Project title:
Predictive Risk Stratification Model: A Trial In Chronic Conditions Management (PRISMATIC)

Background
The ageing population increases the numbers of people suffering from chronic conditions and hence the demands on health and social care. There is consensus that the management of patients with chronic conditions is not optimal. In particular there are too many emergency admissions to hospital, and poor integration of services. The NHS needs new approaches to managing chronic conditions that shift care from hospital to community and general practice where appropriate.

Clinical prediction models assess patients' risk of suffering a specified outcome (e.g. emergency hospital admission) or disease (e.g. diabetes). England and Scotland have many such models for predicting risk. The Welsh Assembly Government (WAG) commissioned the development of a predictive risk stratification model (Prism) that estimates individual's risk of an emergency hospital admission in the following year, and divides the population into four risk categories (or strata). The tool collates data from 37 primary care, hospital care and demographic variables to provide a secure web-based view for approved GP practice staff. The planned introduction of Prism to general practices across Wales provides an opportunity to study the introduction of this new management tool, sound in principle but unproven in practice.

In this study the goal of risk estimation and stratification is to inform general practices and enable them to target resources and see if this improves health care and ultimately patient outcomes. Practices will use Prism to match the care of individual patients to their needs, where possible, and to advise where gaps in service provision exist. However it would be counter-productive and premature to use Prism at regional or national levels before focused and well resourced introduction at practice level is evaluated. This study will describe the adoption of Prism in primary care and evaluate its effect on the care of patients across the spectrum of risk.

Aims and objectives
We aim to describe the introduction of a predictive risk stratification model in primary care in Wales and to estimate its effects on the care of, and resources used by, patients at high estimated risk of emergency hospital admission, and those at lower estimated risk.

Our objectives are:
1 To study the resulting changes in care at individual patient level (rather than population level) across the spectrum of risk.
2 To describe individual and organisational changes initiated by Prism, notably how general practitioners and their staff understand, adopt and use the tool.
3 To estimate the resulting changes in the use of health and social care resources by people across the spectrum of risk.
4 To assess the effect of Prism on patient satisfaction across the spectrum of risk.
5 To assess the technical performance of Prism within and between practices over time.
6 To assess the feasibility of research to estimate the effect of Prism on patient outcomes.

Setting
Prism is currently installed in around 100 practices in Wales, following testing in the CCM Demonstrator sites of Cardiff, Carmarthenshire and Gwynedd, and elsewhere. While this testing has been useful in many regards, a robust study of the implementation and subsequent impact of the

tool has yet to be undertaken and the question of whether Prism can add anything to information already available or enhance clinical judgement remains unanswered.

In addressing this need, we plan to collaborate with Abertawe Bro Morgannwg University Health Board (ABM UHB) to undertake the quantitative elements of the study within the catchment area of this single NHS organisation. This will support the coherent, consistent and timely implementation of Prism in practices across the three clinical localities of Bridgend, Neath Port Talbot and Swansea. We shall invite all 77 general practices within ABM UHB to participate in the quantitative evaluation, with a target recruitment of up to 40 practices representative of small and large practices within each locality. To ensure that we produce rigorous evidence concerning the processes and effects of implementation of Prism in primary care the quantitative components will be supplemented by qualitative investigation of Prism implementation in both ABM and other parts of Wales, including the three Demonstrator host sites.

Design

To meet the need for all interested general practices within ABM UHB to have the opportunity to opt into the implementation and evaluation of Prism, and the need for a rigorous but non-intrusive evaluation, we propose to adopt a progressive cluster randomised trial (also known as a 'randomised multiple interrupted time-series' or 'wedge shape design'). All practices will begin as control practices without Prism; receive the Prism package in a convenient week within the study period (determined at random by the trial coordinating centre in Swansea University College of Medicine); and thereafter use Prism with support from ABM UHB and the trial centre. Though practices will be able to specify inconvenient weeks, they will otherwise be blind to the random sequence till two weeks before their Prism initiation. As the trial progresses, the number of intervention practices will increase and the number of control practices will fall. This design protects against many sources of bias, including arbitrary changes in health policy, the 'resentful demoralisation' of controls deprived of the intervention and other differences between intervention and control sites selected with no element of randomisation.

Intervention

We shall implement and evaluate a complex intervention centred on the Prism software, with training in, and support from ABM UHB and the research team for using Prism to manage patients within primary care. This will comprise: the installation of Prism software, supported by in-practice training for the practice manager and other staff (including the principal responsible for information technology if desired) and a 'help desk' during working hours. During the course of the study ABM practices may also have access to emerging Community Resource Teams (multi-disciplinary teams with experience of managing patients with complex needs in the community) to support patient care and a succinct user-friendly research manual to accompany the 'help desk'.

