Personalising screening of sight-threatening diabetic retinopathy - qualitative evidence to inform effective implementation

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Abstract

Background: Internationally, systematic screening for sight-threatening diabetic retinopathy (STDR) usually includes annual recall. Researchers and policy-makers support extending screening intervals, citing evidence from observational studies with low incidence rates. However, there is little research around the acceptability to people with diabetes (PWD) and health care professionals (HCP) about changing eye screening intervals.

Methods: We conducted a qualitative study to explore issues surrounding acceptability and the barriers and enablers for changing from annual screening, using in-depth, semi-structured interviews analysed using the constant comparative method. PWD were recruited from general practices and HCPs from eye screening networks and related specialties in North West England using purposive sampling. Interviews were conducted prior to the commencement of and during a randomised controlled trial (RCT) comparing fixed annual with variable (6, 12 or 24 month) interval risk-based screening.

Results: Thirty PWD and 21 HCP participants were interviewed prior to and 30 PWD during the parallel RCT. The data suggests that a move to variable screening intervals was generally acceptable in principle, though highlighted significant concerns and challenges to successful implementation. The current annual interval was recognised as unsustainable against a backdrop of increasing diabetes prevalence. There were important caveats attached to acceptability and a need for clear safeguards around: the safety and reliability of calculating screening intervals, capturing all PWDs, referral into screening of PWDs with diabetic changes regardless of planned interval. For PWDs the 6-month interval was perceived positively as medical reassurance, and the 12-month seen as usual treatment. Concerns were expressed by many HCPs and PWDs that a 2-year interval was too lengthy and was risky for detecting STDR. There were also concerns about a negative effect upon PWD care and increasing non-attendance rates. Amongst PWDs, there was considerable conflation and misunderstanding about different eye-related appointments within the health care system.

Conclusions: Implementing variable-interval screening into clinical practice is generally acceptable to PWD and HCP with important caveats, and misconceptions must be addressed. Clear safeguards against increasing non-attendance, loss of diabetes control and alternative referral pathways are required. For risk calculation systems to be safe, reliable monitoring and clear communication is required.

Background

The rising prevalence of diabetes over the past 30 years presents challenging health impacts and costs to individuals, health care systems and wider society. Prevalence rates in the UK rose from 3.2 million people (6% of adults) in 2013 to 4.7 million in 2019, and expected to rise to 5.5 million by 2030 [1,2] Prevalence rates are increasing more rapidly in low and middle income countries.[3] Having diabetes can involve a number of related health issues, including diabetic retinopathy (DR). DR is a major cause of

vision impairment among adults worldwide and is the third most important cause of visual loss in England and Wales.[4]

UK NHS eye screening programmes have offered annual screening to all people with diabetes (PWD) over the age of 12 years for around 10 years. These aim to detect sight threatening diabetic retinopathy (STDR) before it affects a person's sight and when timely, effective treatment can be provided. Evidence suggests that it may be safe to screen low-risk people at longer intervals,[5–11] and the interval has been extended in some countries.[12,13] However this evidence is not conclusive and is based largely on modelling rather than experimental research. In those countries, such as the Netherlands, Iceland and Hong Kong, with extended intervals the population being covered is significantly different. The shift towards varying screening intervals is not restricted to DR. For breast cancer there are moves to identify risk-stratified screening strategies to lower the rates of over diagnosis and to prevent deaths.[14] Such directions illustrate a general move within medicine to personalised health care and potentially to re-allocate resources to those most in need; in the case of DR screening focusing on non-attenders. Risk estimating equations have been developed to allow this personalisation in DR [15, 17] and in other specialties.[14,18] There has been little work on the impact on PWD of changing eye screening intervals and concern amongst health care professionals (HCP) about safety including reduced attendance and loss of diabetes control.[9]

We report upon a qualitative study with PWD and HCP designed to investigate and uncover enablers and barriers to changing from annual to personalised risk-based variable-interval screening and to gain wider insights into perceptions amongst users. Our aim was to develop a detailed understanding the acceptability of and enablers for, successful implementation of personalised screening in England and other countries with similar systems. We followed MRC guidance on developing and evaluating complex interventions. [19]

Methods

Setting: A programme of applied research is developing an enhancement to screening for STDR by introducing and testing an individualised or personalised approach based on measured patient-centred risk. A novel intervention was developed comprising variable-interval screening determined by a risk calculation engine (RCE) informed by real-time demographic, retinal and clinical data from the individual, referenced to local historical data. Intervals were allocated at 6, 12 or 24 months for high, medium or low risk respectively and recalculated at each screening appointment. A randomised controlled trial was designed to compare the efficacy and cost-effectiveness of this individualised approach to standard fixed interval screening.[20] A patient and public involvement (PPI) group was embedded in the programme. This setting allowed, for the first time, the real rather than theoretical investigation of the enablers and barriers around implementation of varying intervals, and the use of a risk calculator, in a population from an established screening programme and in a geographical location where annual fixed interval screening is already established.

