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Background

November 2016: HealthConsult completed the evidence review on the clinical and cost effectiveness of three Pharmacy Practice Incentives (PPI) Medication Adherence Program Initiatives:

- Dose Administration Aids (DAA)
- Staged Supply (SS) support allowances •
Clinical Interventions (CI).

April 2017: HealthConsult completed the evidence review on the clinical and cost effectiveness of four Medication Management Programs (MMPs):

- Home Medicines Review (HMR)
- Residential Medication Management Review (RMMR) •
MedsCheck
- Diabetes MedsCheck.



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DAA - Evidence

Based on nine primary studies that examined the use of a DAA:

- Seven RCTs
- One prospective
- One retrospective matched cohort study
- No Australian studies (one in New Zealand, one in Canada and seven in North America).

Search also identified:

- Two publications: of the Australian DAA project funded under 3CPA.
 - Two previous evaluations: of the DAA initiative funded under the 4CPA and 5CPA. •
- Three systematic reviews: that evaluated a combination of adherence-aimed interventions – not included to avoid confounding findings for DAAs.



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DAA - Findings

Adherence findings:

- Three RCTs and one retrospective study showed DAAs (or similar) significantly improved adherence to medication for diabetes and hypertension, measured by the medication possession ratio (MPR).
- Two of three studies showed no effect when measured by pill count.
- Effect more pronounced when use combined with other interventions (refill reminder).

Clinical outcomes findings:

- Single prospective cohort study (*poor quality*) found that pillbox was not associated with time in therapeutic range (TTR) <60% or international normalised ratio instability.
- Two RCTs (*one fair and one good quality*) showed use of reminder packaging in patients taking antihypertensive medication significantly decreased diastolic but not systolic blood pressure.
- One study (poor quality) did not demonstrate effect of reminder packaging on blood pressure control (or on adherence).
- One RCT (good quality, small size) showed that in patients with poorly controlled diabetes, reminder packaging significantly decreased glycated haemoglobin at eight months of follow up compared with original packaging.



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DAA - Findings

Patient satisfaction findings

- Insufficient evidence to assess patient acceptance or satisfaction with pharmacist-prepared DAAs (or similar).
- Patient satisfaction was reported by only three of the included studies.

Other outcomes:

- No included studies reported outcomes relating to adverse drug events, mortality or health related quality of life.
- No included studies provided information on safety or harms associated with use of DAA (dispensing/packaging errors).
- The three phase 3CPA project undertaken by the University of Queensland included two cost-effective analysis – but relevance to current DAA is problematic.



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DAA - Conclusion

- Identified overseas evidence is generally poor to fair quality and has limited applicability to the Australian DAA initiative.
- Available information is inconclusive as to whether DAAs are effective in improving medication adherence, clinical outcomes, patient satisfaction or are cost effective.
- No studies assessed the impact of an incentive payment to pharmacists.
- Further research is required to make a more robust assessment of the clinical and cost effectiveness of DAAs:
 - a high-quality study of adequate size and duration that assesses the use of DAAs delivered through community pharmacies on medication adherence, clinical outcomes, health care utilisation, and patient satisfaction
 - a robust costing study that measures the unit cost of the delivering of a DAA service in a variety of settings across the community pharmacy sector
 - a translational study that takes the results of the unit cost and outcome measurement work and calculates cost effectiveness.



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SS - Summary

EVIDENCE:

- No studies fulfilled the evidence selection criteria.
- Two previous evaluations of SS service commissioned under 4CPA and 5CPA.

FINDINGS:

- Benefits findings: No evidence found.
- Costs findings: No evidence found.
- Cost effectiveness findings: No evidence found.

CONCLUSION:

- No studies were identified that assessed the impact of SS improving medication adherence or any other health related outcomes
- No conclusion could be made regarding SS services effectiveness or cost-effectiveness.
- Further research is required.



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CI - Evidence

Four Australian studies of CIs funded by the Commonwealth were identified:

- One RCT: compared CI rates after providing pharmacist education and/or remuneration (or neither)
- Three CPA-funded CI projects: related to the DOCUMENT classification system.

Literature search also identified:

- One GuildCare report on CI initiative
- One previous evaluation of the CI initiative funded under the 5CPA.

