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The National Clinical Programme for Early Intervention in Psychosis: A process evaluation of the implementation of a new model of care in three demonstration sites

End of Project report

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List of Abbreviations

AMHT: Adult Mental Health Team

ARMS: At Risk Mental State

BFT: Behavioural Family Therapy

CAMHS: Child and Adolescent Mental Health Service

CBTp: Cognitive Behavioural Therapy for Psychosis

CHO: Community Health Organisation

CMHT: Community Mental Health Team

DUP: Duration of untreated psychosis

EIP: Early Intervention in Psychosis

FEP: First Episode Psychosis

GP: General Practitioner

HSE: Health Service Executive

IPS: Individual Placement and Support

MDT: Multidisciplinary Team

MoC: Model of Care

NCP: National Clinical Programme

TAU: Treatment as Usual

Executive Summary

Early intervention in psychosis (EIP) services support people who are experiencing the symptoms of psychosis for the first time. The Health Service Executive's (HSE) National Clinical Programme for EIP was prioritised within the HSE National Clinical Programme for Mental Health and a new model of care (MoC) was launched in 2019. These services were developed as a new way of organising our mental health services, based on a recovery model of care, which is built on a culture of hope and expectation that the service user can recover from their mental health challenges and build a fulfilling life of their choosing. EIP focuses on the early detection and treatment of symptoms of psychosis during the initial years of the condition. The primary aims of the EIP programme were to standardise quality evidence based practice, improve access and cost effectiveness by clinically led multidisciplinary teams in collaboration with service users and their families within a nationally consistent approach to care. The recommended model for EIP service delivery is the standalone model in urban areas (population >200,000 persons) or a 'hub and spoke' model for rural areas or towns (population <200,000 persons). In the hub and spoke model, EIP services are located within the hub under the clinical leadership of a consultant psychiatrist and supported by EIP roles such as a keyworker, behavioural family therapist (BFT) and a cognitive behavioural therapist with a focus on psychosis (CBTp). The spokes comprise the existing community mental health teams (CMHTs) and their multidisciplinary specialisms which feed into and support the hub. The pillar interventions of EIP have equal weighting and include medication, psychosis specific psychological interventions, psychosis specific family support and interventions, physical health screening and intervention and individual placement support (IPS). IPS can be located in the hub or spokes but must have an EIP dedicated caseload that is not shared with CMHT.

Three areas of Ireland (Cork South Lee, Sligo and Meath) began offering a 'hub and spoke' MoC on a demonstration basis. In 2019, a research team from Trinity College Dublin, were commissioned to conduct a process evaluation of the EIP programme to determine the experience of staff in their attempts to implement and operate this new MoC, identify the barriers and facilitative factors and characterise the experiences of service users and their families attending these services. This report summarises this process evaluation, which included; Study One - a documentary analyses to understand the treatment context before and after teams attempted to implement EIP in the demonstration sites; Study Two - quantitative data collection to assess implementation processes; and Study Three - qualitative data collection to analyse the mechanisms of impact.

Key findings from Study One analyses indicated that EIP demonstration teams changed the assessment (e.g., standardised assessment relevant to EIP at baseline, six, 24 and 36 months; plus review every six months) and treatment interventions (e.g., keyworker, CBTp, BFT, IPS) compared with treatment as usual. The demonstration site in Cork South Lee started quickly. Whereas, Sligo and Meath teams, in particular, had slower starts. Primary barriers to implementation related to the interdependency of staffing and funding. Organograms highlight the differing staffing mixes in the hub and spokes across the three demonstration sites at the start of the process evaluation (Phase 1) and towards the end of the evaluation (Phase 2). The EIP demonstration initiative was a new innovation which was forced to embed itself into an existing health service with its own systems and structures in-situ. The demonstration sites inherited existing problems from within the HSE, such as, those relating to recruitment processes (e.g., delays in staff appointments and start dates). Teams also faced blocks to implementation in terms of derogation of funds (e.g., EIP demonstration sites were funded under new initiatives and funds were not released on time so as to satisfy other operational obligations in local areas; these barriers were further explored in Study Two). None of the three sites were immune to these problems, and as a result implementation was not consistent

across the three demonstration sites. Cork South Lee was more resilient to these challenges due to strong clinical leadership and staff commitment to the EIP MoC. Sligo had a slower start but were eventually able to implement the EIP MoC. Meath was not in a position to offer the EIP service as outlined in the MoC due to challenges with staff recruitment, specifically IPS. This has implications for the viability of demonstration teams to deliver the EIP programme, which in turns threatens fidelity to the primary components of the programme (e.g., rapid assessment and intervention, keyworking, provision of complex psychosocial interventions like CBTp, BFT, IPS). It also prevented standardisation of EIP across all areas.

Study Two findings demonstrated the availability of and engagement with psychosocial interventions for psychosis and other support services. A total of 192 service users' information has been included in this database (Cork South Lee *n*= 141, Sligo *n*= 51; note: Meath quantitative data cannot be included in this report due to a decision by the local research ethics committee). Specifically, the demonstration teams were able to provide rapid assessment of service users among a proportion of service users to facilitate early intervention (57% in Cork South Lee; 34% in Sligo had assessments conducted within 3 working days). The majority of service users engaged with initial appointments in the service (72% in Cork South Lee; 55% in Sligo). In terms of engagement, keyworkers achieved an average of five contacts with service users per month; majority of service users were engaged with CBTp (78% in Cork South Lee; 56% in Sligo), engagement with BFT was well-received (with an average of 60% of those offered BFT engaged in that aspect of the service) and among those who were engaged with IPS, 49% were able to secure employment. There was a positive strong dose relationship between keyworker contacts and psychosocial interventions offered. Specifically, the odds of achieving at least monthly engagement with CBTp (5.76 (2.43-13.64), $p<0.001$)), and BFT (5.52 (1.63-18.69, $p<0.006$)) increased by five-fold with each additional monthly keyworker contact. For IPS, each additional monthly keyworker contact was associated with a three-fold increase in the odds of achieving monthly attendance with IPS (3.73 (1.64-8.48), $p<0.002$). These strong positive effects were observed in spite of challenges with staffing capacity and maternity leave by staff that occurred during the study period. The reach of the demonstration team in Sligo was as anticipated (14.7 observed cases; 15.7 projected cases) whereas, Cork South Lee enrolled significantly more service users than projected (49.0 observed cases; 26.3 projected cases). It is encouraging that both demonstration sites were able to achieve high levels of enrolment and suggests that teams established a strong reach into communities to promote uptake of services amongst people experiencing first episode of psychosis (FEP). However, this does require careful monitoring and resourcing so that caseloads, for example, remain within the identified parameters of the MoC (e.g., each keyworker was to have no more than 15 cases at any one time although this was exceeded in Cork and Sligo during the process evaluation).

Study Three qualitative analyses demonstrated that overall, the EIP programme was strongly supported by both service providers and service users. The availability of the keyworker in particular, as an ongoing contact to monitor and coordinate care was commonly referenced as a facilitator of engagement by service users. CBTp was praised for making significant improvements in specific symptoms and the development of service user coping skills. Service users and family members also reported that BFT was effective for improving interpersonal relationships and increasing family members' understanding of psychosis and psychosis treatment. IPS was highly regarded by many service users, although some participants were only ready for this at later stages in their treatment progression. Although staffing and funding challenges delayed the implementation and availability of specific service components at select demonstration sites, engagement and support for these services was encouraging once implementation occurred and staff were highly motivated to provide the EIP services as designed in the MoC. Primary facilitators included enthusiasm for the concept and philosophy of EIP from staff and positive treatment experiences from service users. It is also

noteworthy that the process evaluation occurred before and during the COVID-19 pandemic. The three demonstration teams adapted to this (e.g., remote engagement) and continued to provide care to service users.

To promote the sustainability and expansion of EIP services, it is recommended that HSE organisational processes related to funding allocation and staffing be radically changed to support the availability of the EIP service. Implementing an electronic data capture system to measure EIP service implementation and engagement would also support the monitoring and evaluation of this MoC in the future.

Policy, Practice and Research Recommendations

1. The EIP demonstration teams developed a strong reach into communities to meet the demand for FEP assessment and treatment and was strongly supported by service users and families. Determining the location of further EIP teams should be underpinned by estimated local incidence of psychosis, which incorporates a range of demographic indicators such as age, ethnicity, population density, and deprivation. Commissioning of services should follow this exercise.
2. The positive dose relationship between the number of keyworker contacts and engagement with psychosocial interventions (e.g., CBTp, BFT and IPS) highlights the importance of keyworking positions. Both the Department of Health and the HSE should agree and establish a grade code to identify the skill mix and case load capacity of these positions.
3. A workforce planning exercise should be undertaken to plan EIP capacity and skill mix required to ensure current and future delivery needs. This is particularly necessary for keyworker roles, and roles requiring specialised training such as BFT and CBTp. Consultant psychiatrists and clinical leads within EIP teams should have protected time for EIP related activities.
4. EIP services should be vigilant to maintain fidelity to providing the full range of psychological, psychosocial, pharmacological and other interventions shown to be effective including support for family members. Monitoring of fidelity and standardisation of care should be conducted through audit and evaluation. Establishing standards for protected time and manageable caseloads will be critical to maximise the benefits of the EIP service generally and the individual services.
5. Clinical teams should ensure that young people also benefit from this standardised approach to the early identification and treatment of psychosis. To this end, robust local arrangements and positive relationships are required between CAMHS services and EIP services (as well as ancillary services like youth settings, peer support and addiction services) so that young people can benefit from these specialist services.

6. Clinical Leads, the National Clinical Lead for Psychosis and Programme Manager should work together to protect the principles and ethos of the EIP MoC which underpins the vision that people who experience psychosis can and do recover. From this all else stems.
7. The National Office relating to the Clinical Programme for EIP which supports teams and sites on the ground should be funded to a comparable standard as other clinical programmes (e.g., a full time programme manager). This Office also should have access to dedicated expertise in data analytics, IT and HR processes.
8. At national, regional and local levels the HR and finance functions in the HSE must work more collaboratively with clinical teams. This includes an agreed consistent and robust process for recruitment of staff for new services, such as EIP. A mechanism to achieve this would be to include a HR function within community health organisations that have the authority to commence people in posts improve the efficiency of recruitment.
9. As this EIP innovation is occurring within the existing public health service (Health Service Executive; HSE), the key enablers to facilitate success of the EIP demonstration sites and any further roll out of same includes the interexchange between human resources (HR), finance and data capture. Efficient funding, IT and HR processes should be established pre-implementation so transformative services such as EIP do not shift operational responsibilities to clinical staff.
10. There should be multi-annual budget plans for major change projects, such as EIP, that have costed budgets which are ringfenced and protected for approved innovative services. This is critical so that other operational service needs do not interfere with strategic priorities such as EIP.
11. Inclusion of a research component within EIP sites is important for service planning and improvement of both quality of care and the assessment of early intervention strategies. These could include an examination of quality of life improvements, the effects of BFT for family dynamics, co-design of services with service users and family members, longer term assessment of employment outcomes and physical and mortality monitoring. An improved process to capture the voice of the family is needed in research relating to EIP.

12. The co-design and development of a data capture infrastructure allowing for the electronic recording and sharing of service user information within EIP teams and across CMHTs is essential. Training of clinical and administrative staff to ensure data literacy, confidence and capability is linked to this.
13. More broadly the HSE should look to develop consistency of ethical and data governance processes in relation to research and evaluation. Coherent research and audit processes will

expedite the research and evaluation of these services so that they can be adapted and tailored to other locations.

Background

Early Intervention in Psychosis

Psychosis describes a state of mind in which delusions, hallucinations and/or disordered thinking are experienced while in a fully conscious state (1). The international incidence of psychotic disorders is 32 per 100,000 person-years (2). There is a general lack of information concerning incidence of psychosis in Ireland with no national database or incidence register, making service planning difficult. A regional study reported an incidence of 31.6 cases per 100,000 of the population per year (3), and a regional prospective study comparing urban South Dublin with rural North East Ireland reported an incidence in urban males of 25.4 per 100,000 population per year (standard error (SE): 3.2) and 13.1 (SE: 2.2) in rural males. In females, the urban rate was 12.3 (SE: 2.1) compared to 9.2 (SE: 1.9) in rural areas. Psychosis incidence is higher in deprived inner-city neighbourhoods, males outnumber females by a ratio of 2: 1, and ethnic minorities are at excess risk of all psychotic disorders (4). A completed but currently unpublished report using census data from Ireland from 2016 places the predicted incidence rate of 22.2 per 100,000 people per year for people aged 18-64 years old (95%CrI: 20.6-24.0) for first episode psychosis (5).

Psychotic disorders are a source of suffering for service users and their families. They can result in a high degree of disability and an increased risk of premature death of up to 25 years (6). There is a 10% lifetime risk of suicide, commonly within the first five years of onset and the risk is highest at the time of first relapse (7). In addition, 88% of service users will experience unemployment in the course of their condition, increasing their risk of social exclusion (8).

First-episode psychosis (FEP) refers to the first episode of schizophrenia, affective psychoses, substance-induced psychosis or organic psychosis, often beginning in a person's late teens to mid-twenties. FEP service users can experience long delays in accessing treatments (9), have high rates of hospitalisation (10), often poor engagement in treatment (11), high levels of psychiatric comorbidity (12), and persistent symptoms (13).

The degree to which a service user receives treatment and support within the first two to five years of symptom onset is vital in determining long-term outcomes (14). It is relatively well established that the first two to three years after psychosis symptoms present are critical to influencing patient trajectory since psychosocial factors such as family and peer relationships, employment and education are at critical developmental stages (15). On average, there is at least a six-month delay before a person seeks help from their general practitioner (GP) after their first episode of psychosis

(16), but the duration of untreated psychosis (DUP) is unknown in Ireland. Longer DUP is associated with poorer symptom recovery, more severe symptoms, poor social functioning and reductions in global improvements (17). However, recent evidence from a systematic review and meta-analyses found that the rate of remission among adults with FEP is 58%, which challenges the characterisation of psychosis as a progressively deteriorating illness (18).

Development of Early Intervention in Psychosis service provision in Ireland

Early Intervention Psychosis (EIP) services were implemented in the UK in 2001 and are common in parts of Canada, Australia and other European countries. There is no national, standardised, comprehensive EIP service in Ireland, despite an estimated total cost of psychosis disorder care of €461 million per year to the State (19).

Ireland's first EIP service, DETECT was established in 2005 in south county Dublin (20), and a second service was established in the Cavan/Monaghan area, named COPE (21). In the Wicklow region, an EIP service called PROTECT was established in 2011 and was funded by a time-limited grant. It delivered a service until 2014. Both COPE and PROTECT have since disbanded. The Department of Health's national mental health policy, *A Vision for Change*, outlined EIP service provision, recommending comprehensive, community-based, recovery focused, service-user centred services (22) but resource provision was limited. A recent updated policy *Sharing the Vision* restates the importance of EIP in the treatment of FEP service users, but no funding commitments were made (23).

A lack of committed funding and resources have impeded the full implementation of EIP services in Ireland. While private provision of care is available, a person experiencing FEP in Ireland most commonly receives treatment through either generic child and adolescent mental health services (CAMHS) (0 to 17 years), adult mental health services (AMHS) (18 to 65 years) or old age (over 65) community-based mental health services within the Health Service Executive (HSE), Ireland's national public health service. Individual care plans and key working are neither universal nor standardised, and the delivery of evidence-based interventions differ between services (24). Some services have developed EIP components, but in the absence of national guidelines and allocated funding, the identification, assessment and available treatment for FEP patients varies widely.

Within the HSE's Clinical Design and Innovation team (formally known as 'Clinical Strategy and Programmes Division') are four National Clinical Programmes (NCP) in mental health, which

comprise initiatives that will bring significant positive developments in the Irish health service. Their overarching aim is to change how care is delivered using evidence-based approaches to health system reform. There are four Mental Health Clinical Programmes, including 'Assessment and management of patients presenting to emergency departments following self-harm', 'Eating disorder services', 'ADHD in adults', and 'Early Intervention in Psychosis'. The HSE's NCP for EIP is a joint initiative between the HSE and the College of Psychiatrists in Ireland.

A Model of Care (MoC) was developed and published in June 2019 (24). The EIP MoC is a blueprint for the development of standardised EIP services in Ireland through the standardisation of evidence-based practice, the improvement of access to services and cost-effectiveness by clinically led, multi-disciplinary teams in collaboration with service users and their families. The MoC aims to optimise care for all service users experiencing FEP, to improve detection rates and reduce delays in accessing treatment, lower risks of progression to more enduring states of psychosis, improve rates of remission, reduce rates of hospitalisation, improve satisfaction with the service and reduce physical complications. The MoC also incorporates the recovery philosophy from the National Framework for Recovery in Mental Health Services 2018-2020(25), which encourages mental health services to embrace a recovery model and build the culture of their services orientated towards hope and expectation that the service user can recover from their mental health challenges and build a fulfilling life. This model also represents a shift from medicalised approaches to mental health that are largely deficit-based, to a more strength based philosophy grounded in capacity building and empowerment.

The MoC states that following full implementation of the model, every person aged 14 to 65 years in Ireland who develops FEP will be offered specialist assessment and treatment at the earliest opportunity which is standardised, high quality, accessible, cost-effective and sustainable throughout the person's recovery period. In March 2022, an implementation plan (26) was published to support the updated mental health policy and many of the EIP MoC principles are reflected in the domains of this refreshed approach to mental health service care (e.g., early intervention, coordination of care, social inclusion).

The Hub and Spoke service delivery model

Many of the EIP services implemented in other jurisdictions incorporate a 'standalone' model. These are standalone specialist services which incorporate all of the EIP components and case-management within one service. A considerable degree of evidence supports the standalone model,

but there is less available evidence on the effectiveness of other types of service models (27). A 'hub and spoke' model generally involves a central specialist EIP team within a hub, with EIP services delivered at spokes within generic adult and child mental health services.

Given Ireland's population is widely dispersed and often rural with areas of very low population density, a hub and spoke model was deemed to be most appropriate for delivering EIP services. A standalone model would in effect require patients to regularly travel long distances to urban centres. As a result, the MoC recommends a standalone specialist for large urban areas with a population greater than 200,000, while for rural areas the hub and spoke model is recommended for populations less than 200,000.

The hub and spoke model outlined in the MoC envisions a core set of EIP services provided by a hub team who provide supervision and provision of complex FEP assessments, interventions, At Risk Mental State (ARMS), and early detection of EIP. The hub team's role is also to provide leadership through the championing of EIP services, communication with adult (AMHT) and child and adolescent mental health (CAMHS) services, and education of EIP principles to AMHT and CAMHS teams. Other functions include governance such as data collection and analysis, quality assurance of all aspects of EIP service provision, the review and evaluation of EIP progress and the development of links to Area Advisory Groups, Area Management Teams and the NCP Office. The MoC states that hub team membership should comprise of a Clinical Lead (a Consultant Psychiatrist), an EIP co-ordinator, EIP keyworkers, a Grade IV Clerical Officer, a Community Health Organisation (CHO) Health Educator, an ARMS clinician, a service user and carer nominee, a Cognitive Behaviour Therapy for Psychosis (CBTp) lead, Psychology Lead, a social worker, family intervention (e.g., Behavioural Family Therapy (BFT)) lead, an Occupational Therapy lead, an Individual Placement and Support (IPS) lead, and a physical health and lifestyle lead. Peer support is not explicitly included in the MoC although is available in some EIP services.

Core services to be provided at EIP spokes within community mental health teams (CMHTs) include the initial assessment of individuals referred with suspected FEP or ARMS. The MoC states that EIP keyworkers will complete full assessments to confirm diagnosis of FEP or ARMS and liaise with the CMHT consultant psychiatrist for review and care planning. If a FEP diagnosis is made, the EIP keyworker engages the service user and their family and carers for up to three years of EIP service provision. The provision of evidence-based psychosocial interventions, psychoeducation, physical healthcare and medication management occurs within the hub or spoke and can be managed by a core member of the hub team or spoke team member. Management of service users with complex needs occurs in collaboration with the hub team clinicians as well as any additional specialist

services like rehabilitation, addiction services, etc. Discharge planning begins at an appropriate time, as indicated by the service user's clinical progress.

EIP Hub and Spoke demonstration sites

While several existing mental health services have elements of EIP services, prior to the establishment of the EIP NCP, none were fully funded or staffed to provide EIP services specifically. Adult mental health sites which were interested in potentially becoming a demonstration site, submitted business cases to the NCP in November 2017 (see Appendix 1 for Letter from the National Clinical Advisor Group Lead for Mental Health inviting Mental Health Services to become demonstration sites for the Hub and Spoke model). It is important to note that submission of these business cases occurred in advance of the publication of the final MoC in June 2019. The resourcing available was based on the draft MoC that was in situ then and was not based on the final published MoC. As such, the staffing of the demonstration sites is not based on the final published version of the MoC. The call for the demonstration sites did not include medical staffing or clinical lead funding and medical time was not funded. This is a deficit in the resourcing of the teams and needs to be remedied in the future EIP services.

In January 2018, three demonstration sites were selected from an open application process by the NCP to test the hub and spoke model in practice, with limited additional resources for each site selected. Recruitment of staff began in Cork South Lee South Lee, Meath Mental Health Services and Sligo/Leitrim Mental Health Services. Initially, Mayo Mental Health Services were selected ahead of Sligo/Leitrim, however, Mayo withdrew their interest in being a demonstration site in September 2018. Each demonstration site includes both a hub and spoke. It is worth noting that the first demonstration site (RISE Cork South Lee) was launched in May 2019, one month in advance of the publication of the MoC in June 2019.

The office of the HSE National Clinical Programme (NCP) for EIP

The national office for the EIP Clinical Programme includes two funded posts, which includes a programme manager (0.33 WTE) and a National Clinical Lead (0.4 WTE). Comparable clinical programmes have a full time programme manager, the clinical lead time is the same (0.4 WTE) at

two days a week. Within the area of mental health the newest Clinical Programme 'Dual Diagnosis' has a full time programme manager for that programme.

With regard to specialist access to data/IT support this is the exception rather than the rule. The Clinical Programme for Self-Harm has access to a data analyst two days per week funded via National Office for Suicide Prevention. This was sought and funding provided via NOSP because of the need for data analyses. It is our understanding that no Clinical Programme has access to dedicated human resources expertise.

Process evaluation study

The HSE commissioned researchers in the Discipline of Public Health and Primary Care at Trinity College Dublin to conduct a process evaluation study to evaluate the implementation of the EIP MoC in the hub and spoke delivery model. A process evaluation provides a framework to examine whether programme structures and activities have been implemented as intended (28).

The establishment of the three demonstration sites represents a complex intervention in an established healthcare setting. A process evaluation of such complex interventions provides vital information on how the interventions work, the conditions which shape implementation of the intervention and future outcomes. This information is critical to decision makers and service providers who may seek to later embed the intervention nationally within usual care settings. This process evaluation adopts as a framework, the UK Medical Research Council's guide to complex interventions (28). Figure 1 displays a diagram showing the key functions of a process evaluation.

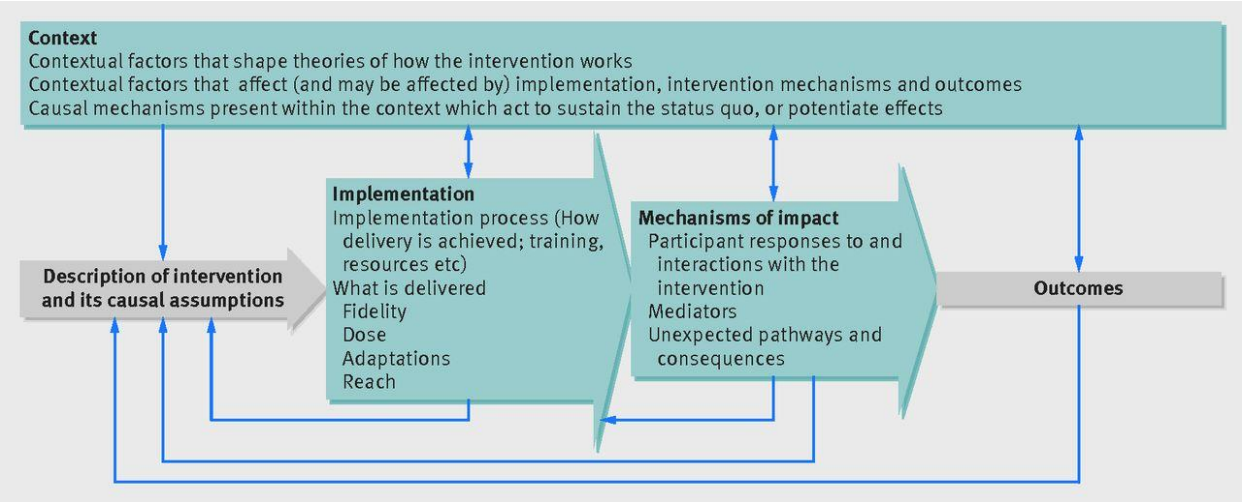


Figure 1. Medical Research Council(27) diagram displaying the key functions of a process evaluation and relationships between each function

Study aims and objectives

The overall objective of the process evaluation study was to determine the experience of staff in their attempts to implement and operate this new MoC, identify the barriers and facilitative factors and characterise the experiences of service users and their families attending these services. See Appendix 2 for the process evaluation Gantt chart.

