COST EFFECTIVENESS OF A HEALTH LITERACY EDUCATION MODULE INTERVENTION ON TYPE 2 DIABETIC PATIENTS

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ABSTRACT

Background: Economic burden of diabetes was expected to continue to grow. In 2017, International Diabetes Federation (IDF) estimated the total healthcare expenditure was USD 727 billion (MYR 3260 billion) (20 – 79 years), which represented an 8% increase compared to 2015. A study had shown that up to 73% of diabetes-related healthcare costs result from hospitalization and ambulatory care, as a result of complications due to poor blood sugar control (IPH, 2015). Analysis by Shafei et al. (2012) showed that improved glycemic control would be likely to bring substantial clinical and economic benefits to the patients, arising primarily from reduced incidence of diabetes complications. HbA1c reduction was associated with reduced costs of treating diabetes complications and an increase in life expectancy. Health literacy intervention is one type of diabetic education approach which integrates self-efficacy and self-care behaviour into the module (Wolff et al., 2009). The aim of the intervention was to reduce the HbA1c by giving knowledge on how to manage their own diabetes.

Materials and Methods: The study design was randomized control trial with health economic evaluation for cost-effectiveness analysis. The intervention group received health literacy education module adapted from DLNET for the study, and control group received conventional health education module. Cost effectiveness ratio (CER) and incremental cost effectiveness ratio (ICER) were calculated. The costs per unit of reducing HbA1c (%) was evaluated in both intervention and control groups, and decision rules were applied to determine cost effectiveness of intervention.

Result: Total cost at final cost centre for the intervention group was RM 68,113 while the total cost at final cost centre for the control group was RM 67,206. The intervention was cost effective with CER of 0.12 and ICER of RM 1,225 per HbA1c improvement.

Conclusion: The study revealed that health literacy education module intervention was cost effective in reducing HbA1c among type 2 diabetic patients at the study hospital.

Keywords: cost effectiveness, health literacy, education module interventionHbA1c, diabetes,
1.0 Introduction

The prevalence of diabetes is increasing worldwide. Type 2 diabetes is one of the most common endocrine disorders, affecting almost 6% of the world's population (Firouzi, Barakatun-Nisak, & Azmi, 2015). It was estimated that around 54% of deaths in developing countries are due to chronic non-communicable diseases which are predicted to rise by 65% by 2030. Annual deaths attributable to diabetes are probably as high as 3 million with more than 80% occur in developing countries. Increasing prevalence of chronic diseases is a major contributor to a rapid rise in health care cost in developing countries since the last decade. Worldwide estimates suggest that the annual direct medical cost for diabetes in total is at least USD129 billion (MYR425 billion) and may be as high as USD241 billion (MYR795 billion), or 2.5% to 15.0% of the global annual health care budget. It was also estimated that there will be almost 50% increase in direct health care costs associated with diabetes from USD286 billion (MYR1087 billion) in 2003 to USD396 billion (MYR1505 billion) in 2025 (Ibrahim, Aljunid & Ismail, 2010).

In Malaysia, rising of health care costs is inevitable. Demographic changes and changes in disease pattern and lifestyle would influence health care costs. The introduction of new technologies and ever-increasing consumer expectation for high-cost quality care are factors contributing to rising health care costs. For the years from 2007-2011, the operating budget allocation for the Ministry of Health has increased from MYR9.57 billion in 2007 to MYR14.30 billion in 2011. Meanwhile, the expenditure for operating budget recorded an increase from MYR9.77 billion in 2007 to MYR14.90 billion for 2011 (Ministry of Health Malaysia Annual Report, 2011). A study by WP et al., (2009) showed that the average provider’s cost of treating inpatients diabetics in Selangor was MYR7,755,139.71 for the year of 2004. As for outpatients diabetics, it was estimated that MYR989,506.70 was spent for hospital’s outpatient and MYR10,415,123.10 spent on Health Clinics. Therefore, the total expenditure on diabetic care year 2004 was MYR18,956,021.51 which was equivalent to 3.4% of the total expenditure on health for the state.

Another study by Rohana (2007) assessing the cost of diabetes outpatient care in one district in Kelantan, Malaysia found that means provider cost per diabetic patient per year for health clinic with a specialist was MYR1127 (MYR906.088) and MYR802.15 (MYR626.266) for health clinic without specialist. Ibrahim et al. (2007) on the other hand looked into inpatient direct provider cost of diabetic foot, found that MYR12, 934.61 (MYR7, 362.49) was spent per patient per admission. The cost effective (CE) threshold for Malaysia was estimated to range between MYR19,929 and MYR 28,470, which is lower than the currently used WHO-recommendation threshold value. Education level, estimated monthly household income, the description of health state scenarios, and age of the respondents are some of the identifiable factors that may have affected the value of the determined CE threshold (Lim et al., 2014).

