

Protocol

# Implementing and Evaluating a National Integrated Digital Registry and Clinical Decision Support System in Early Intervention in Psychosis Services (Early Psychosis Informatics Into Care): Co-Designed Protocol

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**Abstract**

**Background:** Early intervention in psychosis (EIP) services are nationally mandated in England to provide multidisciplinary care to people experiencing first-episode psychosis, which disproportionately affects deprived and ethnic minority youth. Quality of service provision varies by region, and people from historically underserved populations have unequal access. In other disease areas, including stroke and dementia, national digital registries coupled with clinical decision support systems (CDSSs) have revolutionized the delivery of equitable, evidence-based interventions to transform patient outcomes and reduce population-level disparities in care. Given psychosis is ranked the third most burdensome mental health condition by the World Health Organization, it is essential that we achieve the same parity of health improvements.

**Objective:** This paper reports the protocol for the program development phase of this study, in which we aimed to co-design and produce an evidence-based, stakeholder-informed framework for the building, implementation, piloting, and evaluation of a national integrated digital registry and CDSS for psychosis, known as EPICare (Early Psychosis Informatics into Care).

**Methods:** We conducted 3 concurrent work packages, with reciprocal knowledge exchange between each. In work package 1, using a participatory co-design framework, key stakeholders (clinicians, academics, policy makers, and patient and public contributors) engaged in 4 workshops to review, refine, and identify a core set of essential and desirable measures and features of the EPICare registry and CDSS. Using a modified Delphi approach, we then developed a consensus of data priorities. In work package 2, we collaborated with National Health Service (NHS) informatics teams to identify relevant data currently captured in electronic health records, understand data retrieval methods, and design the software architecture and data model to inform future implementation. In work package 3, observations of stakeholder workshops and individual interviews with representative stakeholders (n=10) were subject to interpretative qualitative analysis, guided by normalization process theory, to identify factors likely to influence the adoption and implementation of EPICare into routine practice.

**Results:** Stage 1 of the EPICare study took place between December 2021 and September 2022. The next steps include stage 2 building, piloting, implementation, and evaluation of EPICare in 5 demonstrator NHS Trusts serving underserved and diverse populations with substantial need for EIP care in England. If successful, this will be followed by stage 3, in which we will seek NHS adoption of EPICare for rollout to all EIP services in England.

**Conclusions:** By establishing a multistakeholder network and engaging them in an iterative co-design process, we have identified essential and desirable elements of the EPICare registry and CDSS; proactively identified and minimized potential challenges and barriers to uptake and implementation; and addressed key questions related to informatics architecture, infrastructure, governance, and integration in diverse NHS Trusts, enabling us to proceed with the building, piloting, implementation, and evaluation of EPICare.

**International Registered Report Identifier (IRRID):** DERR1-10.2196/50177

(*JMIR Res Protoc* 2024;13:e50177) doi: [10.2196/50177](https://doi.org/10.2196/50177)

## KEYWORDS

Early Intervention in Psychosis; digital registry; clinical decision support system; participatory co-design; participatory; co-design; registry; psychosis; mental health; psychiatry; decision support; study protocol

## Introduction

### Background

Psychotic disorders, including schizophrenia, are among the most disabling illnesses worldwide and are often accompanied by enormous personal, family, societal, and caregiver burden [1]. Rates of psychosis are unequally distributed throughout the population, with the highest rates found in historically underserved communities, younger populations, and those from minority ethnic backgrounds [2-5]. For example, within the United Kingdom, people from Black ethnic backgrounds (African, Caribbean, and British) are between 3 and 5 times more likely to experience a first episode of psychosis than White British individuals, and there is evidence that the rates are also approximately twice as high for people from Pakistan, Bangladesh, and mixed ethnic backgrounds in England [2,6]. Further, the need for treatment delivered by early intervention in psychosis (EIP) services in England has been identified as highest in several historically underserved regions of England, and in related major conurbations, such as Birmingham, Greater Manchester, Bradford, and parts of inner-city London [6]. This need for EIP care is closely aligned to populations exposed to greater structural disadvantage including multiple deprivation and social fragmentation [6].

EIP is an internationally adopted model of care based largely on social inclusion, service user and caregiver engagement, and relapse prevention. In England, EIP services are nationally commissioned to provide evidence-based, multidisciplinary

care according to eight National Institute for Health and Care Excellence (NICE)-based national standards for people experiencing first-episode psychosis: (1) maximum waiting time of 14 days from initial referral to commencement of treatment; (2) offer of cognitive behavioral therapy for psychosis; (3) take-up of family interventions; (4) offer of clozapine after poor response to at least 2 other antipsychotic medications; (5) take-up of supported employment and education programs; (6) annual physical health assessments; (7) offer of interventions relevant to physical health (for example, smoking cessation, exercise, or substance use programs); and (8) take-up or referral to caregiver-focused education and support programs [7]. Each care standard is evidence-based, often from randomized controlled trials. Each standard has demonstrated improvement in patient outcomes, including remission of symptoms, readmission, recovery, premature mortality, and important social and vocational outcomes [8,9]. Importantly, EIP care is cost-effective relative to other forms of care and management for people with psychosis, and EIP services are highly valued by service users [10,11].

Despite evidence-based standardized targets, only 30%-40% of people experiencing psychotic disorders make a full recovery [12], with evidence of large variation in care [13-16]. Longer-term outcomes are equally poor, with increased rates of physical illnesses [17] and life expectancy reduced by around 15 years compared with people who do not go on to develop severe mental illness [18]. This suggests that much work is needed to understand which elements of EIP services are

working, for whom, and whether they lead to better long-term outcomes [16].

Variation in outcomes may be related to regional or individual disparities in the care offered and received during EIP, particularly in historically underserved communities where the need is greatest, but where there may be insufficient resources to offer standardized care tailored to the needs of local populations. For example, recent data indicate that people with psychosis from Black African and Caribbean backgrounds were 15%-30% less likely to receive the equivalent level of cognitive behavioral therapy for their condition compared to White British people [19]. Cross-sectional survey data from England and Wales has highlighted further inequalities in care, with Black service users being around 44% less likely to be offered clozapine [19], the only existing medication for treatment-resistant schizophrenia [13]. There is also evidence for disparities in outcomes post-EIP, with deprivation related to higher rates of relapse and the need for continuing care in secondary mental health services [20]. Black and Asian racial minoritized groups are also more likely to continue in secondary mental health care 2 years following EIP discharge [21].

