BMJ Open

An evaluation protocol of the implementation of a learning healthcare system in clinical practice: the Connected Health Cities programme in the North of England

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025484
Article Type:	Protocol
Date Submitted by the Author:	03-Aug-2018
Complete List of Authors:	Steels, Stephanie; University of Manchester, School of Health Sciences van Staa, Tjeerd; University of Manchester, School of Health Sciences; Utrecht University
Keywords:	Evaluation, learning healthcare system, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

An evaluation protocol of the implementation of a learning healthcare system in clinical practice: the Connected Health Cities programme in the North of England

Stephanie Steels[1], Tjeerd Pieter van Staa[1,2]

[1]Health e-Research Centre, Farr Institute, School of Health Sciences, Faculty of Biology, Medicine and Health, the University of Manchester, Oxford Road, Manchester, M13 9PL, UK

[2]Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Utrecht, The Netherlands

Corresponding author: Stephanie.steels@manchester.ac.uk

Word count (article): 4132

Number of tables: 3

Number of figures: 2

Abstract

Introduction: The 'learning healthcare system' (LHS) has been proposed to deliver better outcomes for patients and communities by analysing routinely captured health information and feeding back results to clinical staff. This approach is piloted in the Connected Health Cities (CHC) programme in four regions in the North of England. This article describes the protocol of the evaluation of this programme.

Methods and analysis: In designing this evaluation, we have had to take a pragmatic approach to ensure the feasibility of completing the work within one year. Furthermore, we have designed the evaluation in such a way as to be able to capture differences in how each of the CHC regions uses a variety of methods to create their own learning healthcare system. A mixed methods approach has been adopted for this evaluation due the scale and complexities of the pilot study. A documentary review will identify how CHC pilot study deliverables were operationalised. To gain a broad understanding of CHC staff experiences, an online survey will be offered to all staff to complete. Semi-structured interviews with key programme staff will be used to gain a deeper understanding of key achievements, as well as how challenges have been overcome or managed. Our data analysis utilises a 'theory of change' approach where we will triangulate the documentary review, survey and interview data. A thematic analysis using our logic model as a framework will also be used to assess progress against the CHC programme outcomes and to identify recommendations to support future programme decision-making.

Ethics and Dissemination: Ethical approval was granted by The University of Manchester Ethics Committee on the 24th May 2018 (Application reference: 2018-3923-6106). The results will be actively disseminated through peer-reviewed journals, conference presentations, social media, the internet and various stakeholder/patient and public engagement activities.

Key words: Evaluation; protocol; learning healthcare system;

Article Summary

Strengths and limitations

- This study will represent the largest evaluation ever conducted to examine the barriers, facilitators and lessons learned for creating and piloting learning healthcare systems in four regions in the North of England.

- The use of a mixed methods approach will mitigate the risk of not having baseline outcome measures at the start of the pilot study period, as well as the risk of sampling, recruitment and participation bias.

- The use of purposive sample, while based on access to the subject group most appropriate for taking part in this study, will elevate the risk of self-selection bias.

Introduction

The U.K is experiencing rapid changes to its population: an ageing population, increased life expectancy and changing patterns of chronic diseases have led to an increased demand in health and social care services (1). At the same time, the amount of health data being digitally collected and stored is vast and expanding rapidly (2), whilst the technology and analytic tools needed to analyse large datasets has also been developed (3). Therefore, there is the potential for utilising routinely collected health data to drive forward improvements in health outcomes (4–6).

The Connected Health Cities (CHC) (https://www.connectedhealthcities.org/) programme is a U.K government-funded programme that aims to create learning healthcare systems across the North of England. A learning healthcare system (LHS) is defined by the Institute of Medicine (IOM) (7) as a system which:

"science, informatics, incentives, and culture are aligned for continuous improvement and innovation […] with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."

While each learning healthcare system is unique, Friedman (8) describes a common cycle process that can be found in all learning healthcare systems. This is characterised by five steps divided between an afferent and efferent side (8):

Afferent side:

1. Assemble the data from various sources
2. Use a range of analysis on the data
3. Interpret the findings

Efferent side:

4. Feed the findings back into the system in many formats
5. Change practice

Building on this notion of a learning healthcare system, a Connected Health City (CHC) is a civic partnership in which health and care services, science, technology and work culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as a by-product of delivering care. At the centre of a CHC is a secure information system called an 'Ark' which will provide a trustworthy, regional combinatorial

innovation centre for health and social care data analysis, providing timely and actionable information for the care of the population it serves (see Figure 1).

Design of the Connected Health Cities Programme

The Connected Health Cities (CHC) programme is a Northern Health Science Alliance (NHSA) led programme delivered by a consortium of academics and NHS organisations, including NHS Trusts and Clinical Commissioning Groups (CCGs), across the North of England. It consists of two phases of work: there is the overall CHC programme of work that seeks to create LHS across the North of England. This programme has seven core deliverables (Table 1) that will be delivered over a longer period of time (subject to funding) to assist in the delivery of the U.K government's commitment to reducing healthcare need, reducing inequalities and constructing the 'Northern Powerhouse'. However, within the CHC programme of work, a 'foundation phase' has been funded in which 'pilot' CHCs will be established in four regions: Greater Manchester, Yorkshire, North West Coast and North East and North Cumbria.

