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ORIGINAL RESEARCH

Barriers and Facilitators to the Initiation of Injectable Therapies for Type 2 Diabetes Mellitus: A Mixed Methods Study

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ABSTRACT

Introduction: Initiation of injectable therapies in type 2 diabetes (T2D) is often delayed, however the reasons why are not fully understood.
Methods: A mixed methods study performed in sequential phases. Phase 1: focus groups with people with T2D (injectable naïve [*n* = 12] and experienced [*n* = 5]) and healthcare professionals (HCPs; nurses [*n* = 5] and general practitioners (GPs) [*n* = 7]) to understand their perceptions of factors affecting initiation of injectables. Phase 2: video-captured GP consultations (*n* = 18) with actor-portrayed patient scenarios requiring T2D treatment escalation to observe the initiation in the clinical setting. Phase 3: HCP surveys (*n* = 87) to explore external validity of the themes identified in a larger sample.
Results: Focus groups identified patients' barriers to initiation; fear, lack of knowledge and misconceptions about diabetes and treatment aims, concerns regarding lifestyle restrictions and social stigma, and feelings of failure. Facilitators included education, good communication, clinician support and competence. HCP

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barriers included concerns about weight gain and hypoglycaemia, and limited consultation time. In simulated consultations, GPs performed high-quality consultations and recognised the need for injectable initiation in 9/12 consultations where this was the expert recommended option but did not provide support for initiation themselves. Survey results demonstrated HCPs believe injectable initiation should be performed in primary care, although many practitioners reported inability to do so or difficulty in maintaining skills.

Conclusion: People with T2D have varied concerns and educational needs regarding injectables. GPs recognise the need to initiate injectables but lack practical skills and time to address patient concerns and provide education. Primary care nurses also report difficulties in maintaining these skills. Primary care HCPs initiating injectables require additional training to provide practical demonstrations, patient education and how to identify and address concerns. These skills should be concentrated in the hands of a small number of primary care providers to ensure they can maintain their skills.

Keywords: Insulin; GLP1 receptor analogues; Barriers; Initiation; Mixed methods; Primary care; Medical record systems, computerized; Diabetes mellitus, type 2

Key Summary Points

Why carry out this study?
Initiation of injectable therapy is often delayed by several years in type 2 diabetes, however the reasons for these delays are not understood.
The study used multiple methods (focus groups, video-captured simulated consultations, and surveys) to identify barriers and facilitators to the initiation of injectable therapy.
What was learned from the study?
There are multiple patient barriers to initiation which include fear, lack of knowledge, and misconceptions. Good communication, clinician support and education can overcome barriers.
In primary care, clinicians recognise the need to initiate injectable therapies but lack the required practical skills to do so and find it difficult to maintain competence.
Additional training for primary care professionals initiating injectables is needed to support competency in this area.

INTRODUCTION

Only around half of people with type 2 diabetes (T2D) achieve glycaemic targets [1–3]. A major component of suboptimal management is delayed treatment intensification termed "clinical inertia" [4]. Diabetes guidelines recommend stepwise treatment escalation [5, 6]. However, delayed intensification of glucose-lowering medication occurs at every stage of the treatment pathway; initiation of oral medication, addition of further oral medications, initiation of injectable therapies, and escalation of injectable therapies once initiated [7, 8]. The time to initiation of injectable therapies after maximal oral therapy is especially prolonged, with delays of 5–7 years reported [7, 9–11]. The mean threshold at which injectable therapies are initiated is also very high, with mean HbA1c values at initiation over 80 mmol/mol (9.5%) [12, 13]. Delayed intensification to injectable therapy likely increases risk for microvascular and macrovascular complications, reduces quality of life and increases mortality [14, 15].

Multiple factors have been associated with delayed initiation of injectable therapies and been categorised as clinician, patient, and

health service-level factors [11, 16]. Clinician factors include a lack of awareness by general practitioners (GPs) of clinical inertia and lack of understanding of the need to achieve early glycaemic control [11, 17]. It has been hypothesised that both a lack of expert knowledge and consultation time with patients required to initiate insulin are major barriers in primary care [11]. Clinicians' concerns about hypoglycaemia may also contribute [18]. Patient factors include fear of weight gain, hypoglycaemia, and concerns around the burden of injections and reduced quality of life [19, 20]. Improved understanding of the patient-, clinician-, and health service-level factors that influence clinical inertia is urgently needed to facilitate improved glycaemic control and health outcomes in T2D.

This study was designed to describe patients' and healthcare professionals' (HCPs) perceptions of the process of intensification with injectable therapies (insulin and glucagon-like peptide 1 receptor agonists [GLP1 RAs]), and the context within which those decisions are made. The goal was to enhance our understanding of clinical inertia and of what prevents appropriate initiation of injectable therapies in people with uncontrolled T2D despite maximum oral therapy.

METHODS

The study research protocol has previously been reported in full [21]. In brief, we used a mixed methods design consisting of three phases.

- *Phase 1* We undertook separate focus groups with patients and HCPs (GPs and practice nurses) to explore their attitudes and experiences of the initiation of injectable therapies, and to examine their views on the facilitators and barriers to starting injectable therapy.
- *Phase 2* We observed consultations with GPs using fictional patients, played by actors, to simulate scenarios where injectable therapies could be initiated, to describe the context in which injectable therapy initiation takes place, including how well prompts and information from the computerised medical record (CMR) system are recognised in the consultation.
- *Phase 3* We used the results from the previous phases to devise a survey, which we sent to primary care HCPs across England, to describe consensus or discrepancy within and between clinicians and people with T2D about intensification to injectable therapies.

