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Feasibility of a Decision Support Tool for the Pharmacological Management of Depression

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Abstract

Objective: The accurate prescription of antidepressants is technically complex and difficult to achieve. This project therefore sought to evaluate the feasibility of integrating an evidence-based decision support tool (Predictix) into General Practice.

Methods: This was a real-world mixed methods evaluation in N=2 General Practices of the experiences of patients (n=24), General Practitioners (GPs; n=4) and Predictix administrators (n=2). Suitable patients were assessed using Predictix and this produced a recommendation for the likely most efficacious anti-depressant. Two patient study groups were created (a) antidepressant recommended by Predictix and (b) a GP clinical opinion override group. Both groups of patients were followed up at 12-weeks. The PHQ-9 was embedded in the Predictix assessment, and the measure was recompleted at 12-weeks follow-up. Qualitative interviews were conducted with GPs, patients and administrators and a reflexive thematic analysis (RTA) conducted.

Results: It took 20-minutes to administer Predictix and then 3-days for the prescription to be issued. N=19 (88%) received a Predictix selected antidepressant (2 participants dropped out during the Predictix assessment), of whom 8/19 recovered. The N=3 (14%) in the GP override group all recovered. The common qualitative themes across GPs, patients and administrators were managing expectations, individualized care and burden.

Conclusion: Whilst decision support tools have the potential for increasing prescribing accuracy for antidepressants, practical and psychological barriers to implementation need to be identified and resolved.

Keywords: Predictix • Machine learning • Depression • PHQ-9 • Outcome • Mixed methods

Introduction

For General Practitioners (GPs) identification and treatment of Major Depressive Disorder (MDD) can be a complex clinical task [1] requiring rapid diagnosis, a treatment plan and response monitoring [2]. When the treatment is an antidepressant, many fail to receive an efficacious medication, triggering a trial-and-error approach [3]. AI-driven clinical decision support tools (CDST) help through increased personalization of treatment plans [4-6]. There are examples of CDSTs signaling when to change antidepressant dose, begin an augmentation medication or create a new treatment plan [7-9]. CDSTs for MDD need to be easily integrated into the organizational processes and clinical governance of Primary Care [10], be easy to use [11] and be trusted by patients [12].

Predictix is an example of a CDST for personalizing the pharmacological treatment of MDD [13-15] by providing individualized probabilities of remission for specific treatment options via a deep-learning model validated and trained on clinical and demographic baseline data [16]. The clinical algorithm is an operationalized version of the Canadian Network for Mood and Anxiety Treatments [17] guidelines. Predictix was validated on the STAR-D trial [18] and was shown to select suitable antidepressants with a mean balanced accuracy of 70.1%, compared to a 46.8% mean initial response rate in the same set of patients [14]. A previous clinical pilot (N=30) in France found 61.1% met the treatment response definition after receiving a Predictix-decided antidepressant [19].

We wanted to conduct a study in the United Kingdom to better understand the acceptability and effectiveness of this CDST in a real-world Primary Care setting. This study had seven sub-aims: (1) To know how long it takes to complete a Predictix assessment and for GPs then issue the antidepressant prescription, (2) To profile the patients being assessed with Predictix, (3) To know what prescriptions are recommended by Predictix and whether these differ from when GPs decide to override the CDST, (4) Define the rate at which GPs override Predictix, (5) Compare outcomes between GP versus Predictix decided anti-depressant treatment at 3-months follow-up, (6) Assess safety in terms of the serious and untoward incident rate and (7) Qualitatively understand the experience of GPs, patients and Predictix administrators of using Predictix. To meet the aims of the study we sought to recruit one practice site and N=24 patient participants. Guidelines for sample sizes for feasibility studies suggest a range from 24-50, and feasibility studies tend not to have a power analysis [20].

Methods

Setting and design

Two General Practices were recruited. All participants provided written informed consent to participate. This study used a two-arm, mixed-methods naturalistic follow-up design. The two arms were: (1) Participants that were

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assessed with Predictix and the GP issued the associated prescription and (2) Participants that were assessed with Predictix and the GP then decided to issue a different prescription. Qualitative interviews were conducted with GPs, patient participants and Predixtix administrators. The patient participant interview was conducted at three-months follow-up from the prescription being issued. GPs and Predictix administrators were interviewed after all the patient participant data was collected.

Participants

The three inclusion criteria were: (a) patients regardless of gender aged 18-75, with a GP diagnosis of MDD according to the DSM-5 criteria [21], (b) seeking help for depression and (c) able to read and understand the participant information sheet and sign a consent form. The nine exclusion criteria were: (a) no more than two previous failures of pharmacological interventions to treat the current depressive episode, (b) outside the appropriate age range, (c) a diagnosis of psychosis, personality disorder, bipolar disorder, or cyclothymia, (d) pregnant women, (e) taking medications with a strong central nervous system (CNS) effect 30-days prior to starting treatment, (f) at high risk of suicide (according to the clinical judgment of the GP), (g) substance-misuse disorder, intellectual disabilities or dementia, (h) active neurological pathology (e.g., Parkinson's, Alzheimer's, etc.) and (i) unable to read and write English (i.e., because Predictix isn't validated in other languages).

Procedure

Patient participants were identified by the GP as having MDD at an initial consultation and in this consultation GPs considered whether the patient met inclusion/exclusion criteria. If a patient was suitable, Predictix was explained, and patients were invited to participate. The Predictix session was booked by the GP into the practice diary, the patient was sent a text message with the Participant Information Sheet (PIS) and Predictix was then conducted on the telephone by mental health professional (i.e., Psychological Wellbeing Practitioner; PWP). The PWP would gain informed and signed consent, administer Predictix and book a follow-appointment at 12-weeks. GPs received the Predictix report immediately following the session and this would be saved on the patient record. The report contained personalized predicted remission probabilities for various anti-depressants and provided high, medium and low compatibility medication recommendations. GPs would prescribe according to the Predictix decision (GP deciding the dose), or override Predictix, prescribe another antidepressant and decide the dosage.

Predictix

Predictix would ask the following demographic questions (age, gender, accommodation/living situation, employment status, marital status, living with a partner, private health insurance and currently having psychotherapy), physical health questions (upper gastrointestinal problems, neuropathic pain, musculoskeletal problems and endocrine/metabolic problems), mental health questions (appetite change, body image, somatic concerns, avoidance of anxiety, health worries, self-consciousness, libido, compulsions, trauma and sleep quality) and medication questions (current and historical depression medications, current and historical depression medications that parents, siblings or children have taken). Predictix also administered the Patient Health Questionnaire-9 (PHQ-9) [22].

