NHS
National Institute for Health Research

PROGRAMME GRANTS FOR APPLIED RESEARCH

Full proposals should observe the maximum text limits as indicated throughout the form. Please note the maximum text limits include spaces and other non-printing characters. The form should be completed using a font size no smaller than 10 (Arial). **Keep the use of acronyms to a minimum.** Only use acronyms where a term is used frequently throughout the proposal. If you do choose to use an acronym, do not assume that the reader knows what it means, and be sure to define it when first used.

You are strongly advised to use spaces, bullet points, subheadings, etc. to structure the longer sections of the application form (particularly the Research Plan) in such a way that they can be read easily by reviewers. **The use of long passages of dense, unstructured text should be avoided.**

Curricula vitae, references, Gantt chart, and supporting information (including diagrams, pictures, charts, letters of support, and papers in press) should be included as annexes to this application form. **Continuation of text is not permitted, however, and applicants should note that any extra pages will be removed upon receipt and therefore not assessed.** All mandatory fields are identified by an asterisk (*). **Failure to complete the form's mandatory fields will result in your application being rejected on the grounds that it is incomplete.**

The completed form must be submitted online by 22nd October 2007, 5pm.

For office use only

Reference Number:	RP-PG-0407-10184

IMPORTANT
Before completing this form, please read the accompanying Guidance Notes.

1. Application

Programme Title*:	Modelling, evaluating and implementing cost effective services to reduce the impact of stroke		
Programme Duration *: (months)	36.0	**Total funding requested (£'s):**	£1,134.665
Proposed start date if grant awarded *:	01/04/2008 **(dd/mm/yyyy)**		
Lead NHS organisation (which will administer any award) *:	Guy's & St Thomas' NHS Foundation Trust		

2. Lead Applicant's Details

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Surname*:	Wolfe
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Role in programme and % FTE commitment *:	Overall coordination, R&D governance, Public Health link with PCTs

3. Contact details

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Where did you hear about the programme*: (drop down) NIHR website

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Co-applicant 2

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Co-applicant 3

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Role in programme and % FTE commitment:	User involvement in programme. Liaison with User group input to design, monitoring and dissemination.

Co-applicant 6

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Role in programme and % FTE commitment:	Ensure programme runs effectively. Facilitate research in clinical areas. Disseminate findings

5. Summary of Programme*:

Provide a summary of the proposed programme based on the ordered headings (8 to 16) as described below for the full application **(Maximum 5000 characters).**

BACKGROUND: Stroke is the third leading cause of mortality and major cause of adult physical disability, costing over £7 billion a year in England. There is little information on the needs of patients after stroke, particularly longer term and in different ethnic groups.

AIMS AND OBJECTIVES: We aim to provide evidence to underpin the implementation of recommendations in the National Audit Office's report on stroke, the proposed DH Stroke Strategy and 'A Framework for Action' in London. The Programme will utilise population based epidemiological and qualitative data from the South London Stroke Register (SLSR).The innovative aspects of this programme include assessing the risk of stroke and trends over time, estimating long term outcome in a multi ethnic population and using a range of health service research methods to identify innovative ways to manage the longer term burden of stroke.

Objectives (Rationale)
1.To estimate the risk of stroke, including its underlying causes, and trends over time in Black and White populations (improved targeting of prevention strategies and acute care)
2.To estimate the acute and longer term (to 15 yrs post stroke) outcomes and needs after stroke and develop clinical prognostic tools for outcome prediction (improved targeting of care)
3.To estimate the risk of long term stroke recurrence and develop clinical prognostic tools for recurrence (improved targeting of secondary prevention)
4.To estimate trends and predictors of effective stroke care and associations with outcome (improved effectiveness of care)
5.To model cost-effective configurations of care (develop care solutions to implement Stroke Strategy based on need)
6.To understand users' perspectives of longer term need, and policy makers and providers' perspectives of service configurations to address these needs (refine care solutions to implement Stroke Strategy)
7.To develop proposals to underpin current and future policy in stroke care

RESEARCH PLANS: The platform for the programme will be the SLSR, an unbiased community based register of incident stroke patients registered continuously since 1995 with a projected 4,200 patients for study.
Objective 1: Estimate risk of stroke by sociodemographic group and by pathological and aetiological subtype with trends over time and analysis of underlying risk factors contributing to stroke and their trends over time.
Objective 2: Estimate the long term needs in impairment, activity, participation and quality of life. The proportion (and rates) of stroke survivors with specific needs at each year post stroke, up to 15, years will be estimated. Multilevel modelling will identify predictors of individual long term outcome.
Objective 3: Estimate the rates of long term stroke recurrence. Using regression analysis a tool to predict recurrence will be developed and validated.
Objective 4: Report the trends in appropriateness of care, judged against guidelines, and multilevel modelling will identify predictors of appropriate care.
Objective 5: Model cost effective models of care using SLSR data and current guidelines of effective care.
Objective 6: Elicit patient, family and health care professional views of long term needs and service configurations using qualitative methods.
Objective 7: Bring together Objectives 1-6 and through a series of workshops over the programme identify how best to utilise the data and proposed models of care to underpin the implementation of stroke strategies.

RESEARCH TEAM: The applicants lead a multidisciplinary stroke research group and have an established track record in stroke medicine, epidemiology, health services research, complex randomised controlled trials, health economic and health policy evaluations.

RESEARCH ENVIRONMENT: The programme will utilise the SLSR as a research platform and excellent local services. The research group is part of the King's College London Division of Health and Social Care and the South East England Stroke Research Network.

ANTICIPATED OUTPUTS: Objectives 1-4 will produce: estimates of need for stroke care and prevention; clinical predictive tools for long term outcome and recurrence; Objective 5 will identify cost effective models of care that can be further evaluated to underpin service development. Objective 6 will provide data to contextualise the findings from other Objectives and inform service developments.

PUBLIC INVOLVEMENT: Our established Stroke Research Patients and Family Group and the Guy's and St Thomas' Members' Council User Group are integral to the Programme.

JUSTIFICATION FOR RESOURCES: Although representing a significant investment of funds, this proposal offers offers outstanding value for money with a unique opportunity to expand both analyses of existing data sets and a well established research framework. The programme offers 7 interlinked Objectives within an integrated package that we are confident we can deliver on time and to budget. Funding is sought to maintain data coll

6. Abstract (in plain English)*:

Provide a statement, to explain to a lay reader the nature of the proposed research programme, the prospective outcomes and the expected benefits for health service provision, patients and the public **(Maximum 2500 characters).**

Stroke is a common disease and a leading cause of death and adult disability. It is important to have good information about how many people have stroke, the long term effects of stroke, and how well services help people to manage life after stroke. However, this information is lacking.

This programme of research builds on our longstanding commitment to investigating the effects of stroke on patients and carers and developing new ways of meeting their needs. Much of this work has been carried out using the South London Stroke Register (SLSR), an on-going record of people with stroke in south London, set up in 1995. We collect information from stroke patients (with their consent) at the time of stroke, 3 and 12 months later and then annually. This includes information about the patient's age, sex, occupation, ethnic group; health status (blood pressure, cholesterol, diabetes); stroke type; and care received (hospital, GP, social services etc)

The Programme will consist of 7 interconnected work packages that focus on the long term needs of people with stroke (and carers), and how services might better meet these needs.

