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Developing Methods for Systems-Informed Health Impact Assessments (System-HIA)

STUDY PROTOCOL V2.0

Start date: 01/05/2023 End date: 28/02/2023 Duration: 10 months

Purpose The purpose of the Protocol is to describe the study/project and provide information about the procedures for entering participants into the study/project. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary.



This protocol has been authorised by:			
Name Emily Tweed	Role Joint Principal Investigator	Signature	Date 22/06/2023
Name	Role: Study sponsor	Signature	Date



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1. Summary

Health Impact Assessment (HIA) is a set of methods used to systematically identify the potential health and wellbeing impacts of policies, plans, and projects outside the health sector, and to make recommendations about how those impacts may be managed. HIA is an established public health tool used to support the translation of



research evidence as part of a 'health in all policies' or 'healthy public policy' approach.

However, there is increasing recognition that the types of proposal examined by HIA represent interventions in complex systems, characterised by properties such as non-linear relationships, feedback, and emergence. Despite increasing attention to systems approaches in public health, its application to HIA has been very limited, and it is not at present explicitly reflected in guidance for HIA. This may limit the ability of HIA to understand and predict the impacts of proposed interventions, and to make effective recommendations that maximise health benefits, mitigate negative effects, and promote health equity.

We therefore want to investigate the potential contribution of systems approaches (drawing on a range of systems and complexity methods) as part of HIA, with a view to informing practical guidance on conducting HIA. Our interdisciplinary project, led by systems scientists, public health practitioners, and HIA specialists, proposes the following research questions:

1) Which systems approaches and techniques might be applicable to the process of HIA, and at what stages?

2) What are the implications of systems-informed HIA for those undertaking and acting on HIA?

The project has three phases. In Phase A, we will undertake a scoping review of how systems approaches have been applied to impact assessment methods from other fields (such as environmental science) and prepare a collated set of potentially relevant tools from systems science for discussion at the workshops. We will recruit workshop participants representing key stakeholders, including specialists in HIA and other forms of impact assessment, stakeholders from non-health sectors whose proposals may be subject to HIA, public and third sector representatives, and systems scientists. In Phase B, we will undertake a set of three sequential workshops (each run on two separate occasions to maximise attendance across different stakeholder groups and timezones) with these key stakeholders. These workshops will consider how systems tools can be applied to the different stages of HIA with a particular focus on the appraisal of potential health impacts and the development of recommendations. The workshops will also discuss how the use of systems approaches may have changed the process, outputs, and outcomes of three case study HIA (selected by that group from a shortlist of previous HIA undertaken by the study team and our practice partners). This may include both positive and negative effects. In Phase C, we will use emerging findings from the



workshops to pilot systems approaches as part of up to three prospectively conducted HIA by our practice partners.

Based on these activities, we will produce a report detailing recommendations for the use of systems approaches in HIA, as well as an accompanying plain-language briefing and infographic. We will disseminate our findings through special interest networks (such as the Society of Practitioners of Health Impact Assessment); conference presentations; a webinar; and our established social media presence, blog, and podcast series. Members of the research team are involved in HIA guidance development and implementation across the UK and Ireland, which will enable direct translation of findings.



2. Introduction

2.1 Background

Health Impact Assessment (HIA) refers to a set of methods used to systematically identify the potential health and wellbeing impacts of a specific proposal, including potential differential effects on different population groups, and to make recommendations about how those impacts may be managed (1). It is a central part of a 'health in all policies' or 'healthy public policy' approach, which seeks to ensure that policymaking across multiple sectors is informed by consideration of how best to improve health, reduce inequalities, and minimise negative impacts (2).

HIA is one of a suite of impact assessment methodologies, which differ in their scope and statutory basis. These include strategic environmental assessment, environmental impact assessment, and sustainability appraisal; equality impact assessment; and social impact assessment (5, 6). While these other methods may include reference to health outcomes, these are often considered in narrow terms, using a biomedical model of health, and may have limited involvement of public health actors: HIA therefore remains the most widely used method as part of public health efforts to achieve healthy public policy.

