

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

3

4 Impact of findings on practice

- 5 • Medical practice staff were effective at signposting poorly controlled patients to  
6 the drop-in clinic.
- 7 • Increased collaboration with the medical practice and the presence of a second  
8 pharmacist to support dispensary activities may be necessary to facilitate this  
9 kind of service.
- 10 • Pharmacists made a number of recommendations to participants and medical  
11 practices and the clinic was highly regarded by both participants and  
12 pharmacists.
- 13

14 **Introduction**

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

20

21 The main clinical marker for type 2 diabetes is HbA<sub>1c</sub> which, according to national  
22 guidelines should be maintained below 7.5% [3]. However, recent UK National Health  
23 Service (NHS) figures suggest that approximately only 65% of patients are achieving  
24 this target, along with only 40% of patients achieving their target blood pressure and  
25 42% their target cholesterol [4]. In the UK, the National Institute for Health and Care  
26 Excellence (NICE), has published guidelines for the management of patients with  
27 type 2 diabetes, which includes prescribing guidelines for blood pressure and  
28 cholesterol treatment [3]. An audit of prescribing for type 2 diabetes has  
29 demonstrated that it is generally in accordance NICE guidance [5]. Therefore, the  
30 failure of patients to achieve therapeutic targets may be related to medicine doses  
31 not being optimised or sub-optimal medication adherence as well as diet and lifestyle  
32 problems.

33

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

42

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

56

57 International studies have highlighted that the community pharmacist may have a  
58 role in addressing adherence and other concerns in this population of patients  
59 leading to improved blood glucose control [8-15]. A UK study has indicated a  
60 significant difference in HbA<sub>1c</sub> between the intervention and control groups using  
61 RCT methodology in two pharmacies [16]. The intervention, aimed at poorly  
62 controlled patients with type 2 diabetes, involved regular monitoring and  
63 consultations with the community pharmacist for 12 months for a total of six  
64 consultations. The study was mainly conducted in one pharmacy with two permanent  
65 pharmacists and a part time nurse. It consisted of a targeted medicine use review to  
66 discuss any adherence problems if appropriate, lifestyle modification and referral to  
67 the GP if necessary. It also included education about diabetes and its complications.  
68 This was an intensive, repeated intervention service with significant time input and no  
69 cost effectiveness analysis [16]. We believe, to make this service widely available to  
70 patients there would need to be significant change to the ways pharmacists are  
71 currently remunerated. This is because UK pharmacy remuneration is dominated by  
72 fees for dispensing medicines thus spending long periods of time with patients

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

78

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

84

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

90

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

95

#### 96 **Aims of the study**

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

101

102 **Ethical Approval**

103 Essex NHS Research Ethics Committee (Ref: 11/EE/0494) and NHS Norfolk

104 Research and Development committee (Ref: 2011IC01) approved this study.

105

106 **Method**

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

110

111 The diabetes pharmacy drop in clinic specifically targeted patients who were poorly  
112 controlled with respect to one or more of HbA<sub>1C</sub> (>59 mmol/mol), blood pressure  
113 (>140/80mmHg) or lipids (>5 mmol/L) as defined by a national incentive scheme.  
114 Medical practice staff identified eligible patients on behalf of the research team. The  
115 staff were provided with pre-filled envelopes enclosing a letter from the practice  
116 partners and a leaflet advertising the service and were asked to mail these to all  
117 identified poorly controlled patients. The leaflet contained information including clinic  
118 times and what was involved when patients attended the pharmacy. The researcher  
119 had no access to medical records for this process. Informed patient consent was  
120 obtained when the patient presented in the pharmacy and this allowed the  
121 pharmacist to collect biometric data from the medical practice for the purposes of the  
122 research.

123

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

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

138

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

153

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

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

160

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

167

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

171

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

176

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

182

183 **Results**

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

189

190 The medical practices identified and posted the invitation letter and information sheet  
191 to 342 potential participants. Thirty-three participants (9.6% response rate) were  
192 recruited in four of the five pharmacies with each pharmacy seeing between zero and  
193 five participants during each four-hour session. The demographics of the recruited  
194 participants are detailed in table 1. The mean (SD) time for the consultation was 32.5  
195 (12.0) minutes but ranged from 15 minutes to 65 minutes. As part of the  
196 consultations, pharmacists discussed a wide variety of topics and made a number of  
197 referrals to the medical practice including:

198

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

206

207

208 Insert table 1.

209

210 All participants completed the baseline questionnaire and the team received 26  
211 (79%) follow-up questionnaires. There was no difference in any of the questionnaire  
212 measures between baseline and follow-up (tables 2 and 3) apart from the types of  
213 topics that participants were prepared to talk to the pharmacist about. The number of  
214 patients classed as adherent rose from 61.5% at baseline to 76.9% at follow-up.