Only one study (Benrimoj et al (2003)) met the agreed inclusion criteria (that study was also a key input into the initial CI program design).

The lack of a widely accepted definition for CIs was a challenge. The literature search excluded most studies due to the CI in question being more similar to other professional pharmacy services (e.g. asthma medication optimisation and adherence programs).



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CI – Findings & Conclusions

Other than work funded under CPAs, no studies were identified that assessed the clinical and cost effectiveness of providing incentives to community pharmacists to deliver CIs.

- The Benrimoj work was not considered independent evidence and does not directly address the question of clinical and cost effectiveness.
- The PROMISe I, II, and III studies (Peterson et al) are relevant, but provided relatively low level evidence for cost-effectiveness and no corroborating studies could be found.

Complexities:

- CIs are routinely undertaken by community pharmacists, making it difficult to estimate the clinical and economic outcomes of CIs.
- The broad definition of each consequence resulting from a CI and the assumption that a given consequence will result in the same level of disability and health resource utilisation in every patient (regardless of age and co-morbidities).

Further research is required – focus on gathering data about discrete well defined CIs not part of standard practice provided by pharmacists.



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HMR - Evidence

Evidence based on 12 primary studies of pharmacist-led HMR impact on patient outcomes:

- Seven RCTs
- Three retrospective cohort studies
- Two retrospective pre-post-design studies
- Eight Australian studies and one from the UK.

The search also identified:

- A number of systematic reviews that focused on medication reviews but not specific to HMR conducted by pharmacist in a patient's home (could not be extrapolated).
- Five previous evaluations of the HMR initiative funded under the 3CPA, 4CPA and 5CPA.



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HMR - Findings

Hospital Admissions findings

- One RCT reported significant benefit in regards to a composite hospitalisation plus out-of-hospital deaths outcome and fewer unplanned readmission in high risk patients. This RCT suggested similar benefits for the congestive heart failure subpopulation.
- Three other RCTs showed no effect of pharmacist directed HMR on reducing readmissions for patients with heart failure.
- One RCT, that evaluated the impact of HMRs on reducing hospital admission in elderly patients (prescribed four or more oral daily medicines), showed HMR did not lead to reduction in hospital admissions.
- There is lack of clear evidence demonstrating an effect of HMR on hospital admissions.

Time to next hospitalisation findings

- Two Australian retrospective (low quality) studies using DVA data suggested that HMR can temporarily reduce hospitalisation rates for older people living in the community at high risk of medication-related hospital admissions (heart failure and warfarin).
- Effect of HMR appears to be transitory, benefits lost after 12 month period.



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HMR - Findings

Care home admissions findings

- One RCT reported no difference in care home admissions at six month follow-up.

Health care resources findings

- Conflicting evidence – only one RCT showed significant reduction in prescribed items following the provision of an HMR

Mortality findings

- One single RCT reported significantly fewer out-of-hospital deaths and fewer total deaths in high-risk patients receiving HMR post-discharge from an acute care hospital. Analysis of congestive heart failure patient subpopulation did not show similar effect.
- Three studies suggested that pharmacist directed HMR for people recently discharged from hospital with heart failure had no significant effect on reducing deaths.

Quality of life findings

- Five RCTs indicate HMR does not appear to improve quality of life (although trials not of sufficient size).



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HMR - Conclusion

- The available systematic reviews and lower level evidence did not allow a determination to be made on the clinical and cost-effectiveness of HMRs performed by pharmacists.
- There is a larger body of evidence for more comprehensive and multidisciplinary medication reviews interventions focused on improving clinical outcomes – but findings cannot be extrapolated to the HMR program.
- Further research is required – difficult to specify as HMRs have become an accepted part of pharmacy practice. Two options:
 - Identify characteristics of patients that experience adverse medication events and target research towards determining whether HMRs by a pharmacist can prevent those problems occurring
 - Direct research towards developing a multidisciplinary (at the point of care) HMR delivery model.



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RMMR - Evidence

Evidence based on six primary studies that examined pharmacy led RMMR impact on patient outcomes:

- Three RCTs
- Three observational studies
- Two Australian, two from the UK, one from the Netherland and one from Israel.

