

Barriers and facilitators to the initiation of injectable therapies for type 2 diabetes mellitus: a mixed methods study

Supplementary Appendices

Simon de Lusignan^{1,2,3*}, Andrew McGovern^{2,4}, William Hinton^{1,2}, Martin Whyte², Neil Munro², Emily D. Williams⁵, Afrodita Marcu⁵, John Williams^{1,2}, Filipa Ferreira^{1,2}, Julie Mount⁵, Manasa Tripathy^{1,2}, Emmanouela Konstantara², Ben Field², Michael Feher¹

Corresponding author: Simon de Lusignan, simon.delusignan@phc.ox.ac.uk

¹ Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, United Kingdom

² Department of Clinical & Experimental Medicine, University of Surrey, Guildford, United Kingdom

³ Royal College of General Practitioners, Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC), London, UK

⁴ The Institute of Clinical and Biological Sciences, University of Exeter, Exeter, United Kingdom

⁵ School of Health Sciences, University of Surrey, Guildford, United Kingdom

⁶ Eli Lilly and Company, Basingstoke, Hampshire, United Kingdom

Contents

Appendix 1: Focus groups and interviews	4
Topics for focus groups and interviews	4
Analysis of focus groups and interviews	4
Appendix 2: Fictional medical records and scenarios developed for the simulated surgeries	5
Patient 1 (“Jane Smith”)	5
Patient 2 (“John Thompson”)	8
Patient 3 (“Gary Jones”)	11
Appendix 3: The Global Consultation Rating Scale (GCRS) consultation scoring template	14
Appendix 4: The data capture forms for simulated surgeries	15
Appendix 5: Statements assessed in phase 2	18
Appendix 6: The questionnaire used in study phase 3	21
Appendix 7: The representativeness of included GP practices	30
Appendix 8: Themes emerging from focus groups with patients and practitioners	40
Barriers to initiation to injectable therapy	40
Theme 1: Lack of understanding by people with type 2 diabetes	40
Theme 2: Fear	41
Themes: 3. Comorbidities	44
Theme 4: Clinician competence	44
Theme 5: System limitations	46
Facilitators to the initiation of injectable therapy	48
Theme 6: Support for people with type 2 diabetes	48
Theme 7: Education	50
Theme 8: Communication	52
Appendix 9: Survey results	54
Appendix 10. Additional discussion of results	66
Results in the context of the critical realism theoretical framework	66
Context	66
Mechanism	67
The interplay between context and mechanism	68
Aristotelian and Social Learning Theory perspectives	68
Episteme	69
Techne	70

Phronesis.....	71
Knowledge gaps	71
References	72
Supplementary tables	73
Supplementary figures.....	78

Appendix 1: Focus groups and interviews

Topics for focus groups and interviews

Topics for the patient focus groups comprised:

- (i) Views on initiating injectable therapy
- (ii) Facilitators and barriers affecting initiation and adherence to injectable therapy
- (iii) Other factors that affect decision-making to initiate injectable therapies

Topics for HCP focus groups comprised:

- (i) Reflection on their personal decision-making processes regarding diabetes management
- (ii) Their insights into barriers and facilitators to initiation and adherence to injectable therapy.

Analysis of focus groups and interviews

Transcripts were assessed using framework analysis [1] according to a five-step process: (1) familiarisation; (2) identifying a thematic framework; (3) indexing; (4) charting; and (5) mapping and interpretation. Framework analysis is used to identify similarities, discrepancies, and interrelationships among data [2] and has been applied extensively in policy research and elsewhere [3, 4]. Data was processed and analysed using NVivo 11 software.

Appendix 2: Fictional medical records and scenarios developed for the simulated surgeries

Patient 1 (“Jane Smith”)

Scenario

This patient has had T2D for four years. She has a BMI of 28 and HbA1c of 64 mmol/mol. She could not tolerate more than a small dose on metformin initially and had to stop this eventually because of persistent and troublesome GI side effects. Over the years, she has tried several different classes of oral glucose lowering therapies and experienced significant intolerance with all except DPP4 inhibitors and sulphonylureas. She is currently taking a DPP4 and a sulphonylurea. She noticed that her clothes seem looser of late.

Medical record

Name: SMITH, Jane (Mrs)

Date of birth: 11-Jun-1960 (58 years old)

Problems

Active

11-Jun-2018 Adverse reaction to Pioglitazone Hydrochloride
05-Feb-2014 Type 2 diabetes mellitus
12-Sep-1985 Irritable bowel syndrome

Current Medication

Repeat

Mebeverine 135 mg tablets	One to be taken three times a day twenty minutes before food	100 tablet
Simvastatin 20 mg tablets	One to be taken at night	28 tablet
Enalapril 5mg tablets	One to be taken each day	29 tablet
Gliclazide 80mg tablets	Two to be taken twice a day	112 tablet
Alogliptin 25mg tablets	One to be taken daily	28 tablet

Previous Medication

Empagliflozin 10mg	One to be taken each day	28 tablet
Metformin 500mg tablets	Two to be taken twice a day	112 tablet

Adverse reactions / intolerances

11-Jun-2018 Adverse reaction to Empagliflozin
11-Jun-2018 Adverse reaction to Pioglitazone Hydrochloride
11-Jun-2018 Metformin not tolerated

Health status

11-Jun-2018	Cervical smear: negative		
11-Jun-2018	Alcohol consumption	6	U/week
11-Jun-2018	O/E - blood pressure reading	132/80	mmHg
11-Jun-2018	Body mass index	28.1	kg/m ²
11-Jun-2018	O/E - weight	86	kg
11-Jun-2018	O/E - height	175	cm
11-Jun-2018	Cigarette smoker	10	/day

Planned events

11-Jun-2018	ACEi or ARB monitoring advised
11-Jun-2018	No PHQ9 recorded
11-Jun-2018	Offer Diabetes UK Information Prescription
11-Jun-2018	No record of initial alcohol screening

Consultations

11-Jun-2018	Entered via administrator
Examination	O/E - height 175 cm • O/E - weight 86 kg • Body mass index 28.1 kg/m2 • Ideal weight 70.4 kg • O/E - blood pressure reading 132/80 mmHg
Procedure	Cervical neoplasia screen GMS: GMS
Result	Cervical smear: negative
Social	Alcohol consumption 6 U/week Cigarette smoker 10/day
Additional	Takes inadequate exercise
11-Jun-2018	Entered via nurse
Result	O/E - left foot pulses present • O/E - right foot pulses present • 10g monofilament sensation L foot normal • 10g monofilament sensation R foot normal • O/E - Vibration sense of left foot normal • Vibration sense of right foot normal • O/E - Left diabetic foot at low risk • O/E - Right diabetic foot at low risk
16-Jan-2018	Entered via administrator
Examination	O/E - height 175 cm • O/E - weight 89 kg • Body mass index 29.1 kg/m2 • Ideal weight 70.4 kg • O/E - blood pressure reading 126/78mmHg
16-Jan-2018	Entered via nurse
Result	O/E - left foot pulses present • O/E - right foot pulses present • 10g monofilament sensation L foot normal • 10g monofilament sensation R foot normal • O/E - Vibration sense of left foot normal • Vibration sense of right foot normal • O/E - Left diabetic foot at low risk • O/E - Right diabetic foot at low risk
16-Jan-2018	Entered via GP
Problem	Type 2 diabetes mellitus (Review)
Examination	Haemoglobin A1c level - IFCC standardised 64 mmol/mol
Comment	Increase gliclazide to 160mg bd. Review in 6/12
17-Jul-2017	Entered via GP
Problem	Type 2 diabetes mellitus (Review)
Examination	Haemoglobin A1c level - IFCC standardised 54 mmol/mol
Comment	Empagliflozin caused thrush. To stop. Add alogliptin 25mg od Watch gliclazide 80mg bd
05-Jan-2017	Entered via GP
Problem	Type 2 diabetes mellitus (Review)
Examination	Haemoglobin A1c level - IFCC standardised 62 mmol/mol
Comment	Add empagliflozin 10mg and watch gliclazide. Review in 6/12
12-Jul-2016	Entered via GP
Problem	Type 2 diabetes mellitus (Review)
Examination	Haemoglobin A1c level - IFCC standardised 68 mmol/mol
Comment	Metfomin caused GI side-effects (diarrhoea). To stop. Add gliclazide 80mg bd. Review in 6/12

Values and Investigations

11-Jun-2018	Cervical smear: negative		
11-Jun-2018	Alcohol consumption	6	U/week

11-Jun-2018	O/E - blood pressure reading	132/80	mmHg
11-Jun-2018	Ideal weight	70.4	kg
11-Jun-2018	Body mass index	28.1	kg/m2
11-Jun-2018	O/E - weight	86	kg
11-Jun-2018	O/E - height	175	cm
11-Jun-2018	Cigarette smoker	10	/day
11-Jun-2018	Body mass index	28	kg/m2
17-May-2018	Serum cholesterol	4.6	mmol/L
17-May-2018	Urine albumin:creatinine ratio	0.9	mg/mmol
17-May-2018	eGFR	>60	umol/L
17-May-2018	Haemoglobin A1c level - IFCC standardised	64	mmol/mol
16-Jan-2018	O/E - blood pressure reading	126/78	mmHg
16-Jan-2018	Ideal weight	70.4	kg
16-Jan-2018	Body mass index	29.1	kg/m2
16-Jan-2018	O/E - weight	89	kg
16-Jan-2018	O/E - height	175	cm
16-Jan-2018	Haemoglobin A1c level - IFCC standardised	64	mmol/mol
16-Jan-2018	Serum cholesterol	4.3	mmol/L
16-Jan-2018	Urine albumin:creatinine ratio	1.1	mg/mmol
16-Jan-2018	eGFR	>60	umol/L
17-Jul-2017	Haemoglobin A1c level - IFCC standardised	54	mmol/mol

Patient 2 ("John Thompson")

Scenario

This patient has had T2D for five years, a BMI of 29 and is on triple therapy of metformin, sulfonylurea and a DPP4 inhibitor at maximal tolerated doses. He has a history of depression for which he has been hospitalised on two occasions. He has urinary symptoms on close questioning that are more genitourinary than osmotic in origin. He has developed early maculopathy. He has had HbA1c levels that have ranged between 53 and 58 mmol/mol for the last two years. He is very keen on achieving better glycaemic control and has heard that insulin is much the best treatment for T2D in the long run.

Medical record

Name: THOMPSON, John

Date of birth: 01-Jan-1966 (52 years old)

Problems

Active

23-Jan-2018	Background diabetic retinopathy.	Review routine retinal screening
09-Jun-2015	Chronic depression	
14-Apr-2015	Essential hypertension	
27-Feb-2015	[X] Intentional self-harm.	Hospitalised
24-Dec-2014	[X] Severe depressive episode without psychotic symptoms	Hospitalised
14-Aug-2013	Type 2 diabetes mellitus	

Medication

Acute

Repeat

Sertraline 100mg tablets	One to be taken each day	28 tablet
Atorvastatin 20 mg tablets	One to be taken each night	28 tablet
Enalapril 5mg tablets	One to be taken twice a day	56 tablet
Gliclazide 80mg tablets	Two to be taken twice a day	112 tablet
Metformin 500mg tablets	Two to be taken twice a day	112 tablet

Adverse reactions / intolerances

None recorded

Health status

11-Jun-2018	O/E - blood pressure reading	128/78	mmHg
23-Jan-2018	Ex-light smoker	1-9	/day
23-Jan-2018	Alcohol consumption	4	U/week
23-Jan-2018	Body mass index	29	kg/m2
23-Jan-2018	O/E - weight	94	kg
23-Jan-2018	O/E - height	180	cm

Planned events

11-Jun-2018	ACEi or ARB monitoring advised
11-Jun-2018	No PHQ9 recorded
11-Jun-2018	Offer Diabetes UK Information Prescription
11-Jun-2018	No record of initial alcohol screening

Consultations

11-Jun-2018	Entered via nurse
Result	O/E - left foot pulses present • O/E - right foot pulses present • 10g monofilament sensation L foot normal • 10g monofilament sensation R foot normal • O/E - Vibration sense of left foot normal • Vibration sense of right foot normal • O/E - Left diabetic foot at low risk • O/E - Right diabetic foot at low risk
11-Jun-2018	Entered via GP
Problem	Type 2 diabetes mellitus (Review)
History	Background retinopathy maculopathy
Examination	O/E - blood pressure reading 128/78 mmHg • Haemoglobin A1c level - IFCC standardised 58 mmol/mol • eGFR >60 • Urine albumin:creatinine ratio 1.4 mg/mmol • Serum cholesterol 4.4 mmol/L
Comment	Refer Eye Unit
23-Jan-2018	Entered via administrator
Examination	O/E - height 180 cm • O/E - weight 94 kg • Body mass index 29.1 kg/m ² • Ideal weight 74.5 kg
Social	Alcohol consumption 4 U/week • Ex smoker • Stopped smoking (12-Dec-2017) • Ex-light smoker (1-9/day)
Additional	Takes inadequate exercise
23-Jan-2018	Entered via nurse
Result	O/E - left foot pulses present • O/E - right foot pulses present • 10g monofilament sensation L foot normal • 10g monofilament sensation R foot normal • O/E - Vibration sense of left foot normal • Vibration sense of right foot normal • O/E - Left diabetic foot at low risk • O/E - Right diabetic foot at low risk
23-Jan-2018	Entered via nurse
Examination	O/E - blood pressure reading 126/80 mmHg • Haemoglobin A1c level - IFCC standardised 53 mmol/mol • Serum creatinine >60 umol/L • Urine albumin:creatinine ratio 0.8 mg/mmol
23-Jan-2018	Entered via GP
Problem	Type 2 diabetes mellitus (Review)
Examination	Serum cholesterol 5.4 mmol/L
Comment	No change to current therapy. No hypos. Switch simvastatin to atorvastatin 20mg nocte. Review 6/12
24-Jul-2017	Entered via GP
Problem	Type 2 diabetes mellitus (Review)
Examination	Haemoglobin A1c level - IFCC standardised 55 mmol/mol
Comment	Slightly anxious during consultation. Seeing CPN next week. Review diabetic control 6/12.

Values and Investigations

11-Jun-2018	Serum cholesterol	4.4	mmol/L
11-Jun-2018	Urine albumin:creatinine ratio	1.4	mg/mmol
11-Jun-2018	eGFR	>60	umol/L
11-Jun-2018	Haemoglobin A1c level - IFCC standardised	58	mmol/mol
11-Jun-2018	O/E - blood pressure reading	128/78	mmHg
23-Jan-2018	Alcohol consumption	4	U/week
23-Jan-2018	Ideal weight	74.5	kg
23-Jan-2018	Body mass index	29	kg/m ²
23-Jan-2018	O/E - weight	94	kg
23-Jan-2018	O/E - height	180	cm

23-Jan-2018	Urine albumin:creatinine ratio	0.8	mg/mmol
23-Jan-2018	eGFR	>60	umol/L
23-Jan-2018	Haemoglobin A1c level - IFCC standardised	53	mmol/mol
23-Jan-2018	O/E - blood pressure reading	126/80	mmHg
23-Jan-2018	Serum cholesterol	5.4	mmol/L
24-Jul-2017	Haemoglobin A1c level - IFCC standardised	55	mmol/mol

Patient 3 ("Gary Jones")

Scenario

This patient will be a bus driver with a six-year history of T2D. He also has hypertension and hypercholesterolaemia. He has a BMI of 36. His current glucose lowering medication includes metformin, sitagliptin and empagliflozin at maximum recommended doses. He refused to take pioglitazone in case of further weight gain. His HbA1c is 68 mmol/mol. He wants improved glycaemic control as he has now developed early diabetic retinopathy. Whilst he is worried about his elevated HbA1c, he does not want to risk hypoglycaemia. His driving medical is due in 3 months' time.