Setting

We recruited HCPs and patients with T2D from nine volunteer GP practices within the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. The RCGP RSC is a large network of practices distributed across England which provides a broadly representative sample of the national population and high-quality data on diabetes care processes [22, 23].

In the UK, T2D is largely managed in primary care. Consultations are recorded into CMR systems that provide a mechanism to record diagnosis of T2D, prescription records, and pathology results, including HbA1c. Therefore, every time a person with T2D presents, their clinician can readily tell if they are achieving targets, and whether they are receiving appropriate therapy.

Since 2004 GPs have been financially remunerated for care quality in T2D through a pay-for-performance (P4P) system, the Quality and Outcomes Framework (QOF) [24]. CMR-based interventions are known to improve glycaemic control [25] and the introduction of these P4P targets may have improved glycaemic control and reduced inequalities in T2D management [26, 27]. Despite these improvements the majority still have an HbA1c above target [26].

Participant Selection

Within each study practice we recruited adults with T2D; some naïve to injectable therapy, and others with current or prior experience (for Phase 1). We also recruited a mix of GPs and

practice nurses (for Phase 1). We compared practice size, patient demographics, and diabetes QOF indicators of study practices with all practices in England to check representativeness of study practices.

Phase 1: Focus Groups with People with Type 2 Diabetes and Clinicians

We used focus groups as our primary method of data collection in this initial phase, but offered individual interviews to participants as an alternative (n = 1). Four patient and three HCPs focus groups were conducted separately to minimise response bias. A moderator introduced topics (Appendix 1) and ensured all participants were able to share views, and that all topics were covered. Each focus group lasted between 90 and 120 min. Transcripts were analysed using framework analysis (Appendix 1).

Phase 2: Video-Recorded Simulated Surgeries

We conducted simulated consultations (surgeries) with six of the seven GPs from Phase 1. Three fictional patient scenarios were generated (Appendix 2) by experts, using concepts and issues identified in Phase 1:

1. Jane Smith: the appropriate therapeutic action was initiation of insulin.
2. John Thompson: injectable therapy was not needed.
3. Gary Jones: the appropriate therapeutic action was initiation of a GLP1 RA.

Patients' roles were played by professional actors. Historic clinical data were entered into the CMR to produce prompts and access to guidelines that HCPs see to simulate routine surgeries as closely as possible.

Each consultation was video-recorded using the Activity Log File Aggregation (ALFA) toolkit [28]. The ALFA toolkit is a multi-channel video method that captures the minutiae of clinical consultation, such as verbal/non-verbal cues, and the impact of the computer, through simultaneous recording of (1) clinician's upper body, (2) patient's upper body, (3) wider angle capturing both patient and clinician, and (4) computer screen [28, 29].

Assessment of Consultation Quality

Consultation style has a major impact on patient–doctor relationships, substantially affecting the amount of information disclosed by patients [30]. We used The Global Consultation Rating Scale (GCRS) scoring template (Appendix 3), based on the Calgary–Cambridge consultation guide [31], to assess consultation quality [32]. The GCRS has been validated for assessment of simulated patient consultations and demonstrated to have good inter-rater reliability [32].

Assessment of the Interaction Between the GP and the Simulated Patient

A data capture form (Appendix 4) was developed for each simulated surgery to enable us to:

1. Highlight key consultation elements that supported or negated need for action (therapy escalation to injectable treatment) either in patient's history or simulated medical record
2. Note whether each key consultation element was accessed in CMR or recognised during consultation
3. Assess degree of patient or doctor-centeredness of consultation
4. Describe outcome of consultation (captured through free text)

This analysis was carried out independently by two expert reviewers (JW and NM). The reviewers independently identified the six most important key elements, a priori, in the records or history from the simulated patient which should trigger action or prevent action, in this case intensification of therapy with injectable treatment. The videos were then independently reviewed by the experts using the data capture form to see if these triggers were recognised, discussed, and actioned. This peer approach mirrored similar methods used to assess multidisciplinary team meetings [33].

Inter-rater reliability of data capture was assessed using Cohen's kappa.

Consultation outcomes were reported by the reviewers. These were coded as one or more of five potential outcomes:

1. A prescription for insulin or a plan for the initiation of insulin
2. A prescription for a GLP1 RA or a plan for the initiation of a GLP1 RA
3. A prescription for the initiation or a plan for the initiation of a new oral medication
4. A change in dose of a current oral medication
5. No medication changes made

Discrepancies were resolved by a third reviewer (WH) by additional assessment of video data.

Follow-up Focus Groups: Including Assessing Consensus Statements

The GPs were subsequently invited to a follow-up focus group with a diabetologist, to ascertain their views on the scenarios and on factors influencing consultation outcome. In addition, they were presented with statements (Appendix 5) regarding care provision and initiation of injectable therapy in T2D and asked to rate their agreement/disagreement using a Likert scale. These statements were generated using the findings of Phase 1 focus groups and subsequently used to form the survey for Phase 3.

