

You and Type 2 Risk Stratified Pathway Evaluation

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1. Executive summary

Overview

The You and Type 2 Risk Stratification project was a pathway developed by the HIN during the COVID-19 pandemic, in collaboration with both primary and secondary care clinicians across a range of specialties, to prioritise care for people with type 2 diabetes. The pathway involved the risk stratification of 4 practices' type 2 diabetes population. This group were prioritised for recall for their annual diabetes review and offered the You and Type 2 pathway at their care planning meeting. This is a digitally enabled personalised care and support planning pathway developed in South London.

There were 3 key ambitions to this project: (1) to use a risk stratification tool to identify people with diabetes related complications who had not been seen for some time, and in whom there was a risk of disease and complications progression without prompt clinical care; (2) to provide these people with a digital care and support tool to personalise their annual review and care planning consultation in the form of the You and Type 2 programme; (3) to facilitate integration and knowledge sharing between primary care and diabetes specialist services. This was in the form of protocols for escalation and management of diabetes complications thought likely to arise at the annual review created by secondary care specialists for primary care practitioners. Specific advice was also available through the Advice and Guidance platform which allows primary care practices to solicit personalised advice from NHS King's College Hospital specialist services.

This evaluation aimed to describe the demographics of the people identified by the risk stratification search, and the primary care experience of implementing this pathway. The evaluation aimed to identify key learnings for the future use of risk stratification in primary care, and in particular, for the delivery of diabetes care.

Key findings

The risk stratification tool proved an effective way of identifying a manageable subset of the practices' type 2 diabetes population who were at higher risk of both the development and progression of diabetes related complications. Although the stratified type 2 diabetes population subset was manageable in terms of size and in need of clinical review, manual screening of the list was used by some of the practices to further stratify the group. This may have introduced some treatment bias due to this selective practice, which in turn may contribute to health inequalities. For instance, age-based inequalities.

There were significant barriers to adopting the whole of the You and Type 2 pathway at the practice level. These were predominantly due to the large pressures on primary care due to the COVID-19 pandemic, and the continued workforce problems. Staff identified additional opportunities for risk stratification tool to be used as a resource management tool as well as for identifying clinical need.

The secondary care specialist advice documents provided was not utilised by the participating practices, with most staff not recalling receiving the document. When necessary, they chose to use their previous escalation routes instead. Practices still felt that improved integration of primary and secondary diabetes care was important.

Conclusion

The risk stratification search is a useful way for practices to identify people with type 2 diabetes who are at higher risk of developing complications or have deteriorating health, and prioritising them for further care. The overwhelming pressure within primary care services in the UK, however, is a significant barrier to practices being able to adopt new processes and innovate within care provision. This pressure must be considered when working with primary care partners. Taking a phased and stepwise approach to implementation or increasing project support capacity locally would increase the likelihood of new processes and innovations being successfully adopted and embedded.

2. Background

Over 3 million people in England are diagnosed with Type 2 Diabetes¹. Compared to people without diabetes, people with Type 2 Diabetes are nearly 2.5 times more likely to have a heart attack, heart failure or stroke². Effective management of blood glucose levels and lifestyle factors such as good diet and exercise can help reduce an individual's risk of developing the severe complications of diabetes.

The COVID-19 pandemic adversely affected the lives and health of people with diabetes in multiple ways. Pressures on healthcare services meant that routine care for people with diabetes was either paused or significantly reduced. People with diabetes were more likely to suffer from a severe COVID-19 infection³ and COVID-19 related mortality⁴. Furthermore, pandemic control measures such as shielding and lockdowns disrupted peoples' abilities to manage their diabetes through measures such as exercise³.

Stratification of high-risk populations was an important part of the COVID-19 response^{5,6}. As healthcare services began to deliver routine care again, it also became an important part of post-pandemic recovery, and a means of addressing health inequalities. Using a risk stratification tool developed by the HIN in collaboration with specialist teams from NHS King's College Hospital, 4 South London GP practices identified people at higher risk of having developed diabetes complications, or had existing diabetes complications worsen, over the course of the pandemic. These people were then prioritised for recall and offered the You and Type 2 pathway to support their diabetes management.

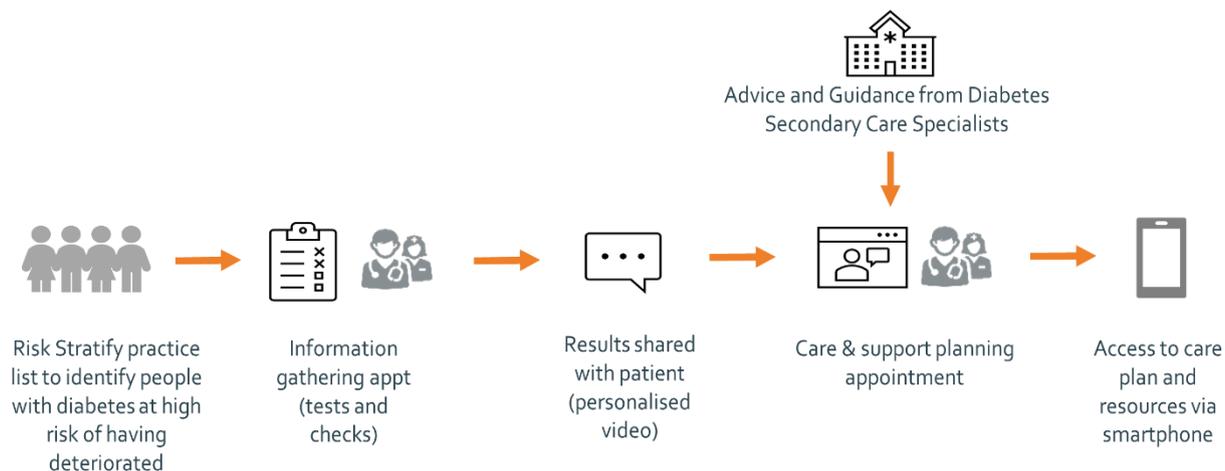
The You and Type 2 pathway aims to support people living with diabetes to manage their diabetes effectively. It is a care and support planning pathway for people living with type 2 diabetes in South London. It is based on the Year of Care⁷ model and through combining innovative digital technologies it provides each person with their own easily accessible personal plan of care, education and support⁸. It is a structured pathway to support GPs to complete annual diabetes reviews.

The risk stratification tool was developed by diabetes primary and secondary care specialists. It aimed to identify people who were showing signs of deterioration from their diabetes, and who, without intervention would likely require the help of secondary care services in the future. The risk stratification tool did not want to identify people with complex diabetes (e.g., active foot ulcers, renal dialysis) or multimorbidity, as existing pathways predicate these people would be attending secondary care services. It aimed to identify and provide support to people with early or mid-stages of the disease, who were most likely to progress and develop complications of diabetes in the future, and less likely to have been seen by healthcare services during the pandemic.

Participating practices were also provided with protocols for the escalation and management of diabetes complications which were created by diabetes secondary care specialists at NHS King's College Hospital. This protocol was presented in a one-page summary and distributed to practices via email. Additionally, practices were able to seek personalised advice from the specialist teams at NHS King's College Hospital via the Advice and Guidance platform.

The You and Type 2 Risk Stratification pathway was developed at a time when NHS partners were being urged to risk stratify to ensure that the limited resources available for diabetes management were being used effectively. This pathway aimed to identify, not only the people who were at higher risk of developing diabetes complications, but also to test if using a care and support planning approach would be effective at preventing these complications from developing. This would benefit both the people with diabetes, and also the stretched acute services by either preventing or delaying referrals.