Medical record

Name: JONES, Gary

Date of birth: 14-Feb-1964 (54 years old)

Problems

Active

11-Jun-2018	Background diabetic retinopathy.	Check in 6/12
11-Jul-2012	Type 2 diabetes mellitus	
12-Jun-2008	Hypercholesterolaemia	
08-April-2008	Essential hypertension	

Current Medication

Acute

Empagliflozin 25mg tablets	One to be taken each day	28 tablet
Amlodipine 5 mg tablets	One to be taken each night	28 tablet

Repeat

Atorvastatin 40 mg tablets	One to be taken each night	28 tablet
Indapamide 1.5mg modified-release tablets	One to be taken each morning	30 tablet
Enalapril 20mg tablets	One to be taken each day	28 tablet
Sitagliptin 100mg tablets	One to be taken each day	28 tablets
Metformin 500mg tablets	Two to be taken twice a day	112 tablet

Previous Medication

Empagliflozin 10mg tablets	One to be taken each day	28 tablet
----------------------------	--------------------------	-----------

Adverse reactions / intolerances

None recorded

Health status

11-Jun-2018	O/E - blood pressure reading	140/84	mmHg
11-Jun-2018	Body mass index	36.2	kg/m ²
11-Jun-2018	O/E - weight	111	kg
11-Jun-2018	O/E - height	175	cm
09-Jan-2018	Cigarette smoker	20	/day
09-Jan-2018	Alcohol consumption	4	U/week

Planned events

11-Jun-2018	ACEi or ARB monitoring advised
11-Jun-2018	No PHQ9 recorded
11-Jun-2018	Offer Diabetes UK Information Prescription
11-Jun-2018	No record of initial alcohol screening

Consultations

11-Jun-2018	Entered via GP
Examination	Haemoglobin A1c level - IFCC standardised 68 mmol/mol • eGFR >60 umol/L • Urine albumin:creatinine ratio 1.3 mg/mmol • Serum cholesterol 5.8 mmol/L
11-Jun-2018	Entered via nurse
Result	O/E - left foot pulses present • O/E - right foot pulses present • 10g monofilament sensation L foot normal • 10g monofilament sensation R foot normal • O/E - Vibration sense of left foot normal • Vibration sense of right foot normal • O/E - Left diabetic foot at low risk • O/E - Right diabetic foot at low risk
11-Jun-2018	Entered via administrator
Examination	O/E - height 175 cm • O/E - weight 111 kg • Body mass index 36.2 kg/m2 • Ideal weight 70.4 kg • O/E - blood pressure reading 140/84 mmHg
Comment	Recheck bp in 1/12 and ? increase enalapril
09-Jan-2018	Entered via administrator
Examination	O/E - height 175 cm • O/E - weight 107 kg • Body mass index 34.9 kg/m2 • Ideal weight 70.4 kg
Social	Alcohol consumption 4 U/week • Cigarette smoker 20/day
Additional	Takes inadequate exercise
09-Jan-2018	Entered via nurse
Examination	O/E - blood pressure reading 146/94 mmHg • Haemoglobin A1c level - IFCC standardised 64 mmol/mol • eGFR >60 umol/L • Urine albumin:creatinine ratio 1.1 mg/mmol • Serum cholesterol 5.0 mmol/L
Medication	Amlodipine 5mg tablets One to be taken each day, 28 tablet
Comment	Increase antihypertensive agents Increase empagliflozin to 25mg od Add amlodipine 5mg od
Result	O/E - left foot pulses present • O/E - right foot pulses present • 10g monofilament sensation L foot normal • 10g monofilament sensation R foot normal • O/E - Vibration sense of left foot normal • Vibration sense of right foot normal • O/E - Left diabetic foot at low risk • O/E - Right diabetic foot at low risk
10-Jul-2017	Entered via GP
Problem	Type 2 diabetes mellitus (First) (11-Jul-2012)
Medication	Empagliflozin 10mg tablets take one daily, 28 tablet
Comment	Weight has increased. HbA1c is now 66. Does not want pioglitazone. Reluctant re injectable therapy. Add empagliflozin 10mg od

Values and Investigations

11-Jun-2018	Serum cholesterol	5.8	mmol/L
11-Jun-2018	Urine albumin:creatinine ratio	1.3	mg/mmol
11-Jun-2018	eGFR	>60	umol/L
11-Jun-2018	Haemoglobin A1c level - IFCC standardised	68	mmol/mol
11-Jun-2018	O/E - blood pressure reading	140/84	mmHg
11-Jun-2018	Ideal weight	70.4	kg
11-Jun-2018	Body mass index	36.2	kg/m2
11-Jun-2018	O/E - weight	111	kg

11-Jun-2018	O/E - height	175	cm
09-Jan-2018	Cigarette smoker	20	/day
09-Jan-2018	Alcohol consumption	4	U/week
09-Jan-2018	Ideal weight	70.4	kg
09-Jan-2018	Body mass index	34.9	kg/m ²
09-Jan-2018	O/E - weight	107	kg
09-Jan-2018	O/E - height	175	cm
09-Jan-2018	Serum cholesterol	5	mmol/L
09-Jan-2018	Urine albumin:creatinine ratio	1.1	mg/mmol
09-Jan-2018	eGFR	>60	umol/L
09-Jan-2018	Haemoglobin A1c level - IFCC standardised	64	mmol/mol
09-Jan-2018	O/E - blood pressure reading	146/84	mmHg

Appendix 3: The Global Consultation Rating Scale (GCRS) consultation scoring template

The GCRS scoring template as reported in: Burt, J., et al., *Assessing communication quality of consultations in primary care: initial reliability of the Global Consultation Rating Scale, based on the Calgary-Cambridge Guide to the Medical Interview*. BMJ Open, 2014. 4(3): p. e004339.

Global Consultation Rating Scale (GCRS)	Good (2)	Adequate (1)	Not done/poor (0)	Not applicable
Initiating the session				
Greets patient				
Introduces self and nature of interview				
Demonstrates interest and respect, attends to patient's physical comfort				
Uses appropriate opening question				
Overall Score for Initiating the Session				
Gathering Information				
Listens attentively, minimising interruption and leaving space for patient				
Encourages patient to tell the story of the problem(s) from when first started to the present				
Checks and screens for further problems and negotiates agenda				
Overall Score for Problem Identification				
Uses open and closed questions, appropriately moving from open to closed				
Facilitates patient's responses verbally and non-verbally e.g. silence, repetition, paraphrasing				
Picks up and responds to verbal and non-verbal cues (body language, speech, facial expression)				
Clarifies statements which are vague or need amplification				
Periodically summarises & invites patient to correct interpretation or provide further information.				
Uses clear, easily understood language, avoids jargon				
Overall Score for Problem Exploration				
Actively determines patient's perspective (ideas, concerns, expectations, feelings, effects on life)				
Appropriately and sensitively responds to and further explores patient's perspective				
Overall Score for Patient's Perspective				
Building the relationship				
Demonstrates appropriate non-verbal behaviour e.g. eye contact, posture, position, movement, facial				
Overall Score for Non-verbal Communication				
Acknowledges patient's views and feelings; is not judgmental				
Uses empathy to communicate appreciation of the patient's feelings or predicament				
Provides support: expresses concern, understanding, willingness to help				
Overall Score for Developing Rapport				
Providing Structure				
Progresses from one section to another using signposting; includes rationale for next section				
Structures interview in logical sequence, attends to timing, keeps interview on task				
Overall Score for Providing Structure				
Providing the correct amount/type of info for the individual patient				
Chunks and checks, using patient's response to guide next steps				
Assesses the patient's starting point (good if carefully tailors explanation)				
Discovers what other information would help patient, seeks and addresses patient's info needs				
Overall Score for providing correct amount and type of information				
Aiding accurate recall and understanding				
Organises explanation (good if uses signposting/summarising)				
Checks patient's understanding (good if asks patient to restate information given)				
Uses clear language, avoids jargon and confusing language				
Overall Score for aiding accurate recall and understanding				
Achieving a shared understanding: incorporating the patient's perspective				
Relates explanations to patient's illness framework				
Encourages patient to contribute reactions, feelings and own ideas (good if responds well)				
Picks up and responds to patient's non-verbal and covert verbal cues				
Overall Score for incorporating the patient's perspective				
Planning: shared decision making				
Explores management options with patient				
Involves patient in decision making (good if establishes level of involvement patient wishes)				
Appropriately negotiates mutually acceptable action plan				
Overall Score for planning and shared decision-making				
Closure				
Contracts with patient re next steps				
Safety nets				
Summarises session briefly and clarifies plan of care				
Final check that patient agrees and is comfortable with plan				
Overall Score for closure				

PLEASE COMPLETE THIS SECTION FOR THE CONSULTATION AS A WHOLE
 Excellent Good Acceptable Borderline Unacceptable

Appendix 4: The data capture forms for simulated surgeries

Stem question for clinical cases: the expert view

What factors should clinicians demonstrate they have reviewed in determining whether to recommend use of injectable therapies in these simulated patients?

* 1. Name of analyst

* 2. Name of GP:

* 3. Case 1: Jane Smith

Are the following factors explicitly reviewed in the video of this consultation:

	Yes	No
Recent diagnosis of Type 2 diabetes	☐	☐
Weight decreased by 3kgs in last 6 months	☐	☐
Looser fitting clothes as described by patient	☐	☐
Increased HbA1c (from 54 to 64 mmol/mol) in last 6 months	☐	☐
Significant intolerance to other OHAs	☐	☐
Ketone status	☐	☐

* 4. To what extent do you feel that the consultation (**Jane Smith**) was doctor or patient centred?

- ☐ Very doctor centred
- ☐ Fairly doctor centred
- ☐ Neutral (well balanced)
- ☐ Fairly patient centred
- ☐ Very patient centred

5. Do you have any comments you would like to make about this consultation?

*** 6. Case 2: John Thompson**

Are the following factors explicitly reviewed in the video of this consultation:

	Yes	No
Glycaemic control stable (53-58mmol/mol over last 2 years)	☐	☐
History of depression and self harm	☐	☐
Patient expectation in respect of insulin therapy	☐	☐
Urinary symptoms - more genitourinary than osmotic	☐	☐
Use of other OHAs c/i or limited by s/e (TZD and SGLT2 inhibitors)	☐	☐
Strategies to improve maculopathy. e.g. smoking cessation	☐	☐

*** 7. To what extent do you feel that the consultation (John Thompson) was doctor or patient centred?**

- ☐ Very doctor centred
- ☐ Fairly doctor centred
- ☐ Neutral (well balanced)
- ☐ Fairly patient centred
- ☐ Very patient centred

8. Do you have any comments you would like to make about this consultation?

* 9. Case 3: Gary Jones

Are the following factors explicitly reviewed in the video of this consultation:

	Yes	No
Occupation bus driver – need to avoid hypoglycaemia	☐	☐
Impending medical – need to improve glycaemic control	☐	☐
High current HbA1c (68 mmol/mol)	☐	☐
High BMI (36 kg/m2)	☐	☐
Patient wishes to improve HbA1c control due to early diabetic retinopathy	☐	☐
Use of other OHA limited by s/e (TZD)	☐	☐

* 10. To what extent do you feel that the consultation (**Gary Jones**) was doctor or patient centred?

- ☐ Very doctor centred
- ☐ Fairly doctor centred
- ☐ Neutral (well balanced)
- ☐ Fairly patient centred
- ☐ Very patient centred

11. Do you have any comments you would like to make about this consultation?

Appendix 5: Statements assessed in phase 2

Study title: Further Insights into the management of Type 2 Diabetes Mellitus (T2D)

Version 1 – 21/08/2018



Thank you for considering taking part in this research. Please state how appropriate you consider the statements below:

Clinicians		Very Strongly Disagree	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Very Strongly Agree
1	When I think a patient should start injectable therapy, I refer them to a specialist (i.e. endocrinologist in secondary care).	☐	☐	☐	☐	☐	☐	☐
Further comments:								
2	My training has prepared me to initiate injectable therapies in patients with T2D.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
3	My role includes supporting patients in ways other than prescribing medication.	☐	☐	☐	☐	☐	☐	☐
Further comments:								

Patients		Very Strongly Disagree	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Very Strongly Agree
4	Patients with a new diagnosis of diabetes should be referred to non-clinical sources of support.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
5	Risk of hypoglycaemia is important when initiating injectable therapies for T2D.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
6	Psychological resistance of patients affects my decision-making regarding the initiation of injectable therapies in T2D.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
7	Patients' <i>clinical factors</i> (e.g. comorbidities) are important when initiating injectable therapies for T2D.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
8	Patients' <i>social circumstances</i> (e.g. employment or living conditions) are important when initiating injectable therapies for T2D.	☐	☐	☐	☐	☐	☐	☐
Further comments:								

	System	Very Strongly Disagree	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Very Strongly Agree
9	The differences in standards between primary and secondary care can affect consistent healthcare provision in T2D.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
10	P4P (QOF) prompts improve the care I provide to patients with T2D.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
11	There is lack in availability of prescribing courses in the local area.	☐	☐	☐	☐	☐	☐	☐
Further comments:								
12	Lack of funding to cover locum costs is a significant barrier to attending training on T2D (e.g. prescribing).	☐	☐	☐	☐	☐	☐	☐
Further comments:								
13	Lack of GLP1 RA prescribing courses is a significant barrier to prescribing them.	☐	☐	☐	☐	☐	☐	☐
Further comments:								

Appendix 6: The questionnaire used in study phase 3

Thank you for your interest in this study. Please read the information below for further details about the study and how you can contribute.

What is the purpose of the study?

This study forms part of the **Further Insights into the management of type 2 diabetes (T2D) project**, carried out by the Section of Clinical Medicine & Ageing at the **University of Surrey**. The purpose of the project is to investigate the delay in intensification to injectable therapy in T2D (insulin and GLP1 RAs) by exploring the perceptions of healthcare professionals and patients.

How can I contribute?

In this survey, you will be provided with 13 statements and the level of agreement (agreement, disagreement, mixed views) to these between experts, as well as themes drawn from their comments. This information was collected in an earlier phase of the project. For example, if all experts have agreed that they disagree with Statement X, then this is marked as 'agreement'. You will be asked to provide your view on the opinions of the experts and their comments. At the end of the survey, we'll ask you some questions about yourself to collate demographic information.

Estimated time for completion of the questionnaire is 5 minutes.

You have the right to withdraw from the study at any point during the testing and analysis phase.

For more detailed information about the purpose of the study, or if you have any questions or require assistance, please contact **Emma Konstantara** at -----

----- Next page -----

Please state your view on the comments from the experts.

Statement 1: When I think a patient should start injectable therapy, I refer them to a specialist (i.e. endocrinologist in secondary care).

Experts' result: Agreement (100% selected "Disagree")

Experts' rationale of their responses:

1. Referral to diabetes nurse
2. Referral to diabetes lead GP

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 2: My training has prepared me to initiate injectable therapies in patients with T2D.

Experts' result: Disagreement (40% selected "Disagree", 20% selected "Agree", 20% selected "Strongly Agree", 20% selected "Neutral")

Experts' rationale of their responses:

Referral to diabetes nurse (out of my remit)

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 3: My role includes supporting patients in ways other than prescribing medication.

Experts' result: Agreement (60% selected "Strongly Agree", 40% selected "Very Strongly Agree")

Experts' rationale of their responses:

Also offer:

1. Holistic care
2. Comorbidities
3. Lifestyle advice
4. Patient education
5. Motivational skills

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 4: Patients with a new diagnosis of diabetes should be referred to non-clinical sources of support.

Experts' result: Agreement (40% selected "Agree", 40% selected "Strongly Agree", 20% selected "Neutral")

Experts' rationale of their responses:

1. Exercise on prescription
2. Referral to DESMOND course
3. Referral to Diabetes UK website

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 5: Risk of hypoglycaemia is important when initiating injectable therapies for T2D.

Experts' result: Agreement (80% selected "Strongly Agree", 20% selected "Very Strongly Agree")

Experts' rationale of their responses:

Yes because insulin can have implications for:

1. Employment
2. Driving license
3. Elderly
4. Interaction with other medication

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 6: Reluctance of patients to initiate injectable therapies is commonly encountered in general practice.

Experts' result: Agreement (80% selected "Agree", 20% selected "Strongly Agree")

Experts' rationale of their responses:

1. Yes because we need to achieve joint ownership so that patient adheres.
2. Still offer injectable but would seek other options.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 7: Patients' clinical factors (e.g. comorbidities) are important when initiating injectable therapies for T2D.

Experts' result: Agreement (60% selected "Strongly Agree", 20% selected "Agree", 20% selected "Neutral")

Experts' rationale of their responses:

1. Weight
2. CVD
3. BP
4. Presence of complications

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 8: Patients' social circumstances (e.g. employment or living conditions) are important when initiating injectable therapies for T2D.

Experts' result: Agreement (60% selected "Strongly Agree", 20% selected "Agree", 20% selected "Neutral")

Experts' rationale of their responses:

Yes, taking into account:

1. Lifestyle / living arrangements
2. Employment status / occupation
3. Family support

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 9: The differences in the level of glycaemia between primary and secondary care.

Experts' result: Disagreement (40% selected "Agree", 20% selected "Very Strongly Agree", 20% selected "Disagree", 20% selected "Neutral")

Experts' rationale of their responses:

1. We only refer to secondary care only when complicated cases (CCG policy).
2. Same standards in both, expecting more clinical inertia in primary care.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 10: P4P (QOF) prompts improve the care I provide to patients with T2D.

Experts' result: Agreement (60% selected "Agree", 40% selected "Neutral")

Experts' rationale of their responses:

1. Reminders are useful.
2. QOF has improved care.
3. IT issues make QOF unreliable.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 11: Lack of funding to cover locum costs is a significant barrier to attending training on T2D (e.g. prescribing).

Experts' result: Mixed views (40% selected "Strongly Agree", 20% selected "Agree", 20% selected "Disagree", 20% selected "Neutral")

Experts' rationale of their responses:

1. Disagree, I would take annual leave to attend a course without need for locum.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 12: Lack of insulin prescribing courses is a significant barrier to prescribing them.

Experts' result: Mixed views (20% selected "Strongly Disagree", 20% selected "Disagree", 20% selected "Neutral", 20% selected "Agree", 20% selected "Strongly Agree")

Experts' rationale of their responses:

No comments were provided by the experts on this statement. Please provide yours below.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Please state your view on the statement below and the comments from the experts.

Statement 13: Lack of GLP1 RA prescribing courses is a significant barrier to prescribing them.

Experts' result: Mixed views (40% selected "Disagree", 20% selected "Agree", 20% selected "Strongly Agree", 20% selected "Neutral")

Experts' rationale of their responses:

1. N/A as not initiating injectables for T2D within practice.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response. _____

----- Next page -----

Demographic Characteristics

What is your role?

- GP
- Nurse in primary care
- Nurse in secondary care
- Specialist (diabetologist)
- Specialist other (please specify)

What diabetes specific training have you received, if any? Please select all that apply.

• Continuing medical education sessions

- Less than 4 hours
- 5-9 hours
- 10+ hours

- Short course (1-6 weeks)
- Postgraduate certificate
- Specialist accreditation
- Other (please specify)

- None

Gender

- Male
- Female
- Other

Which category below includes your age?

- 18 - 24
- 25 - 34
- 35 - 44
- 45 - 54
- 55 - 64
- 65 - 74
- 75 - 84

Please fill in the names of the general practice(s)/hospital(s) and town/city you work in.

Practice(s) / Hospital(s)

Town/City

Choose one option that best describes your ethnic group or background.

