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Predictive risk stratification: impact on care for people with or at risk of chronic conditions

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Predictive risk stratification: impact on care for people with or at risk of chronic conditions

Background An ageing population and the associated increasing numbers of people with chronic conditions are placing unprecedented demands on health and social care services, both nationally and internationally[1-3].

In 2008 the Welsh Audit Office reported that NHS Wales was not providing services that fully supported the effective management of chronic conditions. This conclusion was based on three propositions: (1) many patients with chronic conditions were being treated in an unplanned way in acute hospitals; (2) community services set up to reduce reliance on the acute sector were poorly coordinated; and (3) the planning and development of care for chronic conditions had been insufficiently integrated[4]. The report highlighted that 68% of admissions for chronic conditions were unplanned, and nearly 40% of admissions resulted in stays of less than two days. It suggested that this showed that patients were being managed in the wrong place owing to a lack of community-based alternatives to avoid admissions. Admission to hospital with acute exacerbations is an outcome that is rarely in the best interest of patients and is also costly for the health service.

In 2005 Alder et al had considered the costs of treating individual chronic conditions and concluded that the annual cost of treating Coronary Heart Disease was around £3500 million with additional costs of £3100 million due to lost working days; that of treating Stroke was in excess of £2300 million; that of treating Diabetes was £1300 million; and that of treating Hypertension was £800 million[5]. The Department of Health has estimated that the cost of treating patients with multiple chronic conditions is around six times higher than those with only one[6]. Thus avoiding some of the financial and health-related costs of emergency admissions is a challenge for all healthcare systems in the developed world[7].

Thus new approaches to the management of chronic conditions are needed to shift the balance of care from the acute sector to primary and community sectors[8,9] and improve services locally. There is hope that the provision of community-based support services can help to avoid deterioration in an individual's health, thus reducing emergency admissions and costs of care. A new national policy for chronic conditions management in Wales is seeking to avoid the deterioration of existing chronic conditions by implementing a proactive, planned, integrated and generic approach to chronic conditions management across all sectors[10-12].

Clinical prediction models or risk scores are designed to predict a patient's risk of having (diagnosis) or developing (prognosis) a specified outcome or disease[13]. They use clinical findings (including history, physical examination and test results) to make a diagnosis or predict an outcome[14]. Given the variability among individuals and in the aetiology of disease, a single predictor will rarely give an adequate estimate of prognosis. As doctors either implicitly or explicitly use multiple predictors to assess a patient's prognosis, multi-variable approaches to the design of prediction models are more effective[15]. These quantify the relative importance of particular findings when assessing an individual patient. Such prediction models are intended to help doctors make better decisions by providing more objective estimates of probability as a supplement to other clinical information[15]. Laupacis et al have proposed that the

purpose of prediction rules is to suggest a diagnostic or therapeutic course of action[16]. More ambitiously it has been suggested that prediction rules can "change clinical behaviour and reduce unnecessary costs while maintaining quality of care and patient satisfaction"[17]. Despite providing information on risk, very few prediction models are associated with guidelines proposing treatment for designated risks.

Three major tasks have been identified in multivariable prognostic research: developing the prognostic model; validating its mathematical performance and evaluating its clinical performance[15,18-20]. The third task is crucial: the effect of a developed, validated and (if necessary) updated prognostic model on clinical behaviour and patient outcomes should be evaluated separately[19]. While the number of studies developing prediction models is increasing, fewer have been validated[14], and very few have undergone formal evaluation to generate the standard of evidence needed to assess their effects on patient care. In addition Reilly commented that without evaluation, "clinicians cannot know whether using a prediction rule will be beneficial or harmful". Moons et al have suggested different methodological approaches to the design of validation and evaluation studies[19]. Although studies that formally evaluate the model may not always be required, they can provide an opportunity to study factors that may affect the implementation of a prognostic model in daily care, including the acceptability of use of the prognostic model to clinicians and its ease of use. Moons et al therefore advocated more evaluation studies to assess whether models should be implemented in daily practice. They suggested that comparison of outcomes between intervention and control groups, ideally allocated at random, was the most appropriate approach for evaluating predictive models[19].

Predictive models have been used successfully in England and Scotland to stratify patients into risk levels[21,22]. The King's Fund was among the first to develop a predictive risk model and much of their work has formed the basis for developing similar models elsewhere in the UK. The initial development of the King's Fund model debated what risk to measure. It was agreed that the risk of readmission represented a useful outcome, since a small number of people who account for a disproportionate amount of resource use would be classified as high risk[23]. The main reason for measuring risk was to identify patients for whom an appropriate intervention could improve care and prevent future admission to hospital. The King's Fund and partners suggested that, if appropriate patients could be identified for targeted intervention, this could improve health outcomes, allow efficient resource allocation, reduce future costs and facilitate better planning. This was based on the rationale that acute emergency admissions were poor outcomes for patients' health and providers' costs. Hence if patients at high risk could be identified and made the focus of intensive resources, this would lead to more efficient allocation of resources and better service planning. The basis for assigning risk categories in the King's Fund model was the Kaiser Permanente risk triangle[23 24], in which individuals at the top of the triangle are most at risk of emergency admission. It has been suggested that case management programmes aimed at these individuals could prevent them being admitted. Whether this is the most appropriate level of the triangle on which to focus and whether it is more effective to identify middle-risk patients who are likely to move into the higher risk categories, has been the subject of debate[23].