The search also identified:

- A number of systematic reviews that focused on medication reviews but not specific to RMMR conducted by pharmacist (could not be extrapolated).
- Three previous evaluations of the RMMR initiative funded under the 4CPA and 5CPA – did not satisfy inclusion criteria for evidence base (non-comparative).



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RMMR - Findings

Hospitalisation findings

- Three RCTs suggested that the RMMR does not lead to fewer days in hospitals.
- Little evidence evaluating RMMR impact on other health care resource utilisation.

Medication appropriateness findings

- One RCT and one small observational study showed that RMMR was associated with an improvement in appropriateness of prescribing, using validated instruments.
- Link between improved medication appropriateness and patient-related outcomes was not clear.

Medication-related problems findings

- Three RCTs and two observational studies found evidence that RMMR performed by pharmacists led to identification of medication-related problems and GP acceptance rate for medicines interventions suggested by pharmacists was generally high.
- No study determined whether the identification of medication-related problems through the RMMR led to actual improvements in health outcomes.



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RMMR - Findings

Falls findings

- One RCT demonstrated that a single clinical RMMR resulted in significant reduction in falls and one RCT showed no difference in risk of falling following RMMR.

Drug Burden findings

- One RCT and two observational studies showed significant reduction in the number of prescribed drugs following pharmacists' RMMR recommendations and GP uptake of those recommendations.
- Another RCT demonstrated reduction in mean number of drugs in both the RMMR and control group (no in-between group difference).
- No study investigated link between reduced drug burden and patient-related outcomes.

Mortality findings

- Three RCTs suggested RMMR has no effect on reducing deaths.

Medication costs findings

- Two RCTs found a reduction in costs, one found no difference.



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RMMR - Findings

Clinical outcomes findings

- Two RCTs indicated that RMMR performed by pharmacist does not result in a significant improvements in cognitive, physical or behavioural functioning.

Quality of life findings (*insufficient evidence*).



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RMMR - Conclusion

- Systematic reviews and lower level evidence do not allow a conclusive determination on the clinical and cost-effectiveness of RMMRs performed by pharmacists on residents in aged care facilities.
- Available studies suggest:
 - RMMRs have an impact in terms of pharmacists identifying medication-related problems and making recommendations that GPs are likely to implement.
 - RMMRs have an impact in improving the appropriateness of prescribing and reducing the drug burden on residents of aged care facilities.
- No studies link these interim outcomes to improvements in end-point health outcomes.
- Further research is required:
 - Cost measurement study and a study collecting data on clinical and perhaps patient reported outcomes measures.
 - As RCT not possible, result of cost and outcome measurement studies provide valuable evidence to further inform the refinement of the RMMR program.



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MedsCheck/Diabetes MedsCheck - Evidence

Evidence based on 13 primary studies that examined community pharmacy based medication review similar to the MedsCheck:

- 10 RCTs
- One observational study with pre-post-design
- One retrospective sub-analysis of a cluster RCT
- One study evaluated the cost-effectiveness of a community pharmacy based medication review (cost-utility analysis)
- One study focused on medication review targeting patients with type 2 diabetes
- No Australian studies (mostly USA and Europe).

The search also identified:

- A number of systematic reviews that focused on medication reviews but not specific to MedsCheck or Diabetes Medscheck (could not be extrapolated).
- Two evaluations funded under the 3CPA and the 5CPA - did not meet inclusion criteria as they were non-comparative and took a program evaluation approach.



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MedsCheck/Diabetes MedsCheck - Findings

Clinical outcomes findings

- One RCT showed that a community pharmacy based medication review can lead to significant improvements in clinical outcomes, including blood pressure, glucose levels and triglyceride levels (however, RCT conducted in Jordan).

Hospital admission findings

- Three RCTs found no effect on number of hospital admissions (one RCT also reporting no significant effect on reducing ED visits).
- Evidence from a sub-analysis of a cluster RCT and another pre-post-design study suggested that community based pharmacy medication review results in significant reduction in hospital admissions.
- The studies on pharmacist led interventions have limitations (small samples, no cause and effect analysis and short follow-up duration) – evidence remains uncertain.



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Health Care resource use findings

- One (poor quality) retrospective sub-analysis of one RCT shows medication-related hospital costs were significantly lower for patients receiving a community pharmacy based medication.