Design: Semi-structured interviews [21,22] were conducted to gather views on variable-interval risk-based screening. Interviews with PWD were conducted prior to its implementation (Phase I, baseline) in the setting of the parallel RCT and subsequently with a second group (Phase 2) during the RCT. All interviews with HCP took lace prior to implementation.

The research team and the PPI group created interview topic guides. With PWD these covered understanding about diabetes, self-management, health services contact, responsibility for monitoring diabetes, links between diabetes and eye health and screening intervals. With HCP the guides focussed on diabetes services, current eye screening, future changes to eye screening and DNA rates. All participants received a brief overview of the individualised risk based variable interval screening intervention. Most patient interviews were conducted in participants' homes, though some chose to complete them in the researcher's university office, and one participant completed their interview in their own work office. HCPs were interviewed at their place of work. Interviews lasted between 30 to 90 minutes, with most lasting around 45 minutes.

Participants: PWD participants aged over 16 years attending the eye screening programme were identified in two GP practices in Liverpool. Suitability for participation was confirmed by a GP prior to a letter of invitation and patient information pack with reply slip being posted out. PWD who were interested in participating returned the reply slip or contacted the research team to make arrangements for an interview.

60 PWD were recruited, 30 to phase 1 (baseline) and 30 to phase 2 (post implementation of variable-interval risk-based screening). 34 of 60 were men and 8 had type 1 diabetes . Ages are shown in Table 1 (range 19 - 83). Times since diagnosis were: 1-5 years n=10, 6-10 years n=7, 11-15 years n=4 years, >15 years n=9; range 1 to 40 years. For phase 2, participant allocation to risk based screening intervals was: 6 months n=4, 12 months n=5, 24 months n=21.

PWD participants reported a range of social situations: the occupations described by the sample were very mixed, including a range of professionals as well as students and manual workers, retired and unemployed as well as one person who was unable to work due to long-term ill health.

Table 1

HCPs were identified by personal and professional networks of the research team. To help with time commitments HCPs could participate in individual interviews, in groups, or by completing an open-ended questionnaire to be returned by email. Interviews were conducted at the HCPs' place of work in a private office (one joint interview was completed at a participant's home). Most interviews lasted around 40 minutes. Six of the HCP participants were interviewed as three colleague pairs.

21 HCPs were recruited. 16 participated in interviews whilst five elected to complete questionnaires via email. Professional roles were: screener/grader n=7, consultant ophthalmologist (retina specialist) n=5,

eye screening service manager n=4, optometrist providing DR screening n=2, public health specialist n=2, general practitioner n=1.

Analysis: Interviews were audio-recorded and transcribed verbatim to enable detailed analysis. Semi-structured case summaries were produced by a researcher upon completion of each interview to provide a summary of key themes to enable identification of emerging themes to inform further data collection and analysis. After reading and re-reading the transcripts, data were analysed to identify sections of text that informed understandings of the issues.[23-25] Each concept was assigned a descriptive or analytical code, which was then combined into conceptual categories and broader themes. Each of the datasets were coded using NViVO software, which enabled searching and retrieval of specific data.

A framework approach was used to analyse the interview data. Once the key themes were identified, a number of charts were created, based upon the thematic analysis, to enable comparison of the datasets, taking a framework approach.[26,27] Data from individual participants were entered into cells within the chart to enable comparison on each theme at the level of individual participant and whether they were a PWD or HCP.

Results

Analysis of interviews with PWD and HCP participants identified several themes related to changing screening intervals: the acceptability of changing screening intervals; the safety of the RCE; the conditions and safeguards attached to 6, 12 and 24 months screening intervals; the macro impact of changing screening intervals.

1. Acceptability of changing screening intervals

The majority of PWDs in both Phase I and II expressed the view that variable risk-based screening intervals were potentially acceptable.

The views of PWD are illustrated in the following excerpts, where the concepts of pragmatism and diverting any cost savings towards other PWD who may need to be seen more often.