Table 1: The overall Connected Health City (CHC) Programme outcomes

Deliverable	Description of deliverable
Deliverable 1	The establishment of data sharing strategies and data sharing agreements for each CHC region.
Deliverable 2	The establishment and delivery of governance arrangement for the sharing and usage of data for each CHC region, across the North and the U.K.
Deliverable 3	The optimisation of Ark workforce arrangements, including the identification of long term CPD requirements the establishment of new skill bases.
Deliverable 4	The creation of the Ark as an analytical platform for investigating linked data.
Deliverable 5	The analysis of eight care pathways, identification of any pathway variations and proposals for any improvements if possible.
Deliverable 6	The creation and implementation of frameworks for potential integration with R&D partners and the future rising of Foreign Direct Investment.
Deliverable 7	The production of a CHC business model suitable for scaling across the North and sustainable for delivery in the NHS.

Each of the four regions has been tasked with establishing a LHS, using patient data to create and test innovative solutions for a variety of clinical pathways. This also includes the development of a central development hub to oversee the overall programme of work in relation to seven pilot study outcomes to be delivered (

Table 2). It is this 'foundation phase' (referred to as the CHC pilot study in this protocol) that is being evaluated. The CHC pilot study outcomes are linked to developing the informatics infrastructure to provide data analytical capabilities, as well as public engagement and liaison with governing bodies to define an appropriate governance and ethical framework and establish partnerships with industry.

The CHC pilot study has over sixteen care pathways in the process of delivery. However, whilst the number of pathways differs for each region, the CHC pilot study was tasked with developing at least two pathways per region. As a result, this evaluation will focus on eight care pathways as per the pilot study outlines (Table 2). Table 3 shows the four CHC regions in relation to the eight care pathways with a brief overview of the work undertaken for each pathway. The eight pathways included in this evaluation were selected to showcase the types of data that can be analysed to inform the pathways of a range of health issues.

Table 2: Deliverables for the Connected Health City (CHC) pilot study

Number	Name of deliverable	Description of deliverable
Deliverable 1	Secure data facility	The provision of a secure data facility with at least GP, hospital admission/discharge, hospital laboratory and some social care data integrated and searchable at patient-level.
Deliverable 2	Platform for analysing care pathways	Must be able to feedback variations from guideline-indicated care to practitioners, service managers and guideline developers.
Deliverable 3	Patient and Public Network	A network of patient and public representatives advancing large-scale uses of care data.
Deliverable 4	Skilled workforce	Training in informatics for users of the platform.
Deliverable 5	Care pathways using data	Eight care pathways that optimise data.
Deliverable 6	Process for industry co-development	A process for co-developing care pathway tools with industry while maintaining patient privacy.
Deliverable 7	Platform for researching variations in care	A platform for researching variations in care more fully than at present, including (antimicrobial) prescribing vs. diagnosis, across heterogeneous populations synchronously.

Table 3: Description of care pathways being evaluated by region

Connected Health City (CHC) Region	Title of Care Pathway	Objectives of Care Pathway	Description of Care Pathway
Connected Yorkshire	Supporting community care and reducing demand on A&E services	• To link de-identified routine NHS data to describe a detailed profile of patient demand across both prehospital, primary care and hospital emergency and urgent care settings in Yorkshire.	To collect routine NHS data from a number of emergency and urgent care (EUC) providers and link the data to provide a coherent picture of EUC demand.
	Safer Prescribing for Frailty	• To reduce inappropriate polypharmacy for people with frailty.	To work with GPs to change behaviours related to deprescribing for older people with moderate or severe frailty as identified by electronic Frailty Index scores. This includes developing interventions using which apply evidenced tools to support deprescribing.
Greater Manchester	BRIT – Using data to tackle antibiotic resistance	• To provide the NHS and clinical care teams with better information on what is happening and who is getting antibiotics. • To assist in determining whether the use of antibiotics is reasonable given local resistance patterns to antibiotics	Analysis of patient records from GPs for effectiveness of antibiotic prescribing in general practices. This includes the development of a DataLab feeding back advanced analytics to clinical staff and policy makers and the evaluation of interventions to optimise prescribing.
	Using technology and data to improve the diagnosis and treatment of stroke	• Improve the recognition of stroke by paramedics to maximise the proportion of acute stroke patients taken directly to a specialist stroke centre for timely expert care and minimising the number of non-stroke patients entering the stroke pathway. • Provide timely and focused referral to neurosurgery for patients in Greater Manchester with stroke caused by a brain haemorrhage. • Ensure that all patients get all the right treatments that they need to reduce the risk of another stroke when they are discharged from hospital.	To improve stroke recognition by paramedics by linking ambulance data to data at Salford Royal; using primary and secondary care data to create a large cohort of stroke and TIA patients for creating a predictive model of patients who are at high risk of stroke; and using acute trust data to identify predictive factors of early deterioration and death.
North East North Cumbria	Predictive modelling for unplanned care	• To develop predictive modelling tools for unplanned care forecasting to support demand management and service planning in relevant health and social care services.	To produce statistical models that can be used by health/local authority/other analytics teams to produce daily forecasts up to six months in advance with the pertinent associated uncertainties and variations in urgent and emergency care.
	SILVER: Smart Interventions for Local Vulnerable Families	• To develop data sharing agreements to allow the linking of existing health data across multiple health agencies via one platform that provides recommendations to key workers.	To link data across multiple agencies including health (physical and mental), social care, criminal justice, housing and education to develop a more complete Learning Health System.
North West Coast	Development of a learning system for alcohol	• To be able to inform health professionals about local clinical care. • To define best care or treatments, implement and demonstrate benefits.	Improving the way information is collected, analysed and shared between agencies and service users to bring opportunities for news was to respond collectively.
	Development of a learning system for unplanned care	• To improve how data is used to enhance patient care admitted to hospital for emergency care.	Linking NHS data with social services data to improve the care pathway for patients with COPD and epilepsy.