Despite this, data currently being routinely collected via a patient's electronic health record does not provide accessible, longitudinal, and nationally representative data to determine the magnitude, causes, or consequences of inequitable access to EIP care in England. Relatedly, routine data collected by EIP services in England does not include measures of symptomatic recovery, usually the primary outcome for understanding what treatments work for whom, thus preventing us from developing a national understanding of the clinical effectiveness of treatments in the real world. In turn, neither does it provide a mechanism for immediately improving clinical practice by feeding back real-time actionable insights that would allow treatments to be targeted and tailored to individual patient needs. For example, while all EIP providers send data on broad levels of service use into National Health Service (NHS) Digital's Mental Health Services Data Set, the data set is less suited to ascertain accurate estimates of the incidence of psychotic disorders in England, because current methods of data collection do not differentiate between people engaging in EIP treatment for their first-ever episode of psychosis and those who may have existing psychosis, but are engaging in treatment in a new EIP service for the first time. Further, Mental Health Services Data Set data do not record whether those engaging with EIP treatment later fulfill diagnostic criteria for psychotic disorder. The Mental Health Services Data Set also does not allow us to understand what treatments are delivered to whom and when, nor their impact on patient recovery and other downstream outcomes. Furthermore, the pioneering National Clinical Audit of Psychosis [22], which has assessed service fidelity annually since 2017, is a retrospective, cross-sectional manual audit of up to 100 patients with first-episode psychosis in each EIP team in England [22]. Although plans exist to revise the data collection methodology, the current practice reduces data quality, delays service improvement, and diverts finite EIP resources away from frontline care. There are also no plans for the audit to provide real-time feedback of data to clinical teams. These issues could be eliminated by the provision of a

prospectively collected national digital psychosis registry, able to supply actionable insights in real time to patients, clinical teams, service managers, and policy makers via an embedded clinical decision support system (CDSS).

We propose to revolutionize the use of electronic health record data to improve national, local, and individual clinical decision-making and promote better patient and public health outcomes for people experiencing first-episode psychosis, by carefully developing and demonstrating the effectiveness of a prospectively collected digital registry and CDSS in England, capable of being implemented nationally. This would provide standardized information to understand the treated burden of psychosis in the NHS; ensure equitable, responsive, local resource allocation; support reliable, quick, and efficient identification and targeting of any local, regional, or group-based disparities in access to care; improve patient pathways through care and downstream outcomes, including recovery; and finally, enhance understanding of the relationship between interventions provided and outcomes, as well as the relationship between clinical and social characteristics and outcomes.

The potential for further record linkage to other health and social domains also offers the prospect of integrating prospectively collected data from other routine sources including primary care, the Office for National Statistics mortality, the Office for National Statistics Census, the National Pupil Database, and Hospital Episode Statistics. This would provide a deeply phenotyped, longitudinal database for clinical and policy decision-making. It would also support gold-standard research in clinical psychiatry, experimental medicine, and observational epidemiology, to identify, understand, and address the causes and consequences of disparities in health and patient treatment, as well as improve downstream outcomes for people experiencing psychosis.

Digital registries have been deployed successfully in the United Kingdom for other disease areas such as stroke, cancer, cystic fibrosis, and dementia [23-28]. For example, in the United Kingdom, a national stroke registry has transformed patient care and outcomes, with early recognition of different patterns of stroke presentation, focused treatment on previously untreated risk factors, and targeted interventions for improving cognitive impairment [27]. In cancer care, tailored interventions based on risk profiles have extended the lives of thousands of people [28]. Yet there are no contemporary examples of digital registries for any secondary care-treated mental health condition listed in the Health Research Classification System mental health category, nor within the international literature, and no specific CDSS for any mental health condition. Integration of a patient-centered digital registry and CDSS for psychosis could be equally transformative and give parity of esteem to one of the most common and disabling sets of mental health disorders—psychosis—where there is already a well-developed national infrastructure of EIP services.

To achieve this paradigmatic change in mental health care, our aim is to develop, evaluate, and establish a national psychosis registry and CDSS, known as EPICare (Early Psychosis Informatics into Care) in 3 stages. Stage 1—establish a multidisciplinary and multisector stakeholder network to

co-design, derisk, and define the framework and protocols required to build and implement EPICare as a successful national registry and CDSS. Stage 2—build, pilot, implement, and evaluate the ability of the EPICare platform to improve patient care, enhance service delivery, reduce disparities in care, and demonstrate cost-effectiveness in 5 demonstrator NHS Trusts, serving underserved and diverse populations with substantial need for EIP care in England. Stage 3—subject to successful implementation and evaluation, seek NHS adoption of EPICare for rollout to all EIP services in England.

### Aims and Objectives

In this paper, we report the protocol for the program development phase of our activity (stage 1), in which we aimed to co-design and produce a framework and protocols for onward building, implementation, piloting, and evaluation of a national integrated, patient-centered digital registry and CDSS for psychosis.

To meet this aim, we specifically addressed the following objectives: (1) establish a network with strong patient and public involvement and engagement (PPIE) and other essential

