Evaluation of the Dose Administration Aid program: collection of data and survey responses from community pharmacists, consumers and carers to inform future directions for the program

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Acknowledgements

The authors would like to acknowledge the funding provided by the Australian Government Department of Health and Aged Care for this research project.

The research team acknowledges all study participants, pharmacists, consumers and their carers, for their time and contributions towards this research study.

Executive Summary

INTRODUCTION

One of the most common strategies to improve medication adherence in those taking multiple oral medications is the use of Dose Administration Aids (DAAs). These devices allow the organisation of multiple medications according to their time of administration and dose. In Australia, these devices are provided by community pharmacies either independently or as part of the Commonwealth funded DAA program, to support the quality use of medicines. The aim of the DAA program is to improve medication management and adherence by people in the community, thereby reducing medication misadventure-related hospitalisations and adverse events.

The Australian Government expends approximately $100 million per year on the DAA program, representing approximately 50% of the spending on Seventh Community Pharmacy Agreement (7CPA) Community Pharmacy Programs. This figure includes funding for the Indigenous DAA program (IDAA), which was added to existing funding for the original DAA program, and has coincided with an overall increase in patients on Commonwealth funded DAAs.

A cost effectiveness analysis of the DAA program has never been conducted, due to the absence of relevant data. In 2016, the Medical Services Advisory Committee (MSAC) proposed the Department seek input from the Pharmacy sector to aid in data collection and analysis, but no changes in data collection have occurred since then. Furthermore, evaluation of the 7CPA Community Pharmacy Programs now excludes the DAA program, as the data collected by the Pharmacy Programs Administrator (PPA) do not include the required identifiers for the Australian Institute of Health and Welfare (AIHW) to link DAA use to Pharmaceutical Benefits Scheme (PBS) data.

AIMS

Given the above, the Pharmacy Branch, Technology Assessment and Access Division, Department of Health and Aged Care commissioned research on the 7CPA DAA program, with the following high-level aims, to:

1. determine the level of clinical benefit to consumers,
2. advise which consumers gain the most clinical benefits, and
3. provide recommendations for possible future directions for the program.

To address these aims, the following specific research objectives were agreed:

- To investigate community pharmacists' and consumers' opinions of the DAA program.
- To explore the perceived benefits and shortcomings of the DAA program for community pharmacists, and for consumers and their carers.
- To identify the impact of using a DAA on consumer clinical outcomes.
- To identify the costs associated with the preparation and use of DAAs.
- To assess the factors that influence consumers' choice to use DAA or not.

METHODS

A mixed-methods study was conducted in three stages with two broad groups of participants: community pharmacists, and consumers and/or their carers.

Stage 1: Two reviews of the literature on DAAs

Stage 2: Two qualitative studies using in-depth semi-structured interviews with 1) community pharmacists, and 2) consumers or carers.

Stage 3: Quantitative and Discrete Choice Experiment (DCE) surveys of Australian community pharmacies, and quantitative and DCE surveys of Australian consumers and carers of consumers who: (a) were in the DAA program, (b) were not in the DAA program but were using DAAs, or (c) were not in the DAA program but were on polypharmacy.

Stage 1: Comprehensive review of the literature on DAAs

A systematic review of the literature was conducted to identify studies on (i) the process of delivering DAAs in the primary care setting; (ii) the impact of DAAs on patient medication adherence and clinical outcomes; (iii) barriers and facilitators to the commencement and ongoing use of DAAs; or (iv) economic analysis of DAA delivery. DAAs included compartmentalised plastic boxes, blister or bubble packs, sachet systems, and automated medication dispensing devices g. A second scoping review of the literature was conducted to identify previous DCEs, descriptive studies and qualitative studies assessing preferences and experiences with DAAs. The purpose of this review was to specifically inform the design of the DCE studies with pharmacists and consumers /carers. (Stage 3).

Stage 2: Qualitative in-depth interviews with community pharmacists, and with consumers and/or their carers

Qualitative interviews with community pharmacists

Semi-structured interviews were conducted with community pharmacists across Australia. Purposive sampling via pharmacy networks and organisations was used to recruit pharmacists with experience in the provision of contemporary Australian DAA services. A total of 24 pharmacists participated, of whom 17 were current or previous pharmacy owners or partners, four were pharmacists-in-charge, and three were employee pharmacists.

Qualitative interviews with consumers/carers

Qualitative in-depth interviews were conducted with adult consumers (or their carers, where applicable) across Australia who were either 1) participating in the DAA program or using a DAA but not participating in the DAA program (DAA users group); or, 2) who were on polypharmacy (>= 5 medicines) but not using a DAA (non-DAA users group). Consumers were recruited via Australian community pharmacists, and a market research company. A total of 40 consumers/carers participated in interviews. Of these participants, 20 were DAA users who were either participating (n=7) or not participating (n=4) in the DAA program or did not know if they were part of the DAA program (n=9), and 20 were non DAA users who were on polypharmacy

Data collection and analyses

Separate semi-structured interview guides were developed for the community pharmacists, and consumers/carers, based on the literature and the DAA program. Interviews were recorded, transcribed verbatim, and coded using NVivo 14. Data were first coded deductively, and then inductively using an iterative and dynamic approach of thematic analysis as described by Braun and Clarke (Braun and Clarke 2006).

