1. Protocol details

1.1. Protocol title:

Exploring the local operation and impact of Healthwatch in England five years on: using actor-network theory to optimise patient and public voice in NHS commissioning and service provision.

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1.3 Protocol details

Version number 2

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2. Signature Page

The Chief Investigator and the R&D (sponsor office) have discussed this protocol. The investigators agree to perform the investigations and to abide by this protocol

The investigator agrees to conduct the trial in compliance with the approved protocol, EU GCP, the UK Data Protection Act (1998), the Trust Information Governance Policy (or other local equivalent), the Research Governance Framework (2005' 2nd Edition; as amended), the Sponsor's SOPs, and other regulatory requirements as amended.

Chief investigator

Glenn Robert

Signature	Date

Sponsor Representative

Reza Razavi

Signature	Date

Contents

3. Summary

Title of study	Exploring the local operation and impact of Healthwatch in England five years on: using actor-network theory to optimise patient and public voice in NHS commissioning and service provision.
Protocol Short Title/Acronym	The local operation and impact of Healthwatch in England
Protocol version number and date	v.2 29th September 2020
IRAS Number	252993
REC Reference	King's College London REC LRS-18/19-12587
Study duration	17/06/2019 to 31/05/2021
Sponsor name	King's College London
Chief Investigator	Professor Glenn Robert
Funder	NIHR HS&DR
Medical condition or disease under research	Health services research
Purpose of research	To investigate how Healthwatch creates and sustains relationships locally with key NHS and other stakeholders as a key element of Patient and Public Involvement and Engagement.
Primary objective	The aim of the study is to explore and enhance the operation and impact of local Healthwatch in ensuring effective patient and public voice in the commissioning and provision of NHS services.
Number of subjects/patients	The total UK sample size in phase 1 (survey) is 152 local Healthwatch organisations in England. The total UK sample size is 5 selected organisations in phase 2 (ethnographic fieldwork). We aim to interview up to 12 participants in each study site in phase 2 (maximum = 60). We cannot estimate numbers for on-site observations in phase 2. Some of the interviewees will also take part in our Joint Interpretive Forums at each site and in the cross-site JIF in London. However, some participants might choose not to participate further.

	The total UK sample size is 15 HIP members in phase 3 (HIP member interviews/discussions regarding generalisable statements of good practice, and practices during COVID-19).
Study type	Multi-method design in four related phases: phase 1 national online survey of 152 Healthwatch; phase 2 ethnographic fieldwork at 5 local Healthwatch; phase 3 online interviews and small-group discussions with HIP members to generate statements of good practice and explore practices during COVID-19; phase 4 multi-stakeholder meetings in the format of Joint Interpretative Forums.
Endpoints	Completion of all study objectives
Main inclusion criteria	People working at or with local Healthwatch; current or former NHS patients or carers, or members of the public, who have been involved in local Healthwatch.

4. Summary of Research

Enabling citizens' voices to be heard is a vital part not only of planning for provision of healthcare services in a patient-centred, publicly-funded NHS but also of ensuring that the NHS is accountable to the public, communities and patients that it serves. Healthwatch was set up in 2013 with the ostensible aim of being the 'consumer champion' in health and social care in England, centrally concerned with the quality of and access to healthcare. There are 152 local Healthwatch, which are funded through local authority budgets and which have statutory powers to advise local authorities and NHS commissioners about their communities' needs and concerns relating to the provision of health and social care.

To date there is no robust, theoretically-informed, contextually-specific evidence about the processes through which local Healthwatch influence is created and maintained and how this enables more effective services. This is a significant research gap given Healthwatch's role as a key NHS partner in monitoring the quality - and supporting the development - of health and social care locally by providing NHS England and local authorities with information and advice based on the views of citizens and patients.

Employing a mixed method design, this study will produce the first generalizable evidence base of how local Healthwatch acts through mutually-influencing relations with a broad range of organisations and other stakeholders. At the heart of the study is an Actor-Network Theory (ANT)-informed ethnographic

approach which will allow us to map holistically everyday practices and the broader context in which they take place. We will do this by studying the everyday interactions between local Healthwatch bodies and a range of actors including local authorities, Health and Wellbeing Boards, residents, Trusts, Clinical Commissioning Groups (CCG), other Patient & Public Involvement (PPI) and third-sector organisations, as well as the objects (documents, reports, data and funding) that shape these interactions, to provide a detailed understanding of how these relationships are created and maintained.

The aim of the study is to explore and enhance the operation and impact of local Healthwatch in ensuring meaningful patient and public voice in the commissioning and provision of NHS services. In doing so, we aim to address the following **overarching research questions:**

- What are the strategies, practices and structures that enable Healthwatch to enhance patient and public voice in the NHS?
- How is patient and public involvement made impactful for citizens themselves as well as commissioners, providers and other NHS actors as they are brought together through the daily work of Healthwatch?

Answering these questions will also inform the broader issue of what 'effective PPI' entails from the different perspectives of patients, commissioners, providers and other NHS actors.

To achieve our aims, the study will be organised in four phases. In phase 1 we will design and carry out a nationwide survey of the 152 local Healthwatch in England. Using the phase 1 findings to construct a sampling frame, we will then (phase 2) conduct an ANT-informed ethnographic study in five local Healthwatch. The data from this phase will be analysed in cooperation with a panel of fifteen local Healthwatch staff and volunteers (Healthwatch Involvement Panel – 'HIP' – see Box 1 below) recruited from other local Healthwatch organisations. This will ensure the generalisability of our ethnographic findings beyond the four case study sites. Based on our findings from phase 2, we will conduct a series of online interviews and small-group discussions with members of the HIP to generate emerging statements of good practice as well as exploring the impact of COVID-19 on the work of local Healthwatch during the pandemic (phase 3). In phase 4 we will hold Joint Interpretative Forums (JIF) with each case study site with multiple stakeholders (local authorities, Health & Wellbeing Boards, CCGs, CLAHRCs) engaging them in shared reflection on our findings and analysis. We will complete our interpretation of all four phases and then formulate and disseminate actionable recommendations for policy and practice.

BOX 1 Healthwatch Involvement Panel (HIP)

What is the Healthwatch Involvement Panel (HIP)?

It is a panel of fifteen local Healthwatch staff and volunteers (eleven staff members and four volunteers) recruited from fifteen local Healthwatch organisations which are not case-study sites.

What will the HIP do?

Invited HIP members will receive one-day training in relevant qualitative methods from King's College London. HIP members will then attend 5 half-day meetings during the ethnographic fieldwork phase (Phases 2 and 3). At each HIP meeting, ethnographic data from case-study sites will be presented by research staff conducting the fieldwork. HIP members will be asked to:

- reflect on the data presented and provide interpretation and explanation based on their own experience and knowledge of working at a local Healthwatch;
- look for points of similarity and difference with their own organisational practices to help build a broader picture of local Healthwatch activity across England;
- guide the research team with detailed suggestions on how to develop the ethnographic work in accordance with short and medium-term fieldwork objectives;
- participate in a series of one-to-one online interviews and small-group discussions to generate emerging statements of good practice as well as exploring the impact of COVID-19 on local Healthwatch work during the pandemic.

Why are we involving the HIP in our ethnographic data analysis?

- to provide the basis for ensuring the ongoing generalisability of our finding by ensuring that local Healthwatch members and volunteers have the chance to jointly reflect on the data presented and provide ongoing interpretation and explanation based on their own experience;
- to ensure that our study outputs are meaningful to local Healthwatch staff and volunteers thus improving likelihood of beneficial change in the way in which Healthwatch currently operates;
- to ensure the PPI in this phase through engagement with Healthwatch volunteers.

The study will generate important new understandings and recommendations for key stakeholders helping to enhance patient and public voice at a time when the NHS is facing challenges and undergoing change. The combination of research methods and our innovative, sustained engagement with PPI and relevant stakeholders will ensure that our findings are nationally relevant, contextually sensitive and generalizable. The ongoing involvement of the HIP in phases 2 and 3 - and the JIFs in our case study sites in phase 4 - will increase the likelihood of beneficial change in the way in which Healthwatch currently operates.

