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PROM validation using paper-based or online surveys: Data collection methods affect the sociodemographic and health profile of the sample

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Running head: Data collection methods affect PROM validation sample

Concise summary: Sociodemographic and health profile of samples of people with diabetes differed depending on whether they were recruited to and completed an online or postal survey.

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Abstract

Objective: This study examines the impact of data collection method on the sociodemographic and health profile of samples of people with diabetes who complete either an online or postal patient-reported outcome measure (PROM) validation survey.

Methods: A longitudinal survey of people with diabetes was conducted using online and postal survey versions. The survey consisted of socio-demographic and health questions, a health and self-management PROM (HASMID) and EQ-5D-5L. DAFNE Online, Diabetes UK and social media were used to recruit online survey participants. A panel of patients at a local National Health Service Trust were randomly allocated to participate in either survey version (two-thirds to postal version). Participants were asked to complete the survey again approximately 3 months later.

Results: A total of 2784 participants completed the survey (1908 online, 876 postal). The samples (online versus postal) differed, where the online sample was younger, with a larger proportion of females and respondents with Type 1 diabetes. There were significant differences in sociodemographic characteristics by type of diabetes across data collection mode. The proportion of respondents who responded again at time-point 2 was higher in the postal sample (525 postal, 698 online).

Conclusion: The sociodemographic and health profile of samples of people with diabetes differed depending on whether they completed the online or postal survey. Differences are likely due to different recruitment methods and differences in those choosing to respond to different survey versions. Future PROM validation surveys should select data collection methods carefully as these can impact on sample characteristics and results.

1.0 Introduction

Patient-reported outcome measures (PROMs) are commonly used to capture the impact of conditions and treatments for patients, measuring a wide range of impact including quality of life and health, and encompassing both treatment benefits and side effects. There are increasing pressures around ensuring that the PROMs that are used capture what is relevant to patients, and that their development is methodologically rigorous and includes patient involvement [1-6]. PROMs are increasingly tested before more widespread use to determine their psychometric performance, and to better understand how they perform relative to other PROMs, in order for policy makers to understand evidence that is presented using these measures (a recent example is [7]). This means that PROM development needs to be methodologically rigorous, not too costly and timely to enable use in important clinical studies.

Online data collection has been gaining popularity and is often used as an alternative method to conventional paper-based surveys for obtaining complete data quickly with no need for data inputting. The digital age means that data can be collected in real time, using apps on mobile phones that people can access in any place at any time with little restrictions, with no need for a computer, and wifi-enabled devices mean that having an own internet connection is not even necessary.

Online data collection also enables survey participants to be recruited using a variety of different means, as any person who views a link to a website or app can use this to respond immediately with all data recorded at the point of response. The huge popularity of social media including Facebook and Twitter makes these an attractive option for recruiting survey participants, and email distribution lists from a wide range of organisations and existing market research and patient panels can be used to quickly target respondents with pre-specified health or socio-demographic characteristics. However, the people who choose to respond may differ to respondents choosing to respond using more conventional recruitment strategies, such as through letters from their healthcare provider or telephone interviews.

The increasing availability and practicality of online data collection and the different potential recruitment strategies it provides make this an attractive option. However, it is important to understand how these recruitment strategies and mode of administration may impact on survey results, as otherwise this can lead to policy decisions being influenced by the technique used to generate evidence, meaning that

decisions may not be optimal.

Comparisons of sample profiles across surveys of self-reported health administered using different modes of administrations has been examined in the literature. For example, one study found in a randomized trial that online questionnaires needed to be supplemented with postal reminders to ensure uptake, but the sample profiles did not differ in their socio-demographic characteristics for the online and postal samples [8]. In contrast, another study [9] found in a randomised trial that allocated identified participants to either a postal or online survey both with follow-ups and found that mode and type of follow-up impacted on both response rates and on the sociodemographic characteristics of those who responded. One study examined the impact on sample characteristics when recruiting participants via social media [10], and though this was their only sample their survey participants were not representative of the target population. There are meta-analyses examining measurement equivalence of administering a PROM either online or via post, yet these examine the impact of responses to PROM questions rather than any differences in the sociodemographic characteristics of the populations recruited to answer surveys using different modes of administration (for example, [11]).

This paper examines the impact of data collection method on the sociodemographic and health profile of samples of people with diabetes who completed either an online or postal survey used to validate a recently developed PROM in diabetes. This paper contributes to the literature as it examines the impact of mode of administration combined with possible recruitment strategies that take advantage of what is possible for each mode.