Measures

Patient Health Questionnaire-9: The PHQ-9 measures depression severity [22] and total scores of 5, 10, 15, and 20 are the cut-offs for mild, moderate, moderately severe and severe depression. A reliable reduction in depression occurs when a pre-post score falls by >6 points and this is clinically significant when the post score is <10 (i.e., the follow-up was in the community range). Recovery was defined as when clinical and reliable change occurred.

Adverse events: An adverse event (AE) was defined as any participant being admitted to a psychiatric inpatient setting, requiring referral to secondary mental healthcare, incidences of self-harm requiring assessment at a hospital Emergency Room and death by suicide.

Quantitative analysis plan

A CONSORT summary to display patient flow through the various stages of the project. All analyses to be conducted based on Intention-To-Treat (ITT) principles (i.e., including all participants who completed the Predictix assessment) and last observation carried forward for cases with missing 12-week follow-up data (n=6). Descriptive statistics of the time taken to perform Predictix, what recommendations were produced, and the time taken for the prescriptions to be issued. A binomial test to test whether the proportion of participants in the Predicitix group was greater relative to the GP override group than chance (0.5). An adverse event rate to be calculated for both groups. Pre-post PHQ-9 differences analyzed using non-parametric tests due to the small, uneven sample sizes which violated normality and unequal variances (i.e., Mann-Whitney and Wilcoxon signed-rank tests for between-group and within-group comparisons respectively). Recovery rates on a Jacobson plot with a plot for completers only (i.e., excluding cases with missing data at 12 week follow-up) provided in the Supplementary Materials.

Qualitative interview and analysis plan

All interviews were conducted on the telephone using a semi-structured interview format and the questions used can be seen in online supplementary materials. Reflexive thematic analysis (RTA) [23] followed the six-stages of familiarization, coding, generating initial themes, developing and reviewing themes, refining, defining and naming themes and writing up [24]. To check reliability, a secondary independent analyst completed the initial coding of 25% of the data. An inductive approach was used, the positionality and bias of the analyst (a white female trainee clinical psychologist) were considered, and a critical realist stance was taken [25].

Thematic maps were produced for each group which were synthesized to highlight common themes across the interviews groups. PHQ-9 recovery indices are also included with patient quotes in online supplementary materials.

Results

Patient flow is summarized in the CONSORT diagram (Figure 1). Ninety per cent of referrals were screened for eligibility and there was a 10% refusal rate for Predictix. GPs defined that 48% of depressed patients were eligible for a Predictix assessment. But, 42% of these patients referred by GPs for a Predictix assessment were then found to be ineligible when screened by the PWP (i.e., the main reason being the patient being already prescribed a medication with a strong CNS effect). The study recruitment target was met (N=24), but two participants withdrew during the Predictix assessment. For the N=22 that completed the Predictix assessment, 73% attended at follow-up and 32% participants were interviewed. No significant differences were found between the follow-up and lost to follow-up participants on any demographic or clinical variables. The sample was 64% female and 36% male with a mean age of 35.8 years (SD=14.8 years), predominantly white British (91%), single (68%) and employed (73%). Predictix assessments took 20.5 minutes (SD=5.3; range: 11-35 minutes) and then 3.18 days elapsed before the prescription was issued (SD=4.7; range: 0-18 days).

The Predictix group comprised N=19 (86%) and the GP override group comprised N=3 (14%). Figure 2 reports the group level PHQ-9 outcomes in the ITT analysis. Both group means were above the clinical cut-off of >=10 on the PHQ-9 at the time of the Predictix assessment and all participants were in caseness (Predictix mean=16.90, SD=4.63; GP override mean=15.67). There were no significant differences in the baseline PHQ-9 score between the two groups (Mann-Whitney=26.0, p=.847; rank bacterial correlation r=0.-0.09).The Predictix recommended medications were: Citalopram (n=1), Duloxetine (n=2), Escitalopram (n=4), Mirtazapine (n=6) and Sertraline (n=6). In the GP override group (N=3), one patient had Citalopram changed to Venlafaxine and two patients were referred to the Talking Therapies service and received brief low intensity psychological interventions. The rate at which Predictix-recommended antidepressants were prescribed (proportion=0.86) was significantly greater than chance (p<.001) and the GP override group proportion (0.14) was significantly lower than chance (p<.001). No serious adverse events were recorded.