There were three objectives:

1. *Study One*: *Understanding context*. We aimed to describe the context in which the MoC is delivered and explore the contextual factors that may influence the delivery of the intervention. This information provided evidence of the 'real world' feasibility of delivering the model in the demonstration sites and will enable findings to be translated to other sites.

Method To achieve this we initiated a 'Documentary Analysis' which compared 'treatment as usual' services to what is implemented at each of the demonstration sites. This collected information on a range of factors to allow comparison between old and new ways of working, and the level of implementation between sites. To help visualise the organisation of each demonstration site, we developed organograms in collaboration with local staff that show the organisational structure and activities in the EIP service.

2. *Study Two: Understanding implementation processes*. We aimed to document how the MoC was implemented and the extent to which it was implemented as intended over time and at each demonstration site. This included an assessment of the degree to which elements were delivered (fidelity, dose, adaptations, and reach) and allowed us to identify whether implementation successes or failures may affect EIP delivery and potential future outcomes.

Method: To further understand implementation processes, we assessed the degree to which essential components of the service were delivered. We did this by collecting routine service-level and service-user data to assess the trends in referral, assessment rates and engagement of service users at each site.

3. *Study Three: Mechanisms of impact* We aimed to describe how people participated in and responded to the MoC including service users, family members, HSE clinical staff and HSE management. This will provide a description of intentional and unintentional differences in delivery, and the contextual factors that mediate the relationship.

Method: To investigate the mechanisms of impact, we conducted qualitative interviews with HSE clinical staff, HSE management, services users, and family members, to assess how stakeholders participated in and responded to the MoC.

Research ethics

The project ethics application was submitted to the Royal College of Physicians of Ireland on 21st May 2018 and approved on 18th June 2018 (reference: RCPI RECSAF 79). An amendment was submitted on 12th February 2019 to ensure approval of staff changes and the project timeline. A further amendment was submitted on 30th April 2020 to allow for the completion of remote interviews due to COVID-19. Approval was granted on 21st May 2020.

In relation to the quantitative data for Study Two, and as part of the ethics approval process for this project, the Trinity College Dublin Research Ethics Committee (REC) requested that a Data Protection Impact Assessment (DPIA) be sent to the Trinity Data Protection Officer (DPO). After doing so, the Trinity DPO advised that we were to seek confirmation from the data controller (HSE) that the "project (study 2) is low risk, and therefore does not require explicit consent of individuals (as per amendment to the Health Research Regulations)." We contacted the HSE DPO to seek confirmation and were requested to complete a HSE Privacy Impact Assessment. As there is no centralised Research Ethics Committee within the HSE, local approval was sought from relevant RECs for each of the three sites. Study Two was deemed 'low risk' and therefore not requiring individualised consent from both Sligo (Research Ethics Committee at Sligo University Hospital, February 2021) and Cork South Lee sites (Clinical Research Ethics Committee of the Cork South Lee Teaching Hospitals, June 2021).

However, in relation to the Meath site we attempted to liaise with the HSE North East Area Research Ethics Committee and the local DPO. When we did not receive a response, we submitted the HSE Privacy Impact Assessment along with our ethics application to the HSE North East Area Research Ethics Committee (11th November, 2021). The REC meeting was delayed due to a lack of quorum and on 9th March, 2022 we were informed that Study Two was not approved. The committee suggested that a teleconference be arranged with members of the committee such as the Regional General Manager Consumer Affairs & Deputy Data Protection Officer to discuss the feedback and resubmission. We made multiple attempts to contact the DPO and arrange a meeting but did not receive a response before the next deadline for receipt of revised applications (14th April, 2022). As a result, the study (Study Two) did not receive local ethical approval in relation to the Meath

site. The consequence of this is that we cannot include quantitative data for the Meath demonstration site as a part of this process evaluation.

Research Advisory Group

As a part of good research practice a Research Advisory Group (RAG) was established. Initially, the RAG was due to be established and to meet in April 2020. However, due to COVID-19 this was delayed and the first meeting took place in October 2020. The Terms of Reference and membership of the RAG are included in Appendix 3.

Meetings

The research team were in routine and frequent contact with both the funders of the project and the Clinical Leads/teams within the three demonstration sites. A point of contact was also established within each demonstration site to facilitate easy communication between the research team and the demonstration sites.

Staff changes

A process evaluation study began in December 2019 by researchers in the Discipline of Public Health and Primary Care, Trinity College Dublin. The research was led by Professor Catherine Darker. Professor Joe Barry was also involved in the design of this research until he retired in October 2019. Dr Nicola O'Connell began working full-time on this study on 8th December 2019 as the Research Fellow, but due COVID-19 she was seconded to another study (working 0.2 FTE from May to December 2020). Dr Nicola O'Connell started her maternity leave on May 28, 2021 and has since secured another position. Dr Gail Nicolson replaced Dr Nicola O'Connell and worked full-time on the project as a Research Assistant until January 10th 2022. Dr Hudson Reddon began working on the project on August 6th, 2021 as Professor Catherine Darker's maternity leave cover until April 20, 2022. Dr Katherine Brown was originally the HSE National Clinical Lead for Early Intervention in Psychosis and Dr Karen O'Connor took over this role in January 2020.

Study One: Documentary Analysis and Organograms

Documentary analysis

A Document Analysis template was developed in January 2020 and distributed to each EIP demonstration site team.

This document collected information on essential components of EIP 'treatment as usual' (i.e. treatment that existed pre-MoC) prior to the introduction and implementation of the MoC demonstration sites, and EIP services after the decision to fund three demonstration sites in 2018 and the publication of the MoC in 2019. This document sought to collate information on what each of the EIP demonstration teams' regarded as essential components of EIP service provision. The information sought was informed by existing EIP fidelity scales, including the FEP Services Fidelity scale (29), the Danish FEP Fidelity scale (30), the Early Assessment and Support Alliance Fidelity scale (31), and the EPPIC Model Integrity Tool (32).

Information sought

Domain information was sought on the period both prior to and after MoC publication at a national level, as well as within the demonstration sites in Meath, Cork South Lee and Sligo. Table 1 displays the domain information sought across seven domains.

Table 1 Documentary Analysis: domains and sub-domains of treatment as usual and MoC demonstration site EIP service factors

	Information	Examples of information sought
Domain One	The service model	*What are believed to be the key service elements delivered?*
Domain Two	Physical location – description	*Where within communities are EIP sites based? Co-location with other services? Are waiting rooms available?*
	Physical location-selection criteria	*Were sites chosen based on epidemiological calculations? Is there an urban/rural divide? Are policy makers involved in location of services?*
Domain Three	Organisation – Team management	*Who is the team leader? What is the leader's role? What is the team managerial hierarchy? What is the role of the psychiatrist?*
	Organisation – Structure	*What is the role and number of managers, administrators, nursing, psychiatric, medical and therapy staff?*
	Organisation – MDT structure	*How many meetings occur each week? Who chairs meetings? Who is responsible for follow-up? What is the MDT size? Client: staff ratio?*
	Organisation – MDT staffing	*Number of professionals providing case management in nursing, physio, addiction, supported employment, family education, social and community living skills and case management*
	Organisation – links with other services	*Referral/discharge links with CAMHS, medicine, old age psych, acute services, crisis response lines, A&E, primary care, inpatient and other EIP services*
	Organisation – training	*Training provided in EIP Philosophy, keyworking, prescribing, CBTp, BFT, physical health, IPS and other interventions*
	Organisation – workload/hours	*Staffing hours and workload for mental health generally and EIP specifically – expected contact time with EIP services users/week*
Domain Four	Delivery - DUP	*Mean duration of untreated psychosis*

	Delivery – intake/admission	*Is there a limit on numbers of new service users? What are the services acceptance criteria?*
	Delivery – referral, contact, assessment times	*Acceptable time lapse before contact with referred individuals? Acceptable time between referral and assessment? Involvement of patient and family in assessments? Comprehensive clinical assessment? Rate of referral uptake?*
	Delivery – therapies offered	*Frequency, deliverers, intensity and modifications of clinical, psychosocial needs, risk, substance abuse and structured therapy assessments.*
	Delivery – other MDT inputs	*Proportion of service users assigned a psychiatrist, keyworker*
	Delivery – mode	*How are sessions given e.g face-to-face/telephone? Can service users contact teams out of hours or by email?*
	Delivery – discharge criteria	*When and how are service users discharged? What proportion are discharged per month? What is the average length of stay?*
Domain Five	Service user description	*Service user average age, gender profile, proportion requiring compulsory admissions*
Domain Six	Finance	*How are services funded? How frequently do budgets change?*
Domain Seven	Quality control	*How is adherence assessed? Who audits service? How frequently does it occur and what is the auditors' remit?*

Each team agreed the structure of the documentary analyses document and the domain names included within. Both the phase 1 (pre-2019/treatment as usual) documentary analyses and phase 2 (demonstration site MoC documentary analyses) were received from all three sites. Results were collated. It is important to note that there are no agreed upon standards prior to the MoC on how to treat FEP. In addition, there were some EIP interventions being delivered in select sites across the country. If this was the case in the demonstration sites, we asked teams to consider inputting information on treatment as usual EIP services up to five years ago, to ensure staff did not confuse the new MoC way of working with the old. It should also be noted that the EIP MoC not only included specific services, but also the standardisation of services and specific human resource and finance processes.

Domain One – the service model

In treatment as usual, FEP services users were treated through a combination of generic CMHTs, home-based treatment teams, primary care services, general hospital, psychiatric hospital and private psychiatry.

The demonstration sites were configured into a hub and spoke model with service users having access to specialist staff specific to EIP (e.g., keyworker, CBTp, BFT, IPS). It is within this model of care that service users were assessed and treated by teams.

Domain Two - Physical locations

In terms of physical space, treatment as usual teams were located in various community bases. CMHTs cover geographic populations on a sectorised basis. The location of these services tended to be based upon historical availability of space within existing sites (e.g., a primary care centre, a community hospital). Often the space available for the teams was very limited, with some locations requiring advance booking.

Following the introduction of the MoC demonstration teams, the EIP hubs were based in regional centres where the needs are greatest and close to other agencies and services. The spokes were located further within community regions and related to existing CMHTS locations and structures. Physical facilities like office space remained co-located with other services, especially with regards to the spokes. EIP services were planned based on the existing CMHTs which have long standing geographic boundaries and allow continuation of clinical governance in the spokes.

Domain Three – Organisation

Team and management structures

Under treatment as usual delivery of care was conducted via the team structures within CMHTs. These teams were multidisciplinary, led by consultant psychiatrists and individual care plans and keyworking were not universal or standardised outside of hospital settings. People experiencing FEP were not always prioritised. There was no keyworker structure. In some instances, community nurses may have provided a function akin to a keyworker for short periods of time due to staffing issues (e.g., COVID-19 illness or redeployment).

In the 'hub and spoke' EIP model of care, the structure encompassed a core EIP team at the hub with EIP staff in generic spokes. A new team structure was created which embraced the new types of posts that were created relating to roles outlined in the MoC (e.g., keyworker, CBTp, BFT and IPS support).

Meeting practices

In terms of meeting practices, treatment as usual CMHTs often met on a weekly basis with all MDT members in attendance. Meetings were mostly chaired by the consultant psychiatrist. Interventions and follow-ups offered depended on what was decided by the CMHT and the services available at each site (e.g., addiction counselling, occupational therapy, peer support).

Within the demonstration sites, weekly EIP Hub meetings occur, with inputs and cases raised by the spokes. Hub meetings were attended by EIP team members. Discussion of referrals and complex cases occurred. In Cork South Lee, the weekly RISE meeting was chaired by the Psychological Interventions Lead. Chairing of meetings in Meath and Sligo remain with the consultant psychiatrist.

Links with other services

In terms of links with other services, treatment as usual referrals were made to CMHTs by GPs or acute hospital departments (e.g., emergency departments). Most FEP referrals made in crisis were followed by a hospital admission. These would be triaged to determine their level of urgency and assessments were arranged. Emergency out-of-hours referrals were directed to the local approved centre or emergency department of the acute hospital in the region. MDT members were involved in discharge planning meetings in hospitals. Service users would receive follow-up through the community services, and MDT members were involved.

All three demonstration sites continued to utilise existing links and referral pathways, such as, CMHTs and Liaison Psychiatry within acute hospitals. EIP demonstration teams continued to endeavour to make links with CAMHS although they were not resourced to work with service users from CAHMS services. Regular communication happens with an in-patient unit when a service user is admitted. Outreach educational meetings have taken place with local referral pathways to inform them about the EIP demonstration teams, related MoC and new services offered.

Training, Education and Development

In the context of training, under treatment as usual conditions staff had limited access to EIP training, with BFT training being the only training completed by staff.

Staff from the demonstration sites have accessed online training modules developed in Australia(33) relating to EIP (e.g., six modules which includes, biopsychosocial and at risk assessment; CBT; crisis

intervention and risk management; introduction to physical health in EIP; and case management). Clinicians have engaged in individual training specific to their roles. For example, training has been provided to keyworkers using standardised tools, with guidance and supervision. BFT staff have received training and regular supervision. CBTp clinicians have regular supervision. In Cork South Lee, training on prescription medication was provided to consultants by the Clinical Lead. Since 2020, quarterly half day training webinars in aspects of EIP delivered by international experts have been provided. In 2022, Trinity College Dublin, the National University of Ireland, Galway and the NCP collaborated to develop a module which builds competence in psychosis in CBTp. A family informed care module has been coproduced with agencies such as Shine, Mental Health Reform, and Mental Health Engagement and Recovery to train non-consultant hospital doctors and mental health clinicians to take a family sensitive approach to care.

Caseload

Under treatment as usual conditions the teams reported that it was not possible to establish the caseload associated with service users as there was not a focus on EIP or FEP, and caseload relating to these activities were not recorded.

In the demonstration sites, keyworkers in Cork South Lee hold caseloads of approximately 20 (the MoC guideline is 15 service users per keyworker), a full time CBTp clinician holds approximately twenty to twenty-five cases and half time BFT therapists also holds 10-15 cases. In Sligo, keyworkers hold caseloads of approximately three to eight presently as two new posts were recently filled (previously ten to 12; guideline is to have 15) and one CBT clinician holds approximately 15-20. BFT lead holds caseload of 10-15. In Meath, there are four key workers in post, with a total of 42 service users (range of service users per keyworker is 5-14), one CBTp clinician has 10 service users on caseload, and one BFT therapist has 11 service user families in their caseload. In Sligo for a time period in 2021, new service users were accepted into interventions but could not be allocated a keyworker. In Cork South Lee, there was a freeze in October 2021 in taking new service users on due to capacity issues. Two keyworkers were due to be in place but the second keyworker was delayed. Caseloads were frozen on the basis of capacity and risk (e.g., unfilled maternity leave). Meath have reported that waiting lists have developed for the programme due to delays in the identification, recruitment and agreed start dates of staff in post for the EIP team. It should be noted that the caseloads are a dynamic construct and were highly variable during the evaluation and the qualitative

data indicated that this was mainly attributed to recruitment and HR challenges, as well as COVID-19 staff re-deployment.

Domain Four – Delivery

Referral, admission and assessments

During treatment as usual a record of times from referral to assessment were not kept. For example, a GP may make a referral to a CMHT relating to requesting an assessment for a person that they were querying was experiencing an episode of psychosis. A non-urgent appointment may have taken between six to twelve weeks to be seen, a referral marked as "urgent" would be seen quicker. Self-referrals were not accepted.

In the demonstration sites, the MoC suggests that initial triage should commence within three working days of receipt or referral from inpatient or community settings, according to clinical need. The demonstration site MoC also suggests that service users are seen by consultant psychiatrists in inpatient units or community settings (e.g., home visit) and mixed discipline assessments are recommended. Study Two data provide specific information on the percentage of time teams are meeting this standard. After the MoC was implemented in the demonstration sites, acceptance criteria of new service users into the EIP programme was in line with the MoC guidelines (e.g., service users must present with seven days of psychotic symptoms not better explained by some other reason to be accepted). Sometimes a period of assessment was used if symptoms were unclear. Over the course of the process evaluation, the capacity of teams to accept referrals and offer the range of services suggested by EIP differed depending on whether key posts were in place, which were at times vacant due to problems with backfill or derogation. Self-referrals were still not accepted under the new MoC. The demonstration sites implemented a standardised set of assessments appropriate to this group (e.g., SANS, SAPS, MANSA, MIRECC-GAF, GAF, Dialog), at baseline, six months, 24 and 36 months. Care plans were also completed at baseline and updated as required with a review every six months. Additional measures of assessment were completed when starting and mid-way through specific treatments (e.g., Psyrats, Brief Cope and CORE10 during CBTp). The sites differed on whether they had the capacity to undertake the physical assessments themselves (e.g., Meath and Cork South Lee) or to refer back to the service users GP (e.g., Sligo). In Cork South Lee, a physical health clinic occurs within the CMHT locations and also within the service users home to facilitate assessments. The physical assessments are typically conducted by a clinician (e.g., consultant psychiatrist or psychiatric registrar) or nursing staff.

Therapies offered

Treatment as usual saw considerable variation in the models of service provision and range of multidisciplinary interventions available. The timing of referrals to other disciplines was often very late and dependent on the team and clinical expertise available. This often led to internal discipline waiting times and delays to treatments. Access to psychological interventions were not consistently available. For example, there were no staff who were trained in CBTp. There were trained BFT clinicians, however, they did not have protected time to deliver this therapy consistently. There were also long waiting times to access this aspect of the service. The main consistent intervention was medication. The point of review of service users tended to occur on a three month basis in an out-patient setting.

The types of treatments offered under the new MoC within the demonstration sites differed considerably from TAU. These therapies were possible largely because of the new posts that were created which related to the provision of a keyworker, improved access to psychological interventions relating to CBTp, family support interventions through BFT and link with IPS (see organograms below for site specific details). Assertive but flexible engagement with regular medical reviews were undertaken. Physical health monitoring and related lifestyle advice (e.g., healthy diet and exercise) commenced but this requires further resourcing. Little changed in terms of clinical leadership, with teams continuing to be led by a consultant psychiatrist providing in-patient and outpatient care.

Mode

Treatment as usual delivery mode for services was face-to-face, with some telephone follow-up. In the demonstration sites many of the care and intervention visits such as keyworker contacts, CBT, BFT and IPS were conducted outside of traditional clinical settings (e.g., home, park). During the COVID-19 pandemic some services were delivered remotely (online, telephone etc.), to maintain treatment continuity while being observant of public health and Government advice.

Discharge criteria

In terms of discharge criteria, treatment as usual service users may be discharged due to lack of engagement with treatment options provided and/or non-attendance at scheduled appointments. In

some cases, service users would not be discharged and remain as cases within mental health services.

This differs quite considerably within the MoC where a service user has a planned discharge three years following start of EIP interventions, and this can even be discussed from the very start of the journey through the EIP service. A decision is made with the service user and their family to plan the best approach to discharge. The full EIP team is involved with this process and the keyworker is seen as a pivotal role coordinate discharging the service user. Where appropriate, discharge can involve the transition of care to the CMHT or if the service user has made a good recovery the person may be discharged back to primary care with recommendations for long-term prevention of relapse.

Domain Five – Service User Description

Under treatment as usual, CMHTs would see service users between ages of 18-64 years of age, with the majority being male. Data presented in Study 2 of this report provides an overview of the demography of service users attending the EIP MoC demonstration sites.

Domain Six – Financing

The finance picture of HSE funding is a complex one. The HSE obtains an annual budget from Government each year in October (Budget day). There is then a legal process by which the HSE draft a National Service Plan which sets out what the HSE will deliver based on that budget. Each CHO and service (e.g., mental health, primary care etc.) agrees what it is going to achieve. If new developments are to be funded within the area of mental health services, this is agreed with the Assistant National Director for Mental Health. The '*Vision for Change'* policy(22) advocates for the type of staffing required for a CMHT, and national pay scales for new staff and non-pay costs are included in all budget plans. Nationally, costs relating to an inpatient admission can be estimated but other services like EIP are more challenging due not only to the complexity of cases but also the lack of routinely collected service and service user data. Data on cost savings in the Irish context indicates that cost savings can be made after the introduction of an EIP service which found significant reductions in the rates admitted for treatment and significant reductions of untreated psychosis arising from the EIP programme. (34). Arguably the focus should switch to funding activities that EIP teams are engaged with. These activities would relate globally to the reduction of the amount of time between onset of symptoms and the start of treatment (e.g., duration of untreated psychosis) and also provision of comprehensive treatment plans that promote recovery and minimise

disability(35). This way the funding would not only follow the service user, but teams would be incentivised to meet targets outlined within the MoC.

The funding for EIP was achieved through the concept of the demonstration sites. Year two funding came from the National Clinical Programme for EIP based upon need. To date, there is no multi-annual funding in the HSE generally and EIP has not been allocated funding beyond the demonstration sites. The EIP demonstration sites pilot programme are highlighted within the recent 'Sharing the Vision' policy document and following a positive evaluation *"and additional sites will benefit service users in other regions"* (pg., 55)(23). However, with no multi-annual budget, planning for moving beyond the three demonstration sites to roll out in other regions of the country is very challenging for the NCP to implement. Top down budgetary allocation can also be susceptible to political influence which does not facilitate medium to longer term service planning. For example, time is required to identify appropriate areas, to liaise with existing teams and area management, to identify appropriate staff plus provision of training where necessary, to establish appropriate local governance structures and other related activities. This may take between 2-4 years to complete such necessary steps which underpin a planned and coordinated roll out EIP teams to other areas of the country. This timeframe may coincide with a change in Government and Minister, which could result in a different direction of prioritisation within health services.

Domain Seven – Quality Control

In treatment as usual, audit and service evaluations were challenging within CMHTs due to the chronic lack of investment in hardware and software technologies. The EIP teams are now participating in the National Clinical Audit of Psychosis in RCPsych. This benchmarks the Irish teams against established teams in England and Wales. Of the demonstration sites, Cork participated in 2020. All three demonstration sites participated in 2021 and the National report will be published in Summer 2022.

Organograms

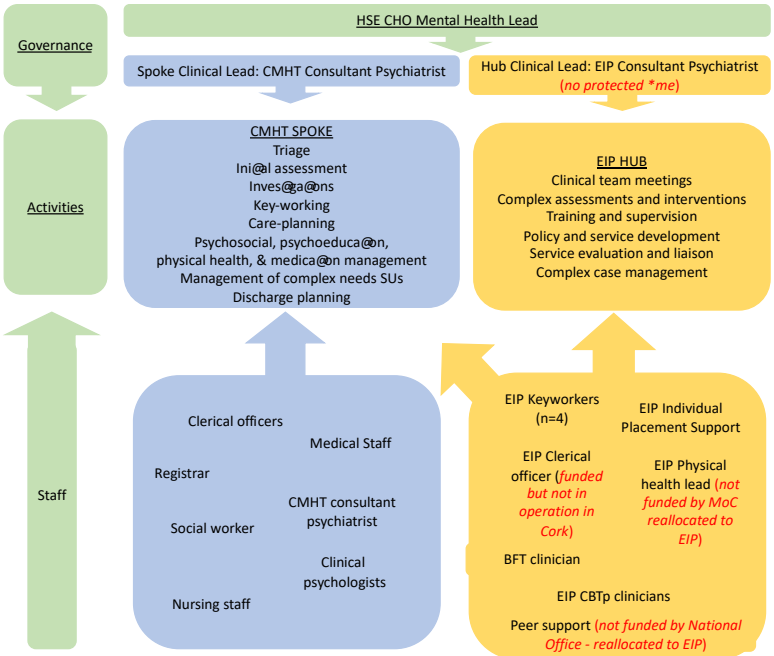
Historically, existing staffing levels, resources and the basic provisions of care for service users vary considerably across the country within mental health services. Appendix 4 includes a summary of the patient demographics from the catchment area each of the three demonstration sites, as well as the additional resources requested for the EIP MoC. Benchmark recommendations on staffing and resources for CMHT are outlined in 'A Vision for Change'(22). This is relevant to the EIP hub and

spoke model which rely on existing CMHT staff to provide general services for EIP service users. The hub and spoke EIP model adds to these existing services for EIP service users to deliver EIP specific interventions. The MoC outlines not only the types of specialisms that should be insitu but also the numbers of staff (i.e., based upon case load). The MoC proposes that EIP teams are multidisciplinary in nature and should have adequate medical staffing (e.g., consultant psychiatrist supported by non-consultant medical staff under their direct clinical supervision). In the hub and spoke model, medical staff may be located at the spokes/CMHTS. Keyworker roles should be in place in each site, the requirement of the numbers of keyworkers are based upon case load (e.g., 15 service users). CBTp therapy is one of the core EIP interventions and should be available to all service users attending for EIP (e.g., estimate of one CBTp therapist for 77 cases). Likewise, behavioural family therapy is also seen as a cornerstone of EIP, and each site should have a BFT. The MoC proposes that in hub and spoke EIP services, occupational therapy will be located within existing CMHTs but have designated time allocated to EIP service users and EIP team meetings. Individual placement support (IPS) relating to employability specialists in supporting EIP service users should also feature. In the hub and spoke model IPS specialists will be located within general CMHTs but will have designated time allocated to EIP service users. The MoC also suggests that physical health monitoring, management and lifestyle advice and should be carried out collaboratively between mental health service team members, GPs and primary care teams.