2.0 Methods

A survey was conducted to enable assessment of the psychometric properties of a newly developed patient-reported outcome measure (PROM) in diabetes and its performance relative to EQ-5D-5L. Both online and paper survey versions were selected to ensure the PROM is appropriate in both modes of administration.

Measures of health and quality of life

The survey included the Health and Self-Management in Diabetes (HASMID) PROM and EQ-5D-5L. HASMID measures the impact of self-management on quality of life in diabetes (see appendix 1). HASMID has four health-related quality of life (HRQoL) dimensions (mood, hypoglycaemic attacks, vitality, social limitations) and four self-management dimensions (control, hassle, stress, support) [12]. The measure has been valued using discrete choice experiments that enable the measure to be used to generate Quality Adjusted Life Years (QALYs) (a measure that can be used to reflect changes in morbidity and mortality) for use in cost-utility analyses, or willingness-to-pay values to use in cost-benefit analyses [13-14]. Although no formal test of measurement equivalence has been undertaken for the paper-based and online versions of HASMID, the instructions, question ordering, formatting of response options and wording were identical in both versions, meaning that we expected measurement equivalence between the different versions (see, for example, [15]). EQ-5D-5L is the most common generic preference-based measure, with 5 dimensions covering mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each with 5 severity levels [16]. The English weights were used to generate EQ-5D-5L utility values [17].

Online sample recruitment

Respondents were recruited using multiple recruitment strategies:

- All DAFNE Online patients had access to an online link via the DAFNE Online website that provided direct access to the online survey. DAFNE Online (see http://www.dafneonline.co.uk/) is a website designed specifically for people with Type 1 diabetes mellitus (T1DM) who have undertaken a DAFNE structured education (over 40,000 people), but the website is also accessible to anyone wishing to find out more about T1DM.
- Diabetes UK members received an electronic link in their online newsletter and a printed link on their printed newsletter to the online survey. Diabetes UK (see http://diabetes.org.uk/) is the main charity for all patients with diabetes in the UK. No reminders were sent.
- Patients from a National Health Service (NHS) Trust received a letter and information sheet through the post introducing the survey with a link to the online version. These patients were recruited from a panel of over 2,300 patients at Sheffield Teaching Hospitals NHS Trust who have agreed in principle to be contacted for the purposes of participating in research. Respondents were randomised to either the postal (described below) or online version in a

1:2 online:postal ratio, as the online survey had multiple recruitment strategies whereas the postal survey only recruited via the NHS Trust. No reminders were sent.

- Participants were recruited by social media, through Twitter from a project-specific account and emailed to a University of Sheffield mailing list of staff and students who have stated they are willing to participate in research surveys (the proportion of people with diabetes is unknown), and via National Institute for Health Research (NIHR).

Online respondents were not offered the opportunity to complete the questionnaire using the postal version. However, a small number of respondents who were sent an online survey from the NHS Trust contacted the Trust to request a postal version, and were then sent a postal version.

Postal sample recruitment

All respondents were recruited via the panel of patients at Sheffield Teaching Hospitals NHS Trust, where respondents were randomised to receive either the postal version or online version where two-thirds of respondents were allocated to receive the postal version (described above). Respondents allocated to the postal version received the survey through the post, with a cover letter and information sheet. Participants were asked to complete the questionnaire and return it to the research team in a pre-paid envelope. No reminders were sent. Respondents were not offered the opportunity to complete the questionnaire online.

The survey

Respondents were first asked to complete sociodemographic questions, their type of diabetesHASMID and EQ-5D-5L questionnaires, general health and general self-management,and further questions about their diabetes. All questions were compulsory in the online survey version. All respondents were offered optional entry into a prize draw for £50 shopping vouchers per 50 respondents.

Analysis

In order to examine the impact of data collection method on the sociodemographic and health profile of the sample, we separated the overall sample by mode of administration (online/postal), time point

(1=baseline/2=follow-up) and type of diabetes (T1DM/T2DM). This generated 8 subsamples: time point 1 online T1DM; time point 1 online T2DM; time point 1 postal T1DM; time point 1 postal T2DM; time point 2 online T1DM; time point 2 online T2DM; time point 2 postal T1DM; time point 2 postal T2DM. This enables an assessment of whether the sample differs by data collection method, whether the data collection method impacted on the sample profile within T1DM and T2DM diabetes (since a change in proportion of respondents with T1DM or T2DM can impact on the sample profile) and whether the data collection method impacted on the sample profile at timepoint 2. Socio-demographic and health characteristics of the 8 subsamples are compared using chi-square and t tests.

