DETAILED PROJECT PROTOCOL

Full title of project

How is cancer care best provided to patients in English prisons? Assessing the disease burden in the prison population, experiences of diagnosis, treatment, and support, and of receiving and providing cancer care

Short study title: How is cancer care best provided to patients in English prisons?

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Research Numbers

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: .... Date: ....../....../......

Name (please print):

Prof Reza Razari..

Position: Vice Principal (Research)...............................

Chief Investigator:

Signature: .... Date: ..14/07./21......

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....

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DR ELIZABETH DAVIES

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Sponsor	King's College London, The Strand, London WC2R 2LS Full contact details including phone, email and fax numbers The sponsor can be defined as the individual, company, institution, or organisation assuming overall responsibility for the initiation and management of the study, and is not necessarily the main funder. Sponsorship responsibilities may be shared by joint- or co-sponsors
Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	NIHR Health Services Delivery & Research Programme
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STUDY SUMMARY

More than 200,000 people are imprisoned each year in England and Wales and often have significant health needs. There is little research on cancer occurrence or care in prison, but recent Ombudsman reports highlight suboptimal service provision. Our study is assessing the burden and cost of cancer in English prisons, equity of access to, and experiences of care in order to develop recommendations to inform English prison cancer care policy. The study will use a mixed methods approach. We will use cancer registry and Hospital Episodes Statistics data to examine comparative national trends (1998-2017) for cancer incidence in people aged >18 serving a prison sentence, disease stage at diagnosis, treatment received, days in hospital, and survival rates. We will estimate the comparative cost of cancer care in prison and of alternative care pathways. We will also undertake qualitative interviews with 20 recently diagnosed or treated patients to understand experiences of diagnosis, treatment, and care. National Cancer Patient Experience Survey (CPES) data for patients in prison will also be examined. Interviews with 30 clinical and custodial staff working in the community or in prison will identify barriers to care and examples of good practice. To ensure our findings inform practice and policy, we will actively involve patient, charity, NHS, Ministry of Justice and public health stakeholders throughout the study. Using workshops and panels to review the implications of the findings we will derive and publish new priorities and recommendations for national prison policy, commissioning and practice for cancer and other long-term conditions.

Study Title	**How is cancer care best provided to patients in English prisons? Assessing the disease burden in the prison population, experiences of diagnosis, treatment and support, and of receiving and providing cancer care**
Internal ref. no. (or short title)	How is cancer care best provided to patients in English prisons?
Study Design	Sequential mixed method explanatory design
Study Participants	Phase 1: Quantitative study: Data recorded within the English Cancer Registry for over 2000 individuals diagnosed with cancer in while in prison between 1998 and 2017
Planned Size of Sample (if applicable)	Phase 2: 40 patients diagnosed or treated with cancer in prison; 10 prison custodial staff; 10 health professionals working in prison and 10 working in the NHS
Follow up duration (if applicable)	
Planned Study Period	May 2018 to Jan 2022
Research Question/Aim(s)	We aim to identify cancer diagnoses, treatment pathways and cancer care experiences for people diagnosed in prisons and the challenges faced by prison staff and health professionals providing cancer care. The purpose of this mixed methods study is to assess and explain the incidence, prevalence, burden and potential cost of cancer in English prisons, equity of access to cancer care, experiences of care, in order to identify areas where the quality of care can be improved, examples of best practice and develop priorities and recommendations to inform and improve local services and English prison cancer care policy.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR Health Service & Delivery Research Programme	**£543,633**
King's College London	**£53,510 for project coordinator role, £604 for audioconference fees, £21,893 to extend length of Research Assistant role by 6 months if required.**
University of Surrey	**£22,000 to support additional interviews with patients in prison and their analysis.**

Summary of research

More than 200,000 people are imprisoned each year in England and Wales and these individuals have significant health needs. To date, prison health research has focused on mental health needs including substance abuse and infectious diseases. Research on non-communicable diseases is neglected despite evidence that people in prison adopt health behaviours that increase their risk of these diseases and that this population is ageing rapidly. There is a paucity of cancer research and recent Prison Ombudsman reports have highlighted suboptimal service provision. The purpose of this mixed methods study is to assess the burden and cost of cancer in English prisons, equity of access to care, experiences of care, identify examples of best practice and aspects of care that can be improved and develop priorities and recommendations to inform and improve local services and English prison cancer care policy.

We will conduct a sequential explanatory study comprising a quantitative epidemiological and health economic analysis of cancer in English prisons and a qualitative study to understand and explain inequalities in the experience of diagnosis, treatment and care from the perspectives of patients, clinicians and prison staff. Using national cancer registry and Hospital Episode Statistics data for prison postcodes, we will examine comparative national trends (1998-2017) for cancer incidence in those aged over 16 serving a prison sentence compared with the English general population and also disease stage at diagnosis, treatment received, days spent in hospital, survival rates and cause of death. We will estimate the prevalence of cancer in the prison population, the comparative cost of cancer care and of alternative care pathways.

We will develop a model to explain how and why discrepancies in experiences of diagnosis, treatment and care occur from the perspectives of patients, custodial and clinical staff using primarily qualitative methods but also comparing the 2010-2016 National Cancer Patient Experience Survey results for patients in prison with those reported for all English cancer patients. We will analyse information on aspects of care collected at in-depth interviews with 15-20 diagnosed or treated patients. We will interview 30 custodial and clinical professionals working in prisons or in the community to identify discrepancies and/or barriers to care and support and examples of good practice and explore how and why they occur. Interviews will be recorded, transcribed verbatim and analysed using framework analysis.

To ensure our findings inform practice and policy, we will actively involve patient, charity, NHS, Ministry of Justice and public health stakeholders throughout the study. Using workshops and panels to review the implications of the findings we will derive and publish new priorities and recommendations for national prison policy, commissioning and practice for cancer and other long-term conditions. We will actively disseminate the research findings and the priorities and recommendations widely using academic and practitioner conferences and networks, publications, specific policy briefings and public engagement events, social media and a digital film. We anticipate the findings will impact on the provision of cancer care in secure environments, including prison, by highlighting gaps in care and explanations of why these occur and providing new information enabling policy makers, local commissioners and providers of cancer care to develop more appropriate and effective cancer services. Ultimately the findings will have a positive impact on the care experience of patients with cancer and other long term-conditions in prison.

Background and Rationale

We aim to assess the incidence, burden and impact of cancer in English prisons. It is of strategic importance to the NHS to identify any inequalities in accessing quality cancer care or hidden costs for patients and staff of current health services such as delays in diagnosis leading to more treatment, admission and staff time. We will explore prisoners' experiences of being treated for cancer to identify whether they receive equivalent care and, if not, the challenges faced by those delivering care. Cancer is a public health problem of increasing importance for the prison population which has increased by 90% since 1990 and is becoming older with a 161% rise in over 50s since 2002 [1]. Key risk factors for cancer such as smoking, drug and alcohol use, obesity and viral infections, are more prevalent in prison populations [2,3], and recent Canadian data shows lung, head and neck, liver and cervical cancers are also more common [4]. It was not possible to confirm cancer diagnoses using existing Ministry of Justice statistics until very recently. However, in an earlier feasibility study we used cancer registration data to identify new cancers diagnosed among prisoners in 7 London adult prisons in each 5-year period between 1986 and 2005 based on prison postcodes [5]. The ageing prison population is now increasing these numbers. The collation of 1995-2013 cancer registry data for this proposal identified 2,212 cases, with numbers increasing to around 200 new diagnoses in each of years 2010-13, making data sufficient for formal incidence and survival analyses. Additionally, the 2016 and 2017 Independent Prison Ombudsman reports have highlighted a lack of strategic approach to meet the health needs of the growing number of older prisoners [6, 7]. More information is therefore needed to determine how cancer treatment and care for prisoners compare to accepted standards, whether there are unnecessary personal and economic costs for patients or services and the potential for policies to improve co-ordination between prison and NHS cancer services.

