Predictive RIsk Stratification Models: AssessmenT of Implementation Consequences (PRISMATIC 2)

Study Protocol

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Abstract

Across the United Kingdom (UK) and internationally, numbers and rates of emergency admissions have risen, despite policy efforts to reduce them. Emergency admissions are costly to the NHS and associated with adverse outcomes for patients, especially older people, including functional decline and hospital acquired infections. One of the most prominent policy initiatives of the past twenty years has been the introduction of emergency admission risk stratification (EARS) tools. Underpinned by algorithmic models using routine patient data, EARS tools produce scores reflecting patients' risk of emergency hospital admission. Such tools have been widely introduced to UK general practices, supported by National Health Service (NHS) policy and funding. It was hoped that this investment would lead to reduced emergency admissions, as general practice and community-based staff provide targeted support to those at higher risk of hospitalisation.

Research in this area has often focussed on the development and technical performance of EARS tools, with an assumption that identifying patients with a high risk of admission enables effective targeting of care. However, implementation of EARS may lead to unintended effects. Our PRISMATIC evaluation in 32 general practices in South Wales found that emergency department (ED) attendances, emergency admissions to hospital, and days spent in hospital all increased following implementation of EARS. It is not clear if this finding is generalisable, or what the mechanisms for change were.

We designed PRISMATIC 2, building on PRISMATIC, to:
1. Assess the effects and costs of introducing EARS software tools across England
2. Investigate how GPs change their practice in relation to managing risk when such new software is introduced
3. Understand patients' views on communication of risk scores by their GP or other primary care staff and potential impact on self-care and health-seeking behaviour.

We will use existing data, aggregated at former Clinical Commissioning Group (CCG) level, to look at changes in emergency admission and other healthcare use that occurred following introduction of EARS. We will apply multiple interrupted time series analysis – an approach well-suited to this context, with a large number of health commissioners across England (n~211) and a range of dates when predictive risk stratification software was implemented. We will include anonymised NHS data on emergency admissions, ED attendances and days spent in hospital between 2010 and 2021, and link in the dates when EARS was introduced in each CCG area.

To understand mechanisms of change we will investigate GP decision-making in detail across practices located within ~30 former CCG areas. Here, we will use routine data to compare case mix, demographics, indicators of condition severity and frailty before and after implementation of EARS to explore whether GPs changed their decision making when EARS became available. For instance, did GPs identify unmet need, or become more risk averse and lower their threshold for admitting patients? We will interview GPs and other healthcare staff (n≤48) at 16 selected practices and associated providers in the West Midlands to explore their views about how patient care may have changed.

We will also conduct two focus groups (n~16) and interviews (n~16) with patients to explore patient experiences and discuss how hearing about their own risk may affect their views and health behaviours, including self-care.

We worked with patients and members of the public to design this research programme. We will continue to involve patient and public involvement (PPI) members in all aspects of research development, management, oversight, delivery and dissemination.

PRISMATIC 2 will build on PRISMATIC, with the same core research team and a strong track record of research delivery, to extend timely learning on this subject. PRISMATIC 2 will give policymakers a better understanding of the effects of EARS software on costs, processes and outcomes of care across a range of settings. Risk stratification approaches have recently been used to identify people for shielding during the UK COVID-19 pandemic, highlighting the importance of understanding not simply the technical performance of risk stratification, but also its impact in practice.

Background

A worldwide discussion on the efficiency of primary health care is focused on re-orienting health systems toward proactive, anticipatory, and integrated care [1, [1]. This shift has emerged in response to a changing population profile, characterised by increased multi-morbidity and complexity of health needs and, in turn, by rising emergency admissions [2].

In theory, many admissions could be prevented by improving patient care in community settings [3]. The subset of admissions potentially amenable to intervention in this way relates to so-called Ambulatory Care Sensitive (ACS) conditions [3]. A 2017 analysis of data from 8,120 English general practices found variation of 55% between high and low rates of ACS admissions by practice [4]. Deprivation, multi-morbidity and the quality of primary care are key factors driving variation [5, 6]. Furthermore, ACS emergency admissions in England have increased at a higher rate than other admissions over recent years [2, 7].