This protocol describes the design of the overall evaluation of CHC programme which aims to answer the following objectives:

1. To evaluate progress and early impact in each of the eight care pathways against the key performance indicators, including identifying factors that helped or hindered progress and achievement of the care pathways.
2. To assess the level of input required from staff, resources and approvals (such as information governance) to create each regional Ark and care pathway.
3. To identify variations in the use of the Ark within two care pathways for each region.
4. To consider the wider applications of the Ark in other care pathways.

The outline of this paper is as follows: first, we describe the analytical framework that underpins the evaluation, discussing the formulation of a logic model and measurable programme outcomes. Next, we discuss the principles guiding the evaluation and the issues that needed to be considered in formulating the research design. Next, we present a summary of the three data collection methodologies to be used in our evaluation: the documentary review, questionnaire for all CHC staff and a semi-structured interview. This is followed by a description of how we will analysis the data collected. Finally, our discussion summarises the key issues and approaches used in our evaluation.

Methods

Analytical framework

The Centre for Disease Control (9) framework for evaluation mentions 'theory of change' and 'logic models' as useful tools to help describe a programme or policy (9,10). The theory of change approach involves setting out the series of outcomes that are expected to unfold as a result of the various components of a programme or intervention (10,11). It follows a logic model which can be visualised as a sequential 'if-then' process (11). This can be used as a basis for planning an evaluation strategy as it allows for the identification of the various steps that need to be fulfilled before one can expect to see the desired outcome from a programme or policy (12,13).

This evaluation will use theory of change as a guiding principle rather than a methodology due to the scale of the CHC pilot study and the different approaches used for each care pathway. Borrowing from Ling et al. (14), the theory of change utilised for this evaluation have five precepts. First, by using a theory of change approach, there is equal focus on the outcomes of the key deliverables and care pathways, as well as the processes involved. Second, the researcher works with all staff

involved in the CHC programme to understand and modify the theory of change. Third, utilising theory of change allows the researcher to construct and reconstruct the sequence of events that connect the inputs, outputs, outcomes and impacts. Fourth, initial theories of change may be modified according to new information emerging through the data collection and analysis processes. This allows the researcher to utilise a more iterative process to reconstruct and identify other factors that may have influenced the programme outcomes, including any unintended outputs.

Logic model

Using theory of change, the evaluation has developed a logic model to assist in assessing both the overall CHC programme and each of the eight care pathways against the programme outcomes (**Error! Reference source not found.**). Logic modelling is a tool that can be useful in the development of monitoring and evaluation plans, identifying short, medium and long-term outcomes that are linked to key activities of a programme (15). Throughout the first month of the evaluation, meetings were held with CHC staff from each of the different regions to gain an overview of the work being completed in relation to the CHC programme deliverables. Information from these meetings was combined with a retrospective documentary review to formulate the logic model featuring input, output, outcome and impact stages. To facilitate the measuring of each outcome both numerically and descriptively, a set of indicators was developed.

Methodology

An evaluation can be described as a systematic process to assess the successes of a programme or intervention and the lessons learned (12,16). It is based on evaluating a set of activities and formulating a judgement based on the evidence collected to increase the knowledge of programme or intervention for learning; informing the decision-making process for future programmes or interventions; and being accountable to stakeholders and donors (16).

This evaluation forms a distinct strand within the overall CHC programme of work, helping to facilitate the successful delivery of the regional Arks and each care pathway, rather than a separate study focussed solely on the scientific understanding of learning healthcare systems. Furthermore, it is important that this evaluation generates evidence to support decision-making within the CHC programme in the future, as well as evidence that assesses progress towards the pilot study outcomes.