Figure 1. Risk Stratification You and Type 2 Pathway



Initially 5 practices and 1 PCN (of 7 practices) expressed interest in the implementing the You and Type 2 Risk Stratification pathway. Of these, 1 practice and the PCN withdrew during initial discussions due to capacity constraints and conflicting priorities. Four progressed to running the risk stratification search in practice, however, only 3 of these were able to fully implement the You and Type 2 Risk Stratified pathway. The fourth practice also withdrew from the project due to capacity constraints. They did, however, provide their risk stratified cohort list for inclusion in the evaluation and practice staff completed interviews with the evaluation team on the challenges they faced implementing the project.

Project Aims

The main aims of this project were to:

- Offer pilot practices a risk stratification approach to be used to identify people at high-risk of developing diabetes complications
- Provide care and support planning through the You & Type 2 pathway to the identified high-risk people
- Test effectiveness of integrated care via specialist input sought out to inform care planning conversations
- Determine staff acceptability and experience of this pathway to inform future models of care

The Risk Stratification Tool

Resources already existed to support primary care staff risk stratify their Type 2 Diabetes population. In creating this risk stratification tool, several of these were identified and mapped to understand the crossovers and gaps in criteria (Appendix 1). These included:

1. COVID-19 DKD Risk Stratification Pathway and search tools produced by the London Clinical Networks
2. Guidance and searches to support the management of high-risk foot disease produced by HIN and SEL CCG
3. Clinical effectiveness Group's Renal Decline EMIS trigger tool
4. UCLPartners Proactive Care Frameworks
5. Ardens COVID-19 Chronic Disease Risk Stratification Searches available in EMIS

From mapping, it was identified that there were some cross-over in biometric criteria between the resources, however, they differed in overall aim. Resources 1 to 3 include risk stratification criteria focused on disease complications (kidney and foot). These searches focused on identifying people who were declining in that disease complication area. The aim being to prioritise recall for these cohorts to prevent further deterioration of existing complications.

The UCL Partners framework (resource 4) and Ardens diabetes risk stratification search (resource 5) risk stratify a practice's entire type 2 diabetes population based on HbA_{1c} and glycaemic control parameters in addition to a complexity score based on either disease state and/or social factors. They therefore identify various groups including high, medium, and low risk cohorts. The aim of these searches was to identify cohorts to be seen urgently that may be most at risk of deteriorating generally, or in relation to COVID-19 infection, during the height of the pandemic.

These resources were put to a group of secondary care specialists from across south London, brought together by Dr Sophie Harris, Deputy Clinical Director of Diabetes at the HIN and Diabetes Consultant at NHS King's College Hospital. Primary care input was provided by the HIN's Diabetes Clinical Director, Dr Neel Basudev and two people living with diabetes attended and contributed to the discussion. In addition to people without a recent HbA_{1c} test, the group felt there was a need to identify people with early-stage disease complications and suboptimal glycaemic control. They felt this cohort should be prioritised for biometric testing to determine their current state, and act accordingly.

The approach agreed on was to consolidate general and disease specific criteria, to focus on people who are high-risk but not currently under secondary care. These people may fall below the threshold of a referral to a specialist service but are at significant risk of developing complications in the next 2-3 years. Additionally, some of these people may have deteriorated over the course of the pandemic and already be at the threshold for referral. This deterioration would not have been captured if they had not had a review during the pandemic period. An EMIS search based on the agreed approach and primary care coding practices was established and distributed to the four participating practices.

Additional Guidance Creation

In addition to the risk stratification tool, the secondary care specialists also developed additional guidance for the primary care staff to use when assessing people identified by the risk stratification search. This was in addition to the usual advice and guidance accessible to practice staff, and focussed on the main diabetes-related complications the specialists felt would be identified in the search population. The document provided guidance on referrals and advice on how to optimise the diabetes management of this person within primary care. This advice was provided in a way that it could be used within the care planning process as part of the You and Type 2 pathway.

This guidance was consolidated into a one-page summary (Appendix 2) which grouped complications by Foot, Kidney and Diabetes. It was distributed to the practices electronically via email.

Evaluation purpose and design

This evaluation uses a mixed methods design to answer the evaluation objectives. The evaluation objectives and the full methodology for each objective are detailed in table 1 below. The evaluation uses information collected from 4 GP practices in South London, 3 of which fully implemented the You and Type 2 Risk Stratification pathway, and 1 which only identified a risk stratified cohort. The evaluation aimed to identify key learnings for the future use of risk stratification in primary care, and in particular, for the delivery of diabetes care.

Table 1. Evaluation Objectives and Methodology

Evaluation Objective	Measure(s) / metrics	Datasource/ methods of collection
<p>1. Determine the number and type of people that were identified as a result.</p>	<p>Number of people identified and their characteristics:</p> <ul style="list-style-type: none"> ▪ Age range ▪ Gender ▪ Ethnicity ▪ Deprivation ▪ Co-morbidities ▪ Duration of condition 	<p>EMIS search from participating practices</p>
<p>2. Explore how risk stratification of type 2 diabetes population at pilot practices was received and implemented</p>	<p>How risk stratification approach was implemented in practices including:</p> <ul style="list-style-type: none"> ▪ Experience of running the search ▪ If any amendments were made to the search ▪ How this cohort was separated from general type 2 recall list ▪ What did and did not work well in operationalising the pathway 	<p>Practice Staff Interviews</p>
<p>3. Understand the need for specialist input for participant cohort identified and HCP experience of this part of the process</p>	<p>Clinician experience of including specialist advice to inform care planning conversation, including.</p>	<p>Practice Staff Interviews</p>

3. Findings

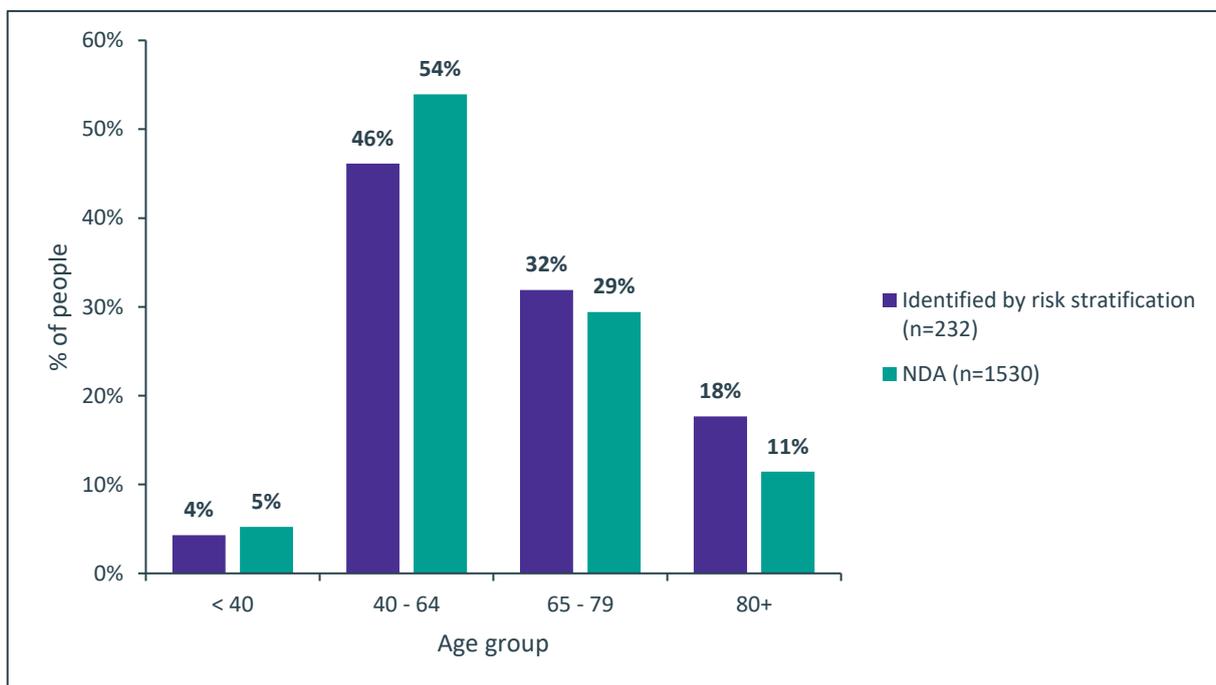
The findings are structured in accordance with the order of the evaluation objectives listed in table 1. They begin by describing the profile of the people identified by the risk stratification tool, before exploring the experiences of primary care using this pathway.