1. We will use SLSR records to identify the types of people at highest risk of stroke, including differences between White and Black ethnic groups. This will help to improve stroke prevention, and plan hospital care.
2. We will use SLSR records to describe the effects of stroke up to 15 years after stroke. This will be used to help plan health and social care.
3. We will use SLSR records to calculate which stroke patients are at risk of further stroke. This will be used to improve care to reduce risk of further strokes.
4. We will use SLSR records to look at patterns of care that people receive and how this affects their recovery.
5. We will conduct economic modelling to propose new ways of organising effective and cost effective services to meet long term needs.
6. We will investigate the experiences and views of people with stroke and their family members by interviews and by following up a small group of patients over one year. This will be compared with information obtained in work packages 1-5 to ensure that patient and carer perspectives are represented.
7. We will use all the information collected in the Programme to bring to the attention of policy makers, commissioners and providers of services the long term needs of stroke survivors and carers, and possible new ways of delivering services to meet needs.

7.Alterations to the proposal*:

Describe how the proposal has changed since the outline application was submitted. Summarise key changes (e.g. in the light of new research or feedback on the outline application) since the outline submission **(Maximum 2500 characters).**

There has been little significant alteration in the major thrust of the programme from the outline proposal. We submitted a programme grant to the first round (RP-PG-0606-1103) and were encouraged to resubmit the elements of that programme relating to the SLSR to a subsequent competition. We have shortened the programme and taken reviewers and panel comments on board in developing this programme.

Since the proposal stage this application has developed the basic objectives and methodologies originally outlined such that a cohesive programme of research is presented, which we believe will deliver significant patient and population benefit during the three years of the programme and beyond. We have refined the research questions and methodologies by extensively reviewing literature, discussion with external peers in the national Stroke Research Network, internal reflections as a group and collaboration with users and health care professionals.

We will set up a Programme Monitoring Group to oversee the scientific direction and management of the programme to ensure we maximise the potential for patient benefit. We have continued to work with users since the preliminary application who are supportive of the work outlined and one of the applicants is a member of our Stroke Research Patients and Family Group.

8. Aims and Objectives*:

Describe the overarching aims of the programme. Number your objectives and address each in your research plans **(Maximum 1500 characters).**

AIMS
To estimate the need for prevention and care and model cost-effective, innovative service configuration solutions with users, commissioners, clinicians and policy makers. The innovative aspects include assessing risk of stroke and long term outcome in a multi ethnic population and modelling innovative ways to manage stroke. Our research will provide evidence to underpin the implementation of national strategy recommendations.

OBJECTIVES (RATIONALE)
1.To estimate the risk of stroke, including its underlying causes, and trends over time in Black and White populations (improved targeting of prevention strategies and acute care)
2.To estimate the acute and longer term (to 15 yrs post stroke) outcomes and needs after stroke and develop clinical prognostic tools for outcome prediction (improved targeting of care)
3.To estimate the risk of long term stroke recurrence and develop clinical prognostic tools for recurrence (improved targeting of secondary prevention)
4.To estimate trends and predictors of effective stroke care and associations with outcome (improved effectiveness of care)
5.To model cost-effective configurations of care (develop care solutions to implement Stroke Strategy based on need)
6.To understand users' perceptions of longer term need, and policy makers and providers' perceptions of service configurations to address these needs (refine care solutions to implement Stroke Strategy)
7.To develop proposals to underpin current and future policy in stroke care.

9. Background*:

Describe the background to the proposed research, including NHS context and relevant literature **(Maximum 2500 characters).**

It is estimated that there are 5.3 million deaths a year from stroke worldwide and over 9 million survivors (1). There are significant variations in incidence world wide (2,3). In the UK, the incidence is 1-2 per thousand population (4,5), with significant variations in risk between ethnic and socio-economic groups in the UK indicating higher stroke risk in ethnic minorities (4,6).
It has been estimated that by 2023 there will be an increase in the absolute number of patients experiencing a first ever stroke of about 30% compared with 1983, although no robust estimates have been made recently taking into accout trends in incidence and differences in risk in ethnic groups (7). One year after a stroke 45% of survivors are functionally dependent, stroke comprising the major cause of adult disability (8). The risk of a recurrent stroke over 5 years varies between 17% and 30% (9,10). Estimates of the prevalence of stroke survivors suggest that there may be as many as 11.8 per 1000 population (11). Epidemiological data suggest that the decline in stroke incidence and mortality seen since the 1970s has plateaued since the mid 1990s (3).
There is considerable evidence that mortality, morbidity, limitation of activity and participation, poor quality of life and resource use can be reduced significantly by coordinated strategies of prevention, acute care and rehabilitation (12). There are significant variations in survival (2) and outcome (13) between countries with evidence that UK is one of the poorer performers in stroke care in Europe. There are significant variations in outcome between ethnic and socio-economic groups in the UK (4,6). The NHS is committed to reducing the impact of stroke as reflected in the National Service Framework for older people and stroke, the Quality and Outcomes Framework targets of Primary Care and guidance on stroke services to Primary Care Trusts (14,15).This Programme will provide robust evidence to underpin the recommendations of The DH's Stroke Strategy, currently being consulted upon and 'A Framework For Action', the review of services in London (16,17). The evidence base on which many services are based is nearly 20 years old and an adequate response to these priorities requires an accurate estimation of the current and future prevention, rehabilitation and long term health care needs of stroke patients living in the community, the range of service available and the expected changes in these needs and services with time.

Explain the importance of the proposed research and its relevance to the priorities and needs of the NHS (including a statement of the significance of the research area, *e.g.* burden of disease, quantifying this where possible) **(Maximum 2500 characters) *.**

It is estimated that up to 80% of stroke survivors are discharged home after initial hospital admission, of whom over half have hemiparesis, 22% cannot walk, 25% have communication problems and 53% are dependent on informal caregivers (18). Caregivers' physical and psycho-social well being is affected with up to 48% of caregivers reporting health problems, two-thirds a decline in social life and high self-reported levels of strain (19). In England and Wales stroke costs over £7 Billion, £2.4 Billion being informal care costs in the community (20). DH initiatives such as Our Healthier Nation, the National Service Framework for Older People and the Stroke Strategy call for surveillance of stroke and effective provision of stroke services (14,16).
The National Sentinel Audit reports improved in-hospital survival and stroke care but also highlights large gaps in community stroke provision (21). There is increased pressure from the Payment by Results tariffs to reduce lengths of hospital stay which requires in-depth understanding of the post discharge needs of stroke survivors and development of appropriate community based services (22).
Despite the anticipated beneficial effects of the new Quality and Outcomes Framework targets for stroke prevention, little is known about what determines whether general practices meet targets and whether this translates into reduced risk. There is evidence of inequality of provision of adequate preventive care to groups such as older people, women and socially deprived groups (23,24). Current primary care based strategies do not adequately address the specific preventive needs of ethnic minority populations who have a twofold higher incidence rate of stroke (2). The National Audit Office report on stroke care in England and Wales shows that progress in the efficiency and effectiveness of stroke treatment provided varies considerably, with scope for savings and improved outcomes (20).
The House of Commons Committee of Public Accounts recommends that stroke services be rearranged more effectively and efficiently, including treating stroke as an emergency and providing more effective delivery of post acute services. The DH's Stroke Strategy group (2 subgroups of which are chaired by the applicants) aims to develop a national strategy to improve stroke prevention and care. The outputs from this programme will inform the strategy regarding the recommendations for 'awareness', 'emergency care' and 'life after stroke' (16).