Various practical guidance and toolkits for supporting Health Impact Assessment are available (7-10). These share a common methodological approach to HIA (Figure 1). The use of HIA therefore represents a key vehicle through which research evidence and local intelligence can be mobilised for public health action; it also contributes to the identification of questions for evidence synthesis and primary research.

Current HIA guidance typically recommends using checklists to consider potential health impacts and their unequal distribution across the population (e.g., by age, gender, sexuality, ethnicity, socioeconomic status, or disability). Such checklists have the advantage of ensuring a systematic and structured approach to assessing potential health and equity impacts.

However, there is increasing recognition that the type of policies, plans, and projects which are the focus of health impact assessment are often interventions in complex systems (11). Complex systems are characterised by multiple interacting components with dynamic inter-relationships, which often show properties such as feedback, adaptation, and emergence (12). Such systems are influenced by past conditions (path-dependence) and current context, as well as external shocks; they change over time and are inherently unpredictable. Considering a system's underlying dynamics, components, relationships, and properties is therefore critical to understanding the potential health and health inequality impacts of an intervention. Systems approaches have become increasingly influential in public health and public policy in recent years, as reflected in guidance documents on evaluation authored by our team and others (13-15).



Systems methods may therefore be valuable in HIA, to help practitioners formally consider how effects interact and accumulate over time; identify leverage points where change will be most impactful; and better understand the distribution of these effects between different populations and geographies. It could also support consideration of potential external factors (e.g., global economic shifts, climate change) with the potential to change rapidly, causing the intervention under consideration to become untenable, ineffective or to have unintended consequences.

However, systems approaches are not at present explicitly included in guidance for undertaking HIA. In preparing this proposal, we searched Web of Science, Medline/Embase, and ASSIA for studies on HIA methods, using terms relevant to health impact assessment in combination with terms relevant to methodology or guidance and systems or complexity. We also contacted the international HIANET mailing list to identify any existing examples of systems theory or methodologies being applied to HIA, and drew on an ongoing review of existing HIA guidance overseen by one of our co-investigators (Douglas). From this scoping, we identified very few examples where complexity or systems approaches have been applied to HIA or other impact assessment processes.

We did identify several methodological reviews and guidance documents acknowledging that current HIA methods are limited in their ability to understand, describe, and predict the complexity of causal pathways between intervention and impact and highlighting this as an area where further work is required (19-23). This is consistent with previous research on the challenges of applying systems approaches to public health, which has recommended further collaboration of researchers and practitioners to clarify the link between systems approaches and everyday public health practice, as well as further development of methods and tools that will encourage systems approaches to public health practice (24).

2.2 Rationale

To our knowledge, no previous study has sought to assess the value or practical implications of applying systems-informed tools as part of HIA. Yet these are important considerations: it is not clear whether the integration of these two methodological traditions will have an overall positive or negative effect on the HIA process, outputs, and outcomes.

There is therefore a need for a detailed investigation of whether the incorporation of systems approaches may help maximise the validity and utility of HIA. This work is timely, given expanded opportunities for HIA presented by new statutory duties in Wales and Scotland; plans by several UK nations to update HIA guidance documents over the coming years; and ongoing interest in the potential of applying complexity and systems approaches to public health.



Our research outputs have the potential to enhance the effectiveness of HIA by providing tools which may improve assessment of health impacts, underlying mechanisms, and points for intervention. Systems-informed methods may also provide additional opportunities to elicit the tacit knowledge and practical wisdom of key stakeholders participating in HIA, hence enhancing engagement and buy-in. Should systems-informed methods prove valuable to HIA, our research may contribute to greater influence on how relevant proposals are developed and implemented and a greater likelihood that these will have beneficial impacts for health, wellbeing, and equity. The global popularity of HIA, and the international composition of our advisory group and participants, will maximise the reach of our findings.

We anticipate that as part of the process of carrying out this research, we may identify important methodological and practical questions for future research and development. It is also likely that the project will contribute to capacity-building and demand in public health practice for both HIA and systems thinking as independent tools in their own right, as well as identifying further opportunities for their joint application. Our participants may also benefit, by extending their own knowledge and understanding of systems thinking and/or HIA methodology as part of the workshops or pilot exercises.