Nevertheless the initial models focused only on those at most risk – on patients over 65 years in Scotland, and on the sickest 1 or 2% in England. Steps to include the whole population are now being taken.

A key feature of the national programme in Wales is the introduction of predictive risk stratification models through general practice[10]. The Welsh Assembly Government (WAG) has commissioned the development of a predictive risk stratification model (PRISM)[25 26] to stratify people into four levels based on their individual risk of suffering emergency admission to hospital during the following year. The proposal is that, over the next two years, each General Practice in Wales will use PRISM with the support of local Care Coordinators and two national agencies – Informing Healthcare (IHC)[26] and the National Leadership and Innovation Agency for Healthcare (NLIAH). Before then three 'demonstrator' sites will implement the system for the purpose of evaluation.

Although similar in many respects to the models developed in England [21] and Scotland [22], the Welsh model was developed from a larger dataset that included individuals of all ages and risk levels. This follows the recommendation that, in developing predictive models large sample sizes as well as representative populations are necessary if the models are to be generalisable to the population at large[15,18-20]. Hence the Welsh model is likely better to reflect the characteristics of the population at large. The support of the local Care Coordinators, IHC and NLIAH, initially in demonstrator sites, should also help to define how to treat individuals within each of the designated strata. Although both English and Scottish models have undergone development and validation, there has been little if any documented research on their acceptability and the effects of their implementation. Wales is ready for evaluation following the development and validation of the PRISM model[25]. Therefore lessons learned in Wales in implementing a predictive stratification model of the risk of emergency admissions, especially about its effects on the process of care, will benefit the rest of the UK. The proposed study to evaluate this model would also have value beyond the UK in addressing the dearth of literature evaluating the effect of predictive models in general.

PRISM has been developed from routinely available data on inpatient, outpatient and primary care episodes and from the Welsh Index of Multiple Deprivation, which includes data on employment, income, housing, environment, education and health. PRISM estimates risk scores for all patients within participating General Practices and summarises those scores by assigning them to one of four risk strata. To enable practices to plan resource allocation, each stratum represents a fixed percentage of the practice population with the top tier of patients being at highest risk of an emergency admission in the following year. The theoretical basis of the model is that patients in each of the four strata need very different targeted resources: the top stratum requires individual case management, the second stratum requires disease management, the third stratum requires supported self-care and the lowest stratum needs prevention of illness and promotion of health and wellbeing[27]. Patients' risk scores will form part of their GP records. The risk score and the resulting assignment to an individual risk stratum is dynamic and is updated monthly by Health Solutions Wales (HSW)[28] on a dedicated database at participating General Practices. Hence practices can influence the future risk scores and designated strata of patients by the resources they allocate.

Although stratification will not in itself lead to improvements in service delivery, it will stimulate the targeting of services. Thus it is intended to influence health care delivery and ultimately patient outcomes. The review by the Welsh Audit Office[4] has generated the expectation that in future health communities will routinely stratify their populations according to risk of hospital admission[10]. Thus stratification based upon assessment of health needs and the risk of hospitalisation should facilitate identification of patients who could benefit from additional support or care.

In theory PRISM can operate at several levels to improve health: (1) at patient level, facilitating the tailoring of care to individual need; (2) at practice level, supporting resource and performance management; (3) at local commissioning level, assisting planning and resource allocation; and (4) at regional and national levels, providing a new tool for monitoring progress.

PRISM is due to be implemented throughout primary care in Wales over the next two years. The performance of the algorithm appears comparable to or better than the English model [25] and a current independent pilot evaluation shows that the level of agreement between PRISM classifications and other schemes employed at practice level are relatively low, indicating potential for impact. However issues related to its ability to be used across practices and at population level have been raised (personal communication, C Phillips, evaluation lead). In addition there are many practical questions about how it will be adopted and used by service providers for each risk stratum. The proposed study will therefore address key questions about the process of adoption and the effect of this new model[15 19] on:

1) the delivery of services to patients in each of the four risk strata;

2) the costs of providing services and tailored care to patients across risk strata;

3) the clinical or operational practice of health professionals; managers; commissioners of services and policy makers; and

4) patients' experience of, and attitudes to, the services they use.

The planned introduction of PRISM provides an excellent opportunity to evaluate its effects while studying its implementation, thus addressing the NIHR Service Delivery Organisation's research interests in diffusion of innovation, new models of service delivery, and the management of primary and community health services.

Specifically this proposal addresses several issues in the research brief (PC254):

Theme 4.1

- New forms of provider organisation, changing organisational roles and changing structures
- The implications for service organisation and efficiency of different approaches to integration of care across secondary and primary care sectors

Theme 4.2

- Identifying what processes are effective in managing the new systems for (rewarding and) monitoring performance and quality

- Managing processes of care for people with complex needs and multiple health problems

Theme 4.3
- The effect of changing roles and new ways of delivering services on the relationship between managers, professionals, para-professionals and patients.

