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Patient Level Cost of Diabetes Self-Management Education Programmes: An International Evaluation

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Patient Level Cost of Diabetes Self-Management Education Programmes: An International Evaluation

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Abstract

Objectives: The objective of this study was to examine the value of Time Driven Activity Based Costing (TD-ABC) in understanding the process and costs of delivering Diabetes Self-Management Education programmes (DSME) in different countries and to identify potential process improvements in the delivery of such programmes.

Setting: Outpatient settings in five European countries (Austria, Denmark, Germany, Ireland, United Kingdom) and two countries outside Europe, Taiwan and Israel.

Participants: Providers of DSME programmes across participating countries (N=15) including educators and managers.

Primary and secondary measures: Time spent by providers in the delivery of DSME and resources consumed in order to compute a cost per patient per education hour.

Results: We found significant variation of how DSME programmes are provided across and within countries. Variations in costs across different sites were caused not only by the number of educators and hours of education provided but also due to significant variations in administrative processes, curriculum and educator type. The findings highlight the value of TD-ABC in calculating a patient level cost and potential of the methodology to identify process improvements in guiding the optimal allocation of scarce resources in diabetes care, in particular for DSME that is often underfunded.

Conclusions: The results of this study will inform clinicians, managers and policy makers seeking to enhance the delivery of DSME programmes at both local and international levels. The findings highlight the benefits of adopting an TD-ABC approach to reviewing and evaluating healthcare services.

Article Summary

Strengths and limitations of this study

- Time Driven Activity Based Costing (TD-ABC) has rarely been applied to care pathways within non-acute settings and as such offers a novel perspective on understanding the costs of providing chronic disease self-management education.
- This is the first cross-national study to compare the costs of DSME across a number of countries within the EU and outside the EU to include Taiwan and Israel.
- While some self-reported health outcome data was collected as part of a wider study, clinical outcomes were not collected alongside the process and cost data, making it difficult to ascertain if value is being achieved in each of the DSME programmes included in this study.

1.0 Introduction

Type 2 diabetes mellitus is one of the major public health threats of the 21st century, currently affecting approximately 59.8 million people within Europe and 415 million worldwide ¹. Further, it has been reported that diabetes medical care accounts for a disproportionate allocation of health

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3 90 service resources across the western world¹. Developing the self-care capacity of patients is critical
4 91 to determining optimal clinical, behavioural and psychosocial outcomes and therefore reducing costs
5 92 ². Diabetes self-management education (DSME) has been shown to improve patient outcomes by
6 93 reducing the onset and/or advancement of diabetes related complications; by improving quality of
7 94 life; strengthening self-efficacy and personal empowerment; assisting with the development of
8 95 healthy coping skills; and by reducing diabetes related distress and depression³.
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15 97 The operation and delivery of DSME varies across the international landscape. They can be either
16 98 professionally led or peer led. Further, they can be group based, individually based, and increasingly
17 99 IT based. In addition, DSME curricula, duration and delivery may vary substantially, both within and
18 100 between countries⁴. It is well established that DSME programmes are a low cost intervention per
19 101 patient and cost effective from a payer perspective. For example, a recent report published by *The*
20 102 *Center For Health Law And Policy Innovation* (Harvard Law School) argues that cost savings can be
21 103 made by public and private insurers in the United States if cost sharing were eliminated and DSME
22 104 were provided free of charge to patients⁵. However, little research has explored why the costs of
23 105 running such interventions vary across different health care systems and jurisdictions, or why these
24 106 costs may differ. This study addresses this gap in the prior literature.
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33 108 Indeed most of the economic analyses has thus far focused on establishing the cost effectiveness of
34 109 DSME by comparing the cost of programmes relative to their clinical effectiveness. Such evaluations
35 110 are usually based on economic modelling, carried out alongside randomised control trials and the
36 111 findings typically suggest that DSME interventions are cost effective relative to usual care⁶⁻¹².
37 112 Despite this, a recent report published by the *Health Information and Quality Authority* (HIQA)¹³ in
38 113 Ireland highlights the large degree heterogeneity in the methodological approaches used in such
39 114 economic evaluations. This, in turn, makes results difficult to compare in any meaningful way. In
40 115 addition, these approaches tend to focus solely on overall cost of running the programmes and
41 116 neglect to explore potential mechanisms through which DSME programmes could be made more
42 117 efficient whilst also maintaining high standards of effectiveness. Furthermore, the majority of
43 118 studies are based on interventions within a US population, and as such may not be generalizable
44 119 across differing health care, social and cultural contexts.
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53 121 This study seeks to address these existing gaps in the literature through an economic evaluation of
54 122 DSME delivery across a number of EU and non-EU countries, namely Austria, Denmark, Germany,
55 123 Ireland, Israel, Taiwan and the UK. The selection of these countries was based on the access of the
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3 124 Diabetes Literacy Consortium¹ to local knowledge and networks required to carry out the necessary
4 125 fieldwork. These countries also represent a diversity of contrasting approaches to the delivery of
5 126 DSME tailored to each country⁴. The findings are part of a wider study conducted by the Diabetes
6 127 Literacy Consortium, the overall purpose of which was to examine the (cost)-effectiveness of
7 128 diabetes education across Europe, Israel, Taiwan and the US². This study specifically addresses the
8 129 following research questions: i.) What is the cost of delivering DSME programmes? ii.) Is TD-ABC a
9 130 suitable methodology for computing a patient level cost i.e. a cost per patient per education hour?
10 131 iii.) Can TD-ABC aid in identifying process improvements in the delivery of DMSE programmes?
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133 2.0 Method

21 136 A Time Driven Activity Based (TD-ABC) costing method was used to map the process of programme
22 137 delivery and to derive patient level costs^{14 15}. TD-ABC has been developed as a viable costing method
23 138 with the healthcare sector by Kaplan and Porter^{16 17} enabling detailed patient level costs to be
24 139 computed alongside the identification of possible process improvements resulting in potential cost
25 140 savings. TD-ABC is particularly compatible with type 2 diabetes care as the model can be applied to
26 141 diverse care pathways, particularly chronic disease management. Adopting a TD-ABC approach in
27 142 this study therefore gave increased visibility into areas of DSME delivery where process
28 143 improvements and cost savings could be made, while still maintaining a high quality of patient
29 144 education. Examples of the application of TD-ABC have been mostly confined to acute clinical
30 145 settings¹⁷⁻¹⁹ This study seeks to add to the body of knowledge on the costs of care within outpatient
31 146 environments through identifying the patient level cost of a variety of DSME programmes both
32 147 cross-nationally and *Intranationally*²⁰. A primary objective was to provide a robust costing
33 148 framework from which future studies could include clinical and quality of life outcomes to determine
34 149 the economic value added to diabetes care through the use of DSME.
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45 151 The TD-ABC method involves seven steps¹⁶ 1) select the medical condition and/or patient
46 152 population to be examined; 2) define the care value chain; 3) develop process maps of each activity
47 153 in patient care delivery; identify the resources involved and any supplies used for the patient at each
48 154 process step; 4) obtain time estimates for each process step; 5) estimate the cost of supplying each
49 155 patient care resource; 6) estimate the practical capacity of each resource provided and calculate the
50 156 capacity cost rate; 7) compute the total costs over each patient's cycle of care. By constructing a
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56 ¹ The Diabetes Literacy Consortium represents a group of countries funded by the European Commission
57 under the Seventh Framework research programme (Grant Agreement Number: 306186).

58 ² <http://www.diabetesliteracy.eu>

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3 157 sequential activity and process step map and care value chain the researcher can analyse the
4 158 maps/care pathway for duplication. These areas can then be explored further to establish if changes
5 159 in the pathway would add value by maintaining/increasing the level of care to the patient whilst
6 160 decreasing the economic cost to the overall healthcare system in terms of providing DSME
7 161 programmes.
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12 163 Each international study team identified the care value pathway in their country and collected the
13 164 activity/time data related to the care value pathway through qualitative semi-structured interviews
14 165 of healthcare providers from each education programme (N=15). These included both educators and
15 166 managers. This information was then entered into an aggregated, de-identified database for
16 167 analysis. All study teams then collected resource and financial data, utilising a standardised costing
17 168 worksheet related to the activities, which were then incorporated into the aggregated database for
18 169 analysis. This methodology was applied to each education programme across each country included
19 170 in the study. The topic guide was developed in the English language and was then subsequently
20 171 translated into the local language by the local research teams in each of the participating countries.
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30 173 All activities associated with the DSME pathway were entered into an aggregate Excel database. All
31 174 activity and time data was collected via the survey instrument, and cost estimates were assigned to
32 175 these activity variables using financial data provided by the local provider organizations.
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36 177 DSME programme costs per patient were derived specifically from the cost of performing each
37 178 activity in the delivery of the programme. All cost data was entered into activity spreadsheets and
38 179 therefore the data collected did not contain any information relating to identifiable individual
39 180 service providers. In the resulting database, all cost information was linked to activities and not to
40 181 individuals. All activity and cost information is reported per DSME programme.
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47 184 *2.1 Study Sample*

48 185 To be selected for inclusion, programmes had to: (1) target type 2 diabetes patients; (2) be
49 186 conducted among the general patient population rather than tailored to the needs of a specific age
50 187 cohort, needs or gender group; (3) include (but not be limited to) newly diagnosed patients; (4) be
51 188 stand-alone programmes rather than an add-on to another programme or part of a wider curriculum
52 189 with (multiple) parallel programs; (5) admit new patients during the time of the baseline data
53 190 collection. The study sample size was driven by the number of programmes involved in the delivery
54 191 of the specific DSME programmes in each country. Table 1 outlines the number of programmes per
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192 country eligible for inclusion in the study. Costs were collected for the duration of each programme,
193 which ranged in duration from one day to those spanning a 12-month timeframe.

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Table 1: Study Sample

COUNTRY	SAMPLE SIZE
AUSTRIA	3
DENMARK	1
GERMANY	3
IRELAND	3
ISRAEL	2
TAIWAN	1
UK	3

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2.2 Analytic approach

200 The Time-Driven Activity-Based Costing (TD-ABC) model was utilised to derive a cost per patient per
201 hour for each education programme studied. This cost figure was then used to compare the
202 programme cost per patient across the various programmes.

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204 Two concepts and measures were drawn upon to develop the TD-ABC model¹⁶, the unit cost of
205 supplying capacity and the time it takes to undertake an activity. First, the model was used to
206 calculate the cost of all the resources supplied to each programme. This included personnel,
207 supervision and overheads rent, equipment and software and insurance. The total cost was then
208 divided by the actual capacity in order to calculate the cost rate. Second, the capacity cost rate was
209 used to assign the programme costs to objects by estimating demand on the resource. Two variables
210 were estimated: the capacity cost rate for the programme and the capacity use by each patient. The
211 capacity cost rate was calculated by:

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$$\text{Capacity Cost Rate} = \frac{\text{Cost of Capacity Supplied}}{\text{Practical Capacity of Resource Supplied}}$$

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215 Practical capacity was used as the denominator in the capacity cost rate equation. Estimating the
216 practical capacity required two time estimates which were gathered from Human Resources and
217 other administrative records: the total number of days that each employee actually worked each
218 year; the total number of hours per day that the employee was available for work. Practical capacity
219 was calculated as 80% of this working time¹⁶. Therefore 20% was attributed to breaks, training and

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3 220 annual leave. This was applied to all countries to ensure consistency and comparability of the
4 221 computed costs.

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6 223 In order to calculate the total cost of each DSME programme per patient, the capacity cost rates
7 224 (including associated support costs) for each resource used was multiplied by the amount of time
8 225 attributed to each patient. This calculation was based on the number of patients enrolled at the
9 226 outset of the programme. The total cost of each programme per patient was the sum of all the costs
10 227 across all the processes within the DSME programme. The costs were collected in the local currency
11 228 and then expressed in international dollar to ensure comparability of the cost per patient per hour.
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19 230 **3.0 Results**

20 231 Table 2 presents the results for each programme for each country included in the study. It outlines
21 232 the anonymised programme name, type of professional educator, the number of sessions per
22 233 programme, the hours of education per programme, the hours of administrative work/preparation
23 234 time per programme, number of patients per programme, cost per patient per programme and cost
24 235 per patient for each education hour, and finally the cost per patient per education hour is expressed
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27 236 in International dollar.
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237 **Table 2: Results Table**

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Country	Programme	Educator	No. sessions per programme	Hours of education per programme	Hours of admin/prep per programme	No. patients per programme.	Cost per patient per programme	Cost per patient per hour	Cost per patient per hour (Int. \$*) ³⁴
AUSTRIA	1	Diabetes educator, Dietician, Physician	5	20	9	12	€41.73	€2.03	\$2.40
	2	Dietician, Physician	4	10	7	6	€72.22	€7.22	\$9.05
	3	Diabetes Educator	7	4.4	1.25	4	€6.23	€1.56	\$1.93
DENMARK	1	Peer led educator x 2	12	30	16.6	11	€34.47	€1.14	\$0.55
GERMANY	1	Nutritionist	5	3	.5	1	€70.31	€23.44	\$29.78
	2	Diabetes nurse	5	11.25	2.25	8	€44.42	€3.95	\$5.02
	3 (opp. cost)	Diabetes patient trained to provide peer-led education	10	15	60	20	€8.76	€0.58	\$0.74
IRELAND	1	Specially trained health professional	1 or 2	7	4.5	9	€86.37	€12.34	\$14.69
	2 (site 1)	Trained dietician	8	23	55	11	€299.22	€13.00	\$15.48

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	2 (site 2)	Trained dietician	8	22	38.6	20	€112.83	€5.13	\$6.11
ISRAEL	1	Specially trained nurse	4	7	8	10	416.62 NIS	58.87 NIS	\$14.68
	2	Social worker, GP, diabetes nurse, physiotherapist/exercise specialist, dietician	6	9	10.75	15	542.43 NIS	60.38 NIS	\$15.28
TAIWAN	1	Diabetes educator	5	1.8	n/a	1	110.33 NTD	61.00 NTD	\$3.75
UK	1	Diabetes specialist nurse, dietician, physiotherapist, podiatrist	5	10	39	13	£78.62	£7.86	\$11.10
	2	Specially trained health care professionals	1 or 2	7.5	5.5	10	£74.59	£9.93	\$14.03
	3	Diabetes specialist nurse, dietician, podiatrist	2	6	6.7	9	£37.71	£6.28	\$8.87

Table 2: Demonstrates the costs of delivering DSME, expressed in international dollar. An international dollar is a hypothetical currency that is used as a means of translating and comparing costs from one country to the other using a common reference point. International dollars are calculated by dividing the DSME cost in a country's home currency by its relevant Purchasing Power Parity conversion factor. The use of the PPP technique minimizes misleading cost comparisons between countries with the use of exchange rates alone. PPP conversion factors are constructed by comparing the national prices of a large basket of goods and services and these rates are then used to translate different currencies into a common currency. The PPP conversion factors used in this study were sourced from the OECD (<http://stats.oecd.org/Index.aspx?DataSetCode=PPPGBP>) and based on 2014 exchange rates. The PPP conversion factors used were as follows: UK 0.708; Israel 4.01; Taiwan 16.25; Ireland 0.84; and Germany 0.787; Denmark 7.48 and Austria 0.808 and were sourced from <http://stats.oecd.org/Index.aspx?DataSetCode=PPPGBP>. Opportunity cost is utilized when the provider of the service/care is not a paid employee, such as in the case of peer led programmes based in Germany and Denmark. This form of cost is considered a measure of economic sacrifice related to the time provided. Calculations are made based upon 25% of the average industrial wage of the related country based on an assumption that leisure time is being sacrificed²¹ All those included in the study reported sacrificing leisure time.

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249 Austria

250 Three programmes from Austria were included in the study. All were group led sessions and had
251 varying practitioners providing the education (see table 2 above). Programme 1 cost €41.73 per
252 patient which equates to €2.03 per patient per hour. When converted into international dollar this
253 programme cost \$2.40 per patient per hour. Programme 2 cost is €72, equating to €7.22 per patient
254 per hour, converted to the international dollar, this programme cost \$9.05 per patient per hour.
255 Programme 3 cost is €109, equating to €1.56 per patient per hour, when converted into the
256 international dollar costs \$1.93 per hour. This data illustrates the significant variation in cost that
257 exists within jurisdictions. This is due to significant variations between the programmes in the
258 number of hours of education, the number of patients participating in these programmes and the
259 number of administration hours.

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261 Denmark

262 Denmark operates both professional-led (from hospital settings and local health centres) and peer-
263 led diabetes self-management education programmes. One peer led programme was included in this
264 study from Denmark (data was not available for the professionally led programmes). This
265 programme cost €34.47 per patient per programme which equates to €1.14 per patient per hour.
266 When converted into international dollar this programme cost \$0.15 per patient per hour. This
267 finding highlights the low cost of peer-led programmes per patient per hour in Denmark.

