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Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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What is already known on this topic

The proportion of people with visual impairment caused by diabetic retinopathy is increasing globally.

The NHS Diabetic Retinopathy Screening is cost-effective at 80% uptake.

The 20% of people who do not attend screening in the UK are at the highest risk of sight-threatening diabetic retinopathy.

There is little evidence about how screening is perceived and experienced by those professionals and patients involved in it, or how this may affect uptake

What this study adds

People with diabetes want to prioritise preserving their vision, but some do not recognise the need to attend their Diabetic Retinopathy Screening.

This is exacerbated by optometry practices undertaking retinal photography outside of the screening service.

Some participants had difficulties making an appointment, problems attending the appointment, and experienced debilitating side-effects of mydriasis drops.

Encouragingly, a coherent approach to addressing professionals' and patients' respective responsibilities may improve Diabetic Retinopathy Screening uptake.

Some people with diabetes have no difficulties in understanding, engaging with, and attending Diabetic Retinopathy Screening.

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ABSTRACT

What is already known: Diabetic retinopathy is a major cause of preventable vision loss globally. Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment. Diabetic Retinopathy Screening is cost-effective, saving patients' sight and the substantial cost of healthcare provision to those with vision loss. However, certain groups of people are both less likely to attend and to have worse retinopathy.

Objective: To examine patients', health professionals' and screeners' experiences of, interactions with and understandings of Diabetic Retinopathy Screening, and how these influence uptake.

Design: Purposive, qualitative design using multi-perspectival, semi-structured interviews and thematic analysis.

Setting: Three UK Screening Programme regions with different service-delivery modes and deprivation levels, across rural, urban and inner-city areas, in GP practices and patients' homes.

Participants: 62 including 38 patients (22 regular screening attenders, 16 non-regular attenders), and 24 professionals (15 Primary Care professionals and 9 screeners).

Results: Antecedents to attendance included knowledge about diabetic retinopathy and screening; antecedents to non-attendance included psychological, pragmatic and social factors. Confusion between photographs taken at routine eye tests and Diabetic Retinopathy Screening photographs was identified. The differing regional invitation methods and screening locations were discussed, with convenience and transport safety being over-riding considerations for patients. Short appointment times were preferred by patients, some of whom experienced severe side-effects from the mydriasis drops used to dilate their pupils.

Conclusions: In this, the first study to consider multi-perspectival experiential accounts, we identified that proactive coordination of care prior to, during and after screening is required. Patient self-management educational interventions, and improved mydriasis drops may improve uptake of Diabetic Retinopathy Screening, reducing preventable vision loss and its associated costs to individuals and their families, and to health and social care providers.

Keywords: Diabetic Retinopathy, Screening, Qualitative, Inequalities

ARTICLE SUMMARY

Strengths and Limitations of the study

- Our purposive sampling strategy recruited several strata of professional groups in GP and optometry practices and screening programmes, and both regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes.

- Not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening.

- The qualitative findings from our purposive sample are not intended to be representative but highlight important insights into barriers and enablers to screening attendance that will inform further research.

INTRODUCTION

Visual impairment is a significant worldwide health problem (1, 2). Approximately 314 million people globally are visually impaired, with over 80% of this impairment being preventable or treatable (1)(3). Diabetic retinopathy is a major cause of preventable vision loss in people with type 1 and type 2 diabetes in Europe, Africa, Asia and Australia (4-9) (10-13) and until recently (Liew, 2014) has been the leading cause of preventable vision loss in European working age populations (4, 8, 10-12). The proportion of vision loss caused by diabetic retinopathy is increasing globally (13). In addition to treatment costs, lost productivity and quality of life for patients with diabetic retinopathy contribute to personal and socio-economic burdens (14).

Initially asymptomatic, this microvascular complication is associated with high blood glucose, high blood lipids, hypertension, smoking, non-attendance at screening, minority ethnicity (15, 16), duration of diabetes (17, 18) and existing diabetic retinopathy (19). Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment (1, 14). In England, routine diabetes care and Diabetic Retinopathy Screening (DRS) are principally managed in primary care, whilst treatment for retinopathy takes place in secondary care. Issues surrounding diabetic retinopathy therefore have practice implications for medical and health professionals working in both settings.

The UK Government's measurement of preventable vision loss from April 2013 recognises this top public health priority. The English NHS Diabetic Eye Screening Programme offers cost-effective annual screening to people with diabetes (Types 1 and 2) over 12 years (20) where 80% uptake is achieved. Screening uptake is assessed at the general practice level. Screening modes differ regionally, taking place either in GP surgeries, hospitals or optometry practices (see Figure 1). Screening typically takes 30 minutes. Mydriasis drops

dilate patients' pupils, affecting their vision for four to six hours. Digital photographs are taken and the images examined by regional NHS retinal grading teams, who identify any pathology. Results are communicated to the patient and GP. Patients with retinopathy requiring monitoring or treatment are referred to the Hospital Eye Service.

However, approximately 20% of people invited for DRS do not attend (23), with those from minority ethnic backgrounds and people living in deprived areas both less likely to attend and to have worse retinopathy (24), (15), (20). Inequalities in access to DRS in England[8] have led to calls for further research (25), including qualitatively (15).

Yet deprivation alone does not explain all the uptake variability between GP practices and regions. For example, misunderstandings about the importance of diabetes and personal risk factors amongst people undergoing diabetes screening and patients' lack of awareness and psychological factors or practical obstacles have been identified as major barriers to attending screening (26). However, as attendance rates vary greatly between neighbouring practices, for example, from 55% to 95% in Gloucestershire (27), research focusing beyond deprivation, risk factors or barriers is required. Little is known about how patients' and professionals' perceptions and experiences of DRS may influence attendance. This paper therefore focusses on experiences around DRS that may affect uptake, from the accounts of people with diabetes and the GP practice and screening staff involved in screening.

Figure 1: Diabetic Eye Screening Programme delivery modes

METHODS

Ethical permission was granted by NRES Committee South West – Cornwall and Plymouth 10/H0203/79 and informed consent was given by all participants. This work was supported by the National Institute of Health Research, Research for Patient Benefit grant reference PB-PG-1208-18043 and sponsored by Gloucestershire Hospitals NHS Foundation Trust.

Design of the research: This multi-perspectival (28), cross-sectional qualitative interview study used purposively sampled GP practices in four UK Primary Care Trusts across three regions, based on Indices of Multiple Deprivation, practice type, mode of screening, and screening uptake (see Table 1).

Practice recruitment: Central England Primary Care Research Network and South West Diabetes Network provided research nurse assistance with GP practice recruitment. Twelve GP practices were approached to participate; two declined (existing research commitments); one withdrew prior to commencement of participant recruitment (staff changes). Characteristics of the nine participating GP practices are detailed in Table 1. The Central Local Research Network paid Service Support Costs of £599.27 to participating GP practices.

[8] http://www.screening.nhs.uk/news.php?id=12156

Table 1: Practice characteristics

Participant recruitment:
Professionals We purposively recruited 24 primary care and screening professionals who had patient contact in differing roles around DRS to ensure a broad spectrum of views and experiences. ***Patients*** Within each practice, patients were purposively sampled based on their screening attendance history, to consider differences in attitudes and experiences. "Regular attenders" had attended all three of their most recent DRS appointments; "Non-regular attenders" had attended none or one of their three most recent DRS appointments. Practice staff telephoned potential participants and sent information packs.

Interviews Semi-structured interviews were conducted either face-to face, at the GP/optometry practice, in patients' homes, or by telephone, at participants' discretion. The multi-perspectival interviews allowed us to understand the dynamics between patients, professionals and the Screening Programme, explore similarities and differences in their perceptions to highlight potentially differing needs and suggestions for improving services. Questions aimed to capture descriptions of participants' experiences before, during and after the screening appointment, from professionals' and patients' perspectives, identifying patient factors they believed influence screening attendance. All interviews were audio-recorded and transcribed verbatim prior to analysis. No additional data is available for data sharing.

Analysis Data were managed using QSR NVivo10 software[9] to code and review themes. AH undertook iterative, thematic analysis, using constant comparison within and across all transcripts. Looking for overarching themes and relations between them, AH identified specific major and minor categories within the themes that might interact to influence screening attendance rates. AH and AL met to discuss these themes and agreed on the definitions of emerging codes. No theme was unique to either regular attenders, or non-regular attenders. Findings were discussed with different project group members until consensus was reached about the interpretation of key themes. Finally, AH checked these interpretations with the existing data.

RESULTS

Characteristics of the sample: 62 participants (33 female) were interviewed between September 2011 and July 2012, by AH, AL and JS. Of the 38 patients, four have Type 1 diabetes (mean age 49); 34 have Type 2 (mean age 60); 22 were regular retinopathy screening attenders, 16 were non-regular attenders (defined above). Of the 24 professionals (mean age 50), eight are primary healthcare professionals, seven are administrative practice staff; and nine are diabetic retinopathy programme screeners.

Table 2: Programme and participant characteristics

[9] www.qsrinternational.com/

Understandings of Diabetic Retinopathy and Screening

GP practice staff, screeners and patients identified several antecedents to attendance and non-attendance at screening. Both regular and non-regular attending patient participants acknowledged the importance of DRS. Yet confusion around screening was clearly identified in all participant groups, as was the need to overcome this.

Understandings of Diabetic Retinopathy:

People with diabetes largely understood causal factors and the potential consequences of Diabetic Retinopathy; protecting the eyes appeared to be a priority for some. Interestingly, a non-regular attender with vicarious experience of sight loss identified herself to the researcher as a regular attender. Others found the process reassuring**.**

> *It's the smallest vessels that go first, and it's one of the quickest ways of seeing the effects is in the eyes. But... the body is so tolerant, you don't recognise that the vision is going until it's too late.* Patient 8 (Region 2, Regular)[10]

> *I: So what is it that encourages you to come [to screening] then?*
> *P: My brother-in-law he was a very bad diabetic... He actually died from it. He went blind first.* Patient13 (Region 3, Non-regular)

> *I like the fact that you instantly see and can get a decent steer on if there is anything negative; it's complete peace of mind – well my results anyway.* Patient 3 (Region 2, Regular)

Psychological, pragmatic and social influences on non-attendance

In response to being asked why people might not attend DRS, both professionals and patients acknowledged that denial of having diabetes could contribute. One patient had missed screening appointments because she disliked the close proximity of the screener. Pragmatic reasons raised by the non-regular attenders for non-attendance included work commitments and post-operative recuperation.

> *Some people just… have their head in the… like the ostrich, they don't have diabetes or they're not taking any notice of it and they will just… yes, not come. Some because they think they can't have the time off work, you know?* Screening Programme 1 (Region 1)

> *It's just the thought of somebody coming close to my eye*. Patient 15 (Region 3, Non-regular)

> *I missed once, because I had an abscess in an awkward place around that time, and I had to have an operation. But the following year I made sure.* Patient 5 (Region 3, Non-regular)

[10] R = region from Table 1; Regular attender/Non-regular attender (as defined above)

Another non-regular attender who identified herself as a regular attender had attempted to access DRS via her GP practice, but was refused because she was in temporary accommodation awaiting rehousing. This highlights the complex social context in which people with diabetes experience screening:

> Int*: So you didn't always come?*
> *Pt: Well, with being homeless for 8 weeks... But they [GP practice] didn't want to know. 'Oh you're not in our area.' I'm in nobody's area because we were in a bed and breakfast; they were my last doctors.* Patient 10 *(*Region 1, Non-regular)

Understandings of Diabetic Retinopathy Screening vs. routine eye test

Patients' perceptions of screening attendance were confused by high street optometry practices routinely taking photographs during a general annual eye check. Patients confused this with DRS even in areas where High Street optometry practices did *not* conduct DRS, confounding attendance:

> Pt *I'm with [high street optometry chain] so I've always, always had my eyes screened.*
> *Int You've had your eyes tested for your vision?*
> *Pt Yes, and I've always had the backs of my eyes and everything screened because that's part of their package.*
> *Int Do they do the actual diabetes screening?*
> *Pt Yes. I never have it done at the surgery, never. ... So when I was diagnosed and I told the optician she said, well we can do that here for an extra £10 and we will just email the surgery. So I thought fine, that's fine. So I just bypass it completely...*
> Patient 4 (Region 2, Non-regular)

> *A lot of people turn up and say, 'well I had my optician's test' and you kind of sit there and explain to them that although it's a great thing to have and they need to have it, we still need to do our tests because it's more accurate, and we're searching specifically for the diabetic retinopathy.* Screening Programme 1 (Region 1)

Perceived responsibility for patients' understandings of Diabetic Retinopathy and screening

Professionals and patients identified the need to improve patients' understandings about DRS and sight threatening retinopathy. For example, one GP accepted that low uptake reflected a failure to deliver the right message. However, more direct input from the health professional team was suggested by one patient who had not understood the screening information, and subsequently developed retinopathy. One screener considered that the lack of media attention to DRS could contribute to low attendance.

> *Why haven't they taken that onus of control, what is it that they don't believe about their diabetes? Where have we gone wrong in trying to get that message across? ...the words "Diabetic Retinopathy Screening", what does that mean to them?*
> Health Professional 1 (Region 3)

As soon as I had diabetes diagnosed somebody should have explained to me more fully what the implications are. Because it's alright them giving you a leaflet and sending you home... but even though you read it, there's this kind of silly thing, 'oh it won't happen to me', attitude. Patient 15 (Region 3, Non-regular)

Lack of patient information. I don't think screening is something that's pushed as much as other screening. I mean retinal screening is…I'd say it's important... but things like breast cancer, there's a lot more press about it. Screening Programme 2 (Region 1)

Accessing Diabetic Retinopathy Screening

This theme highlights participants' varying experiences and perceptions around making the appointment, getting there - and back. Patients had difficulties in making, attending and returning from their screening appointments.

Pre-booked VS. Self-booked appointments:

Invitation methods vary by Region (see Figure 1), with professionals and patients identifying issues around both modalities that could affect uptake. Patients need to be proactive either to make their appointment, or change an inconvenient pre-booked appointment (depending on where they live). All participant groups identified the possibility of patients forgetting to do either, whilst this could be particularly problematic for working patients.

But it does rely on the patient being proactive. You get an appointment, alphabetical order, totally inconvenient, impractical time, what do you do, do you do nothing and forget it or do you ring up and change it? And if you don't ring up and change it then nothing happens, you're just a DNA statistic aren't you really. Screening Programme 3 (Region 1)

Int: *So you get a letter with the appointment pre-booked?*
Pt: Yes. And then if you can't make it you change it.
Int: You wouldn't prefer to be able to ring yourself and make an appointment?
Pt: No, because I think you'd tend to forget wouldn't you, and I think most people would. Patient 3 (Region 1, Regular)

Patients are used to receiving pre-booked appointments for other diabetes clinics, such as seeing the Practice Nurse to be weighed and have their feet checked. Professionals felt that expecting patients to make their own DRS appointment downgraded its perceived importance to patients, or was not patients' responsibility. This was exacerbated by the perceived rigidity of the appointment-booking system in another region.

I think if it's left to the patient a lot of the time they don't think, because they have to do it, it's not that important Health Professional 4 (Region 3)

> *Why should a patient… if it was a blood test… would the GP just say, go and sort it out yourself, and the patient is just registering himself at the hospital, getting a blood test and making sure the GP gets it? That's ridiculous.* Screening Programme 1 (Region 3)

> *I get a letter saying I need to make a phone call between specific times on specific dates and they give you a block of dates ...to make the appointment in advance ...a good 6 weeks* Patient 5 (Region 2, Regular)

Patients in the area that delivers DRS through high street optometry reported an absence of available appointments:

> *Well before the appointment I phoned and they said no, they'd got no appointments for the next three months... The following year again the same thing, I phoned when I had the letter, they said three months waiting*. Patient 5 (Region 3, Non-regular)

Integrating diabetes appointments

Patients in different regions suggested that DRS should be better integrated with their other diabetes care. They understood that this would reduce the inconvenience of attending numerous appointments:

> *Probably would be better if it was done the same time as you have a normal diabetic appointment... I mean I've had to come up here on the Tuesday because they wanted to check my weight and then I think it was the Wednesday to have my eyes done and I'm thinking, do I need to come up twice [laughs].* Patient 8 (Region 1, Regular)

Transport

Getting to and from screening appointments was important pragmatically for many patients, who had to overcome a range of issues. One health professional recognised that transport issues and proximity of screening to patients' homes potentially affected uptake, apparently understanding patients' reticence to travel - although without the insight into the difficulties that some patients experienced:

> *Most patients around here like to go to things that are within walking distance or within a bus stop, if that. So transport is an issue. …they know the surgery, 'oh the surgery is next door, I know the girls there, they're always there'... So maybe I need to have the retinopathy screening done at the surgery and they'd all come [laughs].* Health Professional 1 (Region 3)

Patients are advised not to drive to/from DRS appointments, because the mydriasis drops cause blurred vision and photosensitivity (detailed later). The pragmatic repercussions of this were especially notable for people of working age. However, alternative travel arrangements also emerged as impractical because of an inability to navigate sufficiently with blurred vision.

I am tied to either making them [screening appointments] in the afternoon and then getting home, so I have to work out how to get into work in the morning that doesn't involve driving, or I have to be there [GP practice] earlier, say lunch time or something, I have to take a half day Patient 5 (Region 2, Regular)

Some people will find that hard I think, because of the drops, it makes it difficult for the people's journey...it's like a cobweb on top of your eyes and… No I can't see at all... We have to have the eye drops so it's very hard to either walk it back …I felt I was blinded temporarily and got into a taxi and then got out of the car somehow. I had to cross the road and I was just looking like that [stares blankly] because I was waiting for the taxi and I had to do like that [waves arms]… Patient 5 (Region 3, Non-regular)

Screening Experiences

This theme incorporates patients' experiential accounts of the actual screening appointments. It includes negative experiences of lengthy appointments in High Street optometry practices compared with others' efficient GP practice appointments. Some patients experienced severe side-effects and subsequent adverse affects from the mydriasis drops. Participants discussed strategies to overcome these side-effects.

Appointment length

In one region appointments lasting several hours at optometry practices potentially served as a deterrent. One patient recognised that food abstinence for this long was particularly inappropriate for diabetes patients, whilst another overcame the problem by changing practice.

Yes, the first time I went to... the local optician ...I was there for 5 hours, from 10 o'clock in the morning, and by the time I got out of the door it was 3 o'clock. ... And by then I can remember I was so hungry and I thought, 'well how does that help a diabetic person?' Patient 5 (Region 3, Non-regular)

I had my optician before and he was quite slow, the drops used to sting and he used to take a long time. I had to be there for about two or three hours. But my present optician is good. Patient 1 (Region 3, Regular)

However, in sharp contrast, where screening was delivered in GP practices, satisfaction with short, efficient appointments was reported.

They're quite good actually, see you straight away, well within, you know ...about ten minutes of your appointment if that. Patient 8 (Region 1, Regular)

It doesn't take half an hour I suppose at the outside, even though you've got to have the drops and wait for them to activate, and then the actual screening is about 15 minutes... Patient 1 (Region 2, Regular)

Side effects of drops

Mydriasis drops dilate the pupil, allowing more light into the eye and a clearer retinal photograph to be taken. However, in another important finding, many patients (both regular and non-regular) experienced severe pain, blurred vision and debilitating photosensitivity lasting for several hours. Interestingly, none of the health professionals except the optometrist raised this, suggesting that they were unaware of this issue.

AH: you come and they put the drops in do they?
P: Oh yes. They were like acid burning my eyes this time... It really hurt this time. Patient 1 (Region 1, Non-regular)

Everything else is fine, it's just the drops, they sting like hell. Patient 3 (Region 1, Regular)

And I hate that because it affects my eyes for so long and I can't… put my lenses back in straight away so someone is with me because I can't see... Patient 4 (Region 2, Non-regular)

I would advise anybody to bring sunglasses even if it's not particularly bright... if I had them I'd wear dark goggles so that they're closed in. Like welders goggles [laughs]. Actually no like swimming goggles but darker, to keep all the light out from the sides now, because it's painful. Patient 5 (Region 2, Regular)

If someone tomorrow has drops put in because of the service and they just happen to have a reaction to the drops, and they lose their eyesight... So then who are they going to sue? …if push comes to shove we're the ones who are going to get sued [optometrists]. Screening Programme 1 (Region 3)

DISCUSSION

Results in context

For some patients and practices the DRS Programme worked well and we confirm that a convenient screening location close to home was beneficial (28) and preserving vision was prioritised amongst diabetes patients (29). For others, misunderstandings about the importance of diabetes and personal risk (26) (30), lack of DRS awareness, psychological factors, practical obstacles (26) and the deterrent side-effects of mydriasis (31) represented potential attendance barriers.

No clear distinction between regular and non-regular DRS attenders was identified. In an important new finding, we uncovered confusion between routine retinal photography at optometry practices during eye examinations, and DRS. Whilst optometry photography may represent an important safeguard for non-attenders, it could impair more

comprehensive coverage. Furthermore, making patients responsible for arranging appointments in some regions, combined with encountering delays, could undermine the perceived importance of DRS. We have identified patients' misperceptions about their attendance regularity.

Strengths and Limitations of the study

Strengths of this study include the purposive sampling strategy across several strata of professional groups in GP and optometry practices and screening programmes, and recruiting regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes. However, not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening. The qualitative findings from our purposive sample are not intended to be representative but highlight important insights into barriers and enablers to screening attendance that will inform further research.

Implications for clinicians and policy makers

Some patients lacked information and understanding about DRS, which calls for proactive personal clinical risk communication (17, 18) and attendance information to ensure care coordination. The current guidance to bring sunglasses could be strengthened in the patient information. Some patients confused retinal photography at optometry practices with DRS. Professional Optometry bodies could ensure clarity amongst members, and optometrists should highlight the difference to their patients. Consideration may be appropriate around the responsibility that the NHS has when discharging visually impaired patients in to the community. Culturally sensitive improvements (25) should build upon the recent introduction of patient information leaflets in several languages[11].

Several providers now deliver DRS in the UK, and, since this research was conducted, Public Health England is responsible for delivery; the 2014/15 Quality Outcomes Framework now excludes the DRS indicator. This fast-moving field requires monitoring closely. Building on the successful central appointments system and practice factors that affect DRS attendance (33), may prove useful. The national implementation of the new screening pathway should ensure consistent delivery throughout the country, improving the quality of services and reducing variability (32).

Future research

More work is needed to determine the prevalence of patients' and clinicians' views on the appropriate design and delivery of DRS services to maximise attendance; hospital staff may provide insightful alternatives for service improvement. Encouragingly, many of the attendance barriers identified seem amenable to intervention. Community-based, culturally

[11] http://diabeticeye.screening.nhs.uk/languages

competent, educational interventions (25), supported by a Public Health media campaign should be developed, tested and implemented. The pharmacological reformulation of shorter-acting mydriasis drops to minimise side-effects may reduce disruption to patients and potentially benefit uptake rates, although we acknowledge that this would not address the pain from the osmotic effect of the drops. The extent of confusion about optometry photography needs urgent assessment.

Conclusions

This study uses staff and patients' experiences of Diabetic Retinopathy Screening to start unpicking factors affecting uptake rates. The successful implementation of the new care pathway should ensure proactive care coordination and consistent strategies to identify and address unmet access needs before, during and after screening. Clear guidance from professional bodies, a Public Health media campaign to encourage positive attitudes, and reformulated mydriasis drops, may improve DRS attendance. Used as an international model, this may, in turn, contribute to reducing preventable vision loss globally and its associated costs to individuals and their families, and to primary, secondary and social care providers.

Footnotes

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- **Contributorship statement:** IS had the original idea; PS led the funding application. JS and AL had the idea for the qualitative component of the study. All authors contributed to the development of the protocol and overall supervision of the study. AH, the project manager, obtained ethical approval, and conducted the interviews with AL and JS. AH led the qualitative analysis and drafted the paper. All authors contributed to the writing of the final version of the paper. PS is guarantor.

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- **Competing interest Statement:** PS is the Director of the NHS Diabetic Eye Screening Programme; AH has personal experience of mydriasis drops.

- **Payment:** a £5 High Street voucher was given to patient participants in recognition of their contribution.

- **Transparency statement:** The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

- **Provenance and peer review:** Not commissioned; externally peer reviewed

- **Data-sharing statement:** Copies of the topic guide and participant information sheet can be obtained by emailing the corresponding author.

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Table 1: Practice characteristics

Practice no.	Screening Programme area	Index of Multiple Deprivation (IMD)	Practice type	Screening delivery mode	Uptake rate
Practice 1	Region 1	Deprived	Urban city	GP practice	96%
Practice 2	Region 1	Below average	Rural Town	GP practice	88%
Practice 3	Region 2	Deprived	Rural Town	GP practice	85%
Practice 4	Region 2	Above average	Rural Town	GP practice	75%
Practice 5	Region 1	Deprived	Rural Town	GP practice	73%
Practice 6	Region 1	Below average	Urban City	GP practice	72%
Practice 7	Region 2	Least deprived	Rural Town	GP practice	71%
Practice 8	Region 3	Most deprived	Inner City	High street optometrist	68%
Practice 9	Region 3	Most deprived	Inner City	High street optometrist	57%

Table 2: Programme and participant characteristics

Screening Programme Regional descriptor	**Region 1** Urban city rural town	**Region 2** Rural town	**Region 3** Inner city	**Total**
Number of practices	4	3	2	9
Patients (Non-regular attenders)	14 (5)	8 (1)	16 (10)	38 (16)
Medical practice staff (GPs, optometrist, HCAs, nurses)	2	3	3	8
Administrative practice staff (receptionists, managers)	4	2	1	7
Screeners	4	4	1	9
Total participants	**24**	**17**	**18**	**62**

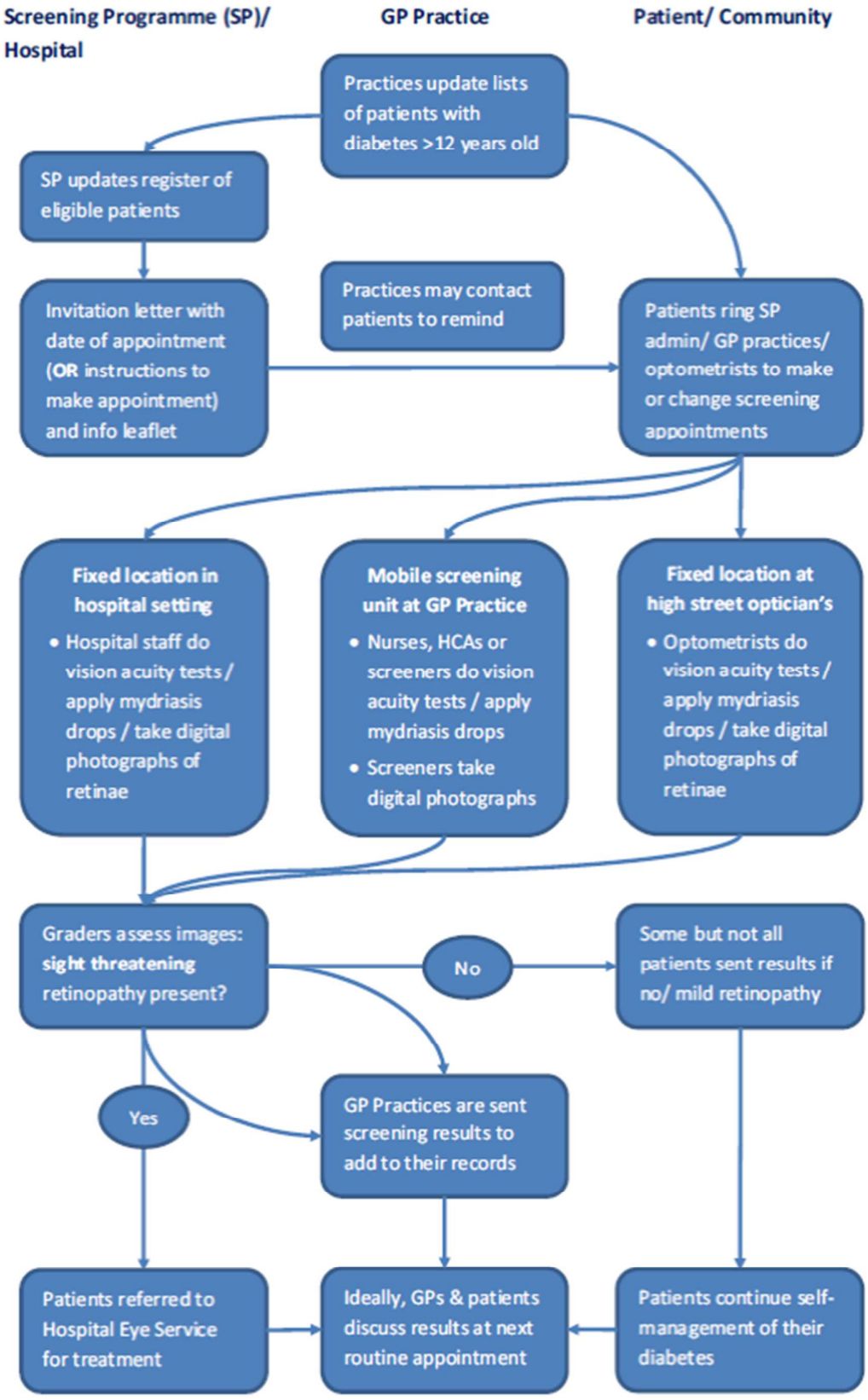

Figure 1: Diabetic Eye Screening Programme delivery modes

THE UNIVERSITY OF WARWICK

Warwick Medical School

Understanding *F*actors leading to *L*ow *U*ptake of diabetic *R*etinopathy sc*R*eening *I*n Primary Care (FLURRI study)

Ethics Protocol

Version 8.2: 14th February 2012

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Research for Patient Benefit Programme

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Section 1: Background to the study

1.1 Lay Summary

Diabetes is a very common condition affecting 1 in 20 UK adults. One complication of diabetes is diabetic retinopathy, which occurs when diabetes damages the small blood vessels at the back of the eye (retina). Symptomless to the patient until it is in the advanced stages, if left untreated this can result in loss of vision and blindness. Diabetic retinopathy is the most frequently reported cause of blindness in the working age population in the UK (Bunce and Wormald, 2006) and is second only to macular degeneration as a cause of blindness in those above 65. People with diabetes are invited to have digital photographs taken of the backs of their eyes (retinae) once a year. This can detect problems at an early stage when they can be treated and prevent further vision loss.

However, a significant number of people invited for retinal photography do not attend, and may be putting themselves at risk of future blindness. Research has shown a relationship with non-attendance at screening and subsequent loss of vision (Zoega, Gunnarsdottir, Bjornsdottir et al., 2005).

We are interested in finding out why people do not attend to have their eyes photographed so that we can use this information to try to increase the number that do. It has been found that those in deprived areas are less likely to attend, but this does not explain all the variability between GP practices. Reasons given to screening programme staff for failure to attend include inconvenient timing of the appointment, the patient forgot, the attitude of the administrative staff booking the appointments and anxiety about screening. There may be cultural and language barriers in ethnic groups.

We will choose GPs in Gloucestershire, Birmingham and Warwickshire, some with good levels of attendance and others with poor attendance, located in areas of high or low health need. Gloucestershire and Warwickshire run screening programmes using retinal screeners in mobile screening locations and, in Warwickshire, at fixed sites. The Birmingham programme uses high street optometrists. We will speak to health professionals in these practices to understand how they inform and educate people with diabetes about retinal screening. We will speak to patients, including those who have attended and those who have not, in order to see if there are ways in which uptake might be improved. We will also speak with retinal screeners and optometrists who undertaking the photographic screening.

1.2 Background to the Study

Diabetic retinopathy occurs when the blood vessels in the retina become blocked, leaky or grow haphazardly, which can damage the retina and prevent it working properly. The risk of diabetic retinopathy developing and progressing can be reduced by maintaining blood glucose, blood pressure, and blood lipid levels as near to normal as possible. Diabetic retinopathy affects nearly all people with Type 1 and almost two thirds of people with Type 2 diabetes, within 20 years of diagnosis, in the UK (Scanlon, 2008). Recently published data show that 2.2 million people now have diabetes in England (Diabetes UK, 2010 http://www.diabetes.org.uk/About_us/News_Landing_Page/Number-diagnosed-with-

diabetes-rises/). With approximately 90 per cent having type 2 diabetes and 10 per cent having type 1, this equates to over 1.4 million people with diabetic retinopathy. The English National Screening programme has estimated that the costs of assessment and treatment in England are £51,243,758 per annum (unpublished data). In 2003, Meads and Hyde reviewed the costs of blindness. The published estimates of the cost of blindness to the NHS in diabetic retinopathy were equated to December 2002 rates and varied from £7,433 per annum to £11,250 per person in 2002 costs. Much of the uncertainty in any sensitivity analysis of the cost of blindness in older people is associated with the cost of residential care. The authors concluded that the excess admission to care homes caused by poor vision is impossible to quantify at the present time (Meads and Hyde, 2003).

Non-attendance at screening is recognised as a risk factor for sight threatening retinopathy (Gray, 2009). The variation in uptake rates is of great concern because only when uptake is above 88 per cent is there any chance that the screening service will be 80 per cent sensitive to detect sight threatening diabetic retinopathy, as those not attending are more likely to have DR. This has been shown recently in a screening programme where high risk patients were invited, then three months later non-attenders were invited again; the non-attenders' level of DR was higher than those who came in the first wave. These were individuals who had already been identified using a high risk algorithm (Stratton, 2010; personal communication).

The English National Screening Programme for Diabetic Retinopathy (DR) aims to reduce the risk of sight loss amongst people with diabetes, by the prompt identification and effective treatment, if necessary, of sight threatening diabetic retinopathy, at the appropriate stage of the disease process. Free annual screening is offered to all people with diabetes over the age of 12 years in England. Patients are systematically invited to have their retinae digitally photographed at their GP surgery, high street optician, or local hospital, depending on which part of the country they live in. For the photograph to be taken properly, drops to dilate (widen) the pupils are put into patients' eyes, affecting their ability to drive for a short while afterwards. People who do not attend their screening are followed up by letter or telephone call, up to three times, by the regional screening teams. Additional screening sessions are held to maximise attendance, including at weekends in some areas. The photograph is sent to trained and accredited regional NHS retinal grading teams, who perform a two- or three-stage image grading process. This identifies any changes that could indicate sight-threatening diabetic retinopathy that requires monitoring or treatment. The grading teams notify any such indicators to the patient and the medical team.

Different types of retinopathy exist. For example, background retinopathy, the least serious, is unlikely to be sight-threatening and requires no treatment other than annual monitoring through the screening programme. However, serious conditions such as proliferative retinopathy, require referral to the patient's hospital opthalmology team for treatment. This condition occurs when the retinal cells become stressed by oxygen deprivation, and new, weak, blood vessels grow. These blood vessels can leak, break off, or bleed, causing potentially sight-threatening damage to the retina. Most of these serious retinopathies are treated by a specialist, using a laser at a hospital outpatients clinic, with patients allowed to return home afterwards. A tiny laser beam is directed onto the abnormal part of the retina and then small bursts of laser light are used to seal leaking blood vessels or to treat areas of retina that are lacking oxygen. Laser treatment reduces the stimulus for the production of

abnormal new blood vessels growing in the retina, which will often regress or fibrose after laser treatment. Whilst vision that has already been lost is not recoverable, laser treatment can prevent further damage from occurring. For some people, however, laser treatment is insufficient and surgical intervention may be required.

A key service objective of the English National Screening Programme for Diabetic Retinopathy is to maximise the number of invited persons accepting the test. In 2007-8, minimum targets of 70% attendance in the first round, and 80% in subsequent rounds were not achieved in at least 30% of programmes. Even in a well established screening programme (Gloucestershire), attendance rates within individual General Practices vary between 55% and 95%. A recent review for the National Screening Committee (Fell, 2007) showed limited primary research in this area, with much drawn from overseas and the research available focussing on population characteristics.

If Diabetic Retinopathy is diagnosed early, it can be effectively treated and sight can be saved or preserved (Bachman and Nelson, 1996; Scanlon, 2008). Furthermore, maintenance of vision is associated with better quality of life and independent living in older people (Chia et al., 2006). Importantly, DR screening has been found to be cost-effective in the English programme (James, Turner, Broadbent et al., 2000). A systematic review of interventions covers publications up to May 2005 (Zhang 2007). This includes 48 studies, 5 in the UK (12 randomised controlled trials, four non-randomised studies, and 32 pre-post studies). All of the UK studies were carried out before the introduction of the English Screening Programme, and interventions shown to be effective in the review (screening programmes, patient leaflets, diabetes registers, involvement of primary care teams) are in place. Unpublished evidence presented at the English National Diabetes Retinal Screening Programme and the National Diabetes Support Team conference in 2008, identified a number of interventions that may improve attendance, including a redistribution of existing cameras, more screening locations, better transport options, additional service, weekend / evening clinics, additional telephone lines, an answer phone, a publicity campaign and leaflet translations improved access. Research that has focussed, quantitatively, on population characteristics showed that patients in the most deprived areas are less likely to attend for screening whilst having worse retinopathy (Scanlon, Carter, Foy, et al., 2008), whereas in SE London younger patients were less likely to attend (Millett and Dodhia, 2006). In Scotland, distance to screening site was not found to be a factor, but duration of diabetes, poor control and smoking were associated with lower uptake (Leese, 2008). In Iceland, a significant relationship between poor screening compliance and poor visual outcome was found (Zoega, 2005). One study in Dublin showed that recommendation by a physician increased participation (Dervan, 2008). No qualitative studies have been undertaken in the UK or elsewhere, to understand the factors affecting uptake of systematic retinal screening from the perspective of patients or professionals.