Evidence explaining why this research is needed now

The UK prison literature focuses predominantly on mental health. A 1994 survey indicated the prevalence of a number of long-term conditions but did not specifically include cancer [8] and has not been repeated. A review of the health needs of inmates in England & Wales found that the needs of women, young offenders, older inmates and those from minority ethnic groups were different to those of the general population [9]. A review of prison health services concluded there needed to be a partnership between prison services and the NHS, together with a model that situates prison healthcare in the context of the community it serves [10]. Whilst no model has been developed, in recognition of the increased healthcare needs of inmates Public Health England (PHE) has developed a Health Needs Assessment tool in order to record more accurately the burden of all long-term conditions, and patients' met and unmet needs [11] underpinned by a strategic direction for Health and Justice [12]. It is established that prisoners should have access to health care of an equivalent standard as the general population [13, 14]. Cancer is a public health issue of increasing importance in English prisons because their population has now reached 85,000 and is also ageing [1]. Hitherto cancer has been a neglected area of concern. Despite the large amount of English research conducted on the experience and outcomes of people with cancer in the community, little is known about pathways to diagnosis and treatment for symptomatic cancer or adherence to NICE guidance for referral or treatment [15] for patients in prison. This study is therefore needed now because no data are available on the incidence, prevalence and cost of cancer in the prison population in England and no study has considered quality of care or explored patients' experiences. There is by necessity overreliance on individual case reports where concerns about care quality have been raised and no systematic investigation to inform policy and practice. There is also no prison-specific guidance on how to care for patients with cancer despite the fact that we know 25% of deaths in prison are due to cancer [16-19]. While studies have shown prison nurses struggle with the ‘boundaries between the cultures of custody and caring’ [20] and the challenges of caring for inmates [21,22], none have looked at prison clinicians experiences of caring for cancer patients or the perspective of hospital-based clinicians on treating patients from prison.

Aims and objectives We aim to identify cancer diagnoses, treatment pathways and cancer care experiences for people diagnosed in prisons and the challenges faced by prison staff and health professionals providing cancer care. The purpose of this mixed methods study is to assess and explain the incidence, prevalence, burden and potential cost of cancer in English prisons, equity of access to cancer care, experiences of care, in order to identify areas where the quality of care can be improved, examples of best practice and develop priorities and recommendations to inform and improve local services and English prison cancer care policy.

Our objectives are to:

1. Describe the burden of cancer within English prisons by examining those aspects of its epidemiology (incidence and prevalence) and potential cost of direct relevance to commissioning NHS cancer care services including:

a) Comparative national trends (1998 to 2017) for new cancer incidence in young people and adults aged over 16 serving a prison sentence with the English general population

b) Comparative disease stage at diagnosis, pathways to diagnosis and treatment, treatments received, days spent in hospital, one and five-year survival rates and cause of death for a cohort of patients diagnosed in prison with the most common cancers compared with other English residents with these cancers

d) Estimates of the prevalence of cancer among the prison population including all cancers diagnosed in patients during a prison sentence and pre-existing cancers requiring further treatment or care, including follow-up, in prison.

e) Comparative costs for cancer in prisons of (i) the cost of care in the community; (ii) the cost of alternative pathways of cancer care in prison.

2. Explore and explain why discrepancies in experiences of diagnosis, treatment, care and support occur from the perspectives of patients in prison, prison staff and clinicians by presenting:

a) Comparative analyses of National Cancer Patient Experience Survey results (2010-2016) for patients in prison with those reported for all English cancer patients.

b) Qualitative analyses of experiences and challenges recounted in individual interviews of people diagnosed or receiving treatment and support during a custodial sentence; and of staff and clinicians caring for patients in prison.

c) An explanatory model that will explain how and why discrepancies in the provision of cancer care to patients in prison occur in order to identify areas for improvement.

3. Develop priorities and recommendations to improve the quality of cancer care in prisons, care of prisoner-patients in hospital and the policy underpinning the commissioning of cancer services and refine the explanatory model where appropriate:

a) Develop vignettes from data generated in phases 1 and 2 above to present in three co-production workshops with patient and staff members to map their experience and the delivery of cancer care to define key areas for improving cancer care delivery .

b) Present the research and co-design workshop findings, w to an expert panel to using a ‘policy lab’ approach to develop priorities and recommendations for practice, policy and future research.

c) Consult with participants to refine the recommendations and identify areas in the care pathway for interventions.

Research Plan/Methods

This mixed method study employs a sequential explanatory design [23] to be carried out in three phases.

Phase 1 will be a quantitative epidemiological comparison of cancer care pathways and health economic analysis of cancer newly diagnosed in the prison population. This will describe the current state of cancer care for people diagnosed while serving a custodial sentence and begin to explain some of differences between the two groups and any consequences.

Phase 2 will be a qualitative interview study to understand the experience of diagnosis, treatment, and care from the perspectives of patients, clinicians and custodial staff. The focus for Phase 2 will, therefore, be to identify individual (patient, prison and NHS professionals) and system level (prisons, NHS) factors that influence the diagnosis, treatment and care of patients with cancer in prison as well as exploring how care might be improved and identifying examples of good practice.

The rationale for using both methodologies is that neither on their own will provide a complete description or explanation of key issues. Results from Phase 1 will therefore guide sample selection and the topics to be discussed in the interviews. Given the paucity of research on the cancer incidence, treatment and patient experience in the prison population and the challenges of undertaking research with this patient group, data from Phases 1 and 2 will be used to develop an explanatory model of how and why discrepancies in cancer care occur for patients in prison. The explanatory model will, in turn, inform development of the vignettes that will be used in Phase 3

Phase 3 will use a participatory approach to develop priorities and recommendations for future policy, practice and research. The method for Phase 3 will be three workshops based on the principles of co-production [24] and a policy lab meeting involving expert patient, prison and NHS clinicians, commissioner and policy makers.

PHASE 1 Quantitative data:

Hypotheses:

1) Based on our previous findings (3,5) and recent Canadian work (4) we hypothesise that the number of new cancer diagnoses has increased in prisons alongside an ageing population over the last 20 years, with cervical cancer diagnosed through opportunistic screening being the most common cancer in women, while smoking-related cancers, particularly lung cancer, is most common in men.

2) Based on clinical experiences reported to us from around the country we hypothesise that for cancer patients in prison, stage of disease for common cancers presenting symptomatically, is more advanced at diagnosis, treatment is underutilised, delayed, or does not follow best practice guidance and survival is lower as a consequence.

3) Based on nursing experiences reported to us from across the country we hypothesise that prisoners are less likely to have access to a named clinical nurse specialist and so report less positive experiences of diagnosis, support and treatment than other cancer patients in England.

4) Based on nursing experiences reported to us from across the country we hypothesise that the cost of cancer care for people in prison is greater than the cost of care for people of equivalent age, sex and year of diagnosis with cancer living in the community.