"…you know if they don't need them every year then yes, why do them every year. And so I would rely on the practitioner to make the best judgement." David (PWD)

"Personally, I don't have a problem with it, because you know you are either low, medium, or high risk, you have to be pigeon-holed somewhere." Vaughn (PWD)

"Yes, you know because if your eyes are not going to go any worse it is saving money and time isn't it, where, they can't fit everybody in can they….it saves all that money and so it gives other people a chance of getting seen doesn't it? So, I agree with that." Susan (PWD)

For HCP participants, the majority were also in favour of introducing variable risk-based screening intervals.

“I think it will be fantastic because as you say there are lots of patients that you can quite happily review in 2 years, or 18 months 2 years, so I think that would be a definite benefit.” Sally (HCP)

“I think in terms of resources it is a brilliant idea. Because obviously, being on this side of the fence, and seeing how stretched a service can become when they have got so many patients and the, you know everyone needs to be screened in 12 months yes that would take a lot of the pressure off.” Frankie (HCP)

“I don’t have any objections, as long as it is evidence based you know if there is evidence for it being 24 months, then I am fine. If there is evidence for a particular group being 10 years, you know if that what the evidence shows, I am very much things have to be supported by evidence.” Andrew (HCP)

However, implementing such changes to eye screening was accompanied by a range of caveats which are discussed below.

2. Safety of the Risk Calculation Engine (RCE):

Many of our participants (both PWD and HCP) indicated that they would be supportive of the introduction of risk-based allocation to variable screening intervals, on the condition or expectation of particular safeguards or service enhancements being introduced. For HCP, their concerns were focused on the safety of the RCE. Specifically, around the quality and availability of data from health care services, both primary and secondary care, into the RCE and any subsequent

“My main concern firstly would be if we could get, if the GPs would be returning that data.” (On which assessments of risk are made and patients are assigned a screening interval). Sara (HCP)

“One of my concerns would be getting the right information about the patient from the GPs, from hospitals.” (Sandy & Liz HCPs)

This issue of information quality and access was mentioned only briefly by a small number of PWD participants, as might be anticipated given their limited exposure to NHS information systems.

“My only slight concern would be how up to date would the information in the (risk) engine [1] if you like would be, in terms of making that decision. And would it be an annual decision that the software made?” (Kevin PWD, Phase 2)

As illustrated above, understanding when the RCE would calculate a PWD screening interval was seen as important. The ISDR RCE calculates the screening interval every time a PWD attends an eye screening appointment; PWD in low and medium risk groups who do not attend are assigned to 12 months for their next invitation and those in the high risk group to 6 months. Some HCPs were concerned that the increased complexity of the RCE and subsequent screening allocation could create increased RISK for

patients, implying that the mix of data and systems could result in incorrect calculations of risk and allocation to the wrong screening interval.

"It is a more complex system, more complex recipe so there may be more opportunities for it to go wrong." John (HCP)

The risk engine uses five unconnected data record systems extracted from primary care, secondary care and the screening programme, all with different administrative teams and access/governance arrangements. Data are screened and cleaned through bespoke processing. Risk is then calculated by a chain Markov model using 6 covariates.[15]

PWD participants had similar questions to HCP around the decision-making involved in allocation to screening intervals. Specifically asking about the process of the RCE and how it is constructed, as below.

"Who decides your risks? That's what I'd like to know." (Arthur PWD, Phase 2)

In addition, PWD and HCP wanted to be able to self-refer, or refer patients back into annual screening if their 'risk-factors' changed between extended screening intervals, as explained below

"I would feel more confident if there were safeguards where I can say, well the nurse can say, oh this is a bit erratic, we will need recourse to the testing place and see if we can get you a quicker appointment… ... in theory if everything stays the same there is no problem with me having the test every three years… so long as there are contingencies in place. If I was confident about safeguards I would be quite happy." (Derek PWD, Phase 1).

There were calls for assurances from PWD that the recall system would need to mitigate against any diabetic changes which would warrant an earlier recall to eye screening.

"In theory, I would be all right as long as my reading stayed the same. So I suppose if my readings went high, and my sugar levels went high, I could say to the nurse well ok, I've got to have my eyes done now ... If my sugar levels go up for some reason, and I can't control them you know, I could have my eyes done." (Jane PWD, Phase 2)

HCP wanted assurances that the risk engine would be robust in identifying and inviting all PWD to be screened. Whilst recognising that the RCE was complex and sophisticated, there had to be obvious checks and balances of the system, and perhaps not relying on computers and software as suggested below.

"There should be some kind of backup where at least there is somebody in the real world who is actually ensuring that things have not gone really haywire. "(Sami and Suzanne HCP)

A further safety concern on extending screening intervals was the potential of missing STDR and the subsequent risk of patients developing visual impairment, as expressed below by a HCP.