In addition to the central CHC Hub that provides support to the overall programme, each of the CHC regions uses a variety of methods to create their own learning healthcare system. Furthermore, each of the eight care pathways within the CHC programme has a different focus with a variety of objectives. Other issues that needed to be taken into account was that at the start of the evaluation, the care pathways were at different points of delivery, with some still in the development stages and others nearing completion. Therefore, the data collection method needed to allow for these differences.

In formulating the research design of the evaluation, the following considerations were also adopted: first, the consideration of research ethics to ensure the informed consent and safety of all research participants and the management of confidential data. Second, it was important to ensure that all CHC staff from all regions had an opportunity to provide feedback through the evaluation. Third, to reduce potential interview and survey fatigue, a sufficiently in-depth methodology to meet the evaluation objectives was needed, but light touch where possible to avoid placing an undue burden on participants.

As a result, a mixed methods approach was deemed the most suitable approach to this evaluation. Utilising a mixed methods approach allows the evaluation to systematically combine and synthesise evidence from the eight care pathways, including a deeper investigation of each care pathway in order to gain a comprehensive understanding of the resources, processes, barriers and facilitators. Furthermore, because baseline data did not exist for all the pathways, utilising a range of data collection methods would ensure triangulation in order to increase the credibility and validity of the results. The evaluation will centre on three approaches to data collection: a documentary review, semi-structured interviews and an online survey. Ethical approval was granted by The University of Manchester Ethics Committee on the 24th May 2018 (Application reference: 2018-3923-6106).

Patient and Public Involvement

Patients and members of the public were not involved in this evaluation. A separate evaluation study is taking place that is focused on patient and public involvement in the wider CHC programme.

Documentary review

A documentary review will be undertaken throughout the duration of the evaluation period. In doing so, we will be able to review pre-existing and new documentation to determine any differences

between the proposed CHC pilot study and the actual programme of implementation. In doing so, the documentary review can highlight issues that can be missed through other means of data collection (17) and will assist in the formulation of semi-structured interview topic guides and the online survey.

To evaluate progress towards the CHC programme deliverables, documents from different time points in the project will be used to identify the structures and procedures used to deliver each care pathway, as well as the overall CHC programme. This will include monthly project reports, meeting documentation, internal evaluation reports, marketing materials and other project reports.

Online survey for CHC staff

As there are 210 members off staff working on the CHC programme, split across four regions in the North of England, it was felt that conducting an online survey that will be offered to all CHC staff to complete, was a practical approach to ensure all CHC staff had an opportunity to contribute to the evaluation. This is to gain a broad understanding of CHC staff experiences across the different pathways in relation to the pilot study outcomes. The questions were developed using the logic model and CHC pilot study outcomes as a guide to ensure questions were relevant to the evaluation. The questionnaire will include the following sections:

- Approaches to creating regional learning health systems and pathways
- Challenges experienced and/or managed
- Unintended outcomes from being involved on the CHC programme
- Recommendations for facilitating future learning health systems and pathways

The questionnaire has substantial sections for free text to all staff to describe their experiences in the CHC programme and care pathways in more detail. These sections will be transcribed for qualitative data analysis. A link to the questionnaire will be emailed to all 210 staff across the CHC programme. In addition to the online survey, staff can also request a paper-based copy of the survey, or to complete the survey over the telephone. Data from responses will be exported from the survey handler and securely stored in Microsoft Excel for initial data cleaning and then to SPSS for data analysis.

Semi-structured interviews

We will conduct semi-structured interviews with key CHC staff from all four regions, as well as the central CHC hub. The aim of the interview is to develop a clearer understanding of staff experiences in the design and delivery of the CHC programme and pathways. A topic guide was developed using the logic model and initial results from the documentary review as a framework in which to formulate interview questions. Key areas that would be explored during the interview include:

- The Learning Healthcare system
- CHC programme deliverables
- Using data in care pathways
- Patient and public involvement
- Creating a skilled workforce
- Working with industry

Using a semi-structured interview methodology would allow the researchers to explore emerging issues during the interview (18). The interviews will take place at the place of work of the participant. All interviews will be audiotaped and transcribed verbatim. Transcribed data will be anonymised to remove any traceable information that could identify the respondent to the transcript (e.g. names of people or place names). Each respondent will be assigned a project code and this will be used in place of real names on all collected data. The 'project key code' linking project codes to identifiable respondent data will be kept electronically on a password protected secure server. Digital recordings of interviews will be stored on a password protected secure server, while hard copies of (anonymised) transcripts and field notes will be kept in a locked filing cabinet, in a locked room.

Analysis

Our data analysis utilises a 'theory of change' approach where we will triangulate the documentary review, survey and interview data to quantify progress towards the CHC programme outcomes. This is because no baseline data was collected for the CHC programme. Even though it is not possible to determine which pathways will provide data that will allow for a more sophisticated data analysis, where the data allows we will aim to measure cost reduction and improvements in patient outcomes for each pathway. We will also create a series of case studies to assist in the explanation of key processes and outcomes.