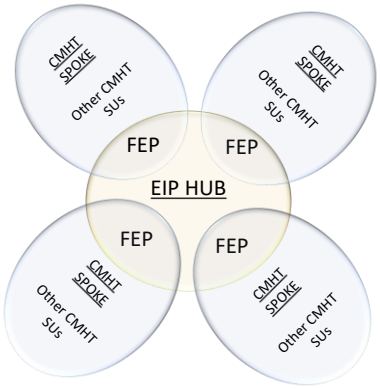
As a part of the process evaluation, team members at each EIP demonstration site assisted us in the development of sets of organograms. An organogram is a chart displaying organisational structures. The aim of these organograms was to visually describe how the governance, clinical activities and staffing structure operated in the hub and spoke model and to look at similarities and differences in each site. This allowed not only the simplification of quite complex information into a visually appealing diagram, but it also allowed us to easily identify subtle yet important differences between demonstration sites in organisational structure and staff complement.

Organograms were developed in 2020 early on in the process evaluation and also repeated again in 2021 to determine any changes over time. The organograms remained relatively unchanged in 2021. Qualitative interview data indicated that this was largely attributed to delays in the recruitment processes that occurred during the time of process evaluation and also during the COVID-19 pandemic (see Study Two).

The figures below (see Figures 2-7) show organograms for Cork South Lee, Sligo and Meath, respectively, for 2020 (phase 1) and 2021 (phase 2). Colour shading in green represents a gain in a post or activity, while colour shading in red represents a loss regarding a post or activity.

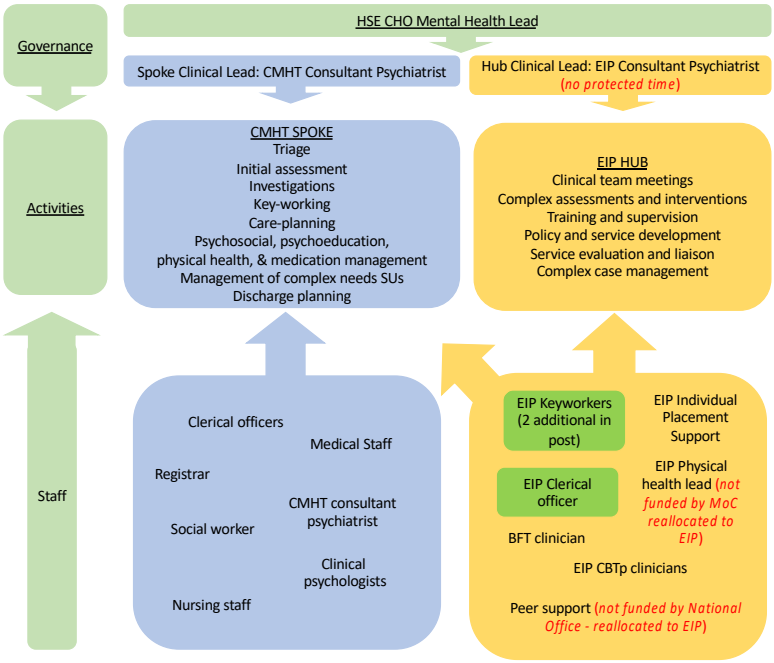


Cork Hub and Spoke model: Phase 1 (March 2020)

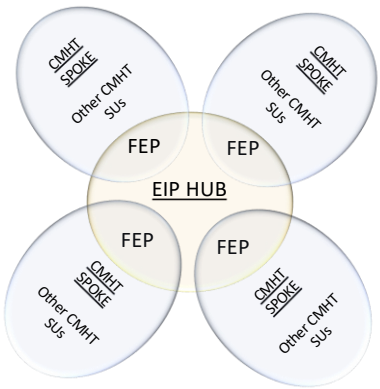


FEP: First episode psychosis service user
CMHT: Community mental health team
SU: Service user

Figure 2. Hub and spoke organogram for Cork South Lee, Phase 1



Cork Hub and Spoke model: Phase 2 (December 2021)

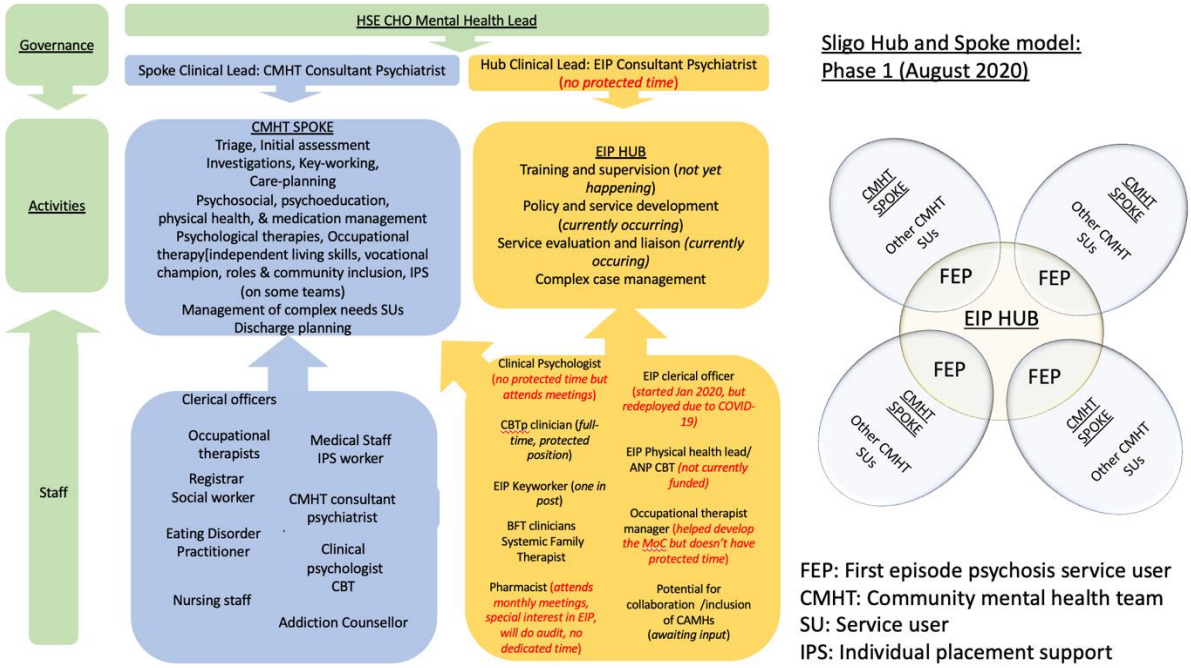


FEP: First episode psychosis service user
CMHT: Community mental health team
SU: Service user

Figure 3. Hub and spoke organogram for Cork South Lee, Phase 2

The Cork South Lee hub in Phase 1, March 2020, included a consultant psychiatrist (but with no protected time for EIP activity), EIP keyworkers (n=4), CBTp clinicians, BFT clinician, IPS person, EIP physical health lead and a peer-support person. It is important to note that two of these roles were not funded directly through the EIP demonstration site project, but were secured based on requests and the individual action of the Clinical Lead (e.g., EIP physical health lead, and the peer support person). EIP hub activities included, inter alia, clinical team meetings, complex assessments and interventions, training and supervision, policy and service development, service evaluation and liaison and complex case management. In Phase 1, the spoke complement of staff included CMHT consultant psychiatrist (spoke clinical lead), other medical staff, nursing, social work, clinical psychologists and clerical officers. Activities included, inter alia, triage, initial assessment, care planning, case management and management of complex needs.

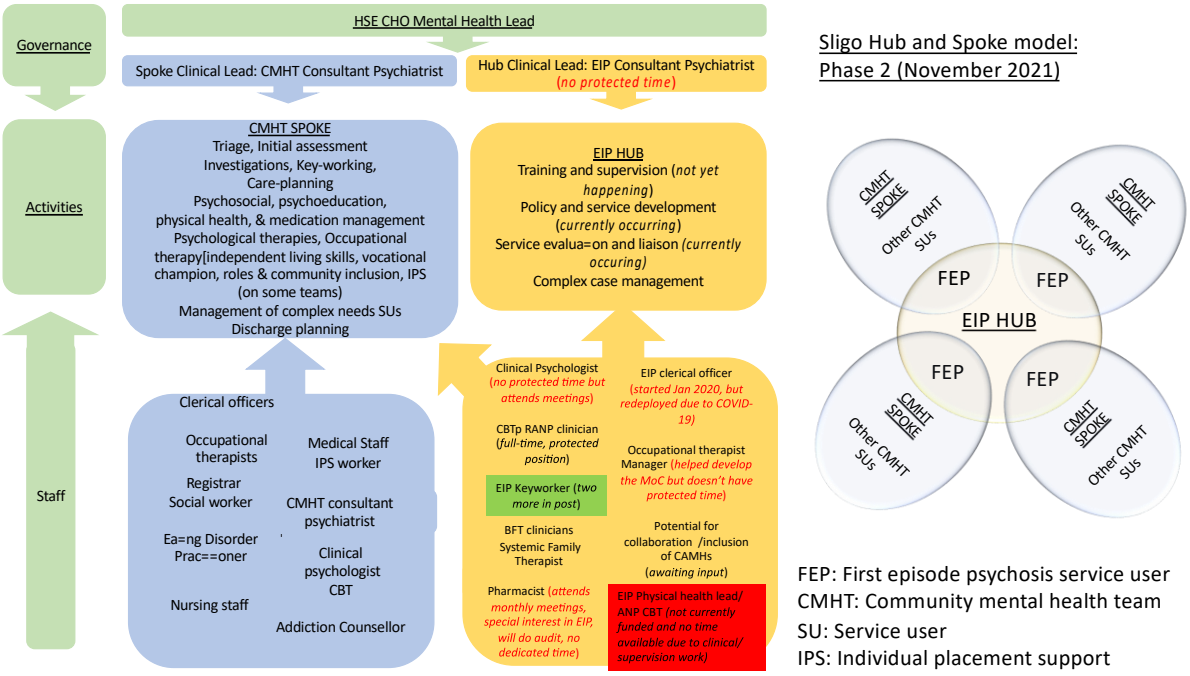
Generally speaking, staffing in the spoke within the Cork South Lee demonstration sites remained unchanged, and related to this the activities in the hub and spokes remained unchanged between the two phases. The hub in Cork South Lee did manage to secure five additional keyworkers, although only two of them were in post in 2021 (shaded in green). A clerical officer (shaded in green) started in post with responsibilities to EIP between Phases 1 and 2, which represents a gain for Cork South Lee.



Sligo Hub and Spoke model:
Phase 1 (August 2020)

FEP: First episode psychosis service user
CMHT: Community mental health team
SU: Service user
IPS: Individual placement support

Figure 4. Hub and Spoke organogram for Sligo, Phase 1



Sligo Hub and Spoke model:
Phase 2 (November 2021)

FEP: First episode psychosis service user
CMHT: Community mental health team
SU: Service user
IPS: Individual placement support

Figure 5. Hub and spoke organogram for Sligo, Phase 2

The Sligo hub in Phase 1, August 2020, included an EIP consultant psychiatrist (but with no protected time for EIP activity), EIP keyworkers, BFT therapist, CBTp clinician, clinical psychologist (no protected time for EIP activity but attended meetings), EIP physical health lead (not funded), occupational therapist manager (no protected time for EIP activity), a pharmacist with a special interest in EIP (important to note that while this may be a welcome addition, this type of role is not suggested in the MoC), and an EIP clerical officer (had been in post but got seconded due to COVID-19 to another area).

Notable spoke team members unique to Sligo included an addictions counsellor and an eating disorders practitioner, (although welcome additions to the spoke teams, these specialities are not technically noted in the MoC as EIP posts) and occupational therapists, who are standard MDT members.

Generally speaking staff in the hub and spokes in Sligo did not change in Phase 2, November 2021, with the exception of two new keyworkers in post. However, the EIP physical health lead/advanced nurse practitioner did note that while their role remains (unfunded), they noted that they had no time available for EIP related activities as due to other areas of clinical and supervision practice. This represent a loss of activity in Sligo between Phases 1 and 2.

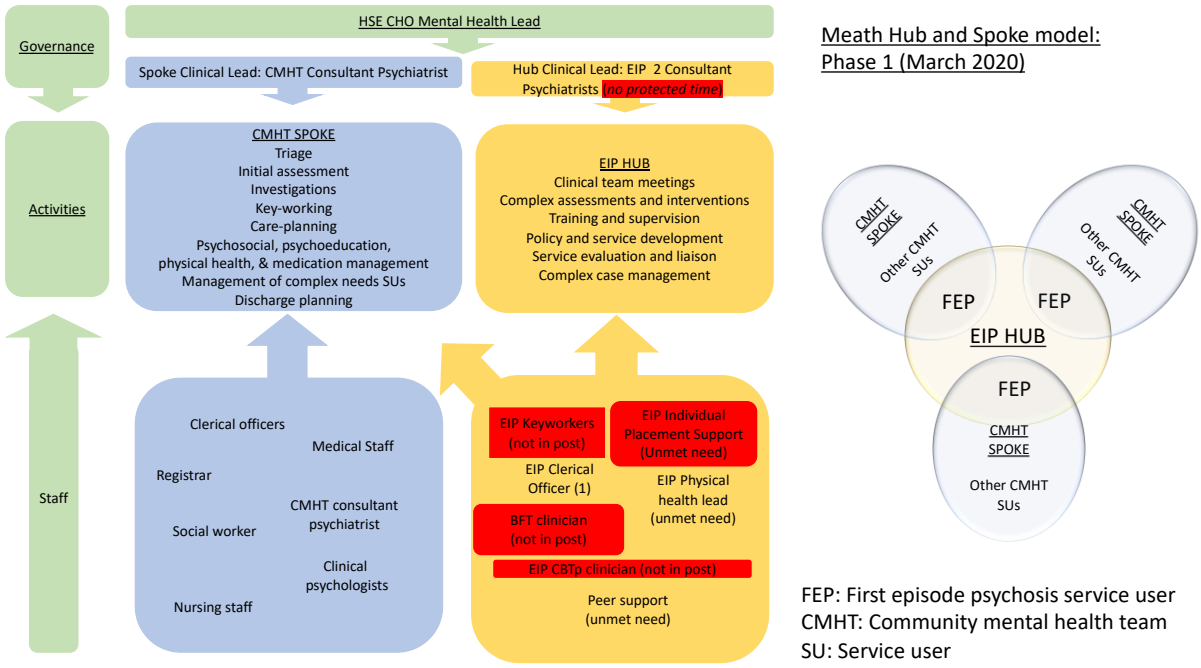


Figure 6. Hub and spoke organogram for Meath, Phase 1

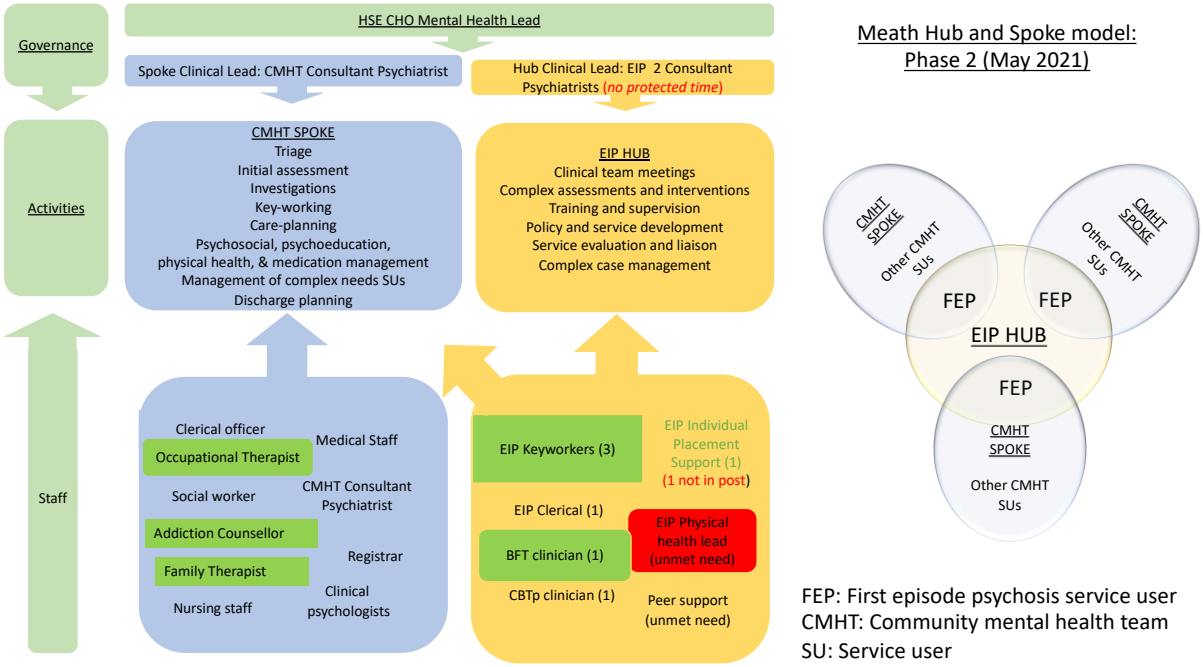


Figure 7. Hub and spoke organogram for Meath, Phase 2

The Meath hub in Phase 1, March 2020, had a lower complement of staff to start with. The Meath hub clinical team included two consultant psychiatrists (neither had any protected time for EIP

activity), and multiple other EIP posts (e.g., BFT, IPS, peer support) did not have anyone in post for significant periods of the process evaluation. In Phase 2 in Meath new posts came on stream relating to key workers, occupational therapy, BFT, and addiction counselling within the 'spokes' (although note addiction counselling is not identified in the MoC as an essential EIP post), a new BFT clinician also commenced working in the hub, alongside a new IPS post in the hub. These posts and related activities represents significant gains in staffing for Meath between Phases 1 and 2. However, Meath did not secure an additional IPS person, nor an EIP physical health lead, nor a peer support person at any stage throughout the process evaluation. This limited Meath in these related activities.

Study Two: Collection of routine service-level data

Database development

The study design for Study Two was based on collation and analysis of routinely collated data provided by the services (referral sources, time to assessment etc). However, this data was not routinely collected in the service with no integrated paper or electronic system to provide the expected data for this analysis.

In response to this lack of available site- and service user-level data, the research team began the development of a purpose-built EIP database, using Access software. Following several site and virtual visits with the Cork South Lee team, an Access database was developed in collaboration with them.

The database was designed to capture two types of information: patient-level information that is static (e.g., date of birth, socio-demographics, the date a patient is referred, diagnostic information at the point of referral), as well as monthly service-level activities that relate to a service user's engagement with keyworkers and the available structured clinical programmes.

Following entry of information on all new referrals to the team (in the 'static' data fields), clinicians entered information on patients each month. The database allowed keyworkers to enter the total monthly number and type of contacts with a patient that month, as well as other information such as the number and type of assessments completed, medications, adverse events, hospitalisations and referrals made to the structured programmes. There was also a section that allowed clinicians who delivered the structured programmes (peer support, psychological services, BFT and IPS) to

capture their monthly activity with each patient. Figure 8 displays an image of the Access database. Please see Appendix 5 for a template of the information collected within the database.

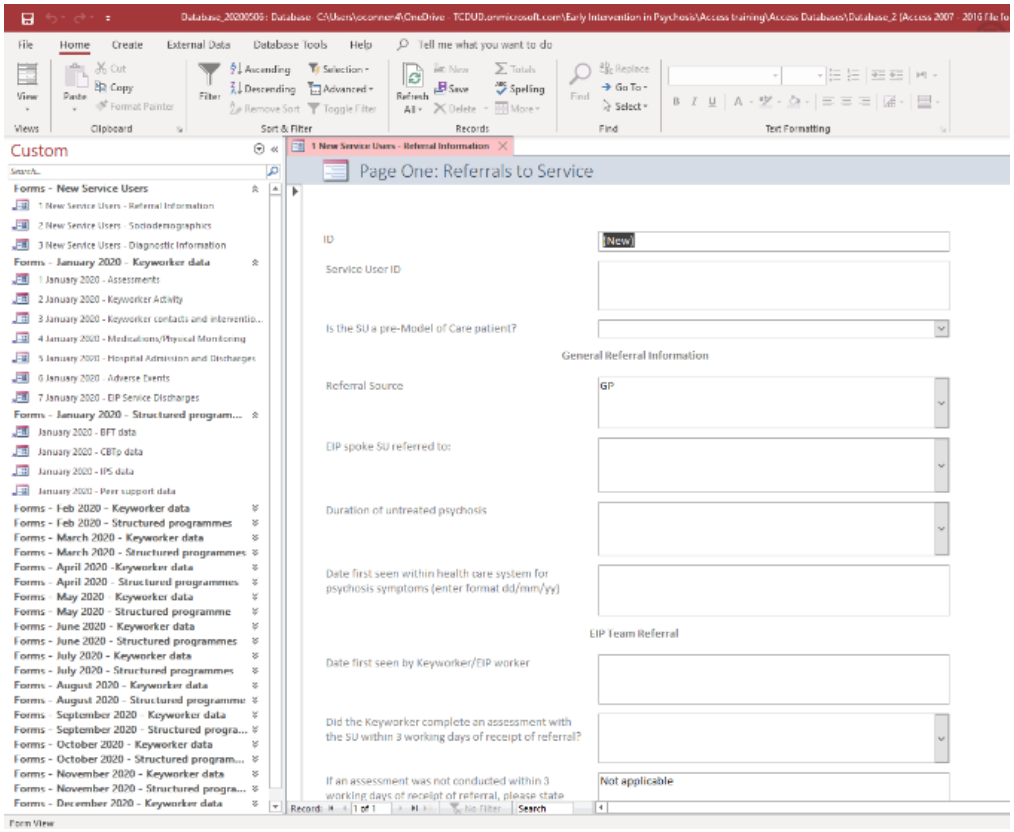


Figure 8. Image displaying the ACCESS database

Database usage

The database has been through several iterations since its initial development in early 2020. A number of training sessions occurred throughout the year, both before staff began to input data and then after data entry had begun. The main purpose of these sessions was to answer any questions on how the database operated, but also to agree and clarify certain questions within the database, to ensure all staff interpret database questions and entered data consistently. In June 2020, the Cork South Lee Rise team began entering monthly data followed by Sligo (January 2021) and Meath (May 2021). A total of 192 service users' information has been included in this database (Cork South Lee *n*= 141, Sligo *n*= 51). The figures below may not include all 192 participants if data were missing for specific variables. Each service users' clinical pathway began to emerge as their contact with each keyworker and clinician was captured on a monthly basis. The data collected at the Meath site

cannot be included in this report due to the decision of HSE North East Area Research Ethics Committee (see Research Ethics).

In January 2021, the research team began to collate and analyse the monthly aggregated data to assess trends in referrals (e.g., the number of EIP referrals each month, the type of referrers), the number of monthly assessments that took place, the time between receipt of referral and the assessment, the number of 'Did not attends' (DNAs), the interventions offered by the EIP team and the number of interventions attended, as well as a range of information on the service user themselves (e.g., their receipt of benefits, their diagnostic status, their inpatient and adverse event history and their discharge status). Information relating to the engagement of service users with different treatment options available (e.g., keyworker contacts; engagement with CBTp etc) is an important factor in understanding the 'dose' of the programme. A number of exploratory analyses were performed to summarise the data and template graphs were developed to allow visualisation of data.

Duration of untreated psychosis

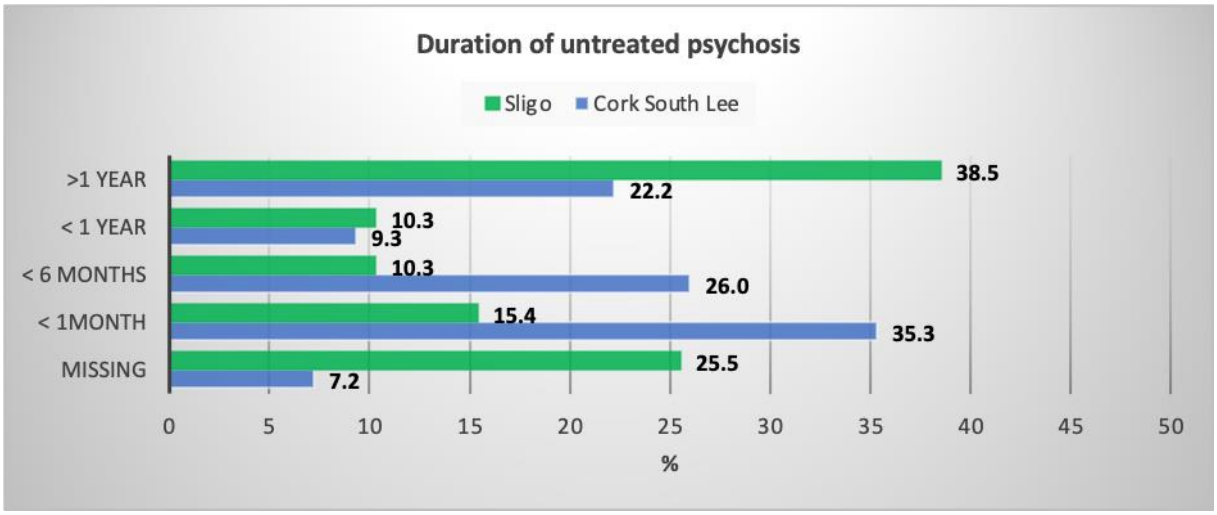


Figure 9. Duration of untreated psychosis among service users in Cork South Lee and Sligo (n=145)

Among patients entering the two services (*n*= 192), a total of *n*= 51 (26%) had a duration of untreated psychosis greater than a year. There were a greater proportion of service users with a duration of untreated psychosis longer than one year in Sligo (38.5%) compared to Cork South Lee (22.2%).