"The danger is the longer you leave a recall of course, the more chance you have of missing that occasional patient, so it is cost isn't, it versus benefits really. And also once you have missed that patient, then trying to deal with them is more expensive." (Mark HCP)

These concerns were echoed among some PWD that extending eye screening intervals was considered risky as illustrated below.

"How do I know nothing is going wrong in all that time?" (David PWD, Phase 1)

PWD participants' willingness to accept longer intervals between screening episodes was often linked to their general diabetes care, such as regular monitoring of blood sugar levels, and liaising with primary care HCP and eye screening services. So the greater the perceived risk, the less willing they were to support an extended screening interval.

Summary: For HCP, and to a lesser extent PWD, the safety of the ISDR risk engine underlying the variable interval was crucial to being accepted into clinical practice. There were salient points raised about the quality and availability of data into the RCE, which also brought up the issue of its complexity, as it uses data from different sources and software systems. Safeguards for the RCE had to be made visible and obvious, especially in relation to the potential of missing STDR. There had to be opportunities for both HCP and PWD to refer or self-refer back into the eye screening programme, if for example for the latter group, there had been changes in the diabetes severity.

3. Acceptability of 6 month screening interval

Within the variable screening model, allocation to a 6 month interval meant that a PWD was considered to be at high risk of developing STDR. However, for some PWD participants, this rationale was not fully understood, with the shorter screening interval interpreted as a security for checking eyes, with the longer screening interval of 24 months unwelcome as it was seen as too prolonged a time to be without eye screening. Additionally, some PWD viewed screening as a preventive measure in developing DR.

"Well, early detection is better for the treatment you know what I mean, if you find something drastically wrong with your sight, and they can repair it, a lot, and if they find it earlier, they could repair it." (Arthur PWD, Phase 2)

Some PWDs, notably in the 55 plus age range, wanted to be screened every 6 months, or even every 3 months, and this related to a belief that they were more susceptible to developing eye disease related to diabetes and consequently needed to be monitored more often.

"When you're over a sort of certain age like say 60 that's when things start going downhill - 60. I'm not saying like everybody - everyone's different, aren't they - but the way I look at it is that I think it should be every six months ... if you're a type 1 diabetic you should have it every three months ... over a certain age every six months." (George PWD, Phase 2)

Those PWD with identified changes in their eye recognised the value of having their eyes screened every six months.

“Now that there’s evidence that there’s some damage to the back of my eye, I think you know more, a six-monthly check rather than 12-monthly check is a good thing for me, because obviously I don’t want it to deteriorate further without, if there was an intervention available I’d want that as soon as possible.” (Stuart PWD, Phase 2)

For HCP, the 6 month interval was welcomed unequivocally as a safeguard for high risk patients, and would have to be clearly communicated to PWD.

“I do like the idea of the medium risk, sorry the high risk ones coming back every 6 months… so I do think that that would be a good thing to have that as a standard if they were high risk, bring them back in the 6 months I think that would be good.” Sarah (HCP)

“…and there certainly are patients who need more closer care, which can’t always be determined just by looking at a picture of their eye ball essentially. You know they may be patients in certain ethnic groups, erm… and certain combinations might, I don’t know, but it might be for example Asian ladies from I am just talking off the top of my head, from a Pakistani origin for example, might it might be part of their societal erm… nature to not necessarily come to attention as much…” Andrew (HCP)

Summary: There are some tensions within PWDs’ understandings about the 6 month screening interval, with it being seen as clinical surveillance which was a reassurance, against the clinical reality that being allocated to this interval means that there is a high risk of developing STDR. Additionally, there was conflation about the purpose of eye screening, where it was commonly perceived to be a preventive measure against DR. For HCP, the shorter interval was welcomed, but also represented an operational issue of managing resources.

4. Acceptability of 12 month screening interval with conditions

As the eye screening service has been in place for over 10 years in England and Wales, it was perhaps unsurprising that some PWD participants felt that annual screening was acceptable and should remain in place. This was often related to their positive experiences of attending eye screening. Any changes made to their screening interval was felt by some PWD to be up to their HCP to decide upon, as shown below.

“I am quite happy with that. Some people may need close screening but I am quite happy with the 12 months. If they wanted to see me more frequent or less frequent, I would just go along with it. Sheena (PWD, Phase 1)

The reliance upon HCP to decide which interval to allocate a PWD was mentioned by several of the participants. For other PWD, the annual eye screening appointment was mistakenly perceived as a reassurance and safety net for any changes in the eyes during this time period, illustrating the misunderstanding of the relationship between diabetic health, DR and screening.

