# Carmarthenshire Housing Project Protocol

| Revision Date | Release | Summary of Changes | Changes Made By |
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| 21/10/2011 | V 0.0 | Derived from Carmarthenshire Housing Project detailed project description | SER |
| 28/10/2011 | V 0.1 | Update for web publication | SER |
| 16/11/2011 | V 0.2 | Removal of comparator region name | SER |
| 25/03/2013 | V 2.0 | Update of REAT validation | SER |
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## Approvals

This document requires the following approvals. A signed copy should be placed in the project files.

| Name | Signature | Title | Date of Issue | Version |
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## Distribution

This document has been distributed to:

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**PHR Protocol – 09/3006/02**
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# Health impact, and economic value, of meeting housing quality standards

| | |
|---|---|
| **Chief investigator** | Ronan Lyons |
| **Sponsor** | Swansea University |
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## 1. Project title:

**Health impact, and economic value, of meeting housing quality standards**

## 2. Background:

### 2.1. Existing research

While adequate housing is widely accepted as a prerequisite for health, there is only limited empirical evidence for this. The evidence for the relationship between housing and health has been summarised in a recent book (1) and a number of systematic reviews (2-4). The review by Thomson and colleagues (3) found only a small number of high-quality studies that offered evidence about changes in health following renewal or refurbishment. While there was some evidence that, for example, energy efficiency measures appeared to improve respiratory symptoms and mental health improved following rehousing or refurbishment, the authors concluded that there was a need for further experimental or quasi-experimental studies.

Many of the studies which have been carried out were criticised in the reviews for poor methodology, low participation rates and high losses to follow-up, or for lacking generalisability (8). Socio-economic status is strongly related to housing quality and disease incidence and may confound many of the relationships reported in cross-sectional studies. These are also subject to the possibility of reverse causation, as poor health may negatively affect housing opportunities (5). Experimental studies have been criticised for ignoring the multi-factorial nature of causality in housing, deprivation and health (6).

**Cardiovascular health:** Much of the research has focussed on inadequate indoor heating and the relationship with excess winter mortality, which is summarised in a recent review by Shepherd and Turley (4). The literature shows reasonably consistent evidence for the relationship between indoor cold and increased risk of strokes, heart attacks and respiratory illness in temperate climates (7, 8) and several studies have demonstrated plausible biological mechanisms to explain the results (9).

**Respiratory Symptoms:** Human health may be affected by mould through allergy, infection or toxicity (10). Many studies, including a large multicentre European study, associate diagnosable respiratory diseases such as asthma, wheezing, cough and phlegm with damp living conditions and exposure to mould, particularly in children (11-13). Burr and colleagues reported improved asthma symptoms and a reduction in rhinitis in a randomised trial of mould removal in south Wales homes (14). Some studies have provided evidence of increased respiratory health problems after thermal insulation of buildings, and the installation of insulated windows and central heating systems (15-17). It is possible that the insulation measures reduce natural air flow within buildings, leading to poorer indoor air quality which may contribute to the development of respiratory symptoms (18). However, the findings that the individual home improvement measures may *increase* the number of reported respiratory symptoms contradict earlier and local findings that upgrading houses *decreases* the number of reported respiratory symptoms (19).

**Mental Health:** A literature review examining the relationship between mental health and housing found that housing quality was positively correlated with psychological well-being (20), though the results could have been influenced by the simultaneous self-assessment of housing and psychological well-being.

**Injuries:** In a previous large scale data linkage study, part of the Housing and Neighbourhood and Health (HANAH) study members of this research group demonstrated excess injury incidence in residents of purpose built apartments and terraced homes (21). However, whether this relationship is due to aspects of housing or is a reflection of differential baseline risk amongst residents of different housing types remains uncertain. Improvements or changes in housing could potentially affect injury rates, particularly in older people prone to falls. Mechanisms for a reduction in injuries may be through removal of hazards or a reduction in

falling in low temperatures. Conversely, new layouts and increased mobility due to improved temperatures could have the effect of increasing injury rates, a phenomenon previously demonstrated in a trial of screening and referral for visual problems (22).