A study of United Kingdom used a population-based intervention based on a sustained, incremental improvement in glycaemic control by everyone with type 1 or type 2 diabetes there could be significant reductions in microvascular complications incurred, translating into a cost avoidance of about GDP340 million (MYR1992 million) over 5 years and as much as GDP5.5 billion (MYR32 billion) after 25 years. The researchers used the IMS CORE Diabetes Model to look at the effect of HbA1c in a representative cohort of adults with type 1 or type 2 diabetes. They then modelled the incidence of microvascular and macro-vascular complications across 5-year periods for 25 years. At the end of the study patients with type 2
diabetes, cost avoidance over 25 years would be between GDP1,280 (MYR7500) per person (with an HbA1c of 7.5%) to GDP2,223 (MYR13025) per person (HbA1c of 8.0% to 9.0%). Calculated out to the entire population, that would equate to a cost reduction of about GDP299 million (MYR1752 million) over 5 years and GDP4.506 billion (MYR26 billion) over 25 years. Treatment of T2DM using NICE guidelines over 25 years would result in cost savings of GDP637 million (MYR3732 million) for eye disease, GDP1.29 billion (MYR7.6 billion) for renal disease, GDP2.57 billion (MYR15.2 billion) for foot ulcers and amputations and GDP2 million (MYR11.72 million) for cardiovascular disease (Leah, 2016).

Health literacy intervention is one type of diabetic education approach which integrates self-efficacy and self-care behaviour into the module. It is targeted towards diabetic patients who have medium to low health literacy score (Wolff et al., 2009). Diabetes Literacy and Numeracy Education Toolkit (DLNET) is one of the diabetic education material which aimed at a specific target group for health literacy intervention. It serves to educate diabetic patients who have medium to low health literacy to achieve their HbA1c target. It encompassed self-care activities and behaviour in the module as well as self-efficacy during the teaching session (Wolff et al., 2009). A study has shown that self-efficacy of diabetes self-management scores showed significant improvements from baseline in all intervention groups using DLNET. There was a statistically significant improvement in Perceived Diabetes Self-Management Scale scores between intervention and control groups (p= 0.029) and for the combined sites (p= 0.018) (Cavanaugh et al., 2009). A study has shown that low health literacy patients who underwent DLNET, their HbA1c post-intervention reduced (-2.1%) compared to patients who received the conventional diabetic education (-1.2%). Patients with low literacy, intervention patients were significantly more likely to obtain HbA1c goal compared to control patients (Rothman et al., 2004). Another study showed, 193 of 217 enrolled patients (88.9%) had complete 12-month follow-up data, patients in the intervention group had significantly greater improvement in HbA1C level than the control group (p = 0.007) (White, DeWalt, Malone, Osborn, Pignone & Rothman, 2010). In two randomized controlled trials, the DLNET was tested as part of an enhanced diabetes-care program compared with standard educational materials. In 198 patients, the use of the DLNET reduced their HbA1C by more than those in the control group (p = 0.005) (Cavanaugh et al., 2009).

2.0 Materials and Methods

In this section study design for the health economic evaluation will be elaborated. The objective of the study was to determine cost effectiveness of health literacy educational module to reduce HbA1c level among T2DM patients attending diabetic clinic in Military Arm Force (MAF) Hospital.

2.1 Study Design

This was a randomised control trial with health economic evaluation for cost-effectiveness analysis (Drummond et al., 2015), whereby 80 participants enrolled to each group; intervention and control. Study duration was 6 month period and study location was at one of the MAF Hospital. The intervention group received health literacy education module intervention. The health literacy education module was adapted for this research from Diabetes Literacy and Numeracy Education Toolkit (DLNET). The control group received the usual
conventional diabetic education (which was not base on health literacy). The costs per unit of reducing HbA1c (%) was evaluated in both intervention and control groups. The effectiveness of the health literacy intervention in reducing the HbA1c among type 2 diabetes patients was determined earlier using general linear model (GLM) and was published under a different topic. The intervention group the HbA1c reduced from 8.52% to 7.68%, 0.84% difference while in the control group the HbA1c reduced from 8.68% to 8.58%, 0.10% difference.

2.2 Assumption of Evaluation and Estimating Cost

Cost on provider prospectus based on operational cost where:

i. Activity Based Costing (ABC) technique was used, MOPD MAF Hospital as the cost centre and the health literacy module programme as the final cost centre. All overhead cost was accumulated at the cost centre.

ii. Type of cost as shown in the flow of ABC (Figure 1).