2.3 Aims/Objectives/Research questions

Aim:

to explore and test the potential contribution of systems approaches to Health Impact Assessment (HIA), with a view to informing practical guidance on conducting HIA.

Research questions:

1) Which systems perspectives and techniques might be applicable to the process of HIA, and at what stages?

2) What are the implications of systems-informed HIA for those undertaking and acting on HIA?

3 Study Design/Methods

3.1 Study Design

Conceptual framework:

This project will seek to explore the integration of two distinct but complementary conceptual and methodological traditions – systems approaches and health impact assessment. The accompanying visual summary illustrates the parallels between the key stages of HIA and different elements of a systems approach, using the simplified 'ROAMEF' model of policy-making as a framework.



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While the latter is undoubtedly an over-simplification, we use it here as a schematic structure to indicate how both traditions relate to the policy process. Further exploration of these relationships will form the basis for the project. We anticipate that our outputs may include a more detailed

and sophisticated conceptual model to illustrate how systems approaches and methods can be integrated into HIA and HIA into the policy process, within the overall context of a systems approach to improving health and reducing inequalities.

Overview of methods:

To address our research questions, we propose a series of workshops with key stakeholders informed by a parallel scoping review, case studies of completed HIA, and prospective pilot exercises. The project will be divided into three phases, each with a set of core research objectives (abbreviated as RO).

The approach described in this protocol (a sequence of three 2.5h workshops, each run on two occasions, followed by an optional shorter session of 1h to provide feedback on recommendations) has been revised from that originally envisaged (six workshops of three hours each with a consistent 'reference group' of stakeholders). This is due to anticipated challenges for the latter approach in recruitment, scheduling, and retention of reference group members for six workshops, especially given that the bulk of the meetings will need to take place over the summer period. The format and attendance at the workshops is described in more detail in the



subsequent sections.



A detailed breakdown of these phases and their ROs is laid out in the study procedures section.

3.2 Settings

The settings will be exclusively professional, online or in person.

Online workshops will be held via Microsoft Teams, with participants joining from their current working location.

Pilot HIA activities may be held online via Microsoft Teams (with participants joining from their current working location) or on-site on institutional premises at Public Health Scotland, Public Health Wales, or the Institute for Public Health in Ireland.

3.3 Sampling

Workshop participants

The workshop participants will serve as our primary 'test-bed' for exploring potential applications of systems approaches and methods within HIA, informed by parallel activities undertaken by the project researchers.





Given our emphasis on shared learning between different disciplinary traditions, the workshops will allow us to obtain detailed insights from a range of key informants and to take an iterative approach across the proposed three events. We will aim to have 15-20 participants at each workshop, representing the following constituencies:

- HIA specialists, whose work primarily consists of undertaking HIA
- Public health practitioners working in local and national settings, who may use HIA as part of their wider portfolio of activities
- Stakeholders from non-health sectors, whose proposals may be the subject of HIA
- Public representatives, who may participate in and/or be affected by the outcomes of HIA
- Third sector organisations, with expertise in sectors which may be the focus of HIA
- Systems scientists, with expertise in the application of systems approaches to intervention appraisal and evaluation
- Specialists in impact assessment methods from other disciplines, such as environmental impact assessment or social impact assessment

To reflect the international reach of HIA and to ensure our recommendations are robust to different contexts, we will recruit workshop participants from the UK and beyond.

Pilot exercises

Identification of suitable Health Impact Assessments for pilot exercises with proposed systems tools will be done through contacts from the co-investigators and advisory group members in Scotland, Wales, and Ireland.

3.4 Study Procedures

3.4.1 Recruitment

Workshop participants

Recruitment of professional and academic stakeholders will be undertaken via existing specialist networks such as the international HIANET mailing list, the international Society Of Practitioners of Health Impact Assessment and the International Association for Impact Assessment; professional organisations for public health (such as the Association of Directors of Public Health and European Public Health Association); professional organisations for other sectors (such as the Local Government Association and the Civil Service Environment Network); and through the research team's existing networks. Recruitment of public representatives will be undertaken via the University of Glasgow's existing public panels and the NIHR People in Research portal: we have already had several expressions of interest from public representatives who commented on this application.





