Understanding and improving the quality of primary care for prisoners: a mixed methods study

Qual-P

Study Protocol

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PROJECT DETAILS

Study Title	Understanding and improving the quality of primary care for prisoners: a mixed methods study
Acronym	Qual-P
Study Design	Mixed methods
Planned Study Period	30 months (1st August 2019 to 31st January 2022)
Research Aim	To explore gaps and variations in the quality of primary care for prisoners and identify quality improvement interventions to promote high quality prison care.
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VERSION CONTROL

VERSION	CHANGES/UPDATES
Qual-P protocol V6 22-5-19	[Original]

Qual-P protocol v6.1 22-5-19 public	Removed names, added formatting & logos
Qual-P protocol v6.2 22-5-19 public	Consensus panel method (p.9) Recruitment/sampling strategy & sample size (pp.11-14) Data collection method (p.14)
Qual-P protocol v6.3 22-5-19 public	Changed dates of research activities in WP2, WP3 and WP4 to reflect Covid-19 related delay in project and agreed +3 no cost extension with funder
CURRENT Qual-P protocol v6.4 22-5-19 public	Addition of Work Package 5 (mental health workstream) and additional +3 no cost extension (p.4, p.6, pp.22-24).

1 AIM & OBJECTIVES

Aim: To explore gaps and variations in the quality of primary care for prisoners and identify quality improvement interventions to promote high quality prison care.

Research objectives:

1. To identify candidate quality indicators based on current national guidance which can be assessed using routinely collected data through a stakeholder panel.
2. To explore perceptions of quality of care, including barriers to and enablers of recommended care and quality indicators, through qualitative interviews involving both ex-prisoners and prison health care providers.
3. To assess the quality of primary care provided to prisoners through quantitative analysis of anonymised and routinely held prison healthcare records.
4. To integrate the above findings within a stakeholder consensus process in order to prioritise and enhance quality improvement interventions which can be monitored by our set of quality indicators.

To report on outcomes for prisoners with mental health problems by exploring perceptions of the quality of mental health care and identifying barriers and enablers of good mental health in prison through thematic analysis of qualitative data collected in WP2; and by conducting statistical analyses of routinely collected data obtained in WP3 to assess the quality of physical health care provided to mental health subgroups.

2 BACKGROUND AND RATIONALE

The prison population experiences a disproportionately higher burden of illness and poorer access to treatment and prevention programmes compared to community populations.

Prisoners consult general practitioners three times more frequently, consult other primary care professionals 80 times more frequently, and receive inpatient care at least 10 times as frequently [1]. They have significant levels of long-term illness and disability [2, 3] and premature mortality [4]. In addition, prison populations have higher rates of communicable disease (including HIV and hepatitis B and C) [5], mental health issues, and drug and alcohol problems [6]. There is clearly a need to ensure that appropriate care of long-term conditions, mental illness and primary prevention is provided to prisoners both during and following their prison sentence. However, relatively little research has examined the quality of primary care provided in prisons, and hence allow comparisons to the general population. Even in the face of continuing pressures [7], United Kingdom primary care is consistently highly ranked in international comparisons [8]. This standing builds upon the recognised value of strong primary care systems [9] with organised preventive and long term condition care underpinned by an information technology infrastructure, the legacy of National Service Frameworks and (to varying extents) by the Quality and Outcomes Framework (QoF), which linked remuneration to the achievement of evidence-based quality indicators [10]. While significant advances have been made in improving care for the population as a whole, variations still exist, not least in relation to those patients with the most complex health needs or marginalised communities [11], such as prisoners.

Most research with prison populations has understandably prioritised drug misuse, mental health and communicable disease. Recent examples include the implementation of indoor smoke free prison facilities [12]; drug treatment of young male prisoners with attention-deficit hyperactivity disorder [13]; care pathways for older prisoners [14], particularly those with cognitive impairment [15]; outcomes for forensic services for people with intellectual and/or developmental disabilities [16]; organisation of care for those, near to and after release, with common mental health problems [17] or with serious mental illness [18]; and, peer-based interventions to maintain and improve offender mental health [19].

However, relatively little attention has been given to common (or even 'routine') conditions which affect the quality and length of life, including cardiovascular and respiratory health (e.g. hypertension, asthma), and which are amenable to evidence-based treatments [20, 21]. There has been little or no exploration of variations in the quality of care across prisons and between particular prisoner groups in the UK, nor work to explain any variations.

Furthermore, providing routine health care is highly challenging within the prison environment; any improvement initiatives need to be realistically based on an in-depth understanding of constraints and norms within prisons. For example, a recent randomised controlled trial found that an Older prisoner Health and Social Care Assessment and Plan (OHSCAP) did not improve the mean number of unmet health and social care needs (primary outcome), compared to usual care [22]. Process evaluation data suggested that the intervention was not implemented as planned, partly attributable to wider challenges in the prison context, including staffing shortages, the loss of specialist support roles for such initiatives, and regime disruption.

Further, little attention has been paid to how specific subgroups of people in prison (such as people with mental health problems) fare in terms of their physical health. Features of the prison system can simultaneously exacerbate mental distress and impede access to healthcare and support, limit opportunities for self-care and can lead to self-harm and (mis)use of prescribed and non-prescribed drugs. People with mental health problems have greater prevalence of obesity, cardiovascular disease, chronic kidney disease, and polypharmacy, which complicate physical health management, and those prescribed atypical antipsychotics often have poorer glycaemic control making people in prison an especially vulnerable, underserved group.

We have previously developed and applied a set of 'high impact' quality indicators for primary care, based on criteria including: burden of illness (e.g. prevalence, severity), potential for significant patient benefit (e.g. longevity, quality of life), scope for improvement upon current levels of achievement, and the feasibility of measurement using routinely collected data [23]. Other indicators are available but not yet routinely applied to prison populations, including primary care quality indicators for people with serious mental illness [24]. We are now in a position to build upon these, understand variations in prison primary care, and initiate strategies to improve prisoner healthcare and outcomes. For example, the detection and management of hypertension reduces avoidable mortality and morbidity [25]; there is scope for improving upon current management in primary care, whereby just over two-thirds of people with hypertension are achieving treatment goals [26]. The detection and treatment gaps in the prison population are unknown, thereby undermining priority setting and planning to reduce avoidable cardiovascular events in this population.