- ☐ **White**
- ☐ English / Welsh / Scottish / Northern Irish / British
- ☐ Irish
- ☐ Any other white background, please specify

- ☐ **Asian / Asian British**
- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Chinese
- ☐ Any other Asian background, please describe

- ☐ **Black / African / Caribbean / Black British**
- ☐ African
- ☐ Caribbean
- ☐ Any other Black / African / Caribbean background, please specify

- ☐ **Mixed / Multiple ethnic groups**
- ☐ Please specify

- ☐ **Other ethnic group**
- ☐ Arab
- ☐ Any other ethnic group, please specify

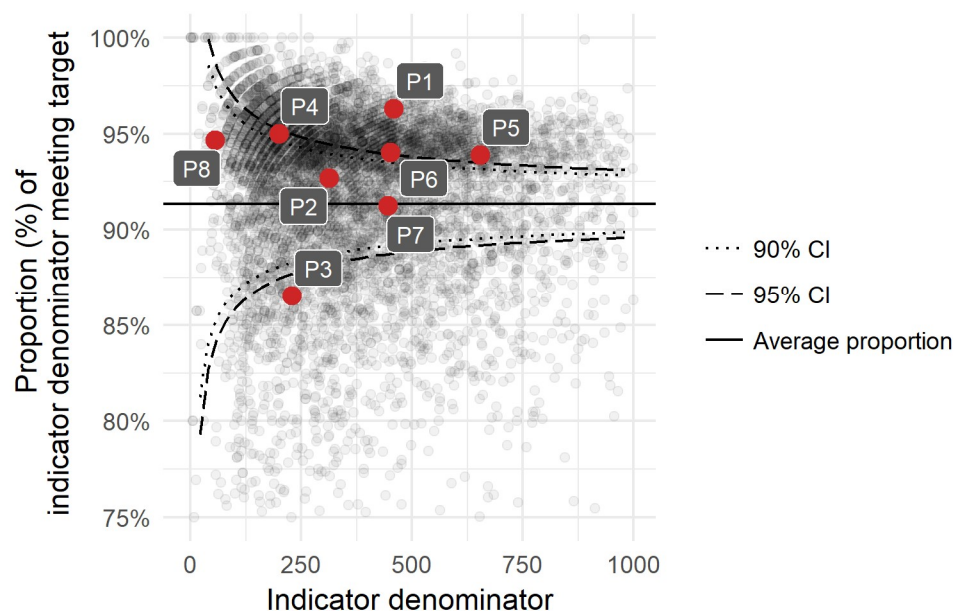
If you would like the results to be sent to you, please write your email address here: _____

----- *Next page* -----

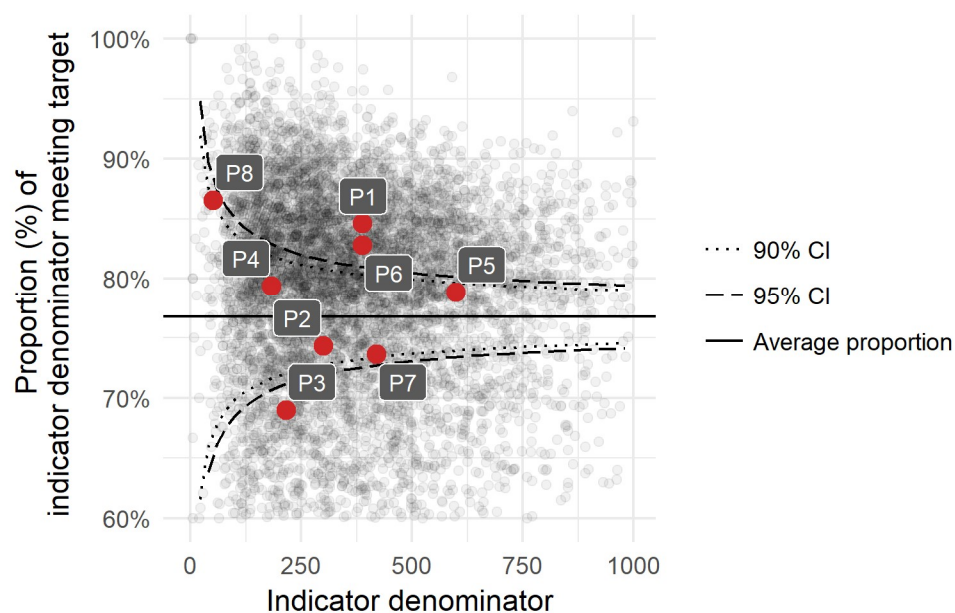
Congratulations, you have completed the survey!

Appendix 7: The representativeness of included GP practices

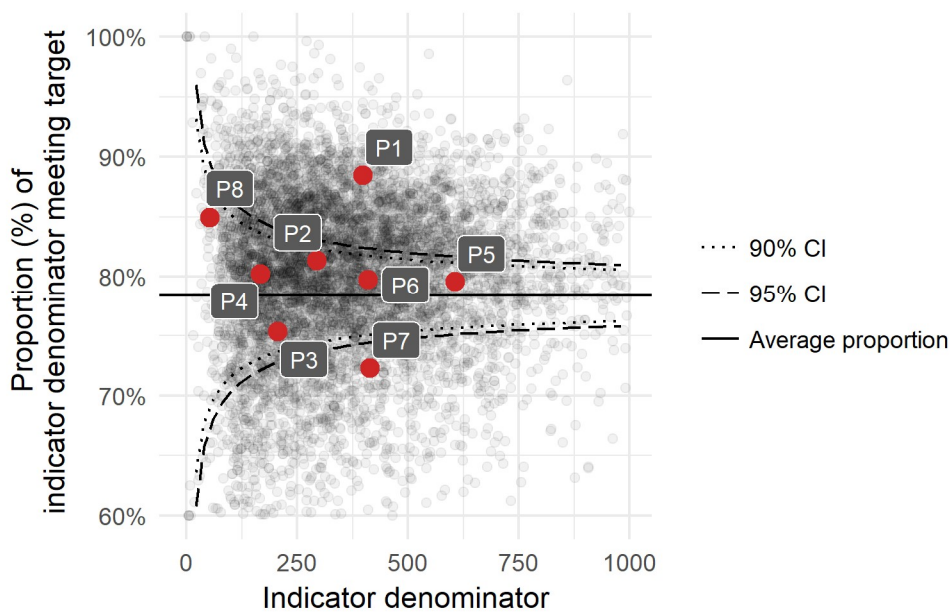
The distribution achievement of QOF diabetes indicators targets of the eight included study practices compared with all other practices in England and Wales.



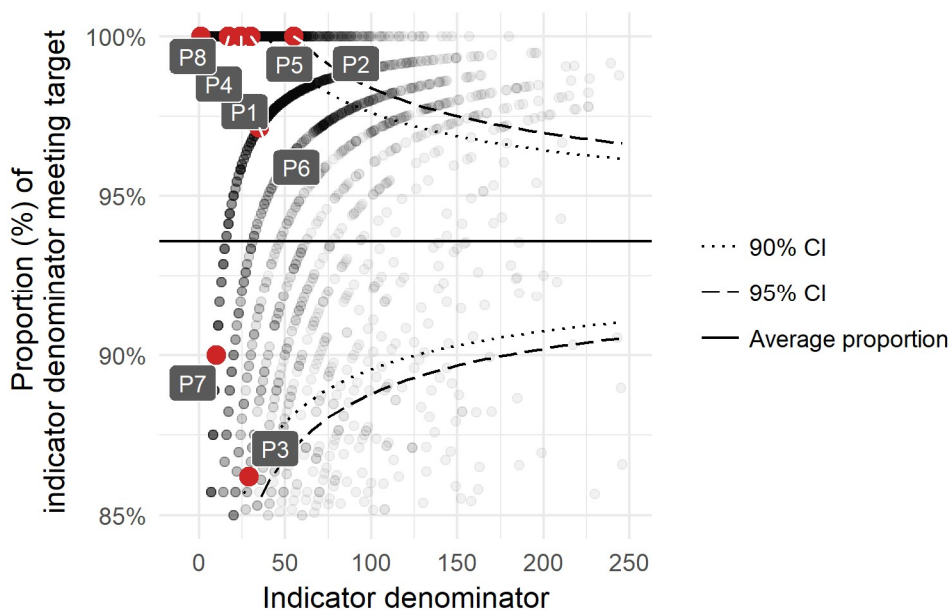
Indicator DM002: The percentage of patients with diabetes, on the register, in whom the last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less.



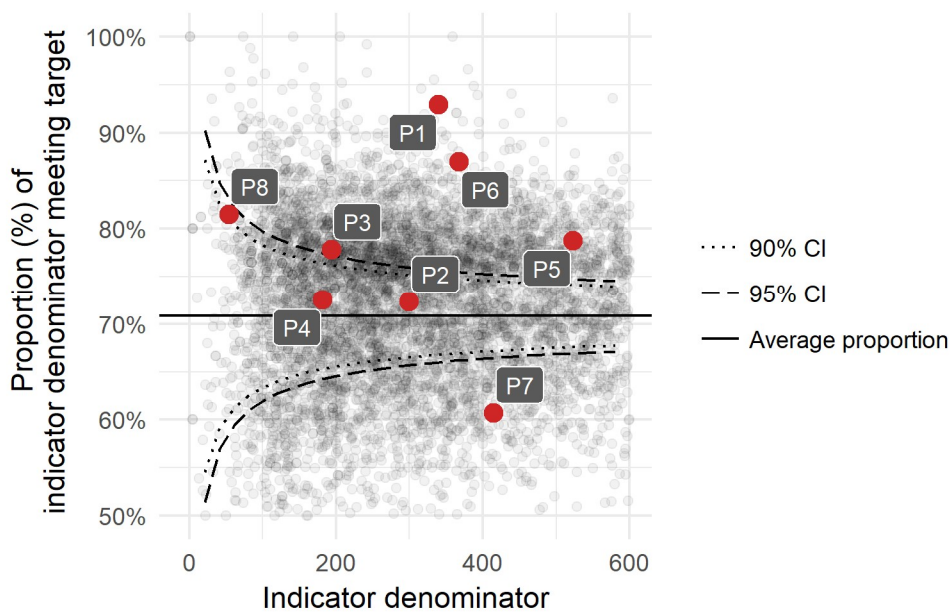
Indicator DM003: The percentage of patients with diabetes, on the register, in whom the last blood pressure reading (measured in the preceding 12 months) is 140/80 mmHg or less.



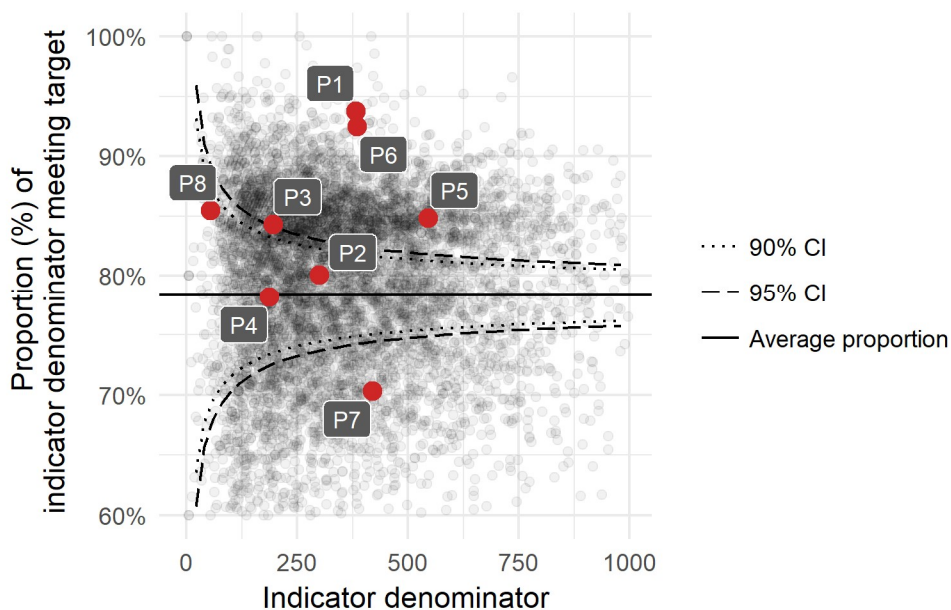
Indicator DM004: The percentage of patients with diabetes, on the register, whose last measured total cholesterol (measured within the preceding 12 months) is 5 mmol/l or less.



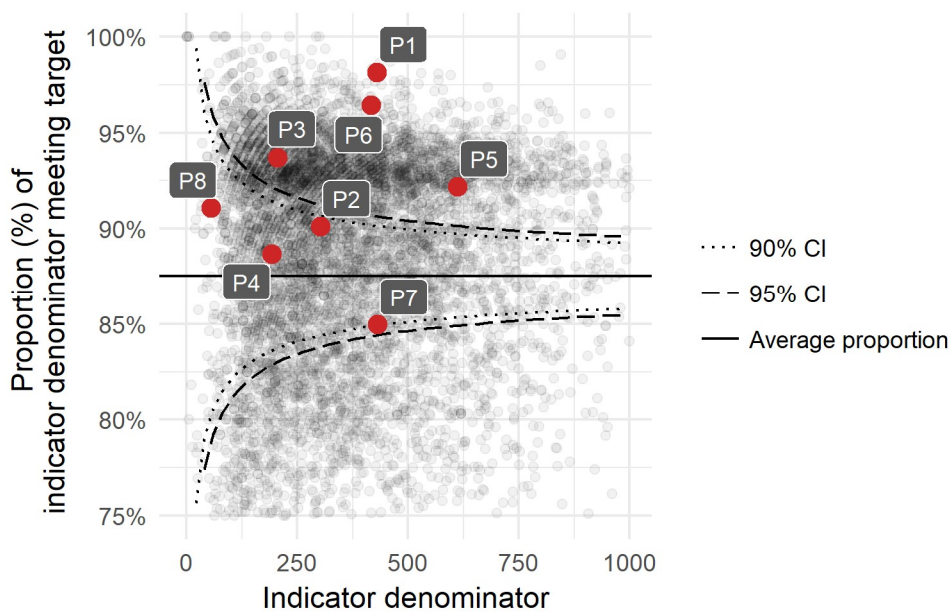
Indicator DM006: The percentage of patients with diabetes, on the register, with a diagnosis of nephropathy (clinical proteinuria) or micro-albuminuria who are currently treated with an ACE-I (or ARBs).



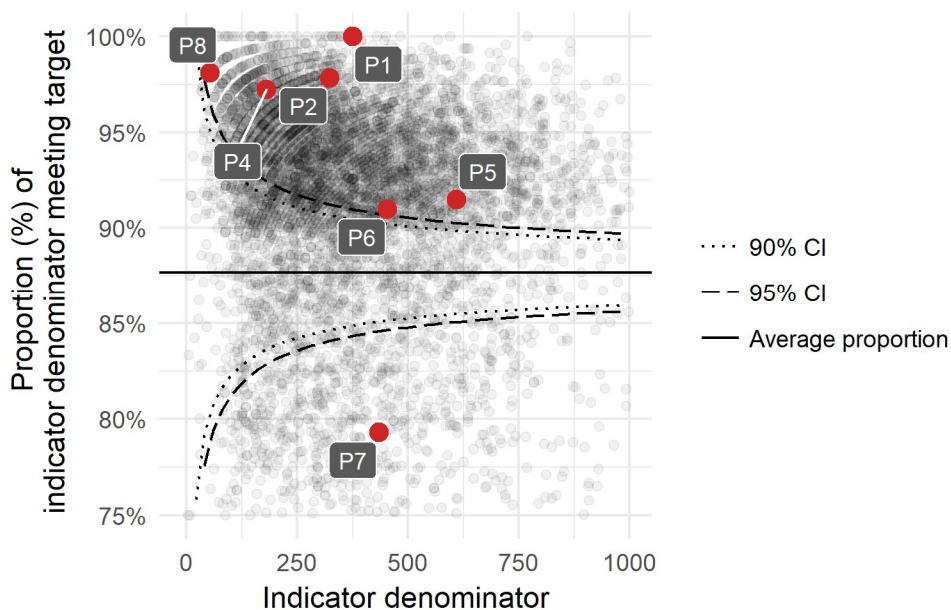
Indicator DM007: The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 59 mmol/mol or less in the preceding 12 months.



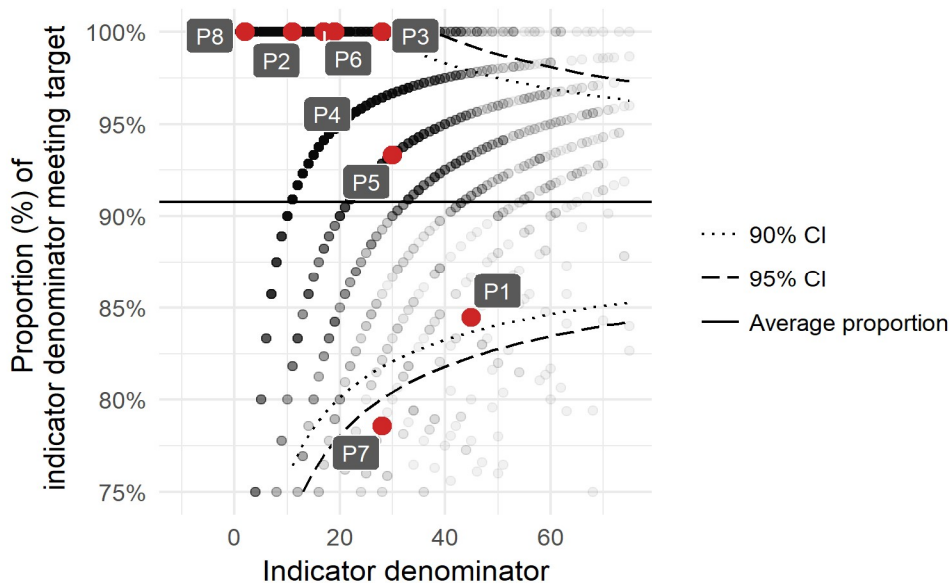
Indicator DM008: The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 64 mmol/mol or less in the preceding 12 months.



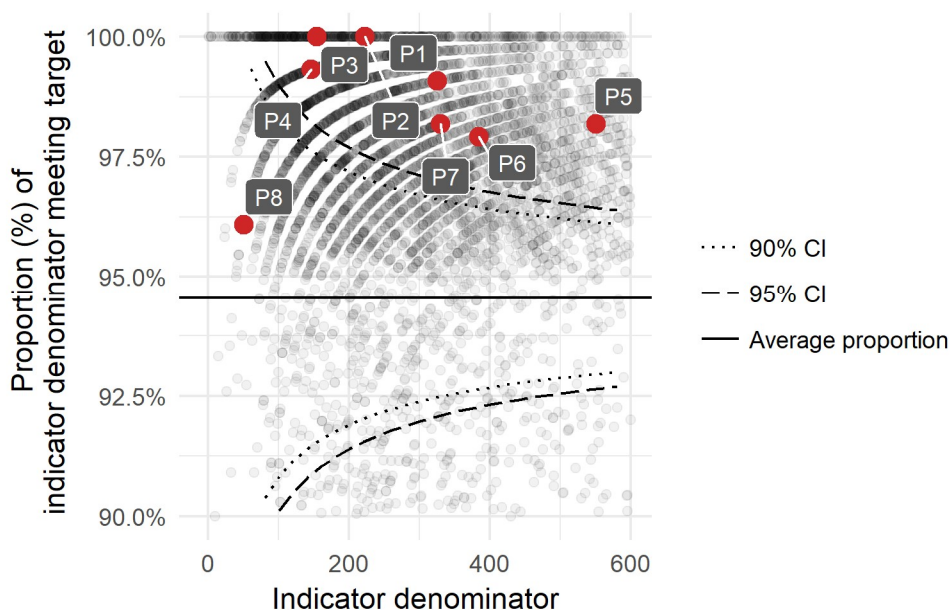
Indicator DM009: The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 75 mmol/mol or less in the preceding 12 months.