Methods

Our main analyses will concern the cohort of males and females diagnosed with cancer while in prison during the years 1998 to 2017. Cancer registration records are initiated by pathology data received from hospitals (or death certificate data) and monthly electronic data feeds received by Public Health England's National Cancer Registration and Analysis Service (NCRAS) from hospitals about new treatments and admissions [25]. These data are carefully checked and linked to a single tumour in one individual by means of their name, sex, date of birth, NHS number, address, and postcode of residence. The address and postcode recorded at diagnosis will be used to identify all invasive and in-situ cancers (but excluding non-melanoma skin cancer) diagnosed in individuals while they were in prison. We will use postcodes of all prisons listed in the Health and Social Care Information Centre's Organisation Data Service, including those now closed [26], supplemented by an additional search of the registration address field for 'Prison', 'HMP' and 'H.M.P'. For the identified patients, we will be able to extract full cancer registration records from the Cancer Analysis System within NCRAS [25]. Based on an initial collation of data for 1995-2013 we expect the final study cohort to be over 2500 individual patients whose diagnosis was made while in prison.

We will examine the total numbers of newly diagnosed cancers in prison for each year to assess the incidence trends over the study period. Cancer diagnoses for five-year periods will be collated to identify changes in the most common types of cancers diagnosed in prison. We will also calculate age-standardised incidence rates of all cancers in male and female prisoners separately and compare these with incidence rates in the English general population using incidence rate ratios and 95% confidence intervals. Estimates of the size of the English prison population will be provided by the Ministry of Justice, and we will standardise using the 2013 European standard population. The relative standard error (RSE) will be examined for specific cancers and male and female age-standardised incidence rates and rate ratios will be presented where numbers are large enough (RSE>0.3).

Information on patient and tumour characteristics (e.g. age, sex, year and stage of disease at diagnosis) and recorded treatment (including cancer surgery, chemotherapy, radiotherapy and hormone therapy) form part of the cancer registration dataset. We will use registration data linked to Hospital Episode Statistics (HES) [27] to determine and examine the number of bed days spent within the first six months of diagnosis.

To assess prevalence of cancer within the prison population which will also have an impact on prison health services we will use in- and outpatient HES episodes for individuals diagnosed with cancer on the basis of cancer registry-linked records.

We will use the linked cancer registration and National Cancer Patient Experience Survey (NCPES) dataset [28] to determine how many and what proportion of eligible prisoners in our cohort completed a survey. We will compare the age, sex and tumour type of patients responding to the survey and compare responses to all questions where more than 40 patients in prison have responded, with non-prisoners' responses matched for age, sex, cancer type and stage of disease. Initial information received from Quality Health, based on questionnaires that were known to have been sent to prison addresses, suggests over 50 questions could be analysed for the years 2010-2014. We will collate the survey years 2010-2016 in order to increase the size of the sample. However, we also anticipate that using the new linked registry NCPES dataset we will identify more patients who received a survey in prison as well as others who received a survey at a later date when they had been discharged from prison. Where patients have completed several surveys, we will include the one completed within one year of their diagnosis (determined by the registry date of diagnosis).

To test our hypothesis that the cost of cancer care in prison is greater than that in the community we will (i) calculate the cost of each cancer care pathway in prison; (ii) calculate the total cost of illness (burden) of cancer care in prisons per year; and (iii) compare the cost of cancer care in prison with that in the community.

To calculate the cost of different cancer care pathways we will use HES and cancer registry data to calculate recorded treatment and inpatient and outpatient cancer related attendances for people diagnosed in prison and report these by cancer type, age, sex and year of diagnosis. We will assess the feasibility of obtaining data on the cost of transfer from prison to hospital to include in the total cost of care. To calculate the total burden of disease we will apply Ministry of Justice data on prison population size and NHS reference cost data [29] to cancer registry and Hospital Episode Statistics (HES) data to calculate the direct costs of cancer care for people diagnosed while in prison by multiplying cases per year by cost of care. To provide information on what we hypothesise is the extra cost of cancer care for people in prison we will report the average cost per patient of the cancer care pathway in prison compared to in the community adjusted by age, gender, cancer diagnosis and year of diagnosis. The cost of cancer care in the community will be obtained from other studies investigating the cost of cancer treatment including NIHR BRIGHTLIGHT, Respect 21 at UCL, as well as eSMART, an EU funded Study with a strand of work led by King's/Surrey (Armes). As part of this work we will use Excel to develop cost of prison care pathways that can be used to test the cost impact of proposed changes to models of cancer care in Phase 3. Applying Ministry of Justice data on prison population size and NHS reference cost data [29] to cancer registry and HES data we will calculate the direct costs of cancer care for people diagnosed while in prison by multiplying cases per year by cost of care. We will assess the feasibility of obtaining data on the cost of transfer from prison to hospital to include in the total cost of care. The above data will also be used to calculate the average cost per patient of the cancer care pathway in prison compared to in the community adjusted by age, gender, cancer diagnosis and year of diagnosis.

Data analysis

To test hypothesis 1, we will present trends in numbers in five-year periods and recent age-standardised incidence rates using the 2013 European standard population and determine the most common cancers in men and women.

To test hypothesis 2, proportions of patients with different disease stage at diagnosis will be compared between prisoners and the English population for the most common cancer types. Logistic regression will be used to determine whether there are differences in the two population groups in terms of whether they were diagnosed with metastatic disease and were recorded as receiving treatment, including cancer surgery, radiotherapy, chemotherapy and hormone therapy as appropriate. Analysis will adjust for the case mix factors usually considered in comparative analysis which include sex, age, year of diagnosis and stage of disease (for treatment analysis). The reason for adjustment is to determine whether it is these factors rather than diagnosis in prison itself that might be explaining any difference between the prison and non-prison groups. Cox regression will be used to determine any differences in time from diagnosis to first recorded treatment, again taking case mix factors outlined above into account. We will present Kaplan-Meier survival curves to examine crude survival separately for males and females diagnosed with different cancer types where appropriate. We will also use Cox regression to compare survival, adjusting for case mix factors.

Power calculations

We have estimated the hypothetical power for detecting a difference in stage distribution of diagnosed cancers and in survival outcomes for lung cancer, it being the most common and lethal cancer in the prison population. The numbers given below are on the conservative side, given that by the proposed start date of the study, we will be able to add another year of cancer registrations to the dataset.

We estimate we will have stage information on 60% of cancer patients who were diagnosed in prison during the period of study where stage was collected nationally (2009 to 2015), and in a population of just over 1,000 people with a cancer diagnosis whilst in prison during that period, we expect to therefore have at least 600 cancers with stage information. When for each person diagnosed in prison, we sample five persons matched on diagnosis year, cancer site, sex and age as controls from the cancer registry, and where we know that 28% of all cancers are diagnosed as advanced stage (stage 4, based on 2009-2015 national figures), we would have at least 90% power to detect an odds ratio of 1.4 or higher for people diagnosed in prison having more advanced stage disease (30).

An initial estimate of the number of people diagnosed lung cancer in prison during the period 1997-2016 is 227. When we consider the median survival of lung cancer being six months, a one-year survival rate of 30%, and include in our analyses the total cancer registry lung cancer cohort that is at least a thousand times the size of the prison-diagnosed patient group, we would have at least 90% power to detect a hazard ratio of 1.4 or higher (31).

Given these examples, we believe our study will be sufficiently powered to detect meaningful associations. Using linked HES data, we will calculate the number of bed days in hospital within six months of diagnosis to estimate length of hospital stay. We will compare the average length of stay for males and females diagnosed with the more common cancer types using t-tests, and use logistic regression to examine any differences between the prison and general populations in terms of a long length of stay (to be defined for each cancer type), adjusting for case mix factors. Where comparison between patients in prison and those in the community reveal large differences in stage of disease at diagnosis, treatments received or survival we will compare time from diagnosis to treatment, and treatment with accepted NHS Cancer standards [32, 33].

Hypothesis 3: If sufficient prison patients have completed the NCPES survey we will compare proportions in each of the prison and non-prison group reporting negative experiences for each question using Chi-squared test, excluding those where responses to the question were ‘not applicable’, ‘do not know’ or ‘cannot remember’, and where an answer was missing.