In summary, the available evidence on housing improvement and health is limited, sometimes conflicting and often affected by biases. In particular, low response rates and high rates of losses to follow up adversely affect validity, generalisability and power to detect important effects in many studies. Our proposed methodology will allow us to evaluate objectively the effect of an ongoing major housing renewal scheme in Carmarthenshire (n=9,256 properties) on the health and wellbeing of social housing residents, whilst avoiding recruitment and follow up biases. We will explore hypotheses linking the four types of regeneration intervention with different health pathways; mental health, respiratory and cardiovascular disorders and injuries. This project will use routinely collected health data and employ data linkage techniques within the Secure Anonymised Information Linkage (SAIL) databank, combined with assessment of architectural form and interventions, using appropriate multilevel statistical analyses (23).

### 2.2. Risks and benefits:

The design of future regeneration programmes should be influenced by the results of our study. Whilst improving the energy efficiency, quality and amenities within homes is expected to improve health overall, there is a small risk that some features, such as decreased ventilation, might adversely affect asthma and that different layouts might pose an injury risk to frail individuals. From the point of view of the research proposed there are no additional risks to participants. Health data will be anonymously linked and evaluated so there is no possibility of identifying the individuals concerned. Residents will be made aware of our research by members of the tenants' association on the project Steering Group.

There is only a negligible chance that the regeneration programme will not be completely funded. The programme is already underway and the funding has been committed, confirmed in a letter of support from Carmarthenshire County Council (Attached). The risk to the NIHR of this group not completing the research is small since we have an established system for holding anonymously linked health data and a number of experienced researchers involved with this project. Additionally, we have a long history of working with this local authority and a scoping study associated with this refurbishment programme has been completed by Wouter Poortinga and Simon Lannon, co-applicants for this project.

### 2.3. Rationale for current study:

This proposal seeks to evaluate the effect of a natural experiment in housing regeneration carried out by Carmarthenshire County Council in Wales. Over 9000 social housing properties have been identified as being in need of improvements, which are being carried out over a period of several years, and this gives an opportunity to assess the benefits by comparing the health of the residents before and after the intervention and with those of similar backgrounds living elsewhere in the area.

The use of natural experiments to evaluate population health interventions was the focus of the PHSRN/MRC Methodology Research Panel workshop (21/1/2010) and much of the first meeting of the UKCRC Centres of Public Health Research Excellence in Cambridge (29/06/2010). Housing interventions are a type of natural experiment, funded by local and central government. The evaluation of such experiments has been difficult due to mismatches of skills and information between local government (interventions and exposures), the NHS (health outcomes) and academia (high quality evaluation). This is largely due to data protection concerns which prevent data sharing at sufficient granularity to avoid major problems with ecological biases and lack of power to detect effects, and too short a time frame to set up pre-intervention measurement. We have developed a system to overcome these difficulties (see below) and propose to use this to evaluate the health impact of a major housing renovation and area regeneration in social housing in Carmarthenshire.

The Secure Anonymised Information Linkage (SAIL) system was designed to overcome data sharing issues and facilitate evaluation of individual and household level interventions to support public health and other interventions. We have developed a system with linkage accuracy >99% (23-25). This system negates the need for baseline data collection since data are available for pre, during and post intervention using routinely collected data stored within our databank. The system includes anonymised but linkable population register, mortality, inpatient, outpatient, and emergency department data across Wales, and, in Carmarthenshire, 50% of GP practices. A meeting with GP practices is planned for October to encourage more to participate with the support of the Local Health Board. As new practices join SAIL all historical data are collected. The development of this databank and novel linkage methods, which rely on the databank and its unique features, provide the basis for our proposed evaluation.

Routine data do not readily include health related quality of life or mental health status (MHI-5) or symptom prevalence. (Symptom prevalence can be estimated from a proxy of GP treatments for anxiety and depression, as mentioned in the outcomes section). However, Carmarthenshire has already funded a survey, to help evaluate the intervention, which covers these issues with design and analyses provided by colleagues in Cardiff University (Poortinga). This is quite separate from the study proposed here but some early results suggest that the intervention appears to have an impact on both housing and health.

The results here were for residents of houses in which the intervention had either not yet started or had been completed. These residents were surveyed using face-to-face interviews; those in properties where renovation had begun were contacted separately. Residents of 553 houses in these categories were approached; 319 interviews were conducted, a response rate of 58%. The two groups were similar in terms of socio-demographic composition.