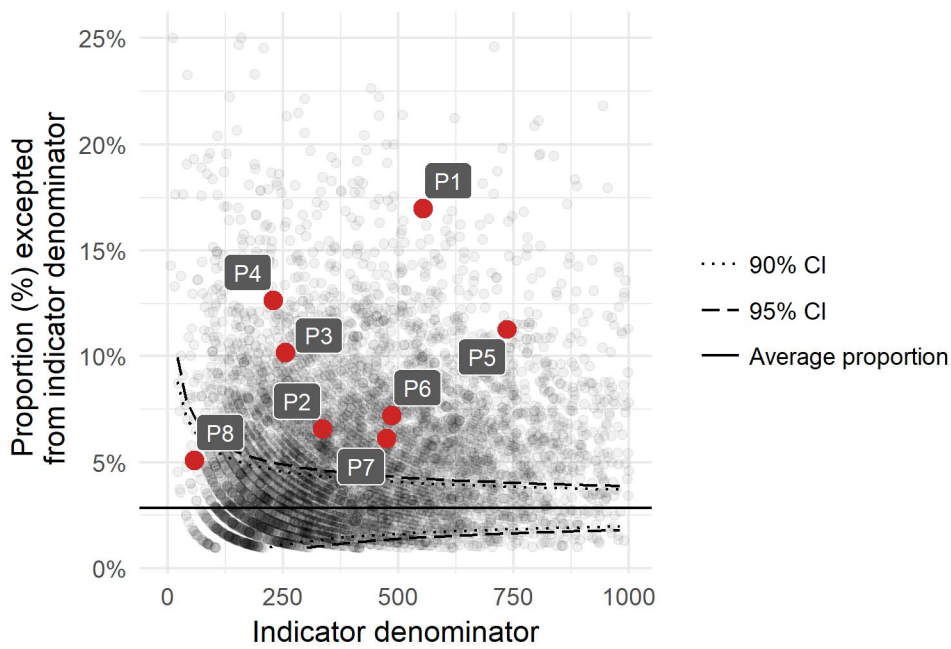
Indicator DM012: The percentage of patients with diabetes, on the register, with a record of a foot examination and risk classification: 1) low risk (normal sensation, palpable pulses), 2) increased risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses plus deformity or skin changes in previous ulcer) or 4) ulcerated foot within the preceding 12 months.



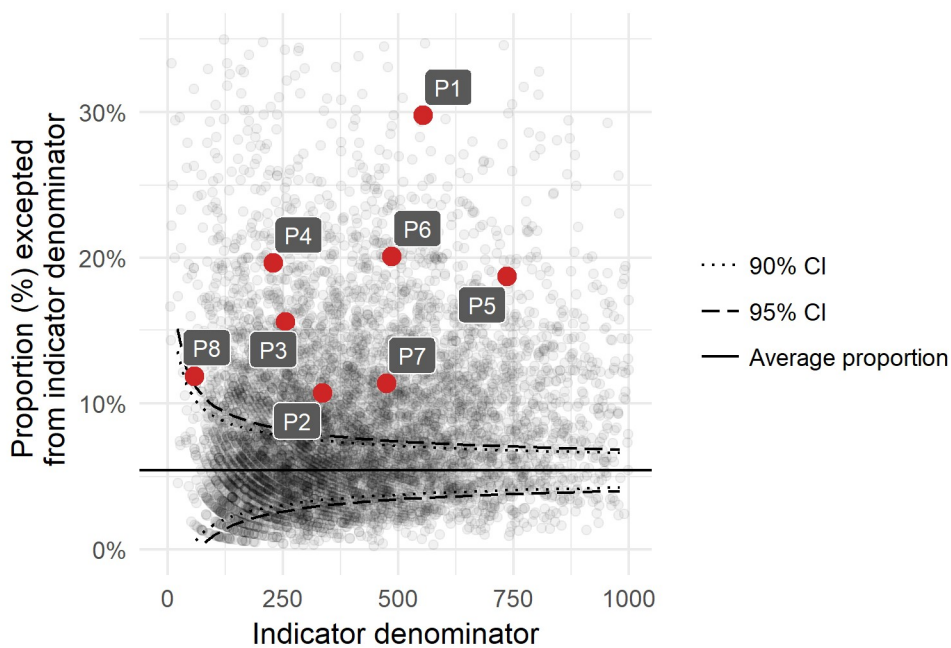
Indicator DM014: The percentage of patients newly diagnosed with diabetes, on the register, in the preceding 1 April to 31 March who have a record of being referred to a structured education programme within 9 months after entry on to the diabetes register.



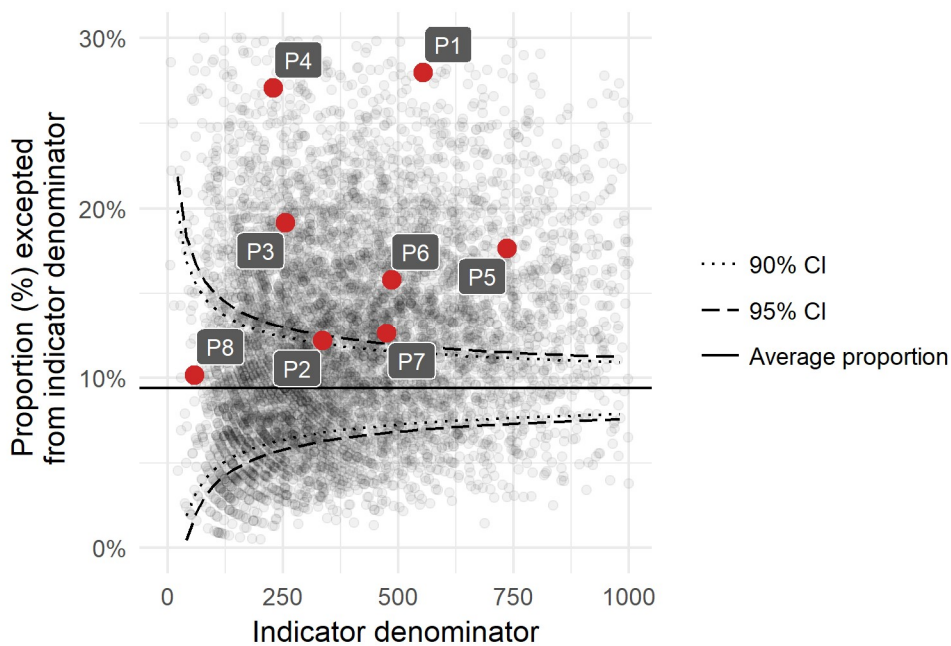
Indicator DM018: The percentage of patients with diabetes, on the register, who have had influenza immunisation in the preceding 1 August to 31 March.



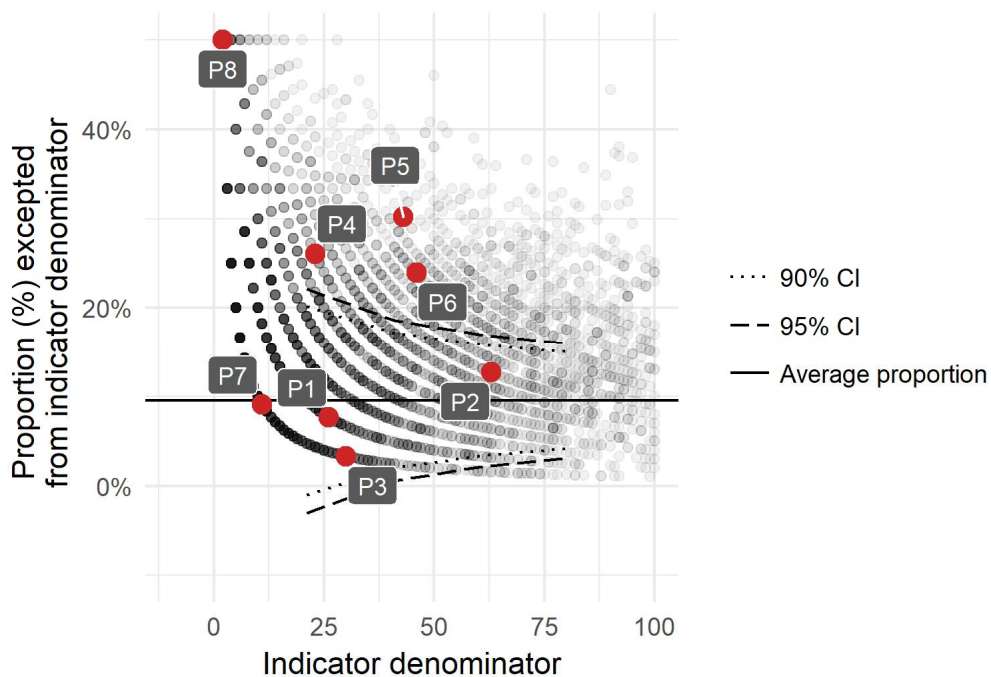
Indicator DM002: The percentage of patients with diabetes who have been exempted from the register with people whose last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less.



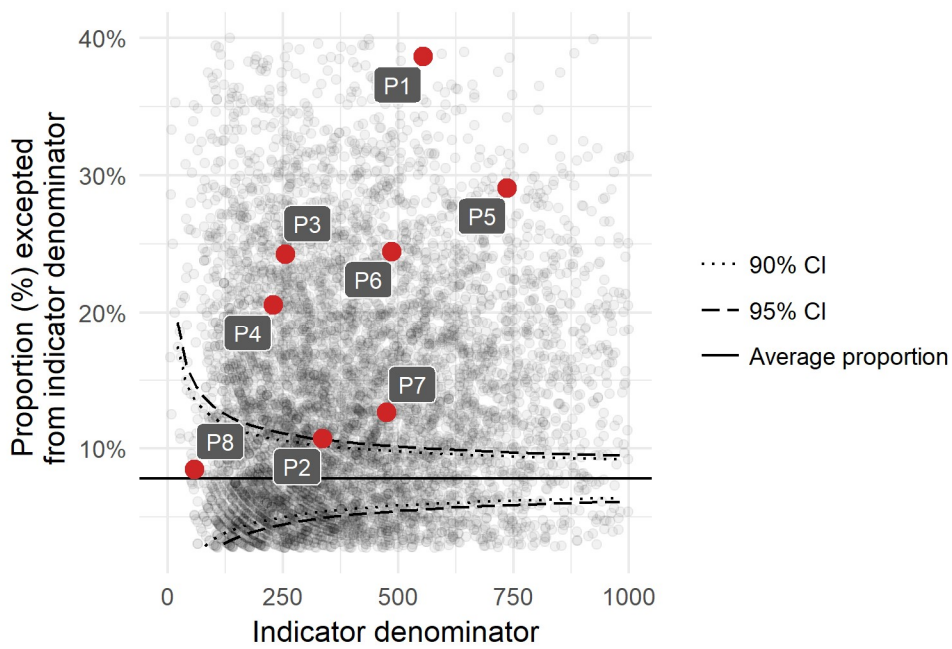
Indicator DM003: The percentage of patients with diabetes who have been exempted from the register with people whose blood pressure reading (measured in the preceding 12 months) is 140/80 mmHg or less.



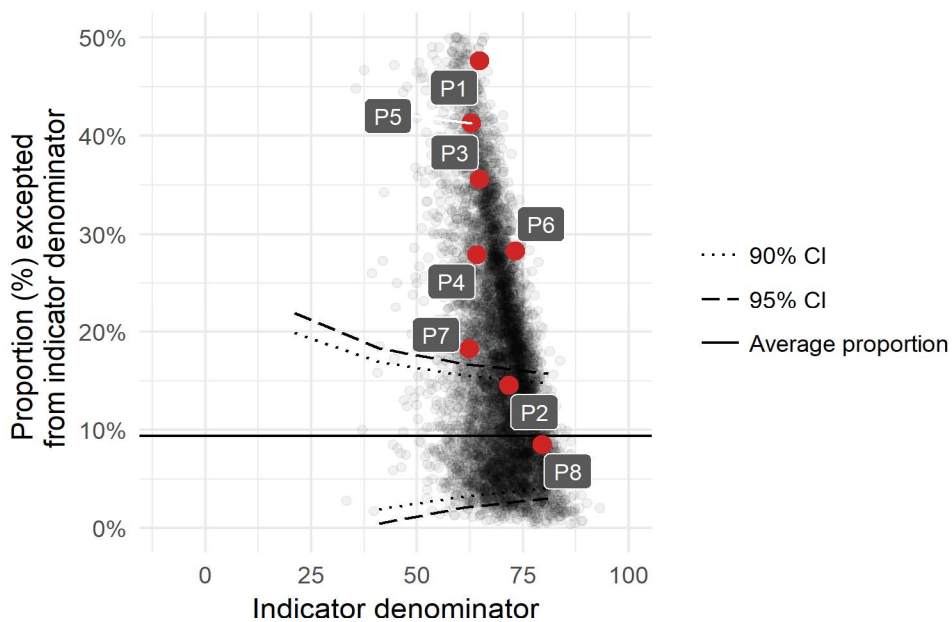
Indicator DM004: The percentage of patients with diabetes who have been exempted from the register with people whose last measured total cholesterol (measured within the preceding 12 months) is 5 mmol/l or less.



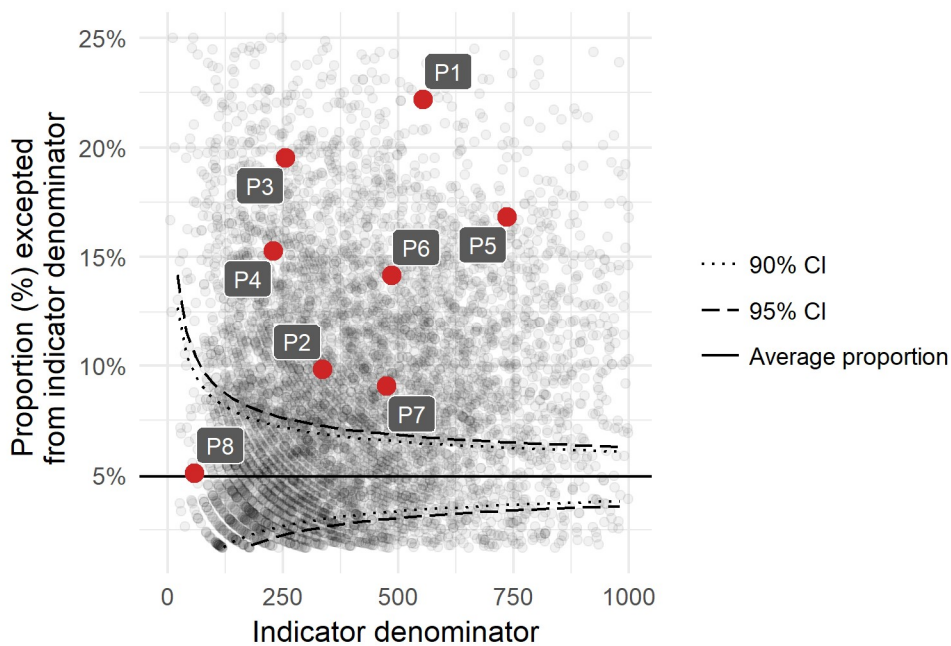
Indicator DM006: The percentage of patients with diabetes who have been exempted from the register with people with a diagnosis of nephropathy (clinical proteinuria) or micro-albuminuria who are currently treated with an ACE-I (or ARBs).



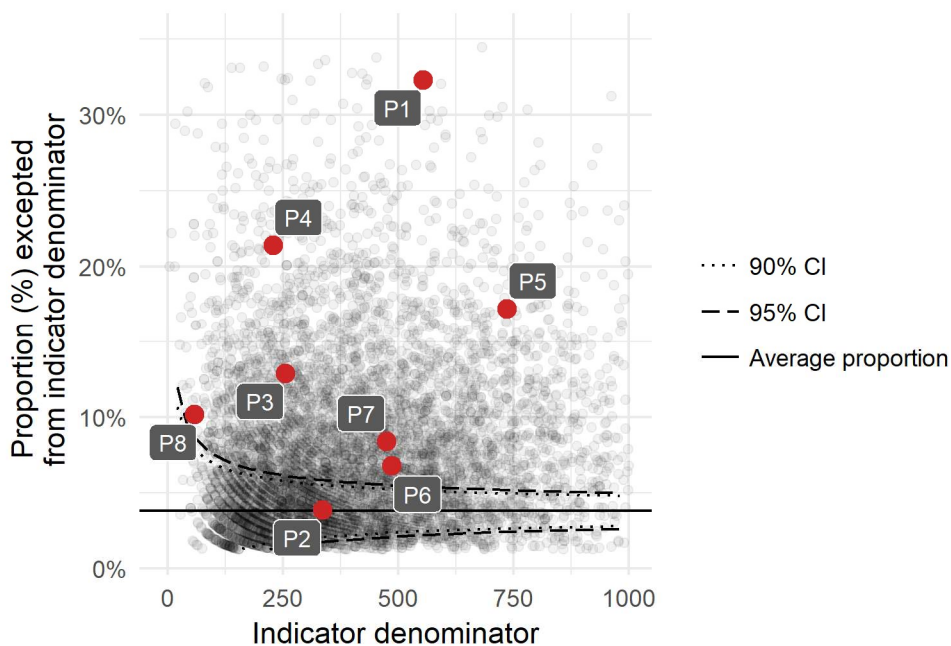
Indicator DM007: The percentage of patients with diabetes who have been exempted from the register with people whose last IFCC-HbA1c is 59 mmol/mol or less in the preceding 12 months.



