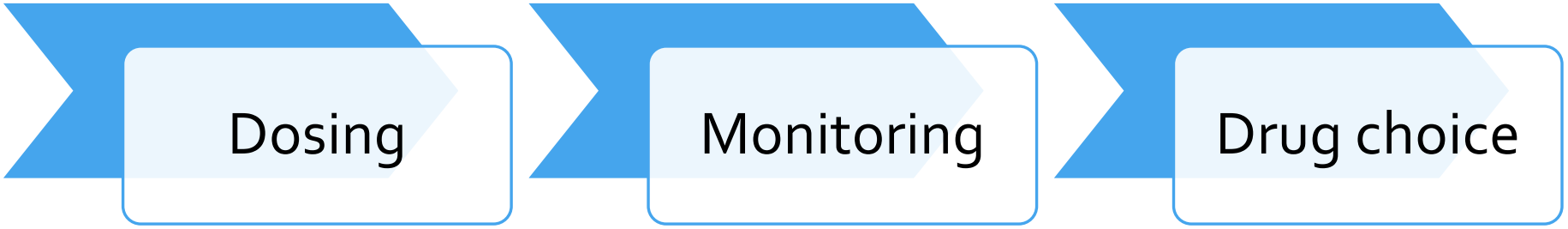
Figure 2. Categories of drugs with actionable pharmacogenomic interactions*

Most common genes:

Medicines *most common

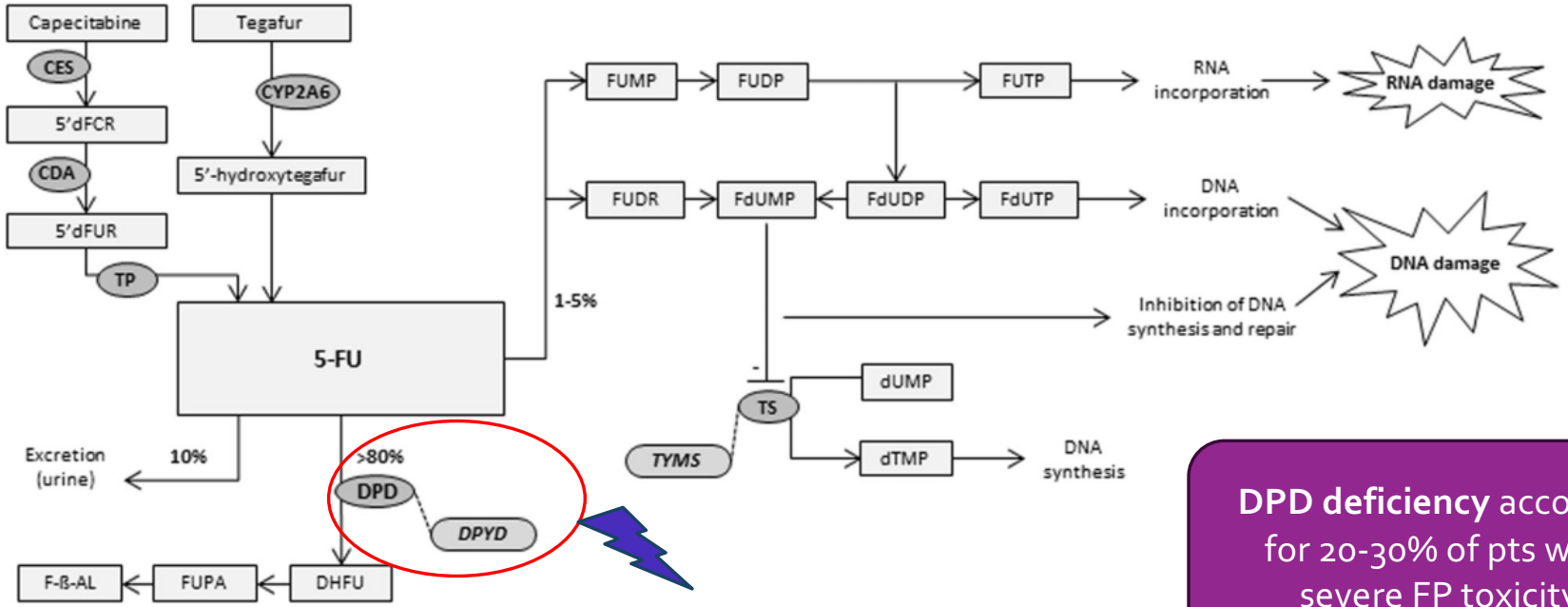
Clinical Pharmacogenomics in Cancer Care

PGx Interventions



DPYD & Fluoropyrimidine Toxicity

- *DPYD* is the gene that encodes DPD (Dihydropyrimidine dehydrogenase) enzyme



↓ Activity in DPYD IM

Minimal activity in DPYD PM

DPD deficiency accounts for 20-30% of pts with severe FP toxicity

Lunenburg et al. European Journal of Human Genetics 2020; 28:508-517

DPD Deficiency

- Early onset (≤ 7 days) toxicity: N+V+D, mucositis, HFS & myelosuppression

DPYD phenotype	DPD enzyme activity	% Pts	Clinical implications
Normal metaboliser	100%	~95%	• Normal enzymatic activity – 'normal risk' of FP tox
Intermediate metaboliser	30-70%	~5%	• Partial enzymatic deficiency
Poor metaboliser	0%	0.01-0.1%	• Complete enzymatic deficiency • **Life-threatening toxicity; uridine triacetate often needed**

- PGx dosing ↓risk of Grade 3/4 toxicities by ~3-fold (RR= 0.32 [95% CI 0.27–0.39], p < 0.00012) [1]
- PGx guided dosing in DPYD IMs significantly ↓ FP-related hospitalisations (p=0.031) and ↓deaths by 3.7% compared to historical controls in the AUS multicentre **PACIFIC-PGx trial** [2]

1. Glewis et al. Br J Cancer. 2022 Jul;127(1):126-136.
2. Glewis et al. Clin Transl Sci. 2024 Dec;17(12):e70083.

DPYD-guided dosing: 5-FU & Capecitabine

DPD Phenotype	CPIC Guidelines PGx Recommendation [1]
Normal Metaboliser	• Initiate standard starting dose
Intermediate Metaboliser	• ↓ Starting dose of fluoropyrimidine by 50% in Cycle 1 • Then ↑dose in subsequent cycles according to toxicity or therapeutic drug monitoring (TDM)*
Poor Metaboliser	• Avoid fluoropyrimidines due to risk of fatal, life-threatening toxicity

*Dose uptitration in DPYD IMs

- eviQ suggests ↑10-12.5% dose increment in DPYD IMs.
- Therapeutic drug monitoring (TDM) facilitates safer/quicker dose titration in DPYD IMs

1. Amstutz et al. Clin Pharmacol Ther. 2018 Feb;103(2):210-216.

PRECISION-ITS: Fluorouracil TDM substudy

Patients

- Pts with met/unresectable CRC receiving cIVI 5-FU (e.g. FOLFIRI, FOLFOXIRI)

Intervention

- Using PK sampling (AUC) to measure plasma 5-FU concentrations to optimise 5-FU dosing in subsequent cycles - **target AUC = 20-30mg-h/L**
- PGx pharmacist sends TDM dosing recommendations to treating clinician

PK Sampling

- On C1D2 (18-40 hrs after start of 5-FU cIVI)
- Unstable at RT

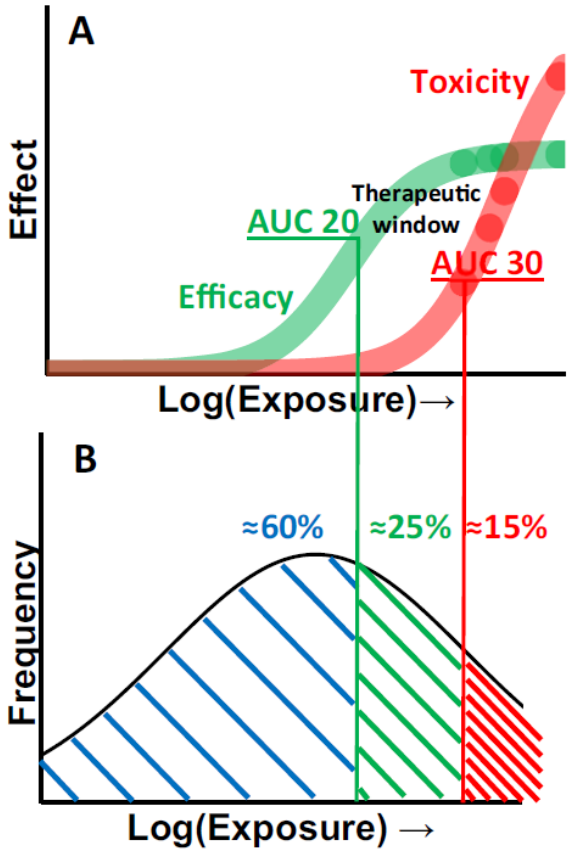


Figure reference: Beumer et al. Clin Pharmacol Ther 2019 Mar;105(3):598-613

Supplementary Table 7: *DPYD* intermediate metabolisers with dose escalation and toxicity post AUC level(s)

No.	First 5FU dose given prior to TDM (%)	AUC level 1	Toxicity 1	% Dose given post AUC level 1	AUC level 2	Toxicity 2	% Dose given post AUC level 2	AUC level 3	Toxicity 3	% Dose given post AUC level 3	AUC level 4	Toxicity 4	% Dose given after AUC level 4	AUC level 5
1[a]	100% bolus, 100% infusion	24.2	G1 dizziness	100% bolus, 100% infusion and continued same dose for 6 cycles	NA	NA	NA							
2[b]	50% bolus, 50% infusion	10.2	None	75% bolus, 75% infusion	15.7	G3 Neutropenia	Cycle 3 delayed, (bolus omitted, 75% infusion given)	NA	NA	NA	NA	NA		NA
3[b]	50% bolus, 50% infusion	10.2	G1 Fatigue	80% bolus, 80% infusion	12.8	G1 fatigue, G1 skin pigmentation	100% bolus 100% infusion	19	G1 fatigue G1 peripheral neuropathy (sensory)	100% bolus, 112% infusion	no level taken due to Lab closure over Christmas period	G1 fatigue, G1 peripheral neuropathy (sensory) G1 skin pigmentation	100% bolus, 112% infusion	20.5
4[b]	50% bolus, 50% infusion	11.6	G1 neurotoxicity unrelated to 5FU	50% bolus, 75% infusion	17.6	G1 nausea G1 diarrhoea G1 peripheral neuropathy sensory unrelated to 5FU, G1 fatigue	50% bolus 87% infusion	28	G1 decreased platelet count G1 neurotoxicity	75% bolus, 87% infusion	NA	NA	100% bolus, 87% infusion[c]	NA

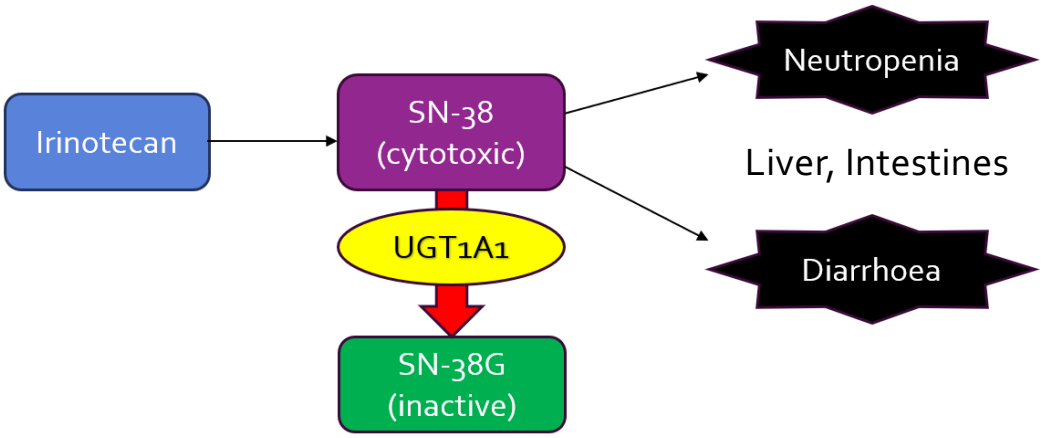
Footnotes: 5FU: 5-fluorouracil, TDM: therapeutic drug monitoring, NM: normal metaboliser, IM: intermediate metaboliser, FN: febrile neutropenia, NA: not applicable, G: grade, AUC: area under the curve, AUC units: mg*h/L.

Dose tolerance in DPYD IMs is variable. TDM is very important for DPYD IMs to prevent underdosing in subsequent cycles

- Gradual dose uptitration is often required to reach full dose

Glewis et al. Br J Clin Pharmacol. 2025;91:1965–1974.

UGT1A1-guided dosing for Irinotecan



- **UGT1A1 PMs have an↑ risk of neutropenia compared to NM & IMs [1]**

Decreased function UGT1A1 variants:

- ***28 variant** = reduced gene expression
- ***6 variant**= reduced enzymatic function

DPWG recommendations based on UGT1A1 Phenotype [1]	
Normal Metaboliser **Intermediate Metaboliser**	**Poor Metaboliser**
• Initiate standard starting dose	• 30% DR to Irinotecan starting dose in Cycle 1 • ↑ Dose according to ANC & toxicity from Cycle 2

1. Hulshof et al. Eur J Hum Genet. 2023 Sep;31(9):982-987.

UGT1A1 & Sacituzumab govitecan

- **SN-38** = ADC payload in SG → ↑ Toxicity in UGT1A1 PMs (*28/*28)

Prescribing Information

Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia; and may be at increased risk for other adverse reactions when treated with TRODELVY.

Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 enzyme activity.