Stage 3: Quantitative and Discrete Choice Experiment (DCE) surveys of Australian community pharmacies, and quantitative and DCE surveys of Australian consumers and carers

There were four parts to this stage:

1. Quantitative census survey of Australian community pharmacies.
2. Quantitative survey with consumers and carers of consumers who were users of DAAs or on polypharmacy.
3. DCE survey with Australian community pharmacists.
4. DCE survey with Australian consumers and carers.

All participants were compensated for their time (as per standard protocols).

Quantitative census survey of Australian community pharmacies

A cross-sectional online census survey collected the perspectives and experiences of Australian community pharmacies on the DAA program and DAAs. Eligible participants were pharmacists working in community pharmacies across Australia. A total of 5622 potential participants were invited.

Quantitative study of consumers and carers

A cross-sectional survey of community dwelling consumers and carers was conducted via an online survey platform (Qualtrics), using a market research company (PureProfile) to recruit participants. Participants were categorised into two broad groups: 1) those who were in the DAA program, or 2) those who were not in the DAA program but were using DAAs, or were not in the DAA program but were on polypharmacy.

Data collection and analyses

The census survey collected data on pharmacy and pharmacist demographics, the current status of the DAA service in Australia, and perceptions on the reimbursement of the DAA program. The consumer and carer survey collected data on consumers' and carers' opinions of the DAA program and using DAAs, their perceived benefits and shortcomings of DAAs and the DAA program for consumers and their carers, the impact of using a DAA on their health outcomes, and the costs associated with the use of DAAs.

Due to the non-normal distribution of the data, the Kruskal–Wallis test was used to analyse continuous variables. Quantile regression analyses were performed to identify any factors affecting pharmacists' perceived value for the pharmacies to be reimbursed for the provision of the weekly DAA service; and consumers'/carers' perspectives on DAA costs.

Discrete Choice Experiment Surveys of community pharmacists and consumers / carers

Pharmacists were provided with a direct link to the DCE survey in their study invitation/reminder emails and at the end of the census survey. Consumers/carers were recruited via PureProfile who provided a link to the DCE survey.

Data collection and analyses

For the pharmacist DCE, NGENE design software was used to generate a DCE design with 72 questions (6 blocks of 12 questions) which presented respondents with a choice between three options: two unlabelled alternative DAA options, and a third fixed no DAA option (d-error=0.0033; s-estimate (minimum sample size)=3 for full design). For the consumer DCE, NGENE design software was used to generate a DCE design with 72 questions (6 blocks of 12 questions) which presented

respondents with a choice between two unlabelled options: one DAA option and one no DAA option (d-error=0.0257; s-estimate (minimum sample size)=3 for full design). Analyses for both DCEs were conducted in NLOGIT using a mixed logit model with 10,000 Halton draws and a panel specification to account for correlated choices within an individual (Hensher et al. 2015).

FINDINGS

Stage 1: Comprehensive review of the literature on DAAs

Systematic review of DAAs

the key finding from this review was the potential of DAAs to improve medication adherence, especially for patients with complex medication regimens, and unintentional non-adherence. There were mixed results on clinical and healthcare utilisation outcomes, reflecting the multi-factorial influences on the outcomes measured and the difficulties in demonstrating meaningful change, as it was often not possible to differentiate the contribution of the DAA versus other concurrent pharmaceutical services in improving adherence and clinical outcomes.

Supporting and enhancing medication adherence and ensuring safe use of medications were the most common reasons for commencing and continuing DAA use, especially where there was polypharmacy or complex dosage regimens, or difficulty by the patient in managing their medications. Convenience, ease of use and device transportability supported continued use of DAAs. Cognitive decline was a factor that usually led to commencement and continued use of DAAs by patients, but when cognitive decline increased significantly, DAA use shifted from consumers to their carers.

Another reported facilitator of DAA provision was the opportunity for pharmacists to collaborate with prescribers and have input into patient medication management. Although patients' ability to use DAAs was reported as a facilitator of DAA use, very few studies have directly evaluated this.

Some of the reported barriers to DAA use included difficulty in using the devices, stigma associated with use, and loss of patient autonomy and disempowerment in medication management. There were also reports of the costs and lack of remuneration associated with packaging and supplying DAAs, for pharmacists and patients.

Included studies highlighted the need for further research to examine the economic aspects of DAAs, when used alone, and in combination with other interventions. Few studies reported on the actual cost associated with DAA services from either the pharmacist or patient perspective. The findings noted the importance of patient involvement in DAA initiation and continued use decision-making processes, and regular quality checks, for optimising DAA implementation and use.

Scoping review on DCEs of preferences for DAAs

This review identified no DCE studies of preferences for a DAA service. As qualitative and descriptive studies of the views/experiences of stakeholders for DAA services were identified in the systematic review, the findings from the two reviews were combined with the findings from Stage 2 to develop appropriate attributes, levels and choice framing for the DCEs in Stage 3.