A consent form, Participant information sheet and privacy notice will be sent to potential participants by email at least one week before the workshop, to allow respondents time to consider the information provided and make an informed decision about participating. Respondents will return consent forms by email.

Pilot exercises

Where a suitable HIA has been identified, the management group for the HIA will be contacted by email to invite participation in this study. If they confirm interest, participant information sheets, privacy notices and consent forms will be offered by email to participants. Respondents will return consent forms by email.

3.4.2 Data Collection

Procedures for the research objectives in the three phases of the project are laid out below.

Phase A

a) We will undertake a **rapid scoping review** of the existing grey and peerreviewed literature to identify examples of the use of systems approaches in impact assessment methodologies from other fields – such as strategic environmental assessment or social impact assessment, which may help us identify potential transferable lessons for the HIA field.

b) We will collate an overview of practical tools relevant to HIA that will form the basis for engagement with workshop participants during Phase B. Our starting point for this exercise will be forthcoming guidance on the use of participatory systems mapping in public health (co-authored by Meier); NIHR guidance on systems approach to local public health evaluation (co-authored by Meier); supplementary guidance to the HM Treasury Magenta Book on handling complexity in policy evaluation (co-authored by Elsenbroich); and the UK Government toolkit on Systems Thinking for Civil Servants. We will draw on the expertise of systems scientists on the co-investigator team and advisory group to identify any other sources and tools as required. We will use these existing guidance documents to produce briefing materials for workshop participants on the fundamental principles of systems approaches and a set of core tools (such as causal loop diagrams and theory of change mapping), including a description of the process, analysis, benefits, and limitations of each technique. The selection of the core tools for discussion at the workshops will be undertaken by the research team and informed by discussions with the advisory group.

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<u>Phase B</u>

The work in this phase will build on the scoping review and tool collation exercise from Phase A through a set of **participant workshops** with key stakeholders and public representatives. The workshops will comprise three distinct sessions, each offered on 2 separate dates: hence six events in total. These three sessions will have a logical flow and it is expected that participants will attend all three, albeit they can choose which of the two dates for each event to attend, according to their availability. These meetings will be 2.5h in length and held virtually via Microsoft Teams, to maximise participation from a geographically diverse range of stakeholders and reduce associated time demands for participants.

These three workshops will then be followed by a shorter optional final session (again run on two different dates), in which participants can discuss and provide feedback on the findings of the pilot exercises and draft recommendations from the project.

Within the workshops, we will facilitate detailed discussions of which systems tools may be applicable and the implications of their use. Given the relatively short length of this project, we will focus our efforts on a small set of six systems tools (identified during phase A, as above) and on those stages of the HIA process where application of systems methods may have the greatest impact.

In each meeting we will work through one or more tools identified in Phase A to discuss their potential utility; practical implications; and any unintended consequences. We will then contextualise this discussion by exploring how each of the case study HIAs might have incorporated these tools within the relevant stage and how this may have affected their process, outputs, and outcomes. This will include practical considerations such as time, cost, staff capacity, and training, and will be informed by the presence and input of leads for each case study.

Table 1 provides an overview of the purpose and activities of each workshop. The tools to be discussed will be defined as part of the preceding stage, as outlined above.



