

GRIT

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ECIAL ISSUE \* MM2022 SPECIAL ISSUE \* MM202

## THE FUTURE OF CONNECTION

Empowering post-pandemic preferences and practice



Knowledge networks and prescribing "alone, but not in isolation"

by SHPA President Tom Simpson

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Making mentorship magic

Supporting the next generation

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An ethical harvest?

Tackling tension between social media and research

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#### In This Issue

Since MM2019 the world has certainly changed, in how we connect and interact, how we consume information, and how we educate and inspire.

'The future of connection' is the theme of our special MM2022 issue of Pharmacy GRIT, as we look ahead to changes

'The ways we connect: Exploring mentorships, preceptorships, and clinical supervision in hospital pharmacy' by Sarah Zekeria (pg 16) discusses three models for facilitating learning in a clinical environment — mentorship, preceptorship, clinical supervision — aimed at adult learners to help support and guide the next generation of pharmacists.

Isabelle Singh et al. discuss a brave new world of connection, the revolutionary and reviled social media. In 'The use of social media and online forums by Australian pharmacists: How can we use this rich data source for good, in an ethical way?' (pg 24) the authors tackle the challenging tension between social media and ethical research. What knowledge and shared experience are pharmacists creating and accessing in online communities, how valuable is this data, and how should it be accessed?

New SHPA President Tom Simpson shares his vision for the Society (pg 4), based on team-based specialisation and integration that centralises the patient, always. "Through SHPA's leadership, delivering advanced education and fostering knowledge networks, Australia can build, train and inspire pharmacists and technicians ready for our future of complex, interconnected care". "In this way, the advances made to ensure medicines safety and optimal outcomes for patients who have acute care touchpoints, can ripple outward to benefit those who don't."

We also hear the latest from the *Australian Pharmacy Students' Journal (APSJ)* — the first peer-reviewed pharmacy students' journal in the world! — from the National Australian Pharmacy Students' Association (NAPSA) (pg 29); SHPA's advocacy team update members on exploring the growing impact of electronic prescriptions and national digital health resources offered by the Australian Digital Health Agency (pg 34); and three 'Research Toolkits' are shared to help emerging researchers find their feet (pg 39).

#### A NEW ERA FOR PHARMACY GRIT

Maximising connection between members and stakeholders is a central goal of SHPA, and with this in mind work continues on a new online home for *Pharmacy GRIT* that makes finding, browsing, reading, and sharing articles easier and more intuitive.

Changes coming in 2023 include increasing opportunities for earlier career pharmacists and Residents to publish scientific papers in the *Journal of Pharmacy Practice* and Research (*JPPR*), through the creation of a new 'Emerging Insights' category. A suite of resources will also be available to strengthen manuscripts when the article becomes available early in the new year.

At the same time, planning continues toward SHPA's new online home for members, where you will find features, opinion pieces, letters, as well as issues of Medication Safety and DrugScan, while staying in touch with your many nationwide SHPA networks. In the meantime, these formats will continue to be published on the SHPA website and shared via SHPA eNews and key member channels.

The way forward for SHPA journals builds on the strengths of each masthead: JPPR as a leading, contemporary, scientific journal that also encourages budding pharmacist and technician researchers, and *Pharmacy GRIT* as a community-led platform for sharing ideas and inspiration that is by members and for members.

We look forward to keeping you updated as the changes progress. ●



## The boundaries of our profession are shifting



**Tom Simpson, SHPA President** 

Tom Simpson addressed Medicines Management 2022, the 46th SHPA National Conference after his election as President by the Board of Directors. This is an edited version of his speech. We stand at an inflection point in Australian pharmacy, and the boundaries of our profession are shifting.

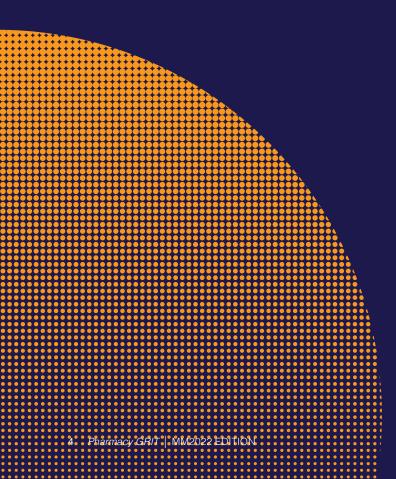
Contemporary healthcare is increasingly complex, specialised, and integrated and I believe pharmacy is defined by these characteristics.

Pharmacist prescribing is a particular flashpoint, it's all over the news, and it's provoking a lot of discussion, but also some disappointing interdisciplinary commentary. Let's also remember that, for the last decade, the new frontier of pharmacist prescribing in Australia has been in the acute care setting.

A key example – Partnered Pharmacist Medication Charting, or PPMC – is a mature, collaborative model now being embedded into practice across five states and territories. It is one of SHPA's primary recommendations to improve medication safety, and is sure to continue to expand and grow.

In stark contrast to some of the Twitter commentary on pharmacist prescribing, PPMC has been met with collegial accord and even acclaim from other disciplines. It is a collaborative approach where both pharmacists and doctors bring their individual expertise to bear on safer, more effective medication management. Everyone in this equation benefits – particularly patients.

SHPA will continue to advocate for the associated changes to state and territory legislation in 2023 and beyond.





#### PRESIDENT'S EDITORIAL

By building broader understanding of complex clinical journeys – and formally recognising the underpinning skills and experience – we can work toward a future in which we are defined more by what we can do, and by the care we can provide, than by where we work.

So, on the very strong foundations of our recent past, where we go over the next few years will be even more important, as we work to embed our leading programs and frameworks into the future of our profession.

The ability to combine SHPA's online CPD offerings with workplace-based Residencies will unlock new models for practitioner development.

And the investments SHPA has made into Specialty Practice will continue to bear fruit as pharmacists are increasingly recognised for their detailed knowledge of medicines in a range of specialist fields of practice.

A third point, equally important, is that we must make sure that as more is asked from us as pharmacists and technicians, we retain our capacity to practice in a manner that is safe for both patient and practitioner.

We know from the last decade that asking our clinicians to do more with the same, or less, resources is simply not sustainable.

It sounds so simple but in the web of competing agendas, in Canberra and across all jurisdictions, we have to remain clear-eyed.

And SHPA will continue fighting this fight.

I want to pay tribute to outgoing President Peter Fowler.

SHPA emerges from this pandemic period, stronger and more assured as a result of your leadership.

You also helped define the character of the SHPA member, who is committed to evidence-based practice on their professional journey, supported by innovative programs and national networks of like-minded practitioners.

I think this defines who we are as an organisation: we are unique in Australia, representing the leading edge of pharmacy through our specialty expertise.

On behalf of a grateful membership I thank you, Peter, and the Board of Directors, for being a strong and steady hand at the wheel during very challenging times as a profession and as a professional family.

Our best days lie ahead of us.

MM2022

MEDICINES MANAGEMENT 2022 CONFERENCE RECAR

# REGINEGIE. HEISENAMENTE

## Finally back together as MM2022 electrifies Brisbane.

After 1,110 long days, Australia's leading community of hospital pharmacists, technicians, peers, and supporters finally gathered to reconnect and rekindle in Brisbane over the first weekend in December.

Australia's largest scientific pharmacy conference was back!



## DAY ONE THURSDAY 1 DECEMBER

We opened with the sounds of Country from **Jahmarley Dawson** (pictured over page, middle right), an emerging Aboriginal leader who lives in Brisbane where he is linked to the Turrbal People through bloodline connection and kinship ties.

To raucous applause, Scientific Program Committee Chair **Anna McClure** (pictured below) declared the conference open, and previewed the massive program — including four plenaries and keynote speakers and 50% more scientific papers — while Co-Chair **Duncan McKenzie** heralded "our long-awaited moment to reconnect and reinvigorate our passion for #pharmacy".

Then SHPA President **Peter Fowler** took to the Brisbane Convention & Exhibition Centre stage: "Not only is this Australia's largest scientific pharmacy conference, it's also the heart and annual highlight of SHPA as an organisation and is central to the character of our professional community".

Peter posed to the plenary: "Who is our member now?"

"With boundaries of health care shifting and technology driving disruption, we can no longer describe our members and ourselves by where we work. What we can do is identify the values, attitudes, and qualities that we have in common".

Hometown hero Professor **Jason Roberts** (pictured over page, middle left, with SHPA President Peter Fowler) rose to accept the **2021 Fred J Boyd Award**. A self-declared "student of history", Jason painted an evocative picture of the early years of the profession and the principles and precedents set by SHPA's Founding President that we carry forward today.

Finally, we were off to Antarctica! Keynote speaker **Tim Jarvis AM** (pictured over page, bottom) presented incredible stories of hardship, perseverance, determination, and destiny, both of individual expeditions and of our shared path on one planet.





With boundaries of health care shifting and technology driving disruption, we can no longer describe our members and ourselves by where we work. What we can do is identify the values, attitudes, and qualities that we have in common.

- SHPA President Peter Fowler (2018-22)











Our frontiers are not what's ahead of us when restricting our view to our current lane, but what's possible when our expertise helps to advance the wider pharmacy freeway.

- SHPA President Tom Simpson



#### DAY TWO FRIDAY 2 DECEMBER

Opening day two, Chief Executive **Kristin Michaels** paid tribute to the "engines" of SHPA: Specialty Practice Leadership Committees and Chairs, state and territory Branches, and the SHPA staff: "Thanks to you, the warmth of our friendships and passion for our profession has not dimmed, and SHPA's connection and energy has remained vibrant".

Plenary Chair Peter Fowler formally announced **Tom Simpson**'s election by the Board as SHPA President, and Tom gave a rousing address mapping out his vision, noting "our frontiers are not what's ahead of us when restricting our view to our current lane, but what's possible when our expertise helps to advance the wider pharmacy freeway".

Then, a very special moment as SHPA Fellows inducted in 2022, 2021, and 2020 (pictured over page) were celebrated together, recognising their achievement, active commitment to SHPA and the profession, and influence as pharmacy leaders.

**Professor Michael Dooley** (pictured, below left) received the **2022 Fred J Boyd Award**, and spoke on the importance of passion, vision, and resilience, and how this combination has made collaborative pharmacists prescribing a reality in hospitals with Partnered Pharmacist Medication Charting (PPMC).

Finally, keynote speaker **Associate Professor Victoria Atkinson** presented a sweeping and inspiring recalibration of who we are, within health care as it stands today: positivity, energy, honesty, trust, and the power of cultural leadership in a changed world.

"How will you lead when you leave this room? How will you think about every interaction? How will you show people the future, the possibilities, while navigating the limitations?" Victoria posed to delegates. "What would your organisation, theatre, practice, department look like if people came to work expecting joy, energy, optimism, and hope?"

On Friday afternoon **Kerry Fitzsimons** (pictured, below centre) formally received the **2021 SHPA Medal of Merit**, recognising her pioneering approach to many quality improvement initiatives in WA Health that have benefited the rest of the country and her essential leadership in the effort to vaccinate Western Australians through state-run COVID-19 vaccination clinics. Kerry thanked the many pharmacists, mentors, colleagues, and friends who have shaped and encouraged her medication safety journey: "Destiny is not determined by the number of times we stumble, but the number of times we get up, dust ourselves off, and keep going."

It was then time for an interactive keynote with a difference: we were all subjects! **Kirk Docker** (pictured, above), creator of 'You Can't Ask That' — the most syndicated TV format in Australian history — brought to the stage the art of the empathetic interview to unlock understanding and level our humanity. Delegates dove into the format and shared the raw side of health care, bringing lots of laughs (and a few tears).

Sally Marotti (pictured, below right) then took to the stage to receive the 2021 Australian Clinical Pharmacy Award, recognising her leadership in pharmacy, research, and education. Sally published the first randomised controlled trial on pharmacists prescribing, sowing seeds for the important discussions we are having today, and presented a compelling worldview of how pharmacists add unique value to patient care.







## DAY THREE SATURDAY 3 DECEMBER

On Saturday afternoon there was a lot of love in the room for **2022 Australian Clinical Pharmacy Award** recipient **Deirdre Criddle**, (pictured upper right with SHPA President Tom Simpson), whose inspiring and emotional oration paid tribute to the many pharmacists who have imparted "enthusiasm, encouragement, wisdom, and grace". "I have had more adventures — and more failures than I care to count. And it's not about to stop any time soon".

Deirdre — recognised for leading research and practice for transitions of care as a pharmacist and pioneering 'lone wolf in the West' complex care coordinator — said we must maintain our awareness. "Awareness of what is so real and essential, so hidden in plain sight all around us, that we have to keep reminding ourselves".

The tales of friendship continued as new SHPA President Tom Simpson awarded the **2022 SHPA Medal of Merit** to fellow Tasmanian, and fellow former music festivalgoer, **Duncan McKenzie** (pictured, right). "A trusted voice", Duncan was recognised for his leadership and innovation in clinical practice and Tasmanian hospital pharmacy governance, as well as critical role in the state's COVID-19 response. He inspired with a love letter to Tasmania and call to enthusiastically ride the road of life. "Your most important mentor, is you. Learn from your decisions, and your failures. Wisdom comes from time spent in the arena".



The MM2022 Scientific Program Committee (L-R): Brenda Shum (WA), Michael Quach (NSW), Anna McClure (SA/NT), Duncan McKenzie (Tas), Rozanna Alameddine (NSW), Richard Bolitho (Qld), Sarah Dinh (Vic) and Ron Cheah (Vic). Bianca Heron (SA/NT), not pictured.





Comedian and nurse **Georgie Carroll** brought the house down with stories from the frontline, before "proud SHPA member" **Emma McBride** MP's closing message thanked hospital pharmacists and technicians for their contribution to Australia's COVID-19 response.

Emma — Assistant Minister for Mental Health and Suicide Prevention and Assistant Minister for Rural and Regional Health — noted the nation-leading innovation in our profession. "Hospital Pharmacists have been prescribing collaboratively with their medical interns, residents, registrars, and consultants for over a decade, informing and recommending prescribing decisions at the bedside with doctors and on ward rounds". "In recent years, this has further expanded with Partnered Pharmacist Medication Charting being rolled out in several jurisdictions, which deliver clear benefits to bed flow and hospital capacity, such as EDs, ICUs and gen med wards".





The "Totally 80s" MM2022 Gala saw the announcement of results after voting in the 2022 SHPA Members' Awards. Amid a riot of colour, several award winners noted they would be immortalised in photos "wearing...this!"

The 2022 SHPA Early Career Pharmacist of the Year is Benita Suckling (Qld), honoured for being a driver of innovation and source of inspiration and mentorship for other early career pharmacists. The 2022 SHPA Technician of the Year is Katie Ambrose (Tas), who was honoured for her tireless contributions as the first technician to work in the newly created role of Statewide Pharmacy Technician Manager and setting up and overseeing the implementation and rollout of the Bedside Medication Management (BMM) Project in Tasmania that will see 30 new FTE of technicians joining the Statewide Hospital Pharmacy team.

The BMM Project (Tas) also took out the 2022 SHPA Hospital Team Innovation of the Year honour, having secured unprecedented funding for ward-based Pharmacy Technicians, to being introduced to all acute public hospitals in the state, with Tara Clayson-Fisher collecting the award.

The **2022 SHPA Resident of the Year** final was won by **Rhiannon Froude** — Resident Pharmacist at Victoria's Royal Melbourne Hospital (pictured, left) — for her research project on 'Hospital pharmacists' understanding of and attitudes towards beta-lactam allergies and de-labelling'.



The conference awards went to:

Best overall oral presentation: Marissa Sakiris,

'Once Slow, Now On The Move: Reshaping Parkinson Disease Medication Management'

Best first-time oral presentation: Kate Grogan,

'Recharging Antimicrobial Stewardship: A multimodal multidisciplinary team model to improve optimal prescribing in rural hospitals'

Best student or intern oral presentation:

**Joanne Wickens**, 'Publishing the Inaugural Australian Pharmacy Students' Journal (APSJ): An International Sensation'

<u>Best overall poster</u>: Cristen Fleming, 'Scaling up for safety: How Virtual Clinical Pharmacy Services helped rural hospitals meet national standards'

Best Friday poster: Belinda Chappell, 'Investigating variance in reporting times of vancomycin concentrations by availability of on-site therapeutic drug monitoring'

<u>Best Saturday poster</u>: Ann Whitaker, 'Intravenous Iron Infusion Resource Toolboxes — Reinvigorating how support is provided for administering clinicians'

**Best Technician poster: Nicola Harper**, 'Preventing high-risk medication incidents in rehabilitation wards — An advanced technician medication safety initiative'

Best student or intern poster: Nadia Zamri, 'Scoping Review of Learning Health Systems and Health Systems Science in Health Professionals' Education'

Best first-time poster: Roya Roohizadegan,

'Investigating postoperative opioid prescribing in a private hospital to improve patient outcomes'

People's choice award for best poster:

**Shelley Phillips**, 'Spoons are for ice-cream, not measuring medicines — suitability of oral dispensers from hospital to home'.

Chair Anna McClure and Co-Chair Duncan McKenzie put it best when they formally closed #MM2022SHPA, describing the experience as a triumph full of "meaningful, relevant, and contemporary pearls of wisdom we will carry with us", as the Scientific Organising Committee were applauded on stage.

"To be in person with friends and peers has been a truly beautiful thing".

Onward to new frontiers... and see you at **#MM2023SHPA!** 















Sarah Zekaria BPharm (Hons), GradCertPharmPrac zekaria.sarah@gmail.com | Clinical Pharmacist1, Subject Matter Expert<sup>2</sup>, Teaching Associate<sup>3</sup>

- 1. Monash Health, Melbourne, Australia
- 2. Australian Pharmacy Council
- 3. University of Tasmania

It has become paramount for healthcare professionals in clinical practice to develop their skill sets in facilitating appropriate learning environments and to use different teaching and learning models to support learners.

Adult learners — through the theory of andragogy have been recognised as having different learning needs in comparison to children and therefore require contemporary teaching and learning models.1 Adult learning and andragogy consider the influence of an adult learner's previous experiences alongside their internal motivations, independence, and self-driven learning capacity. It is becoming increasingly evident that there is a need to shift from conventional didactic teaching approaches to facilitating an environment where students are the drivers for autonomous learning.<sup>1,2</sup> We will reflect on three different support models for facilitating learning in a clinical environment: mentorship, preceptorship, and clinical supervision. My own personal experiences with mentorship through a university-endorsed program with an undergraduate pharmacy student will also be explored

Reflecting on my journey as a mentor, I confidently believe that my mentee has made me a better person and a better pharmacist. They reinvigorated my passion for pharmacy, for learning from others, and for both quality and effective teaching. There is immense satisfaction from being part of an aspiring pharmacist's professional and personal journey and supporting them as a mentor.