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MedsCheck/Diabetes MedsCheck - Findings

Drug burden findings

- Two RCTs that evaluated effect of community pharmacy based medication reviews on reducing number of medications associated with falling were contradictory.
- One observational study showed community pharmacy based medication review reduced the number of medicines, leading to a decrease in % of polypharmacy patients.

Falls findings

- Two RCTs showed that a community based medication review has no effect on reducing falls in high-risk older adults (both on small sample size).

Mortality findings

- Two RCTs did not demonstrate significant effect on mortality in patients with heart disease.

Prescribing appropriateness findings

- One large RCT suggested community pharmacy based medication reviews have no positive effect on improving appropriateness of medication prescribing.



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MedsCheck/Diabetes MedsCheck - Findings

Adherence findings

- Three RCTs (out of four) showed that a community pharmacy based medication review did not have a positive effect on improving patients' adherence to medication.

Health related quality of life findings

- One observational study reported improvement in QoL.
- Four RCTs showed no significant effect.

Patient acceptance/satisfaction findings

- Two RCTs suggested that community pharmacy based medication review has a positive effect on patient satisfaction, especially in relation to treatment and symptom control.

Diabetes MedsCheck finding

- One single small RCT found no significant effect on blood glucose levels, hospital admissions, GP visits, drug burden or QoL. Significant improvement in blood pressure was demonstrated.



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MedsCheck/Diabetes MedsCheck - Conclusion

- Available studies suggest:
 - Effect of MedsCheck on patients outcomes was mixed – some studies showing benefit in certain populations whilst others showing no positive effect.
 - Several studies addressed the effects of a MedsCheck interview on intermediate outcomes (reduction in DRPs) – however improvements in this outcome did not translate to meaningful reduction in ADEs or patient health outcomes.
 - One study with a cost-utility analysis concluded that medication review was cost-effective. Another study comparing input costs using a cost-minimization analysis found the medication review service was more expensive than standard care.
- No studies addressed clinical outcomes of MedsCheck/Diabetes MedsCheck services.
- Further research is required. Two options:
 - Identify characteristics of patients that experience adverse medication events and target research towards determining whether MedsCheck or Diabetes MedsCheck by a pharmacist can prevent those problems occurring
 - Direct research towards an approach where patients using medicines with high risk of adverse events are the target population for MedsCheck.



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MSAC decision

- MSAC considered the evaluation of literature and the available data for all these programs in November 2016 and April 2017, and concluded that there was insufficient evidence and a lack of empirical research to determine the clinical and cost effectiveness of the reviewed programs
- MSAC noted that it was difficult to conduct a comparative assessment of the programs as they were now primarily standard of care expected of a pharmacist.
- MSAC suggested that there was a need for comparative data to determine whether enhancements to the programs provide effective care relative to current practice.



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6CPA - Stage 2

- As a result of Budget Measure announced in 2017/18 Budget, the following new and expanded programs have been rolled out:
 - Dose Administration Aids (DAA) – new
 - Staged Supply (SS) – new
 - MedsCheck – expanded
 - Diabetes MedsCheck – expanded
 - Home Medicines Reviews (HMR) – expanded.
- As part of implementing the Budget Measures, the Department sought assistance with the design, implementation, and monitoring and reporting of the new and expanded community pharmacy programs, which includes the conduct of an activity based costing exercise for the five in-scope programs.



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Stage 2 – Revised Monitoring and Reporting Dataset

HealthConsult has assisted with the development of an expanded dataset for program monitoring and reporting purposes:

- Claims Dataset – to be collected by all participating pharmacies for all patients
- Pharmacy-Provided Minimum Dataset (MDS) – to be collected for a sample of five DAA patients in each participating pharmacy (about 27,500 patients).
- Unit Cost Data – to be measured by HealthConsult using an activity based costing approach for all five new and enhanced program components.