- Product information recommends primary G-CSF prophylaxis for all patients at increased risk of neutropenia
- **PRECISION-ITS trial incorporates UGT1A1-guided dosing interventions & additional supportive care prophylaxis for UGT1A1 PMs. Discovery Program will contribute data for additional & emerging UGT1A1 variants**

FDA prescribing information: TRODELVY® (sacituzumab govitecan-hziy) for injection

TPMT & NUDT15 – guided dosing for Thiopurines

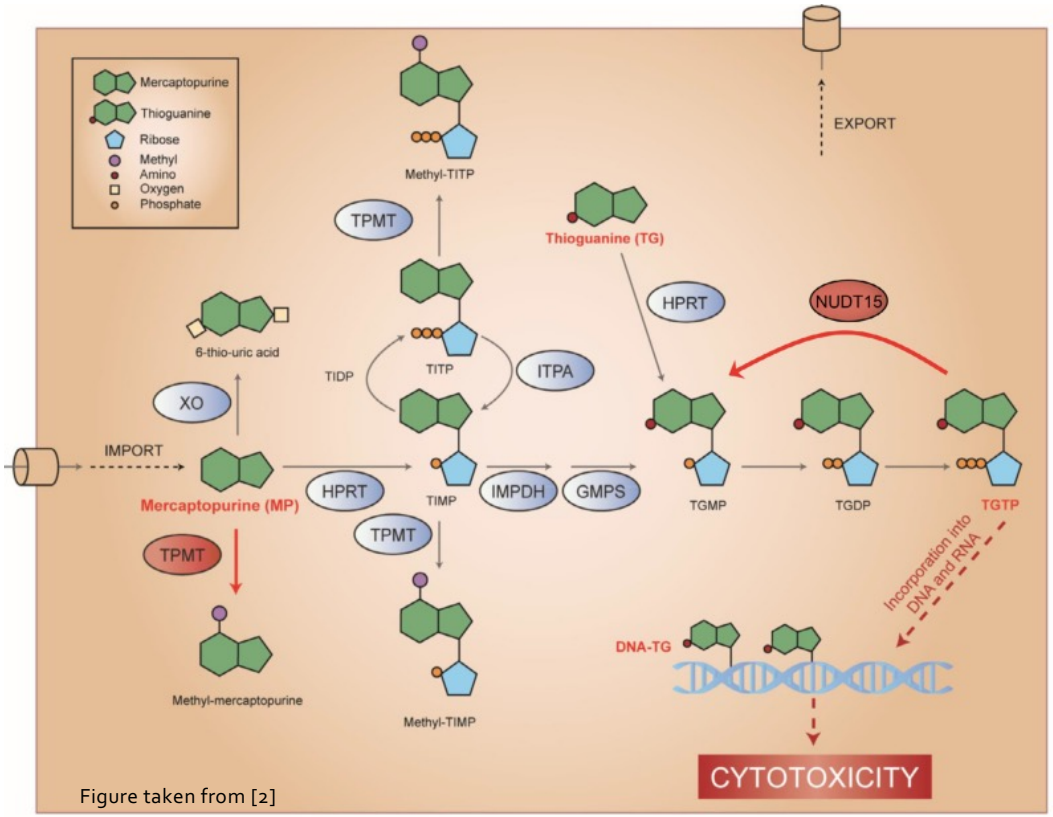


Figure taken from [2]

- PGx used to inform dosing, drug choice & ↓cumulative toxicity

Tioguanine, Mercaptopurine & Azathioprine

- CPIC guideline recommendations depend on TPMT & NUDT15 phenotype combinations [1]
- Starting dose reductions are generally recommended for **TPMT and/or NUDT15 Intermediate & Poor Metabolisers** [1]

1. Maillard et al. Clin Pharmacol Ther. 2026 Apr;119(4):916-927
2. Karol et al. Seminars in Hematology 2020;57:130-136

Example recommendation for TPMT NM + NUDT15 NM/IM/PM

TPMT Phenotype	NUDT15 Phenotype	MERCAPTOPURINE Dosing Recommendation	TIOGUANINE Dosing Recommendation	AZATHIOPRINE Dosing Recommendation
Normal metaboliser	**Normal metaboliser**	**No dose adjustments are required.** Allow for at least 2 weeks for drug to reach steady state after each dose adjustment.		
	Intermediate metaboliser Allow 2-4 weeks for drug to reach study state after each dose adjustment.	**If normal starting dose is ≥75mg/m^2/day or ≥1.5mg/kg/day:** • Reduce starting dose by 20-70% [a] [CPIC] **If normal starting dose is <75mg/m^2/day or <1.5mg/kg/day**: • Dose reduction may not be recommended [CPIC]	**If normal starting dose is ≥40-60mg/m^2/day:** • Reduce starting dose by 20-50% [a] [CPIC] **If normal starting dose is <40mg/m^2/day:** • Dose reduction may not be recommended [CPIC]	**If normal starting dose is 2-3 mg/kg/day:** • Reduce starting dose by 20% - 70% [a] [CPIC] **If normal starting dose is <2 mg/kg/day:** • Dose adjustments may be not recommended [CPIC]
	Poor metaboliser Allow 4-6 weeks for drug to reach steady state after	**For malignant conditions:** • **Initiate** starting dose at 10mg/m^2/day [CPIC]	**For malignant conditions:** • Reduce starting dose by 75% [CPIC]	**For malignant conditions:** • Reduce starting dose by 90% [CPIC]

- Recommendations also differ depending on whether single- or multi-gene test results available (note: only TPMT is MBS-subsidised)

CYP2D6 & Ondansetron/Tropisetron

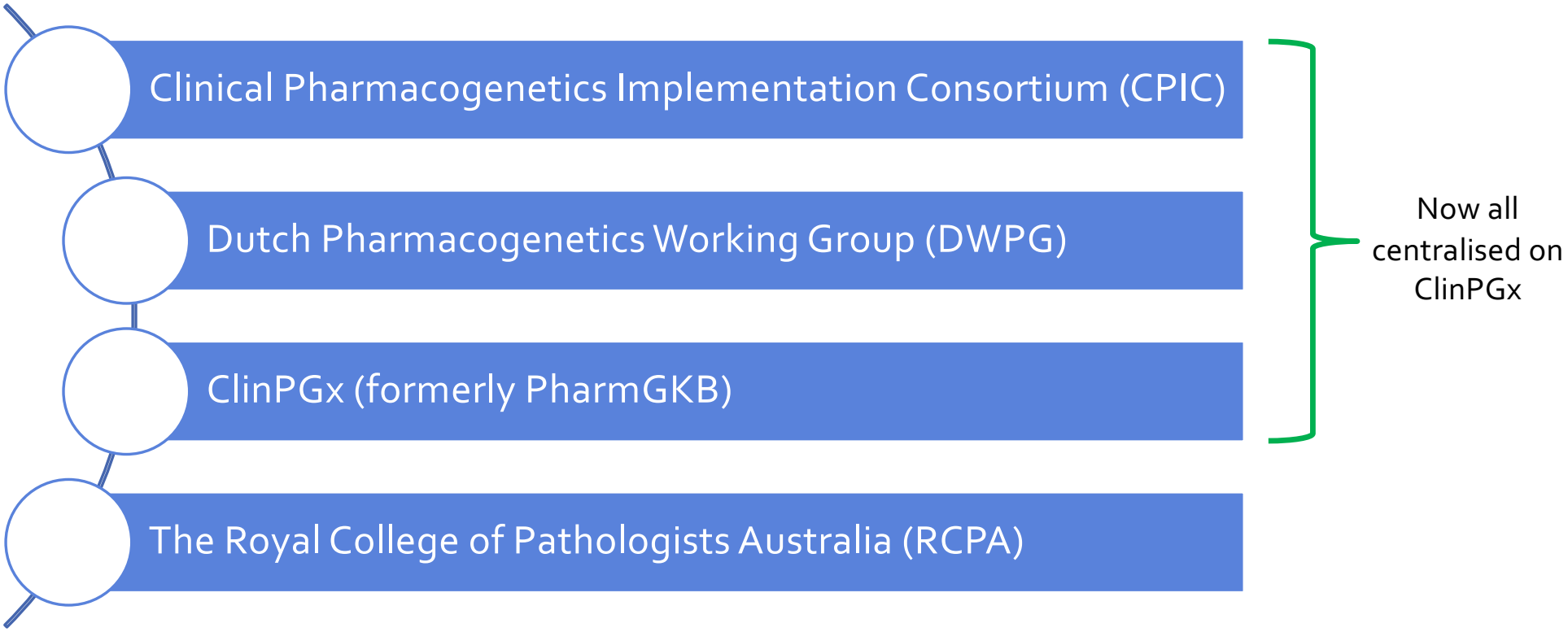
- PGx testing used to inform anti-emetic drug choice

CYP2D6 Phenotype	CPIC guideline recommendation [1]
Ultrarapid metaboliser	• Reduced efficacy → select alternative 5-HT3 antagonist not predominantly metabolised by CYP2D6 (e.g. granisetron)
Normal metaboliser	• Initiate drug at standard starting dose
Intermediate metaboliser	
Poor metaboliser	

1. Bell GC et al. Clin Pharmacol Ther 2017 Aug;102(2):213-218

PGx References & Guidelines

PGx references



The evolution of PharmGKB + CPIC

ClinPGx is a comprehensive clinical pharmacogenomic (PGx) resource created to support and expand PGx knowledge, implementation and education. It integrates the PharmGKB, CPIC and PharmCAT projects, with additional features and content to come. Our goals are to make clinical PGx accessible and facilitate its integration with genomic medicine. ClinPGx is an affiliate grant of the Clinical Genome Resource (ClinGen).

What is ClinPGx? | What is Pharmacogenomics? | ClinPGx Blog

Precision Guidance

Access drug prescribing recommendations from DNA test results.

PharmDOG
Get **focused** PGx guidance on all devices

GSI
Compare PGx guidance from different sources

PharmCAT
Translate **VCF data** into PGx guidance

Learn more about genes and drugs with prescribing guidance.

Genes
See actionable PGx genes

Drugs
See drugs affected by PGx

Pairs
Explore gene-drug associations

Curated PGx Evidence

Gene-drug and allele-drug associations manually curated by ClinPGx scientists.

All Guidelines
Annotated PGx-based clinical guidelines

Drug Labels
Annotated PGx from drug labels
See also: FDA Labels

Literature
Allele-drug associations from published literature

Pathways
Evidence-based drug pathway diagrams

Curates info about gene-drug & genotype-phenotype relationships

Summarises range of PGx guidelines & regulatory advisories

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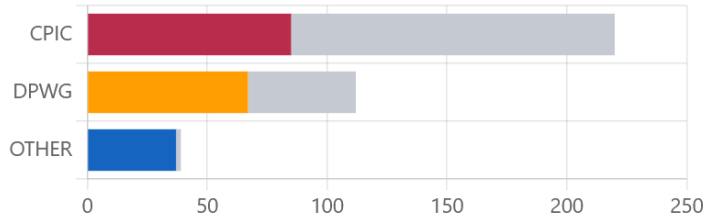
Clinical Guideline Annotations

ClinPGx annotates PGx-based clinical guidelines. Read more about ClinPGx clinical guideline annotations, the guideline sources and the "tags" found in the table below.

Sort and filter the table using the column headers and selection boxes. Download the entire table using the button at the top right of the table.

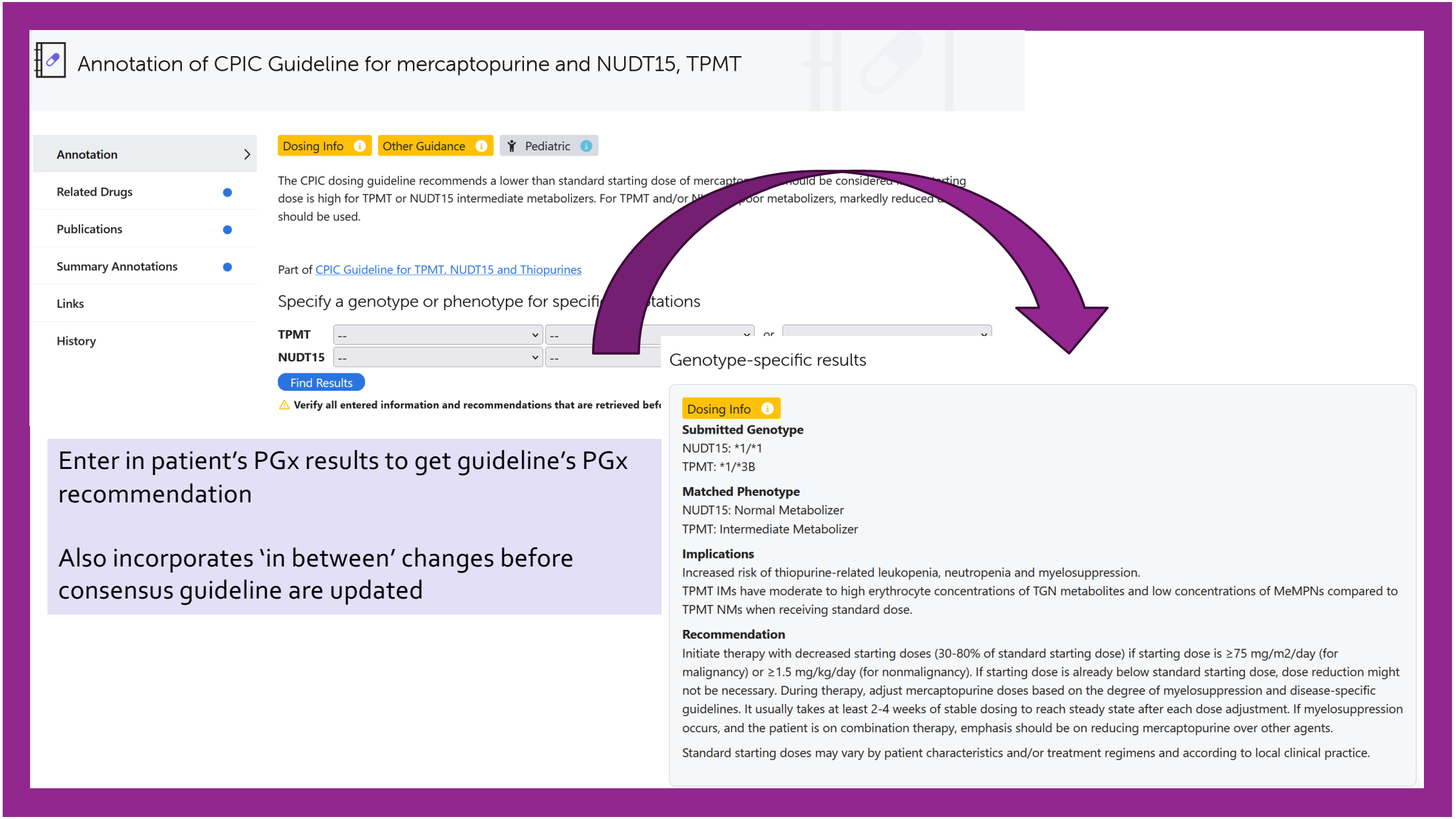
Guideline Videos: ClinPGx has recorded video overviews of the CPIC clinical guidelines. The video overview of a guideline can also be seen on the individual guideline page.



