Keywords: Type 2 diabetes, community pharmacy, adherence, drop-in clinic, medicine use review, MUR, United Kingdom

Impact of findings on practice

- Medical practice staff were effective at signposting poorly controlled patients to the drop-in clinic.
- Increased collaboration with the medical practice and the presence of a second pharmacist to support dispensary activities may be necessary to facilitate this kind of service.
- Pharmacists made a number of recommendations to participants and medical practices and the clinic was highly regarded by both participants and pharmacists.

Introduction

An estimated 17.5 million people were diagnosed with a long term condition in the UK in 2005 [1]. In 2009, 2.1 million were diagnosed with type 2 diabetes and this figure is predicted to rise to 3.2 million (5.9% prevalence) by 2020 [2]. The majority of patients (85%) are diagnosed with type 2 diabetes which is largely controlled by oral medication [3].

The main clinical marker for type 2 diabetes is $HbA1_C$ which, according to national guidelines should be maintained below 7.5% [3]. However, recent UK National Health Service (NHS) figures suggest that approximately only 65% of patients are achieving this target, along with only 40% of patients achieving their target blood pressure and 42% their target cholesterol [4]. In the UK, the National Institute for Health and Care Excellence (NICE), has published guidelines for the management of patients with type 2 diabetes, which includes prescribing guidelines for blood pressure and cholesterol treatment [3]. An audit of prescribing for type 2 diabetes has demonstrated that it is generally in accordance NICE guidance [5]. Therefore, the failure of patients to achieve therapeutic targets may be related to medicine doses not being optimised or sub-optimal medication adherence as well as diet and lifestyle problems.

In 2008, an average adult visited a community pharmacy 16 times per year with 86% of the population visiting at least once per year, 78% of those for health-related reasons [6], thereby providing an opportunity for monitoring and intervention. With the emphasis on both the prescribing of correct medicines and the need for patients to adhere to their medicines, it seems appropriate that a pharmacist can contribute to the care of patients with type 2 diabetes. The majority of patients with type 2 diabetes will be treated with medication dispensed from a community pharmacy in primary care.

In several UK Government policy documents, community pharmacy is specifically targeted as a profession that can be used to improve the care of patients with long term conditions [1, 6, 7]. Pharmacists are already engaged in providing Government-funded, non-appointment based adherence interventions such as the medicine use reviews (MUR) to patients with chronic conditions. The MUR is a consultation generally lasting up to 20 minutes during which the patient is given the opportunity to discuss their thoughts and experiences of their prescribed medicines. If any problems are identified, the pharmacist then agrees a strategy for resolution which may include referral back to the patient's physician. This review does not require access to the patient's medical notes. These services are not condition specific and have a relatively limited evidence base. It may, therefore, be more appropriate to target a specific condition and provide a more tailored service than those currently offered.

International studies have highlighted that the community pharmacist may have a role in addressing adherence and other concerns in this population of patients leading to improved blood glucose control [8-15]. A UK study has indicated a significant difference in $HbA1_C$ between the intervention and control groups using RCT methodology in two pharmacies [16]. The intervention, aimed at poorly controlled patients with type 2 diabetes, involved regular monitoring and consultations with the community pharmacist for 12 months for a total of six consultations. The study was mainly conducted in one pharmacy with two permanent pharmacists and a part time nurse. It consisted of a targeted medicine use review to discuss any adherence problems if appropriate, lifestyle modification and referral to the GP if necessary. It also included education about diabetes and its complications. This was an intensive, repeated intervention service with significant time input and no cost effectiveness analysis [16]. We believe, to make this service widely available to patients there would need to be significant change to the ways pharmacists are currently remunerated. This is because UK pharmacy remuneration is dominated by fees for dispensing medicines thus spending long periods of time with patients

means fewer prescriptions can be checked or dispensed. An alternative funding approach would be to take the existing MUR framework (which only requires a one-off, 20 minute consultation) and make it more specific to patients with diabetes. This will be a small step change in the provision of pharmacy services that would not require a significant operational restructure.

In a series of focus groups with patients with type 2 diabetes, participants drawing on their experience of living with diabetes indicated that they would be willing to engage with a community pharmacy service aimed at improving their condition providing that the pharmacist was working in co-operation with the medical practice and they were not violating the natural line of treatment between them and the doctor [17].