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269 Germany

270 Germany operates both professional and peer-led diabetes self-management education
271 programmes. This study included both programmes due to the high level of peer-led programmes
272 offered within the German health care system. Programme 1 (professional) cost €70.32 per patient
273 which equates to €23.44 per patient per hour. When converted into international dollar this
274 programme cost \$29.78 per patient per hour; programme 2 (professional) cost €44.42 per patient
275 which equates to €3.95 per patient per hour. When converted into international dollar this
276 programme cost \$5.02 per patient per hour; while programme 3 (peer-led) cost €8.76 per patient
277 which equates to €0.58 per patient per hour. When converted into international dollar this
278 programme cost \$0.72 per patient per hour. Here too we observe a significant variation in cost
279 across programmes within the same country. In particular the low cost of peer-led education as was
280 found in Denmark.

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Ireland

Two programmes from Ireland were included in the study and both programmes were group based. Programme 1 cost €86.37 per patient which equates to €12.34 per patient per hour. When converted into international dollar this programme cost \$14.69 per patient per hour. Programme 2 (site 1) cost €299.22 per patient per programme which equates to €13.00 per patient per hour. When converted into international dollar this programme cost \$15.48 per patient per hour; while programme 2 (offered in site 2) cost €112.83 per patient per programme which equates to €5.13 per patient per hour. When converted into international dollar this programme cost \$6.11 per patient per hour. Significant cost variation within a country is again evident. However what is most significant is the different costs within a single programme when delivered across different sites. For example Programme 2 had different administrative hours (55 versus 39 hours), different personnel performing the administrative tasks (a clinical nurse specialist versus an administrator) and different numbers of patient per programme.

Israel

Two programmes from Israel satisfied the inclusion criteria for this study and both programmes provide group based education. Programme 1 cost 416.62 NIS per patient which equates to 58.87 NIS per patient per hour. When converted into international dollar this programme cost \$14.68 per patient per hour and programme 2 cost 523.43 NIS per patient, equating to 60.38 NIS per patient per hour. When converted into international dollar this programme cost \$15.28 per patient per hour. The costs for both programmes are almost identical despite the different mix of educators, the variation in terms of the number of sessions provided, and the greater number of hours of education and administrative hours. This can be explained by the greater number of patients being included in Programme 2 (10 in programme 1 versus 15 in Programme 2) thus leading to only a small cost differential between the programmes despite the variations in how the programmes were run.

Taiwan

One programme from Taiwan and was included in the study. This programme is provided as an individualised or group education programme. One on one Individual programmes are the norm. Group sessions are performed only when there are insufficient numbers of staff to perform individualised education. This programme cost 110.33 DT per patient which equates to 61.00 DT per patient per hour. When converted into international dollar this programme cost \$3.75 per patient per hour. The low cost reflects the low number of contact hours for patients, being only 1.8 hours per programme.

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3 3164 317 **United Kingdom**

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6 318 A total of three UK based programmes satisfied the inclusion criteria for this study. All programmes
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8 319 provide group sessions. Programme 1 cost £78.62 per patient which equates to £7.86 per patient per
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10 320 hour. When converted into international dollar this programme cost \$11.10 per patient per hour;
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12 321 Programme 2 cost £74.59 per patient equating to £9.93 per patient per hour. When converted into
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14 322 international dollar this programme cost \$14.03 per patient per hour; and Programme 3 cost £37.71
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16 323 per patient per programme which equates to £6.28 per patient per hour. When converted into
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18 324 international dollar this programme cost \$8.87 per patient per hour. Once again significant cost
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20 325 variation exists within this country, reflecting significantly high administrative hours in Programme 1.
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22 326 Within Programme 2 we note specially trained healthcare professionals providing the education for
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24 327 this programme. This results in a comparatively high cost per patient per programme despite a lower
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26 328 number of contact hours (7.5 versus 10 hours).
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30 331 **4.0 Discussion**

31 332 Alongside the specific country data Table 2 demonstrates that there is a significant variation of how
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33 333 DSME is provided across countries – the site/institution where the programme is provided, by whom
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35 334 it is provided, the number of sessions per programme, the number of education hours provided, and
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37 335 the curriculum. Further, it highlights that costs differ as a result of these variances in approaches. In
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39 336 particular findings suggest that a number of programmes have extremely high administrative costs
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41 337 associated with the delivery of DSME programmes, this is particularly the case in the UK and Ireland.
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43 338 In other countries, the administrative costs attached to the programmes appear low. This finding is
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45 339 similar to that of Munoz et al. who used TD-ABC in a cost-effectiveness analysis of a red blood cell
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47 340 salvage post total-knee arthroscopy in the US, Switzerland and Austria and highlighted the need for
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49 341 local cost estimations in place of global cost estimates in future replications in cost-effectiveness
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51 342 analysis for this particular procedure²².
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54 344 Whilst it is accepted that administration time/costs related to delivering education, particularly
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56 345 when provided through group sessions, may be significant, future studies could examine what
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58 346 processes and protocols could be put in place in order reduce the number of hours of personnel
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60 347 time spent on administration. Indeed research by Storfjell et al., has shown that the application of
348 TD-ABC in the context of nursing care can facilitate the identification and elimination of non-value
349 added time (NVA) and related the increase in time spent on psychosocial intervention, support and
350 patient education²³.

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352 Findings also point to the significant differences between the various personnel who deliver the
353 education programmes. In this sense research is needed to explore the most appropriate level of
354 expertise required to deliver the programme for optimal patient health outcomes. For example,
355 instead of having a consultant or a Clinical Nurse Specialist delivering the education programmes it
356 may be more appropriate to have well trained experienced nurses or the equivalent performing this
357 role. Furthermore, little attention has been paid to peer-led programmes in terms of their
358 effectiveness. Table 2 illustrates that peer-led programmes cost significantly less than professionally
359 led programmes. Managers may also want to consider whether resources are being deployed
360 effectively within education programmes and whether the expertise would provide better value (in
361 terms of patients' outcomes) elsewhere in the healthcare system. For example one pilot study
362 conducted by Kaplan et al. at The University of Texas Cancer Centre revealed that the matching of
363 clinical skills to the processes led in a 16% reduction in process time, a 12% decrease in costs for
364 technical staff, and a 67% reduction in costs for professional staff¹⁶. However, clinical outcomes
365 data will first be required in order to examine whether the educators level of expertise influences
366 DSME health outcomes¹⁶.

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368 This supports and further highlights what was discussed at the outset of this paper, namely, that the
369 costing and provision of DSME is at an early stage of development with limited empirical knowledge
370 attached to the various strands of its delivery. Thus this study has gone some way to remedying this
371 problem whereby it has outlined a bottom up/patient level cost, and therefore more accurate cost
372 than heretofore, of providing the various education programmes. Thus, it has provided a first layer
373 of information, which in the future will be required to establish whether this model of
374 care/intervention can add value to the health care system once effectiveness outcomes have been
375 determined for each programme, However, there is a long way to go, whereby clinical and Quality of
376 Life outcomes are required to measure the effectiveness of these programmes before a thorough
377 understanding of their added value can be estimated. In this respect it is suggested that future
378 research should explore these areas with a view to using the data from this study to develop a better
379 understanding of the added value derived from providing DSME interventions.

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382 5.0 Limitations

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384 The TD-ABC method is a relatively new method in terms of healthcare costing and to the best of the
385 authors' knowledge has yet to been applied to investigate the costs of a health education

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3 386 intervention. As a result there were limited guidelines surrounding the collection of activity and
4 387 process step data in non-acute settings and thus it was necessary for the research team to develop
5 388 novel data collection tools to meet the requirements of the model. Whilst the tools generated data
6 389 required to answer the research question, there were many lessons learned from this phase of the
7 390 Diabetes Literacy project. Some participants reported difficulties in filling out the survey as a result
8 391 of a lack of familiarity with the terminology surrounding activities and process steps. This resulted
9 392 from a lack of understanding related to the granular level of information that was requested by the
10 393 project researchers. Therefore some elements of the detailed administrative process steps were
11 394 lost. For example, surveys were completed in a manner which reflected the activities and process
12 395 steps related to the education activity but less attention was paid by some respondents to providing
13 396 the same level of detail about the administrative and preparation activities and process steps. This
14 397 detailed information would have provided greater insight into the reasons why administrative costs
15 398 were found to be so high in some countries while not in others. For example, in Ireland the same
16 399 programme, reviewed at two different sites, had significant variation in terms of the
17 400 administrative/preparation time attached to each session provided (55 hours versus 39 hours).
18 401 Moreover, in the UK one programme had almost three times the administrative hours attached to
19 402 each session when compared to educational contact hours (10 hours educational contact time
20 403 versus 39 hours administrative/preparation time). Yet, in Austria educational contact time allocated
21 404 per session was just over double the time attributed to administration/preparation time (20 hours
22 405 educational contact versus 9 hours administration/preparation).
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37 407 In addition, some of the local research teams also experienced difficulties in collecting the required
38 408 financial data. For example, in Belgium, the staff involved in the delivery of DSME programmes
39 409 taking part in this study were unwilling to share salary information at the level of granularity that
40 410 was required to compute a per patient cost. For this reason, the Belgian data had to be excluded
41 411 from this particular study.
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47 413 The study is also limited by a lack of available clinical outcome data from each of the education
48 414 programmes to allow for comparison with cost. While evaluative data was collected in each country
49 415 as part of the FP7 study, it was almost exclusively self-reported in nature, making it difficult to
50 416 substantiate if value was being achieved by these DSME programmes. As Kaplan and Porter point
51 417 out¹⁶, value can only be determined when there is visibility into both costs and clinical outcomes.
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6.0 Conclusion

This paper has demonstrated the variances in the cost of delivering different types of diabetes education programmes, both within and across countries in the EU, as well as Israel and Taiwan. Developing cost effective lifestyle interventions to improve the health literacy and quality of life for people with diabetes may be an important step in preventing the onset of complications associated with type 2 diabetes. The imperative to do so from an economic perspective cannot be underestimated when consideration is given to the implications for healthcare systems associated with the treatment of diabetes related morbidities such as active foot disease, chronic kidney disease, retinopathy and myocardial infarction²⁴.

This study offers the first application of a TD-ABC approach to evaluate the cost of delivering DSME programmes and as a means of comparing the costs of running a healthcare intervention cross-nationally. It contributes to the extant literature by highlighting and describing the vast combinations and permutations of DSME curricula, hours of education, educators, and numbers of attendees and how these variations lead to substantial cost differences. In the process, we identified how there could be potentially unnecessary process steps that, if eliminated, could lead to cost savings in the delivery of DSME programmes, including vast differences in administration time, and exploring different types of personnel delivering the programmes. To what extent value can be improved in these areas can only be determined through future studies.

While it is already established that diabetes education is a low cost intervention and is cost-effective, given the sheer numbers of education programmes that need to be made available to meet the demands resulting from increasing levels of diabetes worldwide, even small process improvements could lead to overall cost savings for healthcare providers. Future studies focusing on the cost-effectiveness of healthcare interventions may consider adopting TD-ABC principles as a means of identifying efficiencies in other chronic disease education programmes.

The study has highlighted the strengths of TD-ABC as a method of bottom up costing in outpatient care and recommends utilising this method in future studies so as to allow for a comprehensive literature to develop in the area, enabling comparative studies to be performed. By developing such literature a comprehensive understanding of the cost of patient education programmes can be developed and compared cross nationally and across time. Healthcare practitioners and educators who wish to convince policy makers and health insurers to reimburse the cost of DSME delivery can adopt a TD-ABC approach in order to demonstrate that such programmes are run efficiently and

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3 455 effectively especially when combined with measures of consequent health outcomes to represent
4 456 value for money.

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16
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20 463 programs in their respective countries.

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53 482 contributed to the data collection.

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3 487 **Contributorship statement** GD initially proposed the study. GD and SG specified the methodology.
4 488 KC carried out the cost analysis. All authors contributed to the protocol design, data collection and
5 489 analysis plan. EQ and SO'D wrote the initial manuscript, and all authors contributed to improving the
6 490 manuscript. All authors approved the final manuscript.

7 491
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9 493

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19 503 aggregated are available should they be requested.
20 504
21 505
22 506

23 507 **References**

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38 573

CHEERS Checklist

Items to include when reporting economic evaluations of health interventions

The **ISPOR CHEERS Task Force Report**, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force*, provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: <http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp>

Section/item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared.	p.3 121
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	p.1 49-73
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	p.3 104
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	p.4 163-166
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	p.4 145
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	p.4 138
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	p.3 123-125
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	p.5 192/193
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	N/A
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	p.4 137
Measurement of effectiveness	11a	<i>Single study-based estimates:</i> Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	p.14 413



1		11b	<i>Synthesis-based estimates:</i> Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	N/A
2				N/A
3				N/A
4				N/A
5	Measurement and	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	N/A
6	valuation of preference			N/A
7	based outcomes			N/A
8	Estimating resources	13a	<i>Single study-based economic evaluation:</i> Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	p.4 151-156
9	and costs			p.4 151-156
10		13b	<i>Model-based economic evaluation:</i> Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	N/A
11				N/A
12				N/A
13				N/A
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17				N/A
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19				N/A
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22				N/A
23	Currency, price date,	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	p. 9 240-247
24	and conversion			p. 9 240-247
25				p. 9 240-247
26				p. 9 240-247
27				p. 9 240-247
28				p. 9 240-247
29	Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	N/A
30				N/A
31				N/A
32				N/A
33	Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	N/A
34				N/A
35	Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	N/A
36				N/A
37				N/A
38				N/A
39				N/A
40				N/A
41				N/A
42				N/A
43	Results			N/A
44	Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	N/A
45				N/A
46				N/A
47				N/A
48				N/A
49				N/A
50	Incremental costs and	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	N/A
51	outcomes			N/A
52				N/A
53				N/A
54				N/A
55	Characterising	20a	<i>Single study-based economic evaluation:</i> Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact	N/A
56	uncertainty			N/A
57				N/A
58				N/A
59				N/A
60				N/A



1		of methodological assumptions (such as discount rate, study perspective).	N/A
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4	20b	<i>Model-based economic evaluation</i> : Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	N/A
5			
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7	Characterising heterogeneity	21	
8		If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	p.13 352-358
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14	Discussion		
15	Study findings, limitations, generalisability, and current knowledge	22	
16		Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	p.12-14 331-417
17			
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20	Other		
21	Source of funding	23	
22		Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	p.16 460-463
23			
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25	Conflicts of interest	24	
26		Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	p. 16 492
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For consistency, the CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

The **ISPOR CHEERS Task Force Report** provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* link or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: <http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp>

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Abstract

Objectives: The objective of this study was to examine the value of Time Driven Activity Based Costing (TDABC) in understanding the process and costs of delivering Diabetes Self-Management Education programmes (DSME) in a multi-country comparative study.

Setting: Outpatient settings in five European countries (Austria, Denmark, Germany, Ireland, United Kingdom) and two countries outside Europe, Taiwan and Israel.

Participants: Providers of DSME programmes across participating countries (N=16) including health care professionals, administrators and patients taking part in DSME programmes.

Primary and secondary measures: Primary Measure: Time spent by providers in the delivery of DSME and resources consumed in order to compute programme costs. Secondary measures: self-report measures of behavioural self-management and diabetes disease/health related outcomes.

Results: We found significant variation in costs and the processes of how DSME programmes are provided across and within countries. Variations in costs were driven by a combination of price variances, mix of personnel skill and efficiency variances. Higher cost programmes were not found to have achieved better relative outcomes. The findings highlight the value of TDABC in calculating a patient level cost and potential of the methodology to identify process improvements in guiding the optimal allocation of scarce resources in diabetes care, in particular for DSME that is often underfunded.

Conclusions: This study is the first to measure programme costs using estimates of the actual resources used to educate patients about managing their medical condition and is the first study to map such costs to self-reported behavioural and disease outcomes. The results of this study will inform clinicians, managers and policy makers seeking to enhance the delivery of DSME programmes. The findings highlight the benefits of adopting a TDABC approach to understanding the drivers of the cost of DSME programmes in a multi-country study to reveal opportunities to bend the cost curve for DSME.

Article Summary

Strengths and limitations of this study

- Time Driven Activity Based Costing (TDABC) has rarely been applied to care pathways within non-acute settings and as such offers a novel perspective on understanding the costs of providing chronic disease self-management education.
- This is the first multi-country study to compare the costs of DSME across a number of countries within the EU and Asia.
- Outcomes of programme participation were measured through self-reported changes, making it difficult to establish if any clinical improvement occurred. Future studies should combine TDABC analysis with clinical outcomes to further assess value in DSME.

1.0 Introduction

Type 2 diabetes mellitus is one of the major public health threats of the 21st century, currently affecting approximately 59.8 million people within Europe and 415 million worldwide ¹. Further, it has been reported that diabetes medical care accounts for a disproportionate allocation of health service resources across the western world ¹. Developing the self-care capacity of patients is critical to determining optimal clinical, behavioural and psychosocial outcomes and therefore reducing costs ². Diabetes self-management education (DSME) has been shown to improve patient outcomes by reducing the onset and/or advancement of diabetes related complications; by improving quality of life; strengthening self-efficacy and personal empowerment; assisting with the development of healthy coping skills; and by reducing diabetes related distress and depression ³.