Anonymised demographic data on the people identified by the risk stratification search was provided by 4 GP practices. This was then analysed and compared with the practice level data from the National Diabetes Audit¹ (NDA) to understand and describe the profile of the people identified. Ten semi-structured interviews were conducted to understand the experiences of primary care in adopting this pathway. These interviews were with a selection of practice managers, practice nurses, GPs and HIN project staff. These were thematically analysed to identify key findings and recommendations. The full interview schedules can be found in Appendix 3 and 4.

3.1 Determine the number of people identified by the risk stratification and their characteristics

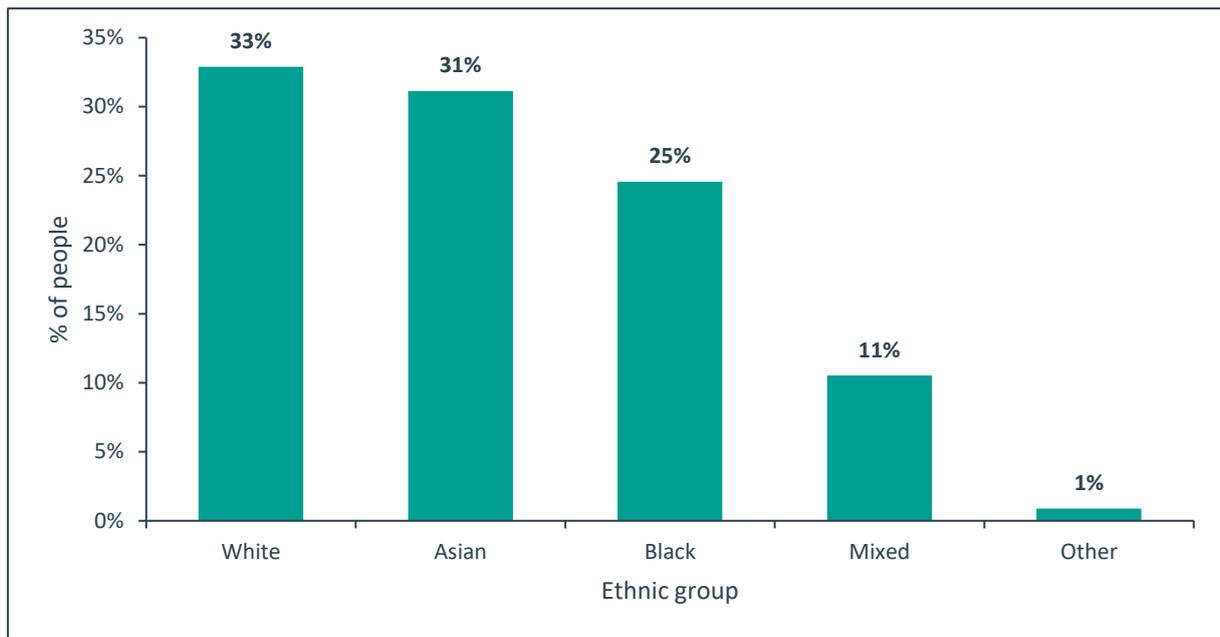
Across the 4 practices, there were 1,530 people identified with type 2 diabetes. The risk stratification search identified a subset of 232 people (15%) for the potential targeted intervention. Of these 232 people, 56% were male and 44% were female. Half of all people identified by the risk stratification tool were of working age and the largest age group identified were aged 40 – 64 years old (see figure 2). Comparison with NDA data shows that the age group identified by the search is slightly older than the total type 2 diabetes population.

Figure 2. Age Group



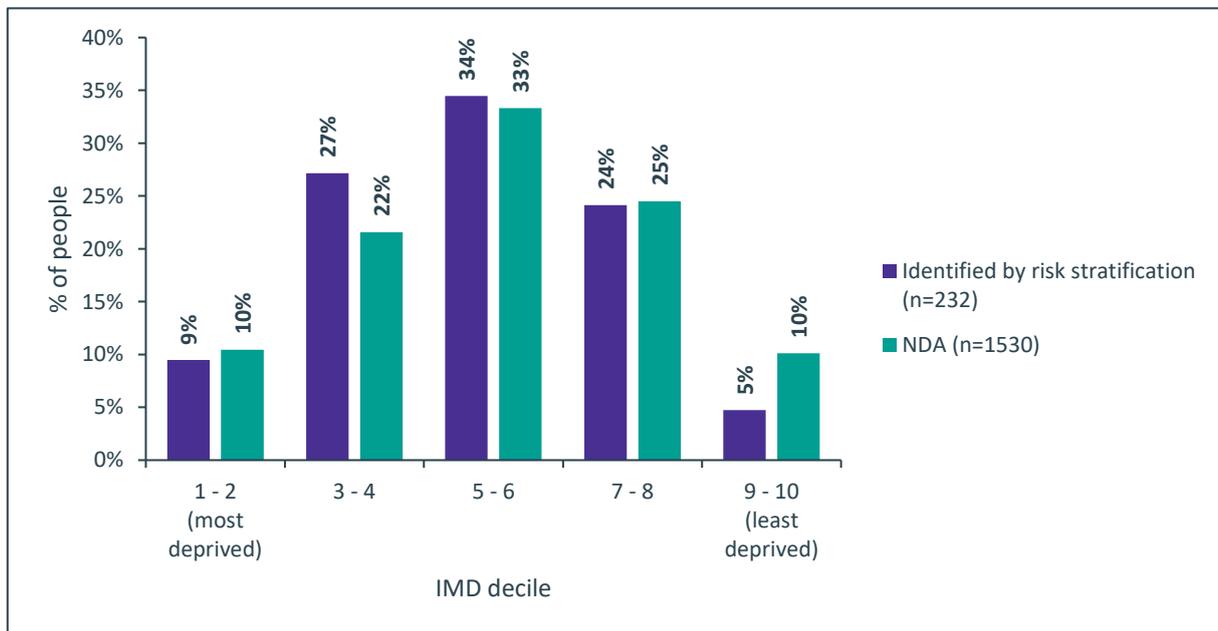
The people identified from the search were from a range of ethnic backgrounds (see figure 3) with 67% being from minority ethnic backgrounds. This was similar to the whole type 2 practice population, where 65% were registered as being from minority ethnic backgrounds. Of the people identified by the risk stratification search, 41 (18%) were listed as requiring an interpreter. This information is not collected by the NDA so comparison against practice level data was not completed.