Our analysis strategy will also use an iterative process, whereby data collection and data analysis will be conducted concurrently. For data collected through our documentary review and interviews, a thematic analysis using our logic model as a framework will also be used to assess progress against the CHC programme outcomes and to identify recommendations to support future programme decision-making. Descriptive analysis of the online survey data will also be used to inform actionable recommendations, which in turn will aid the future development and refinement of the CHC programme and care pathways.

Discussion

Through this evaluation, a range of evidence will be collated and produced to support a series of evaluation judgements aimed at assessing the CHC programme outcomes. This will include a documentary review to identify how CHC programme deliverables were operationalised; an online survey to gain a broad understanding of CHC staff experiences in delivering each pathway; and semi-structured interviews with key programme staff will be used to gain a deeper understanding of key achievements and challenges. Using a three-pronged approach ensures triangulation and increases the validity, reliability and credibility of the results.

In planning this evaluation, we have utilised theory of change to guide the development of the data collection methods. Using a logic model, we have been able to identify and set out our short, medium and long-term outcomes that are linked to the CHC programme deliverables. We do not expect to be able to measure preciously all outcomes due the lack of baseline data, the different pathways in the CHC programme and the different stages of delivery of each pathway. However, the data collected will allow us to assess progress made towards the CHC programme deliverables, as well as to determine the types of contributions made and challenges faced for each region in achieving these outcomes.

We have had to take a pragmatic approach to ensure the feasibility of completing the work within one year. Focusing the evaluation on eight care pathways allows for a systematic approach that will give an overview of the key achievements and challenges for each region, as well as the CHC programme overall. In addition, a key output of this evaluation was to assess progress towards the CHC programme deliverables. As a result of this, some theoretical propositions may be underexplored. However, as each pathway will be independently evaluated we are satisfied that this risk has been managed. Thus, in focusing the evaluation on the overall CHC programme outcomes, the evaluation will be grounded in what the programme set out to do. This has the benefit of

producing findings and recommendations that can be used in present and future CHC programme decision-making.

Ethics and dissemination

The study will be conducted in accordance with The University of Manchester guidance on ethical conduct in research, as well as the approved study protocol. Ethical approval was granted by The University of Manchester Ethics Committee on the 24th May 2018 (Application reference: 2018-3923-6106). All interview participants will receive a participant information sheet with the invitation to interview. All interview participants will complete a consent form prior to participating in this study. This includes consenting to the use of their anonymised interview data in any publications. A detailed participant information sheet will be sent to all participants with the survey invitation. Voluntary completion of the survey implies informed consent to participate. No personally identifiable information will be collected in order to maintain the anonymity of the survey responder.

The findings of the survey will be communicated using a comprehensive dissemination strategy. The strategy will use various forms of media to reach out to a diverse range of stakeholder groups and individuals, at the local, national and international level; this will include the use of academic media (e.g peer-reviewed journal articles, national and international conference presentations), social media (e.g. Twitter), the internet (e.g. links to evaluation on Connected Health Cities programme website), and stakeholder and patient and public engagement activities. All CHC programme staff will be invited to an evaluation event where the results will be presented.

Declarations

Availability of data and materials:

This is study protocol. We will publish the results of the evaluation once this has been completed.

Competing interests:

There are no conflicts of interest declared.

Funding:

This study was part of Connected Health Cities which is a Northern Health Science Alliance (NHSA) led programme. It is funded by the U.K Department of Health and Social Care (DHSC) and delivered by a consortium of academic and NHS organisations across the North of England. NHSA and DHSC have no input into the evaluation to ensure this remains an independent piece of work.

Author Contributions:

SS developed the evaluation methodology and will carry out the data collection, transcribing and data analysis. SS wrote the manuscript with support from TvS. TvS contributed to the design of the evaluation methodology and supervised the evaluation implementation.

Acknowledgments

This study was part of Connected Health Cities which is a Northern Health Science Alliance (NHSA) led programme. It is funded by the U.K Department of Health and Social Care and delivered by a consortium of academic and NHS organisations across the north of England. The work uses data provided by patients and collected by the NHS as part of their care and support. The views expressed are those of the author(s) and not necessarily those of the NHSA, NHS or the Department of Health and Social Care. There are no conflicts of interest declared.

References

1. Chambers E, Farquharson C, Gumbley B, Hughes H, Huxtable B, Jones C, et al. A new settlement for health and social care. 2014 [cited 2018 Mar 7]; Available from: https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/Commission Final interactive.pdf

2. Murdoch TB, Detsky AS. The Inevitable Application of Big Data to Health Care. JAMA [Internet]. 2013 Apr 3 [cited 2018 Mar 7];309(13):1351. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2013.393

3. Sacristán JA, Dilla T. No big data without small data: learning health care systems begin and end with the individual patient. J Eval Clin Pract [Internet]. 2015 Dec 1 [cited 2018 Mar 7];21(6):1014–7. Available from: http://doi.wiley.com/10.1111/jep.12350

