

EXECUTIVE SUMMARY

This report describes Phase 3 of a body of work examining the effectiveness and cost effectiveness of dose administration aids (DAA) services provided by community pharmacies to people in Residential Care Facilities (RCFs) and to people living in the community (Community patients (CPs)).

As a result of the preceding Phases 1 and 2, it was evident that best practice strategies to deliver a safe, effective and efficient DAA service could optimise the effectiveness and cost-effectiveness of this resource intensive and time consuming service. In Phase 3, we set out to develop best practice models and to re-examine the cost-effectiveness of the provision of DAAs to community patients.

AIM

The aims of this Phase 3 project, funded as part of the Third Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia, were to develop:

- (1) Best practice models and tools to facilitate improvements in the way DAAs are used in the RCF and community settings. These models would improve the effectiveness and efficiency of the DAA service and the use of the devices.
- (2) A more sophisticated methodology to re-examine the cost-effectiveness of DAAs in the community setting by measuring and valuing the benefits to the health care system utilising additional data on health service use.

APPROACH

The approach to best practice model development involved the following components:

- Identification and review of existing materials including guidelines, standards and protocols, policy, best practice manuals and current practice and standards of DAA provision.
- Expert advice on aspects of DAA service provision including the legal consequences and the quality of DAA packing processes especially as this related to medication stability in DAAs.
- Integration of the results of this review with the views of stakeholders obtained through focus groups and structured interviews.
- Multivariate modelling of the characteristics of community patients who chose to use a pharmacy-provided DAA rather than original packs (OPs).
- Development of preliminary best practice models based on research findings in Phases 1 and 2, a review of existing materials and consultations undertaken in Phase 3.
- Identification of possible tools including the development of some draft tools; including patient held medication records to resolve problems arising from DAA use, and to facilitate the implementation of the best practice models.
- The use of stakeholder feedback on preliminary best practice models to identify areas for improvement or change and to evaluate the feasibility and impact of the best practice models by identifying the costs and quality implications of implementing the models.

In addition, the economic modelling of DAA services for community patients was examined. The approach included:

- Extraction and analysis of four years of community patient health care service use recorded by the Health Insurance Commission (HIC, now Medicare Australia) and similar data for Department of Veterans' Affairs (DVA) clients.
- Multivariate modelling of the characteristics of community patients who chose to use a pharmacy-provided DAA rather than OPs, including analysis of patient data using propensity scores to adjust for differences in DAA and non-DAA groups resulting from non-random sampling.
- Follow-up of the Phase 2 community patients and evaluation of the retrospective patient/carer reported use of other health service data not recorded through HIC (i.e. respite care, community nursing and residential care admission).
- An economic evaluation of the costs and benefits of DAAs from a limited societal perspective utilising actual service use data (stochastic rather than deterministic analysis).

FINDINGS

The factors that contribute to unsafe practices, reduced effectiveness of DAA services for patients with special needs, and inefficiencies in service provision were identified. There were **six underlying factors that contributed to the problems** (4.4) encountered in the provision of DAAs:

- Poor communication and timely information sharing particularly about medication changes and at hospital discharge.
- Poor awareness of responsibilities and obligations of the various parties that caused systems to fail. A lack of understanding or awareness by the various people involved in the DAA service about each other's roles and constraints (e.g. profession-specific regulations) or practices contributed to these problems.
- Lack of a systematic approach to patient assessment as to whether a DAA was appropriate, monitoring of patients and the service quality itself and, accountability for the service and its outcomes.
- Patients using DAAs had high levels of dependency on others for help with medication management and the risks of disempowerment, reduced medication knowledge and other medication management problems were not routinely addressed or monitored.
- The situation where the costs incurred are borne largely by the community pharmacies without adequate means of remuneration.
- That the information available about medication stability in various DAAs is limited.

Two preliminary best practice models were developed for community (4.5) and RCF (4.6) settings. These models included recommendations addressing:

- Formal, structured and documented patient assessment of ability to use a DAA and possible risks from DAA use prior to a community-based patient starting a DAA.
- Written agreements between parties involved that specified the service to be delivered and obligations, and promoted mutual awareness.
- A template for medication packing (including packed and non-packed medications). A copy of this template was to be carried by a community patient and used by the General Practitioner (GP) to record medication changes.
- The recording of communication about medication change in writing or by electronic means. This would also act as an audit trail.

- Continuity of care to improve the timely flow of medication regimen information and supplies of medications when community and RCF patients were admitted to hospital. The recommendation covered both information to be provided to the hospital and practices in hospital to facilitate patient discharge and transfer of care to the community and RCFs.
- Quality control, quality assurance and monitoring, patient education about drug storage and issues related to the stability of medicines packed into a DAA.
- Efficiency in the pharmacy including ensuring that prescriptions are available when required, reminder systems for doctors and patients, and DAA packing practices (including use and training of non-pharmacist staff).
- Improved the cost-effectiveness of the service i.e. that pharmacists negotiate a appropriate price for the service and target the service to only those community patients who will benefit.
- Monitoring of community patients' ability to use a DAA initially, when they were starting a DAA and on an ongoing basis. This monitoring should include at least quarterly consultations with the GP, the provision of medication information by the pharmacist and monitoring of compliance by returning DAAs. Bi-annual re-assessment of medication management ability, medication knowledge and concordance with medication regimen records (patient, GP and pharmacy) was suggested.
- A tendering process for DAA services in RCF that addressed service expectations quality assurance and payment.
- Regular checks of agreement or concordance between medication regimen records kept by the RCF, GP and pharmacy.
- Registered Nurse checks of packed medicines against the medication chart (appropriate to the pack type) at the time of delivery for any packs where residents are self-medicating or where enrolled nurses (ENs) or personal care assistants (PCAs) assist residents to take their medications from the packs. These checks were to be in addition to usual medication administration practices.