All participants in these focus groups identified that they wanted to take responsibility for their own condition but occasionally they had needs for information and wanted to be able speak to a suitably qualified healthcare professional. As such, participants liked the ease and convenience of speaking to the pharmacist and the lack of need for appointment bookings.

This preparatory work led to the design of a diabetes drop-in clinic in the community pharmacy setting that involved identification of poorly controlled patients by the medical practice, no appointment system and a focus on adherence and lifestyle advice. This paper provides details on the results of a feasibility study.

Aims of the study

To determine whether a community pharmacy diabetes drop-in clinic is feasible and acceptable to patients with poorly controlled type 2 diabetes and assessing which outcome measures would be appropriate for a larger study and describing the content of the consultations.

Ethical Approval

Essex NHS Research Ethics Committee (Ref: 11/EE/0494) and NHS Norfolk Research and Development committee (Ref: 2011IC01) approved this study.

Method

As this was a feasibility study, community pharmacies and medical practices were selected based on convenience and contacts that existed between pharmacists and the academic institution.

The diabetes pharmacy drop in clinic specifically targeted patients who were poorly controlled with respect to one or more of HbA_{1C} (>59 mmol/mol), blood pressure (>140/80mmHg) or lipids (>5 mmol/L) as defined by a national incentive scheme. Medical practice staff identified eligible patients on behalf of the research team. The staff were provided with pre-filled envelopes enclosing a letter from the practice partners and a leaflet advertising the service and were asked to mail these to all identified poorly controlled patients. The leaflet contained information including clinic times and what was involved when patients attended the pharmacy. The researcher had no access to medical records for this process. Informed patient consent was obtained when the patient presented in the pharmacy and this allowed the pharmacist to collect biometric data from the medical practice for the purposes of the research.

The clinic was conducted in five pharmacies with the regular pharmacist in the private consultation room located in the pharmacy. Two pharmacies used a consultation room in the adjoining medical practice as they did not have one on the pharmacy premises. This was usual practice for those pharmacists when conducting MURs. Pharmacists were given extra training in order to provide the service which

included a self-directed learning package and a short face-to-face session with the lead researcher. The clinic was conducted for a four-hour period once a week for four weeks (six weeks in one pharmacy) and patients were able to attend without making a prior appointment. The clinic times were selected to ensure that a variety of days of the week (including Saturdays) and times (morning and afternoon) were covered. The aim was to recruit 30-40 participants between the five pharmacies. A second pharmacist (MT) provided dispensary support to the intervention pharmacist. Patients also had the opportunity to visit the pharmacy outside of the clinic times but were informed that they may have to wait a short while to see the pharmacist.

Before undertaking the consultation participants were asked to complete a short questionnaire containing three validated questionnaires: the Beliefs about Medicines Questionnaire (BMQ) [18], the Satisfaction with Information about Medicines questionnaire (SIMS) [19] and Morisky measure of adherence (MMAS-4) [20] combined with questions regarding how many times and why they have used the community pharmacy over the preceding three months. The MMAS-4 is composed of four questions surrounding a patient's medicine taking behaviours. A score of 4 on this scale is interpreted as the patient being fully adherent while less than four indicates partial adherence. This information was then used by the pharmacist during the consultation with the participant. These outcome measures were selected as the service was designed based on existing community pharmacy services which largely involve information provision and adherence advice. There is evidence to suggest that information satisfaction is related to adherence [19] and that this can also be related to a patient's beliefs and concerns surrounding a particular medicine [21].

The consultation was then conducted by the community pharmacist in the consultation room for a duration determined by the patient. The pharmacist was asked to document the content of the consultation on a standard form. As a feasibility

study and based on the literature, the focus of the interaction was not prescribed by the research team but led by the patient from their discussion with the pharmacist and their responses to the baseline questionnaire.

Post consultation, the participants were asked to complete a satisfaction questionnaire which contained questions regarding the conduct of the pharmacist, the surroundings in which the consultation occurred and their opinions on the consultation. This was posted directly to the lead researcher at the university to minimise social desirability bias which could result from posting to the community pharmacy.

Three months post consultation, patients completed a repeat of the baseline questionnaire which was posted to their address and returned in a pre-paid envelope to the University. Non-return resulted in a full repeat posting after two weeks.

After study completion, all pharmacists undertook a de-brief interview with the lead researcher regarding their thoughts and experiences related to the service. This was conducted as individual interviews and pharmacists provided written consent to be recorded.

