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MUNROS: Health Care Reform: the iMpact on practice, oUtcomes and costs of New roles for health pROfeSsionals: a Study Protocol

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Roles and responsibilities of other groups: The study collaboration comprises nine partner countries (Scotland, England, Netherlands, Germany, Norway, Italy, Czech Republic, Poland, Turkey), the first four of which are represented on the core PMT which is responsible for oversight of the project progress. Other partners join the PMT as required according to the project stage and all partners form a General Assembly for overall project decision making. The study is advised by an International Expert Advisory Board and Country Expert Advisory Groups.

ABSTRACT

Introduction: The workforce is the largest single component of health care expenditure in EU member states. The size and composition of the health workforce are key drivers of both expenditure levels and the performance of health care systems, and are changing; new health professions have been introduced and enhanced roles for established professions have been developed. This project will systematically analyse the contribution of these new professional roles to health service redesign, integration and performance in nine European countries. This paper describes the study protocol for collection of survey data on inputs and outputs of care in three distinct care pathways, and sets this in the context of the wider programme.

Methods: Questionnaires will be distributed to health care professionals (n=14580) , their managers (n=3564) and their patients (n=19440) in three care pathways (breast cancer; type2 diabetes; and coronary heart disease) within twelve hospitals and associated primary care settings in each of nine European countries (Scotland, England, Netherlands, Germany, Italy, Czech Republic, Poland, Norway, and Turkey). Questionnaire topics will include basic demography, details of the different professionals working on the care pathway and the tasks they do, questions about decision making when considering skill mix and integration of care. Patient satisfaction and health care utilisation will also be explored. In later work, register data in some countries and data from patient records in other countries will be used to record clinical outcomes. Descriptive analysis will identify the different models of care which are in current use and multivariate analysis will establish the most clinically and cost effective models.

Ethics and Dissemination: This study protocol was approved by ethical committees in each country. The findings will be disseminated through national and international clinical, health services research and health workforce conferences, and publications in national and international peer-reviewed journals.

ARTICLE SUMMARY

Article Focus

- New models for delivering care are emerging and the roles of health professionals are changing.

Key Messages

- This study will provide information on skill mix for three care pathways in nine countries across Europe.
- The study will identify the most clinically effective and efficient models of care.

Strengths and Limitations

- This will be the first systematic analysis of the contribution of new professional roles to health service redesign, integration and performance.
- The study will be conducted in three major care pathways: breast cancer, type2 diabetes and coronary heart disease.
- The study covers a pan European sample of countries with distinct health care systems, and both secondary and primary care settings.
- Its strength is the use of common, validated questionnaires and validation via policy analysis, case studies and routine data.
- Engagement of all professional groups and good survey responses are needed for the findings to be considered robust.

INTRODUCTION

Background and Rational

Workforce is the largest single component of health care expenditure in EU member states (1). The size and composition of the health care workforce are key drivers of both expenditure levels and the performance of health care systems. Both the size and composition of the health care workforce are changing in many European countries in response to measures to contain health care expenditures, changing needs for health care, and changing working patterns (e.g. feminisation of the workforce, with increasing demands of child care and move to part time working, and implementation of working time legislation).

In a number of countries there have also been substantial innovative developments in health workforce skills. New health professions have been introduced and enhanced roles for established professions have been developed (2). These new professional roles have the potential to contribute to increased effectiveness and efficiency in service delivery (3,4,5,6) and mapping the skills and competencies of the health workforce has been identified as one of the key areas for action by the European Commission (7). As new professional roles become more universal, current approaches to workforce planning will need to be adapted to include these new models of service delivery. Furthermore, at a time when integrated care is regarded as a quality marker it is important to understand how it is affected, if at all, by the deployment of an increasingly diverse workforce.

This paper describes the protocol for surveys in nine countries which are part of a wider programme of work entitled Health Care Reform: The impact on practice, outcomes and costs of new roles for health care professionals (MUNROS: www.abdn.ac.uk/munros). The ultimate aim of the whole MUNROS programme is to inform a workforce planning model based on integrated financial and service planning and the competencies needed to deliver care rather than professional qualifications. The programme will systematically study the workforce issues described above in primary and secondary health care settings in nine countries in Europe (Scotland, England, Netherlands, Germany, Italy, Czech Republic,

Poland, Norway, and Turkey). The design of the overall MUNROS programme is observational and cross sectional, combining the questionnaire surveys described in this paper with patient, hospital and country level data on clinical outcomes as available from routinely held databases, unit costs of care consumption, and a patient completed Discrete Choice Experiment (DCE). Economic modelling using multi-criteria decision analysis (MCDA) will inform a final synthesis to identify optimal models of care and distinguish the critical elements of these models. The findings will be incorporated into a generic multi-professional workforce planning tool; this will be developed by mapping from tasks performed to the skills and competences required to undertake these tasks together with estimates of projected patient need. In each partner country a Country Expert Advisory Group (CEAG) has been convened to support and advise the project. The study is also advised by an international Expert Advisory Board (EAB).

There were three pieces of work undertaken in earlier stages of the MUNROS programme which informed the development of the surveys. Firstly, the key features of the health delivery systems in the nine countries of study were detailed through analysis of routinely collected data from international and national statistical offices and national health services, and a systematic review of published research, policy documents and grey literature was conducted (2). Secondly, again using routinely available data, the skill mix of the health workforce in the primary and secondary care sectors in all European countries was detailed, and then details of new professional roles, and the numbers working in them in each sector in the nine partner countries were described. Following this high level analysis, three care pathways were selected for more in depth study in the remainder of the programme of work, based initially on the clinical areas in which the new professional roles were employed, followed by application of clinical criteria agreed by a group of international experts (see Text box I). The three selected care pathways are: breast cancer, type 2 diabetes and coronary heart disease following an ST elevation myocardial infarction. These clinical conditions can be considered respectively as examples of: a condition requiring a scheduled surgical intervention, post-operative and follow up care; a long term condition managed largely in primary care, but with support from secondary care; a condition presenting acutely and requiring unscheduled hospital care, rehabilitation and long term

care. Finally, case studies were conducted, two in each of the nine partner countries, with each of the three selected care pathways being studied by six countries. The case studies sought to understand the new professional roles that were being delivered, the mechanisms and drivers for greater skill mix in the delivery of care, and the delegation of tasks from medical to other members of the health care team.

Text box I: Clinical criteria for selection of care pathways

- The clinical condition is of high prevalence, significant morbidity and mortality are associated with the condition and data on these exist (i.e. a burden to society).
- Data exists on health outcomes that are related to new professional roles and/or the integration of care: Outcomes of processes (e.g. patient follow up and integration of care, patient satisfaction), intermediate health outcomes (e.g., clinical health outcomes, avoided complications) and final outcomes of care (e.g., patient quality of life).
- Procedures and clinical management are similar across different national boundaries.
- Care could be delivered by a range of health professionals: In at least some of the partner countries care is delivered by either new professions or new roles for existing professions. The contribution of different professions varies across partners.
- Patients have a role in managing the condition.
- Care is delivered in primary and secondary settings and desirably in intermediate and tertiary care settings. Overall at least one care pathway will have a substantial presence in primary care setting and one with a substantial presence in a secondary care setting.

Objectives of the surveys

The overall aim of the surveys is to describe and quantify the use of new professional roles in primary and secondary care sectors in three care pathways in nine European countries, to understand their effects on the quality of care, and on the delivery of integrated care. Later stages of the project will evaluate their clinical and cost effectiveness; select the most effective and efficient service models as benchmarks; and develop a workforce planning tool based on the competences required to meet population needs.

METHODS

Conceptual Framework

The MUNROS project researches the relationship between the inputs to the health service, focusing in particular on the staff input, and the outputs of the health service, focussing on patient outcomes. Where the focus of research is on the quantity and mix of different types of staff, rather than by institution, the appropriate conceptual framework is that of a production function employed in economics. Thus the relationship which is the focus of research can most concisely be defined as:

$$O_{iPH1,C} = f\ (L_{PH1C}, \boldsymbol{K}) \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots (1)$$

Equation (1) states that clinical outcomes, , for a sample of patients, *i (*where *i*= 1…N), in receipt of treatment along care pathway *P*, in hospital H_1, in country *C*, results from the activities of the workforce, identified by L, in pathway *P*, at hospital H_1, in country *C* together with all other non-staff inputs to care, here defined by ***K***.