Socio-demographic information

The majority of the service users were in their early to mid-thirties (35.1 years; sd 12.5 years in Cork South Lee; 32.0 years; sd 12.1 in Sligo). Nearly two thirds of the service users in Cork South Lee (63%) and over half in Sligo (56%) were male.

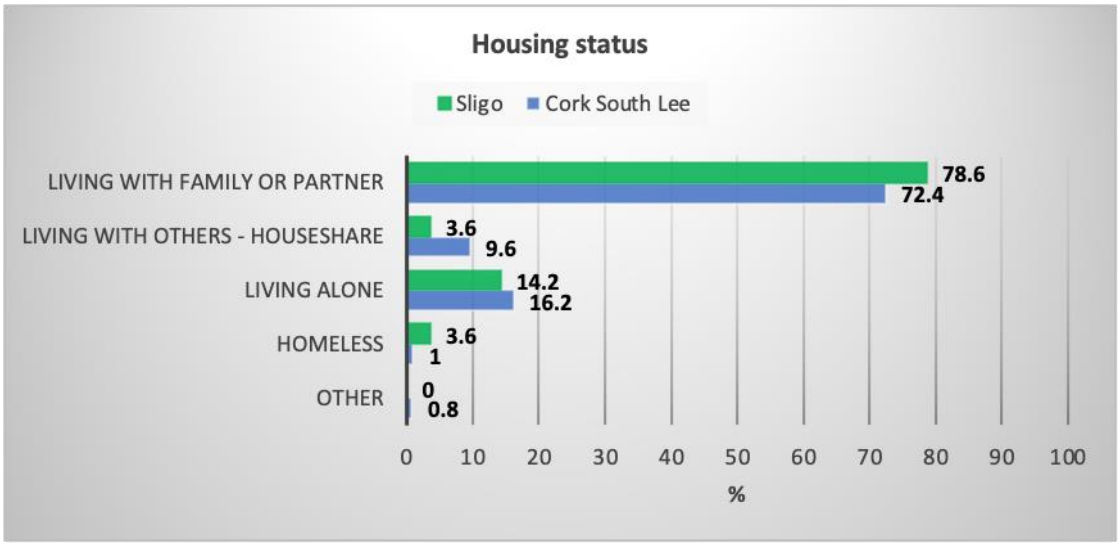


Figure 10. Housing status among service uses in Cork South Lee and Sligo (n=163)

Over three quarters of the service users at both sites were single (73% in Cork South Lee; 89% in Sligo) and living with their family or partner (72% in Cork South Lee; 79% in Sligo). In Cork South Lee, 30% of the service users were medical card holders compared to 21% in Sligo.

Figure 11. Employment status among service uses in Cork South Lee and Sligo (n=158)

Nearly a third of service users in Cork South Lee were employed (31%), compared to 21% in Sligo. There was also a greater percentage of service users in Cork South Lee who were engaged in education (12%) compared to Sligo (4%).

Referral source

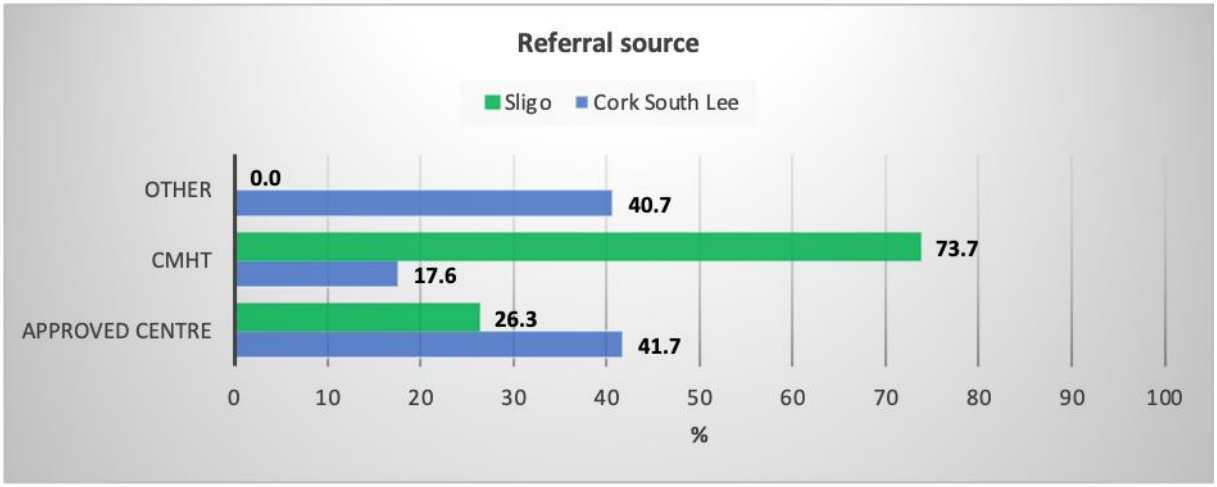


Figure 12. Source of service user referrals in Cork South Lee and Sligo (n=192)

The most common source of referrals at Cork South Lee were approved care centres (42%), whereas Sligo received the majority of referrals from CMHTs (74%).

Speed of assessment

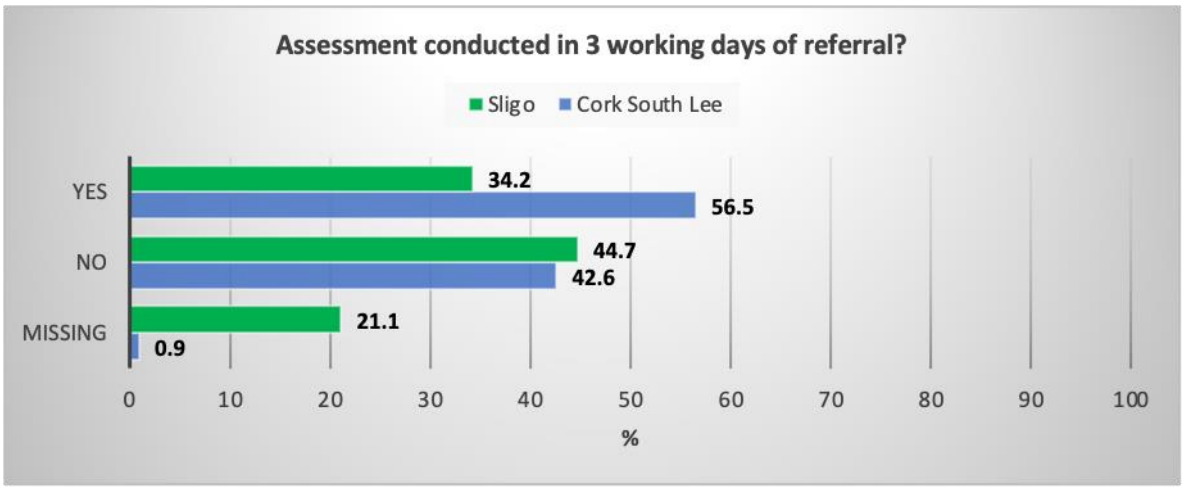


Figure 13. Speed of assessment following referral to the EIP service (n=161)

Amongst the Cork South Lee and Sligo demonstration sites, the average proportion of participants who had an initial assessment conducted within three days of their referral was 57% in Cork South Lee and 34% in Sligo. This is an important measure of programme success since rapid assessment is needed to facilitate early intervention amongst service users.

Attendance at initial appointments

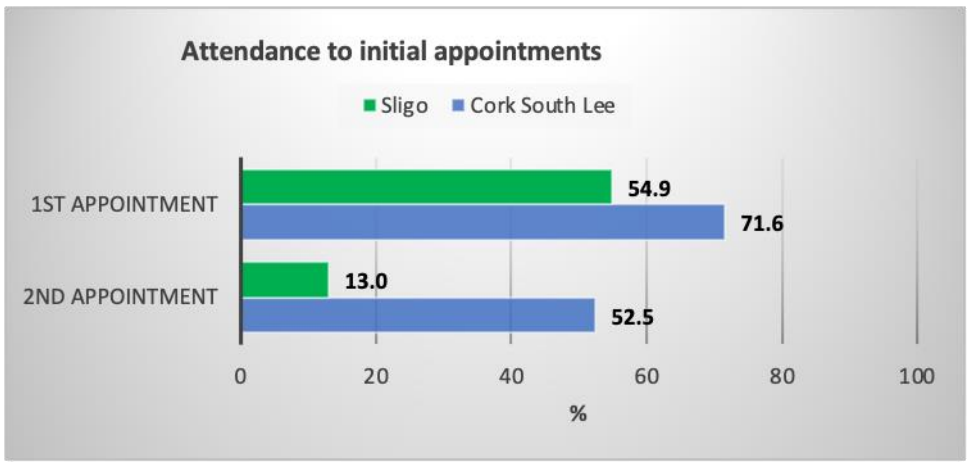


Figure 14. Attendance to initial appointments in Cork South Lee and Sligo (n=192)

Attendance to initial appointments was greater amongst service users in Cork South Lee (72%) compared to service users in Sligo (55%), and this discrepancy was more pronounced among service users attending their second appointments (Cork South Lee = 53%, Sligo = 13%).

Substance use

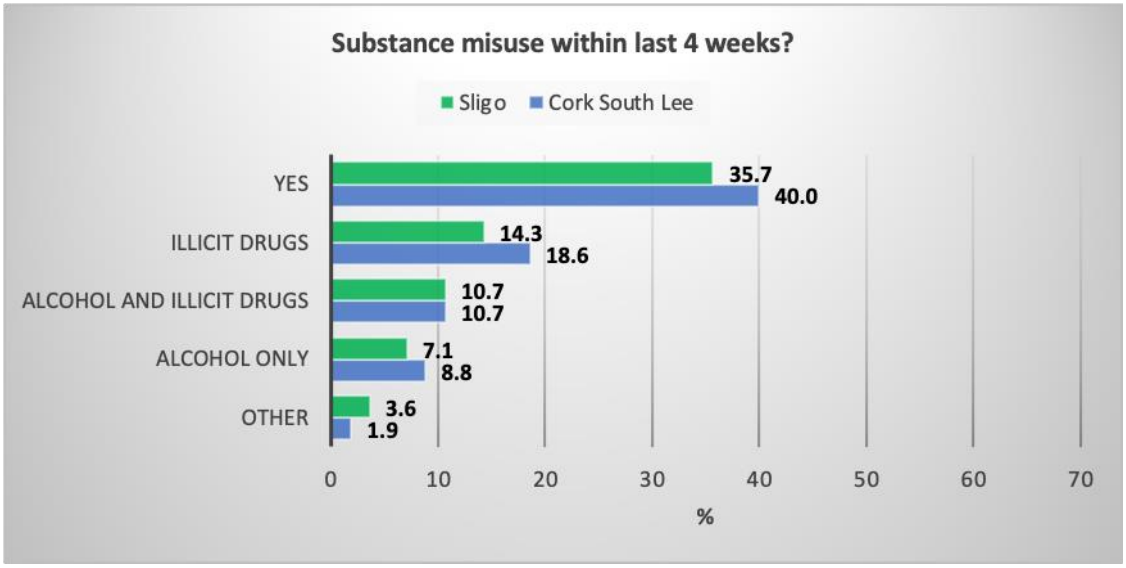


Figure 15. Substance use among service users in Cork South Lee and Sligo (n=166)

Past month substance use was common among service users upon entry into the EIP programme (Cork South Lee = 40%, Sligo = 36%). In Cork South Lee and Sligo, the prevalence of illicit drug use

was 19% and 14%, combined alcohol and illicit drug use was reported by 11% of service users in both sites, and alcohol use alone was reported by 8% and 7% of service users, respectively.

Medication

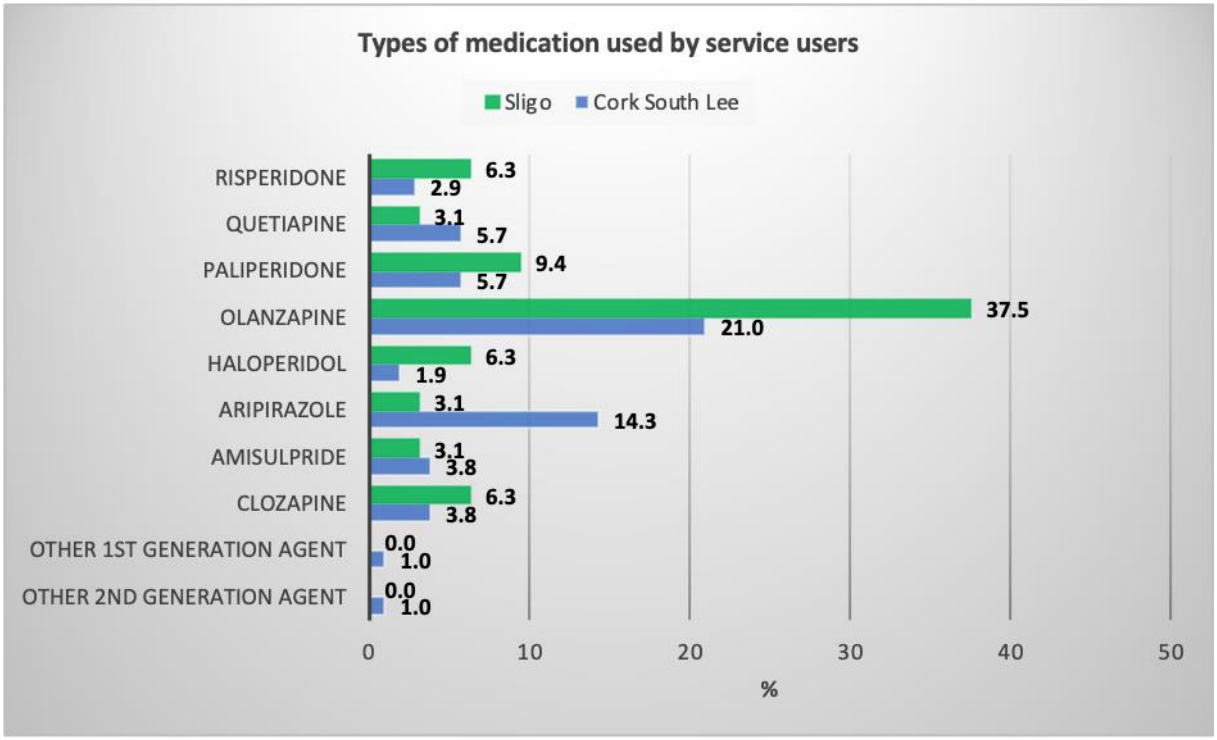


Figure 16. Medication distribution among service users in Cork South Lee and Sligo (n=112)

The most common antipsychotic medication prescribed at both sites was Olanzapine (Cork South Lee = 21%, Sligo = 38%). The percentage of service users receiving any antipsychotic was lower in Cork South Lee (61%) compared to Sligo (75%).

Service contacts – key workers

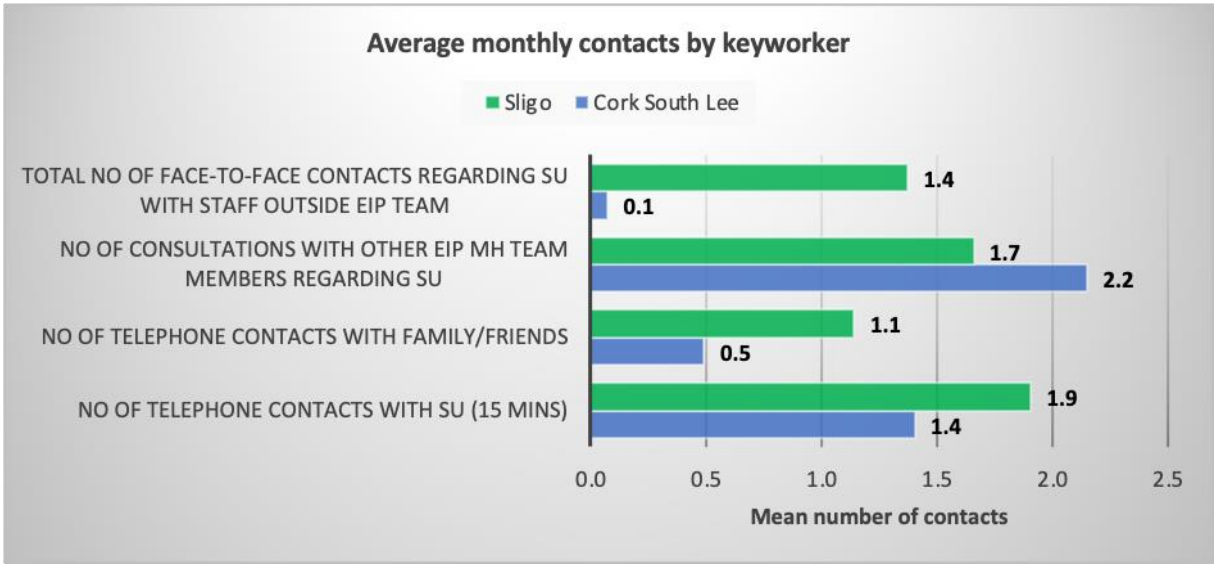


Figure 17. Average monthly keyworker contacts among service users in Cork South Lee and Sligo (n=192)

Service users had an average of five keyworker contacts per month and attended 79% of the psychological appointments offered to them. The most common type of keyworker contact with service users in 2021 were telephone contacts (at least 15 minutes), and service users in Cork South Lee received an average of 1.4 calls per month compared to 1.9 in Sligo. The COVID-19 pandemic was occurring during this time period and Government public health guidelines were in place. This significantly limited in-person visits and many contacts with service users shifted to telephone or virtual contacts. In Cork South Lee there were also three keyworkers who were on maternity leave for periods of 2021, which also limited the number of keyworker contacts at this demonstration site.

Cognitive Behavioural Therapy for psychosis (CBTp) – engagement

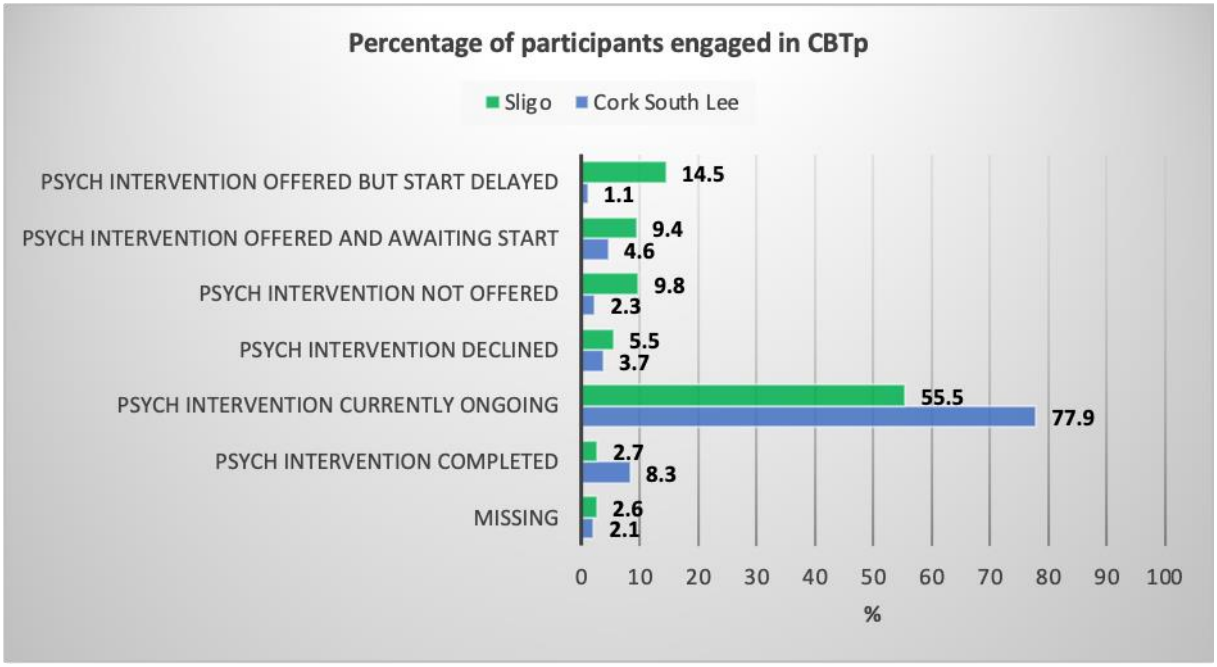


Figure 18. Average proportion of service users engaged in psychological interventions during 2021 in Cork South Lee and Sligo (n=192)

Average monthly engagement with psychological interventions ranged from 56% (Sligo) to 78% (Cork South Lee). A small proportion of service users completed their psychological intervention during 2021 (Cork South Lee = 8.3%, Sligo = 2.7%) and very few participants declined the psychological interventions offered to them (Cork South Lee = 3.7%, Sligo = 5.5%).

Behavioural Family Therapy – engagement

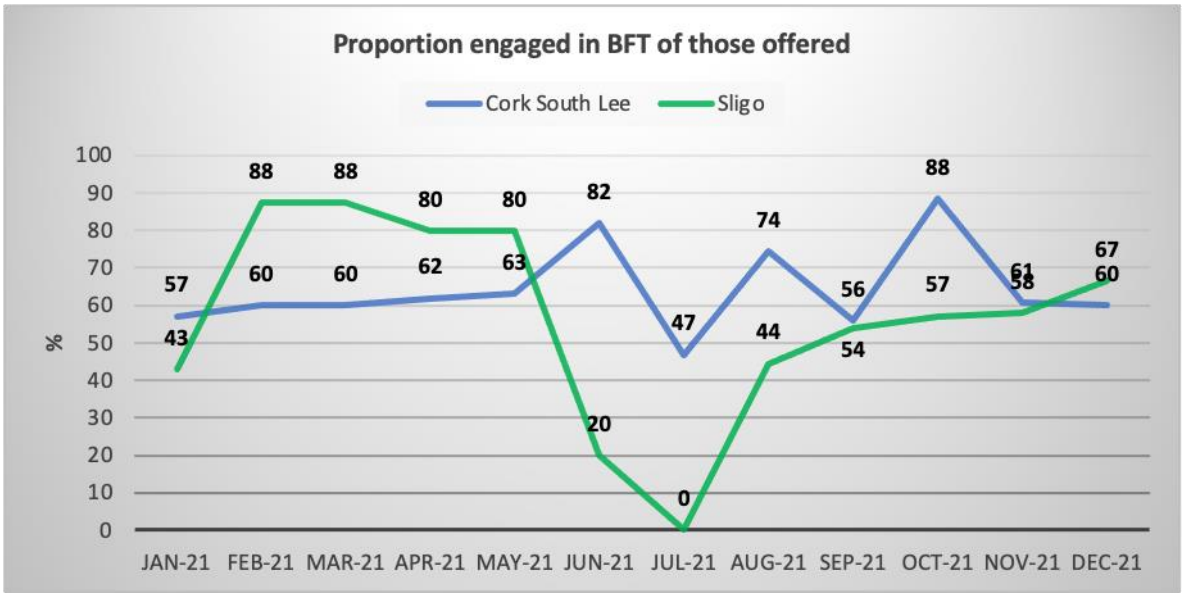


Figure 19. Engagement in BFT among service users in Cork South Lee and Sligo (n=192)

Engagement with BFT fluctuated throughout the model of care implementation, and qualitative data indicated that COVID-19 public health measures caused interruptions with these services. Across both sites, the average proportion of service users engaged in BFT of those who were offered was 60% (sd = 20), indicating strong acceptance of this service among service users. The average number of service users engaged in BFT was 18 (sd = 5) in Cork South Lee and 6 (sd =3) in Sligo. Engagement was defined as participation in at least one BFT session per month.