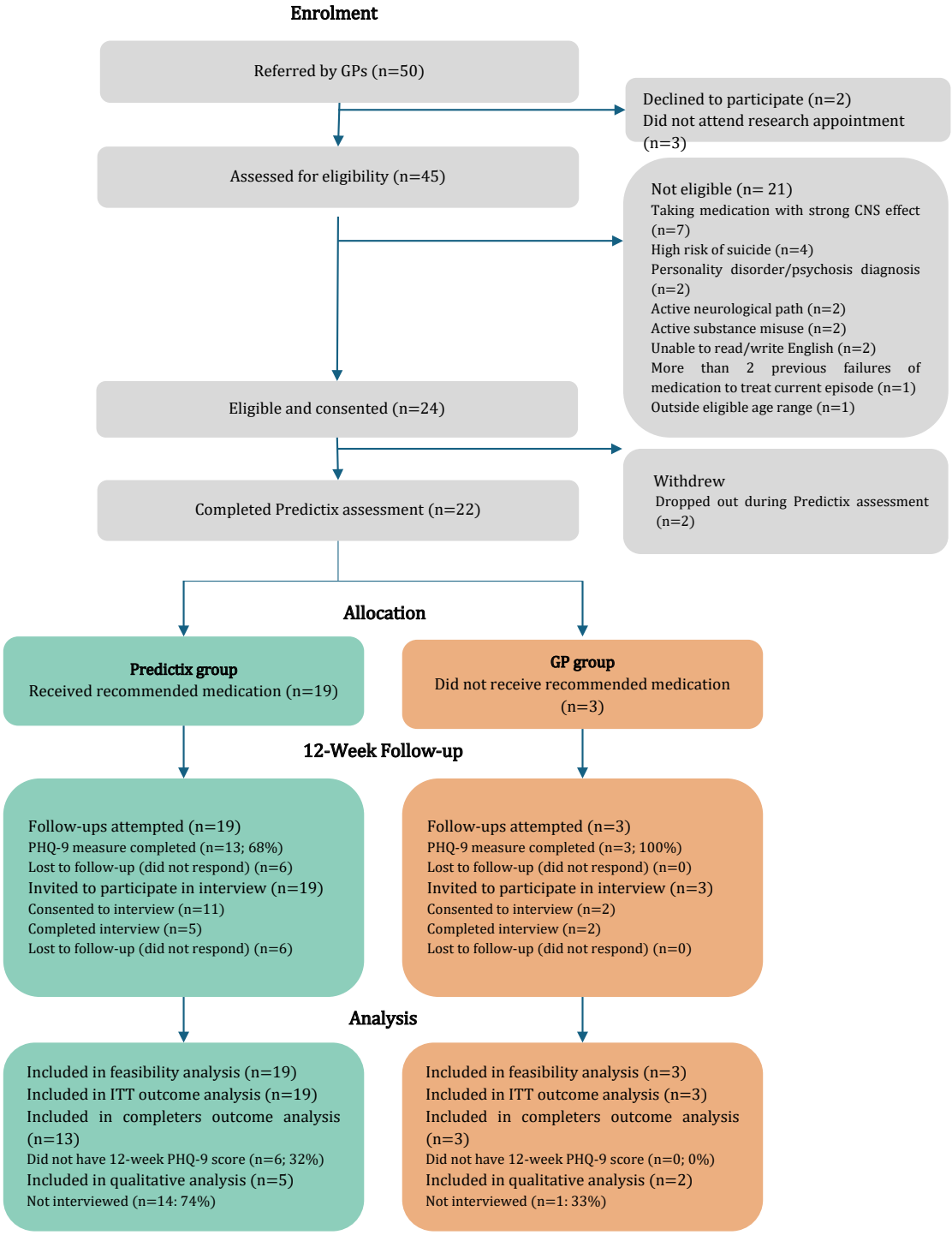

Figure 1. CONSORT summary.

There was no difference between Predictix and GP override groups in the follow-up PHQ-9 scores (Mann-Whitney=20.0, p=.442; r=0.-0.30). There was a significant reduction in PHQ-9 scores in the Predictix group (n=19, Wilcoxon=88.0, p=.003, r=0.93) and the reduction in PHQ-9 scores in GP override group did not reach significance (n=3, Wilcoxon=6.0, p=.250, r=1.0). Figure 3 reports Jacobson plot. In the ITT, Predictix participants, 8/19 (42%) experienced a reliable and clinically significant reduction in depression and no participants met criteria for a reliable deterioration in depression or had been harmed. In the GP override group 3/3 (100%) experienced a reliable and clinically significant reduction in depression.

The qualitative sample consisted of n=7 patient participants (4 men and 3 women, mean age 41.9, SD 17.9 and all White British and 5/7 in part-time or full-time employment), n=2 Predictix administrators (both female) and n=4 GPs.

Supplementary online materials contain the superordinate, subordinate and narrative evidence from each group and the three thematic maps and Figure 4 contains the synthesis of common themes. Predictix was seen as helping in personalizing the treatment of depression, but careful consideration was needed with managing expectations. GPs and administrators shared a concern about the challenge of the research process and GPs and patients sharing a concern about the burden of Predictix.

Discussion

Summary

This study conducted in routine General Practice care met its recruitment

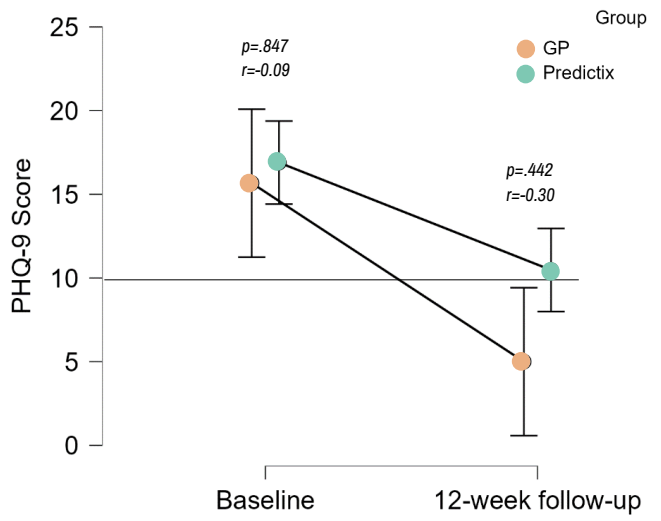

Figure 2. Baseline *vs.* follow-up group depression outcomes on the PHQ-9 (p value and rank biserial correlation (r) effect size for Mann-Whitney test).

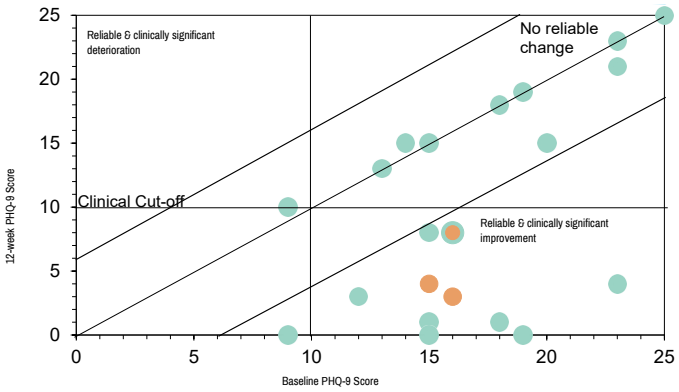

Figure 3. Jacobson plot of case-by-case recovery rates (Green dot= Predictix participant and orange dot= GP override participant).

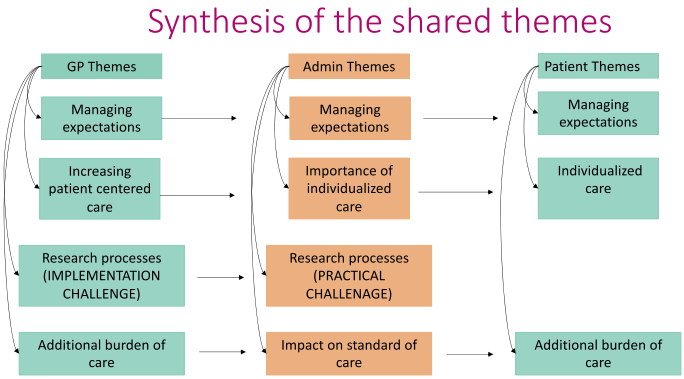

Figure 4. Shared themes across GPs, Predictix administrators and patient participants.

target and explored the acceptability and effectiveness of an AI-driven CDST (i.e., Predictix) used to personalize antidepressant treatment of MDD. The recovery rate was 42% for those receiving the CDST selected antidepressant and the recovery rate was 100% when GPs overrode the CDST. Previous evidence using a less strict PHQ-9 outcome definition showed that 61% of patients benefitted from a Predictix selected antidepressant [19]. There were no adverse incidents in the current study providing preliminary evidence of safety. The average time to complete a Predictix assessment was 20 minutes, and this is longer than the average 10-minute GP appointment. Two patients discontinued being in the study during a Predictix assessment due to being uncomfortable the questions being asked. Overall, Predictix was viewed in an equable manner (i.e. both positives and negatives) in terms of acceptability across GPs, patients and administrators.

