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The evolving profile of cognitive pharmaceutical services in Australia

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ABSTRACT

Globally, the availability and delivery of cognitive pharmaceutical services (CPS) by pharmacists has expanded over time. Australia has been no exception to this trend, with government funding to support the provision of certain CPS significantly increasing over the last two decades. Whilst medication management services have been consistently funded by the government for more than 15 years, fluctuations in the funding of other CPS have been observed; for example, certain disease state management CPS and introduction of funded MedsChecks. Furthermore, legislative changes have broadened pharmacists' scope of practice and the CPS provided, contributing to an increase in user-pay services. Although the literature to date has highlighted positive impacts associated with CPS on economic, clinical and/or humanistic outcomes, context-specific, real world evidence for the benefits of CPS is much needed to ensure the profession engages in evidence-based practice. The aim of this commentary is to outline the changes in CPS provision and funding within the Australian context, the existing evidence for CPS, and highlight the implications for future research.

Introduction

Community pharmacy and pharmacy staff facilitate quality use of medicines (QUM).[1] With the emergence of the concept of pharmaceutical care,[2] patient-centred care within pharmacy practice has gained momentum, challenging the traditional dispensing-oriented role of pharmacists. Evident expansion of the provision of cognitive pharmaceutical services (CPS) within the community pharmacy setting is occurring globally. In Australia, as elsewhere, a significant paradigm shift in pharmacy practice has emerged over the last several decades.

In recent years, Pharmaceutical Benefits Scheme (PBS) reforms and price disclosure, to help reduce PBS expenditure growth,[3] together with proliferation of discount pharmacy business models have led to increased financial pressures across the community pharmacy sector.[4,5] Taking into account the changing landscape of community pharmacy and the resulting financial implications, efforts have been made to explore other potential revenue sources. One important domain is increasing CPS provision. In successive surveys, a majority of Australian pharmacists have consistently perceived CPS provision and the transition towards a service-based model as a core opportunity for community pharmacy when looking ahead.[6–11] The nature and scope of CPS provision by pharmacists is evolving within the community pharmacy setting, with more pharmacists commencing further provision of CPS.[11]

The aim of this commentary is to outline the changes in CPS provision and funding within the Australian context, the existing evidence for CPS, and highlight the implications for future research to ensure that the profession engages in evidence-based practice.

CPS offered in Australian community pharmacies

In Australia, five-yearly Community Pharmacy Agreements (CPAs) between The Pharmacy Guild of Australia and the Australian Federal Government, which commenced in 1990, have secured funding to support community pharmacy initiatives in promoting QUM and the viability of the industry. For the Seventh CPA, the Pharmaceutical Society of Australia has been a co-signatory of the CPA for the first time.[12] Over the years, increased funding has been allocated to the provision of CPS in community pharmacy (Table 1).

Notably, while the Second CPA (1995–2000) pledged a modest amount of funding (up to AUD $4 million per year for CPS),[18] the 6CPA[16] effectively saw a doubling of funds pledged compared to the previous CPA to facilitate remuneration for CPS provision. This provided AUD $613 million in funding to support community pharmacy programs, which comprised many CPS[16]; AUD $50 million for the Pharmacy Trial Program[16]; along with "*access to additional funding of up to [AUD] $600 million over the Term to support new and expanded Community*

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Table 1
Summary of expanded remuneration of cognitive pharmaceutical services in Australia, as funded under the 3CPA to 7CPA.