Figure 3. Ethnic Group



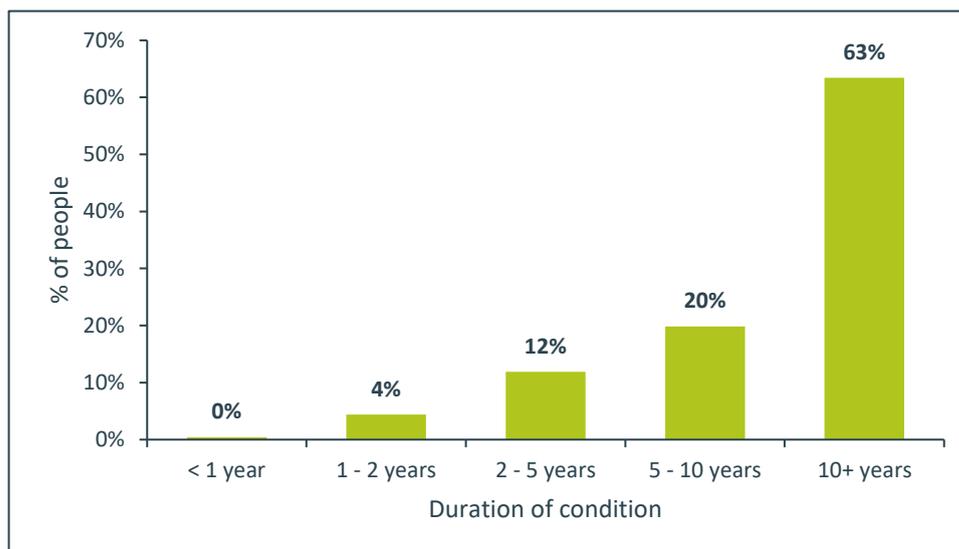
Over half of the people identified by the risk stratification tool were in IMD deciles 3 – 6, with the highest frequency in groups 5 – 6 (see figure 4). The IMD distribution of the risk stratified group is similar to the total type 2 diabetic population at these practices. Over a third (36%) of the people identified by the tool were in the four most deprived IMD deciles. This is slightly higher than the NDA populations registered at these practices (32% in IMD deciles 1 – 4).

Figure 4. Deprivation by IMD Decile



The majority of people identified by the risk stratification tool had been diagnosed with type 2 diabetes for over 10 years (see figure 5). Of those identified, 44% had been prescribed insulin, and 25% had been diagnosed with a mental health condition.

Figure 5. Duration of condition



3.2 Explore primary care experience on implementing the risk stratification

Findings for the primary care experience of implementing the risk stratification pathway have been presented by process step. They start with the experience of identifying the high-risk population and then the system for managing recall. Then an overview of the success and challenges in implementing this pathway is presented based on theme. Finally, a list summary of the suggestions from practice staff on how the pathway could be improved for future usage is presented.

3.2.1 Running and amending the search

Generally, practices found running the risk stratification search on EMIS straightforward. Project staff initially provided practices with a descriptive version of the search (appendix 5) which allowed the practices to build the search themselves locally on EMIS and run it. There were significant delays to some practices being able to run the search. The reasons for this are explored in section 3.2.3. It was then identified that EMIS searches could be created in one practice, downloaded, and then shared with another practice. They could then upload the search and run it. This was much more efficient than the practices building the searches from the description, and the remaining practices ran the search much quicker once this was identified.

Of the four participating practices, two were satisfied with the list of people generated by the search and two were not. In all cases the search was run and the results reviewed by a practice GP. The two practices who were not fully satisfied by the search felt that the risk stratification tool had not identified the correct people. One practice felt that the search was identifying elderly people who were less likely to engage with the digital elements of the You and Type 2 pathway. The other felt that the search was not identifying some of the higher risk people registered with the practice due to different coding practices between the participating GP practice, and the one with which the risk stratification tool had been developed.

Both these practices also felt that the search was identifying a lot of their most complex people who historically had not engaged well with the practice in the management of their care. Given the original focus of the risk stratification tool was to identify those for early intervention, they felt that these people were not part of that original aim.

"[The search] was picking up a lot of our unbelievably complex... heartsink patients, in whom we can't seem to make much difference [with] for love nor money" [Participating practice GP]

These two practices amended the list approached for participation in the You and Type 2 pathway differently. The practice which felt that the wrong people were being identified due to differences in coding practices, worked with one of the HIN's clinical directors to re-create the search. The new search used domains more frequently completed by the participating practice. This created a list based on the same principles as the original search, but used data that was readily available at the participating practice. The other practice reviewed the recall list created, and manually removed people from the list who they felt would not engage well with the You and Type 2 intervention. This was either due to demographic factors such as age, or history of not attending appointments.

3.2.2 Managing recall

Once identified by the risk stratification search, practices separated their lists of people with diabetes differently. Some practices chose to create a code on EMIS termed "Year of Care Annual Diabetes Review" and created different appointment types. This meant that administrative staff would be able to see what type of appointment the person was being recalled for based on the coding, and would then allocate the appointment to a health care professional (HCP) who was trained to deliver the You and Type 2 pathway. Other practices chose to manage a physical list, which they reviewed when recalling people for their annual diabetes review to identify which HCP they should be seen by.

All participating practices recalled people for their diabetes annual review based on their birth month. The original concept of the risk stratification pilot was that practices would use the risk stratified list of people with Type 2 Diabetes, and recall these people sooner for their annual review. This was to avoid high risk people, who were born the month before practices re-started their annual reviews, waiting an additional year before being seen again.

The three practices who did recall people, however, continued to recall people based on birth month and not in a prioritised way. The people identified by the search were offered the You and Type 2 pathway, whilst those who were not on the search list received their usual annual diabetes review check-up.

There were several reasons why the practices did not prioritise recall of the people identified by the search. These are summarised in table 2 below.

Table 2: Rationale for not prioritising recall of risk stratified search

Summary	Description
Logistical challenge of managing two recall lists	Some of the people identified by the search had completed their annual review within the last 3 months and so the practices felt it was inappropriate to approach them again. ¹ Birth month recall is also so embedded within practices that practices felt it was likely that some people would be called in for a prioritised review and then re-contacted in their birth month. The second review would potentially be allocated to a GP who was unaware of the You and Type 2 pilot and so the person would complete two separate annual reviews.
Annual diabetes review used to review other long-term conditions	Many people identified by the risk stratification search had co-morbidities. Their annual diabetes review was used as an opportunity to check on all their conditions. Changing their recall pattern would impact the timeline of review for their other conditions.
High risk people already being seen regularly	Practices already had more frequent reviews with people they considered higher risk. They were not concerned that someone at higher risk of deterioration would not be seen for a whole year by the practice.

¹ The search was designed not to identify anyone with an HbA1c result in the last 2 months unless the result was high, suggesting the need for further review or follow up. Recent HbA1c result being used as a proxy measure for recent annual review in this instance. Practice feedback would suggest that this proxy measure was not fully successful.

<p>Additional psychological and time burden to people living with diabetes to be recalled early</p>	<p>Some felt it was inappropriate to be contacting people for a full diabetes review out of the usual recall pattern to which they were accustomed to, and that this would likely result in poorer engagement.</p> <p><i>"It's from a patient burden [perspective]...people hate being reminded that they're diabetic all the time, and they know they...have an annual full-on review. I think it's more acceptable to have those kinds of discussions at that point."</i> [Practice GP]</p>
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3.2.3 Success and challenges of implementing the risk stratified pathway

Practices and project staff identified many successes and challenges in the implementing of the risk stratified pathway. Several of these have already been described already; however, this section will explore these in further detail.