#### **MENTORSHIP**

Mentorship as a model for facilitating learning in healthcare is not a new concept, and can be defined as "a dyadic relationship between a more experienced or senior person (mentor) and a less experienced or junior person (mentee)".3 Increasingly, universities and professional organisations have established formal mentoring programs, such as Monash University's Alumni to Student Mentoring<sup>4</sup> program (based in Melbourne, Victoria). Mentoring can occur in a myriad of settings, and the feasibility for implementation in an environment may depend on the type of mentoring deployed: classical mentoring (standard notion of mentoring with no specific environment or specificities to the relationship); institutional mentoring (within a business or organisation for the purpose of career enhancement); or formal mentoring (has an element of training and/or formal specifications which differs from classical mentoring).5

#### Benefits for all

A study which explored the value of mentoring programs amongst medical interns identified that learners with a mentor felt more prepared to navigate the intricacies of the healthcare system and experienced a "sense of community".<sup>6</sup> At a facilitator level, a study involving medical school faculty members highlighted the benefits of formal mentor relationships to include "enhanced employee engagement and satisfaction with their department and institution".<sup>7</sup> Benefits for mentors have been noted to include an elevated sense of "giving back" to the profession by influencing future clinicians (i.e. students), enhanced opportunities for developing critical skills such as leadership, and the enhancement of one's professional practice portfolio for career opportunities.<sup>6,7</sup>

The organisation also benefits when mentees and mentors have mutually fulfilling relationships, with these individuals positioned to promote healthier and more supportive work cultures.

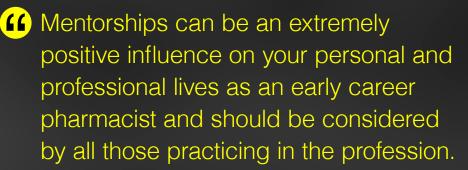
This leads to enhanced employee satisfaction, reducing staff turnover rates, and improved training for early career clinicians.<sup>7</sup> Reflecting on my journey as a mentor, I confidently believe that my mentee has made me a better person and a better pharmacist.

They reinvigorated my passion for pharmacy, for learning from others, and for both quality and effective teaching. There is immense satisfaction from being part of an aspiring pharmacist's professional and personal journey and supporting them as a mentor.

#### **Communication and Managing Expectations**

A range of perceived obstacles preventing some from participating in mentoring relationships are often easily overcome. One such limitation may be time constraints for either party involved, as mentors and mentees often have their own workloads to consider. From my experience, overcoming this barrier can easily be achieved and requires participation from both mentor and mentee. Facilitating initial and ongoing open discussions with my mentee about our expectations and what we had both agreed to tremendously improved our mentoring relationship, making it easier for us to incorporate mentoring into our busy schedules. Another concern with mentoring may be the lack of understanding of what each member's role is in the mentorship with the potential for expectations not being met. By clearly defining the expectations and roles of the relationship at the beginning, such as during an initial first meeting as I have done, both mentor and mentee will be on a pathway to achieving a fulfilling mentoring experience.8 Personally speaking, this is achievable with discussions and written terms that are drafted by either the mentor or mentee, or by the professional organisation your mentoring dynamic is affiliated with (which I ultimately chose as a guide for establishing expectations in this role).

It is important to note that as mentors we are supporters, not assessors, and therefore assessments are not part of mentorships. This is a supporter role, being a part of maximising my mentee's full potential to become a fulfilled individual, and equipping them with the tools they needed to drive their ongoing commitment to developing



themselves (both personally and professionally) was an absolute privilege. Mentorships can be an extremely positive influence on your personal and professional lives as an early career pharmacist and should be considered by all those practicing in the profession.

#### A personal account

Through Monash University's Alumni to Student Mentoring program, I was assigned one mentee based on my tertiary education and experience as a clinical pharmacist. This formed the structural basis of our dyadic relationship, comprising a more experienced mentor and an aspiring mentee within the same profession. Reflecting on my experience as a mentor, I have found that one of the most important characteristics of a mentorship is the level of commitment that is required to support the relationship. This is reflected in the literature.9 Supporting the mentoring relationship involved pre-planning for the educational aspects of the relationship, researching how to support the growth of professional opportunities (such as supporting mentees for job applications and interviews), and maintaining a supportive role in aspects of their personal life.

Mentors need to be able to offer their time, energy, and a genuine interest in their mentee. Maintaining knowledge and skills in clinical pharmacy is a must, as well as being able to coach, counsel when needed, facilitate networking opportunities, and give feedback. Feedback from my mentee regarding our mentoring relationship, reiterated a similar perspective. In a meeting where we reviewed their draft resumes and cover letters, they valued that I had reviewed these documents before our meeting and so, in the meeting, was able to offer advice and suggestions. Having a friendly and approachable disposition can make a drastic difference to any potential stress the mentee may experience with a new mentorship. They may be more likely to discuss matters of concern with you and be more willing to participate in the mentor relationship. To

Meetings were quite fun with my mentee when organised in a variety of settings including face-to-face or video conferencing (my favourite meeting occurring while sipping on boba tea!) where we were able to discuss a wide variety of topics. Some meetings, depending on their nature, may suit certain formats. My mentee voiced that while it was unavoidable to have organised our meeting focusing on interview skills virtually (due to COVID-19 restrictions), a face-to-face format would have been preferable for this.

While both mentee and mentor benefit from the developing relationship, the overall aim is to support the development of the mentee. Mentors can utilise their current skill sets and knowledge to help their mentees fulfil goals and objectives in various focus areas, from career planning and establishing networks, to developing leadership and personal skills. We can be pioneers of education by integrating learning experiences for mentees as part of the mentorship. As an example, I organised with my mentee to shadow a colleague (subacute hospital pharmacist) for a day in a niche geriatric clinical setting. They were able to acquire new knowledge, counsel patients with supervision, and attend multidisciplinary ward governance meetings. My mentee's insight was that they really enjoyed the organised industry experience day and felt that it was a good introduction into geriatric medicine as a specialty area where they had not previously had a clinical placement.

#### **Specialty Practice and the possibilities for mentoring**

If considering other possible avenues for where mentoring can occur, the potential of SHPA's Specialty Practice and mentoring are both exciting and twofold. Specialty Practice, for unfamiliar readers, is one of the key benefits of an SHPA membership and incorporates a network that brings together pharmacists, students, and technicians with interest in a particular specialty. Here, it is possible for students or early-career pharmacists to potentially seek out mentors within their specialty field of interest and facilitate discussions with other like-minded individuals. Moreover, members more established within their specialty practice may be encouraged to take on mentoring roles by networking with pharmacists who have experience in this domain. In comparison to mentoring, the next contemporary learning and teaching model to be explored is the concept of preceptorship.

#### FEATURE `



#### **PRECEPTORSHIP**

Looking now at preceptorship, preceptors — distinct from mentors — within clinical settings play an invaluable role in supporting learners and facilitating optimal learning environments. One definition of preceptorship by Chickerella and Lutz recognises the model as an "individualized teaching/learning method" that involves a learner being "assigned to a particular preceptor (...) so he or she can experience day-to-day practice with a role model and resource person immediately available within the clinical setting". 11 Contrasting to mentorship, preceptors are more clinically involved and serve as important role models for their profession and clinical practice. 12 Preceptorships are often appointed by the organisation within the clinical setting, are shorter-term commitments compared to mentorships, and are intended to clinically develop the learner within their respective field.<sup>5</sup> An example may include pharmacy university students being appointed senior pharmacists as preceptors within a hospital placement allocation, for a specific number of weeks or months.

There are many benefits to preceptor-based supportive models for learning. For the learner, the relationship fosters an ideal environment for applying theory into practice in an everyday "real-life" setting where learners can work toward attaining competence in key clinical activities. Learners in preceptor relationships are able to benefit from practical experience with their preceptor in facilitating patient-centred care and developing communication skills, apply theoretical knowledge into practice, be involved in multidisciplinary practices, and utilise resources when required. 12 For the preceptor, benefits include being able to help develop the clinical competencies of a future generation of clinicians which can improve job and professional satisfaction, and it presents a platform where preceptors may be able to learn from students.

Possible limitations for preceptor-based models include the degree of experience that chosen preceptors may have in teaching, affecting the learner's experiences.11 Being a facilitator for learning is an art form, and training prospective preceptors (with workshops, seminars, etc) can be valuable in providing preceptors with the tools they require to support adult learning in a clinical setting. Another emerging limitation to providing preceptorbased role modelling and support for learners in any profession has been the impact of COVID-19 on face-toface learning. Being an infectious disease that is easily transmittable, students and learners across the world have been impacted in a myriad of ways. The digitalisation of education and learning has been an adaptation response in many learning environments to reduce potential exposures to this virus. By limiting learners who can work on site and by limiting face-to-face patient interactions and experiences, the development of core skills, such as communication, may be compromised. Therefore, it is important for preceptors to be able to adapt and embrace technology (e.g. virtual communication platforms, remote access to electronic medical records) to provide learners with quality clinical experiences.<sup>13</sup>

#### **Preceptorship and Residency**

The model of preceptorship as a way to support learning in healthcare is a concept being adopted by pharmacists within hospital environments globally.<sup>14</sup> An example relevant to readers of Pharmacy GRIT is the SHPA's Foundational Residency program in Australia, which is designed for early career and new to hospital pharmacists to develop their professional scope of practice. Preceptors assigned to residents in this structured two-year training program are experienced pharmacists within their respective fields.<sup>15</sup> Reflecting on the words of a resident glimpsing into the highlights of SHPA's Residency program (with the support of a preceptor), they have noted the enhanced opportunities for delivering education and research with the program, increased engagement in clinical areas of interest, and interprofessional collaboration.<sup>16</sup> The benefits of the preceptor-resident relationship during the residency program may include opportunities to develop competence in clinical skills, job and professional satisfaction, and progression, which are consistent with the above findings. Advanced Training Residencies — another structured training program supported by SHPA — offers opportunities for advancement in specialty areas and may be of interest to readers with more years of foundational clinical experience.



#### **CLINICAL SUPERVISION**

The third model for facilitating learning considered here is clinical supervision. In contrast to the mentorship and preceptorship models, clinical supervision is an integral part of learning within healthcare settings and is commonly seen amongst health professionals, including pharmacists. Not necessarily part of a structured program, clinical supervision can occur in any clinical setting and provides encouragement and educational and administrative support for less experienced learners.<sup>17</sup> It's an avenue for learners in bridging the gap between theory and practice and can accommodate diverse groups of learners, including students, newly registered clinicians, or those recently commencing employment within a new healthcare setting. Methods of clinical supervision may be conducted in a variety of ways including (but not limited to) one-on-one between supervisor and learner, group supervision, or peer supervision which involves at least two experienced health professionals.<sup>17</sup>

#### Advantage of diverse clinical experiences

A positive aspect of this model is that supervisors tend to be variable, depending on the needs of the organisation. This allows for learners to have diverse opportunities for learning from different role models in clinical practice. Conversely, it may be difficult for learners to sustain relationships or build rapport with supervisors that may

With clinical supervisors in a clinical setting have the advantage of being able to apply their learnings to patient-centred activities, while simultaneously having support measures in place to ensure patient safety is not compromised.

change frequently.5 It could be argued that the role of both clinical supervisors and preceptors may overlap when a preceptor undertakes clinical supervision, especially in the clinical context. While this may be true in some instances, preceptors largely focus on preparing clinicians for "clinical skill acquisition"18 and utilise clinical staff for this. Clinical supervisors focus more of their efforts in "progressing clinical practice through reflection", where learning is largely guided via faculty staff, alongside clinical staff.18

Students who are learning 'on the job' with clinical supervisors in a clinical setting have the advantage of being able to apply their learnings

to patient-centred activities, while simultaneously having support measures in place to ensure patient safety is not compromised . Learners have both the opportunity to work within teams and develop a sense of responsibility

which assist in developing their critical skills for future practice. Penefits for supervisors who participate in clinical supervision are similar to that of preceptorship: impacting the clinical competence of learners, increased job satisfaction, and supports a clinician's commitment to lifelong learning. An investigation of clinical supervision amongst midwifery students outlined the benefits of clinical supervision at an organisation level "as a means for safeguarding minimum clinical standards and at best sustains and develops excellence in practice" which also benefits the integrity of a profession as a whole. A strong clinical supervision program established within healthcare environments may "promote recruitment and retention" of clinicians for the benefits these programs provide.

#### The importance of supernumerary

A major limitation for supervisors where clinical supervision models of learning are not necessarily supported by an organisation, may be the difficulties around bearing responsibility of day-to-day clinical services alongside supervising learners, which may prove to be "demanding and frustrating" as both require a large degree of commitment. The importance of prioritising educational services such as clinical supervisors may be recognised by creating a supernumerary role for clinical supervisors, who can be solely dedicated to supervising learners. For instance, clinical nurse educators in practice are devoted to

teaching nurses and nursing students, to improve their practice and improve patient outcomes.<sup>21</sup> Alternatively, for when a supernumerary role is not possible, having time dedicated for elements of the clinical supervision process (e.g. dedicated time for practicing clinical activities with students) may alleviate pressures on clinical supervisors.<sup>20</sup>

#### CONCLUSION

With an increasing demand for contemporary models of facilitating learning in healthcare, clinicians are evolving to incorporate various support models such as mentoring, preceptorships, and clinical supervision to successfully guide adult learners into becoming competent and independent health professionals. These models are being adopted by various professional practice realms in Australia, including clinical pharmacy, and there are various aspects for consideration before implementing these models in the workplace.

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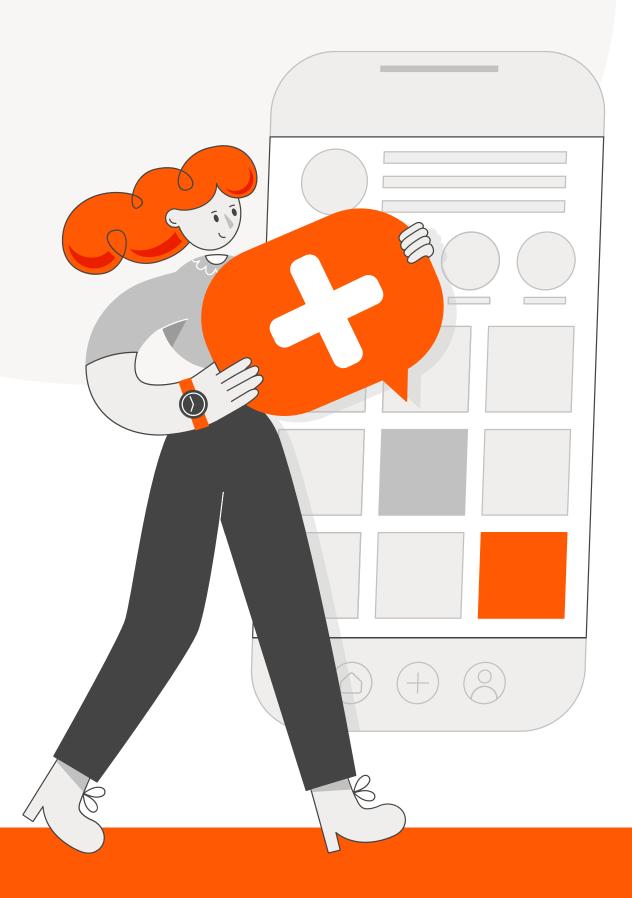
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The use of social media and online forums by Australian pharmacists — how can we use this rich data source for good, in an ethical way?

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- 4. WA Centre for Health & Ageing, School of Allied Health, The University of Western Australia, Perth, Australia
- 5. SA Health, SA Pharmacy, Adelaide, Australia

The rapid growth and availability of health-related information, new drug development, and constant changes in legislation and best practice make it difficult for healthcare professionals to keep up to date with practice-relevant information. Social media platforms such as Linkedln, Twitter, and Facebook, and online forums, are used internationally by a variety of healthcare professions such as medical practitioners, nurses, dentists, and pharmacists for peer support and as educational tools in healthcare.<sup>2</sup>

Current research into pharmacists' use of social media focuses on exploring their perceptions of using social media and characterising how they use it.3 Pharmacists have reportedly used online platforms such as Facebook for patient interactions including health promotion, encouraging appropriate use of medicines, and giving medication reminders to support medicine adherence.4 Social media can also be used for networking, advertising, professional development, education, and patient care. However, current research suggests that pharmacists' use of social media for professional purposes may be limited due to concerns around proper professional use of digital media and the ability to find strategies to separate one's personal and professional presence online.<sup>5</sup> There is a paucity of available evidence assessing the usefulness of social media platforms for pharmacist education; an area of research which has proven valuable among other professions such as general practitioners.

#### **SOCIAL MEDIA FILLING THE GAPS?**

Medical information is readily available online; yet extant literature suggests medical practitioners often identify questions about patient care in their practice for which they are unable to find satisfactory answers.<sup>6</sup> This raises concerns as unanswered question could lead to suboptimal decisions regarding patient care. Further research in this area includes a recent cross-sectional study of general practitioners in Australia and New Zealand, which specifically analysed clinical questions posted to and answers provided on a private Facebook group.<sup>7</sup> The analysis found that questions were commonly asked about a limited number of topics and that the quality of answers provided by fellow social media users varied greatly. Common gaps in the knowledge of practicing general practitioners were identified and further research into the development of educational resources based on these gaps, such as future continuous learning programs and research activities, were proposed.

Similar questions could be raised regarding the use of social media such as Facebook groups or discussion boards by pharmacists. Using our local setting as an example, a cursory search on Facebook for 'pharmacist Australia' suggests there are numerous generalist and specialised pharmacist groups, both public and private: e.g. 'Locum Pharmacists Australia', 'Aussie Pharmacists', 'Consultant Pharmacists Australia', 'Pharmacist Mums — Australia', 'Pharmacist, Pharmacy Owners, Store Manager and pharmacy assistant', 'Retail and Community Pharmacist Forum', and 'Harm Reduction Pharmacists Network'. The characteristics and scope of each group are diverse. Although some groups are open for public discussion; a majority are private groups which require administrative approval following prompts such as 'Are you a registered Australian pharmacist?' and 'Please enter your registration number'. The primary purpose for some pharmacy Facebook groups is information sharing, while others have a greater focus upon social discussions and broader peer support.

