

1. EXECUTIVE SUMMARY

1.1 Objectives

The specific aims of the Diabetes Mellitus Education Program (DMEP) were to examine the role of the community pharmacist in the disease state management for type 2 diabetes; to implement a specialized service for patients with type 2 diabetes; to evaluate the model in terms of process and outcomes indicators; and to investigate patient and pharmacist satisfaction with the service.

1.2 Null Hypotheses

H_0 : There will be no significant difference between Intervention and Control

Groups pre- and post intervention in:

- Patients' knowledge of diabetes and its management
- Compliance with diabetes treatment and monitoring regimens
- The number of patients achieving desired blood glucose and HbA1c levels
- The incidence of hyper- and hypoglycaemic episodes
- Quality of life and well-being scores
- Consumption of health resources

1.3 Research Design

The DMEP utilised a multi-site clustered, randomised control versus intervention, repeated measures design within four socioeconomic regions within the Perth metropolitan area. The eight community pharmacies recruited for the DMEP program came from a representative sample Diabetes Australia Sub-Agencies. The project pharmacies were divided into two groups – Intervention and Control.

Patients in the Control Group received “standard care”. While patients in the Intervention Group were enrolled into the DMEP program which involved:

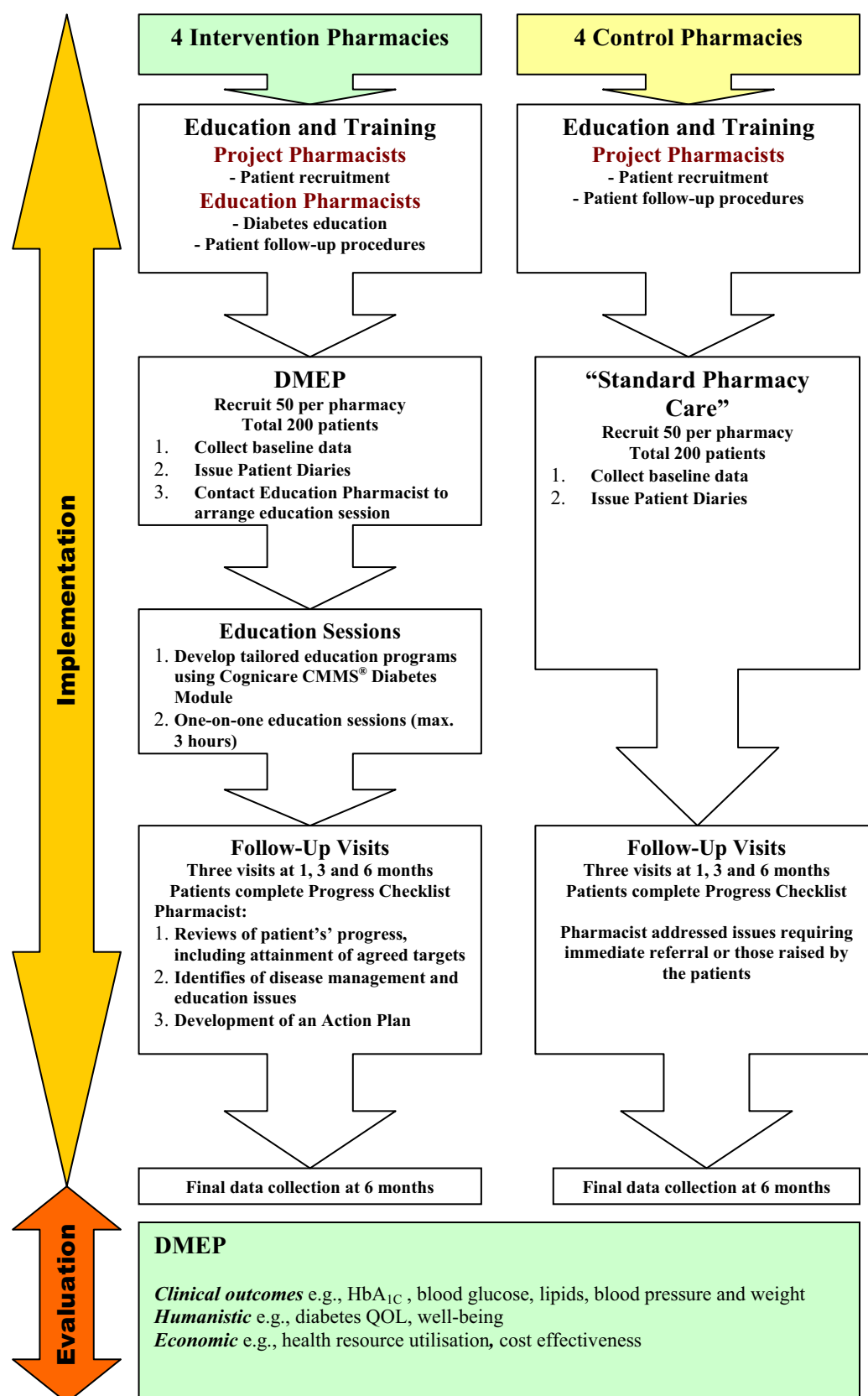
- the administration of a diabetes mellitus specific questionnaire designed to identify individual patient's educational needs