“I’d rather be seen every 12 months to be honest. I think people should be seen even if they’re classed as very low risk. I think even within a year a lot can change. You can suddenly have a bout of you know, I don’t know if having a bout of problems with your sugars would affect your eyes but yes, I just think every 12 months it should be.” Joanne (PWD Phase 1)

Whilst some reported feeling reassured by annual screening, there were misunderstandings about the impact of diabetic health upon eye health and the role of screening.

Summary: As the current annual screening interval is established and embedded into practice, it was foreseeable that PWD felt that this was an appropriate length of time for their eye screening. However, discussions also highlighted misunderstandings about the purpose of eye screening, as a preventive measure against the development of DR, and related to diabetic control.

5. Acceptability of 24 month screening interval with conditions

Extending screening intervals to 24 months provoked the most reaction and responses amongst PWD. The range of views included an unequivocal rejection of a 2 year interval as illustrated below.

“No way!” Melanie (PWD Phase 2)

Other PWD were more nuanced in their responses with concerns about this interval being too long a time period to go without being seen within the eye screening programme.

“It’s an awful long time, 24 months, isn’t it?” Jean (PWD Phase 1)

There were allied concerns about this interval around the potential for changes to the eye over two years and not being screened.

“In two years we could change everything. I mean diabetes is not, it could change in three months. [It could be] something related about your job or, I don’t know, something happened in your personal life, so in two years, it’s way too long really.” Rosa (PWD Phase 2)

“I feel like leaving something for two years can be very risky, because someone could always, all of a sudden be in a low risk and then take a turn for the worst and have like their eyes get really bad, really quickly due to something else. I feel like six and 12 months is good but then I don’t think 24 months is

good, I think it's too long because you wouldn't leave someone who had diabetes for two years and not check their HbA1c, so why would you do it for their eyes?" Polly (PWD Phase 2)

For other PWDs, being assigned to the 2-year screening interval was a positive reflection of their diabetes control.

"I thought well if I don't need it doing every 12 months then good, send it to two years. And I didn't think anything bad about it. I suppose I was quite positive about it really. I thought it was working in my favour if it was going to last two years ... not having another appointment to go to ... I always think, if they extend your visits it means you're on a level playing field you know, things are going smoothly; that's the way I look at it." Mary (PWD, Phase 2)

For HCPs, the move to 2-year intervals was welcomed as they highlighted that with annual screening they have to screen very large numbers of negative patients in order to identify a screen positive patient and that this seems like an inefficient approach.

"I think looking to change the intervals makes sense to me a lot because an awful lot of the screening we do is, there is nothing there. And, even the ones who have mild background retinopathy you see little or no progression over several years…And you are seeing an awful [lot] of patients who are either having no retinopathy whatsoever or very, very mild retinopathy." Gerard (HCP)

"We all know that we can be in a clinic with 50 patients in it and you might see two that have got a microaneurysm, so the vast majority would probably be going through as nothing." Sandy & Liz (HCP)

For HCP, extending the screening interval would enable the better targeting of resources and would benefit patients who, for example are difficult to engage and often do not attend for screening, or who are at higher risk of developing STDR.

"Unless we have the resources to follow all these patients [non-attenders] up, which if we do go to two-years screening we probably would." Frankie (HCP)

Similarly to PWD, HCP were concerned about extending screening intervals for the potential negative impact upon patient behaviour, namely it would affect risk perception around eye screening attendance. HCP anticipated that some patients would interpret extended intervals to mean that eye screening is considered not essential and there would be a concomitant effect upon an increase in non-attendance.

"If you give someone a two-year appointment, they are probably thinking, well it can't be that important if I don't have to come back for two years." Sami & Suzanne (HCP)

Some HCP drew upon their clinical experiences to support an argument about their unease on extending screening intervals being at odds with their embedded narrative to PWD of needing to be screened annually and related to the trust and relationship between PWD and HCP.

"I just don't agree with it. We have spent, well I have spent the last 11 years drumming it into patients how important it is to be screened every 12 months, and now this is just going against everything I have been saying. And 12 months is a long time, and serious, serious damage can happen in them 12 months, even if they have had nothing in the past, I have seen it so many times. So I just don't think it is worth the risk of moving a patient to 24 months." Judith (HCP)

There was a concern that PWDs' trust in the eye screening services would be undermined by any changes to screening intervals along with the potential development of DR. In light of previous comments about the embedded nature of the current annual screening programme for PWD, any changes require careful communication and management.