Engagement in the groups varies considerably; some smaller groups consist of only 1400 members and average 10 posts per week, while the largest Australian pharmacy Facebook group identified has significantly higher engagement, with 11 200 members. On average, public Facebook data indicates this group averages 12+ new posts per day and around 700 posts each month. It appears pharmacists in Australia use online groups to pose ethical, legal, and clinical questions to receive feedback, answers, advice, and solidarity from colleagues around the country. High levels of online engagement indicates that members will commonly seek advice from such pages and suggests that prompt responses follow. As a result, the contents of such pharmacy Facebook groups represent vast amounts of data, the analysis of which has the potential to identify the gaps in the knowledge of practicing pharmacists today and the common topics for which advice is sought. This information could be used to design education and resources to better support the pharmacy profession at large, to facilitate best practice, and ultimately improve patient care.



#### THE ETHICAL QUESTIONS...

The ethics associated with harvesting social media data for research purposes must first be explored, as traditional guidelines do not fully capture the potential risks and benefits of using data extracted from relatively new online platforms.8 It could be argued that data harnessed from public Facebook groups is 'open access' and can therefore be used freely for research, however, the boundary between using data from a public group versus a private group is not always well defined. The privacy rights of users must also be considered; while users have agreed to a set of terms and conditions outlined by each social media platform, this does not necessarily equate to giving informed consent for their data present on a public or private group to be used in research. Concerns around privacy issues could be minimised by extracting posts and comments without user identifiers, leading to questions of whether it is ethically and morally acceptable to use, or not use, anonymously pooled data for the greater good. Facebook group administrators could consider adding reference to the potential for deidentified posts to be used for research in the terms and conditions of the group, to highlight the opportunity to learn and assist in the advancement of the profession.

This raises the following questions — how do Australian pharmacists who are not part of Facebook groups access this information? Can we better utilise this large pool of data available on Facebook groups to provide equal educational support for all pharmacists, whether they are part of pharmacy-related Facebook groups or not? Who should be responsible for supporting the educational needs of pharmacists in this digital era? These are some of the questions that must be considered as we grapple with how to both ensure pharmacists are adequately supported in practice and ensure research of the profession's needs keeps up with an ever-changing online landscape. •

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#### **Introducing the APSJ:**

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**ABOVE, LEFT TO RIGHT:** 

Forrest Tang BPharm (Hons)

Joanne Wickens 4th year BPharm (Hons) Immediate past APSJ Co-Editor-in-Chief

Elissar Mansour 4th year BPharm (Hons) research@napsa.org.au | APSJ Co-Editorin-Chief, Executive Director of Research at the National Australian Pharmacy Students' Association

Elishka Juricka 3rd year BPharm (Hons)/ MPharm

APSJ Co-Editor-in-Chief, APSJ Chair at the National Australian Pharmacy Students' Association

for critical analysis, and problem-solving

identified research as a key area requiring development in the pharmacy profession.<sup>1–5</sup> By targeting this development at the student level, we can foster essential research skills and create a research culture that will positively impact the future of the pharmacy profession. This is the motivation behind the Australian Pharmacy Students' Journal.

The Australian Pharmacy Students' Journal (APSJ) is the first of its kind, being the only peer-reviewed pharmacy students' journal in the world. The APSJ is an open-access and biannual publication that was first established in January 2022 with SHPA as its strategic partner. The purpose of the Journal is to facilitate the projection of the work that pharmacy students and interns conduct in the research sector.



#### WHAT THE *APSJ* HAS ACHIEVED SO FAR

The APSJ has published two issues since its debut in January 2022; consisting of a total of five editorials, four feature articles, nine original research articles, seven opinion pieces, and one letter. In the two published issues, a total of 20 student reviewers and nine academic reviewers participated. Here, we share some highlights from these issues.



Cover of APSJ Summer (Volume 1, Issue 1) 2022

"Being a reviewer exposed me to a myriad of different pharmacy topics I otherwise would not have learnt about this early on in my career"

- Eva Mavropoulos, APSJ Student Reviewer

#### Summer 2022, Volume 1, Issue 1 Highlights

Available <u>here</u>, the theme for the inaugural issue was the benefits and importance of the development of a pharmacy students' journal and included:

• Student-led Research and Undergraduate
Journals: A Scoping Review<sup>6</sup>

Original research conducted by students Vasilios Sotiropoulos and Matthew Perry in 2018 demonstrated the need for a journal like the *APSJ*. A vision that was brought to life in 2022.

• Shaping the Future of the Pharmacy is Profession is Leadership in Practice<sup>7</sup>

An editorial from Professor Michael Dooley revealed "[t]he [APSJ] has the potential to contribute to the development of future pharmacists by instilling research fundamentals within our student workforce".

The Australian Pharmacy Students' Journal:
 Developing Research Culture among
 Students and Young Pharmacists<sup>8</sup>

Co-authored by Verity Boustead and Simon Bell, this collaborative analysis emphasises the importance of student-led research for education and professional development.

• A Prescription for a Green Future9

Aisling McEvoy's article juxtaposes her personal lowwaste lifestyle with the high-waste output at work and in the pharmacy industry and proposes ways to increase sustainability in the pharmacy profession.

 Opinion pieces: "Describe how COVID-19 has impacted your experience as a pharmacy student"

The *APSJ* hosted an opinion piece competition and received 14 submissions from students around Australia. Three of the most impactful pieces, conveying a unique experience were published.<sup>10–12</sup>





#### Winter 2022, Volume 1, Issue 2 Highlights

The <u>second issue</u> focused on breaching an international audience, offering the opportunity and platform for pharmacy students all over the world to publish research they have conducted.

 Australian Pharmacy Students' Journal: A Momentous Step for Health Professional Student Publishing<sup>13</sup>

An editorial by Uma Sreedhar and Joyce Guo of the New Zealand Medical Students Journal depicts the importance of student-led peer-reviewed journals "for better access to research education and publication opportunities for students".

 Fostering International Research: How Australian Students are Paving the Way for Student-led Research<sup>14</sup>

From the International Pharmaceutical Students
Federation (IPSF), Flynn Swift and Max Groves' feature
article expresses the research opportunities and initiatives
IPSF has for pharmacy students all over the world.

 The Cliff's Edge: A Student Perspective of Women's Leadership in Pharmacy<sup>15</sup>

Written by Jack Papworth, Samantha King, Joanne Wickens, and Georgia Bridges, this article identifies a gap in gender parity across pharmacy leadership roles "despite women comprising the majority of the modern pharmacy workforce".

 Same Same but Different: Australian Schedule 8 Medication Legislation<sup>16</sup>

Original research article led by Juliet Contreras is a convenient tool that compares pharmacy legislation from different states. This article attracted a lot of interest, with over 1000 views in less than one week since publication.

 Opinion Piece: "What service/practice would you implement/improve to further the profession of pharmacy in your country?"

Another opinion piece competition was hosted and was open to pharmacy students all over the world. The competition received great interest internationally and received submissions from four international countries including the Philippines, United Kingdom, Malaysia, and Indonesia.



Cover of APSJ Winter (Volume 1, Issue 2) 2022

"The first time taking up the reviewer role for an academic journal is certainly a new experience for me. I had the chance to expand my pharmacy knowledge and get exposed to different research methods and pharmacy-related topics, all of which appear very helpful for me when it comes to conducting my own project as I might be aware of what is expected for the manuscript"

Dinh Thao Nhu,
 APSJ Student Reviewer



- The *Journal* provides **publishing** opportunities exclusively for pharmacy students and interns. Submissions made to the *APSJ* must have a student as the main author to exhibit student-led research. The *APSJ* accepts submissions from pharmacy students studying in Australia as well as students from around the globe. Creation of this inaugural platform has made the process of publishing an article to be an accessible experience for pharmacy students and interns.
- The APSJ has a large pool of <u>student reviewers</u> that play a critical role in the peer-reviewing process where they analyse a peers' submission from an academic viewpoint. Informed by their education and training by the *Journal*'s editorial team, student reviewers anonymously provide feedback to the authors. Student reviewers then have the opportunity to receive feedback and a copy of the review completed by the academic reviewer for that submission. This process provides the opportunity to learn and develop their reviewing skills and techniques.
- The APSJ is a journal created by students for students, and is completely student-run. The two <u>student Co-</u> <u>Editors-in-Chief</u> of the APSJ show great leadership by playing a role in managing and guiding the direction of the *Journal* to offer pharmacy students opportunities in the research facet of pharmacy.
- In the upcoming 2022–2023 term, new leadership roles have been established to help support the publishing of the already rapidly growing APSJ.
   Notably, a sub-committee has been formed to assist with the day-to-day running of the Journal. The new sub-committee consists of multiple copyeditors, an associate editor, and a publications officer.

"As a student reviewer, I developed my interpersonal communication, research evaluation skills, and application skills. I learned to communicate feedback effectively, identify improvements to the methodology and writing of submissions, and applied my knowledge from my university degree to contribute to science"

- Anonymous, APSJ Student Reviewer



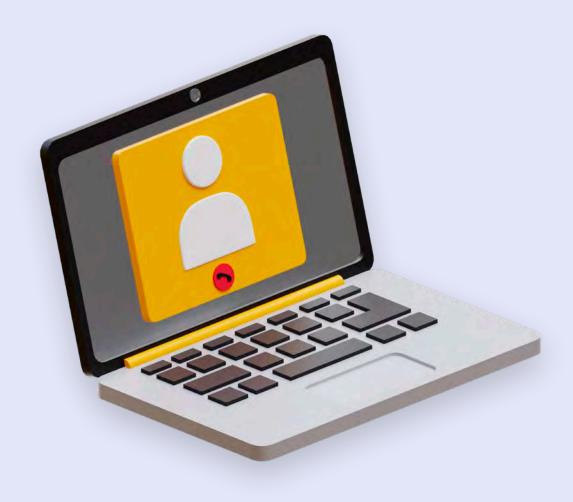
"Since I began reviewing APSJ pieces in my third year of pharmacy, I've been able to acquire invaluable knowledge and skills that I've been able to apply to my own research projects. Being part of the APSJ student reviewing team has facilitated opportunities for me to network with industry research professionals and other pharmacy students from all over Australia. I also think it's really cool to say that I've been part of the peer reviewing process for the world's first pharmacy student journal!"

- Ellie Hawkins, APSJ Student Reviewer

#### WHAT'S NEXT FOR THE APSJ

We are excited to announce that the next *APSJ* issue will be themed as "Rural and Indigenous Health". The *APSJ* can be accessed online at https://apsj.com.au or through our socials — we are on LinkedIn, Instagram, Facebook — and soon Twitter. Please sign up to the *APSJ* website to become involved and receive notifications when new issues are published.

The APSJ is a platform to project student voices to the pharmacy profession. The voices, perspectives, and experiences that students share will help to guide the future of the pharmacy profession. The APSJ aims to create impact in this space by developing a strong research culture amongst pharmacy students and interns.



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1. The Society of Hospital Pharmacists of Australia

Today, Australians have access to telehealth services, electronic prescriptions, My Health Record, and more — many of these rapidly expanded into wider use since the COVID-19 pandemic hit. In this feature, we look back at a few of the digital advances in healthcare delivered in response to the National Digital Health Strategy Framework for Action, starting with one of the catalysts for digital healthcare advancements: electronic prescriptions.

# ARE ELECTRONICPRESCRIPTIONS TAKING OVER?

As an alternative option to paper prescriptions, electronic prescriptions are required to meet relevant Commonwealth, state, and territory legislation. Although electronic prescriptions are not mandatory, more than 72 million electronic prescriptions have been issued since May 2020, by more than 45 000 prescribers — general practitioners (GPs) and nurse practitioners — with 98% of community pharmacies around Australia dispensing them. Most importantly, patients and prescribers are able to choose between a paper and an electronic prescription.

Patients can choose to manage their electronic prescriptions via two methods:

#### 1. Token

- Useful for one-off prescriptions and contains a unique QR Code
- Patients may elect to manage on their mobile devices, which will display the token in a manner suitable for scanning using existing pharmacy equipment
- Can be easily shared with family member/carers who can collect medicines on behalf of the patient
- This <u>video</u><sup>7</sup> explains Electronic Prescription tokens further.

#### 2. Active Script List (ASL)

- As a token management system, an ASL is a list of all active prescriptions and repeats available to be dispensed
- Useful for patients taking multiple medications
- Dispensers can access an electronic prescription for a patient from an ASL following proof of identity
- An ASL removes the need for the patient to retain their tokens
- ASL also overcomes the issue of lost tokens and assists medicine management and adherence
- This <u>video</u><sup>8</sup> explains further Managing Multiple Electronic Prescriptions using Active Script List.

#### What does this mean for patients?

Electronic prescriptions provide greater choice for patients, maintain patient privacy and the integrity of personal information, and support digital health services such as telehealth services.

Removing the need to handle and store a paper prescription increases efficiency in prescribing and dispensing medications as well as providing an alternative, more convenient way for patients to access their prescriptions

#### SHARING IS CARING

Previously, there was no way for pharmacists to share and upload their carefully compiled and updated medication lists to My Health Record following hospital discharge or a medication review. This poses a major risk to ensuring the safe transition of care for patients. Traditional alternatives include faxes, mail, or relying on the patient to self-present to their GP with their updated medication list after discharge from hospital. Now a Pharmacist Shared Medicines List (PSML) can be uploaded to a patient's My Health Record in some healthcare settings making medicines information more readily available to other healthcare providers.

The PSML represents a current, consolidated list of medicines that can be used to assist in the medication reconciliation process in a hospital or primary care setting.

The PSML includes both prescription and nonprescription medicines, including 'over-the-counter' Electronic prescriptions provide greater choice for patients, maintain patient privacy and the integrity of personal information, and support digital health services such as telehealth services.

(OTC) medicines and complementary medicines. It provides a more detailed source of medicines information at a point in time, in addition to existing prescribed and dispensed medicine data in My Health Record. The benefits of PSML include:

- potentially fewer hospitalisations due to better communication between healthcare providers
- improved information sharing between health professionals
- reduced time to complete Medication Reconciliation thus increasing time available for patient education
- more efficient transitions of care with less clinical risks
- improved consumers knowledge of their own medicines
- building consumer trust and confidence in the system and healthcare providers.

In 2020, SHPA produced the report *My Health Record in Hospital Pharmacy Settings: Adoption, Barriers and Challenges*<sup>2</sup> which demonstrated that the majority of hospital pharmacists saw My Health Record as a tool to improve the delivery of safe and high-quality healthcare and reported using it multiple times a day. However, for a significant number of respondents, barriers to greater use were related to a lack of integration with other clinical software.

#### CAN YOU SAY 'INTER-OPER-ABILITY'

Of course, with all the recent digital health advancements comes a few stumbling blocks. Feedback into the next digital health strategy shows 69% of healthcare providers believe a lack of integration with existing processes is a barrier and 52% think that cost or funding models are a barrier to adoption.<sup>3</sup>

Facing other pressures and priorities, many hospitals are implementing Electronic Medical Record (EMR) systems in a fragmented way, without integrating clinical decision-making software, pathology and laboratory data systems, medication administration charts, prescribing and dispensing systems, or covering all areas of the hospital that provide medicines.

This prevents the effective implementation of best practice closed loop medication management and requires transcription and parallel systems of both paper and EMR systems. Ultimately, limiting the benefits of an integrated system that is intended to improve efficiency and reduce prescribing and dispensing errors.

EMRs, which have been implemented in many public hospitals operated by state governments, sit alongside the implementation of My Health Record at a federal level without strong recognition of one another. These dual systems still have varying levels of interoperability which require significant investment from hospitals to connect their EMRs to a patient's My Health Record.

If you speak to many hospital-based doctors and pharmacists who utilise an EMR daily, they will tell you they already have implemented 'electronic prescriptions' in hospitals, where the prescribing of medicines for outpatients, inpatients, and discharging patients is already done electronically on the EMR. These functions also allow utilising the electronic medication charts to undertake medication reconciliation at discharge, produce a medicines list, order medications from pharmacy to supply, and record the administration of medicines to patients.

However, for the purposes of accessing
Pharmaceutical Benefits Scheme (PBS) subsidy
from medicines prescribed in hospitals, hospitals
using EMRs still have to produce a paper-based
prescription. While 'electronic prescriptions'
have been enabled within the hospital's digital
ecosystem, 'electronic prescriptions' in the
form of a token are yet to be implemented
for patients leaving a hospital setting.

Patients can access electronic prescriptions in 98% of community pharmacies.¹ However, implementation in hospital pharmacies with their dispensing software remains in progress and needs to comply with Electronic Prescribing - Conformance Profile v3.0,⁴ which sets

requirements for vendors to develop dispensing software and functionality to a level that ensures the ecosystem is secure. Several electronic prescribing trials and pilots have taken place in hospitals and are now transitioning to broad scale implementation, utilising this digital innovation to support efficient and timelier access to medicines prescribed in hospital outpatient telehealth consultations.<sup>5</sup>

#### A DIGITAL FORECAST

Pharmacy Forecast Australia 2022<sup>6</sup> explores technology as one of its key themes. The majority of pharmacy leaders in the forecast panel believe that by the year 2027:

- 100% of hospital patient records will be seamlessly linked electronically within hospital and health networks of an entire state of territory.
- At least 50% of hospitals will be able to upload their codified medication data into the My Health Record.

This is unlikely to occur without engagement from key stakeholders such as hospital pharmacists. SHPA's *My Health Record in Hospital Pharmacy Settings: Adoption, Barriers and Challenges Report* highlighted that training was a key factor to enhance engagement with My Health Record for hospital pharmacists, with those who have undertaken more training reporting fewer negative concerns.<sup>2</sup>

The Australian Digital Health Agency (ADHA) provides education free of charge for healthcare providers to raise awareness, adoption, and utilisation of national digital health tools such as My Health Record and electronic prescriptions.

A range of educational modules can be accessed through the eLearning portal at: training.digitalhealth.gov.au

Events and webinars are also promoted via the Agency's website: <u>www.digitalhealth.</u> gov.au/newsroom/events-and-webinars

Please also contact the Workforce and Education team at the ADHA for dedicated online training opportunities for your staff by emailing education@digitalhealth.gov.au

While synergy between jurisdictional and federal strategy can be elusive across healthcare, digital health is one area in which we must work together to get it right.