- development and delivery of a tailored education program
- regular monitoring of blood glucose levels (BGLs) and other treatment targets
- progress assessment, and
- Identification of barriers to adherence and interventions to overcome these.

Patients in both groups were provided with diaries in which to record their BGLs and weekly weights, together with episodes of hypo- and hyper-glycaemia, and record other health-related matters. The diaries contained information on diabetes and its management, a current list of the patient's medications and targets for good diabetes care. There was also provision for the patients to record appointments with other health care professionals.

Patients in the Intervention groups were provided with up to 3 hours of one-on-one diabetes education by a trained pharmacist diabetes educator. After the completion of the education sessions patients were followed up at 1, 3 and 6 months. At each of these sessions patients were asked to complete a Patient Checklist, which was used in the monitoring of patient progress and the identification of barriers to adherence. These sessions also involved the provision of further education, goal setting, identification and resolution of drug related problems and where necessary referral of patients to other health care providers. At the completion of these sessions patients were provided with an action plan setting out issues identified and actions required to address these, which were reviewed at subsequent visits. Control patients were assessed also at 1, 3 and 6 months, and were asked to complete a Progress Checklist; however they received no other intervention except for the usual pharmacist's advice/care over the 6 month period.

Figure: DMEP Study Schema



1.4 Key Findings

- Two hundred and forty five patients consented to participate in the study; however 63 failed to complete the enrolment process. Of those who did complete the enrolment process 71.2% (57/80) and 71.6% (73/102) of Intervention and Control Patients respectively completed the study.
- Patients in the Intervention Group received on average 1.5 ± 0.6 tailored education sessions and a total of 106 ± 44 minutes of education.
- The most common topics addressed during the education sessions were hypoglycaemia, hyperglycaemia, carbohydrates and diabetes medications.
- Patients in the Intervention Group reported significantly greater knowledge and understanding of diabetes and its management than Control patients at the completion of the study.
- Over the course of the three DMEP follow-up sessions, Intervention pharmacists identified 165 issues requiring intervention (2.89 per patient); 37.6% related to lifestyle, 33.6% related to medications, and 26% related to disease.
- For the Intervention Patients
 - HbA1c fell from $8.35 \pm 0.20\%$ at baseline to $7.87 \pm 0.22\%$ at exit (-0.48% ; $p=0.003$) for those patients with a baseline HbA1c $> 7\%$
 - Mean systolic BP dropped from 137.8 ± 2.4 mmHg at baseline to 131.2 ± 2.2 mmHg at exit (-6.2 mmHg; $p<0.02$)
 - Weight fell from 84.9 ± 3.7 kg at baseline 83.9 ± 3.5 kg at exit (-1 kg; $p = 0.038$), and the BMI from 31.2 kg/m² to 29.2 kg/m² (-1.6 kg/m²; $p = 0.02$)
- After adjusting for baseline differences between Intervention and Control patients significant improvements in LDL cholesterol (-0.18 mmol/L 95% CI $-0.36, -0.0009$) and HDL cholesterol (0.21 mmol/L; 95% CI $0.04, 0.39$) levels were seen. Whilst, the reductions in systolic BP (-6.3 mmHg; $p = 0.054$) and weight (-0.87 kg; $p = 0.09$) showed strong trend towards a benefit from the Intervention.

