Evaluation and assessment of the usefulness of a mail delivered personalised diabetes information booklet and the association of non-response with clinical risk: the WICKED Project

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Abstract

Introduction: **Patient activation can promote partnership working between people with diabetes and their healthcare professionals. We sent to people with diabetes a personalised, structured information booklet containing the results of their latest nine key care processes in order to inform and activate them. We present the findings of a survey to assess the utility of this report, with an analysis of the association of non-response to the survey, a surrogate for poorer patient activation, with adverse diabetes and clinical outcomes.**

Methods: **All 14,559 people with diabetes in the Wolverhampton health economy received a mailed report of the results of their latest nine diabetes care processes. Of these, 6,282 patients aged <75 years were mailed this report twice; 1000 of these 6,282 patients were selected randomly to receive a structured questionnaire to assess the report's effectiveness.**

Results: **Of 1,000 patients, 419 (42%) responded (mean age 62±10 years, 246 males, 249 Caucasians, 389 had type 2 diabetes). Patients found this report useful (89%), a source of knowledge (78%), a source of increased confidence (74%) and it helped them understand their diabetes (78%). Non-response was associated with significantly higher surrogate markers of micro- and macrovascular risk.**

Conclusion: **A structured and personalised diabetes report, without direct professional or health service intervention, may improve the understanding and confidence of people with diabetes in their self-care and it may help to activate them to take a stronger partnership role in their health care.**

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Non-response as a marker of patient activation is associated with increased clinical risk.

Introduction

The increasing burden of long-term conditions such as diabetes[1] has increased emphasis on improved self-management.[2,3] Care planning is a high priority in modern healthcare, but achieving an equal partnership between healthcare professionals and people with diabetes needs a clear understanding of the nature of the transaction and certainly not the imposition of a plan by the healthcare professional.[4-7] An effective partnership requires enablement, empowerment and engagement of the person with diabetes within a transactional model based on concordance, rather than compliance.[8]

The concept of patient activation encompasses engagement, empowerment and enablement,[9] but seeks to extend this to the measure of specific outcomes, indicating that the person with diabetes has become demonstrably active in their own healthcare. Patient activation may be considered as an outcome of diabetes care provision in its own right,[10] as people who are engaged and actively involved in the management of a long-term condition have better outcomes.[11] Such empowerment is conventionally sought via diabetes education aimed at improving knowledge, awareness and expertise in self-care, facilitating engagement in the proposed dialogue. Unfortunately, the provision of structured education for people with diabetes in the UK is suboptimal with uncertain outcomes,[12,13] and outcomes from current care planning processes are also little understood.[14] Other client-focused interventions promoting health literacy, self-care, access, care experience, service development and, not least, decision making have been found to be effective,[15] including pre-consultation information,[16-18] goal setting[19] and organisational measures.[20,21] The provision of written, individualised information is known to have a positive effect in diabetes consultations.[22] A person with diabetes

provided with good information can enhance their own knowledge,[23] perhaps enhancing further their need to know and act.

Written information is valued,[24] but it remains unclear if such information *per se* can activate people with diabetes (in the sense that we have defined). Accordingly, we have recently demonstrated the perceived benefit to patients and doctors alike of a structured information booklet in the setting of specialist clinic consultations and care planning in our local model of diabetes care, Wolverhampton Interface Care, Knowledge Empowered Diabetes (WICKED).[25] We also demonstrated in a large randomised controlled trial (RCT) that this booklet was associated with a significant increase in patient activation.[26]

We have surveyed the impact of a booklet providing up-to-date information on the results of nine care processes among people with diabetes. Responding to the survey may be a potential marker of patient activation, and we have also analysed the associations between failing to respond and adverse diabetes and cardiovascular outcomes. We believe this to be the first report of the perspective of people with diabetes regarding such information delivered across a whole health economy, independently of the influence of healthcare professional input. It is also, we believe, the first report of the association of adverse diabetes outcomes in relationship to a potential marker of patient activation independent of selection bias relating to surveys in patients who attend care.

