Protocol for the Process Evaluation of the Genomic Clinical Pathway Initiative

A final report of the results of this study will be uploaded to the National Genomics Education Programme (NGE) website and submitted for peer review publication and conference discussion. Findings will also be distributed via the NGE newsletter and social media accounts.

Protocol Summary

Fundamental educational theory is incorporated into the design of the Clinical Pathway Initiative (CPI). Being a new, educational resource, evaluation is imperative to measure success and implementation.

This process evaluation will provide insight into the benefits and challenges of the CPI, to aid future development.

Using a case study approach to process evaluation, we aim to compare whether the CPI methodology is a usable and acceptable tool for practice.

Validated tools in both quantitative and qualitative data collection are used in this study, complimented by grounded theory analysis and triangulation of data.

Conclusions will contribute to the optimisation of the CPI for workforce development, and inform the longitudinal real work evaluation of CPIs in practice.

Introduction

With the increased use of genomics in routine healthcare, the Clinical Pathway Initiative (CPI)[1], developed by NHS England's NGE, formerly Health Education England's Genomics Education Programme, in collaboration with the Academy of Royal Colleges (AoMRC), aims to facilitate at scale and pace workforce education and training. Through mapping routine clinical or patient pathways where consideration of genomic testing and management is to be embedded, CPI's are designed for service leaders, educators, and individuals, to identify the workforce competencies required for successful delivery. Adopting the CPI method allows for a consistent national approach, sharing of and aligning required competencies and identifying existing or gaps in education and training.

This overview describes the protocol for a process evaluation of the CPI to inform the optimisation of the resource in addition to identifying the successes and challenges.

Subject matter authors are invited to submit a clinical pathway to the NGE team. This could either be a pathway which involves genomic testing, or management following a genetic/genomic diagnosis. Larger pathways can be broken down into smaller pathways, (for example pre-test and post-test pathways).

A CPI package has been developed to support authors through the design process [(2)]. The lead author is encouraged to engage a working group for the development of their CPI, which should include those familiar with the pathway and its delivery. The competencies should demonstrate the knowledge, skills or attitudes needed to deliver each step and could be generic to practice, pathway specific, or step specific to the touch points within the pathway.

Each completed pathway is ratified by the NHS England joint workforce steering group and the AoMRC's Genomics Professionals Partnerships Group (GPPG) [(3)] before being published online and nationally disseminated.

Process evaluations provide insight into not only the outcomes of a complex intervention, but also how these effects took place, and why. This is particularly important when the intervention may be implemented in variable settings, where it may be difficult to determine whether any measured outcomes are the result of the intervention itself (CPI framework), or a difference in the way in which subject matter is delivered (i.e. the methods by which the CPI is implemented)[(4, 5)]. Given that CPIs are specifically designed as a high-level competency framework, to be adopted and modified to suit local need, we recognise that fundamental genomic principles and practices need to be preserved, regardless of any differences in delivery. A process evaluation will effectively consider whether the suggested method to create a CPI is adequate to meet the aims of the project, in addition to observing any other unexpected factors which may promote or reduce effectiveness of the CPI.

Process Evaluation Methods and Analysis

Grant et al (2020) proposed that case studies are one of the best research designs to underpin process evaluations, given their ability to capture complexity and context [(6)]. With this in mind, we developed a logic model. The UK Medical Research Council (MRC) recommends the development of a logic model to aid clarity of intervention processes and underpinning theory that is thought to influence change. Logic models are also specifically encouraged to ensure best practice in genomic education and evaluation[(7)], and have been proven to be useful when multiple people are planning and executing a programme[(8)]. Our logic model is shown in figure 1. Understanding the dynamic complexity between the change process and delivery system and setting, we plan to document both intended and unintended outcomes to avoid any oversimplification of conclusions.

Aims and Objectives

The overall aim of this process evaluation is to answer the following question:

Is the CPI methodology an acceptable and useful framework to outline genomic competencies in mainstream genomic clinical pathways?

The objectives of this process evaluation are:

• To quantitatively assess usability of the CPI in a) design (determined by the author) and b) use (determined by the end user).

• To qualitatively assess the experience of the author when developing their CPI.