Download

Filter All guidelines for those with Testing Info Alternate Drug Dosing Info Other Guidance Pediatric

DRUGS (2)	CPIC (2)	DPWG (2)	OTHER (1)
mercap			
mercaptopurine	NUDT15, TPMT 05/11/2026 CPIC Dosing Info Other Guidance Pediatric	TPMT 12/20/2025 DPWG Testing Info Alternate Drug Dosing Info Other Guidance NUDT15 12/20/2025 DPWG Testing Info Alternate Drug Dosing Info Other Guidance	TPMT 04/06/2022 RNPGx Testing Info

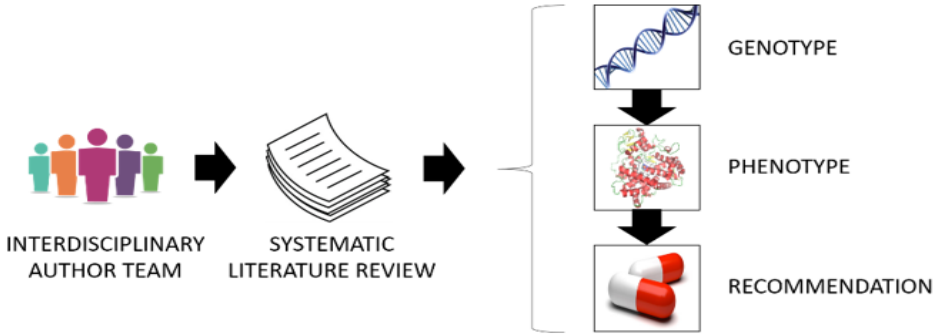


Enter in patient's PGx results to get guideline's PGx recommendation

Also incorporates 'in between' changes before consensus guideline are updated

Clinical Pharmacogenetics Implementation Consortium (CPIC)

- International, peer-reviewed PGx guidelines
- Also provides resources on pharmacogenomics implementation in electronic medical records
- Free to access
- Guidelines focus on PGx optimisation of medicines – *not whether PGx testing should be ordered for the drug*



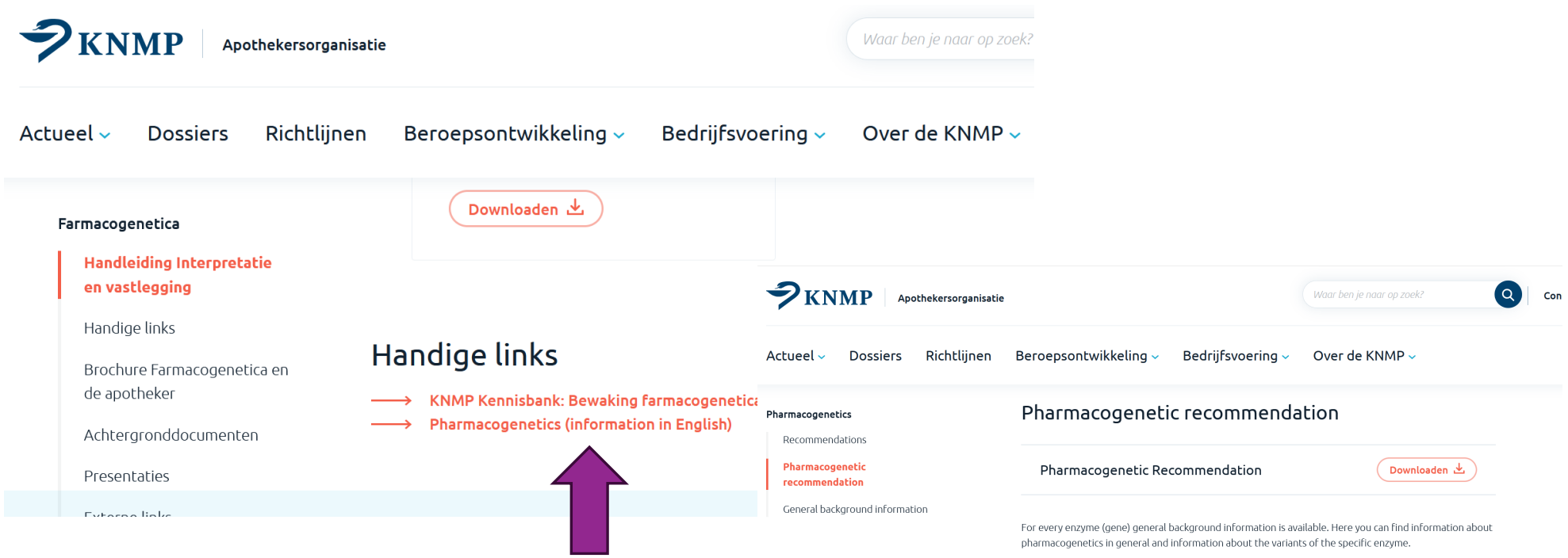
GUIDELINE	DRUGS	GENES
CFTR and Ivacaftor	ivacaftor	CFTR
CYP2B6 and efavirenz	efavirenz	CYP2B6
CYP2B6 and methadone	methadone	CYP2B6
CYP2C19 and Clopidogrel	clopidogrel	CYP2C19
CYP2C19 and Proton Pump Inhibitors	dexlansoprazole esomeprazole lansoprazole omeprazole pantoprazole rabeprazole	CYP2C19
CYP2C19 and Voriconazole	voriconazole	CYP2C19

Dutch Pharmacogenetics Working Group (DPWG)

- International (mainly Europe), peer-reviewed PGx guidelines
- Guideline annotation summary is free to access
- DPWG additionally provides recommendation on whether pre-emptive PGx testing should be done via **Clinical implication score**

Adapted from Table 1 in DPWG risk analysis documents

Potentially beneficial	PGx testing for this gene-drug pair is potentially beneficial. Genotyping can be considered on an individual patient basis. If, however, the genotype is available, the DPWG recommends adhering to the gene-drug guideline	0-2 +
Beneficial	PGx testing for this gene-drug pair is beneficial. It is advised to genotype the patient before (or directly after) drug therapy has been initiated to guide drug and dose selection	3-5 +
Essential	PGx testing for this gene-drug pair is essential for drug safety or efficacy. Genotyping must be performed before drug therapy has been initiated to guide drug and dose selection	6-10 +



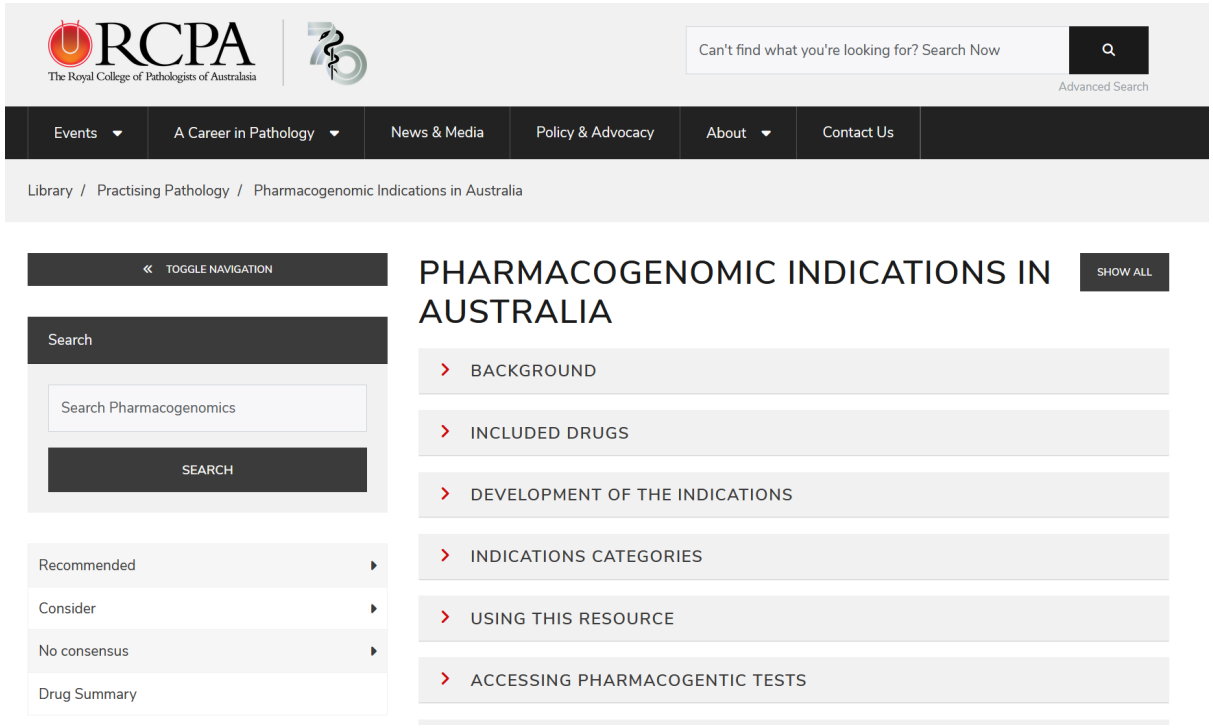
DPWG (KNMP) website can be partially translated into English…

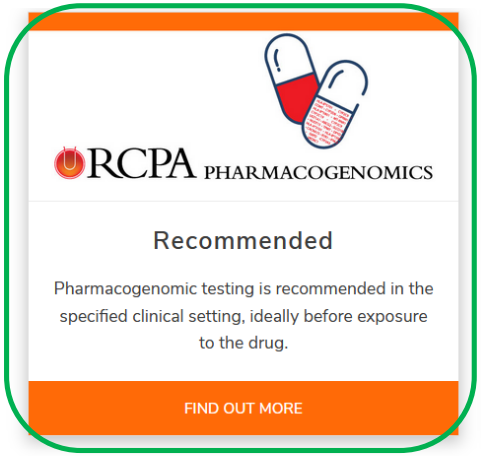
Pharmacogenomic Indications in Australia - The Royal College of Pathologists Australia (RCPA)

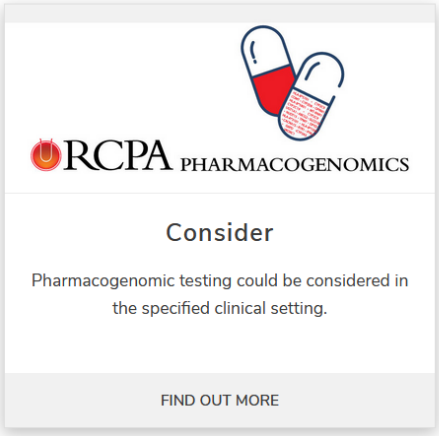
- Australian consensus guidelines for pre-emptive PGx testing developed by multidisciplinary advisory group; established in 2024

Website information:

- Funding/access to PGx test
- Prevalence of relevant PGx variants
- Links to **CPIC guidelines**







Drugs where pre-emptive PGx testing is RECOMMENDED (Oct 2025):

- Abacavir
- Allopurinol
- Capecitabine, Fluorouracil, Irinotecan, Mercaptopurine, Tioguanine, Azathioprine
- Carbamazepine, Oxcarbazepine, Phenytoin
- Clopidogrel
- Voriconazole

PGx Implementation Experience at Peter Mac

Peter Mac
Peter MacCallum Cancer Centre
Victoria Australia

Cancer Nurses Society of Australia
elevate
cancer nursing
innovate | integrate | educate | advocate

28th ANNUAL CONGRESS • 17-19 JUNE 2026
Perth Convention and Exhibition Centre

Patient JC (52 yo F)

Oct 2018

JC received her 1st cycle of capecitabine to treat newly Dx rectal carcinoma

Day 5…

JC presented to ED with mouth pain (describing 9/10).

Day 14…

JC rapidly deteriorated, requiring ICU admission & uridine triacetate (life-saving antidote).

JC died from multi-organ failure secondary to neutropenic sepsis

Coronial case

Referred to local Pharmacy & Therapeutics Advisory Committee for assessment & recommendations

Establishment of PGx Service

Retrospective review

2018/2019: 300 patients per year received FP

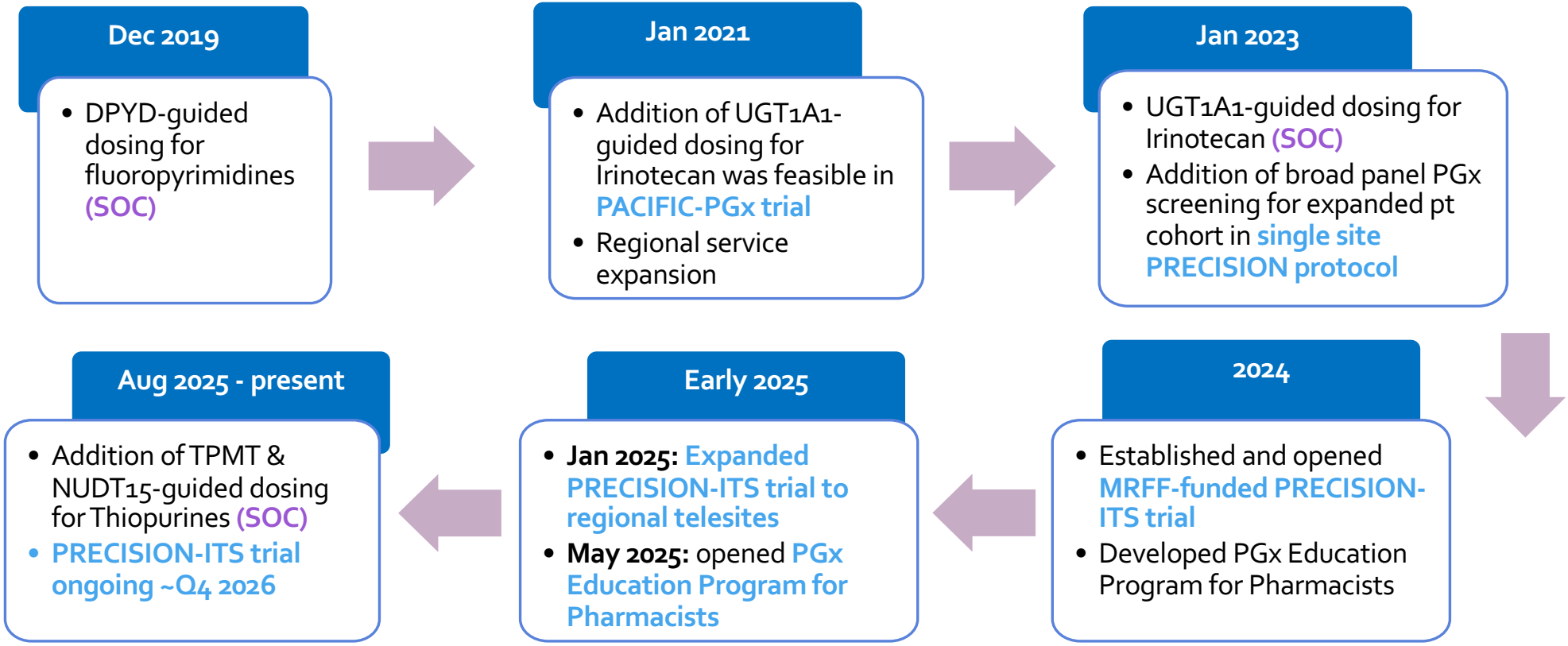
2016-19: 6 cases had long stay ICU admission or antidote

The only life-saving antidote costs ~$130k

2019

PGx clinic established at Peter Mac

Peter Mac PGx Implementation Journey



- Since 2019, ~1900 patients have undergone PGx testing (~10% pts at regional sites)

Pharmacist Role

PGx/TDM turnaround time = 3-7 days

Screening

- Reviewing patients against SOC/trial eligibility criteria
- Assessing clinical need & appropriateness for PGx testing

Consenting

- Obtaining informed consent for PGx testing
- Recruiting & consenting patient to trial

Sample collection (PGx & TDM)

- Facilitating onsite & remote sample collection
- Counselling patient on buccal swab technique
- Coordinating sample delivery to third party labs to ensure results are available before anticancer treatment commencement

Patient follow up

- Pharmacist-led CTCAE assessment (telehealth):
  - Baseline/ C1D1 (-30 days)
  - C1D3-7 for patients newly commencing fluoropyrimidines
  - At W4, W8 & W12 after treatment commencement

Counselling patient

- Counselling patients on PGx results & relevance to anticancer treatment + current medicines
- Explaining caveats with test results

Reporting results

- Reporting PGx / TDM results to clinician before anticancer treatment commencement / next chemotherapy cycle
- Documenting PGx / TDM results in medical record & trial database

PGx documentation in EMR

- PGx pharmacist is responsible for documenting DPYD/UGT1A1 dosing recommendations in medical record