The project design seeks to distinguish hospitals which employ new professions and those which employ both new and established professions within the same care pathway. Using the notation above it seeks to distinguish a hospital H_1 in which only established professions, $L_{1,}$ are employed and a second hospital H_2 in which both established professions, $L_{1,}$ and new professions, L_2, are employed. A comparison of the clinical outcomes for patients along this pathway in these two hospitals, as in equation (1) (above) and equation (2) (below) will then distinguish the impact of employing new professions.

$$O_{iPH2C} = f\ \left(L_{1PH2C,} L_{2PH2C}, \boldsymbol{K}\right) \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots (2)$$

The advantages of this specification are that it:

1. Controls for heterogeneity in the clinical outcome mix, *O*, by moving from the health service as a whole to defined **care pathways** identified in the earlier developmental work. Measures of clinical output which are specific to the patients treated along each pathway will be obtained.
2. Captures differences in service design which result in differences in staff mix.

3. Controls for heterogeneity in **patient characteristics**, *i*, by obtaining details of a wide range of characteristics in the patients' questionnaire and through the use of vignettes in the health professionals' questionnaires. These vignettes present respondents with a standardised clinical episode: a patient presenting at a particular stage in the pathway with a highly specific condition which requires treatment and which is accompanied by a specific set of comorbidities. This eliminates the issue of unmeasured comorbidities in this specific treatment group.
4. Clinical protocols reduce heterogeneity in **other inputs** to health outcomes as indicated by ***K*** for they determine the management of the disease, prescribing the procedures, drugs and technologies used in treatment.

The core of the surveys requires health professionals, managers and patients to identify who does what at each stage along the three care pathways. The tasks needed to deliver care along each pathway, and the professional undertaking those tasks will be identified, together with actual and potential substitutions. When associated ultimately with cost and clinical output data, it will enable the identification of the most efficient combination of skills and competencies to achieve a given level of clinical output, or the combination of skills and competencies that will achieve the highest level of clinical output for a given cost.

Study Design

This is a cross sectional survey using self-completed questionnaires, either distributed by post or handed out at staff meetings or patient clinics for three specific care pathways.

Study Setting

The study setting is 12 hospitals and sixty associated primary care centres (average five per hospital) in each of the nine countries. Careful selection of hospitals enables us to reduce unmeasured heterogeneity. It is reasoned that similar types of hospitals are likely to employ the same technology. Thus *teaching hospitals* are likely to employ some of the latest technology available to the health service and are more likely to be engaged in research

with associated funding opportunities for new developments. Large hospitals may have similar volumes of throughput along a care pathway (assuming that volume of throughput is one determinant of the quality of clinical outcomes).

Countries were selected to reflect the diversity of systems in Europe and the different stages of reform of health care systems. They include those: in the later stages of transition from highly centralised (ex-communist) systems (Czech Republic and Poland), at the forefront of innovation of delivery systems (Netherlands, Scotland and England), with more established and stable systems (Germany, Italy and Norway), and a rapidly developing country (Turkey).

Participants and eligibility

There are two categories of participants who will be identified and recruited from a participating hospital or general practice.

Health Care Professionals and Managers All health care professionals, providing care to patients within one of three selected care pathways from the point of diagnosis to long term follow up, will be invited to take part, together with all health care managers responsible for decision making about the workforce providing care for these patients.

Patients A random sample of patients within one of the three selected care pathways will be eligible to take part as long as they meet the following inclusion criteria.

- Male or female patients aged 21 years and over (note there is no upper age limit)
- Receiving care in one of the three care pathways: breast cancer; type2 diabetes; and coronary heart disease
- Having capacity to understand the purpose of the study and complete the questionnaire

In addition the following disease specific inclusion criteria will be applied:-

- *Coronary Heart Disease patients:* have suffered a ST segment elevation myocardial infarction (STEMI), are stabilised (i.e. may still be during initial hospital admission) or up to two years in follow-up.
- *Breast Cancer patients:* have been diagnosed and received some treatment for Breast Cancer and are between three months to two years post-surgery.
- *Type 2 Diabetes patients:* have been diagnosed with type 2 diabetes and are at least three months post diagnosis to two years in follow-up.

Identification and recruitment of sites and participants

Hospitals and primary care centres

Hospitals vary by type, location, size and population served, and the organisation within which they are managed. All of these factors may influence the extent to which new health care professionals are employed to care for patients. Identification and recruitment of the hospitals will be based on the following, adapted to local circumstances, to ensure representation of each of these dimensions. All hospitals in each country will be listed, and the list stratified by key dimensions: type (teaching hospitals and general hospitals), geographical region, rurality (urban, suburban or rural) and sociodemographic characteristics of the catchment area (deprived and less deprived). Eligible hospitals will be invited to consider taking part by mailing an invitation pack (covering letter, participant information sheet, and expression of interest form) to hospital directors or their delegated deputy. From those expressing interest, 12 hospitals will be selected according to the criteria outlined above under 'Study Setting'. Hospital consent to participate will obtained by mailing invitation packs (covering letter, participant information sheet, and consent forms) either to hospital directors or clinical leads for each condition (or as appropriate in non-UK countries) according to preference of hospital. Ideally hospitals should be providing care along two of the three selected care pathways.

Primary care centres associated with each hospital will be similarly selected. All primary care providers in the catchment area of the recruited hospitals will be contacted by mail with an

invitation pack (covering letter, participant information sheet, and expression of interest forms) and from those expressing interest a maximum variation sample of averagely five (and a maximum of 60 per country) will be purposively selected to give representation of different types, locations and socioeconomic factors (e.g. deprived and wealthier communities, different ethnicities).

Health care professionals and managers

Within each clinical team (i.e. the team providing care to people with one of the three conditions) at each hospital a key contact will be identified. This is likely to be the clinical lead. They will advise on the best method of questionnaire distribution. Invitation packs (covering letter, participant information leaflet (PIL), and questionnaire) will be sent to identified participants using one or a combination of the following methods tailored to national and local arrangements. 1. Where names are in the public domain, participants may be contacted directly by the researchers. 2. Where this is not possible, key contacts or their depute will inform their team about the study and ask those interested in participating to send their contact details to the researchers so the questionnaire packs can be mailed directly. 3. Alternatively, key contacts will distribute questionnaires on behalf of the researchers, with a request to mail the completed questionnaire back to the researchers in a reply paid envelope. 4. Finally, face to face launch meetings will be arranged at each site, at which a member of the research team will give a short summary of the purpose and structure of the project, encourage participation, and distribute questionnaires to those attending. All questionnaires will be identified with a secure identification number, linked to the identity of the recipient, and recorded on a paper log subsequently transcribed to an electronic log. This will allow up to two targeted reminders to be sent to non-responding health care professionals and managers by clinical managers/link people.

The first three of the above four approaches will be adopted in primary care centres. Where there is no primary care doctor with a special interest in one of the three conditions, specific questionnaires will be randomly allocated.

Patients

For each care pathway patients meeting the inclusion criteria will be identified either prospectively as they present in clinic or from clinic lists, according to local preference. Those identified in clinic will be handed an invitation pack (covering letter, participant information leaflet, and questionnaire) by the responsible clinician. They will be encouraged to complete the questionnaire whilst waiting for their appointment. Patients will be asked to complete and return the questionnaires directly to the researchers via a box in the clinic or mailed directly in a reply paid envelope. Those identified from clinic lists will be mailed the invitation pack by clinical staff or their designated representative. A log of patients given the questionnaire, and their contact details, will be maintained by clinic staff to allow response rates to be assessed and one reminder to be sent to non-responders.