3.0 Results

3.1 The sample

Recruitment to the study was successful, with a total of 2784 participants completing the survey in time point 1, with 1908 online respondents and 876 postal respondents in time point 1. Table 1 presents and compares the profiles of the 8 subsamples. The online survey has a significantly higher percentage of female respondents at both time points, and significantly lower mean age at both time points. The online survey has a significantly higher proportion of respondents with T1DM in the online survey for both time points, and significantly higher mean duration of diabetes (though this is likely due to the larger proportion of respondents with T1DM).

The T1DM samples have younger mean age and longer duration of diabetes in comparison to the T2DM samples, which is to be expected given the earlier onset of T1DM in comparison to T2DM. However, there are also differences in the T1DM samples by mode of administration and by time point, and also differences in the T2DM samples by mode of administration and time point. For the T1DM samples, the online samples have a significantly larger proportion of females, significantly lower mean age, and are significantly more likely to be single and less likely to be retired and to own their own home. For the T2DM samples, the online samples have a significantly larger proportion of females, significantly lower mean age, significantly lower mean duration of diabetes, and are significantly more likely to be single, more likely to be employed, less likely to be retired and more likely to rent. EQ-5D-5L scores are not significantly different for the T1DM and T2DM samples by

mode of administration (with the exception of the T2DM sample in timepoint 1), whereas HASMID scores differ for the T1DM and T2DM by mode of administration.

4.0 Discussion

This paper describes the impact of data collection method on the sociodemographic and health profile of samples of people with diabetes who complete either an online or postal survey used to validate a recently developed PROM in diabetes. The results show that the sociodemographic and health profile differs for the online and postal versions by age, gender, duration of diabetes, type of diabetes (36.4% T1DM online cf. 9.8% T1DM postal), and the proportion of respondents completing the follow-up survey again at time-point 2. Significant differences are also apparent when the samples are separated into respondents with T1DM and T2DM. These differences will inevitably impact on any analyses undertaken on these samples. This has important implications for researchers undertaking data collection, in particular these results are informative for those undertaking PROM assessment and validation in diabetes. The larger proportion of people with T1DM using the online version and recruitment strategies suggests that these are good options for recruiting people with T1DM in particular, since the incidence on T1DM in the UK population is around 5-10% meaning these are over-represented in the online data [18].

Researchers and funders are increasingly under pressure to produce high quality reproducible findings, whilst minimising research study costs and timings. One possibility is to consider online collection of data over other modes of administration such as postal surveys. In this study we found advantages and disadvantages to both the postal and online surveys and the different recruitment strategies this enabled. These are summarised in Figure 1, alongside the impact on sample characteristics.

Postal responses required data entry, more stringent data cleaning (both of which are time consuming and labour intensive), and have the complication of missing data.

In contrast, in the online survey missing data was not an issue as respondents were not able to proceed to the next question until they had provided a response. However, this may have meant that respondents who did not wish to answer a particular question exited the survey or provided an

inaccurate response. The online survey enabled fast data collection from a wide geographical area which was not possible using our selected recruitment strategy for the postal survey. Whilst the initial start-up costs of testing and hosting the online survey were expensive, only limited data monitoring and cleaning was required.

One disadvantage of the recruitment strategy used is that it is not possible to generate a response rate for the online data, since we do not know how many potential participants were contacted. In addition, one study limitation is that we did not offer respondents recruited to either the online or postal versions the opportunity to complete the other version, and hence we cannot infer that patients who completed either version preferred using that mode of administration. Another potential study limitation is that the number of people with T1DM requested to complete the postal survey is small, since this relied on recruitment via one NHS Trust.

The use of existing online panels and forums can be criticised for not being representative of the diabetes population. Members of online charities and forums may differ from the general population in that they exclude the computer illiterate and those without access to the internet, whereas the postal survey was inclusive regardless of computer literacy or internet access. The use of social media brings the possibility that respondents may not have had diabetes or who may be non-UK citizens, whereas for the postal survey potential participants were recruited via an NHS Trust meaning their citizenship and diabetes diagnosis is confirmed.

The study has highlighted the advantages of using a combination of data collection methods to generate PROM validation data. However differences between samplescan lead to a more complex interpretation of the results where different results are found in different samples and/or different time points. This also complicates the generation of norms for PROMs, since the selection of which sample should be used – or whether to merge all samples - impacts on the results.