Methods

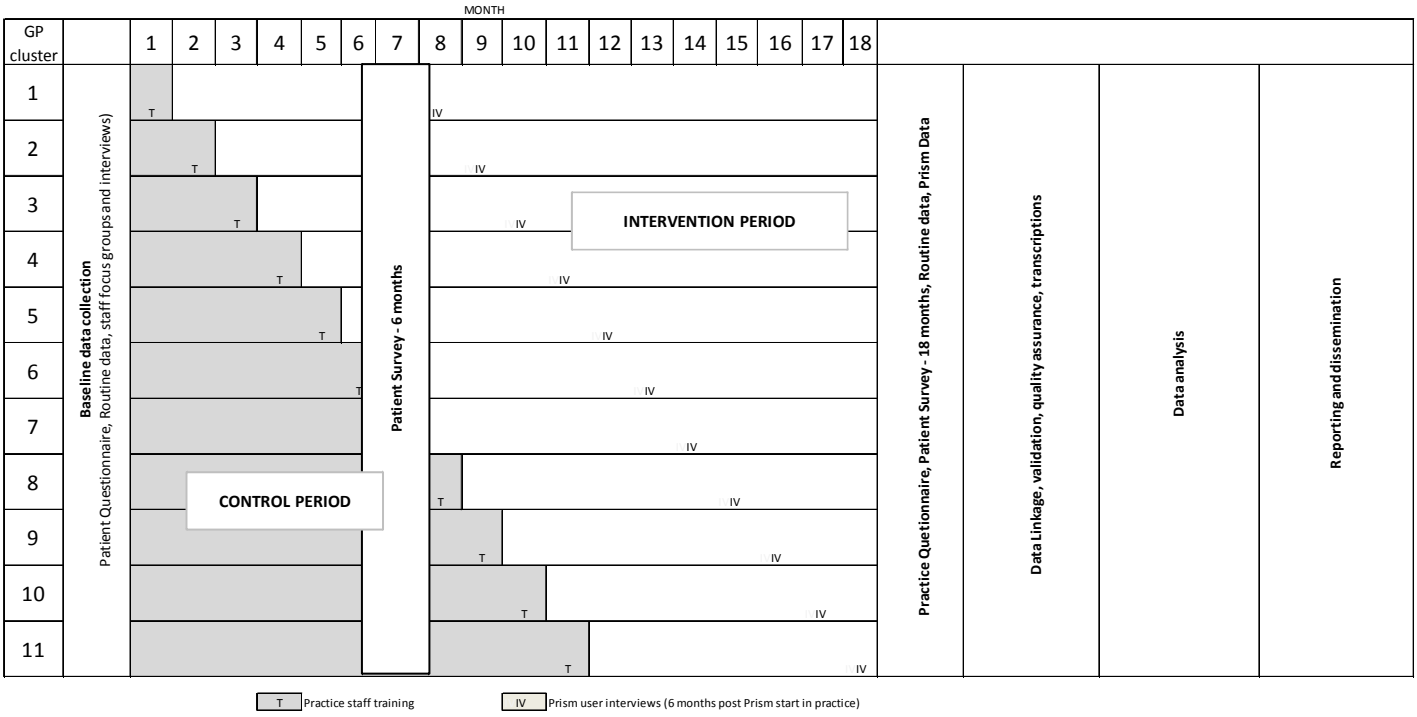
The PRISMATIC study design allows us to make comparisons over time between current intervention and control practices. We propose to assess the technical performance of the Prism tool by analysing the data using a generalised positive predictive approach[1]. We shall send confidential postal questionnaires (including a version of the validated Client Service Receipt Inventory specific to primary care and an anglicised version of the validated Quality of Care Monitor) to all three random samples of patients as outlined in the next section below. We shall use these data to compare acceptability, to patients across the spectrum of risk, of Prism and its implications for care before, during and after implementation (6 and 18 months) of Prism in participating practices. We shall also analyse anonymised routine data from the Prism datasets for all participating practices. This data is fully anonymised and no patient identifiable data will be seen by the Prism researchers (please see data protection section below). We shall use these data to compare the use of NHS and social care resources across the spectrum of risk. Difference in resource utilisation will be multiplied by unit

[1] Which subsumes the screening concepts of sensitivity and specificity

costs, derived from published sources allowingus to consider the cost implications (including opportunity costs) arising from Prism implementation [2]. Costs associated with false positives (those with a high risk score who do not go on to experience an emergency admission) and false negatives (those with a low risk score who do go on to experience an emergency admission) will be considered within the analysis.