Successes

Practice staff were complimentary of the support provided by the project staff. This included the project managers who guided them through the process, and the clinical directors, who provided specialist expertise when the practices were risk stratifying their diabetes annual review list. Practice staff also appreciated how flexible project staff were with delivering the training to the practice, and how responsive staff were to questions.

"You kind of made it super simple and kind of gave us everything we needed, supported us to roll it out...the flexibility you...have shown has been really kind and generous...you made a good project, and I don't think you could have made it easier for us to join." [Practice GP]

Practices also liked the You and Type 2 intervention. For some people, the digital pathway facilitated greater engagement. One practice shared how they had implemented the pathway with a man who historically had not engaged with his annual review. He would attend, but rarely followed the steps agreed at the review. The practice shared how he had really liked having the personalised app interface, and at his more regular check-ups he appeared to be following the plan they had created together.

Staff also liked the underpinning ethos of the You and Type 2 review. One GP shared how she had taken the collaborative approach to care planning inherent in the model, and now uses this to inform her more general practice. This included with people completing their diabetes annual review who had not been identified by the risk stratification tool for the You and Type 2 pathway.

Although practices identified several challenges to managing recall, one practice shared how they found the focus on recall in the pathway helpful. They did not have a systematic method of recalling people for their annual diabetes review locally. They explained that the pathway had acted as a catalyst for a discussion on developing a more robust recall method at the practice.

Challenges

There were also several challenges identified by the practice and project staff to the implementation of the risk stratification pathway. These were broadly divided into two main themes around the technology and operational challenges within practices. A detailed description of the themes is outlined in table 3 below.

Table 3: Challenges to implementing the pathway grouped by theme

Theme	Sub-theme	Description
Technology Challenges	EMIS Coding Reliability	<p>The accuracy of updating and coding for different conditions at different practices varies. HCPs also have different styles of coding on EMIS, with some using more generic terms to identify a long-term conditions and complications and others using specific terms.</p> <p>Therefore, the same search run in two different practices will not necessarily identify the same cohort of people.</p>
	Digital Literacy/Access – People with diabetes	The practices identified some of the people as unable to engage with the You and Type 2 intervention because either they did not have a smart phone, or they were deemed not sufficiently confident in using it.
	Digital Literacy – Staff	Practices identified the digital skills of their staff as a barrier. Some staff did not feel confident using the digital pathway to deliver care. Some practices linked this to the age of their staff, others linked it to how frequently these staff had to use other types of digital platforms in their role.
	Issues with the You and Type 2 Digital Platform	<p>Some of the practices reported issues with using the You and Type 2 digital platform which was hosted by Healum.</p> <p>Some participants received the wrong videos or results. HCPs were unable to access the care plan unless they were with the participant. This resulted in HCPs manually copying the care plan information into EMIS so they could continue to access the information. HCPs also found that sometimes certain boxes or information was greyed out when completing the forms.</p>
Operational Challenges	Competing Priorities: COVID	<p>There was a huge amount of pressure on primary care due to the COVID-19 pandemic which hindered practices' abilities to engage and implement the risk stratification pathway.</p> <p>The pathway was due to go live with the practices in Winter 2021/22. This was when the Omicron variant of COVID-19 had just emerged.</p> <p>Practices were facing staff shortages due to sickness and caring responsibilities which was stretching their limited resources. Practices were also seeing an increase in demand from patients as COVID cases rose. Furthermore, primary care was being asked to step up support with vaccination in response to COVID-19.</p>
	Competing Priorities: Other	Practices were also balancing a range of other priorities. One practice underwent a CQC inspection during the pathway implementation timeline. This resulted in the implementation being paused until the assessment was complete.

		Another practice was implementing an overdue IT migration where they were automating their general recall process from spreadsheets to Ardens. This took up a lot of practice time in terms of project management and training for staff.
	Staffing Levels	<p>Several practices struggled with project critical staff turnover during the implementation of the pathway. One practice lost their IT manager who had been the key driver of the project locally. Another had their practice manager stranded abroad during the pandemic, and then subsequently the deputy practice manager left. Another had a completely new admin team and management team start during the project implementation stage.</p> <p>This high turnover rate of staff was reported as common in primary care following the pandemic. Not only were practices losing staff, but they were also struggling to recruit to vacant positions.</p>
	Staff Capacity	<p>Due to being unable to access the care plans outside of an appointment, staff felt that care planning appointments would take longer as they had to manually move information to EMIS after the appointment.</p> <p>Practices were required to allocate the already stretched staff time to training for the risk stratification pathway. In practices with less digitally confident staff, practices felt that this was a significant time burden.</p>
	Staff Engagement	<p>Some practices reported issues with staff engagement with the pathway. One practice reported that the management and IT staff were very keen on digital innovation at the practice, while clinical staff were less engaged. When there was staff turnover in the management and IT personnel the project lost momentum in the practice.</p> <p>Another had already implemented their own Year of Care inspired model of annual diabetes review. Although it was not digitalised, it had many of the same principles as the You and Type 2 pathway. This meant that when practice management staff became 'overwhelmed' by the amount of demands placed on primary care, delivery of the You and Type 2 pathway was seen as a lower priority.</p>
	Managing two diabetes annual review recall lists	See section 3.2.2

3.2.4 Suggestions for future usage

Having implemented the risk stratified pathway to varying levels, practice staff had several suggestions on how risk stratification for the You and Type 2 pathway could be optimised in primary care in the future. One practice suggested targeting a younger demographic group by specifically including age range on the risk stratification. This

was in order to identify people they felt would be more likely to engage with a digital aspect of the You and Type 2 pathway.

Another practice felt that the risk stratification could focus on people even earlier in the disease progression, who were either largely managing their diabetes well, or were only just showing signs of deterioration. For instance, their biometric tests might be showing indication of decline, although the actual value had not yet reached an abnormal range. They felt that these people would benefit from the care planning support provided by the You and Type 2 pathway, and that prioritising them for the pathway might prevent future deterioration.

This practice also felt that risk stratification could be used as a resourcing tool. If the search was able to identify people at high, medium and low risk of diabetes complications, then the practice could allocate these reviews to be conducted by either a GP, registrar, nurse or HCA depending on the local staffing structure. They could also use the groupings to identify if people would likely need a longer care planning appointment.

This practice had not used the risk stratification tool to prioritise higher risk people for recall due to the challenges of managing two recall lists, and the fact they felt it was potentially inappropriate to hold a care planning appointment outside of the usual review window. They did think, however, that the risk stratification tool could also be used for auditing purposes. The list could be used to identify people at higher risk of complications, and then the practice could review what care they are receiving, and if they have the appropriate reviews booked. If they had concerns, then the practice could pro-actively reach out to the person.

3.3 Explore the clinician experience of including specialist advice to inform care planning conversation

At the time of conducting the evaluation interviews, none of the practices had used the specialist advice document created by the secondary care specialist teams. Some of the practice staff interviewed were unaware that there was a section of the pathway relating to specialist advice. Others remembered that there had been discussions about improving the integration of primary and secondary care at the onboarding stage of the project, however, they were uncertain about what the agreed solution had been. Most of the staff could not recollect receiving the information sheet containing the specialist advice.