Strategies to increase uptake in other screening programmes in England have shown mixed results. Some research has been undertaken in the cervical and breast cancer screening programmes (Sutton et al., 1994; Pfeffer, 2004) and these found that attitudes, beliefs and intentions towards disease and screening – which are potentially changeable through patient education – influenced screening attendance. This included the women's perceptions of their disease risk, and, importantly, non-medical reasons influenced attendance, for example

concerns about the screener's gender, religious grounds, and fears of feeling socially inadequate. However, these invited different population groups for screening and the findings may not be transferable as reasons for non-attendance at the diabetic retinopathy screening programme.

1.2.1 Research team's professional background to the study

The Cheltenham team are based within the National Screening Programme. Dr Scanlon is the Programme Director for the English National DR Screening Programme, overseeing the External Quality Assurance for 91 screening programmes in England and in a strong position to influence, if positive results for improving screening uptake are derived from this research. Findings from the project will be communicated with Screening Programme Managers and Clinical Leads in all 91 screening programmes. The National Programme has six Regional Quality Assurance Managers who communicate regularly with screening programmes in their regions and with the SHA Screening Leads and make recommendations to improve services. The English National Diabetic Retinopathy Screening Programme manages the External Quality Assurance for all 91 programmes and is in regular contact with programmes, Public Health Consultants and commissioners.

The Warwick team are experienced diabetes researchers from primary and secondary care and local retinal screening programmes. Jackie Sturt's interests in the areas of complex interventions such as self-management, structured education, psychological interventions, outcome measurements and user involvement are central to the aims of this project. The team have broad methodological experience with particular expertise in the case study methods employed in this study.

1.2.2 Patient involvement in the development of this study

The original idea for this research came from Irene Stratton and this was further developed with the assistance of a patient representative (Mike Whatmore). Reasons for non-attendance might be clinic related such as location, access to clinic, time/date of appointment, waiting time, welcoming attitude, communication, ease of re-arranging appointment, public transport/walking distance (eye drops prevent driving) or car parking if being taken by relative or neighbour. He felt that there might be patient related reasons such as personal/family commitments (childcare, sickness), weather conditions, independence (mobility, age, eye-sight, confidence), ethnicity needs (language, support, 'permission') and education (understanding the benefits of retinopathy screening, and, that it is in addition to the basic annual eye test at their optician) and are they aware that it is free? Mike has collaborated both with the Gloucestershire and Warwickshire teams and he will continue his active involvement throughout the project. This proposal has been further developed with the collaboration of members of the Warwick Diabetes Research & Education User Group (WDREUG), who have reviewed the research questions, the interview schedule questions, ~~and~~ the sampling processes and new publicity material. This group of approximately 10 people with diabetes have been meeting bi-monthly since 2001 to consult with the diabetes

research team on the development, execution, analysis and dissemination of the research projects and they have been acknowledged in 8 previous publications and contribute to INVOLVE activities. A further 10 members are involved via email. Halfway through the study, the group will be given the results to date, to see whether changes might be needed to the interview schedule and the sampling protocol, to ensure nothing important to patients is missed by the research team. Findings will be disseminated by members both formally and in their multiple contacts with health professionals, Diabetes UK members and newsletters.

Section 2 – Purpose of the Research

2.1 Key research question to be addressed

Why do some people with diabetes not attend their retinopathy screening? What are the personal, social, organisational and professional factors that may combine, leading to low uptake rates of diabetic retinopathy screening? We will seek answers to these questions from the perspectives of patients, health professionals and DR screeners.

2.2 Aims & objectives

The aims of this research are:

2.2.1 To understand the different pathways to screening and how this might influence uptake, from the perspectives of people with diabetes and health professionals;

2.2.2 To understand the informational, educational needs, beliefs, and attitudes of people with diabetes throughout the screening process (i.e. the screening invitation, the screening process, and understanding and acting upon the results) associated with diabetic retinopathy screening;

2.2.3 To understand the informational, educational needs, beliefs, and attitudes of primary care and screening professionals in communicating the importance, consequences, investigations, results and treatment options to their patients;

2.2.4 To understand why some people with diabetes who have been invited for retinopathy screening do not attend, from the perspectives of people with diabetes and screening/ health professionals;

2.3 Why this study is needed

This study will reveal practices, procedures and experiences that people with diabetes and clinicians have found to be beneficial or detrimental to meeting the screening programme standards. These findings can be communicated to the regional programmes and to primary care. This will enable GP practices and regional programmes to reflect on the extent to which these practices, procedures and experiences are represented within their own provision and introduce facilitating strategies and minimise disabling strategies.

Section 3 – Methods

3.1 Design of the research

We propose a qualitative case study design using individual interviews, supplemented by quantitative data for the participants who live with with diabetes. We will invite GP practices in PCTs in three counties (Gloucestershire, Warwickshire and Birmingham) to participate. Each practice represents a case and we will interview two professionals and six people with diabetes from 10-12 purposively selected practices, as described below. Additionally, we will collect quantitative data from participants with diabetes', including average blood sugar test results, Problem Areas In Diabetes (PAID) (Welch et al., 1997) scores and levels of social support, measured with the Social Support Questionnaire (SSQ) (Sarason et al., 1983). The results of the qualitative and quantitative analyses will be synthesised into the final outcomes of the study.

We will use a two-phase, case study design (Yin, 1994; Ragin, 2000 & Griffiths 2007), with each GP practice representing a case. We propose using a case study methodology developed by Ragin (2000) in which we see retinal screening uptake as the outcome of interest and the hypothesis that there are several pathways to the outcome and different degrees to which the outcome will be achieved by using that pathway. Each GP practice or case has its own pathway to retinal screening for its patients and using this method will enable us to understand and describe those pathways. For example, within each practice, we will look for factors that might enable or hinder a positive outcome (patient goes to screening/ high screening rate). In order to attain sufficient numbers of participant interviews to fulfil the study's aims, the case-study design will be supplemented by eligible participants who ~~volunteer to take part in the study,~~ respond, for example, ~~in response~~ to media coverage, or an invitation at the diabetes clinic at their GP practice, or hospital Opthalmology clinic, irrespective of which GP practice they attend. However, it will be very difficult to find out whether any single factor makes a difference as there are so many and they all interact. Therefore we will look for combinations of factors that help or hinder screening which may be very different in different places (e.g. pro-active nurse plus good health professional-patient relationship plus practice close to screening centre); some of this will be easily modifiable, some very difficult to modify, some impossible (e.g. miles to next hospital) and these will enable us to tease out both the simple and the complex strategies for raising screening uptake.

3.2 Sampling strategy

3.2.1 Practice recruitment

We will recruit 10-12 GP practices from Coventry, Warwickshire, Birmingham and Gloucestershire Primary Care Trusts (PCT), in two phases. We have chosen these ~~three~~

PCTs to represent populations living in inner city Birmingham, urban Coventry, the semi-rural towns of Nuneaton and Rugby with pockets of affluence and deprivation, and rural and more affluent locations in Warwickshire and Gloucestershire and where the three models of retinal screening service provision (mobile screening, fixed location and high street optometry) are represented. We will work with the regional Screening Programme Leads and Primary Care Research Networks (PCRN) to recruit practices and patients to this study. National and screening programme datasets will be used to identify practices for purposive recruitment according to high and low levels of health need and high and low uptake of retinal screening services. The Jarman index will be used to identify practices with the most and least health need and retinal screening programme databases will be used to identify high and low uptake practices.

The English Indices of Multiple Deprivation's (IMD) Health deprivation and Disability domain ~~Jarman Index, based on Census data by postcode/ward,~~ gives ~~a~~ scores and ranks that indicate~~s~~ likely demand for Primary Care services (Department for Communities and Local Government, Indices of Deprivation 2010). ~~It considers the numbers of elderly people living alone, single-parent households, under-fives, overcrowded households, unskilled, house-movers, unemployed residents, and people from minority ethnic backgrounds.~~ We will sample GP practices from the top and the bottom thirds of the ~~Jarman Index~~IMD, to identify practices in areas with high and low health need. Additionally, we will identify, with the regional Screening Programme teams, GP practices with high levels of retinal screening, which are defined as those achieving 85% uptake or more, and low uptake practices, which achieve DR screening uptake of 65% or less. If this does not result in sufficient numbers of practices, recruitment of practices who achieve the best 10% and worst 10% of screening uptake will also be included. This spread will allow the identification of barriers and faciltators to screening uptake across different types of GP practice and people with diabetes, to allow for good practice to be shared.

a) Phase 1 Case (GP practice) sampling will be purposive for the first phase of recruitment, where we will identify six practices whose ~~Jarman~~ IMD score indicates high or low population health need and where the retinal screening databases specify they are achieving either very high or low levels of retinal screening uptake. The former will enable us to identify some successful practice and screener related mechanisms for increasing uptake and patient screening related attitudes and behaviours. We will also identify from the lower uptake practices the barriers to uptake at the case level. Evidence suggests that demographic factors such as ethnicity, socio-economic status, and working age, are important factors affecting screening uptake, (Scanlon, Carter, Foy et al., 2008; Millett and Dodhia, 2006), as is time since diagnosis (Leese, 2008). We are prioritising these factors in the first six cases and recognise that we do not know what further factors influence uptake in these populations. Previous qualitative screening studies have been with well populations and our proposed population also live with a complex long-term condition and this may be important. The research team will discuss emerging data from these six cases that may lead to changes to the sampling strategy for cases 7-12.

The pilot case will allow the team to identify any errors or omissions in the interview schedule, and address such issues prior to commencement of the subsequent data-

collection. Table 1 demonstrates the strategy for Phase One sampling cases/GP practice numbers 1-6.

Table 1: Phase 1 sampling strategy for cases 1-6 (GP practices)

	Glocs*	C&W	B'ham	Glocs	C&W	B'ham
PRACTICE	**1***	**2**	**3**	**4**	**5**	**6**
Low Jarman score	X	X				X
High Jarman score			X	X	X	
High uptake	X				X	X
Low uptake		X	X	X		

* Pilot case

b) Phase 2 Sampling for cases 7-12 (the second phase of GP practices recruitment) will be iterative and purposive. In lay terms, this means that the data from the interviews in the first six practices will be analysed for emerging factors that influence screening uptake, particularly factors we are not currently aware of. These data will be used in the selection of the second group of practices and in the patients within those practices. Additionally, Phase 2 will be supplemented by participants who volunteer to take part in the study, for example, in response to media coverage, irrespective of which GP practice they attend.

3.2.2 Participant recruitment

a) Professionals Practice staff: Having identified appropriate GP practices from the regional screening manager, practices will be contacted for their participation. The research team will contact the practice to give an overview of the study and seek their consent to participate. All eligible practice staff will be contacted by the research team, by email/telephone, to be given an overview of the study. With their permission, a Participant Information Pack will be sent postally/electronically.

Screening staff: The Practice Manager or senior administrator will identify the member(s) of the regional screening staff who last visited each practice and provide the researcher with contact details. In Birmingham, where the photographic screening takes place in high street optometry practices, and in parts of Coventry and Warwickshire, where fixed site screening exists alongside mobile screening, regional Screening Programmes will identify the relevant screening staff and provide the researcher with contact details, to follow the above procedure.

Professionals recruited for interviews from each case will include two of the following:

a) Diabetes lead GP or nurse
b) Practice Manager
c) Health Care Assistant;
d) Screening Programme manager
e) Retinal Screener or Optometrist

Health/Screening Professional Inclusion Criteria

- Is aged 18 years or over
- Is able to give informed consent
- Is involved in the English Nationanl Diabetic Retinopathy Screening Programme in their professional capacity

Health/Screening Professional Exclusion Criteria

- Unable to give informed consent
- Withdraws consent

Practice and retinal screener/optometrist interviews will be conducted at the staff member's usual place of work. They will last approximately 30 minutes and be audio-recorded and later transcribed. Please see Appendix 9 for a preliminary interview schedule (subject to minor modifications, should this be required following an initial pilot with one practice). Whilst it is likely that other practice/screening staff will know of a professional's choice to participate in this study (for example, at a single-handed GP practice), the participant's anonymity, the individual practice's anonymity will be protected in all documentation relating to the study. This will ensure that, for example, Commissioners will not know which practices have participated, and patients will not be able to identify professionals.

b) Patients From the first six practices, the regional Screening teams will identify six patients per practice from their database:

- four who have attended none or one of their last three DR screening appointments AND
- two who have attended all three of their most recent screening appointments.

Screening Programme staff will provide practice staff with a list of patients who fulfill the above criteria. Practice staff will use their local knowledge and GP records to purposively recruit patients for diversity according to age, gender, type of diabetes, ethnicity and time since diagnosis, and meet the full inclusion criteria, below. In this way the research team will not receive any patient details prior to informed consent being obtained. GP practice staff will telephone the patients to give an overview of the study, seeking permission to post out or email the participant information pack including consent form. This will be returned to the researcher, who will confirm receipt to the practice, so that practice staff can follow-up those patients who do not return the consent form by telephone and/or sending out another pack.

We recognise that many patients face additional barriers in accessing services, and these groups are also less likely to participate in research, because of, for example, shortcomings in the availability of study materials in the approriate languages. The team have experience in this area (Parken & Sturt, 2009; Lloyd, Sturt et al., 2008; Hipwell, 2009) and also in strategies to increase interview participation, such as employment of a bilingual interviewer, translators, link-workers, practice staff/professionals support. Where Primary Care staff identify a particular language need for a specific patient, linkworkers will be contacted by practice staff to facilitate recruitment. In Gloucestershire, where there is only a very small minority ethnic population, active practice nurse and GP participation in recruitment has increased participation in the past. In order to ensure that this research is culturally competent (Papadopoulos, Tilki and Lees, 2004; Papadopoulos, 2006), every effort will be made within time and budgetary constraints, to facilitate access for people for whom English is not their first language, to participate in this research. A detailed translation and interpretation protocol that details these procedures can be found at Appendix 5. Team members have access to bilingual linkworkers in all three regions, which will allow potential participants to be contacted in an appropriate language, by telephone, in person, or in clinic, to encourage recruitment of non-English speakers. Link workers will liaise closely with practices to identify the relevant linguistic skills needed during recruitment.

To ensure we recruit sufficient numbers of these patients to meet the study's aims we propose introducing a number of additional recruitment strategies in order to attract sufficient low attenders to retinopathy screening to the study. These include:

- Offering to interview patients by telephone, to facilitate their participation. We hope that by minimising potential participants' travelling time, cost and inconvenience, in order to attend research interviews, this may encourage more participants to Consent to take part.

- A flyer advertising the study, to be put up in target GP practice premises, that asks eligible patients to contact the research team; see Appendix 12. This has been circulated to WDREUG and comments taken into account in its design. By avoiding the use of the University logo, we hope that any perception of potential elitism associated with universities by some potential participants may be avoided, thus attracting participants from less educated backgrounds. Similarly, we have not used the term 'interview' as this could be particularly associated with job interviews, again serving to deter potential participants who are not currently active in the jobs market. The flyer does not use the NHS logo or livery, which we hope will serve to underline the research team's autonomy from the clinical team, thus reassuring potential participants about confidentiality.

- Media coverage of the study, appealing for low attenders to contact the team (radio/newspaper interviews, including local Asian networks as appropriate; Press Release). From the experience of the research team, local radio interviews can vastly improve awareness of the study amongst large numbers of potential participants, resulting in successful recruitment. Our contact at local South Asian networks have agreed to facilitate this, including providing language skills lacking in the research team, as appropriate. A University Press Release can simultaneously

be released by the University of Warwick Communications Team, so that local newspaper coverage occurs at the same time, to maximise impact.

- Increasing the High Street participation voucher from £5 to £20. Several team members are aware of other studies that are taking place elsewhere in the country, which are giving participants £20 to cover their time and any disruption that their participation in the research has caused. Dr Scanlon has agreed to fund this from his English National Screening Programme for Diabetic Retinopathy budget.

- GP notes to be 'flagged' to highlight that patient has been identified as eligible. Several GP Practice Managers have suggested that this is a simple way to make sure that potential participants are not missed. When a flagged patient contacts the surgery for any reason e.g. to collect a prescription, see a nurse, they can be asked about participating in the study.

- In GP diabetes clinics and hospital opthalmology clinics, people with diabetes who fulfil our Low Attender' inclusion criteria will be invited to participate irrespective of their GP practice's screening status. It is entirely appropriate for Diabetic Retinopathy Screening to be raised in this context, and in-clinic recruitment when an eligible patient attends an appointment can be easily adopted. Caution will be exercised that the patient does not feel pressured to participate.

Patient interviews will be semi-structured, approximately 30-45 minutes in length (up to double this when working with interpreters) and will be conducted in the GP surgery, home, ~~or~~ in a place of their choosing or by telephone, on an individual basis. Please see Appendix 4 for a preliminary interview schedule (subject to minor modifications following an initial pilot with one practice). Interviews will be audio-recorded and later transcribed verbatim.

We will confirm eligibility of those patients we identify from media and posters etc., by obtaining the patient's permission on their consent form) to check their name, address, attendance record etc with the retinopathy screening team so that we do not have to burden the GP practice.

- The participant Information Packs and Informed Consent Sheets have been amended accordingly (see appendix 1 and Appendox 3).

Patient Inclusion Criteria

- Is aged 18 years or over
- Is able to give informed consent
- Has a confirmed diagnosis of type 1 or type 2 diabetes
- Has
    - Either attended all three of the last three DR screening appointments

- Or has attended none or one of the last three DR screening appointments
- Speaks English or a language that the research team are able to have interpreted at interview/translated study materials

Patient Exclusion Criteria

- Is unable to give informed consent, for example has a learning disability or Alzheimer's Disease
- Is unable to be interviewed in a language that can be translated and interpreted by team
- Withdraws consent

Assuming a positive patient response rate of approximately 30%, up to 18 patients will be invited to participate in the research, per practice.

When the informed consent form is returned to the research team the patient will be contacted by telephone to arrange an interview appointment at the location of the participant's choice. This is likely to be the GP surgery for many participants, although where this is not possible or desirable, interviews will be undertaken in participants' homes. If this is not appropriate, for example for reasons of researcher safety, telephone interviews will be considered, so as not to forego potentially valuable participant data. The interviews with the professionals are anticipated to take place in their normal workplace i.e. GP or high street optometry practice, or hospital outpatients department.

Justification of sample size: Sample size for qualitative studies is determined by the depth of data (perspectives on a single issue e.g. screening vs. detailed narratives of living with illness) and scope of data (possible different perspectives studied). The sample size reflects this methodology (Morse, 2000). Our research aims to elicit a variety of perspectives on a focused issue and we are proposing a relatively large sample size of 24 for the clinicians and 72 for patient participants. In qualitative research, interviews are conducted until one is not hearing anything new, which usually occurs between 12 - 20 interviews but due to the complexity and diversity of the different factors in this research a larger sample size has been used. We expect 96 interviews to be both a robust and efficient sample size.

We expect a 30% patient recruitment rate, based on the team's previous experience. In order to achieve a sample of 6 patients per case we will invite 20 purposively selected patients meeting the inclusion criteria to participate.

Rate of recruitment: We aim to confirm recruitment of one new case/GP practice per week and confirm recruitment of eight interviewees in two weeks. Interviews in each practice will be completed within a further two weeks and transcription in a week. We therefore plan to allow six to eight weeks per practice to complete the case study recruitment and data collection and this time frame will also allow preliminary data analysis of each case.

3.3 Data collection

3.3.1 Data collection: patients

Data collected from patients will aim at discerning factors that may result in patients attending or not attending screening. These may include rapport with the practice, individual understandings of the importance of screening, how difficult it is to get to screening, and experiences of the screening process itself. To gain understanding of the participants' current situation before conducting the interview, we will send participants a brief questionnaire prior to the interview, including demographics, and questions related to potential difficulties with managing diabetes and the social support they receive. These questions will help us to focus on areas that are important to the individual. As an indicator of current diabetes control, we will also obtain average blood sugar test results (HbA1c measurements) from patient records. Information obtained in this way will be included in the analysis alongside qualitative data.

a) The interview The researcher will conduct a semi-structured interview at the patient's GP practice, home or another venue of their choosing, or by telephone. At the beginning of the interview, the researcher will confirm consent and encourage participants who did not complete the questionnaires to do so now. For non-English speaking participants, the interpreter will translate and fill in the questionnaires at this point, having had prior sight of this paperwork. If spouses or other people present make a substantial contribution to the interview, this will be noted on the consent form. Interview questions will focus on the participant's current self management of diabetes, their interactions with their practice and understandings and experiences of attending screening. The interview will also contain open questions to make sure that all important issues can be raised by the participant. The interview schedule will be reviewed at the end of Phase 1 to consider adding questions in response to important issues raised by participants in response to open questions. The review found that the interview schedule is performing well and no significant changes to it are required.

b) HbA1c measurement This will show the participant's average blood sugar level over the previous six to eight weeks, giving a good estimate of how well the diabetes is being managed over time. We will use this information, in combination with qualitative data, to find out about connections between self-management and screening attendance.

c) Problem Areas in Diabetes (PAID) The Problem Areas in Diabetes scale (PAID) measures diabetes-related distress and has been found to be valid and clinically useful in Type 1 and 2 diabetes populations. Low PAID scores are linked to successful self management (Polonsky et al., 1995; Snoek et al., 2000). Knowing about participants' diabetes-related distress will help us to identify possible barriers to attending screening and

focus questions on areas that are especially difficult for the participant. See Appendix 10.1 for a copy of the scale.

d) Social Support Questionnaire (SSQ) Participants will be asked to compete the Social Support Questionnaire (Sarason et al. 1983), in order to show the quality and quantity of their social interactions and aid the interviewer to focus their questions. Social support is a very important factor in diabetes self management (Toljamo 2001), and may be linked to screening attendance as well. See Appendix 10.2 for a copy of the scale. For those participants choosing to be interviewed by telephone, these data will be collected over the phone by the interviewer.

3.3.2 Data collection: health care staff

Data collected from health screening professionals will likewise aim at discerning factors that may result in patients attending or not attending screening. These could be the presence of health professionals with a strong interest in diabetes care, practice location in relation to screening location and the type of screening service used. The researcher will conduct semi-structured interviews with 2 health professionals involved in diabetes care in their practices or usual place of work. If there are difficulties with arranging single interviews, we will also consider joint interviews. At the beginning of the interview, the researcher will confirm consent and collect consent forms. They will also be given a demographic sheet to collect age, gender, professional role in relation to screening and years in practice. The interview schedule will focus on participants' understandings of current screening uptake, barriers and enablers to higher screening, and suggestions for improvements to the service. Additionally, we will collect publicly accessible data on factors that possibly influence screening uptake such as distance from screening centre, size of catchment area and skill-mix within the practice.

3.3.3 Phasing and timescales

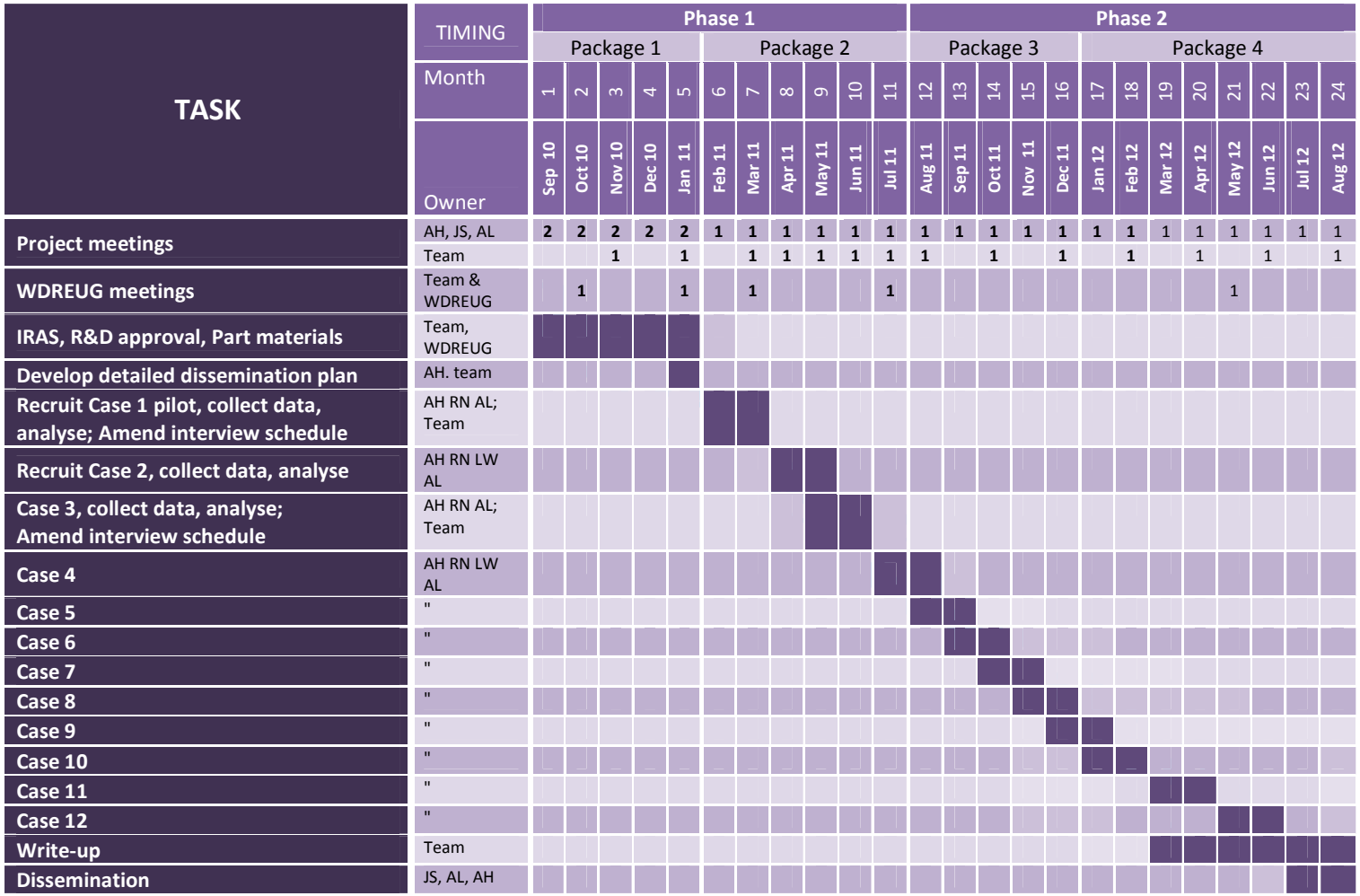
The research will comprise four packages of work in 2 phases, which are detailed on the Gantt chart, overleaf at Figure 1 and summarised below.

a) Package 1: Preparation of the research

Months 1-5: Post-doctoral Research Fellow, Alison Hipwell, into post (1.0 WTE) to finalise protocol and practice and patient materials, obtain ethical and NHS R&D approvals and develop detailed dissemination plan. Package 1 will involve the research team (including all the applicants) and the Warwick Research and Education User Group in finalising the protocol, consent procedures and the interview schedules. Recruit 1 practice, pilot professional and patient interviews, collect quantitative data. Amend interview schedules and structure as necessary.

b) Package 2: Undertaking the Phase 1 fieldwork

Month 6-11: Six GP practices will be recruited by a Primary Care Research Nurse (PCRN) or Practice nurse as appropriate, in collaboration with AH and the Regional Programmes. A PCRN from each of the three areas will join the project during this busiest period of fieldwork, to support practice recruitment, quantitative and qualitative data collection according to the sampling framework. Additionally, a link worker will be assigned, who will facilitate the addition of specific language skills. AH and the research nurse will conduct English-language patient and practice interviews following a 2 professional and 6 patient basis. We will aim for one case to be completed every six to eight weeks. AH and the link worker will conduct non-English interviews as appropriate. AH will continue to undertake interviews, quantitative data-collection and oversee transcription, whilst AL will commence data coding and preliminary analysis observing emerging hypotheses and data saturation. The sampling framework and interview schedule will be examined in light of emergent findings, and amended as appropriate, in discussion with Dr Sturt and Dr Hipwell. Substantial amendment to the Ethics Committee is unlikely, but we have allowed time for this, if it becomes necessary, between months 10-11. The whole research team will meet monthly during this early data collection phase, to discuss the emerging data and assess needs for changes due to data gaps/saturation.



AH = Alison Hipwell RN = Research Nurse LW = Link worker AL = Antje Lindenmeyer JS = Jackie Sturt

Figure 1: Phasing and timescales

c) Package 3: Completing the Phase 2 fieldwork

Months 12-17 recruit remaining six practices and complete quantitative data-collection and interviews according to 2 professionals, 6 patients structure, observing any amendments. Complete one practice every six-eight weeks, where feasible. Undertake analysis concurrently according to developed themes observing absent or saturated themes. As saturation begins to occur, slow practice recruitment down to ensure efficient use of NHS and research resources and ethical research practices.

Package 4: Dissemination, is considered in section 3.5.

3.4 Analysis

For the purposes of data collection, each practice will be considered as a single case with each case contributing to the case series. Phase 1 interview data will be transcribed and entered into *N-vivo* data software package. The research team, led by Dr Antje Lindenmeyer, will conduct a thematic analysis of the data concurrently and following the fieldwork phase, by constant comparison of the data. We will compare within and between data from patient and health professionals interviews to gain insight into factors helping or hindering screening uptake. In order to achieve this, we will conduct an intra-case comparison of patient pathways in participants from the same practice, and also inter-case comparisons of patient pathways and enabling factors between practices. Recurring themes (for example: patient needs for information and support, and health professional views on possible improvements in the screening service) will be noted, and themes may inform changes in the sampling procedures and interview schedules for Phase 2 recruitment and data-collection (Green, 2004). Emergent themes will inform our practice sampling in Phase 2. Phase 2 analysis will follow the same procedure as above, with data analysed using a constant comparison approach, both within and between data from patient and health professionals, and also performing intra- and inter-case comparisons.

Thematic analysis will also aim to identify factors from interview data and other information gathered as part of data collection. As each of the practices sampled presents a unique cluster of these factors and the outcome of interest (participation in screening) may be helped or hindered by the interaction of these different factors we will compare cases to understand whether there are any particular clusters of factors that lead to an improved uptake in screening. We will apply comparative case study methodology developed by Byrne (2005) and Ragin (2000) to investigate whether a set of factors, singly or in combination, contribute to pre-defined outcomes. We will identify a set of these factors both for patients and practices. For example patient factors could be ‘social support’; ‘confidence in self-management’; ‘rapport with health care professional’ or ‘years since diagnosis’; practice factors could include location (distance from screening unit), socio-economic background (Jarman score), or patient characteristics (e.g. a large nursing home in the catchment area). Patients and practices will then be assigned categories for these factors (e.g. good or insufficient social support, long or short distance from screening unit). If both qualitative and

quantitative data are available for a particular factor (e.g. social support scale and interview response regarding social support), the research team will consider both to assign an overall category. We will then enter these categories on a spreadsheet (truth table) and calculate whether particular factors or combination of factors are associated with screening attendance. Results of thematic and comparative elements of the analysis will be compared to arrive at an in-depth understanding of enablers and barriers to screening attendance.

Some of the proposed recruitment strategies may result in participants being recruited who are not from our target cases, for example if they respond to media coverage about the study. This means that there will be a slight adjustment to the analysis, with more thematic, non-case, analysis. Whilst these changes represent a design change to the recruitment methodology, they are not expected to impact scientifically.

3.5 Dissemination of findings

Package 4: Complete analysis and dissemination

Months 16-24: Complete data analysis, write-up and disseminate according to plan at local, national and international professional and patient events. Month 24 finalise research report and papers for publication. In addition to the usual academic and patient routes of dissemination, the English National Diabetic Retinopathy Screening Programme has its own process, which will be accessed with the study's findings. Following an External Peer review visit, which takes place for each programme on a 3 yearly cycle, a report is produced which makes recommendations for improvements in screening services and any findings from this research would be included in the recommendations following peer review. Where the strategies were simple, such as a single telephone reminder, they could be implemented rapidly. More complicated strategies would generate hypotheses for future uptake interventions, which may need testing, rather than immediate national implementation. Strategies contributing to higher uptake of diabetic retinopathy screening will enable at risk patients to receive high quality care at the most appropriate stage in the disease process and reduce the incidence of avoidable blindness.

3.6 Project management

The research team have extensive project management experience and expertise. Dr Peter Scanlon (Director of the National Screening programme and Gloucestershire Screening Programme) and Dr Jackie Sturt (Associate Professor of behavioural Sciences, Warwick Medical School) are joint principal investigators of the proposed study. PS has extensive research experience in digital photographic screening and in implementation and Quality Assurance of the 91 English programmes; JS has expertise in primary care research in diabetes and in intervention development for improving outcomes for people with diabetes. Irene Stratton is a statistician with the National Retinal Screening Programme, analysing data from the screening programmes, and with expertise in diabetes research, specifically in diabetic retinopathy. Roger Gadsby is a GP with a national reputation in primary care diabetes and is member of the English retinopathy screening advisory board. Antje Lindenmeyer is a sociologist with qualitative research expertise in diabetes and Dr Paul O'Hare is Clinical Lead for the Warwickshire programme and has expertise in the United

Kingdom Asian retinopathy study. Alison Hipwell, a health psychologist in the field of self-management, has experience of designing, conducting and analysing cross-cultural research interviews and has a strong interest in Minority Ethnic health inequalities.

3.6.1 Package 1: Project managing the preparation of the research

Months 1-5: As detailed in the Gantt chart at Figure 2, during the early stages of designing and developing the research methodology, AH and JS, and AH and AL will meet twice per month. This will allow minor queries to be resolved quickly, with more substantial queries being referred to the wider team once prior to submission to Research Ethics Committee, and once afterwards, if necessary. Similarly, team members will attend the WREUG meeting once during the development stage, to obtain patients' feedback about the participant materials, and again following REC, as necessary.

3.6.2 Package 2: Project managing the undertaking of the Phase 1 fieldwork

Month 6-11: AH, JS and AL will meet once per month to discuss progress with recruitment, data-collection and analysis. This will allow the resolution of any smaller issues around these areas as they arise, and early identification and discussion of emergent findings. Any more substantial issues, such as changes to recruitment/sampling procedures, in addition to updates about progress to timescales, will be discussed with the wider team at monthly meetings during months 7-11. WDREUG meetings will be attended at the end of the pilot in month 7, to determine whether any changes need to be made to interview questions, sampling/recruitment strategy etc., in the opinion of the patients, and again during month 11, at the end of Phase 1 data collection, for the same reason.

3.6.3 Package 3: Project managing the completion of the Phase 2 fieldwork

Months 12-17: Monthly meetings between AH, JS and AL to discuss progress with recruitment, data-collection and analysis, will continue throughout the third package of work. This will again allow the resolution of any smaller issues around these areas as they arise, and early identification and discussion of emergent findings. Again, updates about progress to timescales, an discussion around any more substantial issues, will be raised with the wider team at meetings every two months, during months 12-17.

3.6.4 Package 4: Project managing the analysis completion and dissemination

Months 16-24: Monthly meetings between AH, JS and AL will continue as above, along with two-monthly project management team meetings. This will enable the team to identify key findings and areas for future development and dissemination, and exchange feedback about conference and paper drafts. Attendance at the WDREUG will ensure feedback to this forum, and a final opportunity for patients comments prior to undertaking dissemination.

Section 4 - Ethical issues

4.1 Informed consent

Informed consent will be sought from all participants, including those who do not speak English as their first language. Please see Appendix 1 for Patients Informed Consent form, and Appendix 9 for Professional Informed Consent form. Participants will be sent an information form detailing the aims of the study and explaining why they are being asked to take part, giving them at least one week to consider this. Where necessary, translations into other languages will be produced, as far as possible in accordance with Bhopal et al.'s (2004) and Birbili's (2000) translation guidance (see Appendix 5), ensuring that conceptual equivalence is achieved, rather than mere literal translation, and that an understandable level of language is used (i.e. not overly formal or 'high'). Participants will be asked to sign and return the Consent form using a pre-paid envelope. Before interviews commence, an opportunity will be provided for potential participants to ask questions prior to deciding whether to take part, to ensure that fully informed consent is given. In the event that a participant is unable to read and write, the principal researcher will, through the NHS interpreter if appropriate, ensure thorough comprehension and the participant's mark will be obtained on the consent form.

4.1.1: Payment of participants

We will fund High Street vouchers for all patient participants – a £~~5~~20 voucher per participant. We will also cover participants' travel expenses, although these are expected to be minimal, as interviews will be conducted at a place convenient to the participant.

4.2 Identity protection for participants

Only the regional screening teams will know which practices are eligible participate, but they will not be informed which practices or patients/professionals have consented to participate. When the data are presented, practice and participant identities will be disguised (for example, by number or pseudonym) to protect the identities of all participants and the case.