Stage 2: Themes from the qualitative in-depth interviews with community pharmacists, and with consumers and/or their carers

Themes derived from interviews with community pharmacists

Benefits of the DAA service for patients and carers: Pharmacist participants consistently alluded to improved medication management (through organisation of medications in a DAA), specifically medication adherence, for patients on a DAA. The DAA device provided a visual aid to enhance adherence to packed and unpacked medicines (such as inhalers). They observed that although DAA recipients may feel a loss of independence from having their medications included in a DAA, paradoxically the DAA service provided independence from the pressure of self-management. Additionally, they noted that DAA recipients valued their interactions with the pharmacist providing a DAA and felt that they were cared for.

Shortcomings of the DAA service for patients and carers: Pharmacist participants believed that the main shortcomings of the DAA service for some patients and carers were loss of autonomy and independence in, as well as reduced knowledge of, medication management.

Perspectives on the impact of DAAs on patient outcomes: Pharmacist participants were unable to definitively comment on patient health outcomes other than medication adherence. A consensus perception was that DAAs contributed to enhanced medication adherence and safe use of medicines, with any improvements in clinical outcomes difficult to demonstrate, especially as clinical outcomes may not be routinely nor regularly evaluated.

Benefits of the DAA service for pharmacists and pharmacies: Pharmacist participants reported that whilst they spent more time and resources in providing a DAA service, they were more engaged in patients' medication management, and they felt a greater sense of professionalism because of this clinical role. They viewed themselves and their colleagues as a valuable conduit between the patient, their GP (or multiple GPs) and their medical specialists who prescribed medications, as they felt that they were, and were viewed by prescribers to be, responsible for the patients' medication management.

Shortcomings and downsides of service provision for pharmacists and pharmacies: The commercial impact of delivering a DAA service was consistently referred to by all pharmacist participants as a cost disadvantage. They referred to the infrastructure required, and the investment in personnel in managing, packing, re-packing, checking and delivering DAAs. Although they believed that providing DAAs assured income for the pharmacy, this was tempered by the knowledge of the total costs of supplying the service.

Challenges in DAA service delivery: Challenges reported by pharmacist participants broadly fell into two related categories, physical and financial aspects of supplying the DAA service. These included pharmacy space, infrastructure and personnel dedicated to DAA service supply; limited information about the suitability of medicines for packaging; delivery issues; and overall costs.

DAAs: It's not just about supply: The consensus among pharmacist participants was that when engaging in the DAA program, pharmacists offered, or were expected to offer, much more than a medicine supply service. Pharmacists were involved from recognising need, referring and initiating DAAs for their patients, to enrolment and set-up, medication reconciliation and follow up of medication and prescription changes with the patients' doctors.

Optimising the service delivery: The most common suggestions were to increase the reimbursement amount and to establish a transparent and needs-based method for calculation of the number of funded DAAs for each pharmacy (the caps). Pharmacist participants felt that they were not adequately reimbursed for the service they provided. Additionally, they believed that many more people would benefit from the DAA service if caps were increased or removed, and the eligibility criteria broadened.

Themes derived from interviews with consumers/carers

DAA service-related processes: Self-enquiry was the most common reason provided by current DAA users for initiating a DAA. Most consumers/carers reported asking a pharmacist about the DAA, which they saw being promoted in the community pharmacy, as an appropriate tool to manage their medications and prescriptions. Pharmacists did mention and initiate a DAA, however, this only occurred for a smaller proportion of the participants. Most of the DAA users described having received clear instructions from the pharmacist on how to use the DAA before starting on the device.

Consumer medication management process: Most of the DAA users described the purpose of the DAAs as ensuring better medication management and believed that DAAs were very helpful in this respect. The majority of non-DAA users kept and carried their medications in the original boxes while the remaining used medication containers that were not DAAs to store their medications.

Perceived positive and negative aspects of DAA service on consumers and carers: Most of the DAA users described a positive experience with the DAA device and with the DAA service provided by their pharmacy. All DAA users and non-DAA users described the DAAs as helpful for medication management, especially to organise their medications, to remember taking their medications and at the right dose and time, and to track the doses taken. A few DAA users mentioned some limitations related to the DAA design, such as blister packs were difficult to open, bulky and not environmentally friendly.

Recommendations for improvement in DAA services or current management of medications: Only a few DAA users mentioned ways to improve the DAAs, for example a smaller size or more environmentally friendly materials. Many commented that the service should be promoted more so more people could benefit. Both DAA and non-DAA users commented on who may benefit from using a DAA, and therefore which specific groups should be targeted by healthcare professionals in providing a DAA service. These included, older people, people taking more than one medication, people with dexterity impairment (e.g., arthritis), with memory difficulties and busy people with multiple chronic health conditions.

Consumer willingness: Most of the DAA users not paying for the DAA service mentioned that they would be willing to pay to use the DAAs with a price range of between $5-$10 per pack. The majority of non-DAA users reported that they would like to either join or know more about the DAA service. Half of the non-DAA users said they would not be willing to pay for the DAA service. Those who expressed that they would pay mentioned a value between $10-$30 per month.