Theme 4.4
- The development of clinical and outcome indicators for community health services.
- Assessing effects on access for patients, quality of care, co-ordination of care, equity of provision, patient experience, effectiveness and efficiency of different approaches to service delivery.

Research question, aims and objectives

Our general research questions are:
Are validated predictive risk stratification models feasible in the NHS?
Do they change clinical behaviour and thus improve the process of care[19]?

The aim of the proposed study is to describe the processes of introducing a predictive risk stratification model (PRISM) in Wales and to estimate the effects on the delivery of care both to patients living with or at risk of developing a chronic condition, and to those with no perceived risk.

Our objectives are:

1) To measure changes in the processes of care for patients across the levels of need defined by the PRISM-based risk strata:
- in general health and social care; and
- in the explicitly preventative aspects of health and social care that PRISM hopes to engender for the bottom risk stratum.

2) To estimate the costs of implementing PRISM and the resulting changes in the delivery of health and social care to people across all four risk strata.

3) To describe individual (including changing roles) and organisational processes of change initiated by PRISM, notably how it is understood, communicated, adopted, and used as a performance management tool by practitioners, managers, local commissioners of services and policy makers.

4) To assess the effect of PRISM on service use and satisfaction on the part of patients across all risk strata.

5) To assess the feasibility of, and establish a basis for, a further study to estimate the effect of PRISM on patient outcomes.

Start Date
1st September 2010. Project duration: 36 months

Need

The study will address several research needs:

- Healthcare need

The management of chronic conditions is placing an increasing burden on health and social care. Many sufferers have multiple conditions, leading to even greater demands on NHS resources[6]. There is concern that chronic conditions are not adequately managed owing to a lack of integrated care with services being delivered in clinical and operational 'silos'. The pressures that lead to emergency hospital admissions may be more social in origin than clinical. In turn these admissions increase the risk of delayed discharge as people lose their independence. By using a new paradigm to address these issues, PRISM will seek to ameliorate the problems. By studying the operation of PRISM, the proposed research will seek to throw light on underlying issues.

- Patient need

Patients with chronic conditions endure years, even decades, of pain, immobility and reduced well-being. The implementation of PRISM along with specific targeting of services to each of the risk strata may help to prevent or delay the development of chronic conditions, to improve their management, and to ameliorate the loss of well-being due to chronic conditions. The proposed research will establish whether PRISM is effective across all risk strata.

- Demographic need

With an ageing population, the numbers of patients with chronic conditions is due to rise. There is therefore a growing need to manage these patients efficiently. As the proposed research will evaluate the implementation of PRISM and its effects on the management of chronic conditions, it also seeks to develop better approaches to the management of chronic conditions and the prevention of chronic conditions in future. It may also provide useful information for the future commissioning of health and social care.

- Scientific need

Although preliminary development and validation studies in Wales have provided a sound foundation for PRISM and its ability to stratify patients' risk[25], there is an urgent scientific and operational need for evaluation. At this stage we do not know whether PRISM and the associated targeting of services is acceptable to service users and effective and cost-effective in reducing the risk of subsequent emergency admission. By examining the costs and consequences of a risk stratification model for primary care that highlights the individual risk of an emergency admission, the proposed research will generate new knowledge relevant to similar models elsewhere in the UK and to predictive modelling research farther afield.

- Service development and organisational (SDO) need

By examining the implementation of PRISM, the proposed research will inform the future organisation of services with the aim of reducing the risk of developing chronic conditions, managing patients with existing chronic conditions and hence reducing the incidence of emergency hospital admissions. It will study, not only the effect of PRISM on the process of care, but also the process of implementing it and factors that help or hinder its adoption. This agenda reflects the key SDO themes 4.1- 4.4.

- Management development need

By studying a new paradigm for chronic condition management, the proposed research has the potential to provide useful information on wider aspects of service delivery within the NHS that could inform the processes of commissioning and policy development.

- Strategic need

England and Scotland already have risk stratification models that categorise patients into appropriate risk strata. By examining the implementation of PRISM in Wales the proposed research will provide useful information to the rest of the UK about the acceptability of such a system and its performance in the differential management of patients at different risks of emergency admission.

Methods

Design and conceptual framework

We propose a mixed-method 'before, during and after' quasi-experimental cohort study in Wales with three intervention ('demonstrator') sites and four concurrent control sites. It exploits the MRC Framework for the Development and Evaluation of Complex Interventions phases I and II – Modelling and Exploratory Evaluation [29]. It also fulfils the last of the three major steps in researching multivariable prognostic models identified by the recent authoritative series in the British Medical Journal [15].

The planned staged national implementation of PRISM across Wales provides a rare opportunity to conduct a rigorous natural experiment. The data already gathered to develop PRISM will provide an unusually robust foundation for this pragmatic study design. The proposed study will measure changes following the implementation of PRISM within intervention and control sites and assess the acceptability of this tool.