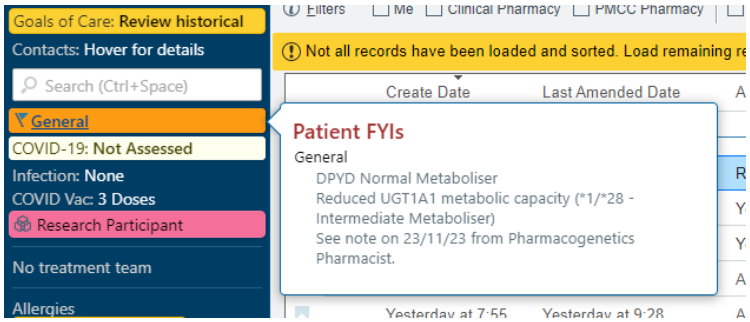
1. From the 5 DPYD gene variants we tested for (c.1905+1G>A, c.1679T>G, c.2846A>T, c.1236G>A and c.557A>G), results show [redacted] is an **Normal Metaboliser, thus does not require any DPYD-related dose modifications**
2. [redacted] is also showing **reduced UGT1A1 metabolic capacity (*1/*28- Intermediate Metaboliser) and has 6TA repeats on the promoter of one UGT1A1 gene and 7TA repeats on the promoter of the other UGT1A1 gene. Despite this there are no UGT1A1 gene-related dose adjustments required, according to the Dutch Pharmacogenetics Working Group (DPWG) guidelines.**

   Note: dose modifications for non-gene related factors may still apply
3. I have emailed [redacted] outlining the test results and recommendations above
4. Placed both DPYD and UGT1A1 results as FYI flags (General category)

   DPYD Normal Metaboliser

   Reduced UGT1A1 metabolic capacity (*1/*28- Intermediate Metaboliser)

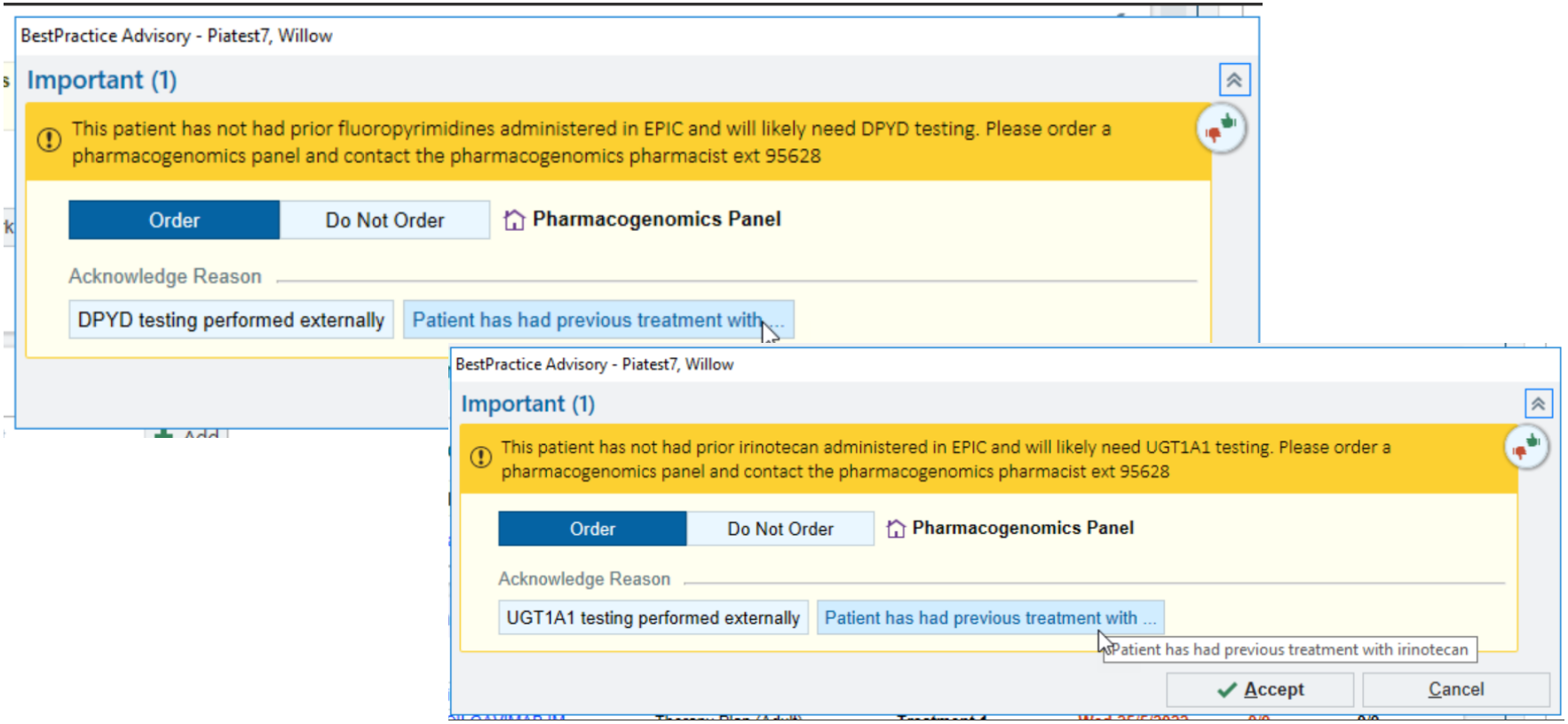
   See note on 23/11/23 from Pharmacogenetics Pharmacist.
5. [redacted] has been given an electronic copy of their DPYD and UGT1A1 gene test results, sent to their email address.



- Lab reports & recommendations are also emailed directly to treating clinician(s)
- Patients also receive their own version of DPYD & UGT1A1 reports

DPYD & UGT1A1 testing EMR alerts

- Alert appears at point of prescribing to prompt prescriber to order PGx panel



Personalised PGx report

- PGx pharmacists drafts, checks & documents report in EMR

PGx pharmacist also counsels patients on:

- Report's purpose / scope / clinical relevance
- Sharing report with community prescribers
- PGx testing caveats – e.g. phenoconversion
- Relevant med-gene interactions

Pharmacogenomic Test Results

Name	Homer Simpson	**Peter Mac URN**	123456
DOB	15/05/1957	**Reported by**	Pharmacist 1
Date reported	08Nov2024	**Authorised by**	Pharmacist 2

GENETIC TEST RESULTS OVERVIEW		
GENE	**GENOTYPE**	**PREDICTED PHENOTYPE**
DPYD	See below	Intermediate metaboliser
UGT1A1	*1/*1	Normal metaboliser
ABCG2 (rs2231142)	CC	Normal transporter function
CYP2B6	*6/*6	Poor metaboliser
CYP2C19	*17/*17	Ultra Rapid metaboliser
CYP2C9	*1/*1	Normal metaboliser
CYP2D6	*1/*2	Normal metaboliser
CYP3A4	*1/*1	Normal metaboliser
CYP3A5	*3/*3	Poor metaboliser
SLCO1B1	*1/*1	Normal transporter function
VKORC1	GG	Normal VKORC1 enzyme level
G6PD	B	Normal levels
HLA-A	*31:01	Negative (Non-carrier)
HLA-B	*15:02	Negative (Non-carrier)
HLA-B	*57:01	Negative (Non-carrier)
HLA-B	*58:01	Negative (Non-carrier)
MT-RNR1	m.827A>G	Normal toxicity risk

DPYD Intermediate metaboliser (Activity score 1)
One normal function allele and one no function allele

SNP	Result	Genotype Interpretation
c.1905+1G>A	GA	one no function and one normal functioning variant
c.1679T>G	TT	two normal functioning variants
c.2846A>T	AA	two normal functioning variants
c.1129-5923C>G	CC	two normal functioning variants
c.557A>G	AA	two normal functioning variants

This pathology result has been produced by a NATA accredited laboratory, meeting stringent quality standards for accuracy and reliability. It is important to interpret the predicted phenotype in the context

Dear Homer Simpson,

Thank you very much for taking part in the ***PRECISION-ITS Project: Pharmacogenomic Medicines Optimisation for People with Cancer***. This research project aims to evaluate how information from a patient's genomic test can improve and personalise their cancer care. Your participation in this project is greatly appreciated.

What did we do?

With your permission, the blood or saliva samples you provided were tested to study your genes. Your genomic test involved analysing selected genes and identifying variations relevant to medicines.

What did we find?

This letter explains gene test results that may affect how medicines are prescribed for you. A full summary of results can be found on the **last two pages**. Please kindly note that the findings outlined in this letter have already been shared with your Peter Mac treating team. These findings may change how your doctor gives you medicines and watches for side effects.

Only medicines with actionable med-gene interactions per the patient's PGx results are listed

CYP2B6 enzyme, poor metaboliser

Your results show that your body has lower activity of CYP2B6, an enzyme that processes medications in the body.

Your body is less able to break down some medications:

Medication(s)	
Sertraline	This medication is used to treat depression or anxiety. You may experience more side effects than other people and need a lower dose of this medication to reduce the risk of side effects. However, this will also depend on your result for CYP2C19, another enzyme that breaks down this medication.

CYP2C19 enzyme, ultrarapid metaboliser

Your results show your body has higher activity of CYP2C19, an enzyme that processes medications in the body.

Your body breaks down some medications very quickly. Some medications may be less effective for you at standard doses:

Medication(s)	
Citalopram, Escitalopram	These medications are used for the treatment of depression or anxiety. You may need a different medication to treat these conditions.
Voriconazole	This medication is used to prevent or treat fungal infections. You may need a different medication to treat this condition.
Lansoprazole, Omeprazole, Pantoprazole	These medications are used to prevent or treat reflux. You may need a higher dose for the medication to be effective.

Medicines outside cancer care also flagged - PGx pharmacist monitors & communicates to other prescribers where imminently relevant

CYP2C19 enzyme, intermediate metaboliser

Your results show your body has lower activity of CYP2C19, an enzyme that processes medications in the body.

Your body is less able to activate some medications. Some medications may be less effective for you at standard doses:

Medication(s)	
Clopidogrel	You may need a different medication for treatment.

Human Leukocyte Antigen-B *15:02 (HLA-B*15:02), Positive (Carrier)

Your results show that you are a carrier of HLA-B*15:02, a gene variant linked to allergic skin reactions from these medications:

Medication(s)	
Carbamazepine, Oxcarbazepine	These medications are used to treat seizures. Carbamazepine can also be used to treat mood disorders or nerve pain. These medications can cause severe (and sometimes fatal) allergic skin reactions. Less than 0.1% of people experience this reaction. The risk is highest during the first few months of treatment. These medications are also affected by HLA-A*31:01, another gene variant linked to serious allergic skin reactions. Your doctor and pharmacist will consider the combined impact of your HLA-A*31:01 and HLA-B*15:02 results if you are prescribed these medications.

Applicable to all of the above medication(s):

Your results predict that you have a higher chance of developing serious allergic skin reactions from these medications.

- If you have not started this medication, your doctor may prescribe a different medication to reduce the risk of serious side effects.
- If you are already taking this medication and have not experienced any allergic skin reactions, it may be appropriate for this medication to be continued. Some people who carry this gene variant can tolerate this medication without severe side effects. Your doctor and pharmacist will consider your personal situation and whether ongoing use of this medicine outweighs this risk.

Patients may self-adjust or self-cease medicines without appropriate PGx counselling

Language re: overall risk of life-threatening AEs included

Cautionary language included in event patient is already taking a flagged medicine

PGx Pharmacist Recommendations

Pharmacist obtains medication history and provides PGx recommendations for medicines the patient is actively taking / planned for

I have conducted a medication history interview and confirmed Homer is taking the following medications with pharmacogenomic prescribing implications in the PRECISION-ITS protocol: codeine .

Homer is not currently taking any medicines with phenoconversion effects for the CYP2C9, CYP2D6, CYP2B6, CYP2C19 or CYP3A5 genes.

I have recommended the below changes to their medications as part of the PRECISION-ITS trial and have advised Homer to not make any changes to their current medication until their doctor has reviewed their pharmacogenomic test results. I have explained to Homer that their doctor may make dose modifications for reasons unrelated to their gene test.

Our pharmacogenomic recommendations based on their pharmacogenomic test results and review of their medication history are provided below:

CYP2D6 Intermediate Metaboliser (*1/*4)	
Medicine	Pharmacogenomic pharmacist recommendation
Codeine	Initiate drug at standard recommended dose and monitor for reduced analgesic response. If no response, switch to a non-tramadol/non-codeine opiate.