Stage 3: Quantitative surveys and discrete choice experiment (DCE) surveys of community pharmacies; and of consumers and carers

Quantitative census of Australian community pharmacies

A total of 1032 completed responses were received from 1032 pharmacies. Most pharmacies were in New South Wales (n=396, 38.3%) and the majority were in metropolitan areas (n=655, 72.7%). Nearly half of the participants (n=466, 45.1%) were pharmacist-in-charge. In seven of the pharmacies, the DAA service had been provided before, but it was not currently being provided. Some of the reasons provided for stopping the service were a reduction in the number of DAA users, costs associated with the DAA service and lack of staff availability to provide the DAA service.

Community patients under the DAA program and residents of residential aged care facilities were the primary recipients of DAAs. Pharmacies were providing an average of 52.6 blister packs and 49.2

sachets per week to community patients under the DAA program, and 48.9 blister packs and 1512.5 sachets to residents of residential aged care facilities. Approximately 18 hours and 15 hours per week was spent packing blister packs and sachets, respectively; whilst it took 283 minutes and 11 minutes, respectively, to check that the DAA had been packed correctly. Of the total of pharmacists providing the DAA service (n=1011), many (n=790, 76.6%) mentioned their pharmacies charge for the provision of the DAA service, particularly community patients under and not under the DAA funded program. The median charge was $5.00.

Pharmacists were likely or very likely the people to take the initiative to start the DAAs for patients under the DAA funded program (pharmacist n=872, 86.3%) and not under the funded program (pharmacists n=594, 58.8%). Participants providing the DAA service indicated that poor medication adherence (n=951, 94.0%) and a complex medication regimen (n=949, 93.8%) were likely or very likely the reasons to initiate a DAA. Pharmacists agreed that patients with cognitive impairment (92% of participants), supported by carers (91.9%) and with chronic medical conditions (91.3%) would benefit the most from using a DAA. Most agreed that DAAs could improve medication adherence (n=989, 95.8%) and medication safety (n=887, 95.6%), and reduce the carer's burden (n=961, 93.1%).

Pharmacists agreed that the most common barriers to implementing the DAA service in community pharmacies were lack of financial support for pharmacies to prepare DAAs (n=775, 75.0%), lack of staff (n=777, 75.2%), and lack of time (n=762, 73.8%). The majority (n=713, 69.0%) said there should not be a cap for the DAA service. Of those who said there should be a cap (n=157), 40 participants (25.5%) said it should be based on clinical needs, for example, patients with cognitive problems, using high-risk medicines, or patients financially not able to pay. Forty-four (28.0%) pharmacists said the cap should be based on the number of medications, for example the use of four or more medications. Some participants mentioned caps should exist to encourage an equitable funding system for pharmacies and enable all pharmacies to provide a DAA service to their local community. Almost all pharmacists (n=1028, 99.6%) believed that pharmacies should be paid for the provision of the DAA service. Of those, most thought the service should be paid for by the government (76.3%) with a median value of $14 per week as a suggestion.

Quantitative study of consumers and carers

A total of 913 consumers and carers responded to the survey, well above the estimated sample size of 630. Of the respondents, 291 were in the DAA program group, 217 were in the non-DAA program group, 86 were past users of DAA currently taking five or more medications (polypharmacy), and 319 were on polypharmacy but had never used a DAA. Of the 508 respondents who used DAAs, 55% used blister packs, 36% used compartmentalised boxes, 16% used sachets, and 7% used automated devices. A total of 452 (89%) reported using a single type of DAA only, while a combination of DAA types was reported by 56 respondents (11%). About 89% of consumers/carers only used medications which were packed in a DAA. Many had received recommendations to use DAAs from their general practitioners (28%) or community pharmacists (25%), and 18% had self-initiated DAA use. The main reasons for initiating a DAA included ease of medication management (58%), convenience (46%), and being prescribed an increased number of medications (41%). Additionally, DAAs helped respondents remember to take their medications (38%) and saved time in medication taking (21%). Half of the respondents reported that their pharmacies did not charge for the DAA service, 20% were required to pay for the service, and 30% were unaware of any costs despite using DAAs. When analysed according to the respondent groups: current DAA users who were part of the DAA program were more likely to recognise the costs associated with DAA services, with 58% reporting no cost and 23% reporting a cost. Approximately 43% of those not part of the DAA program reported no

cost, and 17% reported a cost. Additionally, 40% of current DAA users not part of the DAA program were unaware of the costs. Users in the program reported a median cost of $15 (IQR 5-40). In contrast, DAA users not part of the program and past users reported lower median costs of $9 (IQR 5-15) and $10 (IQR 6-15), respectively, with a narrower range in costs.