Service(s)	Third CPA[13] (3CPA) (2000-2005)	Fourth CPA[14] (4CPA) (2005-2010)	Fifth CPA[15] (5CPA) (2010-2015)	Sixth CPA[16] (6CPA) (2015-2020)	Seventh CPA[12] (7CPA) In first financial year (2020-2021)
Medication management	Medication Management Services (MMS) (AUD $114 million), including: • Domiciliary MMS • MMS for residential aged care facilities residents • Case discussions and care planning • Pharmacist facilitators in General Practice divisions	Medication Management Review (AUD $150 million), including: • Home Medicines Reviews (HMRs) • Residential Medication Management Reviews (RMMRs) • Accreditation incentives • Pharmacy services facilitators	HMRs (AUD $52.11 million) RMMRs (AUD $70 million) Medicines Use Review (MUR) (MedsCheck) (AUD $29.6 million) Diabetes Medication Management (Diabetes MedsCheck) Service (AUD $12.2 million) Clinical interventions (AUD $97 million)	Medication management programs (AUD $178.3 million), including: • HMRs • RMMRs • MedsCheck • Clinical interventions	Medication management programs (AUD $96.4 million), including: • HMRs • RMMRs • Quality Use of Medicines in Residential Aged Care Facilities • MedsCheck • Diabetes MedsCheck
Medication adherence		See Better Community Health below	Medication continuance (AUD $1 million) Support for the provision of dose administration aids (DAAs) (AUD $132 million) Staged supply support allowance (AUD $35 million)	Medication adherence programs (AUD $189.2 million), including: • DAAs • Staged supply	Medication adherence programs (AUD $105.5 million), including: • DAAs • Staged supply
Rural and/or indigenous health	Rural initiatives (AUD $74 million) Aboriginal health services	Rural Pharmacy Allowance and Support (rural programs) (AUD $111 million) Indigenous Access (Aboriginal and Torres Strait Islander Programs) (AUD $27 million)	Rural support programs (AUD $107 million) Aboriginal and Torres Strait Islander programs (AUD $28.9 million)	Rural support programs (AUD $120.3 million) Aboriginal and Torres Strait Islander specific programs (AUD $40 million)	Rural support programs (AUD $24.6 million), including: • Rural Pharmacy Maintenance Allowance • Rural Workforce Programs Aboriginal and Torres Strait Islander specific programs (AUD $12.6 million), including: • QUMAX/S100 Support • Closing the Gap PBS Co-payment Measure • Aboriginal and Torres Strait Islander Workforce Programs
Broad funded programs	Pharmacy Development Program (AUD $188 million) (also see Other[17]) e.g. • Medicines Information for Consumers program (financial incentives for the provision of Consumer Medicines Information (CMI))	Better Community Health (AUD $192 million and supplementary funds), including: • Asthma pilot program • Diabetes pilot program • DAAs • Communicable disease prevention • Improved emergency contraception counselling • Quality Care Pharmacy Program (QCPP) • Patient medication profiling service • Practice change and education initiative scheme • Research and development • Other projects		Pharmacy Trial Program (AUD $50 million) New and expanded Community Pharmacy Programs (up to AUD $600 million)	
Other	QCPP Research and development (AUD $15 million) (relevant to the Pharmacy development program objectives) Information Technology[17]	QCPP E-Health (AUD $20 million) Financial incentives for provision of CMI	Pharmacy Practice Incentive (PPI) and Accreditation (QCPP) (AUD $75 million) Research and development (AUD $10.6 million) Supply and Pharmaceutical Benefits Scheme (PBS) claiming from a medication chart in residential aged care facilities (AUD $3 million) Electronic recording of controlled drugs (AUD $5 million)	E-Health (AUD $61 million) Program administration and audit (AUD $21.2 million) Pharmacy remuneration and regulation review (AUD $3 million)	E-Health, including Electronic Prescription Fee (AUD $18 million) Program administration, oversight and assessment (AUD $11 million)
Approximate total funds allocated to CPS (where amounts were specified in the CPA)	AUD $400 million[14]	AUD $568 million (AUD $500 million + AUD $68 million from remaining funds from 3CPA Pharmacy Development Program)	AUD $663.41 million (AUD $386.41 million (programs and services) + AUD $277 million (additional programs))	Up to AUD $1.26 billion	Up to AUD $1.20 billion (overall funding as per the five-year 7CPA)[12]

Pharmacy Programmes."[16(Subclause 6.1.2(c))] Under the 7CPA, from July 1, 2020, community pharmacies will receive an increase in funding of AUD $100 million over a five-year period, compared to the 6CPA, for program delivery.[19] This trend in increased funds allocation to CPS both reflect and enable the expansion of CPS provision.

Overall, community pharmacy practice in Australia encompasses a range of CPS types (Tables 2 and 3), which include both government-funded CPS (Table 2) and CPS offered at the discretion of individual community pharmacies that may be user-pay or "free" to the consumer (Table 3).

When examining the patterns in government funding allocations for CPS and the range of CPS, it can be seen that:

1. Certain CPS have been consistently funded over the years in Australia;
2. Shifts in the funding allocations have occurred between specific CPS across the various CPAs, with both the ceasing of funding and new allocations observed; and
3. That there is limited or no government funding allocated for certain CPS.