The pharmacist interviews were transcribed and coded by the researcher and themes were developed using content analysis as described in the literature [22]. A second researcher also read the transcripts and familiarised themselves with the participants responses. The two researchers had discussions surrounding the themes to arrive at a consensus and resolve any conflicting views.

Results

Five pharmacies (three independents and two chain pharmacies) and three medical practices were recruited in three locations across Norfolk, UK. Two of the three independent pharmacies were owned by the medical practice that also participated in the project. None of the medical practices had an established relationship with the academic institution at the outset of the study.

The medical practices identified and posted the invitation letter and information sheet to 342 potential participants. Thirty-three participants (9.6% response rate) were recruited in four of the five pharmacies with each pharmacy seeing between zero and five participants during each four-hour session. The demographics of the recruited participants are detailed in table 1. The mean (SD) time for the consultation was 32.5 (12.0) minutes but ranged from 15 minutes to 65 minutes. As part of the consultations, pharmacists discussed a wide variety of topics and made a number of referrals to the medical practice including:

- Providing information sheets on diet and lifestyle
- Advising participants on portion size
- Information provision on medication
- Identification and reporting of adherence issues
- Changes to formulation to aid adherence
- Requests for alternative or additional medicines for cholesterol and other conditions

Insert table 1.

All participants completed the baseline questionnaire and the team received 26 (79%) follow-up questionnaires. There was no difference in any of the questionnaire measures between baseline and follow-up (tables 2 and 3) apart from the types of topics that participants were prepared to talk to the pharmacist about. The number of patients classed as adherent rose from 61.5% at baseline to 76.9% at follow-up.

Insert tables 2 and 3.

Satisfaction questionnaire

In total, 27 completed questionnaires were returned. These results demonstrate that participants were extremely satisfied with the service that they received and they most would recommend the service to another patient with type 2 diabetes. In response to the question regarding how useful the service was to helping manage their diabetes, 100% agreed that it was some or a lot of help. Nearly 60% of participants stated that this experience would make them more likely to consult their pharmacist in future about other conditions with nearly 90% stating that the length of the consultation was about right. A summary of the other questions asked can be found in figure 1 and demonstrates that all aspects of the service and study process were well received.

Insert figure 1.

Pharmacist de-brief interviews

The pharmacist debrief interviews centred on three areas of discussion: training provision, conduct of the service and the benefits arising from the service.

Training provision

The participating pharmacists identified that the training provision for the service which consisted of a self-directed learning package and a short face-to-face training session was adequate to cover their needs for the study. As part of the face-to-face element, pharmacists were informed of the previous work from the focus groups with patients. This helped them to contextualise the clinic within their practice and tailor their consultations with this information in mind. One pharmacist identified that, in her opinion, interaction with her peers would have been useful to determine how each of them was going to implement the service and what they had learnt as a result of the training in diabetes and study documentation thus far whereas another pharmacist wanted interaction with other healthcare professionals.

> "I personally would've liked... time with either the diabetes nurse or one of the doctors at the practice er just to clarify er sort of their guidelines and what they were trying to achieve with their patients." Pharmacist 3

There was a need for this pharmacist to integrate further with the medical practice and determine their patterns and guidelines for treatment as he did not want to go against the wishes of the practice nurse or GP when making suggestions to them for treatment alterations.

Conduct of the service

Once in the consultation, pharmacists identified a number of topics that patients wanted to cover and these varied for each pharmacist.

> "Quite a few people wanted to know about like the prognosis of diabetes…they didn't quite realise that they would be on medication for like a long time" Pharmacist 2

This pharmacist appeared surprised at the content of the consultation, expecting participants to focus on medicines but instead wanting to discuss other matters surrounding their condition. With the pharmacist below, their perception was that participants just wanted reassurance that they were doing the right things to control their diabetes.

> "I think most people came with some ideas, some had things they just wanted reassurances about other people just came to say their diabetes is fine and explain their medications..." Pharmacist 5

The pharmacists felt that because of this wide variation in topics covered during the consultation, this meant they were sat with the patient for an extended period of time, which they felt had its benefits but could only be achieved because another pharmacist was covering their dispensary workload.