4.2.1 Data security

Throughout the study the researcher will strictly follow data protection legislation (Data Protection Act 1998 and subsequent amendments) and University of Warwick Research Governance procedures. Recordings of interviews will be kept in a locked filing cabinet at Warwick Medical School and destroyed when the research is finished (estimated at August 2012). Interview transcripts will identify individuals by ID number or pseudonym only. These will be kept in a locked filing cabinet for 3 years, to ensure that study data are available for research and dissemination purposes. Demographic sheets that could identify participants will not be stored with interview recordings or transcripts, but in a separate, locked, filing

cabinet. Any data entered onto a computer will be password protected and will identify individuals by ID number or pseudonym only.

4.3 Safety issues

4.3.1 Participant safety

No distress is likely to occur to participants as a result of taking part in this study. Discussions with Regional Screening Leads will ensure that no coercion is used to involve potential participants. During recruitment and again prior to taking part in the research interview, potential participants will be informed that taking part is voluntary and that they may withdraw at any time, without giving the reason, until the end of the study. Potential participants will also be advised that withdrawing will have no adverse effect on their treatment (patients) or work (professionals). However, in the unlikely event that any participant should appear distressed, the following steps would be taken:

- The lead researcher, a psychologist, would listen empathically to the individuals' concerns.
- The telephone numbers of voluntary organisations, such as Diabetes UK (0845 120 2690) could be provided if necessary.
- The researcher would offer to contact a family member or friend, if required.

Should participants have any questions or concerns regarding their healthcare, they will be referred to their GP practice or local Patient Advice Liaison Service (PALS) as appropriate.

4.3.2 Researcher safety

The research interviews with people with diabetes and health/screening professionals may be conducted in NHS premises, where no risks are anticipated to occur. The researcher will not access these establishments without the express permission of the individuals responsible for managing them. Some of the interviews with people with diabetes may need to take place in participants' homes if, for example, a patient's condition limits their ability to travel or access the NHS premises. However, this raises the issue of ensuring researcher safety whilst in participants' homes. Although it is unlikely that there will be any threat to the researcher's safety, the following steps will be observed to further minimise the risk:

- The researcher will advise one of the research team of any interview that is scheduled to take place in a participant's home;
- The participants' name, address and telephone number will be given to that member of the supervisory team for the sole purpose of ensuring researcher safety and will be destroyed when that interview has finished;
- The researcher will provide an estimated time of interview completion, allowing between approximately 1 hour and 2 hours 30 minutes;

- The researcher will telephone the supervisor when the interview is complete, to confirm her safety.
- Should the supervisor not receive the confirmatory phone call within the maximum time, s/he will first telephone the researcher's mobile number and if there is no response, take appropriate action.

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APPENDIX 1: Declaration of Informed Consent

(Patients; v2)

Participant ID number……

		Please tick
1.	I have read and understand the 'Patient Information Sheet (v3.1)'.	□
2.	I understand that taking part in this study will involve me being interviewed, providing some personal information, and two short surveys.	□
3.	I understand that the discussion will be recorded and that the recording will be destroyed at the end of the study.	□
4.	I understand that there are no known expected discomforts or risks involved in my participation in this study.	□
5.	I understand that I am free to withdraw from the study at any time prior to the end of the study, without giving a reason, by contacting the e-mail address or telephone number below. This will not affect my care.	□
6.	I give my permission for my GP practice and the Diabetic Retinopathy Screening team to provide access to my diabetes records and that this will be used for the purposes of this research only.	□

If you would prefer to be interviewed in a language other than English, this can be arranged.

Please state the language you wish to use in an interview:……..

I give my informed consent to take part in this study. I understand that although a record will be kept of my participation in the study, my data will be identified by a number or an alternative name (pseudonym) only.

Signed …… Dated ……

Name (please print in full) .....

Phone number(s) .....

Email address: .....

Address:.....

.....Post code: .....

(We will only use this information to contact you about the study)

Please sign this form & return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk
In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 2: Patients Demographic Data Collection

(Patients; v2)

IN CONFIDENCE

Participant ID number……

This sheet will be stored separately from all other information, to protect your identity

1. **Date of birth** (please write in): Date ..... Month…….……. Year……..…..

2. **Sex** (please circle one): Male/Female

3. **What type of diabetes do you have?** (Please tick one):

   Type 1 Diabetes ☐ Type 2 Diabetes ☐

4. **Do you have any other long term conditions?** (Please tick one): Yes/No
   If yes, please state what these are: .....

   .....

5. **Which of the following groups do you consider that you belong to?** (Pease tick one)

White British	□	White Irish	□	White other	□
Black African	□	Black Caribbean	□	Black other	□
Indian	□	Pakistani	□	Bangladeshi	□
Chinese	□	Other	□	Please state.....	

6. **What type of work do/did you do?** .....

   .....

7. **What is the highest level of qualification you have?** .....

   .....

Thank you for your help!

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 3: Patients Information Sheet

(v3.1)

1. Study Title:

Understanding *F*actors leading to *L*ow *U*ptake of diabetic *R*etinopathy sc*R*eening in pr*I*mary care (*FLURRI* study)

2. Invitation:

You are invited to take part in a research study that is being conducted as part of a two year project at the University of Warwick. Before you decide whether to take part or not, you should understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask us if anything is unclear or if you would like more details. Our contact details are at the bottom of every page and in sections 12 and 13. Thank you for reading this information sheet.

3. What is the purpose of this study?

People with diabetes sometimes develop problems with their eyes that can lead to vision loss and blindness. This damage to the eye is known as Diabetic Retinopathy and can be detected early through screening, which involves patients having digital photographs taken of their eyes. These photographs can identify early signs of damage caused by diabetes, before the patient becomes aware of any symptoms. Research has shown that people who attend the Diabetic Retinopathy Screening Programme are less likely to suffer loss of vision or blindness, compared with people who don't attend, because they receive their treatment sooner when less damage has occurred. For more information, please see the enclosed leaflet.

At present, not everyone who is entitled to take part in the screening, actually attends. This research aims to find out why this is, and what would encourage more people to have their eyes photographed every year. The results will be given to the Diabetic Retinopathy Screening Programme managers, so that they are aware of the issues that have been raised. You will not be identifiable as we will keep your personal details confidential and protect your identity.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

4. Why have I been chosen?

You may have offered to take part after hearing about the study in the local media, or at your GP practice. You are eligible to take part if ~~because~~ you have been diagnosed with diabetes, and have previously been asked to have photographs taken of the back of your eyes (we will confirm this with your care team once we have received your signed Consent Form). Your experiences of this process may help us to understand what influences people's decisions whether or not to go to the screening. We are asking for the views of people with diabetes who always attend their diabetic eye screening, those who don't always attend their screening, and will also be asking the views of health professionals involved in the screening programme.

5. Do I have to take part?

It is entirely up to you to decide if you want to take part or not. If you do decide to take part, you will be given this information sheet to keep and asked to sign a form, enclosed, saying that you agree to take part (consent form). You will be free to withdraw from the study at any time before the end of the study (estimated at August 2012), without giving a reason – this will not make any difference to the treatment that you receive. A decision to withdraw or not to take part will not be passed on to your medical team. If we have already collected information from you and you choose to withdraw, we will destroy all the information we hold for you and not use it in the study.

6. What will I have to do?

You are being asked to take part in a research interview, which will last half an hour. This will probably take place at your GP practice, or other venue of your choice (to be confirmed), or by telephone. We will be able to pay your travelling expenses and you will receive a £205 ~~5~~ gift voucher. You will be asked about your experiences of living with diabetes, what you feel might encourage more people to go to the Diabetic Retinopathy Screening Programme and what might put people off going to it.

Before you start talking to the researcher, you will be given a form to fill in with your personal details; the researcher can help you with this if necessary. You will also be asked to fill in two short surveys, which will ask you a few questions about any support that you might get from other people, and aspects of living with diabetes that you find difficult; the researcher can help you with this if necessary. These forms take no more than 15 minutes to complete. Patients come from lots of different backgrounds, so have very different experiences that can affect their diabetes and lead to different views about diabetic eye screening, which we are interested in. We will also ask your GP practice to send us the result of you most recent blood glucose test.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

You will be asked to agree to the discussion being audio recorded (the recording will be destroyed at the end of the study). The recording will then be put into writing and your views will be carefully considered, along with the other participants' views. Any paperwork that is produced as a result of this research study (for example, for the Diabetic Retinopathy Screening Programme management) will refer to you by an ID number only (e.g. 'participant number 10'), or an alternative name (pseudonym).

7. What are the possible disadvantages of taking part

The only disadvantage is likely to be the time that it takes for you to participate in the interview. No other disadvantages are expected.

8. What are the possible advantages of taking part?

The views of everyone who talks to us will be considered carefully. These views will be used to suggest improvements to the Diabetic Retinopathy Screening Programme organisers (we will refer to you by an ID number or an alternative name only). The information we get from this study may help other people in future. You may learn more about your diabetes and eyes and this may help your health. We will give you a £~~5~~20 voucher at the end of the research interview.

9. Will anyone else know I have done this?

Only the lead researcher/interviewer and the member of staff at your GP surgery who sent you this information pack will know exactly who has been invited to take part. Your name or details will not be given to anyone else – you will only be referred to by participant ID number or an alternative name (pseudonym) in any paperwork. So the Diabetic Retinopathy Screening Programme management, hospital specialist etc. will not know that you have done this. No-one else will be told exactly who has taken part. All information will be treated confidentially. Only the research team will have access to your personal details, the audio recording and the written copy of our conversation, which will be kept in locked filing cabinets. The recordings will be password protected and erased at the end of the study (estimated at December 2012). The Data Protection Act (1998) will be followed at all times. The only circumstance in which we might have to pass your details to another person, is if you disclose illegal behaviour. In this case, we will be obliged to inform the authorities, to deal with the matter appropriately. However, such a disclosure will not be shared with anyone else if this not necessary.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

10. Who is organising and funding the research?

This research is being organised by the Gloucestershire Hospitals NHS Foundation Trust and Warwick Medical School at the University of Warwick. It is funded by the NHS National Institute for Health Research's *Research for Patient Benefit Programme*. It has been approved by the NHS Research Ethics Committee, and the NHS trust whose area you live in.

11. What happens to the results of the study?

A summary of the results of the research will be sent to all participants later in the project. The research findings will be passed to the team who organise the English National Diabetic Retinopathy Screening Programme, so that they can see what needs to be done to help more people with diabetes to attend their eye photography. The results will also be distributed at relevant professional conferences, so other people can benefit from your views (you will be identified by an ID number or pseudonym only).

12. I have some questions. Whom can I ask?

If you have any questions, now or at any point in the research, please contact the principal researcher, Alison Hipwell, telephone 024 761 51405, or email a.e.hipwell@warwick.ac.uk.

13. What if something goes wrong?

If you are unhappy about any aspect of this study, you may complain to the University of Warwick. The University has comprehensive public liability insurance. Any complaint should be addressed to In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

14. What do I do now?

If you want to take part in this research, please sign both copies of the Declaration of Informed Consent. Keep one for your records ***and return the other in the envelope provided*** (it does not need a stamp).

Thank you for reading this!

If you want to take part in the research, please sign the enclosed Consent Form, and return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk
In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 4: Patients Provisional Interview Schedule

(v~~2~~3)

- Tell us about yourself and your life at present (Prompts: living alone/ with others; working, caring or retired; social activities)
- Can you describe a typical day living with diabetes? (Prompts: Examples of how it affects your daily life? Compared to how you were before becoming ill/other people who are well?)
- Can you describe a good/bad day living with diabetes?
- Is there anything that you can do to improve your experience of living with diabetes?
- When did you last see your nurse/ GP about you diabetes - and what did you talk about?
- What do you know about eye screening & diabetes?
- How did you first find out about diabetic eye screening?
- Do you know why are you asked to go?
- How do you know when and where you should go?
- Do you know what it involves? (For those who did attend screening: describe in as much detail as possible the last screening they went to)
- How does this screening fit in with the rest of your diabetes care and treatment?
- What happens after your screening – how do you find out your results?
- Have you ever missed an eye screening appointment?
- Have you ever needed any further treatments on your eyes? How did you find out what you needed, what your options were?
- What do you think is responsible for any deteriorating eye sight you might have? Why
- Are there any changes to the service that you could suggest - from invitation to screening, receiving results/treatments options etc. that would make the screening process better for you? (E.g. link with opticians at annual eye test)
- **How would you feel about going once every two years, instead of annually?**
- What would you like to be able to do differently, that would make the screening process better for you?
- What (if anything) puts you off going?

- Have you ever been invited for any other type of health screening e.g. cervical/ breast /bowel – if so, how does it compare?
- **Is there anything you'd like to add that we haven't covered in the interview?**

APPENDIX 5: Translation and Interpreting Protocol

(v1)

A5.1 Study Materials Translation

The language(s) that study materials will need to be translated into is not yet confirmed. As the cost of having all materials professionally translated is prohibitive, the following has been adapted from Bhopal et al. (2004) principles for adapting written research materials into different languages and Birbili's (2000) translating guidance:

- A bilingual person who understands the target language and culture will translate the study's materials into the target language, ensuring conceptual equivalence (not simple literal translation) is achieved;
- As the bilingual person may not be representative of the target population because of education, age, sex etc., if possible, a representative of the target population will assess meaning and acceptability of the translated materials and modifications will be suggested;
- The bilingual person will amend materials as appropriate, comparing translations with the original English-language materials, to ensure conceptual equivalence is maintained;
- A second bilingual person who understands the target language and culture will validate the materials using the target language and English materials;
- The two bilingual people and the principal researcher will meet (if possible) to discuss the back-translations, negotiating a "best fit" to ensure conceptual equivalence is maintained;

  The resultant materials will be piloted with at least two monolingual members of the target population (if possible) to check face and content validity, with further changes suggested if necessary;
- The bilingual people and the principal researcher will again discuss the suggested modifications and amend materials as appropriate, comparing translations with the original English-language materials, to ensure conceptual equivalence is maintained.

A5.2 Non-English-language data-collection

It is anticipated that some potential participants will want to be interviewed in a language other than English, and they are asked to indicate their language of choice on the consent form, before returning it. Funding exists to cover the cost of interpreters for interviews. A three-way interview with AH (interviewer), the participant and an interpreter will allow detailed data-collection to be undertaken in accordance with ethical guidelines. The procedure, used by Hipwell (2009), is represented diagrammatically, in Figure A5.1:

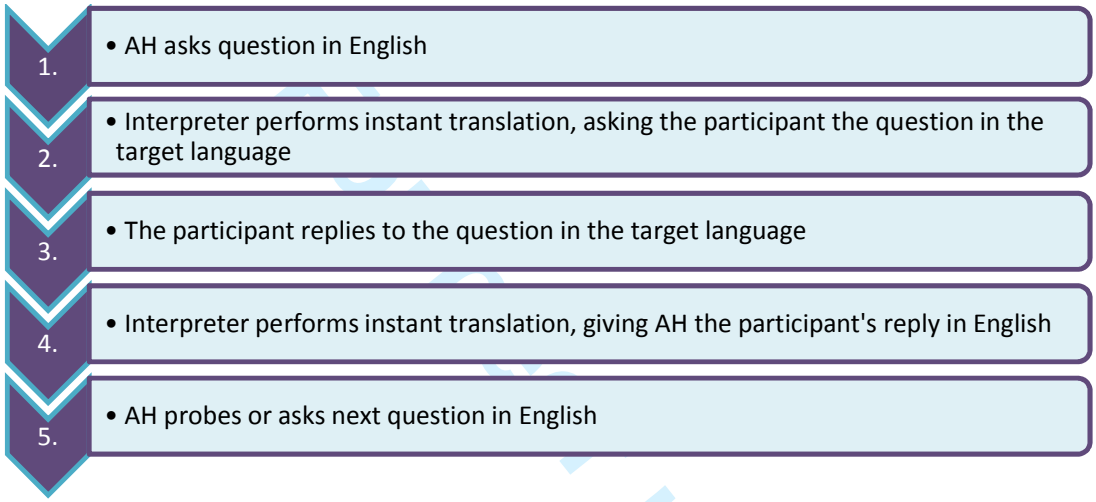

Figure A5.1: Three-way interview process

This three-way interview process will allow participants to convey their experiences to me effectively.

A5.3 Data validation process

Full back translation will be too time and resource inefficient for the current study, therefore an acceptable method of validating the interpreter's work, used by Hipwell (2009), will be used. Following verbatim transcription of the English-language sections of the interviews, a research-trained, fluent speaker of the target language(s) will be employed to validate the accuracy of the translated transcripts, using the audio files and the English transcripts. The 'track changes' function of Microsoft Word will be used by the validator to highlight any areas where discrepancies may have occurred, to alert the researchers conducting the analysis. The interpreter and validator will both be paid the appropriate hourly professional rate for this work.

APPENDIX 6: Health Professionals Demographic Data Collection

(V2)

IN CONFIDENCE

Participant ID number……

1. **Date of birth**: Month…….……. Year……..…..

2. **Sex** (please circle one): Male/Female

3. **What is your role with the English National Diabetic Retinopathy Screening Programme?**

Screening only □ Grading only □ Screening & grading □

Trainer □ Programme manager □ Optometrist □

GP □ Specialist nurse □ Practice manager □

Health Care Asst □ Other (please state) □ .....……..……

4. **How long have you been working with diabetic retinopathy patients in this role?** (Please tick one):

Less than one year □ One to three years □ More than three years □

5. **Which area of the country do you mostly work in** (Please tick one):

Gloucestershire□ Birmingham □ Coventry & Warwicks □

Other (please state) □ .....……..…….....

Thank you for your help!

This sheet will be stored separately from all other information, to protect your identity

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk
In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 7: Health Professionals Information Sheet

(Health professionals v~~2~~3)

1. Study Title:

Understanding Factors leading to Low Uptake of diabetic Retinopathy scReening in prImary care (FLURRI study)

2. Invitation:

You are invited to take part in a research study that is being conducted as part of a two year project by the University of Warwick and your local screening programme, funded by the National Institute of Health Research's Research for Patient Benefit Programme. Ask us if anything is unclear or if you would like more details. Our contact details are at the bottom of every page and in sections 12 and 13. Thank you for reading this information sheet.

3. What is the purpose of this study?

As you will be aware, people with diabetes can develop sight-threatening diabetic retinopathy (DR). Retinopathy screening can identify early signs of damage whilst patients are asymptomatic of DR. Research has shown that people who attend the Diabetic Retinopathy Screening Programme are less likely to suffer loss of vision or blindness, compared with people who don't attend (Gray, 2009). However, DR screening uptake varies across different GP and optometry practices across the country. This research aims to find out why this is, and what would encourage more people to attend their annual DR screening. The results will be given to the DR Screening Programme managers, so that they are aware of the issues that have been raised.

4. Why have I been chosen?

You have been chosen because you have been identified as a health professional who works with patients diagnosed with diabetes and the DR screening programme. Your experiences of this process may help us to understand what influences people's decisions whether or not to attend for screening. We are also asking for the views of people with diabetes who always attend their diabetic eye screening, those who rarely attend their screening, and other health professionals involved in the screening programme.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

5. Do I have to take part?

Participation in this research is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. You will be free to withdraw from the study at any time prior to the end of the study without giving a reason. If you do not wish to participate, or if you choose to withdraw from the study at a later date, it will have no detrimental effect on your employment. If we have already collected information from you and you choose to withdraw, we will destroy all the information we hold for you and not use it in the study.

6. What will I have to do?

You are being asked to take part in a research interview, which will last around half an hour. This will probably take place at your workplace, or other venue of your choice (to be confirmed). You will be asked about your experiences of dealing with patients who have diabetes, what you feel might encourage more people to attend the DR Screening Programme and what might put people off going to it.

Before you start talking to the researcher, you will be given a form to fill in with your personal details. Health professionals have many different experiences, and might have different views about diabetic eye screening. You will be asked to agree to the discussion being recorded. The recording will then be put into writing and carefully considered, along with the other participants' views. Any paperwork that is produced as a result of this research study (for example, for the Diabetic Retinopathy Screening Programme management) will refer to you by an ID number only (e.g. 'participant number 10'), or an alternative name (pseudonym).

7. What are the possible disadvantages of taking part

The only disadvantage is likely to be the time that it takes for you to participate in the interview. No other disadvantages are expected.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

8. What are the possible advantages of taking part?

The views of everyone who talks to us will be considered carefully. These views will be used to suggest improvements to the Diabetic Retinopathy Screening Programme organisers (we will refer to you by an ID number or pseudonym only). The information we get from this study may help other people in future.

9. Will anyone else know I have done this?

Only the principal researcher/interviewer will know exactly who has taken part. Your name or details will not be given to anyone else. So neither the Diabetic Retinopathy Screening Programme organisers, nor your PCT management or Commissioners, will know who has participated in this. No-one else will be told who has taken part. All information will be treated confidentially. Only the principal researcher will have access to your personal details and the recording, and only the principal researcher, study director and the data analyst will have access to the anonymised written copy of our conversation, which will be kept in a locked filing cabinet. The digital recordings will be password protected and erased at the end of the study (estimated at December 2012). The Data Protection Act (1998) will be followed at all times.

The only circumstances in which we might have to pass your details to another person, are if you disclose either unprofessional or illegal behaviour. In these cases, we will be obliged to inform your employing organisation, to be dealt with be dealt with appropriately. However, such a disclosure will not be shared with your peers or managers if this not necessary.

10.What happens to the results of the study?

A summary of the results of this phase of the research will be sent to all participants later in the project. The research findings will be passed to the team who organise the English National Diabetic Retinopathy Screening Programme, so that they can see what needs to be done to help more people with diabetes to attend their eye photography. The results will also be distributed at relevant professional conferences, so other people can benefit from your views (you will be identified by an ID number or pseudonym only).

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

11.I have some questions. Whom can I ask?

12.Who is organising and funding the research?

This research is being organised by the Gloucestershire Hospitals NHS Foundation Trust and Warwick Medical School at the University of Warwick. It is funded by the NHS National Institute for Health Research's *Research for Patient Benefit Programme*. It has been approved by the NHS Research Ethics Committee, and the NHS trust whose area you work in. If you have any questions, now or at any point in the research, please contact the principal researcher, Alison Hipwell, telephone 024 761 51405, or email a.e.hipwell@warwick.ac.uk.

13. What if something goes wrong?

If you are unhappy about any aspect of this study, you may complain to the University of Warwick. The University has comprehensive public liability insurance. Any complaint should be addressed to the study director, Dr Jackie Sturt by telephone 024 765 73753 or email jackie.sturt@warwick.ac.uk.

14. What do I do now?

If you want to take part in this research, please sign both copies of the Declaration of Informed Consent. Please keep one for your records ***and return the other in the envelope provided*** (it does not need a stamp).

Thank you for reading this!

If you want to take part in the research, please sign the enclosed Consent Form, and return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 8: Health Professionals Provisional Interview Schedule

(v1)

Primary Care and Screening Professional Interview schedule: The interview schedule will include questions probing the following:

- What is your role in the diabetic retinopathy screening programme? What routines and procedures does it involve you doing?
    - perceptions of relative usefulness of procedures
- Do you know how many patients attend for retinal screening here? What do you think influences this?
- Do you know what information patients receive about retinal screening, what's involved, why it's important for them? (Patient information/preparation for retinal screening)
- From your perspective, what happens when the patient attends for screening?
    - What (if anything) do you have to do if they don't attend?
- Are you involved in informing patients about the results and any further actions?

- Are there any changes that you can suggest to improve the way your patients are invited to / informed about retinal screening and the service delivered, which would improve uptake?
- Are there any changes that you can suggest regarding (this) practice's response to patients, following communication of screening results?
- How important do you feel retinal screening is for patients alongside their other diabetes screening activity (Prioritisation)
- Why do you think some patients don't attend?
- How big a part of your job is retinal screening?
- How useful do you think the screening results are for informing future patient care?

- **What do you think about screening once every two years, instead of annually?**
- Is there anything you'd like to add that we haven't covered in the interviews?

APPENDIX 9: Declaration of Informed Consent

(Professionals; v3)

Participant ID number……

		Please tick
1.	I have read and understand the 'Professionals Information Sheet (v3)'.	□
2.	I understand that taking part in this study will involve me being interviewed and providing some personal demographic information.	□
3.	I understand that the discussion will be recorded and that the recording will be destroyed at the end of the study.	□
4.	I understand that there are no known expected discomforts or risks involved in my participation in this study.	□
5.	I understand that I am free to withdraw from the study at any time prior to the study's end, without giving a reason, by contacting the e-mail address or telephone number below.	□

I give my informed consent to take part in this study. I understand that although a record will be kept of my participation in the study, my data will be identified by a number or an alternative name (pseudonym) only.

Signed …… Dated ……

Name (please print in full) .....

Phone number(s) .....

Email address: .....

Address:.....

.....Post code: ..... *(We will only use this information to contact you about the study)*

Please sign this form & return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 10: Scales

A10.1 The Problem Areas in Diabetes Scale

Which of the following diabetes issues are currently problems for you? Please circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Not having clear and concrete treatment goals for your diabetes care?	0	1	2	3	4
Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
Feeling scared when you think about living with diabetes?	0	1	2	3	4
Uncomfortable social situations related to your diabetes (e.g. other people telling you what to eat)?	0	1	2	3	4
Feelings of deprivation regarding food and meals	0	1	2	3	4
Feeling depressed when you think about living with diabetes?	0	1	2	3	4
Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
Feeling overwhelmed by your diabetes?	0	1	2	3	4
Worrying about low blood sugar reactions?	0	1	2	3	4
Feeling angry when you think about living with diabetes?	0	1	2	3	4
Feeling constantly concerned about food and eating?	0	1	2	3	4
Worrying about the future and the possibility of serious complications?	0	1	2	3	4
Feeling guilty or anxious when you get off track with your diabetes management?	0	1	2	3	4
Not “accepting” your diabetes?	0	1	2	3	4
Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
Feeling that diabetes is taking up too much mental and physical energy?	0	1	2	3	4
Feeling alone with diabetes?	0	1	2	3	4
Feeling that friends/family are not supportive of your diabetes management efforts?	0	1	2	3	4
Coping with complications of diabetes?	0	1	2	3	4
Feeling burned out by the constant effort to manage diabetes?	0	1	2	3	4

Box A10.1: The Problem Areas in Diabetes (PAID) 20-item scale (from Snoek et al., 2000)

A10.2 The Social Support Questionnaire

The SSQ investigates the number of perceived social supports in a person's life, and the level of satisfaction with each of these. The latter is again rated on a six-point Likert scale, indicating the current level of satisfaction with that item.

1) How many people are there that you can trust, talk to frankly and share your feelings with?_____ (please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

2) How many people are there that you can lean on and turn to in times of difficulty? _____ (please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

3) How many people are there that give you practical help? _____ (please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

4) How many people are there that you can spend time with socially? ____ (please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

APPENDIX 11: Letter to GP

Warwick Medical School

Date

GP name

Surgery name

Street name

Town

County

Post code

Dear *GP name,*

Re: *Patient name,* FLURRI study

I wish to inform you that your patient, above, has participated in the FLURRI study (Understanding ***F***actors leading to ***L***ow ***U***ptake of diabetic ***R***etinopathy sc***R***eening ***I***n Primary Care).

Please see the enclosed information for further details.

Yours sincerely,

Jackie Sturt

(Encs: Patient Information Sheet, Demographic data-collection, PAID & SSQ Scales, Informed consent)

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APPENDIX 12: GP Flyer V3

Diabetes?

- Too busy with work or family to go to your **eye screening**?
- Don't like having it done?
- ***Another reason for not going?***

We'd like to talk to you for **about ½ an hour:**

we'll give you a

£20 High Street voucher!!

- **We're trying to find what puts off people like you, who live around here, from having your annual diabetes eye screening photos**
- **No-one from your GP surgery, the hospital, or the diabetes eye screening service will know what you say**
- **We'll use patients' experiences of problems and ideas for how eye screening can be made better, to improve the service**
- **We are a group of researchers from Warwick Medical School**

If you're interested in talking to us, please call
Alison Hipwell for an informal chat: **02476 151 405**
Or email: **a.e.hipwell@warwick.ac.uk**

BMJ Open

Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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TITLE PAGE

Title: Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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ABSTRACT

Objective: To examine patients', health professionals' and screeners' experiences of, interactions with and understandings of Diabetic Retinopathy Screening, and how these influence uptake.

Design: Purposive, qualitative design using multi-perspectival, semi-structured interviews and thematic analysis.

Setting: Three UK Screening Programme regions with different service-delivery modes, minority ethnic and deprivation levels, across rural, urban and inner-city areas, in GP practices and patients' homes.

Participants: 62 including 38 patients (22 regular screening attenders, 16 non-regular attenders), and 24 professionals (15 Primary Care professionals and 9 screeners).

Results: Antecedents to attendance included knowledge about diabetic retinopathy and screening; antecedents to non-attendance included psychological, pragmatic and social factors. Confusion between photographs taken at routine eye tests and Diabetic Retinopathy Screening photographs was identified. The differing regional invitation methods and screening locations were discussed, with convenience and transport safety being over-riding considerations for patients. Some patients mentioned significant pain and visual disturbance from the mydriasis drops as a deterrent to attendance.

Conclusions: In this, the first study to consider multi-perspectival experiential accounts, we identified that proactive coordination of care involving patients, primary care and the Screening Programmes, prior to, during and after screening is required. Multiple factors prior to, during and after screening are involved in the attendance and non-attendance for DR screening. Further research is needed to establish whether patient self-management educational interventions, and the pharmacological reformulation of shorter-acting mydriasis drops, may improve uptake of Diabetic Retinopathy Screening. This might, in turn, reduce preventable vision loss and its associated costs to individuals and their families, and to health and social care providers, reducing current inequalities.

ARTICLE SUMMARY

Strengths and Limitations of the study

- Our purposive sampling strategy recruited several strata of professional groups in GP and optometry practices and screening programmes, and both regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes.

- Not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening.

- The qualitative findings from our purposive sample are not intended to be representative but highlight important insights into barriers and enablers to screening attendance that will inform further research.

INTRODUCTION

Visual impairment is a significant worldwide health problem (1, 2). Approximately 314 million people globally are visually impaired, with over 80% of this impairment being preventable or treatable (1, 3). Diabetic retinopathy is a major cause of preventable vision loss in people with type 1 and type 2 diabetes in Europe, Africa, Asia and Australia (4-9, 10-13) and until recently (14) has been the leading cause of preventable vision loss in European working age populations (4, 8, 10-12). The proportion of vision loss caused by diabetic retinopathy is increasing globally (13). In addition to treatment costs, lost productivity and quality of life for patients with diabetic retinopathy contribute to personal and socio-economic burdens (15).

Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment (1, 15). In England, routine diabetes care and Diabetic Retinopathy Screening (DRS) are principally managed in primary care, whilst treatment for retinopathy takes place in secondary care. Issues surrounding diabetic retinopathy therefore have practice implications for medical and health professionals working in both settings. The UK Government's measurement of preventable vision loss from April 2013 recognises this top public health priority. The English NHS Diabetic Eye Screening Programme offers cost-effective annual screening to people with diabetes (Types 1 and 2) over 12 years (16) where 80% uptake is achieved. Screening uptake is assessed at the general practice level. Screening modes differ regionally, taking place either in GP surgeries, hospitals or optometry practices (see Figure 1). Screening typically takes 30 minutes. Patients' pupils are dilated with drops, affecting their vision for four to six hours. Digital photographs are taken and the images examined by regional NHS retinal grading teams, who identify any pathology. Results are communicated to the patient and GP. Patients with retinopathy requiring monitoring or treatment are referred to the Hospital Eye Service.

However, approximately 20% of people invited for DRS do not attend (17), with those from minority ethnic backgrounds and people living in deprived areas both less likely to attend and to have worse retinopathy (18), (19), (20). Inequalities in access to DRS in England[8] have led to calls for further research (19), including qualitatively (21).

Yet deprivation alone does not explain all the uptake variability between GP practices and regions. For example, misunderstandings about the importance of diabetes and personal risk factors and patients' lack of awareness, psychological factors or practical obstacles, can represent major barriers to attending screening (22). However, as attendance rates vary greatly between neighbouring practices, for example, from 55% to 95% in Gloucestershire (23), research focusing beyond deprivation, risk factors or barriers is required. Little is known about how patients' and professionals' perceptions and experiences of DRS may influence attendance. This paper therefore focusses on experiences around DRS that may affect uptake, from the accounts of people with diabetes and GP practice and screening staff.

[8] http://www.screening.nhs.uk/news.php?id=12156

METHODS

NRES Committee South West – Cornwall and Plymouth gave ethical permission (10/H0203/79) and all participants gave informed consent . This work was supported by the National Institute of Health Research, Research for Patient Benefit grant PB-PG-1208-18043 and sponsored by Gloucestershire Hospitals NHS Foundation Trust.

Design of the research: This multi-perspectival (24), cross-sectional qualitative interview study used purposively sampled GP practices in four UK Primary Care Trusts across three regions, based on Indices of Multiple Deprivation, practice type, screening mode, and screening uptake (see Table 1).

Practice recruitment: Central England Primary Care Research Network and South West Diabetes Network provided research nurse assistance with GP practice recruitment. Twelve GP practices were approached; two declined (existing research commitments); one withdrew prior to participant recruitment commencing (staff changes). Table 1 details characteristics of the nine participating GP practices. The Central Local Research Network paid Service Support Costs of £599.27 to participating GP practices.

Table 1: Practice characteristics

Participant recruitment:

Professionals We purposively recruited 24 primary care and screening professionals with patient contact in differing roles around DRS, to ensure a broad spectrum of views and experiences. ***Patients*** Within each practice, patients were purposively sampled based on their screening attendance history, to consider differences in attitudes and experiences. "Regular attenders" had attended all three of their most recent DRS appointments; "Non-regular attenders" had attended none or one of their three most recent DRS appointments. Practice staff telephoned potential participants and sent information packs.

Interviews Semi-structured interviews were conducted either face-to face, at the GP/optometry practice, in patients' homes, or by telephone, at participants' discretion. Multi-perspectival interviews allowed us to understand the dynamics between patients, professionals and the Screening Programme, explore similarities and differences in their perceptions to highlight potentially differing needs and suggestions for improving services. Questions aimed to capture descriptions of participants' experiences before, during and after the screening appointment, from professionals' and patients' perspectives, identifying factors they believed influence screening attendance (see Appendices 1 and 2). All interviews were audio-recorded and transcribed verbatim prior to analysis. No additional data is available for data-sharing.

Analysis Data were managed using QSR NVivo10 software[9] to code and review themes. AH undertook iterative, thematic analysis, using constant comparison within and across all transcripts. Looking for overarching themes and relations between them, AH identified specific major and minor categories within the themes that might interact to influence screening attendance rates. AH and AL met to discuss these themes and agreed on the definitions of emerging codes. Findings were discussed with all authors until consensus was reached about the interpretation of key themes. Finally, AH checked these interpretations with the existing data.

RESULTS

Characteristics of the sample: 62 participants (33 female) were interviewed between September 2011 and July 2012, by AH, AL and JS. Of the 38 patients, four have Type 1 diabetes (mean age 49); 34 have Type 2 (mean age 60); 22 were regular retinopathy screening attenders, 16 were non-regular attenders (defined above). Of the 24 professionals (mean age 50), eight are primary healthcare professionals, seven are administrative practice staff; and nine are DRS programme screeners.

Table 2: Programme and participant characteristics

No theme was unique to either regular attenders, or non-regular attenders, which highlights the complex nature of why people do or do not attend appointments.

Understandings of Diabetic Retinopathy and Screening

GP practice staff, screeners and patients identified several antecedents to attendance and non-attendance at screening. Both regular and non-regular attending patient participants acknowledged the importance of DRS. Yet confusion around screening was clearly identified in all participant groups, as was the need to overcome this.

Understandings of Diabetic Retinopathy:

Some (but not all – see later subthemes) people with diabetes understood causal factors and the potential consequences of Diabetic Retinopathy; protecting the eyes appeared to be a priority for some. Interestingly, a non-regular attender with vicarious experience of sight loss identified herself to the researcher as a regular attender. Others found the process reassuring**.**

> *It's the smallest vessels that go first, and it's one of the quickest ways of seeing the effects is in the eyes. But... the body is so tolerant, you don't recognise that the vision is going until it's too late.* Patient 8 (Region 2, Regular)[10]
>
> *I: So what is it that encourages you to come [to screening] then?*

[9] www.qsrinternational.com/

[10] R = region from Table 1; Regular attender/Non-regular attender (as defined above)

P: My brother-in-law he was a very bad diabetic... He actually died from it. He went blind first. Patient13 (Region 3, Non-regular)

I like the fact that you instantly see and can get a decent steer on if there is anything negative; it's complete peace of mind – well my results anyway. Patient 3 (Region 2, Regular)

Psychological, pragmatic and social influences on non-attendance

In response to being asked why people might not attend DRS, both professionals and patients acknowledged that denial of having diabetes could contribute. One patient missed screening appointments because she disliked the proximity of the screener. Pragmatic reasons raised by the non-regular attenders for non-attendance included work commitments and post-operative recuperation.