Methods

A structured diabetes report, 'My Diabetes, My Information, My Plan', containing individualised information about nine key care processes in diabetes was designed by a three-phase development process, as described previously.[25] It contained person-specific information on the nine key diabetes processes that inform UK National Health Service (NHS) diabetes healthcare delivery: HbA_{1c}, body mass index (BMI), blood pressure, urinary albumin:creatinine ratio (ACR), serum creatinine, serum cholesterol, recorded smoking status, digital retinal photography and foot examination. The booklet is available to view online at www.wdconline.org.uk. Each process was scored as 1 if missing and 0 if completed within a 15-month period. Each individual thus had a summary score calculated to assess the accrued process failure, the Failed Process Score (FPS), with range 0–9.

The FPS is used as a direct measure of patient activation, with outcome data from the process measures recorded for the 15-month time frame. Primary coronary heart disease (CHD) risk was calculated using the Framingham method where complete data were available. Secondary macrovascular risk status was defined as the presence of cardiovascular, cerebrovascular or peripheral vascular disease. Data were accrued into the local diabetes information system via data linkage with multiple other systems including the primary care data warehouse. The rolling processes of data quality management have already been published, showing a very high level of data accuracy (>95%).[27]

The study follows on from our previously reported RCT involving 14,559 people with diabetes.[26] The structured report containing individualised information was initially sent to 8,725

people with diabetes in Wolverhampton in the active limb of a RCT which has reported positive 3-month outcomes.[26] The mailing was subsequently repeated after 3 months and, at this stage, included all people with diabetes in Wolverhampton. We selected all patients aged <75 years who had received the booklet twice (n=6,282) followed by a further random selection of 1,000 patients (by Excel 2011 random number generation), and sent them a questionnaire to evaluate the booklet. Initial non-responders received a reminder after 2 weeks and the receipt of returns was closed at 4 weeks. It is the response to this questionnaire that is used as a potential second measure of patient activation.

Data were analysed (SPSS Version 22) using the Student's t-test (means) or the chi-squared test (proportions) with statistical significance taken at p<0.05. Primary 10-year CHD risk was reanalysed in univariate regression analysis after log conversion (non-normal distribution) in order to adjust for age differences between groups.

Results

Subjects

There were no significant differences for any demographic or other characteristic (Table 1) between those who were surveyed (n=1,000) and those who were not (n=5,282).

Of the 1,000 people surveyed, 419 responded. Non-respon-

Table 1 Demographic and clinical parameters of those randomly selected to be surveyed (with p values comparing responders vs. non-responders) and those not surveyed

	Not surveyed (n=5,282)	Surveyed		
		Responders (n=419)	Non-responders (n=581)	p
Age (years)	58.5±10	62±10	56±12	<0.001
Males	3,012 (57)	246 (59)	318 (55)	NS
Ethnicity				<0.001
Caucasian	2,868 (54)	249 (59)	293 (50)	
Asian	1,329 (25)	76 (18)	175 (30)	
African-Caribbean	254 (5)	18 (4)	20 (3)	
Mixed	58 (1)	4 (1)	9 (2)	
Other/unknown	773 (15)	72 (17)	84 (15%)	
IMD score	35.5±15.7	34.4±15.8	36.3±15.3	NS (0.054)
Type 2 diabetes	4,881 (92)	389 (93)	537 (92)	NS
Duration of diabetes (years)	9.7±7.9	9.8±8.2	9.4±7.6	NS

Data shown are mean±SD or number (%).
NS, not statistically significant (p≥0.05); IMD, Index of Multiple deprivation.

Table 2 Responses to a questionnaire relating to an individualised diabetes information booklet categorised in a 4-point scale as: 'Yes definitely'; 'Yes, to some extent'; 'No, not really'; and 'No, definitely not'

Questions	Number answering each question	Answered 'Yes, definitely' or 'Yes, to some extent', n (%)
Did you understand the purpose of this document and what it is meant to be used for?	397	355 (85)
Were the contents of the report easy to read and understand and do they make sense to you?	404	354 (85)
Was the information useful?	414	368 (88)
Did this information give you more knowledge about your diabetes?	410	321 (77)
Did this information help you to understand your diabetes better?	406	302 (72)
Would this information help you to improve your diabetes?	408	317 (76)
Would this information help you make changes in your diabetes?	406	316 (76)
Would this information help you feel more in charge or control of your diabetes?	412	316 (76)
Would you take this information with you to your next diabetes appointment with a doctor or a nurse?	402	312 (74)
Did you think this information will help in your next visit of diabetes review with a doctor or a nurse?	408	325 (78)
Would you like to receive information like this in the future?	409	328 (78)
How often would you like to have this report with this sort of information about your diabetes?	406	358 (85)*
Overall, do you think it is a good idea for people with diabetes to have this sort of report?	413	377 (90)
Overall, do you think people with diabetes will use this information to take better care of them?	414	365 (87)

*Responses for once/twice each year.

ders were younger and less likely to be of non-white Caucasian background compared with responders, but there were no significant differences between these groups for gender, index of deprivation or type or duration of diabetes.