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# Better measurement for better results: A practical guide to strengthening your survey-based research

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Surveys are commonly used in many areas of health research. Accurate, reproducible survey results lead to new discoveries and expand our knowledge in the health sciences. Applying better practices to our research can get us well on the way to achieving such a feat.

One of many factors to consider during the design of a survey is the inclusion of rigorous and trustworthy measures. We have created this guide to give you the know-how to do this. First, we provide you with information about survey research and how measures within a survey can provide a foundation for rigorous results. Then, we delve into the details of collecting evidence to support the rigour of these measures. Armed with this information you will be well on your way to reporting accurate and reproducible results.

# FIRST THINGS FIRST; WORK SMARTER, NOT HARDER

Surveys are commonly used to collect information from respondents about their behaviours, beliefs, attitudes, or intentions. Asking respondents to provide details about themselves is often the only way to measure specific outcomes. This is particularly the case where there are limitations in obtaining accurate, observable, or biological markers such as mental health and wellbeing, perceived psychosocial supports, or attitudinal factors. In the context of survey research, these markers are better known as constructs. They are typically considered subjective and capture an abstract idea such as behaviours, beliefs, or attitudes. Generally, a construct is measured by summing or averaging responses on a scale (other methods exist but these are outside the scope of this guide). Scales are a set of multiple items and provide a good source of information from respondents about a particular construct. For example, a widely used scale to measure the construct psychological distress is the Kessler-10 scale (K10).

You don't have to look too far to find a plethora of existing scales shown to have been rigorously tested. Through extensive testing at the time of their first use, these scales will provide a precise and reliable measure for your construct. Using existing scales will also help you compare the data you gather with data already available.

When designing your study, it can be easy to dismiss an existing scale based on factors such as length, a non-preferred format, or personal dislike of the questions. While developing a scale may sound straightforward, it is a costly and lengthy process including a literature review, focus groups/interviews, question development, pre-testing, and statistical analysis. Throughout this process it is essential you collect evidence to show the new scale is reliable and trustworthy. Ideally, you will collect evidence across time and settings; so, some say gathering this evidence is never really finished.¹ Therefore we recommend you adopt, where feasible, existing scales already tested by others. Investment of your time and effort upfront to find a suitable scale will far outweigh the time and effort you will spend developing your scale.



# WHERE TO FIND EXISTING SCALES AND HOW TO EVALUATE THEM

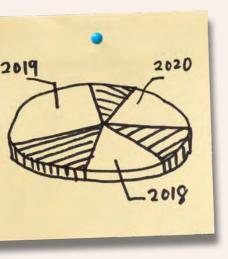
So how do you find and review existing scales? The first step is to clearly define your study aims, the related constructs, and the group of individuals you want to include in your study (target population). This information will help you to narrow your search for suitable scales. Start by searching an academic database like Medline, or using a search engine such as Google Scholar, or identifying relevant books (see Appendix A in Health Measurement Scales: A Practical Guide to Their Development and Use under Helpful Resources).2 Some professional associations also provide helpful resources, so be sure to check out their web pages. Once you have found a scale or multiple scales that appear to suit your needs, conduct a critical assessment of each scale individually. The purpose of this is to make sure the scale aligns with your study aims. We have provided three questions below to get you started for a critical review.

Are the questions in the scale appropriate to your study?

- Is there evidence of validity and reliability reported by the author? You can use this guide as a starting point.
- Has the scale been tested with participants similar to your target population?

If you conclude no suitable scale exists, then this guide will assist you in developing a scale relevant to your desired construct.

**Key message**: Use existing validated scales as much as possible. Critically assess the suitability of existing scales for your research purposes by reviewing the available evidence.



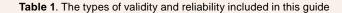
# HOW TO STRENGTHEN THE RIGOUR AND TRUSTWORTHINESS OF YOUR RESEARCH FINDINGS

The validity and reliability of a scale underpin the study results. Validity and reliability not only strengthen your study conclusions but also gives other researchers confidence to use your scale. A reliable scale will give a consistent result regardless of who is responding and regardless of the context. Meanwhile, a valid scale will adequately capture the construct you intend to measure. For example, if our body weight remained stable and we weighed ourselves every day, a reliable set of scales will show the same weight daily (reliability). Whereas an accurate measure of our body weight in kilograms, for example, will show us the scale is valid (validity).

To provide support to your scale, a collection of evidence demonstrating validity and reliability is essential. In the following sections of this guide, we address aspects of validity and reliability while navigating you through the process of scale development. Alternatively, you can use this guide when evaluating the evidence of existing scales. In the remainder of the guide, we concentrate on five different types of validity and reliability (Table 1).

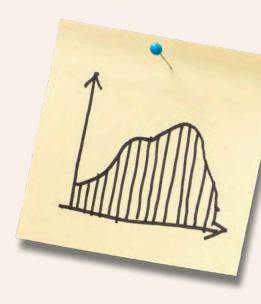
Type of validity/ reliability	Description	Definition	
Content validity	Do the questions capture the construct you want to measure?	Refers to the extent to which items on your scale are representative of the construct you are seeking to measure	
Face validity	Superficially do the questions appear to measure what they should be measuring?	Refers to the degree to which your items appear to be a reasonable or accurate measure of the construct	
Convergent validity	Does your scale have a relationship with a similar measure?	Refers to the extent to which your scale relates with conceptually similar scales	

Discriminant validity	Does your scale lack a relationship with an unrelated measure?	Refers to the degree to which your scale diverges from a measure with a conceptually unrelated construct
Internal consistency (reliability)	Are the scores on each item related to one another and one overall construct?	Refers to the extent to which the items in your scale measure the same construct



Key message: Testing the validity and reliability of your scale is essential in all stages of development. The accumulation of evidence for different types of validity and reliability will support your research results and give other researchers confidence to use your scale.

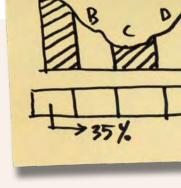




#### **CONTENT VALIDITY: HOW DO** YOU CAPTURE THE CONCEPT **OF YOUR SCALE?**

As a first step, you will need to collect information about the construct you want to measure. Making use of your previous work searching for existing scales will come in handy here. Next, you will need to find information related to your construct. This can come from various sources including focus groups, interviews with people from your target population, and engagement with expert panels. These methods are qualitative in nature and offer an in-depth, rich source of information. A search of existing literature for any current research and identifying themes grounded in theory may also prove helpful.<sup>2</sup> The information gathered during this step will provide you with content for your scale questions (outlined in the next section). If any concept was omitted, the items of your scale might not be representative of the construct you are aiming to measure. This would compromise the content validity of your scale. For example, if a scale aiming to measure depression didn't include a question about low mood, it would probably have poor content validity. For more information on the methods described in this section. see Health Measurement Scales: A Practical Guide to Their Development and Use in Helpful Resources.

**Key message**: Use a variety of methods to capture key information to guide your research questions. Questions that adequately capture your construct will provide evidence for content validity.



# CONTENT AND FACE VALIDITY: HOW DO YOU DEVELOP AND TEST YOUR SCALE?

Now it's time to develop your questions and test your scale. We have provided a checklist below to help you write clear and well-worded questions for your scale.<sup>3,4</sup>

- Aim to write questions rather than statements
- · Avoid asking:
  - > double-barreled questions or two questions in one (e.g. 'The care I received was timely and courteous?')
  - > double negatives (e.g. 'Do you agree long waiting times are not uncommon?')
  - > leading questions (e.g. 'Don't you agree free transport to the hospital would be a good idea?')
  - > ambiguous questions (e.g. 'Do you use drugs?'). It is unclear if the question is asking about illegal drugs, prescription drugs, or over-the-counter drugs.
  - > Write closed-ended questions with options for participants to choose a response. Find existing pre-coded response options that are mutually exclusive and exhaustive (e.g. 0 Never, 1 Rarely, 2 Sometimes, 3 Often, 4 Always). These allow for ease of interpretation and coding.
- Make sure questions share a consistent grammatical person, typically first or second person
- Questions should share a distinct timeframe. Recent events are easier for participants to recall (e.g. 'In the last two weeks, how often did you...').
- Ensure the questions are not conditional on experiencing a specific event, and everyone in your target population can answer them (e.g. 'In the last two weeks, I felt anxious on trains').
- Make sure the questions are clear and well-worded, and the language matches your target population.
   A good way to achieve this is to capture commonly used phrases and terminology when defining the concept of your scale (see the previous section).
- It is also important you consider the feasibility of the scale. A scale may not be useful if it is difficult for people to complete in the intended setting. For example, a scale that requires an expert or interpreter to assist respondents when answering the questions would not be useful. Also, if the burden of completing the scale by the respondent outweighs the usefulness of the scale, consider starting with a shorter set of questions. For example, it is unlikely

a large number of respondents will complete a 20-minute scale that is not relevant to their needs.

It is good practice to identify any issues with your scale early on by pre-testing the questions with colleagues and people in your target population. Pre-testing will give you an opportunity to identify any issues with comprehension, question relevance, question-wording, conceptual ambiguities, unclear reference periods, completion time, and a mismatch between the questions and the response options. Again, qualitative methods will provide a rich source of information. Such methods include expert panels, behavioural coding, focus groups, or cognitive interviewing.<sup>1,3</sup> Cognitive interviewing is a useful technique and explores how respondents interpret the questions and their response options. You can conduct the interviews one-on-one or in a small group setting. If your questions appear to measure the intended construct, you will have collected evidence of face validity. For more information on cognitive interviewing, see 'Research synthesis: The practice of cognitive interviewing' in Helpful Resources.

**Key message**: Make sure your questions are well-considered and clearly written. Pre-test your questions with people in your target population to identify any issues before survey production.

# DO YOUR ITEMS SHOW EVIDENCE OF VALIDITY AND RELIABILITY?

# Convergent and discriminant validity: Is there a relationship with other scales?

After you have collected your data, what now? It's time to assess the evidence of validity and reliability for your scale. Let's start by checking if the score from your scale correlates with a score from a similar scale (convergent validity). Usually an identical scale will not exist, so find one that relates conceptually with evidence of validity and reliability. Once you have the scores from both measures, correlate these using a Pearson r correlation coefficient. Scores for a Pearson r range from -1 to +1. A score between 0.4 and 0.8 will provide evidence that your scale is capturing a similar construct as the existing scale.<sup>2</sup> On the other hand, you can test whether your scale diverges from a conceptually unrelated scale (discriminate validity). A Pearson r correlation coefficient closer to zero will indicate little or no relationship between the measures. General statistical packages include a measure of the Pearson r correlation coefficient, as does Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA). Online resources are available to get you started using Microsoft Excel,5 but also

consider reaching out to an academic researcher or colleague with statistical experience for assistance.

# Internal consistency (reliability): Are the items related to one another?

Let's now focus on how the items relate to one another (internal consistency or reliability). There are a few measures you can use to test the reliability of your scale, such as split-half (odd-even) reliability or Kuder-Richardson. But one popular measure is Cronbach's alpha. A Cronbach's alpha score will be between 0 and 1, with 0 showing your scale is not at all reliable and 1 showing perfect reliability. Generally, an alpha score of 0.7 and above will provide you with evidence of a reliable scale. Most general statistical packages include a measure of Cronbach's alpha. If this doesn't make sense, reach out to an academic researcher or colleague with statistical experience for assistance.

While the previously described process of testing your scale is an important step, you can take this further. There is a range of advanced statistical methods that provide more thorough testing of the validity and reliability of your scale. Also, keep in mind you may need to test your scale again if you want to use it in a different setting. For example, interpretation of the items may vary when testing your scale in a population with different cultural norms. See 'Best Practices for Developing and Validating Scales for Health, Social, and Behavioral Research' in Helpful Resources for information on more advanced statistical methods.

**Key message**: There are a range of methods that may be used to assess evidence for validity (e.g. correlations with existing scales) and reliability (e.g. internal consistency). Administering your scale with other scales during the data collection phase will assist in establishing whether your scale is valid and reliable.



#### SO, WHAT NOW?

By the end of this process, you will have gathered evidence of validity and reliability for your scale. By reporting this evidence, you not only add strength to your study conclusions but provide confidence in the use of your scale by other researchers. For information on reporting this important evidence, see 'Writing your first research paper: A practical guide for Clinicians' and Health Measurement Scales: A Practical Guide to Their Development and Use in Helpful Resources.

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**RESEARCH TOOLKIT** 



## Redcap is when data capture leads to good: An overview and tips for best practice

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If you have been involved in collecting or managing data for research studies, chances are you have heard the word 'REDCap' being thrown around. Here we will run through some basics about what REDCap is, why it is so often considered the preferred tool for your data needs, and provide some key pointers to help you get the most out of your project.

#### WHAT IS REDCAP?

REDCap (Research Electronic Data Capture [Vanderbilt]) is a web-based solution for collecting and managing research data. It was designed by researchers, for researchers, which translates to an intuitive and user-friendly system that ticks a lot of the boxes that are likely to be important to you when designing your project. Let's start by discussing some of key features that make REDCap a valuable platform to help you manage your research data. These are:

- Security and regulatory compliance: Protecting participant data is obviously a priority. However, if you do not have an IT background developing a solution that protects your data and allows you to meet your regulatory responsibilities may seem like a daunting task. Providing a secure platform for your data is one of the key strengths of REDCap. Most institutions have minimum requirements for the handling of research data and REDCap is often listed as a preferred platform. This is because there are a few assurances that are standard in REDCap. Importantly, all data are transmitted over a secure connection by authenticated users and all activities and changes to data are logged. REDCap projects can also be configured to comply with standards such as the US Food and Drug Administration's Title 21 CFR Part 11 and the Health Insurance Portability and Accountability Act Security Rule that can apply to sensitive data.
- Free to institutions belonging to the REDCap Consortium: REDCap is completely free to use for research teams at partner institutions. You can check whether your organisation is a member on this webpage. If not, your institution can join for free but there are a couple of requirements that bear mentioning. Firstly, only non-profit organisations are eligible to join the REDCap Consortium but a fee-based cloud service is available to for-profit organisations. Second, membership is also dependent

#### **RESEARCH TOOLKIT**

on sufficient internal IT infrastructure and support being available at your institution. As the REDCap license agreement prohibits the outsourcing of IT support, this means that your institution must have its own IT department who are willing to support the projects. Note that support in this instance means facilitating the REDCap instance at your institution; you or your team will generally be responsible for building the projects and instruments (or outsourcing this).

If you are planning to apply to join the REDCap Consortium, the <u>technical requirements</u><sup>3</sup> section of the REDCap webpage will come in handy when discussing with your institution's IT department. Staff supporting the REDCap instance can join the <u>REDCap community site</u><sup>4</sup> and gain access to technical documentation, forums, and other resources to assist in their roles.

Unfortunately, REDCap is not currently available for individual or personal use but if you will be running your project through a university, you shouldn't have a problem joining the REDCap Consortium (most Australian universities are already members).

Basic functionality can be extended using external modules: Many external modules are available<sup>5</sup> to technical staff. Software developers contribute these to add specific functionality to REDCap based on the needs of projects around the world. Your administrator (within the IT support staff) can help you to identify and implement external modules that may be appropriate for your project.

- Flexibility in designing instruments: REDCap instruments can be directly distributed to participants as surveys or set up as 'electronic Case Report Forms (eCRF)' for data entry by study staff. These can be linked using a unique participant ID number which means that surveys can be linked to data subsequently collected on site and vice versa. There is no need for double handling survey data as this will automatically be entered into the system. You can also easily share survey links in your recruitment material and, for repeating surveys, reminders and links can automatically be sent to participants who have provided their email addresses.
- Simple design of projects and instruments: There is no coding required for designing your project or your instruments (i.e. surveys and eCRFs). Projects are easily defined using REDCap's web interface. For instruments, you have two options: the online designer and an offline data dictionary. These both contain the same information, and it is easy to switch between them.
  - > Online designer: The online designer is managed entirely on the REDCap web application. You can

- 'point and click' to edit your variables and there are annotations to help you along the way. This is a straightforward way to create instruments but can become tedious for larger instruments.
- > Data dictionary: The data dictionary is a specially formatted spreadsheet which includes all the information about your forms. It can take a little more to get used to than the online designer but once you get the hang of it, it can be easier to work with. This is especially true for larger instruments because you can copy and paste sections that are shared, and you do not have to constantly click to move back and forth when editing variables. Once you have finished making changes, save the file and upload it to REDCap. If you receive an error message, it likely means that you have not adhered to the formatting requirements. These must be strictly followed because they define the format which makes the file readable by REDCap.
- > Every change made in the online designer results in an updated data dictionary being automatically created in REDCap. You can download these for editing at any time. When you are first starting out, it may help to design your first instrument in the online designer, and then download the data dictionary. This will help you to make the connection between what is included in the data dictionary and what is built in the instrument.
- > Instrument Library: REDCap users around the world upload instruments to a shared library. 
  These instruments can then be downloaded and implemented easily by other users. If you have commonly used forms, you may find that someone else has already done the hard work for you! Even if it's not quite right, it might be quicker to edit a template than build a form from scratch.
- Scheduling feature: It is possible to do all of your scheduling in REDCap. Once you have defined the expected interval between study events and an allowable window, REDCap can generate an editable schedule with suggested dates already entered when the first event date is provided. Appointment times and dates can be changed at any point and are automatically added to a useful study calendar.

# DESIGNING YOUR REDCAP PROJECT

When designing your REDCap project, it is important to be mindful of all the purposes collected data will serve in your research. As clinicians, we perhaps first think of the user experience - whether it is straightforward for our patients to use, how we will enter data, what information we would like to have available at visits, and so on. While these are no doubt important, we also need to remember how the collected data will be used. Datasets will ultimately be extracted from REDCap, likely imported into a statistical package such as R (R Foundation for Statistical Computing, Vienna, Austria), and analysed to answer research questions. This raises further considerations, but because these processes are down the line, they can sometimes be overlooked at the design stage. This can unfortunately result in a need for messy retrospective corrective measures if issues with the collected data are identified midway through the project. The time and effort needed for data cleaning at the end of the project can also be reduced by taking care at the initial design stage.

Below are some basic tips for designing your project with consideration given to both REDCap users and to users of the data it manages. However, REDCap is a powerful platform with functionality that can be extended by a wide range of external modules, as previously mentioned. It is impossible to cover everything here, but we believe that following these tips will get you well on your way along a successful REDCap journey.