From April 2013, NHS England became responsible for commissioning all health services (with the exception of some emergency care, ambulance services, out of hours and 111 services) for people in prisons in England through 'Health and Justice' commissioning teams, supported by a national Health and Justice team. NHS England has set a key commissioning strategic goal to reduce the respective gaps in healthcare and health outcomes between those in criminal justice and the rest of the population [27]. Whilst steps have already been taken to bring about equity of care for prisoners, most significantly by integrating prison healthcare into the wider NHS, these steps focus on equality in relation to service configuration, rather than receipt and outcomes of care. Our research aims to drive a new improvement agenda for the primary care of prisoners, which will address inappropriate variations between and within prisons as well as inform strategies to close the likely gaps in health care and outcomes between prison and community populations.

3 METHOD

3.1 DESIGN

This is a mixed methods study, which comprises of five inter-linking work packages:

- WP1 – Stakeholder panel to identify and select quality indicators
- WP2 – Exploratory qualitative study with ex-prisoners and prison healthcare staff
- WP3 – Quantitative analysis of routinely held prison primary care records
- WP4 – Integration of the above findings, using stakeholder consensus process
  WP5 – Mental health workstream (qualitative and quantitative analyses of data collected in WP2 and WP3)

The design of each work-package is described in significantly more detail below.

3.2 SETTING

WP1 and 2 both take place in the community. The prison healthcare records analysed quantitatively in WP3 will be drawn from the cohort of prisons for which Spectrum CIC is the lead provider of prison healthcare. The records will be extracted at Spectrum CIC headquarters based in Wakefield, not in the individual prisons. The records will be anonymised and then analysed by the statistician (Tracey Farragher) at the University of Manchester, following appropriate Service Level agreements being put in place. WP4 takes

place in the community. Healthcare records that will be analysed in WP3 may relate to a prisoner having resided in any of the following establishments for which Spectrum CIC provide healthcare:

- HMP Full Sutton (male, category A and B, East Yorkshire)
- HMP Styal (female, closed, Cheshire)
- HMP Preston (male, category B, Lancashire)
- HMP Kirkham (male, category D, Lancashire)
- HMP Lancaster Farms (male, category C, Lancashire)
- HMP Durham (male, category B, County Durham)
- HMP Frankland (male, category A, County Durham)
- HMP Holme House (male, category C, County Durham)
- HMP Kirklevington Grange (male, category D, North Yorkshire)
- HMP Low Newton (female, closed, County Durham)
- HMP Northumberland (male, category C, Northumberland)
- HMP Liverpool ((male, category C, Merseyside)

3.3 PRISON ACCESS

To conduct all of the research activities described below, our participants and stakeholders will represent a broad range of prison healthcare staff, prison commissioners and people with direct experience of receiving healthcare as a prisoner (most likely to be recently released offenders). Whilst our focus is on prison healthcare, we have realised that we do not need to physically enter prison establishments to conduct the study. Our ethos here is not to unnecessarily burden the prison service, which is already overstretched and at capacity. All the data we require (both qualitative and quantitative) can be obtained from participants in the community. Therefore, in WP1 – 3, we wish to conduct research with prison healthcare staff/commissioners and ex-prisoners in the community. During WP3, we will conduct statistical analyses on a large, anonymised dataset of prison primary care records. The data extraction will be undertaken by a Data Specialist employed at Spectrum CIC at their headquarters in Wakefield. Analysis will be conducted by co-investigator Tracey Farragher at the University of Manchester. It does not involve research staff visiting any prisons.

4 WORK PACKAGE 1: IDENTIFICATION OF QUALITY INDICATORS

4.1 OBJECTIVE

To identify candidate quality indicators based on current national guidance which can be assessed using routinely collected data through a stakeholder panel

4.2 TIMESCALE

Months 1 – 4 (Aug-Nov 19) to conduct scoping review

Months 1 – 5 (Aug-Dec 19) to recruit stakeholder panel members

Month 5 (Dec 19) to convene stakeholder panel

Months 5 – 7 (Dec 19-Feb 20) to write up

4.3 DESIGN

First, we will conduct a focused scoping review to identify any recent qualitative and quantitative research on quality of primary healthcare in prisons. Second, we will use a consensus development process to identify and select quality indicators for the prison population, which can be assessed using routinely collected data.

4.4 PARTICIPANTS

A stakeholder panel will be convened. The panel will comprise 11 people drawn from prison health practitioners, prison officers, probation workers, commissioners and prisoner representatives. We will ensure that each of these groups is represented. At least two panel places will be reserved for participants who have a specific commissioning, practitioner or policy role regarding female prisoner health (and will include one prisoner representative). This will allow strategic consideration of the needs of the female prison population. Consensus groups gain relatively little in reliability exceeding 11 participants [28].

4.5 METHOD

STAKEHOLDER PANEL

We will use a modified RAND process, which is suitable for judgements requiring some degree of deliberation and discussion [28].

The candidate indicators will be drawn from:

- QoF
- NICE prison health guidelines and quality standards
- the Health and Justice health needs assessment toolkit
- a set of indicators for community general practice developed in an earlier NIHR-funded programme [23]
- a set of indicators addressing opioids, gabapentin and pregabalin

This selection will ensure a focus on indicators of quality of care for individuals rather than organisational-level characteristics and performance (which we continue to allow for in the analysis). To ensure coverage of 'mundane' but common aspects of primary care in community settings (e.g. hypertension, smoking status and cessation) and those more prevalent in prison settings (e.g. mental health problems, drug misuse, and infectious disease), the list of candidate indicators will be organised by domain.