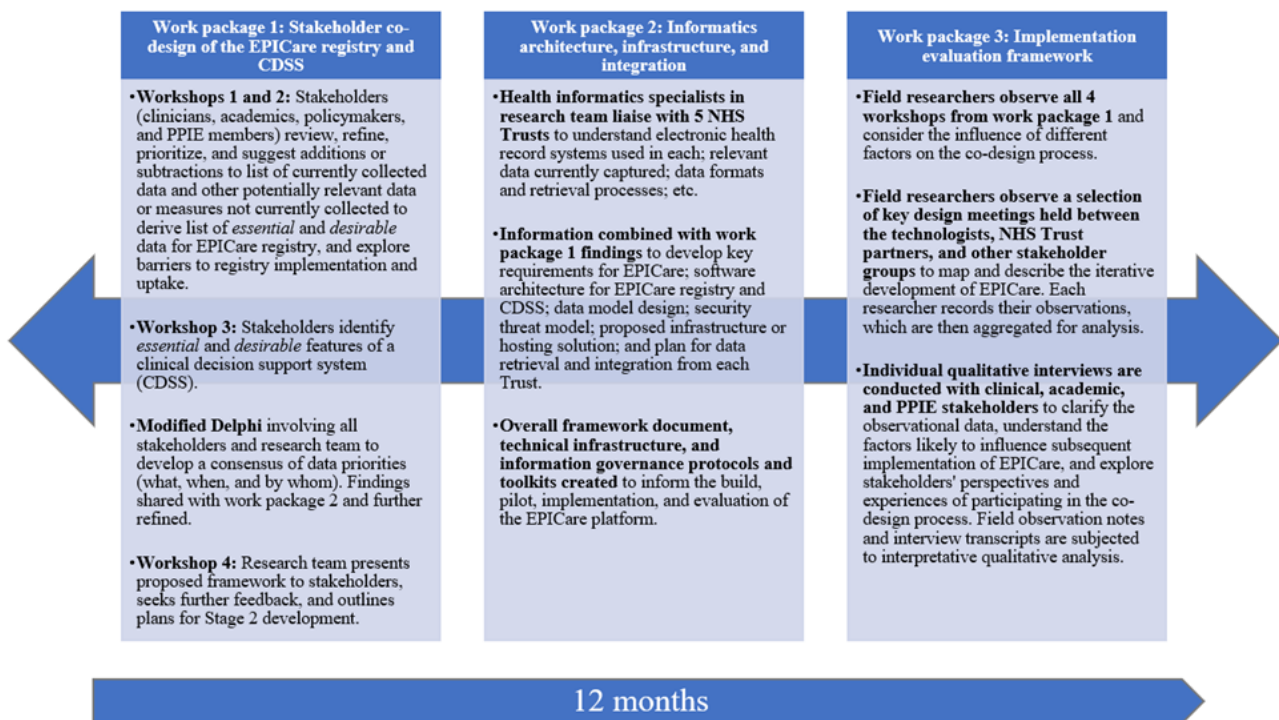
stakeholders to identify essential and desirable elements and minimize unforeseen challenges (work package 1), (2) address key questions on informatics architecture, infrastructure, governance, and integration plans to facilitate onward development and testing of EPICare in diverse NHS Trusts (work package 2), and (3) identify implementation factors from the outset to ensure they are considered in designing, implementing, and maintaining the future deployment of EPICare in a measurable way (work package 3).

### Methods

#### Study Design

We conducted 3 concurrent work packages over 12 months, with reciprocal knowledge exchange between work packages, coordinated via fortnightly program management group meetings. Figure 1 provides a schematic of work packages. The program management group contained a lived experience facilitator, lived experience member, clinicians working in early psychosis, and academic members from epidemiology, NHS health informatics, data, and implementation science.

**Figure 1.** EPICare program development phase study design. CDSS: clinical decision support system; EPICare: Early Psychosis Informatics into Care; PPIE: patient and public involvement and engagement.



#### Work Package 1: Stakeholder Co-Design of the EPICare Registry and CDSS

A participatory co-design framework previously established for informatics in mental health [29] was used to engage a diverse network of stakeholders, including clinicians, academics, policy makers, and PPIE members, in a series of 4 co-design workshops. Due to the COVID-19 pandemic, the workshops were convened online. While this enhanced the scope for collaboration between centers in the study, there were also potential drawbacks of this approach, which included PPIE

members needing to have access to and know-how of technology. Second, hosting face-to-face meetings on neutral ground in an approachable format may have helped to remove traditional power structures. The workshops were in a facilitator-led, semistructured format, including presentations, whole-group discussions, and themed breakout activities (card-sort tasks and small group discussion) with both mixed (random allocation) and streamed group (by broad stakeholder type) sessions on a per-task basis. Essential materials were circulated to stakeholders in advance of each meeting. We also convened additional online preparatory sessions for PPIE

stakeholders, led by our PPIE coordinator, to aid understanding and participation in the main workshops. Registry and CDSS goals were examined by stakeholders, who reviewed, refined, and identified a core set of essential and desirable measures that should be collected in the integrated EPICare registry and CDSS, across 4 domains: sociodemographic measures, treatment measures, patient-reported outcome measures, and clinician-reported outcome measures.

To facilitate this process, stakeholders were provided with a list of data already recorded in electronic health records in EIP services, in addition to information on data relevant to the 8 nationally mandated NICE standards for EIP care [30] and key outcome measures (Health of the Nation Outcomes Scales [HoNOS] on functioning; quality of life and treatment satisfaction [DIALOG]; and patient-reported recovery [QPR]). This was supplemented with a minimal set of other initial measures recognized as potentially relevant by the program management group based on expert knowledge, prior to the first workshop. Examples included symptom ratings, duration of untreated psychosis, and genotyping, among others. In workshops 1 and 2, stakeholders were asked to review, refine, prioritize, and suggest additions or subtractions from this list, with other data that may not currently be routinely collected, but considered by stakeholders to be essential or desirable. The group also explored what barriers to implementation and uptake may be encountered in EPICare (eg, data security and ownership, time for completion, and digitizing of routine data currently collected on paper). Similarly, in workshop 3, stakeholders identified the essential and desirable features of a CDSS to provide timely actionable insights for patients and clinicians, including potential clinician prompts to complete health assessments aligned to NICE standards for EIP care.

After these 3 initial workshops, we synthesized all information gathered via a modified Delphi approach involving all stakeholders and members of the research team, to develop a consensus of data priorities (what, when, and by whom). We shared this with the members of work package 2 to understand technical and governance barriers to implementation to further refine our framework to identify a set of “must have” and “could have” data elements. Finally, in workshop 4, we presented our proposed framework to stakeholders, sought further feedback, and outlined our plans for stage 2 of EPICare development. From our initial stakeholder network, we sought to retain a representative group of stakeholders for our stage 2 activity, who will continue to guide the pilot, testing, and evaluation throughout the project.

### **Work Package 2: Informatics Architecture, Infrastructure, and Integration—Framework, Protocol, and Tool Kit**

Work package 2 aimed to reduce technical and governance challenges in the future full build of EPICare by addressing key questions and unknowns. Based on prior experience and knowledge, the area of biggest technical risk for EPICare is the retrieval of data from electronic health records and the standardization of this into a common data model, while ensuring compliance with information governance and ethical standards. Previous work by the group involved auditing all

EIP services that are part of the National Institute for Health Research (NIHR) Mental Health Translational Research Collaboration in Early Psychosis (MHTRC-Early Psychosis), to inform understanding of the existing infrastructure, capacity, capabilities, and limitations around designing and developing the EPICare platform for potential national implementation. This initial scoping work has highlighted several different electronic health records in use as well as different ways of capturing and storing relevant data in each of the trusts.