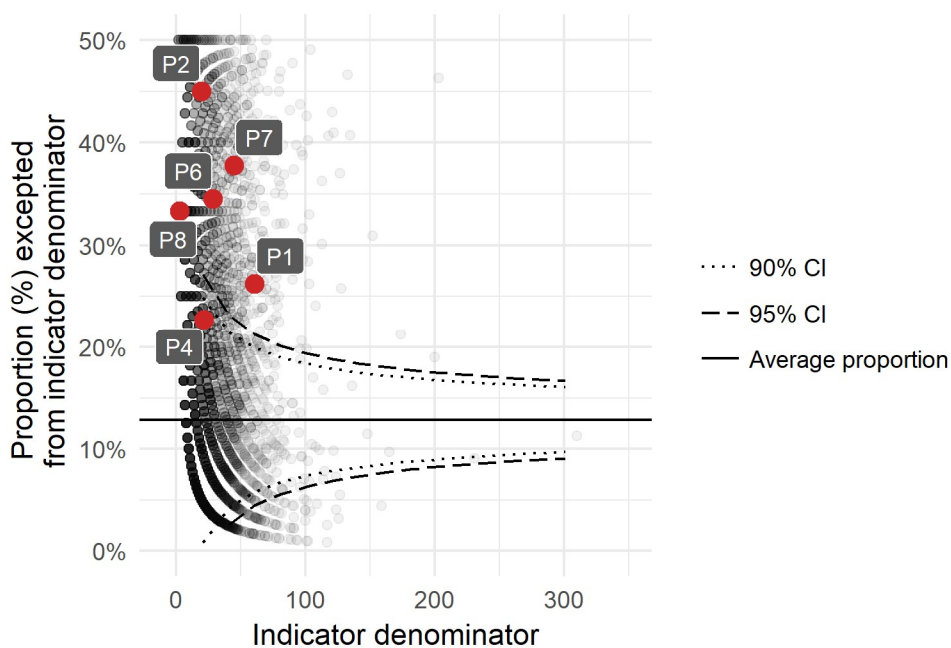
Indicator DM008: The percentage of patients with diabetes who have been exempted from the register with people whose last IFCC-HbA1c is 64 mmol/mol or less in the preceding 12 months.



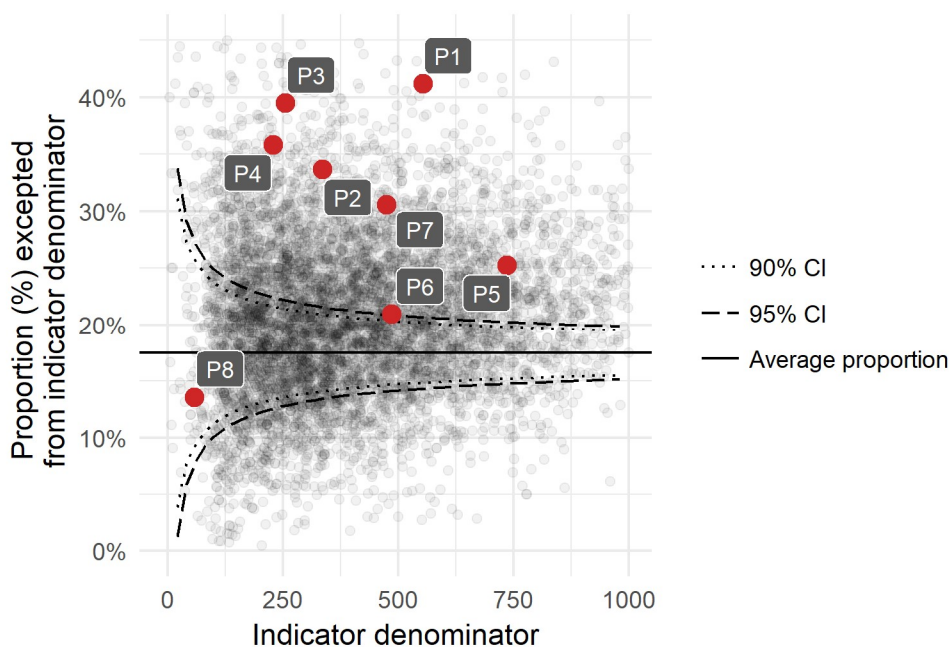
Indicator DM009: The percentage of patients with diabetes who have been exempted from the register with people whose last IFCC-HbA1c is 75 mmol/mol or less in the preceding 12 months.



Indicator DM012: The percentage of patients with diabetes who have been exempted from the register with people with a record of a foot examination and risk classification: 1) low risk (normal sensation, palpable pulses), 2) increased risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses plus deformity or skin changes in previous ulcer) or 4) ulcerated foot within the preceding 12 months.



Indicator DM014: The percentage of patients newly diagnosed with diabetes who have been exempted from the register with people who, in the preceding 1 April to 31 March, have a record of being referred to a structured education programme within 9 months after entry on to the diabetes register.



Indicator DM018: The percentage of patients with diabetes who have been exempted from the register with people who have had influenza immunisation in the preceding 1 August to 31 March.

Appendix 8: Themes emerging from focus groups with patients and practitioners

Barriers to initiation to injectable therapy

Theme 1: Lack of understanding by people with type 2 diabetes

This theme refers to the lack of understanding of diabetes and injectable therapy as demonstrated by the people with T2D in this study.

Misconceptions about causes and impacts of diabetes

Participants with T2D demonstrated poor understanding of diabetes and injectable therapy, which led to many misconceptions, for example about the appropriateness of injectables. The accounts from clinicians in the study also made regular reference to their patients' misunderstanding.

Confusion about how they had developed diabetes was expressed by some of the participants with T2D and this view was supported by the clinicians.

"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).

One misconception concerned the impact of elevated blood glucose. One participant intentionally kept his blood glucose high to avoid the complications that he perceived were associated with fluctuating blood glucose:

"It is better to be slightly high than to have these lows, up and down. The damage that is done is, as you know, when it goes up and down" (P15, male, on insulin, aged 45-54).

There was also a concern from people with T2D that there is a conspiracy between clinicians and pharmaceutical companies to sell more drugs, suggesting lack of trust in medical advice about diabetes; this was highlighted by both participants with T2D and clinicians:

"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).

Misconceptions about injectable therapy

A number of the injectable naïve participants with T2D were unaware that injectable therapy could be needed to treat T2D. Furthermore, clinicians recognised that individuals with T2D did not understand the need for injectable therapy as integrative part of diabetes treatment:

"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).

There was also a clear lack of understanding regarding the role of injectable therapy in reducing serious diabetes-related complications among some people with T2D. The value of maintaining quality of life through the prevention of complications was not discussed by any of the participants with diabetes, with some indicating a fatalist view; clinicians reported their awareness of this lack of understanding.

"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 really honestly don't see the point of it [injectable therapy], you know, I mean I'm not trying to extend myself [live longer]" (P11, female, on oral medication, aged over 75).

"I don't think people really understand the complications" (C2, female, practice nurse, aged 35-44).

"[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).

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

Theme 2: Fear

The words "fear" and "scared" were used 40 times throughout the focus groups, establishing its prominence in relation to insulin injections. People with T2D who were not on injectable therapy voiced apprehension at the thought of injectables. Some expressed this fear in general terms ("I am scared of injections", P12, female, on oral medication, aged 55-64), however the subthemes below reflect the most prominent reasons underpinning fear that were attributed by participants with diabetes and clinicians.

Restriction of lifestyle

Participants with T2D and clinicians most commonly identified restriction of lifestyle as a reason to be fearful of injectables. Clinicians expressed concern that the treatment they were recommending to people would have great impact on their patients' lifestyles and these concerns were stated as reasons for delaying patient initiation onto injectable treatment:

"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).

The clinicians concerns were echoed by the participants with T2D:

"I think it's the way it's going to, it will change my life... I think by going on the injections it will restrict me more than what I actually want it to" (P2, female, on oral medication, aged 55-64).

"Furthermore restrictions, you've got to be conscious about it before you eat, before you take anything, that kind of thing. Further restrictions on life...It's just a nuisance" (P10, female, on oral medication, aged 65-74).

In particular, concerns about the impact of being on injectable therapy on driving and people's occupations (particularly shift-work and professional driving) were raised by a number of people with T2D and clinicians alike.

One notable exception to this narrative of restriction was from a person with T2D who had been using insulin for over ten years. He described no restriction to his life with the introduction of insulin, and in fact, greater flexibility with insulin to accommodate his lifestyle:

"I moved on to insulin. But I've never let it affect my lifestyle. So I think I cope very well... it is better control for the lifestyle I had. And I do have a sugary piece, I do want sugar sometimes" (P15, male, on insulin, aged 45-54).

Self-administration

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 was in contrast to the neutral reactions to self-administration by those already using insulin:

"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).

Hypoglycaemia risk

An interesting area of discordance between people with T2D and clinicians' accounts of fear as a barrier to initiation of injectables was that of hypoglycaemic episodes. While this was raised by clinicians as a significant source of fear for their patients, none of the participants with T2D identified this as a reason for their fear:

"hypos you know, for a lot of patients that's a real concern" (C6, female, GP, aged 25-34).

Pain of injections

Similarly, clinicians identified pain as a source of fear for their patients and yet this was not explicitly mentioned by people with T2D. In contrast, those participants who used injections commented on the absence of pain:

“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)

Stigma

Despite the fear of stigma being raised in relation to diabetes more generally by people with T2D (“Suddenly you’ve got two heads”, P1, male, on insulin, aged over 75), fear of stigma associated with injectables was only discussed by clinicians:

“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’

While not a major (or explicit) fear for people with T2D, the irreversible nature of injectable therapy was described in a number of ways by the clinicians as a source of fear among their patients. This reason for fearing injectables was mentioned only once by a participant with diabetes:

“basically an irreversible step” (C4, female, GP, aged 55-64)

“there’s a fear that...you’ve taken a step which is never a reverse step...I think most patients know it’s a sort of one way route” (C5, male, 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).

Given the prevalence of fear of injectables among the participants, one clinician acknowledged using this fear to motivate her patients to improve their self-management of diabetes:

“It’s something that when things are going wrong we start to mention and it’s yes, probably a bit of a fear tactic for patients and they do get scared when you mention Insulin”

“[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).

According to clinicians, GLP1s did not elicit the same fear from people with T2D; in contrast, clinicians identified patient “excitement” (C8, female, practice nurse, aged 45-54) due to their weight loss effects.

Themes: 3. Comorbidities

This theme comprises the practical issues that predominantly clinicians raised in relation to patient health, which affect their decisions about initiation of injectables.

Practical constraints to initiation/administration

Clinicians recognised the role of comorbidities, such as impaired eyesight, in delaying the initiation of injectable therapy. One person with T2D emphasised the severe impact his comorbidity, arthritis, had on his ability to administer his insulin injections.

"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).

Clinicians also noted that age of people with diabetes acted as a barrier for them to administration of injectables to elderly people with diabetes. Patients' weight was another barrier to initiating injectable therapy for clinicians; clinicians also mentioned that their patients were concerned about the weight gain associated with insulin and that this acted an obstacle for initiation. Interestingly, however, this concern was not reflected in the comments from the participants with T2D:

"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).

"they're worried...the weight gain and you know, 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).

Reported by clinicians only, weight loss acted as a facilitator for clinicians and people with T2D for the initiation of GLP1s. While not discussed as a major barrier, the mention of patient comorbidities by clinicians, alongside their concern for restriction of patients' lifestyle, indicated the holistic way patient health was considered by the clinicians in this study.

Theme 4: Clinician competence

This theme, within the domain summary of barriers to initiation of injectable therapy, shows the role of the clinician in affecting patients' and clinicians' decisions about injectable therapy initiation.

Experience/knowledge of diabetes

Although not in direct reference to initiation of injectables, the perceptions of participants with T2D varied widely in relation to individual clinician competence (referring to clinician experience and knowledge interchangeably). A number of these participants gave examples of clinicians in whom they had confidence and those whose expertise they questioned:

“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).

Clinicians reported more confidence in initiating GLP1 therapy, compared with more complex regimes associated with insulin. There was substantial variation in clinician confidence to initiate insulin therapy, with some clinicians reporting needing more knowledge (training) and experience to feel competent to initiate insulin therapy. While they felt able to discuss the potential for injectables with their patients, some clinicians felt they did not have sufficient experience or knowledge to start this complex process, referring patients for insulin initiation to more experienced specialist nurses or to secondary care diabetes clinics:

“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).

One of the clinicians, despite significant experience, felt “huge responsibility” when initiating patients onto insulin because she is “giving somebody something that could potentially kill them if they didn’t get it right” (C8, female, practice nurse, aged 45-54). Having enough time to explain the process properly (not “wanting to feel rushed”) contributed to her feeling that she had competently initiated a patient onto insulin.

Trust

Clinician competence was closely linked to another subtheme, that of trust. In relation to their diabetes care, where patients perceived their clinician to be competent, they reported having trust in them.

“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).

In relation to the prospect of injectable therapy, one participant with T2D expressed distrust of their clinician:

“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).

Another woman voiced her concern about the effects of multiple drugs, including insulin, on patients, which led to her distrusting the medical profession:

"And if you're taking a certain number..., you know, what is the sort of reaction from one to the other? I cannot read small print, forget it, I'm not going to be looking for all that. I never used to bother, I trusted the doctors before but not anymore." (P11, female, on oral medication, aged over 75).

Clinicians were also aware of the importance of trust; particularly in the initiation of injectables, giving people with T2D the right information and spending "time on that first occasion...you build that trust" (C11, female, practice nurse, aged 35-44).

The data within this theme highlights the crucial role that clinicians and their relationship with their patients play in the decision-making process of initiation of injectables for patients.

Theme 5: System limitations

The final theme pertaining to barriers to initiation to injectable therapy shows that system-level barriers were identified by both sets of focus groups; these incorporated obstacles beyond the control of people with T2D or the healthcare professionals.

System constraints

System constraints were described in the form of constraints on time, resources and cost. Lack of time was a recurrent theme as both clinicians and participants with T2D recognised it as a major limiting factor for overall diabetes care and for the time-consuming initiation of injectable therapy. In general, the participants with T2D recognised that clinicians are under significant time pressure:

"[the clinicians simply] don't have time" (P11, female, on oral medication, aged over 75).

"with the pressures on them you're in there...I've got to absorb the information in possibly not enough time" (P3, male, on insulin, aged 65-74).

Clinicians were particularly conscious of time being a barrier to the initiation of injectables, the majority making explicit reference to it. One participant felt that there was a difference in the time that GP surgeries and secondary care dedicate to the care of people on injectable therapy.

"[Initiation requires] giving the patient a lot of time" (C1, male, GP, aged 55-64).

"the biggest barrier is time, because we have time limited consultations" (C4, female, 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).

One experienced practice nurse, describing time as “our biggest barrier [for initiation]”, emphasised the time needed for the initiation appointment as well as for the follow-up care needed over the proceeding weeks. Furthermore, she raised the issue of time in relation to patients needing to contact clinicians “in the fact that they can’t always necessarily get hold of us” (C11, female, practice nurse, aged 35-44).

“Overwhelming” workloads were identified as another component of system constraints (C7, female, GP, aged 45-54) that contribute to the restricted time available for initiation of injectables.

Cost was raised as an additional constraint by clinicians. While there was an acknowledgement that they are “incentivised financially” (C7, female, GP, aged 45-54) to improve diabetes care, the cost burden associated with patient equipment and choice of drug was also discussed.

“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).

One GP explained that these decisions were “in some regards driven by CCG funding” (C1, male, GP, aged 55-64). Participants with T2D did not mention cost as a barrier to initiation of injectable therapy either for themselves or the healthcare system.

Inconsistency of care

Inconsistency of care was raised by people with T2D and clinicians from a number of perspectives. Firstly, people with T2D reported that a lack of continuity of care (clinicians leaving practices or patients seen by different GPs) led to a decline in the quality of diabetes care they received:

“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. Because I see the GP once a year and I see the nurse once a year” (P15, male, on insulin, aged 45-54).

“I registered the same doctor and then he retired and there was another one in the practice. And I got a bit concerned, and I got the impression that she didn’t know an awful lot about problems with diabetics” (P1, male, on insulin, aged over 75).

“you don’t necessarily see the same GP these days” (P3, male, on insulin, aged 65-74).

“The nurse she was very good. I was surprised that she has left, she was very good” (P14, male, on oral medication, aged 55-64).

Being able to see the same clinician throughout their treatment was viewed in a positive way by people with T2D, especially by those on insulin. Clinicians that participated in this study, however, did not identify a lack of continuity of care as an issue for their diabetes care.

Another area of inconsistency was the variation in management of diabetes care across practices so that when people moved homes they had to deal with lack of familiarity and adapt to the processes within the new practice or the type of clinician who would manage their diabetes care:

“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 hasn’t picked up that I don’t check my blood sugars, they just rely on the blood tests every three months” (*P2, female, on oral medication, aged 55-64*).

Clinicians expressed frustration about the inconsistency of advice that patients received from GPs and diabetes clinics. This variation in medical advice meant that when injectable therapy was raised, patients were reluctant to accept it because they did not understand the need for the escalation in therapy:

“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*).

Another inconsistency apparent within the participants’ responses was the appropriate timing to discuss injectables with people with diabetes. A number of clinicians felt that, at diabetes diagnosis, there was too much information for patients and that the mention of injectables “would be too much for them to cope with” (*C8, female, practice nurse, aged 45-54*). Others, however, believed that all of the information should be provided at diagnosis so that patients should not be surprised later when injectable therapy was recommended.

Facilitators to the initiation of injectable therapy

The facilitators for initiation of injectable therapy clustered into three themes: Support for people with T2D, education and communication. These themes were closely interrelated.

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 to start injectable therapy. All of the participants on insulin raised the significance of clear, well-explained practical advice for people about to start injectables:

“[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*).

In this description, the participant associated adequate support with overcoming two of the most prominent barriers to initiation for people with T2D that we have identified in this dataset (i.e. misconceptions and fear). Similarly, a participant not on insulin explained that a concern about lack of support from clinicians was what drove her reluctance towards injectable therapy:

“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...I think that’s my biggest thing at the minute. 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).

The type of support was also important to the participants with T2D. The need for practical advice, reassurance, and better explanations relating to why injectables were noted. “Better explanations” encompassed the need for more knowledge/education and improved communication by clinicians:

“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)

“If you talk to them, reassure them then it will be ok” (P9, female, on oral medication, aged 65-74).

These views were commensurate with those of the clinicians regarding the type of support that they need to provide to their patients to prepare them for initiation of injectables.

“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).

“get a needle and say this is what you’re going to be using to inject and when they see how tiny and fine it is” (C8, female, practice nurse, aged 45-54).