4. Roski J, Bo-Linn GW, Andrews TA. Creating Value In Health Care Through Big Data: Opportunities And Policy Implications. Health Aff [Internet]. 2014 Jul 1 [cited 2018 Mar 7];33(7):1115–22. Available from: http://content.healthaffairs.org/cgi/doi/10.1377/hlthaff.2014.0147

5. Schneeweiss S. Learning from Big Health Care Data. N Engl J Med [Internet]. 2014 Jun 5 [cited 2018 Mar 7];370(23):2161–3. Available from: http://www.nejm.org/doi/10.1056/NEJMp1401111

6. Guha S, Kumar S. Emergence of Big Data Research in Operations Management, Information Systems, and Healthcare: Past Contributions and Future Roadmap. Prod Oper Manag [Internet]. 2018 Jan 30 [cited 2018 Mar 7]; Available from: http://doi.wiley.com/10.1111/poms.12833

7. Institute of M. Integrating Research and Practice [Internet]. Washington, D.C.: National Academies Press; 2015 [cited 2018 Mar 8]. Available from: http://www.nap.edu/catalog/18945

8. Friedman C, Wong A, Blumenthal D. Achieving a Nationwide Learning Health System. pdfs.semanticscholar.org [Internet]. 2010 [cited 2018 Mar 7]; Available from: https://pdfs.semanticscholar.org/80bf/b6259fc7f89bd19742b8a2d6bb5a7ae4a96f.pdf

9. CDC. CDC EVALUATION WORKING GROUP Summary of the Framework for Program Evaluation. 1999 [cited 2018 Mar 8]; Available from: http://www.cdc.gov/eval

10. CDC. Logic Models - Program Evaluation - CDC [Internet]. 2018 [cited 2018 Mar 8]. Available from: https://www.cdc.gov/eval/logicmodels/index.htm

11. De Silva MJ, Breuer E, Lee L, Asher L, Chowdhary N, Lund C, et al. Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. Trials [Internet]. 2014 Dec 5 [cited 2018 Feb 21];15(1):267. Available from:

http://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-15-267

12. Blamey A, Mackenzie M. Theories of Change and Realistic Evaluation. Evaluation [Internet]. 2007 Oct 24 [cited 2018 Feb 7];13(4):439–55. Available from: http://journals.sagepub.com/doi/10.1177/1356389007082129

13. Moore G, Audrey S, Barker M, Bond L, Bmj CB-, 2015 U. Process evaluation of complex interventions: Medical Research Council guidance. bmj.com [Internet]. 2015 [cited 2018 Feb 21]; Available from: http://www.bmj.com/content/350/bmj.h1258

14. Ling T, Bardsley M, Adams J, Lewis R, Roland M. Evaluation of UK Integrated Care Pilots: research protocol. Int J Integr Care [Internet]. 2010 Sep 27 [cited 2018 Feb 7];10(3). Available from: http://www.ijic.org/article/10.5334/ijic.513/

15. Funnell S, Rogers P. Purposeful program theory: Effective use of theories of change and logic models [Internet]. 2011 [cited 2018 Mar 8]. Available from: https://books.google.co.uk/books?hl=en&lr=&id=A9Iid1tcGwgC&oi=fnd&pg=PT10&dq=theories+of+change+in+evaluation&ots=ZrO0qoALoT&sig=SVWBdUIDQRHZtQvTw0_U4Ho-ER8

16. Vedung E. Public policy and program evaluation [Internet]. 2017 [cited 2018 Mar 9]. Available from: https://books.google.co.uk/books?hl=en&lr=&id=Kx0uDwAAQBAJ&oi=fnd&pg=PT17&dq=evaluation+defined&ots=GSOIpvMXnB&sig=S4B8P6LnIQplFzzUy9ZbG8RfLuQ

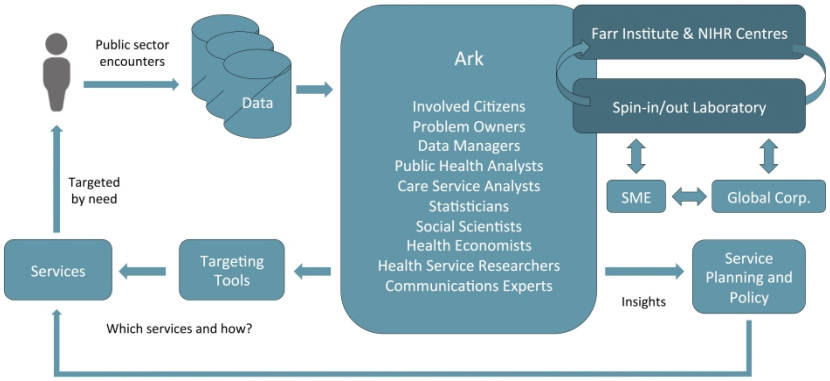
17. Creswell J, Creswell J. Research design: Qualitative, quantitative, and mixed methods approaches. 2017;