To build on this knowledge, health informatics specialists within the research team contacted and liaised with 5 NHS Trusts, including Greater Manchester Mental Health NHS Foundation Trust, Birmingham Women’s and Children’s NHS Foundation Trust, Cambridgeshire and Peterborough NHS Foundation Trust, Nottinghamshire Healthcare NHS Foundation Trust, and Camden and Islington NHS Foundation Trust. Information technology team leads and proposed demonstrator sites were identified, gathering information to further understand what electronic health record system is used by each trust; what relevant data are currently captured in the electronic health record (key foci: 8 NICE standards for first-episode psychosis treatment); how that data can be retrieved, such as via application programming interface or through regular exports; how the data can, and should be secured during retrieval, complying to the highest information governance standards; and the data formats used for each type of data.

Once this information was captured from all trusts, it was then used alongside the information gathered from the stakeholders in work package 1 to develop and document key requirements for the EPICare system; software architecture for the registry and CDSS; data model design including standardization of data items into a common format; security threat model including planned treatments for identified threats; proposed infrastructure to include an appropriate hosting solution, such as a secure cloud environment; and an integration plan for retrieval of data from each trust’s electronic health record.

This was drafted into an overall framework document and set of technical infrastructure and information governance protocols and tool kits to inform the future build, pilot, implementation, and evaluation of the EPICare platform. With all of this in place, the technical and governance challenges for the main program grant for applied research application should be significantly reduced.

### **Work Package 3: Implementation Evaluation Framework**

Working in parallel and in collaboration with the members of work packages 1 and 2, the purpose of this work package was to establish the preliminary implementation framework for the subsequent testing and rollout of EPICare. Founded on the idea that implementation research should be integrated throughout all stages of innovation development rather than at “end-stage,” this involved understanding the distinct and interconnected implementation issues within the stages of problem definition; iterative evidence-building, intervention conceptualization, development, and testing; and subsequent rollout, experimentation, and embedding in different service settings. With particular reference to EPICare, this involved

understanding how the earlier stages of stakeholder engagement contributed to intervention development and, at the same time, how stakeholders perceived challenges to future adoption and use. With regards to PPIE stakeholders (work package 1), this involved understanding views about (1) current challenges in EIP care; (2) how clinical registries and CDSS might influence care and service improvement; (3) expectations about how interventions might be used in standard practice; and (4) participants' experiences of the co-design process. We also studied the early stage activities of the health informatics team (work package 2) to understand the explicit and tacit design assumptions; the contingencies presented by current technological parameters; the influence of prevailing governance arrangements; and importantly, to understand and evidence the interaction between the relative influence of multiple stakeholders in the co-design process. This evidence will be brought together with existing implementation science frameworks, such as normalization process theory (NPT) [31], in conjunction with complementary insights drawn from science and technology studies [32,33].

NPT helps understand how service innovations are implemented, embedded, and normalized within organizations, to the point where new practices are no longer regarded as new. It is different from other implementation models because it focuses on the specific "work" undertaken by social actors to implement innovations into everyday practice while taking into consideration the interplay between actions, contexts, and objects. NPT has 4 linked constructs, "coherence," or the work of making sense of an innovation; "cognitive participation," or the work involved when engaging with an innovation; "collective action," or the combined work of integrating new practices into existing skills, relationships, and contexts; and "reflexive monitoring," or the work of continually appraising and adapting to the introduction of new practices. It has been widely used to explain the factors that shape the implementation of complex interventions [31].

Field researchers directly observed all 4 stakeholder co-design workshops and considered the influence of multiple social, cultural, and organizational factors on the co-design process. They also observed a selection of key design meetings held between the technologists, NHS Trust partners, and other stakeholder groups to map and describe the iterative development of EPICare. Each researcher recorded their observations following an agreed semistructured guide which were then aggregated for analysis.

To clarify the observational data, qualitative semistructured interviews guided by the constructs from NPT were then conducted with all stakeholder groups to understand the factors likely to influence the subsequent implementation of EPICare. An initial set of questions and topics derived from the study objectives were used to systematically code interview transcripts and develop themes. This was piloted on 4 transcripts by 2 researchers, before agreeing to a revised set of codes, followed by further coding of remaining transcripts. Interviews focused on the different cognitive-cultural perspectives of each stakeholder group, their experiences of participating in the co-design process, and their perceptions about their influence

on the co-design, together with their recommendations for subsequent development and testing.

## Study Participants

Participants were recruited between November and December 2021. We recruited 40 participants across all stakeholder workshops (work package 1). This included at least 10 people with lived experience of psychosis, and ideally, lived experience of early intervention, to form the PPIE stakeholder group. PPIE members were recruited from the Birmingham University Youth Advisory Group, Cambridgeshire and Peterborough Foundation Trust, Bristol Lived Experience Advisory Panel, and PPIE networks at University College London, including those associated with the NIHR Mental Health Policy Research Unit. As an acknowledgment of the time and effort involved in taking part in the study, PPIE participants were reimbursed in line with the Involve payment policy [34], which equates to £25 (US \$33.19 at the time of the study) per hour of participation.

The remaining 30 participants were recruited from the breadth of multidisciplinary care in EIP services (psychiatrists, psychologists, occupational therapists, social workers, and nurses), in addition to stakeholders from the charitable sector, NHS England, policy makers, and other academics, for facilitated group meetings. The clinical collaborators were recruited from NHS Trusts serving diverse and underserved areas with a combined population of approximately 3.4 million people (corresponding to 9.1% of the English population eligible for EIP services): Birmingham Women's and Children's Trust, Manchester Health and Care NHS Foundation Trust, Camden and Islington NHS Foundation Trust, Avon and Wiltshire Mental Health Partnership Trust, and Cambridgeshire and Peterborough Foundation Trust. Attendance at the stakeholder group meetings was taken as consent for this process and no individual written consent was required from stakeholders (including PPIE).