One GP listed a number of important components to the types of support that patients need from clinicians, “motivational counselling...and you know, you need to have frequent and long appointments with all the people with the right skills available” (C4, female, GP, aged 55-64). This quote reflected a number of the barriers identified in this dataset, particularly the importance of time

and clinician competence. It also raises an important additional point about patient empowerment, the need to motivate people with T2D to feel confident enough to manage complex injectable therapy regimens.

Follow-up support was also identified as essential to ensure patients feel supported through their initiation of injectables.

“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).

Support from a team of clinicians was also highlighted by one GP (“feeling like you have joined up care from a team” (C7, female, GP, aged 45-54) and this was closely related to the need for consistent care also identified in these findings. Both clinicians and people with T2D saw the clinician’s role as also being to direct their patients to additional diabetes support, for example Diabetes UK, peer support groups (from which the participants with T2D felt that they would benefit), and programmes such as DESMOND.

“[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).

The need to include family members in the initiation process was emphasised by clinicians. This was supported by the narratives from people with T2D, who identified their families as crucial to their diabetes care and management of insulin regimens. Thus both clinicians and people with T2D recognised the role of informal carers in supporting them during treatment:

“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).

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, such as fear and misconceptions (lack of health literacy).

Theme 7: Education

This theme covers education for people with T2D, for clinicians and for the public.

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. A number of participants recognised and raised concerns about their poor knowledge about diabetes:

“[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*).

There was strong concordance across clinicians and participants with T2D that diabetes-related education for patients was the key component of the support that they need to overcome their barriers and accept the initiation of injectables. Clinicians identified patient education as the answer to “persuading” them to start injectable therapy (“I think it is all about the education” C11, *female, practice nurse, aged 35-44*). Because “a lot more time” was needed “to discuss the ins and outs of insulin” (C7, *female, GP, aged 45-54*), 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.

“I don’t think we’ve got the time to do that [educate them] properly” (C5, *male, GP, aged 55-64*).

“whatever intervention [to reduce barriers to initiation of injectable therapy] you come up with, the issue still comes down to time” C11, *female, practice nurse, aged 35-44*).

Providing adequate education to people with T2D was discussed as “giving them confidence to cope” with their injectable regimen on their own (C8, *female, practice nurse, aged 45-54*).

Clinicians also expressed a strong interest in receiving more education and training for injectable therapy themselves in order to provide the confidence and competence to initiate. Some expressed frustration at the lack of training opportunities locally and even those with significant experience indicated their desire for continued training/upskilling.

“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*).

Practice nurses discussed the value of sharing best practice with others through diabetes forums and networks with diabetes specialists as a way to receive regular relevant updates.

Public health campaigns were mentioned by clinicians and people with T2D as a strategy to educate both public and patients about the role of injectables in the management of diabetes:

“[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*).

This expressed need for more public awareness was corroborated by the finding discussed earlier, that the majority of the people with T2D in this study were not aware that injectable therapy is used to treat T2D.

“[the fact that injections might be necessary with T2D] needs more publicity” (*P17, male, on oral medication, aged 65-74*).

Diabetes-related education was one of the principal elements identified in this study as needing to be improved to facilitate initiation to injectables for clinicians and people with T2D.

Theme 8: Communication

This theme focuses on the need for improved communication between people with T2D and clinicians to encourage initiation of injectable therapy.

The need for clearer and more compassionate clinician communication was raised as a facilitator for the initiation of injectables by people with T2D and is closely linked to the role of support and education from the clinician to encourage people to initiate injectable therapy. Some participants' experiences of poor communication by clinicians appeared to have negatively affected people's views of clinicians.

"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*).

The need for the application and communication of complex knowledge and practical advice was a prominent request from the participants with T2D. The participants with T2D stated the need for tailored, applied advice rather than "just reciting" information (*P3, male, on insulin, aged 65-74*).

Clinicians highlighted the need to improve their negotiation skills; when the possibility of injectable therapy is broached during appointments, patients often engage in negotiation to avoid initiation:

"[patients requesting] to be given more time to change, make changes [to their lifestyle to avoid initiation of injectables]" (*C7, female, GP, aged 45-54*).

"[promising] at this time they're going to give their lifestyle a really good look at" (*C2, female, practice nurse, aged 35-44*).

One GP mentioned his desire for training to help him learn how to "persuade" patients that injectable therapy is the best option.

"[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 was a salient component of the diabetes care that the majority of the people with T2D felt that they received. This corresponded with the views of the clinicians, that they included their patients in the decisions about their diabetes care ("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*). Interestingly, participants with diabetes who felt they were not included in decisions about their own care also reported low levels of trust in their clinician.

Along with more education, people with T2D and clinicians were aware of the clear need for improved communication. These key components of support were proposed to enable people with T2D to feel comfortable with the initiation of injectable therapy.

Appendix 9: Survey results

Participants were asked to respond to 13 scenarios. Each consisted of a statement that had been developed from themes debated in prior focus groups, followed by a précis of the opinions of a panel of experts on the validity of the statement. The participants were asked to give their views on the summarised expert opinions, rather than on the statements. Each of the scenarios is reproduced below, followed by a description and analysis of the participants' responses. Minor spelling errors and punctuation omissions in online responses have been edited for clarity.

Statement 1:

"When I think a patient should start injectable therapy, I refer them to a specialist (i.e. endocrinologist in secondary care)."

Experts' result: Agreement (100% selected "Disagree")

Experts' rationale of their responses:

1. Referral to diabetes nurse

2. Referral to diabetes lead GP

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

Amongst GPs, 29 agreed with the experts' unanimous opinion that referral to a specialist in secondary care was not necessary in this setting. Comments were offered by 11 of these 29 GPs, almost all of whom described sufficient skills and knowledge being available within their surgeries for initiation of insulin and/or GLP1 RA therapy. One GP also commented on the need to avoid delay in therapy: *"We have good diabetic specialist nurses. Secondary care is a 4 month wait."* One pharmacist also indicated agreement, stating *"I would anticipate the diabetic nurse or GP being comfortable starting injectables, saving the endocrinologist's time for more complex cases."*

A further 15 GPs chose to indicate disagreement with the expert panel's opinion, and nine of these 15 offered explanatory comments. However, the content of all but one of these comments suggests that the participants had misunderstood the scenario and were, in fact, in agreement with the experts. Each referred to the necessary expertise for initiation of injectable therapy being available within the practice. The remaining comment is ambiguous, merely stating *"Refer diabetes nurse."*

Lastly, five more GPs expressed neutrality with respect to the expert panel opinion, with comments offered by four of five indicating that variation in complexity of cases or of anticipated therapy might cause some people to be referred to a specialist. One of these four commented: *"Depends on the expertise of the nurse or GP, and crucially on whether the work is contracted/funded at a given primary care site."* Another stated: *"Depends on situation and complexity. We do have a diabetes nurse within the practice who is skilled at initiating insulin."*

Amongst nurses in primary care, 20 indicated agreement with the expert panel's opinion, 12 indicated disagreement and two were neutral. However, as with the GPs, the accompanying comments indicated that some responders were confused by the questionnaire format. Of the nine nurses who indicated agreement with the experts and who also offered comments, three were contradictory, as follows: *"I feel that we do not see enough pts to be fully competent with starting injectable therapies,"*

and “*We are a small practice and maintaining competency is an issue due to numbers,*” and “*We are not trained to do so nor do we have time to do so.*”

One of the two neutral responses was accompanied by a comment. This stated that “*The CCG don't commission initiating insulin therapy in primary care where I am based.*” Of the five nurses who indicated disagreement with the experts and also offered comments, one had understood the scenario correctly, stating that “*We always refer to DFN [diabetes facilitator nurse].*” The other four comments indicated that the authors were confident in initiating injectable therapies.

In summary, and ignoring the initial declarations of agreement, disagreement or neutrality, the major theme to emerge from this scenario is that the majority of responders viewed initiation of injectable therapy as being routine practice in primary care. However, some responders specified insulin, rather than all injectable therapies, as being within their experience, implying that GLP1 RAs might not routinely be initiated in every practice that possesses confidence and competence in insulin initiation. Others felt that their practices had insufficient throughput of people with diabetes requiring injectable therapy, making it impractical to maintain the requisite skills within their teams. Furthermore, one comment highlighted that local variations in commissioning practice affect the willingness of GPs and their teams to contemplate initiation of injectable therapies.

Statement 2:

“My training has prepared me to initiate injectable therapies in patients with T2D.”

Experts' result: Disagreement (40% selected "Disagree", 20% selected "Agree", 20% selected "Strongly Agree", 20% selected "Neutral")

Experts' rationale of their responses:

Referral to diabetes nurse (out of my remit)

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

Amongst GPs, there were 18 comments. 11 GPs stated that they had not received training in initiation of injectable therapy. Some additionally commented that this task was not in their remit because, in their practices, initiation was performed by nurses. This implies that they interpreted the content of the statement purely in terms of tuition on injection therapy, rather than also encompassing the decision to prescribe. One GP made this explicit: “*I have not been trained in injectables, I seek out learning to develop this area to support our PN [practice nurse] but they are the ones who initiate.*”

Another GP stated: “*I am used to insulin initiation but not the newer injectables.*” This supports the hypothesis arising from responses to the preceding scenario: that a lack of knowledge about GLP1 RA might inhibit their use in primary care, even in the hands of GPs experienced in management of diabetes, and despite the considerable time for which this class has now been available.

Following this theme, there is a suggestion that provision of education on injectable therapy might not help all HCPs overcome their lack of knowledge. One GP stated; “*I have been on a training course to initiate injectables but I did not follow this up with practical experience.*” More optimistically, another stated “*I was also referring to diabetic lead nurse but now doing training so will be able to initiate myself.*”

Amongst nurses in primary care, 17 comments were offered, of which ten indicated inability to initiate injectable therapies. Amongst these ten comments, there were two nurses indicating that adequate training had been provided but experience was lacking: *"I have had the training and updates but maintaining competency in a small practice is the issue."* Mirroring the comments by GPs, a lack of familiarity and confidence with GLP1 RAs was highlighted by one practice nurse, in a brief comment: *"But only insulin."*

In summary, just over half the comments about this statement, from GPs and from nurses in primary care, indicate reticence about initiating injectable therapy. This reticence arises partly from lack of specific training and partly because of difficulty retaining competence if throughput of people with diabetes is small. Two qualifying points must also be highlighted: firstly, that comments from some GPs imply that they understood the statement to relate solely to initiation, as opposed to prescription, and, secondly, that some GPs and nurses in primary care regard GLP1 receptor agonists as being beyond their experience, even if they feel competent to initiate insulin.

Statement 3:

"My role includes supporting patients in ways other than prescribing medication."

Experts' result: Agreement (60% selected "Strongly Agree", 40% selected "Very Strongly Agree")

Experts' rationale of their responses:

Also offer:

- 1. Holistic care**
- 2. Comorbidities**
- 3. Lifestyle advice**
- 4. Patient education**
- 5. Motivational skills**

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

There was unanimity of agreement to this scenario. 15 comments were received from GPs and another 15 from nurses in primary care, as well as one from a primary care diabetes specialist nurse and another from a pharmacist. Typical statements were: *"I'm predominantly reviewing medication and condition control, considering more aspects than just medication,"* and *"supporting patients in other ways is very important to the total care offered,"* and *"this is bread and butter GP work."*

Statement 4:

Patients with a new diagnosis of diabetes should be referred to non-clinical sources of support.

Experts' result: Agreement (40% selected "Agree", 40% selected "Strongly Agree", 20% selected "Neutral")

Experts' rationale of their responses:

- 1. Exercise on prescription**
- 2. Referral to DESMOND course**
- 3. Referral to Diabetes UK website**

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

For this scenario, 81 of 87 responders indicated agreement with the expert panel. Comments were received from 15 GPs, most of whom reiterated the experts' suggestions, while peer support was also

mentioned as being important by two GPs. Neutral responses were received from two GPs, one of whom justified this by stating *"I find the current dietary advice on educational courses frustrating as I don't believe 'a balanced diet' as it's portrayed allows patients to make big changes."*

Comments from nurses in primary care emphasised the importance of helping people with diabetes to make changes to lifestyle. One nurse stated *"I feel non-clinical support is important but I do not feel there is much available. Much of what is available is run/facilitated via healthcare professionals but the patient to patient support that is garnered through this approach is extremely valuable."*

Comments from pharmacists and primary care diabetes specialist nurses indicated agreement with the expert panel. There were two responses from nurses in primary care indicating neutrality, including one stating that referral *"depends [on] what other sources of support are available and whether these are safe therapies. They could co-exist and be interdependent."* Another two nurses in primary care indicated disagreement, but the accompanying comments in fact implied that non-clinical sources of support were potentially useful.

In summary, provision of non-clinical support was generally viewed as being important for people with a new diagnosis of diabetes. Several responders reported the benefits in their experience of peer support. However, there was recognition that referral to sources of non-clinical support might not result in a person with newly-diagnosed diabetes engaging with that support. Furthermore, one responder reported unease about the scientific basis and clinical benefit of current dietetic advice.

Statement 5:

"Risk of hypoglycaemia is important when initiating injectable therapies for T2D.

Experts' result: Agreement (80% selected "Strongly Agree", 20% selected "Very Strongly Agree")

Experts' rationale of their responses:

Yes because insulin can have implications for:

- 1. Employment**
- 2. Driving license**
- 3. Elderly**
- 4. Interaction with other medication**

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

All but one of the 87 participants indicated agreement with the expert panel. Additional comments were received from 12 GPs, 13 nurses in primary care and one pharmacist. Most GPs simply indicated awareness of the dangers of hypoglycaemia, alongside agreement with the expert panel. For example: *"It's important to think of the implications of hypos on someone's life, taking into account all of the above factors,"* and *"It is vital to protect patients from hypoglycaemia."* However, another GP stated that agreement was based not only upon the *"same reasons as above"* but also that *"patients [are] very scared."*

The only mention of a difference in hypoglycaemia risk between classes of injectable therapy was from a nurse in primary care, who stated: *"It is important absolutely but injectable therapies also include non- insulin therapies such as GLP1 analogues which are less likely to cause hypoglycaemia."*

One nurse in primary care indicated agreement with the expert panel but also drew attention to another reason to strive to avoid hypoglycaemia: *"Hypo is a massive risk particularly in the elderly or*

where driving/occupational risks are present. But the physical effects and detriment to cardiac system is huge and repeat hypos can significantly increase risk of co-morbidities.”

Finally, another nurse in primary care commented that *“the risk has to be acknowledged but it needs to be put in perspective for the patient so that they do not perceive it to be overwhelming [or] frightening. Clear information and access to appropriate support and management is important [–] real time access not clinic visits.”*

In summary, there was considerable awareness amongst HCPs of the negative consequences of hypoglycaemia. The vast majority of responses were simply reiterations of the expert panel’s view. However, one GP highlighted fear of hypoglycaemia as being common amongst people with diabetes, and one nurse reflected this, emphasising the practical need to reassure people facing the prospect of starting injectable therapy. Finally, it is perhaps surprising that just one comment referred to the difference in hypoglycaemia risk between insulins and GLP1 receptor agonists.

Statement 6:

“Reluctance of patients to initiate injectable therapies is commonly encountered in general practice.”

Experts' result: Agreement (80% selected "Agree", 20% selected "Strongly Agree")

Experts' rationale of their responses:

1. Yes because we need to achieve joint ownership so that patient adheres.

2. Still offer injectable but would seek other options.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

Agreement with this scenario was indicated by 70 of 87 participants. Of the five comments from people expressing a neutral response, two stated that they had no opinion, on the basis of having no relevant experience in their practices, and another merely indicated uncertainty. The other two (one GP and one nurse in primary care) drew a distinction between reluctance of people with diabetes, and of HCPs, to initiate injectable therapy. Both made it clear that, in their own practices at least, there was no reluctance amongst HCPs. However, amongst the seven comments from those indicating disagreement with the scenario was a nurse in primary care expressing a directly contrary opinion: *“Patients who have a good relationship with primary care clinicians are usually happy to start an injectable. It is the reluctance of the clinicians not the patients.”*

There were 18 comments from HCPs indicating agreement with the scenario. Amongst these, two used the term *“last resort”* to describe the views of people with diabetes about injections. A third used the same term but attributed it instead to the views of HCPs about injections.

Fear was another common theme, whether expressed directly (e.g. *“Yes, patients fear for their job and think it’s the end”*) or indirectly (*“patients have memories of relatives going on insulin and having problems.”*). Other than in this last comment, no participant mentioned any specific type of injectable therapy.

While nurses tended to refer to the need to help people gain confidence when starting injectable therapy, GPs focused more in their comments on reasons for reluctance. For instance, one GP attributed reluctance *“largely [to] ignorance or fears which need [to be] addressed,”* while another

attributed it to *“multiple issues fear of injections and feeling they have failed [to] act.”* This is the only direct reference to the concept of patient failure within the comments on this scenario.

One further comment (from a GP) reveals that fear of injections might play a role in an individual's diabetes treatment pathway, not only at the point of deciding to initiate an injectable therapy, but also much earlier: *“Often, the threat of [injections] is used by patient or GP/practice nurse to motivate better control without recourse to injectables.”*

In summary, the weight of opinion was that reluctance to initiate injectable therapies was frequently encountered amongst people with diabetes in general practice. A minority of responders commented that HCPs might also exhibit reluctance. The factors that were proposed as contributing to reluctance amongst people with diabetes included fear of injections; fear of diabetic complications that had been witnessed by people with diabetes in family members and/or friends who had started injectable therapy in the past; a fear of requiring “last resort” therapy, and the emotional implications of perceiving that injections are needed as a result of personal failure.

Statement 7: Patients' clinical factors (e.g. comorbidities) are important when initiating injectable therapies for T2D.

Experts' result: Agreement (60% selected "Strongly Agree", 20% selected "Agree", 20% selected "Neutral")

Experts' rationale of their responses:

1. Weight

2. CVD

3. BP

4. Presence of complications

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

The vast majority of participants indicated agreement with the expert panel in this scenario. Four of 24 comments reinforced the panel's emphasis on weight as an important factor, and two others referred to the need to use a holistic approach when determining treatment. One participant also mentioned *“arthritis and conditions affecting dexterity and memory e.g. dementia.”*

Statement 8

Patients' social circumstances (e.g. employment or living conditions) are important when initiating injectable therapies for T2D.