HMRs have been consistently funded as a CPS since 2001[23] (with RMMRs having been funded since 1997[24]). Similarly, financial support for DAA provision has been consistent, with DAAs continuing to be provided to help patients optimise medicines management and adherence, particularly in the context of polypharmacy.

Additional funding opportunities for CPS have also emerged. More recently, as an extension to medication review-related activities conducted by pharmacists, MedsChecks (medication management reviews conducted in the pharmacy[29]) were introduced as a funded CPS.[15] Although clinical interventions may be regarded as a component of usual care, a financial incentive to conduct and document clinical interventions was included in the Pharmacy Practice Incentives (PPIs) Program since 2011,[31] up until the 7CPA.[32] Such remuneration recognises and rewards pharmacists for their contribution to QUM. And despite the change in explicit funding status for clinical interventions, any that are conducted as part of MedsChecks are essentially indirectly funded as part of this service.

Although screening and monitoring initiatives which assist in the management of chronic diseases and support of a healthy lifestyle are offered by some pharmacists as part of their routine practice, government funding for such services has fluctuated over the years. For instance, asthma and diabetes chronic disease management intervention programs were funded under the 4CPA[67,68] but were not sustained as part of subsequent CPAs. However, a modified form of the 4CPA-funded diabetes service was carried over into the 5CPA-funded Diabetes Medication Management Service (Diabetes MedsCheck).[15]

In addition to funding opportunities, notable legislation changes have also enabled pharmacists to expand their roles in CPS provision in recent years, with pharmacist-administered vaccinations[40] being a key example. Others include the ability to provide absence from work certificates (under the Fair Work Act 2009[66]), and facilitate continued dispensing (legislation changed in 2012[40]).

Self-reported CPS provision by pharmacists and funding considerations

In 2012, 81% of pharmacies had reportedly delivered CPS at the time or within the year immediately prior to being surveyed.[7] CPS offered included those delivered under the PPI(s), DAAs, clinical interventions, HMRs, and blood pressure (BP) monitoring.[7] Since then, there have been several initiatives undertaken to better understand reported CPS provision in Australia.[11,69–72] Together with the expanded funding available for CPS provision in Australia, the breadth of self-reported CPS provision by pharmacists highlights the mix of funded and non-funded CPS being offered. When looking at how CPS is remunerated internationally, and where CPS is funded, it is common to see this occurring via

Table 2
Provision of key government-funded CPS in Australia: pharmacists' roles and responsibilities.

CPS type	Nature of CPS
Medication Management Programs • Home Medicines Review (HMR)[20] • Residential Medication Management Review (RMMR)[21] • Quality Use of Medicines (QUM)[22] (HMR included in the Medical Benefits Schedule in 2001[23]; RMMR services funded since 1997 in the 2CPA[24])	A medication management review is provided to an Australian resident either within their own home[20,25] (HMR) or within a residential aged care facility (RMMR).[21,26] The service consists of a review of all medications and medication-related issues and involves an interview with the patient. A report is then compiled for the patient's referring medical practitioner (which can be their general practitioner (GP) or a specialist who is able to refer), as well as other members of the healthcare team as appropriate (and in some cases, the patient), with recommendations regarding ongoing medication management issues. Each initial HMR conducted by an accredited pharmacist upon referral is eligible to be reimbursed at the rate of AUD $222.77 (as per the Program Rules published July 2020),[25] with a Rural Loading Allowance of up to AUD $125.00.[27] This amount is reimbursed directly to the provider of the service. The corresponding rate for an initial RMMR is AUD $112.65 (as per the Program Rules published July 2020).[26] The QUM service is separate to RMMRs and seeks to improve QUM within Australian Government funded residential care facilities via initiatives relevant to medication management advice, education, and continuous improvement.[22]
Medication Management Programs • MedsCheck • Diabetes MedsCheck (Implemented Australia-wide from 01 July 2012[28])	*"MedsCheck and Diabetes MedsCheck services are structured pharmacy services, which take place in the pharmacy, involving face-to-face consultations between the pharmacist and consumer. These services are designed to sit between adhoc medication reviews that occur at time of dispensing and Home Medicines Reviews (HMR)."*[29(p3)] Unlike HMRs, *"MedsCheck and Diabetes MedsCheck services are not comprehensive clinical reviews… [and] are limited by the information available at the time of the consultation."*[29(p3)] The consultation between pharmacist and consumer focuses on improving medicines use and health outcomes through education and support of self-management and medication adherence.[29(p3)] An initial MedsCheck and initial Diabetes MedsCheck are eligible to be reimbursed at the rate of AUD $66.53 and AUD $99.79, respectively.[30]
Clinical interventions[31] (Funded since July 2011 under the 5CPA[31]; however, this service is no longer funded under the 7CPA as of 1 July 2020[32])	A clinical intervention[31] is *"a professional activity undertaken by a registered pharmacist directed towards improving QUM [Quality Use of Medicines] and resulting in a recommendation for a change in the patient's medication therapy, means of administration or medication-taking behaviour."*[33] It excludes *"generic medicine substitution, routine prescription-related counselling, provision of emergency supply medicine under State or Territory law, CMI [Consumer Medicines Information] provision or professional activities directed towards improving QUM undertaken during HMR, RMMR, MedsCheck or Diabetes MedsCheck services."*[33]
Dose Administration Aids[34] (DAAs) (DAA program included in 4CPA[14,35] since 2005)	DAAs[36] facilitate the administration of medicines through the provision of packaging systems or adherence devices. They can include unit dose or multi-dose packing in which medicines are packed into