All respondents were asked to report how much they would be willing to pay each week to receive a DAA from their pharmacy. They reported a median perceived value for DAA services of $9 (IQR 5-20). Twelve percent (n=106) were not willing to pay any amount ($0). When examining respondents' perspectives on DAA costs across the four groups, a wide range of reported costs suggested that the perceived value of DAAs varied significantly. Current DAA users, both in and not in the program, would pay $15 (median value; IQR 5-45) and $10 (median value; IQR 5-20) respectively, which were significantly higher than those who had never used DAAs, who reported $5 (median value; IQR 2-10) ($p<0.001$). The findings of the regression analyses of the median perceived costs for DAA services, adjusting for demographic and socioeconomic variables, showed that DAA usage, age, number of medications, rurality and health literacy level were associated with perceived DAA costs. DAA users who participated in the program expressed the highest desire to pay, suggesting a strong perceived value of DAAs—demonstrated by a median perceived cost up to $7 more than that of respondents who had never used a DAA ($p<0.001$). Respondents managing multiple medications (taking 5 to 10 medications and more than 10 medications) reported lower perceived costs for a DAA, ranging from a median decrease of $6 ($p<0.05$) to $7 ($p<0.01$), respectively, compared to those regularly taking less than 4 medications, likely due to the cumulative burden of medication costs. Younger adults (18-29 years) would pay more than older adults (60-69 years).

Respondents living in regions classified under MMM2-7 reported a lower perceived cost ($2 lower) than those living in metropolitan areas, potentially reflecting accessibility or economic constraints of their locations. The study findings also indicated that those with lower health literacy levels would pay more than those with higher health literacy levels ($p<0.001$). This may suggest that those with higher health literacy levels have a decreased need for DAAs as they can better manage their medications and are more adherent, hence a lower value was placed on using a DAA.

The top five groups of people who respondents believed would benefit from a DAA were people who have difficulties such as opening containers (reported by 91% of study respondents), those with memory problems (90%), people taking high-risk medications and with mental health conditions (86%) and long-term medical issues (85%). Respondents who had never used a DAA were statistically significantly less likely to suggest benefits from DAA use for the various consumer groups, suggesting that those who had never used DAAs may not fully understand who could benefit from the DAA service.

Many respondents recognised the practical advantages of DAAs, noting their convenience (90%), usefulness for travel (89%), saving time (87%), and reduced burden on carers (87%). Approximately 86% felt that DAAs improved their medication management, and 83% believed that they ensured medication safety. Similarly, 83% agreed that DAAs contributed positively to managing prescriptions more effectively. Approximately 77% reported that DAAs improved their quality of life, 69% reported that they felt more cared for by pharmacists through the provision of a DAA service, and 68% reported that their medication knowledge had increased. An improvement in medication effect due to increased medication adherence, was also regarded as a positive impact by current DAA users in the program (71%), and was statistically significantly higher than among respondents who had never used a DAA (68%, $p<0.001$).

Comparison of pharmacist and consumer/carer survey data

A direct comparison was made between the responses provided by community pharmacists (n=1,011) and consumers/carers (n=913) to questions that were identical in both surveys. More than 80% of pharmacists and all four different consumer groups believed that DAAs were beneficial for individuals with cognitive impairment, those with chronic medical conditions, those taking high-risk medications, and those with mental health conditions. In addition, both pharmacists and consumers who currently used or had previously used a DAA strongly agreed that people living independently, and older individuals could benefit from DAAs. However, consumers who had never used a DAA were less likely to recognise these benefits.

Pharmacists strongly agreed that DAAs can reduce carers' burden and improve treatment effects, showing approximately 10% higher agreement compared to consumers. On the other hand, consumers, particularly 76% of current DAA users whether in the program or not, felt that their medication knowledge increased due to DAA use, this impact was perceived less by pharmacists, who showed 61% agreement. Moreover, 46% of DAA users in the program noted difficulties in using DAAs, which was 10% higher than the perceptions of pharmacists (36%).

Among the 850 pharmacies providing only blister packs, only 20% (n=170) did not charge community patients. Interestingly, the survey data revealed a difference between pharmacy charges and consumer perceptions of DAA service costs. Approximately half of the current DAA users, both in the program (58%) and not in the program (43%), reported receiving DAAs free of charge. This result suggests potential inaccuracies in self-reported data from consumers regarding payment.

The study investigated both pharmacy and consumer respondents' perspectives on what should be the cost of DAA services. Pharmacies providing blister packs reported a higher median value of $14 (IQR 10-20) for the provision of a weekly DAA service, while those offering both blister and sachet packs noted a slightly lower median of $13 (IQR 10-20). This was $3-4 higher than the median cost reported by pharmacies providing only sachets, which stood at $10 (IQR 10-15). This price difference suggests that pharmacies utilizing blister packs, which typically require more time for packing and checking, perceive a higher cost for their services compared to those using sachet systems. More than half of current DAA users in the program received the DAA service for free, yet they perceived the highest value of $15 (IQR 5-45) for a DAA service. Moreover, the perceived value by current DAA users in the program was higher than those not in the program ($10, IQR 5-20), and past users ($5, IQR 2-15). This showed that consumers using DAAs place a greater value of the DAA service.

Discrete Choice Experiment Surveys of community pharmacists and consumers / carers

Findings from the consumer/carer DCE indicated that there was an underlying preference for having DAAs, all else being equal. There were differences in preferences for DAA attributes between carer and consumer respondents. Consumers were significantly more price sensitive than carers, and significantly less likely to prefer a DAA service as the price per week (out of pocket cost) for the DAA service increased. Some sociodemographic characteristics of consumers and carers also significantly influenced preferences: age, employment status and annual income.