Some people just… have their head in the… like the ostrich, they don't have diabetes or they're not taking any notice of it and they will just… yes, not come. Some because they think they can't have the time off work, you know? Screening Programme 1 (Region 1)

It's just the thought of somebody coming close to my eye. Patient 15 (Region 3, Non-regular)

I missed once, because I had an abscess in an awkward place, and I had to have an operation. But the following year I made sure. Patient 5 (Region 3, Non-regular)

Another non-regular attender who identified herself as a regular attender had attempted to access DRS via her GP practice, but was refused because she was in temporary accommodation awaiting rehousing. This highlights the complex social context in which people with diabetes experience screening:

Int*: So you didn't always come?*
Pt: Well, with being homeless for 8 weeks... But they [GP practice] didn't want to know. 'Oh you're not in our area.' I'm in nobody's area because we were in a bed and breakfast; they were my last doctors. Patient 10 *(*Region 1, Non-regular)

Understandings of Diabetic Retinopathy Screening vs. routine eye test

Some patients' perceptions of screening attendance were confused by high street optometry practices routinely taking photographs during a general annual eye check. Patients confused this with DRS even in areas where High Street optometry practices did *not* conduct DRS, confounding attendance:

I'm with [high street optometry chain] so I've always, always had my eyes screened. ... So when I was diagnosed and I told the optician she said, well we can do that here for an extra £10 and we will just email the surgery. So I thought fine, that's fine. So I just bypass it completely... Patient 4 (Region 2, Non-regular)

A lot of people turn up and say, 'well I had my optician's test' and you ...explain to them that although it's a great thing to have and they need to have it, we still need to do our tests because it's more accurate, and we're searching specifically for the diabetic retinopathy. Screening Programme 1 (Region 1)

Perceived responsibility for patients' understandings of Diabetic Retinopathy and screening

Professionals and patients identified the need to improve patients' understandings about DRS and sight-threatening retinopathy. For example, one GP accepted that low uptake reflected a failure to deliver the right message. However, more direct input from the health professional team was suggested by one patient who had not understood the screening information, and subsequently developed retinopathy. One screener considered that the lack of media attention to DRS could contribute to low attendance.

Why haven't they taken that onus of control, what is it that they don't believe about their diabetes? Where have we gone wrong in trying to get that message across? ...the words "Diabetic Retinopathy Screening", what does that mean to them? Health Professional 1 (Region 3)

As soon as I had diabetes diagnosed somebody should have explained to me more fully what the implications are. Because it's alright them giving you a leaflet and sending you home... but even though you read it, there's this kind of silly thing, 'oh it won't happen to me', attitude. Patient 15 (Region 3, Non-regular)

I don't think screening is something that's pushed as much as other screening. I mean retinal screening is…I'd say it's important... but things like breast cancer, there's a lot more press about it. Screening Programme 2 (Region 1)

Accessing Diabetic Retinopathy Screening

This theme highlights participants' varying experiences and perceptions around making the appointment, getting there - and back, which patients had difficulties with.

Pre-booked VS. Self-booked appointments:

Invitation methods vary by Region (see Figure 1), with professionals and patients identifying issues around both modalities that could affect uptake. Patients need to be proactive either to make their appointment, or change an inconvenient pre-booked appointment (depending where they live). All participant groups identified that patients could forget to do either, whilst this appeared particularly problematic for working patients.

But it does rely on the patient being proactive. You get an appointment, alphabetical order, totally inconvenient, impractical time, what do you do, do you do nothing and forget it or do you ring up and change it? And if you don't ring up and change it then nothing h s, you're just a DNA statistic aren't you really. Screening Programme 3 (Region 1)

Int: *So you get a letter with the appointment pre-booked?*
Pt: Yes. And then if you can't make it you change it.
Int: You wouldn't prefer to be able to ring yourself and make an appointment?
Pt: No, because I think you'd tend to forget wouldn't you, and I think most people would. Patient 3 (Region 1, Regular)

Patients are used to receiving pre-booked appointments for other diabetes clinics (e.g. Practice Nurse appointments to be weighed and have their feet checked). Professionals felt that expecting patients to make their own DRS appointment downgraded its perceived importance to patients, or was not patients' responsibility. This was exacerbated by the perceived rigidity of the appointment-booking system in another region.

I think if it's left to the patient a lot of the time they don't think, because they have to do it, it's not that important Health Professional 4 (Region 3)

Why should a patient… if it was a blood test… would the GP just say, go and sort it out yourself, and the patient is just registering himself at the hospital, getting a blood test and making sure the GP gets it? That's ridiculous. Screening Programme 1 (Region 3)

I get a letter saying I need to make a phone call between specific times on specific dates and they give you a block of dates ...to make the appointment in advance ...a good 6 weeks Patient 5 (Region 2, Regular)

Patients in the area delivering DRS through high street optometry reported an absence of available appointments:

Well before the appointment I phoned and they said no, they'd got no appointments for the next three months... The following year again the same thing, I phoned when I had the letter, they said three months' waiting. Patient 5 (Region 3, Non-regular)

Integrating diabetes appointments

Patients in different regions suggested that DRS should be better integrated with their other diabetes care as this would reduce the inconvenience of attending numerous appointments:

Probably would be better if it was done the same time as you have a normal diabetic appointment... I mean I've had to come up here on the Tuesday because they wanted to check my weight and then I think it was the Wednesday to have my eyes done and I'm thinking, do I need to come up twice [laughs]. Patient 8 (Region 1, Regular)

Transport

Getting to and from screening appointments was important pragmatically for many patients, who had to overcome a range of issues. One health professional recognised that

transport issues and proximity of screening to patients' homes potentially affected uptake, apparently understanding patients' reticence to travel - although without the insight into the difficulties that some patients experienced:

> *Most patients around here like to go to things that are within walking distance or within a bus stop, if that. So transport is an issue. …they know the surgery, 'oh the surgery is next door, I know the girls there, they're always there'... So maybe I need to have the retinopathy screening done at the surgery and they'd all come [laughs].* Health Professional 1 (Region 3)

Patients are advised not to drive to/from DRS appointments, because the mydriasis drops cause blurred vision and photosensitivity (detailed later). The pragmatic repercussions of this were especially notable for working age people. However, alternative travel arrangements also emerged as impractical because blurred vision caused an inability to navigate sufficiently.

> *I am tied to either making them [screening appointments] in the afternoon and then getting home, so I have to work out how to get into work in the morning that doesn't involve driving, or I have to be there [GP practice] earlier, say lunch time or something, I have to take a half day.* Patient 5 (Region 2, Regular)

> *Because of the drops, it makes it difficult for the people's journey...it's like a cobweb on top of your eyes and… No I can't see at all... We have to have the eye drops so it's very hard to either walk it back …I felt I was blinded temporarily and got into a taxi and then got out of the car somehow. I had to cross the road and I was just looking like that [stares blankly] because I was waiting for the taxi and I had to do like that [waves arms]…* Patient 5 (Region 3, Non-regular)

Screening Experiences

This theme incorporates patients' experiential accounts of the actual screening appointments, including negative experiences of lengthy appointments in High Street optometry practices compared with efficient GP practice appointments. Mydriasis drops caused severe side-effects and subsequent adverse affects for some patients, who discussed strategies to overcome these.

Appointment length

In one region, appointments lasting several hours at optometry practices were potentially a deterrent. One patient recognised that lengthy food abstinence was particularly inappropriate for diabetes patients, whilst another overcame the problem by changing practice.

> *Yes, the first time I went to... the local optician ...I was there for 5 hours, from 10 o'clock in the morning, and by the time I got out of the door it was 3 o'clock. ... And*

by then I can remember I was so hungry and I thought, 'well how does that help a diabetic person?' Patient 5 (Region 3, Non-regular)

I had my optician before and he was quite slow, the drops used to sting and he used to take a long time. I had to be there for about two or three hours. But my present optician is good. Patient 1 (Region 3, Regular)

However, in sharp contrast, where screening was delivered in GP practices, satisfaction with short, efficient appointments was reported.

They're quite good actually, see you straight away, well within, you know ...about ten minutes of your appointment... Patient 8 (Region 1, Regular)

It doesn't take half an hour I suppose at the outside. Patient 1 (Region 2, Regular)

Side effects of drops

Mydriasis drops dilate the pupil, allowing more light into the eye and a clearer retinal photograph to be taken. However, in another important finding, both regular and non-regular patients experienced severe pain, blurred vision and debilitating photosensitivity for several hours. Interestingly, none of the health professionals except the optometrist raised this, suggesting they were unaware of this issue.

AH: you come and they put the drops in do they?
P: Oh yes. They were like acid burning my eyes this time... It really hurt this time.
Patient 1 (Region 1, Non-regular)

Everything else is fine, it's just the drops, they sting like hell. Patient 3 (Region 1, Regular)

And I hate that because it affects my eyes for so long and I can't… put my lenses back in straight away so someone is with me because I can't see... Patient 4 (Region 2, Non-regular)

I would advise anybody to bring sunglasses even if it's not particularly bright... if I had them I'd wear dark goggles so that they're closed in. Like welders goggles [laughs]. Actually no like swimming goggles but darker, to keep all the light out from the sides now, because it's painful. Patient 5 (Region 2, Regular)

If someone tomorrow has drops put in because of the service and they just happen to have a reaction to the drops, and they lose their eyesight... So then who are they going to sue? …if push comes to shove we're the ones [optometrists]who are going to get sued. Screening Programme 1 (Region 3)

DISCUSSION

Results in context

For some patients and practices, the DRS Programme worked well and we confirm previous findings that a convenient screening location near home was beneficial (24) and preserving vision was prioritised amongst diabetes patients (25). We also confirm previous studies, finding that, for others, misunderstandings about the importance of diabetes and personal risk (22) (26), lack of DRS awareness, psychological factors, practical obstacles (22) and the deterrent side-effects of mydriasis (27) represented potential attendance barriers.

No clear distinction between regular and non-regular DRS attenders was identified. In an important new finding, we uncovered confusion between routine retinal photography at optometry practices during eye examinations, and DRS. Whilst optometry photography may represent an important safeguard for non-attenders, it could impair more comprehensive coverage. We observed differences between patients screened at GP vs. optometrist practices, identifying that ease of making the appointment, including its time, navigating home after the mydriasis drops, etc. appeared less problematic at GP practices. Furthermore, making patients responsible for arranging appointments in some regions, combined with encountering delays, could undermine the perceived importance of DRS. We have identified patients' misperceptions about their attendance regularity.

Strengths and Limitations of the study

Strengths of this study include the purposive sampling strategy across several strata of professional groups in GP and optometry practices and screening programmes, and recruiting regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes. However, not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening. The qualitative findings from our purposive sample are not intended to be representative but highlight socio-cultural meanings of health and illness experiences, not simply their frequency, and identify important insights into barriers and enablers to screening attendance amongst our participants that will inform further research.

Implications for clinicians and policy makers

Whilst some patients understood retinopathy and its causation, others lacked information and understanding about DRS. This calls for proactive personal clinical risk communication (28, 29) and attendance information to ensure care coordination between patients, primary care, screeners and Screening Programmes. The current guidance to bring sunglasses could be strengthened in the patient information. Some patients confused retinal photography at optometry practices with DRS. Professional Optometry bodies could ensure clarity amongst members, and optometrists should highlight the difference to their patients. Consideration may be appropriate around the responsibility that the NHS has when discharging visually

impaired patients in to the community. Culturally sensitive improvements (21) should build upon the recent introduction of patient information leaflets in several languages[11].

Several providers now deliver DRS in the UK, and, since this research was conducted, Public Health England is responsible for overseeing delivery and the financial incentive for GPs to record screening uptake has been removed. These changes may affect future practice involvement and patient uptake; this fast-moving field requires monitoring closely. Building on the successful central appointments system and practice factors that affect DRS attendance (30), may prove useful. The national implementation of the new screening pathway should ensure consistent delivery throughout the country, improving the quality of services and reducing variability (31).

Future research

Much more work is needed is this field. A similar exercise should be undertaken amongst a representative national sample of programmes, taking into account demographic variables that we found to be relevant (ethnicity, delivery-mode, deprivation etc.). More work needs to determine the prevalence of patients' and clinicians' views on the appropriate design and delivery of DRS services to maximise attendance; hospital staff may provide insightful alternatives for service improvement. The pharmacological reformulation of shorter-acting mydriasis drops to minimise side-effects may reduce disruption to patients and potentially benefit uptake rates, although we acknowledge that this would not address the pain participants reported. The extent of confusion about optometry photography needs urgent assessment.

Conclusions

This study uses staff and patients' experiences of DRS to start unpicking factors affecting uptake. Factors identified include differing regional invitation methods and screening locations, convenience, transport safety and short appointment times; some patients experienced significant side effects from mydriasis drops. The successful implementation of the new care pathway should address these factors and may improve DRS attendance. Used as an international model, this could, in turn, contribute to reducing preventable vision loss and inequalities globally and its associated costs to individuals and their families, and to primary, secondary and social care providers.

[11] http://diabeticeye.screening.nhs.uk/languages

Footnotes

- **Acknowledgements:** We thank the GP and optometry practices and Screening Programme staff who took part in the study and the patients who gave their time and shared their experiences and thoughts. We acknowledge the input and guidance of patient representative Mr Mike Whatmore on the Steering Group. We thank members of Warwick Diabetes Research Education Group for their constructive feedback on patient materials and early protocols. Kay Webb collected some data.

- **Contributorship statement:** IS had the original idea; PS led the funding application. JS and AL had the idea for the qualitative component of the study. All authors contributed to the development of the protocol and overall supervision of the study. AH, the project manager, obtained ethical approval, and conducted the interviews with AL and JS. AH led the qualitative analysis and drafted the paper. All authors contributed to the writing of the final version of the paper. PS is guarantor.

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- **Competing interest Statement:** PS is the Director of the NHS Diabetic Eye Screening Programme; AH has personal experience of mydriasis drops.

- **Payment:** a £5 High Street voucher was given to patient participants in recognition of their contribution.

- **Transparency statement:** The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

- **Provenance and peer review:** Not commissioned; externally peer reviewed

- **Data-sharing statement:** Copies of the participant information sheet can be obtained by emailing the corresponding author - a.e.hipwell@warwick.ac.uk.

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Table 1: Practice characteristics

Practice no.	Screening Programme area	Index of Multiple Deprivation (IMD)	Practice type	Screening delivery mode	Uptake rate
Practice 1	Region 1	Deprived	Urban city	GP practice	96%
Practice 2	Region 1	Below average	Rural Town	GP practice	88%
Practice 3	Region 2	Deprived	Rural Town	GP practice	85%
Practice 4	Region 2	Above average	Rural Town	GP practice	75%
Practice 5	Region 1	Deprived	Rural Town	GP practice	73%
Practice 6	Region 1	Below average	Urban City	GP practice	72%
Practice 7	Region 2	Least deprived	Rural Town	GP practice	71%
Practice 8	Region 3	Most deprived	Inner City	High street optometrist	68%
Practice 9	Region 3	Most deprived	Inner City	High street optometrist	57%

Table 2: Programme and participant characteristics

Screening Programme Regional descriptor	**Region 1** Urban city rural town	**Region 2** Rural town	**Region 3** Inner city	**Total**
Number of practices	4	3	2	9
Patients (Non-regular attenders)	14 (5)	8 (1)	16 (10)	38 (16)
Medical practice staff (GPs, optometrist, HCAs, nurses)	2	3	3	8
Administrative practice staff (receptionists, managers)	4	2	1	7
Screeners	4	4	1	9
Total participants	**24**	**17**	**18**	**62**

What is already known on this topic

The proportion of people with visual impairment caused by diabetic retinopathy is increasing globally.

The NHS Diabetic Retinopathy Screening is cost-effective at 80% uptake.

The 20% of people who do not attend screening in the UK are at the highest risk of sight-threatening diabetic retinopathy.

There is little evidence about how screening is perceived and experienced by those professionals and patients involved in it, or how this may affect uptake

What this study adds

People with diabetes want to prioritise preserving their vision, but some do not recognise the need to attend their Diabetic Retinopathy Screening.

This is exacerbated by optometry practices undertaking retinal photography outside of the screening service.

Some participants had difficulties making an appointment, problems attending the appointment, and experienced debilitating side-effects of mydriasis drops.

Figure 1: Diabetic Eye Screening Programme delivery modes

Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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Some participants had difficulties making an appointment, problems attending the appointment, and experienced debilitating side-effects of mydriasis drops.

Encouragingly, a coherent approach to addressing professionals' and patients' respective responsibilities may improve Diabetic Retinopathy Screening uptake.

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ABSTRACT

~~**What is already known:** Diabetic retinopathy is a major cause of preventable vision loss globally. Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment. Diabetic Retinopathy Screening is cost-effective, saving patients' sight and the substantial cost of healthcare provision to those with vision loss. However, certain groups of people are both less likely to attend and to have worse retinopathy.~~

Objective: To examine patients', health professionals' and screeners' experiences of, interactions with and understandings of Diabetic Retinopathy Screening, and how these influence uptake.

Design: Purposive, qualitative design using multi-perspectival, semi-structured interviews and thematic analysis.

Setting: Three UK Screening Programme regions with different service-delivery modes, minority ethnic and deprivation levels, across rural, urban and inner-city areas, in GP practices and patients' homes.

Participants: 62 including 38 patients (22 regular screening attenders, 16 non-regular attenders), and 24 professionals (15 Primary Care professionals and 9 screeners).

Results: Antecedents to attendance included knowledge about diabetic retinopathy and screening; antecedents to non-attendance included psychological, pragmatic and social factors. Confusion between photographs taken at routine eye tests and Diabetic Retinopathy Screening photographs was identified. The differing regional invitation methods and screening locations were discussed, with convenience and transport safety being over-riding considerations for patients. Some patients mentioned significant pain and visual disturbance from the mydriasis drops as a deterrent to attendance. ~~Short appointment times were preferred by patients, some of whom experienced severe side-effects from the mydriasis drops used to dilate their pupils.~~

Conclusions: In this, the first study to consider multi-perspectival experiential accounts, we identified that proactive coordination of care involving patients, primary care and the Screening Programmes, prior to, during and after screening is required. Multiple factors prior to, during and after screening are involved in the attendance and non-attendance for DR screening. Further research is needed to establish whether~~P~~ patient self-management educational interventions, and the pharmacological reformulation of shorter-acting mydriasis drops, may improve uptake of Diabetic Retinopathy Screening.~~,~~ This might, in turn, reduc~~e~~ing preventable vision loss and its associated costs to individuals and their families, and to health and social care providers, reducing current inequalities.

Keywords: Diabetic Retinopathy, Screening, Qualitative, Inequalities

ARTICLE SUMMARY

Strengths and Limitations of the study

- Our purposive sampling strategy recruited several strata of professional groups in GP and optometry practices and screening programmes, and both regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes.

- Not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening.

- The qualitative findings from our purposive sample are not intended to be representative but highlight important insights into barriers and enablers to screening attendance that will inform further research.

INTRODUCTION

Visual impairment is a significant worldwide health problem (1, 2). Approximately 314 million people globally are visually impaired, with over 80% of this impairment being preventable or treatable (1)(3). Diabetic retinopathy is a major cause of preventable vision loss in people with type 1 and type 2 diabetes in Europe, Africa, Asia and Australia (4-9) (10-13) and until recently (14) has been the leading cause of preventable vision loss in European working age populations (4, 8, 10-12). The proportion of vision loss caused by diabetic retinopathy is increasing globally (13). In addition to treatment costs, lost productivity and quality of life for patients with diabetic retinopathy contribute to personal and socio-economic burdens (15~~14~~).

~~Initially asymptomatic, this microvascular complication is associated with high blood glucose, high blood lipids, hypertension, smoking, non-attendance at screening, minority ethnicity (15, 16), duration of diabetes (17, 18) and existing diabetic retinopathy (19).~~

Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment (1, 15~~14~~). In England, routine diabetes care and Diabetic Retinopathy Screening (DRS) are principally managed in primary care, whilst treatment for retinopathy takes place in secondary care. Issues surrounding diabetic retinopathy therefore have practice implications for medical and health professionals working in both settings.

The UK Government's measurement of preventable vision loss from April 2013 recognises this top public health priority. The English NHS Diabetic Eye Screening Programme offers cost-effective annual screening to people with diabetes (Types 1 and 2) over 12 years (16~~20~~) where 80% uptake is achieved. Screening uptake is assessed at the general practice level. Screening modes differ regionally, taking place either in GP surgeries, hospitals or optometry practices (see Figure 1). Screening typically takes 30 minutes. ~~Mydriasis drops~~

~~dilate p~~Patients' pupils are dilated with drops, affecting their vision for four to six hours. Digital photographs are taken and the images examined by regional NHS retinal grading teams, who identify any pathology. Results are communicated to the patient and GP. Patients with retinopathy requiring monitoring or treatment are referred to the Hospital Eye Service.

However, approximately 20% of people invited for DRS do not attend (17~~23~~), with those from minority ethnic backgrounds and people living in deprived areas both less likely to attend and to have worse retinopathy (18~~24~~), (~~15~~19), (20~~16~~). Inequalities in access to DRS in England[8] have led to calls for further research (19~~25~~), including qualitatively (~~15~~21).

Yet deprivation alone does not explain all the uptake variability between GP practices and regions. For example, misunderstandings about the importance of diabetes and personal risk factors ~~amongst people undergoing diabetes screening~~ and patients' lack of awareness, ~~and~~ psychological factors or practical obstacles, ~~have been identified as~~ can represent major barriers to attending screening (22~~26~~). However, as attendance rates vary greatly between neighbouring practices, for example, from 55% to 95% in Gloucestershire (23~~27~~), research focusing beyond deprivation, risk factors or barriers is required. Little is known about how patients' and professionals' perceptions and experiences of DRS may influence attendance. This paper therefore focusses on experiences around DRS that may affect uptake, from the accounts of people with diabetes and ~~the~~ GP practice and screening staff ~~involved in screening~~.

Figure 1: Diabetic Eye Screening Programme delivery modes

METHODS

~~Ethical permission was granted by~~ NRES Committee South West – Cornwall and Plymouth gave ethical permission (10/H0203/79) and all participants gave informed consent ~~was given by all participants~~. This work was supported by the National Institute of Health Research, Research for Patient Benefit grant ~~reference~~ PB-PG-1208-18043 and sponsored by Gloucestershire Hospitals NHS Foundation Trust.

Design of the research: This multi-perspectival (24~~28~~), cross-sectional qualitative interview study used purposively sampled GP practices in four UK Primary Care Trusts across three regions, based on Indices of Multiple Deprivation, practice type, screening mode ~~of screening~~, and screening uptake (see Table 1).

Practice recruitment: Central England Primary Care Research Network and South West Diabetes Network provided research nurse assistance with GP practice recruitment. Twelve GP practices were approached ~~to participate~~; two declined (existing research commitments); one withdrew prior to ~~commencement of~~ participant recruitment commencing (staff changes). Table 1 details ~~C~~characteristics of the nine participating GP

[8] http://www.screening.nhs.uk/news.php?id=12156

practices ~~are detailed in Table 1~~. The Central Local Research Network paid Service Support Costs of £599.27 to participating GP practices.

Table 1: Practice characteristics

Participant recruitment:

Professionals We purposively recruited 24 primary care and screening professionals with patient contact in differing roles around DRS, to ensure a broad spectrum of views and experiences. ***Patients*** Within each practice, patients were purposively sampled based on their screening attendance history, to consider differences in attitudes and experiences. "Regular attenders" had attended all three of their most recent DRS appointments; "Non-regular attenders" had attended none or one of their three most recent DRS appointments. Practice staff telephoned potential participants and sent information packs.

Interviews Semi-structured interviews were conducted either face-to face, at the GP/optometry practice, in patients' homes, or by telephone, at participants' discretion. ~~The m~~Multi-perspectival interviews allowed us to understand the dynamics between patients, professionals and the Screening Programme, explore similarities and differences in their perceptions to highlight potentially differing needs and suggestions for improving services. Questions aimed to capture descriptions of participants' experiences before, during and after the screening appointment, from professionals' and patients' perspectives, identifying ~~patient~~ factors they believed influence screening attendance. All interviews were audio-recorded and transcribed verbatim prior to analysis. No additional data is available for data-sharing.

Analysis Data were managed using QSR NVivo10 software[9] to code and review themes. AH undertook iterative, thematic analysis, using constant comparison within and across all transcripts. Looking for overarching themes and relations between them, AH identified specific major and minor categories within the themes that might interact to influence screening attendance rates. AH and AL met to discuss these themes and agreed on the definitions of emerging codes. ~~No theme was unique to either regular attenders, or non-regular attenders.~~ Findings were discussed with ~~different project group members~~ all authors until consensus was reached about the interpretation of key themes. Finally, AH checked these interpretations with the existing data.

RESULTS

Characteristics of the sample: 62 participants (33 female) were interviewed between September 2011 and July 2012, by AH, AL and JS. Of the 38 patients, four have Type 1 diabetes (mean age 49); 34 have Type 2 (mean age 60); 22 were regular retinopathy screening attenders, 16 were non-regular attenders (defined above). Of the 24 professionals (mean age 50), eight are primary healthcare professionals, seven are administrative practice staff; and nine are ~~diabetic retinopathy~~ DRS programme screeners.

[9] www.qsrinternational.com/

Table 2: Programme and participant characteristics

No theme was unique to either regular attenders, or non-regular attenders, which highlights the complex nature of why people do or do not attend appointments.

Understandings of Diabetic Retinopathy and Screening

GP practice staff, screeners and patients identified several antecedents to attendance and non-attendance at screening. Both regular and non-regular attending patient participants acknowledged the importance of DRS. Yet confusion around screening was clearly identified in all participant groups, as was the need to overcome this.

Understandings of Diabetic Retinopathy:

Some (but not all – see later subthemes) ~~P~~people with diabetes ~~largely~~ understood causal factors and the potential consequences of Diabetic Retinopathy; protecting the eyes appeared to be a priority for some. Interestingly, a non-regular attender with vicarious experience of sight loss identified herself to the researcher as a regular attender. Others found the process reassuring**.**

> *It's the smallest vessels that go first, and it's one of the quickest ways of seeing the effects is in the eyes. But... the body is so tolerant, you don't recognise that the vision is going until it's too late.* Patient 8 (Region 2, Regular)[10]

> *I: So what is it that encourages you to come [to screening] then?*
> *P: My brother-in-law he was a very bad diabetic... He actually died from it. He went blind first.* Patient13 (Region 3, Non-regular)

> *I like the fact that you instantly see and can get a decent steer on if there is anything negative; it's complete peace of mind – well my results anyway.* Patient 3 (Region 2, Regular)

Psychological, pragmatic and social influences on non-attendance

In response to being asked why people might not attend DRS, both professionals and patients acknowledged that denial of having diabetes could contribute. One patient ~~had~~ missed screening appointments because she disliked the ~~close~~ proximity of the screener. Pragmatic reasons raised by the non-regular attenders for non-attendance included work commitments and post-operative recuperation.

> *Some people just… have their head in the… like the ostrich, they don't have diabetes or they're not taking any notice of it and they will just… yes, not come. Some because they think they can't have the time off work, you know?* Screening Programme 1 (Region 1)

[10] R = region from Table 1; Regular attender/Non-regular attender (as defined above)

It's just the thought of somebody coming close to my eye. Patient 15 (Region 3, Non-regular)

I missed once, because I had an abscess in an awkward place, and I had to have an operation. But the following year I made sure. Patient 5 (Region 3, Non-regular)

Another non-regular attender who identified herself as a regular attender had attempted to access DRS via her GP practice, but was refused because she was in temporary accommodation awaiting rehousing. This highlights the complex social context in which people with diabetes experience screening:

Int*: So you didn't always come?*
Pt: Well, with being homeless for 8 weeks... But they [GP practice] didn't want to know. 'Oh you're not in our area.' I'm in nobody's area because we were in a bed and breakfast; they were my last doctors. Patient 10 *(*Region 1, Non-regular)

Understandings of Diabetic Retinopathy Screening vs. routine eye test

Some ~~P~~patients' perceptions of screening attendance were confused by high street optometry practices routinely taking photographs during a general annual eye check. Patients confused this with DRS even in areas where High Street optometry practices did *not* conduct DRS, confounding attendance:

I'm with [high street optometry chain] so I've always, always had my eyes screened. ... So when I was diagnosed and I told the optician she said, well we can do that here for an extra £10 and we will just email the surgery. So I thought fine, that's fine. So I just bypass it completely... Patient 4 (Region 2, Non-regular)

A lot of people turn up and say, 'well I had my optician's test' and you ...explain to them that although it's a great thing to have and they need to have it, we still need to do our tests because it's more accurate, and we're searching specifically for the diabetic retinopathy. Screening Programme 1 (Region 1)

Perceived responsibility for patients' understandings of Diabetic Retinopathy and screening

Professionals and patients identified the need to improve patients' understandings about DRS and sight-threatening retinopathy. For example, one GP accepted that low uptake reflected a failure to deliver the right message. However, more direct input from the health professional team was suggested by one patient who had not understood the screening information, and subsequently developed retinopathy. One screener considered that the lack of media attention to DRS could contribute to low attendance.

Why haven't they taken that onus of control, what is it that they don't believe about their diabetes? Where have we gone wrong in trying to get that message across? ...the words "Diabetic Retinopathy Screening", what does that mean to them?
Health Professional 1 (Region 3)

As soon as I had diabetes diagnosed somebody should have explained to me more fully what the implications are. Because it's alright them giving you a leaflet and sending you home... but even though you read it, there's this kind of silly thing, 'oh it won't happen to me', attitude. Patient 15 (Region 3, Non-regular)

~~*Lack of patient information.*~~ *I don't think screening is something that's pushed as much as other screening. I mean retinal screening is…I'd say it's important... but things like breast cancer, there's a lot more press about it.* Screening Programme 2 (Region 1)

Accessing Diabetic Retinopathy Screening

This theme highlights participants' varying experiences and perceptions around making the appointment, getting there - and back, which~~. P~~patients had difficulties with ~~in making, attending and returning from their screening appointments~~.

Pre-booked VS. Self-booked appointments:

Invitation methods vary by Region (see Figure 1), with professionals and patients identifying issues around both modalities that could affect uptake. Patients need to be proactive either to make their appointment, or change an inconvenient pre-booked appointment (depending ~~on~~ where they live). All participant groups identified ~~the possibility of~~ that patients could forget~~ting~~ to do either, whilst this ~~could be~~ appeared particularly problematic for working patients.

But it does rely on the patient being proactive. You get an appointment, alphabetical order, totally inconvenient, impractical time, what do you do, do you do nothing and forget it or do you ring up and change it? And if you don't ring up and change it then nothing happens, you're just a DNA statistic aren't you really. Screening Programme 3 (Region 1)

Int: *So you get a letter with the appointment pre-booked?*
Pt: Yes. And then if you can't make it you change it.
Int: You wouldn't prefer to be able to ring yourself and make an appointment?
Pt: No, because I think you'd tend to forget wouldn't you, and I think most people would. Patient 3 (Region 1, Regular)

Patients are used to receiving pre-booked appointments for other diabetes clinics ~~,(such as seeing the~~ e.g. Practice Nurse appointments ~~to be weighed and have their feet checked~~). Professionals felt that expecting patients to make their own DRS appointment downgraded its perceived importance to patients, or was not patients' responsibility. This was exacerbated by the perceived rigidity of the appointment-booking system in another region.

I think if it's left to the patient a lot of the time they don't think, because they have to do it, it's not that important Health Professional 4 (Region 3)

Why should a patient… if it was a blood test… would the GP just say, go and sort it out yourself, and the patient is just registering himself at the hospital, getting a blood test and making sure the GP gets it? That's ridiculous. Screening Programme 1 (Region 3)

I get a letter saying I need to make a phone call between specific times on specific dates and they give you a block of dates ...to make the appointment in advance ...a good 6 weeks Patient 5 (Region 2, Regular)

Patients in the area ~~that~~ deliver~~ings~~ DRS through high street optometry reported an absence of available appointments:

Well before the appointment I phoned and they said no, they'd got no appointments for the next three months... The following year again the same thing, I phoned when I had the letter, they said three months' waiting. Patient 5 (Region 3, Non-regular)

Integrating diabetes appointments

Patients in different regions suggested that DRS should be better integrated with their other diabetes care as~~. They understood that~~ this would reduce the inconvenience of attending numerous appointments:

Probably would be better if it was done the same time as you have a normal diabetic appointment... I mean I've had to come up here on the Tuesday because they wanted to check my weight and then I think it was the Wednesday to have my eyes done and I'm thinking, do I need to come up twice [laughs]. Patient 8 (Region 1, Regular)

Transport

Getting to and from screening appointments was important pragmatically for many patients, who had to overcome a range of issues. One health professional recognised that transport issues and proximity of screening to patients' homes potentially affected uptake, apparently understanding patients' reticence to travel - although without the insight into the difficulties that some patients experienced:

Most patients around here like to go to things that are within walking distance or within a bus stop, if that. So transport is an issue. …they know the surgery, 'oh the surgery is next door, I know the girls there, they're always there'... So maybe I need to have the retinopathy screening done at the surgery and they'd all come [laughs]. Health Professional 1 (Region 3)

Patients are advised not to drive to/from DRS appointments, because the mydriasis drops cause blurred vision and photosensitivity (detailed later). The pragmatic repercussions of this were especially notable for working age people ~~of working age~~. However, alternative travel arrangements also emerged as impractical because blurred vision caused~~of~~ an inability to navigate sufficiently ~~with blurred vision~~.

I am tied to either making them [screening appointments] in the afternoon and then getting home, so I have to work out how to get into work in the morning that doesn't involve driving, or I have to be there [GP practice] earlier, say lunch time or something, I have to take a half day. Patient 5 (Region 2, Regular)

Because of the drops, it makes it difficult for the people's journey...it's like a cobweb on top of your eyes and… No I can't see at all... We have to have the eye drops so it's very hard to either walk it back …I felt I was blinded temporarily and got into a taxi and then got out of the car somehow. I had to cross the road and I was just looking like that [stares blankly] because I was waiting for the taxi and I had to do like that [waves arms]… Patient 5 (Region 3, Non-regular)

Screening Experiences

This theme incorporates patients' experiential accounts of the actual screening appointments, ~~. It~~ includinges ~~negative~~ experiences of lengthy appointments in High Street optometry practices compared with ~~others'~~ efficient GP practice appointments. Mydriasis drops caused severe side-effects and subsequent adverse affects for ~~S~~some patients, ~~experienced severe side-effects and subsequent adverse affects from the mydriasis drops. Participants~~ who discussed strategies to overcome these ~~side-effects~~.

Appointment length

In one region, appointments lasting several hours at optometry practices were potentially ~~served as~~ a deterrent. One patient recognised that lengthy food abstinence ~~for this long~~ was particularly inappropriate for diabetes patients, whilst another overcame the problem by changing practice.

Yes, the first time I went to... the local optician ...I was there for 5 hours, from 10 o'clock in the morning, and by the time I got out of the door it was 3 o'clock. ... And by then I can remember I was so hungry and I thought, 'well how does that help a diabetic person?' Patient 5 (Region 3, Non-regular)

I had my optician before and he was quite slow, the drops used to sting and he used to take a long time. I had to be there for about two or three hours. But my present optician is good. Patient 1 (Region 3, Regular)

However, in sharp contrast, where screening was delivered in GP practices, satisfaction with short, efficient appointments was reported.

They're quite good actually, see you straight away, well within, you know ...about ten minutes of your appointment... Patient 8 (Region 1, Regular)

It doesn't take half an hour I suppose at the outside~~, even though you've got to have the drops and wait for them to activate, and then the actual screening is about 15 minutes...~~ Patient 1 (Region 2, Regular)

Side effects of drops

Mydriasis drops dilate the pupil, allowing more light into the eye and a clearer retinal photograph to be taken. However, in another important finding, ~~many patients (~~both regular and non-regular patients~~)~~ experienced severe pain, blurred vision and debilitating photosensitivity ~~lasting~~ for several hours. Interestingly, none of the health professionals except the optometrist raised this, suggesting ~~that~~ they were unaware of this issue.

AH: you come and they put the drops in do they?
P: Oh yes. They were like acid burning my eyes this time... It really hurt this time. Patient 1 (Region 1, Non-regular)

Everything else is fine, it's just the drops, they sting like hell. Patient 3 (Region 1, Regular)

And I hate that because it affects my eyes for so long and I can't… put my lenses back in straight away so someone is with me because I can't see... Patient 4 (Region 2, Non-regular)

I would advise anybody to bring sunglasses even if it's not particularly bright... if I had them I'd wear dark goggles so that they're closed in. Like welders goggles [laughs]. Actually no like swimming goggles but darker, to keep all the light out from the sides now, because it's painful. Patient 5 (Region 2, Regular)

If someone tomorrow has drops put in because of the service and they just happen to have a reaction to the drops, and they lose their eyesight... So then who are they going to sue? …if push comes to shove we're the ones [optometrists]who are going to get sued ~~[optometrists]~~. Screening Programme 1 (Region 3)

DISCUSSION

Results in context

For some patients and practices, the DRS Programme worked well and we confirm previous findings that a convenient screening location ~~close to~~ near home was beneficial (24~~28~~) and preserving vision was prioritised amongst diabetes patients (25~~29~~). We also confirm previous studies, finding that, ~~F~~for others, misunderstandings about the importance of diabetes and personal risk (22~~26~~) (26~~30~~), lack of DRS awareness, psychological factors, practical obstacles (22~~26~~) and the deterrent side-effects of mydriasis (27~~31~~) represented potential attendance barriers.