Sample Size

In each country twelve hospitals will be selected, and three care pathways within each of these hospitals, giving 36 care pathways and a total of 324 (36 x 9) care pathways across all partners. We estimate that the average number of health care professionals on a pathway will be thirty giving a total of 9,720 questionnaires distributed (324 x 30) to health care professionals across all partners. We further estimate that there will be an average of 6 health care managers per pathway giving a total of 1,944 (6 x 324). There will be 540 (60 x 9) primary care centres taking part with an estimated 4,860 (9 x 540) questionnaires distributed to health care professionals across all partners and 1,620 (3 x 540) questionnaires distributed to health care managers.

Using the standard procedures described above, and based on experience, we conservatively estimate a response rate to the health professionals and managers' questionnaires of 40% giving a total of 5,832 and 1,425 returned health professionals and managers' questionnaires respectively.

Patient recruitment will continue at each of the 324 hospitals until 30 patients have been approached in total per condition, and at each primary care centre until an average of 6 patients per centre have been approached per condition (or 30 per hospital area). With a conservative estimate of a 50% response rate this will produce 9,720 completed patient

questionnaires. These numbers are judged sufficient to allow estimation of the main outcomes and comparison of main outcomes by country and condition.

Data Collection

Data collection will close at the end of 2015.

Questionnaires

Three questionnaires, each with three versions tailored to the three care pathways, were designed to be completed by: (i) health care professionals; (ii) health care managers of these professionals and; (iii) patients receiving care from these professionals. Draft questionnaires were developed, in English, by an expert group drawn from those partners with the most extensive research experience in this area. Questionnaires were translated and validated through back translation into each of the partner country languages. They were then refined in light of feedback from partners and the CEAG, pre pilots with local colleagues and a formal pilot in which each country piloted the three questionnaires in one hospital for two of the three target conditions (approx. 20 health care professionals, 3 health care managers and 5 patients). Where available, standard instruments and scales have been incorporated. The resource use questions are based on those developed in and widely applied in other research undertaken by partners. Overall design drew on the Cochrane review (8) and uses methods known to encourage high response rates.

Health care professional questionnaire

This questionnaire includes sections on respondent demography, roles, and education (closed questions), who they work with (fixed choice options), the tasks undertaken at different stages of the care pathway, the frequency with which they are undertaken and the time taken for both a standardised patient based on a vignette and for a patient they would typically treat patient (combination of yes/no questions and open responses), their opportunity to undertake new roles, the barriers and facilitators to undertaking new roles (combination of yes/no questions, Likert scales and open responses), the drivers for new roles (combination of yes/no questions, Likert scales and open responses), and the integration (9) and specialisation of care on the relevant care pathway.

Health care manager questionnaire

The health care manager questionnaire was constructed in a similar manner to the health care professional questionnaire, and includes sections on respondent demography, roles, and education (closed questions), the staff they manage (fixed choice options), the tasks undertaken at different stages of the care pathway by different professionals (fixed choice options), the influences on their decision making about staffing changes in the mix of staff working on the relevant care pathway (Likert scales), the drivers for these (combination of yes/no questions, Likert scales and open responses), and the integration (9) and specialisation of care on the relevant care pathway.

Patient questionnaire

The patient questionnaire includes sections on: the patient's health including confirmation of eligibility, the Charlson Index for co-morbidities (10) and the EQ5D-5L as a quality-of-life instrument (11), the care they have received and the professionals who provided the care (tick box yes/no options), their experience of care (Likert scale responses to as series of statements), their satisfaction with care (Likert scale responses to various parameters of care) and their perceptions of the importance of specific characteristics of care, continuity of care, their use of health care services and who they saw (tick box and open questions), the value they place on their care (a willingness to pay question), demographic questions (age, weight, education, employment, income, lifestyle) and effect of condition on daily life. A final question asked them to provide contact details if they would be willing to be contacted again for subsequent stages of the research.

Discrete Choice Experiment (DCE)

A DCE will explore patients' preferences and trade-offs when responding to questions about their preferences for different aspects of care. There will be a focus on comparing treatment by new health care professionals compared to traditional approaches. The DCE will be sent to those patients who in the initial questionnaire give their consent to be contacted about further research. The attributes and levels will be based on the literature and the responses

to relevant items in the patient questionnaire. The DCE will be distributed by mail or email according to national preferences and one reminder will be sent.

Outcomes

The survey outcomes are a description of:

- the health care professionals involved in the delivery of care
- the tasks on the care pathway, the frequency with which they are delivered and by whom
- the patients' expectations, experiences, and preferences for care
- the integration of care
- the drivers for skill mix changes in the team delivering care.

Data management and analysis

Data from returned questionnaires will be entered into an Excel spreadsheet by each partner following agreed data coding rules and data cleaning protocols (e.g. for missing data). Double data entry on 10% of returned questionnaires will be used to check for accuracy. The final dataset will be exported into a STATA database for analysis, using a standard syntax and according to an a priori data analysis plan agreed with all partners. Any identifying data (e.g., hospital name, care pathway) will be anonymised by coding to allow for clustering in the analyses whilst maintaining confidentiality. Partners will hold country level databases and a cross-country dataset will be created for Europe wide analyses to be led by named researchers (i eth the database will not be made generally available to the whole team). Data will be stored securely on password protected computers and the MUNROS study Sharepoint.

Initial analyses will include simple descriptive frequencies and associations between dependent and independent variables using appropriate multivariate techniques. The pooled country database will be analysed using multivariate and multilevel modelling methods and made available to partners to undertake an agreed plan of analysis. Country specific and inter-country analyses will model the relationships between the central dependent and independent variables as specified in equations (1) and (2) of the conceptual

framework, within and across countries. Analysis of the results of the DCEs will distinguish how the preferences of respondents for different care pathways are to be measured and weighted and what inter-country differences exist.

PLANNED WORK TO FOLLOW THE QUESTIONNAIRES

Additional outcome measures not collected by the patient questionnaires will be extracted from register data at hospital and or national level; the data source will vary by country because of different clinical recording systems and health service systems. These data will include standard relevant health and healthcare indicators (e.g. morbidity and mortality) and measures of patient safety, patient turnover, length of inpatient stay, and number of readmissions. Process productivity will then be calculated, measured as consultation times per type of professional and consultation rates per hour. The data will also be used to assess the representativeness of the survey respondents against the wider hospital population of patients receiving care along the same pathway and, in countries where there are aggregated national data, the representativeness of the hospital sample compared to all hospitals.

The economic evaluation will take a health care perspective of the costs and effects associated with the new professional roles, using a state-of-the-art economic evaluation (including a Markov modelling exercise) and MCDA. Only (changes in) costs within the health care system and clinical effects will be considered. The analysis plan will exploit the size and variation in data across all participating countries and the comparability in level of detail, completeness and quality of data across these countries. The analyses will explore whether service redesign leads to cost containment, investigate the balance of cost and benefits and identify incentives for policy makers when increased roles for the new professional roles are introduced.

Optimal models of care will be identified and the critical elements of these distinguished. The analysis is aimed to identify optimal models for 'best' care delivered cost effectively. It will present examples of care integration and of the costs associated with financing these

pathways. It will suggest solutions to barriers identified at organisational and team level informed by examples of good practice using standard theoretical models.

Finally, a workforce planning model for each care pathway will be developed reflecting the dynamic interaction between the number and type of health professionals (allowing for different approaches to labour substitution) and the quality and cost of care for patients and projected patient need. Algorithms and computer modelling will be used to develop the final tool. The information requirements of the planning models will be detailed and the methodological and data improvements required for improved workforce planning models will be distinguished.

The models so developed will enable workforce planners to optimise care delivery along care pathways, taking into account the needs of the population, the tasks required to deliver care to meet these needs and the availability (actual and potential) of the various health professions with the competences to deliver these tasks. Service providers will be able to benchmark against these, to evaluate the efficiency of existing provision and identify the modifiable areas offering the largest efficiency gains.