Individual Placement Support – engagement

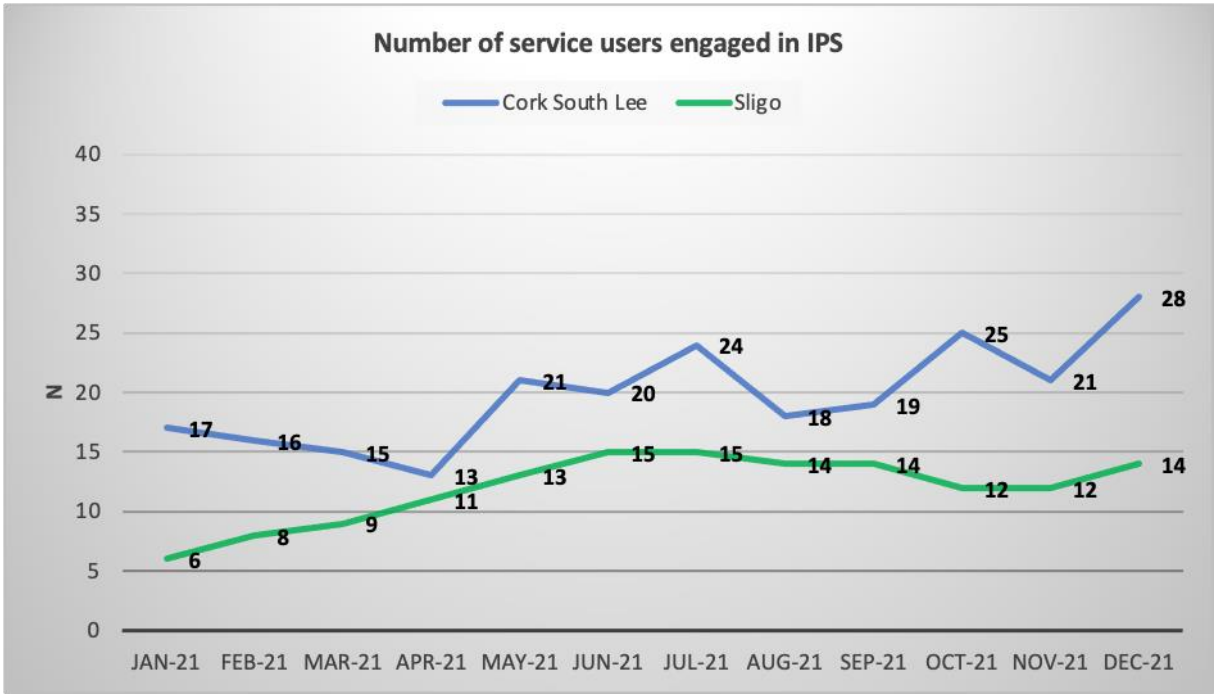


Figure 20. Number of service users engaged in IPS at Cork South Lee and Sligo sites during 2021 (n=47)

The average number of service users engaged in IPS was 20 (sd = 4) in Cork South Lee and 12 (sd = 3) in Sligo. Engagement with IPS generally increased throughout 2021.

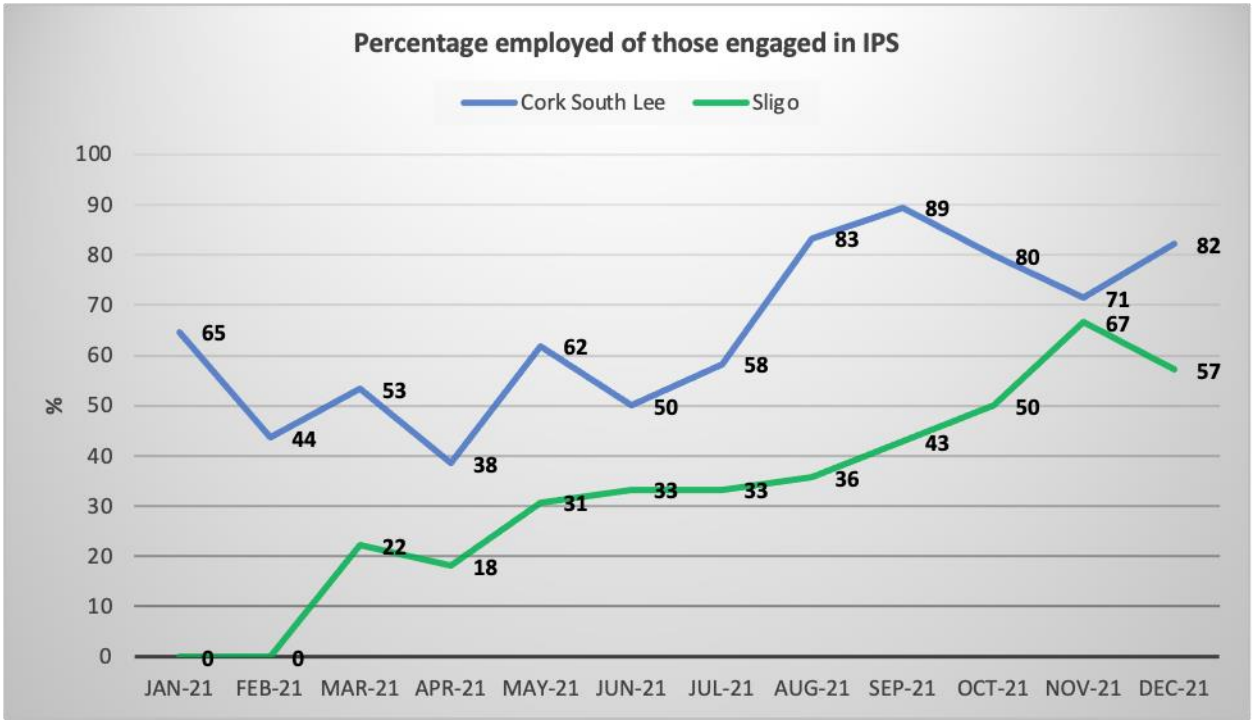


Figure 21. Proportion of service users employed among those engaged in IPS (n=47)

Among those who were engaged in IPS, an average of 49% (sd = 25) were able to secure employment. This indicates that the IPS service was highly effective in facilitating and supporting employment among people experiencing psychosis. The average number of service users engaged in IPS was 20 (sd = 4) in Cork South Lee and 12 (sd =3) in Sligo. Engagement was defined as participation in at least one IPS session per month.

Hospitalisations and adverse events

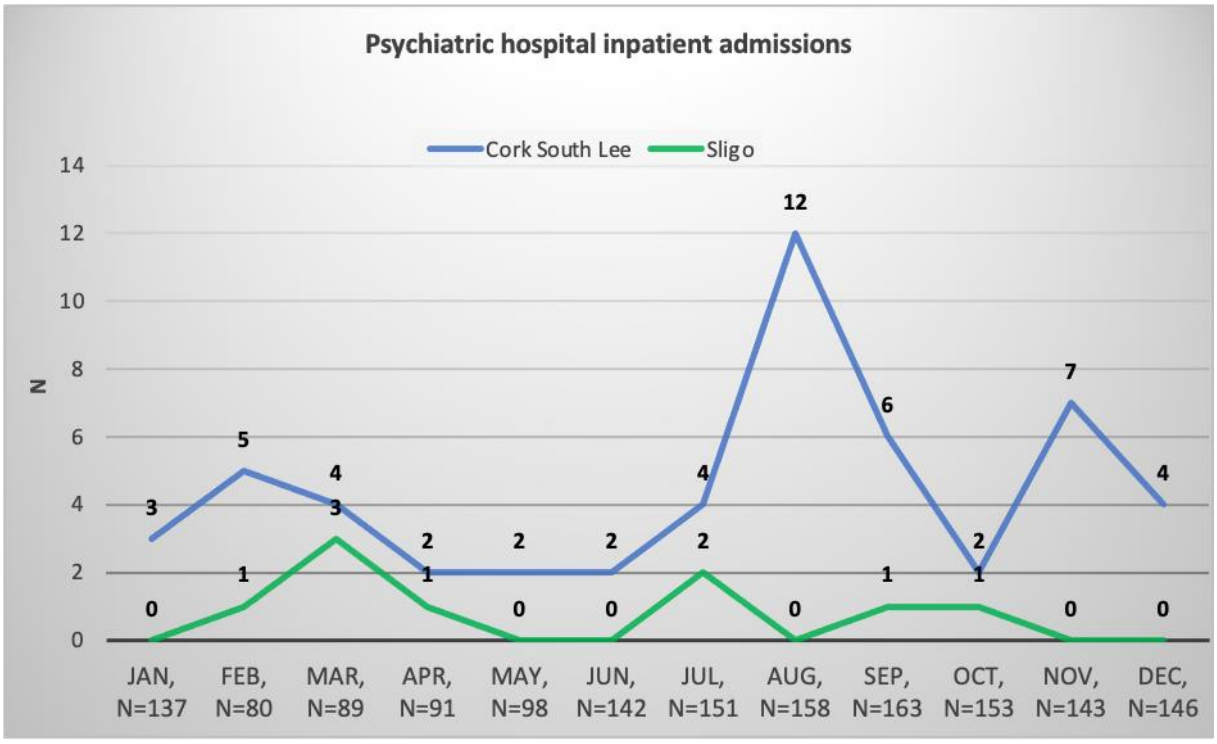


Figure 22. Number of monthly hospitalizations during 2021 in Cork South Lee and Sligo sites (caseloads for each month are represented in the X-axis, n=113)

The number of hospital admissions per month during 2021 in Cork South Lee ranged from 1 – 12, with an annual average of 4 (sd = 3). The number of hospital admissions per month during 2021 in Sligo ranged from 0 - 3, with an annual average of 1 (sd = 1).

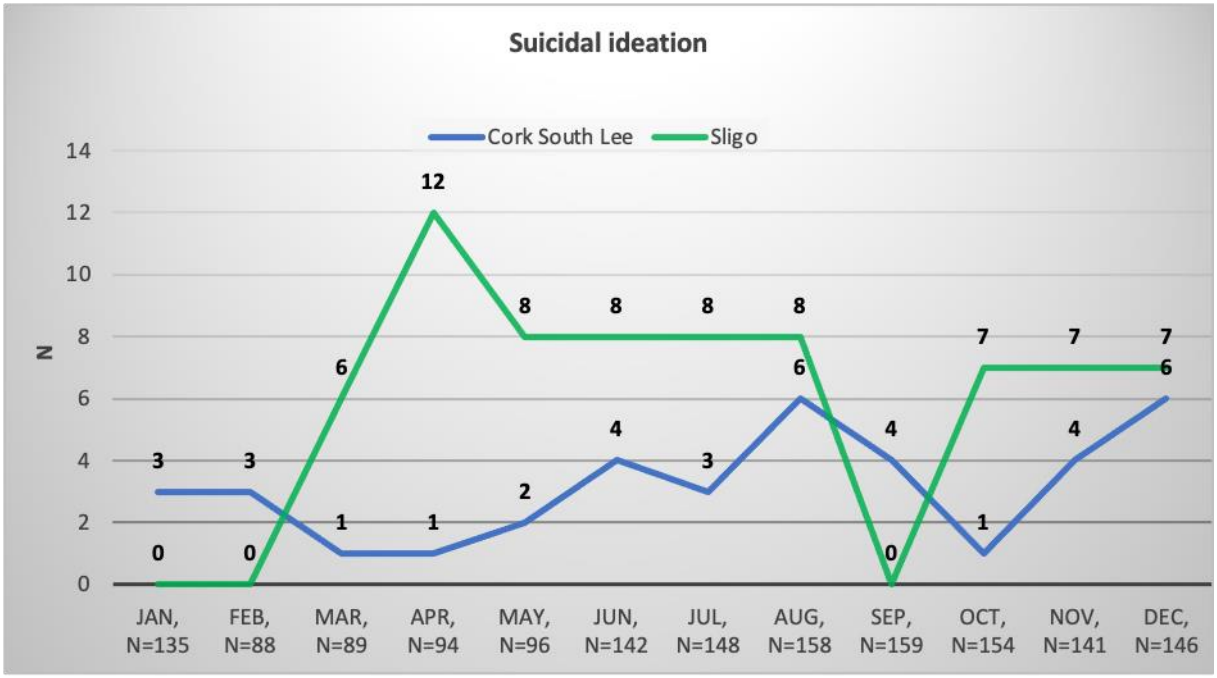


Figure 23. Number of participants reporting suicidal ideation during each month of 2021 in Cork South Lee and Sligo (caseloads for each month are represented in the X-axis)

The average number of service users reporting suicidal ideation per month in Cork South Lee during 2021 was 3 (sd = 2) with a range from 0 – 12. In Sligo, the average number of participants reporting suicidal ideation per month during 2021 was 6 (sd = 4) with a range from 1 – 6.

EIP service discharges

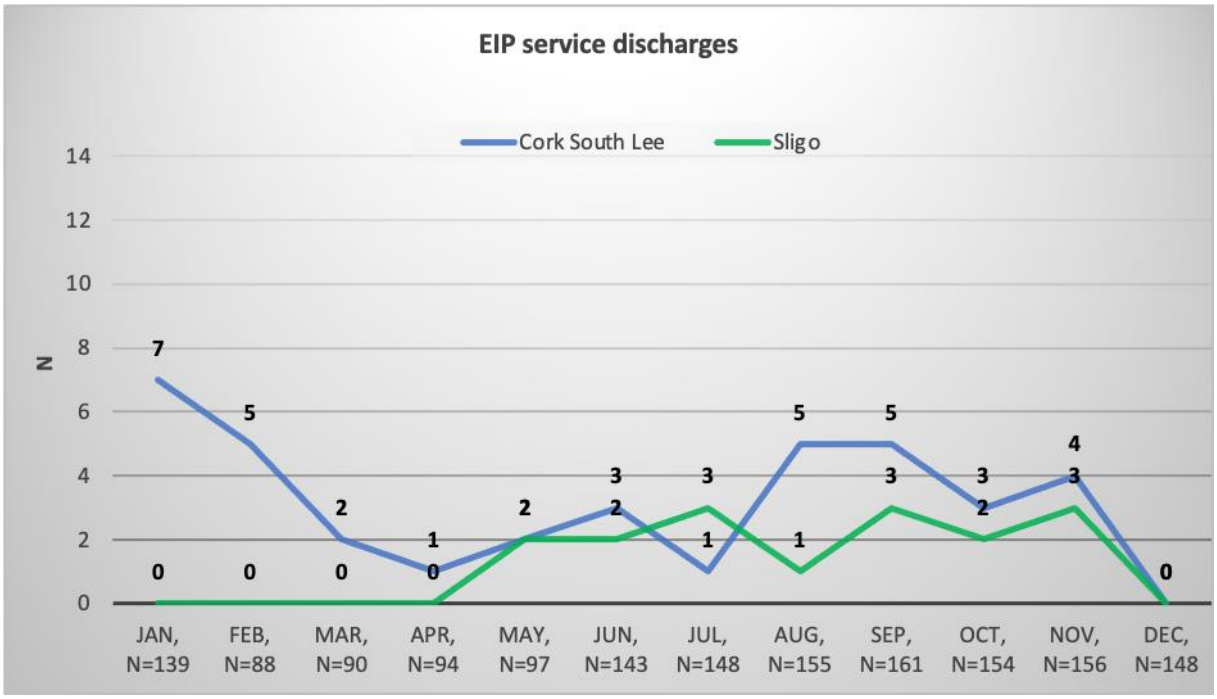


Figure 24. Number of participants discharged from the EIP service each month in Cork South Lee and Sligo (caseloads for each month are represented in the X-axis)

In Cork South Lee, an average of 3 service users (sd = 2) were discharged from the EIP service per month (range= 0 – 7). In Sligo, the average number of service users discharged from the EIP service was 1 (sd = 1) per month (range= 0 – 3).

Dose response – association between keyworker engagement and psychosocial interventions

To evaluate the impact of keyworker engagement among EIP service users, we conducted logistic regression analyses to examine how increased keyworker engagement influenced the use of cognitive behavioural therapy for psychosis (CBTp), behavioural family therapy (BFT) and individual placement and support services (IPS). The primary explanatory variable was the average number of keyworker contacts per month that took place per service user during 2021. Separate analyses were conducted with CBTp, BFT and IPS as the dependent variable. These variables were measured as the average number of contacts with each of these services per month that took place during 2021. For the purposes of these analyses, these variables were dichotomized with values of "1" representing

service users who averaged at least monthly contact with these services. These analyses were adjusted for sex, age, duration of untreated psychosis, housing status (living alone vs. living with family or partner), employment (employed/in education vs. unemployed) and substance use in the last four weeks (yes vs. no). All statistical analyses were performed using SPSS version 21 (IBM Corporation, New York, USA). All tests of significance were two-sided with a significance threshold of p <0.05, see Table 2.

Table 2. Logistic regression analysis of the association between keyworker contacts and engagement with CBTp, BFT and IPS.

	Adjusted	
Outcome variable	**Odds Ratio (95% CI)**	***p* - value**
CBTp	5.76 (2.43 – 13.64)	**<0.001**
BFT	5.52 (1.63 – 18.69)	**0.006**
IPS	3.73 (1.64 – 8.48)	**0.002**

Notes: CBTp= cognitive behavioural therapy for psychosis, BFT= behavioural family therapy, IPS= individual placement and support, CI= confidence interval. All analyses were adjusted for sex, age, duration of untreated psychosis, housing status, employment and substance use in the last four weeks.

The results indicated that increased contacts with keyworkers were significantly associated with increased engagement with CBTp, BFT and IPS. Specifically, the odds of achieving at least monthly engagement with CBTp and BFT increased by five-fold with each additional monthly keyworker contact. For IPS, each additional monthly keyworker contact was associated with a three-fold increase in the odds of achieving monthly attendance with IPS. These findings indicate that keyworker contacts were highly effective in facilitating engagement with additional EIP services after adjusting for socio-demographic, substance use and clinical factors. Given the strong effects of keyworker engagement, EIP services should ensure that there is a sufficient complement of keyworker staff in place to support frequent contact with service users to facilitate engagement with other EIP services including CBTp, BFT and IPS.

Reach – anticipated first episode of psychosis by enrolment within demonstration sites

Reach relates to whether programmes and services are reaching the number of service users that are anticipated to serve within their catchment areas.

Table 3. Number of annual enrolments into the EIP service stratified by demonstration site.

Year	**Cork South Lee (pop.est.200,000)** N (%)	**Sligo (pop.est.115,000)** N (%)	**Both sites combined** N (%)
2019[a]	22 (16.2)	1 (2.3)	25 (13.8)
2020	70 (51.5)	11 (25.6)	83 (45.9)
2021	44 (32.4)	31 (72.1)	73 (40.3)
Total	136	43	181*
Annual Average	**49.0**	**14.7**	**63.7**
Projected annual incidence	**26.3**	**15.7**	**42.0**

[a]=recruitment in 2019 began in May; *=11 cases of missing data.

Table 3 shows the number of service users who enrolled in the EIP service from 2019 to 2021 in the two demonstration sites. In Cork South Lee, enrolment peaked in 2020 with 70 service users and declined to 44 in 2021. In Sligo, enrolment increased throughout the study period and peaked at 31 in 2021. The Cork South Lee demonstration site covers five areas, which include City South East, City South West, Bishopstown Ballincollig, Douglas Carrigaline, Bandon/ Kinsale and Sligo's catchment area includes Sligo, Westport & Leitrim/ South Donegal/ West Cavan. Based on population-level estimates of first-episode psychosis incidence(5), the annual projections of first episode psychosis among the areas covered by the demonstration sites was expected to be 26.3 in Cork South Lee and 15.7 in Sligo. While the Sligo projection of 15.7 is similar to the observed annual average enrolment of 14.3, the Cork South Lee projection is significantly lower than the annual average of service user enrolment that was observed in Cork South Lee (45.3). This means that the Sligo demonstration team was seeing the anticipated numbers of people, while the Cork South Lee demonstration team was seeing nearly double the anticipated numbers of people coming into the EIP service. There are several explanations that may contribute to this finding. First, there may have been a significant backlog of patients experiencing first-episode psychosis who were not able to access appropriate

mental health services before the EIP demonstration sites were implemented. As a result, the EIP service may have addressed an unmet need in these communities and the elevated enrolment could have been due to incoming service users who first experienced their psychosis before 2019 yet were not identified until the EIP demonstration service was implemented. Second, staff in the EIP demonstration sites actively strengthened the referral networks throughout implementation of the EIP programme, so that all referral pathways who could make EIP referrals were fully aware of the referral processes and who was eligible for the EIP service. Increased surveillance and assessment of incoming psychosis patients may have produced increases in first-episode psychosis detection beyond what was included in the population-level estimates from Kirkbride et al(5). Third, the population-level projections from Kirkbride may be an underestimation of the true incidence in these areas, particularly given the increased burden of mental health disorders associated with the COVID-19 pandemic(36), which coincided with the time period of this process evaluation. A combination of these factors may account for why the observed uptake of service users exceeded the predicted incidence of first-episode psychosis in these areas. Nevertheless, it is encouraging that the Cork South Lee and Sligo sites were able to achieve high levels of enrolment. The high levels of service user uptake indicates that early intervention was likely an unmet need in these communities and the EIP demonstration sites established a strong reach to promote service uptake among people experiencing first-episode psychosis.

Fidelity – closeness of service delivery within demonstration sites compared with the MoC

In the context of the current process evaluation, fidelity of delivery examined whether the teams delivered the EIP programme described in the MoC. To make this determination, we examined evidence from all three studies included in the process evaluation. Within Study One the documentary analyses was informed by existing EIP fidelity scales (see Study One) which allowed us to appraise the changes in context in which the teams were attempting to implement the new MoC as they transitioned from treatment as usual. These should also be read in combination with the Organograms which outline the activities within the hubs and spokes, plus the staffing complement contained within each demonstration team. At no one time were all three teams able to implement the MoC as described. There were phases of the study in which partial fidelity to the MoC was possible, and these were directly linked to the combination of staffing and caseload capacity. At other times, for example, in Sligo for a time period in 2021, new service users were accepted into interventions but could not be allocated a keyworker. In Cork South Lee, there was a freeze in

October 2021 in taking new service users on due to capacity issues. In Meath the EIP demonstration team had to allow a waiting list to form due to delays in the identification, recruitment and agreed start dates of staff in post for the EIP team. The MoC cannot be considered fully operational and teams cannot demonstrate fidelity unless they are resourced sufficiently.

Likewise, the MoC is looking to standardise the offering of interventions relating to EIP. Again this is only possible if all component of the programme are operational. Looking at the Organogram data it is clear that not only did each site have different staffing mixes to begin with but also some sites were more successful in being in a position to commence staff in post as the process evaluation timeframe was underway. Despite the gains that Meath had in securing new posts as the process evaluation went on (e.g., OT, BFT), they did not get near to the staff complement that was in place in the Cork South Lee site for example. This meant that not only was Meath limited in activities, there was not the standardisation of delivery of treatment options available to all service users across the three sites. The discrepancies in team structure were not due to differences in funding as all three demonstration sites received the funding that they initially requested. The qualitative data indicated that challenges with recruitment and backfill were the primary cause of staffing shortages at the Meath site and strong clinical leadership in Cork South Lee facilitated some of the staffing and recruitment barriers in implementing the MoC.

A cornerstone of EIP is rapid assessment within three working days following referral. There is still room for teams to improve on this measure with quantitative data in Study Two demonstrating that in over half of cases (57%) in Cork South Lee and over a third (34%) in Sligo was this measure met. This is an important marker in EIP service delivery as it facilitates early intervention amongst vulnerable service users. Likewise the EIP MoC outlines that service users should be appointed a keyworker and where appropriate engage with a range of psychosocial interventions. As detailed above, there were times where the caseload of keyworkers grew so new referrals were restricted within the sites. Notwithstanding this, quantitative data showed that service users were actively engaging with their keyworkers (e.g., an average of five keyworker contacts per month) and there was evidence of good uptake of CBTp, BFT and IPS services. This suggests that during periods of time when the staffing complement was in place, service users were benefitting from the possible range of services on offer. Staff were sensitive to the need to have the correct staff mix in place and were frustrated when this was delayed. Qualitative analyses in Study Three has clearly outlined the problematic process of recruitment and budget derogation on not only clinical leads across the three sites but also all staff interviewed.

Study Three: Qualitative Interviews

A qualitative study took place to assess how stakeholders participated in and responded to the implementation of the new MoC. This study aimed to capture clinical staffs' and managements' experiences of implementing and delivering the new MoC with a specific focus on the barriers to and facilitative factors of implementation. We also aimed to capture the experiences of service users who have received the EIP service within the demonstration sites and their families.

Table 4 outlines the timeline of interviews and the roles of interviewees. Reference to sites A-D include the three demonstration sites plus central managerial and administrative staff. Specific site identifying information is withheld to protect the anonymity of participants. All interviews were professionally transcribed. Interviews took place between February 2020 and February 2022. These interviews (*n*= 40) included 22 EIP team members, nine management and administrative representatives, eight service users, and one family member of a service user. See Appendix 6 for key informant interviews completed by date, role and site.

It is important to note that it was disappointing that only one interview with a family member took place. This was despite efforts to recruit family members, including at the conclusion of all interviews with service users, the research team asked if a family member of theirs would be interested in taking part in an interview to share their experiences of the EIP service. It was outlined about the importance of including family members' experiences in the process evaluation. The research team followed up with service users via text message at least twice encouraging participation, but this did not yield any response. Keyworkers in all three demonstration sites were consulted and agreed to assist in the recruitment of family members. Keyworkers contacted family members of service users encouraging participation in the qualitative interviews to afford them an opportunity to share their views on and experiences of the EIP services. However, this yielded only one family member who was willing to be interviewed.

Professor Darker, Dr O'Connell and Dr Nicolson completed the data analysis using thematic analysis and NVIVO software (QSR International Pty Ltd. Version 12, 2018). Thematic analysis allows the identification of emerging patterns related to themes. These have been reviewed and refined through the development of a robust coding framework (see Appendix 7 for qualitative coding frame).