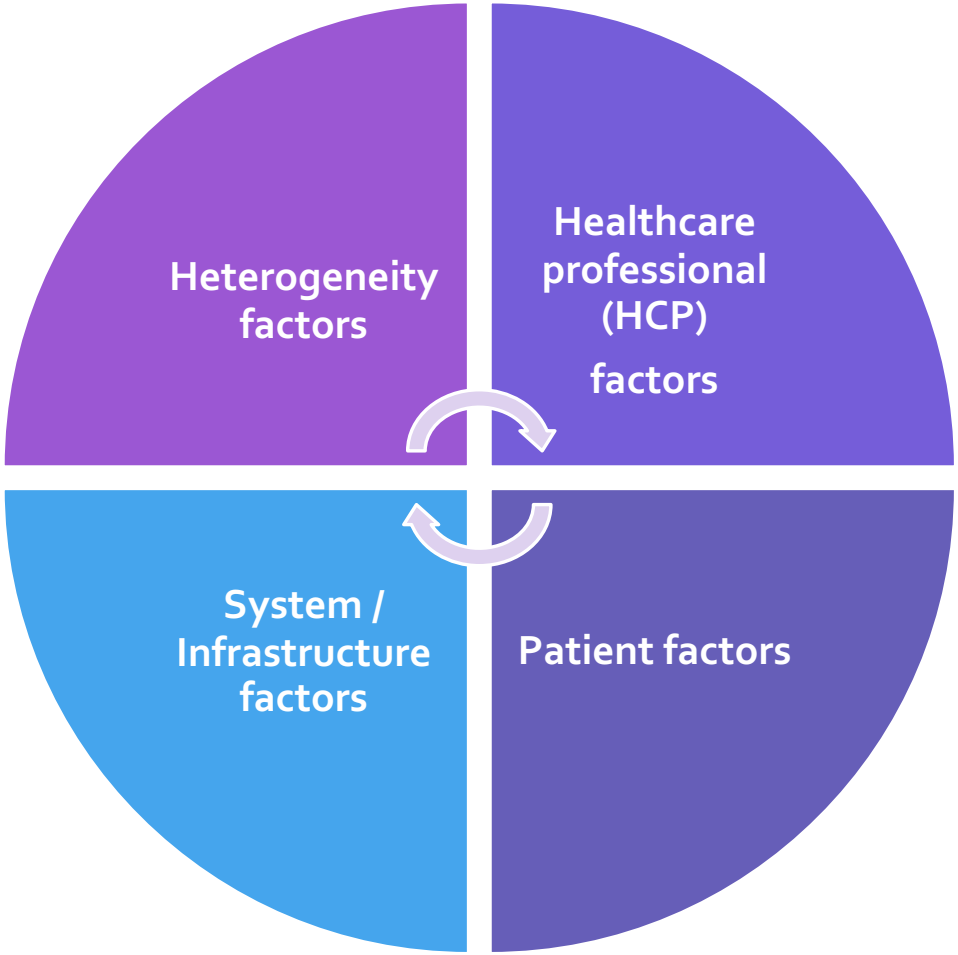
PGx report caveat: Phenoconversion

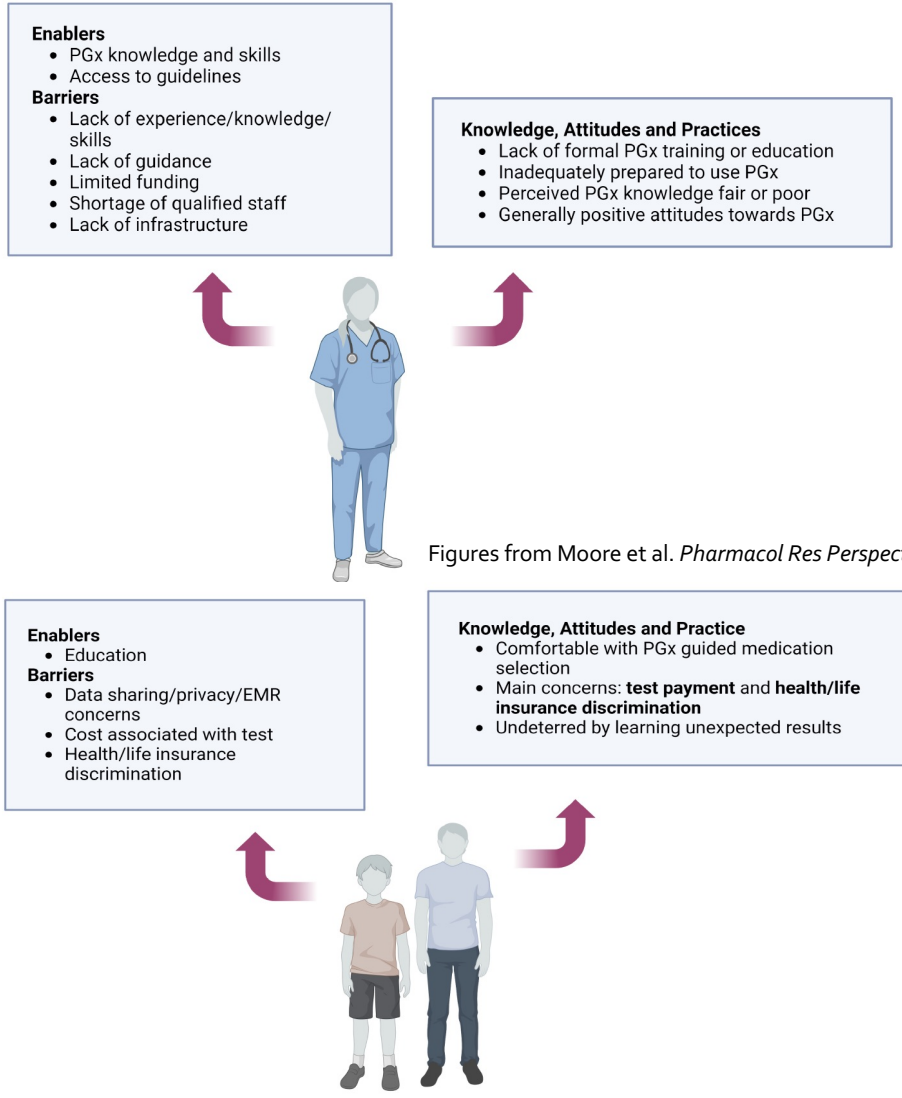
- Concomitant drug inhibitors/inducers can change drug response predicted by gene test

Example: Paroxetine / Abiraterone in pt genotyped as a CYP2D6 normal metaboliser

CYP2D6 intermediate Metaboliser (PHENOCONVERSION-ADJUSTED PHENOTYPE)	
Homer 's genetic results suggest that they are a CYP2D6 Normal Metaboliser * 1 / * 1 . However due to the co-administration of Abiraterone & the presence of phenoconversion, this converts Homer to a intermediate metaboliser. Phenoconversion-adjusted CYP2D6 activity score = 1.0	
Medicine	Pharmacogenomic pharmacist recommendation
Paroxetine	Consider a lower starting dose and slower titration schedule. Uptitrate to standard maintenance dose if needed.

Pharmacogenomic Implementation Challenges





Figures from Moore et al. *Pharmacol Res Perspect.* 2023;11:e01150.

Heterogeneity in…Lab testing

- Comprehensive vs limited gene panels - turnaround times, costings ($140-$250) & scope vary
- Sensitivity of PGx tests depends on variants in panel – this can lead to discordant phenotyping between labs. Some labs are not NATA-accredited

Lipid Lowering Medication	
Atorvastatin	*SLCO1B1, CYP3A4*
Fluvastatin	*SLCO1B1, CYP2C9*
Lovastatin	*SLCO1B1*
Pitavastatin	*SLCO1B1*
Pravastatin	*SLCO1B1*
Rosuvastatin	*SLCO1B1*
Simvastatin	*SLCO1B1*

vs

Mental Health	
Anti-Depressants (SSRIs)	
Citalopram	*CYP2C19*
Escitalopram	*CYP2C19*
Fluvoxamine	*CYP2D6*
Paroxetine	*CYP2D6*
Sertraline (Zoloft)	*CYP2C19*
Anti-Depressants (TCAs)	
Amitriptyline	*CYP2D6, CYP2C19*
Clomipramine	*CYP2D6, CYP2C19*
Desipramine	*CYP2D6, CYP2C19*
Doxepin	*CYP2D6, CYP2C19*
Imipramine	*CYP2D6, CYP2C19*
Nortriptyline	*CYP2D6*

Excerpt from Aus Clinical Labs – PGx Genes & Medication List

Table 1 Assignment of predicted CYP2D6 phenotypes based on diplotypes

Phenotype[a]	Activity score range	Examples of *CYP2D6* diplotypes[b]
CYP2D6 ultrarapid metabolizer	> 2.25	**1/*1xN, *1/*2xN, *2/*2xN*[c]
CYP2D6 normal metabolizer	1.25 ≤ x ≤ 2.25	**1/*10 *1/*41, *1/*9 *10/*41×3 *1/*1, *1/*2 *2×2/*10*
CYP2D6 intermediate metabolizer	0 < x < 1.25	**4/*10 *4/*41, *10/*10 *10/*41 *41/*41, *1/*5*
CYP2D6 poor metabolizer	0	**3/*4, *4/*4, *5/*5, *5/*6*
CYP2D6 indeterminate	n/a	**1/*22, *1/*25, *22/*25*

Crews et al. Clin Pharmacol Ther 2021 Oct;110(4):888-896.

Example: DPYD test variants

DPYD variant allele	Impact on DPD activity	Allele frequency
c.1905+1G > A (DPYD *2A)	No function	• Most well studied variant; 0-0.5% frequency • 0.3-1% of Europeans
c.1679 T > G (DPYD*13)	No function	• 0.08% frequency - rare (<1%)
c.2846 A > T (rs67376798)	Decreased function	• 0-0.6% frequency - rare (<1%)
c.1129-5923 C > G (HapB3, rs56038477)	Decreased function	• 0.06-2.4% multiethnic allele frequency • Highest in Netherlands (2.6%) and Germany (3.3%)
c.557A>G (rsrs115232898)	Decreased function	• 2.1% of patients with African ancestry

- Panel should incorporate variants with high PGx allele frequencies based on local geographic ethnicity data.
- Variant allele frequencies ≥ 0.1% (Tier 1) are recommended for testing due to risk of extreme FP toxicity. [1]

1. Pratt et al. J Mol Diagn. 2024 Oct;26(10):851-863.

Heterogeneity in Guidelines: Irinotecan / UGT1A1

- Differences in PGx guideline advice complicates implementation

DPWG

- **Pre-emptive testing:** Essential
- **Recommendation:** 30% DR in C1

RNPGx

- **Pre-emptive testing:** *Doses < 180mg/m²:* not needed, *180-230mg/m²:* Advisable, *≥240mg/m² :* Essential
- **Recommendation:** 30% DR in C1 for *28/*28 genotype only

eviQ

- **Pre-emptive testing:** Minimal info, advises against reactive testing
- **Recommendation:** advises that DR is needed, but unclear how much – references PK study suggesting 20% DR

Attitudes & Perceptions to PGx (amongst HCPs)

Figure 1: Healthcare professionals support for pharmacogenomics testing

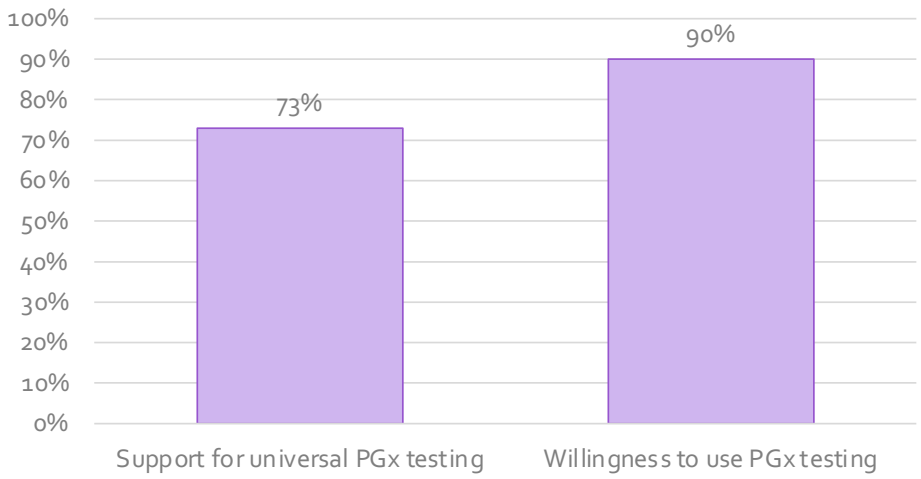
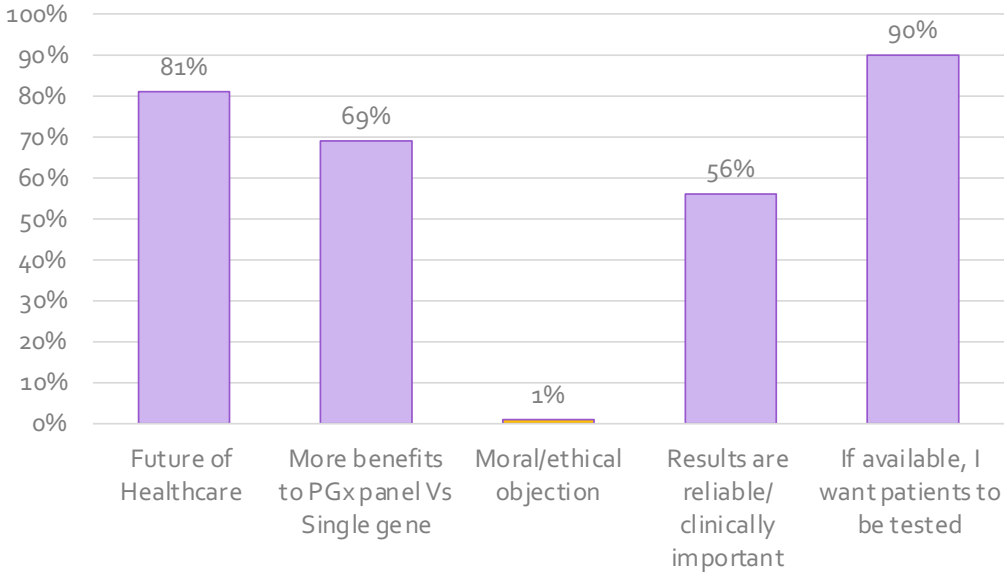


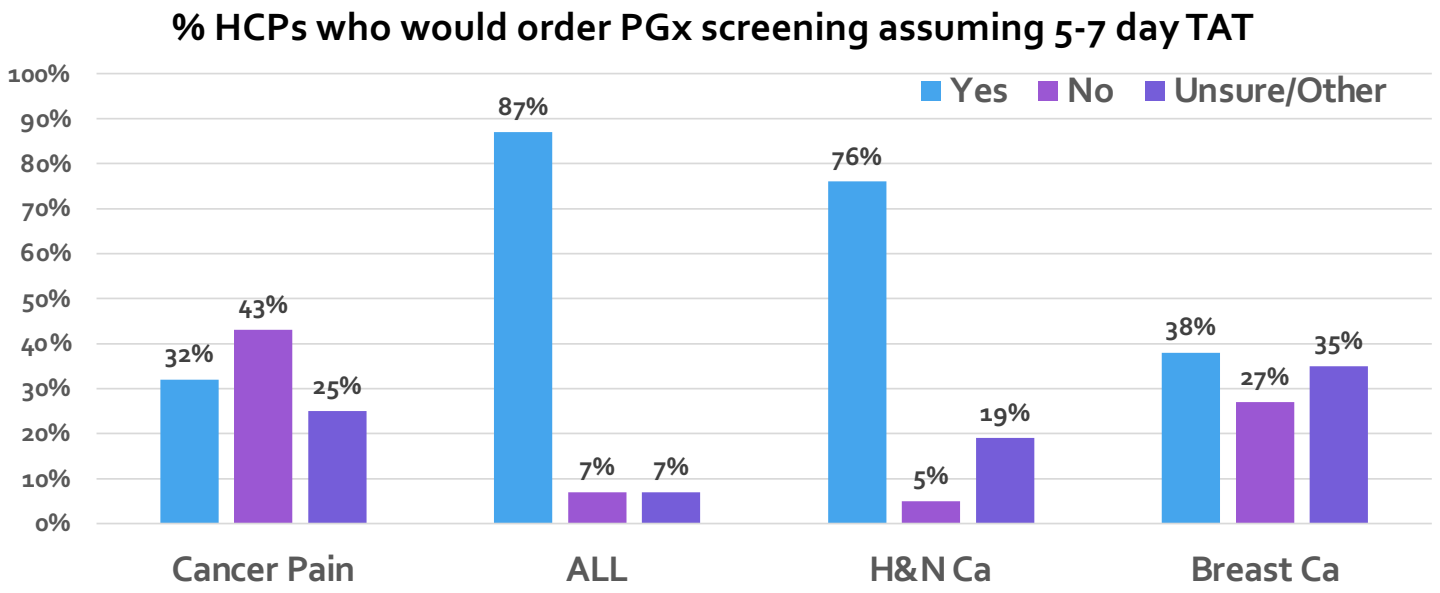
Figure 2: Attitudes and perceptions toward pharmacogenomic testing among healthcare professionals



Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Heterogeneity in…Clinician Uptake

- Lack of perceived utility due to turnaround times (TAT) & clinical titration of response
- The use of PGx was most consistent in thiopurine therapy, but more uncertain in other settings



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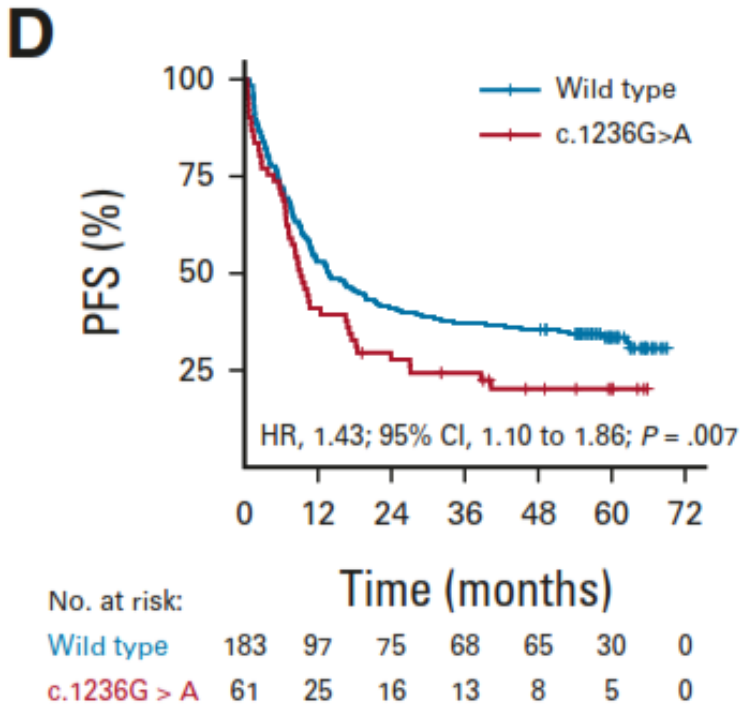
Variable Clinician Uptake: DPYD-guided dosing