Emergency admissions can be lifesaving, may prevent long term morbidity and can facilitate the provision of health and social care services that are difficult to access from the community. However, they are generally unwelcome to the patient; can be associated with adverse outcomes including death, frailty and difficulties regaining independence; and are challenging to manage in terms of quality and safety (e.g., exposure to hospital acquired infections). From a provider perspective, emergency admissions are expensive and limit capacity to deliver planned care [8].

Emergency Admission Risk Stratification tools

In order to reduce these patient and system burdens, health providers have sought strategies to identify and manage those at risk of emergency admissions. One prominent approach has been the introduction of emergency admission risk stratification (EARS) tools, which have been widely installed in GP practices to help identify complex and high-risk patients for targeted preventive care [9-11]. The introduction has often been part of integrated care initiatives [12, 13], with substantial budget allocations linked to financial levers including GP contracts with over £480 million allocated for the Avoiding Unplanned Admissions Enhanced Service in England between 2014 and 2017 [14].

PRISMATIC (1)

Our recent National Institute for Health Research (NIHR) HS&DR-funded PRISMATIC study (a randomised stepped wedge trial, carried out in 32 general practices in South West Wales) found unexpected and unintended effects, with increases in emergency admissions to hospital, Emergency Department (ED) attendances, and days spent in hospital associated with introduction of predictive risk stratification software [15]. Costs to the NHS increased substantially, by an average of £72 per patient per year across the whole population. As a direct result of the trial, health policy in Wales was reversed, and roll out of predictive risk stratification in primary care was halted, saving an estimated £220 million per year across

Wales in avoided costs [15]. Qualitative findings suggest GPs may have changed their attitudes and behaviour towards caring for high risk patients [16]. However, over the past ten to fifteen years, software that predicts risk of emergency admission has been implemented widely in primary care in England, Scotland and Northern Ireland, with more than two-thirds of practices having access to one or more EARS tools [9].

Rationale

This context underpins the case for a natural experiment that builds on the findings of the PRISMATIC trial. Thus in PRISMATIC 2 we seek to assess the effects of the introduction of EARS tools across England; to understand the mechanisms of change by investigating how GPs may alter their practice in relation to managing risk alongside introduction of the new software; and explore how patients view communication of their risk to them by their primary care team.

The importance and relevance of the study is further highlighted by the use of risk stratification approaches to identify people for shielding during the recent COVID-19 outbreak. From the point of view of patients, carers, NHS staff and costs, it is important to reduce emergency admissions to hospital. Although predictive risk stratification has been advocated as one tool to help to do this, its impact and worth as a policy option remains unclear [17]. As recognised in the NHS England paper Next Steps for Risk Stratification in the NHS [18], it is important to understand the consequences of using risk stratification tools, both beneficial and adverse; and to inform future care delivery by providing evidence about the processes and outcomes of their use.

Risk stratification is advocated based on the assumption that identifying patients at high risk of admission to hospital enables effective targeting of services to deliver planned care and prevent emergency admissions [17]. However, the evidence to support this assumption is mixed. Much of the research in this area has focussed on technical performance of the risk stratification algorithms [19], rather than on its impact in context, where unintended effects have been observed [15, 20].

Literature background

As part of the PRISMATIC study, we undertook a systematic review of the costs, effects and implementation of emergency admission predictive risk software in primary care between 2005 and 2015 [21]. We searched electronic bibliographic databases including MEDLINE and CINAHL and undertook citation and reference searches. We identified 13 articles from 11 studies for inclusion in the review.

Of the 11 studies, eight were European, consisting of four studies (in five papers) from England [22-26], two (related) studies in Germany [27, 28], one in Scotland [29] and one in Spain [30]. Three studies were undertaken in North America; one in Canada [31] and two in the US [32-34].

Study designs comprised three randomised control trials (RCTs) [31, 32, 34], three cohort studies [25, 26, 29], one cross sectional study [24] and one further observational study [27]. Three entirely qualitative studies were included [23, 28, 30] with qualitative methods also featuring in two others [22, 24].

Predictive risk stratification was generally used as a tool for identifying patients suitable for a further intervention (e.g., virtual ward), rather than as a formal part of that intervention. In

some cases, a predictive risk stratification tool was used as one of several methods of case-finding. Eight of the studies focused on case (or care) management of patients at high risk of emergency admission to hospital [22-25, 27, 29, 31, 32]. Two studies featured the use of telemedicine [27, 34].