Some of the results refer to housing problems and, not surprisingly, the percentage of respondents identifying housing problems is lower in the renovated houses, though 13% still reported being dissatisfied, compared to 35% in the houses on which work had not started. On health-related matters, only 7% reported treatment for depression in the completed houses compared to 21% in those houses which had not been started, and Table 1 compares the prevalence of respiratory symptoms in the two groups of houses.

**Table 1. Prevalence (%) of reported respiratory symptoms for residents in regenerated and non-regenerated houses.**

| | Not started (n=261) | Completed (n=58) |
|---|---|---|
| Zero | 52 | 67 |
| One | 8 | 5 |
| Two | 15 | 3 |
| Three | 7 | 2 |
| Four or more | 18 | 22 |

While this survey study is quite distinct from our proposals, the results suggest that the intervention will result in substantive changes to the properties and are likely to yield measurable health impact, warranting further and more detailed research.

## 3. Research objectives:

To prepare housing intervention, Residential Environmental Assessment Tool (REAT), GIS datasets at periodic intervals in order to complete the following:

- To generate code to extract health data from the SAIL databank for each condition/treatment related to the different housing regeneration work packages by 2013.

- To determine the effect of housing regeneration on hospital admissions by 2015 and other conditions such as: cardiovascular, respiratory, falls and burns, anxiety and depression.
- To determine costs to the health system associated with substandard housing, and potential health care 'savings' due to housing regeneration schemes, by February 2016.

## 4. Research design:

This proposal seeks to evaluate the impact of a mixture of different types of housing improvements to social housing in Carmarthenshire, between 2009 and 2014, on the health of the residents. By using record linkage of routine longitudinal data, including such health-related aspects as hospital admissions and GP consultations and prescriptions, we plan to compare the health of the residents before and after the interventions and to compare their health changes with those of residents in 13,000 unimproved social houses in a nearby region. The analyses will be conducted in parallel with the results of a series of before and after health and wellbeing surveys already funded by the Council and which is quite separate from this proposal.

The intervention participants are the residents of the 9,256 properties being improved between 2009 and 2014. The intervention comprises up to four separate work packages (internal works/windows and doors/thermal insulation/gardens and estate environment). Properties receiving all four interventions will have different intervention dates for each. The intervention is proceeding stepwise over a considerable period of time, complicating the assessment of the impact. By using routine data, available for a number of years including the whole of this intervention period and preceding years, we hope to overcome the logistical difficulties inherent in other types of evaluation.

The outcomes will be discussed fully later but the primary outcome concerns hospital admissions rates for certain conditions. These will be evaluated for the two years before the whole intervention began, and compared with the time period following the intervention; the length of this period will vary between households with the timing of the interventions. The information within the SAIL database will allow us to identify similar social housing residents (matched on deprivation and demography) in a nearby region (who are not having housing improvements) and we will evaluate comparable admission rates for those households, over periods matched to those in the intervention group. This will enable us to adjust for any systematic changes over time in admission rates.

We will link multiple anonymised datasets at an individual and household level using the Secure Anonymised Information Linkage System (SAIL) operated by the Health Information Research Unit (HIRU) (23, 24).

We have an environment GIS database (eGIS) containing a point location for each residence, along with address data (Ordnance Survey Master Map, Address Layer 2) (26). These data have been used to establish a method of anonymously linking each residence to health data for individuals within the SAIL databank using Residential Anonymous Linking Fields (RALFs) (25). While the environment data are within the eGIS, they are completely separate from health data in SAIL. Therefore we are able to know the location and other information about the house and its local environment, for example neighbourhood quality (REAT- see next paragraph), without compromising confidentiality and privacy. While in the eGIS, we will add house improvement data and other relevant information, specifically the work packages and completion dates, describing the regeneration process.

Each regenerated house and its local area will be linked to a validated reliable objective tool, designed by members of this project team, to measure the quality of the neighbourhood built environment (27). The Residential Environmental Assessment Tool (REAT) is used at a postcode level to measure, using independent observers, the characteristics of the area environment around a home or group of homes. We will update the REAT tool and undertake a REAT assessment of each of the postcodes in which the regeneration has not started to

measure the impacts of interventions undertaken by Carmarthenshire County Council on the outside of the buildings and within the gardens. Under the latest timetable approximately 360, or 50%, of the postcodes affected by the intervention will be assessed pre- and post-intervention. These postcode-level data will then be linked to the key data using the RALFs prior to anonymisation. The updated REAT tool will be validated using questionnaires delivered by the tenant network groups. Questions will assess if the constructs in the REAT tool agree with perceptions of local residents.