DISCUSSION

In most health care teams roles of health care professionals are evolving in different ways. Some traditional roles are being extended, new health care professions are being introduced, tasks are being delegated from one professional to another, for example from a doctor to a specialist nurse and new roles evolve as new technologies are introduced. The clinical and cost effectiveness of these new healthcare workforce configurations has not been systematically explored. Our hypotheses are that increasing skill mix in teams in this way is cost effective and that there is potential to increase it. Our overall objective is to inform evidence based workforce planning.

The current research evidence suggests that new professional roles can help improve access to care and the quality of care (2, 12, 13). The greater deployment of new professional roles could faciltitate increased flexibility and scope for integrated care, and offer new solutions to the challenges of delivering health care to populations with changing and escalating

needs. Existing research has failed to show how changing skill mix could enhance the integration of care, and the research has largely focussed on process rather than clinical outcome measures. It has failed to benchmark best practices regarding the structure of care and it has failed to show how, as the new professional roles have changed care processes and care pathways, patients move through health care organisations, how patient information is shared, and if and how the new professional roles might help integrate care across organisational boundaries. Further there appears to be little robust evidence of how new professional roles might reduce the costs of health care services and no evidence of the impact on efficiency of care. We will fill these lacunae.

DISSEMINATION AND ETHICS

Dissemination

Each partner will produce a *Country Report on Service Design and Professional Roles* which will include an analysis of basic descriptive statistics by country and care pathway. The Country Reports will serve as the basis for producing a *Country Briefing Paper* for each country studied. This will inform key stakeholders and policy makers in each country of the initial, country specific, findings from the project. A Cross-Country report will also be produced drawing wider conclusions by comparing and contrasting across the different health systems. A Europe-wide stakeholder meeting for invited policy makers, workforce planners and academics will be held near the end of the project. A final report will be submitted to the EC and will be available on the MUNROS project website. In addition, findings will be presented at appropriate national and international clinical, health services research and health workforce conferences and publications submitted to peer-reviewed journals in these same fields.

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Ethics Approval: This study protocol was approved by the respective ethical committees in each country. Protocol amendments will be submitted as needed, and communicated to research sites by the Research Fellows in each country.

UK (Scotland and England): Leeds East NRESCommittee UK and area NHS Research and Development Departments

Netherlands: METC Isala Hospital, Zwolle, Academic Medical Centre Amsterdam, Radboud Academic Medical Centre, Erasmus Medical Centre, UMC Utrecht, Maasstad Hospital, Reinier de Graaf Ziekenhuis Delft, Flevoziekenhuis (samenwerking met AMC voor borstkanker), Maastricht UMCU, St Elizabeth Ziekenhuis, Martini Ziekenhuis Groningen, Ikazia Hospital

Germany: Ethikkommission des Instituts für Psychologie und Arbeitswissenschaft (IPA)

Italy: Gemelli teaching hospital, Milan area A, area B, area C and IRCCS ethical committees

Czech Republic: Individual hospital ethical committees

Poland: Not required

Norway: Regional Ethics Committee, REK vest

Turkey: Individual hospital ethical committees

Provenance and Peer Review: Not commissioned, externally peer reviewed

Appendices

English language versions of consent forms and other related documentation given to participants (e.g., questionnaires) are available on request from the authors.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym DONE
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry NOT A TRIAL-NOT RELEVANT
	2b	All items from the World Health Organization Trial Registration Data Set NOT A TRIAL-NOT RELEVANT
Protocol version	3	Date and version identifier DONE
Funding	4	Sources and types of financial, material, and other support DONE
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors DONE
	5b	Name and contact information for the trial sponsor DONE
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities DONE
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) DONE as far as is relevant
Introduction		

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention DONE as far as is relevant
	6b	Explanation for choice of comparators NOT A TRIAL-NOT RELEVANT
Objectives	7	Specific objectives or hypotheses DONE
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) DONE
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained DONE
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) DONE
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered NOT A TRIAL-NOT RELEVANT
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) NOT A TRIAL-NOT RELEVANT
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) NOT A TRIAL-NOT RELEVANT
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial NOT A TRIAL-NOT RELEVANT

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended DONE
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) DONE
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations DONE
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size DONE
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions NOT A TRIAL-NOT RELEVANT
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned NOT A TRIAL-NOT RELEVANT
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions NOT A TRIAL-NOT RELEVANT
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how NOT A TRIAL-NOT RELEVANT

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial NOT A TRIAL-NOT RELEVANT
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol DONE
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols NOT A TRIAL-NOT RELEVANT
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol DONE
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol DONE
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) NOT A TRIAL-NOT RELEVANT
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) NOT A TRIAL-NOT RELEVANT
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed NOT A TRIAL-NOT RELEVANT

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial NOT A TRIAL-NOT RELEVANT
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct NOT A TRIAL-NOT RELEVANT
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor NOT A TRIAL-NOT RELEVANT

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval DONE
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) DONE
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable NOT A TRIAL-NOT RELEVANT
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial DONE
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site DONE
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators DONE

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation NOT A TRIAL-NOT RELEVANT
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions DONE
	31b	Authorship eligibility guidelines and any intended use of professional writers DONE
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code DONE
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates AVAILABLE ON REQUEST
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable NOT A TRIAL-NOT RELEVANT

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

The iMpact on practice, oUtcomes and costs of New roles for health pROfeSsionals: a Study Protocol for MUNROS

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The iMpact on practice, oUtcomes and costs of New roles for health pROfeSsionals: a Study Protocol for MUNROS

Authors: Christine Bond, Hanne Bruhn, Antoinette de Bont, Job van Exel, Reinhard Busse, Matthew Sutton, Robert Elliott on behalf of the MUNROS team

Study identifier: www.abdn.ac.uk/munros

Protocol version: Protocol_v5_29.05.2015

Funding: *Project is funded by the European Commission, Grant Agreement no: 305467*

Roles and responsibilities

Name affiliations and roles of protocol contributors:

Robert Elliott, Professor of Health Economics, and Christine Bond, Professor of Primary Care, University of Aberdeen: Co Principle Investigators with joint responsibility for overall co-ordination of project (via Project Management Team (PMT)), led the writing of the funding proposal and of this paper.

Dr Hanne Bruhn, Research Fellow, University of Aberdeen: Lead researcher and contributed to developing the protocol and writing the paper.

Antoinette de Bont, Associate Professor of Health Care Governance, and Job van Exel, Associate Professor of Health Economics, Erasmus University, Rotterdam: Contributed to the writing of the funding proposal and commented on this paper.

Reinhard Busse, Professor and Head of Department of Health Care Management, Technische Universität Berlin: Contributed to the writing of the funding proposal and commented on this paper.

Matthew Sutton, Professor of Health Economics, University of Manchester: Contributed to the writing of the funding proposal and commented on this paper.

Name and contact for study sponsor

Patricia Burns, University of Aberdeen/NHS Grampian, Research Governance Office, Foresterhill House Annexe, Foresterhill, Aberdeen, AB25 2ZB

Role of sponsor and funder if any: Sponsor ensures adherence to research governance. Sponsor and funder have no input into details of research or decisions to submit for publication.

Roles and responsibilities of other groups: The study collaboration comprises nine partner countries (Scotland, England, Netherlands, Germany, Norway, Italy, Czech Republic, Poland, Turkey), the first four of which are represented on the core PMT which is responsible for oversight of the project progress. Other partners join the PMT as required according to the project stage and all partners form a General Assembly for overall project decision making. The study is advised by an International Expert Advisory Board and Country Expert Advisory Groups.

ABSTRACT

Introduction: The size and composition of the EU health care workforce are key drivers of expenditure and performance; it now includes new health professions and enhanced roles for established professions. This project will systematically analyse how this has contributed to health service redesign, integration and performance in nine European countries (Scotland, England, Netherlands, Germany, Italy, Czech Republic, Poland, Norway, and Turkey[1]). This paper describes the protocol for collection of survey data in three distinct care pathways, and sets this in the context of the wider programme.