Our study will produce practical recommendations and actionable guidance based on formulations of best practice drafted in collaboration with the HIP and our Advisory Board. These outputs will provide evidence-based and contextually sensitive rationales both for how Healthwatch might enhance patient and public voice in healthcare commissioning and provision, and also how CCGs, providers and patients can more effectively participate in these processes.

4.1 Background and Rationale

Every time the NHS undergoes significant reform, its structures and processes for involving patients and the public also change. Since 2000, there have been three major reorganisations of the official systems for patient and public involvement (PPI) (1). Community Health Councils (CHCs) were replaced by PPI Forums in 2002, which were themselves abolished and replaced by Local Involvement Networks (LINks) in 2008. LINks operated for four years and were superseded by Healthwatch, which was established as part of the Coalition Government's 2012 reform of health and social care. Each iteration of official PPI has had different duties, powers, funding, composition and mechanisms for accountability.

Originally conceived as a 'consumer champion', Healthwatch is ostensibly a key NHS partner in monitoring the quality - and supporting the design - of health and social care locally by providing NHS England, CCGs, provider organisations and local authorities with information and advice based on the views of citizens and patients (2, 3). Healthwatch activities include signposting health services, gathering intelligence on people's views and experiences of care and monitoring the standard of health provision locally. Local Healthwatch are awarded contracts by the local authority, the money for which comes from the Department of Health via the Department for Communities and Local Government. Healthwatch bodies are differentiated from LINks by their statutory membership of new strategic local Health and Wellbeing Boards, which were themselves a key plank of the 2012 reforms for integrating health and social care (4, 5). As one commentator has stated, 'local Healthwatch are unique - they are the only organisation that has a helicopter view of an entire local Health and Wellbeing system. In the world of localism and integrated health and care this is key.'(6)

Five years on, there are 152 local Healthwatch bodies across England, supported by a national organisation, Healthwatch England. Though there have been several studies of Healthwatch's predecessors (7-11), our study will be the first comprehensive examination of how local Healthwatch bodies variously build influence and whether and how they are meaningful as a key pillar of citizen and patient involvement in the NHS.

In the period before Healthwatch became operational, a NIHR-funded study looked at how CCGs conduct PPI in relation to long-term conditions; it recommended that 'further research is urgently required to examine how [PPI] is being developed within the reformed … NHS' (12). However, since then there has been little research on the work of Healthwatch. Based on research conducted between September 2014 and February 2015, a King's Fund report examined the initial operation of local Healthwatch, noting the variability of Healthwatch work, identifying activities which make Healthwatch effective and proposing recommendations for change (13).

More recent work by Martin & Carter looking at a local Healthwatch in the East Midlands has pointed to several challenges caused by a lack of clarity of Healthwatch's role in the landscape of health and social care planning and provision (1, 14). One such challenge is the jurisdictional misalignment between local Healthwatch, local authorities, Health and Wellbeing Boards and the NHS organisations with which they must work (4, 14, 15). Other tensions include competition with third sector and PPI organisations and processes, and constrained local authority budgets from which local Healthwatch contracts are awarded for two or three years at a time (1, 14). Reflecting on the design of 'Local Healthwatch Quality Statements' launched in 2016 in order to encourage local Healthwatch organisations to collect information about and assess the quality of their work, Gansu similarly highlighted the importance of local context and the quality of relationships between service managers, local authority leaders, CCG members and Healthwatch (6).

While these studies point to the challenges and tensions faced by local Healthwatch, they provide little contextually-specific evidence about the practices and relationships through which Healthwatch influence is created and maintained and how this enables or hampers more effective services for patients. Building on the available literature and addressing its limitations, our study aims to map the

current practices and relationships of local Healthwatch in England and to provide an in-depth understanding of the ways in which local Healthwatch succeeds or fails to exert influence on key stakeholders.

To achieve this aim, our theoretical framework will be Actor Network Theory (16, 17). Originating in Science and Technology Studies, ANT focuses on the role of 'mutually-influencing relations' (18) between various human and institutional actors as well as the socio-material contexts – e.g. objects, documents, buildings, meetings, technologies, data, policies, strategies, contracts, ideas - in which they operate (see Box 2 below).

BOX 2 What is Actor-Network Theory (ANT)?

- ANT is a theory developed by Bruno Latour, Michel Callon and John Law as part of Science and Technology Studies during the 1980s.
- although it carries 'theory' in its name, it is better understood as a range of methods for doing social science research
- ANT sets out to describe the connections that link together *humans* and *non-humans* (e.g. objects, documents, buildings, meetings, technologies, data, policies, strategies, contracts, ideas). Both humans and non-humans are understood as 'actors' that can have influence on phenomena of interest.
- in particular, ANT describes how these connections come to be formed, what holds them together and what they produce in particular contexts. This system of mutual influence between and among humans and non-humans is called an 'actor-network'.
- to study an actor-network, ANT researchers employ some key qualitative research methods as part of their data collection:
  - participant observation i.e. spending time in the places where the interactions between actors (both human and non-human) happen and decisions about them are taken, and recording them as fieldnotes;
  - interviews with relevant human actors, to discuss their opinions, frustrations, emotions, hopes and beliefs as well as the reasons underlying their practices;
  - collection and analysis of relevant documents, particularly if they play a part in interactions.

In the context of healthcare service and delivery, ANT has typically been advanced as a framework for investigating health care organisations and technologies (19-21) and has been applied successfully in other NIHR-funded studies (22-25). Three members of the proposed project team - GR, AD and GZ - have previously been involved in a NIHR-funded project which used ANT to investigate and optimise the use of patient experience data in acute NHS trusts (Donetto HS&DR 14/156/08) (25). This work explored the mutually-influencing relationship between different forms of patient experience data, technologies and the people and institutions which use or fail to use them to improve the quality of care for patients (26).[1]

[1] GR also previously proposed ANT as potentially offering insights into the process of decommissioning health service (Williams HS&DR 12/5001/25) (24), and the assimilation of technological innovations in healthcare organizations (27). ANT has informed studies of Lean in healthcare organisations (28), the 'invisible work' of nurses in the delivery of care (29, 30) and the effectiveness of quality improvement interventions (31).

Our study of Healthwatch similarly pays attention to these 'mutually-influencing relations' between various human and nonhuman actors in shaping how Healthwatch creates influence in promoting patient and public voice. Using ANT overcomes the limitations of the studies of Healthwatch that have been completed to date in two main ways. Firstly, existing studies have focused on a limited range of human and institutional actors [e.g. (1)] and give inadequate consideration to the ways in which relationships between local stakeholders are shaped and mediated on a daily basis by artefacts such as data, policies, documents, funding arrangements, technologies (i.e. nonhumans). This has provided a partial view of the way local Healthwatch creates influence. (See **Box 3** for examples of human and nonhuman actors).

BOX 3 Examples of 'human' and 'non-human' actors considered in the study

Humans	**Non-humans**
● Healthwatch staff and volunteers ● Patients ● Carers ● Local citizens ● Charities staff and volunteers ● CCG members ● Local authority officers ● Local GPs ● Trust staff (e.g. Patient experience managers, engagement managers, nurses, clinicians, etc)	● Documents (e.g. 'Enter and View' reports, strategy documents, STP plans, Healthwatch Quality Statements) ● Technologies (e.g. computers, software, patient experience data, surveys, internet, email, telephones) ● Funding and funding applications ● Policies ● Buildings ● Contracts ● Ideas

For example, we would look at the work that is undertaken to transform a concern about hospital services collected by a local Healthwatch volunteer into a report containing data that a hospital can act upon. The type of data (e.g. qualitative or quantitative), the quality of the personal relationships between the patient experience team and the local Healthwatch staff, the social media technologies that are used to expose the issue, the NHS and local authority meetings at which the concern is discussed may all play an important role in determining the influence exerted by local Healthwatch.

Secondly, existing studies rely primarily on interviews and surveys which can only provide post-hoc reflections of events (1, 13, 14).[2] These methods do not capture the processual nature of relations, thus obscuring the emergent and unexpected ways in which local Healthwatch enhance patient and public voice, and limiting the validity and utility of recommendations for good practice. By prospectively examining the nature and quality of interaction between local Healthwatch and key stakeholders as well as the nonhuman elements that enable such interaction, our study will provide a timely, contextually-sensitive and robust examination of these key but hitherto neglected organisations.