Four team members (MC, KM, NW & RF) will perform preliminary screening of the ensuing "longlist" of candidate indicators according to two criteria:

- Likely to be amenable to measurement using routinely collected data (Y/N)
- Potential for significant patient or population benefit (Y/N)

We will ask the stakeholder panel to help us produce a balanced range of indicators by domain. We will ask panellists to rate a list of candidate indicators independently, online and before the meeting on a 1-9 scale according on the single criterion of potential for significant patient benefit. We will share the original longlist of indicators with the panel so they can highlight any indicators excluded in the preliminary screening for reconsideration and ask them to suggest any indicators not already identified. As a mixed consensus panel will have insufficient tacit knowledge to understand the feasibility of measurement using routinely collected data, we will ask a data specialist at Spectrum Health CCC to review our list and advise on feasibility.

Aggregate rankings will be fed back at a face-to-face meeting of panel members. Structured discussion will then centre on the recommendation rankings over which there is maximal discordance (provisionally defined as at least three panellists scoring 1–3 and at least three scoring 7–9). Panellists will have the opportunity to clarify aspects of indicators and discuss reasons for low or high rankings. Immediately after this discussion, panellists will again independently rate each indicator.

SCOPING REVIEW

A scoping review of the literature will be conducted to understand quality of primary healthcare in prisons. This will be an international literature review, from 2007 to present. We expect the review will include academic outputs, policy situated grey literature and potentially material from third sector organisations. To uncover the academic literature, the following databases will be searched: Medline, Cinahl Plus, Scopus, Web of Science and Psych INFO. Development of search terms will involve the expertise of an academic librarian. A modified version of a grey literature searching methodology will be undertaken, [29] We will adhere to recently published guidelines on reporting scoping reviews [30] The scoping review will be written up descriptively.

4.6 OUTPUT

Those quality indicators relevant to the prison population with the highest rankings (particularly feasibility) will be taken forward to Work Packages 2 and 3. The interim findings of the scoping review will inform identification of indicators for this current work package and will inform the topic guide in WP2.

5 WORK PACKAGE 2: EXPLORE PERCEPTIONS OF QUALITY OF CARE

5.1 OBJECTIVE

To explore perceptions of quality of care, including barriers to and enablers of recommended care and quality indicators, through qualitative interviews involving both ex-prisoners and prison health care providers.

5.2 TIMESCALE

Months 3–20 (Oct 19-Mar 20), develop all materials and recruit interviewees.

Months 5-20 (Oct 19-Mar 21), conduct interviews and analyse data.
Months 20-24 (Mar 21-Jul 21), write up

5.3 DESIGN

We will use qualitative interviews to explore attitudes, perceptions and experiences.

5.4 PARTICIPANTS

We will recruit approximately 20-25 ex-offenders and 20-25 prison healthcare staff. In keeping with good quality qualitative research, our sampling and recruitment strategies will evolve over the course of the study. We will continually monitor recruitment so that we can identify and address gaps in the sample (including participant characteristics and experiences). This process will be guided and supported by our PPI partners. Accordingly, predicting precise sample size is inappropriate but we would not expect the numbers in each group to exceed 25. This strategy aims to captures sufficient diversity of participant characteristics and experiences. For example, experiences of both male and female ex-offenders with a range of ages, mental/physical health conditions, who have been incarcerated in private and state prisons and have experience of a range of prison healthcare providers. Similarly, we will aim to include prison healthcare staff in a range of roles including GPs, nurses, pharmacists, heads of healthcare and health care assistants.

Recent ex-prisoners will be involved at this stage, rather than current prisoners, in order to relieve pressure on the prison service. Our definition of a 'recent ex-prisoner' will be a person who has been incarcerated and then released within a maximum of the past 18 months. We will not set a minimum limit on how long the ex-prisoner was incarcerated for as it is known that remand prisoners – who are typically sent to prison for shorter periods of time – often receive worse continuity of care.

Purposive sampling will be employed for ex-prisoners will be sampled on age, gender, ethnicity, length of sentence and health status. We will sample prison-based care providers from several establishments in the North of England which provide for a mixture of male, female and remand/sentenced prisoner types. This will at first be an opportunistic sample but then we envisage it will latterly become a snowball sample. Due to the participants

consisting of two distinct groups, our sample size of 30 participants is justified to ensure heterogeneity within each sub sample.

5.5 RECRUITMENT

Spectrum CIC provider prisons tend to cluster around County Durham, Lancashire and Cheshire. Ex-offender participants will be recruited from multiple services that work with ex-offenders in the community in – and very near – these two county locations. The services we engage with could include charities, non-profit and statutory providers.

We will also recruit participants by posting calls for on social media (Twitter account @Qual_P) and via blogs (https://qual-p.org). In addition, all recruitment materials will be made available on our project website. The publicly available project website will also host more general information about the project, the team and related resources (e.g. links to organisations). Using multiple recruitment will maximise our chances of achieving a diverse sample. By providing an alternative, independently accessible source of participant-related and general project information via the website all potential participants (or those recruiting on our behalf) and the public can easily and independently access the information they need.

Prison healthcare staff participants will be invited to take part in an interview in the first instance from the Spectrum CIC bulk e-mail circulation list. This bulk list contains the e-mail of every member of staff employed by Spectrum CIC. As recruitment progresses, it is likely that interviewees may identify others who they think would have something important to say on the topic. Therefore, it is likely that snowball sampling will guide the latter part of healthcare staff recruitment with personalised email invitations.

We will primarily sample and recruit staff from Spectrum Community Health CIC, a social enterprise that provides primary healthcare in 12 prisons in the North of England was a pragmatic decision made to assist with recruitment. We will also recruit staff who are not currently employed by Spectrum Community Health CIC to enable us to develop a more comprehensive picture of the factors that operate to facilitate or hinder the delivery of quality care by different providers in different prisons.

We will conduct interviews by telephone and video call as well as the face-to-face interviews originally planned. Regardless of the method of data collection, all interviews will be conducted in private to enable participants to share confidential information. Participants will be encouraged and supported to conduct calls in a quiet, private room.

5.6 INTERVIEW CONDUCT

We will consider and select two quality indicators identified from WP1 in order to anchor the interviews. Interviews will explore current need for care and screening related to these two quality indicators, prisoner access to care in a general sense and perceptions of the current quality of care provision more widely. We will also concentrate on how quality of care could be improved. Therefore, the dialogue during the interview will be focused broadly on quality of care but also contain concrete foci of the quality indicators. Topic guides will be tailored appropriately for use with the different groups of participants. Interviews will be recorded and fully transcribed.