# Tips for User-Friendly REDCap Surveys and Forms

- For eCRFs, it is good practice to design forms to mimic their paper copies as closely as possible. This makes data entry more intuitive and can reduce the risk of data entry errors. Aim to follow the order of presentation, layout, and data format in the paper copy of the forms. Things like presenting multiple choice options as horizontal rather than vertical (use the custom alignment option for this) or entering data into a table rather than a list (use the field embedding feature for this) can help your electronic forms more closely match their paper sources.
- Users should rarely have to enter the same data twice. You can 'pipe' in previous responses from an earlier event in the same project using the @DEFAULT action tag. This tells REDCap to enter a default value which is the same as some earlier collected/entered variable. This feature can be used if there is a need for the same data to appear on multiple forms. It can also be used for things like medicine lists across visits where it is possible that responses haven't changed. However, if you are using the feature in this way, make sure to be clear that the previous responses have been automatically filled and the user should check their accuracy and update as necessary.
- Branching logic can make the appearance of your forms less cluttered and make it easy to find things.
   This allows you to show or hide items depending on whether defined logical criteria are met. Fields that don't apply can be skipped all together.
- Defining important fields as required is a useful way to minimise missing data due to data entry errors. However, if missing collection is reasonably common for a particular variable, this can be a nuisance for users. In such circumstances, it can be helpful to have a required field asking if the data was collected, and subsequent details to show only if the answer is 'yes' (using branching logic). This has the additional benefit of making it possible to conclude whether data are genuinely missing or whether its entry was omitted in error.
- Considerations for your REDCap Data
- Field validation is useful in making sure that data are being entered in the expected range and format.
   For example, for systolic blood pressure, you can tell REDCap that you want whole numbers only (i.e. integers), and you expect values between 70 and 200. Values outside of the defined range (but not format) will be accepted but will trigger an alert



asking the user to confirm their accuracy. This can prevent simple typos at the time of entry.

- Remember, in both REDCap logical statements and statistical software, variable names will have to be typed out to be called and you (or your statistician) will not want to repeatedly refer to the codebook to know which variable you want. As such, names should be short and intuitive. Spaces are not allowed, and uppercase letters are changed to lowercase. This generally makes it compatible with use in statistical software, but it is still important to choose names that are sensible and make it is easy to infer what is being captured.
- If multiple sites are being used to collect the same data, using the same REDCap instruments (particularly variable names) will mean your data are harmonised and ready to be pooled. Sharing REDCap data dictionaries at the design stage is a simple way to ensure this.
- It is a good idea to work with your statisticians/ data analysis team when designing forms to ensure that the key variables are in the expected format for the planned analyses.

#### TRAINING AND FURTHER READING

The REDCap website<sup>7</sup> has a wide range of videos introducing you to the application and the specifics of how to use it. You can also sign up for a free one-week trial account which allows you to learn your way around REDCap and to practice creating instruments — even if your institution is not a member of the REDCap Consortium. This is probably the best way to become quickly acquainted with the system. You will also find a huge range of resources on YouTube and Google, but it is best to start with the REDCap website before jumping into these.

#### WEBSITES LINKED IN THE ARTICLE

- 1. https://projectredcap.org/partners/
- 2. https://www.redcapcloud.com/
- 3. https://projectredcap.org/software/requirements/
- 4. https://projectredcap.org/resources/community/
- 5. https://redcap.vanderbilt.edu/consortium/modules/index.php
- 6. https://projectredcap.org/resources/library/
- 7. http://www.project-redcap.org/



### An introduction to linear regression

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If you are conducting medical research and want to find whether there is a relationship between your variables in your study, you can use a statistical method called linear regression to analyse your data. Linear regression is widely used in medical research to calculate the correlation between variables (e.g. whether birth weight is linked to weight in childhood). You can also use linear regression to make predictions (e.g. predicting a person's BMI based on their calorie intake). In this article, I will show you how to conduct simple linear regression and multiple linear regression using the statistical applications, R (R Foundation for Statistical Computing, Vienna, Austria) and Stata (StataCorp, College Station, TX, USA), and how to interpret the results.

#### **DEFINITIONS**

In medical research, there are two types of variables. These are independent variables and dependent variables. These types of variables can be seen as the cause and effect, with the independent variable being the cause and the dependent variable being the effect. For example, if your aim is to investigate whether income influences life expectancy, income is the independent variable and life expectancy is the dependent variable. Other names exist for these types of variables, such as predictor variables and outcome variables, or explanatory variables and response variables. In every regression model, there can be one or more independent variables, but there can only be one dependent variable. A simple regression model refers to a regression model where there is only one independent variable. Otherwise, a multiple regression model has two or more independent variables.

#### **ASSUMPTIONS**

There are steps you should consider before deciding to perform linear regression on your research data. If you are conducting a simple linear regression, your variables need to be numerical (i.e. continuous variables) for example, BMI or weight. If the values of the dependent variable are not numerical, for example disease status, then linear regression is not suitable and you should try a different statistical method. If you are conducting a multiple linear regression analysis, at least one of the independent variable/s needs to be numerical.<sup>1</sup>

In statistics, assumptions are all the characteristics that we assume about our data before we run our analysis. These can be thought of as rules that the data need to follow so we can conduct the statistical analysis. If the data does not meet the assumptions required by the statistical method, the results obtained from the analysis may not be accurate.

Here are the assumptions of a linear regression model:

- 1. The relationships between each independent variable (referred to as 'X') and the dependent variable (referred to as 'Y') are linear
- 2. The variance of the residuals is constant for any value of X
- 3. The distribution of the residuals is normal (in small samples)
- 4. There are no other confounding variables.

These assumptions are explained below.

#### Linearity between X and Y

A simple regression model can be expressed as a mathematical formula below.

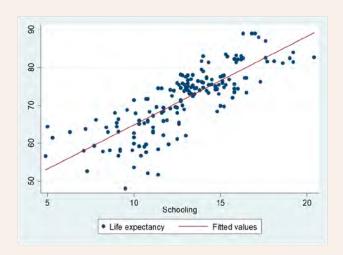
$$Y_i = \beta_0 + \beta_1 X_i + \varepsilon_i$$

In this equation:

- Y<sub>i</sub> is the value of the dependent variable for individual i (i = 1, 2, ... n, where n is the number of individuals in the study).
- β<sub>0</sub> and β<sub>1</sub> are the parameters of the regression model. Parameters are unknown values that we try to calculate using regression analysis.
- ε<sub>i</sub> is a 'random error' with mean zero. (This will be explained later).

Note: If we compare the formula for the simple regression model (excluding  $\epsilon_i$ ) to an algebraic line equation (y = ax + b),  $\beta_0$  would be the y-intercept and  $\beta_1$  would be the slope. We commonly refer to  $\beta_0$  as the constant in statistics.

Linearity means that if the values of X and Y are to be graphed into a scatterplot below, the points follow the shape of a straight line.

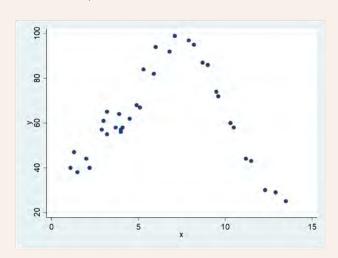


**Figure 1.** Example scatterplot of data which is appropriate for linear regression

The red line in Figure 1 is a straight line that fits most closely with the data points. This is called the **regression line**. The formula for this line is the same as the formula for simple regression but without the 'random errors'.

Note: It is possible to run linear regression commands with only categorical independent variables using Stata and R. However, the results show the averages of the dependent variable values in the categorical group.

If the points do not follow the shape of a straight line, then a transformation or a different statistical method should be considered. The most common form of transformation is the log transformation. This will be explained later in this article.



**Figure 2**. Example scatterplot of data which is not suitable for linear regression. A transformation may be required here

#### Commands on Stata and R

You can check the linearity of the variables my making a scatterplot on your preferred statistical program. We show how to do this on Stata and R.

Our dependent variable is named y and our independent variable is named x in the following examples.

#### On Stata

scatter y x

#### On R

In this example, we have imported the data and named it *data1* before running the following plot command.

with(data1,plot(y,x))

#### Constant variance of the residuals

Recall from the formula for simple regression that there is a 'random error'  $\epsilon$  added to the regression line. These are also called **residuals**. Residuals can be graphed into a residual plot. An example of a residual plot is shown below (Figure 3).

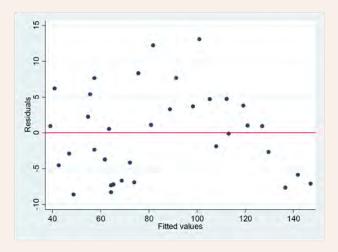
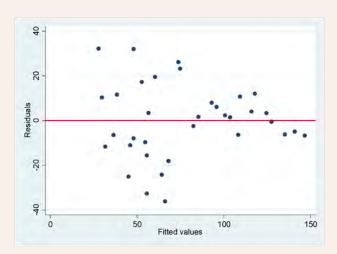


Figure 3. Example residual plot showing constant variance

To meet the assumption of constant residual variance, you want the vertical spread of the data points in the residual plot to be approximately the same across all x axis values. Figure 3 shows an example of the data meeting this assumption.



**Figure 4.** Example residual plot where the variance decreases with increasing x value

If the variance of the residuals is not constant (shown in Figure 4), then you should either use different statistical method or apply a transformation.

# Checking for constant variance of the residuals in Stata and R

#### On Stata

regress y x

The regress command is the command for linear regression in Stata. This command needs to be run before producing the residual plot using the command below.

rvfplot, yline(0)

#### On R

Similarly, the linear regression commands also need to be run on R before producing a residual plot.

fittedvalues = lm(y~x, data=dataname)
residuals = resid(fittedvalues)
plot(dataname\$x, residuals)
abline(0,0)



#### Normal distribution of the residuals

From the simple regression formula, we assume that the errors ( $\epsilon$ ) follow a normal distribution with mean 0 and variance  $\sigma^2$ . This means that most of the residual values are close to 0 while there are fewer values further away from 0.

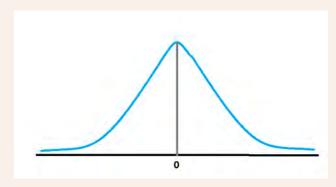


Figure 5. Graph showing the frequency of a normal distribution

In statistical programs, the normality of the residuals can be checked using Q-Q (quantile-quantile) plots.

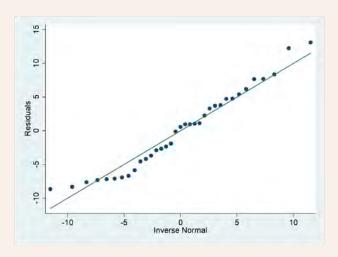


Figure 6. Q-Q plot example of assessment of the normality of residuals

The Q-Q plot in Figure 6 shows a dataset that meets the assumption for the normality of the residuals. Notice that the residual data points follow closely to the diagonal line.

If most of the residual data points stray too far away from the diagonal line, then the assumption is not met. In that case, a transformation or a different statistical method should be considered.

#### Q-Q plots on Stata and R

In this example, our dependent variable is named y and our independent variable is named x. The Q-Q plot can be produced using the qnorm command in Stata or gqnorm if you are using R.

#### On Stata

regress y x
predict res, res
qnorm res

#### On R

fittedvalues = lm(y~x, data=dataname)
residuals = resid(fittedvalues)
qqnorm(residuals)
qqline(residuals)

# No other confounding variables Confounding variables are other variables that are linked to both the independent and dependent variables. A common example of this is the high correlation between ice cream consumption and shark attacks. Obviously

to both the independent and dependent variables. A common example of this is the high correlation between ice cream consumption and shark attacks. Obviously, ice cream consumption is not the cause for the higher number of shark attacks. In this example, the confounding variable is temperature. As the temperature increases, more people are likely to eat ice cream and more people are likely to go swimming. Therefore, if we are to only investigate the amount of ice cream consumption and the number of shark attacks, the correlation between the two would be overestimated because of the effect of the confounding variable temperature.

We should consider all possible confounding variables when conducting research studies. Any confounding variable that is not considered may lead to inaccurate results.

Effects of confounding variables can be adjusted by adding the confounding variables into our multiple regression models. Therefore, when producing the final results for the study, it is best to use the results from a multiple regression model as opposed to a simple regression model. Simple regression models are useful for measuring the confounding effects of possible confounding variables (by comparing the results to a multiple regression model). These findings are usually included in the discussion section of a research article.

# Running multiple regression analyses on Stata and R example

Running multiple regression analyses on Stata and R example.

#### On Stata

regress y x c

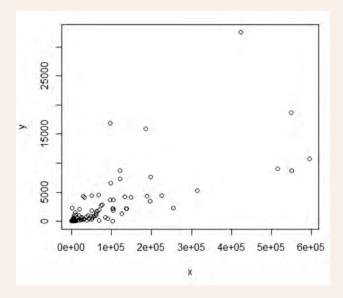
#### On R

fittedvalues = lm(y~x+c, data=dataname)



#### **TRANSFORMATIONS**

Transformations modify all values of a numerical variable the same way. We do this so our data can meet the statistical assumptions. The most widely used transformation is the log transformation (base e). This transformation modifies all the values of a variable by taking the log of it  $(\ln(x))$ . When the values of a variable are spread out but highly concentrated at the lower values, this is a clear sign that a log transformation is needed.



**Figure 7**. Example scatter plot of data that requires log transformation

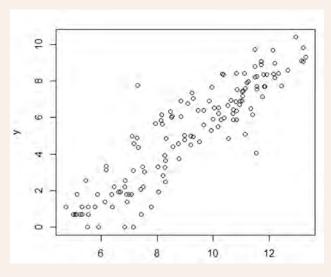


Figure 8. Example scatterplot after log transformation

The data in Figure 7 is unevenly spread out. This suggests the variable should be log transformed. Figure 8 shows the aftermath of the log transformation. Notice how the variable is more linear after log transforming.

#### Log transforming a variable

Below is an example of how to log transform a variable (x).

#### On Stata

gen logx=log(x)

#### On R

#### logx=log(x)

After log transforming a variable, the new variable (logx) is used in the regression model.

Note: that when interpreting the results, we are interpreting the log of the transformed variable.

#### Stata

Source	SS	df		MS		Number of obs	=	17
						F( 2, 170)	=	343.2
Model	9786.33792	2	4893	.16896		Prob > F	-	0.000
Residual	2423.6573	170	14.2	568076		R-squared	=	0.8015
						Adj R-squared	=	0.799
Total	12209.9952	172	70.9	883443		Root MSE	-	3.775
lifeexpect~y	Coef.	Std.	Err.	t	P> t	[95% Conf.	In	terval
incomecomp~s	52.02942	4.602	2456	11.30	0.000	42.9441	6	1.11475
schooling	1680367	.242	2666	-0.69	0.490	6470635		310990
_cons	37.98063	1.343	3106	28.28	0.000	35.32932	4	0.63195

In the above regression output in Stata, the main feature to look for is in the bottom table. This is called the parameter estimates table and it contains the results we are looking for. The most useful columns in this table are 'Coef.', 'P>|t|' and '[95% Conf. Interval]'. When writing the results of your research project, you need to at least include the values under these three columns.

The 'Coef.' column contains the values of the coefficients. The value 52.02942 can be interpreted as the increase in life expectancy for every unit increase in income. Similarly, -0.1680367 is interpreted the same way for schooling. The value 37.98063 is called the constant. This constant is the value of the dependent variable (which is life expectancy in this example) when all the other variables are zero. The multiple regression formula using these values is as follows:

Life expectancy = 37.98063 + 52.02942 \*income + -0.1680367 \* schooling +  $\varepsilon_i$ 

This is similar to the simple regression equation, but it includes other variable(s).

The 'P>|t|' column contains the p-values. These values are the probability that the positive or negative coefficient result is obtained by random chance. For example, there is a 49.0% probability that the negative result for schooling is due to chance. This is very high. Therefore, the result for schooling is deemed insignificant. A common rule of thumb for statisticians is to consider a p-value less than 0.05 as significant. However, some studies use a threshold of 0.01 or 0.1 depending on the nature of the study. In a multiple regression model, variables with insignificant results should be excluded.

The last column shows the 95% confidence intervals. These intervals show the range in which we are 95% confident that the real population coefficient is within the interval. Like p-values, some studies use 90% confidence intervals or 99% confidence intervals.

#### R

Similar to the Stata output, in the R output, the main results are in the bottom table. The 'Estimate' column shows the coefficient values and the 'Pr(>|t|)' column shows the p-values. Note that the asterisks next to the p-values show the significance. Confidence intervals can be calculated on R using the confint command.

#### Calculating confidence intervals on R example

```
reg<-lm(Life.
expectancy~Income.composition.
of.resources+Schooling,data=Data)
summary(reg)
confint(reg,'Income.composition.
of.resources',level=0.95)
confint(reg,'Schooling',level=0.95)</pre>
```

#### CONCLUSION

The statistical method linear regression is an important tool when analysing your data. It allows you to calculate the correlation between variables and to make predictions. In this article, we have demonstrated when to use both simple linear regression and multiple linear regression, how to use the statistical applications R and Stata to conduct linear regression, and provided some guidance about how to best interpret your results. For additional reading on the use of linear regression, *Applied Linear Statistical Models*, 5th edition by Kutner et al. is recommended.

#### **GLOSSARY**

**95% confidence interval**: An interval where we are 95% confident that the real population result is included in

**Coefficient**: the increase in the dependent variable for every 1 unit increase in the independent variable or the decrease in the dependent variable if the coefficient is the negative value

Constant ( $\beta_0$ ): the value of the dependent variable when the values of all independent variables are zero

**Dependent variable (Y)**: a variable whose values depend on the value of the independent variable/s

**Independent variable (X)**: a variable whose values do not depend on another variable

**p-value**: in linear regression, the p-value is the probability that the positive or negative coefficient result obtained is a result of random chance. Because studies use data from a sample of the population, your result of your statistical analysis would most likely not be true for the population. Therefore, there is always a chance that your positive or negative coefficient result from your study could be the opposite of what is actually true for the population

**Regression line**: line that best shows the correlation between two variables. See Figure 1.

**Regression model**: A formula that is created using regression analysis (for example, see the mathematical formula in the section Stata). Models can be used to make predictions.