To test hypothesis 4 on the differing cost of care pathways we will report descriptive statistics (frequencies, means, standard deviations, medians, inter-quartile ranges) of inpatient and outpatient cancer related attendances by cancer diagnosis, age, sex and year of diagnosis for people diagnosed in prison. Using patient level data and appropriate general linear model (GLM) we will report age, gender and diagnosis year adjusted costs for equivalent cancer diagnoses in prison compared to the general population. GLMs will also be used to calculate means, standard errors and 95% confidence intervals for the cost of care. The modelling of the cost of care in the cancer pathway will draw on other work Rachael Hunter is doing as part of RESPECT-21 [34], a HS&DR funded grant to evaluate the implementation of new cancer care pathways in London and Greater Manchester.

PHASE 2 Qualitative interview study:

In Phase 2 we gather and use rich in depth interview data to develop an explanatory model to show how, why and in what situations discrepancies in treatment and care of prisoner-patients with cancer occur from which we will make theoretically-based proposals as to how treatment and care can be improved.

We will work closely with Revolving Doors Agency (RDA) who will identify three services users (at least one male, one female) with experience of serving time in prison from their pool of trained Experts by experience from around the country. They will play an active role in governance via the Project Advisory Group and advise on the development of interview schedules, recruitment, and act as co-facilitators in interviews and take part in the analysis and write up of findings. The service users will be paid members of the team and their views and contributions will be treated as in equal value to that of the research team. We will remain vigilant to any power imbalances in the research process and will negate these further by having people with lived experience on our advisory board.

Sampling

We aim to capture a range of perspectives from both patients and the professionals working with them and so will use purposive sampling.

Group 1: Professionals.

Development of interview schedule

Phase 1 results and advice from our Project Advisory subgroup of two prison Heads of Healthcare, two GPs working in prison and one prison chaplain will inform the development of the interview schedule to ensure that we probe for explanations of any inequalities identified. Topics covered will reflect those covered in patient interviews (see below) but also include governance issues relating to health and safety and the impact of sudden discharge and tagging in each of the settings as highlighted by reports from colleagues.

We will undertake in depth qualitative interviews with 10 Prison Officers, 10 NHS clinicians in the community and 10 clinicians working in prisons. Participants will be purposively selected to ensure maximum variation [35] (male vs female prisons; prison type; discipline and level of seniority). Participants will have experience of caring for an individual in prison who has had a diagnosis of cancer. We will identify such participants using a multi-pronged approach as follows:

1) Prison Officers: We will ask Prison Governors who have agreed to allow recruitment of people with cancer from their prisons to raise awareness of the study with relevant prison staff. We will also advertise the study via the Prison Officers Association, Howard League for Prison Reform, Prison Reform Trust, Clinks, and the National Association for the Care and Resettlement of Offenders (NACRO)
2) Prison Health Professionals: We will advertise the study via the Royal College of Nursing in Justice and Forensic Health Care Forum, NCRI Primary Care Clinical Studies Group, Royal College of GPs' Secure Environments Group, and through Public Health England's Health and Justice National Network
3) NHS Cancer Clinicians: We will advertise the study via National Cancer Research Institute Clinical Studies Groups, UKONS, Macmillan Cancer Support Communities of Practice (including GPs, Cancer Nurses, Allied Health Professionals), Royal College of Nursing Cancer and Breast Care Forum.
4) We will also use the snowball recruitment method for all three professional groups if recruitment is lower than anticipated.

Group 2: Patients.

Development of interview schedule

The topic guides for the interviews will be developed in collaboration with our Experts by Experience and Project Advisory Group colleagues. Based on reports from clinical colleagues from across the UK we anticipate we will include questions that will explore: the diagnostic process and factors that deleteriously affect it; how and why treatment decisions are made and whether or not prisoner-patients receive treatment in accordance with best practice guidance; monitoring and management of treatment or cancer-related toxicities/symptoms (e.g. pain, nausea/vomiting, diarrhoea/constipation); access to a named clinical nurse specialist; communication and co-ordination of care across the different sectors; and issues related to movement between prison institutions.

Inclusion/exclusion criteria

We will undertake in-depth interviews with up to 40 diagnosed patients in prison. Potential participants will include sentenced and remand patients from all types of publicly and privately managed prisons identified through the network of prison healthcare managers. Participants will be purposively selected to ensure maximum variation [35] (male vs female; prison type; cancer and/or treatment type) and their potential to explore/explain findings from Phase 1. Participants will be selected if they have been diagnosed with cancer in the previous 5 years. Patients considered by clinical staff as too distressed by their diagnosis, other conditions or else unable to understand the study information sufficient to be able to give formal consent will be excluded from the study. Patients whom officers consider a risk to the interviewer will also be excluded.

Recruitment

Group 1: Professionals

In response to study advertisements potentially interested participants will be asked to contact the research team if they are willing to participate. The research team will discuss the study verbally and provide a Participant Information Sheet (PIS). Potential participants will have a minimum of 24-48 hours to decide. Written informed consent will be gained prior to undertaking interviews.

Group 2: Patients

Prison clinicians will identity eligible participants and describe the study to them. If the person is willing to consider participation they will provide them with a study flyer and the Participant Information Sheet (PIS) (both will be reviewed using the Flesch-Kincaid Reading Ease Tool to ensure they meet the needs of people with low literacy levels) and gain verbal consent for the research team to make contact. A member of the research team, including Experts by Experience, will explain the study verbally, read out the PIS if appropriate and answer questions. Potential participants will have a minimum of 24 hours to make a decision. Written informed consent will be gained prior to undertaking interviews. Prior to attending to undertake an interview we will check with relevant prison staff whether a potential participant has been suddenly discharged. We will collate information if this occurs and present it with the findings so the likely impact can be incorporated into the findings.

Data Collection

Group 1: Professionals

Interviews will be conducted at a mutually convenient time either in person or via the telephone, according to the interviewees' preference.

Group 2: Patients

Interviews will be conducted face to face in the prison setting at a time that is convenient to the patient and prison personnel. Interviews will be conducted by two people – the Research Associate working on the project and a trained Expert by Experience from Revolving Doors Agency.

Patient and Professional Groups

Interviews will last approximately 60 minutes and be audio-recorded if possible. If audio-recording is not possible from a prison governance perspective one of the interviewers will write verbatim notes on what is discussed. Participants from both groups will be free to withdraw at any time up to and including the actual interview. An interview schedule informed by findings from Phase 1 will be developed by the research team and Experts by Experience from Revolving Doors Agency. The interviews will explore participants' experiences of how care is organised and co-ordinated to ensure timely diagnosis and provision of appropriate treatment and care. Patients will be asked about their experiences of care. In addition, challenges and good practice will also be discussed in relation to individual (patient, prison and NHS professionals) and system level (prisons, NHS) factors that affect care provision.

Data Analysis

Interviews will be verbatim transcribed/typed up, anonymised and the interview transcripts will be managed with NVIVO software. Data will be analysed using Framework Analysis, a widely used matrix-based method for collating, reviewing and understanding qualitative data [37, 38]. In the analysis stage the data is sifted, charted and sorted in accordance with key issues and themes. This involves a five-step process: 1. familiarization; 2. identifying a thematic framework; 3. indexing; 4. charting; and 5. mapping and interpretation [37, 38]. Data from the patients and professional groups will be analysed separately to identify common themes within each group before undertaking a cross-group analysis. Findings will be tabulated and summary tables presented. The explanatory model will be developed through an iterative process during both the within group and across group analyses. We will explicitly include key elements required for developing an explanatory model: context (norms, regulations, procedures, barriers, facilitators); mechanism (how does it work/occur); and outcome (impact at individual and system level). Data analysis will be supported by a subgroup of co-investigators who have qualitative expertise, including the Experts by Experience, and interpretation of the findings will be contributed to by the whole research team. Validity and credibility will be assessed using the criteria developed by Patton: verification, rival explanations, negative cases, and triangulation [39]. Data will be stored securely and fully anonymised.