Comparison with existing literature

Any CDST must be both acceptable to the patient and simultaneously provide information to the GP that is reliable, clinically efficacious, easily understood and can be quickly acted upon with low burden for all [26]. Where medics have previously administered Predictix, they felt that Predictix was easy to use during MDD assessments and did not adversely impact on the therapeutic relationship [19]. The patient participants generally were positive about their experience of the CDST and felt that treatment was being personalized, that Predictix was thorough, and that follow-up was important. This mirrors the evidence base that patients' generally experience precision medicine in a positive manner [27]. GPs also emphasized that Predictix increased patient centered care but noted that patients needed preparing for what Predictix was, were concerned that Predictix could delay treatment and that the exclusion criteria were too restrictive (i.e., a lot of patients were already prescribed other medications with a strong CNS effect). There can be ambivalence in GPs regarding AI-driven personalization, when there is a mismatch with core medical values [28].

Strengths and limitations

Strength of this study is that it is the first of its kind to be conducted in routine practice in the UK and the method allowed GPs to override the AI when they felt this was in the best interests of the patient. The use of mixed methods yielded nuanced results that would have been missed without the qualitative input. Whilst the study met its recruitment target, the sample sizes were still small and unequal, and this limits generalizability. Involvement in the research study may have primed the patient participants to respond positively. It is acknowledged that referring the patient for a Predictix assessment delayed the prescription being issued by 3-days on average, but the participants did benefit from an AI-driven assessment. Lack of randomization, an active control group and the lack of long-term follow-up were also study limitations.

Implications for research and/or practice

The clinical trends recorded by the study need to be researched with larger clinical samples. Because patient preferences are a major factor to consider in the possible future adaptation of AI into clinical decision making regarding treatment of MDD [29], then a patient preference trial would be the most obvious choice of future clinical trial design. Patients could be offered CDST versus GP assessment and those with no strong preference could be randomized. Patient self-completion of Predictix prior to a GP appointment needs to be investigated, and the usability, safety, efficacy and effectiveness of Predictix in Secondary Care researched. Integrating quantitative measures of CDST acceptability will be useful in such projects (e.g. the Shared Decision-Making Questionnaire) [30].

Conclusion

This study indicates the potential utility of an AI-enabled CDST for GPs treating patients with MDD. Overall, GPs found the CDST useful and followed the advice provided. CDSTs for MDD present GPs with an opportunity to actively integrate wider evidence into antidepressant treatment selection, and this feasibility study shows that GPs were largely willing to accept this CDST. GP training and patient psychoeducation are important methods of improving trust and, in turn, increased use of CDSTs for MDD. Sufficiency powered clinical trials are now needed to accurately index effectiveness, and GP and patient preferences need to be carefully considered during study design. Creating a patient self-report version of Predictix could support diligent and compassionate assessment of MDD by GPs, so that any CDST augments rather than replaces diagnostic competency. The best AI–GP ratio for MDD is clearly yet to be discovered.

Data Sharing

The data and the analysis are available from the corresponding author on request.

Competing Interests

None.

Acknowledgements

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Ethical Approval

The study was approved by the East Midlands – Nottingham 2 Research Ethics Committee (22/EM/0266; 320999).

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Supplementary Materials; Qualitative Interview Schedules

GP Interview Schedule

Introduction

Thank you are taking part in the project and agreeing to be interviewed. All the GPs that have used Predictix as part of the project are being interviewed about their experience of the system and the way in which it impacted on the clinical process with the patients and organisational process of your practice. The conversation we are about to conduct will be anonymised and we will conduct an analysis identifying themes across GPs, PWPs and patients. The interview is being recorded and that recording will be stored securely with an anonymous study ID number. It is important that you are honest about your lived experience of Predictix, so we get an accurate picture of what it felt like to use Predictix.

Interviewer

Ask each question in turn providing space for the GP to respond and also ask the GP to expand on areas in which the detail might be thin or the topic area interesting. Do this both for negative and positive aspects of their personal experience.

Question one: Tell us how you heard about the project, how you got involved and what your beliefs were before using Predictix.

Follow up - Did this change over the course of using Predictix?

Question two: How did you find introducing Predictix to patients? What were their responses?

Question three: As a decision-support tool for the identification and management of depression in Primary Care, please appraise Predictix as a decision-support tool.

Question four: Name five words that you would associate with Predictix.

Question five: What did you think of the predictions made and the way they were fed-back?

Question six: How would you improve Predictix for any future practice that was to use it.

Question seven: If it did, in what way did Predictix change organisational practices and what did this feel like?

Question eight: Please tell us anything that is important about your use of Predictix that has not already been asked or spoken about.

Interviewer- Thank the participant and close the interview.

Predictix Administrator Interview Schedule

Introduction

Thank you are taking part in the project and agreeing to be interviewed. PWPs that have used Predictix as part of the project are being interviewed about their experience of the system and the way in which it impacted on the clinical process with the patients and organisational process in the practice. The conversation we are about to conduct will be Anonymized and we will conduct an analysis identifying themes across GPs, PWPs and patients. The interview is being recorded and that recording will be stored securely with an anonymous study ID number. It is important that you are honest about your lived experience of Predictix, so we get an accurate picture of what it felt like to use Predictix.

Interviewer

Ask each question in turn providing space for the PWP to respond and also ask the PWP to expand on areas in which the detail might be thin or the topic area interesting. Do this both for negative and positive aspects of their personal experience.

Question one: Tell us about your thoughts and feeling before using Predictix.

Follow up- Did this change over the course of using Predictix?

Question two: How did you find using Predictix with patients?

Follow up – What was easy and useful?

Follow up – What tricky and difficult?

Question three: As a decision-support tool for the identification and management of depression in Primary Care, please appraise Predictix as a decision-support tool.

Question four: Name five words that you would associate with Predictix

Question five: What did you think of the predictions made and the way they were fed-back.

Question six: How would you improve the Predictix system for any future practice that were to use it.

Question seven: If it did, in what way did Predictix change organisational practices and what did this feel like?

Follow up – Focus on the relationships with the GPs.

Question eight: Can you tell us about any differences in working in this way and the normal role taken up by PWPs in GP practices.

Question nine: Please tell us anything that is important about your use of Predictix that has not already been asked or spoken about.

Interviewer- Thank the PWP participant and close the interview.