Additionally, we will use digital map analysis techniques, developed as a result of EPSRC funding (28), together with internet-based tools such as Google Streetview, to investigate the possibility of replacing REAT assessments in their current form, which require an assessor to visit the area, with a computerised analysis, including map data (29). These data will be compared to the REAT scores data to assess the validity of this semi-automatic method of measuring the environment. If this proved successful, it would allow the assessment on a much larger scale than is presently possible.

These data are sent to Health Solutions Wales where addresses are replaced with a consistent RALF. Now the data may be brought into the SAIL databank and linked to Anonymous Linking Fields (ALFs) for individuals, enabling links to health data to be made. We will create links to variables within several different datasets to enable us to explore potential changes in disease burden for individuals nested within houses, related to housing improvements. We are using this methodology for other studies currently, in particular the development of the Wales Electronic Cohort for Children (circa 700,000 children), funded by NISCHR.

Variations in the intervention are achieved as a result of the four different work packages and the order in which they are completed for each house. Different types of intervention may have different impacts on health; for example exterior work, such as security lighting installation, may make residents feel more secure whereas interventions to improve thermal efficiency may have greater effects on general health, hospital admissions and overall mortality. Specific hypotheses are:

1. Combined housing regeneration improvements will reduce the number of combined condition emergency hospital admissions (see primary outcome measure)
2. Improvements in affordable warmth due to insulation and new boilers will result in fewer cardio-respiratory events
3. Installation of full central heating and new windows and doors will reduce the presence of mould and lead to a reduction in asthma treatments
4. Improved quality of kitchens and bathrooms will improve mental health.
5. Improvements to the exterior of properties, including security light additions, will improve mental health (anxiety and depression treatments)
6. Installation of power points in convenient locations, upgrades of electrical systems and installation of smoke detectors will reduce the number of fall and burn injuries

Other hypotheses may be generated following the literature review. The evidence for these pathways is presented in the background section and Figure 1 shows possible pathways.

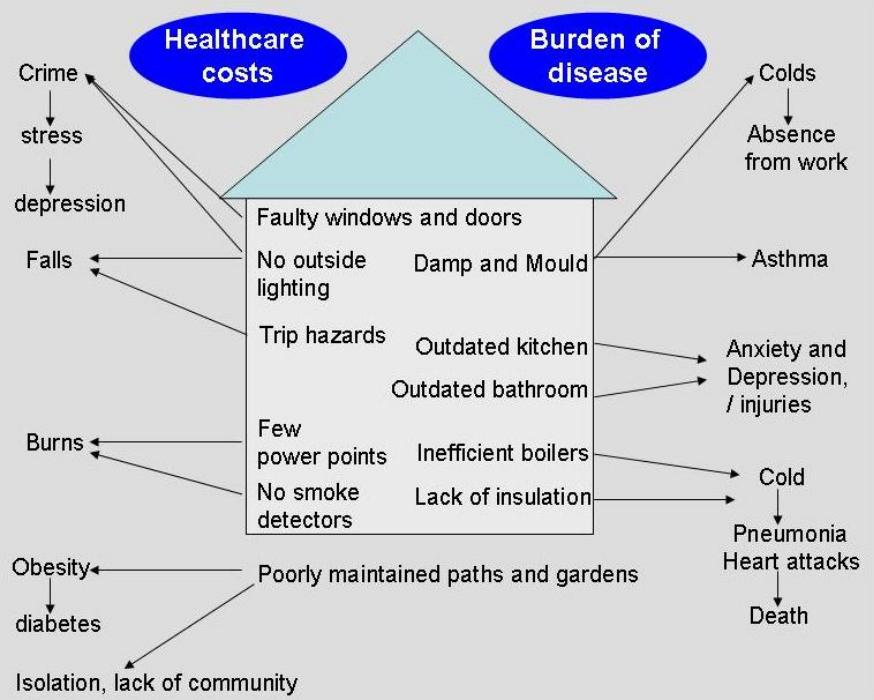


**Figure 1** Pathways of disease burden and potential health benefits due to meeting national housing quality standards

*Economic feasibility study for economic assessment tool*

The aim of the economic evaluation is to investigate the economic value of the housing regeneration programme. A feasibility study for a UK-wide Health Economic Assessment Tool (HEAT) for housing, similar to the WHO HEAT tool for cycling, will be conducted using the health impact economic value data (30). We will assess the viability of making a tool that can be used by local government and private social housing management to assess the benefits of regeneration programmes. The evaluation will estimate the costs of providing the new regeneration programme and determine the extent to which it can be regarded as an efficient use of public funds. The economic evaluation will inform the feasibility of a UK-wide Health Economic Assessment Tool for Housing.