215

216 Insert tables 2 and 3.

217

218 Satisfaction questionnaire

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

229

230 Insert figure 1.

231

232 Pharmacist de-brief interviews

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

235

236 Training provision

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

247

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

251

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

256

257 Conduct of the service

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

260

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

264

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

270

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

274

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

279

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

285

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

290

291 Benefits arising out of the study

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

297

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

302

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

307

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

312

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

318

319 **Discussion**

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

328

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

339

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

344

345 In a larger study, the primary outcome measure would be HbA<sub>1C</sub> and this would need  
346 to be collected for some time after the end of the study and any changes made

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

358

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

370

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

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

383

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

390

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

403

404 However, there still remain unanswered questions regarding the community  
405 pharmacist's role in this group of patients, particularly with reference to the role of the  
406 practice or diabetes nurse in the UK. As a result of this work and the work of others  
407 [16], it appears sensible to undertake further exploratory work to determine the type  
408 of intervention pharmacists should be providing to this group of patients.

409

#### 410 **Conclusion**

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

419

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425

426 **Conflicts of interest:** none

427

428

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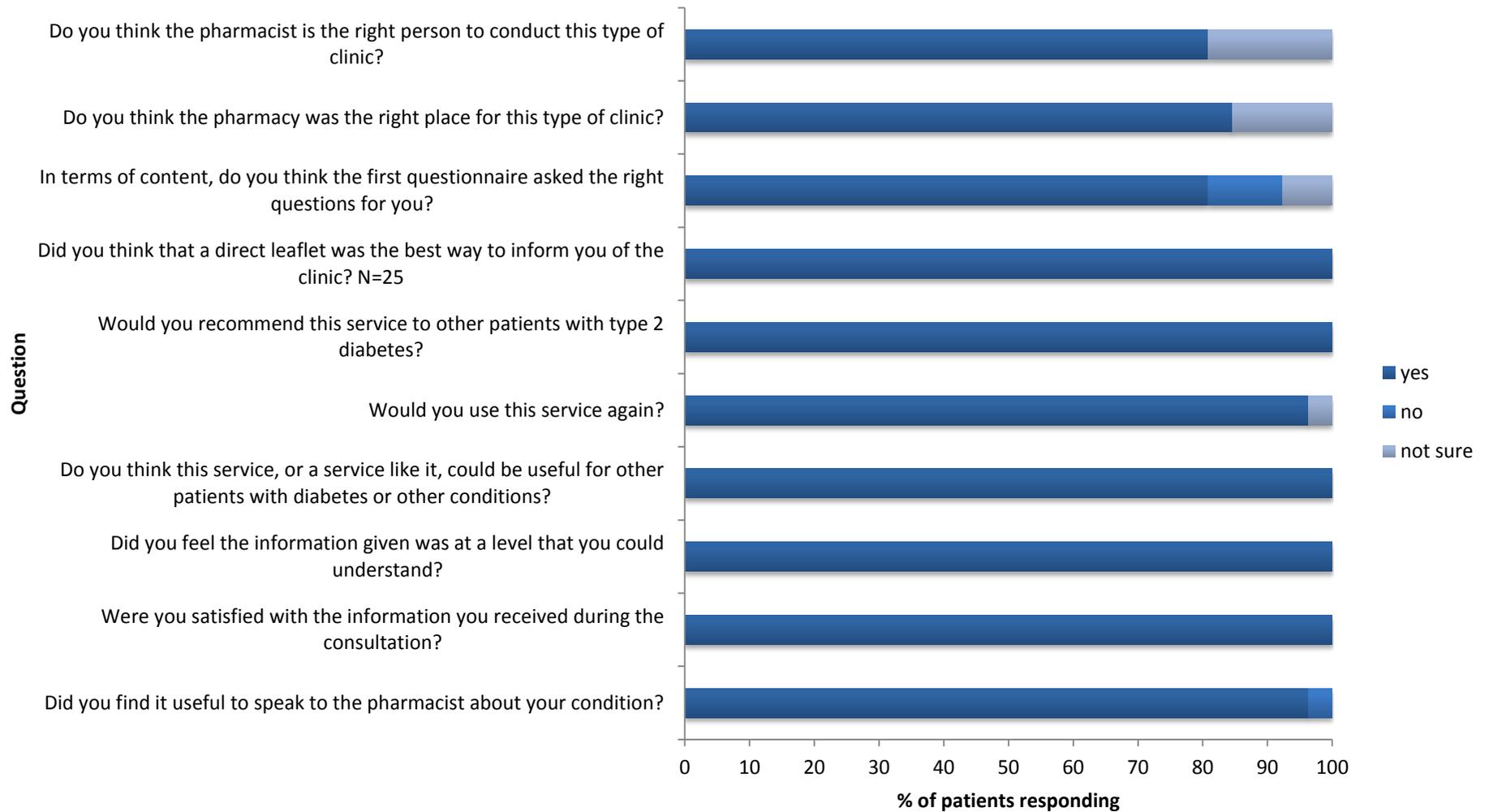


Figure 1 Responses that required a yes/no/not sure answer from the feedback questionnaire

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 <sub>1c</sub> 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	After n=26
	Mean (SD)	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