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	Purpose	Activities
Workshop 1	Establish conceptual basis for application of systems thinking to HIA and areas of	Presentations by research team on fundamentals of (a) systems thinking and (b) Health Impact Assessment – HIA and (c) brief feedback on results of scoping review
	commonality/tension	Group exercises in breakout rooms to discuss questions intended to provoke further reflections on the presentations, such as:
	Gather initial feedback regarding potential	 What examples of complex systems can you identify from your work? Is systems thinking already used in HIA, in your experience?
	applications, tensions, and uncertainties to inform subsequent workshops	 What do you think that systems thinking and HIA have in common? Where do they differ? What might be the value of applying systems thinking to HIA? What might be the drawbacks? What else do you still feel you'd like to know about these methods?
	Begin exploring application of specific systems tools to different stages of HIA	 Exercise on selected systems tool: Presentation on tool Small group activity to test use of tool Facilitated discussion about application of tool to HIA, including – potential utility, practical implications, any drawbacks
Workshop 2	Explore application of specific systems tools to different stages of HIA	Recap from last session Exercise on selected systems tools:
		Presentation on tool Small group activity to test use of tool
		 Facilitated discussion about application of tool to HIA, including – potential utility, practical implications, any drawbacks
Workshop 3	Explore application of specific systems tools to different	Recap from last session
	stages of HIA	 Exercise on selected systems tools: Presentation on tool Small group activity to test use of tool

Table 1. Workshop purpose and activities



		 Facilitated discussion about application of tool to HIA, including – potential utility, practical implications, any drawbacks 	
		Summary and reflections on all three workshops, including further group discussion	
Optional	Seek feedback on findings	Presentation by research team on findings from pilot exercise and draft recommendations	
session 4	from pilot exercises and draft recommendations	Group exercises in breakout rooms to discuss	



Case studies:

Phase B will use three case studies as part of workshop activities, by examining what difference systems approaches might have made to their process, outputs, and outcomes – whether positive, negative, or mixed. This will enable workshop participants to contextualise discussions of how different systems based methods and tools may be applied during each HIA stage. We propose using HIA completed by the research team or our practice partners as case studies, so that workshop participants can draw directly on first-hand insights in their discussions, allowing a rich two-way dialogue about the application of systems approaches to these examples.

As a first step in selecting case studies, we will prepare a shortlist of completed HIA undertaken by the research team or our practice partners. We will aim to include a diversity of sectors; of geographies (e.g., local and national); of intervention types (e.g., policy changes, strategic documents, or planning proposals). Potential candidate HIA include: Brexit in Wales, road space reallocation (e.g., for active travel, greenspace, or other community use), Covid-19 mitigation policies, and a local housing development on a former hospital site. Using this shortlist, we will work with co-investigators to select three final case studies. This exercise will provide an opportunity to consider which HIA may and may not benefit from incorporation of systems methods, with a view to informing guidance for the screening and scoping stages of HIA.

Phase C

Pilot exercises

During this phase, we will test emerging findings from Phases 1 and 2 in pilot exercises, as part of planned HIA being undertaken by our practice partners (including the Welsh Health Impact Assessment Support Unit, Public Health Scotland, the Institute of Public Health in Ireland, and NHS Ayrshire and Arran) or those of two large practice-oriented research consortia led by our co-investigators (SIPHER – Systems Science in Public Health and Health Economics Research, and GALLANT – Glasgow as a Living Lab Accelerating Novel Transformation).

Selection of pilots

To ensure timely completion, we will begin to scope piloting opportunities from the beginning of the project through conversations with practice partners and consortia: however, given the time constraints of this short project, it is likely to be necessary to run some pilot activities in parallel to the last few workshops.

We propose two to three pilot exercises, to be decided by the co-investigators and advisory group, drawing on – and refining – experiences from the process of case study selection in Phase B.



Involvement in pilots

During this phase, members of the research team will embed with the pilot HIA steering group to support the planning and facilitation of the pilot HIA, using findings from Phases A and B to advise on when and how systems approaches could be incorporated. For example, the planning process for a pilot HIA may identify the need to engage with stakeholders to understand potential feedback loops and interdependencies, leading the embedded researcher to work with the team to facilitate a participatory systems mapping exercise during the appraisal process.

We anticipate that the pilots and associated activities will include a mix of virtual and in-person events, which will give us an opportunity to test approaches suitable for each format and to identify both positive and negative impacts of systems-informed HIA.