Background continued*.

Explain the need for research in this area, and the rationale for the particular lines of research you plan to pursue **(Maximum 2500 characters).**

There is a need for robust, up to date information about the size of the problem, deficiencies in current care, how we can best predict those at risk of stroke recurrence and poor outcomes, and what models of service are potentially cost effective and can deliver the proposed strategies. Such data will underpin health care policy and locality based commissioning. We will analyse data from the population-based South London Stroke Register (SLSR), an internationally unique data set, with annual follow-up of all surviving stroke patients in a defined population. These analyses will allow estimates available for professionals, planners and users on areas not covered by routine data such as the current DH ASSET2 tool: incidence by ethnic group, stroke subtypes, aetiology of stroke subtypes and their underlying risk factors, case severity, outcomes, patterns of care and appropriateness compared to national guidance for up to 15 years after stroke. Epidemiological data need to be contextualised, and to take account of user perspectives of the impact of a disease. Therefore we will undertake qualitative studies of the longer term impact of stroke. The evidence base for post-acute stroke care is small and the interventions complex (12). We will use the SLSR data to model alternative cost effective service configuration solutions using both definitive trial data available in the literature and preliminary findings from pilots and ongoing studies, both locally and nationally. This builds on our National Audit Office analyses of the likely benefits of thrombolysis and stroke unit care (20). The programme will synthesise a wealth of information on needs utilising register data and patient, carer and professional pperspectives and on effective interventions available from different sources to propose innovative service strategies that can be implemented within the NHS. Finally, we will develop proposals to underpin the DH's Stroke Strategy and 'A Framework For Action' review of services in London recommendations based on these findings and will address this aspect of the programme in collaboration with the Royal College of Physician's Clinical Effectiveness Unit that has been evaluating stroke care nationally for over 10 years (25).

Describe the past and current research that justifies the proposed work and shows that it will add distinct value to what is already known, or in progress **(Maximum 2500 characters).**

UK stroke incidence rates are comparable with international rates (2,3). Apart from data from Oxford on trends in incidence in the last 20 years (5), there is little information about the changing nature of risk in different population groups. Further data are required on the risk of subtypes of stroke, including different aetiological subtypes and in different socio-demographic and ethnic groups if preventive and stroke services are to be more appropriately targeted. Recovery in some aspects continues up to 5 years after stroke for a sub-sample of younger stroke patients (26). Recovery after stroke plateaus after about 1 year but varies between groups (27). However, these studies are limited in terms of the outcomes assessed and the time points for analysis. In this programme we will be able to overcome these limitations with the SLSR cohort available over the lifecourse of the programme. There is evidence that prior to stroke, risk factors are not well managed (5,23,24). There is also evidence of inequalities in access to stroke care (28).

The evidence base for prevention and early management of stroke is considerable, much of it randomised controlled evidence in areas such as early prevention of recurrence, stroke unit care, early supported discharge, carer education and early rehabilitation (12). Research on organised stroke unit care has resulted in considerable reductions in mortality and institutionalisation of hospitalised stroke patients (29). Up to 80% of patients are discharged home, many with limited abilities, restricted participation in wider activities of daily living, poor quality of life and increased dependence on family members (30).

This Programme will provide long term estimates of risk and prediction of outcome that will be used to model cost effective configurations using epidemiological and health economic techniques that will contribute new scientific knowledge and provide highly relevant data for commissioners and clinicians in developing and running stroke services.

Summarise the work undertaken previously by the research team which has led to the proposed programme of research (e.g. describe any pilot or feasibility studies) **(Maximum 2500 characters).**

NEEDS OF STROKE PATIENTS: Over the past 15 years we have been funded on a series of programme and project grants to estimate the incidence and outcome of stroke in south London and countries in the EU (2,4). The analyses to date have provided the only inner city estimates of incidence by ethnic group in Europe. It is only recently that we have had enough statistical power to begin to look at trends in incidence, incidence by different ethnic groups (Black African; Black Caribbean) and by aetiology. These analyses are needed to improve targeted prevention and management. Outcomes after stroke have been reported to 2 years in a limited fashion and again the power to look at patterns of and prediction of recovery using multilevel modelling has only recently become a possibility (8,27). Examples of research output that have influenced policy include reports for the Stroke Association, the National Audit Office and the OECD (20).

PATTERNS OF HEALTHCARE: We have described inequalities in stroke care and identified predictors of appropriate care in south London (23,24,28), nationally (21,25) and internationally (13) but not trends in appropriateness of care, modelling of health care utilisation to identify efficient, effective solutions or for identifying potential new service delivery packages.

PATIENT PERSPECTIVES: Our systematic reviews of qualitative research and complex intervention evaluations in stroke identify huge gaps in the knowledge base if we are to truly represent user views in service development particularly in areas of adherence to treatments and longer term care (31,32). In a 3 year funded project we are currently developing and evaluating methods to engage with stroke service users in stroke research and service development.

DEVELOPING COMPLEX INTERVENTIONS: The group has produced amongst the first trials in areas of stroke unit care, early supported discharge, hospital at home, family support workers, and carer training that have all been incorporated into Cochrane analyses and national guidance (12). In terms of complex trials in the community we have developed methods for cluster trial design (33) and undertaken trials that have influenced innovative evaluation design (34,35). The Programme will generate models of care that we would propose to evalute using these methodologies in subsequent research proposals.

10. Research Plans*:

Give details of the research to be undertaken. Describe each of the proposed component projects, workstreams or work packages in turn, using sub-headings and spacing, as appropriate. **(Maximum 30,000 characters).**

This programme includes 7 parallel, interconnected Objectives/Work Packages with data collection and analyses informing all work streams in an iterative manner (Figure 1, Annex 4). Annex 2 shows the timeframe for the components of each Objective. Annex 4 outlines the Deliverables (D) for each Objective/Work Package.

OVERVIEW OF SOUTH LONDON STROKE REGISTER (SLSR):

The programme's Objectives utilise the SLSR and qualitative data from users and professionals from the SLSR area. The SLSR is an unbiased population-based register recording first in a lifetime stroke and recurrence of stroke in an inner city population (4). At the 2001 Census, the population was 271,817 with 63% White, 28% Black and 9% other ethnic groups. Twelve overlapping sources of notification are used to document all hospitalised and non-hospitalised stroke patients who are residents in 2 PCTs (Lambeth and Southwark). Sources of notification include all hospitals and general practitioners serving the study area, neurovascular outpatient clinics, nursing homes, community therapists, and a regular screening of death certificates and Office of National Statistics (ONS) death data. All patients are flagged at ONS for death.