**Residuals**: Difference between the fitted values formed from the regression line and the data values

**Statistical methods**: formulas or techniques used to conduct statistical analysis. There many statistical methods and linear regression is one of them

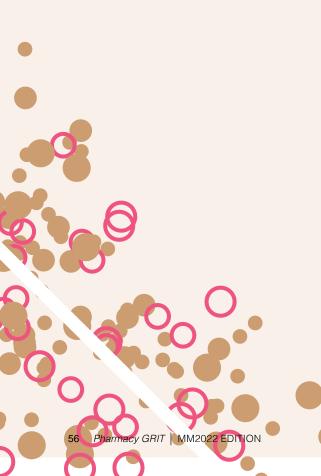
**Transformation**: modifying all the values of the variable the same way. The most used transformation is the log transformation

**Variables**: something we measure that can change and may have more than one value e.g. weight, height, income

Variance: number that shows how spread out the data is

#### REFERENCES

 Kutner M, Nachtsheim C, Neter J, Li W. Applied linear statistical models. 5th edition. Boston: McGraw-Hill/Irwin; 2005.



# Time to define antimicrobial risk: Proposal of a paediatric antimicrobial stewardship risk rating tool

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#### **ABSTRACT**

**BACKGROUND:** There is no national classification system to define and quantify the risk of harm from inappropriate antimicrobial prescribing in paediatric populations.

**AIM:** This article aims to both develop an antimicrobial risk rating tool to quantify inappropriate prescribing in paediatric populations by modifying a locally developed adult tool and identify variations in risk classification of inappropriate prescribing by applying both the paediatric and adult risk tools to recommendations made on paediatric antimicrobial stewardship ward rounds

**METHOD:** A novel paediatric antimicrobial risk rating tool was developed in consultation with a paediatrician, antimicrobial stewardship (AMS) pharmacist, and a clinical paediatric pharmacist based on a locally developed adult tool. Changes made from the adult tool to the paediatric tool related to antimicrobial dosing, spectrum, route of administration, and duration of therapy. Both tools were applied to 12 months of retrospective paediatric AMS ward round recommendations. Variation between risk ratings was compared.

**RESULTS:** A total of 121 recommendations were analysed in this study. Across both the adult and paediatric tools, 36% (n = 43) of recommendations received the same risk rating. With the application of the paediatric tool, 45% (n = 54) of recommendations received a lower risk rating and 20% (n = 24) of recommendations received a higher risk rating when compared to the adult tool.

**CONCLUSION:** A novel paediatric antimicrobial risk rating tool was developed to quantify the risk of inappropriate antimicrobial prescribing in this population. Differences in

risk ratings were observed when the adult and paediatric tools were applied to the same clinical situations. This suggests the need for a population specific tool when assessing risk.

#### **INTRODUCTION**

Antimicrobials can be a lifesaving treatment for children with bacterial infections and are the most commonly prescribed medicine in this population.¹ However, antimicrobials can also result in adverse drug events, medicine toxicity, and detrimental effects on the gastrointestinal microbiota and enteric immune system.² Furthermore, at both the individual and population level, inappropriate antimicrobial prescribing drives the development and transmission of antimicrobial resistance.³.⁴ Judicious use is therefore of paramount importance, yet national surveys indicate that one third of antimicrobial prescribing in paediatric and adult populations in Australian hospitals are non-compliant with treatment guidelines.⁵

An antimicrobial stewardship (AMS) service aims to ensure that antimicrobials are prescribed according to evidence-based guidelines, with antimicrobial choice, dose, and duration selected to optimise clinical outcomes and minimise adverse consequences.<sup>5</sup> Currently there is no national tool to classify and communicate inappropriate antimicrobial prescribing according to the risk posed to the patient. The National Antimicrobial Prescribing Survey (NAPS) offers a system to classify antimicrobials as appropriate or inappropriate, but does not capture the clinical significance of the classification.<sup>5</sup>

At a large, multi-site, metropolitan teaching hospital network with over 2000 beds, the AMS service conducts weekly ward rounds where inpatients, currently prescribed antimicrobial agents, are reviewed. The AMS team consists of an infectious disease physician and an AMS pharmacist who make recommendations to the treating unit to optimise the use of antimicrobials. The recommendations from the AMS team are verbally communicated to prescribers at the time of review and documented in patients' progress notes. Additionally, a copy of these recommendations are recorded by the AMS team using Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA) which includes: treating unit,

age, weight, antimicrobial agent, dose, route, indication, and details of recommendations. Using this data from AMS ward rounds, the local adult AMS service developed a risk assessment tool to quantify the risk of inappropriate antimicrobial prescribing in the adult population.<sup>6</sup>

The adult tool was developed and tailored to AMS using the existing framework from The Society of Hospital Pharmacists of Australia (SHPA) risk classification of pharmacy interventions matrix and the Enterprise Risk Management Framework, developed by Monash Health. 7,8 The adult tool evaluates risk on a 1 to 5 scale, where 1 = minimal risk (such as prescribing for a duration longer than necessary) and 5 = catastrophic (such as prescribing an agent to which the patient has a documented severe allergy to), but does not capture paediatric specific scenarios. A risk rating tool offers the AMS service a consistent classifying system and streamlined approach to communicate inappropriate antimicrobial prescribing to treating doctors and the impact this may have on their patient. Therefore, the aims of this study were to 1) develop an antimicrobial risk rating tool to quantify inappropriate prescribing in paediatric populations by modifying a locally developed adult tool and 2) identify variations in risk classification of inappropriate prescribing by applying both the paediatric and adult risk tools to recommendations made on paediatric AMS ward rounds.

#### **METHOD**

#### Part A: Modifying the adult tool for paediatric patients

A multidisciplinary team consisting of a paediatric infectious disease physician, a paediatric AMS pharmacist, and a clinical paediatric pharmacist undertook a preliminary pilot study. The pilot study applied the adult risk rating tool to 20 AMS paediatric ward round recommendations. Through this pilot study, clinical scenarios were identified where risk was perceived differently in the paediatric population compared with that identified by the adult risk rating tool. These clinical scenarios related to antimicrobial dosing, spectrum, intravenous (IV) therapy, and duration of therapy. This formed the basis for changes made to the adult tool and the subsequent development of the modified paediatric tool in this study. Changes made to the paediatric tool were based on expert opinion from a paediatrician, a paediatric AMS pharmacist, and a clinical paediatric pharmacist, and was supported by published literature.

# Part B: Applying the adult and modified paediatric tool in paediatric patients

A paediatric AMS pharmacist and clinical paediatric pharmacist independently applied both the existing adult tool and the modified paediatric tool retrospectively to 12 months of paediatric AMS ward round data from January to December 2018. This comprised of all 121 AMS recommendations in 91 patients aged between 1 month and 18 years that occurred during the inclusion period. If there was more than one recommendation made regarding the one antimicrobial (i.e. dose too high and antimicrobial spectrum too broad), these were assessed independently as two separate risk ratings. The results from each pharmacist were compared to ensure consistent application of both tools. Discrepancies were independently reviewed by a paediatric infectious disease physician and the final risk rating was allocated based on the most common score between the three reviewers.

#### **RESULTS**

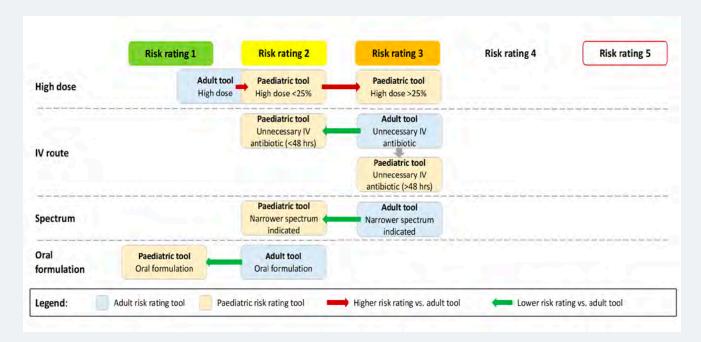
# Part A: Modifying the adult tool for the development of a paediatric tool

Four specific areas required risk rating changes when modifying the adult tool for paediatric use (Figure 1 and Figure 2). No changes occurred in risk ratings 4 (high risk) or 5 (catastrophic risk).

Inappropriate antimicrobial prescribing relating to excessive dosing were classified as risk rating 1 or 2 using the adult tool, but increased to 2 or 3 using the paediatric tool. The paediatric tool classified dose recommendations as a risk category of 2 for doses within 25% of local guidelines and doses greater than 25% above local guidelines were given a risk categorisation of 3.

Antimicrobials prescribed by the IV route for less than 48 hours were classified as risk rating 2 and durations of IV antimicrobials greater than 48 hours were classified as risk rating 3 in the paediatric tool. Irrespective of duration, all inappropriate antimicrobial prescribing relating to the IV route were classified as risk rating 3 in the adult tool. Furthermore, the paediatric tool classified inappropriate IV antimicrobial prescribing relating to spectrum as risk rating 2 as opposed to 3 in the adult tool. For oral antimicrobials relating to spectrum, duration, and unnecessary use, inappropriate antimicrobial prescribing was classified as risk rating 1. This was reduced from risk rating 2 when using the adult tool.

Risk Rating	Criteria
Low risk (1) If no action is taken, there is low risk of harm or treatment failure	<ul> <li>Any recommendation related to topical antimicrobials</li> <li>Unnecessary or too long (oral antimicrobials as per local guidelines)</li> <li>Spectrum too broad due to initial choice or microbiological findings (oral antimicrobials)</li> </ul>
Some risk (2) If no action taken, there is some risk of harm	<ul> <li>Unnecessary or too long (IV antimicrobials &lt;48 hours beyond recommended duration), including IV to oral switch</li> <li>Spectrum too broad due to initial choice or microbiological findings (IV route)</li> <li>Dose too high but within 25% of recommended dose as per local guidelines</li> <li>Dose too low as per local guidelines but risk of treatment failure is low</li> </ul>
Medium risk (3) If no action taken, there is a risk of harm	<ul> <li>Unnecessary or too long antimicrobial (IV &gt;48 hours beyond recommended duration), including IV to oral switch</li> <li>Dose higher than use in adults or dose exceeding 25% of recommended dose as per local guidelines</li> </ul>
High risk (4) If no action taken, there is a risk of treatment failure or clear risk of harm	<ul> <li>Unnecessary or too long antimicrobial (any) if patient has risk factors for increased harm</li> <li>Spectrum too narrow due to initial choice or microbiological findings (both IV and oral) leading to potential treatment failure</li> <li>Dose too low and risk of treatment failure.</li> <li>Dose too high if patient has risk factors for increased harm</li> <li>Prescribing an antimicrobial despite contraindication due to age of patient</li> <li>Incorrect route and risk of treatment failure</li> </ul>
Catastrophic (5) If no action taken, there will be immediate and severe consequences for patient	<ul> <li>Allergy mismatch - prescribed despite severe/immediate allergy</li> <li>Under-treatment with risk of mortality or morbidity</li> </ul>

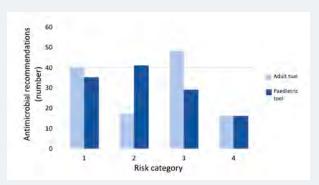


**Figure 1 (top).** Modified paediatric antimicrobial stewardship risk rating tool

**Figure 2 (bottom).** Summary of changes made to the adult risk rating tool for the development of the paediatric specific risk rating tool. No change was made in risk categories 4 (high risk) and 5 (catastrophic).

# Part B: Applying the adult and modified paediatric tool in paediatric patients

A total of 121 recommendations were reviewed and of these, 45% (n = 54) had a reduced risk rating with the application of the paediatric tool (Figure 3). With the application of the paediatric tool compared to the adult tool, 19% (n = 23) of all recommendations received a higher risk rating. The same risk rating was classified across both tools in 36% (n = 43) of recommendations.



**Figure 3.** Comparison of risk categorisation of antimicrobial stewardship recommendation from both the adult and paediatric risk ratings tools. 1 = low risk, 2 = some risk, 3 = moderate risk, 4 = high risk. No recommendations classified as risk rating 5 (catastrophic) were evaluated.

#### Decreased risk rating when comparing the adult to the modified paediatric tool in paediatric patients

For the 17 recommendations classified as risk rating 2 with the adult tool, 82% (n = 14) were reduced to risk rating 1 when the paediatric tool was applied. Of the 48 recommendations classified as risk rating 3 with the adult tool, 75% (n = 36) and 8% (n = 4) were reclassified to risk rating 1 or 2 respectively, with the paediatric tool.

Increased risk rating when comparing the adult to the modified paediatric tool in paediatric patients

Of the 40 recommendations given a risk rating of 1 using the adult tool, 8% (n = 3) and 50% (n = 20) were reclassified to risk rating 2 or 3 respectively when the paediatric tool was applied.

No change in risk rating when comparing the adult and modified paediatric tool in paediatric patients

There was no difference in the proportion of recommendations classified as risk rating 4 between the paediatric and adult tools.

#### **DISCUSSION**

Antimicrobial dosing in the paediatric population is highly complex and dependent on weight, age, as well as physiological factors that change rapidly during a child's development.1 Consequently, dosing errors, particularly the use of excessive doses, are considered to pose more risk to children due to their increased susceptibility to adverse effects.9 This concept was illustrated in our study, where all increases in risk rating from the adult to the paediatric tool for risk categories 1 to 3 were attributed to recommendations relating to excessive doses for both IV and oral routes. Recommendations relating to excessive doses were categorised as a risk 1 or 2 in the adult tool but when the paediatric tool was applied, the risk rating was re-classified as either 2 or 3, dependent on the degree of variation from local guidelines. It's important to note that clinical judgement needs to be executed where incorrect doses have a high risk of harm to the patient and/or treatment failure. In these extreme cases, the risk rating would be classified the same (risk category 4 or 5) across both the adult and paediatric tools.

Special consideration was given regarding how to categorise the risk of prolonged IV antimicrobial use in paediatric patients. Commencement of empiric IV antimicrobials for suspected sepsis is common in children due to clinical presentation being variable and often non-specific. However, cessation of IV therapy is common at 48 hours once microbiological findings are confirmed (i.e. where viral illness is confirmed).<sup>10</sup> Additionally, peripheral venous catheter complications, such as infections, are time dependent and are more likely to occur with prolonged IV antimicrobial durations (beyond 48 hours).<sup>11,12</sup> Therefore, a large proportion of recommendations relating to IV therapy that had not exceeded 48 hours and were classified as risk rating 3 with the adult tool were reduced to risk rating 2 with the paediatric tool. Beyond 48 hours of IV therapy, both tools classified these types of recommendations as risk category 3. Furthermore, as clinical diagnosis can be challenging on initial presentation, paediatric patients who present with suspected serious illness receive short durations of empirical therapy with broad-spectrum antimicrobials until a diagnosis is confirmed.<sup>13</sup> The paediatric tool classified these types of recommendations as lower risk (risk category 2) than in the adult tool (risk category 3).

In the majority of cases, duration and unnecessary use of oral antimicrobials and the risk posed to both adult and paediatric patients, is considered to be less than IV due to the absence of cannula-related infections and thrombophlebitis.<sup>14</sup> To reflect this, as risk rating

of IV antimicrobials was reduced in the paediatric tool, we subsequently reduced oral antimicrobial risk rating to 1 in the paediatric tool. This risk rating was reduced from either 2 or 3 in the adult tool. A large proportion of the results demonstrating a decrease from a risk category of 2 to 1 using the paediatric tool are attributed to recommendations relating to oral antimicrobials. Recommendations with a risk rating of 1 for oral antimicrobials is specific to spectrum, duration, and unnecessary use whereas recommendations relating to dose are classified as higher.

Risk categories 4 and 5, defined as high risk and catastrophic respectively, were the same across both the adult and paediatric tools. The only variation across the tools in categories 4 and 5 was the addition to the paediatric tool classifying age-related contraindications (i.e. ceftriaxone use in neonates) as risk rating 4. This demonstrates that the most serious cases of inappropriate antimicrobial use were perceived equally and that high-risk categories for antimicrobials do not require population specific considerations.

The application of the two tools to AMS recommendations demonstrated variation in classification across risk categories 1 to 3. The variation in risk categories 1 to 3 suggests antimicrobial prescribing risk varies between adult and paediatric population and a paediatric specific risk rating tool may be one strategy to accurately assess risk in this population.

Further research on the validity of a paediatric specific risk rating tool is required.

Implementing an antimicrobial risk rating tool allows AMS services the ability to quantify the risk of prescribing practices and streamlines communication channels between AMS services and prescribers. Continued development and evolution of this practice, alongside research into best use and evaluation of the tool in AMS services, may help optimise future patient outcomes.

There were several limitations in this study. The paediatric risk rating tool is designed to aid risk classification, and clinical judgment needs to be executed when applying the tool and should be done so on a case-by-case basis. Variation in risk perception will differ due to the subjective nature of antimicrobial prescribing. There are many factors that will influence perceptions of risk and there is likely to be inter-individual variability in the prioritisation of these factors. For these reasons the reproducibility of the results of this study are likely to be varied dependent on the researchers' individual risk perception. The lack of dedicated resources available to

this project resulted in the development of the paediatric risk tool based upon the opinion of a few clinicians with experience in paediatrics, AMS, and infectious diseases. Another limitation of this study is the comparison of risk ratings between the adult and paediatric tools. There was minimal input from the team that developed the adult risk tool and therefore the risk ratings applied from the adult tool were the authors' interpretations of the tool.

#### CONCLUSION

Risk associated with inappropriate antimicrobial prescribing is often perceived differently in adult and paediatric populations. The use of a population-specific risk rating tool is one strategy to minimise variation and promote a consistent approach to antimicrobial use. This study demonstrated that many AMS recommendations were considered to pose lower risk in paediatric patients when assessed with a paediatric risk rating tool compared to an adult risk rating tool, however there were specific cases where a higher rating was required. This highlights the importance of developing a validated risk rating tool specific to paediatric populations. •

#### **ETHICS STATEMENT**

This project was approved as a quality and service improvement project involving collection, use, and disclosure of data in a de-identified format to be conducted at Monash Health (Reference number: RES-19-0000-316Q).