The operation and delivery of DSME varies across the international landscape. They can be either professionally led or peer led. Further, they can be group based, individually based, and increasingly IT based. In addition, DSME curricula, duration and delivery may vary substantially, both within and between countries⁴. It is well established that DSME programmes are a low cost intervention per patient and cost effective from a payer perspective. For example, a recent report published by *The Center For Health Law And Policy Innovation* (Harvard Law School) argues that cost savings can be made by public and private insurers in the United States if cost sharing were eliminated and DSME were provided free of charge to patients ⁵. However, little research has explored why the costs of running such interventions vary across different health care systems and jurisdictions, or why these costs may differ. This study addresses this gap in the prior literature.

Indeed most of the economic analyses has thus far focused on establishing the cost effectiveness of DSME by comparing the cost of programmes relative to their clinical effectiveness. Such evaluations are usually based on economic modelling, carried out alongside randomised control trials and the findings typically suggest that DSME interventions are cost effective relative to usual care ⁶⁻¹². Despite this, a recent report published by the *Health Information and Quality Authority* (HIQA) ¹³ in Ireland highlights the large degree of heterogeneity in the methodological approaches used in such economic evaluations. This, in turn, makes results difficult to compare in any meaningful way. In addition, these approaches tend to focus solely on overall cost of running the programmes and neglect to explore potential mechanisms through which DSME programmes could be made more efficient whilst also maintaining high standards of effectiveness. Furthermore, the majority of studies are based on interventions within a US population, and as such may not be generalizable across differing health care, social and cultural contexts.

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3 131 This study seeks to address these existing gaps in the literature through an economic evaluation of
4 132 DSME delivery across a number of EU and non-EU countries, namely Austria, Denmark, Germany,
5 133 Ireland, Israel, Taiwan and the UK. The selection of these countries was based on access of the
6 134 Diabetes Literacy Consortium¹ to local knowledge and networks required to carry out the necessary
7 135 fieldwork. These countries also represent a diversity of contrasting approaches to the delivery of
8 136 DSME tailored to each country⁴. The findings are part of a wider study conducted by the Diabetes
9 137 Literacy Consortium, the overall purpose of which was to examine the (cost)-effectiveness of
10 138 diabetes education across Europe, Israel, Taiwan and the US². The objective of this study is to
11 139 examine the value of Time Driven Activity Based Costing (TDABC) in understanding the process and
12 140 costs of delivering Diabetes Self-Management Education programmes (DSME) in multiple countries
13 141 and sites (7 countries, 16 sites) and to identify potential process improvements in the delivery of
14 142 such programmes to reveal opportunities to bend the cost curve for DSME.
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145 2.0 Method

146 A Time Driven Activity Based Costing (TDABC) method was used to map the process of programme
147 delivery and to derive patient level costs^{14 15}. TDABC has been developed as a viable costing method
148 with the health care sector by Kaplan and Porter^{16 17} enabling detailed patient level costs to be
149 computed alongside the identification of possible process improvements resulting in potential cost
150 savings. TDABC is particularly compatible with type 2 diabetes care as the model can be applied to
151 diverse care pathways, particularly chronic disease management. Adopting a TDABC approach in this
152 study therefore gave increased visibility into areas of DSME delivery where process improvements
153 and cost savings could be made, while still maintaining a high quality of patient education. Examples
154 of the application of TDABC have been mostly confined to medical conditions and to acute clinical
155 settings¹⁷⁻¹⁹. This study seeks to add to this body of knowledge on the costs of care within outpatient
156 environments through identifying the patient level cost of a variety of DSME programmes both
157 *cross-nationally* and *Intranationally*²⁰. A primary objective was to provide a robust costing
158 framework within which future studies could include clinical and quality of life outcomes to
159 determine the economic value added to diabetes care through the use of DSME.
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161 The TDABC method involves seven steps¹⁶ 1) select the medical condition and/or patient population
162 to be examined; 2) define the care value chain; 3) develop process maps of each activity in patient

156 ¹ The Diabetes Literacy Consortium represents a group of countries funded by the European Commission
157 under the Seventh Framework research programme (Grant Agreement Number: 306186).

158 ² <http://www.diabetesliteracy.eu>

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3 163 care delivery; identify the resources involved and any supplies used for the patient at each process
4 164 step; 4) obtain time estimates for each process step; 5) estimate the cost of supplying each patient
5 165 care resource; 6) estimate the practical capacity of each resource provided and calculate the
6 166 capacity cost rate; 7) compute the total costs over each patient's cycle of care. By constructing a
7 167 sequential activity and process step map and care value chain the researcher can analyse the
8 168 maps/care pathway for duplication. These areas can then be explored further to establish if changes
9 169 in the pathway would add value by maintaining/increasing the level of care to the patient whilst
10 170 decreasing the economic cost to the overall health care system in terms of providing DSME
11 171 programmes.
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19 173 Each international study team identified the care value pathway in their country and collected the
20 174 activity and time data related to the care value pathway, through qualitative semi-structured
21 175 interviews of health care providers from each education programme (N=16). These included
22 176 physicians, nurses, educators and managers. This information was then entered into an aggregated,
23 177 de-identified database for analysis. All study teams then collected resource and financial data,
24 178 utilising a standardised costing worksheet related to the activities, which were then incorporated
25 179 into the aggregated database for analysis. This methodology was applied to each education
26 180 programme across each country included in the study. The topic guide was developed in the English
27 181 language and was then subsequently translated into the local language by the local research teams
28 182 in each of the participating countries.
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37 184 All activities associated with the DSME pathway were entered into an aggregated Excel database. All
38 185 activity and time data was collected via the survey instrument, and cost estimates were assigned to
39 186 these activity variables using financial data provided by the local provider organizations.
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45 188 DSME programme costs were derived specifically from the cost of performing each activity in the
46 189 delivery of the programme. All cost data was entered into activity spread-sheets and therefore the
47 190 data collected did not contain any information relating to identifiable individual service providers. In
48 191 the resulting database, all cost information was linked to activities and not to individuals. All activity
49 192 and cost information is reported per DSME programme.
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53 194 To compare the outcomes of the DSME programmes, a multi-centre observational pre-post study
54 195 design was used involving diabetes patients enrolled in each of the DSME programmes. Data from
55 196 the participants were collected at the beginning of the programme and after three to six months.
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3 197 The programmes included in the study were existing programmes using five different modes of
4 198 delivery: individual education in one-on-one sessions, beyond routine treatment provided, group
5 199 education, self-help groups, or a combination of some of the above delivery modes. The content of
6 200 peer-led and structured DSME programmes was not comparable. Therefore the two peer-led
7 201 programmes were excluded from our data analysis.
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203 *2.1 Study Sample*

204 To be selected for inclusion, programmes had to: (1) target type 2 diabetes patients; (2) be
205 conducted among the general patient population rather than tailored to the needs of a specific age
206 cohort, needs or gender group; (3) include (but not be limited to) newly diagnosed patients; (4) be
207 stand-alone programmes rather than an add-on to another programme or part of a wider curriculum
208 with (multiple) parallel programs; (5) admit new patients during the time of the baseline data
209 collection. The study sample size was driven by the number of programmes involved in the delivery
210 of the specific DSME programmes in each country. Costs were collected for the duration of each
211 programme, which ranged in duration from one day to those spanning a 12-month timeframe.
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213 *2.2 Analytic approach*

214 The Time Driven Activity Based Costing (TDABC) model was utilised to calculate a cost per
215 programme. Significant variations in programme costs prevailed despite broadly similar programme
216 curricula across countries and programmes. Data collected revealed significant variation in number
217 of education hours across the programmes, number and types of personnel delivering the
218 programmes, practitioner hours and number of participating patients.
219

219

220 Two concepts and measures were drawn upon to develop the TDABC model¹⁶, the unit cost of
221 supplying capacity and the time it takes to undertake an activity. First, the model was used to
222 calculate the cost of all the resources supplied to each programme. This included personnel,
223 supervision and overheads including rent, equipment and software and insurance. The total cost was
224 then divided by the actual capacity in order to calculate the cost rate. Second, the capacity cost rate
225 was used to assign the programme costs to objects by estimating demand on the resource. Two
226 variables were estimated: the capacity cost rate for the programme and the capacity use by each
227 patient. The capacity cost rate was calculated by:
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$$\text{Capacity Cost Rate} = \frac{\text{Cost of Capacity Supplied}}{\text{Practical Capacity of Resource Supplied}}$$

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3 231 Practical capacity was used as the denominator in the capacity cost rate equation. Estimating the
4 232 practical capacity required two time estimates which were gathered from Human Resources and
5 233 other administrative records: the total number of days that each employee actually worked each
6 234 year; the total number of hours per day that the employee was available for work. Practical capacity
7 235 was calculated as 80% of this working time¹⁶. Therefore 20% was attributed to breaks, training and
8 236 annual leave. This was applied to all countries to ensure consistency and comparability of the
9 237 computed programme costs.

10 238
11 239 In order to calculate the total cost of each DSME programme per patient, the capacity cost rates
12 240 (including associated support costs) for each resource used was multiplied by the amount of time
13 241 attributed to each patient. This calculation was based on the number of patients enrolled at the
14 242 outset of the programme. The total cost of each programme per patient was the sum of all the costs
15 243 across all the processes within the DSME programme. The costs were collected in the local currency
16 244 and then expressed in international dollar to ensure comparability of the costs by using the
17 245 Purchasing Power Parity conversion factors, to control for different standards of living, different
18 246 wage levels across countries and for the particular exchange rate.

19 247
20 248 As suggested by Erhun et al. we performed a quantitative investigation of the differences in
21 249 consumption and pricing of labour resources using cost variance analysis on labour costs. This
22 250 analysis enabled us to quantitatively discern differences between processes at selected sites. The
23 251 cost difference can be divided into two effects, a price (due to different capacity cost rates of labour
24 252 resource (CCR)) and a quantity variance (due to different use of the labour resource across the sites).
25 253 We performed this variance analysis to understand the differences in consumption and pricing of
26 254 labour resources and to understand the drivers of cost variation across capacity cost rate variances,
27 255 mix of personnel and efficiency variances¹⁷

28 256
29 257 To understand the association between programme cost and health outcomes achieved, we mapped
30 258 the cost per programme to self-reported patient outcomes. Due to the significant difference in
31 259 access to clinical data across the participating countries in this study, it was not possible to collect
32 260 comparable clinical data for each country. Therefore comparable data was collected to measure
33 261 outcomes at behavioral and disease/health outcome levels for existing diabetes self-management
34 262 programs. Health outcome data was collected at three levels; individual diabetes self-management
35 263 disposition, behaviour and disease/health related outcomes. (The outcome framework employed in
36 264 this study is summarised in the supplemental file attached.)

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266 A statistically significant improvement was found for six behavioral outcomes (general diet, exercise,
 267 medication use, problem areas in diabetes, foot care and appraisal of diabetes) and three
 268 disease/health outcomes (BMI, health related quality of life and affective well-being) in the total
 269 sample. We analyse these self-reported patient outcomes to the cost per programme.

270

271 3.0 Results

272 Findings highlight that the programmes included in this study provide similar educational content
 273 when delivering diabetes education. Further, we found similar changes in self-reported
 274 behavioural and disease outcomes across programmes. This suggests that factors other than
 275 educational content drives cost variation across programmes and despite reported cost variation,
 276 outcomes appear broadly similar. The cost difference between two sites can be analysed into two
 277 effects: a price variance due to different capacity cost rates of resource and a quantity variance due
 278 to different use of resource:

279

$$\Delta_{1,2} = \sum_{i=1}^{N_L} q_1^i \times r_1^i - \sum_{i=1}^{N_L} q_2^i \times r_2^i$$

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281 Figure 1 presents the price variance across the sites³.

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283 Insert Figure 1 here.

284

285 There are a number of factors which were found to influence cost variation. Firstly, programmes
 286 differed in duration and hours of practitioner time spent on each programme delivery. This reflects
 287 the efficiency variance due to different quantities of total personnel used. For example, Figure 2
 288 highlights that the 'Ireland 2' programme utilises 78 hours of personnel, whereas 'Austria 3' only
 289 uses 5.25 hours of personnel time, yet patient self-reported outcomes are broadly similar. This
 290 suggests that total personnel time is a strong cost driver but not an outcome driver. This efficiency
 291 variance across two sites is expressed as:

292

$$= \left(\sum_{i=1}^{N_L} r_2^i \times \frac{q_2^1}{Q_2} \right) \times (Q_1 - Q_2)$$

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³ For each Figure 1-6 the associated data is included in Supplemental Files attached.

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3 295 Insert Figure 2 here.

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7 299 Secondly, mix of personnel skill used in providing the education is a cost driver. For example, the
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9 300 high salary cost for a consultant physician in Germany and social worker cost in Israel (Figure 3) did
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11 301 not produce any significant improvement in patient self-reported outcomes. These findings suggest
12
13 302 that personnel skill used is a strong cost driver but does not significantly alter patient self-reported
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15 303 outcomes. When comparing two sites this mix variance is measured as follows:
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17 304

$$= \left(\sum_{i=1}^{N_L} \left(\frac{q_1^i}{Q_1} - \frac{q_2^i}{Q_2} \right) \times r_2^i \right) \times Q_1$$

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23 306 Insert Figure 3 here.

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27
28 309 Figure 3 highlights that for most countries the salaries and practical capacity cost rates for those who
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31 310 provide DSME are broadly similar. The exceptions to this include Germany who use a consultant
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33 311 physician for part of the education programme, Israel who have a high salary scale for social workers
34
35 312 and Taiwan who have a low salary rate for the hospital nurses providing patient education.
36 313

37 314 Thirdly, the number of patients who attended each programme was a strong per-patient cost driver
38
39 315 (Figure 4) the more patients who attended the programme the lower the per-patient cost.
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42 317 Insert Figure 4 here.

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47 320 Taking total cost per programme, the median programme was identified as Israel Programme 1. The
48
49 321 key cost drivers identified were then compared to this base programme to explore the behaviour of
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51 322 these variances. Figure 5 summarises this comparison with the base country and reveals that there is
52
53 323 a non-linear relationship between the cost of a programme and each of the key cost drivers,
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55 324 practitioner hours used, the practical capacity rate of the skill mix used and the number of patients
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57 325 participating on the programmes. This reveals the complexity of the cost behaviours and of the cost
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3 326 variations between the programmes despite offering similar curricula and resulting in similar health
4 327 outcomes.

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8 329 Insert Figure 5 here.

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15 333 Figure 6 maps the health outcomes observed with the cost per programme. Very modest
16 334 improvements in each of the self-reported variables were found. More significantly, there was very
17 335 little variation in outcomes across each of the programmes, both within and between countries,
18 336 whatever the mode of delivery, mix of personnel skill used, quantity of total personnel hours,
19 337 quantity of education hours or quantity of participating patients.

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25 340 Insert Figure 6 here.

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32 344 **4.0 Discussion**

33 345 The data illustrates that Diabetes Self Management Education programmes are provided at a low
34 346 cost in every country studied. The data provides evidence that while these costs are low, significant
35 347 cost variations exist both within and between countries. This is due to a combination of cost
36 348 variations between the programmes; the capacity cost rate, the mix of personnel delivering the
37 349 education, the different quantities of total personnel used and the number of patients participating
38 350 in these programmes. This is the first time that such multi-country comparative data has been
39 351 collected.