Completeness of case ascertainment has been assessed indirectly by multinominal-logit capture-recapture models and estimated to be 88% complete (36). All patients with a suspected diagnosis of first or recurrent stroke or transient ischaemic attack ascertained by one of the sources of notification are investigated for eligibility of study inclusion. Specially trained study nurses and field workers collect all data prospectively. A study clinician, along with AR or LK, verifies the diagnosis of stroke and its subtype using clinical and imaging data. Patients are examined within 48 hours of referral to SLSR where possible. The dedicated register team will continue the prospective data collection in this programme to enable more accurate estimates of trends in incidence and longer term needs and outcomes in different groups to be made.

The SLSR has 3,375 registered patients from 1995-2006 with more than 4,200 projected by 2010. Patients are assessed at onset, 3 months and annually up to 15 years after stroke. Annex 4, Table 1 details the data collected and assessments made on all patients. The main domains include sociodemography including ethnicity, case severity and stroke subtypes, use of health and social care resouces and outcomes in the domains of impairment, activity, participation and quality of life. These data are updated at 3 months and annually. All assessments use validated measures.

OBJECTIVE 1: TO ESTIMATE THE RISK OF STROKE, INCLUDING ITS UNDERLYING CAUSES, AND TRENDS OVER TIME IN BLACK AND WHITE POPULATIONS (IMPROVED TARGETING OF PREVENTION STRATEGIES AND ACUTE CARE)

Preliminary analysis of SLSR data has identified a decrease in stroke incidence in Whites between 1995 and 2004 linked with a decrease in most main risk factors except for an increase in diabetes mellitus. In Blacks only a decrease in stroke incidence in women has been observed but with no significant changes in the main risk factors. Overall, higher attack rates were found in Blacks although the Black-White gap in stroke incidence has reduced slightly over time.

To estimate incidence rates we will use SLSR data for 1995 to 2010.The SLSR has 3,375 cases registered (1995-2006), and a projected 4,200 by 2010 (Annex 4). We will use Census data as denominators for incidence rates, and adjust rates to the European population for comparative purposes.

In YEAR 1 we will estimate the current total stroke incidence and incidence by pathological stroke subtype (Deliverable 1 (DI) using data to 2006. In addition, we will investigate changes in the prevalence of underlying prior-to-stroke risk factors in our population (D2). Time trends in incidence and underlying causes of stroke over 12 years will be investigated (D3). Trends in incidence and underlying risk factor status over time will be presented by age, sex, ethnic group and socio-economic status.

In YEAR 2 we will investigate the incidence of aetiological subtypes of ischemic stroke in our population using the mechanism based TOAST classification scheme (D4) (37). Differences in stroke aetiology relating to age, sex, ethnicity and socio-economic status will be estimated.

In YEAR 3 we will repeat the analyses conducted in years 1 and 2 updated with 3 years extra data with increased power to look at trends in stroke rates in distinct ethnic groups (e.g. Black Africans and Black Caribbeans) as well as trends in aetiological subtype (TOAST) of stroke (D5, D6).

These analyses will illuminate trends in risk, particularly of different aetiological subtypes of stroke in different ethnic groups and inform preventive and early treatment strategies in different groups. They will be utilised to extend the DH's ASSET2 tool that is intended to provide epidemiological data at PCT and provider level level (on DH stroke website). This tool used the epidemiological data on risk of stroke from our SLSR analysis of the first 4 years data only and requires updating and expanding in the ways we have proposed here. For example, ASSET2 predicts that by implementing preventive interventions in the Lambeth PCT 70 strokes could be prevented annually and similarly 73 in the Southwark PCT. However, these numbers account neither for the aetiology of the strokes, nor the ethnic mix in the PCT areas or for time trends in stroke risk. The analyses in Objective 1 will provide data that could permit ASSET2 to report risk by sociodemographic and ethnic group and by subtype of stroke, providing a much more tailor made database for PCTs to utilise.

OBJECTIVE 2.TO ESTIMATE THE ACUTE AND LONGER TERM (TO 15 YRS POST STROKE) OUTCOMES AND NEEDS AFTER STROKE AND DEVELOP CLINICAL PROGNOSTIC TOOLS FOR OUTCOME PREDICTION (IMPROVED TARGETING OF CARE)

In YEAR 1 we will estimate the outcomes across the range of relevant domains using the first 12 years of data. The analyses will estimates the proportion of patients with specific needs, across domains, at each year post stroke and also provide a rate for that need/1000 stroke patients (Annex 4 details measures of impairment, activity, participation and quality of life measured acutely, at 3 months and annually up to 12 years after stroke) (D7). These data could be incorporated into the DH's ASSET2 tool that currently has no data on need post stroke that would be relevant for planning services longer term. The outcomes will identify the need for specific services such as early supported discharge, longer term rehabilitation, social support, psychological/psychiatric services and medical follow up. They will provide for the first estimates of the prevalence of people living with disability at different time points after stroke up to 15 years.

In YEAR 2 we will estimate time trends in short and longer term case-fatality stratified for patient characteristics such as stroke subtype, age group, sex, ethnic groups and socioeconomic status (D8). These analyses will inform Objective 4 and provide estimates of the association between quality of stroke care (e.g. receipt of stroke unit care) and mortality. They will also be used to estimate the progress that has been made in implementing effective stroke unit care and their impact on outcome longer term. The association between receipt of interventions and longer term outcome has not previously been reported.

In YEAR 3 multilevel models will be developed to quantify patterns of outcome beyond one year in the domains of impairment, activity and participation and factors that influence outcome (38). The power to estimate outcomes over 5 years or more after stroke will be increased in the latter years of the programme by continuing patient follow up (see Annex 4). Multilevel models account for correlations between observations over time and are particularly suited to sparse data. The impact of patient characteristics, stroke subtype, stroke severity, comorbidities, as well as outcome at previous time points, will be investigated (D9). These estimates will enable us to develop tailor made prediction tools for the individual recovery of a patient at any time point after stroke. In particular, we will examine the impact of initial stroke characteristics and patients' outcomes over time on longer term outcomes after stroke. Such analyses will be used to inform clinical prediction, plan care, communicate prognosis and may be applied in clinical trials.

OBJECTIVE 3. TO ESTIMATE THE RISK OF LONG TERM STROKE RECURRENCE AND DEVELOP CLINICAL PROGNOSTIC TOOLS FOR RECURRENCE (IMPROVED TARGETING OF SECONDARY PREVENTION)

In YEAR 1 we will estimate aspects of long-term risks of recurrence after stroke which has not been undertaken before. We will assess the risk of recurrent stroke in the different stroke subtypes as well as in different ethnic groups. We will compare short and long-term risk beyond 5 years as this has

important implications for continuity of preventive treatment. We will investigate time trends in the risk of stroke recurrence over the 12-year study period and will correlate this with introduction of new secondary prevention regimes, and with the introduction of quality and outcomes targets in primary care (D10).