Methods: Questionnaires will be distributed to health care professionals (n=14580), managers (n=3564) and patients (n=19440) in three care pathways (breast cancer; type2-diabetes; and coronary heart disease) within twelve hospitals and associated primary care settings in each country). Questionnaire topics will include demography, the different professionals working on the care pathway, the tasks they do and the time taken, their decision making when considering skill mix, specialisation and integration of care. Patient satisfaction, health care utilisation and preferences will be explored. In later work, register data and data from patient records will be used to record clinical outcomes. Data will also be collected on workforce and procedure costs. Descriptive analysis will identify the different models of care and multivariate analysis will establish the most clinically and cost effective models.

Ethics and Dissemination: This protocol was approved by ethical committees in each country. Findings will be disseminated through national/international clinical, health services research and health workforce conferences, and publications in national/international peer-reviewed journals.

[1] Turkey straddles both Europe and Asia; it is an associate country of the European Union, and accession negotiations for full membership are ongoing. For the purposes of this research Turkey is referred to as a European country whilst recognising that geographically some data will be collected from locations in Asia.

ARTICLE SUMMARY

Strengths and Limitations

The strengths are:

- This will be the first systematic analysis of the contribution of new professional roles to health service redesign, integration and performance.
- This will be the first study to identify the areas of delegation and substitution: those tasks undertaken by different professionals in different settings and countries
- The study will be conducted in three major care pathways: breast cancer, type2 diabetes and coronary heart disease. The study covers a pan-European sample of countries with distinct health care systems, and both secondary and primary care settings.
- The study uses common, validated questionnaires across all countries and validation via case studies and routine data.

A potential weakness is:

- Variable and low response rates due to the length and complexity of the questionnaires, and challenges of engaging busy clinical colleagues questionnaire design

INTRODUCTION

Background and Rational

Workforce is the largest single component of health care expenditure in EU member states (1). The size and composition of the health care workforce are key drivers of both expenditure levels and the performance of health care systems. Both the size and composition of the health care workforce are changing in many European countries in response to measures to contain health care expenditures, changing needs for health care, and changing working patterns (e.g. feminisation of the workforce, with increasing demands of child care and move to part time working, and implementation of working time legislation).

In a number of countries there have also been substantial innovative developments in health workforce skills. New health professions have been introduced (for example physician associates (PAs) (2)) and enhanced roles for established professions (such as nurses, and pharmacists) have been developed (3,4). The term 'new professional roles' is used in the remainder of this paper to describe both these scenarios. New professional roles potentially lead to the delegation of care from doctors to other health care professionals (in which case the doctor may still retain a supervisory role and remains responsible for overall care of the patient (5)) and the substitution of roles (in which a professional such as a Nurse Prescriber (6), assumes full responsibility for a task (prescribing) previously the preserve of a doctor). Both of these have further ramifications whereby care previously delivered by, for example a nurse is delivered by a health care assistant (7). New professional roles have the potential to contribute to increased effectiveness and efficiency in service delivery (8,9,10,11) and mapping the skills and competencies of the health workforce has been identified as one of the key areas for action by the European Commission (12). As new professional roles become more universal, current approaches to workforce planning will need to be adapted to include these new models of service delivery. Furthermore, at a time when integrated care is regarded as a quality marker it is important to understand how it is affected, if at all, by the deployment of an increasingly diverse workforce.

This paper describes the protocol for surveys in nine countries which are part of a wider programme of work entitled Health Care Reform: The iMpact on practice, oUtcomes and costs of New roles for health care pROfeSsionals (MUNROS: www.abdn.ac.uk/munros). The ultimate aim of the MUNROS programme is to inform a workforce planning model based on integrated financial and service planning, and the competencies needed to deliver care, rather than professional qualifications. The programme will systematically study the workforce issues described above in primary and secondary health care settings, along the three clinical pathways for breast cancer, type 2 diabetes and coronary heart disease following an ST elevation myocardial infarction, in nine European countries (Scotland, England, Netherlands, Germany, Italy, Czech Republic, Poland, Norway, and Turkey[1]). The design of the overall MUNROS programme is observational and cross sectional, combining the questionnaire surveys described in this paper (including a patient completed DCE) with patient, hospital and country level data on clinical outcomes as available from routinely held databases, and unit costs of care consumption. Economic modelling using multi-criteria decision analysis (MCDA) will inform a final synthesis to identify optimal models of care and distinguish the critical elements of these models. The findings will be incorporated into a generic multi-professional workforce planning tool; this will be developed by mapping from tasks performed to the skills and competences required to undertake these tasks together with estimates of projected patient need. In each partner country a Country Expert Advisory Group (CEAG) has been convened to support and advise the project. The study is also advised by an international Expert Advisory Board (EAB).

There were three pieces of work undertaken in earlier stages of the MUNROS programme which informed the development of the surveys. Firstly, the key features of the health delivery systems in the nine countries of study were detailed through analysis of routinely collected data from international and national statistical offices and national health services, and a systematic review of published research, policy documents and grey literature was conducted (3). Secondly, again using routinely available data, the skill mix of the health workforce in the primary and secondary care sectors in all European countries was detailed, and then details of new professional roles, and the numbers working in them in each sector in the nine partner countries were described.

Following this high level analysis, three clinical conditions were selected for more in depth study in the remainder of the programme of work. The conditions were selected from a list generated in early scoping work across the nine partner countries which identified the clinical areas in which the new professional roles were employed. This list was supplemented with suggestions from clinical managers and workforce managers who sat on the each partner's Country Expert Advisory Group (CEAG) and an international Expert Advisory Board. A two day face-to-face meeting of an international stakeholder group, comprising invited expert representatives of the medical and non-medical health care professions, primary and secondary care, managers and patients, reviewed, scrutinised and added to the list of potential conditions and agreed selection criteria (see Text box I).

Text box I: Clinical criteria for selection of care pathways

- The clinical condition is of high prevalence, significant morbidity and mortality are associated with the condition and data on these exist (i.e. a burden to society).
- Data exists on health outcomes that are related to new professional roles and/or the integration of care: Outcomes of processes (e.g. patient follow up and integration of care, patient satisfaction), intermediate health outcomes (e.g., clinical health outcomes, avoided complications) and final outcomes of care (e.g., patient quality of life).
- Procedures and clinical management are similar across different national boundaries.
- Care could be delivered by a range of health professionals: In at least some of the partner countries care is delivered by either new professions or new roles for existing professions. The contribution of different professions varies across partners.
- Patients have a role in managing the condition.
- Care is delivered in primary and secondary settings and desirably in intermediate and tertiary care settings. Overall at least one care pathway will have a substantial presence in primary care setting and one with a substantial presence in a secondary care setting.

Applying the criteria resulted in four clinical conditions and associated care pathways being identified: hip replacement/hip fracture, breast cancer, type 2 diabetes and coronary heart disease following an ST elevation myocardial infarction. These four were then assessed by each of the nine partner countries for use of new health care professionals and availability of routine data (required for assessment of clinical outcomes). As a result of this hip replacement/hip fracture was excluded.

The final three clinical conditions can be considered respectively as examples of: a condition requiring a scheduled surgical intervention, post-operative and follow up care; a long term condition managed largely in primary care, but with support from secondary care; a condition presenting acutely and requiring unscheduled hospital care, rehabilitation and long term care. The care pathways for each of these conditions were then identified as the clinical context for all subsequent research.

Following selection of the pathways, case studies were conducted. The case studies sought to understand the new professional roles that were being delivered, the mechanisms and drivers for greater skill mix in the delivery of care, and the delegation of tasks from medical to other members of the health care team. Each partner conducted case studies in two care pathways selected to ensure that across the nine partners six case studies were conducted in each of the three pathways (13).

Objectives of the surveys

The overall aim of the surveys is to describe and quantify the use of new professional roles in primary and secondary care sectors in three care pathways in nine European countries, to understand their effects on the quality of care, and on the delivery of integrated care. Later stages of the project will evaluate their clinical and cost effectiveness; select the most effective and efficient service models as benchmarks; and develop a workforce planning tool based on the competences required to meet population needs.