Data Integration to form an initial explanatory model

Once analyses from both Phases 1 and 2 of the study are completed, findings will be integrated so that the explanatory account can be further refined. For sequential explanatory mixed methods studies this involves ‘connecting’ the findings in order to make interpretations and draw conclusions [23]. The qualitative data will be used to expand the findings from the quantitative results to create a better understanding and explanation of the challenges faced in diagnosing and delivering cancer care in the prison setting. This will be achieved by connection/triangulation of quantitative and qualitative findings in relation to their convergence, complementarity, and discrepancy so as to develop common themes and meta-themes [40]. The resulting explanatory model will be illustrated as a visual display comprising a summary table showing side-by-side comparison. This will be undertaken by the whole research team led by ED, JA & RT, will make maximum use of the differing data sources and findings and will be presented as initial research findings.

PHASE 3 Co-production of priorities and recommendations for improvement

The overall aim of Phase 3 is to incorporate co-production principles for service development [24] using the explanatory model developed in Phase 1 and 2 into the development of priorities and recommendations to improve quality of cancer care in prisons, care of patients from prison in hospital and the policy underpinning the commissioning of cancer services

Our objectives are:

a) Develop vignettes from the explanatory model generated in phases 1 and 2 to present in workshops with people who have experience of being in prison with cancer and NHS and prison staff to map experience and the delivery of cancer care that may be improved.

b) Present vignettes to co-production workshops of 1) people with experience of being in prison with cancer 2) prison and health care professionals and 3) a mixed workshop group to discuss and develop recommendations for practice and policy and refine the explanatory model where appropriate.

c) Consult with Experts by Experience, clinical and prison staff and stakeholders and policy makers to refine the recommendations and identify priority areas for policy and for interventions in the care pathway.

Stage 1: Vignettes will be developed from the initial explanatory model developed by the research team using composite non-identifiable research findings from the perspective of each of patients, NHS staff, prison officers and prison health care staff. The patient vignette will be co-constructed with Experts by Experience

Stage 2: This will involve three online workshops (people who have been in prison with cancer, and prison and healthcare professionals, and a mix of participants). The workshops will use audio recorded vignettes generated in stage 1 to encourage interactive discussions and generate new thinking, alternative explanations and potential solutions to problems raised. Consensus will not be sought, rather perspectives, opinions and experiences elicited allowing scenario mapping. This will identify key ideas and hypotheses on how prison cancer care could be improved. We will refine the explanatory model where appropriate. The co-design workshops will be facilitated by a health care professional with extensive experience of cancer care, co-design and improvement work. The workshops will also include a scriptwriter linked to Synergy Theatre Project, an organisation using theatre to help rehabilitation of ex-offenders, as an observer. In the third workshop this will be the main group discussions only. The scriptwriter will develop the dialogue to be used to create a ‘talking heads’ film that will describe the overall research findings and will be launched with the final report.

Stage 3: A new panel of experts will be convened (including Experts by Experience, senior healthcare professionals, prison professionals, policy makers, and commissioners) who have not been involved in previous stages. This will be carried out with the King’s Policy Institute using their recently developed and tested ‘Policy Labs’ [41] approach to formulate options for policy design and plan for future policy evaluation. Policy Labs are collaborative workshop sessions that bring together expertise from a range of stakeholders. This will include prison health researchers, expert patients, senior healthcare professionals, prison professionals, policy makers, and commissioners who have not been involved in previous stages. These will be identified from current project advisory group members and networks established during the period of the grant.

A ‘briefing pack’ will be developed based on the collective evidence of all phases of the study, which will be sent in confidence to participants ahead of the Policy Lab. This is to make it easier for participants to work through the available evidence in advance and ensure they have all received the same information. This will potentially include the talking head videos developed in section 6.2. If any of the workshop members have literacy problems, we will arrange virtual meetings for this to be relayed verbally.

The duration of the Policy Lab will depend on whether this is a face-to-face meeting or virtual. If held face-to-face it will be a full day (6-hour event, with breaks) to allow time for discussion and will be held in the dedicated Policy Lab space at King's College London. It will be externally facilitated by an expert in Policy Lab methodology and leading policy discussions. The format of the Policy Lab will depend upon the content of the briefing pack but will include plenary sessions and breakout meetings exploring key questions, for example, Is the evidence compelling or is further research needed to implement change? What are the barriers to implementing change? How can these barriers be overcome? The ideas that are generated in the Lab will form the basis of a report outlining the recommendations.

Stage 4: The analysis and interpretation emerging during the Policy Lab will lead to the writing and refining of an overarching explanatory account for cancer care in prisons. Emerging national standards, pathways of care and core competencies are anticipated. Health economic outcomes from Phase 1 will be used to evaluate the financial impact to HM Prison Service and the NHS of any changes made. This will be circulated to participants and comments considered for the final version. Identification of priority areas for potential intervention and their proposed mechanism of action will be included and recommendations for future empirical evaluation and testing of the effect on outcomes will be proposed.

Recruitment of participants

We will work closely with RDA, Prison Reform Trust, National Association for the Care and Resettlement of Offenders (NACRO), Working Chance, Rehabilitation for Addicted Prisoners Trust and cancer charities such as CLIC Sargent, Macmillan Cancer Support, Breast Cancer Now who will identify services users with experience of serving time in prison from around the country to take part in the workshop and panel meetings together with families and carers.

We will work nationally with cancer charities such as CLIC Sargent, Macmillan Cancer Support, Breast Cancer Care and others, and also prison charities such as Working Chance and Rehabilitation for Addicted Prisoners Trusts to identify people who have been in prison with cancer who may be interested in taking part in the workshops. We will use the same wide range of national professional organisations as in Phase 2 to identify custodial and clinical staff for the workshops, but we expect that by this point there may be a higher element of referral through networks of colleagues who have a particular interest in cancer care in prison. We will ensure that as wide a range of perspectives from staff working in different types of prisons are represented.

Management of workshops

Co-production principles are based on the development of equal partnerships with people who have used services and those who provide them. The underlying values include an appreciation of equality, diversity, accessibility and reciprocity of all participants and a clear but not prescribed approach at each event [24]. We will provide a clear definition at the outset of the goals of the work for all participants informed by Phases 1 and 2 findings and our Project Advisory Group. Some of the factors required for the implementation of activities based upon this approach include changes in organisational culture, structure, practice and reviews of progress. These principles have been extensively tested more often in NHS cancer services, for example, in cancer policy development Experience-based Co-design [41,42] and the work of the National Cancer Research Institute Consumer Liaison Group, than in prison services. An ambitious element of Phase 3 will therefore be to apply this approach to a new health setting and to generate the support and knowledge needed to implement it. Anecdotally, however, we know that prison staff and health professionals are often keen to receive more specific training in cancer care and information resources for their patients, but that this is not always available to them. Taylor and Whelan, who will lead Phase 3, bring experience of developing co-production approaches over many years with teenagers and young adults with cancer. They are aware of the challenges of managing large groups of people discussing sensitive topics and will engage with senior members of charity and prison sectors in this phase.