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## Could your workflow be costing you reimbursement? A re-audit post-intervention of missed dispensing for 10 high-cost parenteral cancer medicines

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#### **ABSTRACT**

**BACKGROUND:** Accurate dispensing of cancer medicines is imperative for Pharmaceutical Benefits Scheme (PBS) reimbursement and the financial viability of healthcare services. For many pharmacies, there is a risk of parenteral cancer medicines being supplied, but not dispensed (termed 'missed dispensing') because they are ordered (prescribed), clinically verified, labelled, and released using software other than the dedicated dispensing software. A 2018 audit at a cancer services pharmacy audited 10 parenteral cancer medicines and found nine of 891 doses were a missed dispensing which equated to over \$76,000 in lost revenue.1 Recommendations from the 2018 audit included an intervention of a sequential four-step process, supported by a pharmacy assistant as an additional resource, and a re-audit post-intervention.

**AIM:** To determine if the recommended four-step process results in less missed dispensing and improved PBS reimbursement accuracy.

**METHOD:** A retrospective re-audit post-intervention was carried out over a four-week period in 2019. Using dispensing software iPharmacy and the oncology information management solution CHARM, the date, time, and order of the four steps of dispensing, releasing, authorising, and administration for doses of 10 cancer medicines was collected. The number and value of any missed dispensing was recorded and compared to the 2018 audit.

**RESULTS:** No missed dispensing occurred in the representative sample of 339 doses, and therefore no loss of PBS reimbursement. While the four steps were completed 100% of the time, the steps were not always completed in the correct sequence.

**CONCLUSION:** The four-step process improves PBS reimbursement accuracy and should be continued; however, reinforcing the recommended sequence of steps may further mitigate the risk of missed dispensing. This research highlights the importance of workflow consideration and auditing.

#### INTRODUCTION

Cancer is a major contributor to morbidity and mortality in Australia.<sup>2</sup> During the past few decades, the paradigm for cancer treatment has evolved from relatively nonspecific chemotherapies to targeted therapies, and more recently, to immunotherapies.<sup>3,4</sup> Cancer medicines are among the highest costing medicines, many of which cost an excess of \$2000 AUD per dose.<sup>5</sup> While the high cost of cancer medicines is multifactorial, a significant proportion of the cost is attributed to drug development, manufacturing, clinical trials, and patenting.<sup>6,7</sup>

Depending on funding arrangements and the indication, some Australian hospitals and healthcare institutions can claim reimbursement for cancer medicines listed on the Pharmaceutical Benefit Scheme (PBS).<sup>8</sup> For these hospitals and healthcare institutions, PBS subsidy is imperative for financial viability, and as such any potential for errors that pose a risk to reimbursement should be mitigated. At the Princess Alexandra Hospital (PAH) Cancer Services Pharmacy, the PBS claim for reimbursement for a cancer medicine is generated at the time the item is dispensed (mostly by paperless

dispensing) via automatic messaging and reimbursed by the Australian Government post the claim period closing.

An audit for 10 high-cost cancer medicines, including medicines such as pembrolizumab and ipilimumab, was completed at the PAH Cancer Pharmacy in 2018 to determine the total number of missed dispensed prescriptions (termed 'missed dispensing') and the related missed reimbursement. When preparing parenteral cancer medicines at the PAH, like many other hospitals and health care institutions in Australia, a different software is used for processing compounded doses than is used for dispensing and claiming PBS reimbursement. Hence to obtain a patient label for the medicine, the medicine does not need to be dispensed in the dispensing software first (in the case of the PAH, iPharmacy [Dedalus Global, Milan, Lombardy, Italy]), but rather in the production unit software (in the case of the PAH, CHARM [Citadel Heath, Melbourne, Victoria, Australia]). Some of the cancer medicines are purchased as compounded doses from external suppliers, and again, dispensing is not required to obtain a patient label, as these compounded medicines are ordered patient-specific and therefore contain a medicines label. As such, the dispensing of the cancer medicine can occur even after administration to the patient. It is therefore possible for a dispensing error to occur, by way of a missed dispensing.

Despite safeguards, hospitals are subject to a high incidence of errors which are often multifactorial.9,10 A systematic review by Aldhwaihi et al. identified four main groups of contributing factors to dispensing errors occurring: work environment, product, team, and task.10 More specifically, the most common work environment factors contributing to dispensing errors were high workload and insufficient staffing. These were two of the factors identified in the 2018 audit that contributed to missed dispensing, as the dispensing was de-prioritised ahead of other more acute tasks, and therefore commonly occurred retrospectively.<sup>1,10</sup> At the audited hospital pharmacy, paid overtime was often required to catch up on the dispensing.1 Another work environment contributing factor identified by Aldhwaihi et al. was "protocols not followed".10 It was found during the 2018 audit that no work instruction (or 'protocol') existed for the stepwise processes required to complete the task including dispensing, and this was thought to be a contributing factor to the missed dispensing. A successful business case submission in 2019 demonstrating how Weighted Activity Unit (WAU) funding could be generated from the pharmacist clinic service resulted in the funding of an extra pharmacy assistant (one full-time equivalent). The rationale behind the extra pharmacy assistant, among

other priorities, was to improve the workflow between the cancer clinic and dispensary. This extra staff resource has helped to address the previously identified work environment factors contributing to missed dispensing by reducing workloads and increasing staffing. To address protocols not followed, the 2018 audit findings recommended a stepwise process be implemented.<sup>1</sup>

In September 2019, a four-step process comprising of dispensing (by the pharmacy assistant), releasing (final checking by the pharmacist of the cancer medicine against the order and release using nondispensing software), authorising the dispensing (by the pharmacist, using dispensing software) and administration of the cancer medicine (by nursing staff) was implemented. It is thought that completing the dispensing process prior to the medicine being delivered to the ward for administration to the patient will mitigate missed dispensing. The previously discussed successful business case enabled a change in the service model using the additional staff resource with the aims being to optimise the workflow from the clinic to the Cancer Pharmacy and facilitate dispensing and authorising, prior to delivery of the medicine.

This study was a re-audit to evaluate if the recommended and implemented stepwise workflow process has been successful in reducing the number of missed dispensing and associated loss of PBS reimbursement. The results were used to inform whether the recommended stepwise workflow should be continued.

#### **METHOD**

#### **Study Design**

The design of this study was a retrospective re-audit post-intervention. The eligibility criteria included patients who had a parenteral cancer therapy order prescribed in CHARM within the four-week timeframe of 16 September 2019 to 13 October 2019 (inclusive). Patients also had to have been prescribed one or more of 10 selected high-cost, PBS eligible cancer medicines. The 10 highcost medicines audited are shown in Table 1. These 10 cancer medicines are the same 10 medicines from the 2018 audit. For the re-audit, a representative sample of 339 doses, from 218 patients, was audited within the designated timeframe to evaluate whether the recommended and implemented workflow decreased the number and value of missed dispensing. The incidence of missed dispensing in the re-audit was compared to the initial audit (Table 2). In addition, the four-week period was analysed by weekly breakdown to investigate if there was higher adherence to the correct workflow as the weeks went on throughout the duration of the audit.

Medicine Name	
Pembrolizumab	Trastuzumab
Rituximab	Nivolumab
Ipilimumab	Cetuximab
Pertuzumab	Bortezomib
Bevacizumab	Azacitidine

Table 1. The 10 audited high cost parenteral cancer medicines

Year	Representative sample size (dispensing)	Number of missed dispensing	Percentage of missed dispensing	Total cost of missed reimbursement
2018	891	9	1%	\$76,783.86
2019	339	0	0%	\$0.00

Table 2. Results of the initial audit and re-audit post-intervention of missed dispensing of 10 high cost cancer medicines

The table shows that there was no missed dispensing, and as a result no cost of missed claims for reimbursement that occurred within the selected timeframe (16/09/2019-13/10/2019) of the re-audit. This is compared to an audit of 891 doses in 2018 which resulted in 1% (n = 9) of missed dispensing, incurring a cost of \$76,783.86 in missed reimbursement.

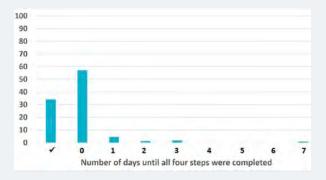
#### **Data Collection**

The required data was obtained from the oncology information management solution, CHARM; pharmacy dispensing system, iPharmacy; and integrated electronic medical records (ieMR [Cerner, North Kansas City, Missouri, USA]). Each patient's hospital number was recorded in a password protected Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA) data collection tool with a patient identifying number. The deceased date (if applicable) of a patient was recorded to determine if a missed dispensing could still be dispensed (pending the prescription had not expired). On a separate password protected Microsoft Excel data collection tool, the de-identified information collected included: the high-cost parenteral cancer therapy and dose, treatment cycle and day, and the date and time of each of the four steps of the cancer medicine being dispensed, released, authorised, and administered (or the date it was intended to be administered, since the majority of cancer therapies are still eligible for PBS reimbursement

under the Efficient Funding of Chemotherapy [EFC] program, if there was an intention to treat the patient prior to them not proceeding). Dispensed refers to when the medicine was dispensed by either a pharmacy assistant or pharmacist in the iPharmacy software (if the pharmacist carries out the dispensing, the authorising [the check of the dispensing in iPharmacy] occurs at this same step). Released refers to when the medicine is released in the CHARM software, after this command is given, a green tick appears next to the patient's name and particular cancer medicine and indicates it is ready to be delivered to Cancer Services Daycare Unit for administration to the patient. Authorised denotes when the medicine was checked and authorised by a pharmacist in iPharmacy. Medicine administration denotes when the medicine was administered by a nurse to the patient and recorded complete in CHARM. In this study, we have assumed that a PBS claim results in PBS reimbursement. Any lost revenue from a missed dispensing was determined by using PBS revenue amounts in iPharmacy.

#### **RESULTS**

339 doses of the 10 high-cost cancer medicines prescribed between 16 September 2019 to 13 October 2019 (inclusive) for 218 patients were audited. There was found to be no missed dispensing (Table 2). However, it was identified that the recommended four steps were only being followed in the correct order 34.2% of the time, as illustrated in Figure 1. The highest incidence of incorrect workflow processes occurred on the same day that the medicines were released from the pharmacy to be administered.



**Figure 1.** The implemented four-step process for dispensing, releasing, authorising, and administering cancer medicines still resulted in an incorrect workflow process, most of the time.

A bar graph illustrates that there was still a high incidence of an incorrect workflow processes present within the selected timeframe (16/09/2019–13/10/2019).

'  $\checkmark$ ' represents correct workflow sequence of steps; '0' represents incorrect sequence of steps, but all steps completed on the same day.

#### **DISCUSSION**

As described earlier, the previous audit of 10 selected high-cost cancer medicines at the PAH Cancer Services Pharmacy in 2018, found that 1% of cancer medicines were not dispensed. All of the 891 doses of the representative sample were eligible for PBS reimbursement at the time of administration and the 1% of missed dispensing (nine doses) equated to a missed reimbursement total of \$76,783.86. Most of this missed reimbursement was able to be retrospectively dispensed and reimbursed with all but one dose unable to be reimbursed due to the patient being deceased (reimbursement is not able to be claimed for deceased patients). The results of this re-audit showed that the four-step workflow process implemented contributed to a reduction in both the number of missed dispensing (n = 0)and the loss of reimbursement in comparison to the 2018 audit for the selected 10 high-cost cancer medicines.

Analysis of the weekly breakdown demonstrates a consistent level of adherence to the order of steps, rather than an improved adherence to the four-step process over time (Figure 2). With the high proportion of occurrences of the four-step process being carried out in the incorrect order (for example, the cancer medicine being released before being dispensed) but all steps completed on the same day, it suggests an urgency to carry out the release step before dispensing, as in many cases, the time in between the release, dispensing, and authorising steps were within minutes of each other. This is not surprising, as it is expected that dispensing and/ or authorisation will be completed as soon as possible, post-release from the pharmacy. If the dispensing is not completed on the same day, it introduces a risk of the CHARM prescription being misplaced or filed before dispensing occurs. There were no known issues with the timeliness of prescriptions being written and patient bookings that could have contributed to carrying out the four-step process in the incorrect order. In addition, the prescription cannot be dispensed if the patient passes away prior to dispensing, further emphasising the importance of adherence to the four-step process.

As described above, analysis of the weekly breakdown of the four-step process revealed no improvement in adherence to the four-step process over the course of the audit. There are potentially many confounding factors that cannot be ascertained such as staffing levels, available time to carry out the four-step process in the correct order, and workload issues on the particular audited days, that may have played a role in this outcome.

It is evident that the new four-step process is one that is sustainable, pending work environment factors such as staff resources and workload remain stable, and could assist in mitigating the risk of missed dispensing. However, there is still room for improvement, especially with regards to ensuring dispensing the medicine is the first step carried out. This new process is accommodating to all staff — irrespective of their experience, as a written work instruction exists and can be competently carried out with the usual skills of a pharmacy assistant with a minimum qualification of Certificate III in Hospital/ Health Services Pharmacy Support. Continued education should be completed to ensure that all dispensing is not only completed properly but are also completed using the correct workflow process. The outcome of this is ideally completely mitigating the occurrence of missed dispensing. However, there is a known limitation of the implemented four-step process, which is utilised for both non-PBS and PBS dispensing, pertaining to non-PBS dispensing. At the cancer pharmacy audited, for non-

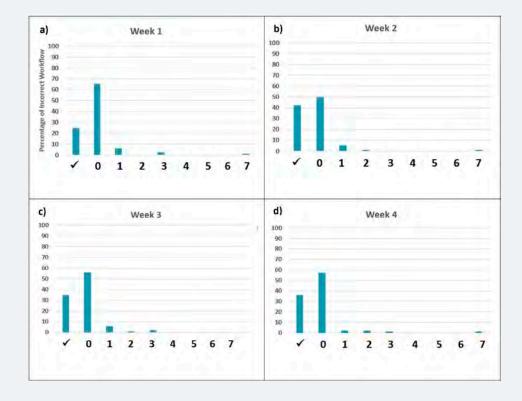


Figure 2. The implemented four-step process for dispensing, releasing, authorising, and administration of cancer medicines resulted in an incorrect workflow process most of the time, in each week of the re-audit.

A bar graph illustrates that there was still a high incidence of an incorrect workflow process, on a weekly basis, throughout the duration of the re-audit. (a), (b), (c), and (d) represent the incidence of incorrect workflow in week one, two, three and four, respectively.

PBS dispensing, there is a stock holding attached to the particular cancer medicines. If there is no medicine stock available in the dispensing system at the time of dispensing due to stock not being receipted, the full sequence of steps cannot be completed on the same day which introduces the risk that a step may be missed.

In terms of other limitations of the study, firstly, the reaudit period was just four weeks (the first four weeks of the new workflow and additional staff resources) and the number of doses audited was 339, compared to the larger 891 doses audited in the initial audit in 2018. A further possible limitation to the results reflecting favourably in the re-audit, was that staff may have been vigilant with the particular 10 high-cost medicines, following the loss of over \$76,000 from the initial audit.

#### **CONCLUSION**

The result of an extra pharmacy assistant from a successful business case submission enabled the implementation of a new four-step dispensing process. This new process was successful with the outcomes that no dispensing and associated claim for PBS reimbursement is being missed. There is room for improvement in staff adherence to the correct order of steps to mitigate risk, which can be addressed though ongoing staff education, staff competency assessment, and further audit. Finally, this study may be relevant to other pharmacies who similarly do not have the requirement to dispense the parenteral cancer medicine as the first step (due to a label for the medicine not being required from that step), prior to release from the pharmacy and administration to the patient. Such pharmacies may benefit from an audit of current workflow, and potentially, a re-audit of a trial workflow, to evaluate their process.

#### **ACKNOWLEDGEMENTS**

Special gratitude is expressed to Rebecca Kele, Pharmacy Assistant, who assisted with data collection for this research.

#### **ETHICS STATEMENT**

Metro South Hospital and Health Service Human Research Ethics Committee (MSHHS HREC) ethics was obtained for this study prior to the commencement of the project (MSHHS HREC: LNR/2019/QMS/57975).

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# **Evolving the structure, role, and function of the Medicines Management Governance system at an Australian tertiary hospital**

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#### **ABSTRACT**

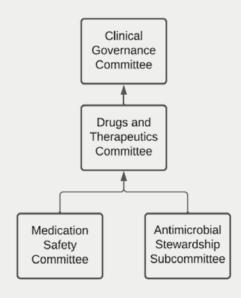
This article aims to share the experience of a tertiary Australian Hospital regarding the evolution of the structure, role, and function of the Medicines Management Governance system over the course of several years. The key role of pharmacists is highlighted. While many useful standards and resources exist, there is a lot of work and expertise required to understand and transform governance systems to align with these standards. Pharmacists are uniquely placed to understand, lead, and translate the required standards of practice. The authors hope that this information will prove useful to peers who may be embarking on similar reforms of the medicines management governance system within their own organisations.

#### INTRODUCTION

Hospital Drugs and Therapeutics Committees (DTCs) are faced with the important challenge of governing medicines management in a complex environment to eliminate or mitigate risks. These challenges can be amplified by inadequate human resource allocation and the absence of contemporary tools and technologies to optimise process efficiency. Members of DTCs are often recruited on a volunteer basis and have limited time to contribute. Some of the present-day issues and challenges that DTCs face are:

- Increasing requirements for Medicines Management Policy Governance
- Increased volume of medicines being prescribed either via formulary request or Individual Patient Approval/Use (IPA or IPU)
- Medicines Access Programs (MAP) governance including understanding any contractual obligations with these requests
- Advising on and reviewing clinical guidelines through clinical governance structures
- Management and monitoring of clinical incidents and responding to trends in medicine- related errors.