Phase 3: Survey

We developed a web-based survey for HCPs (Appendix 6) to quantify the extent to which themes identified in focus groups were representative of HCP views more broadly (by surveying practitioners across the RCGP RSC network). The survey incorporated a series of statements; participants indicated the extent to which they agreed or disagreed with each statement, using a Likert scale and described the rationale for their response.

Participants were also asked to indicate their role, gender, age, ethnicity, workplace location, and to categorise any diabetes-specific training that they had received.

Ethical Approval and Consent to Participate

We received ethical approval from the Health Research Authority, London—Hampstead Research Ethics Committee (Ref 17/LO/1305). Each participant provided informed consent prior to involvement and all data were pseudonymised/anonymised as appropriate. This study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

RESULTS

HCPs from the nine practices participated in the focus groups, simulated surgeries, and helped recruit people with diabetes from their practices. Practices were broadly representative of practices in England and Wales in terms of size, prevalence of people with T2D, and patient sociodemographics. Study practices had a slightly better than average performance on diabetes QOF indicators (Appendix 7).

Phase 1: Focus Groups with People with Type 2 Diabetes and Clinicians

Seventeen people with T2D and 12 HCPs participated in focus groups (Tables S1, S2).

The people with T2D (n = 17) had a median age range of 65–74 years, and median duration of diabetes of 10–19 years. Half were male (53%) and they were an ethnically diverse sample (Table S1). Four participants were currently using insulin injectable therapy, one participant had been on insulin and returned to oral medication only; the remaining participants were naïve to injectable medications. Of the 12 clinicians, the median age range was 45–54, and three were male (25%). Seven clinicians were GPs and five were nurses, with nine reported having had some diabetes-specific training.

Reluctance to Start Injectable Therapy

Of the participants with T2D not on injectable therapy, all expressed a reluctance to start. Although one participant on injectable therapy recalled initial reluctance, all four participants currently on insulin described a positive experience with using it.

Emergent Themes

These are grouped into eight key themes with sample quotations (Table 1 and Appendix 8).

Barriers to the Initiation of Injectable Therapy

Theme 1: Lack of Understanding by People with Type 2 Diabetes

Lack of understanding about diabetes and injectable therapy were common among participants with T2D in this study. Given concordance with the clinicians' views, it would suggest that low health literacy in relation to diabetes was widespread.

Theme 2: Fear

Some participants with T2D expressed fear in general terms, however others were more specific about reasons underpinning their fear. Participants with T2D and clinicians most commonly identified restriction of lifestyle as a reason for fear of injectables. Fear at the thought of self-administration was expressed by one person with T2D who was not on injectable therapy, as well as from clinicians. This contrasted with neutral reactions from those already using insulin. Areas of discordance between people with T2D and clinicians' accounts of fear as a barrier to initiation of injectables were hypoglycaemic episodes, pain and fear of stigma. While these were raised by clinicians, these were not identified as significant sources of fear by people with T2D.

Themes 3: Comorbidities

Clinicians recognised comorbidities, such as impaired eyesight, overweight/obesity and age, as barriers for them to initiate administration of injectables for some patients.

Theme 4: Clinician Competence

The perceptions of participants with T2D varied widely in relation to individual clinician competence (clinician experience and knowledge used interchangeably). There was substantial variation in clinician confidence to initiate insulin therapy. While they felt able to discuss the potential for injectables with patients, some clinicians felt they did not have sufficient experience or knowledge to start this complex process. Clinicians acknowledged the importance of trust, particularly in the initiation of injectables. Where patients perceived their clinician to be competent, they reported having trust in them.

Theme 5: System Limitations

Lack of time was recognised as a major limiting factor for overall diabetes care and for the time-consuming initiation of injectable therapy by both clinicians and participants with T2D. High workloads were identified as another component of system constraints contributing to restricted time available for initiation of injectables. Cost was raised as an additional constraint by clinicians; the cost burden associated with patient equipment and choice of drug was also discussed. A lack of continuity of care was perceived to lead to a decline in the quality of diabetes care received by participants with T2D (but not by clinicians). Clinicians expressed frustration about the inconsistency of advice that patients received from GPs and diabetes clinics. Another inconsistency apparent within clinicians' responses was the appropriate timing to discuss injectables with people with T2D; a number of clinicians felt that, at diabetes diagnosis, there was too much information for patients, while others believed that all information should be provided at diagnosis.

Table 1 Illustrative quotations from patients and clinicians demonstrating the barriers and facilitators to injectable initiation