In YEAR 2 we will develop and validate a simple numerical score/tool that allows clinicians to predict risk of recurrence (D11). Using semi-parametric regression analysis, independent predictors of recurrence up to 5 years will be identified. We will address prognostic features at time of index event, including demographic characteristics, comorbidities, clinical characteristics, diagnostic tests results and underlying stroke aetiology. Given a recurrence rate among stroke survivors of about 10% in the first year after stroke and 5% in subsequent years we have more than 300 recurrent events out of 3000 first stroke events for study. This provides sufficient events to allow the development of a semi-parametric prognostic model for time to recurrence. The regression coefficients of this model will be used to develop a prognostic tool that can be easily used in daily practice. The tool can be used to select patients at high risk of recurrent stroke for prevention trials as well as for communicating risk of stroke recurrence. Trajectories of transition between one pathological and aetiological type of stroke and another, as well as the likelihood of having other vascular events, will be investigated.

In YEAR 3 the tool will be validated externally by using the prognostic model to predict outcomes in a second independent database, for example the population-based Erlangen Stroke Register from Germany which collects identical data items with similar definitions as the SLSR and with whom we have a close collaboration (37) (D11).

OBJECTIVE 4. TO ESTIMATE TRENDS AND PREDICTORS OF EFFECTIVE STROKE CARE AND ASSOCIATIONS WITH OUTCOME (IMPROVED EFFECTIVENESS OF CARE)

We have previously identified inequalities in stroke care but the analyses did not have the power to identify predictors of receipt of effective care (23,24,28) and were performed on data collected up until 2002.

In YEAR 1 we will estimate the provision and predictors of effective care (risk management, prior to stroke acute stroke management (including emerging new treatments e.g. thrombolysis), early rehabilitation) over time since stroke and over the 15 years of data collection, using the relevant guidelines at the various time points as the gold standard (12).

In YEAR 2, using SLSR long term follow up data (Objective 2), we will estimate the proportion of patients receiving appropriate care at different time points post stroke and identify predictors of appropriate care (D13). Appropriateness will be assessed by whether individuals receive the appropriate evidence based intervention outlined in the Royal College of Physicians Guidelines (12).

In YEAR 3 multilevel modelling will be used to quantify the impact of specific health care interventions at different time points on long term outcome, including treatment and management procedures during the acute phase, specific rehabilitation inputs after discharge, social support and secondary prevention over time. These analyses will be controlled for confounders such as case severity and stroke subtype. Of particular interest will be sociodemographic inequalities in care such as ethnic group, gender and socio-economic status. The data in SLSR will allow us to look at the relationship between appropriateness of care and longer term outcome and hence understand the implications of implementing fully some of these interventions. These scenarios will be further addressed in Objective 5 from a health economics perspective.

OBJECTIVE 5. TO MODEL COST-EFFECTIVE CONFIGURATIONS OF CARE (DEVELOP CARE SOLUTIONS TO IMPLEMENT STROKE STRATEGY BASED ON NEED)

This part of the proposal will pursue 3 Objectives in YEAR 2 (D15) developing the fundings in Objectives 1-5:
(a) development of a health economic risk model based on patient level data from the SLSR to use in a predictive manner;
(b) estimation of patient level resource and cost use associated with different treatments will be calculated using data on the long term care pathways defined by SLSR;
(c) modelling different treatment options, outcomes and costs using the developed risk model and the estimated costs as based on data from the SLSR.

These objectives will for the first time allow a data-led risk model of stroke to be developed, based on

patient level SLSR information for a variety of interventions. We have previously undertaken such an approach for stroke unit care for the National Audit Office Stroke report (20). This will be used as a basis to consider the impact of changing stroke treatments on a population in terms of health outcomes and treatment costs through adjustment of the defined variable levels in the health economic risk model. Thus we will be able to model the recommendations in the DH's Stroke Strategy and address their cost effectiveness at a population level.

We have recently undertaken an extensive literature review for the Department of Health to identify the range of effective interventions for stroke and the research required to implement the new strategy. This review will be updated in YEAR 2 to inform the risk model of the types of intervention that are effective and the magnitude of effect. We will use SLSR data and model potential changes in outcomes in the SLSR population arising from these proposed interventions. Thus if it is found for example that a specific treatment alters a risk factor this alteration will be incorporated into the model and then the adjusted predictions of treatment outcome gained from the model will be taken as representative of the treatment effect.

The documented information on treatment costs will then be used to estimate the impact of these treatment changes on the cost of this treatment provision. In a similar manner we will also model the recommendations in the DH strategy and 'A Framework For Action' review of services in London using inferred treatment implications to adjust the risk model and associated costs.This will allow a range of alternative treatment strategies for stroke to be assessed in terms of relative cost-effectiveness and, through the use of the prevalence data and the treatment cost data, budget impact.

The deliverable from this part of the project is the development and use of a risk model constructed from the SLSR patient data to identify the impact that different treatment initiatives would have on health outcomes, treatment costs and subsequently health budgets. This will help identify cost-effective treatment strategies in the area of stroke as well as the costs incurred and outcomes achieved implied by stroke policy initiatives.

OBJECTIVE 6. TO UNDERSTAND USERS' PERSPECTIVES OF LONGER TERM NEED, AND POLICY MAKERS AND PROVIDERS' PERSPECTIVES OF SERVICE CONFIGURATIONS TO ADDRESS THESE NEEDS (REFINE CARE SOLUTIONS TO IMPLEMENT STROKE STRATEGY)

Patient experience should be a driver of NHS modernisation; and the need to involve patients and the public in research and health and social service development has been enshrined in policy for a decade. In this Objective we will undertake a series of qualitative studies to triangulate the epidemiological and health service use data (Objectives 2-4) by setting them within the context of user and professional experiences and priorities, and local conditions and national policy influences. This will inform the development of potential pilot interventions.

The following studies will be undertaken:

1) QUALITATIVE INTERVIEW STUDY OF PATIENTS' AND CARERS' PERCEPTIONS OF LONG TERM NEEDS (YEAR 1; D15)

To triangulate findings from Objective 2, we will conduct qualitative in-depth interviews with up to 30 long-term stroke survivors sampled from the SLSR and their primary caregivers (defined as non-professional carer e.g. spouse). Interviews will focus on patient and carer perspectives of long term needs and experiences of efforts to meet these. Interviewees will be asked for written consent and provided with written information about the purpose of the study. Maximum variation sampling will be used to purposively select potential interviewees reflecting a range of factors including age, ethnicity (White, Black Caribbean, Black African, south Asian) disability, whether living alone and time since stroke (1 year, 2 years, 3-5 years, 6-11 years). People with aphasia will not be excluded and adapted written materials will be used to contact them and to assist with interviews. The final sample number will be determined when saturation is judged to have been achieved through on-going preliminary analysis and review of interview data (39). The sample size and sampling strategy are appropriate for this type of qualitative study where the aim is to generate rich data rather than provide generalisable results based on standardised questions with limited response categories (40).