Below we highlight results from eight themes:

Implementation successes

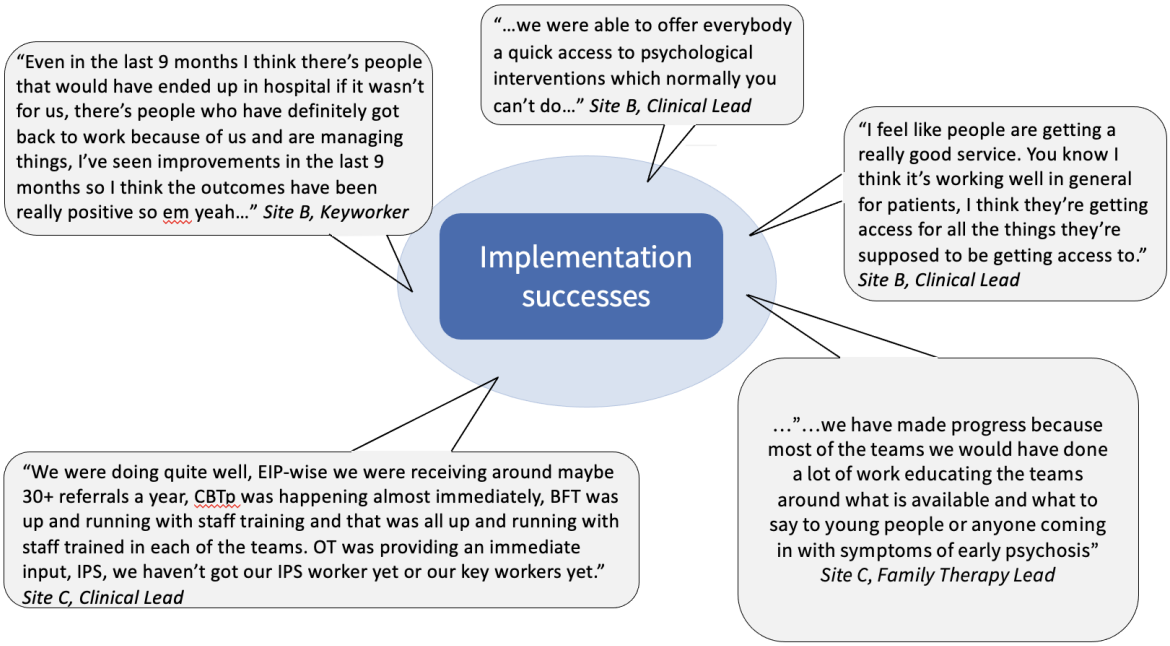


Figure 25. Quotations related to the theme of 'Implementation Successes'

There was a strong sense that staff within the hub and spokes were positive about the new EIP service and the new way of working. Staff within one site were very satisfied with the service that had been established and they were confident that they were providing a better service for people experiencing psychosis for the first time than what was on offer before the implementation of the service.

A key component of this success was the ability to make quick assessments and referrals to structured programmes, something that had not been possible under TAU. This ability to quickly refer was also noted with a degree of caution however, as some clinicians noted the possibility of over-burdening service users in the early stages of treatment with referral to too many diverse treatments. However, it was noted that having access to a range of treatment options is important and that the EIP teams can stagger the interventions so as to not overwhelm a service user while still offering them an individualised approach to care. As many of these clinical programmes are newly available and have a relatively low waiting list, there may be a tendency to refer, even though it was understood to be too soon in a service user's journey to truly benefit from that aspect of the EIP programme. Therefore, waiting lists for interventions are a reflection of people who are 'on hold' as they may not be ready for the intervention, rather than there being a lack of capacity to treat them.

This may be worth considering in the full roll out of services nationwide. This is useful learning for new teams that care needs to be individualised and timed to the needs of service users.

Enthusiasm for the concept of EIP

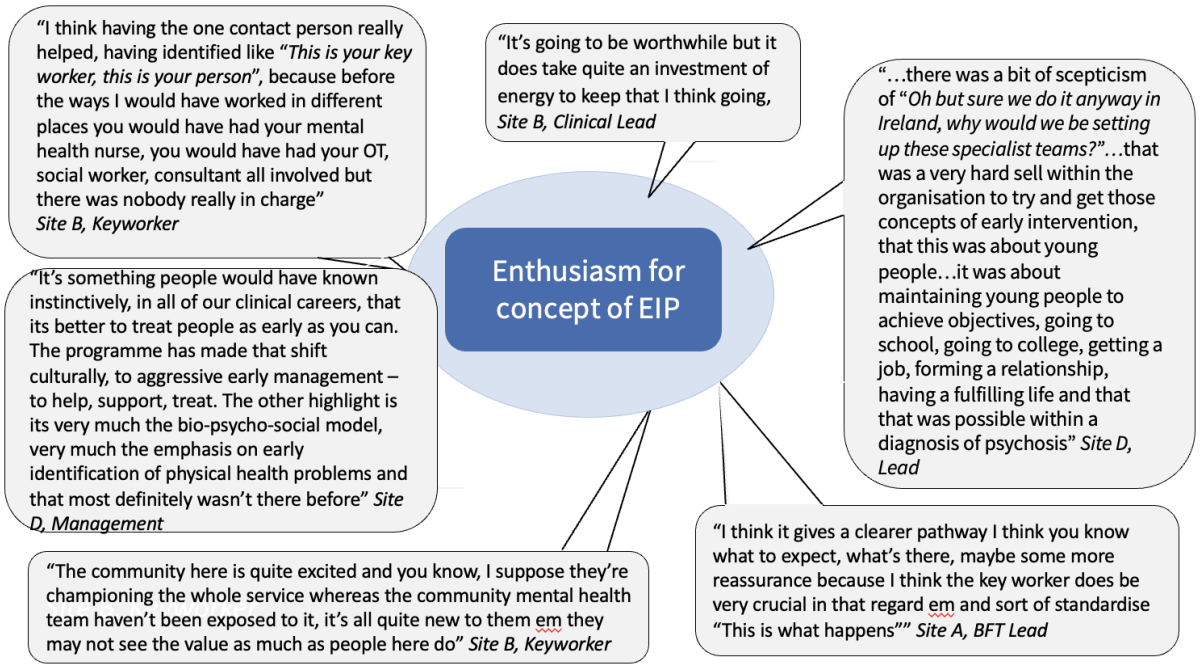


Figure 26. Quotations related to the theme 'Enthusiasm for the concept of EIP'

There was a real sense of buy-in and belief in the philosophy of EIP. This was acknowledged by both regional and central management, plus clinical teams members. Participants routinely stated their belief in its value and worth. Staff identified several aspects of the new way of working that they believed were most effective and worthwhile. Most commonly, this was the newly devised key working component of the new EIP services. Staff described how this way of working allowed patients to receive a continuity of care that had not been previously available, allowed families and patients to have one point of contact through which a strong relationship could be built, and allowed queries and concerns to be directed to one person where they could expect a swift response. A participant expressed the view that the new way of work improved the service as it was standardised and allowed for a certain level of quality of service that was becoming routine in their practice. This included the welcome expansion of services to assess and treat a service users physical health needs too.

There was a palpable sense of excitement and enthusiasm for the new model and staff described how working within the hub with clinicians with similar training and enthusiasm allowed for a sense

of excitement and interest, that may not be as apparent within a CMHT, where staff deal with a variety of mental health conditions and severity of cases.

Obstacles to recruitment

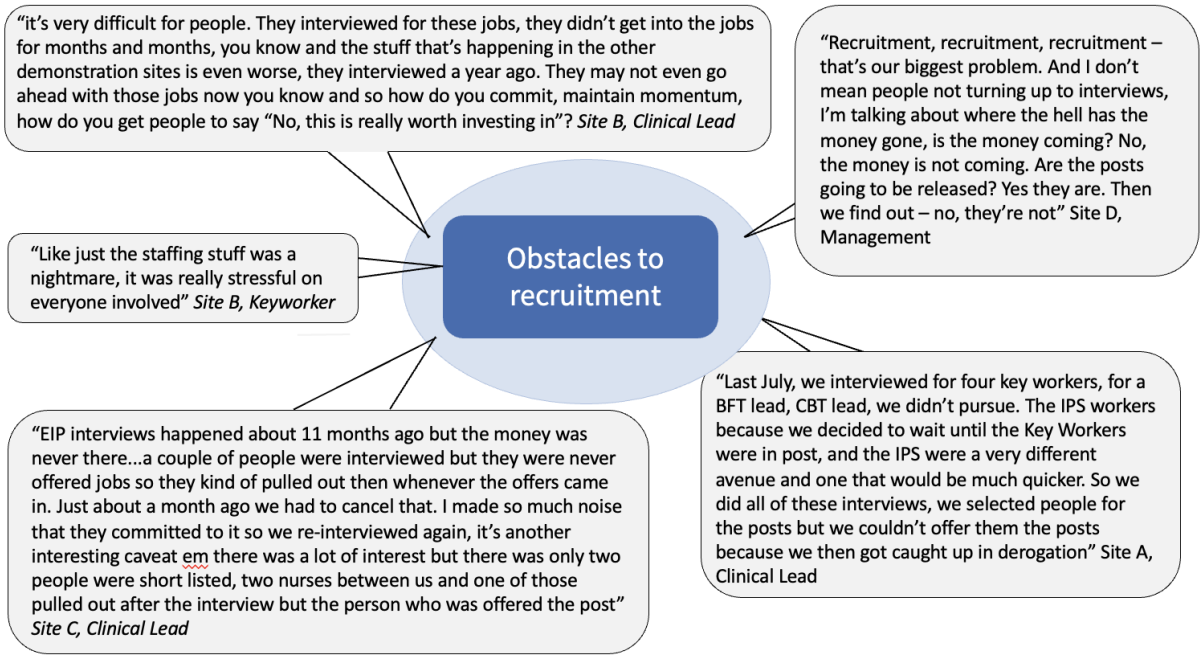


Figure 27. Quotations related to the theme 'Obstacles to recruitment'

While staff expressed enthusiasm for the concept of EIP and had noted areas where implementation had been successful, there emerged areas where implementation had not run smoothly. The ability to successfully recruit and appoint clinical staff proved to be a serious stumbling block. Staff described how they had applied for posts but had not heard anything back for many months. This meant that some of the enthusiasm for working within EIP had begun to erode as they had grown doubtful as to whether they would ever begin working in the position.

Clinical leads of services described how they had been allowed to advertise positions and interview candidates, but not offer jobs as the funding was diverted temporarily to satisfy other operational needs within the health service. In addition, there were issues around appointing staff as many of these staff members came from other parts of the health service. If a staff member working in an inpatient setting applied for an EIP post, they could not take up the role until a replacement for the inpatient post had been secured. This happened particularly with the keyworker roles. This lead to

long delays in appointments. Complications and delays surrounding the release of secured funds also played a role which is explored in the next theme.

Budgets and permission to draw down

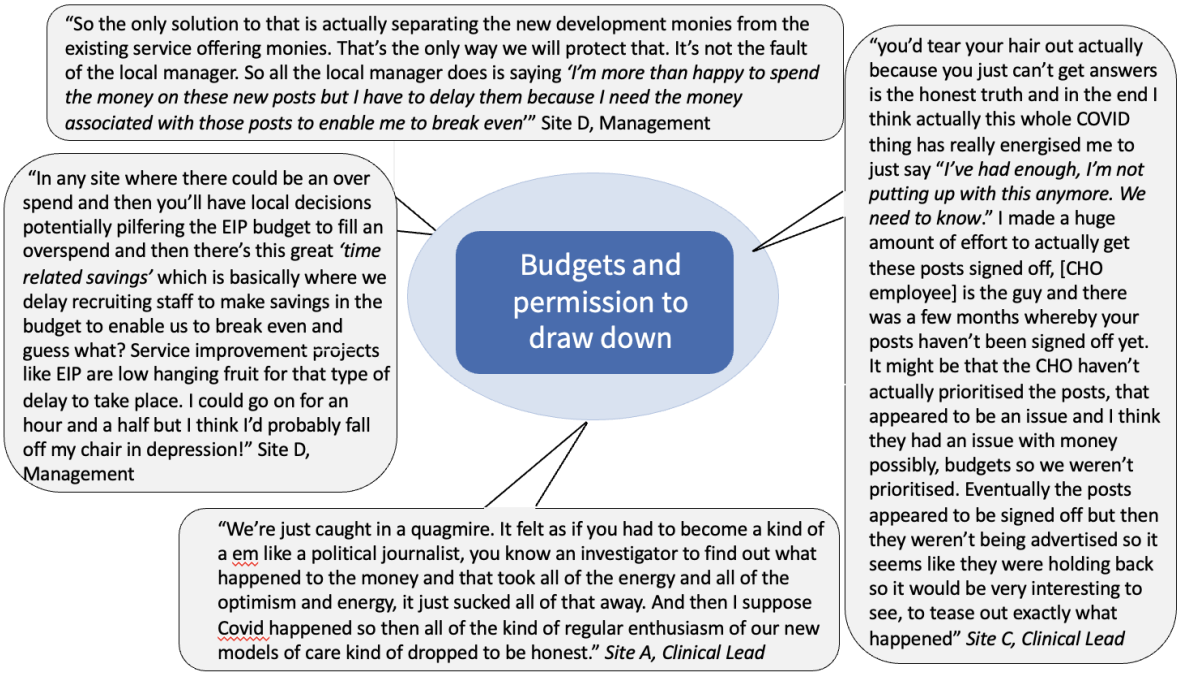


Figure 28. Quotations related to the theme 'Budgets and permission to draw down'

The ability to access the appropriate funding to appoint staff was a theme that emerged at each site and served as a major barrier to implementation. Staff had applied for agreed EIP demonstration site funding and been successful in their bid. This funding was delivered to local financial officers within CHOs, and in some cases not released based on decisions to divert funding elsewhere. Clinical leads described long and arduous attempts at uncovering how and why monies were not made available. This financial investigation often took time and an emotional toll on clinical staff who struggled to navigate what was described as an archaic system with few forthcoming answers.

Financial issues were worsened by the development of COVID-19 at the beginning of 2020, as money that had been originally ring-fenced for implementation of the EIP service, no longer seemed to be available as the EIP service was no longer seen as a priority. Other issues that emerged were 'time related savings' which involves the retention of unspent monies in order to reduce an areas budget. There was a sense that the strategic programmes were being sacrificed in order to make short-term financial savings due to pressure from upper HSE management. It was also noted that mental health

in particular struggles to operate services on the budgets they are allocated, partly because they receive considerably less money than can meet demand. Management were not unaware of these issues but there was a sense that since these were long established practices within the HSE regarding budget and financial operations that teams, and even local and regional management, were powerless to change them. A solution was proposed which entailed the separation of monies relating to new development initiatives from monies associated with existing operations.

A confluence of these factors meant long delays in the release of appropriate money to each demonstration site and an unfortunate consequence of this was the draining of enthusiasm and energy in clinical leads and other staff members. The timely release of promised funding was the most serious barrier to implementation of services due to the very serious implications for appropriate staffing, but also the psychological effects on enthusiastic and specialised mental health teams.

Due to concerns that these delays could disrupt the implementation of the project, the Principal Investigator sent a letter (dated 2nd October 2020) to the National Clinical Lead in Early Intervention in Psychosis and Programme Manager in Mental Health Clinical Programmes to outline some of the concerns emerging from focus groups. See Appendix 8 for a copy of this letter.

Experiences of treatment from service users

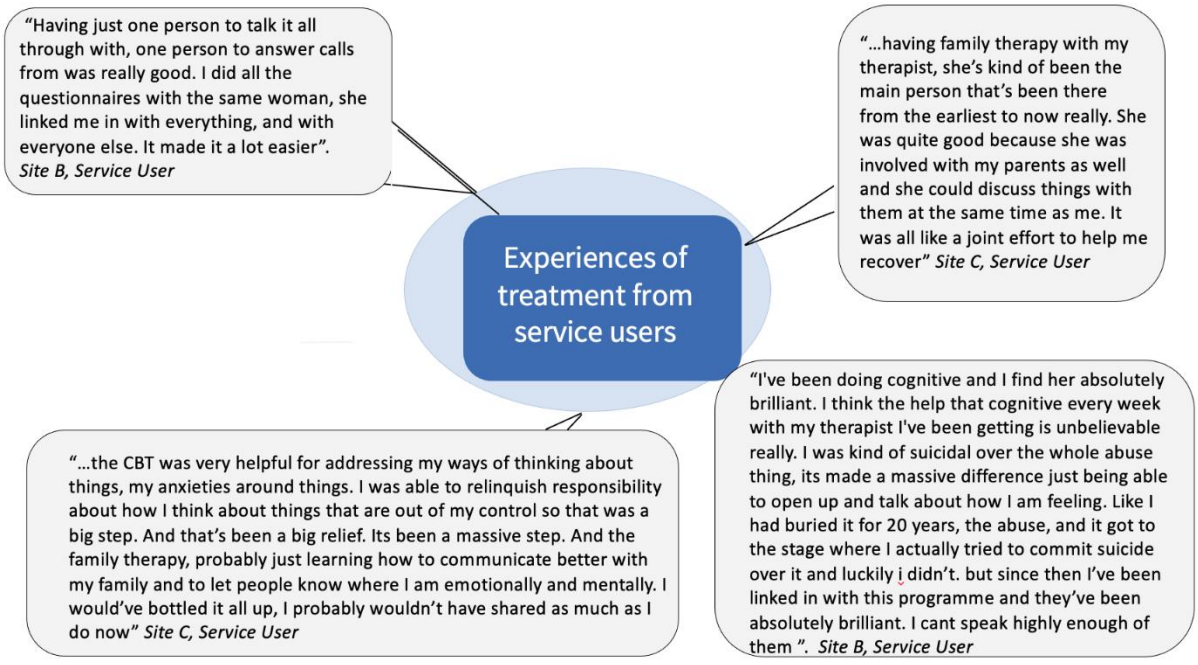


Figure 29. Quotations related to the theme 'Experiences of treatment from service users'

Praise and appreciation of the EIP service components and staff members was a common theme that emerged from the experiences of service users. The availability of the keyworker in particular, as an ongoing contact to monitor and coordinate care was commonly referenced as a facilitator of engagement with the service. When participants were struggling with their health or felt overwhelmed by the service options, the keyworkers were often cited as a valuable resource to navigate these challenges. CBTp was also praised for making significant improvements in specific symptoms and the development of patient coping skills. A challenging treatment experience mentioned by multiple participants was difficulty initially managing their medications. They often reported working with their prescribing psychiatrist by trying multiple medications before finding dosing protocols that were effective with tolerable side effect profiles. However, each participant interviewed reported being satisfied with their medication after this adjustment period.

Participants also reported that BFT was effective for improving interpersonal relationships and increasing family members' understanding of psychosis and psychosis treatment. Multiple service users identified BFT as the most helpful service they received in the MoC, which may reflect the challenging familial circumstances of incoming patients and the importance of social support in facilitating recovery. IPS was highly regarded by many service users, although some participants were only ready for this at later stages in their treatment progression (i.e., when they had less severe symptoms and were in more advanced stages of their recovery journey). Due to funding and staffing challenges, the IPS services were also unavailable at some sites during the study period.

Service level data collection processes

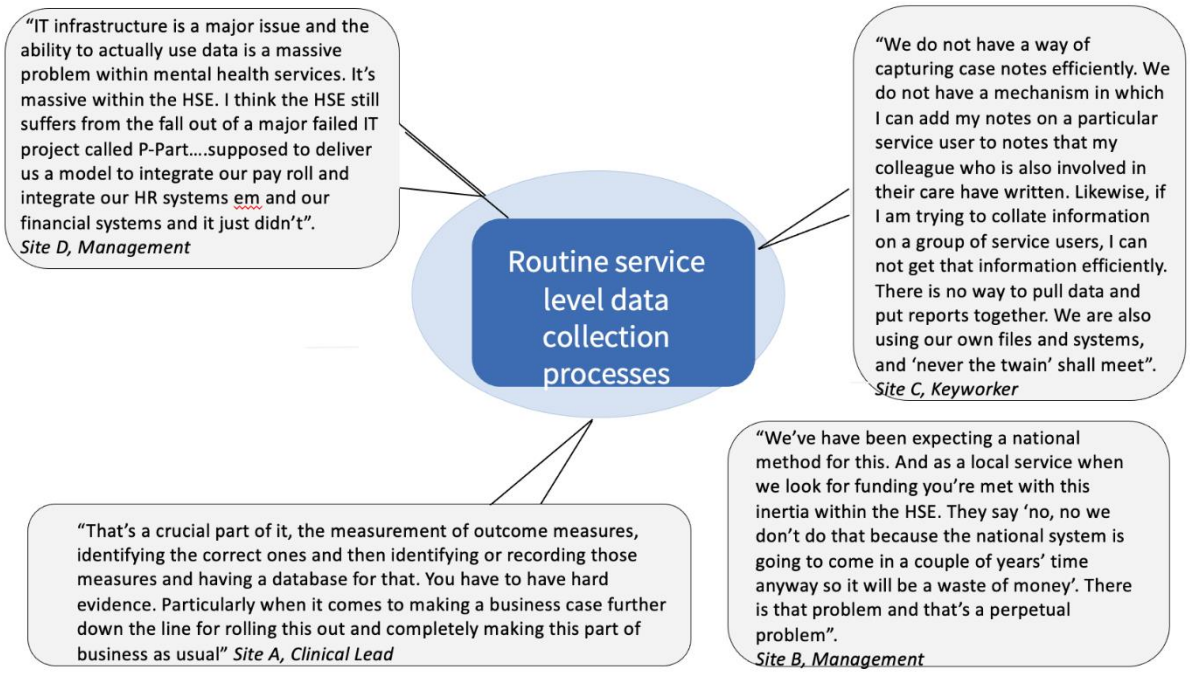


Figure 30. Quotations *relating to the theme of 'Routine service level data collection processes'*

Significant gaps exist within Ireland's health information systems and health data infrastructure. Many team members and managers expressed frustration at the lack of computer hardware and software. The current information technology (IT) systems in the HSE have not embraced advanced health information and management systems. The clinical teams in the three demonstration sites do not have electronic patient medical records in which to record, share and integrate treatment information relating to service users in their care. This is extremely limiting and was a source of deep frustration. However, as one participant reported that when they have enquired about the possibility of developing local solutions to IT problems they are often met with the recommendation to wait to develop anything locally in advance of a national solution being forthcoming. Likewise, managers also expressed frustration at IT systems not being integrated in terms of Human Resources and financial functions. Participants were aware of the interplay between having robust systems in which to record outcomes, database management practices and the role of how data can be utilised to make a business case for continued programme funding.

Factors for standardisation and growth of EIP beyond the demonstration sites

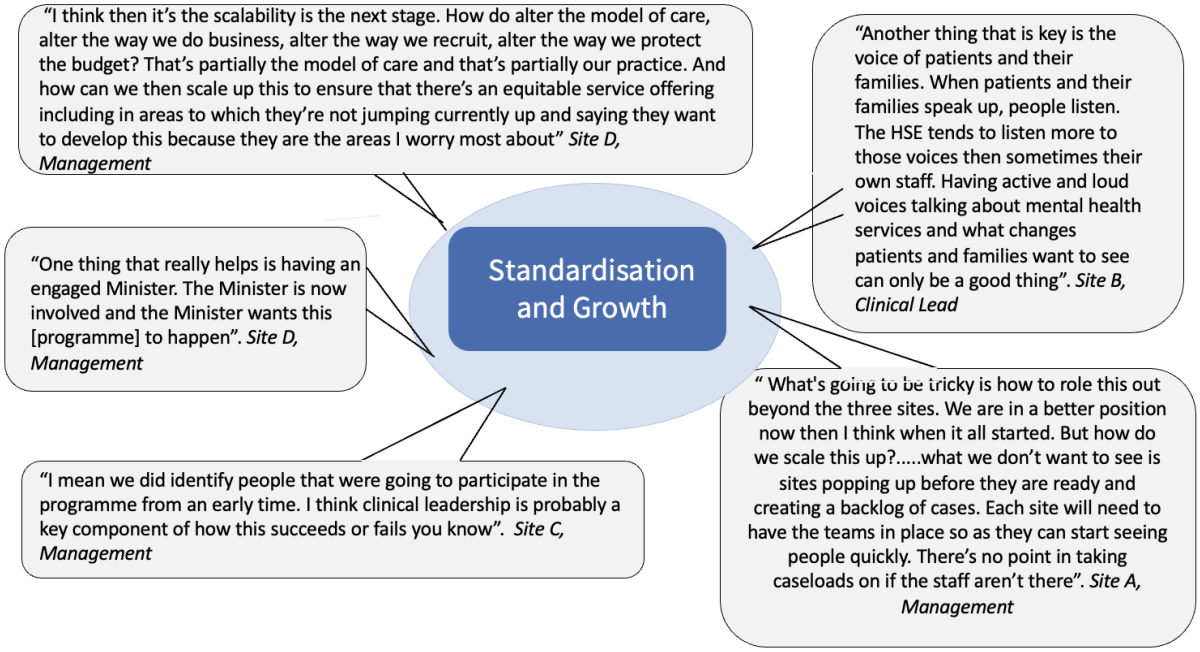


Figure 31. Quotations relating to the theme 'Standardisation and growth of EIP services'

Multiple participants spoke about the importance of clinical leadership. Many cited the strong role that clinical leaders within the demonstration sites took on. This included time spent championing the vision which was outlined within the MoC both within teams, with CMHT colleagues and HSE management. Clinical Leads were also recognised in their endeavours relating to arguing the case for posts, trying to unblock delays in backfilling of posts, and also constant advocacy for timely release of funding. Participants also spoke about the importance of Ministerial buy-in and having a Minister that is supportive and interested in the concept of early intervention being vital. There was a recognition that service users and their families members can be very strong positive advocates for change when they are encouraged and supported to be vocal. Participants did recognise that it would be important for future sites to have the correct skills mix in place so as service users are offered the full range of timely assessments, and therapies. Also within this, participants consistently spoke of how the full staff complement is important and that they could not see any component of the MoC being easily removed without significant negative consequences to the overall perceived effectiveness of the programme.