Theme	Illustrative quote
Theme 1: Lack of understanding by people with type 2 diabetes	
Misconceptions about causes and impacts of diabetes	"I just feel normal all the time. I was very surprised that I got a diagnosis" (*P14, male, on oral medication, aged 55–64*)
	"They feel fine, they don't think they've got any symptoms anyway" (C7, female, GP, aged 45–54)
	"People [are] given meds to make money for pharma…People are getting addicted" (P10, female, on oral medication, aged 65–75)
	"Our worst controlled patient…he says that this is all an NHS plot with the pharmaceutical companies to overprescribe" (C5, male, GP, aged 55–64)
	"[There is] a lack of understanding of the reality of the risk of complications, until it's too late" (C4, female, GP, aged 55–64)
Misconceptions about injectable therapy	"Of course I know type 1 always have injections, but for type 2 it is the first time that you tell me" (P17, male, on oral medication, aged 65–74)
	"A lot of the time [they] don't feel bad, so why inject themselves…?" (C2, female, practice nurse, aged 35–44)
	"It's life threatening I'll take it [injectable therapy], otherwise not…Just leave, let life pass away and end itself." "Will it [injectable therapy] cure the diabetes? 100%? Can you guarantee it?" (P10, female, on oral medication, aged 65–75)
	"I don't think people really understand the complications" (C2, female, practice nurse, aged 35–44)
Theme 2: Fear	
Of restriction of lifestyle	"I think another thing with the insulin is it sort of takes over their lives…they could potentially be having five injections in one day, that might mean testing their blood sugar six times a day. It affects them socially, you know" (C8, female, practice nurse, aged 45–54)
	"I think it's the way it's going to, it will change my life" (P2, female, on oral medication, aged 55–64)
	"You've got to be conscious about it before you eat, before you take anything,…Further restrictions on life…It's just a nuisance" (P10, female, on oral medication, aged 65–74)

Table 1 continued

Theme	Illustrative quote
Of self-administration	"But you have me do it myself, I don't…no!" (P6, male, on oral medication, aged over 75)
	"They [are]…nervous basically, having to inject themselves" (C7, female, GP, aged 45–54)
	"It is just that tiny little needle which sticking it in my, in here, I have no problem at all of doing it and just you don't know it's done" (P3, male, on insulin, aged 65–74)
	"To me, injections are that meaningless, they don't mean anything to me" (P15, male, on insulin, aged 45–54)
Of hypoglycaemia risk	"Hypos you know, for a lot of patients that's a real concern" (C6, female, GP, aged 25–34)
Of pain of injections	"They [are]…nervous…how the needles are painful" (C7, female, GP, aged 45–54)
	"That pain is not there" (P15, male, on insulin, aged 45–54)
Of stigma	"A daily injectable therapy…that puts a bigger sort of illness label" (C4, female, GP, aged 55–64)
	"The social embarrassment…very real sense that in public there's a sense of shame, disability, dysfunction" (C9, male, GP, aged 65–74)
'End of the road'	"Basically an irreversible step" (C4, female, GP, aged 55–64)
	"They think it's the end of the road" (C8, female, practice nurse, aged 45–54)
	"If you start taking injections, I think you don't stop" (P13, female, on oral medication, aged over 75)
	"[I] use it as a, 'You don't want to go on Insulin, that's not what you want, try and improve your control,' sort of a bit more like a threat so really heavily encouraging diet and exercise" (C6, female, GP, aged 25–34)
Themes: 3. Comorbidities	
Practical constraints to initiation/ administration	"Other comorbidities, you're not going to burden them with, you know, too much aggressive therapy" (C4, female, GP, aged 55–64)
	"They don't go together arthritis and taking insulin" (P1, male, on insulin, aged over 75)
	"There's no way we're going to get glycaemic control without insulin, then it's going to be trebly, quadruply hard for them to lose that weight" (C4, female, GP, aged 55–64)
	"That's the real sad thing about a lot of treatment for diabetes is you're always trying to get them to lose weight and the tablets and the insulin you put them on they gain weight. So it is with trepidation they start insulin" (C8, female, practice nurse, aged 45–54)

Table 1 continued

Theme	Illustrative quote
Theme 4: Clinician competence	
Experience/knowledge of diabetes	"When I was diagnosed and things weren't going right I was referred to the dietician, oh that was a waste of space…' "the GP…he was just brilliant. He had all the time in the world for me" (P2, female, on oral medication, aged 55–64)
	"That female doctor…I got the impression that she didn't know an awful lot about problems with diabetics, right." 'My GP and the practice nurse who's very good" (P1, male, on insulin, aged over 75)
	"With insulin, yes, I think I would always, you know, initially refer" (C4, female, GP, aged 55–64)
	"I don't feel confident in what I know about insulin yet to really do much with it' (C2, female, practice nurse, aged 35–44)
Trust	"They did have a practice nurse, a diabetic nurse and she was absolutely fantastic, she was brilliant and then she retired and they, the one that replaced her, well yeah, it is that bond, that trust and I didn't feel that I was getting the information and level of support" (P2, female, on oral medication, aged 55–64)
	"I've got a lot of faith in the nurses… When they've got diabetic nurse in their name I think great, they're the people to talk to' (P1, male, on insulin, aged over 75)
	"Doctors needing to sell this injection because I think pharmaceutical companies push these injections and medicines and that's why I have no trust in these injections or these medications…I don't think the GPs have got any interest to find out whether it's good for us or bad for us" (P10, female, on oral medication, aged 65–74)
	"I trusted the doctors before but not anymore" (P11, female, on oral medication, aged over 75)