Experts' result: Agreement (60% selected "Strongly Agree", 20% selected "Agree", 20% selected "Neutral")

Experts' rationale of their responses:

Yes, taking into account:

1. Lifestyle / living arrangements

2. Employment status / occupation

3. Family support

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

As with the previous scenario, the vast majority of participants indicated agreement with the members of the expert panel. Comments were received from 27, amongst whom, four people mentioned the importance of considering whether someone's ability to drive would be affected by choice of medication. Alongside driving, one GP included an additional factor: *"Language and driving in particular."* The importance of ease of communication, and the potential for social circumstances to interrupt this, was also referred to by another GP: *"Patients need support and stable home environment - or they won't comply, they won't come to follow-ups, it's also tricky if they don't have a telephone to do review and stepwise increase insulin."* Along similar lines, a nurse in primary care indicated that social circumstances can have adverse effects on the range of available therapies and, hence, on subsequent health outcomes: *"Sometimes other therapies are the safer option and accepting sub optimal control."*

In summary, the responses to this scenario make it clear that social circumstances are routinely considered when deciding whether to initiate injectable therapy. Whilst HCPs' comments address the relevance of social factors to efficacy and safety of treatment, it would also be possible to speculate that social circumstances might sometimes result in inequality of access to appropriate therapy.

Statement 9

The differences in the level of glycaemia between primary and secondary care.

Experts' result: Disagreement (40% selected "Agree", 20% selected "Very Strongly Agree", 20% selected "Disagree", 20% selected "Neutral")

Experts' rationale of their responses:

1. We only refer to secondary care only when complicated cases (CCG policy).

2. Same standards in both, expecting more clinical inertia in primary care.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

This scenario prompted 29 neutral responses, including comments from five GPs and three nurses in primary care who indicated that they found the logical structure of the scenario to be unclear.

In other respects, the indicated extent of agreement with the expert panel did not predict the content of comments, and is therefore ignored. A minority of participants offering comments (two GPs and five nurses in primary care) expressed the view that diabetes tended to be managed more effectively in primary, rather than diabetes specialist, care. Examples include: *"Secondary care seem to be happier with higher levels,"* and *"Secondary care do not have QOF targets so can be happier with higher levels, more interested in improvement than perfect results."*

One GP additionally expressed frustration that the attitude of some people with diabetes towards primary care HCPs can change after interaction with specialist care: *"Personally I find that hospital patients aren't as well controlled and they don't get their other checks e.g. blood pressure and cholesterol - patients misguidedly think if they are under the hospital they are getting all their checks - hospitals seem to forget about everything apart from the 'sugars' which is frustrating for GPs as patients won't then come in to see us as they don't think it's important."*

The majority of participants, however, acknowledged that case mix differs between primary and specialist care settings. Examples of relevant comments from GPs are: *“Our control is generally on a par with secondary care if not better but we will not be looking after the most complicated,”* and *“Probably poorer overall control in secondary care as they are referred the most complicated patients with worst control.”* One primary care diabetes specialist nurse commented that *“We use them for extra support for difficult cases.”* Specifically with reference to intensification of therapy and, hence, to initiating injectable therapies, one GP stated: *“Only refer when further management is needed. In many occasions seeing someone in secondary care may help the patient to accept further management is required.”*

Comments from those who nevertheless attempted to address the topic revealed that awareness of the effect of case mix on health outcomes varied between participants. However, many participants stated or implied that measures of glycaemia tended to be better amongst people with diabetes who are managed in primary care, compared to those managed in specialist clinics. At a minimum, this might be felt to provide some reassurance that the study recruitment strategy was effective in identifying HCPs in primary care who were engaged routinely in caring for people with diabetes.

Statement 10

P4P (QOF) prompts improve the care I provide to patients with T2D.

Experts' result: Agreement (60% selected "Agree", 40% selected "Neutral")

Experts' rationale of their responses:

- 1. Reminders are useful.**
- 2. QOF has improved care.**
- 3. IT issues make QOF unreliable.**

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

Amongst GPs, 35 indicated agreement with the scenario, eight disagreed, and six were neutral. Comments from those indicating neutrality expressed concern that Quality and Outcomes Framework (QOF) targets are not suitable for every person with diabetes. For example: *“Mixed picture - QOF drives us towards tick box medicine, we need to see the problem in the whole context of the patient. May have multiple other pathologies and different priorities at any point in time.”* A similar concern was expressed by one GP who indicated disagreement with the scenario. However, the clear majority of GP responders felt that QOF has had a beneficial effect on diabetes management. Examples include: *“QOF has helped standardise care,”* and *“Useful prompt and reminder,”* and *“We have moved beyond the accidental care provided by prompts, care is proactive and planned,”* and *“I fear checks won’t get done when QOF goes.”*

One of two primary care diabetes specialist nurses expressed an opinion in keeping with that of GPs who had indicated neutrality, stating *“QOF is just a guide, but patients are most important.”* This view was also put forward by one of twelve nurses in primary care who offered comments. However, entirely distinct from the views of GPs, several nurses in primary care felt that QOF was incidental to care provision: *“QOF is data collection. Parameters for care come from guidelines and care standards and my own professional code,”* and *“Work more with regards to NICE guidelines than QOF,”* and *“It*

does not change anything. I would be doing all the QOF things anyway even if QOF didn't exist." In contrast to the opinions of GPs, only a minority of nurses in primary care (5 of 12) offered comments reflecting a positive view of QOF targets and prompts.

With a viewpoint that differed from every other responder to this scenario, one GP stated: "QOF targets are unrealistic and not linked to evidence-based outcomes. They can lead to more hypos. What is the point of testing cholesterol every year on a statin? None!"

In summary, views on this scenario tended to diverge distinctly between HCP professions. GPs tended to feel that QOF targets and payments have improved care for people with diabetes, primarily by encouraging standardisation of care. In contrast, nurses in primary care felt that QOF was incidental to their work.

Statement 11

Lack of funding to cover locum costs is a significant barrier to attending training on T2D (e.g. prescribing).

Experts' result: Mixed views (40% selected "Strongly Agree", 20% selected "Agree", 20% selected "Disagree", 20% selected "Neutral")

Experts' rationale of their responses:

1. Disagree, I would take annual leave to attend a course without need for locum.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

For this scenario, there was no relationship between the indicated extent of agreement or disagreement by individual participants and the comments that they provided. However, there was once again a clear dichotomy of views between professions. With the exception of primary care DSNs, nurses in primary care reported that they never experienced difficulty in obtaining adequate training. Typical comments included: *"No problem where I work to attend courses,"* and *"My surgery allows all time for training."* In contrast, primary care DSNs encountered more difficulty in attending training: *"Funding is often an issue, need to often get funding from reps."*

Amongst GPs, the majority of comments suggested that it was difficult to take time away from work to attend training. One stated that it was *"Better to train the nurses,"* while another complained that a *"lack of funding/ resource is typical of the move in so many areas of trying to push more and more work into primary care."* There was also a reaction from several participants against the suggestion from the expert panel that training should take place in annual leave; one comment also coupled this reaction with another explanation of the difficulty of taking time out of the surgery: *"Unethical to take holiday to go to a work course. If it needs doing it should be in the workload. Experts tend to be overly martyristic about the "expert" area. The problem locally isn't the money, there just are no locums to cover."*

In summary, nurses in primary care did not experience any significant barriers to obtaining training on T2D mellitus but this was not true for primary care DSNs. An absence of cover, whether because of a lack of funding for locums or from a scarcity of locum doctors, was reported by a majority of GPs, while a minority reported no such difficulty.

Statement 12

Lack of insulin prescribing courses is a significant barrier to prescribing them.

Experts' result: Mixed views (20% selected "Strongly Disagree", 20% selected "Disagree", 20% selected "Neutral", 20% selected "Agree", 20% selected "Strongly Agree")

Experts' rationale of their responses:

No comments were provided by the experts on this statement. Please provide yours below.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

For this scenario, 33 participants indicated agreement, 24 indicated disagreement, and 30 were neutral. Comments were received from 32 participants; in contrast to the preceding scenario, there were no marked differences in responses between professions. The largest proportion of participants reported no difficulty in identifying suitable courses. Examples of comments include *"Courses are locally available and often funded,"* and *"There is good access to these courses within my CCG."* Some participants qualified this by referring to a lack of opportunity to use skills: *"Courses are there and good - maintaining competency is the issue."* This led one participant to state: *"The course may be present but if not pitched correctly it is not helpful. However, if we are not prescribing regularly then [we] get deskilled, so little and often may be better approach."*

Interestingly, amongst participants who described having received ten or more hours of diabetes-specific training, and/or a postgraduate certificate, there was no clear consensus on whether a lack of insulin prescribing courses was a barrier to prescribing. One participant who indicated neutrality to the scenario commented: *"We have a good relationship with our secondary care team who come out into the community to do shared clinics, they have provided a lot of training for us, also have the MERIT which is excellent training."* Another participant, who indicated agreement with the scenario, nevertheless provided a similar view of interactions with their local specialist diabetes service: *"[It] does seem to be starting to be addressed with the Topical 2 course and the Cedar centre course and the Cambridge online training."* Another participant who agreed with the scenario acknowledged the potential value of training, with: *"I think more primary care HCP would feel more confident if more courses/training were available."*

Some participants, who had indicated elsewhere that insulin was not initiated in their practices, highlighted the distinction between prescribing insulin, as per the scenario statement, and initiating it. Examples of comments are: *"Yes to initiating but am happy to prescribe on clinical specialist advice,"* and *"Time is the main constraint to primary care starting insulin. We do prescribe it as guided by secondary care."*

Among participants who stated that they had received fewer than four hours of diabetes-specific training, there was a clear appetite, and unmet need, for insulin prescribing courses. Example comments include: *"I would attend a course if available,"* and *"Easy access to free course would help,"* while a GP stated *"Seems that courses more aimed at nurses. I would be interested in attending a short course for GPs."*

In summary, a majority of HCPs felt that a lack of insulin prescribing courses was not a barrier to prescribing in their localities. Several reported valuing short courses, including those provided by their

local specialist diabetes services. Participants who had not received much diabetes-specific training were keen to attend insulin prescribing courses. Others drew a distinction between prescribing and initiating; of these, some, but not all, stated that access to courses on initiating insulin would be helpful. Lastly, among the minority of participants who felt that maintaining competencies was challenging without an adequate caseload, some did not regard courses as useful but, in contrast, others wished to attend them on a frequent, regular basis.

Statement 13

Lack of GLP1 RA prescribing courses is a significant barrier to prescribing them.

Experts' result: Mixed views (40% selected "Disagree", 20% selected "Agree", 20% selected "Strongly Agree", 20% selected "Neutral")

Experts' rationale of their responses:

1. N/A as not initiating injectables for T2D within practice.

Do you agree or disagree with the experts and their rationale? Please explain the reason for your response.

As with some other scenarios, the requirement to respond to the expert panel opinion resulted in confusion. As the extent of indicated agreement or disagreement provides little guide to the content of accompanying comments, it is ignored in this analysis.

Amongst the 12 nurses in primary care who offered comments, only two indicated that they were familiar with GLP1 initiation. One stated *"Plenty of updates/ courses in my CCG to help guide diabetes practice including injectable therapies,"* while the other referred to a previous answer, in which the MERIT course had been praised. Two other nurses in primary care commented that GLP1 therapies were only initiated by specialists, while others indicated simply that prescribing of GLP1 therapies was not within their experience. One diabetes specialist nurse in primary care expressed regret at the relative lack of use of GLP1 therapies: *"as a diabetic specialist lack of prescribing a GLP1 is a barrier. Many could benefit from this drug."*

Amongst the ten GPs who offered comments, four stated that courses were available locally, while another stated that, in their practice, GLP1 therapies were started by nurses. One other GP referred to an inability to access GLP1 therapies, rather than a lack of courses, as the principal barrier to prescribing: *"Funding and CCG policies are the problem."*

Another four GPs indicated unfamiliarity with GLP1 therapies. Comments from three of these four suggested that they experienced a lack of opportunity for training, as follows: *"Easy access webinar would help,"* and *"Less educational stuff around about these and the new treatments. Much less than for insulin,"* and *"Need training in order to initiate and prescribe safely. Training needs to be concise and practical."* Another GP stated that *"Courses [are] available but need to be pitched correctly and regular reminders helpful as easy to get deskilled particularly with newer options on the market."*

In summary, and in contrast to responses to the scenario on access to insulin prescribing courses, a minority of participants felt that they had adequate access to training on GLP1 therapies. The more common experience was that training was either not available locally or was directed principally towards insulin prescribing. Notably, no fewer than three participants referred to GLP1 therapies as being *"new,"* or *"newer,"* despite the first member of this class being approved for use in the UK in

2006. A related, and commonly mentioned, theme was that, if GLP1 therapies were used at all, this was only with input from specialist diabetes services.

Appendix 10. Additional discussion of results

Results in the context of the critical realism theoretical framework

In this section we amalgamate the results from all three study phases using Pawson and Tilley's realist evaluation [5]. This was the predefined approach for interpretation of our results although we found that additional interpretation Aristotelian and Social Learning Theory perspectives was required to frame our results for correct interpretation.

Context

The majority of care in people with T2D in the UK is provided in primary care by GPs or practice nurses. This context provides a number of potential facilitators to good diabetes care and the initiation of injectable therapies: Care provider access is usually easily available to people with diabetes in their home locality, and continuity of care with practitioners is often possible with the opportunity to build a trusted relationship. Primary care practitioners will also have access to the complete medical record required to identify when injectable therapy should be initiated.

Additional context factors also impact on the initiation of injectable therapies in primary care such as national guidelines (from NICE), GP pay for performance targets as part of QOF, and HCP diabetes knowledge.

Access to primary care

The national GP Patient Survey demonstrated that the majority of people in the UK report easy access to primary care services with an appropriate range of appointment times. The average travel time to a GP practice in the UK is around 10 minutes [6]. Primary care is therefore a relatively accessible service. This easy access to the service provides a major opportunity to provide high quality care.

One potential limitation is access to a single patient preferred HCP. In the most recent national GP Patient Survey just over half of all patients (53.7%) reported having a GP they prefer to see and of these only half (50.2%) reported they saw them always, almost always or a lot of the time. People with chronic conditions are more likely to have a preferred care provider and therefore the ability to access this continuity of care may be particularly important in diabetes. This variable access to continuity of care may limit the development of patient trust in their HCP. However, the vast majority of patients (95.6%) surveyed in the most recent GP Patient Survey report confidence and trust in their primary care HCP [7]. Our patient focus groups demonstrated that patients can be sceptical about the efficacy of diabetes treatments; in particular they may have concerns about being prescribed ineffective, for the benefit of the company selling the medication. In this context, relationship building and trust are essential to providing care quality.

Lack of continuity of care may also reduce clinician comfort with escalating treatment to injectable therapy. Clinicians may feel less comfortable initiating an injectable therapy when meeting a patient for the first time. In our simulated surgeries a few of the decisions to escalate treatment were deferred to a follow-up appointment which may have been in part for this reason.

Guidelines and commissioning influences

Many other contextual factors influence the initiation of injectable therapies. National and international guidelines provide a treatment framework which can be used by HCPs to guide

treatment decisions [8-10]. For T2D management in the UK the most influential guidelines are those produced by NICE. These guidelines suggest the use of injectable therapies primarily in people with an HbA1c above target as a third- or fourth-line agents; i.e. they are placed at the end of the flow diagram of treatment options. This approach is consistent with the views of our surveyed and interviewed HCPs who described injectable therapies as a last line option.

Another important care influencing factor in UK primary care are the pay for performance targets which comprise the QOF. In our survey doctors and nurses differed in their views on whether QOF improved care quality for people with T2D; overall GPs felt QOF was beneficial whereas nurses were indifferent. There are no specific QOF T2D indicators relating to injectable therapy prescribing but remuneration for achieving HbA1c targets has the ability to facilitate treatment escalation. Currently GPs are remunerated for the proportion people with diabetes with an HbA1c below 64 mmol/mol and 75 mmol/mol as two of 17 QOF diabetes indicators. Some work has suggested that the QOF targets have a modest effect on the quality of diabetes care in the UK, although studies have been unable to determine causality [11] so this remains unclear.

Diabetes knowledge

Our simulated surgeries demonstrated that GPs have a good working knowledge of diabetes and are able to provide a high-quality consultation for the diabetes patient. They also have the ability to identify cues to action which should prompt treatment escalation and the initiation of injectable treatments. In our simulated surgeries GPs also prescribed injectable therapies but did not provide instructions on how to use the medication. Our survey data suggested that HCPs were generally able to access courses on insulin therapy but that they struggle to maintain skills due to limited patient numbers.

People with diabetes had wide and varying misconceptions and misunderstanding of T2D, and its treatment options. They also appeared to lack insight into the rationale for treatment. This was a limitation widely recognised by healthcare professionals but not something addressed by GPs in our simulated consultations.

Mechanism

The process of initiation of injectable therapy occurs in the clinical consultation. This is the primary mechanism by which this process occurs. Clinical consultations most commonly with GPs or nurses but other HCPs such as physician associates can also occur. In UK primary care routine GP appointments are ten minutes although appointments for reviewing people with chronic disease are longer, typically 15 or 20 minutes. Within this limited time frame a clinician and patient must make a mutual decision to escalate therapy. Additional appointments may be required to go through some of the practical elements of initiating injectable therapies; these are usually performed by a nurse with a specialist interest in diabetes.

Information for the consultation is recorded in the patient record. This also contains patient blood results and other recorded measures such as weight. The electronic record system enables clinicians to browse these elements which is often done within the consultation. In our simulated surgeries we included a complete simulated electronic patient record. We found that GPs used this competently and efficiently to identify important cues which suggested the patient needed escalation of treatment to injectable therapies. These included an ability to identify trends in blood glucose as measured using

HbA1c and they were able to identify previous therapies which had been tried and the reasons why these were discontinued. These data are often not available in secondary care in the UK as primary and secondary care records are not currently widely linked.

The interplay between context and mechanism

In order to achieve an appropriate outcome, in this case the initiation of injectable therapies where they are needed, context and mechanism must combine to provide a favourable *milieu* for change. In general, the primary care setting provides an excellent context for the initiation of injectable therapies. National survey data demonstrate that people with diabetes have a high degree of confidence and trust in their primary care practitioners and there is a good opportunity for continuity of care if planned carefully. There are also significantly shorter waiting times than those experienced in secondary care. In our simulated surgeries it was clear that, within the context of the clinical consultation, GPs had the tools and ability to recognise people with diabetes who required escalation to injectable therapies. Healthcare providers widely felt that the QOF framework within which they provide care was either beneficial in terms of supporting care quality in diabetes or they viewed it as neutral.