Patient Participants (PPs) Qualitative Interview Schedule

Introduction

Thank you for taking part in the project and agreeing to be interviewed. Patient participants in the GP practice that that were assessed using the Predictix system (i.e., when you had the specialist assessment that asked you a lot of questions about your depression) are being interviewed about their experience of the system. The conversation we are about to conduct will be Anonymized and we will conduct an analysis identifying themes across GPs, PWPs (i.e., the professional that conducted the Predictix assessment) and patient participants. The interview is being recorded and that recording will be stored securely with an anonymous study ID number. It is important that you are honest about your lived experience of Predictix, so we get an accurate picture of what it felt like to have Predictix as part of your clinical care.

Interviewer

Ask each question in turn providing space for the PP to respond and also ask the PP to expand on areas in which the detail might be thin or the topic area interesting. Do this both for negative and positive aspects of their personal experience.

Question one: Tell us about what it was like to have a Predictix assessment?

Follow up- Get the PP to elucidate.

Question two: Rate how happy you were in terms of the antidepressant decision that was made 0 (not happy) to 100 (happy).

Question three: If you think Predictix improved or negatively affected the care you received for depression in the GO practice then please tell us in what ways.

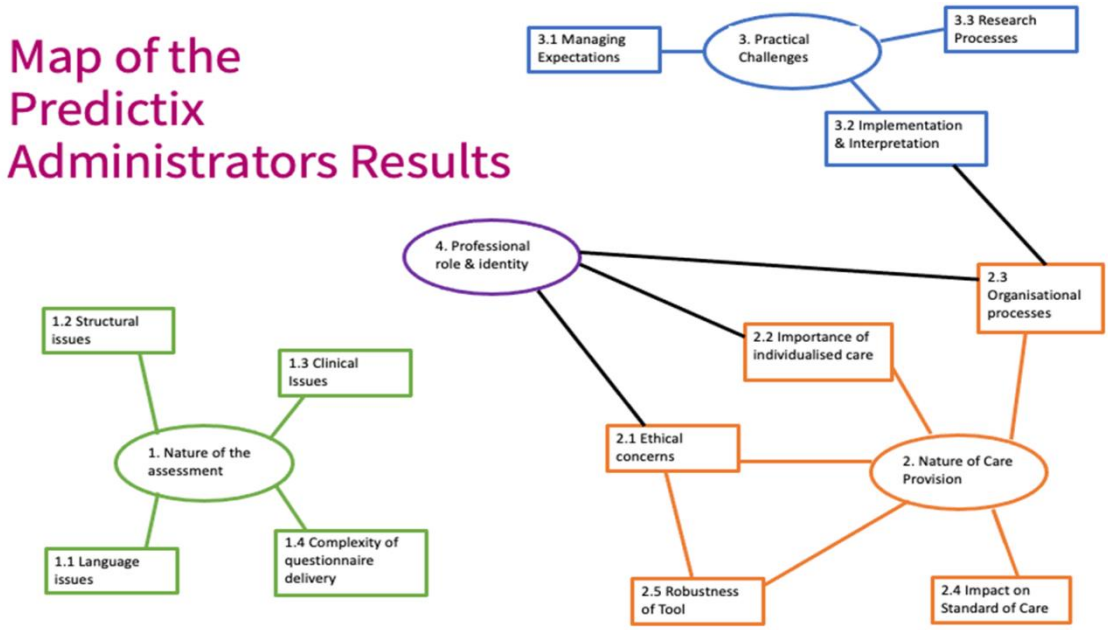
Question four: Name five words that you would associate with Predictix.

Question five: If your Predictix experience could have been improved what would have been different?

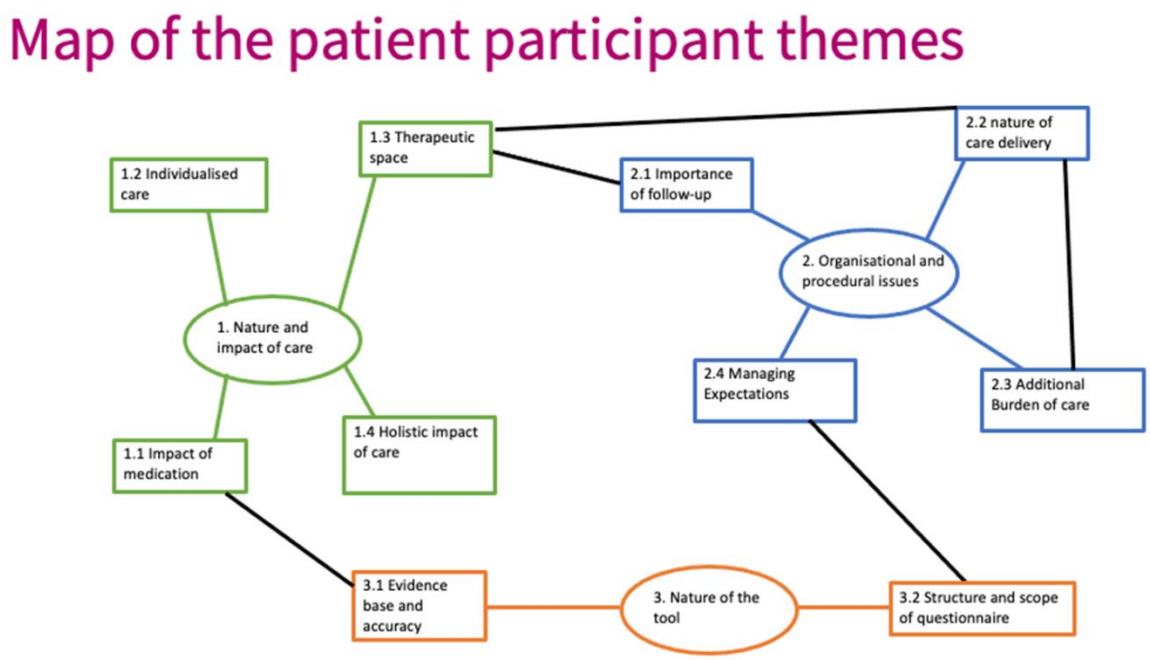
Question six: Please tell us anything that is important about your experience of Predictix that has not already been asked or spoken about.

Interviewer**-** Thank the PP and close the interview.