4.2 Evidence explaining why this research is needed now

There is a legal duty for the NHS to consider public involvement in commissioning and providing health care, and at all stages in major healthcare planning decisions (33). This is a cornerstone of a patient-centred NHS and does positively impact design and provision of care (34). There is increasing evidence of a positive association between public involvement and more 'innovative, effective and efficient ways

[2] Similarly, the data collection method for the new 'Local Healthwatch Quality Statements' is largely survey-based (32).

of designing, delivering and joining up services' (3). It is argued that NHS managers and staff are better equipped to understand the needs of the community they serve and to make better decisions about how to use limited resources when they listen to what matters to citizens (3).

While it is recognised that Healthwatch is well-placed to provide this, it is also clear that it is not fulfilling its full potential (1, 13, 14). Commissioners and providers, as well as national NHS bodies, need Healthwatch to be more influential in ensuring the impact of patient and public voice on their decision-making processes (35). Healthwatch England have also expressed a need for this work and contributed to its design through the involvement of Jacob Lant, Head of Policy and Partnerships, in our PPI activities, and will assist in its execution and dissemination of findings via our Advisory Group.

The research is timely. The lack of evidence of how Healthwatch works is particularly problematic given the changes underway in the organisation of English health and social care. As the NHS responds to the *Five Year Forward View* (36) and develops Sustainability & Transformation Plans (STPs), policy and decision-makers need to have a contemporary and in-depth understanding of the strengths and weaknesses of Healthwatch and how local Healthwatch activities and relationships might be optimised to maximise their contribution to shape and advise on the changes to come. A 2017 King's Fund report on the progress of the STPs noted that local NHS leaders have not hitherto adequately and meaningfully engaged patients, citizens and local authorities in their development; doing so is described as an 'urgent priority' (37).

Understanding and optimising the work of local Healthwatch in relation to these processes will not only ensure that more informed decisions about resources are made by NHS management; it is also argued that more participatory decision-making increases the likelihood of building sustainable support for changes to services among local communities (24).

There is no robust, theoretically-informed evidence about the processes through which local Healthwatch influence is created and maintained. The combination of research methods and our innovative, on-going engagement with relevant stakeholders through the HIP, JIFs and the Advisory Group will ensure that our findings are nationally relevant, contextually sensitive and generalizable. In particular, the national online survey in phase 1 of the study will provide an up-to-date and integrated assessment of the current state of Healthwatch practices and impact across England. The ethnographic data produced in phase 2 will provide the basis for the first-ever evidence-based analysis of the daily work of local Healthwatch, allowing connections to be made between activities, relationships and intended outcomes. The online interviews and small-group discussions with HIP members in phase 2 will generate emerging statements of good practice, as well as helping contextualise the work of local Healthwatch in England in their response to COVID-19. Drawing on these different sets of data, our research findings will offer the most securely evidenced set of contemporary 'good practices' for local Healthwatch to date.

4.3 Aims and objectives

The aim of the study is to explore and enhance the operation and impact of local Healthwatch in ensuring effective patient and public voice in the commissioning and provision of NHS services. We will achieve this aim by pursuing four objectives:

1. To establish current priorities, activities (e.g. advocacy, signposting, surveys, inspections) and organisational arrangements (e.g. staffing, funding, nature of contract, jurisdictions) of the 152 local Healthwatch in England;

2. To explore the particular processes and interactions that link local Healthwatch to a range of individual and institutional actors (such as commissioners, GPs, CCGs, Trusts, patients, local authority staff, care homes, third-sector organisations, and Healthwatch England) and to the wider contexts through which they operate (such as funding, contracts, reports) in order to assess their impact on local healthcare commissioning and provision;
3. To build consensus about what might constitute 'good practice' in terms of the operation of local Healthwatch;
4. To distil and then disseminate generalizable principles around what facilitates and/or limits the influence of local Healthwatch as a key element of patient and public voice in the NHS.

Doing so will help us answer our two key research questions:

- What are the strategies, practices and socio-material structures that enable Healthwatch to enhance patient and public voice in the NHS?
- How is patient and public involvement made impactful for citizens themselves as well as commissioners, providers and other NHS actors as they are brought together through the daily work of Healthwatch?

5. Study design (including data collection and analysis) and flowchart

5.1 Study design

Overall design and theoretical/conceptual framework:

Our study will produce the first robust account of the organisational strategies and practices that shape how local Healthwatch influence commissioning and provision of health and social care. As discussed above, there is little evidence about how local Healthwatch work in practice, how its relationships are established and maintained and how these help or hinder the ability of local Healthwatch to represent the views and interests of their local communities. To achieve its aims, the study will use a mixed method design across four phases. The core data will be produced through an ethnographic study of the relationships through which the work of Healthwatch is performed.

Phase 1: nationwide online survey

We will design and carry out an online nationwide survey of the 152 local Healthwatch bodies in England. The survey will provide an up-to-date account of the institutional contexts of Healthwatch operations. Elements of the survey (those looking at jurisdictional contexts – see Box 4 below) will be used to construct the sampling strategy for recruitment of case-study sites participating in the ethnographic phase (Phase 2).

Sampling:

All 152 local Healthwatch bodies in England.

Setting/context: all 152 local Healthwatch bodies in England.

Data collection: the survey will ask questions across key variables, some of which are indicated by the existing literature and others which were raised during the project team's initial PPI work. The set of variables to be explored will be finalised in discussion with our advisory group prior to the survey being undertaken. In Box 4 we list the main areas the survey will cover in order to map the organisational, bureaucratic and financial arrangements of local Healthwatch.

BOX 4 Key variables considered in Phase 1 national online survey with examples

Variable	Rationale for inclusion	Examples
1. Local Healthwatch priority areas[3]	Importance of priorities highlighted during a pre-study PPI Focus Group	o Mental Health o Social care o Primary care o Children and young people's experiences of health and social care o The experiences of seldom heard groups, including BAME communities
2. Range of activities	Highlighted in Gilburt et al (2015)	o providing information and advice about services o gathering people's views and experiences of services o monitor the standard of provision in local health and social care services (e.g. 'enter and view' privileges) o bringing together and analysing the views of local people and making reports and recommendations o influencing health and social care providers and commissioners o operating as a member of the Health and Wellbeing Board o sharing information and escalating concerns to the Care Quality Commission o sharing information and intelligence with Healthwatch England
3.Organisational structure	Highlighted in Martin and Carter (forthcoming)	o staffing (number of employed staff and volunteers) o length and type of contract from the local authority o amount of funding and funding arrangements o whether the organisation which runs Healthwatch services is a standalone enterprise or runs other Healthwatch elsewhere as well.

[3] 2017 priorities as listed on Healthwatch England website (http://www.healthwatch.co.uk/news/healthwatch-network-reveals-public's-health-and-care-priorities-2017), accessed 09/09/17.

4.Jurisdictional context	Highlighted in Carter and Martin (2016)	o urban/suburban/rural location o size of population covered o number of health and social care providers in the area o number of organisations where local Healthwatch has formal representation (e.g. Boards or Committees where local Healthwatch sit at Trusts, CCGs etc). o involvement with STPs

Data analysis: The survey data and analysis will comprise descriptive statistics consisting of single variables and include frequency and percentage response distributions, measures of central tendency, and dispersion measures such as the range and standard deviation. All open comment responses will be analysed using open coding and constant comparison.

Phase 2: ethnographic study

We will carry out an ANT-informed ethnographic study (38-40) to map the everyday interactions of five local Healthwatch bodies with a range of other institutional actors (e.g. local authorities, CCGs), and the nonhuman entities (e.g. data, documents, strategies, funding structures) that mediate and shape relations. Data in this phase will comprise fieldnotes of non-participant observation, interviews and primary documents; these will be analysed by the study team in collaboration with the HIP comprising members from fifteen local Healthwatch which are not case-study sites.