Interviews will be conducted using a topic guide which will be developed drawing on i) group discussion with the Stroke Research Patient and Family Group; ii) published literature on experiences of stroke; iii) previous work of this kind undertaken by the applicants (41,42). Topics to be covered will include experiences of life with stroke in the time since the event; clarification of long term needs; sources of

support; development of own strategies to meet need, including self-management skills; perceptions of unmet need, expectations of recovery and variations in these according to age, socio-economic status and ethnicity.

Interviews will be digitally recorded, transcribed and entered onto NVivo for data management. Analysis of qualitative data will follow standard approaches of data organisation through coding, category development and testing (43). Analysis will be undertaken primarily by the research associate, supervised by the PI. Preliminary analyses will be fed back to our Stroke Research Patients and Family Group as a method of triangulation (31). Analysis will focus on construction of informant perceptions of long term need, comparing these with clinically defined need identified through analysis of data collected by standardised instruments, as well as successful and unsuccessful strategies employed to meet long term need.

2) ETHNOGRAPHIC STUDY OF THE ORGANISATION OF POST-ACUTE SERVICES AND PATTERNS OF CARE (YEARS 2-3; D16)

To triangulate findings from Objective 4, we will conduct an ethnographic study to better understand how variations in service provision arise in practice. Ethnographic research, originally derived from social anthropology, is a prospective approach to data collection, using a range of methods, notably participant observation to investigate beliefs and practices in a specific context. It is increasingly recognised as a useful and appropriate method of investigating complex clinical and organisational issues. (44,45)

The aim here is to explicate the observed patterns of service use identified in Objective 4 through investigation of practices that lead to different patterns of care, including decision making (46) organisational and structural factors influencing the provision and uptake of services (41), and patient/carer actions and choice.

We will follow the health and social service trajectory over one year of approximately 12 patients from discharge from two local clinical services (AR,LK). The sample will be purposively selected in terms of disease severity, age, and ethnicity. The research will entail:

1.observations at multi-disciplinary team meetings, family meetings, community team meetings, and service delivery (such as rehabilitation sessions) to collect data about key practices (such as discharge process, transfer from one sector to another) that we hypothesize will influence care trajectories;

2.interviews with the patient and carer at 3 time points over the year of data collection to investigate perceptions of recovery, met and unmet need, accessibility and appropriateness of services; as in the qualitative interview study above, we will be alert to factors related to social position (age, ethnic group, socio-economic status) that might be important in shaping participants' responses;

3.interviews with key health and social care providers involved in the care of participating patients at 3 time points over the year of data collection to investigate decision making processes, as well as organisational and resource constraints thought to influence the care package delivered to the patient.

Observational data will be recorded using ethnographic fieldnotes. Interviews will be digitally recorded for transcription in full. Data will be managed and analysed qualitatively as detailed above (Qualitative interview study of patients' and carers' perceptions of long term needs).

3) CONSULTATION WITH USERS, CARERS AND PROVIDERS OF PROPOSED COST-EFFECTIVE CONFIGURATIONS OF CARE DEVELOPED IN OBJECTIVE 5 (YEAR 3; D17)

To consult with users, carers and providers on the proposed models of care developed in Objective 5, we will develop and organise a series of facilitated workshops. Meetings with carers and users will be organised through the King's College London Stroke Research Patients and Family Group and the Guy's and St Thomas' Members' Council User Group. Meetings with health and social care providers will be organised where possible through existing fora, such as GP practice meetings, community service team meetings. The workshops will present the proposed new configurations of care and invite comment and feedback. User and provider views will be recorded and collated by the research assistant and fed back to the study applicants to inform the subsequent development of proposals for novel service configuration outlined in Objective 7.

OBJECTIVE 7.TO DEVELOP PROPOSALS TO UNDERPIN CURRENT AND FUTURE POLICY IN STROKE CARE (YEARS 1-3; D18)

Using the outputs from Objectives 1-6 we will work with policy makers, commissioners and users and health care professionals to identify how useful such data and analyses generated in the programme are to the commissioning process and how best to utilise these data on need, service provision and its quality and the health economic modelling of potential new services. How such data can monitor the implementation of the stroke strategy will be identified.

The DH Stroke Strategy, the development of NICE guidelines for acute stroke and transient ischaemic attack, new research developments (e.g. NICE health technology appraisal of thrombolysis in acute stroke) and the implementation of 'A Framework for Action' in London together with findings from Objectives 1-6 of this programme, provide an opportunity to influence the implementation phase of the proposed initiatives. The development of practice-based commissioning, particularly for the management of long term illnesses, provides a parallel opportunity to study how best to utilise the outputs from studies such as this on the commissioning process.

In years 1-3 we will present the Deliverables from Objectives 1-6 to local PCTs, users and health care professionals at a series of workshops with the aims of identifying how the data can be used for commissioning and delivering care and generating proposals for further research to develop the models of care identified in Objectives 5 and 6.

The workshops will also be held at a national level with the DH Cardiovascular team who will be developing the Stroke Strategy implementation plans and the Royal College of Physician's Clinical Effectiveness Unit who run the national stroke audit.

These workshops will be facilitated by the qualitative research associate employed for Objective 6 under the supervision of CM and NF and the outputs detailed in D18.

10a. Research Plans (continued)

Continue details of research plans. **(Maximum 10,000 characters).**

11. Research Team*:

Explain why the group is well qualified to do this research. If the salary costs of members of the research team are not being sought *via* this application, explain how their contribution will be supported **(Maximum 2000 characters)**

The programme builds on our track record in stroke service innovation and research excellence in assessing population needs, quality of care and evaluating complex interventions from population, clinical and user perspectives. The research applicants lead a unique multidisciplinary research group (25 researchers) with expertise in stroke medicine, rehabilitation, epidemiology, statistics, health economics, social science and health policy.

Research income is over £10M since 2001 from DH, MRC, EU, Wellcome and Charities and we have published over 250 peer reviewed stroke papers. We have built capacity, with national training Fellowships and have superviseded MD and PhD students.

The clinical manager (MH) leads acute services and links with the clinicians involved in a Stroke Modernisation Programme. We have undertaken trials in stroke unit care, care at home, early supported discharge, longer-term rehabilitation, family support workers and carer education that have contributed to national and international guidance. We undertook the economic analysis for the NAO Stroke report. Two members Chair sub groups of the DH Stroke Strategy group, Dr Rudd is Director of the Stroke Programme at the Royal College of Physicians and runs the national audit. We have an established User group that will be central to the work. Internationally, we collaborate with the WHO, German national audit and centres throughout Europe.

A Programme Management Group will oversee the work plan. The team have the following responsibilities: CW lead, CW/PH design and analysis of SLSR data, MT/AG/MG statistical expertise/analysis. CM/NF qualitative study design and analysis. LK/AR clinical links and data analysis. AM/AG health economic modelling. MH link with services in Borough. KM/CM User involvement.