<table>
<thead>
<tr>
<th>Overhead cost:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Administration (no of staff)</td>
</tr>
<tr>
<td>- Utility (water supply, electricity)</td>
</tr>
<tr>
<td>- Teaching room (building more than 8 years)</td>
</tr>
<tr>
<td>- Furniture (cupboards, chairs and tables more than 8 years)</td>
</tr>
<tr>
<td>- Laboratories (HbA1c examination)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Direct cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Teaching delivery</td>
</tr>
<tr>
<td>- Printing material</td>
</tr>
<tr>
<td>- Teaching material</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indirect cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Training the trainer course</td>
</tr>
</tbody>
</table>

Figure 1. Flow of ABC

2.3 Price

The price was adjusted to a common year using the Gross Domestic Product (GDP) per capita of Malaysia 2017. The currency used was in Ringgit Malaysia (RM).

2.4 Cost Effectiveness Ratio (CER)

Cost-effectiveness Ratio (CER) is the average cost of HbA1c reduced per respondent in the intervention group over the average cost of HbA1c reduced per respondent in the control group (Drummond et al., 2015).
Figure 2. Analysis Model to Determine CER

The cost in the intervention group:
Cost of HbA1c reduced in the intervention group (xa)
Cost of HbA1c not reduced in the intervention group (xb)

The cost in control group:
Cost of reducing HbA1c in the control group (yc)
Cost of not reducing HbA1c in the control group (yd)

CER = xa / yc

Where,
- CER < 1, means the intervention is cost effective
- CER > 1, means the intervention is not cost effective

2.5 Incremental Cost Effectiveness Ratio (ICER)

Incremental cost-effectiveness ratio is defined by the difference in cost between control and intervention module activity, divided by the difference in their effect (difference of reduction of HbA1c). It represents the average incremental cost associated with one additional unit of the measure of effect (Drummond et al., 2015).

\[
\text{ICER} = \frac{\text{Cost of intervention} - \text{cost of control}}{\text{HbA1c diff in intervention} - \text{HbA1c diff in control}}
\]

\[
= \frac{xa - yc}{\text{difference in a%} - \text{difference in c%}}
\]
Decision rules (Figure 3):

i. If the incremental cost is negative and the incremental effect is positive (SE quadrant), the intervention is unequivocally cost-effective (it is dominant, achieving better outcomes at lower cost).

ii. If the incremental cost is positive and the incremental effect is negative (NW quadrant), the intervention is unequivocally not cost-effective (it is dominated, achieving poorer outcomes at a higher cost).

iii. If both the incremental cost and the incremental effect are negative (SW quadrant) or both the incremental cost and the incremental effect are positive (NE quadrant) no such unequivocal statements can be made. Determining whether the intervention is cost-effective depends on a threshold value ($\lambda$), defined as the maximum amount society is willing to pay for an incremental health gain or, equivalently, as the minimum amount society is willing to accept for foregoing an incremental health gain. The intervention would be regarded as cost-effective if its incremental cost-effectiveness ratio is lower than the threshold ($\Delta C/\Delta E < \lambda$) for ICERs in the NE quadrant or higher than the threshold ($\Delta C/\Delta E > \lambda$) for ICERs in the SW quadrant (Hartwell et al., 2011). The threshold value ($\lambda$) for CE in Malaysia was estimated to range between RM 19,929 and RM 28,470 (Lim et al., 2014).

![Cost Effectiveness Plane for Intervention Compared with Control](image)

Figure 3. Cost Effectiveness Plane for Intervention Compared with Control
Notes: NE= north east, SE= south-east, SW= south-west, NW= northwest

The inequalities ($\Delta C/\Delta E < \lambda$ for ICERs in the NE quadrant and $\Delta C/\Delta E > \lambda$ for ICERs in the SW quadrant) can be re-arranged to give equivalent inequalities on the cost scale (incremental net monetary benefit) or on the effect scale (incremental net health benefit) (Briggs et al., 2006):

Incremental net monetary benefit:

$$\lambda \times \Delta E - \Delta C > 0$$

Incremental net health benefit:

$$\Delta E - \Delta C / \lambda > 0$$
3.0 Result

3.1 Cost Effectiveness Analysis

Cost effectiveness was calculated after determined the effectiveness of the health literacy module in reducing HbA1c. These were done by incorporating all costs, from overhead costs, direct costs and indirect costs of the final cost centre for intervention and control groups. Activity Based Costing (ABC) was used to determine the costs for both groups. Obtaining the cost of reducing HbA1c for 1 unit (1%) allowed the calculation of the cost-effectiveness ratio (CER) and incremental cost-effectiveness ratio (ICER).