> "They don't normally get to spend a long time talking to the doctor or nurse, they are often rushed… I think it's quite well received by patients...I think it would be very difficult to run that kind of service if I didn't have any locum cover or second pharmacist cover... they [patients] feel less intimidated disturbing what you are doing." Pharmacist 5

This statement confirmed that the pharmacists would not have been able to conduct this service had a second pharmacist not been available to them, it allowed them to focus on the needs of the patient as well as completing all of the relevant paperwork required for the study.

Benefits arising out of the study

Pharmacists identified that participating in this study had benefits to patients, themselves as healthcare professionals and their interaction with the medical practice. Pharmacists highlighted that a positive aspect of the study was that they had had participants return to them after the consultation to update them on their progress, which is something that, as pharmacists, they are not used to.

> "…we've already had somebody come in this morning to say how his levels… have improved as a result of just having a chat. I think it is fantastic if we… get away from checking prescriptions and providing a service like this its great" Pharmacist 4

Most pharmacists highlighted that participating in the study was beneficial to their wider practice as well as the drop-in clinic and that it had given them more confidence to speak to this group of patients. One final benefit that was highlighted was the increased collaboration with the medical practice.

> "I think it has strengthened the link with the diabetes nurses 'cause a lot of the time we have had further questions about a patient whose medication I couldn't change and I've referred to the diabetes nurse… it's a been a good link" Pharmacist 5

All of the pharmacists saw this kind of service as benefitting the relationship with the medical practice and demonstrating where the community pharmacist could help when trying to control patients with type 2 diabetes. They also stated that this would help to raise the profile of pharmacy more generally within the medical practice, which could only be positive for pharmacy.

Discussion

The primary aim of this study was to determine if a drop in clinic based on patient preferences aimed at those with poorly controlled type 2 diabetes and conducted in the community pharmacy was feasible and acceptable to patients and pharmacists. It has demonstrated that patients will access community pharmacy services if identified via the medical practice and that they have significant information needs in relation to their condition and medicines that can be addressed by the pharmacist. It also set out to examine which outcome measures may be appropriate in a future study and ascertain the focus of the consultation.

In terms of feasibility testing, this study has been successful. The medical practices were willing to approach patients on behalf of the service, pharmacists could conduct the consultations and patients found them acceptable and were willing to engage with the process. However, this study could only be conducted with a second pharmacist that allowed the intervention pharmacist to spend the length of time they did with the participants and is unclear how cost-effective this would be on a larger scale. It would also need to be investigated whether this length of time spent with the patient represents a good use of resources. On reflection, the one pharmacy that did not recruit any patients felt that this was due to the lack of prescription volume from the medical practice associated with the study.

Questionnaire results from baseline to follow-up demonstrated no differences in the measures of satisfaction with information or beliefs about medicines. There was a slight increase in the percentage of participants classed as adherent at the end of the study. This indicates that these measures may not be appropriate for a larger study.

In a larger study, the primary outcome measure would be HbA_{1C} and this would need to be collected for some time after the end of the study and any changes made

requested by the pharmacist as a result of the clinic would need to be followed-up to determine their implementation rate. The extent to which both of these can be achieved was not tested during this study. Adherence was characterised using a self-report method which may be less reliable than other forms of adherence measurement e.g. prescription refill data [23]. Both HbA_{1C} and refill data may be more useful outcome measures for a future study and would also reduce the participant questionnaire burden. Along with self-report adherence, participants self-selected for this service and they were therefore more likely to be motivated to engage with an intervention aimed at their condition. However, despite this limitation the study only invited patients who were poorly controlled and therefore any improvement in their condition will be beneficial to the patient and the NHS.

Participant satisfaction with the service was high with most suggesting that they thought it would help them manage their diabetes better and that this kind of service should be available to all patients. They identified that the pharmacists appeared knowledgeable, professional and approachable with some participants noting that the pharmacist did not appear to rush them and was not distracted by other work in the dispensary. This has previously been identified as a problem and may indicate a potential reason why a patient may not engage with the pharmacist [17]. One limitation of the questionnaire includes the phrasing of the questions regarding community pharmacy use in the last three months. Participants may have included the study consultation in their responses and therefore these results should be interpreted with caution.