5.7 ANALYSIS

Analysis will proceed on two levels. Firstly, an inductive thematic analysis [32] will take place which will focus on answering the research objectives. That is, the barriers and levers of quality of prison healthcare will be explicitly drawn out alongside an understanding of what is important to the participants themselves regarding this issue. This approach will be iterative as preliminary insights gathered during fieldwork will then assist in partially shaping the resultant coding framework. The data arising from the different participants groups will be compared and contrasted, with discordant cases actively sought. We may find that the different groups of participants are in broad agreement or that their views contrast with each other. This thematic analysis will involve a process of organising the data, descriptive coding, interpretive coding, writing and theorising. *NVivo* software will be used to aid sorting and categorisation of the data.

Secondly, a conceptual analysis will be undertaken based on an existing theoretical framework pertaining to improving the quality of healthcare [33]. This framework purports that change in quality of care is dependent on a multi-level approach, consisting of: the individual (attitudinal), the group/ team (clinical microsystems and team culture), the organisation (staffing/ resource allocation), the larger system (policy/commissioning

decisions). Conducting such an analysis will allow us to understand factors that are operating at the micro, meso, macro and super macro levels. This style of analysis will allow for conceptual understandings of the data to be generated and will move beyond the descriptive approach which will be undertaken in the traditional thematic analysis stated above. The thematic analysis allows the participants voices to be heard and gives credence to their stated perceptions and experiences. The conceptual analysis moves beyond 'what the participants' said' to attempt understanding how quality of care can be improved with reference to the theoretical change management literature, and what the levers for change are. An abductive approach to analysis will be taken [34]. This involves iterative cycles of analytical interpretation between the theoretical literature and empirical data.

6 WORK PACKAGE 3: ASSESSING THE QUALITY OF CARE

6.1 OBJECTIVE

To assess the quality of primary care provided to prisoners through statistical analysis of anonymised and routinely held healthcare records.

6.2 TIMESCALE

Months 4-14 (Nov 19-Sep 20), develop algorithms for quality indicators
Months 15-19 (Oct 20-Feb 21), Data Specialist extracts data from healthcare records
Months 19-21 (Feb-Apr 21), analysis of data for quality indicators
Months 20-24 (Mar-Jul 21), write up

6.3 DESIGN

We will statistically analyse routinely collected data held in healthcare records for which Spectrum CIC is the healthcare provider. Analysis will be based on the quality indicators identified in WP1. We will explore variations in the quality of care according to prisons, particular prisoner groups and conditions. These data will be analysed to determine the quality of care that prisoners received across the years for each of the quality indicators, along with the use and uptake of preventive services.

6.4 SAMPLING AND SETTING CONTEXT

The data will be extracted for those prisons where Spectrum CIC provide primary care services. This will be done via SystmOne Prison, the IT system that currently holds the data

for prison-based health care for all prisons in England. Spectrum CIC are currently responsible for primary healthcare in 12 adult prisons: three category A (high security); four category B (remand); five category C (training); and one category D (open). These collectively have a capacity of approximately 8,560 prisoners in total (range 280 to 1,350).

6.5 DATA EXTRACTION

SystmOne Prison contains:

- prisoner demographics (automatically updated from the Prison National Offender Management System)
- health screening data from a prisoner's first reception in prison
- data related to ongoing care including morbidity data (Read codes)
- pathology results
- prescribing records

It allows transfer of records between prisons, ensuring a complete patient health record regardless of where a term is served.

The extraction of the anonymised quality indicator data will be carried out by a Data Specialist employed by and based at Spectrum CIC. The Data Specialist already has the necessary permissions and security clearance to have direct access to the records held on SystmOne Prison. The research team already has an initial agreement with Spectrum CIC to extract the quality indicators for the 12 prisons where they are responsible for healthcare. Where existing algorithms for routinely used indicators do not exist, the Data Specialist will develop algorithms to examine the receipt of recommended care and achievement of targets, under the guidance of the research team. She will then apply the algorithms and anonymise the data. Co-investigator Tracey Farragher is leading this work package and will perform the statistical analysis. The data made available to Tracey will be anonymised (e.g. age groups provided rather than date of birth, Index of Multiple Deprivation score rather than addresses in community).

Individual-level data including achievement of the various indicators, demographic, screening and clinical information will be obtained for the period 1 April 2016 to 31 March 2019.

Relevant prison-level data (e.g. prison category) will also be included for each individual. This 36 month timeframe will ensure that we encapsulate the various potential sentences of prisoners (long term through to a number of short sentences) and also include sufficient retrospective follow-up to monitor achievement of some of the indicators (e.g. QoF period). We will also account for amendments, removals and additions to quality indicators over the time frame. A Service Level Agreement will be in place between Spectrum CIC and University of Manchester (where TF is based) to transfer the anonymised data.

6.6 DATA ANALYSIS

ANALYSIS

We will determine:

- percentage achievement of quality indicators for the prisoner population as a whole
- comparisons of percentage achievement by:
  - prison type
  - sentence duration
  - age
  - gender
  - other relevant characteristics
- whether there are systematic differences in quality for these variables

One hypothesis is that long stay prisoners are likely to have relevant quality indicators recorded in prison, whilst those serving shorter sentences (e.g. <3 months) may be overlooked or even not apply in the time they are in prison. Exploring prisoner characteristics, such as age, is particular pertinent with the growing number of elderly prisoners (both in absolute terms and as a proportion of the prison population); and the accompanying poorer health of aging prisoners [35].

An initial descriptive and Bayesian analysis will be undertaken and then multi-level logistic regression modelling and a latent variable analysis. The initial analysis will provide the necessary information (i.e. achievement numbers, rates and levels) to assess whether further analysis is appropriate (see credibility and sense checking section below for further details). Multi-level logistic regression models will identify the factors that are associated with

achievement of the quality indicators. These types of models can appropriately account for the potential correlations between outcomes at multiple time-points and between-prison variation. The initial descriptive and Bayesian analysis will provide contextual background to understand achievement levels for the quality indicators across prisons. These between-prison differences will need to be accounted for, while exploring variations in attainment. With likely strong associations between the different quality indicators, latent variable models will be developed to identify factors common across all indicators. This unifying model will explore which factors are associated with quality in care in prisons as measured by all these indicators.