The approach to be adopted in this evaluation of the scheme is to conduct a cost-consequences analysis (CCA) from the perspective of the public sector and the wider social perspective (31, 32). The costs of delivering the programme will be collected by scrutiny of routinely collected datasets held within the Secure Anonymised Information Linkage (SAIL) system, relevant financial documents, discussion with key staff involved with the programme and finance staff from the constituent organisations. The costs associated with utilisation of hospital and GP services (NHS reference costs) will be collected to calculate resource utilisation over time in conjunction with the costs of delivering the programme. Primary and secondary outcome measures will be used in the CCA.

Cost-consequences will be assessed within the study duration and additional modelling will be undertaken to estimate cost-consequences and outcomes beyond the end date of the study. Future costs and benefits will be discounted at the prevailing rate to bring into present values as required by assessment agencies. Changes in resources utilised over time, as well as changes in primary and secondary outcomes, will be calculated and used in conjunction with the costs of delivering the programme to generate the net cost of programme delivery. A series of one-way sensitivity analyses will be undertaken to assess the extent to which changes in the variable employed affect the baseline estimates. Probabilistic sensitivity analysis will be undertaken to ascertain the probability that the scheme represents value for money.

## 5. Study population:

All residents of the 9,256 houses undergoing improvement in Carmarthenshire will be included. We can achieve close to a 100% 'participation' rate due to the anonymous and comprehensive nature of the SAIL databank; the only condition for inclusion in SAIL is that residents occupied one of these houses at the start of the intervention programme and are registered with a GP. We have not yet made the anonymous links to the residences specifically for this intervention population as this requires funding, but we estimate the number will be about 21,000.

## 6. Socioeconomic position and inequalities:

This proposal evaluates the health benefits of a regeneration programme. It is targeted specifically at residents of social housing, who are mostly located within less affluent neighbourhoods. We will assign each residence a measure of deprivation (Welsh Index of Multiple Deprivation (33)) based its location within a Lower Super Output Area (LSOA). The relevant deprivation scores will be included in the statistical analysis to investigate differential benefits for the most deprived category. In addition to overall deprivation scores we will complete analyses using deprivation sub domains, for example income. The areas regenerated are likely to be among the more deprived parts of Carmarthenshire and so any benefit from the programme compared to the rest of the county is likely to help to reduce inequalities.

## 7. Planned interventions:

UK governments are investing enormous amounts of money to improve housing standards in social housing. The programmes have different names across jurisdictions and minor differences in housing specifications but essentially are similar and aim to provide homes which are warm, weatherproof and have reasonably modern facilities. In England the programme is called Decent Homes (34) and in Wales it is the Welsh Housing Quality Standard (WHQS) (35).

In Wales over £3 billion is being invested in WHQS. Carmarthenshire Council is implementing the WHQS with some minor variations in 9,256 properties between 2009 and 2014. We aim to evaluate the effect on health of this major intervention. The objective is to ensure that the Council's housing stock is in a good state of repair, free from damp and condensation, structurally safe and located in a safe and attractive environment. The most important intervention improvement is energy-efficient condensing boilers/central heating, double-glazing, and wall/loft insulation. The programme of work that will ensure that the housing will be brought up to the CHS is split up into four separate work packages. The *internal works* package includes upgrading all kitchen units and bathroom suites, ensuring downstairs toilets in all houses, full gas or oil central heating with energy-efficient condensing boilers, and rewiring to provide sufficient sockets in all rooms. The *windows and doors* package includes the provision of double-glazed windows and doors with secured locks. The *thermal insulation* package includes cavity wall or external wall insulation and loft insulation where possible. The *gardens and estate* package includes the provision of boundary garden fencing, outdoor security lights, and paths that are in good condition.