Objective 1: We shall use postal questionnaires (including the widely used Client Service Receipt Inventory[30]) and routine data from the PRISM dataset (accessible through Health Solutions Wales) to compare primary, community and social care services delivered to stratified random samples of patients across the four strata of risk of emergency hospital admission both before (baseline) and 12 and 24 months after the implementation of PRISM in intervention and control sites.

Objective 2: We shall estimate the costs of implementing PRISM in intervention and control sites and of the resulting changes in the processes of care across the four risk strata.

Objective 3: We shall invite GPs, practice managers, case managers and specialist nurse practitioners to take part in one of two Focus Groups in each of the three intervention and four control sites, both at baseline and 24 months after the implementation of PRISM, yielding a total of 28 meetings. They will explore the individual and organisational processes of change and judge how well PRISM works in care planning and performance management. In addition we shall interview a purposive sample of three key individuals in each site engaged in commissioning, planning or managing health and social care. These interviews will also take place at baseline and 24 months after implementation, yielding a total of 42 interviews. We

shall develop separate semi-structured interview schedules for the first and second rounds of interviews. We shall record all interviews and transcribe them in full.

The information gleaned from the focus groups will inform the cost estimate of implementing PRSIM and the resulting processes of care (Objective 2).

Objective 4: The postal questionnaires sent to the stratified random samples of patients across the four risk strata before and after PRISM implementation (at baseline, and after 12 and 24 months) will include an anglicised version of the Quality of Care Monitor[31] to assess the acceptability to patients of the predictive risk stratification approach and its sequelae.

Objective 5: The conduct and findings of the proposed study will test the feasibility, and inform the design, of a subsequent study to evaluate the effect of implementing PRISM on patient outcomes. This will be done by the collection of SF-12 data at each time point.

Intervention Group (Early implementers)
All General Practices within four PRISM 'demonstrator' sites [Cardiff Local Health Board (LHB), Carmarthenshire LHB, Gwynedd LHB and Wrexham LHB] are eligible for inclusion in the intervention group. These sites are implementing PRISM ahead of the planned implementation across the rest of Wales. These sites also have access to formal support from Informing Healthcare (IHC) and the National Leadership and Innovation Agency for Healthcare (NLIAH) in implementing the Wales Chronic Conditions Management (CCM) Model and Framework. The key features of the model include PRISM, the development of integrated CCM Community Teams comprising generic CCM support workers and locality Care Coordinators, improved access to specialised personnel, and 'telecare' interventions.

Control Group (Late implementers)
The 37 General Practices in four other LHBs in South Wales – Bridgend, Neath Port Talbot, Swansea and Torfaen – that contributed data to the development of PRISM will form the control group. At these sites PRISM itself will become available over the next two years. Initially, however, no proactive programmes of care or formal support will be available from IHC or NLIAH in the use of PRISM to manage patients in these sites.

Although both intervention and control sites will eventually have access to PRISM, the key differences between the two groups are that intervention sites will implement PRISM earlier ***and*** underpinned by integrated care teams and central support. Hence it is important to explore the differences between the supported and unsupported implementation of PRISM. Isles and Sutherland state "Success (in bringing about change) is likely to depend as much on the quality of implementation, on the sensitivity to different points of view, and on the degree of support from influential organisation members as on the soundness of the principles of the change approach adopted"[32]. Thus the proposed study will provide us with the opportunity to compare the processes of implementation and change occurring in the study group with that in the control group; and to relate this comparison to several key SDO themes. Isles and Sutherland also stress: the importance of different models of care in examining and understanding organisational change; the multidimensional effects of change, and the

need to measure all these effects; and the wide range of perspectives likely to arise from different stakeholders, notably in their measures of success[32]. By using a wide range of methods and a wide range of service providers, the proposed study will seek insights into the wide range of potential effects of PRISM implementation.

Sampling

We excluded the demonstrator site of Gwynedd as its rural geography differs from that of all the control sites. Fortunately the remaining three demonstrator sites (Cardiff, Carmarthen and Wrexham) are together similar in demography and geography to the control sites together (Bridgend, Neath Port Talbot, Swansea and Torfaen). We shall therefore invite all 100 or so general practices from these three demonstrator sites to become 'intervention' practices alongside the 37 'control' practices who have already provided data for the development of PRISM, and agreed to continue to provide relevant data on their patients.

For the initial questionnaire survey, we shall draw a random sample of patients, stratified to yield 25 respondents in each of the four risk strata at each of the seven sites (3 intervention and 4 control), totalling 700 respondents in all. As patients with multiple chronic conditions in the top risk stratum are less likely to respond to questionnaires, we shall oversample them to yield 25 responses per stratum per site. Though we shall adopt the same basic design for each of the two later surveys (after 12 and 24 months), we shall draw half of each sample from previous respondents and half anew from PRISM registers. This sampling strategy strikes a balance between the potential for continuing respondents to characterise longitudinal change and the scope for new respondents to maintain the representativeness of the sample as a whole. The total of 2100 respondents will allow us to detect changes between intervention and control sites in resource use in individual strata. For example we shall have 80% power when using a 5% significance level to detect changes of 15% in the proportion of patients in a defined stratum receiving a specified resource, like case management in the top stratum or support to quit smoking in the bottom stratum.