Overall, the primary care context and mechanism support the correct introduction of injectable therapies. One of the main limiting factors may be short consultation times. People with diabetes generally reported a lack of clinician time. Within our simulated surgeries there were some elements which were not addressed by GPs which may have been related to a lack of available time. Primarily, GPs did not explore the patients' understanding of their condition or of the aims of treatment. In our focus groups it was clear that practitioners are aware that there is a low level of health literacy in T2D and that this is a barrier to successful treatment. Factors other than time constraints may be responsible for this omission in our observed consultations; clinicians may have altered their behaviour given that the patients were actors or due to the nature of being filmed (although, as discussed above, previous data do not support this [12]), or they may not engage in this level of detailed discussion when meeting a patient for the first time.

In general, we found that the context and mechanism were not the primary barriers to the initiation of injectable therapy. We therefore explore the role of knowledge as a facilitator and barrier in the following section.

Aristotelian and Social Learning Theory perspectives

It is clear that one of the most influential factors governing the initiation (or non-initiation) of injectable therapies in T2D is knowledge; both of the patient and the healthcare provider. Knowledge may help overcome patients' fears, and current learning provided to healthcare providers appears to leave them knowing what to do, but possibly not how to actually do what is needed in their clinical context.

We have elected to explore this particular element in additional detail using a classical framework; the Aristotelian theory of knowledge. Aristotle classified knowledge into three distinct groups; episteme (theoretical knowledge), techne (technical knowledge), and phronesis (practical wisdom). Below we consider the knowledge of people with diabetes and HCPs in each of these areas.

Episteme

In this context we consider episteme to be a scientific understanding of diabetes and its implications and of injectable therapies including their characteristics, effects and adverse effects.

We observed that the episteme (theoretical knowledge) of HCPs in T2D was generally satisfactory. They have a good working level of knowledge of T2D medications and are aware of the types of injectable therapy available for glucose lowering in T2D. They were also aware of their adverse effects and the possible lifestyle implications for people with diabetes. There was some evidence of difficulty recognising progressive beta cell failure and worsening insulinpaenia.

From the focus groups it was clear that HCPs understand that glycaemic control is important to reduce the risk of complications and this is something they consider when making treatment decisions. Across all study phases it was clear that HCPs were aware of hypoglycaemia and weight gain as two of the most important adverse effects of insulin treatment and they considered these in their practice. They also recognised the weight loss benefit of using GLP1 RAs. HCPs were also aware of particular groups where these adverse effects maybe most undesirable such as hypoglycaemia in the elderly, or weight gain in the most overweight.

HCPs also recognised that people with diabetes have a fear of starting injectable therapies and some reported that they used this as a scare tactic to try to encourage lifestyle change in people who were naïve to injectable therapies.

People with T2D often demonstrated misunderstanding of their condition and of the aims of treatment. They reported not feeling unwell and therefore reported they were not certain about their need for treatment. They did however express a desire for better understanding of their condition and how to manage it. Some people with T2D did not see the purpose of taking a treatment where the aim was not to 'cure' them. They also appeared not to have very little understanding that the purpose of treatment was to prevent diabetes complications. People with T2D did not seem to be aware of GLP1 RAs as a treatment option, and some were even unaware that insulin was a treatment option for people with T2D. Others were concerned about the use of medications as a pharmaceutical company conspiracy.

Clinicians were aware of many of these factors and areas where people with diabetes lacked a theoretical understanding of their condition and the treatment. They reported encouraging people with diabetes to go on education courses to improve their knowledge although one practitioner in our survey commented on the lack of non-clinical patient support available. Clinicians, particularly nurses, also recognised the importance of including the patients' family in consultations to provide wider education.

People with diabetes who were insulin naïve did not mention hypoglycaemia risks or other adverse effects associated with insulin treatment. People with diabetes who were injectable therapy naïve also did not mention that possible benefits of improved blood sugar control with injectable therapies in terms of reducing the risks of long-term complications. People with diabetes with experience of insulin found it beneficial but also did not consider the implication on complications longer term.

Overall HCPs have a good working understanding of T2D and its treatments. People with diabetes had varying misunderstandings and misconceptions in both areas but reported being keen to understand more. HCPs were aware of many of the patients' knowledge gaps and reported approaches they used to address these including referral for education sessions.

Technique

In this context we consider the technique to include a technical knowledge of how injectable therapies are used and how they are initiated. This includes the process of collecting, administering, and monitoring the injectable therapies as well as the process of educating people with diabetes in these elements and the process of prescribing the medications. We also consider that additional HCP skills falling under this category include an ability to utilise the electronic patient record and an ability to perform a competent clinical consultation. From a patient perspective, technique includes the ability to collect prescriptions and to administer an injectable therapy. It also includes an ability to undertake relevant blood glucose tests and an understanding of any lifestyle implications that administering an injectable therapy may have.

The technical knowledge of how to use and monitor injectable therapies in T2D was not universally present amongst HCPs. GPs in particular reported a lack of practical knowledge on how to talk a patient through the process of initiating an injectable therapy. This skill set was more common amongst nurses. However, many practice nurses reported being on training courses covering injectable initiation but felt unable to maintain their competence up because of insufficient opportunity in practice. A number of practitioners reported familiarity with injecting insulin but a lack of familiarity with initiating GLP1 RAs.

In our simulated surgeries we observed the technical ability of GPs to perform a consultation with people with T2D and their ability to elicit cues that they may require treatment escalation. The GPs universally performed highly on consultation quality scores and also universally identified which people with diabetes required treatment escalation. They experienced no problems navigating the computer systems and were easily able to identify cues from the medical record that treatment escalation was required. Where GPs did initiate injectable therapies, providing prescriptions, they did not spend time explaining the process of giving the injection.

People with diabetes who were injectable therapy naïve reported being fearful of injections although some of the data suggested that the thought of injecting a medication was the primary concern rather than the pain of injecting. This contrasted strongly with those who had experience of insulin who reported no problems with giving the injections and generally did not find them painful. People with diabetes who were injectable therapy naïve reported a desire to be educated on the use of injectable treatments through practical demonstration; they wanted to see the device and be shown how to use it. HCPs, particularly nurses, were aware of this desire and reported going through this process with people with diabetes.

Injectable naïve people with diabetes were concerned about the potential lifestyle implications that moving on to injectable therapies might mean although these were not described in depth. HCPs were aware of this concern; in particular the potential social embarrassment of using injectable medications on front of others.

In summary, we found that the technical abilities of GPs within the clinical consultation with people with T2D was of a high standard. They widely reported that they didn't have the ability to support patients in developing the technical ability to give themselves injectable therapies. This ability was more commonly present in nurses, although many reported difficulties maintaining competence. This was an important patient requirement when starting injectable therapies.

Phronesis

Phronesis is the practical wisdom to do the right thing, some describe this as professionalism [13, 14]. In this context we consider this to include knowing when to initiate injectable therapies and how to do so successfully in the context of the primary care setting. This includes identification of people with diabetes in whom injectable therapies should be initiated and doing so in line with guidelines and the medical literature. In addition, it includes recognising time barriers and the limits of the HCPs' own knowledge and abilities and making appropriate arrangements to overcome these when needed.

When presented with scenarios where injectable medications were required, this was recognised by GPs within a short appointment and steps were taken to initiate injectable medication. The majority of GPs did initiate injectable therapies in our scenarios although this was almost universally GLP1 RAs. Whilst this might be a particular feature of the GPs included in our study, the positioning of GLP1 RAs before insulin in many guidelines means this is likely to be a stance taken more widely. What was interesting was the use of GLP1 RAs in a patient below the minimum BMI recommended for their use by NICE. GPs did not arrange for referral to a practice nurse to explain the procedure for injecting GLP1 RAs. No protocol or procedure for supporting the patient through this was clear and in our survey many HCPs reported a lack of confidence in this area.

Knowledge gaps

People with diabetes with T2D have significant knowledge gaps and misunderstandings about diabetes in general and of injectable therapies. Clinicians were aware of these but did not assess them in the simulated surgeries we recorded, possibly suggesting this was not part of their routine practice in T2D. Patient misconceptions and lack of knowledge are clear barriers to the successful introduction of injectable therapies in T2D. People with diabetes also reported needing a practical demonstration of any injectable medication in order to feel able to use it correctly.

Clinicians have an excellent theoretical understanding of diabetes, the purpose of treatment and the treatment options available. In primary care the technical expertise to support people with diabetes with injectable initiation resides primarily with practice nurses, although many reported difficulties maintaining competence in practice. GPs are able to recognise people with diabetes who require initiation of injectable therapies and the ability to prescribe treatment but not the expertise to demonstrate the practical component to the patient.

References

1. Bryman, A. and B. Burgess, *Analyzing qualitative data*. 2002: Routledge.
2. Gale, N.K., et al., *Using the framework method for the analysis of qualitative data in multi-disciplinary health research*. BMC Medical Research Methodology, 2013. **13**(1): p. 117.
3. White, D. and D. Hind, *Projection of participant recruitment to primary care research: a qualitative study*. Trials, 2015. **16**(1): p. 473.
4. Tierney, S., et al., *What influences physical activity in people with heart failure?: a qualitative study*. Int J Nurs Stud, 2011. **48**(10): p. 1234-43.
5. Pawson, R., N. Tilley, and N. Tilley, *Realistic evaluation*. 1997: Sage.
6. Moyce, R. and F. Corvaglia *Journey Time Statistics 2016* [online]. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/710462/journey-time-statistics-2016.pdf. 2016.
7. NHS England GP Patient Survey [Online]. <https://www.england.nhs.uk/statistics/statistical-work-areas/gp-patient-survey/>. 2019.
8. Association, A.D., 8. *Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2018*. Diabetes Care, 2018. **41**(Supplement 1): p. S73.
9. National Institute for Health and Care Excellence *Type 2 diabetes in adults: management. NICE guideline [NG28]*. 2017.
10. Davies, M.J., et al., *Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)*. Diabetes Care, 2018: p. dci180033.
11. Forbes, L.J.L., et al., *The role of the Quality and Outcomes Framework in the care of long-term conditions: a systematic review*. British Journal of General Practice, 2017. **67**(664): p. e775.
12. Coleman, T., *Using video-recorded consultations for research in primary care: advantages and limitations*. Family Practice, 2000. **17**(5): p. 422-427.
13. Hilton, S.R. and H.B. Slotnick, *Proto-professionalism: how professionalisation occurs across the continuum of medical education*. Med Educ, 2005. **39**(1): p. 58-65.
14. Hilton, S., *Education and the changing face of medical professionalism: from priest to mountain guide?* Br J Gen Pract, 2008. **58**(550): p. 353-61.

Supplementary tables

Pseudonym	Age category (years)	Duration of diabetes (years)	Ethnicity	Medication
John	75+	20-29	White - British	Oral and injectable
Helen	55-64	20-29	White - British	Oral
Alan	65-74	10-19	White - British	Oral and injectable
Paul	75+	20-29	White - British	Oral
Oliver	65-74	5-9	White - British	Oral
Connor	75+	10-19	Black - British	Oral
Lucy	75+	1-5	White-Other	None
Mary	45-54	10-19	Black-African	Oral and injectable
Beth	65- 74	10-19	White - British	Oral
Alice	65-74	<1	Asian - Bangladeshi	None
Elizabeth	75+	<1	Asian - Indian	None
Thomas	55-64	1-5	Asian - Pakistani	Oral
William	75+	NR	Asian - Pakistani	Oral
Charlie	65-74	20-29	Asian - Chinese	Oral
Mark	45-54	20-29	Asian - Indian	Oral and injectable
Margaret	75+	5-9	Asian - Indian	Oral
Sarah	55-64	NR	Asian - Pakistani	Oral

Supplementary Table S1. Characteristics of the people with T2D participating in the phase 1 focus groups. NR = Not reported

Pseudonym	Age category (years)	Occupation	Healthcare experience (years)	Diabetes specific experience (years)	Ethnicity	Highest qualification
Oscar	65-74	GP	≥40	Not as special interest	Chinese	Postgraduate
David	55-64	GP	30-39	20-29	White - British	Postgraduate
Amelia	35-44	Practice nurse	10-19	1-5	White - British	Undergraduate
Megan	45-54	Practice nurse	10-19	1-5	White - Other	Undergraduate
Susan	55-64	GP	30-39	10-19	White - British	Undergraduate
Michael	55-64	GP	30-39	30-39	White - British	Postgraduate
Victoria	25-34	GP	5-9	None	Asian - Indian	Postgraduate
Anne	45-54	GP	20-29	20-29	Asian - Indian	Postgraduate
Hannah	45-54	Practice nurse	30-39	5-9	White - British	Undergraduate
Daniel	65-74	GP	30-39	1	White - British	Undergraduate
Rachel	45-54	Research nurse	30-39	None	White - British	Undergraduate
Louise	35-44	Practice nurse	10-19	6-9	White - British	Undergraduate

Supplementary Table S2. Characteristics of the HCPs participating in the phase 1 focus groups and interview.

Pseudonym	Age (years)	Healthcare experience (years)	Diabetes specific experience (years)	Ethnicity	Highest qualification
Anne	45-54	20-29	20-29	Asian - Indian	Postgraduate
Daniel	65-74	30-39	1	White - British	Undergraduate
David	55-64	30-39	20-29	White - British	Postgraduate
Lisa	35-44	5-9	0	Asian - Other	NR
Michael	55-64	30-39	30-39	White - British	Postgraduate
Susan	55-64	30-39	10-19	White - British	Undergraduate

Supplementary Table S3. Characteristics of the HCPs participating in the phase 2 simulated surgeries and follow-up focus groups. NR = Not reported

Scenario	Pseudonym of GP						Mean
	Anne	Daniel	David	Lisa	Michael	Susan	
Case 1 (JS)	16	17.5	13	14	13	13.5	14.5
Case 2 (JT)	14.5	17	14.5	12.5	13	12.5	14.0
Case 3 (GJ)	15.5	19	11	13	13.5	13	14.2
Mean	15.3	17.8	12.8	13.2	13.2	13.0	14.2

Supplementary Table S4. The overall scores for each of the GP's consultations assessed using the GCRS. The highest possible score is 24. These scores are at the higher end of the spectrum when compared with other scores reported in the literature.¹ The agreement between the two expert reviewers on the GCRS was a weighted Cohen's kappa value of 0.68 (95% CI 0.43 – 0.93). This rating is 'high-moderate' agreement and consistent with the inter-rater reliability reported between two expert reviewers using the GCRS elsewhere.²

1. Burt J, et al. Assessing communication quality of consultations in primary care: initial reliability of the Global Consultation Rating Scale, based on the Calgary-Cambridge Guide to the Medical Interview. *BMJ Open* 2014;4:e004339.
2. Sarwar N, et al. Diabetes mellitus, fasting blood glucose concentration, and risk of vascular disease: a collaborative meta-analysis of 102 prospective studies. *Lancet* 2010;375:2215-2222.

Scenario	Pseudonym of GP						Mean
	Anne, n	Daniel, n	David, n	Lisa, n	Michael, n	Susan, n	n
Case 1 (JS)	4.5	2.0	4.0	3.5	2.0	3.5	3.3
Case 2 (JT)	5.0	3.0	4.0	3.5	3.5	4.0	3.8
Case 3 (GJ)	4.0	6.0	3.0	4.0	4.5	3.5	4.2

Supplementary Table S5. The number of key prompts (maximum 6) identified for each consultation as reported by two expert assessors.

Scenario	Are the following factors explicitly reviewed in the video of this consultation?	Cohen's kappa (95% CI)
Case 1 (JS)	Increased HbA1c (from 54 to 64 mmol/mol) in last 6 months	1.00 (1.00-1.00)
	Significant intolerance to other oral agents	1.00 (1.00-1.00)
	Looser fitting clothes as described by patient	-0.56 (0.25-1.00)
	Weight decreased by 3kgs in last 6 months	-0.19 (0.18-0.56)
	Recent diagnosis of Type 2 diabetes	1.00 (1.00-1.00)
	Ketone status	1.00 (1.00-1.00)
Case 2 (JT)	Glycaemic control stable (53-58mmol/mol over last 2 years)	1.00 (1.00-1.00)
	Patient expectation in respect of insulin therapy	1.00 (1.00-1.00)
	Urinary symptoms - more genitourinary than osmotic	1.00 (1.00-1.00)
	History of depression and self-harm	-0.42 (0.33-1.00)
	Use of other oral agents contraindicated or limited by side effects	-0.12 (0.57-1.00)
	Strategies to improve maculopathy. e.g. smoking cessation	0.00 (0.00-0.00)
Case 3 (GJ)	Occupation bus driver – need to avoid hypoglycaemia	1.00 (1.00-1.00)
	High current HbA1c (68 mmol/mol)	1.00 (1.00-1.00)
	High BMI (36 kg/m ²)	1.00 (1.00-1.00)
	Patient wishes to improve HbA1c control due to early diabetic retinopathy	1.00 (1.00-1.00)
	Use of other oral agents limited by side effects (TZD)	-0.56 (0.25-1.00)
	Impending driving medical – need to improve glycaemic control	1.00 (1.00-1.00)

Supplementary Table S6. The inter-rater reliability of our assessment of the identification of key consultation factors assessed by two expert reviewers; each factor was assessed by each reviewer across five consultations (one with each GP). Assessment performed using an unweighted Cohen's kappa.

Age (years)		25 to 34		35 to 44		45 to 54		55 to 64		Total
	Sex	M	F	M	F	M	F	M	F	
General Practitioner			2	5	11	10	5	9	7	49
Primary care DSN							1		1	2
Nurse practitioner							1			1
Nurse prescriber							1			1
Nurse in primary care			3		7	1	10		9	30
Research nurse			1				1			2
Pharmacist		1				1				2
Total		1	6	5	18	12	19	9	17	87

Supplementary Table S7. Distribution of survey responders by age and gender (DSN, diabetes specialist nurse; M, male; F, female)

Category	Sub-category	Responses
White	English / Welsh / Scottish / Northern Irish / British	76
Asian / Asian British	Chinese	1
	Indian	9
Unspecified		1

Supplementary Table S8. Distribution of self-reported ethnic group or background of survey participants.

Supplementary figures



Supplementary Figure S1. A map showing the approximate locations of survey responders.