A range of primary care and community staff delivered, or were proposed to deliver, the interventions. This included the use of community matrons [22-25] - senior nurses with a care coordination role [23], introduced following Department of Health funding in support of the care of patients with long term conditions [35]. The intended use of multi-disciplinary teams was noted in five studies [23, 26, 29, 31, 32, 34] and virtual wards featured in three [23, 26, 31].

No studies reported comparative data about processes or outcomes related to predictive risk stratification. In each of the RCTs, predictive risk stratification tools were used to identify patients eligible for the trial – and were therefore used in both trial arms. Consequently, it is not possible to separate out effects of the predictive risk tool from those of the associated (secondary) intervention in these published studies, as none reported comparative data about processes or outcomes related to predictive risk stratification.

A handful of studies included staff feedback on the use of risk prediction tools. These data indicated that, although there was support for the use of the tools, there were concerns over the accuracy of models and access to data. The review revealed a deficit of evidence regarding patient perspectives.

To assess the latest literature, we updated the systematic review searches for MEDLINE for June 2015 to January 2021. This produced 3414 results of which seven articles representing six primary studies [10, 36-40] and one review [41] met the original review criteria. They originated from UK (2), USA (2), Spain (2), and Singapore (1). Only one examined risk stratification as a stand-alone aspect [38], considering differing approaches to case dentification. A study related to Accountable Care Organisations in the USA [36] showed positive effects on admissions of integrated care, particularly for ACS conditions, but improvements took time to bed in. A study in the UK, looking at NHS Vanguard sites [39] found, as in PRISMATIC, unintended consequences, potentially due to unmet need. A comprehensive, patient-centred, integrated care intervention which included both a stratification strategy and an integrated care intervention was associated with a lower risk of hospital admission among prioritised patients, but not among patients who were not prioritised to receive the intervention [10]. A limitation of many of the studies, acknowledged by Stokes [39] is that follow up was often short, and typically 12 months or less. We also noted that no patient perspectives were included in any of the studies. Overall, the updated literature confirms ongoing interest and application of EARS, and the need for further definitive evidence to support the development and implementation of policy.

Evidence is needed on whether the effects observed in the PRISMATIC study – in relation to one particular tool, in one administrative area – are replicated throughout England, and over a longer follow up period. Further evidence is also required about the mechanisms by which EARS has an effect (whether intended or unintended). PRISMATIC 2 employs a ‘natural experiment’ approach to address this [42].

Aim

We aim to assess effects, mechanisms, costs, and patient and healthcare professionals' views related to the introduction of EARS tools in England.

Objectives

Our objectives are to:

A. Determine the effects of the introduction of EARS tools across all patients and in subgroups including those with Ambulatory Care Sensitive (ACS) conditions on:

- emergency admissions;

- Emergency Department (ED) attendances;

- admissions to Intensive Care Units (ICU);

- time spent (bed days) in hospital and ICU;

- deaths;

- NHS costs.

B. Assess effects of the introduction of emergency admission predictive risk stratification tools on clinician behaviour related to admission decisions, including how the threshold or case mix characteristics for admission change.

C. Describe perspectives of GPs and other practitioners in primary care, ED and working on admission avoidance about use of EARS tools on their management and communication of risk.

D. Capture the views of patients on risk management and how communication of risk (scores) may affect their own behaviours, including self-care.

Study Design

We will use mixed methods to investigate effects, mechanisms and patient perspectives on the implementation of EARS. The study builds on previous findings from a single centre trial, to investigate whether results are replicated elsewhere and, if so, what those effects are. Although NHS policy has encouraged and supported the implementation and adoption of EARS tools in primary care, evidence about effects on processes and outcomes of care has been lacking, and an underpinning programme theory for the intervention has not been clearly specified. In line with the latest version of the MRC guidance on the evaluation of complex interventions[43], we will address this throughout PRISMATIC 2, to build a logic model [44] describing the underpinning programme theory that includes inputs, mechanisms and effects – both intended and unintended - from the different ways in which EARS, and the information it generates is used. Our development of the logic model will be informed by the work of Mills et al. [44] who have proposed a 'Type 4' logic model to describe complex interventions in a dynamic context. We will be informed by an understanding of the processual nature of implementation of the intervention, paying attention to different contextual and process-related mediators of implementation, including the differing approaches to facilitating implementation of the prediction tools in GP practices. We will use Normalisation Process Theory [45] to examine processes of adoption by clinicians - as applied in the first PRISMATIC study. We will also draw, as appropriate, on other theoretical framings of implementation including technology adoption [46]; the diffusion of innovations

[47]; the individual and collective work of embedding new practices [45]; the potential of boundary objects to drive collective understanding and action [48]; and cognitive task analysis [49].