CREDIBILITY AND SENSE CHECKING

We will compare the initial summary and descriptive analysis of the attainment rates of the indicators by prison and prisoner groups with the contextual background elicited in WP1 and 2 to check the credibility of the indicators. We will also be able to triangulate and 'sense check' the data completeness and validity of our proposed indicators and findings with existing prison Health Needs Assessments (HNAs) via our links with the Health and Justice commissioning teams and the prison health care provider. In addition, a Bayesian analysis will allow us to estimate the false negative and positive rates of the attainment rates for the prisons and prisoner groups, which would provide further information on the completeness and reliability of the data [36]. We will also compare the QoF-based quality indicator achievement rates for these prisons with published QoF rates to assess the quality of healthcare of prisoners relative to current community primary care.

Furthermore, as part of the contract management process between commissioners and prison healthcare providers, Spectrum CIC extract data quarterly for the North of England Commissioning Support Unit (NECSU). NECSU is then responsible for processing these data to provide a dashboard for providers and commissioners. The research team will have access to these anonymised dashboards for Spectrum, via NS and an appropriate Service Level Agreement. These dashboards are likely to include some of our planned quality indicators, thereby allowing a quality control comparison with data extracted and processed by the Data Specialist at Spectrum.

The length of sentence and the potential number of sentences over the timeframe needs to be considered when assessing achievement of the quality indicators. For example, if someone is diagnosed with hypertension and their blood pressure is measured and treated whilst in the community, they might not require monitoring while in prison for a short sentence (e.g. couple of months). Therefore, the timing, duration and number of sentences for each person will be important to consider when assessing achievement of particular quality indicators.

6.7 SAMPLE SIZE CONSIDERATIONS

This WP aims to explore variations in the quality of primary care provision for prisoners. As such a formal sample size calculation is not appropriate as the aim is to describe the current provision. However a consideration of the characteristics of the study population shows the potential to explore the variation in prisoner groups and prisons. Taking a potential health condition with a relatively low prevalence - mental illnesses (schizophrenia, bipolar affective disorder and other psychoses), we would expect 77 prisoners to be diagnosed from the 11 prisons (0.9% prevalence based on QoF for England 2015-16). This expected number of prisoners diagnosed does not take into account the probable higher prevalence in prisoners nor the throughput of prisoners which would increase the sample population over the 3 years and so those diagnosed. For example, as a remand prison Durham has on average 60% of prisoners transferred within 50 days. If we use the lowest achievement (49%) of the QoF indicator 'The percentage of patients with a comprehensive care plan documented in the record, in the preceding 12 months', we would expect 38 of the 77 prisoners to achieve the QoF indicator. If we use the rule of thumb that logistic models should be used with a minimum of 10 events per factor/predictor variable, based on simulation studies [37], then we would be able to explore approximately three factors simultaneously as to whether they are associated with achievement of the indicator. Furthermore, using multi-levels and latent models, will likely result in the number of records required to be reduced and allow more factors to be explored with the same number of records. Therefore even with the lowest prevalence of both the condition and achievement of indicator, based on community data, we have potentially a more than sufficient study population size to explore the factors associated with variation in quality indicators.

7 WORK PACKAGE 4: IDENTIFICATION OF INTERVENTIONS TO IMPROVE PRISONER HEALTH

7.1 OBJECTIVE

To integrate the findings from work packages one, two and three within a stakeholder consensus process in order to prioritise and enhance quality improvement interventions which can be monitored by our set of quality indicators.

7.2 TIMESCALE

Months 22-25 (May-Aug 2021), synthesis of work package one, two and three findings and consensus panel preparation

Months 26-29 (Sep-Dec 2021), convene x3 stakeholder panels

Months 30-33 (Jan-Apr 2022), write up

7.3 PARTICIPANTS

As for WP1, the consensus panel of up to 11 members will be drawn from key stakeholders involved in commissioning and delivering primary care, along with prisoners and their advocates. These 11 people do not necessarily need to be the same as those who participated in WP1. We will seek consensus on key areas for intervention, and on what kinds of quality improvement interventions need to be enhanced or adopted to improve quality of care.

7.4 METHOD

We will share our findings from WPs1-3, with the panel and take them through the following steps:

a. Review findings from WP3 to identify priorities for improvement based each indicator such as low performance or groups of prisoners associated with lower achievement of indicators, (e.g. older people, longer or shorter term prisoners).

b. Consider findings from WP2 to understand barriers to and enablers of good quality of care, considering levers for change at individual, team, organisational and wider system levels.

c. A briefing summarising the range of approaches (interventions) potentially available to support the implementation of quality indicators, drawn from a broad overview of systematic reviews (or most recent updates then available).

d. Mapping of implementation interventions to identified barriers and enablers. Examples are as follows: (i) if clinical staff or teams are unaware of their poorer performance relative to other clinical staff and teams, then audit and feedback comparing data on performance can help identify erroneous perceptions and use social comparisons and goal setting to motivate change; (ii) if clinical staff under pressure within time-limited consultations are unable to recall key information about patients or knowledge of care pathways, then specifically targeted computerised prompts and templates can support decision-making and action; or (iii) if prisoners with long term conditions, such as asthma, do not consistently understand the importance and consequences of requesting or taking preventive treatment (or how to do so), targeted patient information and instruction from clinical staff can support treatment adherence. These examples illustrate types of approaches requiring planning and action at individual, team, organisational and system levels.

e. Application of APEASE criteria (affordability, practicability, effectiveness, acceptability, safety and equity) [38]. For each intervention, we need to consider likely adaptability to and sustainability within the prison healthcare environment.

We will plan three consecutive, half day panel meetings to allow sufficient time and reflection to work through these five sets of considerations.