No clear distinction between regular and non-regular DRS attenders was identified. In an important new finding, we uncovered confusion between routine retinal photography at optometry practices during eye examinations, and DRS. Whilst optometry photography

may represent an important safeguard for non-attenders, it could impair more comprehensive coverage. We observed differences between patients screened at GP vs. optometrist practices, identifying that ease of making the appointment, including its time, navigating home after the mydriasis drops, etc. appeared less problematic at GP practices. Furthermore, making patients responsible for arranging appointments in some regions, combined with encountering delays, could undermine the perceived importance of DRS. We have identified patients' misperceptions about their attendance regularity.

Strengths and Limitations of the study

Strengths of this study include the purposive sampling strategy across several strata of professional groups in GP and optometry practices and screening programmes, and recruiting regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes. However, not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening. The qualitative findings from our purposive sample are not intended to be representative but highlight socio-cultural meanings of health and illness experiences, not simply their frequency, ~~highlight~~ and identify important insights into barriers and enablers to screening attendance amongst our participants that will inform further research.

Implications for clinicians and policy makers

Whilst ~~S~~some patients understood retinopathy and its causation, others lacked information and understanding about DRS.~~,~~ ~~which~~This calls for proactive personal clinical risk communication (28, 29~~17, 18~~) and attendance information to ensure care coordination between patients, primary care, screeners and Screening Programmes. The current guidance to bring sunglasses could be strengthened in the patient information. Some patients confused retinal photography at optometry practices with DRS. Professional Optometry bodies could ensure clarity amongst members, and optometrists should highlight the difference to their patients. Consideration may be appropriate around the responsibility that the NHS has when discharging visually impaired patients in to the community. Culturally sensitive improvements (21~~25~~) should build upon the recent introduction of patient information leaflets in several languages[11].

Several providers now deliver DRS in the UK, and, since this research was conducted, Public Health England is responsible for overseeing delivery and~~.~~; ~~t~~The 2014/15 Quality Outcomes ~~Framework now excludes the DRS indicator, which will allow GPs to adopt flexibility in appointment setting based on clinical need.~~ the financial incentive for GPs to record screening uptake has been removed. These changes may affect future practice involvement and patient uptake; ~~T~~this fast-moving field requires monitoring closely. Building on the successful central appointments system and practice factors that affect DRS attendance

[11] http://diabeticeye.screening.nhs.uk/languages

(3032), may prove useful. The national implementation of the new screening pathway should ensure consistent delivery throughout the country, improving the quality of services and reducing variability (3133).

Future research

Much more work is needed is this field. A similar exercise should be undertaken amongst a representative national sample of programmes, taking into account demographic variables that we found to be relevant (ethnicity, delivery-mode, deprivation etc.). More work ~~is~~ needsed to determine the prevalence of patients' and clinicians' views on the appropriate design and delivery of DRS services to maximise attendance; hospital staff may provide insightful alternatives for service improvement. ~~Encouragingly, many of the attendance barriers identified seem amenable to intervention. Community-based, culturally competent, educational interventions (25), supported by a Public Health media campaign should be developed, tested and implemented.~~ The pharmacological reformulation of shorter-acting mydriasis drops to minimise side-effects may reduce disruption to patients and potentially benefit uptake rates, although we acknowledge that this would not address the pain participants reported~~from the osmotic effect of the drops~~. The extent of confusion about optometry photography needs urgent assessment.

Conclusions

This study uses staff and patients' experiences of ~~Diabetic Retinopathy Screening~~ DRS to start unpicking factors affecting uptake ~~rates~~. Factors identified include differing regional invitation methods and screening locations, convenience, transport safety and short appointment times; some patients experienced significant ~~pain and visual disturbance~~ side effects from ~~the~~ mydriasis drops. The successful implementation of the new care pathway should address these factors and~~ensure proactive care coordination and consistent strategies to identify and address unmet access needs before, during and after screening. Clear guidance from professional bodies, a Public Health media campaign to encourage positive attitudes, and reformulated mydriasis drops,~~ may improve DRS attendance. Used as an international model, this ~~may~~could, in turn, contribute to reducing preventable vision loss and inequalities globally and its associated costs to individuals and their families, and to primary, secondary and social care providers.

Footnotes

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- **Contributorship statement:** IS had the original idea; PS led the funding application. JS and AL had the idea for the qualitative component of the study. All authors contributed to the development of the protocol and overall supervision of the study. AH, the project manager, obtained ethical approval, and conducted the interviews with AL and JS. AH led the qualitative analysis and drafted the paper. All authors contributed to the writing of the final version of the paper. PS is guarantor.

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- **Competing interest Statement:** PS is the Director of the NHS Diabetic Eye Screening Programme; AH has personal experience of mydriasis drops.

- **Payment:** a £5 High Street voucher was given to patient participants in recognition of their contribution.

- **Transparency statement:** The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

- **Provenance and peer review:** Not commissioned; externally peer reviewed

- **Data-sharing statement:** Copies of the topic guide and participant information sheet can be obtained by emailing the corresponding author.

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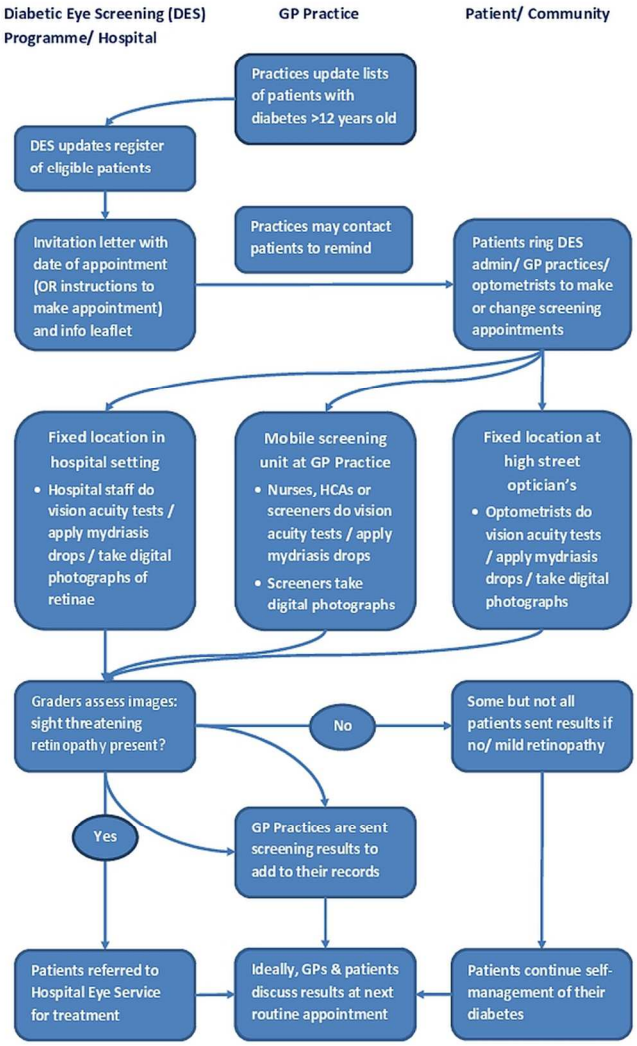

Figure 1: Diabetic Eye Screening Programme delivery modes

90x116mm (300 x 300 DPI)

APPENDIX 1

Patients Semi-structured Interview Schedule (v3)

- Tell us about yourself and your life at present (Prompts: living alone/ with others; working, caring or retired; social activities)
- Can you describe a typical day living with diabetes? (Prompts: Examples of how it affects your daily life? Compared to how you were before becoming ill/other people who are well?)
- Can you describe a good/bad day living with diabetes?
- Is there anything that you can do to improve your experience of living with diabetes?
- When did you last see your nurse/ GP about you diabetes - and what did you talk about?
- What do you know about eye screening & diabetes?
- How did you first find out about diabetic eye screening?
- Do you know why are you asked to go?
- How do you know when and where you should go?
- Do you know what it involves? (For those who did attend screening: describe in as much detail as possible the last screening they went to)
- How does this screening fit in with the rest of your diabetes care and treatment?
- What happens after your screening – how do you find out your results?
- Have you ever missed an eye screening appointment?
- Have you ever needed any further treatments on your eyes? How did you find out what you needed, what your options were?
- What do you think is responsible for any deteriorating eye sight you might have? Why
- Are there any changes to the service that you could suggest - from invitation to screening, receiving results/treatments options etc. that would make the screening process better for you? (E.g. link with opticians at annual eye test)
- How would you feel about going once every two years, instead of annually?
- What would you like to be able to do differently, that would make the screening process better for you?
- What (if anything) puts you off going?
- Have you ever been invited for any other type of health screening e.g. cervical/ breast /bowel – if so, how does it compare?
- Is there anything you'd like to add that we haven't covered in the interview?

APPENDIX 2

Health Professionals Provisional Interview Schedule (Primary Care and Screening Professionals) (v1)

- What is your role in the diabetic retinopathy screening programme? What routines and procedures does it involve you doing?
    - perceptions of relative usefulness of procedures
- Do you know how many patients attend for retinal screening here? What do you think influences this?
- Do you know what information patients receive about retinal screening, what's involved, why it's important for them? (Patient information/preparation for retinal screening)
- From your perspective, what happens when the patient attends for screening?
    - What (if anything) do you have to do if they don't attend?
- Are you involved in informing patients about the results and any further actions?
- Are there any changes that you can suggest to improve the way your patients are invited to / informed about retinal screening and the service delivered, which would improve uptake?
- Are there any changes that you can suggest regarding (this) practice's response to patients, following communication of screening results?
- How important do you feel retinal screening is for patients alongside their other diabetes screening activity (Prioritisation)
- Why do you think some patients don't attend?
- How big a part of your job is retinal screening?
- How useful do you think the screening results are for informing future patient care?
- What do you think about screening once every two years, instead of annually?
- Is there anything you'd like to add that we haven't covered in the interview?

BMJ Open

Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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TITLE PAGE

Title: Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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ABSTRACT

Objective: To examine patients', health professionals' and screeners' experiences of, interactions with and understandings of Diabetic Retinopathy Screening, and how these influence uptake.

Design: Purposive, qualitative design using multi-perspectival, semi-structured interviews and thematic analysis.

Setting: Three UK Screening Programme regions with different service-delivery modes, minority ethnic and deprivation levels, across rural, urban and inner-city areas, in GP practices and patients' homes.

Participants: 62 including 38 patients (22 regular screening attenders, 16 non-regular attenders), and 24 professionals (15 Primary Care professionals and 9 screeners).

Results: Antecedents to attendance included knowledge about diabetic retinopathy and screening; antecedents to non-attendance included psychological, pragmatic and social factors. Confusion between photographs taken at routine eye tests and Diabetic Retinopathy Screening photographs was identified. The differing regional invitation methods and screening locations were discussed, with convenience and transport safety being over-riding considerations for patients. Some patients mentioned significant pain and visual disturbance from the mydriasis drops as a deterrent to attendance.

Conclusions: In this, the first study to consider multi-perspectival experiential accounts, we identified that proactive coordination of care involving patients, primary care and the Screening Programmes, prior to, during and after screening is required. Multiple factors prior to, during and after screening are involved in the attendance and non-attendance for DR screening. Further research is needed to establish whether patient self-management educational interventions, and the pharmacological reformulation of shorter-acting mydriasis drops, may improve uptake of Diabetic Retinopathy Screening. This might, in turn, reduce preventable vision loss and its associated costs to individuals and their families, and to health and social care providers, reducing current inequalities.

ARTICLE SUMMARY

Strengths and Limitations of the study

- Our purposive sampling strategy recruited several strata of professional groups in GP and optometry practices and screening programmes, and both regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes.

- Not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening.

- The qualitative findings from our purposive sample are not intended to be representative but highlight important insights into barriers and enablers to screening attendance that will inform further research.

INTRODUCTION

Visual impairment is a significant worldwide health problem (1, 2). Approximately 314 million people globally are visually impaired, with over 80% of this impairment being preventable or treatable (1, 3). Diabetic retinopathy is a major cause of preventable vision loss in people with type 1 and type 2 diabetes in Europe, Africa, Asia and Australia (4-9, 10-13) and until recently (14) has been the leading cause of preventable vision loss in European working age populations (4, 8, 10-12). The proportion of vision loss caused by diabetic retinopathy is increasing globally (13). In addition to treatment costs, lost productivity and quality of life for patients with diabetic retinopathy contribute to personal and socio-economic burdens (15).

Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment (1, 15). In England, routine diabetes care and Diabetic Retinopathy Screening (DRS) are principally managed in primary care, whilst treatment for retinopathy takes place in secondary care. Issues surrounding diabetic retinopathy therefore have practice implications for medical and health professionals working in both settings. The UK Government's measurement of preventable vision loss from April 2013 recognises this top public health priority. The English NHS Diabetic Eye Screening Programme offers cost-effective annual screening to people with diabetes (Types 1 and 2) over 12 years (16) where 80% uptake is achieved. Screening uptake is assessed at the general practice level. Screening modes differ regionally, taking place either in GP surgeries, hospitals or optometry practices (see Figure 1). Screening typically takes 30 minutes. Patients' pupils are dilated with drops, affecting their vision for four to six hours. Digital photographs are taken and the images examined by regional NHS retinal grading teams, who identify any pathology. Results are communicated to the patient and GP. Patients with retinopathy requiring monitoring or treatment are referred to the Hospital Eye Service.

However, approximately 20% of people invited for DRS do not attend (17), with those from minority ethnic backgrounds and people living in deprived areas both less likely to attend and to have worse retinopathy (18), (19), (20). Inequalities in access to DRS in England[8] have led to calls for further research (19), including qualitatively (21).

Yet deprivation alone does not explain all the uptake variability between GP practices and regions. For example, misunderstandings about the importance of diabetes and personal risk factors and patients' lack of awareness, psychological factors or practical obstacles, can represent major barriers to attending screening (22). However, as attendance rates vary greatly between neighbouring practices, for example, from 55% to 95% in Gloucestershire (23), research focusing beyond deprivation, risk factors or barriers is required. Little is known about how patients' and professionals' perceptions and experiences of DRS may influence attendance. This paper therefore focusses on experiences around DRS that may affect uptake, from the accounts of people with diabetes and GP practice and screening staff.

[8] http://www.screening.nhs.uk/news.php?id=12156

METHODS

NRES Committee South West – Cornwall and Plymouth gave ethical permission (10/H0203/79) and all participants gave informed consent . This work was supported by the National Institute of Health Research, Research for Patient Benefit grant PB-PG-1208-18043 and sponsored by Gloucestershire Hospitals NHS Foundation Trust.

Design of the research: This multi-perspectival (24), cross-sectional qualitative interview study used purposively sampled GP practices in four UK Primary Care Trusts across three regions, based on Indices of Multiple Deprivation, practice type, screening mode, and screening uptake (see Table 1).

Practice recruitment: Central England Primary Care Research Network and South West Diabetes Network provided research nurse assistance with GP practice recruitment. Twelve GP practices were approached; two declined (existing research commitments); one withdrew prior to participant recruitment commencing (staff changes). Table 1 details characteristics of the nine participating GP practices. The Central Local Research Network paid Service Support Costs of £599.27 to participating GP practices.

Table 1: Practice characteristics

Participant recruitment:

Professionals We purposively recruited 24 primary care and screening professionals with patient contact in differing roles around DRS, to ensure a broad spectrum of views and experiences. ***Patients*** Within each practice, patients were purposively sampled based on their screening attendance history, to consider differences in attitudes and experiences. "Regular attenders" had attended all three of their most recent DRS appointments; "Non-regular attenders" had attended none or one of their three most recent DRS appointments. Practice staff telephoned potential participants and sent information packs.

Interviews Semi-structured interviews were conducted either face-to face, at the GP/optometry practice, in patients' homes, or by telephone, at participants' discretion. Multi-perspectival interviews allowed us to understand the dynamics between patients, professionals and the Screening Programme, explore similarities and differences in their perceptions to highlight potentially differing needs and suggestions for improving services. Questions aimed to capture descriptions of participants' experiences before, during and after the screening appointment, from professionals' and patients' perspectives, identifying factors they believed influence screening attendance (see Appendices 1 and 2). All interviews were audio-recorded and transcribed verbatim prior to analysis. No additional data is available for data-sharing.

Analysis Data were managed using QSR NVivo10 software[9] to code and review themes. AH undertook iterative, thematic analysis, using constant comparison within and across all transcripts. Looking for overarching themes and relations between them, AH identified specific major and minor categories within the themes that might interact to influence screening attendance rates. AH and AL met to discuss these themes and agreed on the definitions of emerging codes. Findings were discussed with all authors until consensus was reached about the interpretation of key themes. Finally, AH checked these interpretations with the existing data.

RESULTS

Characteristics of the sample: 62 participants (33 female) were interviewed between September 2011 and July 2012, by AH, AL and JS. Of the 38 patients, four have Type 1 diabetes (mean age 49); 34 have Type 2 (mean age 60); 22 were regular retinopathy screening attenders, 16 were non-regular attenders (defined above). Of the 24 professionals (mean age 50), eight are primary healthcare professionals, seven are administrative practice staff; and nine are DRS programme screeners.

Table 2: Programme and participant characteristics

No theme was unique to either regular attenders, or non-regular attenders, which highlights the complex nature of why people do or do not attend appointments.

Understandings of Diabetic Retinopathy and Screening

GP practice staff, screeners and patients identified several antecedents to attendance and non-attendance at screening. Both regular and non-regular attending patient participants acknowledged the importance of DRS. Yet confusion around screening was clearly identified in all participant groups, as was the need to overcome this.

Understandings of Diabetic Retinopathy:

Some (but not all – see later subthemes) people with diabetes understood causal factors and the potential consequences of Diabetic Retinopathy; protecting the eyes appeared to be a priority for some. Interestingly, a non-regular attender with vicarious experience of sight loss identified herself to the researcher as a regular attender. Others found the process reassuring**.**

> *It's the smallest vessels that go first, and it's one of the quickest ways of seeing the effects is in the eyes. But... the body is so tolerant, you don't recognise that the vision is going until it's too late.* Patient 8 (Region 2, Regular)[10]

> *I: So what is it that encourages you to come [to screening] then?*

[9] www.qsrinternational.com/

[10] R = region from Table 1; Regular attender/Non-regular attender (as defined above)

P: My brother-in-law he was a very bad diabetic... He actually died from it. He went blind first. Patient13 (Region 3, Non-regular)

I like the fact that you instantly see and can get a decent steer on if there is anything negative; it's complete peace of mind – well my results anyway. Patient 3 (Region 2, Regular)

Psychological, pragmatic and social influences on non-attendance

In response to being asked why people might not attend DRS, both professionals and patients acknowledged that denial of having diabetes could contribute. One patient missed screening appointments because she disliked the proximity of the screener. Pragmatic reasons raised by the non-regular attenders for non-attendance included work commitments and post-operative recuperation.

Some people just… have their head in the… like the ostrich, they don't have diabetes or they're not taking any notice of it and they will just… yes, not come. Some because they think they can't have the time off work, you know? Screening Programme 1 (Region 1)

It's just the thought of somebody coming close to my eye. Patient 15 (Region 3, Non-regular)

I missed once, because I had an abscess in an awkward place, and I had to have an operation. But the following year I made sure. Patient 5 (Region 3, Non-regular)

Another non-regular attender who identified herself as a regular attender had attempted to access DRS via her GP practice, but was refused because she was in temporary accommodation awaiting rehousing. This highlights the complex social context in which people with diabetes experience screening:

Int*: So you didn't always come?*
Pt: Well, with being homeless for 8 weeks... But they [GP practice] didn't want to know. 'Oh you're not in our area.' I'm in nobody's area because we were in a bed and breakfast; they were my last doctors. Patient 10 *(*Region 1, Non-regular)

Understandings of Diabetic Retinopathy Screening vs. routine eye test

Some patients' perceptions of screening attendance were confused by high street optometry practices routinely taking photographs during a general annual eye check. Patients confused this with DRS even in areas where High Street optometry practices did *not* conduct DRS, confounding attendance:

I'm with [high street optometry chain] so I've always, always had my eyes screened. ... So when I was diagnosed and I told the optician she said, well we can do that here for an extra £10 and we will just email the surgery. So I thought fine, that's fine. So I just bypass it completely... Patient 4 (Region 2, Non-regular)

A lot of people turn up and say, 'well I had my optician's test' and you ...explain to them that although it's a great thing to have and they need to have it, we still need to do our tests because it's more accurate, and we're searching specifically for the diabetic retinopathy. Screening Programme 1 (Region 1)

Perceived responsibility for patients' understandings of Diabetic Retinopathy and screening

Professionals and patients identified the need to improve patients' understandings about DRS and sight-threatening retinopathy. For example, one GP accepted that low uptake reflected a failure to deliver the right message. However, more direct input from the health professional team was suggested by one patient who had not understood the screening information, and subsequently developed retinopathy. One screener considered that the lack of media attention to DRS could contribute to low attendance.

Why haven't they taken that onus of control, what is it that they don't believe about their diabetes? Where have we gone wrong in trying to get that message across? ...the words "Diabetic Retinopathy Screening", what does that mean to them? Health Professional 1 (Region 3)

As soon as I had diabetes diagnosed somebody should have explained to me more fully what the implications are. Because it's alright them giving you a leaflet and sending you home... but even though you read it, there's this kind of silly thing, 'oh it won't happen to me', attitude. Patient 15 (Region 3, Non-regular)

I don't think screening is something that's pushed as much as other screening. I mean retinal screening is…I'd say it's important... but things like breast cancer, there's a lot more press about it. Screening Programme 2 (Region 1)

Accessing Diabetic Retinopathy Screening

This theme highlights participants' varying experiences and perceptions around making the appointment, getting there - and back, which patients had difficulties with.

Pre-booked VS. Self-booked appointments:

Invitation methods vary by Region (see Figure 1), with professionals and patients identifying issues around both modalities that could affect uptake. Patients need to be proactive either to make their appointment, or change an inconvenient pre-booked appointment (depending where they live). All participant groups identified that patients could forget to do either, whilst this appeared particularly problematic for working patients.

But it does rely on the patient being proactive. You get an appointment, alphabetical order, totally inconvenient, impractical time, what do you do, do you do nothing and forget it or do you ring up and change it? And if you don't ring up and change it then nothing h s, you're just a DNA statistic aren't you really. Screening Programme 3 (Region 1)

Int: *So you get a letter with the appointment pre-booked?*
Pt: Yes. And then if you can't make it you change it.
Int: You wouldn't prefer to be able to ring yourself and make an appointment?
Pt: No, because I think you'd tend to forget wouldn't you, and I think most people would. Patient 3 (Region 1, Regular)

Patients are used to receiving pre-booked appointments for other diabetes clinics (e.g. Practice Nurse appointments to be weighed and have their feet checked). Professionals felt that expecting patients to make their own DRS appointment downgraded its perceived importance to patients, or was not patients' responsibility. This was exacerbated by the perceived rigidity of the appointment-booking system in another region.

I think if it's left to the patient a lot of the time they don't think, because they have to do it, it's not that important Health Professional 4 (Region 3)

Why should a patient… if it was a blood test… would the GP just say, go and sort it out yourself, and the patient is just registering himself at the hospital, getting a blood test and making sure the GP gets it? That's ridiculous. Screening Programme 1 (Region 3)

I get a letter saying I need to make a phone call between specific times on specific dates and they give you a block of dates ...to make the appointment in advance ...a good 6 weeks Patient 5 (Region 2, Regular)

Patients in the area delivering DRS through high street optometry reported an absence of available appointments:

Well before the appointment I phoned and they said no, they'd got no appointments for the next three months... The following year again the same thing, I phoned when I had the letter, they said three months' waiting. Patient 5 (Region 3, Non-regular)

Integrating diabetes appointments

Patients in different regions suggested that DRS should be better integrated with their other diabetes care as this would reduce the inconvenience of attending numerous appointments:

Probably would be better if it was done the same time as you have a normal diabetic appointment... I mean I've had to come up here on the Tuesday because they wanted to check my weight and then I think it was the Wednesday to have my eyes done and I'm thinking, do I need to come up twice [laughs]. Patient 8 (Region 1, Regular)

Transport

Getting to and from screening appointments was important pragmatically for many patients, who had to overcome a range of issues. One health professional recognised that

transport issues and proximity of screening to patients' homes potentially affected uptake, apparently understanding patients' reticence to travel - although without the insight into the difficulties that some patients experienced:

> *Most patients around here like to go to things that are within walking distance or within a bus stop, if that. So transport is an issue. …they know the surgery, 'oh the surgery is next door, I know the girls there, they're always there'... So maybe I need to have the retinopathy screening done at the surgery and they'd all come [laughs].* Health Professional 1 (Region 3)

Patients are advised not to drive to/from DRS appointments, because the mydriasis drops cause blurred vision and photosensitivity (detailed later). The pragmatic repercussions of this were especially notable for working age people. However, alternative travel arrangements also emerged as impractical because blurred vision caused an inability to navigate sufficiently.

> *I am tied to either making them [screening appointments] in the afternoon and then getting home, so I have to work out how to get into work in the morning that doesn't involve driving, or I have to be there [GP practice] earlier, say lunch time or something, I have to take a half day.* Patient 5 (Region 2, Regular)

> *Because of the drops, it makes it difficult for the people's journey...it's like a cobweb on top of your eyes and… No I can't see at all... We have to have the eye drops so it's very hard to either walk it back …I felt I was blinded temporarily and got into a taxi and then got out of the car somehow. I had to cross the road and I was just looking like that [stares blankly] because I was waiting for the taxi and I had to do like that [waves arms]…* Patient 5 (Region 3, Non-regular)

Screening Experiences

This theme incorporates patients' experiential accounts of the actual screening appointments, including negative experiences of lengthy appointments in High Street optometry practices compared with efficient GP practice appointments. Mydriasis drops caused severe side-effects and subsequent adverse affects for some patients, who discussed strategies to overcome these.

Appointment length

In one region, appointments lasting several hours at optometry practices were potentially a deterrent. One patient recognised that lengthy food abstinence was particularly inappropriate for diabetes patients, whilst another overcame the problem by changing practice.

> *Yes, the first time I went to... the local optician ...I was there for 5 hours, from 10 o'clock in the morning, and by the time I got out of the door it was 3 o'clock. ... And*

by then I can remember I was so hungry and I thought, 'well how does that help a diabetic person?' Patient 5 (Region 3, Non-regular)

I had my optician before and he was quite slow, the drops used to sting and he used to take a long time. I had to be there for about two or three hours. But my present optician is good. Patient 1 (Region 3, Regular)

However, in sharp contrast, where screening was delivered in GP practices, satisfaction with short, efficient appointments was reported.

They're quite good actually, see you straight away, well within, you know ...about ten minutes of your appointment... Patient 8 (Region 1, Regular)

It doesn't take half an hour I suppose at the outside. Patient 1 (Region 2, Regular)

Side effects of drops

Mydriasis drops dilate the pupil, allowing more light into the eye and a clearer retinal photograph to be taken. However, in another important finding, both regular and non-regular patients experienced severe pain, blurred vision and debilitating photosensitivity for several hours. Interestingly, none of the health professionals except the optometrist raised this, suggesting they were unaware of this issue.

AH: you come and they put the drops in do they?
P: Oh yes. They were like acid burning my eyes this time... It really hurt this time.
Patient 1 (Region 1, Non-regular)

Everything else is fine, it's just the drops, they sting like hell. Patient 3 (Region 1, Regular)

And I hate that because it affects my eyes for so long and I can't… put my lenses back in straight away so someone is with me because I can't see... Patient 4 (Region 2, Non-regular)

I would advise anybody to bring sunglasses even if it's not particularly bright... if I had them I'd wear dark goggles so that they're closed in. Like welders goggles [laughs]. Actually no like swimming goggles but darker, to keep all the light out from the sides now, because it's painful. Patient 5 (Region 2, Regular)

If someone tomorrow has drops put in because of the service and they just happen to have a reaction to the drops, and they lose their eyesight... So then who are they going to sue? …if push comes to shove we're the ones [optometrists]who are going to get sued. Screening Programme 1 (Region 3)

DISCUSSION

Results in context

For some patients and practices, the DRS Programme worked well and we confirm previous findings that a convenient screening location near home was beneficial (24) and preserving vision was prioritised amongst diabetes patients (25). We also confirm previous studies, finding that, for others, misunderstandings about the importance of diabetes and personal risk (22) (26), lack of DRS awareness, psychological factors, practical obstacles (22) and the deterrent side-effects of mydriasis (27) represented potential attendance barriers.

No clear distinction between regular and non-regular DRS attenders was identified. In an important new finding, we uncovered confusion between routine retinal photography at optometry practices during eye examinations, and DRS. Whilst optometry photography may represent an important safeguard for non-attenders, it could impair more comprehensive coverage. We observed differences between patients screened at GP vs. optometrist practices, identifying that ease of making the appointment, including its time, navigating home after the mydriasis drops, etc. appeared less problematic at GP practices. Furthermore, making patients responsible for arranging appointments in some regions, combined with encountering delays, could undermine the perceived importance of DRS. We have identified patients' misperceptions about their attendance regularity.

Strengths and Limitations of the study

Strengths of this study include the purposive sampling strategy across several strata of professional groups in GP and optometry practices and screening programmes, and recruiting regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes. However, not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening. The qualitative findings from our purposive sample are not intended to be representative but highlight socio-cultural meanings of health and illness experiences, not simply their frequency, and identify important insights into barriers and enablers to screening attendance amongst our participants that will inform further research.

Implications for clinicians and policy makers

Whilst some patients understood retinopathy and its causation, others lacked information and understanding about DRS. This calls for proactive personal clinical risk communication (28, 29) and attendance information to ensure care coordination between patients, primary care, screeners and Screening Programmes. The current guidance to bring sunglasses could be strengthened in the patient information. Some patients confused retinal photography at optometry practices with DRS. Professional Optometry bodies could ensure clarity amongst members, and optometrists should highlight the difference to their patients. Consideration

may be appropriate around the responsibility that the NHS has when discharging visually impaired patients in to the community. In Scotland, a 3-stage screening procedure is used; stage one is one field non-mydriatic photography, stage two is dilation, with the Scottish Screening Programme dilating approximately 34% of their population. The English Screening Programme developed following the evidence provided for 2-field digital photography by the Scanlon (32) study which recommended dilated two-field imaging. Culturally sensitive improvements (21) should build upon the recent introduction of patient information leaflets in several languages[11].

Several providers now deliver DRS in the UK, and, since this research was conducted, Public Health England is responsible for overseeing delivery and the financial incentive for GPs to record screening uptake has been removed. These changes may affect future practice involvement and patient uptake; this fast-moving field requires monitoring closely. Building on the successful central appointments system and practice factors that affect DRS attendance (30), may prove useful. The national implementation of the new screening pathway should ensure consistent delivery throughout the country, improving the quality of services and reducing variability (31).

Future research

Much more work is needed is this field. A similar exercise should be undertaken amongst a representative national sample of programmes, taking into account demographic variables that we found to be relevant (ethnicity, delivery-mode, deprivation etc.). More work needs to determine the prevalence of patients' and clinicians' views on the appropriate design and delivery of DRS services to maximise attendance; hospital staff may provide insightful alternatives for service improvement. The pharmacological reformulation of shorter-acting mydriasis drops to minimise side-effects may reduce disruption to patients and potentially benefit uptake rates, although we acknowledge that this would not address the pain participants reported. The extent of confusion about optometry photography needs urgent assessment.

Conclusions

This study uses staff and patients' experiences of DRS to start unpicking factors affecting uptake. Factors identified include differing regional invitation methods and screening locations, convenience, transport safety and short appointment times; some patients experienced significant side effects from mydriasis drops. The successful implementation of the new care pathway should address these factors and may improve DRS attendance. Used as an international model, this could, in turn, contribute to reducing preventable vision loss and inequalities globally and its associated costs to individuals and their families, and to primary, secondary and social care providers.

[11] http://diabeticeye.screening.nhs.uk/languages

Footnotes

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- **Contributorship statement:** IS had the original idea, making substantial contributions to the conception of the work; PS led the funding application. JS and AL made substantial contributions to the qualitative component of the study. All authors contributed to the early design of the work. AH, the project manager, obtained ethical approval, and conducted the interviews with AL and JS. AH led the qualitative analysis and interpretation of data and drafted the paper. All authors contributed to writing or revising it critically for important intellectual content and approve of the final version of the paper. PS is guarantor. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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- **Competing interest Statement:** PS is the Director of the NHS Diabetic Eye Screening Programme; AH has personal experience of mydriasis drops.

- **Payment:** a £5 High Street voucher was given to patient participants in recognition of their contribution.

- **Transparency statement:** The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

- **Provenance and peer review:** Not commissioned; externally peer reviewed

- **Data-sharing statement:** Copies of the participant information sheet can be obtained by emailing the corresponding author - a.e.hipwell@warwick.ac.uk.

FIGURE LEGEND

Figure 1: Diabetic Eye Screening Programme delivery modes

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Table 1: Practice characteristics

Practice no.	Screening Programme area	Index of Multiple Deprivation (IMD)	Practice type	Screening delivery mode	Uptake rate
Practice 1	Region 1	Deprived	Urban city	GP practice	96%
Practice 2	Region 1	Below average	Rural Town	GP practice	88%
Practice 3	Region 2	Deprived	Rural Town	GP practice	85%
Practice 4	Region 2	Above average	Rural Town	GP practice	75%
Practice 5	Region 1	Deprived	Rural Town	GP practice	73%
Practice 6	Region 1	Below average	Urban City	GP practice	72%
Practice 7	Region 2	Least deprived	Rural Town	GP practice	71%
Practice 8	Region 3	Most deprived	Inner City	High street optometrist	68%
Practice 9	Region 3	Most deprived	Inner City	High street optometrist	57%

Table 2: Programme and participant characteristics

Screening Programme Regional descriptor	**Region 1** Urban city rural town	**Region 2** Rural town	**Region 3** Inner city	**Total**
Number of practices	4	3	2	9
Patients (Non-regular attenders)	14 (5)	8 (1)	16 (10)	38 (16)
Medical practice staff (GPs, optometrist, HCAs, nurses)	2	3	3	8
Administrative practice staff (receptionists, managers)	4	2	1	7
Screeners	4	4	1	9
Total participants	**24**	**17**	**18**	**62**

What is already known on this topic

The proportion of people with visual impairment caused by diabetic retinopathy is increasing globally.

The NHS Diabetic Retinopathy Screening is cost-effective at 80% uptake.

The 20% of people who do not attend screening in the UK are at the highest risk of sight-threatening diabetic retinopathy.

There is little evidence about how screening is perceived and experienced by those professionals and patients involved in it, or how this may affect uptake

What this study adds

People with diabetes want to prioritise preserving their vision, but some do not recognise the need to attend their Diabetic Retinopathy Screening.

This is exacerbated by optometry practices undertaking retinal photography outside of the screening service.

Some participants had difficulties making an appointment, problems attending the appointment, and experienced debilitating side-effects of mydriasis drops.

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Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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Attitudes, access and anguish: A qualitative interview study of staff and patients' experiences of Diabetic Retinopathy Screening

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This is exacerbated by optometry practices undertaking retinal photography outside of the screening service.

Some participants had difficulties making an appointment, problems attending the appointment, and experienced debilitating side-effects of mydriasis drops.

Encouragingly, a coherent approach to addressing professionals' and patients' respective responsibilities may improve Diabetic Retinopathy Screening uptake.

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ABSTRACT

~~**What is already known:** Diabetic retinopathy is a major cause of preventable vision loss globally. Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment. Diabetic Retinopathy Screening is cost-effective, saving patients' sight and the substantial cost of healthcare provision to those with vision loss. However, certain groups of people are both less likely to attend and to have worse retinopathy.~~

Objective: To examine patients', health professionals' and screeners' experiences of, interactions with and understandings of Diabetic Retinopathy Screening, and how these influence uptake

Design: Purposive, qualitative design using multi-perspectival, semi-structured interviews and thematic analysis.

Setting: Three UK Screening Programme regions with different service-delivery modes, minority ethnic and deprivation levels, across rural, urban and inner-city areas, in GP practices and patients' homes.

Participants: 62 including 38 patients (22 regular screening attenders, 16 non-regular attenders), and 24 professionals (15 Primary Care professionals and 9 screeners).

Results: Antecedents to attendance included knowledge about diabetic retinopathy and screening; antecedents to non-attendance included psychological, pragmatic and social factors. Confusion between photographs taken at routine eye tests and Diabetic Retinopathy Screening photographs was identified. The differing regional invitation methods and screening locations were discussed, with convenience and transport safety being over-riding considerations for patients. Some patients mentioned significant pain and visual disturbance from the mydriasis drops as a deterrent to attendance. ~~Short appointment times were preferred by patients, some of whom experienced severe side-effects from the mydriasis drops used to dilate their pupils.~~

Conclusions: In this, the first study to consider multi-perspectival experiential accounts, we identified that proactive coordination of care involving patients, primary care and the Screening Programmes, prior to, during and after screening is required. Multiple factors prior to, during and after screening are involved in the attendance and non-attendance for DR screening. Further research is needed to establish whether~~P~~ patient self-management educational interventions, and the pharmacological reformulation of shorter-acting mydriasis drops, may improve uptake of Diabetic Retinopathy Screening.~~,~~ This might, in turn, reduce~~ing~~ preventable vision loss and its associated costs to individuals and their families, and to health and social care providers, reducing current inequalities.