For the qualitative component of the study, we shall sample two general practices in each site to take part in Focus Groups. We shall select these practices purposively to achieve high intra-practice response rates while providing contrasts in characteristics like size and rurality. We shall also purposively sample three senior managers responsible for commissioning, planning or managing health and social care for semi-structured interviews in each site.

Data collection

Objective 1: The postal survey of patients will use the validated Client Service Receipt Inventory (CSRI)[30] to estimate the use of defined primary, community and social care at baseline, and 12 and 24 months. We shall use routine data from PRISM to complement these data.

Objective 2: We shall derive the health and social care costs of implementing PRISM from the resulting CSRI and PRISM data and compare them between Intervention and Control sites within each of the four risk strata. We shall value all these resources in monetary terms using published unit costs[33].

Objective 3: In each of the seven sites (three intervention and four control), we shall conduct two meetings, at baseline and after two years, of two Focus Groups with key staff in and associated with general practices to explore current practice in chronic conditions management, attitudes to predictive risk stratification in general, expectations of PRISM itself, experience of using it in practice, and perceived barriers to, and facilitators of, its use. The Focus Groups will also explore the views of participants about how well PRISM works as a performance management tool. The issue of re-directing resources between patients at different levels of risk will also be explored with the Focus group participants. We have chosen Focus Groups to address these questions as they stimulate successful exploration of the perspectives of participants in greater depth than in individual interviews. This is because the expression of differing views generates interaction and debate. Focus Groups also provide an effective approach to understanding organisational change[34], and the success or failure of specified programmes[35]. We recognise however that Focus Groups need careful facilitation to encourage everyone to participate, clarify ambiguous statements, enable participants to finish their sentences, and explore interesting and unexpected avenues[36].

We aim to include 6 to 8 participants in each Focus Group, so as to achieve an optimal balance between informative discussions and a manageable group[35]. We shall develop topic guides for these Focus Groups from the study objectives, the existing literature on prognostic research in general and predictive risk stratification in particular, and consultations with the developers and implementers of the PRISM model. At baseline the groups will focus on current practice in chronic conditions management, attitudes to predictive risk stratification, and expectations of PRISM and of barriers to its use. Two years later the groups will focus on the experiences of participants, their perceptions of how PRISM worked in practice, and their success in managing change. We shall ask them: what factors facilitated or hindered the use of PRISM; how effective PRISM was in managing patients in each stratum; how useful it was in managing performance in practice; and whether and how in principle and in practice to improve and implement PRISM and the associated support systems.

Two researchers will conduct the Focus Groups, one to lead the discussion and the other to take notes, for example to link text to speakers and to record non-verbal communications including indications of agreement or consensus and signs of emotional responses like anger or anxiety.

In contrast we have chosen semi-structured interviews to address analogous questions with three senior managers in each site responsible for commissioning, planning and delivering health and social care. This is because we judge that senior managers will be less inclined to contribute to Focus Groups or be more inhibited in such groups These interviews will also take place at baseline and 24 months after the intervention. We shall develop interview schedules analogous to topic guides for the Focus Groups, namely from study objectives, the literature on prognostic research and consultations with the developers and implementers of the PRISM model.

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Objective 4: The postal questionnaires sent to stratified random samples of 700 patients at baseline and after 12 and 24 months will include an anglicised version of the Quality of Care Monitor (QCM)[31]. The outpatient and primary care version of this widely used and rigorously validated questionnaire measures patients' perceptions of

quality of health care on seven scales – Medical Care, Nursing Care, Diagnostic Services, Medical Outcome, Service Characteristics, Waiting Time and Reception Process. Recognising that PRISM is likely to affect different scales to different extents, we shall develop a rigorous analysis sub-plan for the QCM in consultation with external Co-applicants responsible for implementing PRISM. As the US version has shown construct validity, predictive validity and internal consistency, we shall undertake concurrent revalidation of the anglicised version at baseline. In doing so we shall adopt the methods described by Streiner and Norman[37]. In particular we shall complete the analysis of this concurrent revalidation and finalise the anglicised Quality of Carte Monitor before undertaking any primary analysis.

Objective 5: The primary purpose of this study is to examine the effect of PRISM on processes. It would be premature and financially imprudent to evaluate the effect of implementing PRISM on patient outcomes before completing the proposed study to estimate the effects of PRISM on the processes of care. We do however recognise that the ability to examine the effect of PRISM on outcomes will be lost once PRISM has been fully implemented across Wales. We are therefore proposing to include an SF-12 questionnaire to patients at each time point that will facilitate the collection of patient health related quality of life data. This will allow the collection of patient related outcome measure data that will examine the effect of PRISM implementation on patient outcomes to be measured. SF-6D scores will be generated from the SF-12 data which can be utilised in the health economics analyses. One of the deliverables at the end of the study will be the development and submission of a protocol for further funding that will allow a full scale cost-effectiveness analysis of this outcome data.

The flow diagram at the end of this document summarises the methods and timing of data collection in the proposed study.