Based on willingness to pay values, having a doctor discuss starting a DAA was the most highly valued DAA attribute for both carers and consumers. For carers this was followed by having the DAA delivered. For consumers, the next most valued attribute was avoiding having a family member discuss starting a DAA with them, followed by having a DAA delivered.

Findings from the pharmacist DCE indicated that there was an underlying preference for providing DAAs, all else being equal. DAA services were less likely to be provided if more consumers

experienced a decline in control over their medications, additional staff minutes were required to provide a DAA service, and the existence of a cap on the number of funded DAA service provisions. Pharmacists were more likely to provide a DAA service when more consumers experienced an improvement in their medication adherence, and as the average government fee received by the pharmacy per consumer per week, increased.

There were small differences in the value attached to the government fee attribute for pharmacy owners and non-owners. The type of patient considered for the DAA service (relative to an older patient ≥65 years old) and level of patient copayment did not significantly influence preferences for providing a DAA for these respondents. Pharmacists' sociodemographic characteristics (gender, age, education level, pharmacy owner status, and geographical location of the pharmacy) did not significantly influence their preferences.

Based on willingness to accept values, avoiding a cap on the number of DAA service provisions per week by pharmacies was the most valued DAA program characteristic, followed by patients experiencing an improvement in their medication adherence while on a DAA, and avoiding additional minutes of staff time required per patient per week to provide a DAA service.

The lowest valued attribute for both pharmacy owners and non-owners was the likelihood of a patient experiencing a decline in medication control, consistent with findings of the consumer DCE. Overall, the pharmacy owners were willing to accept smaller reductions in the government fee than the pharmacy non-owners to avoid a cap on the number of funded DAA service provisions that pharmacies can provide.

SYNTHESIS OF FINDINGS

The level of clinical benefit of DAAs to consumers

Directly evaluating medication adherence and consequent clinical outcomes as a result of the use of a DAA was outside the scope of this research project. The literature review findings highlighted mixed results on the direct impact of DAAs on clinical and healthcare utilisation outcomes as DAAs were one part of more complex interventions. During qualitative interviews with pharmacists and consumers and carers, participants could not comment on whether DAA use impacted patient clinical outcomes or healthcare utilisation. However, 71% of current DAA users reported (in the survey) that their DAA use led to an improvement in medication effect due to increased medication adherence.

Whilst improved medication adherence is not a clinical benefit, it is related to improved clinical outcomes. The literature review revealed the potential that DAAs can have in improving medication adherence, especially for patients with complex medication regimens, and where non-adherence may be unintentional due to forgetfulness or confusion around what medications should be taken and when. During the qualitative interviews, pharmacist participants noted that DAAs enhanced medication adherence, and led to safe use of medications. These findings were corroborated by the findings of the quantitative survey of pharmacies.

Consumers and carers interviewed commented on the positive impact of DAAs on medication management and keeping track of their prescription medications by being a reminder for medication taking. These findings were corroborated in the survey responses.

Whilst it is important to isolate the impact of DAAs on patients' medication adherence, clinical and healthcare utilisation outcomes, it can also be argued that DAAs should not be a standalone service, and that their impact may be maximised when integrated with other healthcare services.

Facilitators for DAA use

Several advantages and disadvantages of DAAs, as well as barriers and facilitators to DAA use, from the perspectives of pharmacists and consumers/carers were identified. There was some degree of overlap in the barriers, facilitators, advantages and disadvantages reported, with all factors having an actual or potential influence on the commencement and/or continued use of DAAs.

The literature confirmed that DAAs enhanced the safe use of medications and medication adherence, especially in cases of polypharmacy or complex medication regimens. Similarly, qualitative interviews with community pharmacists and consumers and carers also identified the positive impact of DAAs on medication adherence. Interviews with pharmacists, patients and carers reported that DAAs provided a visual reminder for both packed and unpacked medication taking, preventing missed doses, double dosing, incorrect dosing, and mixing up medications. Similar findings were reported in the survey of pharmacies and consumers and carers.

Cognitive decline was identified as a reason for commencing people on a DAA, as the DAA was an effective reminder tool to support medication taking. As cognitive decline worsened, it became a barrier to appropriate DAA use by consumers, whilst becoming a facilitator for appropriate medication administration by carers.

Another important facilitator to DAA provision identified in the literature was the opportunity provided by a DAA service for pharmacists to collaborate with prescribers and have input into a patient's medication management. Pharmacists in the qualitative study reported that providing a DAA service was beneficial to them as they believed that they optimised medication management for patients, they demonstrated a professional clinical role, they were more accountable for their patients' medication management, and were a valuable conduit between the patient, their GP or multiple GPs, and specialists who prescribed medications. However, these rich findings were not replicated in the quantitative survey, and were not raised by consumers/ carers. Instead, consumers and carers reported that their experiences of the DAA service were positive, which not only reflects the benefits of the device but also the service provided by pharmacists when giving out a DAA. They felt that more people should benefit from such a service, and that the service needs to be better promoted to increase people's awareness.

Other advantages of DAAs which facilitated their use were convenience, ease of use and device transportability, reduced carer burden and improved medication knowledge.