There are no problems with compliance as all those offered housing renovation improvements at no cost to them have accepted the improvements to date. Loss to follow up will result from a small percentage moving house (see Sample size section). The £234 million required to deliver the intervention is being met by Carmarthenshire County Council through Welsh Assembly Government and other funding sources. We have attached a letter from the council showing their support for this project.

## 8. Proposed outcome measures:

*Primary outcomes*

The primary outcome measure is the change in the proportion of residents aged at least 60 who have emergency admissions to hospital for selected conditions (cardiovascular and respiratory conditions, falls and burns). Data on these conditions are available for all of Carmarthenshire within SAIL.

*Secondary outcomes include changes in:*

(1) Emergency admission to hospital for **cardiovascular** conditions,
(2) Emergency admission to hospital for **respiratory** conditions,
(3) Emergency admission to hospital for **injuries** (falls and burns),
(4) **Emergency department attendances** with all injuries occurring at home,
(5) GP prescriptions for **asthma** treatments (amounts of relievers, preventers and total prescribed),
(6) GP attendances for **respiratory conditions**,
(7) Incidences of GP treated **anxiety and depression** (prescriptions),
(8) **All-cause mortality**,
(9) **Costs** associated with utilisation of health service resources.

SAIL contains hospital admission and mortality data for all of Carmarthenshire to provide secondary outcome measures 1-3 and 8. SAIL also contains the Emergency Department Data Set to provide secondary outcome measure 4. Currently SAIL contains anonymised records from half the GP practices in Carmarthenshire and our comparator region. Given the much greater frequency of outcomes 5-7 (GP attendances and treatments) than the primary outcome (hospital admissions/death) on which the sample size estimation is based (see Section 10), we are confident of having sufficient power to detect meaningful changes in these outcomes. A meeting with all GPs in Carmarthenshire is planned in October, supported by the local Health Board and Director of Public Health, to encourage the remainder to sign up to SAIL. It is envisaged that many will join and the ensuing data extract will include all the historical data in the system; the timing of joining is not crucial. However, in the unlikely event that none join we will still have sufficient data because of the high frequency of events. Service usage has published unit costs, which will be used in a cost-consequences analysis, to assess changes associated with housing improvements.

## 9. Assessment and follow up

### 9.1. Assessment of efficacy/effectiveness:

The evaluation of a housing improvement stepwise intervention in a large number of homes is essentially a form of a natural experiment. Unfortunately, it is not possible to randomise the scheduling of the intervention as this has already been agreed and much has been completed or is underway. Effectiveness in this context is more equivalent to a pragmatic rather than randomised trial as the components and extent of improvement will depend on the individual state of each property. Effectiveness will be assessed by absolute and relative changes using a variety of routinely collected data.

Since this project is based on routine data, we can easily recreate the health status of participants at any point in time, thereby allowing efficacy and effectiveness to be calculated for all relevant time periods. Therefore the “outcome measures” will be assessed pre intervention in addition to several time points throughout study after the work packages have been completed for known residences. The statistical power and techniques are also discussed in the study design section, along with the health and cost impacts of the regeneration scheme.

### 9.2. Assessment of harms:

Harm from the housing intervention is unlikely, but net negative changes in respiratory conditions could theoretically result from more air-tight houses. Similarly, changes in layout could result in an increase in fall/scald injuries. We will assess the potential for adverse effects in the evaluation of routine data, as described in the research design section.

## 10. Proposed sample size:

The primary outcome is the rate of hospital admissions for specified ICD codes in the population aged at least 60. In the 2001 census there was an average of 2.33 persons per household in Carmarthenshire. Assuming this applies in the 9256 houses in the regeneration

areas, there will be approximately 21,500 residents. Also based on the 2001 Census data, 25% of the population were aged at least 60, giving approximately 5400 over 60 in the regeneration areas at the start of the intervention.

Some of these will move away from the area. It has not been possible, without funding, to identify the 9256 houses within SAIL; instead a random sample of 9256 households in Carmarthenshire was chosen. 2529 residents aged at least 60 were identified; over the five year period 16% of these moved house, although nearly 90% stayed within Carmarthenshire (Table 2). A further 19% died; these are directly relevant to secondary outcome (8) and some will be relevant to the primary outcome. The nature of the outcomes, from routine data held by SAIL, means that the response rate will be close to 100%. A conservative estimate is that there will be data on follow-up and baseline periods for 3500 aged 60+.