All stakeholders were also invited to participate in individual qualitative interviews in work package 3 to ensure that we selected a representative subset of each stakeholder group from our work package 1 stakeholder meetings. Written informed consent was obtained and interviewees were given a unique participant identification number, which was used throughout the transcription of interviews to ensure anonymity.

Given the online group format of the stakeholder workshops, individual participants attending these workshops were identifiable to each other and to the authors. However, the identities of participants who consented to an individual qualitative interview were known only to the interviewer, and as noted above, interviewees were assigned a unique participant identification number to ensure their anonymity during the transcription of their interviews.

## Ethical Considerations

The EPICare study was reviewed and granted full ethical approval by the Health Research Authority on November 8, 2021 (306234). Attendance at the stakeholder group meetings in work package 1 was taken as consent for this process and no individual written consent was required from stakeholders, including PPIE contributors. Written informed consent was

obtained from all stakeholders who participated in individual qualitative interviews as part of work package 3.

Given the online group format of the stakeholder workshops, participants attending these workshops were identifiable to each other and to the authors. However, the identities of participants who consented to an individual qualitative interview were known only to the interviewer, and interviewees were assigned a unique participant identification number to preserve the anonymity of their interview transcripts. PPIE contributors were reimbursed £25 (US \$33.19 at the time of the study) per hour for their participation in the study, in line with the Involve payment policy [34].

## Results

### Work Package 1: Stakeholder Co-Design of the EPICare Registry and CDSS

In work package 1, we established a network with representation from PPIE and other essential stakeholder groups (clinicians, academics, and policy makers) and engaged stakeholders in a series of 4 workshops, using a modified Delphi approach to identify essential and desirable elements of the EPICare registry and CDSS and to develop a consensus of data priorities. The 4 co-design workshops took place in December 2021, February 2022, May 2022, and September 2022, respectively.

### Work Package 2: Informatics Architecture, Infrastructure, and Integration—Framework, Protocol, and Tool Kit

Work package 2 occurred in parallel with work packages 1 and 3, between December 2021 and September 2022. In this work package, we collaborated with NHS informatics teams to address key questions about informatics architecture, infrastructure, governance, and integration plans to facilitate onward development and testing of EPICare in diverse NHS Trusts.

### Work Package 3: Implementation Evaluation Framework

Work package 3 also took place between December 2021 and September 2022. In this work package, we conducted individual qualitative interviews with representative stakeholders and took notes during observation of the stakeholder workshops to identify implementation factors from the outset and ensure they are considered in designing, implementing, and maintaining the future deployment of EPICare in a measurable way. All interviews were recorded and transcribed. For quality control, transcript summaries were shared with participants and feedback was elicited as to their veracity. Observation notes of the stakeholder workshops and transcripts of the individual interviews were subject to interpretative qualitative analysis, guided by the NPT implementation science framework. Preliminary data analysis of observation notes involved producing short descriptive summaries of field observations, for the purpose of summarizing and sharing data with the study team. NVivo software (Lumivero) was used to organize the qualitative observational and transcribed interview data. An iterative coding process was followed with data being subject to systematic close reading and coding. Through sharing and

deliberating preliminary codes and interpretations with the wider study team and through the processes of constant comparison, secondary inductive, and interpretative themes were developed. At this stage, the constructs of NPT were used to further analyze and explain the study findings. Through discussion and disputation with PPIE, clinicians, and the project team, inferences were made about how the implementation science framework should be further refined.

Stage 1 of the EPICare study is now complete and we are currently preparing a paper detailing our findings from work package 3 activities (ie, field observations of the stakeholder workshops and qualitative interviews). Data collected and decisions made in the stage 1 program development phase of the project will directly inform the stage 2 building, piloting, implementation, and evaluation of the EPICare platform and CDSS in 5 demonstrator NHS Trusts serving underserved and diverse populations with substantial need for EIP care in England. If successful, this will be followed by stage 3, in which we will seek NHS adoption of EPICare for rollout to all EIP services in England.

## Discussion

In this program development phase (stage 1), we co-designed a framework and protocols for the onward building, implementation, piloting, and evaluation of the EPICare registry and CDSS. We achieved this by adopting a participatory design with input from diverse relevant stakeholders, including lived experience experts and clinical, academic, technologist, and organizational stakeholders. By engaging multiple stakeholders in an iterative co-design process, using qualitative methods to capture and synthesize rich data representing a variety of perspectives, we have met our work package 1 objectives of establishing a network with representation from PPIE and other essential stakeholder groups to collaboratively identify essential and desirable elements of the EPICare platform and CDSS. In addition, we have addressed key questions related to informatics architecture, infrastructure, governance, and integration in diverse NHS Trusts (in line with our work package 2 objectives), and in doing so, have identified and minimized potential challenges and barriers to uptake and implementation (thereby meeting our work package 3 objectives).

We are now ready to build, implement, and evaluate a national patient-centered digital registry and CDSS for psychosis (EPICare) to improve national, local, and individual clinical decision-making and promote improved outcomes for people experiencing first-episode psychosis. While similar efforts to leverage routinely collected data in EIP services are currently underway in other parts of the world; for instance, in Canada [35] and Australia [36]; the EPICare registry and CDSS potentially represent a paradigmatic shift, as they would be the first national patient-centered digital registry and integrated CDSS for psychosis, one of the most common and disabling mental health disorders disproportionately affecting deprived and disadvantaged youth. By combining routine, standardized, prospective data collection via a national digital registry with real-time actionable insights delivered to patients, clinical teams, service managers, and policy makers via an embedded CDSS,

the overall aim of EPICare is to improve patient care, enhance service delivery, reduce disparities in care, and further our understanding of the relationship between the interventions offered to, and received by, young people receiving EIP care and outcomes. Insights provided by the EPICare registry will also enable more equitable, responsive resource allocation and more rapid, reliable identification of local, regional, or group-based disparities in access to care and treatment outcomes and will support clinical and policy decision-making and research on various aspects of early psychosis. The registry may also improve access to much-needed stratified trials (eg, for clozapine and neurostimulation) and facilitate the development of novel treatments.

While we have achieved all of the objectives set out for the first phase of this study, it is worth noting that adoption and integration of all the desirable elements identified by stakeholders may not be feasible or pragmatic for the initial build of the EPICare platform and CDSS. This will be tested in our next stage, as noted above.