Keywords: Diabetic Retinopathy, Screening, Qualitative, Inequalities

ARTICLE SUMMARY

Strengths and Limitations of the study

- Our purposive sampling strategy recruited several strata of professional groups in GP and optometry practices and screening programmes, and both regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes.
- Not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening.
- The qualitative findings from our purposive sample are not intended to be representative but highlight important insights into barriers and enablers to screening attendance that will inform further research.

INTRODUCTION

Visual impairment is a significant worldwide health problem (1, 2). Approximately 314 million people globally are visually impaired, with over 80% of this impairment being preventable or treatable (1)(3). Diabetic retinopathy is a major cause of preventable vision loss in people with type 1 and type 2 diabetes in Europe, Africa, Asia and Australia (4-9) (10-13) and until recently (14) has been the leading cause of preventable vision loss in European working age populations (4, 8, 10-12). The proportion of vision loss caused by diabetic retinopathy is increasing globally (13). In addition to treatment costs, lost productivity and quality of life for patients with diabetic retinopathy contribute to personal and socio-economic burdens (15~~14~~).

~~Initially asymptomatic, this microvascular complication is associated with high blood glucose, high blood lipids, hypertension, smoking, non-attendance at screening, minority ethnicity (15, 16), duration of diabetes (17, 18) and existing diabetic retinopathy (19).~~

Adequate diabetes control, regular screening and timely laser treatment can prevent visual impairment (1, 15~~14~~). In England, routine diabetes care and Diabetic Retinopathy Screening (DRS) are principally managed in primary care, whilst treatment for retinopathy takes place in secondary care. Issues surrounding diabetic retinopathy therefore have practice implications for medical and health professionals working in both settings.

The UK Government's measurement of preventable vision loss from April 2013 recognises this top public health priority. The English NHS Diabetic Eye Screening Programme offers cost-effective annual screening to people with diabetes (Types 1 and 2) over 12 years (16~~20~~) where 80% uptake is achieved. Screening uptake is assessed at the general practice level. Screening modes differ regionally, taking place either in GP surgeries, hospitals or optometry practices (see Figure 1). Screening typically takes 30 minutes. ~~Mydriasis drops~~

~~dilate p~~Patients' pupils are dilated with drops, affecting their vision for four to six hours. Digital photographs are taken and the images examined by regional NHS retinal grading teams, who identify any pathology. Results are communicated to the patient and GP.

Patients with retinopathy requiring monitoring or treatment are referred to the Hospital Eye Service.

However, approximately 20% of people invited for DRS do not attend (17~~23~~), with those from minority ethnic backgrounds and people living in deprived areas both less likely to attend and to have worse retinopathy (18~~24~~), (~~15~~19), (20~~16~~). Inequalities in access to DRS in England[8] have led to calls for further research (19~~25~~), including qualitatively (~~15~~21).

Yet deprivation alone does not explain all the uptake variability between GP practices and regions. For example, misunderstandings about the importance of diabetes and personal risk factors ~~amongst people undergoing diabetes screening~~ and patients' lack of awareness, ~~and~~ psychological factors or practical obstacles, ~~have been identified as~~ can represent major barriers to attending screening (22~~26~~). However, as attendance rates vary greatly between neighbouring practices, for example, from 55% to 95% in Gloucestershire (23~~27~~), research focusing beyond deprivation, risk factors or barriers is required. Little is known about how patients' and professionals' perceptions and experiences of DRS may influence attendance. This paper therefore focusses on experiences around DRS that may affect uptake, from the accounts of people with diabetes and ~~the~~ GP practice and screening staff ~~involved in screening~~.

Figure 1: Diabetic Eye Screening Programme delivery modes

METHODS

~~Ethical permission was granted by~~ NRES Committee South West – Cornwall and Plymouth gave ethical permission (10/H0203/79) and all participants gave informed consent ~~was given by all participants~~. This work was supported by the National Institute of Health Research, Research for Patient Benefit grant ~~reference~~ PB-PG-1208-18043 and sponsored by Gloucestershire Hospitals NHS Foundation Trust.

Design of the research: This multi-perspectival (24~~28~~), cross-sectional qualitative interview study used purposively sampled GP practices in four UK Primary Care Trusts across three regions, based on Indices of Multiple Deprivation, practice type, screening mode ~~of screening~~, and screening uptake (see Table 1).

Practice recruitment: Central England Primary Care Research Network and South West Diabetes Network provided research nurse assistance with GP practice recruitment. Twelve GP practices were approached ~~to participate~~; two declined (existing research commitments); one withdrew prior to ~~commencement of~~ participant recruitment commencing (staff changes). Table 1 details ~~C~~characteristics of the nine participating GP

[8] http://www.screening.nhs.uk/news.php?id=12156

practices ~~are detailed in Table 1~~. The Central Local Research Network paid Service Support Costs of £599.27 to participating GP practices.

Table 1: Practice characteristics

Participant recruitment:
Professionals We purposively recruited 24 primary care and screening professionals with patient contact in differing roles around DRS, to ensure a broad spectrum of views and experiences. ***Patients*** Within each practice, patients were purposively sampled based on their screening attendance history, to consider differences in attitudes and experiences. "Regular attenders" had attended all three of their most recent DRS appointments; "Non-regular attenders" had attended none or one of their three most recent DRS appointments.

Practice staff telephoned potential participants and sent information packs.

Interviews Semi-structured interviews were conducted either face-to face, at the GP/optometry practice, in patients' homes, or by telephone, at participants' discretion. ~~The m~~Multi-perspectival interviews allowed us to understand the dynamics between patients, professionals and the Screening Programme, explore similarities and differences in their perceptions to highlight potentially differing needs and suggestions for improving services. Questions aimed to capture descriptions of participants' experiences before, during and after the screening appointment, from professionals' and patients' perspectives, identifying ~~patient~~ factors they believed influence screening attendance. All interviews were audio-recorded and transcribed verbatim prior to analysis. No additional data is available for data-sharing.

Analysis Data were managed using QSR NVivo10 software[9] to code and review themes. AH undertook iterative, thematic analysis, using constant comparison within and across all transcripts. Looking for overarching themes and relations between them, AH identified specific major and minor categories within the themes that might interact to influence screening attendance rates. AH and AL met to discuss these themes and agreed on the definitions of emerging codes. ~~No theme was unique to either regular attenders, or non-regular attenders.~~ Findings were discussed with ~~different project group members~~ all authors until consensus was reached about the interpretation of key themes. Finally, AH checked these interpretations with the existing data.

RESULTS

Characteristics of the sample: 62 participants (33 female) were interviewed between September 2011 and July 2012, by AH, AL and JS. Of the 38 patients, four have Type 1 diabetes (mean age 49); 34 have Type 2 (mean age 60); 22 were regular retinopathy screening attenders, 16 were non-regular attenders (defined above). Of the 24 professionals (mean age 50), eight are primary healthcare professionals, seven are administrative practice staff; and nine are ~~diabetic retinopathy~~ DRS programme screeners.

[9] www.qsrinternational.com/

Table 2: Programme and participant characteristics

No theme was unique to either regular attenders, or non-regular attenders, which highlights the complex nature of why people do or do not attend appointments.

Understandings of Diabetic Retinopathy and Screening

GP practice staff, screeners and patients identified several antecedents to attendance and non-attendance at screening. Both regular and non-regular attending patient participants acknowledged the importance of DRS. Yet confusion around screening was clearly identified in all participant groups, as was the need to overcome this.

Understandings of Diabetic Retinopathy:

Some (but not all – see later subthemes) ~~P~~people with diabetes ~~largely~~ understood causal factors and the potential consequences of Diabetic Retinopathy; protecting the eyes appeared to be a priority for some. Interestingly, a non-regular attender with vicarious experience of sight loss identified herself to the researcher as a regular attender. Others found the process reassuring**.**

> *It's the smallest vessels that go first, and it's one of the quickest ways of seeing the effects is in the eyes. But... the body is so tolerant, you don't recognise that the vision is going until it's too late.* Patient 8 (Region 2, Regular)[10]

> *I: So what is it that encourages you to come [to screening] then?*
> *P: My brother-in-law he was a very bad diabetic... He actually died from it. He went blind first.* Patient13 (Region 3, Non-regular)

> *I like the fact that you instantly see and can get a decent steer on if there is anything negative; it's complete peace of mind – well my results anyway.* Patient 3 (Region 2, Regular)

Psychological, pragmatic and social influences on non-attendance

In response to being asked why people might not attend DRS, both professionals and patients acknowledged that denial of having diabetes could contribute. One patient ~~had~~ missed screening appointments because she disliked the ~~close~~ proximity of the screener. Pragmatic reasons raised by the non-regular attenders for non-attendance included work commitments and post-operative recuperation.

> *Some people just… have their head in the… like the ostrich, they don't have diabetes or they're not taking any notice of it and they will just… yes, not come. Some because they think they can't have the time off work, you know?* Screening Programme 1 (Region 1)

[10] R = region from Table 1; Regular attender/Non-regular attender (as defined above)

It's just the thought of somebody coming close to my eye. Patient 15 (Region 3, Non-regular)

I missed once, because I had an abscess in an awkward place, and I had to have an operation. But the following year I made sure. Patient 5 (Region 3, Non-regular)

Another non-regular attender who identified herself as a regular attender had attempted to access DRS via her GP practice, but was refused because she was in temporary accommodation awaiting rehousing. This highlights the complex social context in which people with diabetes experience screening:

Int*: So you didn't always come?*
Pt: Well, with being homeless for 8 weeks... But they [GP practice] didn't want to know. 'Oh you're not in our area.' I'm in nobody's area because we were in a bed and breakfast; they were my last doctors. Patient 10 *(*Region 1, Non-regular)

Understandings of Diabetic Retinopathy Screening vs. routine eye test

Some ~~P~~patients' perceptions of screening attendance were confused by high street optometry practices routinely taking photographs during a general annual eye check. Patients confused this with DRS even in areas where High Street optometry practices did *not* conduct DRS, confounding attendance:

I'm with [high street optometry chain] so I've always, always had my eyes screened. ... So when I was diagnosed and I told the optician she said, well we can do that here for an extra £10 and we will just email the surgery. So I thought fine, that's fine. So I just bypass it completely... Patient 4 (Region 2, Non-regular)

A lot of people turn up and say, 'well I had my optician's test' and you ...explain to them that although it's a great thing to have and they need to have it, we still need to do our tests because it's more accurate, and we're searching specifically for the diabetic retinopathy. Screening Programme 1 (Region 1)

Perceived responsibility for patients' understandings of Diabetic Retinopathy and screening

Professionals and patients identified the need to improve patients' understandings about DRS and sight-threatening retinopathy. For example, one GP accepted that low uptake reflected a failure to deliver the right message. However, more direct input from the health professional team was suggested by one patient who had not understood the screening information, and subsequently developed retinopathy. One screener considered that the lack of media attention to DRS could contribute to low attendance.

Why haven't they taken that onus of control, what is it that they don't believe about their diabetes? Where have we gone wrong in trying to get that message across? ...the words "Diabetic Retinopathy Screening", what does that mean to them? Health Professional 1 (Region 3)

As soon as I had diabetes diagnosed somebody should have explained to me more fully what the implications are. Because it's alright them giving you a leaflet and sending you home... but even though you read it, there's this kind of silly thing, 'oh it won't happen to me', attitude. Patient 15 (Region 3, Non-regular)

~~*Lack of patient information.*~~ *I don't think screening is something that's pushed as much as other screening. I mean retinal screening is…I'd say it's important... but things like breast cancer, there's a lot more press about it.* Screening Programme 2 (Region 1)

Accessing Diabetic Retinopathy Screening

This theme highlights participants' varying experiences and perceptions around making the appointment, getting there - and back, which. ~~P~~patients had difficulties with ~~in making, attending and returning from their screening appointments~~.

Pre-booked VS. Self-booked appointments:

Invitation methods vary by Region (see Figure 1), with professionals and patients identifying issues around both modalities that could affect uptake. Patients need to be proactive either to make their appointment, or change an inconvenient pre-booked appointment (depending ~~on~~ where they live). All participant groups identified ~~the possibility of~~ that patients could forget~~ting~~ to do either, whilst this ~~could be~~ appeared particularly problematic for working patients.

But it does rely on the patient being proactive. You get an appointment, alphabetical order, totally inconvenient, impractical time, what do you do, do you do nothing and forget it or do you ring up and change it? And if you don't ring up and change it then nothing happens, you're just a DNA statistic aren't you really. Screening Programme 3 (Region 1)

Int: *So you get a letter with the appointment pre-booked?*
Pt: Yes. And then if you can't make it you change it.
Int: You wouldn't prefer to be able to ring yourself and make an appointment?
Pt: No, because I think you'd tend to forget wouldn't you, and I think most people would. Patient 3 (Region 1, Regular)

Patients are used to receiving pre-booked appointments for other diabetes clinics ~~,(~~ ~~such as seeing the~~ e.g. Practice Nurse appointments to be weighed and have their feet checked~~)~~. Professionals felt that expecting patients to make their own DRS appointment downgraded its perceived importance to patients, or was not patients' responsibility. This was exacerbated by the perceived rigidity of the appointment-booking system in another region.

I think if it's left to the patient a lot of the time they don't think, because they have to do it, it's not that important Health Professional 4 (Region 3)

Why should a patient… if it was a blood test… would the GP just say, go and sort it out yourself, and the patient is just registering himself at the hospital, getting a blood test and making sure the GP gets it? That's ridiculous. Screening Programme 1 (Region 3)

I get a letter saying I need to make a phone call between specific times on specific dates and they give you a block of dates ...to make the appointment in advance ...a good 6 weeks Patient 5 (Region 2, Regular)

Patients in the area ~~that~~ deliverings ~~-~~ DRS through high street optometry reported an absence of available appointments:

Well before the appointment I phoned and they said no, they'd got no appointments for the next three months… The following year again the same thing, I phoned when I had the letter, they said three months' ~~-~~ waiting. Patient 5 (Region 3, Non-regular)

Integrating diabetes appointments

Patients in different regions suggested that DRS should be better integrated with their other diabetes care as~~. They understood that~~ this would reduce the inconvenience of attending numerous appointments:

Probably would be better if it was done the same time as you have a normal diabetic appointment… I mean I've had to come up here on the Tuesday because they wanted to check my weight and then I think it was the Wednesday to have my eyes done and I'm thinking, do I need to come up twice [laughs]. Patient 8 (Region 1, Regular)

Transport

Getting to and from screening appointments was important pragmatically for many patients, who had to overcome a range of issues. One health professional recognised that transport issues and proximity of screening to patients' homes potentially affected uptake, apparently understanding patients' reticence to travel - although without the insight into the difficulties that some patients experienced:

Most patients around here like to go to things that are within walking distance or within a bus stop, if that. So transport is an issue. …they know the surgery, 'oh the surgery is next door, I know the girls there, they're always there'... So maybe I need to have the retinopathy screening done at the surgery and they'd all come [laughs]. Health Professional 1 (Region 3)

Patients are advised not to drive to/from DRS appointments, because the mydriasis drops cause blurred vision and photosensitivity (detailed later). The pragmatic repercussions of this were especially notable for working age people ~~of working age~~. However, alternative travel arrangements also emerged as impractical because blurred vision caused~~of~~ an inability to navigate sufficiently ~~with blurred vision~~.

I am tied to either making them [screening appointments] in the afternoon and then getting home, so I have to work out how to get into work in the morning that doesn't involve driving, or I have to be there [GP practice] earlier, say lunch time or something, I have to take a half day. Patient 5 (Region 2, Regular)

Because of the drops, it makes it difficult for the people's journey...it's like a cobweb on top of your eyes and… No I can't see at all... We have to have the eye drops so it's very hard to either walk it back …I felt I was blinded temporarily and got into a taxi and then got out of the car somehow. I had to cross the road and I was just looking like that [stares blankly] because I was waiting for the taxi and I had to do like that [waves arms]… Patient 5 (Region 3, Non-regular)

Screening Experiences

This theme incorporates patients' experiential accounts of the actual screening appointments, ~~. It~~ includinges ~~negative~~ experiences of lengthy appointments in High Street optometry practices compared with ~~others'~~ efficient GP practice appointments. Mydriasis drops caused severe side-effects and subsequent adverse affects for ~~S~~some patients, ~~experienced severe side-effects and subsequent adverse affects from the mydriasis drops. Participants~~ who discussed strategies to overcome these ~~side-effects~~.

Appointment length

In one region~~,~~ appointments lasting several hours at optometry practices were potentially ~~served as~~ a deterrent. One patient recognised that lengthy food abstinence ~~for this long~~ was particularly inappropriate for diabetes patients, whilst another overcame the problem by changing practice.

Yes, the first time I went to... the local optician …I was there for 5 hours, from 10 o'clock in the morning, and by the time I got out of the door it was 3 o'clock. ... And by then I can remember I was so hungry and I thought, 'well how does that help a diabetic person?' Patient 5 (Region 3, Non-regular)

I had my optician before and he was quite slow, the drops used to sting and he used to take a long time. I had to be there for about two or three hours. But my present optician is good. Patient 1 (Region 3, Regular)

However, in sharp contrast, where screening was delivered in GP practices, satisfaction with short, efficient appointments was reported.

They're quite good actually, see you straight away, well within, you know ...about ten minutes of your appointment... Patient 8 (Region 1, Regular)

It doesn't take half an hour I suppose at the outside~~, even though you've got to have the drops and wait for them to activate, and then the actual screening is about 15 minutes...~~ Patient 1 (Region 2, Regular)

Side effects of drops

Mydriasis drops dilate the pupil, allowing more light into the eye and a clearer retinal photograph to be taken. However, in another important finding, ~~many patients (~~both regular and non-regular patients)~~ ~~experienced severe pain, blurred vision and debilitating photosensitivity ~~lasting~~ for several hours. Interestingly, none of the health professionals except the optometrist raised this, suggesting ~~that~~ they were unaware of this issue.

AH: you come and they put the drops in do they?
P: Oh yes. They were like acid burning my eyes this time... It really hurt this time.

Patient 1 (Region 1, Non-regular)

Everything else is fine, it's just the drops, they sting like hell. Patient 3 (Region 1, Regular)

And I hate that because it affects my eyes for so long and I can't… put my lenses back in straight away so someone is with me because I can't see... Patient 4 (Region 2, Non-regular)

I would advise anybody to bring sunglasses even if it's not particularly bright... if I had them I'd wear dark goggles so that they're closed in. Like welders goggles [laughs]. Actually no like swimming goggles but darker, to keep all the light out from the sides now, because it's painful. Patient 5 (Region 2, Regular)

If someone tomorrow has drops put in because of the service and they just happen to have a reaction to the drops, and they lose their eyesight... So then who are they going to sue? …if push comes to shove we're the ones [optometrists]who are going to get sued ~~[optometrists]~~. Screening Programme 1 (Region 3)

DISCUSSION

Results in context

For some patients and practices, the DRS Programme worked well and we confirm previous findings that a convenient screening location ~~close to~~ near home was beneficial (24~~28~~) and preserving vision was prioritised amongst diabetes patients (25~~29~~). We also confirm previous studies, finding that, ~~F~~for others, misunderstandings about the importance of diabetes and personal risk (22~~26~~) (26~~30~~), lack of DRS awareness, psychological factors, practical obstacles (22~~26~~) and the deterrent side-effects of mydriasis (27~~31~~) represented potential attendance barriers.

No clear distinction between regular and non-regular DRS attenders was identified. In an important new finding, we uncovered confusion between routine retinal photography at optometry practices during eye examinations, and DRS. Whilst optometry photography

may represent an important safeguard for non-attenders, it could impair more comprehensive coverage. We observed differences between patients screened at GP vs. optometrist practices, identifying that ease of making the appointment, including its time, navigating home after the mydriasis drops, etc. appeared less problematic at GP practices. Furthermore, making patients responsible for arranging appointments in some regions, combined with encountering delays, could undermine the perceived importance of DRS. We have identified patients' misperceptions about their attendance regularity.

Strengths and Limitations of the study

Strengths of this study include the purposive sampling strategy across several strata of professional groups in GP and optometry practices and screening programmes, and recruiting regular and less regular attending patients. Additionally, we recruited from diverse city, town and rural locations, and included programmes with different regional invitation and delivery-modes. However, not every permutation between location type, deprivation and delivery-mode was studied. We did not recruit any practice that delivers screening in a mobile unit or hospital outpatients department so did not interview Hospital Eye Service staff, and only two practices provided optometrist screening. The qualitative findings from our purposive sample are not intended to be representative but highlight socio-cultural meanings of health and illness experiences, not simply their frequency, ~~highlight~~ and identify important insights into barriers and enablers to screening attendance amongst our participants that will inform further research.

Implications for clinicians and policy makers

Whilst ~~S~~some patients understood retinopathy and its causation, others lacked information and understanding about DRS. ~~which~~This calls for proactive personal clinical risk communication (28, 29~~17, 18~~) and attendance information to ensure care coordination between patients, primary care, screeners and Screening Programmes. The current guidance to bring sunglasses could be strengthened in the patient information. Some patients confused retinal photography at optometry practices with DRS. Professional Optometry bodies could ensure clarity amongst members, and optometrists should highlight the difference to their patients. Consideration may be appropriate around the responsibility that the NHS has when discharging visually impaired patients in to the community. In Scotland, a 3-stage screening procedure is used; stage one is one field non-mydriatic photography, stage two is dilation, with the Scottish Screening Programme dilating approximately 34% of their population. The English Screening Programme developed following the evidence provided for 2-field digital photography by the Scanlon (32) study which recommended dilated two-field imaging. Culturally sensitive improvements (21~~25~~) should build upon the recent introduction of patient information leaflets in several languages[11].

Several providers now deliver DRS in the UK, and, since this research was conducted, Public Health England is responsible for overseeing delivery and~~.; t~~The ~~2014/15 Quality Outcomes Framework now excludes the DRS indicator, which will allow GPs to adopt flexibility in appointment setting based on clinical need.~~ the financial incentive for GPs to record screening uptake has been removed. These changes may affect future practice involvement and patie[nt] uptake; ~~T~~this fast-moving field requires monitoring closely. Building on the

successful central appointments system and routine factors that affect DRS attendance

[11] http://diabeticeye.screening.nhs.uk/languages

(30~~32~~), may prove useful. The national implementation of the new screening pathway should ensure consistent delivery throughout the country, improving the quality of services and reducing variability (31~~33~~).

Future research

Much more work is needed is this field. A similar exercise should be undertaken amongst a representative national sample of programmes, taking into account demographic variables that we found to be relevant (ethnicity, delivery-mode, deprivation etc.). More work ~~is~~ needs~~ed~~ to determine the prevalence of patients' and clinicians' views on the appropriate design and delivery of DRS services to maximise attendance; hospital staff may provide insightful alternatives for service improvement. ~~Encouragingly, many of the attendance barriers identified seem amenable to intervention. Community-based, culturally competent, educational interventions (25), supported by a Public Health media campaign should be developed, tested and implemented.~~ The pharmacological reformulation of shorter-acting mydriasis drops to minimise side-effects may reduce disruption to patients and potentially benefit uptake rates, although we acknowledge that this would not address the pain participants reported~~from the osmotic effect of the drops~~. The extent of confusion about optometry photography needs urgent assessment.

Conclusions

This study uses staff and patients' experiences of ~~Diabetic Retinopathy Screening~~ DRS to start unpicking factors affecting uptake ~~rates~~. Factors identified include differing regional invitation methods and screening locations, convenience, transport safety and short appointment times; some patients experienced significant ~~pain and visual disturbance~~ side effects from ~~the~~ mydriasis drops. The successful implementation of the new care pathway should address these factors and~~ensure proactive care coordination and consistent strategies to identify and address unmet access needs before, during and after screening. Clear guidance from professional bodies, a Public Health media campaign to encourage positive attitudes, and reformulated mydriasis drops,~~ may improve DRS attendance. Used as an international model, this ~~may~~could, in turn, contribute to reducing preventable vision loss and inequalities globally and its associated costs to individuals and their families, and to primary, secondary and social care providers.

Footnotes

- **Acknowledgements:** We thank the GP and optometry practices and Screening Programme staff who took part in the study and the patients who gave their time and shared their experiences and thoughts. We acknowledge the input and guidance of patient representative Mr Mike Whatmore on the Steering Group. We thank members of Warwick Diabetes Research Education Group for their constructive feedback on patient materials and early protocols. Kay Webb collected some data.

- **Contributorship statement:** IS had the original idea, making substantial contributions to the conception of the work; PS led the funding application. JS and AL ~~had the idea for the~~ made substantial contributions to the qualitative component of the study. All authors contributed to the early design of the work. ~~development of the protocol and overall supervision of the study~~. AH, the project manager, obtained ethical approval, and conducted the interviews with AL and JS. AH led the qualitative analysis and interpretation of data ~~led the qualitative analysis~~ and drafted the paper. All authors contributed to ~~the~~ writing or revising it critically for important intellectual content and approve of the final version of the paper. PS is guarantor. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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- **Competing interest Statement:** PS is the Director of the NHS Diabetic Eye Screening Programme; AH has personal experience of mydriasis drops.

- **Payment:** a £5 High Street voucher was given to patient participants in recognition of their contribution.

- **Transparency statement:** The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

- **Provenance and peer review:** Not commissioned; externally peer reviewed

- **Data-sharing statement:** Copies of the topic guide and participant information sheet can be obtained by emailing the corresponding author.

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Table 1: Practice characteristics

Practice no.	Screening Programme area	Index of Multiple Deprivation (IMD)	Practice type	Screening delivery mode	Uptake rate
Practice 1	Region 1	Deprived	Urban city	GP practice	96%
Practice 2	Region 1	Below average	Rural Town	GP practice	88%
Practice 3	Region 2	Deprived	Rural Town	GP practice	85%
Practice 4	Region 2	Above average	Rural Town	GP practice	75%
Practice 5	Region 1	Deprived	Rural Town	GP practice	73%
Practice 6	Region 1	Below average	Urban City	GP practice	72%
Practice 7	Region 2	Least deprived	Rural Town	GP practice	71%
Practice 8	Region 3	Most deprived	Inner City	High street optometrist	68%
Practice 9	Region 3	Most deprived	Inner City	High street optometrist	57%

Table 2: Programme and participant characteristics

Screening Programme Regional descriptor	**Region 1** Urban city rural town	**Region 2** Rural town	**Region 3** Inner city	**Total**
Number of practices	4	3	2	9
Patients (Non-regular attenders)	14 (5)	8 (1)	16 (10)	38 (16)
Medical practice staff (GPs, optometrist, HCAs, nurses)	2	3	3	8
Administrative practice staff (receptionists, managers)	4	2	1	7
Screeners	4	4	1	9
Total participants	**24**	**17**	**18**	**62**

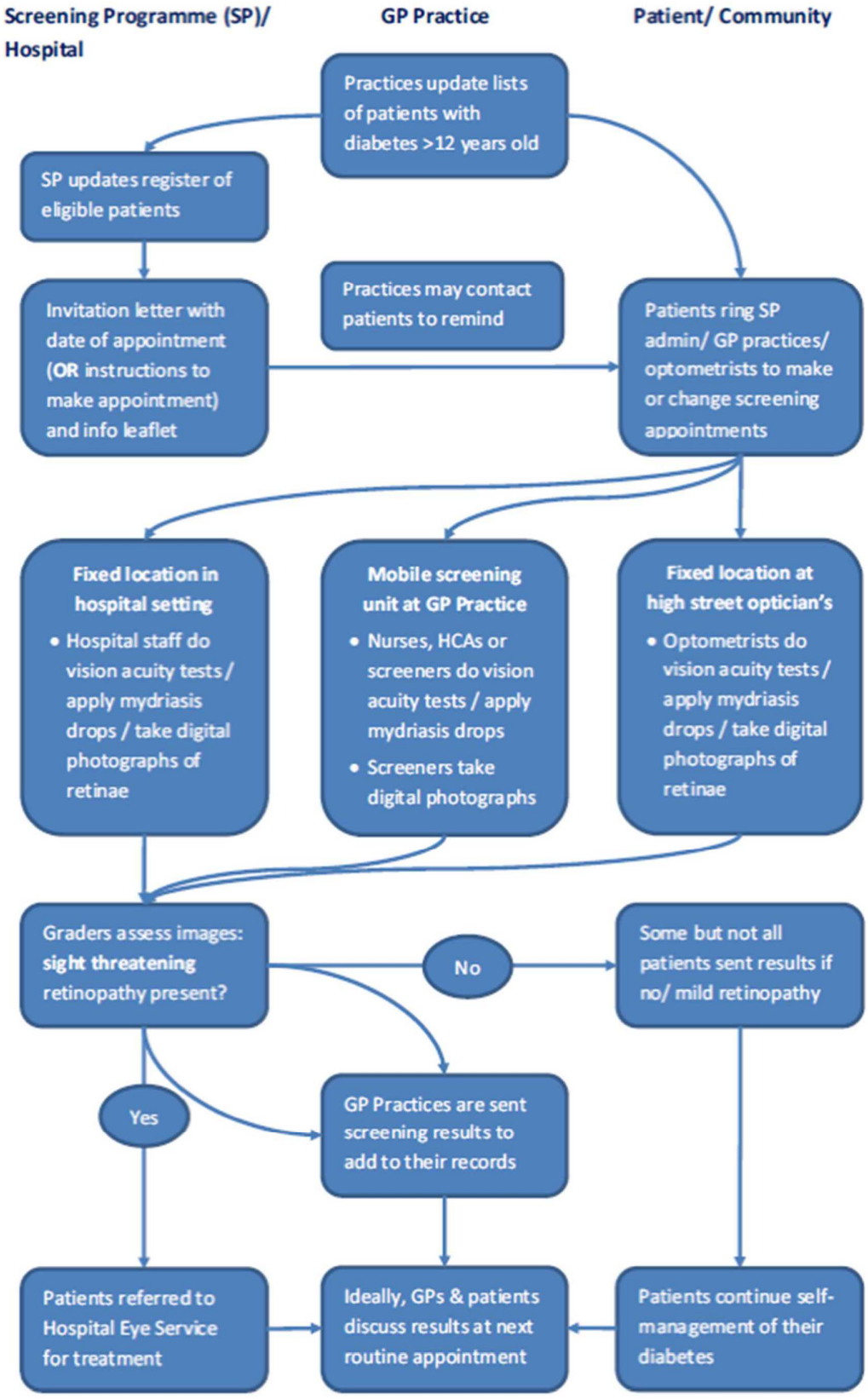

Figure 1: Diabetic Eye Screening Programme delivery modes

THE UNIVERSITY OF WARWICK

Warwick Medical School

Understanding *F*actors leading to *L*ow *U*ptake of diabetic *R*etinopathy sc*R*eening *I*n Primary Care (FLURRI study)

Ethics Protocol

Version 8.2: 14th February 2012

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Research for Patient Benefit Programme

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Section 1: Background to the study

1.1 Lay Summary

Diabetes is a very common condition affecting 1 in 20 UK adults. One complication of diabetes is diabetic retinopathy, which occurs when diabetes damages the small blood vessels at the back of the eye (retina). Symptomless to the patient until it is in the advanced stages, if left untreated this can result in loss of vision and blindness. Diabetic retinopathy is the most frequently reported cause of blindness in the working age population in the UK (Bunce and Wormald, 2006) and is second only to macular degeneration as a cause of blindness in those above 65. People with diabetes are invited to have digital photographs taken of the backs of their eyes (retinae) once a year. This can detect problems at an early stage when they can be treated and prevent further vision loss.

However, a significant number of people invited for retinal photography do not attend, and may be putting themselves at risk of future blindness. Research has shown a relationship with non-attendance at screening and subsequent loss of vision (Zoega, Gunnarsdottir, Bjornsdottir et al., 2005).

We are interested in finding out why people do not attend to have their eyes photographed so that we can use this information to try to increase the number that do. It has been found that those in deprived areas are less likely to attend, but this does not explain all the variability between GP practices. Reasons given to screening programme staff for failure to attend include inconvenient timing of the appointment, the patient forgot, the attitude of the administrative staff booking the appointments and anxiety about screening. There may be cultural and language barriers in ethnic groups.

We will choose GPs in Gloucestershire, Birmingham and Warwickshire, some with good levels of attendance and others with poor attendance, located in areas of high or low health need. Gloucestershire and Warwickshire run screening programmes using retinal screeners in mobile screening locations and, in Warwickshire, at fixed sites. The Birmingham programme uses high street optometrists. We will speak to health professionals in these practices to understand how they inform and educate people with diabetes about retinal screening. We will speak to patients, including those who have attended and those who have not, in order to see if there are ways in which uptake might be improved. We will also speak with retinal screeners and optometrists who undertaking the photographic screening.

1.2 Background to the Study

Diabetic retinopathy occurs when the blood vessels in the retina become blocked, leaky or grow haphazardly, which can damage the retina and prevent it working properly. The risk of diabetic retinopathy developing and progressing can be reduced by maintaining blood glucose, blood pressure, and blood lipid levels as near to normal as possible. Diabetic retinopathy affects nearly all people with Type 1 and almost two thirds of people with Type 2 diabetes, within 20 years of diagnosis, in the UK (Scanlon, 2008). Recently published data show that 2.2 million people now have diabetes in England (Diabetes UK, 2010 http://www.diabetes.org.uk/About_us/News_Landing_Page/Number-diagnosed-with-

diabetes-rises/). With approximately 90 per cent having type 2 diabetes and 10 per cent having type 1, this equates to over 1.4 million people with diabetic retinopathy. The English National Screening programme has estimated that the costs of assessment and treatment in England are £51,243,758 per annum (unpublished data). In 2003, Meads and Hyde reviewed the costs of blindness. The published estimates of the cost of blindness to the NHS in diabetic retinopathy were equated to December 2002 rates and varied from £7,433 per annum to £11,250 per person in 2002 costs. Much of the uncertainty in any sensitivity analysis of the cost of blindness in older people is associated with the cost of residential care. The authors concluded that the excess admission to care homes caused by poor vision is impossible to quantify at the present time (Meads and Hyde, 2003).

Non-attendance at screening is recognised as a risk factor for sight threatening retinopathy (Gray, 2009). The variation in uptake rates is of great concern because only when uptake is above 88 per cent is there any chance that the screening service will be 80 per cent sensitive to detect sight threatening diabetic retinopathy, as those not attending are more likely to have DR. This has been shown recently in a screening programme where high risk patients were invited, then three months later non-attenders were invited again; the non-attenders' level of DR was higher than those who came in the first wave. These were individuals who had already been identified using a high risk algorithm (Stratton, 2010; personal communication).

The English National Screening Programme for Diabetic Retinopathy (DR) aims to reduce the risk of sight loss amongst people with diabetes, by the prompt identification and effective treatment, if necessary, of sight threatening diabetic retinopathy, at the appropriate stage of the disease process. Free annual screening is offered to all people with diabetes over the age of 12 years in England. Patients are systematically invited to have their retinae digitally photographed at their GP surgery, high street optician, or local hospital, depending on which part of the country they live in. For the photograph to be taken properly, drops to dilate (widen) the pupils are put into patients' eyes, affecting their ability to drive for a short while afterwards. People who do not attend their screening are followed up by letter or telephone call, up to three times, by the regional screening teams. Additional screening sessions are held to maximise attendance, including at weekends in some areas. The photograph is sent to trained and accredited regional NHS retinal grading teams, who perform a two- or three-stage image grading process. This identifies any changes that could indicate sight-threatening diabetic retinopathy that requires monitoring or treatment. The grading teams notify any such indicators to the patient and the medical team.

Different types of retinopathy exist. For example, background retinopathy, the least serious, is unlikely to be sight-threatening and requires no treatment other than annual monitoring through the screening programme. However, serious conditions such as proliferative retinopathy, require referral to the patient's hospital opthalmology team for treatment. This condition occurs when the retinal cells become stressed by oxygen deprivation, and new, weak, blood vessels grow. These blood vessels can leak, break off, or bleed, causing potentially sight-threatening damage to the retina. Most of these serious retinopathies are treated by a specialist, using a laser at a hospital outpatients clinic, with patients allowed to return home afterwards. A tiny laser beam is directed onto the abnormal part of the retina and then small bursts of laser light are used to seal leaking blood vessels or to treat areas of retina that are lacking oxygen. Laser treatment reduces the stimulus for the production of

abnormal new blood vessels growing in the retina, which will often regress or fibrose after laser treatment. Whilst vision that has already been lost is not recoverable, laser treatment can prevent further damage from occurring. For some people, however, laser treatment is insufficient and surgical intervention may be required.

A key service objective of the English National Screening Programme for Diabetic Retinopathy is to maximise the number of invited persons accepting the test. In 2007-8, minimum targets of 70% attendance in the first round, and 80% in subsequent rounds were not achieved in at least 30% of programmes. Even in a well established screening programme (Gloucestershire), attendance rates within individual General Practices vary between 55% and 95%. A recent review for the National Screening Committee (Fell, 2007) showed limited primary research in this area, with much drawn from overseas and the research available focussing on population characteristics.