From the de-brief interviews, pharmacists stated that they enjoyed providing the drop-in clinic as it allowed them to use the knowledge that they had learnt from their training. This allowed them to interact with patients for longer and they especially enjoyed the feedback and hearing from patients about their progress once the study

had finished. In terms of the feedback on the consultation, the pharmacists identified that one of the most important aspects to the service was the dispensary support provided as part of the research. This enabled them to focus on the patient and not feel distracted by events in the dispensary. Another central point that the pharmacists focused on was the need to talk to the practice nurse or doctor about local treatment guidelines to ensure that they were not providing conflicting advice. This demonstrates the need for pharmacists to be better integrated within the primary healthcare team and is something the patients have identified as important [20].

The study achieved a response rate of 9.6% from the postal invitation, something that has implications for generalisability of the results. A low response rate such as this may imply that only motivated patients were encouraged to participate in the study and therefore these patients may not be representative of the wider population with diabetes. This response rate for also has implications for calculating the required number of participants for a larger study.

The consultations themselves lasted significantly longer than GP consultations [24] with the mean time at approximately 32 minutes. This allowed the pharmacist to spend longer with the participants discussing all aspects of their care but may prove an expensive intervention when compared to a similar nurse-led service [25], however the pharmacist is more likely to have capacity for this type of intervention. This could have implications for this type of community pharmacy service in primary care and means that there will need to be a further defining of the intervention in order to make it distinct from current nurse provision, which is less expensive. If pharmacists have the time to spend with patients in this manner, then it may be appropriate for the intervention to focus on using behaviour change techniques, which have been found to have a positive effect on adherence [26] rather than on a wider variety of (unfocussed) topics.

However, there still remain unanswered questions regarding the community pharmacist's role in this group of patients, particularly with reference to the role of the practice or diabetes nurse in the UK. As a result of this work and the work of others [16], it appears sensible to undertake further exploratory work to determine the type of intervention pharmacists should be providing to this group of patients.

Conclusion

The diabetes community pharmacy drop-in clinic was well received by patients and pharmacists and was feasible to conduct in this particular setting. However, there still remain questions regarding the input of the community pharmacist in the care of this group of patients, particularly with such a strong nurse-led service already provided to them in the UK setting. With a significant number of patients still remaining uncontrolled with respect to national guidelines it is therefore appropriate to conduct further work to determine if and how the pharmacist can support the wider primary care team in improving treatment for patients with type 2 diabetes.

Acknowledgements The research team would like to thank the medical practices and pharmacies for volunteering to participate in this project. The pharmacies and medical practices were not paid for participating in the study.

Funding: This work was funded jointly by Numark Pharmacy Ltd and the UEA.