- **Initial concerns re: potential underdosing & limited evidence re: antitumour efficacy**



Retrospective, exploratory analysis matching survival outcomes in DPYD IMs/PMs compared to NMs for **capecitabine/5-FU:**

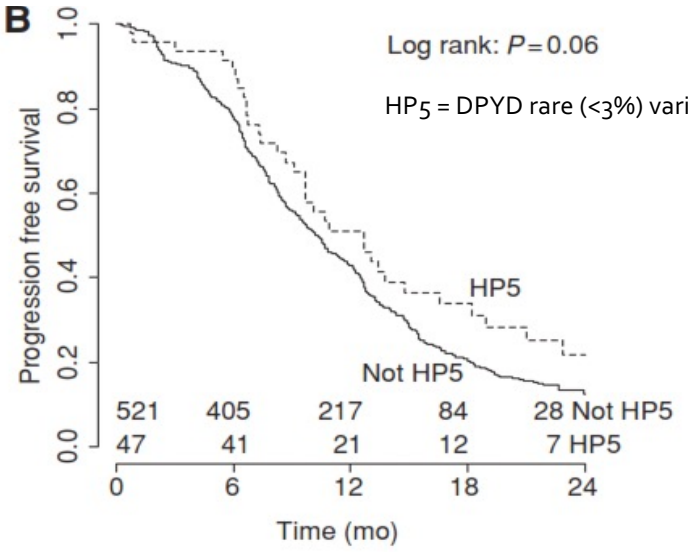
- Subgroup analyses identified lower PFS in c.1236G>A variant carriers [1]
- 75.8% of c.1236 G>A carriers remained on 25% DR throughout whole treatment [1]
- 0.223% of c.1236 G>A variant carriers may not have c.1129-5923 C>G (HapB3) variant [2]

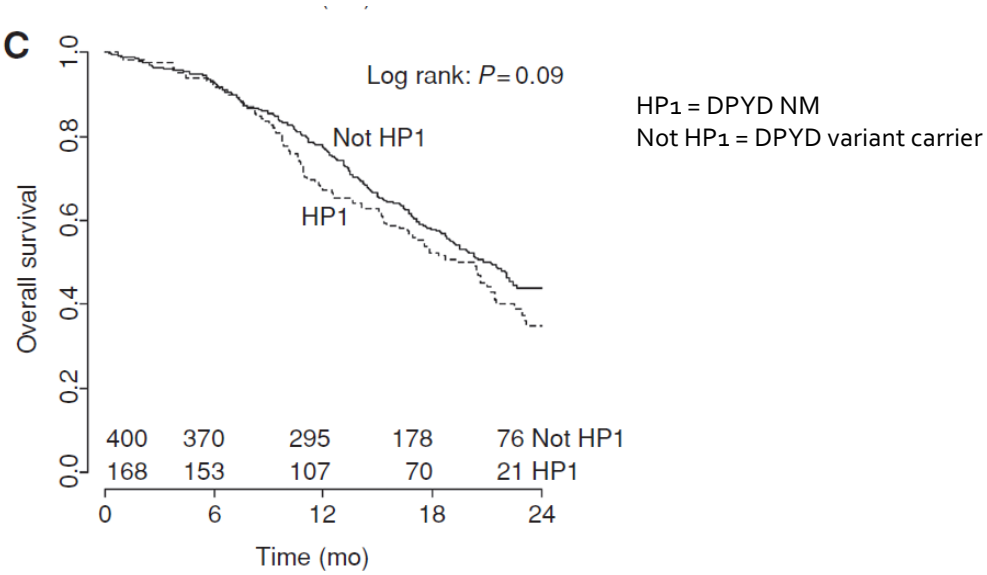
1. Knikman et al. J Clin Oncol 41;5411-5421
2.Turner et al. Clinical Transl Sci. 2024;17:e13699

DPYD-guided dosing: antitumour efficacy

Retrospective analysis comparing survival outcomes between DPYD NM & DPYD variant carriers (who received 25-50% DR) with advanced CRC treated with **capecitabine** (n=568) [1]

- **DPYD-guided dose reductions in variant carriers did not reduce PFS and OS**

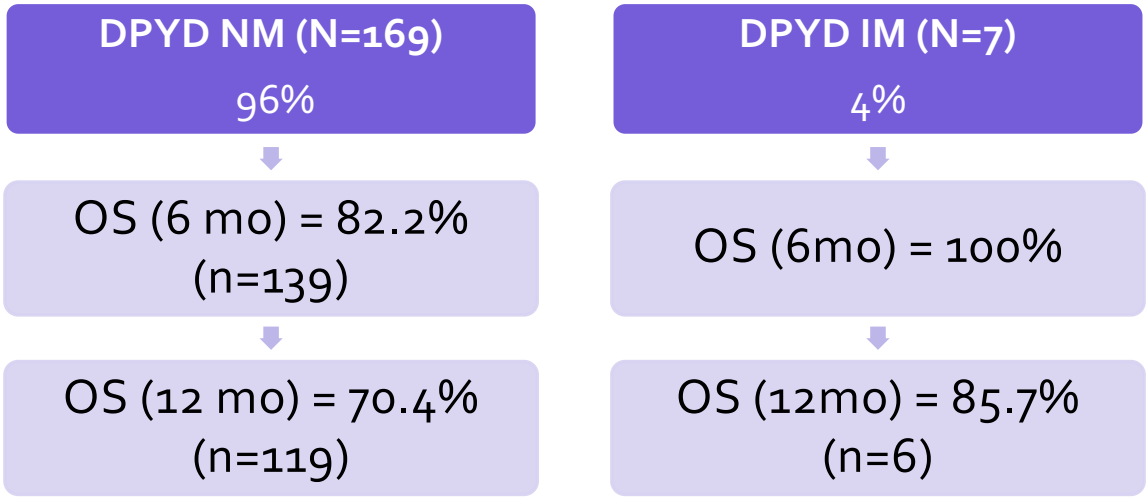




1. Deenan et al. Clin Cancer Res 2011 May 15;17(10):3455-68

PACIFIC-PGx Survival Analysis

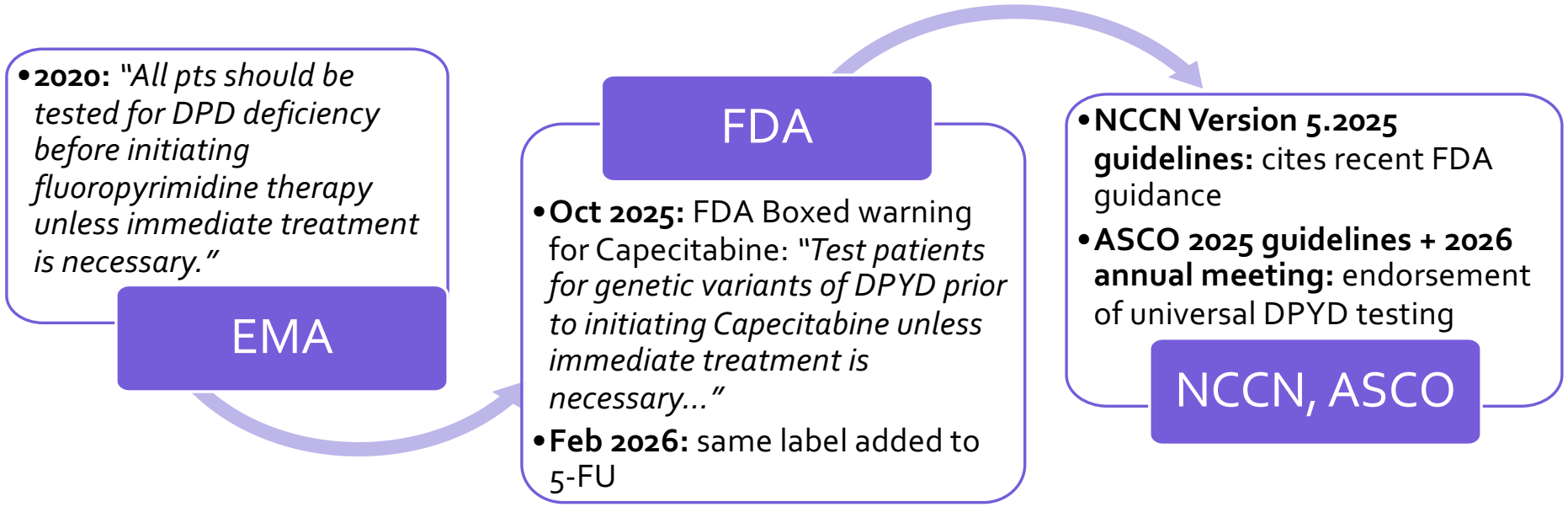
- Pre-specified, exploratory survival analysis comparing DPYD variant carriers vs DPYD wildtype in prospective, PACIFIC-PGx trial (n=176; PMC site only)



- Despite the limited number of *DPYD* IM, **OS rates in this heterogeneous cohort aligned with larger studies, showing no evidence that upfront FP dose reductions compromise efficacy.**

Glewis et al. J Oncol Pharm Pract 2026 May 21:10781552261445956.

Regulatory PGx warnings often precede Guideline Endorsement



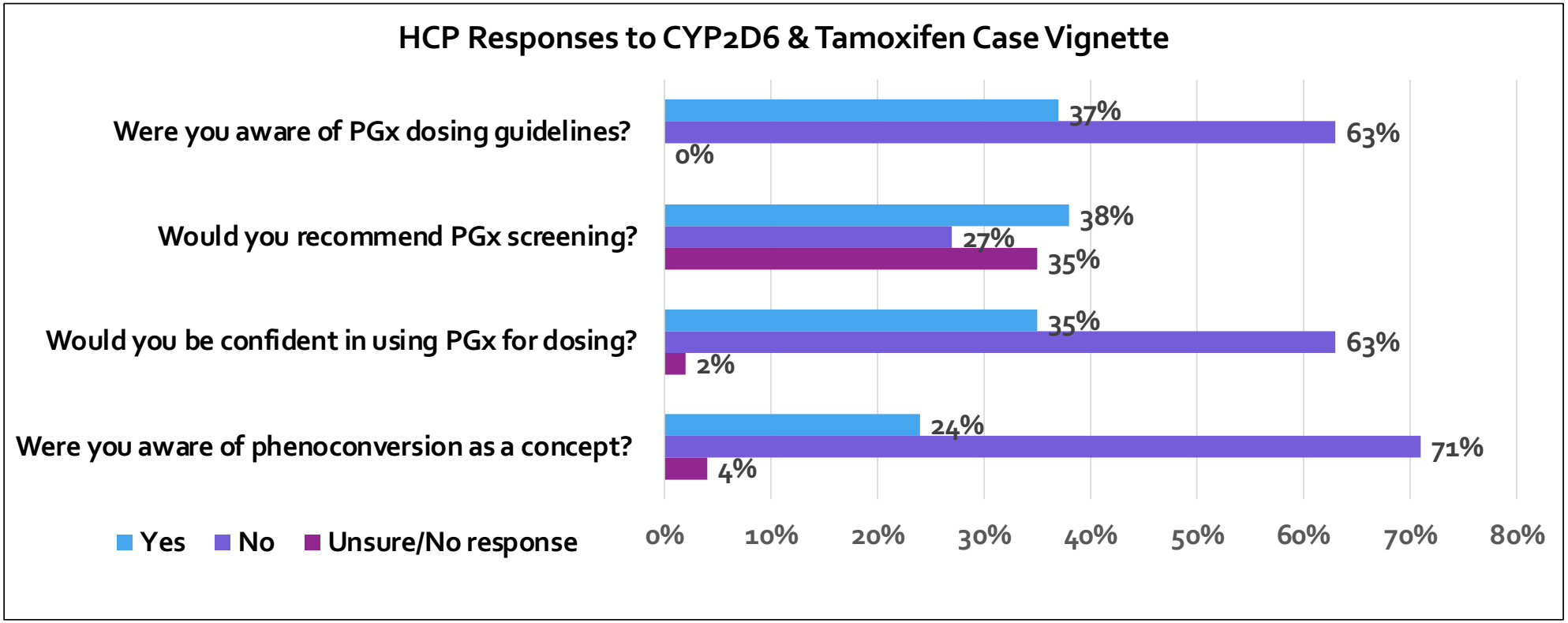
Endorsement by oncology guidelines was more frequently identified as an enabler of successful PGx implementation compared to PGx guidelines (70% vs 30%) [1]

1. Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Gaps…in PGx Knowledge & Expertise amongst HCPs

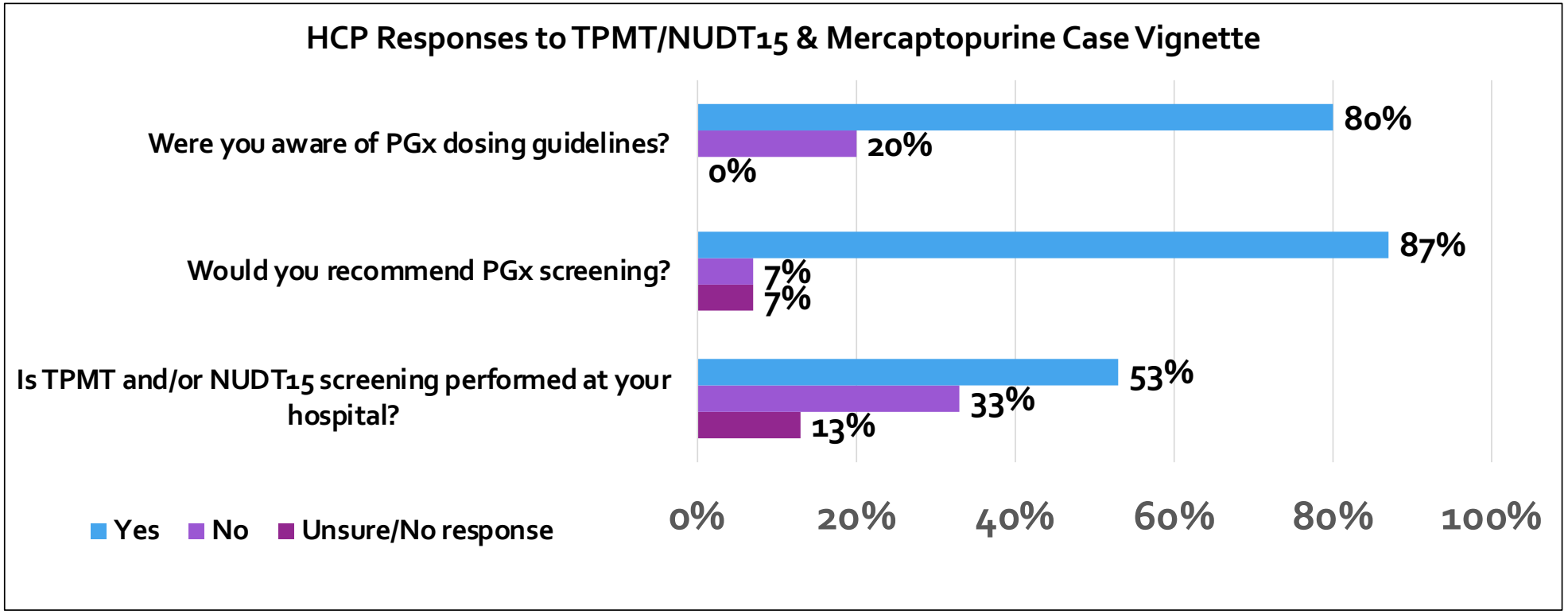
- 81% of HCP respondents reported baseline PGx knowledge as fair-to-exceptional
- **However, only 31% HCPs felt confident applying PGx in clinical practice, with variation across professional disciplines**

Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia



- **29.5% HCPs selected dosing strategies concordant with guideline recommendations.**
- When presented with a duloxetine–tamoxifen drug-drug-gene interaction scenario, **39% were unsure how to respond, and only a minority would seek specialist PGx input**

Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia



- 60% HCPs selected dosing strategies concordant with guideline recommendations.
- Only 13% HCPs reported both *TPMT* and *NUDT15* screening at their hospital

Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Knowledge, Attitudes & Perceptions to PGx (amongst Consumers)

Figure 1: Knowledge & support for PGx testing

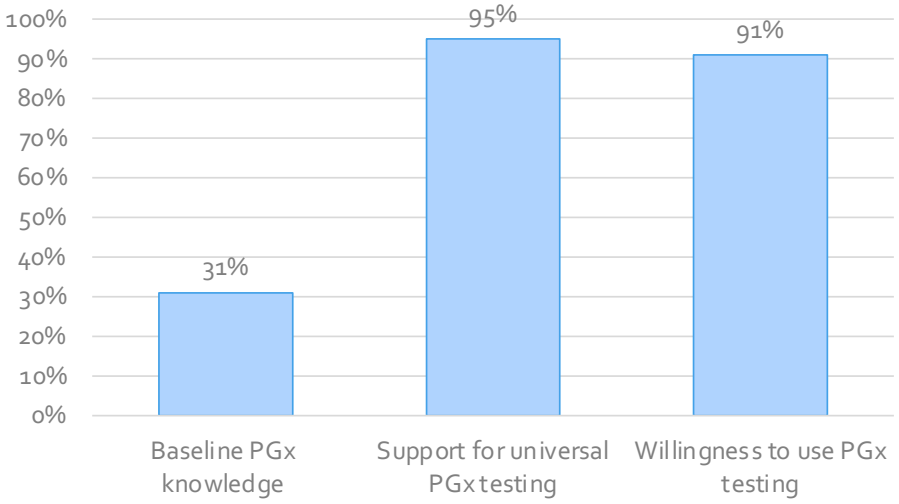
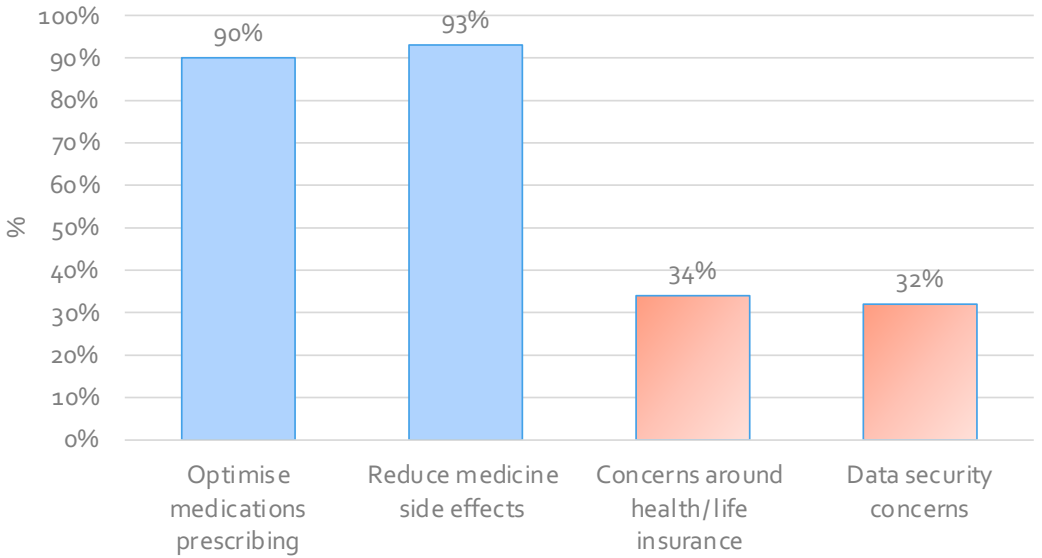


Figure 2: Attitudes and perceptions toward PGx testing



- **Following education, patients were more likely than HCPs to support universal PGx testing (95% vs 73%)**

Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Genetic discrimination: Insurance

- **Predictive gene testing has potential implications for risk-based insurance policies** (e.g. life insurance, total disability, income protection insurance)

> Depending on the condition, your family history may impact your risk assessment.
>
> 3. **You have consented for a genetic/genomic test before securing insurance cover that is higher than the financial limits set out in the Moratorium:**
>
> If you have consented to a genetic test (for example, by signing a genetic test consent form), you will need to tell the insurer about this. In this case, the insurer considers that a genetic test is planned. The insurer can use the planned test to assess your ability to obtain cover, or the cost or terms of the policy. They may delay considering your application until the result has been provided.

> The Moratorium states that life insurance companies will not ask for or use genetic test results as part of an insurance application up to the value of $500,000 (for death and total permanent disability), $200,000 for trauma and $4,000 a month for income protection. If an application for cover is greater than any of these amounts, genetic test results can affect the cover or its cost.
>
> You must tell your insurer about any diagnosed health conditions, regardless of the cost of the policy.

- **Insurers can request/use genetic results to deny cover if total cover amount exceeds certain limits**
- No risk to health insurance cover in Aus **(community-based policy) –** but reports of employee discrimination in USA

NSW Government Health Centre for Genetics Education. Accessed 8/6/26: https://www.genetics.edu.au/SitePages/Life-insurance-products-and-genetic-testing-in-Australia.aspx

From 8 Oct 2026, genetic testing protections will be applied to risk-based insurance policies in AUS

Current Rules: Under a voluntary industry moratorium, Australians can apply for new life insurance policies or increase existing coverage, up to certain financial limits without providing previous genetic test results or undergoing genetic testing. For coverage beyond these limits, life insurers may request relevant genetic information, and they may deny or place conditions on coverage based on the results.

Privacy Assurance: Your healthcare professional will not share your genetic test results with an insurer without your consent.

Upcoming Changes: On 8 October 2026, the *Treasury Laws Amendment (Genetic Testing Protections in Life Insurance and Other Measures) Act 2026* will come into effect. These changes stop life insurers from using genetic testing information to decide: whether to offer a person life insurance, and how much it will cost. Life insurers are still allowed to use other information such as family history, and/or diagnosed diseases. This means Australians can get the genetic tests they need and take part in research without worrying that it could impact their ability to get life insurance.

Australian Government: Genomics Australia. Accessed 8/6/36: https://www.genomicsaustralia.gov.au/individuals/your-private-genomic-data

Incidental Findings: Disease Risk

PGx testing generally does not have clinical implications beyond medication response

- **UGT1A1 *28 variant:** hereditary hyperbilirubinaemia syndromes (e.g. Gilbert's Syndrome, Criger-Niggar syndrome) - ↑ risk of gallstones & hyperbilirubineaemia.
- **G6PD Deficiency:** haemolytic anaemia after exposure to certain meds / dietary triggers (e.g. broad/fava beans)

Medications that can trigger G6PD deficiency	
Dapsone	Primaquine
Rasburicase	Toluidine blue
Methylene blue	Tafenoquine
Nitrofurantoin	Pegloticase

Incidental findings: new PGx variants of significance

Table 3 Tier 2 *DPYD* Variants

Variant (NM_000110.4)	Legacy name	CPIC defined function	Activity value	rsID	*DPYD* RefSeqGene (LRG_722)	GRCh38.p13 chr 1	HGVS protein nomenclature	Reference material available†	Multiethnic allele frequency, %
c.299_302del	*7	No function	0	rs72549309	NG_008807.2: g.185642TCAT[1]	NC_000001.11: g.97740411ATGA[1]	NP_000101.2: p.Phe100fs	Yes	0–0.01
c.703C>T	*8	No function	0	rs1801266	NG_008807.2: g.234284C>T	NC_000001.11: g.97691776G>A	NP_000101.2: p.Arg235Trp	No	0–0.03
c.1314T>G	N/A	Decreased function	0.5	rs186169810	NG_008807.2: g.352275T>G	NC_000001.11: g.97573785A>C	NP_000101.2: p.Phe438Leu	Yes	0–0.05
c.1475C>T	N/A	No function	0	rs72549304	NG_008807.2: g.376451C>T	NC_000001.11: g.97549609G>A	NP_000101.2: p.Ser492Leu	No	0–0.02
c.1774C>T	N/A	No function	0	rs59086055	NG_008807.2: g.475870C>T	NC_000001.11: g.97450190G>A	NP_000101.2: p.Arg592Trp	Yes	0–0.08
c.2639G>T	N/A	No function	0	rs55674432	NG_008807.2: g.827444G>T	NC_000001.11: g.97098616C>A	NP_000101.2: p.Gly880Val	No	0–0.08

- **If new clinical implications arise for a gene a patient has previously tested for, it is treating team's responsibility to contact patient re: new findings**

Pratt et al. J Mol Diagn. 2024 Oct;26(10):851-863.

Data Sharing & Security Concerns

- Australian-based services protect patients' PGx results through privacy laws

> **Key points**
>
> - Provided certain conditions are met, you can use or disclose a patient's genetic information to genetic relatives with or without the patient's consent where you reasonably believe the use or disclosure is necessary to lessen or prevent a serious threat to the life health or safety of a genetic relative of the patient.
> - In a situation where consent has not been given the use or disclosure must also be in accordance with the s 95AA guidelines of the *Privacy Act 1988* (Privacy Act).

- PGx is unlikely to pose a serious threat to a genetic relative's life or health that would require urgent disclosure, **but patients need to be educated about lifetime relevance of PGx report.**
- **Disclosure of PGx results remains at patient's discretion and requires explicit permission.** PGx results can be uploaded onto My Health Record after consent is obtained by patient

Australian Government: Office of the Australian Information Commissioner. Accessed 8/6/26: https://www.oaic.gov.au/privacy/privacy-guidance-for-organisations-and-government-agencies/health-service-providers/guide-to-health-privacy/chapter-8-using-and-disclosing-genetic-information-in-the-case-of-a-serious-threat

HCPs more frequently supported sharing PGx results with GPs & community pharmacists. Consumers preferred PGx discussions primarily with doctors.

Figure 3: Preferences for PGx result sharing across healthcare settings (among HCPs and consumers)

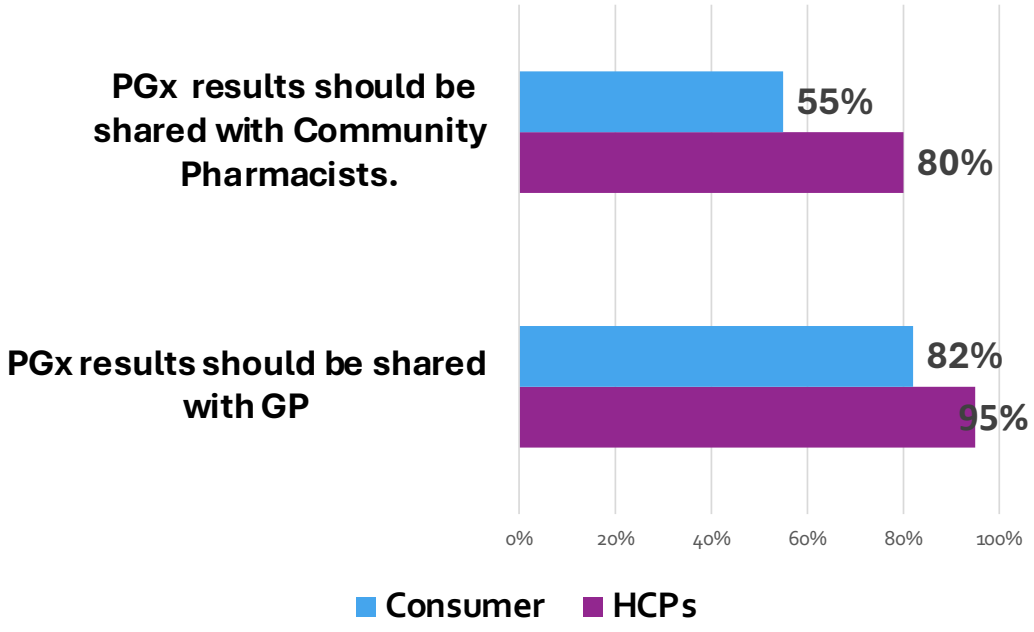
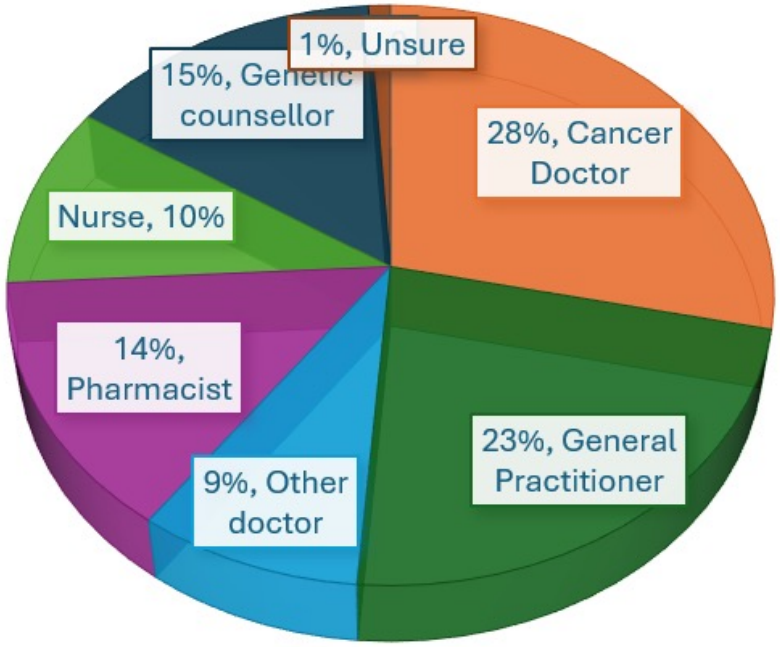


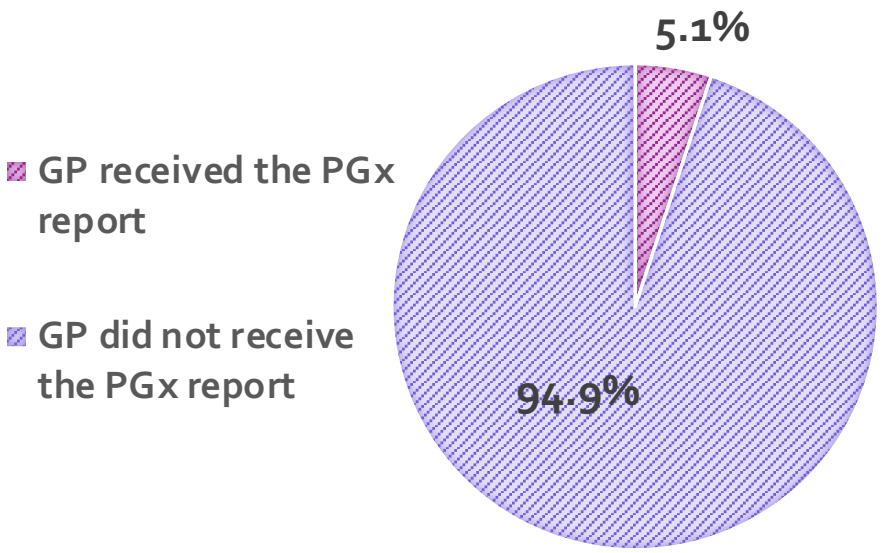
Figure 4: Preferences for communication and discussion of PGx results (among consumers)