Additionally, with a potential increase in non-attendance, there were concerns about the length of time a patient would go without being seen in the screening service and the possible impact upon a patient developing DR and the related costs to the NHS.

"What would happen if they DNA if we went onto the two-yearly intervals and they DNAd that two-yearly one? It would be four years then. And that would be more expense wouldn't it towards the NHS, I think that would cost more because we would have more things going wrong." Janine & Hannah (HCP)

Summary: For PWD and HCP, there were a range of responses to extending screening intervals to 2 years. For some PWD, an extension was welcome as it reflected good diabetes self-care, contrasted with outright rejection for others over concerns about developing eye disease in the extended time period. For HCP, 2-year intervals were acceptable in the context of many patients having minimal or no disease. However, there was some apprehension about the perceptual impact upon patients of changing screening intervals, with PWD feeling that screening was not as important if changed to a 2-year interval.

6. Macro impact of changing screening intervals

Whilst there were many comments about the safety of the ISDR model and its three screening intervals, there were other more wide-ranging comments about the macro effect of changing screening intervals. For example, there was recognition by HCPs that the current eye screening system would not be able to manage demands in light of the ever increasing numbers of PWDs and the related future cost of screening

"From a burden of health and competing priorities, the NHS finance, we probably would say, there is a recognition that this [risk-based variable screening] is probably for the increasing diabetic population on an annual screen. " Alice (HCP)

Whilst recognising the impact of increasing rates of diabetes on screening, there were some concerns voiced by HCP on their job security with the introduction of variable-interval screening.

"…I think the primary thing everyone is worried about is their jobs. That is, because again we don't know how many people are going to go to 24 months and how many people are going to go to 6 months, potentially it could you know, cut a lot of people off our list…we are quite concerned about our jobs." Janine and Hannah (HCP)

There were suggestions that the complexity of the variable screening may serve to disadvantage particular groups of patients. In particular, those groups who do not engage well with services and as a result are at higher risk of developing STDR.

"It will certainly disadvantage this group that we don't get. We have got to find some way of getting these young, you know, sort of 20s to 40s probably, and a little bit beyond. Because I think you give them an inch that you don't need them to come for two years – we will never see them for longer." Sandy & Liz (HCP)

PWD participants also voiced similar views that variable risk-based screening should enable better targeting of resources and would benefit patients who, for example are difficult to engage and often do not attend for screening, or who are at higher risk of developing STDR.

In the scenario suggested below, there is a recognition that the NHS has finite resources and as such they need to be allocated in a more effective manner.

"We'll have less demand on the service, therefore we'll be able to do a better service for other people who need it. That's my logic. I think it's sensible to do ... If the evidence shows you that it's feasible and worthwhile well it just makes sense to refine what you're doing in a way which is more productive. It doesn't jeopardise the patient, and it's a better use of resources which are limited. Makes sense, ticks the boxes, doesn't it? ... I'm glad it's happening as a process; it needs to be done." Sid (PWD, Phase 1)

Other PWD voiced a suspicion that extending intervals between screening episodes for the majority of people with diabetes was financially driven. But instead of being redistributed to be more productive, the cost-savings were aimed at restricting patients' access to health services.

"I don't know, if it's like cost-effective you know, they're saving money. You feel like they're saving money to say we don't want to see you for two years. In your mind you think it's about the money, otherwise you'd be screening people every six months anyway." Ray (PWD, Phase 1)

Of note, was that some PWD participants imagined ways in which they could continue to have their eyes screened on a yearly basis, such as staggering other eye appointments, as expressed below.

"If they said you only need it 12 months that will do because I have a second one in the optician anyway." David (PWD Phase 2)

Such comments demonstrate misunderstanding about the rationale for different eye appointments and their purpose. Whilst the ISDR model re-calculates a PWD screening interval at every visit, the gaps in

understanding of eye screening appointments are a significant issue in supporting PWD to manage all aspects of their diabetes and related care.

“If I go to the optician and I can stagger those visits so one year it’s the diabetes test and the next year it’s the optician’s test, because the optician does look at the back of your eye, then that’ll be ok for me.” Becky (PWD Phase 2)

As mentioned elsewhere in this paper, there were many examples of confusion amongst PWDs about diabetes, eye disease and eye screening, and, as illustrated above, conflated health beliefs are unhelpful in managing any changes within the eye screening service.

Summary: There was a recognition that against a backdrop of increasing numbers of PWD, current screening intervals are unsustainable. Additionally, it was also seen as an inefficient use of finite resources, which would be better deployed in targeting PWDs who do not attend eye screening appointments. It was recognised that variable screening may save money, but this was also perceived to be a practice to restrict access to health care services. There was considerable conflation and misunderstanding about different eye related appointments within secondary care and at opticians. Changing the message to PWDs from regular, annual check-ups to extended eye screening will be a challenging message to convey positively.