Potential threats to the EIP programme

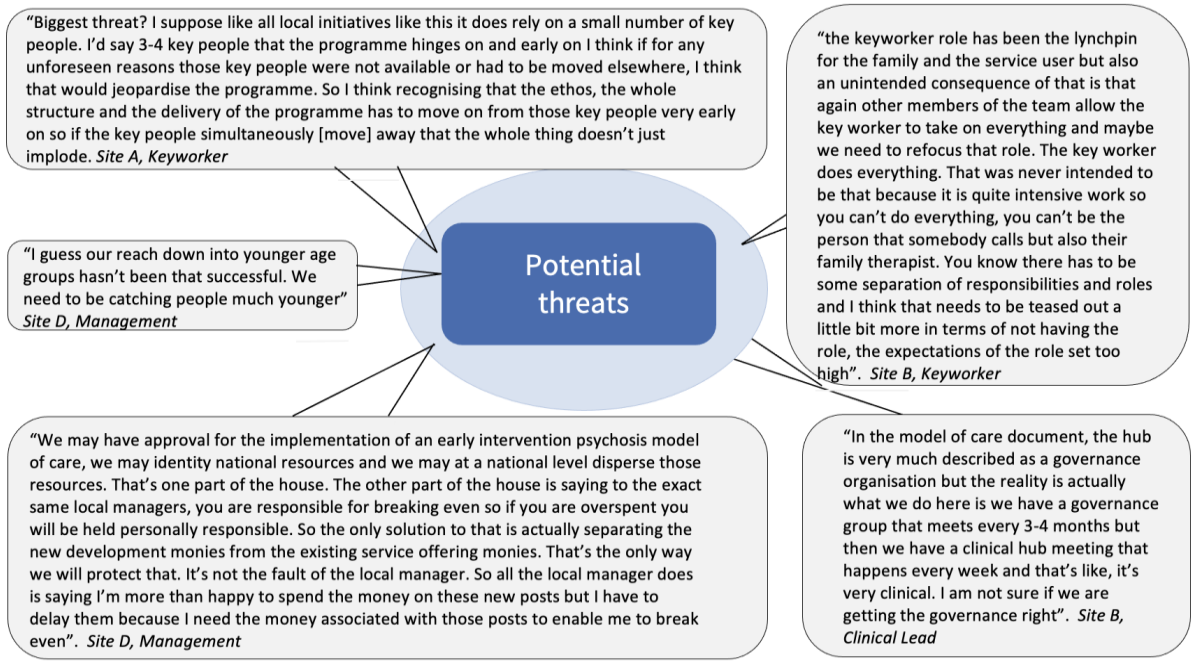


Figure 32. Quotations relating to the theme 'Potential threats to the EIP programme'

Any new innovation is at risk of not progressing beyond the initial pilot phase. Participants were asked to share their thoughts on what they perceived could be a threat to the roll out of the EIP service nationally. The inter exchange between funding mechanisms and staffing levels was a dominant theme. The duality of management being informed that EIP would be a priority, with requisite national resources identified, alongside the same management being told to delay releasing that money so that the budget for the area can break even was highlighted. The potential loss of individuals who have been such enthusiastic leaders within the clinical sites and within the National Clinical Office was considered a risk. Participants spoke of this potentially being an acute risk if these individuals moved roles before the EIP service had a chance to become embedded. Issues were raised relating to the governance of the hub and spoke model. There was a sense that integrating a new service within an existing community mental health structure is complex and requires sensitivity. Time to reflect and consider the appropriateness of the governance structure was highlighted. Governance was also discussed in terms of improving communication and linkage between EIP services and geographically corresponding CAMHs services. This was considered

important as a further mechanism to detect and intervene as early as possible with people experiencing psychosis.

Auxiliary Study: Systematic Review

While the clinical effectiveness of EIP services is well established, no previous research has collated evidence from previous process evaluations to learn from the implementation of EIP services in other jurisdictions.

In order to support this process evaluation, we completed a systematic review of previously published studies which describe EIP implementation in other contexts. This was not originally included in the original project scope, however, we hope that the findings from this study will guide the overall process evaluation and will support recommendations for future implementation practices both within Ireland and within international health systems. This study has been published(37).

The aim of this review was to describe the content, implementation and delivery of established EIP services. We also aimed to collate qualitative data on the views and experiences of services users, families, carers and clinicians on how implementation was experienced and the enablers and barriers to implementation. We sought to identify any frameworks which underpin EIP service implementation and describe the participation rates and fidelity of these services.

A librarian within Trinity College Library formulated a robust search strategy using MeSH terms to identify relevant literature. With the aid of two TCD medical students, this search was implemented and studies were imported and abstracts were screened using Covidence software (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia). The figure below displays a PRISMA flowchart showing the systematic review screening process.

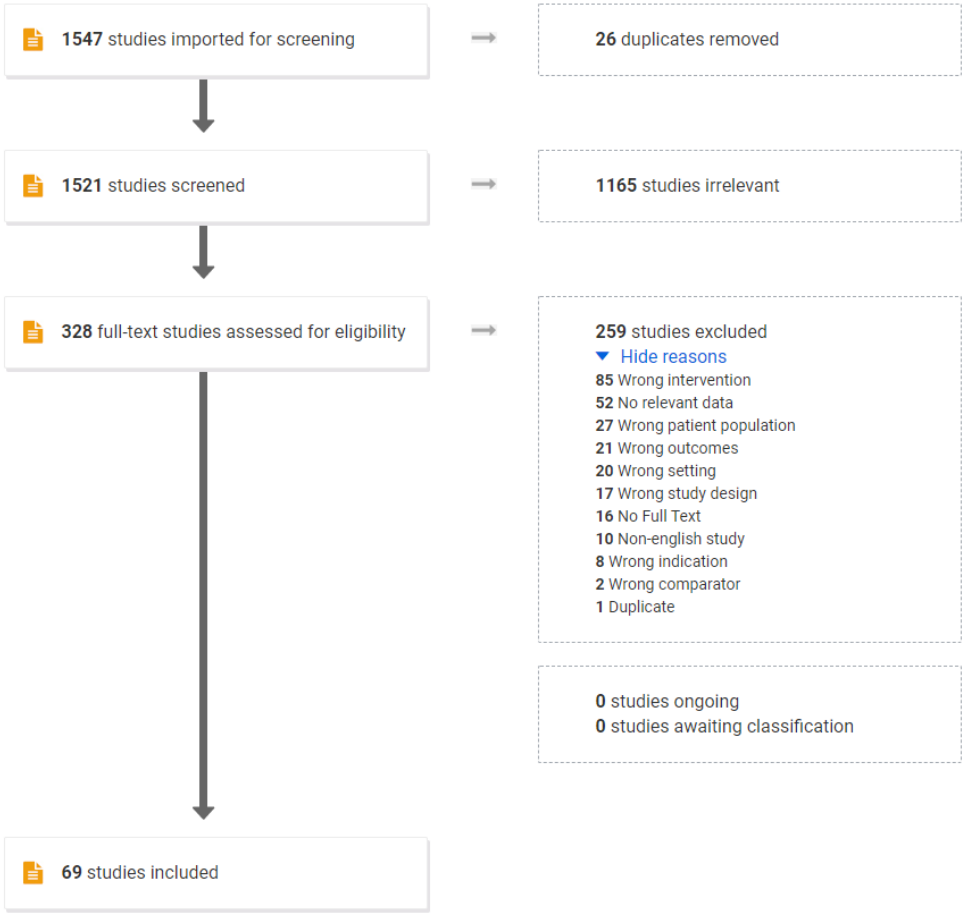


Figure 33. PRISMA flow diagram showing the systematic review screening process

Findings: Barriers and facilitators to implementation

The results from this review suggest a number of potential implementation barriers and facilitators to EIP implementation that exist across three domains: systems level factors, service level factors, and staff experiences and attributes. There were 14 associated subdomains and many of the barriers and facilitators to EIP implementation were shared across countries and jurisdictions.

Lack of appropriate funding was the most common barrier and affected service implementation across multiple phases and many associated processes. For example, insufficient funding negatively affected the pre-implementation landscape, staff training, referral and outreach services, caseload management and the capacity for service evaluation. Another common barrier was recruitment difficulties and high staff turnover in the early stages of a service being established. Under-funding of services can mean inappropriately high case loads, staff expected to work long hours and a pressure to meet targets.

Provincial EIP networks were seen as more important for implementation than local policy makers or research evidence. A view was expressed amongst staff that a key to success was for policy makers to allow for adaptations to local conditions. Some views emerged that where spoke EIP clinicians were embedded within generic CMHTs, CMHT staff could perceive their service as under-resourced or undervalued compared to the EIP service, and this can be exacerbated by competition for resources between rural and urban areas.

Staff also felt short time periods for implementation were a barrier to success. They believed measurable objectives were key to the establishment of consistent services. Some believed there were difficulties in ensuring psychiatrists and acute care clinicians were engaged in practice and clinical change, and cited over-ambitious expectations, excessive and duplicative documentation, a lack of specificity in the timing, targeting and duration of clinical training and the loss of key staff adversely affected implementation. Table 4 displays Hetrick et al's(38) findings on barriers that risk the dilution of EIP implementation.

Table 4 Hetrick et al.'s proposed barriers that can dilute EIP implementation

Hetrick et al's proposed barriers that dilute EIP implementation	
Skills	- *Lack of knowledge about EIP model, tools to use and safety/risk management*
Role	- *Providing CBTp not seen as part of professional role or lack of clarity on role*
Capabilities	- *Lack of confidence in delivering components*
Resources	- *Lack of tools for screening/diagnosing* - *Lack of culture of learning* - *No geographical catchment areas defined in model* - *Lack of prompts/reminders to use tools for regular review*
Optimism	- *Lack of optimism* - *Overly optimistic approaches to recovery trajectories*
Emotion	- *Feeling overwhelmed by number of implementation standards*

Further findings: Carer, service user and staff experiences

Much of the research gathered through the systematic review search is qualitative in nature. This captures the views of carers, service users and EIP staff members. These descriptions were overwhelmingly positive.

Carers describe the optimism, relief and hope that is instilled through contact with EIP services, for example, "There are now systems in places, terms of reference in place and I feel an awful lot more confident". Other carers described how contact with the EIP service provided a sense of mastery over the everyday, practical impact of caring for a family member with psychosis and it was a

process which helped normalise their experience. The collaborative care and the emphasis on recovery was seen as a very positive part of their experience and positive relationships with staff enable carers to feel more confidence in their own support of their family member, particularly when supporting them through acute episodes.

Service users described how being part of EIP services reduced feelings of loneliness and isolation, often instilled a sense of agency and helped them develop insight into their experiences. The keyworker role in particular was identified as a channel through which a person could access support, increase knowledge about psychosis, address expectations of recovery and improve understanding other available services and resources. The EIP team helped normalise often distressing experiences and reduced feelings of detachment from the world. Contact with teams also helped them move away from symptom avoidance towards positions of symptom acceptance.

Finally, studies on staff experiences were similarly positive with staff conceptualising their role as initially helping patients in crisis and addressing basic needs like food, shelter through to guiding them through the stages of recovery. They also described their attempts to reduce stigma surrounding psychosis and feeling professional fulfilment when they witnessed their patients achieve the goals they set out at the start of treatment and gaining functional recovery. Finally, staff described some issues with the structures related to formal supervision, particularly within the nursing profession, with this often being lacking or unavailable to them.

Strengths and Weaknesses

This process evaluation had a number of strengths. These included that the study commenced close to service initiation and captured the newness of the EIP service across the demonstration sites. This included documenting issues arising from embedding a new service within an existing complex system as well as how staff responded to challenges like COVID-19. The process evaluation was based upon a mixed methods approach which included both quantitative and qualitative data collection approaches. This study was conducted by an independent research team from Trinity College Dublin and therefore the researchers were not affiliated to the staff or demonstration sites. However, the drawback of this was that we as the research team needed to take time to familiarise ourselves with site personnel, the MoC and also operational aspects of how the HSE conducts its business.

This process evaluation had a number of weaknesses. These included that the research team had to develop our own data capture system that took project time and may not have captured the service nuances as well as a routine service database would. Due to two maternity leave absences, there were changes to study personnel. The demonstration site teams referred the service users to us for qualitative interviews, rather than the research team randomly selecting participants. This may have introduced bias. We were only able to recruit one family member to be interviewed as a part of Study Three. This lack of the families voice relating to their experiences of the EIP demonstration teams was missing from this process evaluation. Despite tenacious efforts to engage with the research ethics committee associated with the Meath demonstration site we were unable to secure ethical approval for the release of quantitative service and patient level data as that research ethic committee deemed this aspect of the process evaluation as high risk. We were able to include data from Cork South Lee and Sligo demonstration sites as the associated research ethics committee judged the project to be of low risk.

Summary and Conclusion

Psychosis is characterised by a person losing touch with reality. It often includes experiences such as hallucinations (e.g., the person sees things that other people do not), delusions (e.g., the person holds strong beliefs that other people do not share) and a disordered way of thinking (e.g., the person's thoughts are moving very quickly from idea to idea, and seeing meaning between things that other people do not see). This can cause considerable distress and disability for the person and their family. Internationally, the evidence shows that intervening early can have a positive and significant influence on longer term outcomes(39).

The overall objective of this process evaluation study was to identify and characterise the barriers and facilitators of implementing the new MoC of EIP within the existing mental health system in Ireland. In addition to providing early intervention, standardisation of assessment and treatment and multidisciplinary evidence-based interventions, the EIP MoC is grounded in a recovery philosophy adopted from the National Framework for Recovery in Mental Health Services 2018-2020(25). This approach encourages a health service culture orientated towards hope and expectation that the service user can recover from their mental health challenges and build a fulfilling life. This model also incorporates a strength based philosophy grounded in capacity building and empowerment rather than traditional medicalised approaches to mental health that are largely deficit-based(40).

Implementation of the MoC within the three demonstration sites has not been easy. Challenges have been met since the beginning. These barriers are mostly in the areas of organisational practices that are outside of the control of clinical teams and even local, regional and national programme management. Systems within the HSE relating to human resources and financial budgeting were the main implementation barriers. At times, each of the three sites struggled to embed the initiative fully into an existing service. These barriers are consistent with system-level funding and recruitment barriers reported throughout international studies of EIP service implementation(37). As a result, programmes adapted as best as they could to local constraints and conditions. While the MoC allows for necessary adaptations it is important that fidelity to the MoC continues to be monitored in the future (a process best facilitated by fully-funded and operational electronic health record systems) so as that clinical practice does not 'drift' away from that outlined. Issues relating to capacity to deliver the service as described and the closeness of service delivery in real time compared with the MoC is co-dependent. The volume of cases also plays a roll. In Sligo the demonstration teams were seeing the anticipated numbers of FEP cases, but in Cork South Lee the demonstration team were seeing far in excess of the predicted numbers of cases. Close scrutiny and ongoing monitoring of this is required so as that teams can have the correct number of staff in place to meet the demand from the communities that they serve. Previous studies have also found that the management of caseloads and electronic data capture systems to monitor deviations in implementation guidelines are significant service-level barriers to EIP implementation(37).

Facilitative factors predominately related to the clinical staff and management associated with the EIP MoC demonstrating resilience and tenacity throughout the two years of this process evaluation. The goals and proposed standards are well described in the MoC document. Teams demonstrated 'therapeutic optimism' and very much embraced and supported the strong philosophy of recovery from psychosis which is the foundation of the EIP approach. There was evidence that service users accepted EIP in terms of its assessment processes, cases being managed by a keyworker, and therapeutic offerings. Teams were supported by effective leadership from the National Clinical Lead and Programme Manager who championed EIP within central HSE. The impact of these facilitative factors is consistent with previous studies of EIP implementation(37). However, the benefits of having a keyworker as a constant point of contact for care management was continually highlighted as a key feature of the MoC by service users. This was not emphasised to the same degree in previous studies. Both the qualitative and quantitative data provided strong support for the keyworker role in facilitating the EIP service user engagement at the MoC demonstration sites.

Between the three demonstration sites, there was evidence of some variability in the organisational structure within the EIP hubs and the CMHT spokes. There was variability in the number of hub

clinical leads (e.g., two in Meath, one in Cork South Lee and one in Sligo). No clinical lead at any of the three demonstration sites had any protected time for EIP related activities. EIP services also differed across the three demonstration sites due to challenges with staffing and funding. These barriers effected the availability and timing of implementing specific service components throughout the EIP process evaluation. The documentary analysis indicated that compared to the treatment as usual (pre-2019) practice, the EIP demonstration teams produced increased standardisation of care, improved coordination of treatment, more protected time for psychosis management and more efficient intake, admission and referral processes. Just over half of cases were having their initial assessment conducted within three days in Cork South Lee and just over a third of cases were being seen within that timeframe in Sligo. Across the demonstration sites, service users averaged at least weekly contact with their keyworkers and attended over 75% of the psychosocial appointments offered to them.

The conceptualisation and measurement of the dose of complex interventions like EIP has important implications for understanding how programmes produce their effects, and for whether and how programmes should be resourced and scaled up(41). Health services management and policy makers want to know what they need to fund and implement to produce population-level health gains, while clinicians want to know 'how much' they need to do to ensure that programmes like EIP 'work' within their services. Looking at the MoC and from quantitative date captured in Study 2 and appraisals of key ingredients of the EIP programme captured in Study 3 data, we found evidence of a strong positive relationship between the number of keyworker contacts and engagement with other psychosocial interventions provided by demonstration teams. This is an important finding as it demonstrates an interaction with the dynamic properties of the EIP programme, and it also helps clinicians and policy makers to know where to concentrate resources in the future.

There was patchy evidence of teams' ability to undertake physical assessments and evoke treatment plans relating to same (e.g., Meath and Cork South Lee could undertake this activity themselves but Sligo had to refer back to the service users GP). Both the quantitative study (Study Two) and qualitative analyses (Study Three) demonstrated that teams were severely hampered in their ability to accurately record and distil clinical information relating to treatment and delivery of the MoC. This underinvestment in information data management systems severely restricted both the research team and, more importantly, the clinical teams throughout the process evaluation. Going forward, this will curtail teams and clinical leads from presenting robust data for the continuation of funding for the programme and any potential expansion to other sites beyond this demonstration project phase. Future research should move to establishing an agreed outcomes dataset which will

allow for a determination of the effectiveness of the EIP MoC in an Irish context. A cost effectiveness analysis should be considered.

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Appendix 1: Letter inviting mental health services to become demonstration sites

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

20th October 2017

To: Mental Health Service Leads, ECD's, Clinical Leads and Chairs HSCP Groups

Re: Development of First Episode Psychosis Demonstration Sites in a number of Mental Health Services in 2018

Dear Colleagues,

The National Clinical Programme for Early Intervention in Psychosis National Working Group has been developing a Model of Care (MOC) for Early Intervention in Psychosis. This document is now at an advanced stage and is going through the review stages both externally with the College of Psychiatrists of Ireland and internally within the HSE. In addition work has been progressing on a number of key interventions including family work, supported employment and cognitive behavioural therapy. It is estimated that 1500 people develop psychosis annually in Ireland although there is very little Irish data available to support this currently. The overall expected incidence based on international data is 32 cases per 100,000 population although this can vary considerably depending on demographics, population density and socio-economic factors.

The Model of Care will require significant resources as well as a programmatic response by mental health services to deliver its aims. As part of the work for the group drafting the MOC different models of service provision were reviewed and considered. The recommendations in the MOC are for a "hub and spoke" model of service provision for most of the country with a **maximum** population of 200,000 served by any hub team. For urban areas with a population of 250,000 population a "standalone team" is recommended.

We now wish to invite applications from Mental Health Services to become demonstration sites for the Hub and Spoke model of FEP service provision. The National Clinical Programme has a limited number of resources available for allocation. It is expected that 2 to 3 Hub and Spoke teams will be

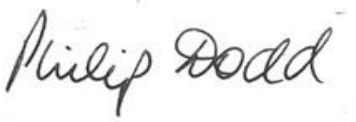
selected from the applications received depending on population size for the Hub and Spoke Model. Training will be provided to the demonstration sites. A development and process evaluation of the demonstration sites with all of the elements of FEP service provision and based on a hub and spoke model of service provision will be carried out. This will allow us to demonstrate the feasibility and effectiveness of the Hub and Spoke Model of FEP service provision and provide data and information on how teams can successfully implement the model in clinical practice. An independent evaluation will be included.

We would appreciate if you would bring this notice to the attention of your senior management team for discussion. I have attached the application document.

An information session will be held in Dublin on 15th November to which 2-3 members of your service may attend. Following this we will accept applications up until 23rd November. Services will be notified of results in early December.

If you have any questions please contact Rhona.jennings@hse.ie.

Kind regards,



Dr. Philip Dodd
National Clinical Advisor Group Lead for Mental Health Division

Appendix 2: Study Gantt Chart

Gantt Chart		**Project Year 1**				**Project Year 2**			
	Pre-Activities	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Post Doc Researcher – advertising & recruitment	◆								
Ethics submission/approval	◆								
Training qualitative & quantitative research methods		◆	◆	◆					
Meet with local study sites		◆							
Set up Research Advisory Group		◆							
Literature review		◆	◆						
Protocol development		◆	◆						
Submit protocol for publication				◆					
Develop dissemination & knowledge exchange strategy			◆						
Good clinical practice & data protection training			◆						
Develop/finalise study instruments			◆	◆	◆				
Database design				◆	◆				
Data collection (quantitative & qualitative)					◆	◆	◆	◆	◆
Data entry						◆	◆	◆	◆
Data validation						◆	◆	◆	◆
Data analyses						◆	◆	◆	◆
Dissemination – Conferences									
Submission of papers to peer reviewed journals									
Annual report to RCPI Ethics Committee					◆				
Annual analyses and reports to funders					◆				
Final report to RCPI Ethics Committee									◆
Final report to funders									◆

Appendix 3: Research Advisory Group Terms of Reference and membership

Document Purpose

The purpose of this document is to set out the terms of reference for the proposed Research Advisory Group (RAG) for the Early Intervention in Psychosis (EIP) process evaluation undertaken by the Department of Primary Care and Population Health at Trinity College Dublin in conjunction with the Health Service Executive.

RAG Remit

The proposed purposes of the RAG are to:

- Monitor progress of the EIP project in terms of project milestones and deliverables
- Monitor appropriate use of the research budget
- Provide a governance function in terms of oversight of the quality of the scientific and ethical processes and procedures undertaken by the research team

Membership Structure

Research Advisory Group membership will:

- Consist of no more than 10 members;
- Include members of the Research Management Team (KOC, RJ, CD, NOC);
- Include up to three additional nominated representatives from the HSE, one of which must be a patient/service user; and
- Include up to three additional nominated representatives from academia.

Chairperson

- The Chairperson shall be elected from amongst the members of the RAG

Duration of Service

- The group will meet throughout the two-year project timeline.
- The project has been extended into 2022 due to the researcher's secondment to another project.

Meeting Timetable

- The RAG shall meet three times a year; and
- Six members shall constitute a quorum.

RAG Membership

	Name	Role	Nominated by
Chair	Sinead Reynolds	General Manager, HSE Mental Health Operations & Performance	HSE
Other members	Rhona Jennings	Programme Manager, Mental Health Clinical Programmes, HSE	HSE
	Karen O'Connor	Consultant Psychiatrist, RISE EIP, National Clinical Lead Early Intervention in Psychosis, HSE	HSE
	Michael Norton	National Engagement and Recovery Lead, Office of Mental Health Engagement and Recovery, HSE	HSE
	Catherine Darker	Associate Prof in Health Services, Discipline of Public Health & Primary Care, TCD and Project PI	TCD
	Nicola O'Connell	Project Research Fellow, Discipline of Public Health & Primary Care, TCD	TCD
	Agnes Higgins	Prof in Mental Health, School of Nursing & Midwifery, TCD	TCD
	Mary Clarke	Senior Lecturer, Dept of Psychology, RCSI	TCD

Appendix 4: Summary of patient demographics and additional EIP resources requested for the MoC in each of the demonstration sites

	Cork South Lee	**Sligo**	**Meath**
Estimated population	200,000	115,000	200,000
Demographics of catchment area	The AMHS encompass one entirely urban city sector (population 54,670), two suburban city/rural sectors (population 45,518 and 50,734) and one largely rural sector, which includes two provincial towns (population 39,678). The urban sector City South East/ City South West (CSE/CSW) includes significant areas of socioeconomic deprivation, high levels of substance use, a significant homeless population in hostels and a transient student population.	Urban/Rural mix: Sligo/Leitrim/South Donegal/West Cavan It is a rural area, bordered with Northern Ireland, sparsely populated with the highest levels of unemployment, deprivation and highest dependency ratio of all CHO's.	Navan and Ashbourne are in the top 5 youngest towns in Ireland, with Navan mean age 33.1, Ashbourne mean age 33.2, national average age 37.4 (Census 2016) Navan and Ashbourne are urban areas of Meath and the remainder of Meath is largely rural.
Additional resources requested for MoC	• EIP key workers: 3 • BFT clinicians: 2.5 (0.5 BFT lead, 2.0 clinicians) • CBTp clinicians: 2.5 (0.5 level 3, 1.0 level 2, 1.0 level 1) • IPS staff: 2 • Admin:1	• EIP Key Workers: 2-AMHS, 0.5-CAHMS • BFT Clinician: 1 • CBTp: 1 • IPS staff: 1 • Admin: 0.5	• EIP Key Workers: 3 • BFT Clinician: 2 (0.5 lead, 1.5 clinicians) • CBTp: 3 • IPS staff: 2 • Admin: 0.5
Notes: AMHS=adult mental health service, CAHMS=child and adolescent mental health service, BFT=behavioural family therapy, CBTp=cognitive behavioural therapy for psychosis, IPS=individual placement and support.			