METHODS

Conceptual Framework

The MUNROS project researches the relationship between the inputs to the health service, focusing in particular on the staff input, and the outputs of the health service, focussing on patient outcomes. Where the focus of research is on the quantity and mix of different types of staff, rather than by institution, the appropriate conceptual framework is that of a production function employed in economics. Thus the relationship which is the focus of research can most concisely be defined as:

$$O_{iPH1,C} = f\ (L_{PH1C}, \boldsymbol{K}) \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots (1)$$

Equation (1) states that clinical outcomes, *,* for a sample of patients, *i (*where *i*= 1…N), in receipt of treatment along care pathway *P*, in hospital H_1, in country *C*, results from the activities of the workforce, identified by L, in pathway *P*, at hospital H_1, in country *C* together with all other non-staff inputs to care, here defined by ***K***.

The project design seeks to distinguish hospitals which employ new professions and those which employ both new and established professions within the same care pathway. Using the notation above it seeks to distinguish a hospital H_1 in which only established professions, $L_{1,}$ are employed and a second hospital H_2 in which both established professions, $L_{1,}$ and new professions, L_2, are employed. A comparison of the clinical outcomes for patients along this pathway in these two hospitals, as in equation (1) (above) and equation (2) (below) will then distinguish the impact of employing new professions.

$$O_{iPH2C} = f\ \left(L_{1PH2C,} L_{2PH2C}, \boldsymbol{K}\right) \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots \ldots (2)$$

The advantages of this specification are that it:

1. Controls for heterogeneity in the clinical outcome mix, *O*, by moving from the health service as a whole to defined **care pathways** identified in the earlier developmental work. Measures of clinical output which are specific to the patients treated along each pathway will be obtained.

2. Captures differences in service design which result in differences in staff mix.
3. Controls for heterogeneity in **patient characteristics**, *i*, by obtaining details of a wide range of characteristics in the patients' questionnaire and through the use of vignettes in the health professionals' questionnaires. These vignettes present respondents with a standardised clinical episode: a patient presenting at a particular stage in the pathway with a highly specific condition which requires treatment and which is accompanied by a specific set of comorbidities. This eliminates the issue of unmeasured comorbidities in this specific treatment group.
4. Clinical protocols reduce heterogeneity in **other inputs** to health outcomes as indicated by ***K*** for they determine the management of the disease, prescribing the procedures, drugs and technologies used in treatment.

The core of the surveys requires health professionals, managers and patients to identify who does what at each stage along the three care pathways. The tasks needed to deliver care along each pathway, and the professional(s) undertaking those tasks will be identified, together with actual and potential substitutions. When associated ultimately with cost and clinical output data, it will enable the identification of the most efficient combination of skills and competencies to achieve a given level of clinical output, or the combination of skills and competencies that will achieve the highest level of clinical output for a given cost.

Study Design

This is a cross sectional survey using self-completed questionnaires, either distributed by post or handed out at staff meetings or patient clinics for three specific care pathways (breast cancer, type 2 diabetes and coronary heart disease following an ST elevation myocardial infarction).

Study Setting

The study setting is 12 hospitals and sixty associated primary care centres (average five per hospital) in each of the nine countries. Careful selection of hospitals enables us to reduce

unmeasured heterogeneity. It is reasoned that similar types of hospitals are likely to employ the same technology. Thus *teaching hospitals* are likely to employ some of the latest technology available to the health service and are more likely to be engaged in research with associated funding opportunities for new developments. Large hospitals may have similar volumes of throughput along a care pathway (assuming that volume of throughput is one determinant of the quality of clinical outcomes).

Countries were selected to reflect the diversity of systems in Europe and the different stages of reform of health care systems. They include those: in the later stages of transition from highly centralised (ex-communist) systems (Czech Republic and Poland), at the forefront of innovation of delivery systems (Netherlands, Scotland and England), with more established and stable systems (Germany, Italy and Norway), and a rapidly developing country (Turkey).

Participants and eligibility

There are two categories of participants who will be identified and recruited from a participating hospital or general practice.

Health Care Professionals and Managers All health care professionals, providing care to patients within one of three selected care pathways from the point of diagnosis to long term follow up, will be invited to take part, together with all health care managers responsible for decision making about the workforce providing care for these patients.

Patients A random sample of patients within one of the three selected care pathways will be eligible to take part as long as they meet the following inclusion criteria.

- Male or female patients aged 21 years and over (note there is no upper age limit)
- Receiving care in one of the three care pathways: breast cancer; type2 diabetes; and coronary heart disease
- Having capacity to understand the purpose of the study and complete the questionnaire

In addition the following disease specific inclusion criteria will be applied:-

- *Coronary Heart Disease patients:* have suffered a ST segment elevation myocardial infarction (STEMI), are stabilised (i.e. may still be during initial hospital admission) or up to two years in follow-up.
- *Breast Cancer patients:* have been diagnosed and received some treatment for Breast Cancer and are between three months to two years post-surgery.
- *Type 2 Diabetes patients:* have been diagnosed with type 2 diabetes and are at least three months post diagnosis to two years in follow-up.

Identification and recruitment of sites and participants

Hospitals and primary care centres

Hospitals vary by type, location, size and population served, and the organisation within which they are managed. All of these factors may influence the extent to which new health care professionals/new professional roles are employed in the care of patients. Identification and recruitment of the hospitals will be based on the following, adapted to local circumstances, to ensure representation of each of these dimensions. All hospitals in each country will be listed, and the list stratified by key dimensions: type (teaching hospitals and general hospitals), geographical region, rurality (urban, suburban or rural) and sociodemographic characteristics of the catchment area (deprived and less deprived). Eligible hospitals will be invited to consider taking part by mailing an invitation pack (covering letter, participant information sheet, and expression of interest form) to hospital directors or their delegated deputy. From those expressing interest, 12 hospitals will be selected according to the criteria outlined above under 'Study Setting'. Hospital consent to participate will obtained by mailing invitation packs (covering letter, participant information sheet, and consent forms) either to hospital directors or clinical leads for each condition (or as appropriate in non-UK countries) according to preference of hospital. Ideally hospitals should be providing care along two of the three selected care pathways.

Primary care centres associated with each hospital will be similarly selected. All primary care providers in the catchment area of the recruited hospitals will be contacted by mail with an

invitation pack (covering letter, participant information sheet, and expression of interest forms) and from those expressing interest a maximum variation sample of averagely five (and a maximum of 60 per country) will be purposively selected to give representation of different types, locations and socioeconomic factors (e.g. deprived and wealthier communities, different ethnicities).

Health care professionals and managers

Within each clinical team (i.e. the team providing care to people with one of the three conditions) at each hospital a key contact will be identified. This is likely to be the clinical lead. They will advise on the best method of questionnaire distribution. Invitation packs (covering letter, participant information leaflet (PIL), and questionnaire) will be sent to identified participants using one or a combination of the following methods tailored to national and local arrangements. 1. Where names are in the public domain, participants may be contacted directly by the researchers. 2. Where this is not possible, key contacts or their depute will inform their team about the study and ask those interested in participating to send their contact details to the researchers so the questionnaire packs can be mailed directly. 3. Alternatively, key contacts will distribute questionnaires on behalf of the researchers, with a request to mail the completed questionnaire back to the researchers in a reply paid envelope. 4. Finally, face to face launch meetings will be arranged at each site, at which a member of the research team will give a short summary of the purpose and structure of the project, encourage participation, and distribute questionnaires to those attending. All questionnaires will be identified with a secure identification number, linked to the identity of the recipient, and recorded on a paper log subsequently transcribed to an electronic log. This will allow up to two targeted reminders to be sent to non-responding health care professionals and managers by clinical managers/link people.

The first three of the above four approaches will be adopted in primary care centres. Where there is no primary care doctor with a special interest in one of the three conditions, specific questionnaires will be randomly allocated.