Practice staff identified staff turnover as a key reason for why this had occurred. Many of the practices had experienced staff turnover during the course of the You and Type 2 risk stratification project. It was felt that in some practices this had led to a lack of local leadership with the implementation of the pathway. This may have resulted in documents and information not being shared across all practice staff involved with the project. Furthermore, the project manager at the HIN also changed several times during the duration of the project. The passing of the project between staff during the implementation phase was also identified as a reason why not all practice staff were aware of the specialist advice.

Some practices had also not completed any annual reviews where they felt the person required a referral for onwards specialist support. When questioned on whether they would use the specialist guidance sheet if they were to require support, many reported they would not. This was because they already had their own referral pathways set up which they were familiar using. Some of these referral routes drew upon relationships with specific specialist teams that worked in their local area. One practice GP in particular expressed a preference for seeking support via this route.

4. Discussion

Search Group Demographic

The original aim of the search was to identify people who were in the early or mid-stages of the disease, who were at higher risk of developing diabetes complications. It did not aim to identify the people with the most complex forms of the disease, as it was assumed they were already receiving support from secondary care services.

Analysis of the demographics of the people identified by the risk stratification search indicate that the search went part way to identifying this cohort of people, e.g., the largest group of people identified by the search were of working age. The risk of developing diabetes increases with age and the likelihood of developing diabetes complications increases with duration of the condition. Therefore, the fact that the search has identified a young cohort of people indicates that the search terms are identifying people for whom review, and action would be timely to prevent future complications.

Although a young population, most people identified by the search received their diabetes diagnoses 10+ years ago. Given the correlation between length of diagnosis and development of diabetes complications, this suggests that the population identified might be at a more advanced stage of the disease than aimed for. This is further supported by the high proportion of the risk group identified who have already been prescribed insulin.

Ethnicity and level of deprivation were not demographic factors included in the risk stratification search. Ethnicity and deprivation status were similar between the risk stratified cohort and the overall NDA practice population. This suggests that this intervention is unlikely to exacerbate existing health inequalities. It should be noted, however, that the demographic data analysed is of those identified by the search. It does not capture whether the people identified subsequently when on to engage with the pathway. Engagement will ultimately determine the impact of the pathway on reducing or exacerbating health inequalities.

The existence of co-morbidities was also not included within the search criteria. Demographic analysis identified that a quarter of those identified by the risk stratified search also had a mental health condition diagnosis. This is important as people with diabetes and mental health conditions are more likely to develop complications of diabetes⁹. The Diabetes UK report identified fewer than one-quarter of people with diabetes felt they received the emotional and psychological treatment they needed from the NHS, and 30% of GPs agreed that current resources to support the mental health of people with diabetes were inadequate¹⁰. Given that the You and Type 2 pathway specifically aims to provide a more holistic approach to diabetes management and care planning, this pathway should particularly benefit people with diabetes who wish to discuss their mental health and the impacts it is having on their diabetes management.

Interviews revealed, however, that practices were manually screening the cohorts identified by the risk stratification search, and excluding people based on their own knowledge and experience of engaging with this person. People with a long history of non-engagement or non-attendance were not approached for the intervention based on the assumption that they would not engage with the You and Type 2 pathway. This assumption introduces a treatment bias resulting in people who have been historically less engaged with their care remaining at higher risk of developing diabetes complications, as they are not approached for the new intervention. The example from one practice of a person who historically did not engage with diabetes management support really engaging with the You and Type 2 pathway, however, indicates that this treatment bias could result in excluding people from a pathway that they would have engaged with.

Intervention Adoption

The NASSS framework¹¹ can be used to understand why certain technological healthcare innovations succeed or fail at being adopted. The framework breaks down interventions into 7 key domains: the disease, the technology,

the value proposition, the adopter system, the organisation, the wider system and embedding and adapting over time. If all domains are 'simple' the innovation will be readily adopted. If several domains are deemed 'complicated' then the programme will be difficult, expensive, and slow to implement and sustain. If several are deemed 'complex' then it will be almost impossible to achieve sustained and widespread adoption of the programme.

Breaking down the You and Type 2 Risk Stratified pathway into these domains it can be understood why there were significant challenges in both developing and implementing the pathway. Although a relatively short and seemingly straightforward pathway, several of the domains are either 'complicated' or 'complex' by the NASSS framework definitions.

Type 2 Diabetes is a complex disease that is caused by a variety of genetic, epigenetic and environmental factors. It presents differently in different people and requires a complex set of interlinking actions in order to manage it effectively. The complexity of the disease provided challenges for the first stage of the intervention: defining the target group for the intervention. The aim was to focus on those who were at high risk of developing diabetes complications. This was based off a consensus reached by the secondary care specialists. The practice GPs, however, although on board with the overall aim of the risk stratification tool, identified people they felt should have been included and excluded from the search. This highlights the subjectivity of defining risk among clinicians. This is a phenomenon observed in other clinical risk based decision making moments^{12,13} and shows how this intervention was likely to be complex from the outset.

The technology of the intervention was also complicated. It was not an 'off the shelf' product that could be used in each practice. The risk stratification tool had to be adapted in practices due to variations in coding style and also the overall demographic of the practice population. Large changes also had to occur to the adopter system to allow for the intervention to run. Practices were required to adapt their own recall systems and retrain their staff to use the new pathway. There were several different models for recall and annual diabetes review that were being used by the practices, so not only were they required to change to the new system, but they were all changing from different starting points.

The adoption of the intervention was also significantly hindered by the capacity of the organisations involved. The primary care system was overwhelmed by high levels of care demanded and struggling with a workforce crisis prior to the pandemic¹⁴. The COVID-19 pandemic has exacerbated this to unsustainable levels with GP appointments reaching record levels, new demands on primary care to deliver the COVID-19 vaccination programmes and an increasingly understaffed and burnt out workforce¹⁵.

Once implemented the risk stratification pathway should not add significant additional burden to the practices delivering it. Interviews revealed, however, that the participating practices had extremely limited capacity to absorb the time requirements of being involved in the development of the intervention, and the transformational change required to embed the new pathway. This was the largest barrier to the implementation of the intervention. It caused significant delays to the project timeline and resulted in one practice dropping out part way through the pilot.

The additional specialist input at the end of the pathway was also a complicated part of the intervention. It also required practice staff to adapt their current ways of working to a new system. This system was not integrated with the software or pathways they had been using for years. Furthermore, due to the complex nature of NHS care provision, different practices historically also engaged with different secondary care providers. The final part of the pathway was therefore trying to navigate an incredibly complex system, and requiring input from resource stretched primary care clinicians to do this. It is not surprising, therefore, that the participating practices did not adopt this part of the pathway successfully.

5. Conclusions

The intervention met an identified need in post-pandemic recovery of diabetes care and was seen by primary and secondary care clinicians as an appropriate intervention to meet this need. However, significant barriers to the adoption of the You and Type 2 Risk Stratified pathway were identified. Using the NASSS framework¹¹ it can be seen how the You and Type 2 Risk Stratified pathway was actually a complex intervention. The complexity of the disease, technology and organisation domains explain why primary care practices found such difficulty in adopting the intervention.

This project demonstrates how current pressures on primary care can constrain practices' ability to innovate within care. This echoes concerns being raised more widely across the sector¹⁵⁻¹⁷. This evaluation has highlighted that when considering what interventions are possible for primary care practices to deliver with their limited capacity, the requirements of delivering the change should also be considered. Transformational change requires time and engagement. These are factors that are in limited supply in primary care.