PRISMATIC 2 is split into four work packages (WPs).

Work package 1 (WP1): Anonymised routine linked data

We will use Multiple Interrupted Time Series (MITS) analysis [50] to look at changes in trends in data, aggregated at CCG level, that are related to the introduction of EARS. This approach is powerful and well suited to this context, with a relatively large number of CCGs (n= ~211 study sites); a range of dates when EARS was implemented; and at least 36 monthly time points before and 48 monthly time points after implementation can be incorporated in most cases.

We will undertake WP1 using routine data for the whole population of England, categorised by the former CCG of residence. Although CCGs were replaced by Integrated Care Systems (ICS) in April 2022, these changes occur after our routine data collection period and will not therefore be a factor in our sampling.

Using routine data sources (HES supplemented by ONS & ECDS, via NHS Digital), we will analyse aggregated routine anonymised data on emergency admissions, ED attendances and days spent in hospital and in ICU at study site (CCG) level between 2010 and 2021, linked to the dates of introduction of EARS tools. We will then assess whether there are any changes that are associated with introduction of EARS, over and above any other underlying trends, and adjusting for differences in demographics and case-mix as summarised from routine data sources. We will be able to summarise the age, gender, ethnicity (2011 UK Census categories), frailty (e.g. Hospital Frailty Risk Score [51]); and socio-economic (e.g.: using Index of Multiple Deprivation deciles) profiles at the CCG-level. We will look at effects for all patients and for pre-specified subgroups, including those at highest risk (using frailty scores) and those with ACS conditions, which include for example diabetes, epilepsy and high blood pressure [52]. We will also estimate the costs of healthcare resource use from routine anonymised data before and after the introduction of EARS to explore the impact on NHS budgets.

Work package 2 (WP2): Investigation of mechanisms of change using anonymised routine primary care data

Using individual-level general practice data, we will explore effects on thresholds for (general practice initiated) emergency admission decisions and the case mix of those admitted in a sample of CCG areas. We will profile and compare the demographic and clinical characteristics of patients admitted before and after introduction of EARS, across the population and in subgroups akin to those in WP1. We will access data from GP practices within former CCGs through the Clinical Practice Research Datalink (CPRD, https://cprd.com/) - a primary care data repository with coverage across the UK.

We will include all CPRD contributing practices in ~30 English CCGs in which the use of EARS was approved in May-June 2014, and request data on referrals for two years either side of this period. This approach allows before and after comparisons (within practices), while maintaining anonymity of individual practices and CCGs within our cohort. Additionally, we will request data from a control group of practices within former CCGs where EARS was approved after June 2016 or not at all.

We will request that CPRD data be linked with HES data, to obtain a more in-depth picture of the effect of the introduction of the software at this subset of practices.

Work package 3 (WP3): Semi-structured interviews with practitioners

We will undertake qualitative work in one region of England (West Midlands), recruiting 16 practices which are diverse in terms of location and patient demographics. We will work with West Midlands Clinical Research Network (CRN) to seek expressions of interest from practices and follow up with a purposive sample. With staff from recruited practices we will aim to investigate whether practitioners perceive that primary care clinicians' attitudes to risk and/or decision-making behaviour changed with introduction of EARS. We will interview GPs and other primary care staff involved in emergency admission decision making (n~40, up to 3 per practice) to capture their views about how introduction and use of the software may have changed their perceptions of risk and accountability, and how their practice related to emergency admission decision making may have changed. We will ask them about key inputs, mechanisms and effects, both intended and unintended.

We will also interview ED clinicians and ICS/former CCG staff with responsibility for admission avoidance (n=8) in order to understand their perspectives on the effect and role of EARS.

Work package 4 (WP4): Focus groups and interviews with patients

We will select four of the participating practices as the setting for qualitative work with patients (n~32). We will conduct focus groups and interviews to explore how patients perceive that communication of individual risk scores might affect their experiences and health seeking behaviours, including self-care.