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43 353 The variance analysis performed surrounding costs and outcomes illustrates total personnel hours as
44 354 a strong cost driver (Figure 2). Practitioners such as nurses and diabetes nurse specialists can
45 355 produce similar outcomes to physicians but at a lower salary and practical capacity cost. This is likely
46 356 to be a more effective use of resources, particularly in relation to optimizing use of personnel at
47 357 their level of expertise. Further research is needed to explore the most appropriate level of expertise
48 358 required to deliver the programme for optimal patient health outcomes. For example, instead of
49 359 having a consultant physician or a Clinical Nurse Specialist delivering the education programmes it
50 360 may be more appropriate to have well trained experienced nurses or the equivalent performing this

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3 361 role. A pilot study conducted by Kaplan et al. at The University of Texas Cancer Centre revealed that
4 362 matching clinical skills to the processes led in a 16% reduction in process time, a 12% decrease in
5 363 costs for technical staff, and a 67% reduction in costs for professional staff¹⁶. However clinical
6 364 outcomes, in addition to behavioural and psychosocial outcomes, are necessary to determine fully
7 365 whether the educators' level of expertise really influences all DSME health outcomes¹⁶.
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12 367 In some countries the cost of the same programme varied by site. For these programmes, we
13 368 observed significant variation in administrative hours and this was not associated with the number
14 369 of participating patients. This finding is similar to that of Munoz et al. who used TDABC in a cost-effectiveness
15 370 analysis of a red blood cell salvage post total-knee arthroscopy in the US, Switzerland and Austria
16 371 and suggest that tighter control of administrative costs may reduce what appear to be non-value
17 372 added hours for the patients²¹.
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24 374 Integrating data on the number of patients participating on each programme (Figure 4) with the
25 375 outcome data suggests that the number of patients in attendance did not impact on patient self-
26 376 reported outcomes. These findings suggest that there is room for cost savings in DSME regarding
27 377 the amount of hours of education provided, who provides the education and the number of patients
28 378 in attendance at each programme, without negatively impacting patients self-reported outcomes.
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34 380 A number of learnings emerged from this study: firstly, all programme curricula covered similar
35 381 topics, this suggests that there is a shared consensus on what information requires dissemination
36 382 and highlights that variation relates to process delivery rather than curricula; secondly, the
37 383 administrative burden on programmes varies greatly and as such is an area of programme
38 384 development which requires planning and streamlining; thirdly, the skill mix of professionals
39 385 delivering the programme varies greatly suggesting a lack of empirical knowledge surrounding the
40 386 most effective educator; fourthly, the duration and hours of education varies significantly across
41 387 sites, again highlighting a lack of consensus in terms of the most efficacious course construct; and
42 388 finally, such cost variation exists across sites despite the programme content being broadly similar.
43 389 The granular mapping of the DSME programmes and the derivation of a cost per programme is the
44 390 first step in generating a better understanding of the DSME arena internationally.
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53 392 Analysis of the self-reported outcome data found that these outcomes were similar irrespective of
54 393 the education programme or the country (albeit that the sample size was small and the standard
55 394 deviation high). Across each programme, a statistically significant improvement was found for six
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3 395 behavioral outcomes (general diet, exercise, medication use, problem areas in diabetes, foot care
4 396 and appraisal of diabetes) and three disease/health related outcomes (BMI, health related quality of
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6 397 life and affective well-being).
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9 399 The costing and provision of DSME is at an early stage of development globally with limited empirical
10 400 knowledge of the most efficient and effective mode of delivering DSME. Thus this study has gone
11 401 some way to remedying this problem whereby it has outlined a bottom up/patient level cost using
12 402 estimates of the actual resource costs used to educate patients through self-management programs
13 403 and therefore a more accurate cost than heretofore of providing various education programmes.
14 404 Thus, it has provided a first layer of information, which in the future will be required to establish
15 405 whether this model of care/intervention can add value to the health care system once clinical
16 406 effectiveness outcomes have been determined for each programme. Storfjell et al., show that the
17 407 application of TDABC in the context of nursing care can facilitate the identification and elimination of
18 408 non-value added time (NVA) and related the increase in time spent on psychosocial intervention,
19 409 support and patient education²². However, there is a long way to go, whereby clinical and Quality of
20 410 Life outcomes are required to measure the effectiveness of DSME programmes before a thorough
21 411 understanding of their added value to patients can be estimated. The methods and results of the
22 412 current study will inform future research to achieve a better understanding of the added value
23 413 derived from providing DSME interventions. We suggest that future studies include a rigorous
24 414 collection of clinical outcomes pre and post DSME.
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37 417 **5.0 Limitations**

38 418 The TDABC method is a relatively new method in terms of healthcare costing and to the best of the
39 419 authors' knowledge has yet to been applied to investigate the costs of a health education
40 420 intervention. As a result there were limited guidelines surrounding the collection of activity and
41 421 process step data in non-acute settings and thus it was necessary for the research team to develop
42 422 such a protocol that was fit-for-purpose across different international study sites. In practice, many
43 423 participants were unfamiliar with the costing and activity terminology and the level of detail
44 424 required on all forms of activity, for TDABC. We observed that participants appeared to provide less
45 425 detail on administrative and programme preparation activity compared with education activity. This
46 426 detailed information would have provided greater insight into the reasons why administrative costs
47 427 were found to be so high in some countries while not in others.
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3 429 In addition, some of the local research teams also experienced difficulties in collecting the required
4 430 financial data. For example, in Belgium, the staff involved in the delivery of DSME programmes
5 431 taking part in this study were unwilling to share salary information at the level of granularity that
6 432 was required to compute a programme cost. For this reason, the Belgian data had to be excluded
7 433 from this particular study.
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11 434
12 435 The study is also limited by a lack of available clinical outcome data from each of the education
13 436 programmes. While important self-reported health and psycho-social outcome data was collected in
14 437 each country it was not possible to determine the clinical-effectiveness of these DSME programmes
15 438 in terms of glycemetic control due to the absence of any clinical measures. As Kaplan and Porter point
16 439 out¹⁶, value in health care can only be determined when there is visibility into both costs and *clinical*
17 440 outcomes. Furthermore, the reliability of self-reported outcomes data was undermined by small
18 441 sample sizes in each country. Secondly, self-reported measures of health behavior are susceptible to
19 442 social desirability bias, and response styles can vary by culture and setting^(23, 24). Nonetheless, the
20 443 similarity in outcomes across each of the sites regardless of the amount of money invested in each
21 444 programme raises questions surrounding the value being achieved per Euro/ dollar spent.
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31 446 The peer-led programmes found in Denmark and Germany were excluded from the analysis.
32 447 However, they were provided at the lowest cost of Int \$0.15 and Int \$0.74 per patient per hour of
33 448 education respectively. When self-assessed outcome data was measured for each programme, the
34 449 outcomes were similar for peer-led and specialist-led programmes. We suggest that further research
35 450 is needed surrounding peer-led education and measurement of associated clinical health outcomes.
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42 453 **6.0 Conclusion**

43 454 This paper has demonstrated the variances in the cost of delivering different types of diabetes
44 455 education programmes, both within and across countries in the EU and Asia. Developing cost
45 456 effective lifestyle interventions to improve the diabetes knowledge and self-management skills and
46 457 quality of life for patients may be an important step in preventing the onset of complications
47 458 associated with type 2 diabetes. The imperative to do so from an economic perspective cannot be
48 459 underestimated when consideration is given to the implications for health care systems associated
49 460 with the treatment of diabetes related morbidities such as active foot disease, chronic kidney
50 461 disease, retinopathy and myocardial infarction²⁵.
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3 463 This study offers the first application of a TDABC approach to evaluate the cost of delivering DSME
4 464 programmes and as a means of comparing the costs of running a healthcare intervention cross-
5 465 nationally. It contributes to the extant literature by highlighting and describing the vast
6 466 combinations and permutations of delivery of DSME curricula, practitioner hours, hours of
7 467 education, mix of educators, numbers of attendees and how these variations lead to substantial cost
8 468 differences. Our variance analysis revealed that the key drivers of cost variation arose from differing
9 469 capacity cost rates, the mix of personnel delivering the education, the different quantities of total
10 470 personnel used and the number of patients participating in these programmes. In the process, we
11 471 identified how there could be potentially unnecessary process steps that, if eliminated, could lead to
12 472 cost savings in the delivery of DSME programmes, including vast differences in administration time,
13 473 and exploring the mix of personnel skill alongside the total personnel time used.

14 474
15 475 While it is already established that diabetes education is a low cost intervention and is cost-effective,
16 476 given the sheer numbers of education programmes that need to be made available to meet the
17 477 demands resulting from increasing levels of diabetes worldwide, even small process improvements
18 478 could lead to overall cost savings for healthcare providers. Future studies focusing on the cost-
19 479 effectiveness of healthcare interventions may consider adopting TDABC principles and variance
20 480 analysis as a means of identifying efficiencies in other chronic disease education programmes.

21 481
22 482 The study has highlighted the strengths of TDABC as a method of bottom up costing in outpatient
23 483 care and recommends utilising this method in future studies so as to allow for a comprehensive
24 484 literature to develop in the area, enabling comparative studies to be performed. By developing such
25 485 literature a comprehensive understanding of the cost of patient education programmes can be
26 486 developed and compared cross nationally and across time. Health care practitioners and educators
27 487 who wish to convince policy makers and health insurers to reimburse the cost of DSME delivery can
28 488 adopt a TDABC approach in order to demonstrate that such programmes are run efficiently and
29 489 effectively especially when combined with measures of consequent clinical health outcomes to
30 490 represent value for money.

31 491

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7 497

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25 515 contributed to the data collection.
26

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31 520 **Contributorship statement** GD initially proposed the study. GD and SG specified the methodology.
32 521 KC carried out the cost analysis. All authors contributed to the protocol design, data collection and
33 522 analysis plan. EQ and SO'D wrote the initial manuscript, and all authors contributed to improving the
34 523 manuscript. All authors approved the final manuscript.
35

36 524

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38 526

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43 531

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46 534

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535 **Data sharing statement** The Excel spreadsheets showing how the individual activity costs were
536 aggregated are available should they be requested.

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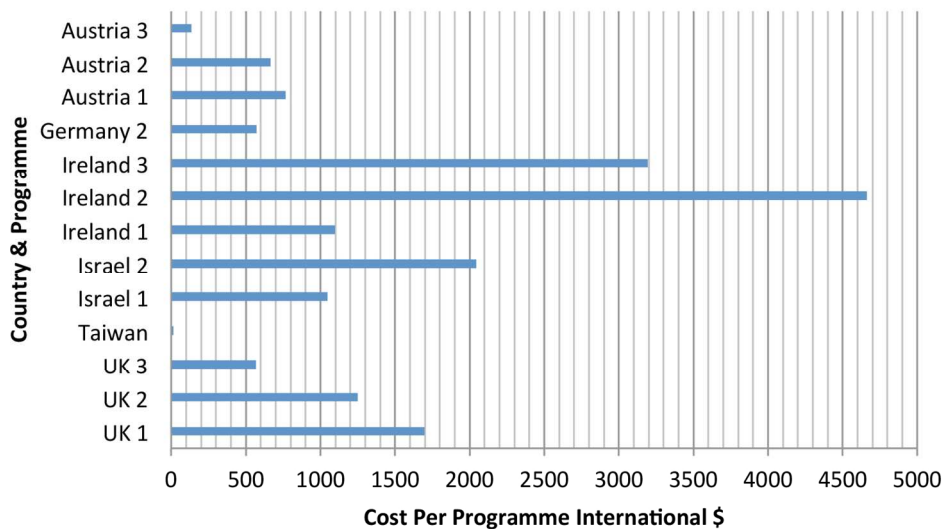


Figure 1: Cost Per Programme in International Dollars
Figure 1
145x84mm (300 x 300 DPI)

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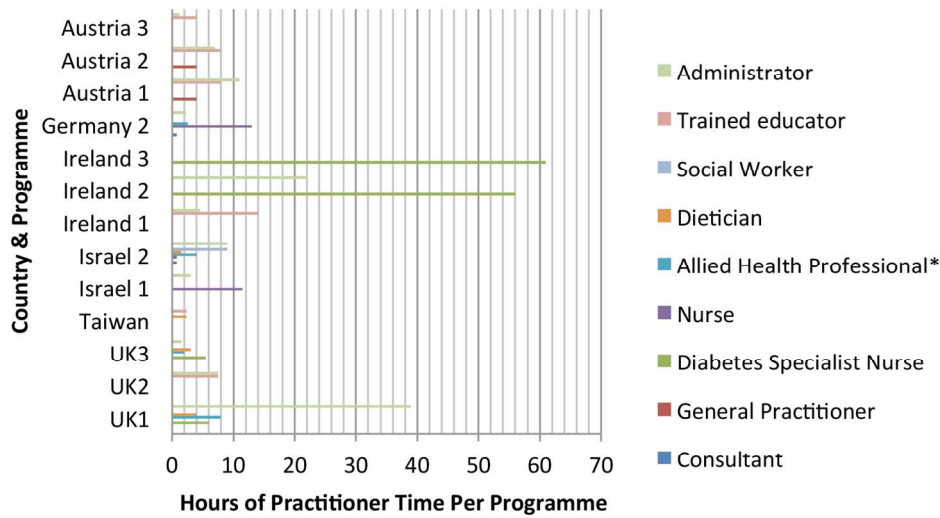


Figure 2: Hours of Practitioner Time Per Programme
 *Allied Health Professional = podiatrist, physiotherapist, health promoter, sore assistant, laboratory scientist, social worker

Figure 2
 145x83mm (300 x 300 DPI)

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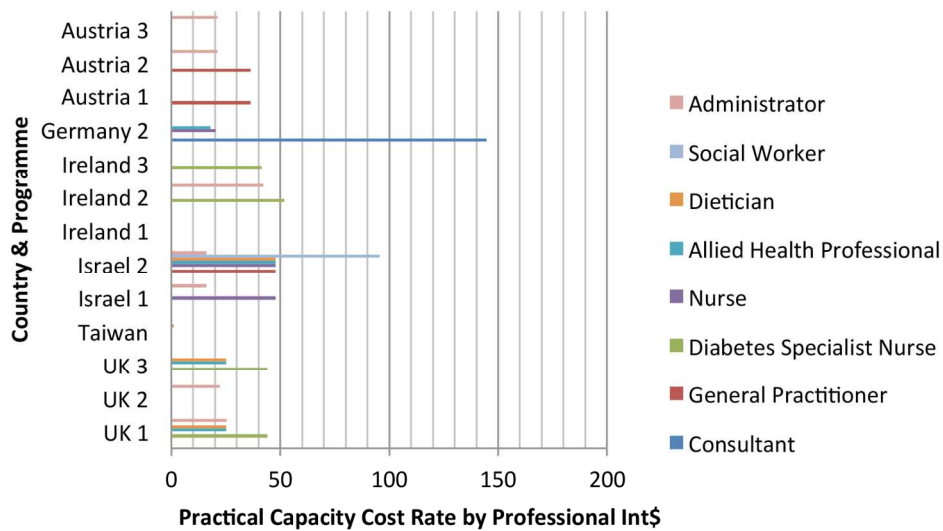


Figure 3: Practical Capacity Cost Rate by Professional Int \$
 Figure 3
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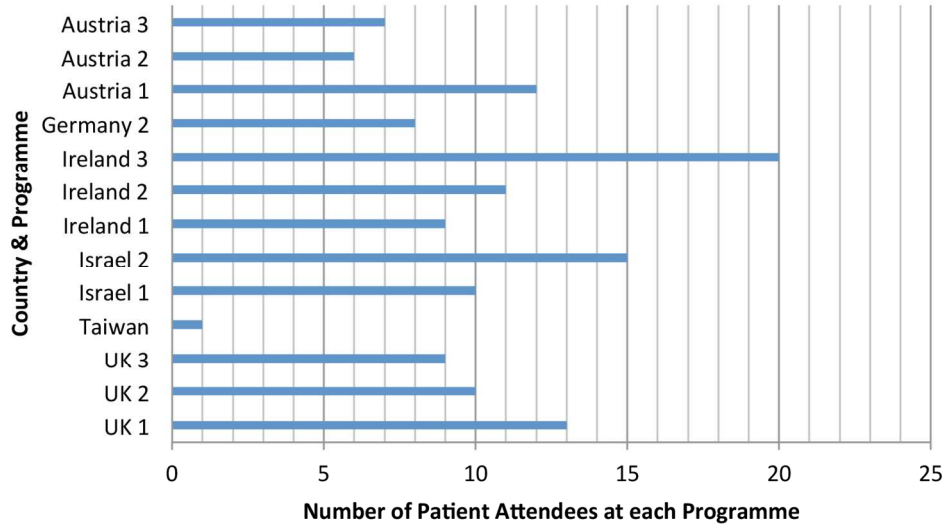


Figure 4: Number of Patient Attendees at each Programme

Figure 4
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Variations from the median programme (Israel 1)

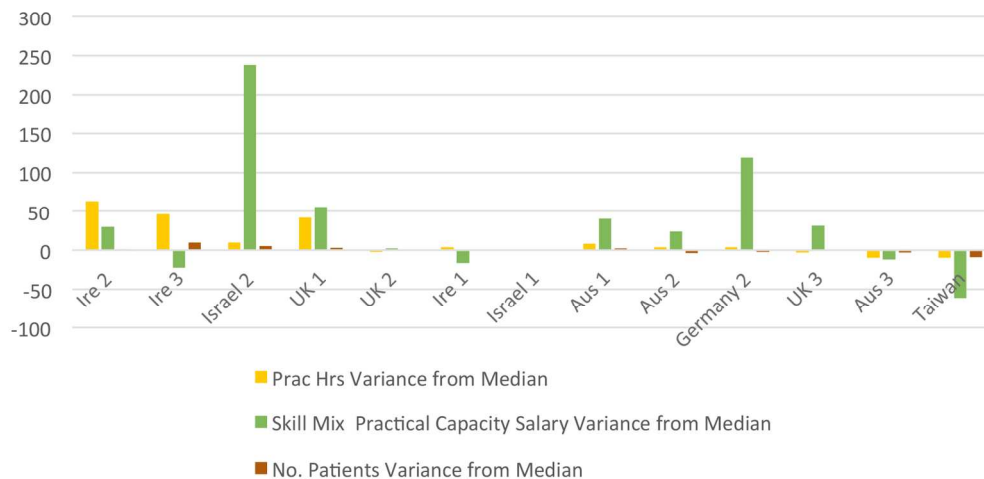


Figure 5: Variations from the median programme (Israel 1) – variations in practitioner hours, practical capacity rate and number of patients