Settings, accessibility participants costs

Experience of RDA and Prison Reform Trust is that online workshops are feasible for people who have previously been in prison. We can provide 2GB of mobile phone data but participants must have a mobile phone or computer access). We will ensure materials are well-prepared and information is available in audio form for those with literacy problems. We will offer participants expenses to cover childcare costs or a voucher of up to £50 for their time, whichever is preferred.

Data analysis

We will undertake a scenario analysis to develop an understanding of the cost implications to HM Prison Service and the NHS of the proposed changes. This will involve modelling the new care pathway and applying unit cost data to the new models of cancer care in prison multiplied by expected number of patients. Prevalence data will be taken from Phase 1. We will include an estimated cost of implementation. We will report yearly budget impact to different stakeholders.

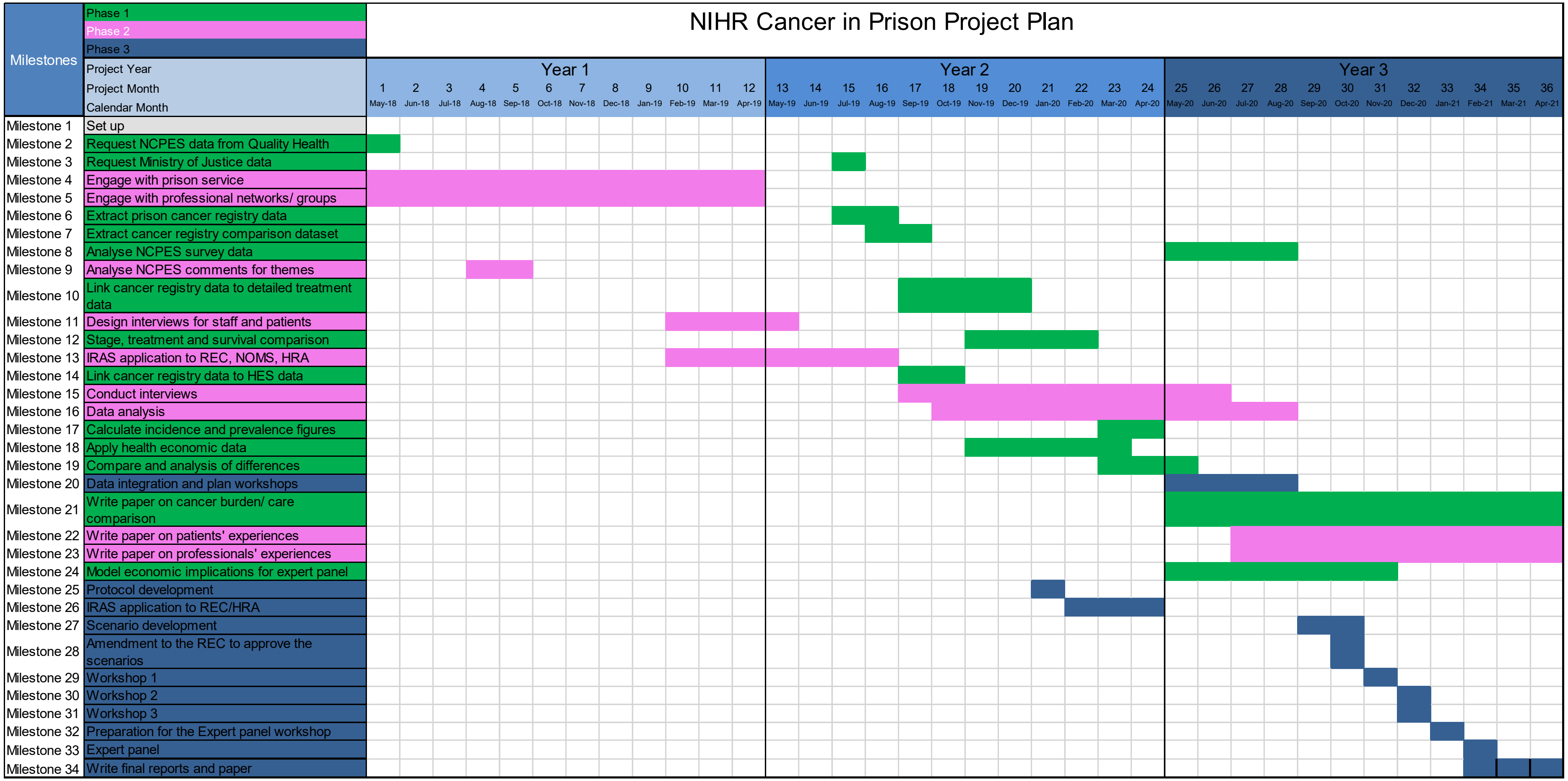
Study dissemination and projected outputs

We will actively disseminate eight knowledge outputs for different audiences to raise awareness of our findings and influence the environment for policy and practice change. We will reach academics, clinicians and commissioners by presenting 5 papers on 1) cancer burden and outcomes 2) patients' experiences 3) staff experiences 4) overall explanatory model 5) co-production of recommendations at NCRI and PHE national conferences, The Academy for Justice Commissioning Forum, the European Cancer Organisation, and WHO Europe Prison Health Research and Engagement Network. We will publish in open access international journals e.g. Lancet Oncology, British Medical Journal, European Journal of Cancer; British Journal of Cancer. To reach policy makers the Policy Institute at King's will help produce a targeted policy report and briefing document explaining our findings and their implications. These will be devised with the Institute's network of former ministers, senior civil servants, parliamentarians and philanthropic leaders who have experience of translating knowledge into policy options and launched at a House of Lord's policy event. King's and PHE press offices will disseminate these outputs using infographics to national media, websites, social media, online forums and newsletters of professional groups, prisoners and collaborating organisations. With Science Gallery London we will engage with artists and ex-offenders working with Synergy Theatre to produce a short digital film which portrays the main findings of the research. This will aim to humanises the experience of patients in prison and present ethical issues raised by our findings. We will disseminate this in digital media used by harder to reach younger audiences and explore showing this in prisons to generate a new public presence, engagement, and discussion to complement traditional audiences accessing mainstream media outlets. Our strategy will also be informed by our Project

Advisory Group, independently chaired by Baroness Delyth Morgan. Members will include Rupert Bailie, Head of Custodial Health and Wellbeing, HMPPS; Fiona Gossick and Mark Gillyon-Powell Lead members of NHS England Commissioning, Eamonn O'Moore, National Lead, Health and Justice PHE; three Experts by Experience from Revolving Doors Agency; two prison heads of healthcare; Dr Kat Holgate Prison GP; Rev Tim Bryan HMPPS Chaplaincy Advisor; Mr Pete Small, Governor HMP Rye Hill, John Podmore, Criminal Justice Consultant, Christine Allmark, NCRI Consumer Liaison Group, and, Dr Karen Roberts, Chief Nurse, Macmillan Cancer Support.

We anticipate the following effects and impact of the above outputs:
1. On knowledge: By collating existing data we will increase research capacity, and identify where data can be better exploited, collected or linked together. We will show how interviews with patients inform ways of providing care and support in prisons, and how the needs and coping of patients' family or carers may be studied. Our workshop and panel meetings will involve patients, carers and influential stakeholders in co-developing new research and implementation questions. Our outputs will identify implications for other conditions common in ageing prison populations including mental health, cardiovascular, and musculoskeletal problems, and we will advocate for knowledge forums and conferences to sustain this focus.
2. On health: Our work throughout with patients will identify what matters to them about improving cancer care experiences and reducing inequalities. The established expertise of The Policy Institute at King's will help translate the findings and panel recommendations directly into a policy report and briefing and so sustain emerging policy interest in prison standards for long term conditions. By engaging senior NHS commissioners, we will inform local strategic needs assessments, integrated physical and mental health care pathways, effective liaison between settings, advocacy for routine publication of cancer in prison statistics, and new NICE guidance for prisoners.
3. On health services: We will identify areas of good practice in referral, risk assessment and recommendations for core care competencies. Interviews with health and prison professionals will define larger surveys to inform staff training in implementing new care models while better health economic data will show their cost impact on prison and NHS services. Our stakeholder workshop and panel meetings will draw on members' networks to involve the Royal Colleges Nursing in Justice and Criminal Health Forum and General Practitioners Secure Environments Group, The Ministry of Justice, NHS England, Macmillan Cancer Support, Cancer Research UK, the All Parliamentary Group Against Cancer and individual prisons.
4. On society: Science Gallery London connects art, science and health to drive innovation. By actively engaging young people in our findings they will bring their voices to our discussions with policy makers, greatly extend the reach of our outputs, and help feed our findings back to patients in prison.