This paper contributes to the methodological literature on the impact of mode of administration on measuring health, in particular in relation to PROM validation in people with diabetes. The study found that the sociodemographic and health profile of samples of people with diabetes differed depending

on whether they completed the online or postal survey. These observed differences are likely due to both different recruitment methods and differences in those choosing to respond to different survey versions. It is recommended that future PROM validation surveys should select data collection methods carefully, and where possible use a combination of both online and postal survey versions.

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Figure 1 Impacts on data collected in this study from mode of administration

Online survey	**Postal survey**
Comparative advantages • Quicker response time • Complete data collection • No data entry • Wide geographic reach	**Comparative advantages** • Includes computer illiterate and those without internet access or who do not regularly go online • Cost-effective set up • Known response rate • All respondents guaranteed to have diabetes • Ability to check acceptability of individual items
Comparative disadvantages • Excludes computer illiterate and those without internet access or who do not regularly go online • Expensive set up • Response rate cannot be generated • Cannot guarantee all respondents have diabetes • Cannot examine acceptability of individual items using missing data	**Comparative disadvantages** • Time delay for response • Incomplete data collection • Data entry required • Geographic reach limited to one Trust
Sample implications • Higher response rate from people with type 1 diabetes • Higher proportion of younger participants	**Sample implications** • Proportion of people with T1DM/T2DM representative of national proportion • Higher proportion of older participants
• Significant differences in sociodemographic characteristics in total and by T1DM and T2DM	

Table 1 Sample, by type of diabetes, data collection mode of administration and time point

	Time point 1 (%)				Time point 2 (%)				Time point 1		Time point 2	
	Online		Postal		Online		Postal		P value for MOA		P value for MOA	
	T1DM (n=708)	T2DM (n=1200)	T1DM (n=87)	T2DM (n=789)	T1DM (n=202)	T2DM (n=323)	T1DM (n=62)	T2DM (n=636)	T1DM	T2DM	T1DM	T2DM
Gender									<0.001	<0.001	0.051	<0.001
Male	29.0	43.1	52.9	64.1	34.2	45.5	48.4	65.9				
Female	71.0	56.7	47.1	35.7	65.8	54.2	51.6	34.1				
Transgender	0.0	0.2	0	0.1	0	0.3	0	0				
Age												
18-44 years	56.6	9.7	19.5	3.0	45.5	5.9	11.3	2.4				
45-64 years	36.3	61.8	48.3	28.6	45.1	58.8	50.0	24.5				
65-74 years	5.2	23.2	16.1	38.0	7.4	28.8	21.0	39.6				
75-84 years	1.3	3.5	9.2	18.1	1.0	5.3	8.1	20.0				
85+ years	0.1	0.8	3.5	4.3	0	0.6	3.2	4.6				
Mean (SD)	41.1 (15.3)	58.2 (10.7)	55.7 (16.0)	67.8 (10.5)	44.4 (14.8)	60.3 (10.3)	59.4 (13.7)	68.8 (10.5)	<0.001[a]	<0.001[a]	<0.001[a]	<0.001[a]
Duration of DM												
< 5 years	14.7	36.3	13.8	28.7	14.4	33.1	13.1	22.4				
5-9 years	11.9	25.7	12.6	25.9	5.0	25.4	9.8	27.2				
10-19 years	28.0	29.6	26.4	34.8	26.7	30.7	23.0	38.7				

	Time point 1 (%)				Time point 2 (%)				Time point 1		Time point 2	
	Online		Postal		Online		Postal		P value for MOA		P value for MOA	
	T1DM (n=708)	T2DM (n=1200)	T1DM (n=87)	T2DM (n=789)	T1DM (n=202)	T2DM (n=323)	T1DM (n=62)	T2DM (n=636)	T1DM	T2DM	T1DM	T2DM
20-29 years	19.9	7.4	17.2	9.0	18.8	9.6	14.8	9.7				
30+ years	25.6	1.1	29.9	1.7	35.2	1.2	39.3	2.1				
Mean (SD)	19.7 (13.7)	8.4 (6.8)	22.3 (18.0)	9.4 (6.7)	22.9 (14.8)	9.1 (6.8)	26.0 (19.4)	10.2 (7.1)	0.111[a]	<0.001[a]	0.192[a]	0.026[a]
Marital status									0.001	<0.001	0.008	<0.001
Single	27.4	11.2	19.5	8.6	23.3	10.5	14.5	8.0				
Married/partner	63.7	71.6	66.7	70.2	69.3	70.3	71.0	70.0				
Separated/divorced	5.7	11.2	3.5	8.8	5.5	12.4	3.2	8.5				
Widowed	1.6	5.2	10.3	12.4	1.5	5.9	11.3	13.5				
Other	1.7	0.9	0	0	0.5	0.9	0	0				
Education												
Education continued after minimum school leaving age	75.6	59.4	73.6	57.2	84.2	70.9	72.6	57.1	0.693	0.003	0.038	<0.001
Degree or equivalent professional qualification	49.6	36.8	50.6	36.6	55.9	47.1	51.6	36.8	0.910	<0.001	0.563	0.003
Main activity												
Employment/self-employment	63.8	41.8	51.7	20.7	61.9	40.6	48.4	18.1	0.034	<0.001	0.076	<0.001