Table 1 continued

Theme	Illustrative quote
Theme 5: System limitations	
System constraints	"[The clinicians simply] don't have time" (P11, female, on oral medication, aged over 75)
	"With the pressures on them…I've got to absorb the information in possibly not enough time" (P3, male, on insulin, aged 65–74)
	"[Initiation requires] giving the patient a lot of time" (C1, male, GP, aged 55–64)
	"It's quite time-consuming to initiate, quite complicated" (C7, female, GP, aged 45–54)
	"Consultants in the diabetic clinic… when he sees you, obviously they discuss a little bit more. Now surgeries are pushed a lot for time. So time factor is big" (P15, male, on insulin, aged 45–54)
	"We've been under financial pressures to reduce prescribing of the blood testing strips over the years so patients only [get them] when they're on injectables" (C7, female, GP, aged 45–54)
	"There was a big move from NovoMix 30 to Humulin M3 because of course it's cheaper" (C8, female, practice nurse, aged 45–54)
Inconsistency of care	"The diabetic nurses are being changed too often now…So the new person comes in, doesn't know your history. So it would be nice to have one nurse" (P15, male, on insulin, aged 45–54)
	"You don't necessarily see the same GP these days" (P3, male, on insulin, aged 65–74)
	"My old GP practice they were the ones that diagnosed me with diabetes, they were the ones that set everything up and sort of monitored me and managed me really well and got me to that point. And then we've moved and this practice…they just rely on the blood tests every three months" (P2, female, on oral medication, aged 55–64)
	"Clinicians at the [diabetes clinic] seem to have a much more laid back approach to glycaemic control than QOF requests of us to have… So and they'll [the patients] come and say, 'Well I went to the clinic two weeks ago and they said it was fine,' and…it's actually then very difficult to say, 'But you know, you need to lose three stone, you need to go for a walk every day and we need to give you an additional treatment,' so that's another barrier" (C4, female, GP, aged 55–64)

Table 1 continued

Theme	Illustrative quote
Theme 6: Support for people with type 2 diabetes	
	"[People not on injectables need a clinician to talk] through the whole process of what's involved because they might have some preconceived ideas that are a bit scary" (P1, male, on insulin, aged over 75)
	"It's like hit and miss as to who you get as to the level of support…that instils you with confidence that they know what they're talking about, can reassure your fears and allay your fears and put you on the right path that you need to be on to gain the confidence that you need that you can manage it… It's probably not the fact that I've got to have injections, it's the fact of having somebody that I feel confident with that is going to teach me and guide me down the path that I need to go down to manage it" (P2, female, on oral medication, aged 55–64)
	"Take time to show you how to do it" (P4, male, on oral medication, aged over 75)
	"[What] I'd want to see is them actually producing what the instrumentation is, what are you going to be dealing with physically" (P1, male, on insulin, aged over 75)
	"[Clinicians have] got to explain to people why you're doing it and what's the usefulness about it" (P10, female, on oral medication, aged 65–74)
	"Communicate what you need to do, why you need to do it, rather than just reciting" (P3, male, on insulin, aged 65–74)
	"Physical face-to-face support whether that be with a nurse or an experienced clinician" (C7, female, GP, aged 45–54)
	"Show them the devices, maybe get them to do a dry injection" (C11, female, practice nurse, aged 35–44)
	"So it's almost giving them confidence that there is somebody there to help them at any time of the night or day" (C8, female, practice nurse, aged 45–54)
	"[The benefit of peer support groups] it would be therapeutic, you know…because you realise that you're sharing something" (P11, female, on oral medication, aged over 75)
	"Obviously trying to encourage them to go to the DESMOND educational sessions is I think hugely important because they can get a lot more time with a DESMOND educator than they can with our nurse" (C9, male, GP, aged 65–74)
	"I like them to bring in their partner" (C8, female, practice nurse, aged 45–54)
	"I think making it a whole family thing…is a good idea" (C2, female, practice nurse, aged 35–44)

Table 1 continued

Theme	Illustrative quote
Theme 7: Education	
	"[I] just want more knowledge of knowing how to deal with it" (P10, female, on oral medication, aged 65–74)
	"[I am] living without knowledge literally" (P11, female, on oral medication, aged over 75)
	"I don't think we've got the time to do that [educate them] properly" (C5, male, GP, aged 55–64)
	"I think education's one of those things, it's ongoing isn't it? I think we all need regular updates," (C11, female, practice nurse, aged 35–44)
	"[There is a] need for more sort of publicity and public health education about diabetes" (C4, female, GP, aged 55–64)
	"Publicity probably on a national level, about diabetes, about the importance of following advice and being monitored regularly, some easy-to-follow YouTube videos on how good it is to be on insulin, how it's not the end of the world, how easy it is to manage, how the control can get better, so good-feel videos" (C1, male, GP, aged 55–64)
Theme 8: Communication	
	"Absent from his [the doctor's] vocabulary and mental kit was human nature…a lot of the professionals they classroom-learn but they don't learn the application or they're not taught how to communicate it" (P3, male, on insulin, aged 65–74)
	"[Promising] at this time they're going to give their lifestyle a really good look at" (C2, female, practice nurse, aged 35–44)
	"[I would like] a lot of guidance on…more the motivational type support, for how to persuade our patients that this is the best alteration to their therapy at this point in their illness progression." "[The initiation process] often takes a while to negotiate" (C1, male, GP, aged 55–64)
	Shared decision-making: "ultimately, they've got to live with their treatment and so you know…They have to make that decision" (C8, female, practice nurse, aged 45–54)

Facilitators to the Initiation of Injectable Therapy

Theme 6: Support for People with Type 2 Diabetes

People with T2D and clinicians recognised the importance of adequate support for people being initiated onto injectable therapy. Support from their leading clinician was reported as of paramount importance for people with T2D feeling willing/able to start injectable therapy. Adequate support helped with overcoming two of the most prominent barriers to initiation for people with T2D (i.e. misconceptions, fear). The need for practical advice, reassurance, and clearer rationale for needing injectables was noted by people with T2D and clinicians. Follow-up support was also identified as essential to ensure patients feel supported through their initiation of injectables.