To evaluate the feasibility and benefits of these **preliminary best practice models**, the impacts of the best practice models (e.g. on costs) and quality implications, structured feedback was obtained from sixty-eight individual stakeholders (5.2.1). The evaluation of these models **found that they are likely to be beneficial in achieving improvements in practice and generally feasible** (5.2.2 and 5.2.3). Implementation of some recommendations in the models would require only small changes to existing systems but others would require substantial change, and particularly in the case of continuity of care guidelines, time. The evaluation of the models also identified aspects of the models and recommendations that could be improved but also highlighted areas of disagreement among stakeholders about what direction changes should take, for example, about standardisation versus flexibility and individualisation or RN checks of packs at delivery. Agreement among stakeholders on such key principles needs to be reached to provide direction for further revision of the preliminary best practice models.

While individual practitioners have and could implement aspects of the best practice models, further development of the best practice models, supporting tools, resources (such as improved access to information about drug stability in DAAs) and procedures with **the consultation and participation of stakeholders is required before wide spread implementation** (5.2.4). Revision of the model will also be required with the

advent of changes to the health care system such as changes to the Pharmaceutical Benefits Scheme (PBS) and the introduction of e-health initiatives (10.1.3).

In developing the best practice models, a review of the evidence supporting the stability of medication in DAAs undertaken showed that the **stability information available to pharmacists is extremely limited** (4.3). A range of strategies to promote good packing practices to improve the current situation (4.3.5 and 10.2.1) and to acquire more evidence on which to make decisions about the likely stability of medications in DAAs have been suggested (10.2.2).

The modelling of the provision of DAA services to community patients highlighted that people receiving DAA services from community pharmacies are fundamentally sicker and have greater care needs than patients using medications in original packs (OP) (8.2). Analysis of HIC service use showed that users of pharmacy-provided DAAs had the same service use costs (pharmaceutical and medical benefit scheme costs) despite having greater care needs and illness burden than OP users (7.2). Follow-up of community patients from Phase 2 at one year supported these findings (6.2). As expected for a group with higher care needs, there was a higher rate of death and RCF admission at one year for DAA users, but OP users who had died at one year had better function and health in Phase 2 compared to DAA users. This suggests an **additional benefit of DAA use** that using a pharmacy-provided DAA maintains people with higher care needs in the community (10.3.1). This may reflect better control of medication management and service use associated with the enhanced relationships within the health care team needed to provide a DAA service.

The characteristics of community patients receiving DAAs largely agrees with current recommendations and literature (10.3.1). Characteristics of community patients found to predict perceived benefit as indicated by a choice to continue DAA use included:

- Any hospitalisation in the preceding year as reported by the patient;
- Age;
- Admission of adherence problems by response to the question “Do you ever forget to take your medications”;
- Greater care needs as indicated by regular community health worker visits and impaired instrumental activities of daily living (IADL) score.

Community pharmacies appear to be providing a needed service to a fairly specific needs group. The economic modelling indicated that this was largely at a cost to themselves (10.3.2).

In Phase 2, the use of **DAAs in RCFs was shown to minimised overall costs**. For community patients outcomes such as better satisfaction and confidence in managing medications and reduced carer burden were described in Phase 2, however, the cost effectiveness for community patients was less favourable than for RCFs. Follow-up at one year (6.2) and analysis of HIC service use data (7.2) suggests additional benefits (10.3) but the additional economic modelling undertaken in this phase (Chapter 9) did not alter the conclusions regarding the cost effectiveness of DAA services for community patients derived in Phase 2. With the negotiation of funding for a subsidised DAA service for community patients, there is an opportunity to **better understand the cost-effectiveness** of the service by **developing an evaluation plan in parallel with the implementation plan** for this service and collecting data prospectively as the new

program is rolled out (10.4.2). The preliminary best practice model for the provision of DAA services to community patients should be used to inform the implementation plan for this new service.

RECOMMENDATIONS

The following recommendations relate to both services to community patients and to RCFs. The recommendations are shown separately for convenience although a number of recommendations are duplicated.