Patients

For each care pathway patients meeting the inclusion criteria will be identified either prospectively as they present in clinic or from clinic lists, according to local preference. Those identified in clinic will be handed an invitation pack (covering letter, participant information leaflet, and questionnaire) by the responsible clinician. They will be encouraged to complete the questionnaire whilst waiting for their appointment. Patients will be asked to complete and return the questionnaires directly to the researchers via a box in the clinic or mailed directly in a reply paid envelope. Those identified from clinic lists will be mailed the invitation pack by clinical staff or their designated representative. A log of patients given the questionnaire, and their contact details, will be maintained by clinic staff to allow response rates to be assessed and one reminder to be sent to non-responders.

Sample Size

In each country twelve hospitals will be selected, and three care pathways within each of these hospitals, giving 36 care pathways and a total of 324 (36 x 9) care pathways across all partners. We estimate that the average number of health care professionals on a pathway will be thirty giving a total of 9,720 questionnaires distributed (324 x 30) to health care professionals across all partners. We further estimate that there will be an average of 6 health care managers per pathway giving a total of 1,944 (6 x 324). There will be 540 (60 x 9) primary care centres taking part with an estimated 4,860 (9 x 540) questionnaires distributed to health care professionals across all partners and 1,620 (3 x 540) questionnaires distributed to health care managers. The above distribution is designed to generate a sample large enough to capture representation of a range of site characteristics likely to affect workforce diversification while recognising the differences between the three clinical conditions.

Using the procedures described above, and extrapolated from researchers' recent experience (14), we estimate a response rate to the health professionals and managers' questionnaires of 40% giving a total of 5,832 and 1,425 returned health professionals' and managers' questionnaires respectively.

Patient recruitment will continue at each of the 324 hospitals until 30 patients have been approached in total per condition, and at each primary care centre until an average of 6

patients per centre have been approached per condition (or 30 per hospital area). With an estimate of a 50% response rate (based on recent work of the applicants (15)) this will produce 9,720 completed patient questionnaires. These numbers are judged sufficient to allow estimation of the main outcomes and comparison of main outcomes by country and condition.

Data Collection

Data collection will close at the end of 2015.

Questionnaires

Four questionnaires, each with three versions tailored to the three care pathways, were designed to be completed by: (i) health care professionals; (ii) health care managers of these professionals; (iii) patients receiving care from these professionals and (iv) a DCE survey sent to patients who had agreed in (iii) to participate further. Draft questionnaires were developed, in English, by an expert group drawn from those partners with the most extensive research experience in the area. Questionnaires were translated and validated through back translation into each of the partner country languages.

Questionnaires (i) to (iii) above were then refined in light of feedback from partners and the CEAG, pre pilots with local colleagues and a formal pilot in which each country piloted the three questionnaires in one hospital for two of the three target conditions (approx. 20 health care professionals, 3 health care managers and 5 patients). Where available, standard instruments and scales have been incorporated. The resource use questions are based on those developed in and widely applied in other research undertaken by partners. Overall design drew on the Cochrane review (16) and uses methods known to encourage high response rates.

The questionnaires are as follows:

Health care professional questionnaire

This questionnaire includes sections on respondent demography, roles, and education (closed questions), who they work with (fixed choice options based on a

list generated in consultation with local clinical colleagues to ensure all those providing health care along the care pathway are included, and including an 'Other' option), the tasks undertaken at different stages of the care pathway (based on detailed discussions with local clinical colleagues), the frequency with which they are undertaken and the time taken for both a standardised patient based on a vignette and for a patient they would typically treat (combination of yes/no questions and open responses), their opportunity to undertake new roles, the barriers and facilitators to undertaking new roles (combination of yes/no questions, Likert scales and open responses), the drivers for new roles (combination of yes/no questions, Likert scales and open responses), the integration (17) and specialisation of care on the relevant care pathway, and whether care was seen as being team based or doctor led.

Health care manager questionnaire

The health care manager questionnaire was constructed in a similar manner to the health care professional questionnaire, and includes sections on respondent demography, roles, and education (closed questions), the staff they manage (fixed choice options, as above), the tasks undertaken at different stages of the care pathway by different professionals (fixed choice options), the influences on their decision making about staffing changes in the mix of staff working on the relevant care pathway (Likert scales), the drivers for these (combination of yes/no questions, Likert scales and open responses), and the integration (17) and specialisation of care on the relevant care pathway.

Patient questionnaire

The patient questionnaire includes sections on: the patient's health including confirmation of eligibility, the Charlson Index for co-morbidities (18) and the EQ5D-5L as a quality-of-life instrument (19), the care they have received and the professionals who provided the care (tick box yes/no options), their experience of care (Likert scale responses to as series of statements), their satisfaction with care (Likert scale responses to various parameters of care) and their perceptions of the

importance of specific characteristics of care, continuity of care and how care was organised (team based or doctor led), their use of health care services and who they saw (tick box and open questions), the value they place on their care (a willingness to pay question), demographic questions (age, weight, education, employment, income, lifestyle) and effect of condition on daily life. A final question asked them to provide contact details if they would be willing to be contacted again for subsequent stages of the research.

Discrete Choice Experiment (DCE)

A fourth questionnaire, a DCE survey, will explore patients' preferences and trade-offs for different aspects of care. The questionnaire will elicit preferences for treatment by new health care professionals compared to traditional approaches. The DCE will be sent to those patients who in the initial questionnaire give their consent to be contacted about further research and provide contact details. The attributes and levels will be based on the literature and the responses to relevant items in the patient questionnaire. Based on pilot data these are likely to be as shown in Figure 1. The respondents will be asked to imagine a scenario in which their acute condition has been stabilised and they are in follow-up care. The questionnaire will also include questions to confirm eligibility, basic demographic questions (sex, date of birth, household members, educational level, household income) and questions about the way they complete the choice sets, their attitudes to health, their health status (excellent, very good, good, fair poor), their health expectations in the next two years if they have and do not have follow up care, the importance of each of the attributes to them (rated from 1, not important to 5 very important) and their willingness to pay for an ideal follow up visit. The DCE will be distributed by mail or email according to national preferences and one reminder will be sent.

{Insert Figure 1 about here}

Outcomes

The survey outcomes are a description of the:

- health care professionals involved in the delivery of care

- tasks on the care pathway, the frequency with which they are delivered and by whom
- patients' expectations, experiences, and preferences for care
- integration of care
- drivers for skill mix changes in the team delivering care.

Data management and analysis

Data from returned questionnaires will be entered into an Excel spreadsheet by each partner following agreed data coding rules and data cleaning protocols (e.g. for missing data). Double data entry on 10% of returned questionnaires will be used to check for accuracy. The final dataset will be exported into a STATA database for analysis, using a standard syntax and according to an a priori data analysis plan agreed with all partners. Any identifying data (e.g., hospital name, care pathway) will be anonymised by coding to allow for clustering in the analyses whilst maintaining confidentiality. Where terms for different health care professionals vary in the different partner countries these will be coded to internationally recognised high level categories (eg consultant doctor, junior doctor, nurse, advance practice nurse). Partners will hold country level databases and a cross-country dataset will be created for Europe wide analyses to be led by named researchers (ie the database will not be made generally available to the whole team). Data will be stored securely on password protected computers and the MUNROS study Sharepoint.

Initial analyses will include simple descriptive frequencies and associations between dependent and independent variables using appropriate multivariate techniques. The pooled country database will be analysed using multivariate and multilevel modelling methods and made available to partners to undertake an agreed plan of analysis. Country specific and inter-country analyses will model the relationships between the central dependent and independent variables as specified in equations (1) and (2) of the conceptual framework, within and across countries. Analysis of the results of the DCEs will distinguish how the preferences of respondents for different care pathways are to be measured and weighted and what inter-country differences exist.