Figure 5
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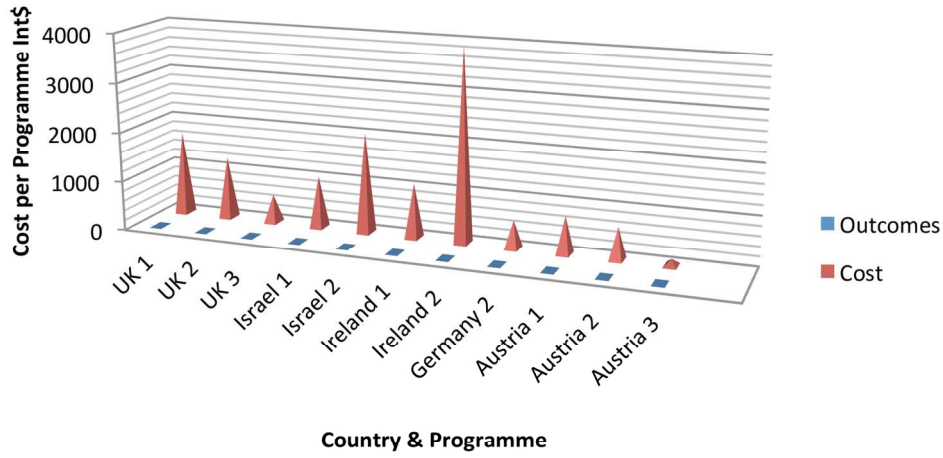


Figure 6: Cost Per Programme (Int\$) and Self-Reported Patient Outcomes

Figure 6
145x84mm (300 x 300 DPI)

review only

Data to Support Figures 1-5

Programme	Total Cost per-programme (home currency)	Total Cost per-programme (Int\$)
UK 1	£1201.83	1697.50
UK 2	£883.60	1248.02
UK 3	£402.03	567.83
Taiwan	227.71NTD	14.01
Israel 1	4196.90 INS	1046.61
Israel 2	8196.08 INS	2043.91
Ireland 1	€923.38	1099.26
Ireland 2	€3918.31	4664,65
Ireland 3	€2682.40	3193.33
Germany 2	€451.52	573.72
Austria 1	€619.68	766.93
Austria 2	€536.28	663.71
Austria 3	€109.97	136.10

Figure 1 Data: Cost Per Programme (Salary and Overheads)

Cost Driver 1: Number of Practitioner Hours Spent on each programme

Staff (hrs)	Consultant	GP	DSN	Nurse	AHP	Dietician	Social Worker	Trained Educator	Administrator	Total time
Programme										
UK 1	-	-	6	-	8	4	-	-	39	57
UK 2	-	-	-	-	-	-	-	7.5	5.5	13
UK 3	-	-	5.5	-	2	3	-	-	1.5	12
Taiwan	-	-	-	-	-	2.4	-	2.4	-	4.8
Israel 1	-	-	-	11.5	-	-	-	-	3	14.5
Israel 2	-	.75	-	.75	4	1.5	9	-	9	25
Ireland 1	-	-	-	-	-	-	-	14	4.5	18.5
Ireland 2	-	-	56	-	-	-	-	-	22	78
Ireland 3	-	-	60.6	-	-	-	-	-	-	60.6
Germany 2	.75	-	-	13	2.5	-	-	-	2.25	18.5
Austria 1	-	4	-	-	-	-	-	8	11	23
Austria 2	-	4	-	-	-	-	-	8	7	19
Austria 3	-	-	-	-	-	-	-	4	1.25	5.25

Figure 2 Data: Number of Practitioner Hours Spent on each Programme Course

Cost Driver 2: Practitioner Type and Hourly Practical Capacity Salary (in Int \$)

Staff (PC Salary)	Consultant	GP	DSN	Nurse	AHP	Dietician	Social Worker	Trained Educator	Administrator	Total
Programme										
UK 1	-	-	44.10	-	25.24	25.24	-	-	25.44	120.02
UK 2	-	-	-	-	-	-	-	44.10	22.10	66.20
UK 3	-	-	44.10	-	25.24	25.24	-	-	-	94.58
Taiwan	-	-	-	-	-	1.26	-	1.26	-	2.52
Israel 1	-	-	-	47.73	-	-	-	-	16.03	63.76
Israel 2	-	47.73	-	47.73	47.73	47.73	95.45	-	16.03	302.40
Ireland 1	-	-	-	-	-	-	-	47.51	-	47.51
Ireland 2	-	-	51.74	-	-	-	-	-	42.15	93.89
Ireland 3	-	-	41.50	-	-	-	-	-	-	41.50
Germany 2	144.65	-	-	20.32	17.84	-	-	-	-	182.81
Austria 1	-	36.26	-	-	-	-	-	30.45	21.09/37.66	104.37
Austria 2	-	36.26	-	-	-	-	-	30.45	21.09	87.80
Austria 3	-	-	-	-	-	-	-	30.45	21.09	51.54

Figure 3 Data: Practitioner Type and Hourly Practical Capacity Salary in Int\$ for comparison

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Cost Driver 3: Number of Attendees at Each Programme

Programme	Number of participants
UK 1	13
UK 2	10
UK 3	9
Taiwan	1
Israel 1	10
Israel 2	15
Ireland 1	9
Ireland 2	11
Ireland 3	20
Germany 2	8
Austria 1	12
Austria 2	6
Austria 3	7*

Figure 4 Data: Number of Patients who Attend each Programme Course

*This programme runs for insulin and non-insulin users – insulin typically have 4 patient attendees and non-insulin typically have 9 patient attendees. We took the median number = 6.5 rounded to 7.

Programme	Total Cost	Price Variance from Median	Practitioner Hours	Prac Hrs Variance from Median	Skill Mix Hourly Practical Capacity Salary	Skill Mix Practical Capacity Salary Variance from Median	No. of Patients	No. Patients Variance from Median
Ire 2	4664	3,618	78	63	94	30	11	1
Ire 3	3193	2,147	61	46	42	-22	20	10
Israel 2	2043	997	25	10	302	238	15	5
UK 1	1697	651	57	42	120	56	13	3
UK 2	1248	202	13	-2	66	2	10	0
Ire 1	1099	53	19	4	48	-16	9	-1
Israel 1	1046	0	15	0	64	0	10	0
Aus 1	766	-280	23	8	104	40	12	2
Aus 2	633	-413	19	4	88	24	6	-4
Germany 2	573	-473	19	4	183	119	8	-2
UK 3	567	-479	12	-3	95	31	9	-1
Aus 3	136	-910	5	-10	52	-12	7	-3
Taiwan	14	-1032	5	-10	3	-61	1	-9

Median Programme = Israel 1

Figure 5 Data: Variances from the median programme (Israel 1) – variances in practitioner hours, practical capacity rate and number of patients

Diabetes Self-Management Outcomes Framework

Program form		Outcome I. Individual DSM dispositions	Outcome II. AADE7 Behavior	Outcome III. Disease/Health	
1. Program Context	2. Program characteristics	3. Characteristics of program participants (Specifically health literacy)	4. Increase diabetes specific self-efficacy, focus of control	11. Healthy Eating	
			5. Increase diabetes knowledge	12. Being Active	18. Disease related Outcomes
			6. Change attitudes, believes towards diabetes	13. Self-Monitoring	19. Reduced health risks
			7. Raise diabetes awareness	14. Taking Medication	20. Health related quality of life
			8. Increase perceived social support/desirability of DSM behaviors	15. Problem Solving	21. Mental comorbidity
			9. Enhance self-reflection on DSM behaviors	16. Reduced Risk Behavior	
			10. Improve DSM skills	17. Healthy coping	

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	N	Gen Diet	SD	Special Diet	SD	Problem Solving	SD	Reduced Risk Behaviour	SD	Health Coping	SD	Diabetes Health Literacy	SD	Fdhl	SD	CrDhl	SD
UK 1	2	0	0	1.33	.94	0.5	3.54	1.25	0.17	-1	2.83	0.07	0.2	0	0.28	0.25	0
UK2	21	0.02	.73	-0.21	1.75	0.81	2.89	0.11	0.94	1.33	3.23	-0.19	0.37	-0.3	0.48	-0.17	0.59
UK3	27	0.09	1.26	0.32	1.01	1.81	4	0.49	0.84	0.85	3.45	-0.04	0.35	-0.09	0.46	-0.01	0.69
GER2	5	0	1.87	0.07	1.44	2.6	1.5	0.89	1.11	3.14	3.58	0.13	0.11	0.11	0.3	0.26	0.5
IS1	11	0.59	1.11	-0.39	2.33	4.18	5.96	0.41	1.4	3.73	3.93	-0.03	0.27	0.07	0.59	-0.25	0.8
IS2	64	0.38	3	-0.22	2.33	0.58	5.34	0.23	1.75	1.17	4.53	0.07	0.52	0.05	0.91	0.04	0.8
IR1	13	0.73	1.59	-0.74	1.42	5	4.28	0.17	1.71	3	4.08	0.21	0.59	-0.12	0.74	0.35	0.85
IR2	5	-0.2	0.45	-0.07	1.83	4.6	5.98	0.55	1.05	3	2.74	0.2	0.45	0.36	0.26	-0.05	0.59
AUS1	6	0.5	1.1		1.48	1.5	3.62	1.38	0.92	3.5	3.08	0.07	0.25	-0.3	0.37	0.42	0.47
AUS2	2	1.5	1.12	1.83	4.95	-1.5	4.95	3	1.77	0.5	4.95	0.25	0.25	-0.2	0.42	0.5	0.28
AUS3	5	0.3	.72	0.93	3.49	1.2	3.49	0.3	1.2	4.4	3.44	-0.43	0.42	-0.28	0.46	-0.75	0.41

Figure 6 Data: Self-Reported Patient Outcomes (SD=Standard Deviation)

For Figure 6, General Diet was taken as one example of the health outcome data achieved when mapped with cost per programme. To include each health outcome would make Figure 6 too complex and the main finding that health outcomes were similar across all programmes would not be clear to the reader.

CHEERS Checklist**Items to include when reporting economic evaluations of health interventions**

The **ISPOR CHEERS Task Force Report**, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force*, provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* or via the ISPOR Health Economic Evaluation Reporting Standards – CHEERS: Good Reporting Practices webpage: <http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp>

Section/item	Item No	Recommendation	Reported on page No/line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared.	<u>p.4/ 131</u>
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	<u>p.2/ 50-78</u>
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	<u>p.4/ 138-142</u>
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	<u>p.6/ 204-211</u>
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	<u>p.2/ 54-55</u>
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	<u>p.5-6/ 188-201</u>
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	<u>p.6/ 204-211</u>
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	<u>p.6/ 211</u>
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	<u>N/A</u>
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	<u>p.5-6/ 194-201</u>
Measurement of effectiveness	11a	<i>Single study-based estimates:</i> Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	<u>p.6-8/ 213-269</u>



Consolidated Health Economic Evaluation Reporting Standards – CHEERS Checklist 2

			N/A
	11b	<i>Synthesis-based estimates:</i> Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	N/A
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	p.5-6/ 194-201
Estimating resources and costs	13a	<i>Single study-based economic evaluation:</i> Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	p.4-5/ 146-201
	13b	<i>Model-based economic evaluation:</i> Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	N/A
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	p.7/ 243-206
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	N/A
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	N/A
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	p.6-8/ 214-269
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	N/A
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	p 8-13/ 272-348
Characterising uncertainty	20a	<i>Single study-based economic evaluation:</i> Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact	N/A



		of methodological assumptions (such as discount rate, study perspective).	N/A
	20b	<i>Model-based economic evaluation</i> : Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	N/A
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	<u>p.8-13/ 272-348</u>
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	<u>p.13-17/ 350-495</u>
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	<u>p.17/ 498-501</u>
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	<u>p.18/ 530</u>

For consistency, the CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

The **ISPOR CHEERS Task Force Report** provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* link or ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: <http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp>

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Patient Level Cost of Diabetes Self-Management Education Programmes: An International Evaluation

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Secondary Subject Heading:	Diabetes and endocrinology, Health policy, Health services research
Keywords:	Time Driven Activity Based Costing, Health literacy, Cost, Diabetes Mellitus, Type 2, Self-Management

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Patient Level Cost of Diabetes Self-Management Education Programmes: An International Evaluation

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Abstract

Objectives: The objective of this study was to examine the value of Time Driven Activity Based Costing (TDABC) in understanding the process and costs of delivering Diabetes Self-Management Education programmes (DSME) in a multi-country comparative study.

Setting: Outpatient settings in five European countries (Austria, Denmark, Germany, Ireland, United Kingdom) and two countries outside Europe, Taiwan and Israel.

Participants: Providers of DSME programmes across participating countries (N=16) including health care professionals, administrators and patients taking part in DSME programmes.

Primary and secondary measures: Primary Measure: Time spent by providers in the delivery of DSME and resources consumed in order to compute programme costs. Secondary measures: self-report measures of behavioural self-management and diabetes disease/health related outcomes.

Results: We found significant variation in costs and the processes of how DSME programmes are provided across and within countries. Variations in costs were driven by a combination of price variances, mix of personnel skill and efficiency variances. Higher cost programmes were not found to have achieved better relative outcomes. The findings highlight the value of TDABC in calculating a patient level cost and potential of the methodology to identify process improvements in guiding the optimal allocation of scarce resources in diabetes care, in particular for DSME that is often underfunded.

Conclusions: This study is the first to measure programme costs using estimates of the actual resources used to educate patients about managing their medical condition and is the first study to map such costs to self-reported behavioural and disease outcomes. The results of this study will inform clinicians, managers and policy makers seeking to enhance the delivery of DSME programmes. The findings highlight the benefits of adopting a TDABC approach to understanding the drivers of the cost of DSME programmes in a multi-country study to reveal opportunities to bend the cost curve for DSME.

Article Summary

Strengths and limitations of this study

- Time Driven Activity Based Costing (TDABC) has rarely been applied to care pathways within non-acute settings and as such offers a novel perspective on understanding the costs of providing chronic disease self-management education.
- This is the first multi-country study to compare the costs of DSME across a number of countries within the EU and Asia.
- Outcomes of programme participation were measured through self-reported changes, making it difficult to establish if any clinical improvement occurred. Future studies should combine TDABC analysis with clinical outcomes to further assess value in DSME.

96 1.0 Introduction

97 Type 2 diabetes mellitus is one of the major public health threats of the 21st century, currently
98 affecting approximately 59.8 million people within Europe and 415 million worldwide ¹. Further, it
99 has been reported that diabetes medical care accounts for a disproportionate allocation of health
100 service resources across the western world ¹. A recent US study performed an analysis of the
101 spending on personal and public health across 155 conditions across time (1996-2013) and found
102 that spending on diabetes (alongside low back and neck pain) increased the most over this period
103 (\$64.4 billion). Furthermore the study found that diabetes had the highest health care spending in
104 2013 (\$101.4 billion), a disease attributable to behavioural or metabolic risk factors including diet,
105 obesity, high fasting plasma glucose, tobacco use and low physical activity. ² Developing the self-care
106 capacity of patients is critical to determining optimal clinical, behavioural and psychosocial outcomes
107 and therefore reducing costs³. Diabetes self-management education (DSME) has been shown to
108 improve patient outcomes by reducing the onset and/or advancement of diabetes related
109 complications; by improving quality of life; strengthening self-efficacy and personal empowerment;
110 assisting with the development of healthy coping skills; and by reducing diabetes related distress
111 and depression ⁴.

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113 The operation and delivery of DSME varies across the international landscape. They can be either
114 professionally led or peer led. Further, they can be group based, individually based, and increasingly
115 IT based. In addition, DSME curricula, duration and delivery may vary substantially, both within and
116 between countries⁵. It is well established that DSME programmes are a low cost intervention per
117 patient and cost effective from a payer perspective. For example, a recent report published by *The*
118 *Center For Health Law And Policy Innovation* (Harvard Law School) argues that cost savings can be
119 made by public and private insurers in the United States if cost sharing were eliminated and DSME
120 were provided free of charge to patients ⁶. However, little research has explored why the costs of
121 running such interventions vary across different health care systems and jurisdictions, or why these
122 costs may differ. This study addresses this gap in the prior literature.