Data analysis

Quantitative data:

We shall comply with the Statistics Standard Operating Procedure (SOP) of the West Wales Organisation for Rigorous Trials in Health & Social Care (WWORTH). Early in the project we shall develop for approval by the Research Management Group an explicit analysis plan for all data, notably PRISM and questionnaire data. This plan will espouse four key principles.

First we shall use ***two-sided significance tests*** throughout rather than prejudge the likely effects of risk stratification. Secondly primary analysis will be by ***intention to treat***: as patients have potential to move between risk strata every month, this principle will distinguish between those who move between strata and those who stay in the same stratum throughout. The analysis plan for 'movers' will focus on how and when care received responds to changes of stratum; and that for 'stayers' on the extent to which previous, potentially erratic patterns of care converge on the 'norm' for their single stratum. Thirdly we shall address ***regression to the mean*** (ie the potential of patients in the higher risk strata, especially recent arrivals in those strata, to revert to previous patterns of care) by careful comparison of intervention and control sites; this will enable us to distinguish between regression to the mean that is a direct and desirable consequence of PRISM and that which is a statistical artefact of our

longitudinal study design. Finally we shall use ***analysis of covariance*** to adjust these comparisons of intervention and control sites for imbalances at baseline in risk factors like age, sex and morbidity as measured by service use in the year preceding the baseline.

Economic analysis

The proposed research will undertake an economic evaluation of PRISM from the perspective of NHS Wales and personal social services over the study period of 24 months. We shall derive the costs of implementing PRISM and the resulting changes in care processes from routine data collected by the PRISM system and designed data collected by the CSRI over 24 months. This will enable us to estimate the size of differences in resource use between intervention and control sites within each of the four risk strata and overall. We shall value these resources in monetary terms using published unit costs[33] and derive estimates of the cost of reducing the risks or emergency hospital admissions.. By aggregrating these analyses we shall estimate the net budgetary effect of the new paradigm of care. Finally a series of univariate sensitivity analyses will assess the extent to which changes in the basic assumptions of the economic analysis affect the incremental cost-effectiveness ratio. The results of this economic evaluation will inform the nature of - and perspective to be employed in - the subsequent study that will assess the effect of PRISM on patient outcomes and determine the extent to which it can be regarded as representing value for money.

Qualitative data With the permission of participants we shall record all interviews and Focus Groups and transcribe them in full. Two researchers will independently undertake thematic analysis, supported by the NViVO computer package for qualitative analysis. A consistent comparative process will draw out common themes from the Focus Groups and staff interviews. We shall compare the perspectives and emergent themes of the various staff groups both within and across the intervention and control sites.

Contribution to collective research effort and research utilisation

Hence the proposed study will provide information particularly at primary care level on: the effectiveness of PRISM as a predictive risk stratification model and change management tool; the perceived barriers to and difficulties with its implementation; whether it can be used as a performance management tool; and its perceived value in managing patients with chronic conditions and preventing ill-health that could subsequently lead to the development of chronic conditions. Thus we shall promote the dissemination of the results to those responsible for policy decisions on the best approach to the management of patients with chronic conditions or at risk of developing one. More generally we shall seek to get the findings to those who develop policies for allocating healthcare resources or for general health promotion.

We shall disseminate the results through academic and NHS fora including appropriate National and International Health Services conferences. Within Wales we plan presentations to Health Boards where PRISM has been implemented, and to Informing Health Care and to the Welsh Assembly Government. We shall submit articles to appropriate high-impact peer-reviewed journals including the British Medical Journal and the British Journal of General Practice.

Plan of investigation and timescale

The study will start on 1st September 2010 and finish on 31st August 2013. Project milestones are highlighted below:

Pre-study tasks:

Feb 2010	PRISM implementation to start in Demonstrator (Intervention) sites.
March 2010	First Research Management Group (RMG) meeting.
July 2010	Begin IRAS application to gain MREC and Research governance approvals.
July/Aug 2010	Advertise and interview for research and clerical posts. Agree arrangements with Health Solutions Wales and GPs regarding use of PRISM datasets.

Main Study tasks:

September 2010	Gain Ethics and Research Governance approval. Obtain GP details for eligible Intervention and Control sites. Recruit eligible GPs to Intervention and Control sites. First download of PRISM data. Research and clerical staff start. Finalise protocols, study documents, questionnaires and qualitative schedules.
December 2010	Send baseline questionnaires to patients at Intervention and Control sites.
January 2011	Complete downloads of baseline PRISM data for Intervention and Control sites. Send repeat questionnaires to non-responders. Conduct baseline Focus Groups and interview senior managers
March 2011	Complete baseline Focus Groups. Submit progress report 1 to NCCSDO
April 2011	Begin analysis of baseline Focus Groups and Interviews
September 2011	First download of PRISM 12 month follow-up data. Submit progress report 2 to NCCSDO.
December 2011	Send 12 month questionnaires to patients at Intervention and Control sites.
January 2012	Complete downloads of routine 12 month PRISM follow-up data for Intervention and Control sites. Send repeat questionnaires to non-responders
March 2012	Submit progress report 3 to NCCSDO
September 2012	First download of PRISM routine data 24 month follow-up data. Submit progress report 4 to NCCSDO.
December 2012	Send 24 month questionnaires to patients at Intervention and Control sites.
January 2013	Final downloads of PRISM routine 24 month follow-up data. Send repeat questionnaires to non-responders. Conduct final Focus Groups and interview service providers
March 2013	Submit progress report 5 to NCCSDO. Complete 24-month Focus Groups and Interviews.
June 2013	Complete data analysis.
July 2013	Draft peer review articles and final report to NCCSDO.