12. Research Environment*:

Describe how the clinical or academic environment(s) in which the research will be undertaken will increase the chances of success **(Maximum 2000 characters).**

The local PCTs, acute trusts and King's College London have stroke as a priority, and work closely with the Guy's and St Thomas' Charity in running a Modernisation Programme for Stroke that builds on excellent hospital services with thrombolysis and stroke unit care available. The Modernisation Programme has a management board on which the chief executives of hospitals and PCTs sit, providing a forum for dissemination and implementation of our programme findings. The Trusts have a joint R&D strategy and NHS R&D governance structures and the PI is a Trust Director of R&D.

The programme has the support of both the Comprehensive Biomedical and Patient Safety and Service Quality Centres recently funded by the NIHR (NF is Director of PSSQ Centre). The applicants are in the Division of Health and Social Care Research (KCL) that provides the focus for multidisciplinary health services research with academic management support and peer review systems (See http://hscr.kcl.ac.uk/). Research proposals are discussed and developed at Divisional away days and special interest groups. Dedicated staff provide computing and statistical software support with well developed IT facilities. There is a Divisional PhD programme with a research handbook, postgraduate support and writing groups, training for supervisors and a mentorship scheme.

Applicants are involved in managing local services, having positions on the local trust and College executives. Applicants are on the local Stroke Research Network Board (SRN) and specialist groups of the national SRN. We are represented on the DH's vascular board and stroke strategy group. The programme will strengthen and formalise the links between the applicants and the Royal College of Physicians Clinical Effectiveness Unit. We have representation on the executives of the Stroke Association, British Association of Stroke Physicians and UK Stroke Forum and will use these links for dissemination/implementation.

13. Anticipated outputs, outcomes and impact of this research on the health of patients and/or the public, and on the NHS*:

Describe the anticipated outputs, outcomes and impact of the proposed research on the health of patients and/or the public and on the NHS, quantifying the impact at a population level, where possible. **(Maximum 3000 characters).**

OBJECTIVE 1: Estimates of risk of stroke in populations, with a focus on ethnicity and aetiological subtype and trends over time. These estimates can be incorporated into the DH's ASSET2 tool enabling commissioners and providers to plan service based on robust estimates. Estimates of stroke incidence rates in different socioeconomic and aetiological groups over time will identify the trends in needs for acute care, patterns of preventive treatments and secondary preventive practice.
OBJECTIVE 2: Estimates of longer term needs will identify those most prevalent needs that require management, thereby informing a more focused approach to delivering 'life after stroke' services and identifying areas of need that require the development of effective services. These estimates can be incorporated into ASSET2. The clinical prognostic tool will be utilised by clinicians to predict individual patient recovery, plan care more rationally, and may be used to select patients for trials.
OBJECTIVE 3: Estimates of longer term risk of recurrence will be an adjunct for ASSET2. Risk models will be produced that enable prognostication of subgroups of patients. These data will be developed into tools for clinical management, used for identifying groups for trials of new drugs and more complex trials of post stroke secondary prevention.
OBJECTIVE 4: Analyses of the inequalities and deficiencies in stroke care particularly longer term will inform commisioners and clinicians of the gaps in diffusion of evidence based practice. The links between appropriateness of care and outcome will also be addressed.
OBJECTIVE 5: Using outputs from 1-4 and 6, health economic models will identify potential cost effective models of care that can then be developed and tested. These modelling techniques we have used in the NAO report to quantify the impact on the NHS of increased uptake of stroke unit care and thrombolysis.
0BJECTIVES 6&7: The perspectives of users, clinicians and commissioners on the analyses will enable their appropriate local and national use and interpretation. In this way we will identify the most effective way of using such data to assess need and develop services.

The results will feed into local practice based commissioning and will be utilised by the DH stroke strategy groups, Royal College of Physician's Clinical Effectiveness Unit, Stroke Association and professional societies we are already strongly linked with. Deliverables will be posted on our website. The results will be disseminated in a wide number of forums to ensure users, health care professionals and commissioners and managers are aware of the research output. We will publish in high impact journals and present at international, national and local conferences in a breadth of disciplines. Overall this programme will have a major impact on the planning and delivery of stroke services, particulary longer term care.

14. Please provide details of public involvement in the proposed research*:

(Maximum 2000 characters).

We have collaborated with users in developing the original and final proposals and will continue to ensure their involvement at all levels of the research process, including consultation for further refinement of research questions; development of methods to seek users' views of potential new service configurations, through feedback of preliminary analysis and dissemination of study findings.

CM leads a 3-year programme to involve people with stroke/carers in research. This led to the establishment of the King's College London Stroke Research Patients and Family Group. The group meets every 6 weeks to discuss stroke research, advise researchers and generate ideas for new research. Outputs to date from this group include: a pilot study on the personal cost of stroke; FORWARD - a biannual newsletter for users disseminating research findings; and redesigned research consent forms. (See http://www.mystrokeservices.net/__data/assets/pdf_file/5539/Forward_Newsletter_-_June07.pdf). User involvement in service development takes place via user groups working on specific projects (e.g. improve information provision, develop peer support) and participation in project management. (via the KCL stroke research programme) and service development (via the Lambeth & Southwark Stroke Modernisation Initiative).

The user involvement programme is being evaluated in an ethnographic study to identify effective processes and to document outcomes of user involvement on research and service development.

In this proposed programme will also collaborate with the Patient Experiences Working Group, established by The Members Forum of Guy's & St Thomas' Foundation Trust, whose remit is to advise the Trust Board on how to provide best service to patients. The Trust is currently in the process of establishing a Special Interest Group for User Involvement in Research to support the work of the proposed Biomedical Research Centre, and we would anticipate collaborating with this group.

15. If you do not plan active public involvement in the research, please explain why not *:

(Maximum 2000 characters).

16. Proposed level and nature of public involvement in the research*:

Please tick all relevant boxes

	Consultation	Collaboration	User led / user controlled
Development of the grant application	☒	☐	☐
Design and management of the research	☒	☐	☐
Undertaking the research	☐	☒	☐
Analysis	☐	☒	☐
Dissemination of research findings	☐	☒	☐

Consultation
Researchers consult members of the public about the research e.g. through individual contacts, one-off meetings.

Collaboration
This includes active, ongoing partnerships between researchers and members of the public e.g. involvement of members of the public in the research team, or as research partners in the programme.

User led / user controlled
Members of the public lead the research and are in control of the research. This is often through a community or voluntary organisation led by service users.

17. Ethical Implications*:

Describe briefly any ethical issues associated with this research. Describe the ethical review and research governance arrangements that would apply to the work to be undertaken. **(Maximum 2000 characters).**

All proposals for the programme will be subject to peer review by the Division of Health and Social Care (https://www.kcl.ac.uk/depsta/medicine/divisions/hscr/staffonly/PeerReviewJune2006.doc) and by Guy's and St Thomas' Acute Medicine Directorate R&D peer review group. All projects will be registered with the trust R&D office, for inclusion on the National Research Register. All investigators on projects will be trained in all aspects of research governance by the trust R&D office and particularly in data protection, informed consent, and Good Clinical Practice. The Stroke Register has approval from St Thomas' Research Ethics Committee for register data collection and for the analyses in Objectives 1-5. Separate applications for ethics approval will be made where necessary for individual components of the programme.