We shall use the focus groups and face-to-face interviews to explore individual and organisational processes of change and perceptions of the effectiveness and other implications of Prism. By collecting quality of life data (using the SF-12 validated questionnaire) from each of the three patient samples we plan to test the feasibility, and inform the design, of a subsequent study to evaluate the effect of Prism on patient outcomes, which would also be likely to include an assessment of resource-effectiveness.

Figure 1: Research Overview



Study Population

Research participants will include patients, service providers, commissioners and policy makers. We shall seek random samples of 800 patients stratified across the spectrum of risk to complete brief questionnaires at three points – baseline, 6 and 18 months. The Prism tool will identify a random sample of around 50-70 patients per practice, who will be allocated study identification numbers and will be eligible to receive questionnaire packs – including consent forms. The packs will be sent from the surgeries in line with data protection principles. Participating patients will return their questionnaire and consent form to a designated contact at Swansea University using a supplied Freepost envelope. On receipt, the consent forms will be separated from the questionnaires and filed securely. The questionnaires will then be processed anonymously with questionnaire data subsequently matched to Prism data using a study ID.

[2] E.g. in the control phase, an expected higher use of secondary care resources by those at high risk, has an opportunity cost of the ability to provide more appropriate care in primary care - which Prism seeks to address

We shall invite general practitioners from participating practices, and corresponding community staff to take part in a focus group (at baseline) and one or two short follow up interviews (timing to be confirmed). To ensure we have a point of comparison, we will be seeking at least one participant from each practice at the baseline and 6 month follow up points.

Senior health board managers from across Wales, including those with a primary and community care remit, will also be invited for interviews to provide perspectives at baseline and follow up.

Incentives and Support

Recognising that to achieve the projected benefits for patients and the NHS, practices themselves need resources, support and simplicity, participating practices will be further supported through:

1. Welsh Assembly Government Service support costs of the order of £1000-£1250 per practice to reimburse them for the time of principals, practice managers and staff in contributing to the research.
2. Access to a supportive local research team including research practitioners from the National Institute for Social Care and Health Research Clinical Research Centre (NISCHR CRC), who will be available to assist practice staff in completing research documentation and any other research related activities.

Data Protection

At all stages, we will implement and follow appropriate information governance procedures, with robust technological and data management processes, strict permissions and data access arrangements and independent reviews. The study has been approved by the National Research Ethics Service, ABM UHB Research and Development, and the Information Governance Review Panel (in relation to SAIL data linkage). Data collected through the research endeavours will only be used for the purposes of this research study.

What happens to the data during the study?

All research data will go through the SAIL system (developed by the Health Information Research Unit (HIRU) at Swansea University) which is a secure means of linking anonymised, person-based data using a split-file approach that separates identifiable demographic data (File Type 1) from clinical data (File Type 2). Data leaving practices will be anonymised, with only non-identifiable data used in the study. Prism data from practices will be combined with questionnaire data (from consenting participants) which will be held by the research team. The different files are linked (to form File Type 3) by an anonymous linked field (ALF) that is unique to each individual patient, but that cannot be matched by to any identifiable data by any one organisation. **The research team will only be able to access data within the SAIL system, and will not have access to patient records nor any other identifiable data.** The use of SAIL is governed by an external review panel - the Information Governance Review Panel - which includes representatives of the National Research Ethics Service, Involving People, NHS Wales Informatics Service, and the British Medical Association.

How is consent obtained?

Patients randomly selected to participate (and deemed suitable by practice staff) will be sent a pack from their respective practice which includes an information sheet, consent form and questionnaire. They will be asked to return the questionnaire and consent form in a freepost envelope to a designated contact at Swansea University. Completed consent forms will be immediately separated from the questionnaires and securely filed in a locked cabinet. Questionnaire data will then be processed and the file uploaded to SAIL where it can be matched with Prism data using anonymised linking fields. To minimise potential bias, practices will not be told which of their patients have consented to take part in the research study.

Any patients who inform the research team that they do not wish to have their routine data used in the study will be excluded from the data linkage. Their data will not be used. The participant

information sheet and questionnaire letter provides contact details so that patients can advise the research team.

What happens to the research data after the trial?
Following validation of the final data collected at 18 months, patient identifiable information will be destroyed. Once the overall trial has finished, the final, cleaned databases will be locked, dismounted and archived for audit and storage in accordance with standard operating procedures for the West Wales Organisation for Rigorous Trials in Health (WWORTH-SOP07SiteClosure and WWORTH-SOP08Archiving). These will not contain any identifiable information. Patient consent forms - or records that consent forms had been checked – will be kept for 25 years. All other hard copy documentation and electronic data files will be kept for a minimum of five years after the end of the trial, before data is destroyed (paper electronic media will be shredded, and electronic files deleted) in line with WWORTH-SOP07SiteClosure.

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Figure 2: PRISMATIC research Flowchart