3.2 Final Cost Centre of Intervention Group and Control Group

Table 1 showed the cost of final cost centre (intervention module activity and existing module activity). The overhead cost used by both groups was pooled from the cost centre (Administration of Medical Department MAF Hospital) according to allocated proportion. Direct cost and indirect cost for both activities were shown in the same table. Total cost at final cost centre for the intervention group was RM 68,113 while the total cost at final cost centre for the control group was RM 67,206. There was RM 907 difference between both groups.
### Table 1. Final cost centre of intervention and control group

<table>
<thead>
<tr>
<th>Overhead Cost</th>
<th>Cost driven</th>
<th>Total expenditure 2017 (RM)</th>
<th>Proportion for programme</th>
<th>Cost per unit (RM)</th>
<th>Unit used</th>
<th>Final cost (RM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>No. of Staff</td>
<td>1,670,000</td>
<td>3%</td>
<td>50,100</td>
<td>1 staff</td>
<td>Intervention: 50,100; Control: 50,100</td>
</tr>
<tr>
<td></td>
<td>Floor Area</td>
<td>56,000</td>
<td>10%</td>
<td>5,600</td>
<td>1</td>
<td>Intervention: 5,600; Control: 5,600</td>
</tr>
<tr>
<td>Laboratory</td>
<td>No. of HbA1c Test</td>
<td>868,700</td>
<td>1%</td>
<td>54</td>
<td>160 test</td>
<td>Intervention: 8,687; Control: 8,687</td>
</tr>
</tbody>
</table>

Furniture (chairs, tables, cupboards)  
Hospital building and furniture were more than 8 years

<table>
<thead>
<tr>
<th>Direct Cost</th>
<th>Cost per unit (RM)</th>
<th>Intervention</th>
<th>Control</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching delivery</td>
<td>19 / hour</td>
<td>4 hours</td>
<td>76</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Printing material</td>
<td>I = 45, C = 35</td>
<td>80</td>
<td>3,600</td>
<td>2,800</td>
<td></td>
</tr>
</tbody>
</table>
| Teaching material  
- Can food  
- Can drink *same can was used in all group | 6, 2 | 6, 2 |

<table>
<thead>
<tr>
<th>Indirect Cost</th>
<th>Cost per unit (RM)</th>
<th>Intervention</th>
<th>Control</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Train the trainer course</td>
<td>50</td>
<td>50</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL** (RM)  
Intervention: 68,113  
Control: 67,206

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3.3 Cost of 1% Reduction of HbA1c between Intervention and Control Groups

The intervention group the HbA1c reduced from 8.52% to 7.68%, 0.84% difference while in control group the HbA1c reduced from 8.68% to 8.58%, 0.10% difference. Below showed the calculation of reduction of HbA1c of 1% between intervention and control group.

**Intervention**
- Mean difference HbA1c = 8.52% - 7.68% = 0.84%
- Cost of 1% of HbA1c reduction needed RM 68,113

**Control**
- Mean difference HbA1c = 8.68% - 8.58% = 0.10%
- Cost of 1% of HbA1c reduction needed RM 67,206

### 3.4 Cost-Effectiveness Ratio (CER)

Cost-Effectiveness Ratio (CER) was obtained by utilizing the cost per unit of the intervention group divided by the cost per unit of the control group.

\[
\text{CER} = \frac{\text{Cost of intervention}}{\text{Cost of control}} = \frac{68,113}{67,206} = 0.12 \text{ (Table 2)}
\]

Decision rules:
- CER < 1 is cost-effective
- CER > 1 is not cost-effective

From this study CER = 0.12, CER < 1. Therefore, the intervention module activity is cost effective compared to the control group activity. Sensitivity analysis was done to evaluate the sensitiveness of the test. The critical component (HbA1c) varies from 3% to 8% the result of CER insensitive.

### 3.5 Incremental Cost-Effectiveness Ratio (ICER)

Incremental cost-effectiveness ratio is defined by the difference in cost between control and intervention module activity, divided by the difference in their effect (difference of reduction of HbA1c). It represents the average incremental cost associated with one additional unit of the measure of effect.

\[
\text{ICER} = \frac{\text{Cost of intervention} - \text{cost of control}}{\text{HbA1c difference in intervention} - \text{HbA1c difference in control}}
\]

\[
= \frac{68,113 - 67,206}{0.84 - 0.10} = \frac{907}{0.74} = RM 1,225 / \text{HbA1c (Table 2)}
\]

Figure 4 showed the decision rule of the ICER. CER was at northeast (NE) quadrant, incremental cost and effect were positive which mean no such unequivocal statement can be made.
Decision rules:

The intervention would be regarded as cost effective if its’ incremental cost effectiveness ratio is lower than the threshold \( (\Delta C / \Delta E < \lambda) \) (Hartwell et al., 2011). The threshold value \( (\lambda) \) for cost effectiveness (CE) in Malaysia was estimated to range between RM 19,929 and RM 28,470 (Lim et al., 2014). This study took RM 19,929 as the threshold.