18. Flick U. An introduction to qualitative research [Internet]. 2014 [cited 2018 Feb 19]. Available from: https://books.google.co.uk/books?hl=en&lr=&id=HB-VAgAAQBAJ&oi=fnd&pg=PP1&ots=kDp20OmXXl&sig=Ksfl5hN6o4FEGN5vXI-j-C_ClEw

Figure Legends:

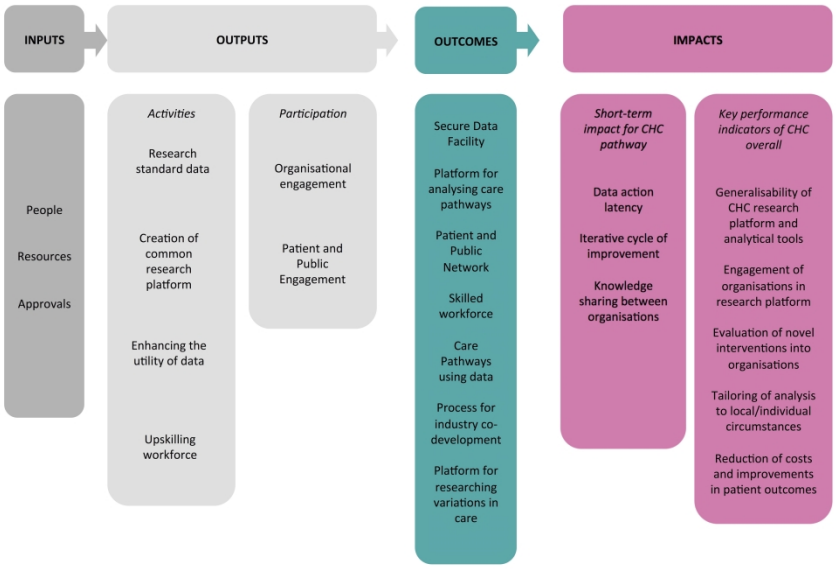
Figure 1: Connected Health City: Ark-enhanced Information Flows

Figure 2: Logic Model for the Connected Cities (CHC) Pilot Study Evaluation



Connected Health City: Ark-enhanced Information Flows

2500x1766mm (72 x 72 DPI)



Logic Model for the Connected Cities (CHC) Pilot Study Evaluation

2500x1766mm (72 x 72 DPI)

BMJ Open

An evaluation protocol of the implementation of a learning healthcare system in clinical practice: the Connected Health Cities programme in the North of England

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025484.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Dec-2018
Complete List of Authors:	Steels, Stephanie; University of Manchester, School of Health Sciences van Staa, Tjeerd; University of Manchester, School of Health Sciences; Utrecht University
Primary Subject Heading:	Health informatics
Secondary Subject Heading:	Evidence based practice, Health services research, Research methods
Keywords:	Evaluation, learning healthcare system, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

An evaluation protocol of the implementation of a learning healthcare system in clinical practice: the Connected Health Cities programme in the North of England

Stephanie Steels[1], Tjeerd Pieter van Staa[1,2]

[1]Health e-Research Centre, Farr Institute, School of Health Sciences, Faculty of Biology, Medicine and Health, the University of Manchester, Oxford Road, Manchester, M13 9PL, UK2

[2]Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Utrecht, the Netherlands

Corresponding author: Stephanie.steels@manchester.ac.uk

Word count (article): 4889

Number of tables: 2

Number of figures: 2

Abstract

Introduction: The 'learning healthcare system' (LHS) has been proposed to deliver better outcomes for patients and communities by analysing routinely captured health information and feeding back results to clinical staff. This approach is piloted in the Connected Health Cities (CHC) programme in four regions in the North of England. This article describes the protocol of the evaluation of this programme.

Methods and analysis: In designing this evaluation, we have had to take a pragmatic approach to ensure the feasibility of completing the work within one year. Furthermore, we have designed the evaluation in such a way as to be able to capture differences in how each of the CHC regions uses a variety of methods to create their own learning healthcare system. A mixed methods approach has been adopted for this evaluation due the scale and complexities of the pilot study. A documentary review will identify how CHC pilot study deliverables were operationalised. To gain a broad understanding of CHC staff experiences, an online survey will be offered to all staff to complete. Semi-structured interviews with key programme staff will be used to gain a deeper understanding of key achievements, as well as how challenges have been overcome or managed. Our data analysis will triangulate the documentary review, survey and interview data. A thematic analysis using our logic model as a framework will also be used to assess progress against the CHC programme deliverables and to identify recommendations to support future programme decision-making.

Ethics and Dissemination: Ethical approval was granted by The University of Manchester Ethics Committee on the 24th May 2018 (Application reference: 2018-3923-6106). The results will be actively disseminated through peer-reviewed journals, conference presentations, social media, the internet and various stakeholder/patient and public engagement activities.

Key words: Evaluation; protocol; learning healthcare system;

Article Summary

Strengths and limitations

- This study will represent the largest evaluation ever conducted to examine the barriers, facilitators and lessons learned for creating and piloting learning healthcare systems in four regions in the North of England.