Recommendations for DAA service provision to community patients

1. Dose Administration Aids (DAAs) should be targeted to community patients with a need for and likelihood of benefit from the service.
2. Criteria need to be defined to assess need and likelihood of benefit for community patients. Modelling conducted in this and other studies should be used to inform the criteria.
3. A structured patient assessment protocol for community patients should be developed to determine need for a Dose Administration Aid. This assessment should be repeated at intervals to monitor the effects of the service.
4. The Pharmaceutical Society of Australia (PSA) in conjunction with the Therapeutics Good Administration (TGA) should develop a “current good packing practice” document using the code of good manufacturing practice as a frame work. The good DAA packing practice code should include staff training and competencies. These could be developed by PSA and the Pharmacy Guild and included in the Quality Care Pharmacy Program (QCPP) and in dispensary technician training programs.
5. The strategies identified in this study to better define drug stability in Dose Administration Aids should be implemented.
6. There needs to be an overarching emphasis on quality in the provision of Dose Administration Aids services.
7. A Dose Administration Aid service should reflect best practice to optimise the provision of a safe effective and efficient DAA service.
8. It needs to be recognised that such a model involves the effective collaboration of the patient care team including the doctor, the pharmacist and community nurses, patients and carers, and government.
9. The quality assurance measures included in the best practice model should be seen as a priority for implementation.
10. The issues and strategies included in the preliminary best practice model should be widely disseminated and the principles integrated into existing QUM and safety and quality initiatives such as the APAC guidelines (continuity of care and community), PSA guidelines, QCPP, Aged Care Assessments, Divisions of General Practice Aged Care, Home and Community Care, Commonwealth Department of Health and Ageing, Department of Veterans’ Affairs and state health programs.
11. Further consultation among stakeholder peak bodies is needed to reach agreement on and to define that desired future direction of the best practice models. This should include defining a continuing development plan for the models and an implementation plan for DAA best practice initiatives.

12. The preliminary best practice model and findings of its evaluation should be used to inform the development of the implementation plan for a subsidised DAA service for community patients.
13. The Pharmacy Guild of Australia should convene a working party including appropriate stakeholder representation (see 5.2.4.2) and participation to develop an implementation plan for a community DAA service that embraces best practice, accountability and quality principles.
14. An evaluation plan should be developed in parallel to an implementation plan to prospectively collect data to inform future program evaluation. Patient assessment can provide data for both eligibility checking and future evaluation.
15. The implementation working party should seek input from, and convene technical advisory panels of experts to advise on (1) further development of the knowledge base about drug stability in DAAs, (2) the evaluation of the health economics of the subsidised community DAA service, and (3) refinement of eligibility criteria.
16. Any business rules developed for subsidised DAA service to community patients should embrace the principles of best practice described in the preliminary best practice model developed in this study or any subsequent revision.
17. It is recommended that an online system be used to register and assess eligibility for subsidised DAA provision to increase efficiency and to capture data for later evaluation.
18. The development of documents and protocols to support best practice in the implementation of a subsidised DAA service should include trialling and use document/web design expertise.
19. It is recommended that the government support the use of Dose Administration Aids services in the community where patients meet the appropriate access criteria and the service provided reflects best practice.

Recommendations for DAA service provision to RCFs

1. Appropriate Dose Administration Aids services should be encouraged in RCFs and the role of the service in minimising overall medication management costs in RCFs should be recognised for appropriate funding to the suppliers of the service.
2. The Pharmaceutical Society of Australia (PSA) in conjunction with the Therapeutics Good Administration (TGA) should develop a “current good packing practice” document using the code of good manufacturing practice as a frame work. The good DAA packing practice code should include staff training and competencies. These could be developed by PSA and the Pharmacy Guild and included in the Quality Care Pharmacy Program (QCPP) and in dispensary technician training programs.
3. The strategies identified in this study to better define drug stability in Dose Administration Aids should be implemented.
4. There needs to be an overarching emphasis on quality in the provision of Dose Administration Aids services.
5. A Dose Administration Aid service should reflect best practice to optimise the provision of a safe effective and efficient DAA service.

6. It needs to be recognised that such a model involves the effective collaboration of the patient care team including the doctor, the pharmacist, RCF staff, patients and carers, and government.
7. Systems whereby a legal order on a medication chart can act as a prescription as part of a supply claim mechanism should be established to improve the safety, effectiveness and efficiency of DAA provision to RCFs. This may require changes to state and commonwealth regulations, and current Medicare payment claim procedures. Any new system should address accountability, safety and regular medication review.
8. The quality assurance measures included in the best practice model should be seen as a priority for implementation.
9. The issues and strategies included in the preliminary best practice model should be widely disseminated and the principles integrated into existing QUM and safety and quality initiatives such as the APAC guidelines (residential care and continuity of care), Aged Care Standards, PSA guidelines, QCPP, Divisions of General Practice Aged Care, Commonwealth Department of Health and Ageing, Department of Veterans' Affairs and state health programs.
10. Further consultation among stakeholder peak bodies is needed to reach agreement on and to define that desired future direction of the best practice models. This should include defining a continuing development plan for the models and an implementation plan for DAA best practice initiatives.
11. The Pharmacy Guild should convene a working party including appropriate stakeholder representation (see 5.2.4.2) and participation to develop an implementation plan for an RCF DAA service that embraces best practice, accountability and quality principles.
12. The requirement for the operation for a best practice DAA service should be included into existing programs for RCF accreditation, recognising that best practice is not solely the responsibility of the pharmacy providing the DAA services.