Data collection for pilots

Data collection during this phase will consist of:

- completion of a structured reflective template by embedded researchers during the planning process and after delivery of HIA activities, to capture their experience and learning
- debriefing interviews with leads for each HIA steering group about their perceptions and experience of how the use of systems approaches affected the identification and appraisal of impacts; the recommendations made; the potential impact of the recommendations; any logistical or practical considerations (such as time, cost, or staff training and skills); and any unforeseen consequences
- online or paper surveys (depending on event format) of other participants (e.g., stakeholders attending an appraisal workshop) about their perceptions and experience of the process.

Development of recommendations & study report

Based on findings from all three phases, we will prepare a draft set of recommendations for the application of systems approaches to HIA. As described above, we will offer participants the opportunity to attend a final optional session where the team present findings from the pilot exercises and draft recommendations and invite participant feedback.

The study report will be drafted by the research team on an ongoing basis throughout the project: we will circulate a draft to co-investigators and the advisory group to seek their feedback during Phase C, before submission at the end of the project.



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3.4.3 Withdrawal

Participants will be free to withdraw from the study at any time by informing the PIs or RAs directly.

If they do decide to withdraw, they will be asked if information obtained from them prior to withdrawal may be retained for use in the research or should be removed completely where possible, and the data processed accordingly.

Withdrawal of individual participant data will be possible up until the completion of interview or survey. Following said completion, data analysis can commence at any time and it will no longer be possible to withdraw individual data as it will be synthesised. Similarly, withdrawal of individual data from workshop participation will not be possible following commencement of the workshop.

Once analysis has commenced data cannot be withdrawn and its ongoing processing is justified in accordance with the General Data Protection Regulations. Research into public health is a 'public task' which requires the retention and processing of data. This research is in the public interest and is an official function of the MRC/CSO Social and Public Health Research Unit.

This information will be given in the participant information sheet, and repeated if a participant choses to withdraw.

Withdrawal of participation will be logged in with a record of date and records updated accordingly as a change in participation status if the information obtained can still be used, or as a withdrawal, and all data relating to the participant will be destroyed. Records of interest in receiving a summary about the study's findings, or alteration to consent for data sharing will be updated accordingly.

3.5 Data Analysis

1) Online workshop series with key stakeholders:

These workshops will be recorded using the Microsoft Teams recording function and the recordings transcribed by a company with whom our unit has an established working relationship (1st Class transcription). Transcripts will be analysed thematically.

2) Piloting of materials/toolkit as part of ongoing Health Impact Assessment activities:

(a) Reflective template:

Contents of the reflective template will be analysed thematically.

(b) Interviews:



Recordings of interviews will be transcribed and the transcripts will be analysed thematically.

(c) Questionnaires:

Results will be analysed using simple descriptive statistics (for binary and quantitative questions) and thematic analysis (for free text responses).

3) Synthesis:

Results of analysis of outputs from all of the above activities will be combined through thematic analysis in order to produce study outputs in the form of recommendations for the use of systems tools in HIA and an accompanying research paper.

4. Research Governance and Regulatory Issues

4.1 Ethical issues

Research Ethics Committee: College Of Social Sciences Research Ethics Committee for Non-Clinical Research involving Human Participants/Data

Research Ethics Committee Reference: 400220331

As this is a methodological project, participants will be contributing their views in a professional – rather than personal – capacity. Workshops and pilot exercises will not be covering sensitive topics or requesting that participants share personal information. The project will not specifically target populations from any of the groups listed in the risk guidance nor employ any of the higher-risk procedures noted.

In order to ensure appropriate scrutiny and governance of the elements involving the participant workshops and pilot exercises, we will seek ethical approval for the project from the University of Glasgow College of Social Sciences ethics committee.

Key potential risks to participants are highlighted below.