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Table 2 (*continued*)

CPS type	Nature of CPS
	a compartment/sachet/blister for individual patients.
Staged Supply[37] (service for prescribed medicines) (Funded as part of 5CPA[15] since 2010)	Staged supply[38] of medicine is the supply of medicine in instalments rather than supplying the full amount upfront. This is usually done at the request of the prescriber for certain patient groups such as those with adherence issues or those who are prone to misuse/abuse. Staged supply also offers the pharmacist more opportunity for consultation with the patient.
Continued Dispensing[39] (also known as medication continuance) (Permitted under Commonwealth law since 2012[40])	Continued dispensing or medication continuance[39] involves dispensing certain PBS medicines without a prescription. A continued dispensing PBS claim may therefore be made.[41] This service involves PBS medicines prescribed on an ongoing basis, where therapy is stable (with prior clinical review to support continuation) and it is a safe and appropriate medicine for the patient.[40]
Aboriginal and Torres Strait Islander (ATSI) Quality Use of Medicines Service[42] (Quality Use of Medicines Maximised for ATSI Peoples (QUMAX) service conceptualised and supported since the 4CPA[43] (2005-2010))	Quality Use of Medicines Maximised for ATSI Peoples (QUMAX) aims *"to improve QUM and medication compliance and to support improved access to medicines under the PBS, by addressing cultural, transport and financial barriers."*[42(p1)] Specifically, QUMAX supports efforts of eligible community pharmacies together with Aboriginal Community Controlled Health Organisations[44] to facilitate *"implementation of service-level QUM work plans. These plans can include provisions for DAA arrangements, QUM pharmacy support, HMR models of support, QUM devices, QUM education, cultural awareness and transport arrangements."*[42(p1)] In addition, the S100 Pharmacy Support Allowance[45] is paid to certain community pharmacies or hospital authorities to help provide QUM services linked with S100 supply arrangements (enabling access to essential medicines), supporting CPS provision for remote area Aboriginal Health Services.
Return Unwanted Medicines[46] (RUM)	RUM involves the collection and disposal of unwanted medicines. The not-for-profit program operates nationwide and is funded by the Commonwealth government.[47] It has been in place since 1998, with support for the program operation provided by community pharmacies in conjunction with wholesalers.[47] It also provides pharmacists with an additional opportunity to review the medicines of the person who utilises the RUM service.

fee-for-service models,[73] with governments as the key remunerating bodies.[73,74] In Australia, most government-funded CPS remuneration is provided to the respective pharmacies/pharmacy owners (with the exception of specific services, such as HMRs, RMMRs that are conducted by accredited pharmacists). Some CPS may also be directly paid for by users of the service e.g. DAAs[75] and pharmacist-administered vaccinations. However, regardless of whether or not the specific service is government funded, it is important to consider the available evidence supporting the benefits of the CPS delivered in community settings.

Economic, clinical and/or humanistic outcomes of CPS delivered in community settings: systematic reviews of available published evidence

Since a literature review published in 1996[76] that yielded Australian and international evidence of CPS provision in community pharmacy,

Table 3
Provision of key non-government-funded CPS in Australia: pharmacists' roles and responsibilities.