The need to include family members in the initiation process was emphasised by clinicians. This was supported by narratives from people with T2D, who identified their families as crucial to their diabetes care and management of insulin regimens. Clinicians indicated that QOF targets and NICE guidelines support their decision-making for injectable therapy.

There was an overriding view that if people with T2D received the support they needed, they would overcome many of the barriers to initiation of injectable therapy.

Theme 7: Education

Both participants with T2D and clinicians identified improved diabetes-related education for patients as a major factor facilitating diabetes care and the initiation of injectable therapy. There was strong concordance across clinicians and participants with T2D that diabetes-related education for patients was key to the support that they need to overcome their barriers and accept initiation of injectables. Lack of time was recognised as a major obstacle to providing sufficient education that people with T2D require to fully understand the need for injectables.

Clinicians also expressed a strong interest in receiving more education/training for injectable therapy to provide the confidence and competence to initiate. Public health campaigns were mentioned by clinicians and people with T2D as a strategy to educate both the public and patients about the role of injectables in diabetes management.

Theme 8: Communication

Clear and more compassionate clinician communication was raised as a facilitator for initiation of injectables by people with T2D and links with the role of support and education from clinicians to encourage people to initiate injectable therapy. The participants with T2D stated the need for tailored, applied advice. Clinicians highlighted the need to improve their negotiation skills; when injectable therapy is broached during appointments, patients often engage in negotiation to avoid initiation.

Shared decision-making was a salient component of the diabetes care that the majority of the people with T2D felt that they received. Interestingly, participants with T2D who reported not being included in decisions about their own care also reported low levels of trust in their clinician.

Phase 2: Video-Recorded Simulated Surgeries

Six GPs participated in the simulated surgeries and follow-up focus groups (Table S3). The majority of participating GPs had over 30 years of healthcare experience. Each GP participated in a simulated surgery with all three patient actors. The mean consultation time was just over 13 min (range 9:25–16:49). Consultation quality was uniformly high across all the participating GPs (Supplementary Table S5).

Consultation Outcomes

The consultation outcomes for the three simulated patients are shown in Table 2. In case 1 (Jane Smith), none of the consulting GPs opted for the expert-recommended option of initiating insulin, although one clinician recommended further review after additional blood tests with potential for adding insulin. Three

Table 2 Consultation outcomes of the 18 simulated consultations (six consultations for each scenario)

Scenario	Outcomes					
	Insulin initiation	GLP1 RA initiation	New oral medication	Oral medication dose change	No medication change	Deferred decision
Case 1 (Jane Smith)	0[a]	3	1	1	0	1[b]
Case 2 (John Thompson)	0	0	1	0	5[a]	0
Case 3 (Gary Jones)	0	4[a]	0	0	1	1[c]

[a]The expert-recommended optimal outcomes

[b]For additional blood results and then consideration of insulin

[c]For more time to do a notes review and then for consideration of a GLP1 or oral option if there was something not yet tried

clinicians initiated a GLP1 RA despite the patient not being above the minimum BMI recommended for initiation in the UK. For case 2 (John Thompson), 5/6 consulting GPs opted for the expert-recommended option of making no changes. For case 3 (Gary Jones), 4/6 of GPs suggested addition of a GLP1 RA. One GP arranged for a further appointment to consider a GLP1 RA or other oral medication when the patient could provide additional information. Injectable devices or techniques were not discussed in any of the consultations.

Identification of Key Consultation Elements

GPs identified a mean of 3.8 of the six key elements needed to make a decision about escalation or maintenance of treatment across all simulated consultations (Table S5). Key elements relating to glycaemic control (e.g. HbA1c, osmotic symptoms) and patients' expectations/wishes were well recognised by GPs, although other elements were less well explored (Table 3). Inter-rater reliability for clinician identification of key elements was excellent for majority of domains assessed (Table S6).

Phase 3: Survey

There were 87 HCP survey respondents, from 63 primary care workplaces distributed across the RCGP RSC network (Fig. S1): 41% (n = 36) were nurses and 56% were GPs (n = 49); the remainder were pharmacists (n = 2). All but one of the nurses was female, whereas the gender distribution was almost equal among GPs (Tables S7, S8). Participants described a wide range of prior diabetes-specific training.

An in-depth analysis of the survey results is provided in Appendix 9 and summarised in Table 4. The majority of survey respondents felt that initiating injectable therapies in people with T2D was usual practice in primary care without specialist input, stating that this would be done by a diabetes lead GP or nurse with diabetes expertise within the practice. Where respondents indicated that this was not done in their practices, this was either because a small number of people with diabetes meant they could not develop the required expertise or because this service was not commissioned locally. Where services were not commissioned in primary care, practitioners relied entirely on local specialist diabetes services for initiation of injectable therapies. Only half of the GPs and nurses surveyed reported the ability to initiate injectable therapy themselves, citing lack of training and lack of frequent exposure as reasons for their reticence.