Risk	Mitigating controls
Unauthorised disclosure of participant personal information	 All staff trained in data protection and familiar with SPHSU SOP on data management and protection All staff familiar with and signatories to study data management plan Measures to ensure secure information storage and transfer, as

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	 Ose of secure folders on OoG servers accessible only to research team to store all study data Research data stored separately to participant personal information Password protection and use of secure file transfer when sending recordings to transcription company Anonymisation of completed transcripts and study outputs 	
Reputational damage to organisations or individuals identified (explicitly or implicitly) in research data	 Identifiable details removed from completed transcripts and study outputs as far as possible whilst still ensuring research data remains meaningful Participants made aware of potential deductive disclosure if unusual or unique situations described in detail, and encouraged to be mindful of this eventuality 	

If you <u>do not think that ethical approval is required for your study</u>, you should indicate by ticking this box that you have consulted the

4.2 Data Monitoring/Quality Assurance

A study advisory group will be convened and will have responsibility for governance and oversight of the research, including monitoring that it is being carried out as approved. It will meet on every two months throughout the course of the study.

4.3 Data Management

The study data management plan is located here: T:\projects\System HIA S00626\01_StudyMasterFile\Section04_DataManagementDocuments\a_DataManag ementPlan_DMP

4.4 Data Storage and Retention



As described in the study data management plan.

5 **Project Management**

5.1 Project Manager

The Project Manager with responsibility for the day to day management of the project is: E. Tweed

5.2 Project Management Group

For the purposes of this project, the Investigators group will serve as a Project Management Group. The Investigators group consists of the PIs, Co-Investigators, and Project Team members (e.g., staff employed on or contributing to the project).

The Investigators group consists of the following members:

Name	Role on project
Emily Tweed	Principal Investigator
Corinna Elsenbroich	Principal Investigator
Margaret Douglas	Co-investigator
Liz Green	Co-investigator
Monica O'Mullane	Co-investigator
Petra Meier	Co-investigator
Elizabeth Inyang	Research Assistant
Roxana Pollack	Research Assistant
Rebecca Turner	Study administrator

The joint PIs and research assistants will meet every week or fortnight throughout the project, with the wider co-investigator team will attending monthly.

Notes of Investigator meetings will be taken to log key decisions and actions.

5.3 Advisory Group

The project will be guided by a advisory group comprised of stakeholder and public representatives. The purpose of the advisory group will be to provide independent



oversight for the planning, delivery, and dissemination of the research. A copy of the draft terms of reference for this group is attached.

5.4 Project Filing Structure

The electronic project files will be kept on: T:\projects\System HIA S00626

No paper project files will be created or stored.

6. Dissemination

6.1 Communication method

The key communications channels are:

- Journal Articles
- Conference Papers
- Written summary of results
- Study report and slide deck for funders
- Blogs, videos, and briefing papers

6.2 **Publication Policy**

All publications and presentations relating to the project will be authorised by the Project Management Group. Authorship of publications will comply with SPHSU protocols.

6.3 Public Engagement and Knowledge Exchange

Participation is a core value of both HIA and systems approaches: we will therefore include stakeholders affected by or involved in HIA – both public and professional – throughout study planning, conduct, and dissemination. Other application sections describe in more detail our approach to PPI: here we provide a brief overview within the context of our detailed research plans.

In terms of public involvement, we will seek public representatives to join both workshops and study advisory group, enabling their views to be heard as part of both data collection and study oversight respectively.

In terms of professional stakeholders, they will also contribute directly to data collection and study oversight through the workshops and advisory group, respectively.

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Tweed will act as PPI lead, taking responsibility for recruitment of public representatives, in collaboration with the SPHSU's communications & engagement team; supporting their involvement through pre-meeting briefings; liaising with the project administrator to ensure timely reimbursement following each meeting; and ensuring that study outputs are appropriately tailored and disseminated to public audiences.

7. Project Milestones / Timelines

A project timeline will be maintained on a regular basis by the study team and reviewed at team and advisory group meetings. It will be stored at: T:\projects\System HIA S00626\ProjectManagement_And_GANTTcharts

8. Project Risk Assessment

The risks relevant to the project are recorded in the risk assessment form and contained in the initial Project Risk/Issue log on: T:\projects\System HIA S00626\01_StudyMasterFile\Section12_Logs\d_ProjectRisk_Log

The Risk Log will be reviewed and updated at Project Management Group meetings.

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System-HIA Study Protocol v2.0