Sampling**:**

We will build our sampling strategy for the selection of five case study sites from the results and analysis of the Phase 1 survey, focusing particularly on the findings associated with variable 4, 'Jurisdictional contexts'. This choice is justified by our theoretical approach which gives prominence to the analysis of mutually-influencing relations between and among humans and nonhumans in identifying how impact is created in the daily work of local Healthwatch as it interacts with a range of other organisations. As Carter & Martin have discussed, 'local authority areas may not be coterminous with CCG or provider organisations' catchment; consequently some local Healthwatch must deal with multiple commissioners and providers that have different administrative and geographical boundaries' (14). The choice of focussing on variable 4 also addresses the expressed need to better understand how these relationships work in the context of the changing geographies of health promoted by STPs and moves towards integrating health and social care.

Focusing on this variable will allow us to select local Healthwatch based on the complexity of the jurisdictional context in which they operate and with whom they interact. This includes, for example, the number of health and social care providers, the number and type of organisations where local Healthwatch has formal representation (i.e. the number of Boards or Committees local Healthwatch participate in at Trusts, CCGs, local authorities), and the type of local authority (unitary or county)[4]. The exact nature and number of connections used to sample case study sites will be established on the basis of the results and analysis of the Phase 1 survey. We will select five local Healthwatch to be our organizational case studies which - taken together - provide a sufficiently wide range of examples of jurisdictional complexity to inform our overall findings and produce good practice for Healthwatch and other key stakeholders.

Healthwatch involvement Panel (HIP): We will invite 15 Healthwatch to participate in the HIP. The inclusion criteria are that they will have responded to the Phase 1 survey and indicated a willingness to

[4] An earlier study of Health & Wellbeing Boards found differences in operation between those in unitary local authorities and those in county council areas (4).

participate. The exclusion criteria are that they have been selected as one of the five case study sites. In the event that we receive more positive responses than needed (n=15), we will aim to ensure maximum variation of HIP members based on the same criteria used for the sampling strategy for recruitment of case study sites.

Interviews: During Phase 2, we will invite Healthwatch staff, volunteers, and relevant stakeholders from the five case studies to take part in individual semi-structured interviews (12 per site; 60 in total). We will aim to interview a sample of staff, managers, volunteers, local CCG members, local authorities, local Health and Wellbeing Board members and relevant provider representatives e.g. Trust patient experience managers, patients and patient organizations who are involved in the daily work of local Healthwatch.

Setting/context:

Following successful recruitment of the case-study sites and before the start of the fieldwork, we will conduct a preliminary visit to each of the five Healthwatch in order to formally introduce the aims, objectives and methods of the project. We will carry out ethnographic data collection at the five selected local Healthwatch across England. We will base our observational practice in Healthwatch offices as well as accompanying the staff and volunteers to relevant daily activities and meetings (for example, visits to NHS Trusts, Health and Wellbeing boards, GP surgeries, community meetings and local authority presentations).

Data collection: we will map the everyday interactions between the five local Healthwatch and a range of actors including local authorities, citizens, Trusts, CCGs, and charities. An ANT approach will allow us to attend to the socio-material environments (documents, reports, data and funding) that shape the interactions between individual and institutional actors (1). We will collect 3 forms of data:

- ethnographic fieldnotes (nine 3-days visits at each site; total 135 days) e.g. attending meetings; accompanying staff and volunteers on data gathering, outreach and inspection activities; attending training and observing the daily work in offices.
- individual semi-structured interviews (12 per site; 60 in total; 60-90 minutes each) with employed staff of all levels, volunteers, CCG members, Health and Wellbeing Board members, local authorities and relevant provider representatives e.g. Trust patient experience managers, patients and patient organizations.
- documentary evidence such as internal documents, reports, Health and Wellbeing Board minutes, local Healthwatch and Healthwatch England strategy documents.

At each local Healthwatch, we will identify key interactions between human and non-human actors and observe the practices in which these interactions are embedded. As part of our ethnographic work, we will record our observations of office work, meetings, the production and circulation of reports, the collection of data, everyday interactions between Healthwatch members and external actors such as the CCG, local GPs, Health and Wellbeing Board, patient experience and engagement managers at Providers. The role of social care commissioning and provision in our study of local Healthwatch will be considered as it arises in the observed work of the five local Healthwatch selected as case-study sites (and among the additional 15 Healthwatch that form the HIP). For instance, how and why might a local Healthwatch's focus on issues of social care commissioning and provision help it build influence in ways that are different to those of health care commissioning and provision? What examples are there of Healthwatch engaging in social care commissioning and provision and what are the implications of this for their operation and effectiveness?

We will pay equal attention to interactions between human and nonhuman actors (for example, strategy documents, funding applications, data, 'Enter and View' reports) as they take place and produce effects.

Observational data will be recorded as written fieldnotes. Occasional still photographs will be taken of meetings and daily activities. In each of our five case study sites we will also carry out individual semi-structured interviews with a range of local Healthwatch staff and volunteers, CCG members, Trust staff, Health and Wellbeing Board members, local authority officers. This will enable us to explore themes that emerge through the other two forms of data collection (non-participant observation and documentary evidence), as well as elicit opinions from research participants, test hypotheses, and obtain targeted information.

The discussions of emerging findings at 5 half-day meetings with the Healthwatch Involvement Panel (HIP) during phases 2 and 3 will be minuted to serve as a record of proceedings and enable data analysis. These meetings will take place on King's College London premises or online.

Data analysis:

Data from documents, interviews, observations and still photographs will be triangulated to develop detailed descriptions of the daily work, relationships and strategies of the five local Healthwatch case study sites. These data sources will provide both contextual information and specific insights into how local Healthwatch creates influence in their daily interactions with key actors. ANT is primarily concerned with giving equal analytical prominence to the relations between and among nonhumans as well as humans; that is, the way in which people and objects shape each other through ongoing mutual relations. In interrogating our ethnographic data, we will prioritise and foreground the detailed, contextualised description of interactions and relations between various actors (both human and non-human) that constitute the work of local Healthwatch. We will generate topical word codes, which will have an indexing function as the ethnographic work progresses through Phase 2, and thus help us to order our analytical framework. The codes will consist of key words, concepts and ideas, some of which may be 'in vivo' i.e. provided by research participants themselves. We will place codes at the top of fieldnote entries and at appropriate points in the text as they are written at the time of fieldwork; these will be refined as fieldnotes are read and re-read during data analysis. Likewise, codes will be attached to interview transcripts and documentary material. Case-study site researchers will conduct case-by-case analysis; cross-site analysis will be conducted at study team meetings and in collaboration with the Healthwatch Involvement Panel (HIP).

Data analysis will be an iterative process alongside data collection and will include 5 half-day meetings with the HIP. In advance of the first data analysis meeting, HIP members will attend a one-day training session on ethnographic data collection and analysis run by AD and GZ and facilitated by the HIP Chair SB. At each HIP meeting, data from case-study sites will be presented using a PowerPoint presentation by the research staff conducting the ethnographic fieldwork. HIP members will be asked:

- to reflect on the data presented and provide interpretation and explanation based on their own experience and knowledge of working at a local Healthwatch;
- to look for points of similarity and difference with their own organisational practices to help build a broader picture of local Healthwatch activity across England;
- to guide the research team with detailed suggestions on how to develop the ethnographic work in accordance with short and medium-term fieldwork objectives.

The core purpose of the HIP is to provide the basis for ensuring the ongoing generalisability of our findings.

Phase 3: online interviews and small-group discussions with HIP members to generate emerging statements of good practice (and lessons emerging from COVID-19 pandemic)

Sampling: 15 members of the HIP (representing 15 local Healthwatch which are not case study sites for ethnographic fieldwork in phase 1).

Setting/context: online/telephone interviews

Data collection: Online interviews and small-group discussions will be arranged with HIP members. For small-group discussions, we will hold online meetings for groups of 3-5 members. Based on our phase 2 findings we will create statements of good practice which we will discuss and refine through an iterative process with HIP members and through the JIFs (see phase 4 below). These statements will be generalisable though they will not all apply equally to all Healthwatch. With the help of the HIP members we will seek to advise on contexts where they might apply and work best. These statements of good practice will not necessarily be linked to the COVID-19 pandemic (although the pandemic has highlighted and catalysed existing practices and relationships which may well constitute examples of 'good practice'). We will therefore ask HIP members questions relating to the local management of the pandemic and the work and role of local Healthwatch during this time. Researchers will take notes during these sessions. Online sessions will also be recorded and transcribed by our approved transcriber.