**Table 2: Summary of house moves over 5 years in a random sample of anonymised Carmarthenshire residents over 60+ years old. *movers and deaths subtracted**

| Year | RALF subtractive sample* | Died | Moved | % Moved | Moved out Carmarthenshire | % Moved far |
|---|---|---|---|---|---|---|
| 2002 | 2,529 | na | na | na | na | na |
| 2003 | 2,336 | 100 | 93 | 3.98% | 15 | 0.64% |
| 2004 | 2,099 | 140 | 97 | 4.62% | 11 | 0.52% |
| 2005 | 1,933 | 90 | 76 | 3.93% | 7 | 0.36% |
| 2006 | 1,745 | 89 | 99 | 5.67% | 15 | 0.86% |
| 2007 | 1,619 | 66 | 60 | 3.71% | 8 | 0.49% |
| | | 19.18% | 16.81% | **4.38%** | **Average moves per year** | |

Data on rates of admissions for the selected primary outcome ICD codes in a pilot study of Carmarthenshire over 60s suggest an annual rate of 4.4%. The sliding scale nature of the interventions means that the follow-up period, once the intervention has been completed, will vary across the regeneration areas. There should be at least two years of follow-up for the vast majority within the project timescale. Over a two year period some of the residents may be admitted more than once; we will assume that, without the intervention, about 8% of residents aged at least 60 would have a hospital admission.

By including a similar number of controls from social housing in our comparator region then we would have over 80% power for detecting a reduction in the two year admission rate from 8% to 6.2%. Obtaining twice as many controls from comparator region – and these are based entirely on electronic records - would produce over 80% power for detecting a reduction to 6.5%. These calculations have ignored the possible effect of clustering, which would reduce the power. As we have no information on the magnitude of any clustering effect it is hard to incorporate it into an estimation of the power. On the other hand the definitive analysis will look at the change between hospitalisation rates pre- and post-intervention, and that should increase the power. To increase the power we will also perform an analysis based on person-years at risk to allow those who moved or died to be included. We believe the estimated power is realistic.

## 11. Statistical analysis:

Key health indicators of conditions likely to be improved due to regeneration will be derived by the research analyst. These key indicators will be extracted from the SAIL databank for the statistician to analyse using multilevel modelling techniques.

Initially the data set will be created by the project Research Officer (databank) who will query several datasets within the Secure Anonymised Information Linkage databank. The data will be explored by the RO before the multilevel modelling approach is applied.

The primary method of analysis will be multilevel modelling, as the data are hierarchical with

individual residents nested within households nested within lower super output areas. For modelling results over more than one time period an extra level of time will be included at the bottom level in the model. Modelling sources of variation at these nested levels is important so that effect sizes are estimated properly and, in particular, their standard errors are calculated appropriately so that inferences drawn are valid.

Explanatory variables will include socio-demographic information at the individual and household level, including age, gender, and household type. LSOA-level variables will include the Wales Index of Multiple Deprivation and the ONS rurality classification.

The exact details of the multilevel models will vary with outcome measure. Most models will have a discrete outcome. Some will be binary, and the appropriate model will be a logistic one. Other outcomes may be counts and appropriate models will use Poisson regression. We will check for over-dispersion and, if present, consider negative binomial, models or other possibilities such as zero-inflated models if the need arises. We will also include an analysis based on the number of person-years at risk, to allow for variable periods of follow-up, including on those who moved or died.

The simplest models will only involve houses in the regeneration areas and we will look at changes over time, as a way of estimating the effects of the regeneration programme. We will explore interactions to explore if the benefits vary by population subgroups. Controls from non-regenerated social housing in a nearby region will then be included to control for changes affecting the whole area.

The models will incorporate random intercepts at the different levels in the hierarchy. The possibility of random slopes, indicating that the effect of an explanatory variable varies over different units such as LSOAs, will be explored. Calculation of intra-class correlation coefficients will give some insight into the importance of sources of variation, not explained by the models, arising at different spatial levels.

A health economics appraisal will be included and has been discussed in the design section.