Survey evaluation of 'My Diabetes, My Information, My Plan'

The results of the evaluation of 'My Diabetes, My Information, My Plan' from the 419 respondents are presented in Table 2. A positive response was expressed for every question: 72–85% of respondents answered 'Yes definitely' or 'Yes to some extent' to every question relating to whether the report would improve their own diabetes care, and 87–90% gave one of these answers to questions relating to the utility of the report for anyone with diabetes. A frequency of once or twice/year for the report was supported by 85%.

Patient activation and outcomes

The FPS was significantly worse in non-responders than in responders, as was process attainment in every single one of the nine subsidiary processes (Table 3). Among those where outcomes were ascertainable and who had process measures within the 15-month time frame (Table 4), non-responders had a higher HbA_{1c}, BMI, serum cholesterol and were more likely to be smokers (there was no significant difference in mean systolic BP). Significantly more non-responders had HbA_{1c} >9% (74 mmol/mol) and serum cholesterol >6 mmol/L, while there was a trend towards a higher proportion with systolic BP >160 mmHg. The

10-year primary CHD risk score was adjusted for differences in age between groups in univariate analysis and was significantly worse in non-responders (Figure 1), independently of age (F=22.2, p<0.001). However, the effect was not statistically different between groups within separate age bands, despite the apparent separation among the middle age bands.

Based on these data, an estimated 27 additional adverse cardiovascular events might be expected to occur over the following 10 years in the non-responder group, based on their CHD risk at the time of the evaluation. There were no significant differences in the crude prevalence of established microvascular disease (eye, foot or renal) or established secondary macrovascular disease.

Discussion

The intervention we described is a simple but systematically constructed and personalised information booklet for people with diabetes. In this article we have sought to evaluate this patient-centric intervention ability to promote patient activation; to extend our understanding of the co-associations of poorer patient activation with adverse demographic and clinical outcome; and to reiterate the feasibility of navigating poorer patient activation and thus potentially influence the recognised associated adverse outcomes.

Our explanation relates to Kilpatrick's four levels of evaluation[27] (KP 1–4), bearing in mind that the meaning of evaluation and assessment are often confused. In this context, evaluation should be taken as what the recipients – our patients – thought of what was done (KP 1) and assessment as being that which the

Table 3 Failed Process Scores and uncompleted individual key diabetes process evaluations

	Not surveyed (n=5,282)	Surveyed		
		Responders (n=419)	Non-responders (n=581)	p
Failed Process Score	1.3±2.0	0.8±1.1	1.7±2.3	<0.001
Uncompleted individual key processes				
HbA$_{1c}$	517 (10)	19 (5)	76 (13)	<0.001
Blood pressure	405 (8)	13 (3)	63 (11)	<0.001
Body mass index	644 (12)	31 (7)	97 (17)	<0.001
Cholesterol	581 (11)	31 (7)	87 (15)	<0.001
Smoking status	846 (16)	47 (11)	112 (19)	<0.001
Retinal screen	832 (16)	33 (8)	120 (20)	<0.001
Albumin: creatinine ratio	969 (18)	53 (13)	159 (27)	<0.001
Serum creatinine	453 (9)	15 (4)	77 (13)	<0.001
Foot examination	1343 (25)	83 (20)	167 (29)	<0.01

Data shown are mean±SD or number (%).