Data analysis: We will read session transcripts and our fieldnotes. We will generate topical word codes, which will have an indexing function across the interviews and thus help us to order our analytical framework. The codes will consist of key words, concepts and ideas, some of which may be 'in vivo' i.e. provided by research participants themselves. We will place codes at the top of fieldnote entries and at appropriate points in the text as they are written at the time of our interviews; these will be refined as fieldnotes are read and re-read during data analysis. Likewise, codes will be attached to interview transcripts and documentary material. Analysis across the interviews and small-group discussions will be conducted at study team meetings and in collaboration with the Healthwatch Involvement Panel (HIP).

Phase 4: Joint Interpretive Forums (JIFs)

Joint Interpretative Forums (46) will engage multiple stakeholders in joint reflection and interpretation of findings from phases 1, 2 and 3. A cross-site JIF with key stakeholders from the five case study sites and national policy makers and representatives from patient organisations will take place in London or online to enable cross-sites exchanges and dissemination. This will be followed by local JIFs conducted with individual study-sites and their particular stakeholders. This will take place at the study-site or online.

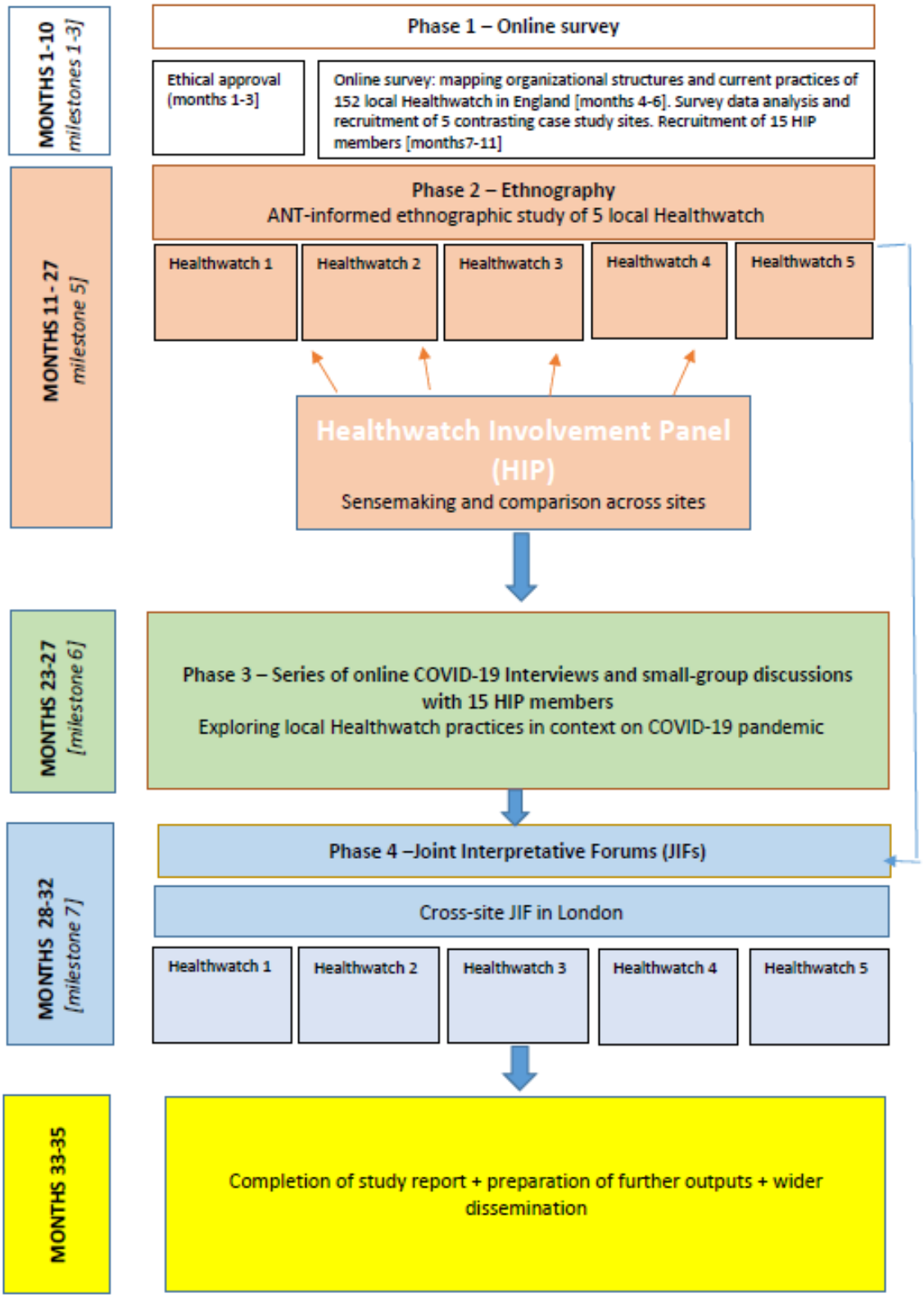
Sampling: Participants in JIFs at each case-study site locality will comprise local Healthwatch staff and volunteers, CCG members, local authority officials, Health and Wellbeing Board members, GP surgeries, Trust staff involved in patient experience and engagement, citizens and patients, relevant members of local CLAHRC, with the addition of policymakers for the cross-site JIF. These will have been purposively identified on the basis of their involvement in networks associated with local Healthwatch and their willingness and availability to participate. We will aim to involve 8 participants at each case-study JIF (of which 2 participants are patients or public) and 16 participants at the cross-site JIF (of which up to 10 will be key stakeholders from case study sites).

Setting/context: The initial cross-site JIF will be held in London or online and will involve representatives from all case study sites as well as policy makers and representatives from patient organisations. One JIF will then be held at each of the five case-study sites selected for the ethnographic work in phase 2 or online. Each JIF will last no more than two hours.

Data collection: At each JIF, members of the research team will present the background to the study and the findings from Phases 1, 2 and 3. The participants at this JIF will be asked to interpret verbally the emerging statements from Phase 3 with the aim of converting them into principles of good practice for local Healthwatch. Discussion will be facilitated by one member of the study team. The proceedings of each JIF will be audio-recorded and transcribed.

Data analysis: JIF transcripts will be analysed thematically with the specific purpose of developing practical and generalizable recommendations for policy and practice to optimise patient and public voice in NHS commissioning and service provision.

5.2 Flowchart



6. Subject selection

Participants will be selected based on their association with five local Healthwatch study sites. See ‘Sampling’ sections above for further details.

6.1 Subject inclusion criteria

Staff and volunteers of local Healthwatch organisations in England

NHS staff, patients/carers, adult social care users (all over 18 years), and local residents who engage with local Healthwatch organisations in England and are able to give informed consent.

Staff of non-Healthwatch, non-NHS organisations such as employees of local authorities, third-sector bodies, Health and Wellbeing Boards, who have working relationships with local Healthwatch.

6.2 Subject exclusion criteria

Patients/carers/social care users (under 18 years) who engage with local Healthwatch organisations in England

Patients/carers/social care users of any age unable to give informed consent

7. Study procedures

7.1 Subject recruitment

Healthwatch staff:

With sensitivity to the work demands of staff, researchers will identify practices to observe at each case study site and which staff to interview at which site. Researchers will establish, through informal conversations with members of staff in managerial as well as front-line roles, which practices to observe and who to invite for semi-structured individual interviews. The researchers will also identify, in consultation with staff, those routine group practices that might be still photographed.

Potential participants will be approached by a member of the research team or by a member of staff who will then inform the researcher of this member of staff's interest in the study. At this time the researcher will briefly explain the study to that individual, invite and answer any questions and give them the Healthwatch Staff Participant Information Sheet. Brief contact details (e.g. work mobile number) may be requested only from that individual and only if it is not possible for the researcher and individual to plan appropriate times for data collection

personally. Not less than 48 hours later the researcher will contact that member of staff again to check their continued interest, to request and answer any further questions about the research or the interview, and to arrange a suitable interview place and time. Researchers from the team will have sole responsibility for providing detailed information about the study and ensuring that potential participants are aware and informed of the study.