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124 Indeed most of the economic analyses has thus far focused on establishing the cost effectiveness of
125 DSME by comparing the cost of programmes relative to their clinical effectiveness. Such evaluations
126 are usually based on economic modelling, carried out alongside randomised control trials and the
127 findings typically suggest that DSME interventions are cost effective relative to usual care ⁷⁻¹¹³.
128 Despite this, a recent report published by the *Health Information and Quality Authority* (HIQA) ¹⁴ in
129 Ireland highlights the large degree of heterogeneity in the methodological approaches used in such
130 economic evaluations. This, in turn, makes results difficult to compare in any meaningful way. In

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3 131 addition, these approaches tend to focus solely on overall cost of running the programmes and
4 132 neglect to explore potential mechanisms through which DSME programmes could be made more
5 133 efficient whilst also maintaining high standards of effectiveness. Furthermore, the majority of
6 134 studies are based on interventions within a US population, and as such may not be generalizable
7 135 across differing health care, social and cultural contexts.
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13 137 This study seeks to address these existing gaps in the literature through an economic evaluation of
14 138 DSME delivery across a number of EU and non-EU countries, namely Austria, Denmark, Germany,
15 139 Ireland, Israel, Taiwan and the UK. The selection of these countries was based on access of the
16 140 Diabetes Literacy Consortiumⁱ to local knowledge and networks required to carry out the necessary
17 141 fieldwork. These countries also represent a diversity of contrasting approaches to the delivery of
18 142 DSME tailored to each country⁵. The findings are part of a wider study conducted by the Diabetes
19 143 Literacy Consortium, the overall purpose of which was to examine the (cost)-effectiveness of
20 144 diabetes education across Europe, Israel, Taiwan and the USⁱⁱ. The objective of this study is to
21 145 examine the value of Time Driven Activity Based Costing (TDABC) in understanding the process and
22 146 costs of delivering Diabetes Self-Management Education programmes (DSME) in multiple countries
23 147 and sites (7 countries, 16 sites) and to identify potential process improvements in the delivery of
24 148 such programmes to reveal opportunities to bend the cost curve for DSME.
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35 151 2.0 Method

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37 152 A Time Driven Activity Based Costing (TDABC) method was used to map the process of programme
38 153 delivery and to derive patient level costs¹⁵⁻¹⁶. TDABC has been developed as a viable costing method
39 154 for the health care sector by Kaplan and Porter¹⁷⁻¹⁸ enabling detailed patient level costs to be
40 155 computed alongside the identification of possible process improvements resulting in potential cost
41 156 savings. TDABC is particularly compatible with type 2 diabetes care as the model can be applied to
42 157 diverse care pathways, particularly chronic disease management. Adopting a TDABC approach in this
43 158 study therefore gave increased visibility into areas of DSME delivery where process improvements
44 159 and cost savings could be made, while still maintaining a high quality of patient education. Examples
45 160 of the application of TDABC have been mostly confined to medical conditions and to acute clinical
46 161 settings¹⁸⁻²⁰. This study seeks to add to this body of knowledge on the costs of care within outpatient
47 162 environments through identifying the patient level cost of a variety of DSME programmes both
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56 ⁱ The Diabetes Literacy Consortium represents a group of countries funded by the European Commission under
57 the Seventh Framework research programme (Grant Agreement Number: 306186).

58 ⁱⁱ <http://www.diabetesliteracy.eu>
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3 163 *cross-nationally and Intranationally*²¹. A primary objective was to provide a robust costing
4 164 framework within which future studies could include clinical and quality of life outcomes to
5 165 determine the economic value added to diabetes care through the use of DSME.
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9 167 The TDABC method involves seven steps¹⁷ 1) select the medical condition and/or patient population
10 168 to be examined; 2) define the care value chain; 3) develop process maps of each activity in patient
11 169 care delivery; identify the resources involved and any supplies used for the patient at each process
12 170 step; 4) obtain time estimates for each process step; 5) estimate the cost of supplying each patient
13 171 care resource; 6) estimate the practical capacity of each resource provided and calculate the
14 172 capacity cost rate; 7) compute the total costs over each patient's cycle of care. By constructing a
15 173 sequential activity and process step map and care value chain the researcher can analyse the
16 174 maps/care pathway for duplication. These areas can then be explored further to establish if changes
17 175 in the pathway would add value by maintaining/increasing the level of care to the patient whilst
18 176 decreasing the economic cost to the overall health care system in terms of providing DSME
19 177 programmes.
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22 179 Each international study team identified the care value pathway in their country and collected the
23 180 activity and time data related to the care value pathway, through qualitative semi-structured
24 181 interviews of health care providers from each education programme (N=16). These included
25 182 physicians, nurses, educators and managers. This information was then entered into an aggregated,
26 183 de-identified database for analysis. All study teams then collected resource and financial data,
27 184 utilising a standardised costing worksheet related to the activities, which were then incorporated
28 185 into the aggregated database for analysis. This methodology was applied to each education
29 186 programme across each country included in the study. The topic guide was developed in the English
30 187 language and was then subsequently translated into the local language by the local research teams
31 188 in each of the participating countries.
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34 190 All activities associated with the DSME pathway were entered into an aggregated Excel database. All
35 191 activity and time data was collected via the survey instrument, and cost estimates were assigned to
36 192 these activity variables using financial data provided by the local provider organizations.
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39 194 DSME programme costs were derived specifically from the cost of performing each activity in the
40 195 delivery of the programme. All cost data was entered into activity spread-sheets and therefore the
41 196 data collected did not contain any information relating to identifiable individual service providers. In
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197 the resulting database, all cost information was linked to activities and not to individuals. All activity
198 and cost information is reported per DSME programme.

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200 To compare the outcomes of the DSME programmes, a multi-centre observational pre-post study
201 design was used involving diabetes patients enrolled in each of the DSME programmes. Data from
202 the participants were collected at the beginning of the programme and after three to six months.
203 The programmes included in the study were existing programmes using five different modes of
204 delivery: individual education in one-on-one sessions, beyond routine treatment provided, group
205 education, self-help groups, or a combination of some of the above delivery modes. The content of
206 peer-led and structured DSME programmes was not comparable. Therefore the two peer-led
207 programmes were excluded from our data analysis.

208

209 *2.1 Study Sample*

210 To be selected for inclusion, programmes had to: (1) target type 2 diabetes patients; (2) be
211 conducted among the general patient population rather than tailored to the needs of a specific age
212 cohort, needs or gender group; (3) include (but not be limited to) newly diagnosed patients; (4) be
213 stand-alone programmes rather than an add-on to another programme or part of a wider curriculum
214 with (multiple) parallel programs; (5) admit new patients during the time of the baseline data
215 collection. The study sample size was driven by the number of programmes involved in the delivery
216 of the specific DSME programmes in each country. Costs were collected for the duration of each
217 programme, which ranged in duration from one day to those spanning a 12-month timeframe.

218

219 *2.2 Analytic approach*

220 The Time Driven Activity Based Costing (TDABC) model was utilised to calculate a cost per
221 programme. Significant variations in programme costs prevailed despite broadly similar programme
222 curricula across countries and programmes. Data collected revealed significant variation in number
223 of education hours across the programmes, number and types of personnel delivering the
224 programmes, practitioner hours and number of participating patients.

225

226 Two concepts and measures were drawn upon to develop the TDABC model¹⁷, the unit cost of
227 supplying capacity and the time it takes to undertake an activity. First, the model was used to
228 calculate the cost of all the resources supplied to each programme. This included personnel,
229 supervision and overheads including rent, equipment and software and insurance. The total cost was
230 then divided by the actual capacity in order to calculate the cost rate. Second, the capacity cost rate
231 was used to assign the programme costs to objects by estimating demand on the resource. Two

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3 232 variables were estimated: the capacity cost rate for the programme and the capacity use by each
4 233 patient. The capacity cost rate was calculated by:

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$$\text{Capacity Cost Rate} = \frac{\text{Cost of Capacity Supplied}}{\text{Practical Capacity of Resource Supplied}}$$

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13 237 Practical capacity was used as the denominator in the capacity cost rate equation. Estimating the
14 238 practical capacity required two time estimates which were gathered from Human Resources and
15 239 other administrative records: the total number of days that each employee actually worked each
16 240 year; the total number of hours per day that the employee was available for work. Practical capacity
17 241 was calculated as 80% of this working time¹⁷. Therefore 20% was attributed to breaks, training and
18 242 annual leave. This was applied to all countries to ensure consistency and comparability of the
19 243 computed programme costs.

20 244

21 245 In order to calculate the total cost of each DSME programme per patient, the capacity cost rates
22 246 (including associated support costs) for each resource used was multiplied by the amount of time
23 247 attributed to each patient. This calculation was based on the number of patients enrolled at the
24 248 outset of the programme. The total cost of each programme per patient was the sum of all the costs
25 249 across all the processes within the DSME programme. The costs were collected in the local currency
26 250 and then expressed in international dollar to ensure comparability of the costs by using the
27 251 Purchasing Power Parity conversion factors, to control for different standards of living, different
28 252 wage levels across countries and for the particular exchange rate.

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30 254 As suggested by Erhun et al. we performed a quantitative investigation of the differences in
31 255 consumption and pricing of labour resources using cost variance analysis on labour costs. This
32 256 analysis enabled us to quantitatively discern differences between processes at selected sites. The
33 257 cost difference can be divided into two effects, a price variance (due to different capacity cost rates
34 258 of labour resource (CCR)) and a quantity variance (due to different use of the labour resource across
35 259 the sites). We performed this variance analysis to understand the differences in consumption and
36 260 pricing of labour resources and to understand the drivers of cost variation across capacity cost rate
37 261 variances, mix of personnel and efficiency variances¹⁸

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39 263 To understand the association between programme cost and health outcomes achieved, we mapped
40 264 the cost per programme to self-reported patient outcomes. Due to the significant difference in

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265 access to clinical data across the participating countries in this study, it was not possible to collect
266 comparable clinical data for each country. Therefore comparable data was collected to measure
267 outcomes at behavioral and disease/health outcome levels for existing diabetes self-management
268 programs. Health outcome data was collected at three levels; individual diabetes self-management
269 disposition, behaviour and disease/health related outcomes. (The outcome framework employed in
270 this study is summarised in the Supplemental File attached.)

271

272 3.0 Results

273 Findings highlight that the programmes included in this study provide similar educational content
274 when delivering diabetes education. Further, we found similar changes in self-reported
275 behavioural and disease outcomes across programmes. This suggests that factors other than
276 educational content drives cost variation across programmes and despite reported cost variation,
277 outcomes appear broadly similar. The cost difference between two sites can be analysed into two
278 effects: a price variance due to different capacity cost rates of resource and a quantity variance due
279 to different use of resource:

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$$\Delta_{1,2} = \sum_{i=1}^{N_L} q_1^i \times r_1^i - \sum_{i=1}^{N_L} q_2^i \times r_2^i$$

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282 Figure 1 presents the price variance across the sitesⁱⁱⁱ.

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284 Insert Figure 1 here.

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287 There are a number of factors which were found to influence cost variation. Firstly, programmes
288 differed in duration and hours of practitioner time spent on each programme delivery. This reflects
289 the efficiency variance due to different quantities of total personnel used. For example, Figure 2
290 highlights that the 'Ireland 2' programme utilises 78 hours of personnel, whereas 'Austria 3' only
291 uses 5.25 hours of personnel time, yet patient self-reported outcomes are broadly similar. This
292 suggests that total personnel time is a strong cost driver but not an outcome driver. This efficiency
293 variance across two sites is expressed as:

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ⁱⁱⁱ For each Figure 1-6 the associated data is included in Supplemental Files attached.

$$= \left(\sum_{i=1}^{N_L} r_2^i \times \frac{q_2^1}{Q_2} \right) \times (Q_1 - Q_2)$$

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296 Insert Figure 2 here.

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299 Secondly, mix of personnel skill used in providing the education is a cost driver. For example, the
 300 high salary cost for a consultant physician in Germany and social worker cost in Israel (Figure 3) did
 301 not produce any significant improvement in patient self-reported outcomes. These findings suggest
 302 that personnel skill is a strong cost driver but does not significantly alter patient self-reported
 303 outcomes. When comparing two sites this mix variance is measured as follows:

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$$= \left(\sum_{i=1}^{N_L} \left(\frac{q_1^i}{Q_1} - \frac{q_2^i}{Q_2} \right) \times r_2^i \right) \times Q_1$$

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306 Insert Figure 3 here.

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309 Figure 3 presents the weighted average capacity cost rate, the weights representing the percentage
 310 of total time used of each personnel type. This highlights both the variety of personnel type used
 311 across DSME programmes and countries in addition to the differing percentage of total time used of
 312 each personnel type.

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314 Thirdly, the number of patients who attended each programme was a strong per-patient cost driver
 315 (Figure 4), generally the more patients who attended the programme the lower the per-patient cost.

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317 Insert Figure 4 here.

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320 Taking total cost per programme, the median programme was identified as Austria Programme 1.
 321 The key cost drivers identified were then compared to this base programme to explore the
 322 behaviour of these variances. Figure 5 summarises this comparison with the base country and
 323 reveals that there is a non-linear relationship between the cost of a programme (dependent
 324 variable) and each of the key cost drivers (independent variables); practitioner hours used, the

325 weighted average capacity cost rate and the number of patients participating on the programmes.
326 In general for practitioner hours, weighted average CCR and patient numbers, as the price variance
327 from the median increases, so too do of these independent variables. However there are some
328 exceptions to this general trend; UK 2 and Ireland 1 where a lower number of practitioner hours are
329 used, Israel 2 and UK 2 where a lower weighted average CCR can be observed and Ireland 2 and UK 2
330 where there is a lower number of participating patients.

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332 All programmes with a lower cost than the median do have lower practitioner hours, lower weighted
333 average CCR and a lower number of patients, but not proportionately lower. Programme UK 2
334 appears to be the programme which has a cost higher than the median and yet consistently has a
335 lower number of practitioner hours, lower weighted average CCR and lower patient numbers than
336 the median. This reveals the complexity of the cost behaviours and of the cost variations between
337 the programmes despite offering similar curricula and resulting in similar health outcomes.

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339 Insert Figure 5 here.

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342 There was very little variation in outcomes across each of the programmes, both within and
343 between countries, whatever the mode of delivery, mix of personnel skill used, quantity of total
344 personnel hours, quantity of education hours or quantity of participating patients. For simplicity,
345 Figure 6 maps the health outcomes of one particular variable only, general diet, alongside the cost
346 per programme (Figures 6a and 6b). Very modest improvements in general diet were achieved after
347 participation in DMSE and higher cost programmes did not result in better health outcomes. For
348 example, Israel 2 programme recorded the largest change in health outcomes at a low cost in
349 comparison with the most expensive programme, Ireland 2, which resulted in a very small change in
350 health outcomes. Although only general diet is illustrated here, other outcome data show that
351 DSME was only weakly helpful or in some cases had no effect at all on the health outcomes of
352 participants. (Supplemental File Outcomes Framework and Outcomes Data: Table 2: Self-reported
353 Patient Outcomes.)

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355 Insert Figures 6a and 6b here.