CPS type	Nature of CPS
Chronic disease management[48]	Pharmacists play a significant role in chronic disease management (and related medication management). Pharmacists offer support through services such as patient education around adherence and assisting patients of all health literacy levels to facilitate self-management of chronic disease(s). Screening and monitoring services are important in chronic disease management and complement lifestyle support programs also offered in community pharmacies, such as weight management and smoking cessation programs.
Healthy lifestyle support[49]	Community pharmacies now offer several healthy lifestyle support services. These include weight management, smoking cessation (see below), among others. These are aimed at educating patients and providing structured programs to facilitate a healthier lifestyle.
Smoking cessation[50]	Community pharmacists play a role in educating patients about smoking cessation, including advice on existing smoking cessation programs. They also play an important role in providing support and counselling throughout the patient's cessation attempt.
Screening/monitoring activities[51] (health checks)	Screening/monitoring activities (which have also been regarded as *"health checks"*[7]) can include, and are not limited to, screening and/or monitoring of[51]: • Cardiovascular disease (CVD) risk/CVD (e.g. blood pressure (BP), cholesterol levels, International normalised ratio (INR)/anticoagulant therapy) • Diabetes-related markers (e.g. AUSDRISK™, blood glucose, glycosylated haemoglobin (HbA1c)) • Asthma/COPD (e.g. lung function) • Osteoporosis (e.g. bone mineral density) • Chlamydia • Bowel cancer • Sleep disorders
Compounding services[52]	Compounding services involve the extemporaneous preparation of a medicine by a pharmacist. Individualised treatments for specific needs include paediatric formulations which are not readily available and specific chemotherapy for cancer patients, among others.
Vaccination[53] (Vaccinations have been more broadly administered by pharmacists since 2015-2016 (depending on when relevant State/Territory legislation changes were implemented)[54])	Pharmacist-led influenza vaccination services are now widely available in pharmacies across Australia. In addition, pharmacists are also able to administer other vaccines in accordance with relevant State/Territory legislation. The spectrum of vaccines that can be administered differs between States/Territories, but generally include diphtheria-tetanus-acellular pertussis (dTpa) and measles-mumps-rubella (MMR) vaccines.[54]
Sleep apnoea services[55]	Community pharmacists have a role in identification of patients at risk of sleep apnoea through the diagnosis process

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Table 3 (*continued*)

CPS type	Nature of CPS
	and if applicable, provide support with supply of continuous positive airway pressure equipment and appropriate lifestyle advice (such as weight loss).
Sexual health services[56]	Sexual health services in community pharmacies relate to emergency oral contraceptive provision, where sale and advice for both prescription and OTC contraceptive and fertility devices and medications have been provided through community pharmacy for some time. The provision of these services would enable discussion around general sexual health information and advice.
Mental health services[57]	Mental health services provided in a community pharmacy setting aim to promote medication adherence and increase self-awareness through education around mental health issues, including drug misuse. The community pharmacy setting is also well placed to offer lifestyle support programs.
Maternal and infant services[58]	Maternal and infant services involve provision of advice around health care of the nursing mother, the pregnant woman, and the infant. This includes, but is not limited to, the provision of infant formula and advice around breastfeeding and immunisation of the infant.
Continuity of care, including through community pharmacy liaison services[59]	Community pharmacy liaison services integrate a community pharmacist in the general health management plan for a patient. Facilitating communications around medication management between health care providers at the time of discharge, in residential aged care, and/or palliative care settings could enable a smooth transition for the patient between different health care settings. The pharmacist would be involved with the review of medications and management of associated issues (e.g. adherence, misadventure risk, need for DAAs).
Wound management[60]	First aid and wound management products are available through most community pharmacies in Australia, with pharmacists and pharmacy staff offering important advice and/or assistance regarding their appropriate use.
Advice on minor ailments[61]	Community pharmacists advise on medicines and treatment for minor ailments such as coughs, colds, headaches, skin disorders, diarrhoea, constipation, and eye infections, among others.
Provision of Pharmacist Only (Schedule 3) medicines, including Pharmacist Only Medicine Notifiable[62]	Pharmacists play a critical role in ensuring the quality use of OTC medicines, where Pharmacist Only medicines in particular must be supplied by pharmacists. Pharmacist Only Medicine Notifiable[62] include Schedule 3 medicines such as products containing pseudoephedrine. These medications must be given out by a pharmacist and details of the patient are recorded. Project STOP is used to assist in monitoring pseudoephedrine use.[40]
Complementary and alternative medicine (CAM)[63]	Community pharmacists are in a position to counsel patients around the evidence to support the use of CAM.
Opioid dependence treatment[64] (ODT)	ODT services primarily consist of the provision of individual (sometimes takeaway) doses of opioid medications as a replacement for illicit opioid-dependent patients. Legislation exists in each jurisdiction regarding relevant dispensing and prescribing requirements.[40]
Medication Adherence Programs[65]	Adherence programs are developed to alert the pharmacist to potential non-adherence issues experienced by patients with their medication management. Programs are often incorporated into the pharmacy's dispensing software.
Absence from work certificates[66] (The Fair Work Act 2009, currently in force, has continued to permit pharmacists to provide absence from work certificates[66])	The pharmacist is able to provide certification that the person is unable to attend work due to illness or injury that the pharmacist is qualified to assess. An absence from work certificate may be issued in relation to either personal or carer's leave.[66]