NHS staff, employees of other organisations and patients/carers/social care users who have engaged with local Healthwatch:

The approach will first be by a member of the local Healthwatch team who has previously been in contact with the potential participant and who will ask them if they are happy for their details to be passed on to the researcher. Potential participants will be identified in liaison with appropriate Healthwatch staff. The appropriate Participant Information Sheet will be given to the potential participant when their initial interest in the study has been established in a short, face-to-face, conversation with the researcher. The researcher will allow at least 48 hours between giving the participant information sheet and contacting the participant. At this contact the researcher will check that the potential participant is still interested in participating and ask for and answer any further questions concerning the research or the participants' role within it.

Researchers will always seek informed consent for group observation or interview.

7.2 Obtaining informed consent

Informed, written consent will be sought for all interviews (with Healthwatch staff, NHS staff, staff of other organisations and patients/adult social care users/carers); for non-participant observation of routine practice focused on single individuals (Healthwatch staff only); and for all occasional still photographs of group events of routine meetings (Healthwatch staff). Written and verbal informed consent will be obtained from participants only by a member of the research team.

For as long as possible before group observations, and at least 48 hours before observations of individual routine practice and interviews, participants will be given time to consider the information contained in their respective participant information sheets before written consent for participation is sought. All research participants will be informed in their respective participant information sheets, and verbally reminded by the researcher prior to his/her seeking informed consent, of their right to withdraw from the study at any time, without having to give a reason, and irrespective of their signing or agreeing to informed consent. Research participants will be able to withdraw their research data from the study until data analysis commences.

Consent for Healthwatch, NHS staff, employees of other organisations' semi-structured interviews:

Consent will be signed for by that member of staff on the research participant consent sheet. It will be explained to participants that they can withdraw their consent to interview prior to and during the interview even though they have signed the consent form. Where interviews take place over the telephone/online, the researcher will audio-record - with permission - the consent procedure over the telephone/online. Participants will be able to decline audio-recording of the interview, at any point during the interview, even though the consent procedure is recorded.

Consent for patient/social care user semi-structured interviews

Consent from patients will be obtained from patients/social care users/carers who have engaged with Healthwatch following a careful information-giving process involving at least two contacts with the researcher, with 'opt out' available to patients at each stage of this engagement. Prior to obtaining consent, the researcher will check that the patient/social care user/carer understands the study and their part within it and will ask for and answer any questions that the potential participant may have concerning the study and their role within it. Consent will be obtained only by the named researcher and, wherever possible, this researcher will be the same researcher who engages with the participant throughout the recruitment process. Consent will be obtained immediately prior to participant interview. It will be explained to the participant that they can withdraw consent prior to, and at any time during, the interview irrespective of their signing the consent form.

In the case of face-to-face interview, consent will be established in writing by the patient consent sheet. Where interviews take place over the telephone or online, the researcher will audio-record - with permission - the consent procedure over the telephone/online. It will be explained to these participants that they will be able to decline audio recording of the interview, at any point during the interview even though the consent procedure is recorded.

Consent for non-participant observations of individual practice:

As noted above, written informed consent will be obtained from the individual Healthwatch staff member who is the focus of data collection of routine individual practice. These observations could be undertaken in public areas or private areas (such as a staff or meeting room). In such cases some staff members (those who are not the individual focus of non-participant observation of routine practice) will not be individually consented but verbally informed of the study and the role of the researcher in that context (ie. to observe an individual's routine practice). They will be asked to inform the researcher if they do not wish to be observed (opt out) and informed of their entitlement to withdraw any data collected relating to them at any time until data analysis begins.

Consent for non-participant observation of group practices:

A researcher from the study team will obtain verbal consent from all people involved in non-participant observations. During observations that extend beyond individuals to meetings, it

will not be feasible to seek individual consent from all possible participants. In these situations, the presence of the researcher will be explained and permissions for attendance will be sought from Chairs. Meeting participants will be informed verbally of the of the study and the role of the researcher in that context. They will be asked by the researcher to inform him/her if they wish for discussions or activities directly involving them to be excluded from data collection. They will be assured that this request can be made at any time up to data analysis and can be made without the need to give a reason. In addition to always seeking written or verbal consent from individual participants, permission to observe group practices at meetings will be sought at relevant managerial level. Members of Healthwatch staff will be informed in advance by key collaborators at the sites.

Consent for an occasional still photograph of group activities focused on routine practices

The use of still photographs of routine group practices will be identified in collaboration with appropriate Healthwatch management staff. The researchers will seek to give as long a period as possible for research participants to consider if they want to be photographed as part of a group activity and to give written consent for this. If a participant does not want to be photographed, they will not be included in the taking of the picture.

Consent for participation in Joint Interpretive Forums (JIFs):

Detailed information about JIFs will be provided to potential participants in advance of the meetings and easy access to clarifications and further information provided. Voluntary participation in these group discussions will be considered consent to taking part. This will be clearly stated at the beginning of each JIF and verbal confirmation that participants are clear about the terms of their involvement and the ground rules for the discussion will be sought at the start of the meetings.

7.3 End of study definition

The end of the study will be triggered when the Final Report is submitted to NIHR for review. No subject recruitment will take place after this.

8. Assessment of safety

No serious adverse events are expected to occur during this study.

8.1 Safety of participants

Patients, carers, adult social care users and members of Healthwatch, NHS and other organisations' staff will be asked about their experiences of interacting and working for local Healthwatch organisations. They will not be asked about intimate or potentially distressing care or work place experiences. However, the following steps will still be in place to minimise the risk of distress:

1. Interviews, as well as all informed consent processes, will be carried out only by named and experienced researchers from the study team. Both the researchers are highly experienced in interviewing patients on sensitive and less sensitive research topics. They are also all experienced in offering as well as seeking support for interviewees should the interview event caused distress.

2. Should a participant become distressed during interview or observation participation, the researcher will stop the procedure and recommence only if/when the participant tells them that they are comfortable to continue.

3. We will ensure the availability of information on local NHS systems and personnel for the provision of expert support (e.g. from local Patient Advice and Liaison Service).

4. Joint Interpretive Forums (JIFs) involving Healthwatch, NHS and other organisations' staff, and patients and carers may also trigger group dynamics proving uncomfortable for some. In view of the topics to be discussed at JIFs, this is unlikely, however. JIF discussions will be facilitated by members of the research team, all of whom are experienced in the management of complex group dynamics and the minimisation of possible participant distress. Furthermore, advice will be sought from the advisory group, and its patient/carer members in particular, on how to best prevent and/or handle potential tensions in the
groups.

The burden of research time for Healthwatch, NHS and other organisations' staff involved in the study will be minimised by the following:

1. Interviews with staff will be organised flexibly and outside of most pressured work periods.

2. Interviews will be conducted in private areas that are close to routine work (eg. usual offices or quiet rooms)

3. An option for telephone/online interview will be offered.

4. Interviews will not exceed 90 minutes (and are likely to be 45 minutes for most staff)

5. Opportunity to participate in observation research (comprising minimum research time burden) will be available without staff interview participation.

6. Participation in JIF events will be available locally.

8.2 Safety of researchers

The location (local Healthwatch organisations), participant groups (Healthwatch staff, NHS staff, employees of other relevant organisations, patients/carers) and topic of the research represent a low risk for researchers. However, there are inevitable risks associated with fieldwork and with lone working of researchers. In this study, the main risks relate to travelling to and around a number of unfamiliar locations. The study will follow King's College London's Procedure and Guidance for the Management of Fieldwork Activities. A Staff Safety Procedure will be followed. The researcher will notify his/her line manager, colleague or other person (as most appropriate) of their travel plans, expected destinations and times, and will check in with them at the end of each day. Each researcher will have a mobile phone for maintaining contact with this manager, colleague or appropriate person during fieldwork activities.

8.3 Study Advisory Group

The project is overseen by an Advisory Group of 11 people who meet in person for a total of 5 meetings over the study period. They will advise on any safety and ethical issues.

8.4 Ethics and regulatory approvals

The study has been approved by King's College London Research Ethics Committee (LRS-18/19-12587). It has been categorised as a 'low-risk' study.