Discussion

Our findings show general support by PWD and HCP for the introduction of variable-interval risk-based screening. Key factors for our users were the increasing prevalence of diabetes and finite resources for healthcare. Support was more clearly expressed by HCPs, likely related to a better understanding of the aims and current pressures in screening. Our findings are reassuring for policy makers and service providers who are considering introducing variable interval screening, either stratified based on retinal grading or variable intervals based on risk estimation. Our findings also have relevance to other screening programmes with fixed intervals and help to mitigate in part the concerns raised recently in cancer screening.[28]

Against these generally supportive findings are a number of important concerns attached to the processes around risk based allocation and to the screening intervals themselves, clearly expressed by both user groups. These need to be comprehensively addressed to ensure successful implementation, where success can be considered to be early detection of DR, attendance at eye screening and increased understanding of the relationships between diabetes, self-care, and eye screening.

Both groups of participants expressed concerns about the potential safety of the RCE linking to it being a more complex system, and uncertain reliability of the source data. Lessons learnt from the lengthening of screen intervals in other screening programmes, such as breast screening in 2018,[28, 29] show that to address these concerns requires careful explanation of the RCE and transparency about the systems involved. For HCP, the effectiveness of variable screening intervals was linked to a robust RCE and a

pragmatic recognition that there would always be outliers in a population who unexpectedly developed DR.

PWD and to a greater extent HCP welcomed a 6 month interval for people at higher risk. PWD perceived the interval as reassuring, while recognising that it meant a higher risk of developing sight threatening disease for them personally. A 6 month interval has been introduced in England for subgroups of people with screen positive DR not requiring treatment. This evidence suggests that extending this early rescreening option into community based screening will generally be supported. The 12 month interval was perceived as the standard care. The several misunderstandings of its purpose indicate that change will not be straightforward. The 24 month interval was controversial for PWD with mixed responses from reassurance to rejection. Most HCP were supportive. Both groups expressed apprehension about potential impact on care of diabetes by PWD. There had to be opportunities for both HCP and PWD to refer or self-refer back into the eye screening programme, if for example for the latter group, there had been changes in the diabetes severity.

An important theme underlying any change to screening interval, whether variable or extended, is the need to disentangle health and illness beliefs in PWD around diabetes and eyes, and to develop a clearer understanding of the aims of screening. There continues to be conflation and misunderstanding of these concepts along with their interconnectedness and purpose, as previously reported.[30,31] Furthermore, any changes to eye screening services could potentially fracture the trust that PWD hold about the current system and in HCP, and by default impact upon diabetes self-care. Thus, introduction of any changes requires thought and consideration, further complicated by the annual screening programme having been in place for over a decade. Old habits die hard, implementing large changes to embedded clinical practice, beliefs and understanding comes with significant challenges and any modifications will require effort by the diabetes care team and the screening programme to explain and consolidate pertinent information.

There are a number of issues related to eye screening that remain problematic. For example, non-attendance at screening is a risk factor for STDR,[32,33] with a range of reasons for non-attendance, such as anxiety about screening,[34] little understanding by PWDs of the link between diabetes and eye disease,[30] and the frequency of screening in preventing the development of DR,[31] which was echoed by HCPs.[35] Amongst the multiple health-care related appointments for diabetes, there are misunderstandings by PWDs of NHS systems and other appointments with HCPs, or eye related tests, such as those with an optometrist [36,37] which will lead to misinterpretations about the differences between DR screening and routine eye tests. PWD also had limited understanding around the purpose of DR screening confusing the detection of stages of DR that could threaten sight with the screening itself preventing DR.

So how should we go about introducing a change in systematic screening while considering the effect of perceptions of the users of the system? Any changes in health services provision can be problematic for individuals and organisations and can be amplified by routinised practice and behaviours, systemic factors, and local discrepancies in service provision and practice.[38-40] Implementing evidence based

practice is challenging and needs to address societal, political, cultural, individual and organisational barriers. To take into account all of these variables and their interaction requires a sophisticated theoretical model. Implementation science [41] is emerging as a broad theoretical umbrella with a range of frameworks and strategies.