Table 4 Diabetes and clinical outcomes

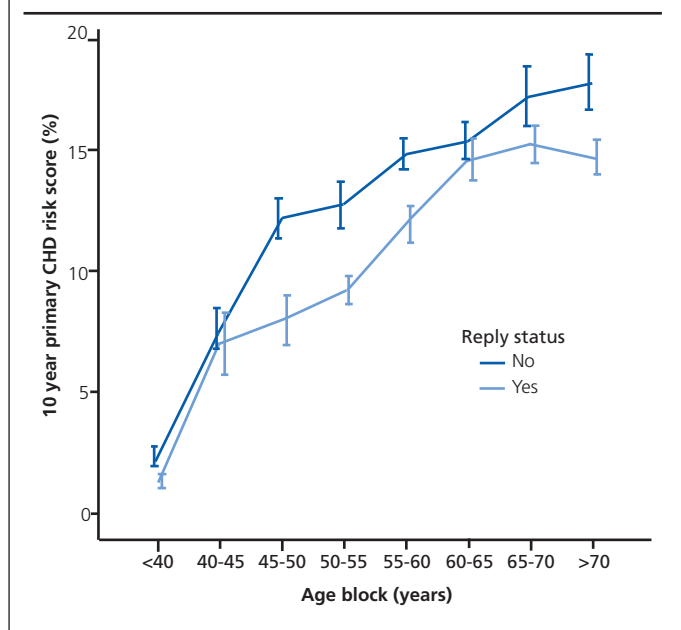|	Not surveyed (n=5,282)	Surveyed		
		Responders (n=419)	Non-responders (n=581)	p
HbA$_{1c}$	7.7±1.7	7.5±1.4	8.0±1.9	<0.001
SBP	133±15	133±14	134±16	NS
Body mass index	31.5±7.2	30.6±6.4	32.0±6.7	<0.01
Cholesterol	4.4±1.1	4.3±1.0	4.6±1.2	<0.001
Vascular risk (secondary)*	1009 (19)	94 (22)	107 (18)	NS
Primary 10-year CHD risk†	13.3±7.2	12.4±6.2	13.3±7.2	NS
Age-adjusted primary 10-year CHD risk (antilog)	10.7±2.1	9.3±1.8	12.0±1.8	<0.001
Current smoker	753 (14)	39 (9)	102 (18)	<0.001
Albumin: creatinine ratio	8.8±33.8	7.5±30.1	11.8±44.4	NS
Serum creatinine	85±41	85±34	84±55	NS
Retinopathy				NS
Vision-threatening	464 (10)	36 (9)	62 (13)	
Background	1384 (31)	115 (30)	137 (30)	
None	2602 (59)	235 (61)	262 (57)	
Foot risk				NS
High	551 (14)	56 (17)	55 (13)	
Intermediate	1113 (28)	85 (25)	110 (27)	
Low	2275 (58)	195 (58)	249 (60)	
HbA$_{1c}$ ≥9%	835 (16)	50 (12)	113 (19)	<0.001
SBP ≥160 mmHg	240 (5)	18 (4)	40 (7)	NS (0.054)
Cholesterol ≥6	280 (5)	12 (3)	39 (7)	<0.01
Any	1182 (22)	75 (18)	168 (29)	<0.001

Data shown are mean±SD or number (%).
* Presence of cardiovascular, cerebrovascular or peripheral vascular disease.
† Assessed in individuals with sufficient data on cardiovascular risk factors for Framingham risk scoring: 661 (not surveyed), 288 (responders), 373 (non-responders).
CHD, coronary heart disease; NS, not statistically significant (p≥0.05); SBP, systolic blood pressure

service measured as an outcome relating to an intended benefit (KP 2–4).

In this sense, KP level 1 was initially considered in a small-scale published pilot evaluation of the information booklet by our patients.[25] Here, a much more rigorous and systematic survey, without any form of selection bias, again indicates clearly that people with diabetes want to have their individualised information in a structured, easily understandable format and that they found it beneficial in a number of domains relating to their diabetes care. We emphasise that KP-1 does not and cannot prove that the booklet was effective in relation to patient activation, and it simply shows that patient evaluation of the booklet was very high; they liked it, hopefully as a result of the considerable effort in design and pilot testing. We acknowledge the limitation of this evaluation, and the response rate to our survey is a potential source of bias. The response rates to health surveys average around 60%[28] when using maximal techniques,[29] with response rates of about 50% typical of surveys with two reminders.[30] There are many confounding factors determining response rates to surveys that are epidemiologically based, but a crucial key factor is the resampling of populations that have participated in previous surveys,[31] which in itself is a perverse bias, as is the sampling of those that are engaged in care (e.g. attenders). We thus emphasise that our survey population was a random sample that did not differ significantly in any regard from the wider cohort, with no selection of any description. This mitigates the potential for bias arising from surreptitious selection, but certainly will be associated with a more realistic non-response rate. Additionally, the findings were exactly in line with the outcomes from our much smaller scale pilot in which the response rate was greater than 60%.[25]

Figure 1. Mean±SEM Framingham 10-year primary CHD risk score (%) in those who did or did not respond to the questionnaire.