• To qualitatively assess the experience of the CPI end-user when considering application for their local need.

For the process evaluation the team have decided to focus on the CPI for Familial Hypercholesterolaemia (FH). This CPI was chosen to be a priority due to it being one of the national transformation projects outlined by the NHS long term plan[9] and was one of the first CPIs to be published for national use, therefore providing an exemplar for future CPI development.

Data Collection and Analysis

This process evaluation will be conducted using a mixed methods approach.

Quantitative data will be gained using a modified System Usability Scale (SUS) [10]. The SUS is used to provide an assessment of overall usability as defined by the International Organisation for Standardisation (IOS). The scope of the IOS extends to systems and services, including:

• Effectiveness: can users successfully achieve their objectives.

• Efficiency: how much effort and resource are expended in achieving those objectives.

• Satisfaction: Was the experience satisfactory.

By definition, service is a “means of delivering value…by facilitating results that the (user) wants to achieve” [24]. Although originally designed for digital evaluation, we argue that the SUS is a validated, reproducible scale that can be adapted for evaluation of the CPI, given that our authors and end users approach, navigate and respond to the CPI project in the same way that they would with any digital resource, and that evaluative goals in this project are aligned. An SUS score of 68 is considered above average. A comparison will be made to determine usability during the CPI writing process, and that experienced by end users.

Additional scores from questionnaire rating scales will also supplement quantitative data.

Qualitative data will be gained through interview and a questionnaire. Select questions from the Consolidated Framework for Implementation Research Interview Guide Tool have been adapted from a menu of known constructs associated with effective implementation[11] .Qualitative data will undergo conductive analysis using the "Framework Method" [12], in which similarities and differences are identified within the dataset, relationships generated and themes concluded. Themes will be initially created through "unrestricted" coding, and later refined, by two members of the evaluation team. Thematic categories will be developed until data saturation has been achieved, or until all qualitative data had been utilised. Content of primary categories will then be reviewed, and relationships grouped together to create a working analytical framework. Imperatively, each participant remains linked to other aspects of their anecdotal record so that context is not lost. This approach has been commonly utilised in semi-structured interviews[13].

The process evaluation will encompass 2 key stages of the FH CPI implementation:

1) FH CPI development:

The evaluators aim to seek feedback from the FH CPI author and key stakeholders involved in the development. This will include their quantitative scores using an adjusted SUS to consider the ease of the CPI writing process.

For qualitative feedback, select interview questions will help the evaluating team to understand who was involved in the FH authoring process and their roles, how the FH authors planned and developed their CPI, perceived confidence (or lack of) in the tool, and other constructs aligned to successful implementation of the framework. A sample number of 5 individuals will be invited for interview by the evaluating team and/or the FH CPI lead author. This number was recommended by the CPI lead author as the number of stakeholders actively involved in the CPI writing process.

A brief questionnaire will also be distributed to additional authors and reviewers (those not actively involved in authoring) of the FH CPI to capture profession, geographical data, and to capture surface acceptability, usability, and motivations of use. This data, along with qualitative themes and quantitative scores in each step, will supplement triangulation of results to aid reliability [14].

2) End Users (Intended service leads/educational providers):

Given that the FH CPI is not yet uploaded onto the NGE website at the time of this process evaluation, known users of CPI will be invited by the author and evaluation team to participate in the study. Select interview questions will assess the acceptability and usability of the CPI for their workforce need. A sample size of up to

5 end users is intended, with the acknowledgement that a smaller number may be necessary due to the limited current distribution of the CPI.

Ethics and Dissemination

Ethical review and approval are not required for service development and evaluation, in accordance with the local legislation and institutional requirements. Results of this study will be available on the NGE website, and be submitted for peer reviewed publication and discussion at conferences. This process evaluation will be reported back to the CPI lead in the NGE team, to influence adaptation of the CPI framework where necessary.

Conclusion

Our approach to process evaluation reflects recommendations from the MRC, and best practice in genomic education and evaluation, for the design and reporting of such studies. The evaluators have outlined the proposed design and analysis to compare CPI usability and experience by authors and CPI end users. Such information will allow further development of the CPI, with the ambition to optimise utility and effectiveness for future practice.

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