Two potential methods to reduce the burden on primary care when implementing new innovations include: the recruitment of additional project management or support resource at practices to provide increased capacity, or, delivering the intervention in a phased approach. As identified through the NASSS framework, the complexity of several aspects of the You and Type 2 Risk Stratified pathway were a major barrier to implementation. Taking a phased approach, such as implementing the You and Type 2 pathway first, and then using it on a risk stratified cohort would have reduced the number of complex dimensions practices were dealing with simultaneously.

Risk stratification itself was viewed positively by the participating practices. Although there were challenges to delivering the whole You and Type 2 risk stratified pathway, the search was able to successfully identify a subset of higher risk people with type 2 diabetes registered at the participating practices. The demographics of the group identified also showed how taking a risk stratified approach based purely on biomedical markers would likely not exacerbate health inequalities.

The potential treatment bias introduced through the manual screening of the cohort list by GPs, however, challenged the project's aim of engaging with people with complex diabetes and potentially needing further care. Taking a phased approach to the implementation might have reduced this bias. It would have allowed healthcare professionals the opportunity to become confident with using, and more aware of the benefits of, the You and Type 2 pathway before approaching the people with the most complex diabetes and a history of non-engagement.

The practices involved also identified that there are several other ways a risk stratification tool could be used within primary care, both in terms of prioritising care and appointment resourcing. Given the scale of the pressures being faced by primary care, using risk stratification tools to prioritise care delivery and manage staff resourcing should be explored further. This could help alleviate some of the pressures being faced by practices.

Finally, although this project was not successful in improving the integration between primary and secondary care, practice staff were still very engaged with this idea and felt it was an important aim for the wider system. The provision of a guidance sheet was a simple intervention, however, this evaluation has shown that the complexities of the wider environment, including the different practices having different escalation processes and limited capacity, reduced their ability to engage with the change. Furthermore, the lack of integration of the new guidance with existing IT systems and pathways used by GPs made it less attractive to use.

Given the continued interest from primary care practices for better integration of care, and the benefits that this would have for people with diabetes, further investigation should be done into this area. Interventions working in this space should consider the limited capacity of primary care to deliver transformational change as part of their design, as well as the diverse range of relationships between primary and secondary care providers across the system.

6. Recommendations

- The risk stratification search created by this project was able to identify a subpopulation of people at higher risk for diabetes complications within primary care. Risk stratification projects should continue to be considered and used by commissioners and service providers for the delivery of diabetes related care.
- Future projects that require primary care practices to significantly redevelop pathways or adapt protocols should be implemented in a phased approach or include funds for the recruitment of additional project staffing resource. This would ease the barriers to delivering transformation change quickly within primary care and promote successful implementation. Tools such as NASSS-CAT² can be used in the planning stage to identify where the barriers to delivery may occur.
- In future risk stratification projects, there needs to be clarity at a practice level of how the risk stratified population will be managed separately to the main diabetes list. This includes what their patient journey and recall process will be like.
- Healthcare professionals should continue to offer new forms of health interventions to people, even if that person has historically not engaged with other forms of health interventions. It may be that the person would engage with this new method of care.
- There should be further investigation into the feasibility of using risk stratified lists within healthcare settings not just focus on intervention prioritisation, but also for staff resourcing for care provision.
- Commissioners should continue to facilitate projects focussing on improving the integration between primary and secondary diabetes care. These would likely be more successful if they were stand-alone projects rather than embedded within larger, more complex, projects that are inherently more difficult to deliver.

² www.phc.ox.ac.uk/research/resources/copy_of_nasss-cat-tools

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8. Appendices

Appendix 1. Comparison of Different Risk Stratification Tools

		ASSETS				
		UCL Partners: Proactive Care Framework for Type 2 Diabetes*	London Clinical Networks: COVID-19 DKD Risk Stratification Pathway and search tools	HIN/SEL CCG: Guidance and searches to support the management of high-risk patients and high-risk foot disease	Clinical effectiveness Group: Renal Decline EMIS Trigger Tool	
		Category/Criteria				
FRAMEWORK TYPE	Type	General / Specific	General	Renal	Foot	Renal
	Workforce required	GP, Diabetes Lead, Prescribing clinician	High-risk level			?
		Pharmacist, Nurse	Medium-risk level			
		other HCP i.e. HCA	Low-risk level			
		Specialist (i.e. referred to MDT foot or renal team)				?
	Stratification criteria	Clinical				
		Ethnicity				
		Social				
		Age				
	Different risk levels	High-risk				?
Medium-risk					?	
Low-risk						
IDENTIFY	Searches	HbA1c > 90	High-risk: priority 1			
		HbA1c > 75 + any of: BAME / Social complexity** / severe frailty / insulin or other injectables / heart failure	High-risk: priority 1			
		HbA1c >75	High-risk: priority 2			
		Any HbA1c + any of: Foot ulcer in last 3 years / MI or stroke/TIA in last 12 / months / Community diabetes team codes / eGFR < 45 / Metabolic syndrome	High-risk: priority 2			

	HbA1c 58-75 + any of: BAME / Mild to moderate frailty / Previous coronary heart disease or stroke/TIA >12 / months previously / BP≥140/90 / Proteinuria or Albuminuria	Med-risk: priority 3			
	HbA1c 58-75	Med-risk: priority 4			
	Any HbA1c + any of: eGFR 45 60 / BP≥140/90 / Higher risk foot disease or PAD or neuropathy / Erectile Dysfunction / Diabetic retinopathy / BMI >35 / Social complexity / Severe frailty / insulin or other injectables / Heart failure	Med-risk: priority 4			
	All other T2D patients	Low-risk: priority 5			
	HbA1c >= 75 + >50yrs + BMI >30				
	Co-morbidity patients (regardless of HbA1c)				
	Insulin initiation / intensification during Covid				
	Patients with previous diabetic foot disease				
	Diabetes patients + most recent eGFR reading of <45 compared to previous eGFR reading of <45 At risk IF: a drop of >10 between two results OR most recent eGFR is<30 (+ prioritise patients with an elevated HbA1c and a BMI>25kg/m2				
	EMIS monthly trigger tool to review CKD cases with an eGFR fall of ≥ 10 from the previous value				

**UCL Partners Framework and Ardens EMIS stratification search is built on the same underlying search, so only included once in the table.*

*** Social complexity includes Learning disability, homeless, housebound, alcohol or drug misuse*

Category/Criteria		ASSETS				
		UCL Partners: Proactive Care Framework for Type 2 Diabetes	London Clinical Networks: COVID-19 DKD Risk Stratification Pathway and search tools	HIN/SEL CCG: Guidance and searches to support the management of high-risk patients and high-risk foot disease	Clinical effectiveness Group: Renal Decline EMIS Trigger Tool	
MANAGE	Contact method	Phonecall (with/without HCP scripts)				
		Preliminary text prior to phonecall				
		Protocol template / proforma to complete				
		Book primary care review for CKD				
	Medication - Topics	Adherence	All risk levels			
		Titration & intensification as appropriate	All risk levels			
		Explore/check understanding	Low risk level only			
		Confirm supply and delivery	Low risk level only			
		Test strips and lancets required for blood sugar level testing at home?				
		If they check ketone-levels (blood/urine) are new strips required?				
		Medication review				
	Monitoring - Topics	Blood sugar control & personal targets	High+Med risk levels			
		Agree HbA1c targets	High risk level only			
		Lipids / lipid lowering therapy	High+Med risk levels			
		BP optimisation	High risk level only			
		Screen and manage diabetic foot disease	High+Med risk levels			
		Screen and manage diabetic kidney disease	High+Med risk levels			
		BP and proteinuria	Medium risk level only			
		Treat hyperlipidaemia to target				