7.5 ANALYSIS

We will use ratings by panellists for steps A (priority setting) and E (appraising applicability of candidate interventions). As for WP1, for each of these panellists will independently rate each priority or feature of an intervention (e.g. affordability) on a 1-9 scale, where scores of '1' indicates the strongest disagreement and scores of '9' indicate strongest agreement. We will collate the scores for each and feedback the median and range scores to all participants for a face-to-face discussion. We will discuss ratings, focusing on those with maximal discordance, defined as at least three panellists rating a priority or intervention feature 1–3

and at least three rating 7–9. Participants will then independently rate each item again. This process offers a relatively transparent and inclusive approach to select priorities and interventions, so that those with the highest aggregate scores are carried forward. Written notes will be taken by participating members of the research team during and after workshops and these, together with any materials developed by participants as part of their evaluation, will be included in the analysis. Some sections of the workshops (with participants' permission) may be recorded and transcribed to allow us to check and review any key decisions and recommendations. Using the findings from the workshops a prioritised list of quality indicators and a suite of implementation interventions relevant to the prison healthcare setting will be identified, likely to be based around the commissioning of prison healthcare, development and sharing of patient records, and delivery of prison-based primary care.

7A WORK PACKAGE 5: MENTAL HEALTH WORKSTREAM (QUALITATIVE AND QUANTITATIVE ANALYSES OF DATA COLLECTED IN WP2 AND WP3)

7A.1 OBJECTIVE

To report on outcomes for prisoners with mental health problems by exploring perceptions of the quality of mental health care and identifying barriers and enablers of good mental health in prison through thematic analysis of qualitative data collected in WP2; and by conducting statistical analyses of routinely collected data obtained in WP3 to assess the quality of physical health care provided to mental health subgroups.

7A.2 TIMESCALE

Months 37-39 (May 22-Jul 22)

7A.3 DESIGN

QUALITATIVE DESIGN

We will undertake a qualitative analysis of the qualitative data collected in WP2, focusing on the receipt and provision of mental health care.

QUANTITATIVE DESIGN

We will statistically analyse routinely collected data obtained in WP3. We will identify and describe three mental health subgroups and explore variations in the quality of their physical care as compared to the rest of the prison population.

7A.4 SAMPLING AND SETTING

Both our qualitative and quantitative data were collected in the Clinical Research Network regions with the highest prevalence of mental health conditions (Greater Manchester, North west Coast, North East and North Cumbria).

QUALITATIVE DATA

The qualitative data was collected from 23 people who had lived in prison and 21 prison healthcare staff. The entire dataset will be included in the mental health focused analysis.

QUANTITATIVE DATA

The quantitative data was extracted from all prison healthcare records held at 13 prisons for the years 2017-2020. Data will be analysed for three subgroups:

The proportion of the population across 13 prisons:

(i) with any mental health diagnosis
(ii) prescribed any psychotropic drugs
(iii) with any mental health diagnosis NOT prescribed a psychotropic

7A.5 ANALYSIS

QUALITATIVE ANALYSIS

We will conduct an inductive, reflexive thematic analysis (Braun & Clarke, 2019) of the entire qualitative dataset collected in WP2. Analyses conducted for WP2 have already identified data relating to experiences of poor mental health, barriers to achieving good mental health and strategies for overcoming these barriers. This additional analysis will involve:

- Re-reading the entire dataset (44 transcripts)
- Conducting focused coding around the broad topic of mental health and wellbeing
- Identification of themes and sub-themes

QUANTITATIVE ANALYSIS

We will determine:

- percentage achievement of quality indicators for the three mental health subgroups
- comparisons of percentage achievement in the wider prison population by:
  - prison type
  - sentence duration
  - age
  - gender
  - other relevant characteristics
- whether there are systematic differences in quality for these variables

One hypothesis is that achievement for the indicators will be lower for these subgroups compared to the rest of the prison population. Findings from analyses undertaken in WP3 suggests variations across prisons, and that sentence length and other individual characteristics (such as age and gender) have the potential to affect achievement but we do not know if this will hold true for these three subgroups whose demographic may differ from the wider population.

We will repeat the approach taken in WP3 by performing an initial descriptive and Bayesian analysis, followed by multi-level logistic regression modelling to identify factors associated with achievement of the quality indicators.

8 DISSEMINATION AND PROJECTED OUTPUTS

8.1 COMMISSIONERS, PROVIDERS AND POLICY MAKERS

We shall use an explicit framework developed within the Leeds Institute of Health Sciences (LIHS) to guide our knowledge transfer strategy [38, 39]. The networks and positions of team members will ensure that the findings of the study feed into the relevant commissioning and provider bodies. For example, NW and KM have direct experience in the organisation and delivery of care through Spectrum Community Health CIC and Care UK, which provide health care to over 50 prisons and are at the forefront of a range of

initiatives in the sector. NS is Lead for Health and Justice Commissioning Support at NECS (North of England Commissioning Support) – embedded within NHS England, the lead commissioner of Health and Justice related services for patients in a prison setting. RF shares research findings with and advises NICE, particularly via its Implementation Strategy Group, the Healthcare Quality Improvement Partnership and a number of national clinical audits.

We will contact *Inside Time* to elicit interest in our work and its dissemination. We will also enquire as to whether *Inside Time* would be interested in an article explaining our project and informing readers about our planned data collection shortly after requisite ethical and governance approvals are in place.

A social media strategy will be developed in order to promote the study during its life course and engage with appropriate national and regional level people of interest. This could include but is not limited to: ex-prisoners, prison advocates and representatives, commissioners in both the NHS and prison service, providers of prison healthcare, policy makers at all levels and academics interested in prison research, criminal justice and healthcare quality more widely. The engagement of the intended audience will reach a critical mass over time and this will make a vibrant forum for discussion and promotion of our peer reviewed findings. LS will lead this social media presence, predominantly through Twitter, with assistance from the Programme Manager.

8.2 DISSEMINATION WORKSHOP

During the last phase of the study, a workshop will provide a forum for engaging with key stakeholders, including prisoners and their advocates (e.g. Howard League), and will include those who have not participated in the study, thereby widening dissemination.