August 2013 Submit final report to NCCSDO.

Approval by Ethics Committees

We shall seek approval from the Wales Multi-centre Research Ethics Committee before the start of the study. We shall also seek Caldicott approval for each of the participating sites. We shall seek informed consent from eligible general practices to participate in the study. As the Wales Assembly Government plans to implement PRISM across Wales, we shall ask participating practices to inform patients about this through their surgery handbook. They will tell patients that they will be using PRISM to plan services, and that they need to share relevant data with third parties for management and research purposes unless patients opt out. With the support of the research team, each practice will sample and vet patients for postal questionnaires and distribute these on behalf of the research team. We shall ask all patient participants completing questionnaires for written informed consent, together with service providers taking part in Focus groups and interviews.

Project management

Strategic management of the proposed study will be the responsibility of a Research Management Group (RMG) meeting quarterly and comprising the Chief Investigator, all Co-applicants, all research staff, two service users (ideally one patient and one carer) and two local participating General Practitioners. Operational management will be the responsibility of the Research Team meeting every month and comprising the researchers, clerical support, the Principal Investigator (HAS) and one of the Co-applicants (HAH). HAH will be Research Manager responsible for the operational management of the project from day to day. Strategic and methodological support will be available throughout the project from the Welsh Assembly Government lead (HHowson), the Informing Healthcare leads (LL and DW), the quantitative research lead (IR), the health economic lead (CP), the social care research lead (PH) and the qualitative research leads (BE and AP). The PI and Research Manager will ensure adherence to the planned timescale, detailed plans for data management and analysis, and all relevant Standard Operating Procedures of the West Wales Organisation for Rigorous Trials in Health & Social Care (WWORTH).

Service users

Engagement with stakeholders

The proposed study engages several disciplines including primary and secondary healthcare, social services, IT, public health and patients. It reflects the Framework of Research and Evaluation of Effectiveness (FREE) of Chronic Conditions Policy in Wales[34] by using a multi-agency approach covering policy makers, academics, health providers and other stakeholders in the delivery and evaluation of healthcare in Wales. The study is managed by a team of academics, service providers and policy makers. This multidisciplinary approach, including all key players in policy, service delivery and research, is vital to effective development and evaluation of such a wide-ranging intervention in such a broad context.

Including service and research users

In accordance with the WWORTH Standard Operating Procedure for Service User Inclusion, at least two patients or carers will be members of all formal research groups, including the RMG, and the Research Team. We shall recruit them through the 'Involving People' research network which is funded by the CRC Cymru Co-ordinating Centre, co-ordinated from Swansea University, and the subject of Bridie Evans' PhD.

Involving People has recently recruited through national open advertisement, a panel of 20 people who have, or care for someone with, chronic conditions and also have an interest in contributing to research. The panel has met several times and, with the support of Co-applicant Bridie Evans, has developed a model of service user inclusion in which the panel provides training and support for members to contribute to a range of research activities including advisory committees, research management and hands-on data analysis. Thus the panel provides an effective source of people interested in participating in the proposed study and comprehensive support for their contributions to the proposed study. If funded the study will therefore contribute to the evaluation of this model.

Expertise and justification of support required

We have a strong research team that includes university health services researchers and methodologists, clinicians, stakeholders, policy advisors and service users. The research team is led by a Professor in Health Services Research whose main research interest is in Emergency Care and who is a member of the Welsh Assembly Government's Chronic Conditions Management Group. For this study she has brought together a highly experienced team of specialists and researchers representing the disciplines of: health and social services research (Ian Russell, Helen Snooks, Hayley Hutchings, Peter Huxley), methodology and statistics (Ian Russell), health economics (Ceri Phillips), emergency care research (Helen Snooks), primary care (Jeremy Dale), qualitative methods (Bridie Evans, Alison Porter). Co-applicants include the Project Director of one of the PRISM demonstrator sites (Leo Lewis), the Research and Evaluation Manager of Informing Healthcare (Daniel Warm) and the Senior Health Strategy Advisor on Chronic Conditions Management to the Welsh Assembly Government (Helen Howson). This confirms the strong commitment of the NHS and Government and provides a direct route for liaison and negotiation. In addition to providing the expert advice expected of all co-applicants, each of these three will play a key role in project management.