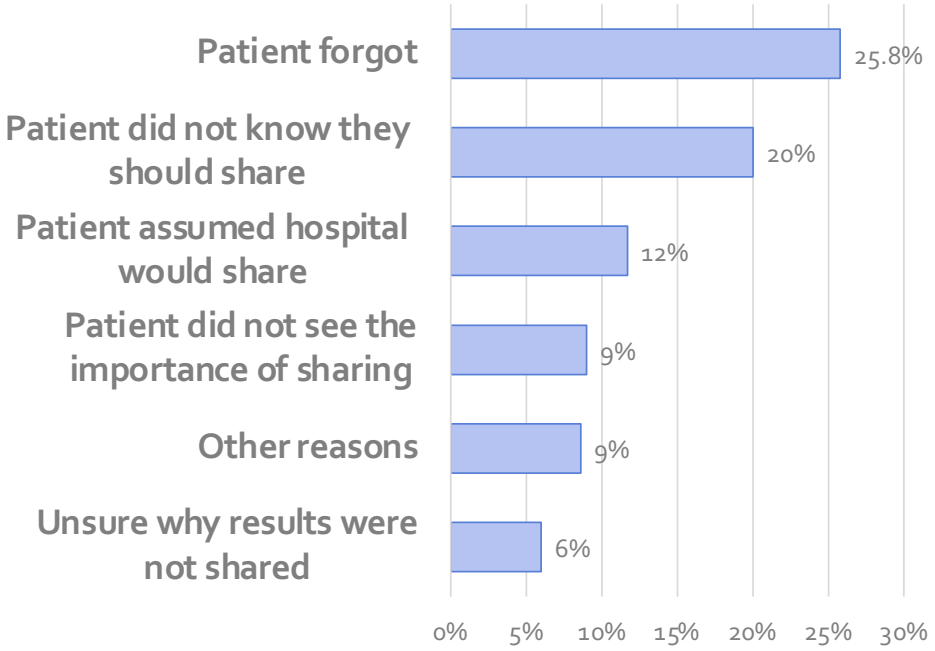


Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Gaps in… Data Sharing Infrastructure

Cross-sectional implementation sub-study included participants enrolled in PRECISION who had received PGx testing (N=279)





Reliance on patient-mediated transfer constrained effective use of PGx results. Lifetime impact can only be achieved if PGx report is widely available.

Shen V, Melhem H, Alexander M et al. (2026). *Pharmacogenomic results without translation: real world evidence of lost clinical utility across care boundaries.* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Gaps in Clinical Decision Support at Point-of-Care Prescribing

Medications with aPGx were frequently prescribed during follow-up (largely without reference to available PGx results) in hospital cancer care.

- Drugs with aPGx were more frequently prescribed in inpatient settings (n=83, 56.8%) compared to outpatient setting (n=63, 43.2%)

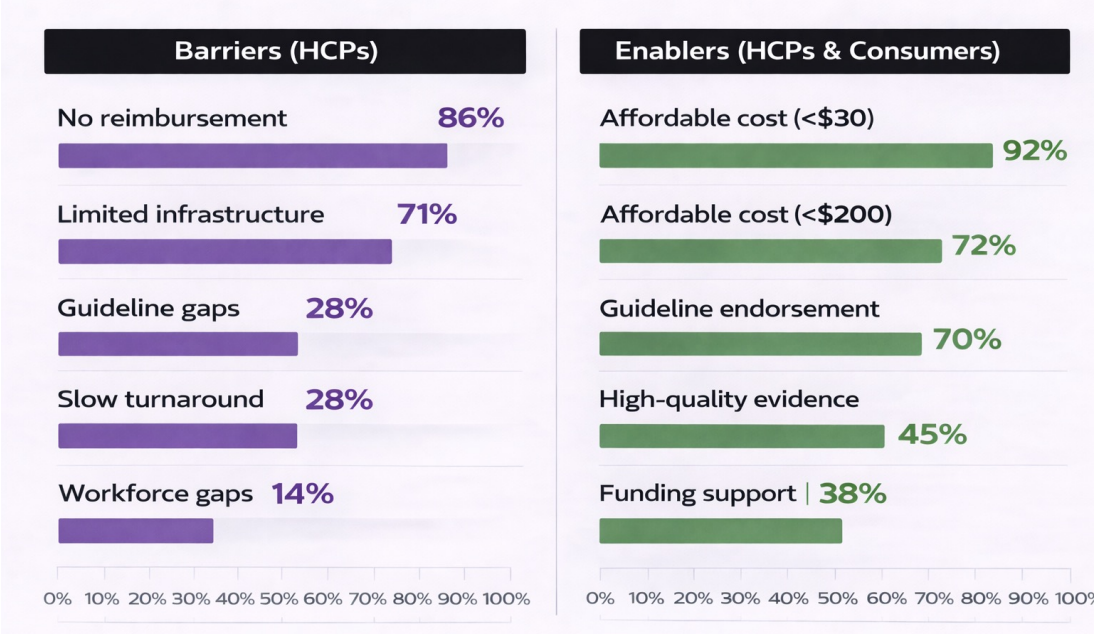
Enzyme	Drugs
DPYD	5-fluorouracil (4)
ABCG2	Allopurinol (2), Rosuvastatin (5)
CYP2C19	Amitriptyline (8), Escitalopram (7), Sertraline (3) Lansoprazole (11), Omeprazole (4), Pantoprazole(28) Clopidogrel (1)
CYP2C9	Celecoxib (7), Ibuprofen (5)
CYP2D6	Codeine (10), Tramadol (6), Haloperidol (6), Paroxetine (1), Ondansetron (7)
SLCO1B1	Atorvastatin (3)
UGT1A1	Irinotecan (4)

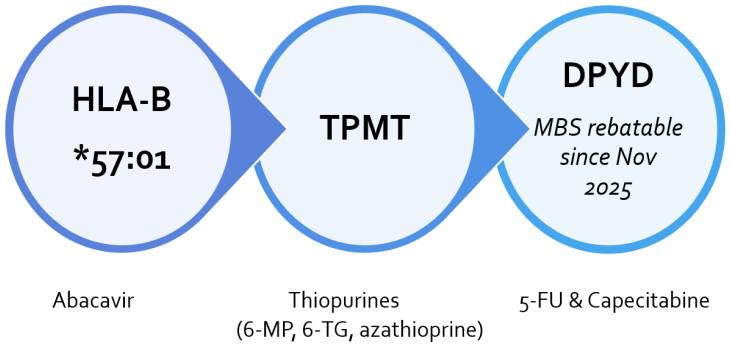
Absence of point-of-care CDS and system triggers in EMR limits practical utility of PGx results even if they are available

Shen V, Melhem H, Alexander M et al. (2026). *Pharmacogenomic results without translation: real world evidence of lost clinical utility across care boundaries.* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Gaps in…Funding Infrastructure

- Lack of reimbursement is a frequently cited barrier amongst HCPs & consumers





MBS-subsidised PGx tests

- Majority of PGx funding still lies with consumers

Darwish M, Glewis S, Hussainy SY et al. (2026). *Implementing pharmacogenomics in oncology: alignment and divergence between healthcare professional and consumer perspectives* [Unpublished manuscript]. Department of Pharmacy, Peter MacCallum Cancer Centre, Victoria, Australia

Pre-emptive DPYD genotyping is cost-effective in Australia

Study Design

- Single-arm, cost-effectiveness & cost-utility analysis comparing pre-emptive DPYD screening **(in PACIFIC-PGx trial)** vs SOC prescribing (published literature) in AUS

Findings: Pre-emptive DPYD screening is likely cost-saving in AUS Healthcare Setting through avoidance of high-grade toxicity & hospitalisations.

- 20% reduction in grade 3+ toxicity
- 5% reduction in hospitalisations

Estimated cost savings = $1499.21 per two chemotherapy treatment cycles

ICER ($AUD)	ICER Metric
$6014.5	per QALY gained
$7815.69	Per Grade 3+ AE avoided
$27,426.29	Per Hospitalisation avoided
Willingness to pay (WTP) = $50,000 AUD	

ICER = Incremental cost-effectiveness ratio;
QALY = quality-adjusted life years

Glewis et al. Clinical Drug Investigation (2025) 45:945–956

Equity in PGx testing

- Arguments for targeted vs universal PGx testing

  Example: Allopurinol & HLA-B*58:01 testing

  - PGx is used to avoid **severe, cutaneous adverse reactions (SCARs)** from allopurinol (e.g. SJS, TENS, DRESS)
  - **+ve carriers of HLA-B*58:01** have ↑ ↑ ↑ risk of SCARs
  - **Risk of SCARs is not completely eliminated with PGx testing**
    - 78% sensitivity & 96% specificity
    - Positive predictive value (PPV) = 1.8% (↑ to 15% in renal impairment)

- Increasingly more evidence suggesting PGx testing is cost-effective, safe, feasible
- Genetically diverse populations in research are needed to build PGx evidence base

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Established

80+
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30+
Disciplines

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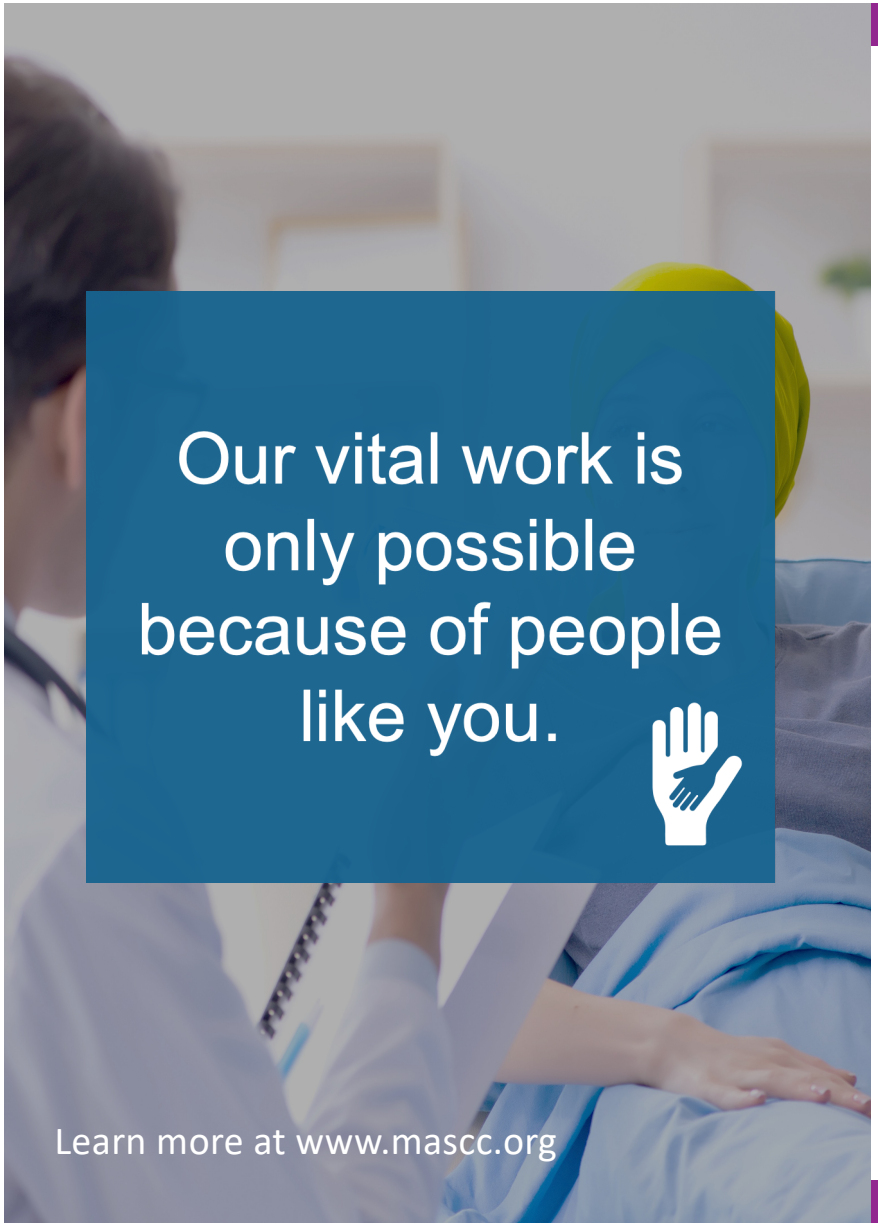
Supportive care aims to improve the quality of rehabilitation, secondary cancer prevention, survivorship, and end-of-life care.

Learn more



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Meeting Themes

Overarching Theme: Coordinated and Individualized Supportive Cancer Care

- **"Mind the Gap" Maximizing Access to Supportive Care for All.** Our theme focuses on research and improved care access for underrepresented communities (including but not limited to, remote/rural, gender and sexually diverse, culturally and linguistically diverse, older age, lower SOE, LMI countries, and First Nations).
- **Lifestyle and Behavioral Support in Cancer Care.** We focus on health services and the role of exercise, diet, integrative medicine, psychotherapy, and health tracking technologies to support care during and after active cancer treatment.
- **Optimizing Toxicity Management of Novel Therapies.** This theme focuses on toxicity screening, monitoring, assessing burden and interventions for novel and emerging therapies In addition, there will be a strong focus on mechanisms and prediction of toxicity.

Meeting Venue

Melbourne Convention Exhibitor Centre (MCEC) | 1 Convention Centre Pl, South Wharf - VICTORIA 3006, Australia

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Discussion Activity

Discussion points

- **Does your workplace have any institutional policies / procedures for PGx testing?**

- **Thinking about your workplace, how would you be able to get your senior leadership to support the implementation of pharmacogenomics?**

Institutional policies

- At Peter Mac, pre-emptive PGx testing is limited to gene-drug interactions in cancer with high strength of evidence / avoidance of toxicity (Fluoropyrimidines, Irinotecan & Thiopurines only)

Policies should consider:

- Patient population
- Testing strategy (e.g. pre-emptive vs reactive; single vs multi gene panel)
- Evidence-based recommendations: level of evidence, prevalence of drug toxicities, availability of guideline recommendations
- Interpretation of results and application to clinical care
- Clear referral pathway - roles of each person in testing/reporting Cost/reimbursement models
- Management of drug toxicities

Supporting PGx implementation

Senior leadership needs to see:

- A clear clinical and operational benefit based on evidence and best practices.
- Expected improvements in patient outcomes (e.g. reductions in adverse drug reactions, preventable hospital admissions and treatment delays)
- Cost effectiveness & analysis of resourcing/timelines/opportunity costs
- Widespread stakeholder support
- Examples of notable organisations that have successfully implemented PGx will help business case

Thank you!

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