Barriers for DAA use

An important barrier identified from studies in the literature, and supported by the qualitative studies' findings, was cognitive decline. With increasing cognitive decline, patients may not be able to correctly use their DAA. However, as noted above, the DAAs became a facilitator for correct medication administration by carers and therefore ensured improved medication adherence.

A significant disadvantage of using DAAs identified through the literature review and the qualitative interviews with pharmacists was the loss of autonomy or independence in medication management and knowledge about medications. This led to a reliance on their DAAs. However, this was not confirmed in the survey of pharmacies and consumers/carer, in which improved medication knowledge was reported with the use of DAAs.

The interviews also highlighted the loss of patient contact. This was viewed as a significant disadvantage especially if the carers were responsible for collecting the DAAs. Whilst no specific

solutions were suggested, pharmacists reported that for continued patient care, it is important that the DAA service includes periodic direct contact (in person or telehealth) with the patients.

A barrier to the use of DAAs identified during the qualitative interviews was the limited information about the suitability of medications which can be packed. Whilst many had solutions, they were not always optimal, and could easily compromise patient safety. Other barriers from the literature included difficulty in using and the stigma associated with using DAAs. Participating consumers reported that the device itself can be a barrier to use especially if the DAA is bulky, difficult to open and not environmentally friendly.

Financial barriers identified in the literature were twofold: lack of remuneration for the preparation and delivery of DAAs and delivery of an associated pharmaceutical service, and the cost of DAAs for patients. However, there was limited information available in the literature on an economic evaluation of a DAA service which focused on the cost to the pharmacy and the patients. The qualitative interviews and surveys with pharmacists highlighted the cost disadvantage of the DAA service to pharmacies. They reported that the cost of providing a DAA included infrastructure set up, space, ongoing costs, personnel, and their own time. Many reported that providing a DAA was a commercial decision.

Census survey respondents noted that to set up a DAA service in their pharmacy, they needed incentives for patients and financial support for their pharmacies. Specifically, they requested funding for patients who do not fall in the category of current DAA program funding, changes to patient eligibility criteria to be part of the DAA program, financial incentives from Medicare, and more dispensary support. The support requested corroborates the comments made in the qualitative interviews. The DCE findings showed that the two most significant barriers to community pharmacists wanting to provide a DAA service were the lack of acceptable government reimbursement and the current constraint of a cap on the number of funded DAA service provisions by the pharmacy.

Which consumers gain the most clinical benefit

Based on the literature review findings and the results of the research studies conducted, the following consumers / patients are those who are likely to gain the most from a DAA service, as reported by both pharmacists and consumers/carers:

- People on polypharmacy and/or complex medication regimens.
- Anyone who is having difficulty adhering to their medication regimen, primarily because of forgetfulness, or unable to plan their daily medication taking.
- People with mild cognitive decline who can still use a DAA.
- Carers of patients or people who are responsible for medication administration.
- The elderly, who tend to be on polypharmacy, complex medications regimens, have cognitive decline, have memory difficulties and some dexterity issues.
- Busy people with multiple chronic health conditions and on multiple medications.

Issues related to cost

Pharmacists believed that they were not adequately remunerated for the provision of a DAA service, where the service includes the technical and professional roles of DAA preparation and delivery, the professional roles and responsibilities for medication management, medication adherence, patient

education and other health-related services, and the additional interprofessional communication and collaboration to ensure optimal medication management. They believed that more patients would benefit from DAAs, and therefore believed that the cap should be increased. They suggested a transparent and needs-based method for calculating the number of funded DAAs for each pharmacy (referred to as 'caps') is established. For example, by introducing a government-endorsed tiered or structured fee, depending on the indication for the DAA, ranging from improved convenience for the patient / carer to assisting medication adherence and overall management to patients at-risk of medication misadventure (e.g. polypharmacy, declined cognitive function).

Non-DAA users did not value the DAA service as much as DAA users, and consequently would pay less for such a service. A significant variability in consumers/carers perspectives on DAA costs was identified from the consumer/carer studies. The findings of the quantitative survey showed that this variability was influenced by factors such as age, income, number of medications, rurality, and health literacy. These factors should be considered when providing DAA services to those who use DAAs and/or are eligible for the government-funded DAA program and need support to start using DAAs. Particularly, residents of rural areas, as well as those with lower health literacy level, who may find the DAA costs potentially prohibitive.

Collectively, the DCE findings suggest that the current government fee for the DAA program and the current cap on the number of funded DAA service provisions provided by a pharmacy are two program aspects that are potentially modifiable to increase the likelihood that pharmacists would choose to provide a DAA service, even considering the extra staff time that would be required with increased DAA services. Increasing the weekly government fee for the funded DAA program and/or removing the cap on the number of funded DAA service provisions for the pharmacy would increase the likelihood of pharmacists (both pharmacy owners and non-owners) to choose to provide a DAA service. Findings from the consumer DCE suggested that it is necessary for pharmacists to want to continue to provide a funded DAA service, as all else being equal, consumers (both consumers and carers) also have an underlying preference for the DAA service (compared to no DAA service) and see value in the provision of this service by community pharmacists.