A national psychosis digital registry—leveraging routine data to provide real-time actionable insights—will be vital to improving real-world outcomes, identifying and preventing inequalities in care, and ensuring that individuals receive the most appropriate treatments at the right time to promote recovery and maximize life chances.

## Acknowledgments

Early Psychosis Informatics into Care (EPICare) is fully funded by the National Institute for Health Research (NIHR) Programme Development Grants (PDG) Mental Health Call 2021 (grant NIHR203669). Birmingham Women's and Children's National Health Service (NHS) Foundation Trust agreed to act as sponsor for this study. This research is supported by the NIHR Oxford Health Biomedical Research Centre, the NIHR University College London Hospitals (UCLH) Biomedical Research Centre, the NIHR Cambridge Biomedical Research Centre (NIHR203312), and the NIHR Applied Research Collaboration East of England. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

## Data Availability

Data sharing is not applicable to this article as no data sets were generated or analyzed during this study.

## Authors' Contributions

RU and JBK are joint project leads and hold joint senior authorship. SLG drafted the paper with further input from RU and JBK. SJ, GKM, MAP, NC, JW, JA, RJD, MM, SMA, TW, JBK, YL, TB, and SAS also contributed to the study as well as provided comments on the paper. All authors approved the final version.

## Conflicts of Interest

GKM has received consultancy fees from ieso. RU reports speaker fees from Sunovion, Springer Healthcare, Otsuka, and Vitaris outside the submitted work and holds unpaid officership with the British Association for Pharmacology—Honorary General Secretary 2021-2024 and is deputy editor of the British Journal of Psychiatry. JA is funded by the NIHR Manchester Biomedical Research Centre. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health.

## References

1. an der Heiden W, Häfner H. The epidemiology of onset and course of schizophrenia. *Eur Arch Psychiatry Clin Neurosci*. 2000;250(6):292-303. [doi: [10.1007/s004060070004](https://doi.org/10.1007/s004060070004)] [Medline: [11153964](https://pubmed.ncbi.nlm.nih.gov/11153964/)]
2. Kirkbride JB, Errazuriz A, Croudace TJ, Morgan C, Jackson D, Boydell J, et al. Incidence of schizophrenia and other psychoses in England, 1950-2009: a systematic review and meta-analyses. *PLoS One*. 2012;7(3):e31660. [[FREE Full text](https://doi.org/10.1371/journal.pone.0031660)] [doi: [10.1371/journal.pone.0031660](https://doi.org/10.1371/journal.pone.0031660)] [Medline: [22457710](https://pubmed.ncbi.nlm.nih.gov/22457710/)]
3. Jongsma HE, Turner C, Kirkbride JB, Jones PB. International incidence of psychotic disorders, 2002-17: a systematic review and meta-analysis. *Lancet Public Health*. May 2019;4(5):e229-e244. [[FREE Full text](https://doi.org/10.1016/S2468-2667(19)30056-8)] [doi: [10.1016/S2468-2667\(19\)30056-8](https://doi.org/10.1016/S2468-2667(19)30056-8)] [Medline: [31054641](https://pubmed.ncbi.nlm.nih.gov/31054641/)]
4. March D, Hatch SL, Morgan C, Kirkbride JB, Bresnahan M, Fearon P, et al. Psychosis and place. *Epidemiol Rev*. 2008;30:84-100. [[FREE Full text](https://doi.org/10.1093/epirev/mxn006)] [doi: [10.1093/epirev/mxn006](https://doi.org/10.1093/epirev/mxn006)] [Medline: [18669521](https://pubmed.ncbi.nlm.nih.gov/18669521/)]
5. O'Donoghue B, Roche E, Lane A. Neighbourhood level social deprivation and the risk of psychotic disorders: a systematic review. *Soc Psychiatry Psychiatr Epidemiol*. Jul 2016;51(7):941-950. [doi: [10.1007/s00127-016-1233-4](https://doi.org/10.1007/s00127-016-1233-4)] [Medline: [27178430](https://pubmed.ncbi.nlm.nih.gov/27178430/)]
6. McDonald K, Ding T, Ker H, Dliwayo TR, Osborn DPJ, Wohland P, et al. Using epidemiological evidence to forecast population need for early treatment programmes in mental health: a generalisable Bayesian prediction methodology applied to and validated for first-episode psychosis in England. *Br J Psychiatry*. Jul 2021;219(1):383-391. [[FREE Full text](https://doi.org/10.1192/bjp.2021.18)] [doi: [10.1192/bjp.2021.18](https://doi.org/10.1192/bjp.2021.18)] [Medline: [34475575](https://pubmed.ncbi.nlm.nih.gov/34475575/)]
7. QS80: psychosis and schizophrenia in adults. National Institute for Health and Care Excellence. 2015. URL: <https://wels.open.ac.uk/research-project/caren/node/2782> [accessed 2024-02-24]