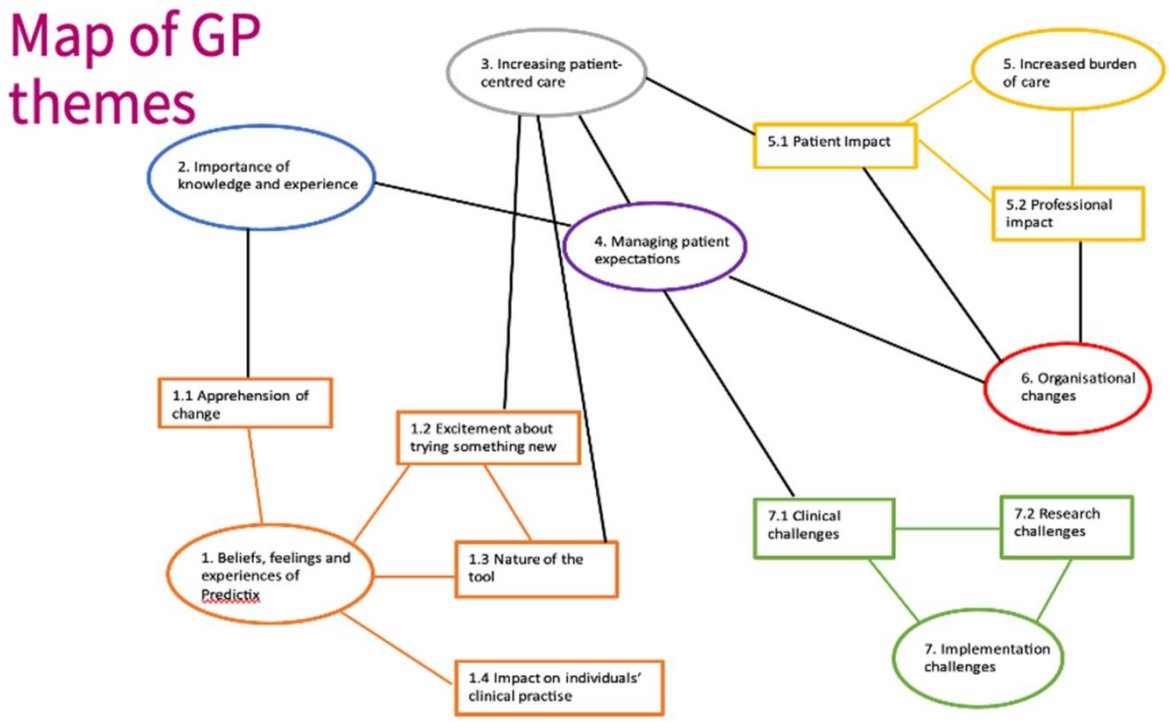
Supplementary materials; Thematic Maps for GPs, administrators and Patient Participants



Thematic map for predictix administrators.



Thematic map for patient participants.



Thematic map for GPs.

Qualitative evidence for Predictix Administrators: Superordinate, subordinate themes and evidence.

Superordinate Theme	Subordinate Theme	Evidence
Nature of the assessment	Language issues	"The translation isn't perfect. […] I wrote a whole script out and made it more English friendly" "It doesn't sound like you're engaged or interested in what they've got to say and but then also some of the questions were quite confusing" ""I think some of the language could be more accessible as well. So you know […] rather than psychotherapy, you know, they could maybe replace it with therapy for your mental health."
	Structural issues	"The order of the questions could be improved or thought so and it in all areas where they. So whether it is sort of you know the demographic, clinical, physical health, but mainly the demographic and clinical. But like they jumped around a lot so." ""a lot of the questions, they had multiple choice answers, but they didn't fit with what the participants experienced and that they commented on the on that basically. So you know they found it quite reductive or inflexible."
	Clinical issues	"They've got anxiety, not depression. So you know that in that sense it probably wasn't even used properly, the GP wasn't referring appropriately, and even on their notes it

		said depression, but they obviously, unless the patient was just, you know, dismissing that that was either being ignored" "but most of them said they were anxious and not depressed" "It's very kind of anxiety heavy in terms of the questions that they asked."
	Complexity of questionnaire delivery	"It was quite like user friendly in terms of like the actual computer programme" "In terms of the system, we've had quite a few technical issues. So we had some reports not being saved and we had some reports that weren't letting us go all the way through it" "I think the way that it would be most helpful for GPS is if a patient could do it themselves" I think originally they were thinking maybe for patients or participants to sort of use the tool independently and I don't think that could ever happen."
Nature of Care Provision	Ethical Concerns	"I always really thought it's got to be a small piece of the pie rather than a full piece of the pie" "but my concerns are that it would not be a side tool" "They'd come and then they'll tell us a lot of personal information and then we'd say sorry, you're not eligible for it. You know they were expecting to receive something, you know they didn't receive it" "we've not sought permission from their family members, you know what I mean for their, you know, for the person that we're speaking to, to disclose that information"
	Importance of Individualised Care	"the patient or the person at the centre of care and there's gonna be a lot of factors which are missed, you know in in relation to depression" "I just think humans are humans and their complex and you need to speak to them. And I think, you know, yeah, I I'd say overall is going in the opposite direction of what I think we need to be doing." "The GP, […] they are discussing all the options and that they've kind of used it in that way for it to be all the options rather than doing it the like […] going down whichever path"
	Organisational Processes	"[I'm a] little bit concerned that GPs wouldn't necessarily want to use this sort of thing and relinquish that control" "I think cause there's [lists stakeholders]. I think all three of us have different ideas. So [its] getting those all to line up has been well they're still not lined up" "what was meant to happen was they were meant to see a patient tell them about the study and then text them a link to the participant information sheet and that GP surgery refused to do it"
	Impact on Standard of Care	"it's just not fair on the patient and then all you know it's also wasted time for and where they could have just gone to their initial appointment with their doctor and just been prescribed something" "it was a little bit tricky cause it was sort of like, yeah, like I said, it's just it's a delay, isn't it? In them receiving their care."

	Robustness of the Tool	“Yeah, I always want to know sort of the the why or how does it work, but I don't, I don't know the answer to that one.” “I'm not convinced that I'm getting all the right information that's been put into it.” “It's a feasibility trial. So that made me feels more comfortable about it. The fact that it was like, […] been tried and tested in other countries anyway, and we're just seeing if it's feasible”
Practical Challenges	Managing Expectations	“It kind of demonstrated that actually this isn't necessarily right for everyone”. “I didn't want to like zhuzh it up so it sounded like something else, you know, to make it sound amazing. So, you know, I've described it to them as sort of a computer programme.”
	Implementation and Interpretation	“It's not not as simple and it is quite lengthy, you know, I know we've got the phq 9 on there, but there's still quite a few questions. You know, you would need a longer than a 10 minute slots that GPS get.” “You get sort of the recommendation for least effective, medium effective, most effective. Sometimes it's just in medium and most effective for instance, and like for most effective you can have like 3 kind of different ones that they might suggest and like we never really, we've still not got to the bottom of whether its kind of All of those 3 equal in terms of, you know, the like being as effective as each other or are they in an order so the top one is more effective than the 2nd and then the third or is it just like they're rolled in the highly effective bracket”
	Research Processes	“We had a lot of exclusion criteria’s which I assume really needed to be there based on kind of what the tool is and how they've designed it, and it made it really hard to get anyone that was that could that could you know that could sort of use the tool” “[the gps would] even sort of ask. Ohh, I know they're not suitable for the study, but can they use it anyway? Think no they can't.” “they said, you know, that that yeah, the answers that are given to me, they don't fit. so I don't want to continue”
Professional Role &Identity		“The demographic and clinical questions […] quite a lack of definition of sort of what they were asking” “Might even just made a difference if we would have had a bit more training on how to kind of use the tool itself […]this part is asking this kind of thing, you know what I mean? So leave them in this direction if they ask questions about it. There wasn't any” “I was feeling ambivalent” “I guess maybe with the PWP there might be lots of different ways you might sign posts, someone you might they might get these different types of therapy, it might be different you know disorders where is like we're predictive cause it's the set questions it's just depression.”