Plan of investigation and timetable



NIHR Cancer in Prison Project Plan

🟩 Phase 1
🟪 Phase 2
🟦 Phase 3

Milestones	Project Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
	Project Year	Year 1												Year 2												Year 3											
	Calendar Month	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21
Milestone 1	Set up																																				
Milestone 2	Request NCPES data from Quality Health	🟩																																			
Milestone 3	Request Ministry of Justice data															🟩																					
Milestone 4	Engage with prison service	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪																								
Milestone 5	Engage with professional networks/ groups	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪																								
Milestone 6	Extract prison cancer registry data															🟩	🟩																				
Milestone 7	Extract cancer registry comparison dataset																🟩	🟩																			
Milestone 8	Analyse NCPES survey data																									🟩	🟩	🟩	🟩								
Milestone 9	Analyse NCPES comments for themes				🟪	🟪																															
Milestone 10	Link cancer registry data to detailed treatment data																	🟩	🟩	🟩	🟩																
Milestone 11	Design interviews for staff and patients										🟪	🟪	🟪	🟪																							
Milestone 12	Stage, treatment and survival comparison																			🟩	🟩	🟩	🟩														
Milestone 13	IRAS application to REC, NOMS, HRA										🟪	🟪	🟪	🟪	🟪	🟪	🟪																				
Milestone 14	Link cancer registry data to HES data																	🟩	🟩																		
Milestone 15	Conduct interviews																	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪										
Milestone 16	Data analysis																		🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪								
Milestone 17	Calculate incidence and prevalence figures																							🟩	🟩												
Milestone 18	Apply health economic data																			🟩	🟩	🟩	🟩	🟩													
Milestone 19	Compare and analysis of differences																							🟩	🟩	🟩											
Milestone 20	Data integration and plan workshops																									🟦	🟦	🟦	🟦								
Milestone 21	Write paper on cancer burden/ care comparison																									🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩
Milestone 22	Write paper on patients' experiences																											🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪
Milestone 23	Write paper on professionals' experiences																											🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪	🟪
Milestone 24	Model economic implications for expert panel																									🟩	🟩	🟩	🟩	🟩	🟩	🟩					
Milestone 25	Protocol development																					🟦															
Milestone 26	IRAS application to REC/HRA																						🟦	🟦	🟦												
Milestone 27	Scenario development																													🟦	🟦						
Milestone 28	Amendment to the REC to approve the scenarios																														🟦						
Milestone 29	Workshop 1																															🟦					
Milestone 30	Workshop 2																																🟦				
Milestone 31	Workshop 3																																🟦				
Milestone 32	Preparation for the Expert panel workshop																																	🟦			
Milestone 33	Expert panel																																		🟦		
Milestone 34	Write final reports and paper																																		🟦	🟦	🟦

Project management

The core staff will meet monthly organised and led by Davies and will include phase leads and key personnel working in each phase. Phase leads (P1: Lüchtenborg, P2: Armes, P3: Taylor/Whelan) will oversee their areas and report to the co-applicant team which will continue to meet regularly, monthly in the set up period and initial period of recruitment in phase 2, continuing as indicated to bi-monthly. Co-applicants are based in three localities (SE London, North London, Guildford,) so will use teleconferencing and face-to-face meetings to coincide with attendance for PHE Health & Justice and other London meetings. Additional support will be Phase 1: Hunter, Plugge, Taylor, Whelan; Phase 2: Breedvelt, Plugge, Taylor; Phase 3: Armes, Breedvelt,, Hunter, Plugge.

Core staff will be based at King's College London and University of Surrey. Davies will be responsible for the study operation, co-ordination, progress monitoring of objectives and milestones, for identifying and resolving any emerging liaison, communication, ethical, and governance risks or issues. She will be responsible for completing and submitting the six-monthly progress reports (supported by the phase leads). A research assistant will support analysis for phase 1 under supervision of Davies at King's College London and Lüchtenborg when working on secondment within PHE. The research associate for Phase 2 will work under the supervision of Armes.

The Project Advisory Group, with its independent chair, will provide clinical, contextual, methodological and ethical guidance. This group will be convened to meet at 4 months and approximately 6 monthly thereafter. Terms of reference defining the role and operation of the Group will be developed for initial agreement by members and reviewed. In particular, we recognise that we are studying a potentially vulnerable population and we will ensure a rapid response to any ethical concerns which arise, through the co-applicant team and with escalation to the Project Advisory Group as required. We will maintain close links to the cancer and prison community throughout with a communication strategy providing regular updates on recruitment and results.

Approval by ethics committees

Davies and Armes will be responsible (supported by Breedvelt, Plugge and Taylor) for securing the appropriate ethical reviews and approvals for this study and will begin drafting these before funding begins.

We do not anticipate needing ethical approval to begin Phase 1 by analysing existing cancer registry, hospital, cancer survey and population or health economic data. This is because these will take place within the National Cancer Registration and Analysis Service (NCRAS) within Public Health England in secure data areas that are covered by section 60 of the Health and Social Care Act 2001 which specifically enables the analysis and reporting of cancer data for population and health services uses. NCRAS is currently developing guidance in partnership with other NHS and charitable stakeholders whereby newly diagnosed patients are given information about the collection and use of their data and opportunity to opt out of these if they wish.

All data requested from the Ministry of Justice on the age and sex structure of the prison population will be anonymous and so their analysis will not need ethical approval.

However, National Offender Management Service (NOMs) approval will be needed for the overall study and ethical approval specifically for patient and prison staff interviews from Her

Majesty Prison and Probation Service (HMPPS). An application will be made through the IRAS system for Research Ethics Committee (REC), NOMs, and Health Research Agency (HRA) approval.   Approval for any amendments to the protocol will be submitted for approval as appropriate to NOMs or REC. A separate King's Research Ethics Committee application will be made for the Phase 3 co-design workshops. These events will involve recruitment of members of the public rather than potentially vulnerable patients through HMPPS or NHS services as will be the case in phase 2.

We will need Phase 1 results to inform the content of the interview schedules for Phase 2 and these will need to be at an advanced stage of detailed preparation before the IRAS application can be submitted. We will also need letters of support from prison governors, from staff professional networks and we will need to arrange the method of access and procedure for recruiting and conducting interviews with individual prisons. We will therefore need funding for this developmental phase before obtaining ethical approval. We expect to obtain approval to start interviews by September 2019 and complete interviews by June 2020.

Ethical issues to be considered

1) Consent: We will ensure that consent is given voluntarily with no coercion or deceit, by individuals fully informed about the study and with capacity to give written consent [44]. We will exclude those with severe mental health issues which prevent this. We will make it clear to potential participants in written and verbal information that although they are detained against their will, they are free to participate or decline without affecting their imprisonment or health care. Potential participants will have 24-48 hours to make their own decision.

2) Low levels of literacy: These mean we must ensure that information is pitched at an appropriate level (user input will be invaluable here).