8. Bird V, Premkumar P, Kendall T, Whittington C, Mitchell J, Kuipers E. Early intervention services, cognitive-behavioural therapy and family intervention in early psychosis: systematic review. *Br J Psychiatry*. Nov 2010;197(5):350-356. [FREE Full text] [doi: [10.1192/bjp.bp.109.074526](https://doi.org/10.1192/bjp.bp.109.074526)] [Medline: [21037211](https://pubmed.ncbi.nlm.nih.gov/21037211/)]
9. Anderson KK, Norman R, MacDougall A, Edwards J, Palaniyappan L, Lau C, et al. Effectiveness of early psychosis intervention: comparison of service users and nonusers in population-based health administrative data. *Am J Psychiatry*. May 01, 2018;175(5):443-452. [doi: [10.1176/appi.ajp.2017.17050480](https://doi.org/10.1176/appi.ajp.2017.17050480)] [Medline: [29495897](https://pubmed.ncbi.nlm.nih.gov/29495897/)]
10. McCrone P, Craig TKJ, Power P, Garety PA. Cost-effectiveness of an early intervention service for people with psychosis. *Br J Psychiatry*. May 2010;196(5):377-382. [doi: [10.1192/bjp.bp.109.065896](https://doi.org/10.1192/bjp.bp.109.065896)] [Medline: [20435964](https://pubmed.ncbi.nlm.nih.gov/20435964/)]
11. Lester H, Marshall M, Jones P, Fowler D, Amos T, Khan N, et al. Views of young people in early intervention services for first-episode psychosis in England. *Psychiatr Serv*. Aug 2011;62(8):882-887. [doi: [10.1176/ps.62.8.pss6208\\_0882](https://doi.org/10.1176/ps.62.8.pss6208_0882)] [Medline: [21807826](https://pubmed.ncbi.nlm.nih.gov/21807826/)]
12. Lally J, Ajnakina O, Stubbs B, Cullinane M, Murphy KC, Gaughran F, et al. Remission and recovery from first-episode psychosis in adults: systematic review and meta-analysis of long-term outcome studies. *Br J Psychiatry*. Dec 2017;211(6):350-358. [doi: [10.1192/bjp.bp.117.201475](https://doi.org/10.1192/bjp.bp.117.201475)] [Medline: [28982659](https://pubmed.ncbi.nlm.nih.gov/28982659/)]
13. Stokes I, Griffiths SL, Jones R, Everard L, Jones PB, Fowler D, et al. Prevalence of treatment resistance and clozapine use in early intervention services. *BJPsych Open*. Sep 17, 2020;6(5):e107. [FREE Full text] [doi: [10.1192/bjo.2020.89](https://doi.org/10.1192/bjo.2020.89)] [Medline: [32938513](https://pubmed.ncbi.nlm.nih.gov/32938513/)]
14. Rammou A, Fisher HL, Johnson S, Major B, Rahaman N, Chamberlain-Kent N, et al. Negative symptoms in first-episode psychosis: clinical correlates and 1-year follow-up outcomes in London Early Intervention Services. *Early Interv Psychiatry*. Jun 2019;13(3):443-452. [doi: [10.1111/eip.12502](https://doi.org/10.1111/eip.12502)] [Medline: [29148264](https://pubmed.ncbi.nlm.nih.gov/29148264/)]
15. Marwaha S, Thompson A, Upthegrove R, Broome MR. Fifteen years on - early intervention for a new generation. *Br J Psychiatry*. Sep 2016;209(3):186-188. [doi: [10.1192/bjp.bp.115.170035](https://doi.org/10.1192/bjp.bp.115.170035)] [Medline: [27587758](https://pubmed.ncbi.nlm.nih.gov/27587758/)]
16. Griffiths SL, Lalouis PA, Wood SJ, Upthegrove R. Heterogeneity in treatment outcomes and incomplete recovery in first episode psychosis: does one size fit all? *Transl Psychiatry*. Nov 17, 2022;12(1):485. [FREE Full text] [doi: [10.1038/s41398-022-02256-7](https://doi.org/10.1038/s41398-022-02256-7)] [Medline: [36396628](https://pubmed.ncbi.nlm.nih.gov/36396628/)]
17. Firth J, Siddiqi N, Koyanagi A, Siskind D, Rosenbaum S, Galletly C, et al. The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness. *Lancet Psychiatry*. 2019;6(8):675-712. [doi: [10.1016/S2215-0366\(19\)30132-4](https://doi.org/10.1016/S2215-0366(19)30132-4)] [Medline: [31324560](https://pubmed.ncbi.nlm.nih.gov/31324560/)]
18. Hjorthøj C, Stürup AE, McGrath JJ, Nordentoft M. Years of potential life lost and life expectancy in schizophrenia: a systematic review and meta-analysis. *Lancet Psychiatry*. Apr 2017;4(4):295-301. [doi: [10.1016/S2215-0366\(17\)30078-0](https://doi.org/10.1016/S2215-0366(17)30078-0)] [Medline: [28237639](https://pubmed.ncbi.nlm.nih.gov/28237639/)]
19. Morris RM, Sellwood W, Edge D, Colling C, Stewart R, Cupitt C, et al. Ethnicity and impact on the receipt of cognitive-behavioural therapy in people with psychosis or bipolar disorder: an English cohort study. *BMJ Open*. Dec 15, 2020;10(12):e034913. [FREE Full text] [doi: [10.1136/bmjopen-2019-034913](https://doi.org/10.1136/bmjopen-2019-034913)] [Medline: [33323425](https://pubmed.ncbi.nlm.nih.gov/33323425/)]
20. Puntis S, Oke J, Lennox B. Discharge pathways and relapse following treatment from early intervention in psychosis services. *BJPsych Open*. Sep 2018;4(5):368-374. [FREE Full text] [doi: [10.1192/bjo.2018.50](https://doi.org/10.1192/bjo.2018.50)] [Medline: [30202598](https://pubmed.ncbi.nlm.nih.gov/30202598/)]
21. Griffiths SL, Bogatsu T, Longhi M, Butler E, Alexander B, Bandawar M, et al. Five-year illness trajectories across racial groups in the UK following a first episode psychosis. *Soc Psychiatry Psychiatr Epidemiol*. Apr 2023;58(4):569-579. [FREE Full text] [doi: [10.1007/s00127-023-02428-w](https://doi.org/10.1007/s00127-023-02428-w)] [Medline: [36717434](https://pubmed.ncbi.nlm.nih.gov/36717434/)]
22. National clinical audit in psychosis audit. Healthcare Quality Improvement Partnership. 2021. URL: <https://www.hqip.org.uk/a-z-of-nca/national-clinical-audit-of-psychosis/> [accessed 2024-02-24]
23. Heuschmann PU, Grieve AP, Toschke AM, Rudd AG, Wolfe CDA. Ethnic group disparities in 10-year trends in stroke incidence and vascular risk factors: the South London Stroke Register (SLSR). *Stroke*. Aug 2008;39(8):2204-2210. [doi: [10.1161/STROKEAHA.107.507285](https://doi.org/10.1161/STROKEAHA.107.507285)] [Medline: [18535279](https://pubmed.ncbi.nlm.nih.gov/18535279/)]
24. Kelsey EA, Njeru JW, Chaudhry R, Fischer KM, Schroeder DR, Croghan IT. Understanding user acceptance of clinical decision support systems to promote increased cancer screening rates in a primary care practice. *J Prim Care Community Health*. 2020;11:2150132720958832. [FREE Full text] [doi: [10.1177/2150132720958832](https://doi.org/10.1177/2150132720958832)] [Medline: [33016170](https://pubmed.ncbi.nlm.nih.gov/33016170/)]
25. Taylor-Robinson D, Archangelidi O, Carr SB, Cosgriff R, Gunn E, Keogh RH, et al. CF-EpinNet collaboration. Data resource profile: the UK Cystic Fibrosis Registry. *Int J Epidemiol*. Feb 01, 2018;47(1):9-10e. [FREE Full text] [doi: [10.1093/ije/dyx196](https://doi.org/10.1093/ije/dyx196)] [Medline: [29040601](https://pubmed.ncbi.nlm.nih.gov/29040601/)]
26. Stephan BCM, Siervo M, Brayne C. How can population-based studies best be utilized to reduce the global impact of dementia? Recommendations for researchers, funders, and policymakers. *Alzheimers Dement*. Oct 2020;16(10):1448-1456. [doi: [10.1002/alz.12127](https://doi.org/10.1002/alz.12127)] [Medline: [32573915](https://pubmed.ncbi.nlm.nih.gov/32573915/)]
27. Langhorne P, Taylor G, Murray G, Dennis M, Anderson C, Bautz-Holter E, et al. Early supported discharge services for stroke patients: a meta-analysis of individual patients' data. *Lancet*. 2005;365(9458):501-506. [doi: [10.1016/S0140-6736\(05\)17868-4](https://doi.org/10.1016/S0140-6736(05)17868-4)] [Medline: [15705460](https://pubmed.ncbi.nlm.nih.gov/15705460/)]
28. Mazo C, Kearns C, Mooney C, Gallagher WM. Clinical decision support systems in breast cancer: a systematic review. *Cancers (Basel)*. Feb 06, 2020;12(2):369. [FREE Full text] [doi: [10.3390/cancers12020369](https://doi.org/10.3390/cancers12020369)] [Medline: [32041094](https://pubmed.ncbi.nlm.nih.gov/32041094/)]