there has been a plethora of CPS research conducted internationally. Subsequent Australian systematic reviews on CPS have been conducted; in particular, to establish the value of CPS relevant and/or delivered in community settings in Australia and internationally.[77–79]

The CPS literature reviews (randomised controlled trials (RCTs)) from 1990 to 2005 found no Australian RCTs pertaining to pharmacist-led clinic services, medication reviews in the outpatient setting, patient education services, OTC medication use, and pharmacist-led immunisation.[78,79] Furthermore, the literature reviews encompassed CPS that had been part of trials and therefore may not have necessarily been translated into routine practice. However, this lack of evidence of effectiveness from RCTs did not preclude the possibility of benefits associated with such services on patient outcomes when implemented in practice. Indeed, many of the aspects of these CPS, such as patient education and clinical interventions, could have been introduced and are now considered part of "usual care" or the current practice of community pharmacists. Similarly, expanded pharmacist roles (e.g. pharmacist-led vaccination) are expected to yield benefits to patients and the health care system overall.

A number of subsequent reviews and/or meta-analyses pertaining to CPS delivered in the community setting have focused on remunerated CPS (broadly[73,74] or remunerated medication review specifically[80]), CPS delivered in middle-income countries,[81] economic evaluations (cost-effectiveness) of CPS,[82,83] or the impact of CPS in general.[84,85] An overview of systematic reviews published in 2013 by Mossialos et al.[86] relating to interventions by community pharmacists noted that many reviews provide mixed evidence of the impact of CPS. Although the evidence is still inconclusive, there are many positive findings that should be highlighted.

Pharmacist-delivered CPS have been shown to have a positive impact on key clinical indicators of disease control relevant in chronic disease management in the community setting. Meta-analyses conducted regarding smoking cessation interventions[87,88] supported the effectiveness of community pharmacy-delivered smoking cessation interventions in comparison to usual care. Similarly, interventions targeting BP control/patients with hypertension also favoured pharmacist intervention for the lowering of both systolic[84,89–92] and diastolic[84,90–92] BP.

With respect to medication management/review-related interventions, meta-analyses found decreased chances of hospitalisation for patients with diabetes[93] and heart failure,[93] as well as improved achievements of target BP[80] and low-density lipoprotein (LDL).[80] The positive effects of medication reviews conducted by pharmacists were also upheld in an overview of systematic reviews conducted by

Jokanovic et al.[94] Furthermore, a meta-analysis conducted by Tan et al.[95] found that the co-location of pharmacists in GP practices contributed to significant reductions in mean BP (systolic and diastolic), HbA1c, LDL, total cholesterol, and 10-year Framingham risk scores.[95]

Pharmacist interventions have been shown to have a positive effect on clinical control measures across a range of medical conditions however there is limited evidence to support the superiority of pharmacist-led CPS interventions in community settings on quality of life.[80,85,89,93,96–100] Moreover, there is no evidence of their impact on hard clinical endpoints such as major adverse cardiac events or other diabetes complications.[101]

Considerations regarding previously conducted systematic reviews

The study types and quality of evidence available and included in systematic reviews inevitably have implications on the conclusions that can be drawn, as well as implications for practice. Where some systematic reviews and/or meta-analyses included only certain controlled study types (i.e. RCTs, non-RCTs, and/or controlled before-after),[80,81,84,87,88,91,92,95,97,99,100,102–110] other systematic reviews included a broader range of study designs and/or did not specify restrictions on study design type for inclusion.[73,74,85,89,90,93,96,98,111–127] Importantly, studies that evaluate the impact of currently implemented CPS in practice are needed. Whilst data from pilot studies or small-scale research studies relating to CPS are valuable, the comprehensive impact of actual CPS operating in practice within an international context, whether user-pay or remunerated via a third party, should be the focus.