## 12. Ethical arrangements:

As this study is an evaluation of an existing housing regeneration programme which is already underway, there are no additional interventions for participants over and above the work of the regeneration programme. The design of the study does not include randomisation and does not influence the implementation of the regeneration work packages. This evaluation is based on a system of anonymously linked data, which form a research database within the Secure Anonymised Information Linkage (SAIL) system, the national e-health facility for Wales. The design of this system involves an NHS Information Organisation (Health Solutions Wales) carrying out identity matching and subsequent encryption of NHS numbers and address identities without access to any clinical or intervention content. Subsequent second stage encryption and linkage of anonymised datasets at Swansea University means that the team carrying out the evaluation cannot identify individuals or addresses. Multi-stage preparation of data for analysis by trained health analysts working to ONS guidance ensures that individuals cannot be identified through small numbers. Data categories are collapsed masked before analysis is carried out by a separate statistician using the remote access secure SAIL Gateway facility modelled on the ONS micro laboratory.

As we cannot identify individuals it is not possible to inform individual residents of the study and seek consent. As this study involves analysis of retrospective and prospective routinely collected data from individuals in properties undergoing regeneration, and from the general population, it is not possible to obtain individual consent. Participant consent is also not required because the study data will be anonymised before it is incorporated into the SAIL databank and anonymously linked with other datasets. As the SAIL databank is anonymised it does not fall into the remit of the National Information Governance Board who provide section 251 (formerly

section 60) exemption to use *identifiable* data without consent.
SAIL was designed following consultation with the Information Commissioner's Office in Wales, extensively reviewed by NHS Information governance bodies (including Informing Healthcare and Health Solutions Wales– the Welsh equivalents of Connecting for Health and the NHS Information Centre) and externally assessed before such organisations agreed to provide data to the system. An Information Governance Review Panel assesses whether all proposals for analysis meet the strict information governance arrangements set out in the multiple data access agreements, ensures anonymity and does not require referral to NRES. IGRP includes members from the BMA, NRES, Public Health Wales NHS Trust, Informing Healthcare and lay members. An application will be made to the IGRP for this study.

We have sought additional advice from NRES in relation to this proposal and have been informed that NHS Research Ethics Committee review is not required for the study as it does not involve NHS patients or staff but falls under the category of an anonymised research database. These do not need approval under current NRES guidance.
http://www.nres.npsa.nhs.uk/applications/guidance/research-guidance/?esctl1349488_entryid62=66997

### 13. Research Governance:

A multi-disciplinary and multi-agency study steering committee (SSC) will be established to oversee and guide project activities. The SSC will be constituted to include the lead and co-applicants, and will have representation from Swansea University, Cardiff University, Carmarthenshire County Council and Hywel Dda Local Health Board. As well as this, we will invite members of the Carmarthenshire Tenant Networks* to be part of the SSC to ensure tenants are engaged in the study. The SSC will agree terms of reference, frequency of meetings and *modus operandi* to support optimum management and development of the project throughout its life-cycle.
* http://www.sirgar.gov.uk/english/housing/pages/tenantparticipation.aspx

### 14. Project timetable and milestones:

A Gantt chart with a number of milestones and will be used to ensure the project proceeds in a timely manner. The housing regeneration is underway and will conclude by 2014; some internal work has been completed for all residences (e.g. loft and cavity insulation). Several work packages such as installation of new kitchens and bathrooms are progressing steadily. Windows and doors will be completed in 2011. External work will be completed towards the of the regeneration scheme. Additionally several important project milestones have been detailed here:

- Development of key health indicators for primary and secondary outcome measures will be completed by April 2013
- Development of intervention list by property, property type and work package intervention category by 2014
- Completion of all REAT surveys for pre-intervention by April 2012, followed by post-intervention by April 2014
- A research officer to complete the multilevel modelling and cost consequence analyses will be recruited and appointed by April 2014
- Multilevel modelling will be completed by April 2015
- Cost-consequence analyses will be completed by February 2016
- Health improvement results of this project will be disseminated through publications and conference attendance, so government decision makers and others' spending council money are aware of regeneration effects on population health.
- In addition to regular progress reports, a final report will be written and submitted by the 2016 deadline.

### 15. Members of the Public:

This application does not include direct recruitment or contact with those whose homes are

undergoing refurbishment. However, public involvement with the research process will occur through engagement with tenant representatives on the Study Steering Group and also by lay representation on the Information Governance Research Panel which adjudicates on proposed research projects using the SAIL databank.

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