If Diabetic Retinopathy is diagnosed early, it can be effectively treated and sight can be saved or preserved (Bachman and Nelson, 1996; Scanlon, 2008). Furthermore, maintenance of vision is associated with better quality of life and independent living in older people (Chia et al., 2006). Importantly, DR screening has been found to be cost-effective in the English programme (James, Turner, Broadbent et al., 2000). A systematic review of interventions covers publications up to May 2005 (Zhang 2007). This includes 48 studies, 5 in the UK (12 randomised controlled trials, four non-randomised studies, and 32 pre-post studies). All of the UK studies were carried out before the introduction of the English Screening Programme, and interventions shown to be effective in the review (screening programmes, patient leaflets, diabetes registers, involvement of primary care teams) are in place. Unpublished evidence presented at the English National Diabetes Retinal Screening Programme and the National Diabetes Support Team conference in 2008, identified a number of interventions that may improve attendance, including a redistribution of existing cameras, more screening locations, better transport options, additional service, weekend / evening clinics, additional telephone lines, an answer phone, a publicity campaign and leaflet translations improved access. Research that has focussed, quantitatively, on population characteristics showed that patients in the most deprived areas are less likely to attend for screening whilst having worse retinopathy (Scanlon, Carter, Foy, et al., 2008), whereas in SE London younger patients were less likely to attend (Millett and Dodhia, 2006). In Scotland, distance to screening site was not found to be a factor, but duration of diabetes, poor control and smoking were associated with lower uptake (Leese, 2008). In Iceland, a significant relationship between poor screening compliance and poor visual outcome was found (Zoega, 2005). One study in Dublin showed that recommendation by a physician increased participation (Dervan, 2008). No qualitative studies have been undertaken in the UK or elsewhere, to understand the factors affecting uptake of systematic retinal screening from the perspective of patients or professionals.

Strategies to increase uptake in other screening programmes in England have shown mixed results. Some research has been undertaken in the cervical and breast cancer screening programmes (Sutton et al., 1994; Pfeffer, 2004) and these found that attitudes, beliefs and intentions towards disease and screening – which are potentially changeable through patient education – influenced screening attendance. This included the women's perceptions of their disease risk, and, importantly, non-medical reasons influenced attendance, for example

concerns about the screener's gender, religious grounds, and fears of feeling socially inadequate. However, these invited different population groups for screening and the findings may not be transferable as reasons for non-attendance at the diabetic retinopathy screening programme.

1.2.1 Research team's professional background to the study

The Cheltenham team are based within the National Screening Programme. Dr Scanlon is the Programme Director for the English National DR Screening Programme, overseeing the External Quality Assurance for 91 screening programmes in England and in a strong position to influence, if positive results for improving screening uptake are derived from this research. Findings from the project will be communicated with Screening Programme Managers and Clinical Leads in all 91 screening programmes. The National Programme has six Regional Quality Assurance Managers who communicate regularly with screening programmes in their regions and with the SHA Screening Leads and make recommendations to improve services. The English National Diabetic Retinopathy Screening Programme manages the External Quality Assurance for all 91 programmes and is in regular contact with programmes, Public Health Consultants and commissioners.

The Warwick team are experienced diabetes researchers from primary and secondary care and local retinal screening programmes. Jackie Sturt's interests in the areas of complex interventions such as self-management, structured education, psychological interventions, outcome measurements and user involvement are central to the aims of this project. The team have broad methodological experience with particular expertise in the case study methods employed in this study.

1.2.2 Patient involvement in the development of this study

The original idea for this research came from Irene Stratton and this was further developed with the assistance of a patient representative (Mike Whatmore). Reasons for non-attendance might be clinic related such as location, access to clinic, time/date of appointment, waiting time, welcoming attitude, communication, ease of re-arranging appointment, public transport/walking distance (eye drops prevent driving) or car parking if being taken by relative or neighbour. He felt that there might be patient related reasons such as personal/family commitments (childcare, sickness), weather conditions, independence (mobility, age, eye-sight, confidence), ethnicity needs (language, support, 'permission') and education (understanding the benefits of retinopathy screening, and, that it is in addition to the basic annual eye test at their optician) and are they aware that it is free? Mike has collaborated both with the Gloucestershire and Warwickshire teams and he will continue his active involvement throughout the project. This proposal has been further developed with the collaboration of members of the Warwick Diabetes Research & Education User Group (WDREUG), who have reviewed the research questions, the interview schedule questions, ~~and~~ the sampling processes and new publicity material. This group of approximately 10 people with diabetes have been meeting bi-monthly since 2001 to consult with the diabetes

research team on the development, execution, analysis and dissemination of the research projects and they have been acknowledged in 8 previous publications and contribute to INVOLVE activities. A further 10 members are involved via email. Halfway through the study, the group will be given the results to date, to see whether changes might be needed to the interview schedule and the sampling protocol, to ensure nothing important to patients is missed by the research team. Findings will be disseminated by members both formally and in their multiple contacts with health professionals, Diabetes UK members and newsletters.

Section 2 – Purpose of the Research

2.1 Key research question to be addressed

Why do some people with diabetes not attend their retinopathy screening? What are the personal, social, organisational and professional factors that may combine, leading to low uptake rates of diabetic retinopathy screening? We will seek answers to these questions from the perspectives of patients, health professionals and DR screeners.

2.2 Aims & objectives

The aims of this research are:

2.2.1 To understand the different pathways to screening and how this might influence uptake, from the perspectives of people with diabetes and health professionals;

2.2.2 To understand the informational, educational needs, beliefs, and attitudes of people with diabetes throughout the screening process (i.e. the screening invitation, the screening process, and understanding and acting upon the results) associated with diabetic retinopathy screening;

2.2.3 To understand the informational, educational needs, beliefs, and attitudes of primary care and screening professionals in communicating the importance, consequences, investigations, results and treatment options to their patients;

2.2.4 To understand why some people with diabetes who have been invited for retinopathy screening do not attend, from the perspectives of people with diabetes and screening/ health professionals;

2.3 Why this study is needed

This study will reveal practices, procedures and experiences that people with diabetes and clinicians have found to be beneficial or detrimental to meeting the screening programme standards. These findings can be communicated to the regional programmes and to primary care. This will enable GP practices and regional programmes to reflect on the extent to which these practices, procedures and experiences are represented within their own provision and introduce facilitating strategies and minimise disabling strategies.

Section 3 – Methods

3.1 Design of the research

We propose a qualitative case study design using individual interviews, supplemented by quantitative data for the participants who live with with diabetes. We will invite GP practices in PCTs in three counties (Gloucestershire, Warwickshire and Birmingham) to participate. Each practice represents a case and we will interview two professionals and six people with diabetes from 10-12 purposively selected practices, as described below. Additionally, we will collect quantitative data from participants with diabetes', including average blood sugar test results, Problem Areas In Diabetes (PAID) (Welch et al., 1997) scores and levels of social support, measured with the Social Support Questionnaire (SSQ) (Sarason et al., 1983). The results of the qualitative and quantitative analyses will be synthesised into the final outcomes of the study.

We will use a two-phase, case study design (Yin, 1994; Ragin, 2000 & Griffiths 2007), with each GP practice representing a case. We propose using a case study methodology developed by Ragin (2000) in which we see retinal screening uptake as the outcome of interest and the hypothesis that there are several pathways to the outcome and different degrees to which the outcome will be achieved by using that pathway. Each GP practice or case has its own pathway to retinal screening for its patients and using this method will enable us to understand and describe those pathways. For example, within each practice, we will look for factors that might enable or hinder a positive outcome (patient goes to screening/ high screening rate). In order to attain sufficient numbers of participant interviews to fulfil the study's aims, the case-study design will be supplemented by eligible participants who ~~volunteer to take part in the study,~~ respond, for example, ~~in response~~ to media coverage, or an invitation at the diabetes clinic at their GP practice, or hospital Opthalmology clinic, irrespective of which GP practice they attend. However, it will be very difficult to find out whether any single factor makes a difference as there are so many and they all interact.

Therefore we will look for combinations of factors that help or hinder screening which may be very different in different places (e.g. pro-active nurse plus good health professional-patient relationship plus practice close to screening centre); some of this will be easily modifiable, some very difficult to modify, some impossible (e.g. miles to next hospital) and these will enable us to tease out both the simple and the complex strategies for raising screening uptake.

3.2 Sampling strategy

3.2.1 Practice recruitment

We will recruit 10-12 GP practices from Coventry, Warwickshire, Birmingham and

PCTs to represent populations living in inner city Birmingham, urban Coventry, the semi-rural towns of Nuneaton and Rugby with pockets of affluence and deprivation, and rural and more affluent locations in Warwickshire and Gloucestershire and where the three models of retinal screening service provision (mobile screening, fixed location and high street optometry) are represented. We will work with the regional Screening Programme Leads and Primary Care Research Networks (PCRN) to recruit practices and patients to this study. National and screening programme datasets will be used to identify practices for purposive recruitment according to high and low levels of health need and high and low uptake of retinal screening services. The Jarman index will be used to identify practices with the most and least health need and retinal screening programme databases will be used to identify high and low uptake practices.

The English Indices of Multiple Deprivation's (IMD) Health deprivation and Disability domain ~~Jarman Index, based on Census data by postcode/ward,~~ gives ~~a~~ scores and ranks that indicates ~~likely~~ demand for Primary Care services (Department for Communities and Local Government, Indices of Deprivation 2010). ~~It considers the numbers of elderly people living alone, single-parent households, under-fives, overcrowded households, unskilled, house-movers, unemployed residents, and people from minority ethnic backgrounds.~~ We will sample GP practices from the top and the bottom thirds of the ~~Jarman Index~~IMD, to identify practices in areas with high and low health need. Additionally, we will identify, with the regional Screening Programme teams, GP practices with high levels of retinal screening, which are defined as those achieving 85% uptake or more, and low uptake practices, which achieve DR screening uptake of 65% or less. If this does not result in sufficient numbers of practices, recruitment of practices who achieve the best 10% and worst 10% of screening uptake will also be included. This spread will allow the identification of barriers and faciltators to screening uptake across different types of GP practice and people with diabetes, to allow for good practice to be shared.

a) Phase 1 Case (GP practice) sampling will be purposive for the first phase of recruitment, where we will identify six practices whose ~~Jarman~~ IMD score indicates high or low population health need and where the retinal screening databases specify they are achieving either very high or low levels of retinal screening uptake. The former will enable us to identify some successful practice and screener related mechanisms for increasing uptake and patient screening related attitudes and behaviours. We will also identify from the lower uptake practices the barriers to uptake at the case level. Evidence suggests that demographic factors such as ethnicity, socio-economic status, and working age, are important factors affecting screening uptake, (Scanlon, Carter, Foy et al., 2008; Millett and Dodhia, 2006), as is time since diagnosis (Leese, 2008). We are prioritising these factors in the first six cases and recognise that we do not know what further factors influence uptake in these populations. Previous qualitative screening studies have been with well populations and our proposed population also live with a complex long-term condition and this may be important. The research team will discuss emerging data from these six cases that may lead to changes to the sampling strategy for cases 7-12.

The pilot case will allow the team to identify any errors or omissions in the interview schedule, and address such issues prior to commencement of the subsequent data-

collection. Table 1 demonstrates the strategy for Phase One sampling cases/GP practice numbers 1-6.

Table 1: Phase 1 sampling strategy for cases 1-6 (GP practices)

	Glocs*	C&W	B'ham	Glocs	C&W	B'ham
PRACTICE	**1***	**2**	**3**	**4**	**5**	**6**
Low Jarman score	X	X				X
High Jarman score			X	X	X	
High uptake	X				X	X
Low uptake		X	X	X		

* Pilot case

b) Phase 2 Sampling for cases 7-12 (the second phase of GP practices recruitment) will be iterative and purposive. In lay terms, this means that the data from the interviews in the first six practices will be analysed for emerging factors that influence screening uptake, particularly factors we are not currently aware of. These data will be used in the selection of the second group of practices and in the patients within those practices. Additionally, Phase 2 will be supplemented by participants who volunteer to take part in the study, for example, in response to media coverage, irrespective of which GP practice they attend.

3.2.2 Participant recruitment

a) Professionals Practice staff: Having identified appropriate GP practices from the regional screening manager, practices will be contacted for their participation. The research team will contact the practice to give an overview of the study and seek their consent to participate. All eligible practice staff will be contacted by the research team, by email/telephone, to be given an overview of the study. With their permission, a Participant Information Pack will be sent postally/electronically.

Screening staff: The Practice Manager or senior administrator will identify the member(s) of the regional screening staff who last visited each practice and provide the researcher with contact details. In Birmingham, where the photographic screening takes place in high street optometry practices, and in parts of Coventry and Warwickshire, where fixed site screening exists alongside mobile screening, regional Screening Programmes will identify the relevant screening staff and provide the researcher with contact details, to follow the above procedure.

Professionals recruited for interviews from each case will include two of the following:

a) Diabetes lead GP or nurse
b) Practice Manager
c) Health Care Assistant;
d) Screening Programme manager
e) Retinal Screener or Optometrist

Health/Screening Professional Inclusion Criteria

- Is aged 18 years or over
- Is able to give informed consent
- Is involved in the English Nationanl Diabetic Retinopathy Screening Programme in their professional capacity

Health/Screening Professional Exclusion Criteria

- Unable to give informed consent
- Withdraws consent

Practice and retinal screener/optometrist interviews will be conducted at the staff member's usual place of work. They will last approximately 30 minutes and be audio-recorded and later transcribed. Please see Appendix 9 for a preliminary interview schedule (subject to minor modifications, should this be required following an initial pilot with one practice). Whilst it is likely that other practice/screening staff will know of a professional's choice to participate in this study (for example, at a single-handed GP practice), the participant's anonymity, the individual practice's anonymity will be protected in all documentation relating to the study. This will ensure that, for example, Commissioners will not know which practices have participated, and patients will not be able to identify professionals.

b) Patients From the first six practices, the regional Screening teams will identify six patients per practice from their database:

- four who have attended none or one of their last three DR screening appointments AND
- two who have attended all three of their most recent screening appointments.

Screening Programme staff will provide practice staff with a list of patients who fulfill the above criteria. Practice staff will use their local knowledge and GP records to purposively recruit patients for diversity according to age, gender, type of diabetes, ethnicity and time since diagnosis, and meet the full inclusion criteria, below. In this way the research team will not receive any patient details prior to informed consent being obtained. GP practice staff will telephone the patients to give an overview of the study, seeking permission to post out or email the participant information pack including consent form. This will be returned to the researcher, who will confirm receipt to the practice, so that practice staff can follow-up those patients who do not return the consent form by telephone and/or sending out another pack.

We recognise that many patients face additional barriers in accessing services, and these groups are also less likely to participate in research, because of, for example, shortcomings in the availability of study materials in the approriate languages. The team have experience in this area (Parken & Sturt, 2009; Lloyd, Sturt et al., 2008; Hipwell, 2009) and also in strategies to increase interview participation, such as employment of a bilingual interviewer, translators, link-workers, practice staff/professionals support. Where Primary Care staff identify a particular language need for a specific patient, linkworkers will be contacted by practice staff to facilitate recruitment. In Gloucestershire, where there is only a very small minority ethnic population, active practice nurse and GP participation in recruitment has increased participation in the past. In order to ensure that this research is culturally competent (Papadopoulos, Tilki and Lees, 2004; Papadopoulos, 2006), every effort will be made within time and budgetary constraints, to facilitate access for people for whom English is not their first language, to participate in this research. A detailed translation and interpretation protocol that details these procedures can be found at Appendix 5. Team members have access to bilingual linkworkers in all three regions, which will allow potential participants to be contacted in an appropriate language, by telephone, in person, or in clinic, to encourage recruitment of non-English speakers. Link workers will liaise closely with practices to identify the relevant linguistic skills needed during recruitment.

To ensure we recruit sufficient numbers of these patients to meet the study's aims we propose introducing a number of additional recruitment strategies in order to attract sufficient low attenders to retinopathy screening to the study. These include:

- Offering to interview patients by telephone, to facilitate their participation. We hope that by minimising potential participants' travelling time, cost and inconvenience, in order to attend research interviews, this may encourage more participants to Consent to take part.

- A flyer advertising the study, to be put up in target GP practice premises, that asks eligible patients to contact the research team; see Appendix 12. This has been circulated to WDREUG and comments taken into account in its design. By avoiding the use of the University logo, we hope that any perception of potential elitism associated with universities by some potential participants may be avoided, thus attracting participants from less educated backgrounds. Similarly, we have not used the term 'interview' as this could be particularly associated with job interviews, again serving to deter potential participants who are not currently active in the jobs market. The flyer does not use the NHS logo or livery, which we hope will serve to underline the research team's autonomy from the clinical team, thus reassuring potential participants about confidentiality.

- Media coverage of the study, appealing for low attenders to contact the team (radio/newspaper interviews, including local Asian networks as appropriate; Press Release). From the experience of the research team, local radio interviews can vastly improve awareness of the study amongst large numbers of potential participants, resulting in successful recruitment. Our contact at local South Asian networks have agreed to facilitate this, including providing language skills lacking in the research team, as appropriate. A University Press Release can simultaneously

be released by the University of Warwick Communications Team, so that local newspaper coverage occurs at the same time, to maximise impact.

- Increasing the High Street participation voucher from £5 to £20. Several team members are aware of other studies that are taking place elsewhere in the country, which are giving participants £20 to cover their time and any disruption that their participation in the research has caused. Dr Scanlon has agreed to fund this from his English National Screening Programme for Diabetic Retinopathy budget.

- GP notes to be 'flagged' to highlight that patient has been identified as eligible. Several GP Practice Managers have suggested that this is a simple way to make sure that potential participants are not missed. When a flagged patient contacts the surgery for any reason e.g. to collect a prescription, see a nurse, they can be asked about participating in the study.

- In GP diabetes clinics and hospital opthalmology clinics, people with diabetes who fulfil our Low Attender' inclusion criteria will be invited to participate irrespective of their GP practice's screening status. It is entirely appropriate for Diabetic Retinopathy Screening to be raised in this context, and in-clinic recruitment when an eligible patient attends an appointment can be easily adopted. Caution will be exercised that the patient does not feel pressured to participate.

Patient interviews will be semi-structured, approximately 30-45 minutes in length (up to double this when working with interpreters) and will be conducted in the GP surgery, home, ~~or~~ in a place of their choosing or by telephone, on an individual basis. Please see Appendix 4 for a preliminary interview schedule (subject to minor modifications following an initial pilot with one practice). Interviews will be audio-recorded and later transcribed verbatim.

We will confirm eligibility of those patients we identify from media and posters etc., by obtaining the patient's permission on their consent form) to check their name, address, attendance record etc with the retinopathy screening team so that we do not have to burden the GP practice.

- The participant Information Packs and Informed Consent Sheets have been amended accordingly (see appendix 1 and Appendox 3).

Patient Inclusion Criteria

- Is aged 18 years or over
- Is able to give informed consent
- Has a confirmed diagnosis of type 1 or type 2 diabetes
- Has
    - Either attended all three of the last three DR screening appointments

- Or has attended none or one of the last three DR screening appointments
- Speaks English or a language that the research team are able to have interpreted at interview/translated study materials

Patient Exclusion Criteria

- Is unable to give informed consent, for example has a learning disability or Alzheimer's Disease
- Is unable to be interviewed in a language that can be translated and interpreted by team
- Withdraws consent

Assuming a positive patient response rate of approximately 30%, up to 18 patients will be invited to participate in the research, per practice.

When the informed consent form is returned to the research team the patient will be contacted by telephone to arrange an interview appointment at the location of the participant's choice. This is likely to be the GP surgery for many participants, although where this is not possible or desirable, interviews will be undertaken in participants' homes. If this is not appropriate, for example for reasons of researcher safety, telephone interviews will be considered, so as not to forego potentially valuable participant data. The interviews with the professionals are anticipated to take place in their normal workplace i.e. GP or high street optometry practice, or hospital outpatients department.

Justification of sample size: Sample size for qualitative studies is determined by the depth of data (perspectives on a single issue e.g. screening vs. detailed narratives of living with illness) and scope of data (possible different perspectives studied). The sample size reflects this methodology (Morse, 2000). Our research aims to elicit a variety of perspectives on a focused issue and we are proposing a relatively large sample size of 24 for the clinicians and 72 for patient participants. In qualitative research, interviews are conducted until one is not hearing anything new, which usually occurs between 12 - 20 interviews but due to the complexity and diversity of the different factors in this research a larger sample size has been used. We expect 96 interviews to be both a robust and efficient sample size.

We expect a 30% patient recruitment rate, based on the team's previous experience. In order to achieve a sample of 6 patients per case we will invite 20 purposively selected patients meeting the inclusion criteria to participate.

Rate of recruitment: We aim to confirm recruitment of one new case/GP practice per week and confirm recruitment of eight interviewees in two weeks. Interviews in each practice will be completed within a further two weeks and transcription in a week. We therefore plan to allow six to eight weeks per practice to complete the case study recruitment and data collection and this time frame will also allow preliminary data analysis of each case.

3.3 Data collection

3.3.1 Data collection: patients

Data collected from patients will aim at discerning factors that may result in patients attending or not attending screening. These may include rapport with the practice, individual understandings of the importance of screening, how difficult it is to get to screening, and experiences of the screening process itself. To gain understanding of the participants' current situation before conducting the interview, we will send participants a brief questionnaire prior to the interview, including demographics, and questions related to potential difficulties with managing diabetes and the social support they receive. These questions will help us to focus on areas that are important to the individual. As an indicator of current diabetes control, we will also obtain average blood sugar test results (HbA1c measurements) from patient records. Information obtained in this way will be included in the analysis alongside qualitative data.

a) The interview The researcher will conduct a semi-structured interview at the patient's GP practice, home or another venue of their choosing, or by telephone. At the beginning of the interview, the researcher will confirm consent and encourage participants who did not complete the questionnaires to do so now. For non-English speaking participants, the interpreter will translate and fill in the questionnaires at this point, having had prior sight of this paperwork. If spouses or other people present make a substantial contribution to the interview, this will be noted on the consent form. Interview questions will focus on the participant's current self management of diabetes, their interactions with their practice and understandings and experiences of attending screening. The interview will also contain open questions to make sure that all important issues can be raised by the participant. The interview schedule will be reviewed at the end of Phase 1 to consider adding questions in response to important issues raised by participants in response to open questions. The review found that the interview schedule is performing well and no significant changes to it are required.

b) HbA1c measurement This will show the participant's average blood sugar level over the previous six to eight weeks, giving a good estimate of how well the diabetes is being managed over time. We will use this information, in combination with qualitative data, to find out about connections between self-management and screening attendance.

c) Problem Areas in Diabetes (PAID) The Problem Areas in Diabetes scale (PAID) measures diabetes-related distress and has been found to be valid and clinically useful in Type 1 and 2 diabetes populations. Low PAID scores are linked to successful self management (Polonsky et al., 1995; Snoek et al., 2000). Knowing about participants' diabetes-related distress will help us to identify possible barriers to attending screening and

focus questions on areas that are especially difficult for the participant. See Appendix 10.1 for a copy of the scale.

d) Social Support Questionnaire (SSQ) Participants will be asked to compete the Social Support Questionnaire (Sarason et al. 1983), in order to show the quality and quantity of their social interactions and aid the interviewer to focus their questions. Social support is a very important factor in diabetes self management (Toljamo 2001), and may be linked to screening attendance as well. See Appendix 10.2 for a copy of the scale. For those participants choosing to be interviewed by telephone, these data will be collected over the phone by the interviewer.

3.3.2 Data collection: health care staff

Data collected from health screening professionals will likewise aim at discerning factors that may result in patients attending or not attending screening. These could be the presence of health professionals with a strong interest in diabetes care, practice location in relation to screening location and the type of screening service used. The researcher will conduct semi-structured interviews with 2 health professionals involved in diabetes care in their practices or usual place of work. If there are difficulties with arranging single interviews, we will also consider joint interviews. At the beginning of the interview, the researcher will confirm consent and collect consent forms. They will also be given a demographic sheet to collect age, gender, professional role in relation to screening and years in practice. The interview schedule will focus on participants' understandings of current screening uptake, barriers and enablers to higher screening, and suggestions for improvements to the service. Additionally, we will collect publicly accessible data on factors that possibly influence screening uptake such as distance from screening centre, size of catchment area and skill-mix within the practice.

3.3.3 Phasing and timescales

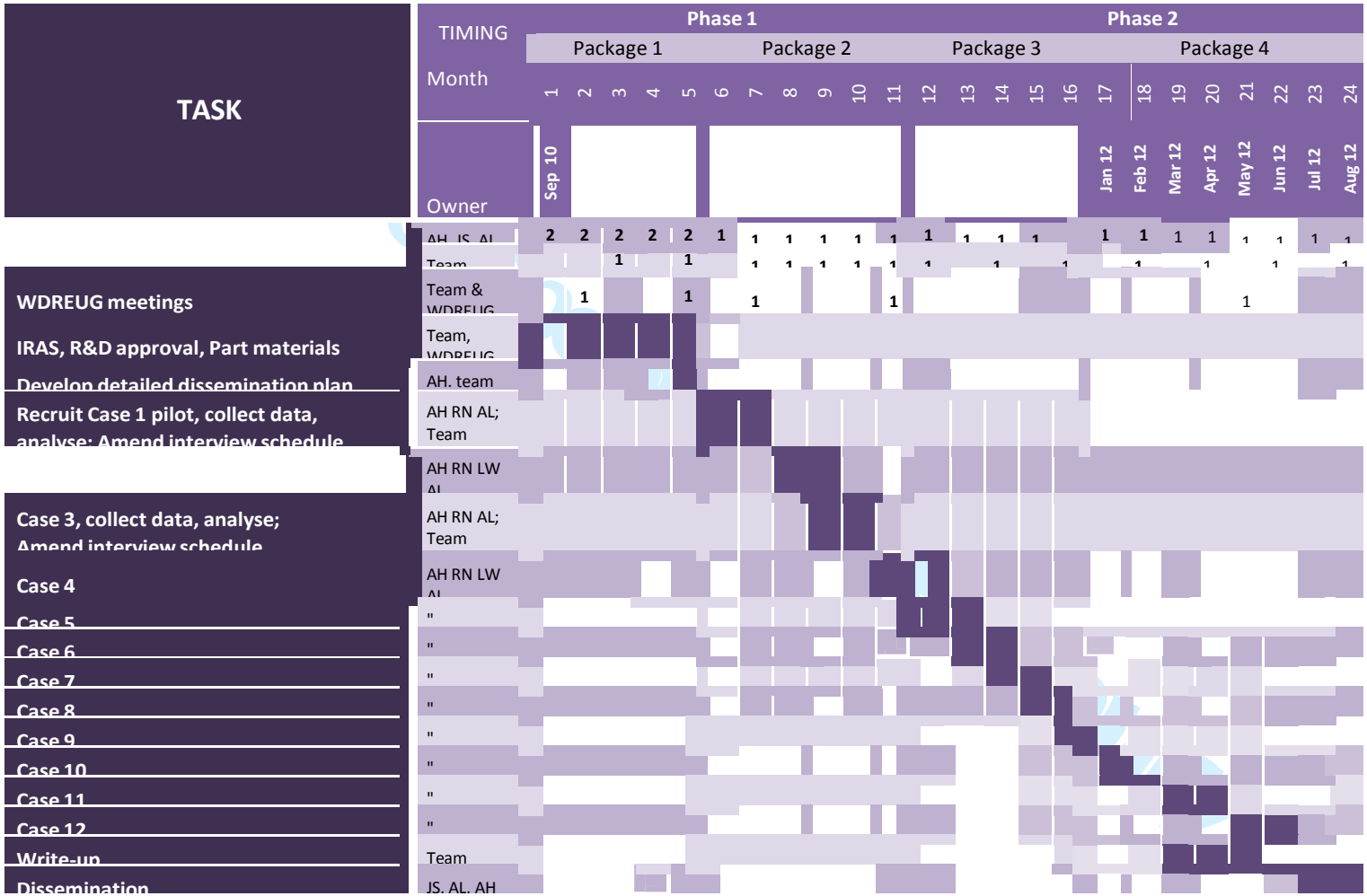
The research will comprise four packages of work in 2 phases, which are detailed on the Gantt chart, overleaf at Figure 1 and summarised below.

a) Package 1: Preparation of the research

Months 1-5: Post-doctoral Research Fellow, Alison Hipwell, into post (1.0 WTE) to finalise protocol and practice and patient materials, obtain ethical and NHS R&D approvals and develop detailed dissemination plan. Package 1 will involve the research team (including all the applicants) and the Warwick Research and Education User Group in finalising the protocol, consent procedures and the interview schedules. Recruit 1 practice, pilot professional and patient interviews, collect quantitative data. Amend interview schedules and structure as necessary.

b) Package 2: Undertaking the Phase 1 fieldwork

Month 6-11: Six GP practices will be recruited by a Primary Care Research Nurse (PCRN) or Practice nurse as appropriate, in collaboration with AH and the Regional Programmes. A PCRN from each of the three areas will join the project during this busiest period of fieldwork, to support practice recruitment, quantitative and qualitative data collection according to the sampling framework. Additionally, a link worker will be assigned, who will facilitate the addition of specific language skills. AH and the research nurse will conduct English-language patient and practice interviews following a 2 professional and 6 patient basis. We will aim for one case to be completed every six to eight weeks. AH and the link worker will conduct non-English interviews as appropriate. AH will continue to undertake interviews, quantitative data-collection and oversee transcription, whilst AL will commence data coding and preliminary analysis observing emerging hypotheses and data saturation. The sampling framework and interview schedule will be examined in light of emergent findings, and amended as appropriate, in discussion with Dr Sturt and Dr Hipwell. Substantial amendment to the Ethics Committee is unlikely, but we have allowed time for this, if it becomes necessary, between months 10-11. The whole research team will meet monthly during this early data collection phase, to discuss the emerging data and assess needs for changes due to data gaps/saturation.



AH = Alison Hipwell RN = Research Nurse LW = Link worker AL = Antje Lindenmeyer JS = Jackie Sturt

Figure 1: Phasing and timescales

c) Package 3: Completing the Phase 2 fieldwork

Months 12-17 recruit remaining six practices and complete quantitative data-collection and interviews according to 2 professionals, 6 patients structure, observing any amendments. Complete one practice every six-eight weeks, where feasible. Undertake analysis concurrently according to developed themes observing absent or saturated themes. As saturation begins to occur, slow practice recruitment down to ensure efficient use of NHS and research resources and ethical research practices.

Package 4: Dissemination, is considered in section 3.5.

3.4 Analysis

For the purposes of data collection, each practice will be considered as a single case with each case contributing to the case series. Phase 1 interview data will be transcribed and entered into *N-vivo* data software package. The research team, led by Dr Antje Lindenmeyer, will conduct a thematic analysis of the data concurrently and following the fieldwork phase, by constant comparison of the data. We will compare within and between data from patient and health professionals interviews to gain insight into factors helping or hindering screening uptake. In order to achieve this, we will conduct an intra-case comparison of patient pathways in participants from the same practice, and also inter-case comparisons of patient pathways and enabling factors between practices. Recurring themes (for example: patient needs for information and support, and health professional views on possible improvements in the screening service) will be noted, and themes may inform changes in the sampling procedures and interview schedules for Phase 2 recruitment and data-collection (Green, 2004). Emergent themes will inform our practice sampling in Phase 2. Phase 2 analysis will follow the same procedure as above, with data analysed using a constant comparison approach, both within and between data from patient and health professionals, and also performing intra- and inter-case comparisons.

Thematic analysis will also aim to identify factors from interview data and other information gathered as part of data collection. As each of the practices sampled presents a unique cluster of these factors and the outcome of interest (participation in screening) may be helped or hindered by the interaction of these different factors we will compare cases to understand whether there are any particular clusters of factors that lead to an improved uptake in screening. We will apply comparative case study methodology developed by Byrne (2005) and Ragin (2000) to investigate whether a set of factors, singly or in combination, contribute to pre-defined outcomes. We will identify a set of these factors both for patients and practices. For example patient factors could be ‘social support’; ‘confidence in self-management’; ‘rapport with health care professional’ or ‘years since diagnosis’; practice factors could include location (distance from screening unit), socio-economic background (Jarman score), or patient characteristics (e.g. a large nursing home in the catchment area). Patients and practices will then be assigned categories for these factors (e.g. good or insufficient social support, long or short distance from screening unit). If both qualitative and

quantitative data are available for a particular factor (e.g. social support scale and interview response regarding social support), the research team will consider both to assign an overall category. We will then enter these categories on a spreadsheet (truth table) and calculate whether particular factors or combination of factors are associated with screening attendance. Results of thematic and comparative elements of the analysis will be compared to arrive at an in-depth understanding of enablers and barriers to screening attendance.

Some of the proposed recruitment strategies may result in participants being recruited who are not from our target cases, for example if they respond to media coverage about the study. This means that there will be a slight adjustment to the analysis, with more thematic, non-case, analysis. Whilst these changes represent a design change to the recruitment methodology, they are not expected to impact scientifically.

3.5 Dissemination of findings

Package 4: Complete analysis and dissemination

Months 16-24: Complete data analysis, write-up and disseminate according to plan at local, national and international professional and patient events. Month 24 finalise research report and papers for publication. In addition to the usual academic and patient routes of dissemination, the English National Diabetic Retinopathy Screening Programme has its own process, which will be accessed with the study's findings. Following an External Peer review visit, which takes place for each programme on a 3 yearly cycle, a report is produced which makes recommendations for improvements in screening services and any findings from this research would be included in the recommendations following peer review. Where the strategies were simple, such as a single telephone reminder, they could be implemented rapidly. More complicated strategies would generate hypotheses for future uptake interventions, which may need testing, rather than immediate national implementation. Strategies contributing to higher uptake of diabetic retinopathy screening will enable at risk patients to receive high quality care at the most appropriate stage in the disease process and reduce the incidence of avoidable blindness.

3.6 Project management

The research team have extensive project management experience and expertise. Dr Peter Scanlon (Director of the National Screening programme and Gloucestershire Screening Programme) and Dr Jackie Sturt (Associate Professor of behavioural Sciences, Warwick Medical School) are joint principal investigators of the proposed study. PS has extensive research experience in digital photographic screening and in implementation and Quality Assurance of the 91 English programmes; JS has expertise in primary care research in diabetes and in intervention development for improving outcomes for people with diabetes. Irene Stratton is a statistician with the National Retinal Screening Programme, analysing data from the screening programmes, and with expertise in diabetes research, specifically in diabetic retinopathy. Roger Gadsby is a GP with a national reputation in primary care diabetes and is member of the English retinopathy screening advisory board. Antje Lindenmeyer is a sociologist with qualitative research expertise in diabetes and Dr Paul O'Hare is Clinical Lead for the Warwickshire programme and has expertise in the United

Kingdom Asian retinopathy study. Alison Hipwell, a health psychologist in the field of self-management, has experience of designing, conducting and analysing cross-cultural research interviews and has a strong interest in Minority Ethnic health inequalities.

3.6.1 Package 1: Project managing the preparation of the research

Months 1-5: As detailed in the Gantt chart at Figure 2, during the early stages of designing and developing the research methodology, AH and JS, and AH and AL will meet twice per month. This will allow minor queries to be resolved quickly, with more substantial queries being referred to the wider team once prior to submission to Research Ethics Committee, and once afterwards, if necessary. Similarly, team members will attend the WREUG meeting once during the development stage, to obtain patients' feedback about the participant materials, and again following REC, as necessary.

3.6.2 Package 2: Project managing the undertaking of the Phase 1 fieldwork

Month 6-11: AH, JS and AL will meet once per month to discuss progress with recruitment, data-collection and analysis. This will allow the resolution of any smaller issues around these areas as they arise, and early identification and discussion of emergent findings. Any more substantial issues, such as changes to recruitment/sampling procedures, in addition to updates about progress to timescales, will be discussed with the wider team at monthly meetings during months 7-11. WDREUG meetings will be attended at the end of the pilot in month 7, to determine whether any changes need to be made to interview questions, sampling/recruitment strategy etc., in the opinion of the patients, and again during month 11, at the end of Phase 1 data collection, for the same reason.

3.6.3 Package 3: Project managing the completion of the Phase 2 fieldwork

Months 12-17: Monthly meetings between AH, JS and AL to discuss progress with recruitment, data-collection and analysis, will continue throughout the third package of work. This will again allow the resolution of any smaller issues around these areas as they arise, and early identification and discussion of emergent findings. Again, updates about progress to timescales, an discussion around any more substantial issues, will be raised with the wider team at meetings every two months, during months 12-17.

3.6.4 Package 4: Project managing the analysis completion and dissemination

Months 16-24: Monthly meetings between AH, JS and AL will continue as above, along with two-monthly project management team meetings. This will enable the team to identify key findings and areas for future development and dissemination, and exchange feedback about conference and paper drafts. Attendance at the WDREUG will ensure feedback to this forum, and a final opportunity for patients comments prior to undertaking dissemination.