Data Collection

Quantitative data

Data collection across WP1-WP2 will be based on the study's overarching Data Management & Analysis Plan (DMAP), compliant with Swansea Trials Unit's Standard Operating Procedures, and drafted and agreed by the study's Research Management Group in advance of any data request or collection. The DMAP will specify: details of the data items to be requested from routine datasets; the management of data flows within the study, and; the creation of study databases supporting the analyses outlined.

Our data curation will recognise that reconfigurations and consolidations of CCGs have occurred during the study window, with varying numbers of CCGs in existence at different timepoints. Using NHS Digital's Technology Reference data Update Distribution (TRUD) resource, we will: (i) define map-sets of CCGs for various time points within the study window reflecting the CCG configuration at that time; (ii) identify a map-set which most closely aligns with the introduction of the software; and (iii) associate each referred ED attendance with a CCG in each map-set, validating this by analyses of linked CPRD and HES data at selected sites. The primary analysis will each use the map-set at (ii) with other map-sets supporting sensitivity analyses.

Work package 1: Anonymised routine linked data

We will request HES Accident and Emergency (AE), HES Admitted Patient Care (APC) and ONS data (HES-ONS linked mortality data) from NHS Digital, with an application via its Data Access Request Service (DARS) portal. Although the intention is to analyse data aggregated by CCG (study site), our DARS application will, with the appropriate research permissions and Information Governance (IG) approvals, be for patient-level data, including a unique anonymised ID to indicate multiple attendances. This will also allow us to address CCG mergers over time as noted above. We will, to support the DARS submission, develop a comprehensive data items table (part of the study's DMAP) and request data on:

- admission discharge dates and times;
- discharge dates and times;
- age, gender, ethnicity and socio-economic categories;
- health event date and time, admission source, attendance category including visit status (first attendance or re-attendance);
- investigations, diagnosis (including indicators of ACS conditions), treatment (including Healthcare Resource Group; HRG) and disposition codes.

These detailed data will allow us to undertake various sensitivity analyses and robustness assessments of key data processing conventions. We will aggregate data at study site level across pre-specified short periods (fortnight/monthly) to define times series data for each site. We are aware that various factors, some localised or site-specific, are likely to affect the quality of the requested routine data, which may then influence one or more outcome measures. We will undertake, across study sites, an assessment of the data quality - essentially, sense checking for the completeness of outcomes, and the presence of unexpected features (e.g., “spikes”) or trends. These explorations will be presented and interpreted in the context of the sites’ known history over the study window. As far as possible, we will seek reasons for such data “spikes”, omissions, or unexpected variations over time which may reasonably be attributed to local circumstances or complexities.

Work package 2: Investigation of mechanisms of change using anonymised routine primary care data

We will analyse the linked study data drawn from CPRD and HES (demographic, case mix, and clinical, with a focus on severity of condition and frailty of patients admitted) on thresholds for emergency admission decisions before and after introduction of EARS.

The inclusion of CPRD data here, rather than in WP1, reflects logistical constraints: not all GP practices/CCGs contribute data to CPRD. For those that do, CPRD maintains two separate databases, depending on the electronic patient record system software used - Aurum for practices that use EMIS Web; and Gold for those that use Vision.

We will request CPRD data on referrals for a four year period centred on May-June 2014 (based on EARS software approval dates), and request linkage with HES data.

This request will be supported by a comprehensive data items table (part of the study’s DMAP). We will undertake, across these sites, an assessment of CPRD data quality; and address any limitations in our analysis plan.

Qualitative data

For WP3 and WP4, we will implement an overall qualitative plan with further detail and operational plans for recruitment, sampling, data collection and analysis. All interviews and focus groups will be recorded, with permission of participants, and transcribed in full, to support analysis. Data collection for focus groups and interviews will be conducted by experienced qualitative researchers (led by AP, MK).

Work package 3: Semi-structured interviews with practitioners

We will undertake qualitative work to investigate whether practitioners perceive that primary care clinicians’ attitudes to risk and/or decision-making behaviour changed with introduction of EARS. We will ask them about key inputs, mechanisms and effects – both intended and unintended. We will interview GPs and other primary care staff involved in emergency admission decision making (n~40) at a sample of practices (n=16) to capture their views about how introduction and use of the software may have changed their perceptions of risk

and accountability, and how their practice related to emergency admission decision making may have changed. We will also interview ED clinicians (n~4) and staff with responsibility for admission avoidance (n~4) in order to understand their perspectives on the effect and role of risk prediction software.