3) Co-morbidity: We expect many potential participants to be aged over 50 years with co-morbidities [45]. To ensure they have opportunity to participate we will develop information with larger font sizes and that interviews occur in accessible places.

4) Data management: All qualitative data and other identifying information will be anonymised and demographic information kept separately and securely with access restricted to the research team. Transcription will exclude identifying details and transcribers will sign confidentiality agreements. Any publications will anonymise individuals or services. All quantitative data will be maintained within the secure NCRAS data servers which are accessed through the Section 251 areas of the offices in PHE London and Nottingham.

5) Confidentiality & Participant safety: Participants will be informed that certain disclosures, such as intent to harm themselves, someone else, or to escape, will be reported after discussion.

6) Researcher safety: researchers will undergo training before visiting prisons. Participants who pose a threat to their safety, as determined by custodial staff will be excluded.

7) Unexpected adverse effects: It is not anticipated that participation will have any adverse consequences on study participants. However, we recognise that discussions regarding health and health care may sometimes be distressing. We will ensure the researcher is able

to respond through training and by agreeing written guidelines for managing distressed participants with each prison. We will ensure the researcher has time to discuss their concerns with them and that very distressed participants are referred immediately or sign posted to other services if appropriate. We think this scenario unlikely but believe it is important to plan for it.

The conduct of the entire study will adhere to the standards set out in the Department of Health's Research Governance Framework for Health and Social Care, Second edition (2005).

Patient and public involvement

The aim of the patient and public involvement in this study are to make the research more grounded in the experiences and concerns of people affected my cancer and so make the research more accurate in representing experience and ultimately more effective in achieving change. People with experience of cancer and of working in a prison setting have been involved in identifying and prioritising questions for the research, designing the study, and developing the proposal. People with lived experience of being in prison and of receiving a cancer diagnosis will be involved in managing and undertaking the research, analysing and interpreting the results and disseminating its results.

Ms Christine Allmark will link the study to the large and influential national network of the National Cancer Research Institute Consumer Liaison Group by being a member the Advisory Group. She has experience of working in an educational role within prison and will ensure the research is done 'with rather than to users.' RDA will identify and support one male and one female user representative with experience of cancer diagnosis or care in prison to contribute to study governance as members of the Advisory Group. RDA Research Manager, supported by RDA Involvement Manager, will take an active and equal role in the Phase 2 qualitative research. RDA will enable input from its large network of Experts by Experience with direct experience of prison care into the interview schedule development and sense checking of materials used in recruitment. They will also act as a co-facilitator in patient interviews and take an active role in the data analysis and dissemination of findings. RDA will also recruit patients with experience of cancer diagnosis or care in prison to participate in Phase 3 workshop and panel meetings. Supported by RDA, users will play an active role in the dissemination of the findings at conferences and policy meetings.

Expertise and justification of support required

Dr Davies directed the Thames Cancer Registry and PHE London Knowledge and Intelligence Team working with many stakeholders to report local and national cancer inequalities. She will lead and co-ordinate this project.

Dr Lüchtenborg leads PHE national lung cancer analysis. She has quality assured the linked registry Cancer Patient Experience Survey data and will lead their analysis and presentation in Phases 1 and 3. Revolving Doors Agency brings extensive expertise in engaging ex-prisoners in research to support Phases 2 and 3.

Ms Hunter is a Health Economist who brings extensive expertise and experience of working with prison and HES data. She will lead the analysis and presentation of cost of care work in Phases 1 and 3.

Dr Plugge works with the WHO UK Collaborating Centre Health in Prisons Programme in the Health & Justice Team, PHE. She brings expertise in mixed methods prison health research and policy to support all phases.

Dr Armes has chaired the NCRI Psychosocial Oncology & Survivorship Clinical Studies Group and has extensive qualitative and mixed methods research expertise. She will lead Phase 2 and support Phase 3.

Ms Breedvelt has managed research for The Rehabilitation for Addicted Prisoners Trust and The Mental Health Foundation. She brings expertise in mixed methods to support Phases 2 and 3.

Dr Taylor is project lead for BRIGHTLIGHT, an NIHR programme evaluating teenage and young adult cancer services and directs the UCLH Centre for Nursing, Midwifery, Allied Health Professions and Pharmacy-Led Research. She brings expertise in using qualitative and quantitative data and co-production methods to co-lead Phase 3.

Professor Whelan leads a large research programme on specialist sarcoma and young people's cancer services. He brings clinical and policy expertise to co-lead Phase 3

How this research provides value for money

This research provides value for money by bringing together and making innovative use of major national datasets currently under-exploited for prison population research. The data linkage work has already been undertaken and quality assured by the PHE team and significant costs for this will not be required. The research benefits from strong existing relationships. Drs Davies and Lüchtenborg have worked together for many years and established efficient ways of working that make best use of their differing skillsets and avoid duplication of effort. PHE is not requesting funding for Dr Lüchtenborg's supervision time but instead for data extraction and researcher support and secondment costs. Dr Davies and Professor Whelan have worked together on policy and cancer registry research projects and the latter has in turn worked closely with Dr Taylor on major NIHR projects. Dr Armes has been a close colleague to all for many years on national and local groups. This means that we do not need to spend significant amounts of time establishing ways of working but focus instead on co-producing the work, developing the skills of the junior researchers, supporting them to produce analyses with impact and influence and so develop new research capacity in this field. Additionally, Ms Breedvelt, Ms Hunter and Dr Plugge together bring extensive experience of prison services, healthcare research, and patients' experiences to the cancer team. Their more specific knowledge of prison health complements others' expertise in clinical cancer, nursing, health services, epidemiology and public health research. This will enable us to apply quantitative and qualitative data analyses appropriately to this under-researched group and to draw out and derive the implications of our findings for people with cancer and for those with other long- term conditions. Phase 3 also represents a cost-effective way of generating priorities and recommendations by engaging patients, clinical and prison experts. King's Policy Institute will ensure we identify and influence all policy levers while Science Gallery London engages an important younger demographic and gives us worldwide reach through the Science Gallery network. We will make full use of user service bursaries, early bird conference rates, existing attendance at conferences, and advance travel options for meetings. We will use existing licensing and software and communicate between meetings using Skype calls where possible

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Version	Changes made	By whom and date
Version 2 (Original detailed project proposal)	**Page 13: Addition of snowballing method for recruitment of health professionals** **Page 14: Removal of audio version of consent form after MOJ advice** **Page 14 onwards: Change of 'peer researcher' to 'Expert by Experience' as used by Revolving Doors Agency** **Page 18: Revision of timetable for recruitment** **Page 19: Revision of dates for recruitment to interview**	**JArmes 28 May 2019**
Version 3	**Page 10: Removal of use of MOJ clinical record data on advice of the Project Management Group** **Page 19: Removal of names of original co-applicants no longer involved**	**EDavies 11 Nov 2019**
Version 4	**Page 1: Addition of formal front sheet including organisation research numbers and signature page** **Page 4: Addition of table for study title, design, sample and research questions, acknowledgement of NIHR funding support and additional funding support from King's College London and University of Surrey.** **Page 12: Power calculation subheading added** **Page 14: Inclusion/exclusion criteria for patients added** **Page 19: Revision of PAG membership to reflect those no longer involved** **Page 20 and 21: Deletion of timetable and replacement with Gant Chart** **Page 22: Deletion of grant amounts for payment of specific phases** **Page 28: Addition of change log table**	**EDavies 20 Feb -24 March 2020**
Version 5	**Page 17 Revision of stage 3 design to accommodate online events due to Covid**	**E Davies 25 March 20 - June 2021.**