	Time point 1 (%)				Time point 2 (%)				Time point 1		Time point 2	
	Online		Postal		Online		Postal		P value for MOA		P value for MOA	
	T1DM (n=708)	T2DM (n=1200)	T1DM (n=87)	T2DM (n=789)	T1DM (n=202)	T2DM (n=323)	T1DM (n=62)	T2DM (n=636)	T1DM	T2DM	T1DM	T2DM
Retired	9.6	36.2	29.9	66.9	15.4	43.3	40.3	72.8	<0.001	<0.001	<0.001	<0.001
Housework	4.2	5.1	1.2	2.2	4.0	2.8	1.6	1.9				
Student	8.8	1.2	2.3	0.6	9.4	1.2	0	0.5				
Unemployed/seeking work	3.1	2.6	1.2	7.1	2.5	1.2	0	4.7				
Long-term sick	8.5	11.6	9.2	1.7	6.4	9.9	4.8	1.1				
Other	2.0	1.6	4.6	20.7	0.5	0.9	4.8	18.1				
Home ownership/rental status									<0.001	<0.001	0.006	<0.001
Own home outright/with mortgage	54.1	63.0	78.2	77.7	66.8	70.6	82.3	79.7				
Rent from local authority	18.2	21.6	11.5	16.4	8.4	15.5	8.1	13.2				
Rent from private sector	27.7	15.4	6.9	5.1	24.8	13.9	8.1	5.8				
HASMID score (SD)	0.562 (0.190)	0.648 (0.188)	0.674 (0.184)	0.775 (0.166)	0.585 (0.188)	0.685 (0.177)	0.719 (0.156)	0.784 (0.162)	<0.001	<0.001	<0.001	<0.001
EQ-5D-5L score (SD)	0.791 (0.227)	0.743 (0.266)	0.804 (0.239)	0.789 (0.242)	0.819 (0.197)	0.784 (0.241)	0.831 (0.210)	0.789 (0.240)	0.609	<0.001	0.689	0.766

Notes:

Chi-square p-values generated using Fischer's exact test that allows for sample size. [a] A t-test has been used to test statistical significance.

Appendix 1: Health and self-management in diabetes (HASMID) classification system

Dimension	**Level**	Wording
Mood	**1**	You never find yourself losing your temper over small things
	2	You sometimes find yourself losing your temper over small things
	3	You usually find yourself losing your temper over small things
	4	You always find yourself losing your temper over small things
Hypoglycaemic attacks	**1**	You never worry about going hypo
	2	You sometimes worry about going hypo
	3	You usually worry about going hypo
	4	You always worry about going hypo
Vitality	**1**	You are never tired
	2	You are sometimes tired
	3	You are usually tired
	4	You are always tired
Social Limitations	**1**	Your days are never tied to meal times
	2	Your days are sometimes tied to meal times
	3	Your days are usually tied to meal times
	4	Your days are always tied to meal times
Control	**1**	You feel you have a lot of control of your diabetes
	2	You feel you have some control of your diabetes
	3	You feel you have little control of your diabetes
	4	You feel you have no control of your diabetes
Hassle	**1**	You find your life with diabetes is never a hassle
	2	You find your life with diabetes is sometimes a hassle
	3	You find your life with diabetes is often a hassle
	4	You find your life with diabetes is always a hassle
Stress	**1**	You find your life with diabetes is never stressful
	2	You find your life with diabetes is sometimes stressful
	3	You find your life with diabetes is often stressful
	4	You find your life with diabetes is always stressful
Support (All support you have; from family, friends and health care professionals)	**1**	You feel totally supported with your diabetes
	2	You feel you have a lot of support with your diabetes
	3	You feel you have a little support with your diabetes
	4	You feel you have no support with your diabetes