An effective and traditional governance structure for medicines management historically included a DTC operating as the peak governance body with support from focused subcommittees, such as a Medication Safety Subcommittee and an Antimicrobial Stewardship Subcommittee (Figure 1).<sup>1,2</sup>



**Figure 1.** Traditional Medicine Management Governance Structure

Pharmacists who provide support to an organisation's clinical governance structure via either a DTC or Medication Safety Committee (MSC) (or equivalent) play an important role. They contribute specialist

medicines knowledge to ensure the organisation's medicines management governance structure is performing to the appropriate standards, including alignment with the Council of Australian Therapeutic Advisory Group (CATAG) *Achieving effective medicines governance*<sup>2</sup> and the *National Safety and Quality Health Service Standards* (NSQHS) Standards 1 and 4 — Clinical Governance and Medication Safety.<sup>3</sup>

Pharmacists are embedded in diverse medicines management processes, and as medicines management experts, need to navigate varying complexities such as clinical, safety, financial, and regulatory requirements. Early in their training, pharmacists are orientated to the importance of process and legislation as these are fundamental to the requirements of a practicing pharmacist. Successful and functional clinical governance structures also depend on these requirements, and pharmacists are pivotal in understanding, upholding, and translating these standards. The importance of pharmacist involvement in medicines management governance is further acknowledged in the Society of Hospital Pharmacists of Australia's 'Standards of Practice for Medication Safety' that recommend these programs are led by pharmacists.4

These governance reforms were undertaken at a large 600 bed specialist tertiary hospital in Western Australia. Historically, the organisation's DTC had operated as a clinical reference group with a specific focus on evaluating clinical appropriateness of medicines via formulary submissions, Individual Patient Approvals (IPA), and clinical guideline review. In 2018, reform of the organisation's clinical governance structure revealed a lack of strategic focus and priorities relating to the governance of medicines management. At the time, strategic functions around medicines management governance, including policy governance, were not delegated to the DTC. Instead, they were governed by the hospital executive, with advice sought from the DTC when required. These reforms, however, acknowledged that this work should be devolved to the DTC.

The new responsibilities were scheduled to be transferred and absorbed by the DTC on top of existing responsibilities and workload, without a corresponding increase in support or review of membership to ensure the DTC had the capacity, capability, and expertise to deliver these new activities. The inability to recognise the importance of capability transformation through evidence-based change management approaches, and their relation to human resource principles is not unique to this site — or indeed overseas health care settings — and is critical to supporting functional

clinical governance structures. Internationally published studies indicate the absence of a proactive approach to build a suitable foundation from which a new structure and associated responsibilities can flourish, is evident within healthcare organisations.<sup>5</sup>

Requests for additional resources to support important ongoing medicines management governance were not supported. As such, an innovative approach to build capacity to offset the resourcing deficit was required. After consideration, addressing this need through the governance structure was considered the most appropriate approach.

#### **METHODS**

We considered recognised foundational change management strategy and tactics and looked to translate these as applicable to the healthcare setting.<sup>6,7</sup> The site level clinical governance reforms were recognised by the organisation's Pharmacy Leadership (comprising the Head of Department, Executive Officers of DTC, and the Medication Safety Pharmacist) as an opportunity to address many longstanding gaps and risks, provided change could be adequately managed to optimise operations within the new structure. A comparative review and reconciliation of the current medicines management governance structure of the site against the CATAG Achieving effective medicines governance guiding principles<sup>2</sup> was conducted to identify gaps and appropriate reforms required to improve the function of the medicines management system. Colleagues were consulted in other health services across Australia to identify current and contemporary themes and solutions relating to medicines management governance structures. It was hypothesized that by improving systems, skills, and associated processes to better align with relevant standards, the resultant medicine management governance structure would be more accountable.

Further structural reforms were designed that aligned with best practice recommendations and contemporary themes, as well as solutions which had been previously identified in the discovery phase of the reforms. Proposed solutions were subject to risk versus benefit analysis to demonstrate that potential or perceived risks could be mitigated and off-set with greater efficiencies. Findings and proposed solutions were summarised and presented in writing and in-person presentations to executive sponsors and relevant committees for discussion and decision. Discussions and presentations were tailored to their relevant audiences. For example, discussions with executive sponsors were centred around improved assurance and risk-mitigation

capability while conversations with committees focused on reducing their workload by clarifying and adapting the workload and scope of the relevant groups in line with the skills of the membership. The entire reform process understood and acknowledged the prevailing leadership style and what was required to align with shared values including analysing and reforming skills, staff, and systems to accompany the strategy and structure, as required to achieve successful change.<sup>6</sup>

Following approval, changes were implemented with a plan and approved and overseen by the executive sponsors which included formulation and amendment of the terms of references, KPI reporting requirements, and targeting membership more appropriately against the newly defined scope.

#### **RESULTS**

The key theme identified was the need for medicines management governance to operate strategically: providing leadership and risk management functions, whilst also retaining the pre-existing clinical reference group function.

Critical to this task was comparing the current operation and function of the organisation's DTC against the CATAG principles.<sup>2</sup> It was identified that additional subcommittees of the DTC may be required to assist with workload and allow the new task of medicines policy governance to be undertaken. Specifically, CATAG guiding principle statement 6 states that DTCs may establish subcommittees to manage specific tasks, such as<sup>2</sup>:

- Medication Safety
- Antimicrobial stewardship
- Drug Use Evaluation.

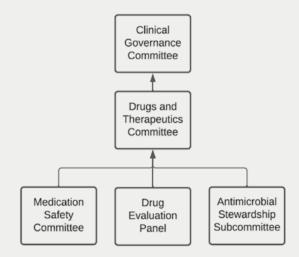
It was considered appropriate that a Drug Evaluation Group could perform the pre-existing functions of the clinical reference group as another subcommittee of the DTC. This would allow a newly formed DTC to perform more high-level strategic functions relating to the governance of medicines management. It was acknowledged that the membership (staff) and skill set already operating under the title 'DTC' was best suited to a subcommittee of the DTC. As a result, the pre-existing DTC was renamed the Drug Evaluation Panel (DEP) with the following tasks delegated to the DEP by the DTC:

- Non-Formulary prescribing requests (IPA and MAP)
- Clinical guideline review
- Clinical audit review and action.

A new DTC was established, and the membership tailored to ensure strategic functions were carried out in the best interest of reducing organisational risk relating to the medicines management cycle (Figure 2):

- Director of Clinical Services (Sponsor and Chair)
- Director of Nursing
- Head of Pharmacy Department
- Director of Safety, Quality and Performance
- Chairs of Respective subcommittees e.g. DEP, Antimicrobial Stewardship Subcommittee, and Medication Safety Subcommittee
- Executive Officer and Senior Pharmacist (Secretariat).

The new DTC assumed overarching responsibility of medicine management governance and monitors the performance of individual subcommittees through a pre-determined set of Key Performance Indicators (KPIs). The DTC provides central oversight as the organisation's peak medicines management body.



**Figure 2.** Proposed Medicines Management Governance Structure with additional subcommittees.

The updated Terms of Reference clearly delineate the remit and scope of the DTC with operational medicines management issues delegated to the relevant subcommittees. This allows the DTC to consider and focus on strategic management of medicines-related issues such as overseeing policy development and performance (KPIs). For example, the ongoing monitoring of trends in medication incidents is delegated to the Medication Safety Committee, with regular reports provided to the DTC. The DTC has also delegated policy implementation to the relevant subcommittee.

#### **DISCUSSION**

Medicines management governance structures and functions are well supported by national and international best practice recommendations.<sup>1-4</sup> Formation of DTCs may predate many of the contemporary standards that are available. It is suggested that hospitals may need to review their structures and function as evidenced above to ensure they align with best practice recommendations and standards. Our contemporary example of DTC reform was prompted by the hospital's review of its clinical governance structure and led by the organisation's Pharmacy Leadership. As the role of pharmacists in clinical governance continues to expand and adapt, governance structures must have the capability to support new activities and mitigate the risks of increasing demand. Acknowledging the human resource implications these reforms create will assist to support appropriate medicines governance.8

At the time of writing, these reforms had gained good support from the hospital executive and administration team and the DTC was successfully overseeing the implementation of multiple area and state-wide medicines management policies. Clarifying scope and supporting the work required through creation of an additional committee allowed the DTC to develop capacity to perform a more strategic focus and become more aware of risks relating to the medicines management system. The interface between the DTC and its parent Clinical Governance Committee (CGC) has remained static but the CGC now has greater assurance and expectation that the DTC is functioning and monitoring organisational risks effectively. Through the new structure, the DTC and its subcommittees report with more rigour and frequency with annual KPIs and an activity schedule comprising reporting every three months.

It is anticipated clinical governance systems, particularly in relation to digitisation, will expand in their complexity as medicines management functions continue to diversify. Medicines management governance has become more robust; however, we recognise the need to be agile, dynamic, and strategic about new risks and how they must be managed.

#### **ETHICS STATEMENT**

Ethics approval was not required for this article.

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## Vitamin A use in pregnancy

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#### Introduction

In pregnancy, Vitamin A is essential for the development of the foetus. It aids ocular integrity and has systemic effects on the foetal skeleton and some organs. During pregnancy, a 10–20% increase in maternal vitamin A is required. The greatest need for vitamin A occurs during the third quarter of pregnancy when there is increased foetal development.

In Australia, and many other developed countries, diets usually contain adequate amounts of vitamin A and so routine vitamin A supplementation during pregnancy is not recommended.<sup>1,2</sup> Where no maternal vitamin A deficiency (VAD) exists, vitamin A supplements are of little to no benefit for the prevention of maternal and infant morbidity and mortality and excessive vitamin A intake, particularly during the first two months after conception, may have teratogenic effects such as spontaneous abortion and congenital malformations of the cardiovascular and central nervous systems.<sup>1,2</sup> Despite vitamin A not being routinely recommended for Australian women during pregnancy, some pregnancy multivitamins available in the country can be found to contain beta-carotene, a type of vitamin A, and many overseas products marketed towards pregnancy also contain vitamin A.

#### **Case report**

A medicine review was conducted for a woman who was 31 weeks' gestation. She had been living in Australia for many years however had immigrated from Sri Lanka. Prior to conception and throughout her pregnancy, the patient had been taking a Sri Lankan pregnancy vitamin that contained 2500 IU (750 mcg) of vitamin A. The type of vitamin A contained in the product was not able to be identified.

This patient had no history of bariatric surgery or other medical conditions. After review from the pharmacist, dietician, and obstetrician, the vitamin A supplement was ceased as there was no clear benefit. The dietician thought her regular diet contained adequate vitamin A. This was also confirmed with a blood test where VAD was excluded.

#### **Discussion**

In Australia, routine vitamin A supplementation during pregnancy is not recommended. However, in many developing countries, VAD is thought to affect almost 19 million pregnancies and is a major public health concern.<sup>1,2</sup> Worldwide, VAD is the leading cause of preventable blindness.<sup>1,2</sup> Therefore, vitamin A supplementation during pregnancy is recommended in areas where VAD is a public health concern.<sup>1,2</sup>

Vitamin A is vital for the development and maintenance of the embryo, healthy ocular function, and the prevention of xeropthalmia for both the mother and foetus.<sup>1,2</sup> Xeropthalmia is a term used to describe the many ocular symptoms of VAD, ranging from night blindness to more severe symptoms such as corneal xerosis, ulceration, and necrosis which can cause permanent blindness.<sup>2</sup> VAD has poor outcomes for maternal mortality and reduces the ability of the mother and baby to fight infections.<sup>1,2</sup>

Vitamin A can be stored in the liver as retinyl ester, or found as active forms such as retinal, retinol, and retinoic acid.¹ The two main sources of vitamin A are preformed vitamin A (retinol and retinyl ester) and pro-vitamin A (carotenoids including beta-carotene).¹ Preformed vitamin A can be found in animal products such as dairy, liver, and fish oils.¹ Pro-vitamin A is found in fruits and vegetables such as carrots, pumpkin, spinach, and mangoes.¹

To maintain adequate vitamin A levels in the body, the consumption of animal products containing preformed vitamin A is usually necessary as the absorption of provitamin A is generally poor. Additionally, as the absorption of vitamin A is linked to lipid absorption, vitamin A is not well absorbed for people whose diet contains minimal fat. According to the World Health Organization (WHO), plasma or serum retinol concentrations less than 0.7 µmol/L or 0.35 µmol/L indicates subclinical or severe vitamin A deficiency respectively.

In areas where VAD is a public health concern, the WHO recommends vitamin A supplementation to prevent night blindness.<sup>2</sup> During pregnancy, the recommended daily intake of vitamin A is 800 mcg.<sup>4</sup> Due to the potential

teratogenic effects associated with an excessive intake of vitamin A and use during the first two months of pregnancy, the WHO recommends that women in VAD affected areas can safely take up to 10 000 IU (3000 mcg) daily or 25 000 IU (7500 mcg) weekly after the first two months of pregnancy.<sup>1,2</sup> It is recommended that the supplement is taken for a duration of at least 12 weeks during pregnancy until delivery.<sup>1,2</sup> Importantly to note, beta-carotene, which is found more frequently in supplements than retinol and is also found in some pregnancy multivitamins available in Australia, has not been associated with congenital defects when taken at high doses.<sup>1</sup>

The recommended daily intake of vitamin A for pregnant women in Australia is 800 mcg, with the upper limit of intake being 3000 mcg daily.<sup>4</sup> The average vitamin A intake of all Australian women is estimated to be 815 mcg daily, indicating that no additional vitamin A supplementation is usually required. The exception to this recommendation is if women have had bariatric surgery.<sup>1</sup> Due to the poor absorption of vitamins, these patients might be commenced on beta-carotene supplementation.

Based on this information, it was likely that the patient involved in this case study was likely consuming approximately 5216 IU (1565 mcg) vitamin A through her diet and supplementation. Although the vitamin A supplement was ceased following the medicine review and after vitamin A deficiency was excluded, the dose was unlikely to be a major concern as it was less than the 10 000 IU daily limit recommended by the WHO. However, the supplement was used during the first 60 days of conception, so the risk of teratogenicity was still a potential.

The woman went on to have an emergency caesarean section due to foetal distress, but this was not attributed to the use of a vitamin A supplement. Thankfully, the woman

and baby appeared to be happy and well at the time of discharge with no teratogenic effects noted.

This case study highlights the variation in public health concerns across the world and the impact this may have on patients' healthcare when relocating between countries. As Australia has a diverse, multicultural population, this demonstrates the importance of reviewing patients in a holistic sense, taking into consideration cultural and societal factors, as well as reviewing the ingredients and clinical appropriateness of complementary supplements or medicines unfamiliar to the pharmacist.

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Letters to the Community is a place for members to share ideas and opinions with the rest of the Society – especially when you might not have any other forum where you can share these ideas and opinions. In the *Pharmacy GRIT* spirit, it is a place for boldness, innovation, and reports from the frontline of practice. Be candid and constructive – and be heard!

#### To the SHPA Community,

This letter aims to encourage discussion of a novel class of drug and its perioperative management. Upadacitinib is a cytokine modulator indicated for the treatment of moderate to severe rheumatoid arthritis (RA).<sup>1,2</sup> Introduced in 2020 as a selective and reversible inhibitor of Janus kinase (JAK) 1, the oral administration of upadacitinib makes it an appealing treatment option when compared to the existing market of injectable modulators. However, current guidelines<sup>3,4</sup> do not provide guidance specific to the management of upadacitinib perioperatively. In the absence of evidence-based guidance, it is hoped the experience of a recent clinical case provides an interesting contribution to an emerging knowledge base for the perioperative management of a new medicine.

The JAK family of enzymes comprise of several different subtypes, JAK 1, JAK2, JAK3, and TYK 2. They transduce cytokine mediated signals via the JAK–STAT pathway, modulating gene expression and protein synthesis. Disregulation is thought to be the basis of a variety of disease states, including RA. JAK 1 modulates inflammatory signalling and targeted inhibition will maintain anti-inflammatory effects whilst minimising effects on red blood cell, platelet production, and lymphopoiesis via JAK 2 and JAK 3 pathways. 2.5.6 As such, reducing the risk of venous thromboembolism, anaemia, and infection. This will potentially offer an advantage over the existing less selective JAK inhibitors marked in Australia, tofacitinib and baricitinib. To date there have been no head-to-head trials comparing JAK inhibitors. 2.7

A recent clinical case presents an interesting consideration to the perioperative management of upadacitinib. A 61-year-old woman presented for pharmacist pre-admission review via tele-health, prior to a cystoscopy. Presenting symptoms included recurrent UTI, straining to void, increased frequency, urge incontinence, and occasional haematuria. Relevant medical history included RA, resolved stage 1B2 squamous cell

cervical carcinoma (treated with chemotherapy and radiation in 1998), total knee replacement, sciatica, and osteoporosis. Medicines included upadacitinib MR 15mg mane (commenced 12 months ago), glucosamine, estriol vaginal cream, denosumab, and as quoted by the patient, "a nibbled corner" of a trimethoprim 300mg tablet (i.e. a significantly subtherapeutic dose of trimethoprim) as needed when UTI symptoms presented.

Although standard practice recommends withholding cytokine modulators perioperatively<sup>3,8</sup> as a new medicine, there is a lack of advice for upadacitinib. In the class of JAK inhibitors, a specific recommendation relates only to tofacitinib and suggests withholding seven days prior to surgery. It is noted that this recommendation is based on low level, indirect evidence from systematic reviews and meta-analyses of tofacitinib versus placebo. It has been suggested that this recommendation may change in the future as physician and patient experience evolves.<sup>8</sup>

Based on a reading of current literature and consultations with both the urology team and a private rheumatologist, a plan was formulated to withhold upadacitinib the morning of the procedure, restarting after two days. The patient was reluctant to withhold upadacitinib as, during a previous interruption, she had reported the return of pain within 24 hours with permanent loss of functioning in her finger. Taking in to account the once daily dosing interval of upadacitinib, the 'clean' nature of the procedure, and the patient's anxiety concerning a treatment interruption, missing one dose before the procedure and restarting two days post-procedure was deemed appropriate.

After the procedure, pharmacist follow up revealed a UTI had developed and ciprofloxacin 500mg BD was prescribed. Following two doses, the patient developed severe diarrhoea and perfuse sweating, self-reported to be the worst she has ever felt. The UTI was resolved on completion of a trimethoprim course and, the patient again reported the return of pain within 24 hours of treatment interruption. An adverse

event report was submitted to the TGA detailing the incidence of UTI and lack of efficacy within 24 hours.

Patients with rheumatic e have been found to be at increased risk of postoperative infection either due to the pathophysiology of the disease itself or due to the use of concurrent immunosuppressant therapies. The optimal strategy for managing these medicines perioperatively to mitigate the risk of infection whilst minimising disease flare is not fully known.<sup>3,4</sup> In hindsight, predisposing risk factors such as RA and immunosuppressant therapy, a long-standing history of UTI, and previous localised chemoradiation meant that post cystoscopy, bladder irritation and UTI were more likely for this patient. Potentially she may have benefited from a longer treatment interruption.

From this clinical case, the lack of efficacy with one missed dose and ongoing concerns with UTI may suggest that upadacitinib is not the most appropriate long-term RA therapy. More broadly, the appropriateness of upadacitinib in patients with a pre-disposition for UTI would certainly benefit from future research.

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