29. Ospina-Pinillos L, Davenport T, Mendoza Diaz A, Navarro-Mancilla A, Scott EM, Hickie IB. Using participatory design methodologies to co-design and culturally adapt the Spanish version of the mental health eClinic: qualitative study. *J Med Internet Res*. Aug 02, 2019;21(8):e14127. [[FREE Full text](#)] [doi: [10.2196/14127](https://doi.org/10.2196/14127)] [Medline: [31376271](https://pubmed.ncbi.nlm.nih.gov/31376271/)]
30. National Institute for Health and Care Excellence (NICE). *Psychosis and Schizophrenia in Adults: Treatment and Management*. London, UK. Royal College of Psychiatrists; 2014.
31. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med*. Oct 20, 2010;8:63. [[FREE Full text](#)] [doi: [10.1186/1741-7015-8-63](https://doi.org/10.1186/1741-7015-8-63)] [Medline: [20961442](https://pubmed.ncbi.nlm.nih.gov/20961442/)]
32. Robertson A, Cresswell K, Takian A, Petrakaki D, Crowe S, Cornford T, et al. Implementation and adoption of nationwide electronic health records in secondary care in England: qualitative analysis of interim results from a prospective national evaluation. *BMJ*. Sep 01, 2010;341:c4564. [[FREE Full text](#)] [doi: [10.1136/bmj.c4564](https://doi.org/10.1136/bmj.c4564)] [Medline: [20813822](https://pubmed.ncbi.nlm.nih.gov/20813822/)]
33. Ainsworth J, Harper R. The PsyGrid experience: using web services in the study of schizophrenia. *IJHISI*. 2008;2(2):365-386. [doi: [10.4018/978-1-60566-050-9.ch030](https://doi.org/10.4018/978-1-60566-050-9.ch030)]
34. Involve. URL: <https://www.involve.org.uk/> [accessed 2024-02-24]
35. Ferrari M, Iyer S, LeBlanc A, Roy MA, Abdel-Baki A. A rapid-learning health system to support implementation of early intervention services for psychosis in Quebec, Canada: protocol. *JMIR Res Protoc*. Jul 19, 2022;11(7):e37346. [[FREE Full text](#)] [doi: [10.2196/37346](https://doi.org/10.2196/37346)] [Medline: [35852849](https://pubmed.ncbi.nlm.nih.gov/35852849/)]
36. Thompson A, Fitzsimons J, Killackey E, Ahern S, Amminger P, Alvarez-Jimenez M, et al. The Australian Early Psychosis Collaborative Consortium (AEPCC): improving clinical care in early psychosis. *Australas Psychiatry*. Jun 2023;31(3):306-308. [doi: [10.1177/10398562231174691](https://doi.org/10.1177/10398562231174691)] [Medline: [37171091](https://pubmed.ncbi.nlm.nih.gov/37171091/)]

## Abbreviations

**CDSS:** clinical decision support system

**EIP:** early intervention in psychosis

**EPICare:** Early Psychosis Informatics into Care

**HoNOS:** Health of the Nation Outcomes Scales

**MHTRC-Early Psychosis:** Mental Health Translational Research Collaboration in Early Psychosis

**NHS:** National Health Service

**NICE:** National Institute for Health and Care Excellence

**NIHR:** National Institute for Health Research

**NPT:** normalization process theory

**PPIE:** patient and public involvement and engagement

**QPR:** The Questionnaire about the Process of Recovery

*Edited by A Mavragani; submitted 23.06.23; peer-reviewed by S Sabarguna, K Uludag; comments to author 02.10.23; revised version received 21.01.24; accepted 21.02.24; published 19.03.24*

*Please cite as:*

Griffiths SL, Murray GK, Logeswaran Y, Ainsworth J, Allan SM, Campbell N, Drake RJ, Katshu MZUH, Machin M, Pope MA, Sullivan SA, Waring J, Bogatsu T, Kane J, Weetman T, Johnson S, Kirkbride JB, Uptegrove R

*Implementing and Evaluating a National Integrated Digital Registry and Clinical Decision Support System in Early Intervention in Psychosis Services (Early Psychosis Informatics Into Care): Co-Designed Protocol*

*JMIR Res Protoc* 2024;13:e50177

URL: <https://www.researchprotocols.org/2024/1/e50177>

doi: [10.2196/50177](https://doi.org/10.2196/50177)

PMID: [38502175](https://pubmed.ncbi.nlm.nih.gov/38502175/)

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