Models of behaviour change have been used extensively within clinical and public health arenas to mitigate against illness behaviours.[42-44] There have been moves away from a deficit model, where primarily patients are perceived as lacking in their understanding and simply needing "more education" about their condition to resolve any issues. Behaviour change models, such as the Behaviour Change Wheel (BCW) are more inclusive of all the factors involved in any modifications to behaviour, and also recognise the dynamics and interrelation between factors.[45] The BCW approach offers screening service commissioners and providers a structure to develop intervention strategies around the themes we have identified and to change behaviour, and has been successfully used in a number of other clinical arenas.[46,47] Further gaps in the implementation of research results into health-related policy and practice [38,40] include individual and organisational barriers, timing within a policy process, and engaging policymakers.[48-51]

Normalisation Process Theory (NPT) is one approach to recognise and find ways to mitigate against any barriers that can support the successful implementation and integration of interventions into everyday clinical medicine.[52-54] NPT provides a structure which covers four areas: how can variable screening be understood by its users, both PWD and HCP (coherence)? How are these groups enrolled into using this new system (cognitive participation)? How exactly is this new approach enacted into practice (collective action)? And how is variable screening monitored by its users (reflexive monitoring)? Each of these questions can cover many of the caveats which our participants brought up when discussing risk-based variable screening. For example, rolling out variable interval screening requires a number of approaches to explain it's rationale and information around its safety. As discussed above, some of our PWD were suspicious about cost savings and some HCP participants expressed concerns about the quality of the data into the RCE. Both of these concerns can be dealt with under the coherence label, through a transparent policy of diverting any cost savings back into the screening programme, specifically to support non-attenders. As was apparent from our results, there were misunderstandings and misrepresentation of the purpose of eye screening for some PWD and HCP. Again, these issues can be put under the umbrella of coherence, where roadshows, co-produced information, and a marketing approach to HCP in their understanding of screening can be implemented. For safety concerns, there are a number of options, including the use of champions, experts who are respected in their field, to present and discuss the risk engine to other professionals. Another example, relates to reflexive monitoring, where regular updates on the stability and accuracy of variable screening can be fed back to clinicians.

Our qualitative study has run in parallel with a RCT which has shown that variable interval risk based screening is safe and effective when compared to annual screening (manuscript under review). Cost-effectiveness is greatly improved allowing resources to be reallocated, including for hard to reach and

vulnerable groups. 22% of people declined to participate in the study explicitly stating that they wished to remain in annual screening or did not want a change of interval, further evidence of a level of resistance to changing intervals. However dropout in the 2265 PWD randomised to variable interval screening was very low.

Strengths and limitations: Our PWD participants represented a broad range of individuals with diabetes giving a variety of views from their experiences. Our HCP informants were multidisciplinary and with a range of ages and experience. This affords a breadth of experiences and views, enhanced by our purposive sampling approach and co-produced topic guide. The study was informed by our PPI group who commented on all aspects of the research process and were able to inform the content of the topic guides based on their own experiences of diabetes and eye screening.

Our participants may have been motivated to take part in interviews as a way of expressing their views on particular topics related to diabetes care, or wanting social contact. PWD participants in Phase I were not the same individuals as in Phase II.

Conclusions

Extending intervals and introducing a fully personalised approach is gathering momentum in screening for diabetic retinopathy and other areas of disease prevention. Our qualitative work sheds new light on the issues around implementing variable risk-based, and stratified screening. Our findings offer key elements to consider for both the public and professionals, highlighting areas of uncertainty and doubt as well as positive views that should be considered when introducing personalised screening.

It is reassuring for implementing variable intervals into clinical practice that PWD and HCP users appear supportive. But for successful implementation, important caveats and misconceptions must be addressed. Interpretable and clear safeguards for individual PWD are required against increasing non-attendance, loss of diabetes control and system failures. Alternative referral pathways are required for those lost to follow-up or whose risk factors change substantially over longer intervals. For risk calculation systems, reliable monitoring and clear communication is necessary. Utilising the frameworks for changing health services provision in BCW and NPT is likely to improve implementation.

Declarations

Abbreviations

DR diabetic retinopathy

HCP health care professionals

PPI patient and public involvement

STDR sight threatening diabetic retinopathy

Ethics approval and consent to participate: The qualitative work was approved by the NHS Health Research Authority, North West – Preston Research Ethics Committee: 13/NW/028716/NW/0061. All participants gave written informed consent to taking part in the study and for their data to be used anonymously for publication.

Availability of data and materials: The data generated and analysed during this study is available from the corresponding author on reasonable request.

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Table

Table 1: Age distribution (years) of participants who were people with diabetes in phase 1 and 2

	18-34	35-54	55-64	65-74	75+
Phase 1	5	5	8	10	2
Phase 2	4	6	8	11	1