	Monitor renal function				
	Current urine output and any recent urinary symptoms				
	Currently under specialist renal services?				
	Currently under a Foot team (community/hospital)?				
	Foot condition (various Qs in high-risk diabetic foot proforma)				
	How patient can monitor feet				
Education - Topics	Sick Day Rules	All risk levels			
	DVLA Guidance	All risk levels			
	Flu jab	All risk levels			
	Signpost to online resources (i.e. DUK etc)	Med+low risk levels			
	Risk factors (diet/lifestyle/smoking)	Low-risk only			
	Advise and signpost re Diabetic Foot disease	Low-risk only			
	Signpost to weight loss services and/or exercise on prescription if BMI>30				
	Trend UK Type 2 Diabetes and diabetic ketoacidosis information				
Review / Discuss red flag - Topics	Vision: floaters/flashing lights				
	Blood sugar control: hypos	High+Med risk levels			
	Infections	High+Med risk levels			
	Signposting and Escalation	High+Med risk levels			
	Diabetes community + secondary care team/advice	High risk level only			
	Recall and code	All risk levels			

Appendix 2. Additional Guidance for Practices

Risk Stratified Diabetes Patients receiving You & Type 2 Care Planning Pathway

IDENTIFY those at Higher Risk -> **Confirm** current clinical situation (BP, bloods, foot exam) -> **Optimisation** with **Specialist** input (if needed) -> **Care planning**

STEP 1 – IDENTIFY AT RISK POPULATION: EMIS built risk stratification search lead by disease criteria

STEP 2 – Optimisation OF AT RISK POPULATION

Specialty	Triage criteria when new results come in	Outcome
Foot	New confirmed loss of Protective Sensation	Refer to community foot protection service
	New confirmed peripheral arterial disease	
Foot	Foot deformities (with pressure areas / significant callus or pain)	URGENT Referral to MDFT: <ul style="list-style-type: none"> • SEL via foot navigators gst-tr.sel_navigator@nhs.net • Pathfinder podiatrist for the diabetic foot clinic at St Georges: Kathryn.Dennies@stgeorges.nhs.uk
	Acute foot ulceration	
Kidney	eGFR <30ml/min/1.73m ³	Refer to specialist service
	Sustained decrease in GFR of 25% or more, and a change in GFR category or sustained decrease in GFR of 15 ml/min/1.73 m ² or more within 12 months	Refer to specialist service
	uACR >30mg/mol + haematuria	Refer to specialist service
	uACR >70mg/mol	Refer to specialist service
	uACR 3.1-30mg/mol not meeting other referral criteria	Optimise renoprotective management via London kidney network guidance (currently being signed-off – we will update you on this but in the interim use: SGLT-2 Inhibition in Adults with Kidney Disease The UK Kidney Association)
	Suspected renal artery stenosis	Refer to specialist service
	eGFR <60ml/min with either: <ul style="list-style-type: none"> • Absence of retinopathy or • Haematuria 	Refer via advice and guidance
Hypertension poorly controlled on 4 antihypertensive drugs at therapeutic doses	Refer via advice and guidance	
Diabetes	HbA1c >10% (86mmol/mol)	Refer: via Advice & Guidance for specialty advice (multimorbid)
	HbA1c 10 (86)-7.5% (58 mmol/mol)	Optimise: Consider community diabetes referral or increased practice input
	HbA1c <6%(42 mmol/mol)/6.5% (48) if on hypoglycaemic agents	Consider reducing diabetes medications (especially if frail or worsening eGFR)

You and Type 2 Risk Stratified Pathway Practice Staff Interview Schedule

Questions:

1. What was your role in the You and Type 2 Risk Strat project?
2. Did you adapt the patient list the risk stratification tool created at all? Why?
 - Prompt: Manually adapted list or changed search
3. Did the clinical decision maker (GP) review the list and manually remove some patients that may not have been appropriate? Why?
4. How was the identified cohort separated from general type 2 diabetes annual review recall list? (i.e. through batch coding)
5. How was the recall of the identified people managed?
 - Prompt: Prioritisation
6. What did and did not work well in operationalising risk stratification in the practice?
 - Prompt: Delays
7. What did you think of the risk stratification element of it?
 - Prompt: Was it helpful?
8. Having been involved in the pilot, do you see a role for risk stratification in routine primary care?
9. If clinician: Did you include any of the specialist clinical advice provided as part of the pathway?
10. If yes: Does this approach create additional burden for you?
11. If yes: Are there more referrals happening now for this cohort / or are referrals more timely?

You and Type 2 Risk Stratified Pathway Practice Staff Interview Schedule

Questions:

1. What was your role in the You and Type 2 Risk Strat Project?
2. How do you think it has gone?
3. How was the risk stratification search developed?
4. How was the additional support from a secondary care specialist developed?
5. What do you think the main challenges to the project / part of the project you were involved with have been?
6. What has worked well in the project?
7. What do you think the opportunities of the project are going forwards?
8. Is there anything else you think it is important for me to know when evaluating this project?

Appendix 5 – Final Version of the Risk Stratified Search

Type 2_DKD Heart failure and Foot Risk Strat FINAL (2)					
Details	Definition	Age / Sex	Trend	Population Included	Population Excluded
Parent Population Currently registered regular patients					
Rule 1		If Rule Passed : Goto Next Rule		If Rule Failed : Exclude from final result	
Include Patients with Clinical Codes where: the Clinical Code is Type 2 diabetes mellitus					
Rule 2		If Rule Passed : Goto Next Rule		If Rule Failed : Exclude from final result	
Either	Include Patients with Clinical Codes where: the Clinical Code is Proteinuria				
Or	Include Patients with Clinical Codes where: the Clinical Code is Microalbuminuria				
Or	Include Patients with Clinical Codes where: the Clinical Code is Chronic kidney disease stage 3				
Or	Include Patients with Clinical Codes where: the Clinical Code is Chronic kidney disease stage 4				
Or	Include Patients with Clinical Codes where: the Clinical Code is O/E - Right diabetic foot at high risk, O/E - Left diabetic foot at high risk, Left Foot High Risk, Right Foot High Risk, etc...				
Or	Include Patients with Clinical Codes where: the Clinical Code is Congestive heart failure, Heart failure, Chronic congestive heart failure, Right heart failure, Chronic systolic heart failure, etc...				
Or	Include Patients with Clinical Codes where: the Clinical Code is Urine albumin:creatinine ratio Ordering by Date select the latest and check that: the Value is more than or equal to 3				
Rule 3		If Rule Passed : Exclude from final result		If Rule Failed : Goto Next Rule	
Include Patients with Clinical Codes where: the Clinical Code is Haemoglobin A1c level - International Federation of Clinical Chemistry and Laboratory Medicine standardised and the Date is after 9 months before the search date and before 2 months before the search date and the Value is less than or equal to 64					
Rule 4		If Rule Passed : Exclude from final result		If Rule Failed : Include in final result	
Include Patients with Clinical Codes where: the Clinical Code is Haemoglobin A1c level - International Federation of Clinical Chemistry and Laboratory Medicine standardised and the Date is after 2 months before the search date					