Table 3 Mean number of times each key patient element was identified by GPs across six consultations by six different GPs as reported two expert assessors

Scenario	Are the following factors explicitly reviewed in the video of this consultation?	Correctly identified, *n*
Case 1 (Jane Smith)	Increased HbA1c (from 54 to 64 mmol/mol) in last 6 months	6.0
	Significant intolerance to other oral agents	5.0
	Looser fitting clothes as described by patient	4.0
	Weight decreased by 3 kg in last 6 months	2.5
	Recent diagnosis of type 2 diabetes	2.0
	Ketone status	0.0
Case 2 (John Thompson)	Glycaemic control stable (53–58 mmol/mol over last 2 years)	6.0
	Patient expectation in respect of insulin therapy	6.0
	Urinary symptoms—more genitourinary than osmotic	6.0
	History of depression and self-harm	3.0
	Use of other oral agents contraindicated or limited by side effects	1.5
	Strategies to improve maculopathy, e.g. smoking cessation	0.5
Case 3 (Gary Jones)	Occupation bus driver—need to avoid hypoglycaemia	6.0
	High current HbA1c (68 mmol/mol)	6.0
	High BMI (36 kg/m^2)	5.0
	Patient wishes to improve HbA1c control because of early diabetic retinopathy	5.0
	Use of other oral agents limited by side effects (TZD)	2.0
	Impending driving medical—need to improve glycaemic control	1.0

HCPs reported the major factor causing the anxiety associated with starting injectable therapy is fear—of hypoglycaemia, injections, diabetic complications, and the implicit accusation of failure to manage lifestyle adequately. Nurses were more likely than GPs to respond to these fears by emphasising the importance of reassuring people with diabetes, and they valued the beneficial effects of peer support for people with T2D starting injections. HCPs broadly agreed that people with diabetes were reluctant to start injectable therapy. All HCPs were likely to consider social factors in relation to the likely efficacy/safety of treatment.

Regarding diabetes services organisation, nurses in primary care regarded QOF as incidental to the care that they provided. In contrast, while GPs did not universally endorse QOF treatment targets, they tended to believe that payments for performance had incentivised standardisation of care processes and raised the quality of diabetes care by their practices. Most HCPs felt that a lack of insulin prescribing courses was not a barrier to prescribing insulin in their localities but many, whilst keen, had not been on such a course. In contrast, a minority of participants felt that they had adequate access to training on GLP1 RA therapies. Whilst nurses generally did not report difficulty taking time out of clinical work to attend courses, GPs stated this was often difficult. The majority of nurses in primary care who participated in this study were not prescribers, but they were more likely than

Table 4 Summary of results from the healthcare professionals survey

Statement posed		Summary of responses
Clinician-related factors		
1	When I think a patient should start injectable therapy, I refer them to a specialist (i.e. endocrinologist in secondary care)	The vast majority of responders viewed initiation of injectable therapy as being routine practice in primary care and disagreed with this statement
2	My training has prepared me to initiate injectable therapies in patients with T2D	Just over half the comments about this statement, from GPs and from nurses in primary care, indicate reticence about initiating injectable therapy. Partly from lack of specific training and partly because of difficulty retaining competence
3	My role includes supporting patients in ways other than prescribing medication	There was unanimity of agreement to this statement
Patient-related factors		
4	Patients with a new diagnosis of diabetes should be referred to non-clinical sources of support	Provision of non-clinical support was generally viewed as being important for people with a new diagnosis of diabetes
5	Risk of hypoglycaemia is important when initiating injectable therapies for T2D	There was agreement from 86/87 responders. Only one response highlighted the lack of hypoglycaemia risk with GLP1 RAs
6	Psychological resistance of patients affects my decision-making regarding the initiation of injectable therapies in T2D	HCPs reported a reluctance to initiate injectable therapies was frequently encountered amongst people with diabetes in general practice
7	Patients' *clinical factors* (e.g. comorbidities) are important when initiating injectable therapies for T2D	There was general agreement with this statement. HCPs stated patient weight was an important consideration
8	Patients' *social circumstances* (e.g. employment or living conditions) are important when initiating injectable therapies for T2D	The responses make it clear that social circumstances are routinely considered by HCPS in primary care when deciding whether to initiate injectable therapy
System-related factors		
9	The differences in standards between primary and secondary care can affect consistent healthcare provision in T2D	There were mixed and neutral responses to this statement with no clear consensus
10	P4P (QOF) prompts improve the care I provide to patients with T2D	GPs tended to feel that QOF targets and payments have improved care for people with diabetes. In contrast, nurses felt that QOF was incidental to their work
11	Lack of funding to cover locum costs is a significant barrier to attending training on T2D (e.g. prescribing)	Nurses in primary care did not experience any significant barriers to obtaining training but GPs found it difficult

Table 4 continued

Statement posed	Summary of responses
12 Lack of insulin prescribing courses is a significant barrier to prescribing	Most people felt that lack of training was not a significant barrier but there were concerns reported around maintaining competence
13 Lack of GLP1 RA prescribing courses is a significant barrier to prescribing them	The majority reported a lack of training courses available and many stated initiation only occurred with specialist input

Statements are numbered

GPs to be the go-to people in their practices for initiation of injectable therapies.