8.3 ACADEMIC DISSEMINATION

We aim to publish six papers (one with the main findings of the study, one for each WP 2-4 and two for WP5) in relevant target journals. It is likely that we will target BMJ for findings of interest to a general readership and International Journal of Prisoner Health or BJGP for findings of specific interest to primary and prison healthcare professionals. We will prioritise open access publishing as a means of enabling wider access to our findings and therefore

potentially faster uptake and implementation. We will also disseminate our findings at two or more relevant national conferences, most likely the Society for Academic Primary Care and Offender Health Research Network Annual Conferences.

9 PROJECT MANAGEMENT

The named Principal Investigator (LS) will be overall strategic lead but will work closely with the Co-Principal Investigator (RF). Through this joint responsibility and mentoring, we will contribute to the development of LS's leadership abilities and capitalise upon RF's experience. LS and RF will gain the required ethical and research governance approvals prior to the project start and then LS will line manage the two research staff employed at the University of Leeds. NW will line manage the Data Specialist based at Spectrum CIC.

Individual team members will lead on specific work packages according to their skills and experience:

WP1: identification of quality indicators (RF and TF as lead, NW, KM)

WP2: qualitative work (LS as lead, NW, EM, NS),

WP3: analysis of routine data (TF as lead, EM, RF),

WP4: identification of interventions (RF as lead, NW, KM, EM, LS, NS).

WP5: mental health workstream (LS as lead, TF).

A Project Management Team will meet monthly, with individual leads convening WP specific meetings as required. The Research Programme Manager will be responsible for PPI liaison and recruitment.

A Steering Group will meet quarterly to oversee progress and assist in interpretation of results, with the research team in attendance. Other collaborators, as Steering Group members, will provide advice from a range of perspectives: e.g. Kate Davies is Director of Health & Justice, Armed Forces and Sexual Assault Services Commissioning, NHS England,

(which has overall responsibility for commissioning prison health services); Dr Linda Harris is Chief Executive of Spectrum CIC. Additional, ad-hoc meetings may be arranged depending on the advisory needs of the Research Team.

9.1 STAFF ROLES AND RESPONSIBILITIES

LS (30%) as PI will have overall responsibility for achieving objectives and milestones, with specific lead responsibility for WP2 (qualitative interviews)

RF (10%) as Co-PI will have joint responsibility for the study and provide mentoring support to LS. RF will have lead responsibility for the identification of indicators (WP1 – co-lead) and consensus panel development of interventions (WP4)

TF (10%) has lead responsibility for the analysis of the prisoner primary care records (WP3) and co-lead on identifying quality indicators (WP1);

NW (8%), EM (5%) and KM (5%), will provide clinical and methodological input, conduct consensus panels as well as identifying appropriate participants for the stakeholder panel (WP1), interviews (WP2) and intervention development (WP4). Furthermore NW will provide ongoing liaison with Spectrum Community Health CIC in accessing the primary care prisoner data.

NS (10%) as Health & Justice Lead for North of England Commissioning Support (NECS) will provide expertise on commissioning offender health services, including strategic and operational level knowledge and identify appropriate participants for WP1-4s with access to her team and resources.

Research programme manager (50% - to be appointed) will project manage the day-to-day aspects of the project, liaise with and co-ordinate the involvement of co-applicants, organise and convene the quarterly steering committee, take the lead for PPI strategy and management and work closely with Spectrum People, primary stakeholder engagement, agree and implement all SLAs and collaboration agreements, budget management. Appropriate admin and clerical support (20%), will be provided, with interview transcription.

Qualitative researcher (100% - to be appointed) will be involved throughout the study but in a more focused manner in WP2 where they will lead the qualitative fieldwork and analysis. This person will assist in both the preparation and delivery of the stakeholder and consensus workshops in WP1 and WP4. They will be responsible for delivery of the scoping review which now occurs in WP1.

Data Specialist (60%) will be based at Spectrum CIC and will primarily be responsible for extracting the primary care including development of algorithms for the selected quality indicators, but will also be involved in both stakeholder and consensus workshops.

10 PERMISSIONS AND APPROVALS

	Research activity	Participants/ Data	Setting
WP1	Stakeholder consensus panel One half day panel exercise with brief online preparatory work beforehand	Up to 11 people with a significant interest in prisoner health. All prison healthcare clinicians taking part will be employed by Spectrum CIC. Prisoners representatives will be ex-offenders	City centre hotel venue
WP2	30 qualitative interviews Each interview is expected to last between 30 and 60 minutes	15 interviews with Spectrum CIC employed prison healthcare staff 15 interviews with ex-prisoners in the North East/ North West of England	Private rooms at prison visitor centres, situated next to but outside the prison. Or private rooms at Spectrum head offices in Wakefield. Private rooms at third sector

			services/ charities engaging with offenders
WP3	Statistical analysis of routinely collected data held in prison healthcare records	Spectrum CIC held prison healthcare records for the period 1st April 2016 to 31st March 2019	Extraction of data at Spectrum CIC headquarters in Wakefield. All data will be anonymised and then sent securely to University of Manchester for statistical analysis
WP4	Stakeholder consensus panel Three half day panels	Up to 11 people with a significant interest in prisoner health. All prison healthcare clinicians taking part will be employed by Spectrum CIC. Prisoners representatives will be ex-offenders	City centre hotel venue

When designing this study about the quality of prison healthcare, we were mindful of not putting pressure on the prison service which is known to be very overstretched in its capacity to allow and to have the capacity to escort research teams around establishments. To answer our research questions, it is not necessary for the research team to enter any prison establishments. All research activities can be conducted in the community.

The participants we will involve are previous patients and current staff of a third sector healthcare provider (Spectrum CIC). They are not NHS patients or staff and we are not asking them about receipt or provision of NHS services. Statistical analysis of routinely collected data is based on healthcare records held by Spectrum CIC. The data will be extracted by a Data Specialist who already has all necessary permissions and clearances to undertake this work. Data will be anonymised and then securely transported to the

statistician (Tracey Farragher) at University of Manchester. The research team is experienced in handling these sorts of data and in maintaining appropriate levels of security and confidentiality, with standard operating procedures already in place. We will apply the same standards that we have already applied in our previous studies about collecting and analysing data to assess the quality of care for community general practice populations. Data extraction will occur with the provider organisation and only anonymised data stripped of strong identifiers will be released outside of this setting for analysis.