Appendix 5: Access database template

NEW SERVICE USER INFORMATION

1. New Service Users – Referral Information

Service User ID	
General Referral Information	
Is the SU a pre-Model of Care patient?	Yes/No
Referral Source **Note:** Emergency department= Any one seen by liaison/ out of hours NCHD in the ED Emergency Dept- Acute assessment= Assessment Hub Approved Centre- AMHU, CUH	GP/Emergency Dept/Emergency Dept – Acute Assessment/Approved Centre/CMHT/Other
EIP spoke SU referred to:	HBTT/Douglas Carrigaline/Kinsale Bandon/Ballincollig
Duration of untreated psychosis	Less than one week to more than one year
Date first seen within health care system for psychosis symptoms That's any part of the specialist mental health team i.e. OPD, Acute assessment in ED/ AMHU/ Hub. Seen and diagnosed with psychosis… or query psychosis.	
EIP Team Referral	
Date first seen by Keyworker/EIP worker	
Did the Keyworker complete an assessment with the SU within 3 working days of receipt of referral?	Assessment conducted within 3 working days/assessment not conducted within 3 working days
If an assessment was not conducted within 3 working days of receipt of referral, please state reason OR state 'Not applicable'	
How did keyworker first meet SU? (Face-to-face, telephone or via video?)	Face-to-face/telephone/video
SU attendance at EIP	
Date of first offered appointment with team I think this is first appointment with any member of CMHT/ HBTT- as they are the way in to any member of RISE.	
Did the SU DNA the first appointment?	SU DNA'd/SU attended/Clinician cancelled
Please specify the reason first appointment did not occur OR state 'Not applicable'	
If the SU did not attend for any reason, was the SU offered a second appointment within 2 weeks?	Yes/No/Not applicable – attended 1st appointment
Date of second offered appointment? Leave blank if not applicable	
Did the SU DNA the second appointment offered with Keyworker?	SU DNA'd/SU attended/Clinician cancelled/Not applicable
Please specify the reason the second appointment did	

not occur OR state: 'Not applicable'	
EIP Team Acceptance	
Information on acceptance to service	Attended first appointment and accepted into service/Attended second appointment and accepted into service/Did not attend any appointment and discharged/Discharged for other reason
If you chose 'Discharged for other reason' please state the reason or state: 'Not applicable'	
If the SU was referred but not accepted to team, please complete Sociodemographics and Diagnostic Forms. If SU was referred and accepted, please complete Keyworker and structured programme monthly forms for all active SUs.	

NEW SERVICE USER INFORMATION

2. Socio-demographics

Service User ID	
Basic Information	
Gender	Male/Female
Age	
Civil Status	Single/Married/Re-Married/Registered Same Sex Civil Marriage/Separated/Divorced/Widowed
Housing Status	Living alone/living with partner or family/Living with others – house share/In residential care/Homeless/Other living arrangement
Month and year of birth (add 1st of each month for day of year)	
Country of Birth	
Ethnic background	
Current employment or education status	
Holds private medical insurance	
Medical card holder?	
Benefit Information	
Does the SU currently receive one or more benefit payments from the Dept of Social Protection?	
If yes:	
Receives Disability Allowance?	
Receives Invalidity Pension?	

Receives Unemployment Assitance/Benefit?	
If you chose 'Discharged for other reason' please state the reason or state: 'Not applicable'	

NEW SERVICE USER INFORMATION

3. Diagnosis

Service User ID	
Diagnoses	
Primary Diagnosis	
ICD 10 Primary Admission Diagnosis (Please enter using 'FXX.X' format)	
ICD 10 Secondary diagnosis (if applicable)	
ICD 10 Secondary Diagnosis (Please enter using 'FXX.X'. If not applicable enter FXX.X)	
Substance Misuse	
Substance misuse within previous 4 weeks - yes or no?	
If yes, please describe or choose 'Not applicable'	

KEYWORKER DATA

1. Month 2020 - Assessments

Service User ID	
Baseline Assessments	
Short form SAPS/SANS at baseline?	Yes/No/Not applicable
GAP-MIRECC at baseline?	Yes/No/Not applicable
MANSA at baseline?	Yes/No/Not applicable
EQ-5D-5L at baseline?	Yes/No/Not applicable
Mode baseline assessments completed?	Face-to-face/video/telephone/Not applicable
6-Month Assessments	
Short form SAPS/SANS at 6-months?	Yes/No/Not applicable
GAP-MIRECC at 6-months?	Yes/No/Not applicable
MANSA at 6-months?	Yes/No/Not applicable
EQ-5D-5L at 6-months?	Yes/No/Not applicable
Mode 6-months assessments completed?	Yes/No/Not applicable
12-Month Assessments	
Short form SAPS/SANS at 12-months?	Yes/No/Not applicable
GAP-MIRECC at 12-months?	Yes/No/Not applicable
MANSA at 12-months?	Yes/No/Not applicable
EQ-5D-5L at 12-months?	Yes/No/Not applicable
Mode 12-months assessments completed?	Face-to-face/video/telephone/Not applicable
24-Month Assessments	
Short form SAPS/SANS at 24-months?	Yes/No/Not applicable
GAP-MIRECC at 24-months?	Yes/No/Not applicable
MANSA at 24-months?	Yes/No/Not applicable
EQ-5D-5L at 24-months?	Yes/No/Not applicable
Mode 24-months assessments completed?	Face-to-face/video/telephone/Not applicable
36-Month Assessments	
Short form SAPS/SANS at 36-months?	Yes/No/Not applicable
GAP-MIRECC at 36-months?	Yes/No/Not applicable
MANSA at 36-months?	Yes/No/Not applicable
EQ-5D-5L at 36-months?	Yes/No/Not applicable
Mode 36-months assessments completed?	Face-to-face/video/telephone/Not applicable

KEYWORKER DATA

2. Keyworker Activity

Service User ID	
General Information	
Does the SU have a keyworker?	Yes/No/Not applicable
Does the SU have a care plan?	Yes/No/Not applicable
Has the SU's benefits status changed this month?	Yes/No/Not applicable
If yes, please state. Otherwise state Not applicable	Yes/No/Not applicable
Psychological referral	
Has the SU received psychoeducation?	Yes/No/Not applicable
Mode through which psychoeducation was delivered?	Face-to-face/video/telephone/Not applicable
If the SU has not receive a CBTp referral, please write the reason why. Otherwise state 'Not applicable"	
Date of CBTp assessment. Leave blank if not applicable	
Mode CBTp assessment occured, if applicable	Face-to-face/video/telephone/Not applicable
CBTp assessment complete?	
If CBTp assessment is not complete please state, reason. Otherwise state 'Not applicable'	
SU given information about CBTp?	
If SU not given information about CBTp, please state reason, otherwise state 'Not applicable'	
Coping Skills Manual delivered by EIP keyworker/CMHT member?	
If SU not given Coping Skills Manual, please state reason	
Current CBTp status	
If SU was assessed for CBTp but clinician decided not to refer or SU declined treatment, please state the reason. Otherwise state 'Not applicable'	
If SU did not receive a CBTp referral, was another	

psychological intervention offered?	
Other Referrals	
Referral to addiction services?	
If yes, date of referral to addiction services. If 'No', leave blank.	
Referral to occupational therapy?	
If yes, date of referral to occupational therapy. If no, leave blank	
Referral to social work?	
Date of referral to social work. If 'No', leave blank	
Referral to psychology?	
If yes, date of referral to psychology. If no, leave blank	

3. Keyworker contacts and interventions

Service user ID	
Telephone contacts this month	
Total no of telephone contacts about SU with any party this month	
No of telephone contacts with SU (10 mins or more) this month	
No of telephone contacts with family/friends re-SU this month	
No of telephone consultations with GP re-SU this month	
No of telephone consultations with other agencies re-SU this month	
Face-to-face contacts this month	
Total no of face-to-face contacts with any person (outside team) regarding SU	
No of consultations with other MH team members regarding SU	
No of sessions with SU for support/review/rapport building	
No of face-to-face contacts with family re-SU	
No of psychoeducaton sessions with SU	
No of physical health care sessions with SU	
No of medical education sessions with SU	
No of housing/accommodation sessions with SU	
No of assistance with education sessions with SU	
No of lifestyle groups attended with SU	
No of physical activity groups attended with SU	
Video contacts this month	
No of video contacts with any person regarding SU	
No of video contacts with SU this month	

4. Medications/Physical monitoring

Service user ID	
Medications	
Is the SU currently prescribed Clozapine?	
Is the SU currently prescribed an antipsychotic?	
If an antipsychotic agent is prescribed, please choose or choose, 'Not applicable'	
Is the SU currently prescribed a 2nd antipsychotic agent?	
If a 2nd antipsychotic is prescribed, please choose or choose 'Not applicable'	
Is the SU currently prescribed an antidepressant?	
Is the SU currently prescribed a mood stabiliser?	
If SU is currently prescribed a mood stabiliser, please choose or state 'Not applicable'	
Physical health monitoring	
3-month metabolic monitoring completed?	
12-month metabolic monitoring completed?	
24-month metabolic monitoring completed?	
36-month metabolic monitoring completed?	

KEYWORKER DATA

5. Hospital admission and discharges

Service user ID	
General Information	
State the number of voluntary admissions the SU had this month	
State the number of involuntary admissions the SU had this month	
State the number of hospital discharges the SU had this month	
State the total number of bed days the SU had this month	

Dates	
Date of first hospital admission this month, if applicable. Otherwise leave blank	
Date of first hospital discharge this month, if applicable. Otherwise leave blank	
Date of second hospital admission this month, if applicable. Otherwise leave blank	
Date of second hospital discharge this month, if applicable. Otherwise leave blank	

KEYWORKER DATA

6. Adverse Events

Service user ID	
General Information	
Did the SU attempt suicide this month?	
Did the SU express suicidal ideation this month?	
Did the SU die by suicide this month?	
Did the SU die by any other cause this month?	
If the SU died by any other cause than suicide this month, please state the cause or state 'Not applicable'	

7. EIP Service Discharges

Service user ID	
Discharged from EIP Service?	
Discharged from pre-EIP service caseload? (SU was never accepted)	
If yes, date of discharge. Leave blank if not applicable	
Reason for Discharge if Applicable	
Discharged from EIP service as disengaged?	
Discharged from EIP service as transferred?	
Discharged from EIP service due to SU's death?	
Discharged from EIP service due to completing	

programme as planned?	
Further Information	
Discharged from EIP service to CMHT?	
Discharged to GP?	
Discharged to other service?	
If discharged to other service, please state or write 'not applicable'	

STRUCTURED PROGRAMMES

BFT data

Service user ID	
Referral Information	
Date of BFT referral receipt	
Date of initial engagement	
BFT offered, yes or no?	
If no, please explain or state 'Not applicable'	
BFT Sessions	
Number of BFT sessions offered?	
Number of BFT sessions attended?	
Number of BFT sessions DNA'd	
Number of family members engaged in BFT	
BFT Total Contacts	
Number of telephone contacts with SU and family this month	
Number of face-to-face contacts with SU and family this month	
Number of video contacts with SU and family this month	
Role of person completing this form	
Was the SU discharged from BFT this month?	
If yes, please state the date of discharge. Otherwise leave blank	

STRUCTURED PROGRAMMES

IPS data

Service user ID	

Referral Information	
Date of IPS referral	
Date of IPS assessment	
Accepted into BFT treatment?	
If not accepted, please explain or state 'Not applicable;	
Contact information	
How many face-to-face meetings with SU?	
How many telephone contacts with SU this month?	
Number of video contacts with SU this month?	
Number of sessions DNA'd, if applicable	
Employment Information	
Employment status this month	
Has the SU found paid work this month?	
Number of employment offers received this month, if applicable	
Hours in employment per week, if applicable	
Has the SU been discharged from your service this month?	
If yes, please state date of IPS discharge	

STRUCTURED PROGRAMMES

Peer Support Data

Service user ID	
Referral Information	
Date of peer support worker received referral	
Date of initial engagement	
Peer support offered, yes or no?	
If no, please explain	
Contact information	

No of peer support sessions planned and/or offered	
No of peer support sessions attended	
No of peer support sessions DNA'd	
No of telephone contacts with SU this month	
No of face-to-face contacts with SU this month	
No of video contacts with SU this month?	
Discharge Information	
Was the SU discharged from peer support this month?	
If SU was discharged, please state date. If SU was not discharged leave blank	

STRUCTURED PROGRAMMES

Psychological Intervention Data

Service user ID	
Psychological intervention offered to SU?	
Psychological intervention status	
Sessions offered and attended	
Type of psychological intervention offered	
Number of psychological intervention sessions offered?	
Number of psychological intervention sessions attended, if applicable	
Number of psychological intervention sessions DNA'd, if applicable	
Psychological Intervention Dates	
Psychological intervention assessment date, if applicable	
Psychological intervention start date, if applicable. Leave blank if not applicable	
Psychological intervention end date, if applicable. Leave blank if not applicable	
Was the SU discharged from the psych intervention this month?	
If yes, please state date of discharge. If not	

applicable for any reason, leave blank	
Other Information	
Does the SU qualify as a complex case?	
If complex case, referral to psychological intervention lead?	
Number of face-to-face psychological intervention-related contacts with SU this month?	
Number of telephone psychological intervention-related contacts with SU this month?	
Number of video psychological intervention-related contacts with SU this month	
Role of person completing this form	

Appendix 6: Key informant interviews timeline, role and site

Date of interview	Role	Site
February 2020	Keyworker	B
February 2020	Clinical Lead Consultant Psychiatrist	B
June 2020	Family Therapy Lead	C
June 2020	Clinical Lead Consultant Psychiatrist	C
July 2020	Clinical Lead Consultant Psychiatrist	A
July 2020	BFT Lead	A
November 2020	National Clinical Programme representative	D
November 2020	National Lead, Integrated Care.	D
November 2020	ECD for CHO	D
November 2020	National Clinical Advisor	D
November 2020	Head of Mental Health Services in CHO	D
April 2021	Service User	B
April 2021	Service User	B
April 2021	Service User	B
May 2021	Service user	B
July 2021	BFT Lead	B
July 2021	CBTp	B
September 2021	IPS	B
September 2021	Clinical Lead Consultant Psychiatrist	C
September 2021	Service User	C
October 2021	IPS	C
October 2021	Keyworker	A
October 2021	EIP Consultant Psychiatrist	B
October 2021	Keyworker and Occupational Therapist	B
October 2021	HSE Management	B
October 2021	CBTp	C
October 2021	BFT Lead	C
October 2021	Keyworker	C
October 2021	Keyworker	A
October 2021	Clinical Lead and EIP Consultant Psychiatrist	B
October 2021	Service User	C
November 2021	Lead CBTp	A
November 2021	Service User	C
November 2021	Keyworker	A
December 2021	Clinical Lead and EIP Consultant Psychiatrist	A
December 2021	Executive Clinical Director CHO	D
December 2021	Executive Clinical Director CHO	D

January 2022	Service User	C
January 2022	Head of Mental Health Services	D
February 2022	Service User Family Member	C

Appendix 7: Qualitative coding framework

1. **History of EIP**
   a. Nationally/internationally
   b. Locally
   c. Reason for applying to become demonstration site
   d. Comparisons between old model and new MOC (*same or different as 2g?)

2. **Descriptions of EIP**
   a. Referral pathway
   b. Intake assessment
   c. Case load
   d. Prescribing habits
   e. Assessment of symptomatology (e.g., assessor, indicators of assessment, physical assessments)
   f. Physical health of patients
   g. Recovery model
   h. Comparisons between old and new MOC (*same or different as 1d?)
   i. Staffs' knowledge/understanding of the MoC (e.g., degree to which engagement with MoC has occurred)
   j. Support for MoC
   k. Leadership/shared responsibility

3. **Treatment experience**
   a. Staff perceptions of MoC impact on patients and family members
   b. Staff view of patient journey (pre- and within the demonstration sites)
   c. Staffs' expectations/hopes for patients and families
   d. Patient autonomy (e.g., extent patient has autonomy in treatment received)
   e. Patient profile (e.g., psychosis, demographics)
   f. Access/speed of referral

4. **Resources - Staffing**
   a. Role conflict/identity/boundary (e.g. perception of the boundaries of their clinical role, role within the hub and the role in the spokes, benefits and challenges of working/training with other disciplines)
   b. Training (e.g. upskilling)
   c. Capacity
   d. Managing expectations
   e. Challenges
   f. Successes

5. **Human resources - Processes**
   a. Identification of eligible/trained staff
   b. Recruitment ban and locum hiring/permission to advertise/offers of posts and attendant effects on staff
   c. Backfill
   d. Derogation
   e. Budget balancing

6. **Roles specific to EIP**
    a. EIP keyworker
    b. IPS Employment Specialists
    c. CBTp
    d. BFT
    e. Administration

7. **Roles generally within the Team**
    a. Psychiatry
    b. Nursing
    c. Psychology
    d. OT
    e. Roles not funded but in operation (e.g., peer support)

8. **Service Delivery**
    a. Philosophy/ways of working and differences with old ways of working (e.g., early intervention, individualised treatments, holistic, focus on functionality, inter-disciplinary working, continuity of care through key working, working in the patients' homes, specialisation in psychosis, time-intensive treatments, flexibility)
    b. Meetings (e.g., function and frequency)
    c. Physical/virtual locations
    d. Team function

9. **Resources - Funding**
    a. Allocation
    b. Permission to draw down/spend
    c. Business case
    d. Challenges

10. **COVID-19**
    a. Staff redeployment
    b. Changes to provision of treatment/online interactions
    c. Effect on patients

11. **Governance**
    a. Distinction between clinical and organisation governance
    b. Hub and spoke (e.g., function of both/managerial links or hierarchies within and between)
    c. CAMHS
    d. Interactions with other services (e.g., generic CMHTs and specialist services)/colleagues in GAMH/other consultant leads in non-MoC sites/inpatient facilities/communities
    e. Authority/Autonomy (e.g., authority within disciplines/authority within teams, role of consultant – flat or stacked hierarchies)
    f. Decision making and responsibility/management styles
    g. Standard Operating Procedures

12. **Data collection and measurement**
    a. Data collection/systems for service reporting/monitoring
    b. Computer software/hardware

c. Audit, evaluation, research

13. **HSE 'corporate'/central**
    a. NCGAL
    b. Communication
    c. Finance office (both local and national)
    d. Prioritisation of EIP at national level
    e. Prioritisation of mental health within the HSE

14. **Attitudes towards EIP/implementation progress**
    a. Positive
        a.i) Enthusiasm for concept of EIP
        a.ii) Opportunities to specialise/upskill
    b. Negative
        b.i) Erosion of good will
        b.ii) Lowering of expectations in management
        b. iii) Fatigue
        b. iv) Frustration
        b. v) Navigation of administrative system
        b. vi) Uncertainty in job security and effect on staff mental health

15. **Implementation of MoC**
    a. Challenges (e.g., over-treatment due to small numbers of clients, uncertainty)
    b. Facilitators
    c. Failures
    d. Successes
    e. Pace of implementation/timing of implementation (variability in staff recruitment start dates)/implementation without funding
    f. Implementation factors

16. **Sustainability of the EIP service**

17. **Growth/standardisation of EIP service beyond demonstration sites**
    a. Concern (e.g., growth of workload)

18. **Miscellaneous**

Appendix 8: Letter sent outlining emerging issues in implementation

Trinity College Dublin
The University of Dublin

2nd October 2020

Dear Karen

I wanted to provide you with a summary overview of some key findings to date arising from the process evaluation that Trinity is undertaking with regards to the early intervention in psychosis (EIP) programme.

The HSE have dedicated time, energy and a partnership approach to the development of a new Model of Care in EIP based upon the work of the National Working Group and Clinical Advisory Group of the College of Psychiatrists in Ireland. In 2017 the HSE announced and called for three demonstrations sites to be identified which would pilot the programme. In 2019 the HSE funded ourselves in Trinity to conduct a process evaluation of the barriers and facilitators to implementation of the programme with a view that should the evaluation find in favour of the programme that this would then be rolled out nationally as the new standard Model of Care within geographically appropriate areas of the country.

Inherent in this timeline is the implicant understanding that the requisite resources would be released to the demonstrations site teams to test this new model against the previous traditional model of care. However, in two of the three demonstration sites this has not be the case to date. Our process evaluation has been in the field since December 2019.

During this time both myself and my Research Fellow, Dr Nicola O'Connell, have joined the teams in many meetings, alongside formally interviewing both the clinical leads at each site and a team member central to EIP delivery to determine their experiences and views on implementation so far. During the course of these six in-depth interviews, the individuals shared with us their reflections and insights into the challenges and successes to date.

The successes to date have been the deep enthusiasm and belief that this new Model of Care for patients experiencing an early episode of psychosis could be genuinely transformative to their treatment, care and indeed future recovery. Staff expressed a deep commitment to the principle of EIP generally, and to the care and support of services users and their families. Many attempted to act as champions for the principle of EIP across the health service. Unfortunately, staff were forced to contend with a major challenge – the issue of 'human resources and funding'. The application to become a demonstration site, a proposal and business case were required. These required teams to describe how they would organise their governance structures to deliver EIP through the 'hub and spoke' model, as well as how they would reorient their co-working relationships with other mental health teams in their locale. These business cases set out the identification of what new posts would be necessary in order to deliver the EIP Model of Care as set out in a comprehensive document published in June 2019. These include, administrative, technical, clinical and organisational guidelines.

Each interviewee expressed intense and deep frustration at the delays of filling posts due to a toxic combination of recruitment embargos, problems with securing backfill and derogation. This has meant that many of the key posts necessary for the delivery of EIP are still not in place. This situation

is particularly acute in two of the three demonstration sites. Also it was apparent from the interviews that there was a complete lack of clarity on what was required from the Leads during this time.

The Clinical Leads in all three sites are Consultant Psychiatrists. They did not describe to us challenges in terms of the clinical technical delivery of the Model of Care but rather the transformation of their role into that of administrators and financial detectives. While there is no doubt that many senior positions have to develop some competence across these important areas, this should not consume the majority of their time. These are our most senior clinical physicians within our health service, and their training and skillset lie predominantly within clinical practice and direct patient care. To be 2 forced into a position in which they need to redirect their use of time on admin and finance is wasteful not only of talent and skill, but it is an inefficient use of expensive senior clinical time and resources.

One referred to themselves as a 'Detective' who devoted extensive time and resources to understanding where the money allocated to the EIP service had gone. It transpired that the business case presented had been successful in terms of monies identified for posts but on further investigation the Lead was informed that the money had been ring fenced and it would not be released. This derogation has led to immense frustration, a sense of nihilism and powerlessness on behalf of the Clinical Leads. During the course of the interviews I can state that the views expressed in relation to HR processes were testament to burn out. One Lead informed us that they went against the very nature of their personality by getting angry because they felt nobody was listening and nothing was changing. ("You have to just make as much noise as you possibly can. It appears to be and it is hard work, that's not my style but it seems like there's no other way to actually, this wouldn't have happened otherwise, we wouldn't have had the posts advertised by HR I don't think if I hadn't done this. I had to really get angry.")

I too work in a large public sector organisation so I am not naïve to the challenges that such an institution can bring in terms of practical restrictions relating to recruitment, retention and redeployment of staff, especially within the context of years of chronic underinvestment. However, what I have born witness to within the first 10 months of this evaluation is an account of an organisation which has developed processes that work against its own staff. The 'system' both at national and indeed local level have put into place barriers that are outside the control of the Leads to overcome – they are simply insurmountable by individuals. This has resulted in only one of the three demonstration sites being operational and as a consequence has led to a serious drain on the energy, optimism and good will of many dedicated clinicians.

The only reason the three demonstration sites have not ground to a halt is the dedication, creativity and tenacity of teams present and their steadfast belief that the new EIP Model of Care could be truly transformative for patients and their families. The HSE has a window here; act now - and there is a chance to preserve the good will of the teams, to unblock these barriers identified and to conduct a true test of EIP. Fail to act – and the HSE will squander an opportunity to test EIP in Ireland, plus cause reputational damage of the organisation within its own staffs' minds. This is not the spirit in which these teams entered into this process as being demonstration sites. You will lose them Karen forever when they lose faith in the process – and this is fast approaching.

The above alongside the other areas of activity of the evaluation will form the cornerstone of our interim report at the end of year one of the project. However, I felt the need to write to you now in advance of this, such was the depth of feeling but also the seriousness of the situation presented. My motivation in writing to you is singular. I want to raise these issues as a 'red flag'. They

jeopardise the internal integrity of the EIP programme and the ability and capacity of the demonstration sites to genuinely test this model of service delivery.

There is no doubt that COVID-19 has meant that clinical services are under pressure both nationally and locally like never before. However, please do not take away that the above is as a result of COVID. This is simply not the case. These barriers long pre-dated the arrival of COVID-19 to Ireland.

Sincerely,

Catherine Darker

PI, process evaluation of three demonstration sites model of care for early intervention in psychosis
Associate Professor, Health Services Research (interim) Head of Discipline