Key messages

- People with diabetes like to receive personalised information about their diabetes in a simple, but structured, format
- Such information can promote users to play an active role in partnership with their healthcare professionals
- A poor response may reflect poor patient activation and is associated with increased risk of coronary heart disease

We did not measure KP level 2 by intention, which would have amounted to a knowledge test. Here, our *a priori* interest was not in knowledge acquisition but in action outcomes (i.e. performance). However, we have published the 3-month outcomes of a large RCT equating to KP levels 3 and 4. The intended benefit, a true measurable outcome – in other words, our assessment – was demonstrating that patient activation occurred as the measureable impact of the patient booklet.[26] We will shortly submit the 1-year outcomes which not only show improvements in failed processes but also a significant benefit in HbA$_{1c}$. To our knowledge, this is the first prospective demonstration of the use of an information tool (as an intervention) to improve patient activation in that its use resulted in a significant improvement in the completion of diabetes processes as shown by a reduced FPS.[26,32-34]

Patient activation is a broad concept that encompasses patient engagement, empowerment and partnership working.[33] Four levels of patient activation have been described, where the individual (1) does not play an active role in their health; (2) does play a role but lacks confidence or knowledge; (3) is beginning to take action to improve their health; or (4) is able to self-manage and self-care.[33] Cross-sectional studies suggested that poorer patient activation may be associated with poorer outcomes in the general population as well as in people with diabetes.[10,35] We did not use a validated patient activation measure tool,[36] which was beyond the remit of our project, but we took FPS and a failure to respond to the survey as indirect measures of patient activation. This is a limitation of our study, but highlights the conundrum that formal measurement of patient activation can only be undertaken in those who engage in care. A poor FPS score and low survey response may reflect poorer pa-

tient activation which may in turn be associated with measurable increased risk. In the present study, non-response to the survey (suggesting potentially poorer patient activation) was not only significantly associated with a worse FPS as another marker of activation, but also with adverse clinical risk as reflected by HbA$_{1c}$, BMI, cholesterol, smoking and primary CHD risk score.

However, poorer patient activation, reflected in non-response, does not mean that the information booklet is necessarily ineffective in modifying that risk. Our preceding publication clearly demonstrated a greater impact on diabetes access and process measure outcomes in the poorer FPS categories.[26] Increased access and process attainment, followed by subsequent intervention, may therefore modify the adverse clinical profile in these hard-to-reach patients.

In summary, people with diabetes are able to understand their most important diabetes-related information when it is presented to them in a simple but structured format. The booklet is easy to generate and its low-tech presentation belies the high standard and governance of data integration and quality assurance required to produce it. The booklet should be easily reproducible in other health economies and it can be disseminated independently of healthcare professionals and distributed systematically across a whole population. It provides for people with diabetes an opportunity to reflect on their own status and take action, facilitates their consultations with healthcare professionals[25] and promotes patient activation, even amongst those with a poorer baseline FPS score.[26]

Whether its prospective use improves key clinical diabetes outcomes via the enhancement of patient activation remains a key question. However, the ultimate intention of promoting patient activation is that of improving measurable surrogate and hard endpoint clinical outcomes. We hope to address this in the final analysis of our current RCT at 1 year post-intervention, potentially influencing the relationship between poorer patient activation and adverse clinical risk.

Study registration The study was registered in the UK national research database (UK CRN ref: DRN 795, available at http://public.ukcrn.org.uk/ Search/ StudyDetail.aspx?StudyID=14324) and at clinicaltrials.gov (NCT02200965). Ethical permission was obtained from NHS Health Research Authority (NRES committee North East-York, REC Ref: 13/NE/0052) and further clarification was obtained from National Information Governance Board..

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