PLANNED WORK TO FOLLOW THE QUESTIONNAIRES

Additional outcome measures not collected by the patient questionnaires will be extracted from register data at hospital and or national level; the data source will vary by country because of different clinical recording systems and health service systems. These data will include standard relevant health and healthcare indicators (e.g. morbidity and mortality) and measures of patient safety, patient turnover, length of inpatient stay, and number of readmissions. Process productivity will then be calculated, measured as consultation times per type of professional and consultation rates per hour. The data will also be used to assess the representativeness of the survey respondents against the wider hospital population of patients receiving care along the same pathway and, in countries where there are aggregated national data, the representativeness of the hospital sample compared to all hospitals.

The economic evaluation will take a health care perspective of the costs and effects associated with the new professional roles, using a state-of-the-art economic evaluation (including a Markov modelling exercise) and MCDA. Only (changes in) costs within the health care system and clinical effects will be considered. The analysis plan will exploit the size and variation in data across all participating countries and the comparability in level of detail, completeness and quality of data across these countries. The analyses will explore whether service redesign leads to cost containment, investigate the balance of cost and benefits and identify incentives for policy makers when increased roles for the new professional roles are introduced.

Optimal models of care will be identified and the critical elements of these distinguished. The analysis is aimed to identify optimal models for 'best' care delivered cost effectively. It will present examples of care integration and of the costs associated with financing these pathways. It will suggest solutions to barriers identified at organisational and team level informed by examples of good practice using standard theoretical models.

Finally, a workforce planning model for each care pathway will be developed reflecting the dynamic interaction between the number and type of health professionals (allowing for different approaches to labour substitution) and the quality and cost of care for patients and projected patient need. Algorithms and computer modelling will be used to develop the

final tool. The information requirements of the planning models will be detailed and the methodological and data improvements required for improved workforce planning models will be distinguished.

The models so developed will enable workforce planners to optimise care delivery along care pathways, taking into account the needs of the population, the tasks required to deliver care to meet these needs and the availability (actual and potential) of the various health professions with the competences to deliver these tasks. Service providers will be able to benchmark against these, to evaluate the efficiency of existing provision and identify the modifiable areas offering the largest efficiency gains.

DISCUSSION

In most health care teams roles of health care professionals are evolving in different ways. Some traditional roles are being extended, new health care professions are being introduced, tasks are being delegated from or substituted by one professional to another, and new roles evolve as new technologies are introduced. The nature and detail of this delegation has not been previously documented and the clinical and cost effectiveness of the new healthcare workforce configurations has not been systematically explored. Our hypotheses are that increasing skill mix in this way is likely to be cost effective and that there is potential for wider implementation of these workforce configurations . Our main objective is to inform evidence based workforce planning.

The current research evidence suggests that new professional roles can help improve access to care and the quality of care (3, 20,21). The greater deployment of new professional roles could facilitate increased flexibility, and offer new solutions to the challenges of delivering health care to populations with changing and escalating needs. Existing research has failed to show how changing skill mix enhances or inhibits the integration of care within and between organisations, and has largely focussed on process rather than clinical outcome measures. It has failed to benchmark best practices regarding the composition of health care teams and it has failed to show how as the new professional roles change care processes and care pathways, patients move through health care organisations There

appears to be little robust evidence of how new professional roles might reduce the costs of health care services and no evidence of the impact on efficiency of care. We will fill these lacunae.

DISSEMINATION AND ETHICS

Dissemination

Each partner will produce a *Country Report on Service Design and Professional Roles* which will include an analysis of basic descriptive statistics by country and care pathway. The Country Reports will serve as the basis for producing a *Country Briefing Paper* for each country studied. This will inform key stakeholders and policy makers in each country of the initial, country specific, findings from the project. A Cross-Country report will also be produced drawing wider conclusions by comparing and contrasting across the different health systems. A Europe-wide stakeholder meeting for invited policy makers, workforce planners and academics will be held near the end of the project. A final report will be submitted to the EC and will be available on the MUNROS project website. In addition, findings will be presented at appropriate national and international clinical, health services research and health workforce conferences and publications submitted to peer-reviewed journals in these same fields.

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Ethics Approval: This study protocol was approved by the respective ethical committees in each country. Protocol amendments will be submitted as needed, and communicated to research sites by the Research Fellows in each country.

UK (Scotland and England): Leeds East NRESCommittee UK and area NHS Research and Development Departments

Netherlands: METC Isala Hospital, Zwolle, Academic Medical Centre Amsterdam, Radboud Academic Medical Centre, Erasmus Medical Centre, UMC Utrecht, Maasstad Hospital, Reinier de

Graaf Ziekenhuis Delft, Flevoziekenhuis (samenwerking met AMC voor borstkanker), Maastricht UMCU, St Elizabeth Ziekenhuis, Martini Ziekenhuis Groningen, Ikazia Hospital

Germany: Ethikkommission des Instituts für Psychologie und Arbeitswissenschaft (IPA)

Italy: Gemelli teaching hospital, Milan area A, area B, area C and IRCCS ethical committees

Czech Republic: Individual hospital ethical committees

Poland: Not required

Norway: Regional Ethics Committee, REK vest

Turkey: Individual hospital ethical committees

Provenance and Peer Review: Not commissioned, externally peer reviewed

Data sharing:

English language versions of consent forms and other related documentation given to participants (e.g., questionnaires) are available on request from the authors.

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Figure 1 Potential attributes/characteristics, descriptors and levels

Characteristic	Description	Possible levels
Length of visit	This is the time you will spend with the health care professional at your follow-up appointment	10 minutes 15 minutes 20 minutes 30 minutes
Frequency of visits	This is how often you are scheduled for your regular follow-up visits.	Every month Every 3 months Every 6 months Every 12 months
Care provider	Health care can be provided by a range of different health care professionals. Your appointment may be with a specialist doctor, a specialist nurse or a generalist doctor or nurse.	Specialist doctor/consultant Junior doctor/resident Generalist doctor Nurse: advanced /specialist Nurse: general
Cost of care	This is the amount of money you have to pay for each follow-up appointment out of your own pocket. Please remember that money spend on having the appointment cannot be spend on something else.	£10 £20 £30 £50

188x175mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym DONE
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry NOT A TRIAL-NOT RELEVANT
	2b	All items from the World Health Organization Trial Registration Data Set NOT A TRIAL-NOT RELEVANT
Protocol version	3	Date and version identifier DONE
Funding	4	Sources and types of financial, material, and other support DONE
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors DONE
	5b	Name and contact information for the trial sponsor DONE
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities DONE
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) DONE as far as is relevant
Introduction		

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention DONE as far as is relevant
	6b	Explanation for choice of comparators NOT A TRIAL-NOT RELEVANT
Objectives	7	Specific objectives or hypotheses DONE
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) DONE
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained DONE
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) DONE
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered NOT A TRIAL-NOT RELEVANT
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) NOT A TRIAL-NOT RELEVANT
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) NOT A TRIAL-NOT RELEVANT
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial NOT A TRIAL-NOT RELEVANT

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended DONE
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) DONE
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations DONE
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size DONE
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions NOT A TRIAL-NOT RELEVANT
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned NOT A TRIAL-NOT RELEVANT
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions NOT A TRIAL-NOT RELEVANT
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how NOT A TRIAL-NOT RELEVANT

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial NOT A TRIAL-NOT RELEVANT
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol DONE
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols NOT A TRIAL-NOT RELEVANT
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol DONE
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol DONE
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) NOT A TRIAL-NOT RELEVANT
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) NOT A TRIAL-NOT RELEVANT
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed NOT A TRIAL-NOT RELEVANT

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial NOT A TRIAL-NOT RELEVANT
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct NOT A TRIAL-NOT RELEVANT
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor NOT A TRIAL-NOT RELEVANT

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval DONE
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) DONE
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable NOT A TRIAL-NOT RELEVANT
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial DONE
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site DONE
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators DONE

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation NOT A TRIAL-NOT RELEVANT
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions DONE
	31b	Authorship eligibility guidelines and any intended use of professional writers DONE
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code DONE
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates AVAILABLE ON REQUEST
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable NOT A TRIAL-NOT RELEVANT

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.