Work package 4: focus groups and interviews with patients

We will recruit participants (n~32) from four of the practices participating in WP3, with practices sampled to provide contrast in terms of local demographics. We recognise the challenges there may be in recruiting patients to take part, so we will take a pragmatic approach to recruitment, using two routes in parallel. We will conduct two focus groups, each with up to eight patients, identified through existing patient networks within the study area, e.g., patient liaison groups or condition-specific advocacy organisations. Covid restrictions permitting, focus groups will take place in local venues convenient to the participants. We will also conduct up to 16 one-to-one interviews (either in person or remotely by telephone or video call) with patients recruited via participating practices via letter and telephone follow-up. We will aim to recruit patients for interview across risk categories, ensuring that we include people in the higher risk categories; and aim to include a range of ages, ethnicity, conditions and experience of emergency admission to hospital.

We will sample purposively to ensure that we include vulnerable people including those who make high use of emergency services. Where appropriate we will translate patient invitation materials and offer interpretation to those in need. If patients wish, they may invite a carer to take part in the interview as well. All patients (in focus groups and interviews) will be offered a £25 voucher as a thank you for their contribution.

Data analysis

Quantitative: We will calculate various site-level measures from patient-level data to summarise and compare sites, using monthly aggregation for primary analysis, supplemented by fortnightly aggregation in sensitivity analyses. Aggregate outcome measures include the total number and rate of ED attendances, admissions, proportion of re-attendances, and the proportion admitted as an inpatient. We will also calculate the average patient age; the gender split, and ethnicity profile. Diagnoses, reported using ICD10 codes, will be explored to ascertain modal causes of attendance, and to identify pre-specified sub-groups (e.g.: patients diagnosed with an ACS condition).

We will consider how the presence of EARS might affect each outcome measure, assessing any (gradual) change in the slope (gradient) of trends in outcome measures over time. We will first use exploratory time series methods using aggregated site-level outcomes. Here, we will assess trends in each outcome measure before and after the introduction of EARS and support these by comparing appropriate numerical summaries before and after introduction. We will include a suitable control group consisting of practices within former CCG areas, where risk stratification modelling was not in use, using the same date ranges of our experimental group. This will provide a comparison to help better understand and interpret our statistical analyses.

We will assess data for seasonal patterns and outliers. We will analyse the data for two time periods, starting in 2010 – a longer period, including the COVID-19 pandemic period to 2021 (subject to availability of routine data on approval of our data request) and a shorter pre-pandemic one, ending on 1/3/20. We feel it is important to understand whether any effects of implementation of EARS were sustained during this unusual period of NHS activity.

We will then use MITS models to test the null hypothesis that the introduction of EARS has no effect on the trend in outcome measures. This hypothesis will be parameterised by specific indicator variables in our segmented regression analyses.

Statistical power considerations: MITS models currently require simulation-based assessments of their power [53, 54] and focus on a single series, rather than panel data available here. Further complications include: combining two elements of change in trend (level and slope) into a single effect size; specifying pre- and post-intervention splits in data; and specifying the extent of autocorrelation within data. We will have at least 120 monthly values for any outcome. Based on assessment of HES AE data within this period, we expect moderate autocorrelation, in the range of 0.2 to 0.5, for a lag of one month. Interpolating from available tables, we should, using 90% power and 5% significance, be able to detect an effect of size in the range of 0.5 to 0.8 for a single series; with concomitantly greater power in analysing panel data.

We will develop and agree a detailed Statistical Analysis Plan (SAP), part of the study's DMAP, specifying both the range of exploratory and descriptive summaries, and the more formal MITS models used to analyse outcomes. The DMAP will outline: proposed adjustments for case mix and other potential confounding factors; statistical modelling strategy underpinning comparisons; and reporting of analyses. It will also cover the planned analyses of data on thresholds for emergency admission decisions before and after introduction of the software, and the Health Economics analyses.