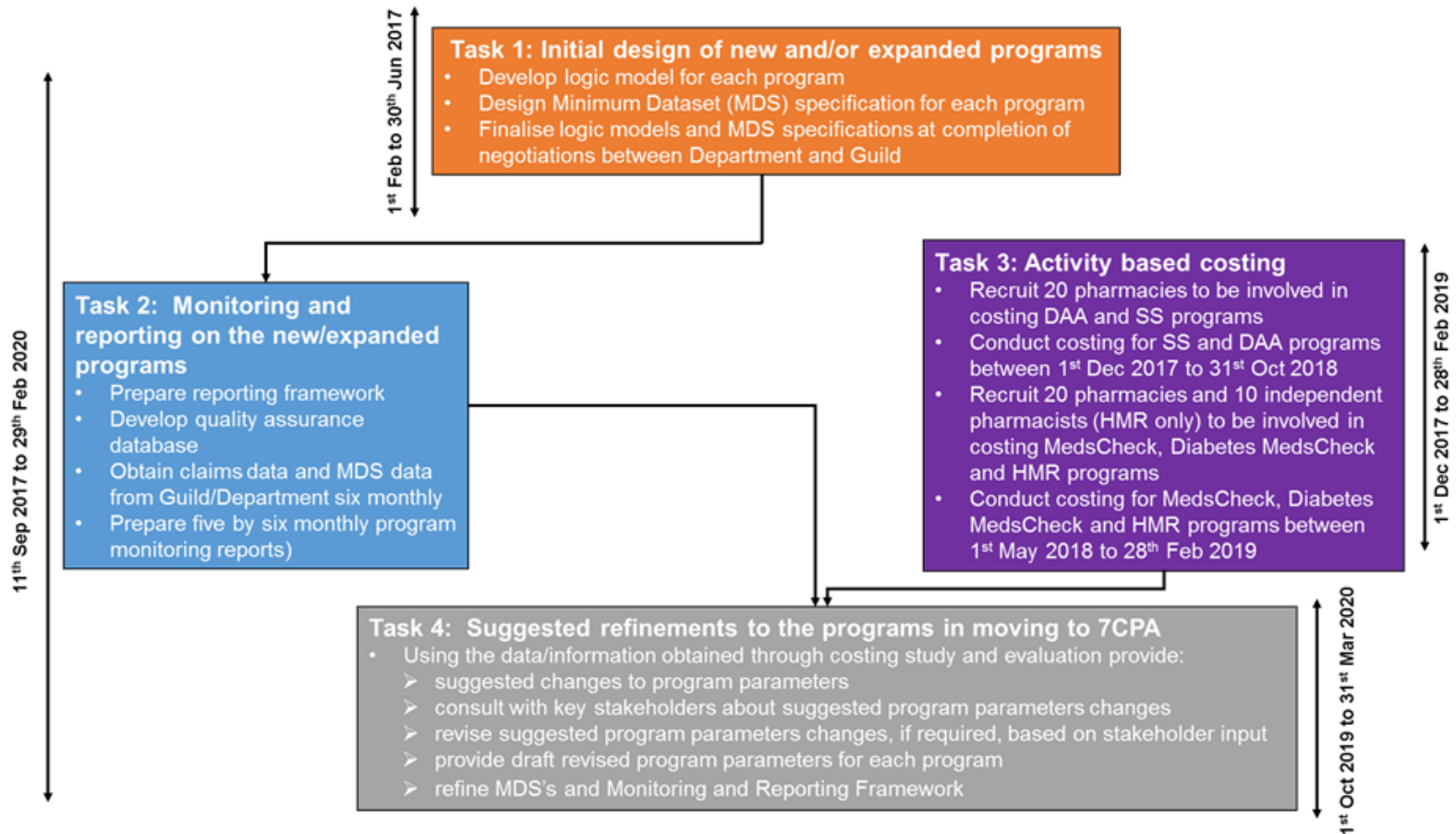


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Stage 2 – Key activities





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Stage 2 – Deliverables

Monitoring and Reporting:

- Monitoring and reporting frameworks.
- Bi-annually reporting according to the monitoring and reporting frameworks:
 - Reporting Period 1: 1st July to 31st December 2017 (simplified version based on available data)
 - Reporting Period 2: 1st January to 30th June 2018
 - Reporting Period 3: 1st July to 31st December 2018
 - Reporting Period 4: 1st January to 30th June 2019
 - Reporting Period 5: 1st July to 31st December 2019.

Activity based costing:

- Estimates of a representative unit cost pharmacies to deliver a service under each of the in-scope programs.
- Estimates of the cost to consumers (direct costs).
- Estimates of the cost to government.
- All five unit cost estimates will be available by early 2019.