Our Stroke Research Patients and Family Group provides a forum for discussing research ethics issues with users. In fact the applicants have recently worked with the Stroke Research Patients and Family Group to radically redesign research information literature and consent forms for the SLSR, ensuring that these fully address the information needs of people recruited to the register.

20. Monitoring information

Department of Health monitoring*
In order to categorise applications, the following list of research areas has been provided. Please categorise your research using the following selection boxes. This information will be used solely for monitoring.

Main subject of the research – choose most appropriate category from the UKCRC Health Categories list AND most appropriate from UKCRC detailed list of Research Activity Codes. For guidance please see the UKCRC Health Research Analysis which can be found at http://www.ukcrc.org/

(For example: Health Category – Cardiovascular and Research Activity – 6.4 Evaluation of Treatment, surgery).

Health Categories: (Please tick all that apply…..)

Blood	☐	Musculoskeletal	☐
Cancer	☐	Neurological	☐
Cardiovascular	☐	Oral and Gastrointestinal	☐
Congenital Disorders	☐	Renal and Urogenital	☐
Ear	☐	Reproductive Health and Childbirth	☐
Eye	☐	Respiratory	☐
Infection	☐	Skin	☐
Inflammatory and Immune System	☐	Stroke	☒
Injuries and Accidents	☐	Generic Health Relevance	☐
Mental Health	☐	Other	☐
Metabolic and Endocrine	☐		

Research Activity Codes: (For each category please tick all that apply…..)

1 Underpinning Research

1.1 Normal biological development and functioning	☐
1.2 Psychological and socioeconomic processes	☐
1.3 Chemical and physical sciences	☐
1.4 Methodologies and measurements	☐
1.5 Resources and infrastructure (underpinning)	☐

2 Aetiology

2.1 Biological and endogenous factors	☐
2.2 Factors relating to physical environment	☐
2.3 Psychological social and economic factors	☐
2.4 Surveillance and distribution	☐
2.5 Research design and methodologies (aetiology)	☐
2.6 Resources and infrastructure (aetiology)	☐

continued…..

3 Prevention of Disease and Conditions and Promotion of Well-Being	
3.1 Primary prevention interventions to modify behaviours or promote well-being	☐
3.2 Interventions to alter physical and biological environmental risks	☐
3.3 Nutrition and chemoprevention	☐
3.4 Vaccines	☐
3.5 Resources and infrastructure (prevention)	☐
4 Detection Screening and Diagnosis	
4.1 Discovery and preclinical testing of markers and technologies	☐
4.2 Evaluation of markers and technologies	☐
4.3 Influences and impact	☐
4.4 Population screening	☐
4.5 Resources and infrastructure (detection)	☐
5 Development of Treatments and Therapeutic Interventions	
5.1 Pharmaceuticals	☐
5.2 Cellular and gene therapies	☐
5.3 Medical devices	☐
5.4 Surgery	☐
5.5 Radiotherapy	☐
5.6 Psychological and behavioural	☐
5.7 Physical	☐
5.8 Complementary	☐
5.9 Resources and infrastructure (development of treatments)	☐
6 Evaluation of Treatments and Therapeutic Interventions	
6.1 Pharmaceuticals	☐
6.2 Cellular and gene therapies	☐
6.3 Medical devices	☐
6.4 Surgery	☐
6.5 Radiotherapy	☐
6.6 Psychological and behavioural	☐
6.7 Physical	☐
6.8 Complementary	☐
6.9 Resources and infrastructure (evaluation of treatments)	☒
7 Management of Diseases and Conditions	
7.1 Individual care needs	☐
7.2 End of life care	☐
7.3 Management and decision making	☐
7.4 Resources and infrastructure (disease management)	☐
8 Health and Social Care Services Research	
8.1 Organisation and delivery of services	☒
8.2 Health and welfare economics	☒
8.3 Policy ethics and research governance	☐
8.4 Research design and methodologies	☐
8.5 Resources and infrastructure (health services)	☒

For each category below please tick all that apply

Research Team:

Allied health professional	☒
Clinical academic	☒
NHS Doctor	☒
NHS Manager	☒
NHS Scientist	☐
Non-clinical academic	☒
Nurse	☒
Patient	☒
Other (please specify)	☐

Type of research/methodology:

Clinical trial – phase I, II, III or IV	☐
Cohort study	☒
Epidemiological	☒
Meta analysis	☐
Qualitative study	☒
Retrospective review	☒
Survey	☒
Systematic review	☐
Other (please specify)	☒

Setting in which research will take place:

Primary care	☐
Secondary care	☐
Specialist centre	☐
Community	☐
Interface (between any of the above)	☐

Subjects of research:

Children	☐
Elderly	☒
Other (please specify)	☒

For each question please select a response from the drop down box below.

Region in which research will take place:	London
Is the research multicentre?	NO
Place of work of lead applicant:	Medical School If Other, please specify:
Profession of lead applicant:	Clinical Academic

21. Declarations and signatures *

Please print this page, have it authorised and return it by post to the address below.

In order for your application to be accepted you are required to gain approval from the relevant authorities within your institution. These approvals are required to ensure that the costs submitted are agreed by the host institution as an accurate estimate of the cost of undertaking the proposed research. These approvals must be in the form of a "wet ink" signature. Failure to submit this agreement will result in your application being rejected.

The application forms and the "wet-ink" Declaration and signatures section of this form must be completed and returned by 29th October 2007, 5pm.

Programme Reference: ……

Title: ……

……

Lead applicant ……

Host Institution ……

Institutional stamp

I confirm that the information given on this form is complete and correct, that all co-applicants mentioned on this form have seen a copy of this application and that I shall be actively engaged in this programme and responsible for its overall management. **Signed:** …… **Date** …… **(Lead Applicant)**
I confirm that I have checked the financial details of application (RP-PG-0407-10184) and that this institution is prepared to carry out this research programme at the stated costs and to administer the award if made. The staff grades and salaries quoted are correct and in accordance with the normal practice of this institution. **Signed** …… **Date** …… **(Finance Officer)**
I confirm that I have read this application and that, if funded, the work will be accommodated and administered in this institution and that the applicants for whom we are responsible may undertake this work. **Signed** …… **Date** …… **(Representative of the institution hosting the research *e.g.* clinical director, R&D manager or Chief Executive.)**

IN ORDER FOR YOUR APPLICATION TO BE ACCEPTED, THE DECLARATIONS AND SIGNATURES SECTION OF THIS FORM MUST BE SIGNED BY THE RELEVANT AUTHORITIES FROM YOUR INSTITUTION AND RETURNED TO THE POSTAL ADDRESS BELOW, BY THE DEADLINE ABOVE.

NIHR-CCF
PO BOX 407
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TW11 0XX