This research does not meet any of the mandates for NHS REC review. While the project involves interviews/observations of NHS patients this will only be done following appropriate written consent. These patients are recruited into the study due to their connection with Healthwatch (as a Non-NHS organisation); NHS patients are not identified in the context of, or in connection with, their past or present use of the NHS or adult social care services.

The NHS staff involved in the project are identified and recruited due to their professional relationship with NHS services, as key stakeholders in the NHS/Healthwatch interface. We received HRA approval on 5th August 2019 (project number 252993) and they have judged we do not need NHS REC review. The study is REC exempt.

REC Governance Arrangement 2018 states:

"2.3.5 REC review as described in this document <u>is required</u> if a specific research project involves any of the following:

a. *potential research participants identified in the context of, or in connection with, their past or present use of the services listed above (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls*

2.3.14 Employers owe a duty of care to their employees that is different from the duty of care that care providers owe to users of their services. RECs are not expected to assume employers' responsibilities or liabilities, or to act as a substitute for employers' proper management of health and safety in the workplace. It is for employers to ensure that they are fulfilling their duties as employers when their employees take part in research. Research involving staff of the services listed in paragraph 2.3.4, who are recruited by virtue of their professional role, does not therefore require REC review except where it would otherwise require REC review under this document (for example, because there is a legal requirement for REC review, or because the research also involves patients or service users as research participants)".

9. Compliance and withdrawal

9.1 Withdrawal of subjects

We will not withdraw participants unless they ask to be withdrawn. If a study-site proves unsuitable or unable to support the research once the study begins, we will aim to replace the study site with another local Healthwatch.

For all participants, the burden of withdrawing from the study, should they choose this, will be minimised as follows:

1. The entitlement and process for all participants to withdraw themselves, or their data, from the study - irrespective of the signed consent process - will be explained in the appropriate Participant Information Sheets and will be explained verbally by the researcher during the process of acquiring informed consent.

2. Those participants who are part of indirect or group observations will be informed of their entitlement to inform the researcher that they do not want to participate and to have any data directly involving them withdrawn from the study, without having to explain why.

3. All patients and social care users will be reassured that non-participation in the study will not affect their treatment or care or their relationship with their local Healthwatch.

4. All participants will be informed that they can withdraw their data from the study until the point at which data analysis begins.

9.2 Protocol compliance

The study team will make periodic reports of protocol compliance to the NIHR by way of interim reports every six months during the life of the study. We will document and report non-compliance to the Sponsor.

10. Data handling and record keeping

All individuals will be identified only according to a unique ID code and the key to the code will be stored on a password protected secure server separate to the data.

No identifiable information will be reported in the dissemination of findings. Interview transcripts and field notes will be coded for anonymity.

Audio recorders used for interviews will contain encryption software to enhance interviewee confidentiality.

All occasional still photographs of group events will be pixillated immediately after taking to ensure that all personal and organisational identifiers are removed from the image.

No photographs will be taken of research participants (patients, social care users, or Healthwatch, NHS or other staff) during or immediately before or after interview and photographs will only be taken of routine group activities.

The anonymised interview audio recordings will be sent (using secure data transfer) to a King's College London approved company (that has also signed a confidentiality agreement) for transcription.

It is intended that anonymous abstracts from the interviews may be used in publications arising from this research but any materials will not be used without the full consent of participants.

No identifiable information will be reported in the dissemination of findings. Interview transcripts and field notes will be coded for anonymity.

The research team will ensure that it adheres to the Research Governance Framework with respect to confidentiality and anonymity.

All electronic data will be stored in encrypted King's College London computer systems or on password-protected portable hard drive. All hard copy documentation (e.g. fieldnotes, printouts of interview transcripts, organisational documentation) will be stored securely in a locked cabinet in the researchers' lockable office.

The Chief Investigator is responsible for data management.

11. Financing and insurance

The study is funded by NIHR HS&DR and the primary contract for delivery of the project is between NIHR and King's College London.

Any liabilities arising from the study are covered by King's College London's insurance.

12. Reporting and dissemination

Our research study will produce practical recommendations and actionable guidance based on formulations of good practice. These outputs will not only provide evidence based but contextually sensitive rationales for how Healthwatch might enhance patient and public voice in healthcare commissioning and provision, but also how CCGs, providers and patients can more effectively participate in these processes. The ongoing involvement of the HIP in Phase 2, their input into the emerging statements of good practice and exploration of the implications of COVID-19 on the practices of local Healthwatch in Phase 3 - together with the Joint Interpretive Forums in our case study sites in Phase 4 - will increase the likelihood of our findings and recommendations being generalizable and relevant to the way in which local Healthwatch currently operate across England.

Sally Brearley as a core team member and PPI representative will be co-authoring all outputs and dissemination activities. Patients and members of the public will be invited to the dissemination events to be held at the five local Healthwatch sites to encourage engagement with the research. We will also disseminate specifically to the Research Expert Group at St George's/Kingston University, which comprises interested members of the public and was involved at an early stage of designing our research proposal.

A range of other dissemination approaches will be used to target different audiences. We will produce a final research report for the NIHR Journals Library detailing all the work undertaken and including an abstract and executive summary focussed on findings and suitable for use separately from the report as a briefing for NHS managers. We will also prepare a set of 10 PowerPoint slides presenting the main research findings and designed for use by the research team and others in disseminating the findings to the NHS, Healthwatch and local authorities, along with an accompanying podcast series of four episodes (15 minutes) to maximise reach. The content of the podcasts will be decided towards the end of the study. Possible topics will include the range of work that local Healthwatch do, how they build relationships and how health services users and citizens can become more involved in their activities. The slides, report and podcast will be made available on the HS&DR programme website.

We will prepare at least 2 high impact academic papers (one focusing on how patient and public voice can be better embedded in the planning and provision of health and social care; the other aimed at academics interested in the everyday processes of health citizenship). We will submit abstracts for presentation at 2 national and 1 international academic conferences related to patient and public participation in healthcare. These may include, for example, the BSA Medical Sociology and HSRUK conferences.

We will also prepare short articles for the Health Services Journal and the Healthwatch England Bulletin and share our findings with organizations with a strong interest in this area of research (such as the King's Fund and the Health Foundation). Further specific routes for dissemination relevant to Healthwatch were identified at our second PPI Focus Group (as part of formulating this proposal) and include:

- National Healthwatch Conference
- Local Healthwatch assemblies
- NHS Confederation conference

- Local Government Association Annual Conference

The cross-site JIF with key stakeholders from the five study sites will be held in London or online at the end of the study and will represent an opportunity for cross-site exchanges and dissemination. It will be open to local authority health commissioners, CCGs, Providers, patient groups, interested third-sector organisations and citizens. Dissemination events will be held at the end of the study at each case-study site to engage a range of local stakeholders and members of the public.

We will establish a Twitter account for the project through which we will engage members of the public and solicit responses for specific aspects of our study.

A key output of the research will be robust evidence about the organisational strategies and practices that shape how local Healthwatch influence commissioning and provision of health and social care. There is little evidence about how local Healthwatch works, how its relationships are established and maintained and how these help or hinder the ability of local Healthwatch to represent the views and interests of their local communities. Our findings will provide a map of current practices of local Healthwatch in England and an in-depth understanding of the ways in which local Healthwatch succeeds or fails to exert influence on key stakeholders in a sample of organisations. From these, 'good practice' will be extracted and shared with NHS commissioners, providers, local Healthwatch and Healthwatch England, local authorities, NHS England and policymakers.

The study incorporates two main pathways to impact which combined will ensure that the outputs are tailored and reach the diverse audiences for which they are intended. The HIP will meet five times in Phases 2 and 3 and include local Healthwatch managers, staff and volunteers, providing a forum for sustainable engagement and long-term reflection on everyday strategies and challenges of local Healthwatch work. This ongoing commitment will help us refine our research focus and dissemination strategies to ensure that our study outputs are meaningful to local Healthwatch staff and volunteers.

The study will be overseen and steered by an Advisory Group which will meet twice a year and will consist of a broad body of key stakeholders. Members who have already agreed to participate include two PPI researchers at different NIHR CLAHRCs (East of England and South West England), representatives from NHS England, the Department of Health and Healthwatch England. The involvement of the latter will guarantee that our outputs are shared with the wider Healthwatch network and will have an impact on national Healthwatch strategies. Other invited members of the Advisory Group include two Health and Wellbeing Board members, local authority and NHS commissioners, patient experience and engagement managers at NHS Trusts, Healthwatch Regional Networks, patients (e.g. patient participation group members) and charities. This combination of members will enable us to target our outputs to create maximum impact.