Section 4 - Ethical issues

4.1 Informed consent

Informed consent will be sought from all participants, including those who do not speak English as their first language. Please see Appendix 1 for Patients Informed Consent form, and Appendix 9 for Professional Informed Consent form. Participants will be sent an information form detailing the aims of the study and explaining why they are being asked to take part, giving them at least one week to consider this. Where necessary, translations into other languages will be produced, as far as possible in accordance with Bhopal et al.'s (2004) and Birbili's (2000) translation guidance (see Appendix 5), ensuring that conceptual equivalence is achieved, rather than mere literal translation, and that an understandable level of language is used (i.e. not overly formal or 'high'). Participants will be asked to sign and return the Consent form using a pre-paid envelope. Before interviews commence, an opportunity will be provided for potential participants to ask questions prior to deciding whether to take part, to ensure that fully informed consent is given. In the event that a participant is unable to read and write, the principal researcher will, through the NHS interpreter if appropriate, ensure thorough comprehension and the participant's mark will be obtained on the consent form.

4.1.1: Payment of participants

We will fund High Street vouchers for all patient participants – a £~~5~~20 voucher per participant. We will also cover participants' travel expenses, although these are expected to be minimal, as interviews will be conducted at a place convenient to the participant.

4.2 Identity protection for participants

Only the regional screening teams will know which practices are eligible participate, but they will not be informed which practices or patients/professionals have consented to participate. When the data are presented, practice and participant identities will be disguised (for example, by number or pseudonym) to protect the identities of all participants and the case.

4.2.1 Data security

Throughout the study the researcher will strictly follow data protection legislation (Data Protection Act 1998 and subsequent amendments) and University of Warwick Research Governance procedures. Recordings of interviews will be kept in a locked filing cabinet at Warwick Medical School and destroyed when the research is finished (estimated at August 2012). Interview transcripts will identify individuals by ID number or pseudonym only. These will be kept in a locked filing cabinet for 3 years, to ensure that study data are available for research and dissemination purposes. Demographic sheets that could identify participants will not be stored with interview recordings or transcripts, but in a separate, locked, filing

cabinet. Any data entered onto a computer will be password protected and will identify individuals by ID number or pseudonym only.

4.3 Safety issues

4.3.1 Participant safety

No distress is likely to occur to participants as a result of taking part in this study.

Discussions with Regional Screening Leads will ensure that no coercion is used to involve potential participants. During recruitment and again prior to taking part in the research interview, potential participants will be informed that taking part is voluntary and that they may withdraw at any time, without giving the reason, until the end of the study. Potential participants will also be advised that withdrawing will have no adverse effect on their treatment (patients) or work (professionals). However, in the unlikely event that any participant should appear distressed, the following steps would be taken:

- The lead researcher, a psychologist, would listen empathically to the individuals' concerns.
- The telephone numbers of voluntary organisations, such as Diabetes UK (0845 120 2690) could be provided if necessary.
- The researcher would offer to contact a family member or friend, if required.

Should participants have any questions or concerns regarding their healthcare, they will be referred to their GP practice or local Patient Advice Liaison Service (PALS) as appropriate.

4.3.2 Researcher safety

The research interviews with people with diabetes and health/screening professionals may be conducted in NHS premises, where no risks are anticipated to occur. The researcher will not access these establishments without the express permission of the individuals responsible for managing them. Some of the interviews with people with diabetes may need to take place in participants' homes if, for example, a patient's condition limits their ability to travel or access the NHS premises. However, this raises the issue of ensuring researcher safety whilst in participants' homes. Although it is unlikely that there will be any threat to the researcher's safety, the following steps will be observed to further minimise the risk:

- The researcher will advise one of the research team of any interview that is scheduled to take place in a participant's home;
- The participants' name, address and telephone number will be given to that member of the supervisory team for the sole purpose of ensuring researcher safety and will be destroyed when that interview has finished;
- The researcher will provide an estimated time of interview completion, allowing between approximately 1 hour and 2 hours 30 minutes;

- The researcher will telephone the supervisor when the interview is complete, to confirm her safety.
- Should the supervisor not receive the confirmatory phone call within the maximum time, s/he will first telephone the researcher's mobile number and if there is no response, take appropriate action.

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APPENDIX 1: Declaration of Informed Consent

(Patients; v2)

Participant ID number……

		Please tick
1.	I have read and understand the 'Patient Information Sheet (v3.1)'.	□
2.	I understand that taking part in this study will involve me being interviewed, providing some personal information, and two short surveys.	□
3.	I understand that the discussion will be recorded and that the recording will be destroyed at the end of the study.	□
4.	I understand that there are no known expected discomforts or risks involved in my participation in this study.	□
5.	I understand that I am free to withdraw from the study at any time prior to the end of the study, without giving a reason, by contacting the e-mail address or telephone number below. This will not affect my care.	□
6.	I give my permission for my GP practice and the Diabetic Retinopathy Screening team to provide access to my diabetes records and that this will be used for the purposes of this research only.	□

If you would prefer to be interviewed in a language other than English, this can be arranged. Please state the language you wish to use in an interview:……..

I give my informed consent to take part in this study. I understand that although a record will be kept of my participation in the study, my data will be identified by a number or an alternative name (pseudonym) only.

Signed …… Dated ……

Name (please print in full) .....

Phone number(s) .....

Email address: .....

Address:.....

.....Post code: .....

(We will only use this information to contact you about the study)

Please sign this form & return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk
In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 2: Patients Demographic Data Collection

(Patients; v2)

IN CONFIDENCE

Participant ID number……

This sheet will be stored separately from all other information, to protect your identity

1. **Date of birth** (please write in): Date ..... Month…….. Year……

2. **Sex** (please circle one): Male/Female

3. **What type of diabetes do you have?** (Please tick one):

   Type 1 Diabetes ☐ Type 2 Diabetes ☐

4. **Do you have any other long term conditions?** (Please tick one): Yes/No
   If yes, please state what these are: .....

   .....

5. **Which of the following groups do you consider that you belong to?** (Pease tick one)

White British	□	White Irish	□	White other	□
Black African	□	Black Caribbean	□	Black other	□
Indian	□	Pakistani	□	Bangladeshi	□
Chinese	□	Other	□	Please state.....	

6. **What type of work do/did you do?** .....

   .....

7. **What is the highest level of qualification you have?** .....

   .....

Thank you for your help!

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 3: Patients Information Sheet

(v3.1)

1. Study Title:

Understanding *F*actors leading to *L*ow *U*ptake of diabetic *R*etinopathy sc*R*eening in pr*I*mary care (*FLURRI* study)

2. Invitation:

You are invited to take part in a research study that is being conducted as part of a two year project at the University of Warwick. Before you decide whether to take part or not, you should understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask us if anything is unclear or if you would like more details. Our contact details are at the bottom of every page and in sections 12 and 13. Thank you for reading this information sheet.

3. What is the purpose of this study?

People with diabetes sometimes develop problems with their eyes that can lead to vision loss and blindness. This damage to the eye is known as Diabetic Retinopathy and can be detected early through screening, which involves patients having digital photographs taken of their eyes. These photographs can identify early signs of damage caused by diabetes, before the patient becomes aware of any symptoms. Research has shown that people who attend the Diabetic Retinopathy Screening Programme are less likely to suffer loss of vision or blindness, compared with people who don't attend, because they receive their treatment sooner when less damage has occurred. For more information, please see the enclosed leaflet.

At present, not everyone who is entitled to take part in the screening, actually attends. This research aims to find out why this is, and what would encourage more people to have their eyes photographed every year. The results will be given to the Diabetic Retinopathy Screening Programme managers, so that they are aware of the issues that have been raised. You will not be identifiable as we will keep your personal details confidential and protect your identity.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

4. Why have I been chosen?

You may have offered to take part after hearing about the study in the local media, or at your GP practice. You are eligible to take part if ~~because~~ you have been diagnosed with diabetes, and have previously been asked to have photographs taken of the back of your eyes (we will confirm this with your care team once we have received your signed Consent Form). Your experiences of this process may help us to understand what influences people's decisions whether or not to go to the screening.

We are asking for the views of people with diabetes who always attend their diabetic eye screening, those who don't always attend their screening, and will also be asking the views of health professionals involved in the screening programme.

5. Do I have to take part?

It is entirely up to you to decide if you want to take part or not. If you do decide to take part, you will be given this information sheet to keep and asked to sign a form, enclosed, saying that you agree to take part (consent form). You will be free to withdraw from the study at any time before the end of the study (estimated at August 2012), without giving a reason – this will not make any difference to the treatment that you receive. A decision to withdraw or not to take part will not be passed on to your medical team.

If we have already collected information from you and you choose to withdraw, we will destroy all the information we hold for you and not use it in the study.

6. What will I have to do?

You are being asked to take part in a research interview, which will last half an hour. This will probably take place at your GP practice, or other venue of your choice (to be confirmed), or by telephone. We will be able to pay your travelling expenses and you will receive a £205 gift voucher. You will be asked about your experiences of living with diabetes, what you feel might encourage more people to go to the Diabetic Retinopathy Screening Programme and what might put people off going to it.

Before you start talking to the researcher, you will be given a form to fill in with your personal details; the researcher can help you with this if necessary. You will also be asked to fill in two short surveys, which will ask you a few questions about any support that you might get from other people, and aspects of living with diabetes that you find difficult; the researcher can help you with this if necessary. These forms take no more than 15 minutes to complete. Patients come from lots of different backgrounds, so have very different experiences that can affect their diabetes and lead to different views about diabetic eye screening, which we are interested in. We will also ask your GP practice to send us the result of you most recent blood glucose test.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

You will be asked to agree to the discussion being audio recorded (the recording will be destroyed at the end of the study). The recording will then be put into writing and your views will be carefully considered, along with the other participants' views. Any paperwork that is produced as a result of this research study (for example, for the Diabetic Retinopathy Screening Programme management) will refer to you by an ID number only (e.g. 'participant number 10'), or an alternative name (pseudonym).

7. What are the possible disadvantages of taking part

The only disadvantage is likely to be the time that it takes for you to participate in the interview. No other disadvantages are expected.

8. What are the possible advantages of taking part?

The views of everyone who talks to us will be considered carefully. These views will be used to suggest improvements to the Diabetic Retinopathy Screening Programme organisers (we will refer to you by an ID number or an alternative name only). The information we get from this study may help other people in future. You may learn more about your diabetes and eyes and this may help your health. We will give you a £520 voucher at the end of the research interview.

9. Will anyone else know I have done this?

Only the lead researcher/interviewer and the member of staff at your GP surgery who sent you this information pack will know exactly who has been invited to take part. Your name or details will not be given to anyone else – you will only be referred to by participant ID number or an alternative name (pseudonym) in any paperwork. So the Diabetic Retinopathy Screening Programme management, hospital specialist etc. will not know that you have done this. No-one else will be told exactly who has taken part. All information will be treated confidentially. Only the research team will have access to your personal details, the audio recording and the written copy of our conversation, which will be kept in locked filing cabinets. The recordings will be password protected and erased at the end of the study (estimated at December 2012). The Data Protection Act (1998) will be followed at all times. The only circumstance in which we might have to pass your details to another person, is if you disclose illegal behaviour. In this case, we will be obliged to inform the authorities, to deal with the matter appropriately. However, such a disclosure will not be shared with anyone else if this not necessary.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

10. Who is organising and funding the research?

This research is being organised by the Gloucestershire Hospitals NHS Foundation Trust and Warwick Medical School at the University of Warwick. It is funded by the NHS National Institute for Health Research's *Research for Patient Benefit Programme*. It has been approved by the NHS Research Ethics Committee, and the NHS trust whose area you live in.

11. What happens to the results of the study?

A summary of the results of the research will be sent to all participants later in the project. The research findings will be passed to the team who organise the English National Diabetic Retinopathy Screening Programme, so that they can see what needs to be done to help more people with diabetes to attend their eye photography. The results will also be distributed at relevant professional conferences, so other people can benefit from your views (you will be identified by an ID number or pseudonym only).

12. I have some questions. Whom can I ask?

If you have any questions, now or at any point in the research, please contact the principal researcher, Alison Hipwell, telephone 024 761 51405, or email a.e.hipwell@warwick.ac.uk.

13. What if something goes wrong?

If you are unhappy about any aspect of this study, you may complain to the University of Warwick. The University has comprehensive public liability insurance. Any complaint should be addressed to

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

14. What do I do now?

If you want to take part in this research, please sign both copies of the Declaration of Informed Consent. Keep one for your records ***and return the other in the envelope provided*** (it does not need a stamp).

Thank you for reading this!

If you want to take part in the research, please sign the enclosed Consent Form, and return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 4: Patients Provisional Interview Schedule

(v23)

- Tell us about yourself and your life at present (Prompts: living alone/ with others; working, caring or retired; social activities)
- Can you describe a typical day living with diabetes? (Prompts: Examples of how it affects your daily life? Compared to how you were before becoming ill/other people who are well?)
- Can you describe a good/bad day living with diabetes?
- Is there anything that you can do to improve your experience of living with diabetes?
- When did you last see your nurse/ GP about you diabetes - and what did you talk about?
- What do you know about eye screening & diabetes?
- How did you first find out about diabetic eye screening?
- Do you know why are you asked to go?
- How do you know when and where you should go?
- Do you know what it involves? (For those who did attend screening: describe in as much detail as possible the last screening they went to)
- How does this screening fit in with the rest of your diabetes care and treatment?
- What happens after your screening – how do you find out your results?
- Have you ever missed an eye screening appointment?
- Have you ever needed any further treatments on your eyes? How did you find out what you needed, what your options were?
- What do you think is responsible for any deteriorating eye sight you might have? Why
- Are there any changes to the service that you could suggest - from invitation to screening, receiving results/treatments options etc. that would make the screening process better for you? (E.g. link with opticians at annual eye test)
- **How would you feel about going once every two years, instead of annually?**
- What would you like to be able to do differently, that would make the screening process better for you?
- What (if anything) puts you off going?

- Have you ever been invited for any other type of health screening e.g. cervical/ breast /bowel – if so, how does it compare?
- **Is there anything you'd like to add that we haven't covered in the interview?**

APPENDIX 5: Translation and Interpreting Protocol

(v1)

A5.1 Study Materials Translation

The language(s) that study materials will need to be translated into is not yet confirmed. As the cost of having all materials professionally translated is prohibitive, the following has been adapted from Bhopal et al. (2004) principles for adapting written research materials into different languages and Birbili's (2000) translating guidance:

- A bilingual person who understands the target language and culture will translate the study's materials into the target language, ensuring conceptual equivalence (not simple literal translation) is achieved;
- As the bilingual person may not be representative of the target population because of education, age, sex etc., if possible, a representative of the target population will assess meaning and acceptability of the translated materials and modifications will be suggested;
- The bilingual person will amend materials as appropriate, comparing translations with the original English-language materials, to ensure conceptual equivalence is maintained;
- A second bilingual person who understands the target language and culture will validate the materials using the target language and English materials;
- The two bilingual people and the principal researcher will meet (if possible) to discuss the back-translations, negotiating a "best fit" to ensure conceptual equivalence is maintained;

  The resultant materials will be piloted with at least two monolingual members of the target population (if possible) to check face and content validity, with further changes suggested if necessary;
- The bilingual people and the principal researcher will again discuss the suggested modifications and amend materials as appropriate, comparing translations with the original English-language materials, to ensure conceptual equivalence is maintained.

A5.2 Non-English-language data-collection

It is anticipated that some potential participants will want to be interviewed in a language other than English, and they are asked to indicate their language of choice on the consent form, before returning it. Funding exists to cover the cost of interpreters for interviews. A three-way interview with AH (interviewer), the participant and an interpreter will allow detailed data-collection to be undertaken in accordance with ethical guidelines. The procedure, used by Hipwell (2009), is represented diagrammatically, in Figure A5.1:

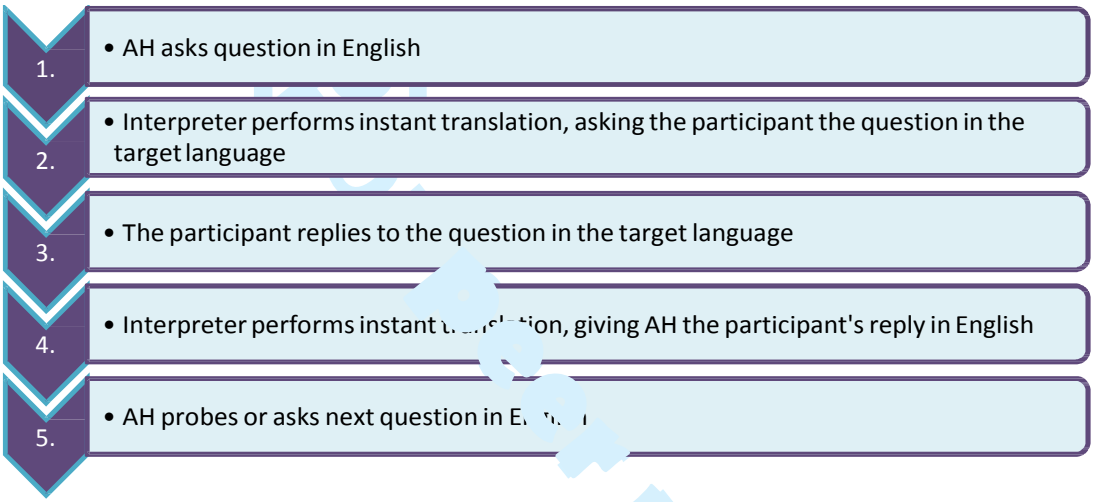

Figure A5.1: Three-way interview process

This three-way interview process will allow participants to convey their experiences to me effectively.

A5.3 Data validation process

Full back translation will be too time and resource inefficient for the current study, therefore an acceptable method of validating the interpreter's work, used by Hipwell (2009), will be used. Following verbatim transcription of the English-language sections of the interviews, a research-trained, fluent speaker of the target language(s) will be employed to validate the accuracy of the translated transcripts, using the audio files and the English transcripts. The 'track changes' function of Microsoft Word will be used by the validator to highlight any areas where discrepancies may have occurred, to alert the researchers conducting the analysis. The interpreter and validator will both be paid the appropriate hourly professional rate for this work.

APPENDIX 6: Health Professionals Demographic Data Collection

(V2)

IN CONFIDENCE

Participant ID number……

1. **Date of birth**: Month……..…… Year……..

2. **Sex** (please circle one): Male/Female

3. **What is your role with the English National Diabetic Retinopathy Screening Programme?**

Screening only □ Grading only □ Screening & grading □

Trainer □ Programme manager □ Optometrist □

GP □ Specialist nurse □ Practice manager □

Health Care Asst □ Other (please state) □ .....……..

4. **How long have you been working with diabetic retinopathy patients in this role?** (Please tick one):

Less than one year □ One to three years □ More than three years □

5. **Which area of the country do you mostly work in** (Please tick one):

Gloucestershire□ Birmingham □ Coventry & Warwicks □

Other (please state) □ .....……..

Thank you for your help!

This sheet will be stored separately from all other information, to protect your identity

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 7: Health Professionals Information Sheet

(Health professionals v~~2~~3)

1. Study Title:

Understanding Factors leading to Low Uptake of diabetic Retinopathy scReening in prImary care (FLURRI study)

2. Invitation:

You are invited to take part in a research study that is being conducted as part of a two year project by the University of Warwick and your local screening programme, funded by the National Institute of Health Research's Research for Patient Benefit Programme. Ask us if anything is unclear or if you would like more details. Our contact details are at the bottom of every page and in sections 12 and 13. Thank you for reading this information sheet.

3. What is the purpose of this study?

As you will be aware, people with diabetes can develop sight-threatening diabetic retinopathy (DR). Retinopathy screening can identify early signs of damage whilst patients are asymptomatic of DR. Research has shown that people who attend the Diabetic Retinopathy Screening Programme are less likely to suffer loss of vision or blindness, compared with people who don't attend (Gray, 2009). However, DR screening uptake varies across different GP and optometry practices across the country. This research aims to find out why this is, and what would encourage more people to attend their annual DR screening. The results will be given to the DR Screening Programme managers, so that they are aware of the issues that have been raised.

4. Why have I been chosen?

You have been chosen because you have been identified as a health professional who works with patients diagnosed with diabetes and the DR screening programme. Your experiences of this process may help us to understand what influences people's decisions whether or not to attend for screening. We are also asking for the views of people with diabetes who always attend their diabetic eye screening, those who rarely attend their screening, and other health professionals involved in the screening programme.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

5. Do I have to take part?

Participation in this research is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. You will be free to withdraw from the study at any time prior to the end of the study without giving a reason. If you do not wish to participate, or if you choose to withdraw from the study at a later date, it will have no detrimental effect on your employment. If we have already collected information from you and you choose to withdraw, we will destroy all the information we hold for you and not use it in the study.

6. What will I have to do?

You are being asked to take part in a research interview, which will last around half an hour. This will probably take place at your workplace, or other venue of your choice (to be confirmed). You will be asked about your experiences of dealing with patients who have diabetes, what you feel might encourage more people to attend the DR Screening Programme and what might put people off going to it.

Before you start talking to the researcher, you will be given a form to fill in with your personal details. Health professionals have many different experiences, and might have different views about diabetic eye screening. You will be asked to agree to the discussion being recorded. The recording will then be put into writing and carefully considered, along with the other participants' views. Any paperwork that is produced as a result of this research study (for example, for the Diabetic Retinopathy Screening Programme management) will refer to you by an ID number only (e.g. 'participant number 10'), or an alternative name (pseudonym).

7. What are the possible disadvantages of taking part

The only disadvantage is likely to be the time that it takes for you to participate in the interview. No other disadvantages are expected.

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

8. What are the possible advantages of taking part?

The views of everyone who talks to us will be considered carefully. These views will be used to suggest improvements to the Diabetic Retinopathy Screening Programme organisers (we will refer to you by an ID number or pseudonym only). The information we get from this study may help other people in future.

9. Will anyone else know I have done this?

Only the principal researcher/interviewer will know exactly who has taken part. Your name or details will not be given to anyone else. So neither the Diabetic Retinopathy Screening Programme organisers, nor your PCT management or Commissioners, will know who has participated in this. No-one else will be told who has taken part. All information will be treated confidentially. Only the principal researcher will have access to your personal details and the recording, and only the principal researcher, study director and the data analyst will have access to the anonymised written copy of our conversation, which will be kept in a locked filing cabinet. The digital recordings will be password protected and erased at the end of the study (estimated at December 2012). The Data Protection Act (1998) will be followed at all times.

The only circumstances in which we might have to pass your details to another person, are if you disclose either unprofessional or illegal behaviour. In these cases, we will be obliged to inform your employing organisation, to be dealt with be dealt with appropriately. However, such a disclosure will not be shared with your peers or managers if this not necessary.

10.What happens to the results of the study?

A summary of the results of this phase of the research will be sent to all participants later in the project. The research findings will be passed to the team who organise the English National Diabetic Retinopathy Screening Programme, so that they can see what needs to be done to help more people with diabetes to attend their eye photography. The results will also be distributed at relevant professional conferences, so other people can benefit from your views (you will be identified by an ID number or pseudonym only).

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

11.I have some questions. Whom can I ask?

12.Who is organising and funding the research?

This research is being organised by the Gloucestershire Hospitals NHS Foundation Trust and Warwick Medical School at the University of Warwick. It is funded by the NHS National Institute for Health Research's *Research for Patient Benefit Programme*. It has been approved by the NHS Research Ethics Committee, and the NHS trust whose area you work in. If you have any questions, now or at any point in the research, please contact the principal researcher, Alison Hipwell, telephone 024 761 51405, or email a.e.hipwell@warwick.ac.uk.

13. What if something goes wrong?

If you are unhappy about any aspect of this study, you may complain to the University of Warwick. The University has comprehensive public liability insurance. Any complaint should be addressed to the study director, Dr Jackie Sturt by telephone 024 765 73753 or email jackie.sturt@warwick.ac.uk.

14. What do I do now?

If you want to take part in this research, please sign both copies of the Declaration of Informed Consent. Please keep one for your records ***and return the other in the envelope provided*** (it does not need a stamp).

Thank you for reading this!

If you want to take part in the research, please sign the enclosed Consent Form, and return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 8: Health Professionals Provisional Interview Schedule

(v1)

Primary Care and Screening Professional Interview schedule: The interview schedule will include questions probing the following:

- What is your role in the diabetic retinopathy screening programme? What routines and procedures does it involve you doing?
    - perceptions of relative usefulness of procedures
- Do you know how many patients attend for retinal screening here? What do you think influences this?
- Do you know what information patients receive about retinal screening, what's involved, why it's important for them? (Patient information/preparation for retinal screening)
- From your perspective, what happens when the patient attends for screening?
    - What (if anything) do you have to do if they don't attend?
- Are you involved in informing patients about the results and any further actions?
- Are there any changes that you can suggest to improve the way your patients are invited to / informed about retinal screening and the service delivered, which would improve uptake?
- Are there any changes that you can suggest regarding (this) practice's response to patients, following communication of screening results?
- How important do you feel retinal screening is for patients alongside their other diabetes screening activity (Prioritisation)
- Why do you think some patients don't attend?
- How big a part of your job is retinal screening?
- How useful do you think the screening results are for informing future patient care?
- **What do you think about screening once every two years, instead of annually?**
- Is there anything you'd like to add that we haven't covered in the interviews?

APPENDIX 9: Declaration of Informed Consent

(Professionals; v3)

Participant ID number……

Please tick

1. I have read and understand the 'Professionals Information Sheet (v3)'. □
2. I understand that taking part in this study will involve me being interviewed and providing some personal demographic information. □
3. I understand that the discussion will be recorded and that the recording will be destroyed at the end of the study. □
4. I understand that there are no known expected discomforts or risks involved in my participation in this study. □
5. I understand that I am free to withdraw from the study at any time prior to the study's end, without giving a reason, by contacting the e-mail address or telephone number below. □

I give my informed consent to take part in this study. I understand that although a record will be kept of my participation in the study, my data will be identified by a number or an alternative name (pseudonym) only.

Signed …… Dated ……

Name (please print in full) .....

Phone number(s) .....

Email address: .....

Address:.....

.....Post code: ..... *(We will only use this information to contact you about the study)*

Please sign this form & return it in the envelope provided

In case of any query, please contact the lead researcher: Alison Hipwell 02476 151405 or a.e.hipwell@warwick.ac.uk

In case of complaint, please contact Nicola Owen 024 7652 2785 or Nicola.Owen@warwick.ac.uk

APPENDIX 10: Scales

A10.1 The Problem Areas in Diabetes Scale

Which of the following diabetes issues are currently problems for you? Please circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Not having clear and concrete treatment goals for your diabetes care?	0	1	2	3	4
Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
Feeling scared when you think about living with diabetes?	0	1	2	3	4
Uncomfortable social situations related to your diabetes (e.g. other people telling you what to eat)?	0	1	2	3	4
Feelings of deprivation regarding food and meals	0	1	2	3	4
Feeling depressed when you think about living with diabetes?	0	1	2	3	4
Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
Feeling overwhelmed by your diabetes?	0	1	2	3	4
Worrying about low blood sugar reactions?	0	1	2	3	4
Feeling angry when you think about living with diabetes?	0	1	2	3	4
Feeling constantly concerned about food and eating?	0	1	2	3	4
Worrying about the future and the possibility of serious complications?	0	1	2	3	4
Feeling guilty or anxious when you get off track with your diabetes management?	0	1	2	3	4
Not "accepting" your diabetes?	0	1	2	3	4
Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
Feeling that diabetes is taking up too much mental and physical energy?	0	1	2	3	4
Feeling alone with diabetes?	0	1	2	3	4
Feeling that friends/family are not supportive of your diabetes management efforts?	0	1	2	3	4
Coping with complications of diabetes?	0	1	2	3	4
Feeling burned out by the constant effort to manage diabetes?	0	1	2	3	4

Box A10.1: The Problem Areas in Diabetes (PAID) 20-item scale (from Snoek et al., 2000)

A10.2 The Social Support Questionnaire

The SSQ investigates the number of perceived social supports in a person's life, and the level of satisfaction with each of these. The latter is again rated on a six-point Likert scale, indicating the current level of satisfaction with that item.

1) How many people are there that you can trust, talk to frankly and share your feelings with? _ (please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

2) How many people are there that you can lean on and turn to in times of difficulty? _____(please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

3) How many people are there that give you practical help? _ (please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

4) How many people are there that you can spend time with socially? _ (please write in)

How satisfied are you with this type of support in your life? (please circle one)

Very satisfied	Fairly satisfied	A little satisfied	A little dissatisfied	Fairly dissatisfied	Very dissatisfied

APPENDIX 11: Letter to GP

Warwick Medical School

Date

GP name

Surgery name

Street name

Town
County

Post code

Dear *GP name,*
Re: *Patient name,* FLURRI study

I wish to inform you that your patient, above, has participated in the FLURRI study (Understanding ***F***actors leading to ***L***ow ***U***ptake of diabetic ***R***etinopathy sc***R***eening ***I***n Primary Care).

Please see the enclosed information for further details.

Yours sincerely,

Jackie Sturt

(Encs: Patient Information Sheet, Demographic data-collection, PAID & SSQ Scales, Informed consent)

Dr Jackie Sturt
Associate Professor in Social & Behavioural Sciences
Primary Care Research Group lead
Principal Investigator, *FLURRI* study
Division of Metabolic & Vascular Health
Warwick Medical School
University of Warwick
Coventry CV4 7AL
Direct line (+44) 02476 573753
Email Jackie.sturt@warwick.ac.uk

APPENDIX 12: GP Flyer V3

Diabetes?

- Too busy with work or family to go to your **eye screening**?
- Don't like having it done?
- ***Another reason for not going?***

We'd like to talk to you for **about ½ an hour:**

we'll give you a

£20 High Street voucher!!

- ➢ **We're trying to find what puts off people like you, who live around here, from having your annual diabetes eye screening photos**
- ➢ **No-one from your GP surgery, the hospital, or the diabetes eye screening service will know what you say**
- ✡ **We'll use patients' experiences of problems and ideas for how eye screening can be made better, to improve the service**
- ✡ **We are a group of researchers from Warwick Medical School**

If you're interested in talking to us, please call
Alison Hipwell for an informal chat: **02476 151 405**
Or email: **a.e.hipwell@warwick.ac.uk**

Patients Semi-structured Interview Schedule (v3)

- Tell us about yourself and your life at present (Prompts: living alone/ with others; working, caring or retired; social activities)
- Can you describe a typical day living with diabetes? (Prompts: Examples of how it affects your daily life? Compared to how you were before becoming ill/other people who are well?)
- Can you describe a good/bad day living with diabetes?
- Is there anything that you can do to improve your experience of living with diabetes?
- When did you last see your nurse/ GP about you diabetes - and what did you talk about?
- What do you know about eye screening & diabetes?
- How did you first find out about diabetic eye screening?
- Do you know why are you asked to go?
- How do you know when and where you should go?
- Do you know what it involves? (For those who did attend screening: describe in as much detail as possible the last screening they went to)
- How does this screening fit in with the rest of your diabetes care and treatment?
- What happens after your screening – how do you find out your results?
- Have you ever missed an eye screening appointment?
- Have you ever needed any further treatments on your eyes? How did you find out what you needed, what your options were?
- What do you think is responsible for any deteriorating eye sight you might have? Why
- Are there any changes to the service that you could suggest - from invitation to screening, receiving results/treatments options etc. that would make the screening process better for you? (E.g. link with opticians at annual eye test)
- How would you feel about going once every two years, instead of annually?
- What would you like to be able to do differently, that would make the screening process better for you?
- What (if anything) puts you off going?
- Have you ever been invited for any other type of health screening e.g. cervical/ breast /bowel – if so, how does it compare?
- Is there anything you'd like to add that we haven't covered in the interview?

Health Professionals Provisional Interview Schedule (Primary Care and Screening Professionals) (v1)

- What is your role in the diabetic retinopathy screening programme? What routines and procedures does it involve you doing?
    - perceptions of relative usefulness of procedures
- Do you know how many patients attend for retinal screening here? What do you think influences this?
- Do you know what information patients receive about retinal screening, what's involved, why it's important for them? (Patient information/preparation for retinal screening)
- From your perspective, what happens when the patient attends for screening?
    - What (if anything) do you have to do if they don't attend?
- Are you involved in informing patients about the results and any further actions?
- Are there any changes that you can suggest to improve the way your patients are invited to / informed about retinal screening and the service delivered, which would improve uptake?
- Are there any changes that you can suggest regarding (this) practice's response to patients, following communication of screening results?
- How important do you feel retinal screening is for patients alongside their other diabetes screening activity (Prioritisation)
- Why do you think some patients don't attend?
- How big a part of your job is retinal screening?
- How useful do you think the screening results are for informing future patient care?
- What do you think about screening once every two years, instead of annually?
- Is there anything you'd like to add that we haven't covered in the interview?

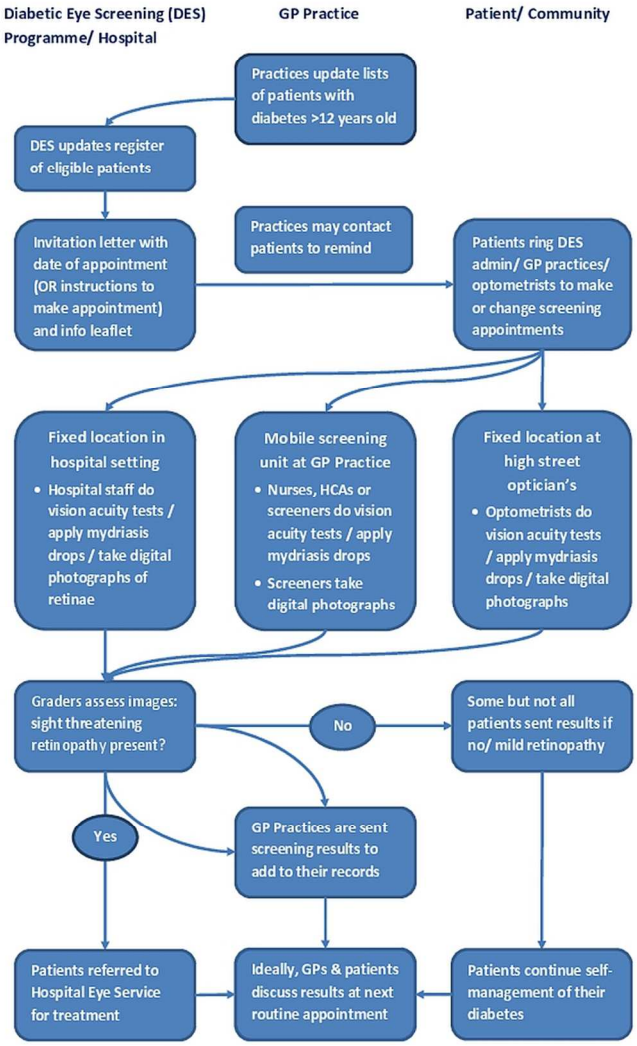

Figure 1: Diabetic Eye Screening Programme delivery modes

90x116mm (300 x 300 DPI)

APPENDIX 1

Patients Semi-structured Interview Schedule (v3)

- Tell us about yourself and your life at present (Prompts: living alone/ with others; working, caring or retired; social activities)
- Can you describe a typical day living with diabetes? (Prompts: Examples of how it affects your daily life? Compared to how you were before becoming ill/other people who are well?)
- Can you describe a good/bad day living with diabetes?
- Is there anything that you can do to improve your experience of living with diabetes?
- When did you last see your nurse/ GP about you diabetes - and what did you talk about?
- What do you know about eye screening & diabetes?
- How did you first find out about diabetic eye screening?
- Do you know why are you asked to go?
- How do you know when and where you should go?
- Do you know what it involves? (For those who did attend screening: describe in as much detail as possible the last screening they went to)
- How does this screening fit in with the rest of your diabetes care and treatment?
- What happens after your screening – how do you find out your results?
- Have you ever missed an eye screening appointment?
- Have you ever needed any further treatments on your eyes? How did you find out what you needed, what your options were?
- What do you think is responsible for any deteriorating eye sight you might have? Why
- Are there any changes to the service that you could suggest - from invitation to screening, receiving results/treatments options etc. that would make the screening process better for you? (E.g. link with opticians at annual eye test)
- How would you feel about going once every two years, instead of annually?
- What would you like to be able to do differently, that would make the screening process better for you?
- What (if anything) puts you off going?
- Have you ever been invited for any other type of health screening e.g. cervical/ breast /bowel – if so, how does it compare?
- Is there anything you'd like to add that we haven't covered in the interview?

APPENDIX 2

Health Professionals Provisional Interview Schedule (Primary Care and Screening Professionals) (v1)

- What is your role in the diabetic retinopathy screening programme? What routines and procedures does it involve you doing?
    - perceptions of relative usefulness of procedures
- Do you know how many patients attend for retinal screening here? What do you think influences this?
- Do you know what information patients receive about retinal screening, what's involved, why it's important for them? (Patient information/preparation for retinal screening)
- From your perspective, what happens when the patient attends for screening?
    - What (if anything) do you have to do if they don't attend?
- Are you involved in informing patients about the results and any further actions?
- Are there any changes that you can suggest to improve the way your patients are invited to / informed about retinal screening and the service delivered, which would improve uptake?
- Are there any changes that you can suggest regarding (this) practice's response to patients, following communication of screening results?
- How important do you feel retinal screening is for patients alongside their other diabetes screening activity (Prioritisation)
- Why do you think some patients don't attend?
- How big a part of your job is retinal screening?
- How useful do you think the screening results are for informing future patient care?
- What do you think about screening once every two years, instead of annually?
- Is there anything you'd like to add that we haven't covered in the interview?