11 PATIENT AND PUBLIC INVOLVEMENT

A previous female co-applicant and a nominated male PPI representative, both with lived experience as prisoners, had worked with the research team in developing the grant application and fed the prisoner perspective into each work-package. Unfortunately, both these people had to step down their formal involvement with the study during the formation of the grant.

We are working with Spectrum People as our PPI partner organisation. Spectrum People is a charity and a subsidiary of Spectrum CIC. Its remit is to work with vulnerable people in order to aid their better integration into society. Bridget Gill, the manager of Spectrum People, has agreed that service users are willing to support this research study in order to provide advice and guidance throughout. This may take the form of ad hoc requests but will also representation on the steering committee. The Programme Manager will develop a comprehensive PPI strategy with Bridget and service users in the first few months of the study period. After the PPI strategy has been developed, it is anticipated that we will work with a small group of service users throughout the study who are interested in the research topic. We are mindful that service users' involvement with Spectrum People waxes and wanes as people move on with their lives. Therefore, this small group of service users may not be consistently the same people throughout. This should not matter too much for most activities but if service user attendance at the steering committee proves to be inconsistent, Bridget has agreed to attend in order to provide a proxy PPI voice in circumstances where it could be challenging to provide consistent representation.

By involving people with lived experience of being in prison, we can draw on their unique perspectives to identify outcomes relevant to them, and appropriate strategies to improve

the quality and continuity of care they receive. PPI reps will be crucial to the identification and development of interventions through their involvement in stakeholder panels (WP1) and consensus workshops (WP4). They will also be involved in co-designing and facilitating workshops and co-producing project materials for offenders and appropriate support/funding is provided for them. Provision will be made for gender balance throughout the duration of the PPI input. The Research Programme Manager will support the meaningful involvement of PPI reps within project meetings and the steering committee (e.g. by providing a glossary of terms and by acting as a mentor).

12 GLOSSARY

Care Quality Commission (CQC)

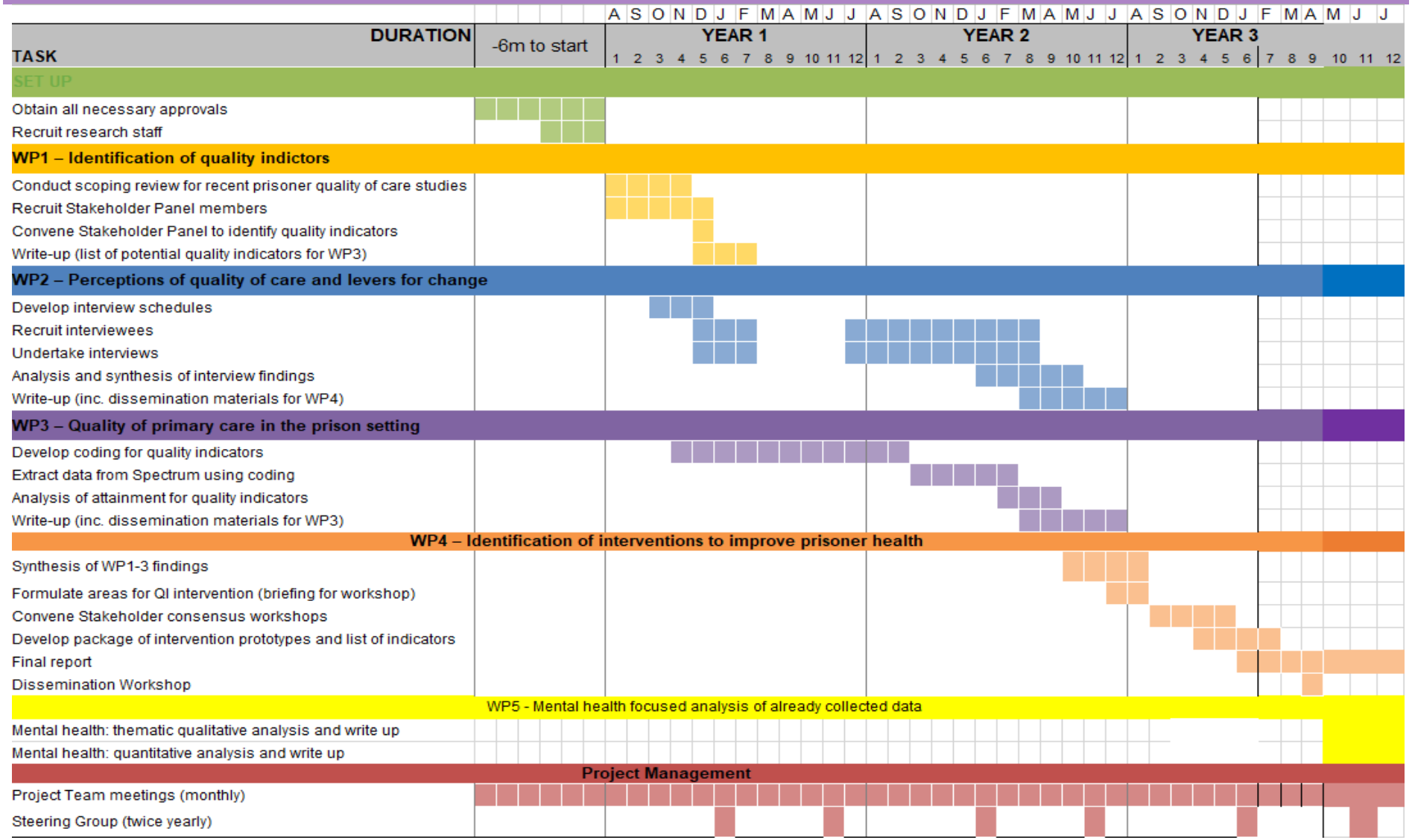
Health and Justice Indicators of Performance (HJIPs)

National Institute for Health and Care Excellence (NICE)

Public Health England (PHE)

Quality and Outcomes Framework (QoF)

13 GANTT CHART



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