- Significant reductions in the frequency of hyper- and hypo-glycaemic episodes were seen in the Intervention Group, which correlated with a significant increase in self-reported knowledge and understanding of hyper- and hypoglycaemia amongst Intervention patients compared to Controls.
- At the completion of the study there was significantly greater willingness amongst Intervention patients compared to Controls to work toward improving their diabetes care.
- Patients in the Intervention Group recorded lower scores in all six dimensions of the Diabetes Symptoms Checklist-Revised at the completion of the study compared to Control patients; with the changes statistically significant in two suggesting a better level of well-being.
- Based on responses to the SF-36 Short Form questionnaire Intervention patients demonstrated higher scores across all dimensions except “Role-Physical”. The improvement only reach statistical significant for Social Functioning; although based on the one SEM criteria clinically significant improvements were achieved in the dimensions of Physical Functioning, Vitality, Social Functioning, Role – Emotional and Mental Health.
- Patients reported great satisfaction with the DMEP, citing accessibility to the program, improvements in their knowledge about diabetes, and ongoing support in the management of their diabetes as major benefits.
- Pharmacists also expressed great satisfaction with their involvement in the delivery of DMEP and saw an opportunity to extend their role in diabetes care in the future.
- The Intervention was not associated with any statistically significant changes in health resource utilisation, although there were some reductions in Medicare and HIC expenditure, the acuity of hospital admissions and duration of hospital stay.
- The pharmacoeconomic benefits of the study are summarised in the Addendum entitled: “Economics of Providing the DMEP Service.”

1.5 Conclusions

The Diabetes Mellitus Education Program (DMEP) demonstrated that community pharmacists can enhance patients’ knowledge and understanding of

their diabetes and its management. Further that its can deliver meaningful outcomes to participants, namely a reduction in hypo- and hyper-glycaemic episodes, which translate into improvement in quality of life. The cost of avoiding hypo- and hyper-glycaemic episodes was low; supporting the notion that the DMEP is a clinically and cost effective professional service which may be implemented in a wide range of community pharmacies in Australia. The patients and pharmacists involved in the DMEP were very satisfied with education and follow-up sessions provided as part of the program. Further they felt that such a community pharmacy-based program should be more widely available, and expressed a preparedness to participate in such a program on an ongoing basis.

Community pharmacists' role in patient education has been acknowledged by patients and health care professionals alike. It is also acknowledged that diabetes education is an ongoing process, designed to support patients in self-management of their disease. The DMEP allows community pharmacists to be engaged in this process of ongoing care; assisting patients achieve the best outcomes from their disease management. To maximise their success and professional satisfaction, pharmacists who wish to participate in this process should undergo specialised training in diabetes education and management.

Community pharmacies provide an ideal environment for the provision of enhanced pharmacy services. Pharmacists are ranked second only to doctors as sources of information on disease management. Whilst the provision of disease state management services, such as the DMEP, may be confronting to some traditional community pharmacy clients, their uptake by patients is likely to be driven by the convenience of attending a community pharmacy and patients' perceived health benefits derived from participating in such programs. Given self-management is the cornerstone of diabetes management, and that this is greatly enhanced through patient education, it appears likely that future provision of extended services, such as the DMEP, would be adopted and supported by patients in Australian community pharmacies. Furthermore, as was the case with the Pharmacy Diabetes Care Program, subsidisation by the

Australian Government would enable widespread uptake of the DMEP by community pharmacy.

In conclusion, DMEP services implemented in this study have the potential to contribute to improved patient self-efficacy in their management of their diabetes, and with that associated improvements in health outcomes and quality of life.