Qualitative evidence for the Patient Participants: superordinate, subordinate themes and evidence.

Superordinate Theme	Subordinate Theme	Evidence	PP ID	Was RCSC* achieved?
Nature and impact of care	Holistic impact of care	"[Predictix is] treating it as it's an important issue as opposed to ohh we're just but just ring in and that's it. To tick a box. It doesn't feel like it's a tick. The box. That's it."	237	No
		"You've helped me through life. Feel like you're pushing; push me into the right direction all time. And, done things up suit me and helping me. "	236	No
		"My daughter, because she's on antidepressants so she knows what I'm going through, and I know what she's going through"	236	No
	Impact of medication	"Yeah, she did explain it. You know, the doctor explained to me, sent me information about it. And so I was quite happy with what I received. Medication wise. Yeah, definitely."	237	No
		"And so actually the one that I'm on, I'm really happy with and it's I just feel like a completely different person and I've had literally hardly any side effects at all"	215	Yes
	Individualised care	"at least on the back of the survey I did, if I had gone onto medication, I'd have had more understanding to why they thought that was better, but they understand my answers and my, you know, my history and my experiences to make that informed decision."	215	Yes
		"My GP actually overrode that decision. So he's giving me a different one to what the study had come up with. And so, as I understand it, she did check with someone, and I and I was able to be told that was citalopram that came up as the best one. And they have had that before. But because I had some side effects"	215	Yes
	Therapeutic space	"The actually, let me talk then as well. If I had something else to like kind of say that wouldn't stop me like they would pick up on it and talk to me about it. Like the actual listening to me instead of just nodding"	221	Yes
		"I can only compare it to the doctor's. When I went to the doctors, it was absolutely awful and I feel like I couldn't speak to them"	221	Yes
		"But I just think when you're time constrained as a doctor	261	Yes

		and you've got the 10 minutes and you've got to move on, sometimes unfortunately you don't have the opportunity [to talk]"		
Organisational and procedural issues	Importance of Follow up	"No, I think it's been really good if I'm honest, because I genuinely didn't think I. I knew there would be a follow up appointment, but actually there's been quite a few follow-ups which is I obviously cause. I've never experienced this type of thing before, it was it was nice, it was nice to have the follow-ups"	237	No
		"I kind of express once along tablets last time there's no follow up, there's no aftercare. It's just you're and you're on them for good. And I didn't want to have that experience again."	261	Yes
	Nature of care delivery	"you go through the as you've just said the spiel and to go through that information is time consuming"	253	Yes
		"Overall fine experience was fine, yeah."	237	Yes
		"I kind of liked it. I think it was the best thing ever."	221	Yes
	Additional burden of care	"With it being additional, it could be like potentially overwhelming"	200	Yes
		"I didn't see the reasoning for it to be quite honest, but you know its defined by the GP so um the assessment was for the research purposes I would assume"	253	Yes
		"More succinct conversations, more succinct questions really"	253	Yes
	Managing Expectations	"Because I had an appointment, it was one that I I knew I could Base my day around it […] I weren't, caught off guard or anything and it were everyone's been completely honest with the timeframes"	200	Yes
		"Explain it a bit more than it would be the you know you'll get multiple answers […] that you can choose from. So yeah, I think that just needs to be a bit more explained, but other than that, yeah"	237	No
Nature of the tool	Evidence base and accuracy	"It helps minimise human error."	200	Yes
		"Because I think a person's opinions, like an educated person's opinions really good on it. But if you can get data alongside it as well"	200	Yes
	Structure and scope of the questionnaire	"I just found some of the questions […] difficult to answer cause of the vagueness of them."	200	Yes
		"I think cause they the quite unique circumstances it it would just quite hard to get [reflected in multiple choice] I	200	Yes

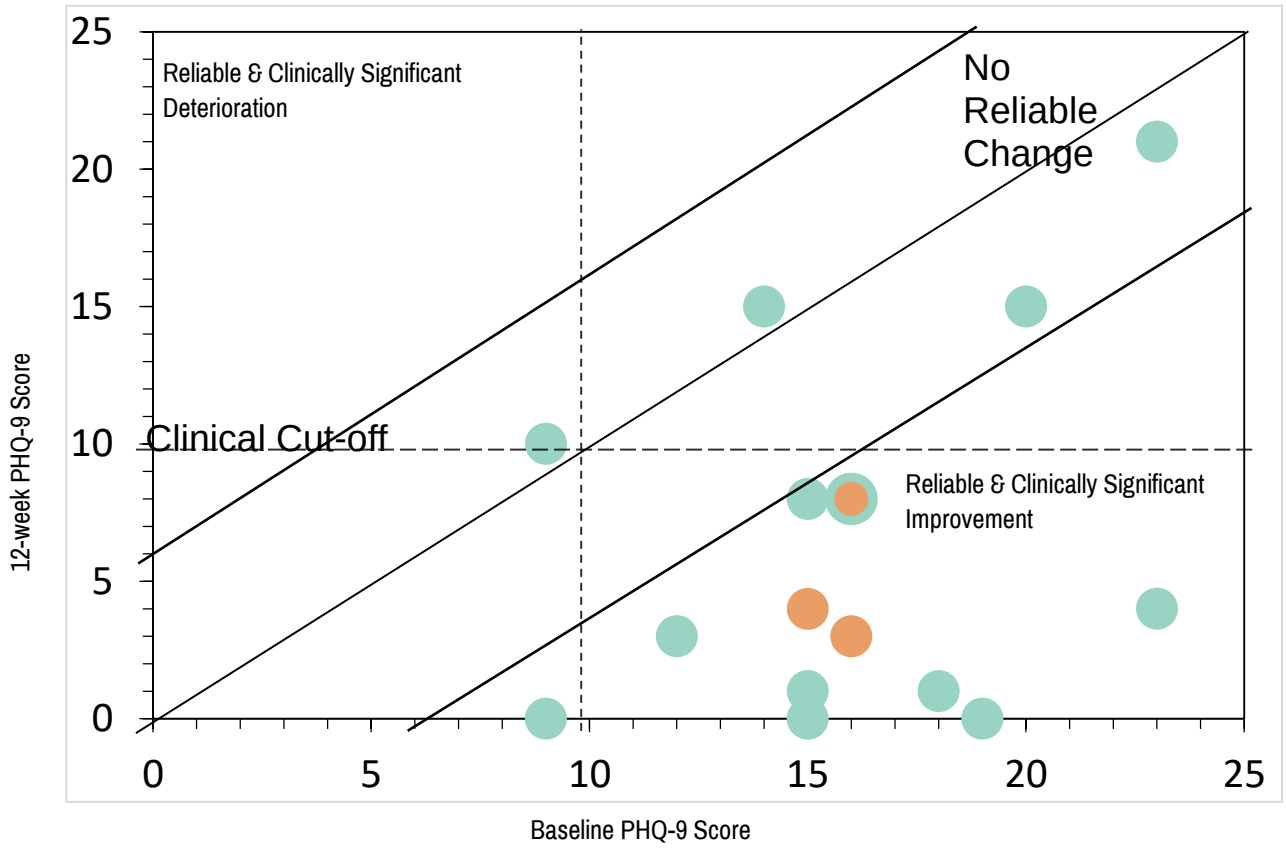
		don't know what I'd suggest"		
		"I didn't answer a question that I didn't think were necessary and I didn't answer one that I thought weren't. Yeah, well, was it relevant."	200	Yes
		*RCSC = Reliable Clinically Significant Change.		