Systematic reviews effectively highlight current gaps in the literature. For example, some systematic reviews that focused on specific CPS included fewer RCTs, for instance in relation to osteoporosis management services,[108] sleep apnoea services,[118] weight management services,[121] and chronic pain patient education services.[109] This likely indicates that there is limited higher quality evidence to support these CPS being delivered in community settings by pharmacists. Furthermore, there is less evidence from RCTs available for emerging areas such as community pharmacy-based vaccinations.[122] Increasing evaluation research of these CPS is important to build a stronger evidence base to prospectively highlight their impact and support effective CPS implementation.

When considering the number of remunerated CPS identified in the systematic reviews conducted by Chan et al.[73] and Houle et al.[74] in comparison to the number of full economic evaluations included in the systematic reviews published by Malet-Larrea et al.[82] and Perraudin et al.,[83] there appears to be a gap in full economic evaluations available for CPS implemented in community pharmacy settings at present. Future health and economic outcomes evaluation for some CPS would be beneficial in order to better understand the work value of community pharmacists.

When attempting to contextualise the findings from these systematic reviews in relation to CPS provided in Australia, a gap between research evidence and knowledge translation is expected i.e. in relation to the broader uptake of CPS. Furthermore, despite community pharmacy practice comprising aspects of CPS as part of usual care, some CPS are not currently formally implemented in Australia e.g. minor ailment schemes.[123] To ensure that practice remains evidence-based, it is important that current practice also seeks to generate evidence to enable continuous improvement of CPS provision and demonstration of the actual impact that CPS have on patient-related outcomes.

Examining the evidence: caveats and opportunities

When examining evidence generated from systematic reviews, depending on their scope, one must consider that they may have included studies on CPS that are not widely implemented. This signals the need for further outcomes research on CPS currently delivered in community pharmacy settings. This will help to ensure that real world evidence is generated to highlight both the effectiveness and any room for improvement inherent in current CPS initiatives.

In the Australian context, CPS currently provided in community pharmacies that are not remunerated via established systems such as the CPA (i.e. CPS paid for by users of the service) may vary in nature and scope between pharmacies. Such variation may be due to many factors including an absence of national guidelines to guide implementation as a result of limited published evidence that support their effectiveness. Future studies evaluating the impact of the breadth of CPS provided in community settings are much needed to corroborate the critical role that pharmacists play in the provision of primary care services and facilitating QUM.

Promisingly, embedded within the 6CPA was a new clause stating that all CPS funded under the CPA will undergo cost-effectiveness analyses, which was not routine previously. Clause 6.1.3 states:

> *"The Community Pharmacy Programmes set out in Appendix B will continue from 1 July 2015 until the Minister determines otherwise and will be subject to a cost-effectiveness assessment by an independent health technology assessment body (such as the Medical Services Advisory Committee or the PBAC) as determined by the Minister."*[16(p15)]

Thus, new emerging evidence of the work value of community pharmacists, specific to CPS provided in the Australian context, is expected. Other countries that do not have mandatory cost-effectiveness evaluations for publicly funded or third party-funded CPS should also consider the introduction of mechanisms to establish the effectiveness of their pharmacist-delivered services. Importantly, components of CPS may also overlap with usual care and thus, the full value of pharmacists working in the community setting on economic, clinical, and/or humanistic outcomes may not have been accurately captured in previous studies.

Conclusions

Changes to legislation and funding in Australia have helped broaden the scope of practice of community pharmacists and aided the facilitation of CPS provision and accessibility of these services for consumers. Pharmacists are now being remunerated for services for which funding was not previously available. New CPS delivered in Australian community pharmacies do not solely comprise CPA-funded CPS. Evidence from broader systematic reviews provide evidence to support the expanding role of community pharmacists and reinforce the need to ensure the implementation and expansion of evidence-based, value-added CPS. However, further longitudinal studies and RCTs are required to better ascertain the clinical and cost-effectiveness of both funded and non-funded CPS from the perspectives of the health care system, patients, and service providers.

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None.

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