DISCUSSION

Focus groups demonstrated the barriers to initiation of injectable therapies in T2D include patient fear; a lack of knowledge and misconceptions about diabetes amongst those with T2D; concerns about potential lifestyle restrictions and social stigma; feelings of failure; concerns from clinicians about the interplay between insulin and comorbidities such as obesity or arthritis; and fear of adverse effects in both patients and clinicians. Facilitators to initiation include patient support, education, good communication, and clinician competence. In simulated consultations, GPs recognised the need for injectables and arranged initiation, although they preferred GLP1 RAs even where insulin was more appropriate. The reasons for this apparent preference are not clear but may include the weight loss benefit, lack of hypoglycaemia risk, or potential weekly administration of a GLP1 RA when compared with insulin. Survey results demonstrated HCPs feel injectable therapy initiation should be performed in primary care although many reported lack of skills to do so and difficulty in gaining and maintaining experience.

Interpreting our data collectively (see extended discussion—Appendix 10) we found that clinicians have reasonable scientific and theoretical knowledge of T2D and its treatments and an understanding of patient barriers to injectable therapy initiation. GPs also broadly have the ability to identify the need to escalate to injectable therapy in practice. However, they lack the technical know-how to initiate injectable treatment (skills that were more common in nurses) and did not always select the appropriate injectable therapy in simulated consultations. However, nurses within primary care also reported difficulties in achieving and maintaining the skills to initiate injectable therapy. This lack of technical know-how may lead to a mismatch between the perceived and actual role of primary care in initiation of injectable therapies.

In agreement with previous studies, we found that patients were generally reluctant to use injectable treatments. Many of the patient factors potentially contributing to delayed initiation that we identified have been previously recognised, including misconceptions, concerns regarding social stigma, association of insulin with personal failure [18, 20, 34, 35]. To initiate injectable therapies, patients reported needing skilled and compassionate healthcare providers who they trusted. These factors have also been previously recognised as demonstrated by a recent systematic review of qualitative studies [36]. They also felt the need for additional education about diabetes in general, to be given reasons for treatment, and a practical demonstration of the injection method. Practical demonstration of GLP1 RA injection has previously shown to influence patient medication preference [36, 37]. The unique perspective in our study, compared with previous similar analyses [36], was the video-recorded simulated surgeries. These have led us to identify a barrier which appears not to have been fully appreciated in previous studies, namely the potential mismatch between the perceived role of primary care in initiation of injectable therapies and the available technical skills to deliver this.

Implications for Clinical Practice

The barriers identified here are modifiable targets. There is a need to upskill practitioners with the technical skills to support patients with the initiation of injectable therapies. Given the reports of small numbers of patients within each practice going through this process and care providers' difficulties in maintaining competence, this skill set should be concentrated in the hands of one or two care providers within each practice or group of practices. These practitioners require familiarity with different options for injectable therapies, to be able to select appropriate treatment options, and an ability to demonstrate their use to patients. In addition, they should be able to provide the education patients require to understand treatment rationale and be able to identify and address patients' personal concerns or fears. It should also be recognised that this process is complex and requires adequate time and follow-up. A well-structured national training programme is required to address these current issues and should be carefully scrutinised for effectiveness.

Strengths and Limitations

We have previously reported key strengths (representativeness of the sample, the high fidelity of the simulated surgeries, and benefits of both a micro and macro perspective) and limitations (limiting to English language participants, potential for interference of video in the observed consultations) of the study design [21].

Some additional limitations are noteworthy: firstly, data collection was designed to examine barriers to initiation of insulin and GLP1 RAs, yet we were unable to recruit any people with diabetes with GLP1 RA experience; therefore, the data presented focused on insulin. The HCPs had some limited experience of GLP1 RAs. Secondly, it is near impossible to prepare the patient actors to correctly answer all possible questions they may get asked during the consultation, and therefore some answers given may have been misleading in the consultation. We identified a few minor examples of this but our expert reviewers felt that this did not have a major effect on any of the consultations. Finally, for the video-studies we were required to inform the GPs about the overall purpose of the study. They were therefore aware that the research was exploring barriers and facilitators to the initiation of injectable therapies in T2D. This knowledge may have biased decision-making in the simulated consultations although we still found that GPs did not initiate insulin in our first scenario.

CONCLUSIONS

Primary care in the UK provides an appropriate setting for the initiation of injectable therapies and care providers widely report they feel initiation of injectables should be performed in primary care. However, whilst practitioners

readily recognise patients requiring treatment escalation, they lack the technical know-how to select and initiate the correct therapy. Patients are also often not ready to initiate injectable therapies as a result of a lack of knowledge, misconceptions and fear. Improving the knowledge, skills and confidence of a selected group of practitioners in primary care would facilitate provision of knowledge and practical skills required to successfully initiate injectable therapies for people with T2D.

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Compliance with Ethics Guidelines. As described in the methods this study used a sequential design where patient responses in study Phase 1 were utilised to inform the subsequent study phases. We received ethical approval from the Health Research Authority, London—Hampstead Research Ethics Committee (Ref 17/LO/1305). Each participant provided informed consent prior to involvement and all data were pseudonymised/anonymised as appropriate. This study was performed in

accordance with the Helsinki Declaration of 1964 and its later amendments.

Data Availability. To protect patient confidentiality data from this study cannot be made publicly available. Limited anonymised data can be made available to bona fide researchers on a case-by-case basis. Please contact the corresponding author to make a request.

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