Qualitative evidence for the GP's superordinate, subordinate themes and evidence.

Superordinate Theme	Subordinate Theme	Evidence
Beliefs, Feelings and Experiences of Predictix	Apprehension about change	"Initially I think I was very hesitant" "t just sounded like a way of kind of like reducing GP input" "[a way of] deskilling us and using protocols"
	Excitement about Trying Something New	"We were asked, you know, to refer anyone that we wanted to start on antidepressants who you had maybe only tried one in the past, or they were new to trying that medication. So I thought, you know, well, I'll go for it " "I've been really, as I say, pleasantly surprised" "I thought it was an interesting concept"
	Nature of the Tool	"I think the way Dr [name] would describe it is that the tool is already proved like clinically proven" "In terms of organising, as very simple. Very easy to use" "I would certainly be happy for as long as it's continuing in in practise to you know it is now in my mind set as depression."
	Impact on Individuals' Clinical Practice	"I like the feedback that we got from the interview in terms of most suitable medications and what I found was. That it was presenting options that just weren't in my regular armoury for depression"
Importance of Knowledge and Experience		"I was very grateful that a colleague had had experience with a patient already, because I think the feedback that he gave me was invaluable." "I got better the second time I learned from the first time I did it better the second time patient was a bit happier" "I haven't seen a lot of a lot of actually how the decision is made and what criteria they base it on. I think it's, you know I understand some of it might be based on you know you know previous experience of antidepressants or you know, presumably if they're more anxious or low in mood or what have you. But I haven't seen the actual tool itself interestingly, left that for the PWP."
Increasing Patient		"It threw up duloxetine as a medication that actually when I looked at profile of those medications helping with sleep and depression, that actually is like, I don't know why I hadn't thought of this myself before" "I think it also gave the patient a little bit more time with someone else to talk through their experiences as well and that can be helpful for them as well to kind of liaise with

Centred Care		someone else who's got some background in order to kind of give themselves advice as well" "I think it's enhanced my clinical care without deskilling me or feeling like we're gonna be replaced by robots"
Managing Patient Expectations		"they were expecting more of a sort of touchy-feely assessment rather than a questionnaire" "I felt I was much better informed and being able to tell my patients what to expect in that session with the PWP" "it might be that I hadn't prepared them properly for what it was gonna be, but they found the actual that I wonder if they're almost expecting some kind of level of counselling as they went, rather than a kind of a more of a slightly more straight forward tick box exercises"
Increased Burden of Care	Patient Impact	"They are the only slight worry was that? Ohh you know how often is that? How often they been? Are they being checked to see whether they've been booked in and how precise the telephone call was and things like that" "Patients sometimes to get a bit, you know they build up a bit of a sort of a sense that they really have finally come to see somebody about it and then and then they're having a delay in getting the treatment really. So I think I think a reduction in the delay is helpful"
	Professional Impact	"it obviously creates a little bit more work because as a clinician, I felt I needed to contact the patient again after that interview because I just wasn't happy to say in a text message this is the medication that we're gonna use." "With suicidal thoughts, risk of that increasing in the first couple of weeks, you know, and if it works then we look at a minimum of six months. So I I kind of pre-empt all that, but I just didn't feel happy about initiating medication without having that final conversation. So it does create a little bit more work" "I think that's again the front loading, isn't it? I and I don't think I've had either of those patients back beyond the initial kind of two week follow up. So it's obviously been quite successful"
Organisational Changes		"I think getting it to work smoothly without it impacting on a on clinician time was helpful. The other thing is making sure it isn't just [...] the GP's, it's also the GP trainees that know about it and the Advanced Nurse practitioners and our physician associate and remembering that you know, anybody who might be advising on mental health really [...] sometimes it ends up being a bit focused on just on GPS" "But in terms of the in terms of our process it it, yeah, I mean, it was really, it was quite smooth really. I thought in the end, I mean the only the only thing we need to do is we needed to add the appointment system on"
	Clinical Challenges	"You think that you know you put everything into a bit of IT machinery and it will come up and say prescribe this one and actually what you end up doing is saying, well, you could prescribe this or this or that"

		"The problem that came back from both of mine is that I got given options rather than a single one. I think they were both mitazapine or sertraline and being quite different and were different side effect profiles"
Implementation Challenges	Research Challenges	"I think the biggest problem I had and still have is the exclusion criteria" "What can be referred? What ought not to be, and because I think what happens is we're very, very we're very simple people. And if someone says use it and then don't, or if there's any kind of not negativity but any kind of inappropriate use, then people just don't want to cause they think I'm doing something wrong" "Often these patients were already on tablets and coming to me and saying that they weren't helping. Can we increase the dose or can we try a different one? And again, that's not really what predictix for" "They want to be reliant on a tablet, but the tablet's not gonna fix the fact that their neighbours are causing them problems or they're having a relationship breakdown or something like that"



Supplementary Figure: Jacobson plot of depression outcomes for completers (N=16) – blue dot Predictix participants and orange dot GP override participants.