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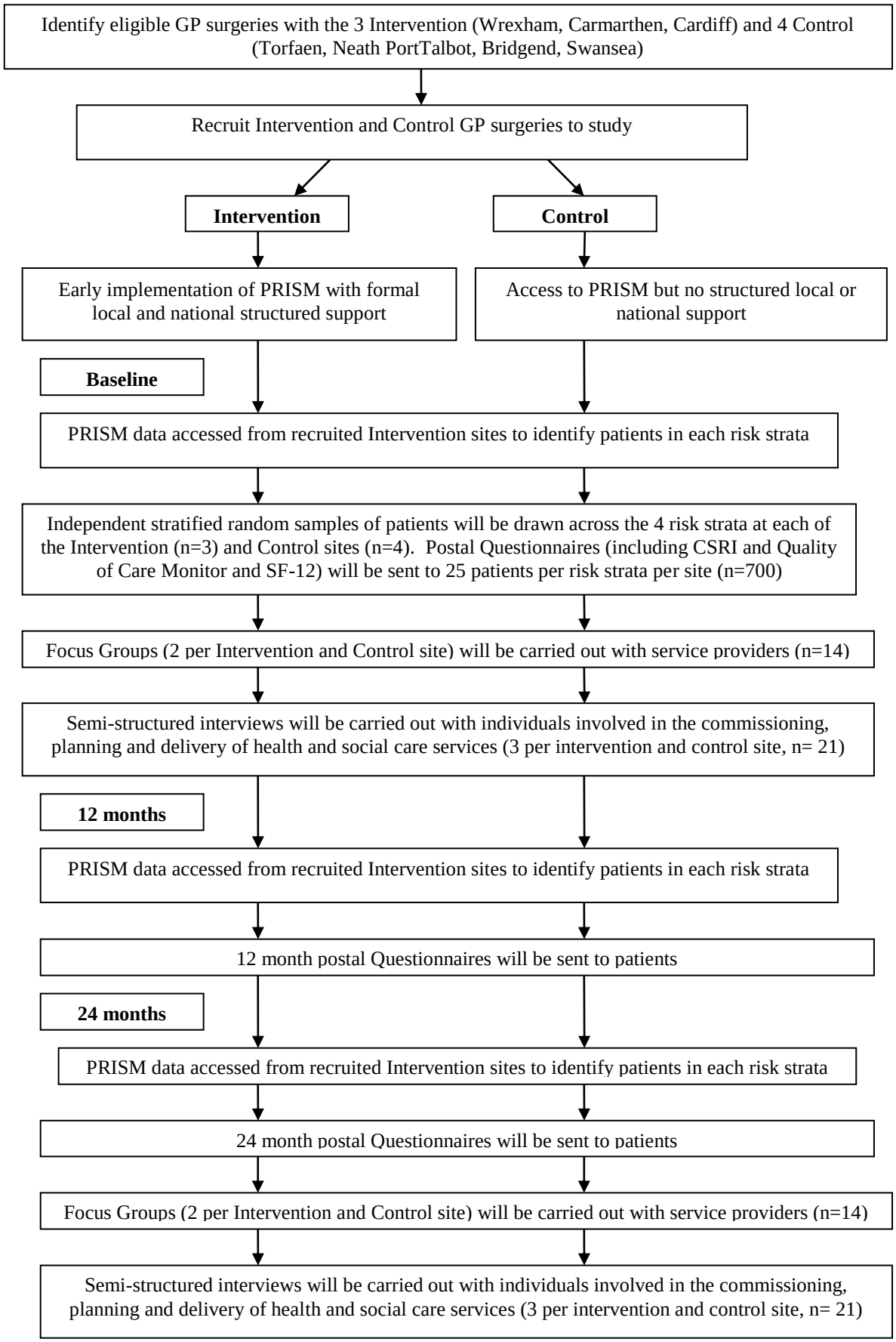
Identify eligible GP surgeries with the 3 Intervention (Wrexham, Carmarthen, Cardiff) and 4 Control (Torfaen, Neath PortTalbot, Bridgend, Swansea)
Recruit Intervention and Control GP surgeries to study
Intervention
Control
Early implementation of PRISM with formal local and national structured support
Access to PRISM but no structured local or national support
Baseline
PRISM data accessed from recruited Intervention sites to identify patients in each risk strata
Independent stratified random samples of patients will be drawn across the 4 risk strata at each of the Intervention (n=3) and Control sites (n=4). Postal Questionnaires (including CSRI and Quality of Care Monitor and SF-12) will be sent to 25 patients per risk strata per site (n=700)
Focus Groups (2 per Intervention and Control site) will be carried out with service providers (n=14)
Semi-structured interviews will be carried out with individuals involved in the commissioning, planning and delivery of health and social care services (3 per intervention and control site, n= 21)
12 months
PRISM data accessed from recruited Intervention sites to identify patients in each risk strata
12 month postal Questionnaires will be sent to patients
24 months
PRISM data accessed from recruited Intervention sites to identify patients in each risk strata
24 month postal Questionnaires will be sent to patients
Focus Groups (2 per Intervention and Control site) will be carried out with service providers (n=14)
Semi-structured interviews will be carried out with individuals involved in the commissioning, planning and delivery of health and social care services (3 per intervention and control site, n= 21)

This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the SDO programme or the Department of Health.