References

1. Martin GP and Carter P. (2017) Patient and public involvement in the new NHS: Choice, voice, and the pursuit of legitimacy. In M. Bevir and J.J. Waring (eds) De-centred Health Policy: Learning from the British Experiences in Healthcare Governance. London: Routledge.

2. Department of Health. Local Healthwatch: a strong voice for people - the policy explained. London: Department of Health; 2012.

3. NHS England. Patient and public participation in commissioning health and care: statutory guidance for CCGs and NHS England. 2017.

4. Coleman A, Checkland K, Segar J, McDermott I, Harrison S, Peckham S. Joining it up? Health and Wellbeing Boards in English Local Governance: Evidence from Clinical Commissioning Groups and Shadow Health and Wellbeing Boards. Local Government Studies. 2014;40(4):560-80.

5. Humphries R. Health and wellbeing boards: policy and prospects. Journal of Integrated Care. 2013;21(1):6-12.

6. Gansu M. 2015. [11/09/17].
Available from: https://localdemocracyandhealth.com/2015/12/07/what-do-people-think-about-localhealthwatch-andwhy/?utm_campaign=crowdfire&utm_content=crowdfire&utm_medium=social&utm_source=twitter

7. Baggott R. A Funny Thing Happened on the Way to the Forum? Reforming Patient and Public Involvement in the NHS in England. Public Administration. 2005;83(3):533-51.

8. Hogg CNL. Patient and public involvement: What next for the NHS? Health Expectations. 2007;10(2):129-38.

9. Martin GP. Whose health, whose care, whose say? Some comments on public involvement in new NHS commissioning arrangements. Critical Public Health. 2009;19(1):123-32.

10. Taylor J, Tritter JQ. Local Involvement Networks: learning from the early adopter programme. Coventry: National Centre for Involvement, 2007.

11. Centre for Public Scrutiny. Smoothing the way: developing local Healthwatch through lessons from Local Involvement Networks. London: CFPS, 2012.

12. Peckham S, Wilson P, Williams L, Smiddy J, Kendall S, Brooks F, et al. Commissioning for longterm conditions: hearing the voice of and engaging users–a qualitative multiple case study. 2014.

13. Gilburt H, Dunn, P, Foot C. Local Healthwatch: progress and promise. The King's Fund, 2015.

14. Carter P, Martin G. Challenges Facing Healthwatch, a New Consumer Champion in England. International Journal of Health Policy and Management. 2016;5(4):259-63.

15. Hunter DJ, O'Leary C, Visram S, Adams L, Finn R, Forrest A, Gosling, J. Interim report no. 2: Mapping the configuration and operation of Health and Wellbeing Boards across England. 2015.

16. Law J, Hassard J. Actor network theory and after. 1999.

17. Latour B. Reassembling the social : an introduction to actor-network-theory. Oxford: Oxford University Press; 2005.

18. Akrich M, Callon M, Latour B, Monaghan A. The key to success in innovation part I: the art of interessement. International Journal of Innovation Management. 2002;6(02):187-206.

19. Cresswell KM, Worth A, Sheikh A. Actor-Network Theory and its role in understanding the implementation of information technology developments in healthcare. Bmc Med Inform Decis. 2010;10.

20. Cresswell K, Worth A, Sheikh A. Implementing and adopting electronic health record systems: How actor-network theory can support evaluation. Clinical Governance: An International Journal. 2011;16(4):320-36.

21. Nguyen L, Bakewell L, Wickramasinghe N, Haddad P, Muhammad I, Moghimi H, et al. Transition from Paper to Electronic Nursing Documentation in Residential Aged Care: an Actor Network Theory Analysis. Electron J Health In. 2015;9(1).

22. Greenhalgh T. Developing theory and method for studying resistance to big IT programmes in healthcare. An NIHR HS&DR project. 2013;10(1011):01.

23. Tomlin Z, Peirce SC, Elwyn G, Faulkner A. The adoption space of early-emerging technologies: evaluation, innovation, gatekeeping (Pathways to Adoption of Technologies in Healthcare-PATH). 2013.

24. Williams I, Harlock J, Robert G, Mannion R, Brearley S, Hall K. Decommissioning health care: identifying best practice through primary and secondary research–a prospective mixed-methods study. National Institute of Health Research. 2017. HS&DR 12/5001/25.

25. Donetto S. Exploring the impact of patient experience data in acute NHS hospital trusts in England: using actor-network theory to optimise organisational strategies and practices for improving patients' experiences of care. National Institute of Health Research. HS&DR 14/156/08.

26. Desai A, Zoccatelli G, Adams M, Allen D, Brearley S, Rafferty AM, et al. Taking data seriously: the value of actor-network theory in rethinking patient experience data. Journal of Health Services Research & Policy. 2017;22(2):134-6.

27. Robert G, Greenhalgh T, Macfarlane F, Peacock R. Adopting and assimilating new nonpharmaceutical technologies into health care: A systematic review. Journal of Health Services Research & Policy. 2010;15(4):243-50.

28. Papadopoulos T, Radnor Z, Merali Y. The role of actor associations in understanding the implementation of Lean thinking in healthcare. International Journal of Operations & Production Management. 2011;31(2):167-91.

29. Allen D. Understanding context for quality improvement: Artefacts, affordances and socio-material infrastructure. Health-London. 2013;17(5):460-77.

30. Allen D. The invisible work of nurses : hospitals, organisation and healthcare.

31. Broer T, Nieboer AP, Bal RA. Opening the black box of quality improvement collaboratives: an Actor-Network theory approach. Bmc Health Serv Res. 2010;10.

32. Healthwatch England. Local Healthwatch Quality Statements. 2016.

33. Department of Health. The NHS Constitution for England. 2015.

34. Mockford C, Staniszewska S, Griffiths F, Herron-Marx S. The impact of patient and public involvement on UK NHS health care: a systematic review. International Journal for Quality in Health Care. 2012;24(1):28-38
.
35. NHS England. Planning and delivering service changes for patients. 2013.
36. NHS England. NHS Five Year Forward View. 2014.

37. Ham C, Alderwick H, Dunn P, McKenna H. Delivering sustainability and transformation plans: from ambitious proposals to credible plans. London: The King's Fund, 2017.

38. Hammersley M, Atkinson P. Ethnography: principles in practice. 3rd ed. ed. London: Routledge; 2007.

39. Mol A. The body multiple: ontology in medical practice. Durham, N.C.; London: Duke University Press; 2003.

40. Latour B, Woolgar S. Laboratory life: the construction of scientific facts. 2nd ed. ed. Princeton, N.J.: Princeton University Press; 1986
.
41. Robert G, Gabbay J, Stevens A. Which are the Best Information Sources for Identifying Emerging Health Care Technologies?: An International Delphi Survey. International journal of technology assessment in health care. 1998;14(4):636-43.

42. Robert G, Milne R. A Delphi study to establish national cost-effectiveness research priorities for positron emission tomography. European journal of radiology. 1999;30(1):54-60.

43. Robert G, Harlock J, Williams I. Disentangling rhetoric and reality: an international Delphi study of factors and processes that facilitate the successful implementation of decisions to decommission healthcare services. Implementation Science. 2014;9(1):123.

44. Linstone HA, Turoff M. The Delphi method: Techniques and applications: Addison-Wesley Reading, MA; 1975.

45. Mullen PM. Delphi: myths and reality. J Health Organ Manag. 2003;17(1):37-52.

46. Mohrman SA, Gibson CB, Mohrman AM. Doing research that is useful to practice a model and empirical exploration. Academy of Management Journal. 2001;44(2):357-75.

47. Martin GP. Public and user participation in public service delivery: tensions in policy and practice. Sociology Compass. 2009;3(2):310-26.

48. Learmonth M, Martin GP, Warwick P. Ordinary and effective: the Catch-22 in managing the public voice in health care? Health Expectations. 2009;12(1):106-15.