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357 **4.0 Discussion**

358 The data illustrates that Diabetes Self Management Education programmes are provided at a low
359 cost in every country studied. The data provides evidence that while these costs are low, significant

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3 360 cost variations exist both within and between countries. This is due to a combination of cost
4 361 variations between the programmes; the capacity cost rate, the mix of personnel delivering the
5 362 education, the different quantities of total personnel used and the number of patients participating
6 363 in these programmes. This is the first time that such multi-country comparative data has been
7 364 collected.
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12 366 The variance analysis performed surrounding costs and outcomes illustrates total personnel hours as
13 367 a strong cost driver (Figure 2). Practitioners such as nurses and diabetes nurse specialists can
14 368 produce similar outcomes to physicians but at a lower salary and practical capacity cost. This is likely
15 369 to be a more effective use of resources, particularly in relation to optimizing use of personnel at
16 370 their level of expertise. Further research is needed to explore the most appropriate level of expertise
17 371 required to deliver the programme for optimal patient health outcomes. For example, instead of
18 372 having a consultant physician or a Clinical Nurse Specialist delivering the education programmes it
19 373 may be more appropriate to have well trained experienced nurses or the equivalent performing this
20 374 role. A pilot study conducted by Kaplan et al. at The University of Texas Cancer Centre revealed that
21 375 matching clinical skills to the processes led to a 16% reduction in process time, a 12% decrease in
22 376 costs for technical staff, and a 67% reduction in costs for professional staff¹⁷. However clinical
23 377 outcomes, in addition to behavioural and psychosocial outcomes, are necessary to determine fully
24 378 whether the educators' level of expertise really influences all DSME health outcomes¹⁷.
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36 380 In some countries the cost of the same programme varied by site. For these programmes, we
37 381 observed significant variation in administrative hours and this was not associated with the number
38 382 of participating patients. This finding is similar to that of Munoz et al. who used TDABC in a cost-
39 383 effectiveness analysis of a red blood cell salvage post total-knee arthroscopy in the US, Switzerland
40 384 and Austria and suggest that tighter control of administrative costs may reduce what appear to be
41 385 non-value added hours for the patients²².
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48 387 Integrating data on the number of patients participating on each programme (Figure 4) with the
49 388 outcome data suggests that the number of patients in attendance did not impact on patient self-
50 389 reported outcomes. These findings suggest that there is room for cost savings in DSME regarding
51 390 the amount of hours of education provided, who provides the education and the number of patients
52 391 in attendance at each programme, without negatively impacting patients self-reported outcomes.
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55 392 A number of learnings emerged from this study: firstly, all programme curricula covered similar
56 393 topics, this suggests that there is a shared consensus on what information requires dissemination
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3 394 and highlights that variation relates to process delivery rather than curricula; secondly, the
4 395 administrative burden on programmes varies greatly and as such is an area of programme
5 396 development which requires planning and streamlining; thirdly, the skill mix of professionals
6 397 delivering the programme varies greatly suggesting a lack of empirical knowledge surrounding the
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8 398 most effective educator; fourthly, the duration and hours of education varies significantly across
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10 399 sites, again highlighting a lack of consensus in terms of the most efficacious course construct; and
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12 400 finally, such cost variation exists across sites despite the programme content being broadly similar.
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14 401 The granular mapping of the DSME programmes and the derivation of a cost per programme is the
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16 402 first step in generating a better understanding of the DSME arena internationally.
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19 404 A separate analysis of the self-reported outcome data was conducted by Peer et al. analysing the
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21 405 DSME data for all programmes in aggregate²³. They found that these outcomes were similar
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23 406 irrespective of the education programme or the country (albeit that the sample size was small and
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25 407 the standard deviation high). When the programmes were analysed in aggregate, a statistically
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27 408 significant improvement was found for six behavioral outcomes (general diet, exercise, medication
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29 409 use, problem areas in diabetes, foot care and appraisal of diabetes) and three disease/health related
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31 410 outcomes (BMI, health related quality of life and affective well-being). (Please see the Supplemental
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33 411 File Outcomes Framework and Outcomes Data Table 3 and related note explaining the precise scales
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35 412 used.)
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38 414 The costing and provision of DSME is at an early stage of development globally with limited empirical
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40 415 knowledge of the most efficient and effective mode of delivering DSME. Thus this study has gone
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42 416 some way to remedying this problem whereby it has outlined a bottom up/patient level cost using
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44 417 estimates of the actual resource costs used to educate patients through self-management
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46 418 programmes and therefore a more accurate cost than heretofore of providing various education
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48 419 programmes. Thus, it has provided a first layer of information, which in the future will be required to
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50 420 establish whether this model of care/intervention can add value to the health care system once
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52 421 clinical effectiveness outcomes have been determined for each programme. Storfjell et al., show
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54 422 that the application of TDABC in the context of nursing care can facilitate the identification and
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56 423 elimination of non-value added time (NVA) and related the increase in time spent on psychosocial
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58 424 intervention, support and patient education²⁴. However, there is a long way to go, whereby clinical
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60 425 and Quality of Life outcomes are required to measure the effectiveness of DSME programmes before
426 a thorough understanding of their added value to patients can be estimated. The methods and
427 results of the current study will inform future research to achieve a better understanding of the

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3 428 added value derived from providing DSME interventions. We suggest that future studies include a
4 429 rigorous collection of clinical outcomes pre and post DSME.

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7 431 **5.0 Limitations**

8 432 The TDABC method is a relatively new method in terms of healthcare costing and to the best of the
9 433 authors' knowledge has yet to been applied to investigate the costs of a health education
10 434 intervention. As a result there were limited guidelines surrounding the collection of activity and
11 435 process step data in non-acute settings and thus it was necessary for the research team to develop
12 436 such a protocol that was fit-for-purpose across different international study sites. In practice, many
13 437 participants were unfamiliar with the costing and activity terminology and the level of detail
14 438 required on all forms of activity, for TDABC. We observed that participants appeared to provide less
15 439 detail on administrative and programme preparation activity compared with education activity. This
16 440 detailed information would have provided greater insight into the reasons why administrative costs
17 441 were found to be so high in some countries while not in others.

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21 443 In addition, some of the local research teams also experienced difficulties in collecting the required
22 444 financial data. For example, in Belgium, the staff involved in the delivery of DSME programmes
23 445 taking part in this study, were unable to disclose personal salary information, which was not
24 446 otherwise available from a public source, as in other countries. This related to data protection
25 447 legislation (enacted 1992, subsequently amended 1998, 2003), together with the fact that there
26 448 is no professional category of diabetes educator in Belgium. For these reasons, the Belgian data had
27 449 to be excluded from this particular study.

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31 451 The study is also limited by a lack of available clinical outcome data from each of the education
32 452 programmes. While important self-reported health and psycho-social outcome data was collected in
33 453 each country it was not possible to determine the clinical-effectiveness of these DSME programmes
34 454 in terms of glycemetic control due to the absence of any clinical measures. As Kaplan and Porter point
35 455 out¹⁷, value in health care can only be determined when there is visibility into both costs and *clinical*
36 456 outcomes. Furthermore, the reliability of self-reported outcomes data was undermined by small
37 457 sample sizes in each country. Secondly, self-reported measures of health behavior are susceptible to
38 458 social desirability bias, and response styles can vary by culture and setting^{25 26} Nonetheless, the
39 459 similarity in outcomes across each of the sites regardless of the amount of money invested in each
40 460 programme raises questions surrounding the value being achieved per Euro/ dollar spent.

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3 462 The peer-led programmes found in Denmark and Germany were excluded from the analysis.
4 463 However, they were provided at the lowest cost of Int \$0.15 and Int \$0.74 per patient per hour of
5 464 education respectively. When self-assessed outcome data was measured for each programme, the
6 465 outcomes were similar for peer-led and specialist-led programmes. We suggest that further research
7 466 is needed surrounding peer-led education and measurement of associated clinical health outcomes.
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13 469 **6.0 Conclusion**

14 470 This paper has demonstrated the variances in the cost of delivering different types of diabetes
15 471 education programmes, both within and across countries in the EU and Asia. Developing cost
16 472 effective lifestyle interventions to improve the diabetes knowledge and self-management skills and
17 473 quality of life for patients may be an important step in preventing the onset of complications
18 474 associated with type 2 diabetes. The imperative to do so from an economic perspective cannot be
19 475 underestimated when consideration is given to the implications for health care systems associated
20 476 with the treatment of diabetes related morbidities such as active foot disease, chronic kidney
21 477 disease, retinopathy and myocardial infarction²⁷.
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29 479 This study offers the first application of a TDABC approach to evaluate the cost of delivering DSME
30 480 programmes and as a means of comparing the costs of running a healthcare intervention cross-
31 481 nationally. It contributes to the extant literature by highlighting and describing the vast
32 482 combinations and permutations of delivery of DSME curricula, practitioner hours, hours of
33 483 education, mix of educators, numbers of attendees and how these variations lead to substantial cost
34 484 differences. Our variance analysis revealed that the key drivers of cost variation arose from differing
35 485 weighted average capacity cost rates representing the percentage of total time used of each
36 486 personnel type, the mix of personnel delivering the education and the number of patients
37 487 participating in these programmes. In the process, we identified how there could be potentially
38 488 unnecessary process steps that, if eliminated, could lead to cost savings in the delivery of DSME
39 489 programmes, including vast differences in administration time, and exploring the mix of personnel
40 490 skill alongside the total personnel time used.
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50 492 While it is already established that diabetes education is a low cost intervention and is cost-effective,
51 493 given the sheer numbers of education programmes that need to be made available to meet the
52 494 demands resulting from increasing levels of diabetes worldwide, even small process improvements
53 495 could lead to overall cost savings for healthcare providers. Future studies focusing on the cost-
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3 496 effectiveness of healthcare interventions may consider adopting TDABC principles and variance
4 497 analysis as a means of identifying efficiencies in other chronic disease education programmes.

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8 499 The study has highlighted the strengths of TDABC as a method of bottom up costing in outpatient
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10 500 care and recommends utilising this method in future studies so as to allow for a comprehensive
11 501 literature to develop in the area, enabling comparative studies to be performed. By developing such
12 502 literature a comprehensive understanding of the cost of patient education programmes can be
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14 503 developed and compared cross nationally and across time. Health care practitioners and educators
15 504 who wish to convince policy makers and health insurers to reimburse the cost of DSME delivery can
16 505 adopt a TDABC approach in order to demonstrate that such programmes are run efficiently and
17 506 effectively especially when combined with measures of consequent clinical health outcomes to
18 507 represent value for money.

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28
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32 513 programs in their respective countries.

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36
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43 521 Sarah Gibney

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45 523 *Maastricht University, Department of International Health*, The Netherlands: Helmut Brand, Kristine
46 524 Sörensen, Timo Clemens, Marjo Campmans

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48 526 *Clalit Health Services*, Israel: Diane Levin-Zamir, Ziv Har-Gil.

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528 *Taipei Medical University, Taiwan: Peter Chang, Candy Kuo, Alice Lin, Duong Van Tuyen, Becky Sun.*

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538 analysis plan. EQ and SO'D wrote the initial manuscript, and all authors contributed to improving the
539 manuscript. All authors approved the final manuscript.

540

541 **Competing interests** None declared.

542

543 **Ethics Approval** All methods were approved by the SVUH group Research and Ethics Committee, by
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547

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550

551 **Data sharing statement** The Excel spreadsheets showing how the individual activity costs were
552 aggregated are available should they be requested.

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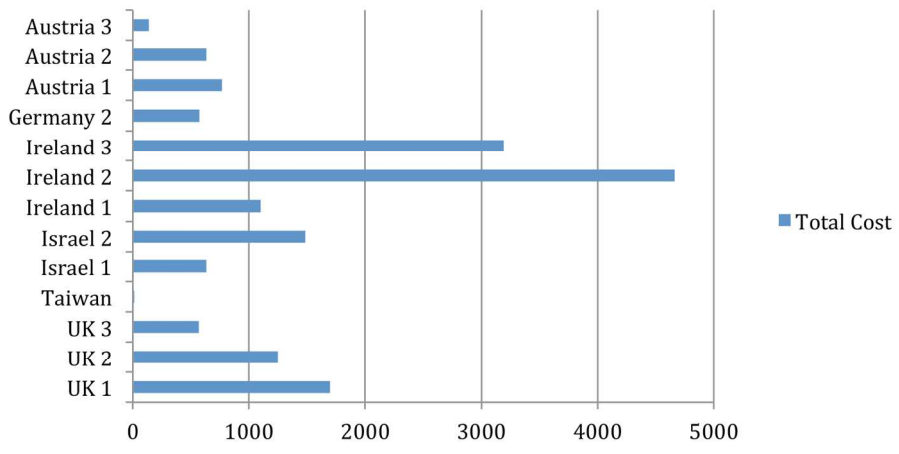
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3 627 **Figure Legend:**
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5 629 **Figure 1: Cost Per Programme (Salary and Overheads) in International \$**
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7 631 **Figure 2: Percentage of total personnel time used per site**
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9 633 **Figure 3: Weighted Average Capacity Cost Rate per Site**
10 634
11 635 **Figure 4: Number of Participants per Programme**
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13 637 **Figure 5: Variance from Median Programme (Austria 1)**
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15 639 **Figure 6a: Total Cost per Programme**
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17 641 **Figure 6b: Change in Health Outcomes (General Diet) Following Participation across different**
18 642 **DSME Sites**
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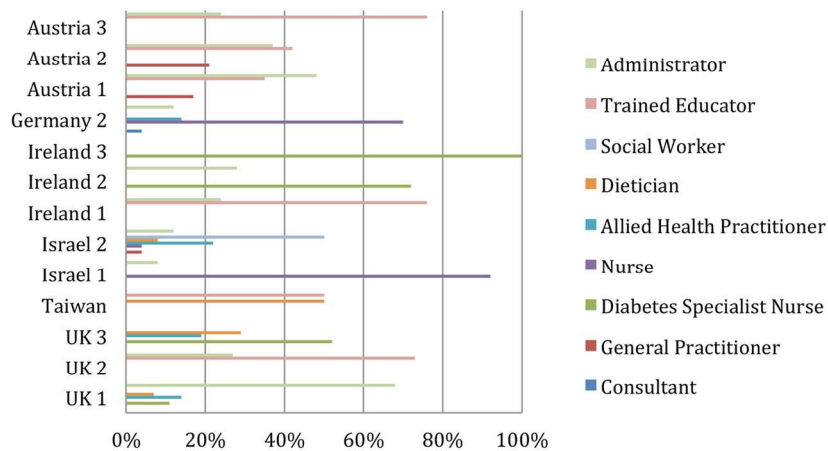
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Cost per programme (salary and overheads) in Int\$

Cost per Programme (Salary and Overheads) in International \$
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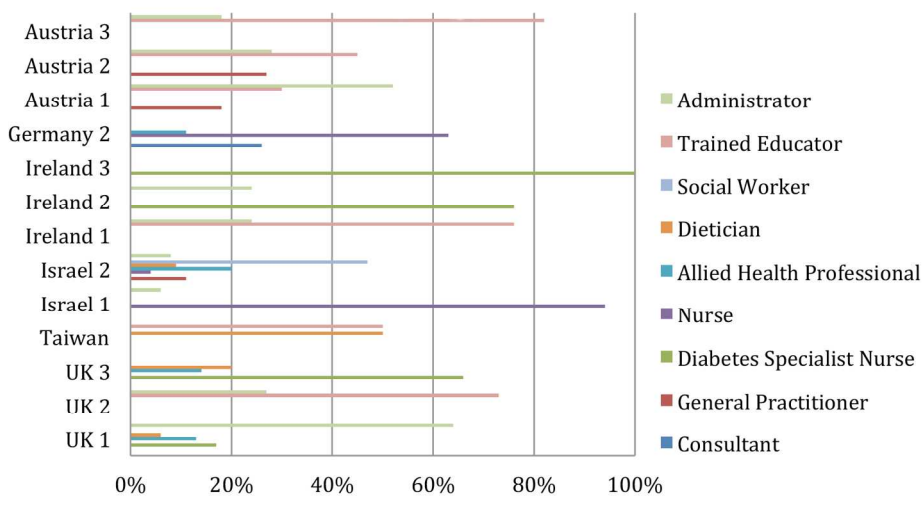
Percentage of total personnel time used per site

Percentage of Total Personnel Time Used per Site
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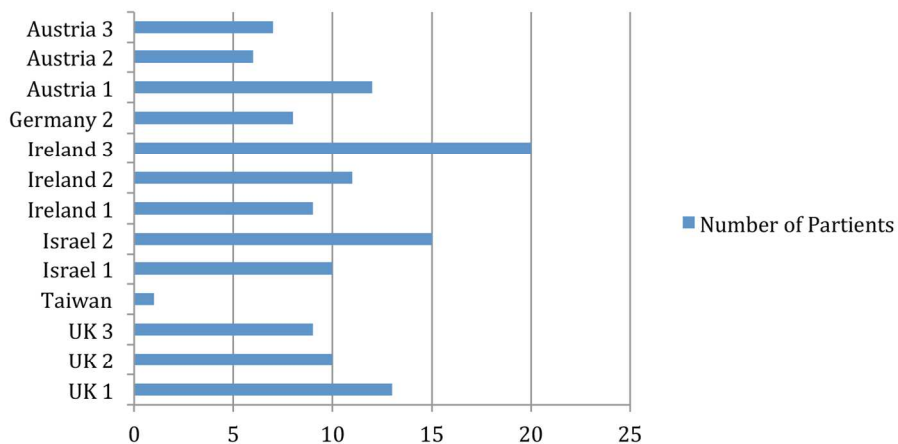
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Weighted Average Capacity Cost Rate Per Site
(weights representing the percentage of total time used of each personnel type)

Weighted Average Capacity Cost Rate Per Site
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Number of Participants per Programme

Number of Participants Per Programme
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Programme	Total Cost	Price Variance from Median	Practitioner Hours	Prac Hrs Variance from Median	Weighted Average CCR	Weighted Average CCR Variance from Median	No. of Patients	No. of Patients Variance from Median
Ire 2	4664	3,898	78	55	3,825	3,022	11	-1
Ire 3	3193	2,427	61	38	2,515	1,712	20	8
UK 1	1697	931	57	34	1,560	757	13	1
Israel 2	1485	719	25	2	482	-321	15	3
UK 2	1248	482	13	-10	452	-351	10	-2
Ire 1	1099	333	19	-4	879	76	9	-3
Aus 1	766	0	23	0	803	0	12	0
Israel 1	633	-133	15	-8	346	-457	10	-2
Aus 2	633	-133	19	-4	536	-267	6	-6
Germany 2	573	-193	19	-4	417	-386	8	-4
UK 3	567	-199	12	-11	369	-434	9	-3
Aus 3	136	-630	5	-18	148	-655	7	-5
Taiwan	14	-752	5	-18	6	-797	1	-11