Health Economics: As in PRISMATIC, we will closely align a Cost Consequences Analysis (CCA) with the main clinical effectiveness analysis. We will use aggregated anonymised routine patient-level data, between 2010 and 2021 to estimate healthcare resource use (including emergency admissions, ED attendances and days spent in hospital and in ICU). Weighted standard unit costs, tariffs and national costs of the healthcare resources will be obtained from NHS reference costs NHS England [55] and the most up to date version of the costs of health and social care published by the Personal Social Services Research Unit [56]. These will be applied to resource use data based on Healthcare Resource Group (HRG) codes, if possible and appropriate, to calculate the cost associated with healthcare use. This will be linked to the dates of introduction of EARS to allow comparison of healthcare resource use and cost (e.g. total number and cost of ED attendances, admissions, number and cost of re-attendances, and inpatient cost) before and after introduction of the software. We will explore costs for the total study population and for subgroups as specified in the SAP and present disaggregated resources, their unit costs and a range of outcomes together with estimates of mean costs with appropriate measures of variation. Our primary CCA will be supplemented by sensitivity analyses, to account for uncertainty in parameters estimates. Deterministic one-way sensitivity analysis will examine the impact of changes in key parameters by modifying the value within a plausible range (e.g., upper/lower 95% confidence intervals, +/-30% to key parameters, as clinically advised). Discounting will be applied at the standard rate where follow-up periods exceed one year. As implementation costs per patient found in PRISMATIC were very low, we do not propose to repeat this costing exercise, but to add commissioning costs (which were not applicable in the Welsh setting) and extrapolate previous costs for the CCA to PRISMATIC 2.

Qualitative analysis: This will follow a framework analysis approach [57, 58] which uses a structured method to analyse the data and is suitable for a collaborative approach to analysis by a multi-disciplinary team to generate policy-relevant evidence. A qualitative analysis sub-group will be formed including clinicians and PPI members. Members of the team will familiarise themselves with the transcripts of interviews and focus groups, and devise codes drawn from these. An initial analytical framework will be agreed by the analysis

sub-group, drawing on both data sets (patients and health care providers) then sub-group members will chart data onto the framework. Each transcript will be read by a minimum of two members of the research team. The qualitative sub-group will discuss interpretation and emerging themes and consider any contradictions or inconsistencies. Analysis will take place first within groups (health professionals; patients) and then across the groups. Findings will be written up structured around themes, with verbatim quotations used for illustration. We will formally synthesise the qualitative and quantitative analysis results, sequentially, using a triangulation protocol as described by O'Cathain et al. in 2010 and the analytical approach outlined by Östlund et al. in 2011 [59, 60].

The qualitative sub-group will draw on the analysed data to revise the initial version of a logic model describing the intended and unintended effects of predictive risk stratification tools, the mechanisms by which these effects might be achieved, and the inputs (context and resources) which lead to these effects. This initial version of the logic model will be developed by the wider Research Management Group in the early stages of the study. Findings will both be grounded in the first-hand accounts of technology implementation and impact and have transferability to other settings and technologies within healthcare.

Project management

The study will be supported by comprehensive project management systems underpinned by strategic and operational management structures. These comprise the following groups:

A **Research Management Group** (RMG) to provide overall strategic guidance and management for the study with expertise in policy, patient perspectives, clinical practice, methodological and research conduct.

A **Core Team** to manage the day-to-day operational aspects of the study.

An independent **Study Steering Committee** (SSC) to provide oversight and external expertise and support to the study, with representatives from primary and emergency care, commissioners, statistics, Patient and Public Involvement (PPI) and subject expertise in risk stratification and integrated care.

Ethics / Regulatory Approvals

This study is observational, and carries minimal risk to patients, staff or researchers. Quantitative data analyses will be undertaken on routine data without any identifying information and will be subject to strict rules about presentation of outputs, designed to protect privacy. The study has received a favourable opinion from London - Harrow NHS Research Ethics Committee Reference 23/LO/0036) and we will seek appropriate information governance permissions e.g. from NHS Digital and CPRD.

Patient and Public Involvement

We are strongly committed to the involvement of patients and the public in all of our research studies, in line with good practice [61]. The UK Standards for Public Involvement [62] will be followed throughout the study. Two patient/public contributors sit on the study's RMG and a further two on the independent SSC. Patient/public contributors were involved in research

development and two are co-applicants to the study. Expenses and honoraria for all involvement is paid at NIHR rates.

Disclaimer

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Version History

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