Conflicts of interest: none

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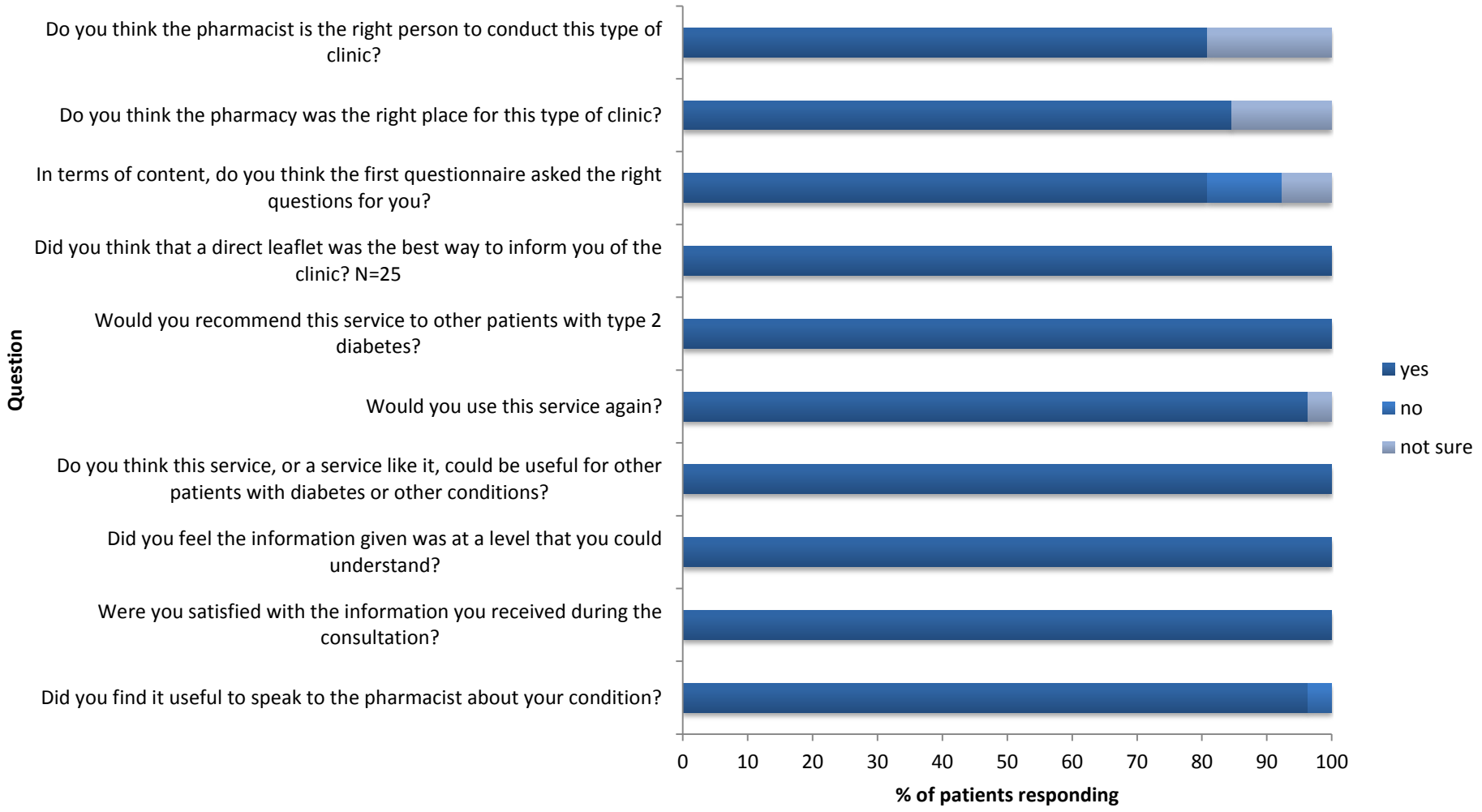

Figure 1 Responses that required a yes/no/not sure answer from the feedback questionnaire

Table 1 Participant Demographics

	N	Mean (SD)	% of patients uncontrolled
Distance travelled to clinic (miles)	33	3.1 (2.7)	n/a
Most recent HbA_{1C} result (mmol/mol)	27*	63.5 (13.2)	44.5
Most recent SBP result (mmHg)	27*	133.6 (21.7)	74.1
Most recent DBP result (mmHg)	27*	78.8 (16.1)	81.5
Most recent total cholesterol result (mmol/L)	27*	4.4 (1.4)	48.1
Number of medicines prescribed	29*	8.8 (4.2)	n/a
Years since diagnosis	29*	8.1 (5.0)	n/a

*Data unobtainable for some participants presenting at pharmacy 4. SBP: systolic blood pressure; DBP: diastolic blood pressure; data normally distributed.

Table 2 Baseline and follow-up questionnaire data

Measure	Before N=33 (median (quartiles))*	After N=26 (median (quartiles))*
BMQ – necessity scale /25	20 (17 – 23)	20 (17 – 22)
BMQ – concerns scale /25	14 (11 – 18)	16 (12.75 – 18)
BMQ – differential score	6 (2 – 9)	4.5 (-0.25 – 8.25)
SIMS – actions and usage score /9	7 (4 – 8)	7 (5 – 9)
SIMS – potential problems score /8	4 (2.5 – 7)	5.5 (2.25 – 7.25)
SIMS – total score /17	11 (8 – 13)	11 (7.75 – 16)

BMQ: beliefs about medicines; SIMS: satisfaction with information about medicines scale

Table 3 Community pharmacy use before and after the study

Not counting today, how many times in the last three months have you:	Before n=33 Mean (SD)	After n=26 Mean (SD)
Visited the pharmacy	3.37 (2.82)	3.37 (2.65)
Spoken to the pharmacist	0.96 (1.54)	1.91 (2.51)
What have you spoken to the pharmacist about?	% responding 'yes'	% responding 'yes'
Your condition	0	38.5
Your medication	15.2	34.6
Over-the-counter advice	18.2	23.1
Lifestyle	6.1	19.2
Dietary advice	9.1	26.9
Other medical conditions	12.1	26.9
Minor ailments	9.1	19.2
Medicine supply	21.2	53.8