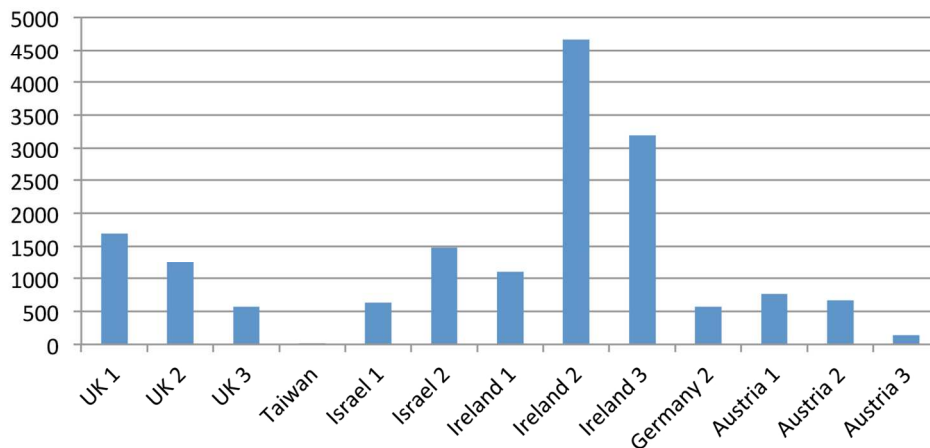
Variance from Median Programme (Austria 1)

Variance from Median Programme (Austria 1)

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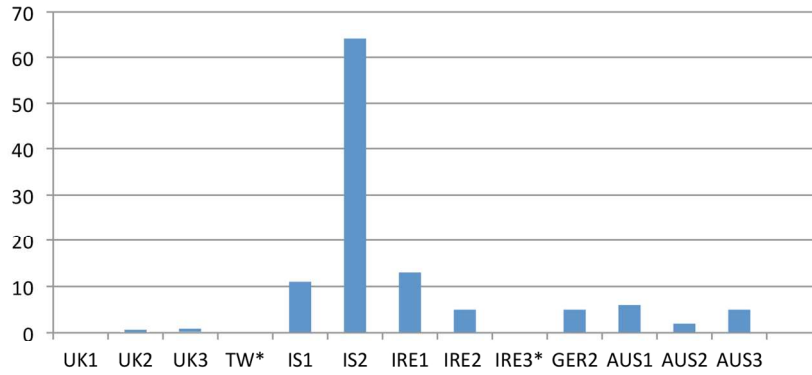
Total Cost per Programme

Total Cost Per Programme
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**Change in Health Outcomes (General Diet)
following participation across different DSME sites**

Change in Health Outcomes (General Diet) Following Participation across DSME Sites
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Data to Support Figures 1-5

Programme	Total Cost per-programme (home currency)	Total Cost per-programme (Int\$)
UK 1	£1201.83	1697.50
UK 2	£883.60	1248.02
UK 3	£402.03	567.83
Taiwan	227.71 NTD	14.01
Israel 1	2532.47 ILS	633.11
Israel 2	5952.05 ILS	1484.52
Ireland 1	€923.38	1099.26
Ireland 2	€3918.31	4664.65
Ireland 3	€2682.40	3193.33
Germany 2	€451.52	573.72
Austria 1	€619.68	766.93
Austria 2	€536.28	663.71
Austria 3	€109.97	136.10

Figure 1 Data: Cost Per Programme (Salary and Overheads)

Cost Driver 1: Percentage of total personnel time used per site

Staff (Hours) Programme	Consultant	GP	DSN	Nurse	AHP	Dietician	Social Worker	Trained Educator	Administrator	Total time (Hours)
UK 1	-	-	6 (11%)	-	8 (14%)	4 (7%)	-	-	39 (68%)	57 (100%)
UK 2	-	-	-	-	-	-	-	15 (73%)	5.5 (27%)	20.5 (100%)
UK 3	-	-	5.5 (52%)	-	2 (19%)	3 (29%)	-	-	-	10.5 (100%)
Taiwan	-	-	-	-	-	2.4 (50%)	-	2.4 (50%)	-	4.8 (100%)
Israel 1	-	-	-	11.5 (92%)	-	-	-	-	1 (8%)	12.5 (100%)
Israel 2	-	.75 (4%)	-	.75 (4%)	4 (22%)	1.5 (8%)	9 (50%)	-	2 (12%)	18 (100%)
Ireland 1	-	-	-	-	-	-	-	14 (76%)	4.5 (24%)	18.5 (100%)
Ireland 2	-	-	56 (72%)	-	-	-	-	-	22 (28%)	78 (100%)
Ireland 3	-	-	60.6 (100%)	-	-	-	-	-	-	60.6 (100%)
Germany 2	.75 (4%)	-	-	13 (70%)	2.5 (14%)	-	-	-	2.25 (12%)	18.5 (100%)
Austria 1	-	4 (17%)	-	-	-	-	-	8 (35%)	11 (48%)	23 (100%)
Austria 2	-	4 (21%)	-	-	-	-	-	8 (42%)	7 (37%)	19 (100%)
Austria 3	-	-	-	-	-	-	-	4 (76%)	1.25 (24%)	5.25 (100%)

Figure 2 Data: Percentage of time for each personnel type per site

Cost Driver 2: Percentage of total salary cost (Int \$) across personnel type and site

Total staff cost per personnel type /prog.	Consultant	GP	DSN	Nurse	AHP	Dietician	Social Worker	Trained Educator	Administrator	Total salary cost (Int \$) per site
UK 1	-	-	264.60 (17%)	-	201.92 (13%)	100.96 (6%)	-	-	992.16 (64%)	1559.64 (100%)
UK 2	-	-	-	-	-	-	-	11.50 (3%)	121.55 (27%)	452.30 (100%)
UK 3	-	-	242.55 (66%)	-	50.48 (14%)	75.72 (20%)	-	-	-	368.75 (100%)
Taiwan	-	-	-	-	-	3.02 (50%)	-	6.02 (100%)	-	6.04 (100%)
Israel 1	-	-	-	325.60 (94%)	-	-	-	-	20.22 (6%)	345.82 (100%)
Israel 2	-	55.36 (11%)	-	21.23 (4%)	94.80 (20%)	42.47 (9%)	227.53 (47%)	-	40.45 (8%)	481.84 (100%)
Ireland 1	-	-	-	-	-	-	-	65.00 (76%)	213.75 (24%)	878.75 (100%)
Ireland 2	-	-	2897.44 (76%)	-	-	-	-	-	927.30 (24%)	3824.74 (100%)
Ireland 3	-	-	2514.90 (100%)	-	-	-	-	-	-	2514.90 (100%)
Germany 2	108.48 (26%)	-	-	264.16 (63%)	44.60 (11%)	-	-	-	-	417.24 (100%)
Austria 1	-	145.04 (18%)	-	-	-	-	-	23.60 (30%)	414.26 (52%)	802.90 (100%)
Austria 2	-	145.04 (27%)	-	-	-	-	-	23.60 (5%)	147.63 (28%)	536.27 (100%)
Austria 3	-	-	-	-	-	-	-	21.80 (82%)	26.36 (18%)	148.16 (100%)

Figure 3 Data: Weighted Average Capacity Cost Rate (Percentage of total salary cost (Int \$) across personnel type and site)

Cost Driver 3: Number of Attendees at Each Programme

Programme	Number of participants
UK 1	13
UK 2	10
UK 3	9
Taiwan	1
Israel 1	10
Israel 2	15
Ireland 1	9
Ireland 2	11
Ireland 3	20
Germany 2	8
Austria 1	12
Austria 2	6
Austria 3	7*

Figure 4 Data: Number of Patients who Attend each Programme Course

*This programme runs for insulin and non-insulin users – insulin typically have 4 patient attendees and non-insulin typically have 9 patient attendees. We took the median number = 6.5 rounded to 7.

Programme	Total Cost	Price Variance from Median	Practitioner Hours	Prac Hrs Variance from Median	Weighted Average CCR	Weighted Average CCR Variance from Median	No. of Patients	No. of Patients Variance from Median
Ire 2	4664	3,898	78	55	3,825	3,022	11	-1
Ire 3	3193	2,427	61	38	2,515	1,712	20	8
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UK 2	1248	482	13	-10	452	-351	10	-2
Ire 1	1099	333	19	-4	879	76	9	-3
Aus 1	766	0	23	0	803	0	12	0
Israel 1	633	-133	15	-8	346	-457	10	-2
Aus 2	633	-133	19	-4	536	-267	6	-6
Germany 2	573	-193	19	-4	417	-386	8	-4
UK 3	567	-199	12	-11	369	-434	9	-3
Aus 3	136	-630	5	-18	148	-655	7	-5
Taiwan	14	-752	5	-18	6	-797	1	-11

Median Programme = Austria 1

Figure 5 Data: Variances from the median programme (Austria 1) – variances in practitioner hours, weighted average capacity cost rate and number of patients

Table 1: Diabetes Self-Management Outcomes Framework

Program form			Outcome I. Individual DSM dispositions	Outcome II. AADE7 Behavior	Outcome III. Disease/Health
1. Program Context	2. Program characteristics	3. Characteristics of program participants (Specifically health literacy)	4. Increase diabetes specific self-efficacy, focus of control	11. Healthy Eating	18. Disease related Outcomes 19. Reduced health risks 20. Health related quality of life 21. Mental comorbidity
			5. Increase diabetes knowledge	12. Being Active	
			6. Change attitudes, beliefs towards diabetes	13. Self-Monitoring	
			7. Raise diabetes awareness	14. Taking Medication	
			8. Increase perceived social support/desirability of DSM behaviors	15. Problem Solving	
			9. Enhance self-reflection on DSM behaviors	16. Reduced Risk Behavior	
			10. Improve DSM skills	17. Healthy coping	

Note:
 The sub-categories of the DSMOF served as a basis for the selection of outcome measures for the study. Items were selected to measure diabetes self-management behaviors, health indicators, health literacy measures and program information as well as socio-demographic information. Thereby all outcome measures are self-reported, i.e. no biomarkers and no HbA1c was measured.

Table 2: Self-Reported Patient Outcomes

	N	Gen Diet	SD	Special Diet	SD	Problem Solving	SD	Reduced Risk Behaviour	SD	Health Coping	SD	Diabetes Health Literacy	SD	Fdhl	SD	CrDhl	SD
UK 1	2	0	0	1.33	.94	0.5	3.54	1.25	0.17	-1	2.83	0.07	0.2	0	0.28	0.25	0
UK2	21	0.02	.73	-0.21	1.75	0.81	2.89	0.11	0.94	1.33	3.23	-0.19	0.37	-0.3	0.48	-0.17	0.59
UK3	27	0.09	1.26	0.32	1.01	1.81	4	0.49	0.84	0.85	3.45	-0.04	0.35	-0.09	0.46	-0.01	0.69
GER2	5	0	1.87	0.07	1.44	2.6	1.5	0.89	1.11	3.14	3.58	0.13	0.11	0.11	0.3	0.26	0.5
IS1	11	0.59	1.11	-0.39	2.33	4.18	5.96	0.41	1.4	3.73	3.93	-0.03	0.27	0.07	0.59	-0.25	0.8
IS2	64	0.38	3	-0.22	2.33	0.58	5.34	0.23	1.75	1.17	4.53	0.07	0.52	0.05	0.91	0.04	0.8
IR1	13	0.73	1.59	-0.74	1.42	5	4.28	0.17	1.71	3	4.08	0.21	0.59	-0.12	0.74	0.35	0.85
IR2	5	-0.2	0.45	-0.07	1.83	4.6	5.98	0.55	1.05	3	2.74	0.2	0.45	0.36	0.26	-0.05	0.59
AUS1	6	0.5	1.1		1.48	1.5	3.62	1.38	0.92	3.5	3.08	0.07	0.25	-0.3	0.37	0.42	0.47
AUS2	2	1.5	1.12	1.83	4.95	-1.5	4.95	3	1.77	0.5	4.95	0.25	0.25	-0.2	0.42	0.5	0.28
AUS3	5	0.3	.72	0.93	3.49	1.2	3.49	0.3	1.2	4.4	3.44	-0.43	0.42	-0.28	0.46	-0.75	0.41

Figure 6 Data: Self-Reported Patient Outcomes (SD=Standard Deviation)

For Figure 6, General Diet was taken as one example of the health outcome data achieved when mapped with cost per programme. To include each health outcome would make Figure 6 too complex and the main finding that health outcomes were similar across all programmes would not be clear to the reader.

Note:

Behavioral outcomes: Behavioral self-management was assessed by selected subscales of the *Summary of Diabetes Self-care Activities* questionnaire (SDSCA). Participants thereby specified how many days in the last week they have followed a general and diabetes specific diet, exercised, checked their blood glucose level, took their prescribed medication and cared for their feet properly. In addition the reversed scores of the *Problem Areas in Diabetes* questionnaire (PAID20) and the *Appraisal of Diabetes Scale* (ADS) were used as indicators to operationalize diabetes specific problem solving and healthy coping respectively.

Covariates: In addition to the behavioral and health outcomes, socio-demographic variables and health literacy were measured as potential covariates likely to influence the effectiveness of DSM interventions. For socio-demographic variables, information on gender, age, years of education, self-perceived social status measured on a ten point scale, and ethnicity measured by own or parental migration experience was collected. Health literacy was assessed using a six item short form of the HLS-EU questionnaire and a diabetes specific health literacy (DHL) scale. The intervention dose in terms of attended sessions was also assessed, but had to be excluded from the analysis, since some respondents had difficulty in providing this information.

Table 3: Overall effectiveness of DSME programs in Aggregate (Number of participants = 366)

Indicator	Baseline	Follow-Up	X ² or t	P	Cohen's d
<i>Behavioral outcomes</i>					
Diet (mean ± SD)	4.49 ± 2.18	4.85 ± 1.92	3.67	< .001	0.187
Diabetes specific diet (mean ± SD)	4.26 ± 1.49	4.34 ± 1.42	0.48	.163	
Exercise ≥ 1 d/wk (%)	78	84	7.22	< .001	
Blood glucose monitoring ≥ 6 d/wk (%)	28	32	3.32	.068	
Taking medication 7 d/wk (%)	88	92	5.30	.021	
Problem areas (mean ± SD)	12.63 ± 5.49	13.76 ± 5.44	5.01	< .001	0.262
Foot care (mean ± SD)	4.18 ± 1.53	4.72 ± 1.53	6.73	< .001	0.362
Appraisal of diabetes (mean ± SD)	24.77 ± 4.56	25.83 ± 4.71	5.14	< .001	0.269
<i>Disease/health outcomes</i>					
BMI (mean ± SD)	30.11 ± 6.60	29.89 ± 6.43	3.45	< .001	0.181
Health related quality of life (mean ± SD)	53.73 ± 19.33	57.90 ± 19.54	4.68	< .001	0.255
Affective well-being (mean ± SD)	59.24 ± 24.82	61.78 ± 23.87	2.21	.014	0.115

Figure 6 Data: Overall effectiveness of DSME programs in Aggregate (Source: Peer et al., 2016)

Note:

Disease/Health outcomes: Three disease and health outcomes were assessed: (1) the BMI was calculated to assess health risks, (2) the general health perception subscale of the *SF36* was used to quantify health related quality of life, and (3) the *WHO-5* was used to operationalize affective well-being as a reverse indicator for mental comorbidity.

CHEERS Checklist**Items to include when reporting economic evaluations of health interventions**

The **ISPOR CHEERS Task Force Report**, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force*, provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* or via the ISPOR Health Economic Evaluation Reporting Standards – CHEERS: Good Reporting Practices webpage: <http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp>

Section/item	Item No	Recommendation	Reported on page No/line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared.	<u>p.4/ 131</u>
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	<u>p.2/ 50-78</u>
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	<u>p.4/ 138-142</u>
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	<u>p.6/ 204-211</u>
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	<u>p.2/ 54-55</u>
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	<u>p.5-6/ 188-201</u>
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	<u>p.6/ 204-211</u>
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	<u>p.6/ 211</u>
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	<u>N/A</u>
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	<u>p.5-6/ 194-201</u>
Measurement of effectiveness	11a	<i>Single study-based estimates:</i> Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	<u>p.6-8/ 213-269</u>



Consolidated Health Economic Evaluation Reporting Standards – CHEERS Checklist 2

			N/A
	11b	<i>Synthesis-based estimates:</i> Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	N/A
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	p.5-6/ 194-201
Estimating resources and costs	13a	<i>Single study-based economic evaluation:</i> Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	p.4-5/ 146-201
	13b	<i>Model-based economic evaluation:</i> Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	N/A
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	p.7/ 243-206
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	N/A
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	N/A
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	p.6-8/ 214-269
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	N/A
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	p 8-13/ 272-348
Characterising uncertainty	20a	<i>Single study-based economic evaluation:</i> Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact	N/A



Consolidated Health Economic Evaluation Reporting Standards – CHEERS Checklist 3

		of methodological assumptions (such as discount rate, study perspective).	N/A
	20b	<i>Model-based economic evaluation</i> : Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	N/A
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	<u>p.8-13/ 272-348</u>
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	<u>p.13-17/ 350-495</u>
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	<u>p.17/ 498-501</u>
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	<u>p.18/ 530</u>

For consistency, the CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

The **ISPOR CHEERS Task Force Report** provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* link or ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: <http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp>

The citation for the CHEERS Task Force Report is:
 Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS)—Explanation and elaboration: A report of the ISPOR health economic evaluations publication guidelines good reporting practices task force. *Value Health* 2013;16:231-50.