From this study:
\[
\Delta C / \Delta E < \lambda = RM 1,225 < RM 19,929
\]
Therefore, the intervention was cost effective.

**Figure 4. Cost effectiveness Plane for Intervention Compared with Control**

**Table 2. CER and ICER of the Cost Effectiveness Analysis**

<table>
<thead>
<tr>
<th>OPTION</th>
<th>NET COST (RM)</th>
<th>( \Delta ) COST (RM)</th>
<th>( \Delta ) HbA1c %</th>
<th>CER</th>
<th>ICER (( \Delta )COST / ( \Delta )HbA1c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTROL (existing module)</td>
<td>67,206</td>
<td>n/a</td>
<td>0.10</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>INTERVENTION (health literacy module)</td>
<td>68,113</td>
<td>907</td>
<td>0.84</td>
<td>0.12</td>
<td>1,225</td>
</tr>
</tbody>
</table>

**4.0 Discussion**

This study showed that using health literacy intervention was cost effective compared to the usual diabetes education. The effectiveness was supported by significant improvement of HbA1c in the intervention group compared to control group (0.84 vs 0.10). Analysis by Shafei et al. (2012) showed that improved glycemic control would be likely to bring
substantial clinical and economic benefits to the patients, arising primarily from reduced incidence of diabetes complications. A 1% reduction in HbA1c was associated with reduced costs of treating diabetes complications and an increase in life expectancy. Undiscounted life expectancy was improved by 0.36 years following HbA1c reduction (7.53 versus 7.17 years). The time alive and free of any diabetes complications increased from 0.31 years to 0.40 years in the HbA1c reduction group. Over patient lifetimes, improved HbA1c was associated with cost savings of EUR 682 (MYR 3,067) (EUR 2,745 (MYR 13,607) versus EUR 3,427 (MYR 16,674)). The greatest cost savings were associated with renal complications avoided.

Glasgow et al. (1997) calculated that the cost of a social cognitive theory-based lifestyle intervention, effective in decreasing cholesterol and in improving food habits, was USD137 (MYR345) per patient. This study used health literacy intervention where self-efficacy and self-care theory incorporated. After 6 months it managed to reduce the HbA1c by 0.84% improvement with the cost of MYR 851 per patient. The cost was slightly higher compared to the previous study. This due to time-consuming and the material used for the health literacy intervention was real (an example can food and can drink to teach patients on the food label).

A study by Schechter et al. (2012) in New York showed that the costs of a telephonic intervention for diabetes self-management support was moderate and commensurate to the modest associated improvement in glycaemic control. This was shown by the intervention cost USD176.61 (MYR553) per person in the telephone group achieved a mean of 0.36% of HbA1C improvement. The ICER was USD490.58 (MYR1538) per incremental percentage point of HbA1C improvement and USD2,617.35 (MYR8199) per person over a 1-year intervention in achieving the HbA1C goal (< 7.0%). This study ICER was MYR 1,225 per HbA1c improvement. This was less compared to the study. This was due because health literacy intervention used classroom teaching and communication was face to face with participants.

5.0 Conclusion and recommendation

In conclusion, health literacy intervention was cost effective in reducing HbA1c among type 2 diabetic patients at MAF Hospital. It was shown by CER of 0.12 and ICER of RM 1,225 per HbA1c improvement. The reduction of 0.84% of HbA1c in 6 months was beneficial for patients to avoid diabetic complications.

It is recommended that MAF Medical Corps to implement the health literacy intervention to other MAF hospitals due to the effectiveness of the intervention and its’ cost effective. The intervention booklet could change to pdf and make as a soft copy materials for benefit of all. This will benefit the organisation hoping that this will reduce the disease burden of type 2 diabetes among MAF personals. This will ensure the money allocation is not wasted to chronic disease burden due to complications.

Acknowledgement

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This study was approved by the Medical Research Ethics Committee, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia and MAF Medical Core Public Health Committee.

Declaration

Authors declare that there is no conflict of interest regarding publication of this article.

Authors contribution

Author 1: Draft of proposal, field work, research activities, draft the manuscript
Author 2: Statistical analysis and review the manuscript
Author 3: CEA analysis and final review of manuscript

References