Increasing out of pocket costs for consumers significantly reduced patient and carer preferences for a DAA service. Additionally, pharmacists did not prefer higher out of pocket consumer costs. So, while it is possible to increase pharmacy remuneration via increasing consumer copayments, it does not appear that this would be a preferred solution for either consumers or pharmacists and would instead likely negatively impact patient uptake, with potential for flow on effects to health outcomes of patients.

CONCLUSIONS AND RECOMMENDATIONS FOR POSSIBLE FUTURE DIRECTIONS

Overall, most consumers/carers and almost all pharmacists were in support of a DAA service. DAAs supported medication adherence, and consumers/carers saw value in receiving this service. Participating pharmacists and current DAA users placed a greater value on the weekly DAA service provided / received than the currently funded DAA program's median cost of $6.17. However, the consensus amongst pharmacists was that when engaging in the DAA program, pharmacists offered, or were expected to offer, much more than a medicine supply service, including recognising need for DAAs, to providing DAAs, to medication reconciliation, and overall medication management. They felt that they were not adequately reimbursed for the full service delivered, and that other income and services delivered in the pharmacy subsidised the DAA service. They frequently assessed whether they can financially continue providing the DAA service. However, the benefits they derived from the service either directly, such as increased professionalism, or indirectly, through the benefits

gained by their patients (e.g. better medication management, improved medication adherence), encouraged them to continue providing the service.

Level of clinical benefit to consumers from using DAAs

Although the direct measurement of clinical outcomes was out of scope for the current research, improved medication adherence is a valid proxy measure for clinical benefit. The most cited advantages by pharmacists and consumers/carers were improved consumer medication adherence, medication management and medication safety. These were also facilitators for DAA initiation and continued use. However, to truly understand the direct impact of DAAs on consumers' medication adherence, clinical outcomes and healthcare utilisation, it is important to conduct randomised controlled trials where the impact of DAAs alone can be evaluated against interventions that integrate the DAA as part of a medication adherence support service or other medication management services (such as home medicines reviews).

Recommendations:

1. Appropriate consideration should be given to the design and conduct of high-quality **randomised controlled trials** to determine the direct impact of DAAs on clinical outcomes in the Australian context.

2. Appropriate systems could be implemented in primary care (including community pharmacies) to regularly and accurately collect **real world data** on consumer demographics, medical conditions, medication regimens, medication adherence, healthcare utilisation, and other data to determine the direct and longitudinal impact of DAAs and DAA services on humanistic, clinical and economic outcomes of DAA users.

Consumers who benefit the most from DAAs

Both groups of participants in all studies agreed that people on polypharmacy and/or complex medication regimens; people with mild cognitive decline who can still use a DAA; the elderly, who tend to be on polypharmacy, complex medications regimens, have cognitive decline, have memory difficulties and some dexterity issues; patients who have carers administering their medications; and anyone who is having difficulty adhering to their medication regimen, will benefit from a DAA service.

Recommendations:

3 Consider initiatives to increase **public and healthcare professional awareness** of the availability of DAAs from community pharmacies and the effectiveness of DAAs for medication management.

Possible future directions for DAA services

The suggestions for future directions for DAA services are underpinned by the most cited disadvantages of DAAs (costs and the current cap for pharmacists), the groups reported to benefit the most from a DAA service, and the gaps in current research and clinical outcomes data.

Cost was a significant barrier for continued DAA service delivery for pharmacists. Equally, cost and the fee charged for DAA preparation and delivery were considerations for consumers and carers. Notably, pharmacists felt that more consumers could benefit from a DAA service and believed that the overall funding for the DAA program should be increased, not only to provide increased reimbursement to community pharmacies, but also to ensure that more patients can benefit from receiving DAAs and the accompanying service. Consumers/carers felt that more people could benefit from a DAA service, and there should be increased promotion and availability of the DAA service.

Recommendations:

4 **Consider review and update of existing protocols and guidelines** for the provision of DAAs and a DAA cognitive service for primary care consumers. Based on the experience of the current pharmacist participants of the DAA program, such a review and update of the protocols and guidelines should ensure standardisation across all existing documents, and consider (but not be limited to) the following:

a) that DAA services should not rely entirely on consultations with the carer but be designed to include periodic consultations directly with the patient;

b) a compendium of medicines that cannot be packed in DAAs should be developed, to ensure that medicines are appropriately packed, and that patients are accessing quality medicines;

c) that DAA service providers are encouraged to provide DAA devices that are easy to use, transport and dispose of.

5 **Further consideration of funding arrangements** for DAA services to ensure that the provision of these services is based on a transparent, needs-based model and the level of reimbursement adequately covers the costs of providing these services. This could include consideration of:

a) the provision of additional targeted support for specific populations to access DAA services. Subsidies for DAA services should be adjusted to account for the number of medicines, rurality, and health literacy.

b) the costs of providing consumer education, adherence monitoring, and DAA use monitoring.

c) different service models to maintain uptake and continuity of service provision, recognising that the benefits of DAAs range from improved convenience for the patient/care, through to improved overall management of patients at-risk of medication misadventure (e.g. persons with declined cognitive function, dementia, vision impairment, multi-morbidities, or polypharmacy).