- The use of a mixed methods approach will mitigate the risk of not having baseline outcome measures at the start of the pilot study period, as well as the risk of sampling, recruitment and participation bias.

- The use of purposive sample, while based on access to the subject group most appropriate for taking part in this study, will elevate the risk of self-selection bias.

Background

The U.K is experiencing rapid changes to its population: an ageing population, increased life expectancy and changing patterns of chronic diseases have led to an increased demand in health and social care services [1]. At the same time, the amount of health data being digitally collected and stored is vast and expanding rapidly [2], whilst the technology and analytic tools needed to analyse large datasets has also been developed [3]. Therefore, there is the potential for utilising routinely collected health data to drive forward improvements in health outcomes [4–6].

The Connected Health Cities (CHC) (https://www.connectedhealthcities.org/) programme is a U.K government-funded programme that aims to create learning healthcare systems across the North of England. A learning healthcare system is defined by the Institute of Medicine (IOM)[7] as a system which:

"science, informatics, incentives, and culture are aligned for continuous improvement and innovation […] with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."

Friedman[8] describes a common cycle process that can be found in all learning healthcare systems. This is characterised by five steps divided between an afferent and efferent side [8]:

Afferent side:

1. Assemble the data from various sources
2. Use a range of analysis on the data
3. Interpret the findings

Efferent side:

4. Feed the findings back into the system in many formats
5. Change practice

Building on this notion of a learning healthcare system, a Connected Health City (CHC) is a civic partnership in which health and care services, science, technology and work culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as a by-product of delivering care. At the centre of a CHC is a secure information system called an 'Ark' which will provide a trustworthy, regional combinatorial innovation centre for health and social care data analysis, providing timely and actionable information for the care of the population it serves (see Figure 1).

This protocol describes the design of the evaluation of the CHC programme which aims to answer the following objectives:

1. To evaluate progression and early impact of each CHC region against seven Department of Health and Social Care deliverables.
2. To identify the benefits, additionality and added value of the CHC programme.
3. To identify the challenges of implementing a Learning Healthcare System in four regions in the North of England and how these have been overcome.
4. To assess the level of input required from staff, resources and approvals (such as information governance) to create each regional Ark and care pathway.

The outline of this paper is as follows: first, we provide a summary of the overall CHC programme, outlining the deliverables for the programme and pilot study, as well as the eight pathways that have been chosen for inclusion in the evaluation. Then we describe the analytical framework that underpins the evaluation, discussing the formulation of a logic model and programme deliverables. Next, we discuss the logic model and the issues that needed to be considered in formulating the research design. Next, we present a summary of the three data collection methodologies to be used in our evaluation: the documentary review, questionnaire for all CHC staff and a semi-structured interview. This is followed by a description of how we will analyse the data collected. Finally, our concluding remarks summarise the key issues and approaches used in our evaluation.

Design of Connected Health Cities Programme

The Connected Health Cities (CHC) programme is a Northern Health Science Alliance (NHSA) led programme delivered by a consortium of academics and NHS organisations, including NHS Trusts and Clinical Commissioning Groups (CCGs), across the North of England. It is being funded by the Department of Health and Social Care (DHSC) to assist in the delivery of the U.K government's commitment to reducing healthcare need, reducing inequalities and constructing the 'Northern Powerhouse'. The CHC programme covers four regions: Greater Manchester, Yorkshire, North West Coast and North East and North Cumbria. Each region has been tasked with establishing a LHS, using patient data to create and test innovative solutions for a variety of clinical pathways. This also includes the development of a central development hub to oversee the overall programme of work in relation to seven deliverables (Table 1): establishment of data sharing strategy and agreements for each region; establishment and delivery of governance arrangements for the sharing and usage of data for each region; workforce arrangements optimised and CPD requirements identified;

creation of Arks as analytical platforms; pathway analysis, variation assessment and improvements identifications; frameworks and integration with R&D partners; and the production of a business model suitable for scaling and sustainable for delivery in the NHS.

The CHC programme has over sixteen different care pathways in the process of delivery. However, whilst the number of pathways varies for each region, the CHC programme was tasked with developing at least two pathways per region. Our funders requested that eight care pathways were included as part of the evaluation process. Table 2 shows the four CHC regions in relation to the eight care pathways with a brief overview of the work undertaken for each pathway. The eight pathways included in this evaluation were selected to showcase the types of data that could be analysed to inform the pathways of a range of health issues.

Table 1: The Connected Health City (CHC) Programme deliverables

Deliverable	Description of deliverable
Deliverable 1	The establishment of data sharing strategies and data sharing agreements for each CHC region.
Deliverable 2	The establishment and delivery of governance arrangement for the sharing and usage of data for each CHC region, across the North and the U.K.
Deliverable 3	The optimisation of Ark workforce arrangements, including the identification of long term CPD requirements the establishment of new skill bases.
Deliverable 4	The creation of the Ark as an analytical platform for investigating linked data.
Deliverable 5	The analysis of eight care pathways, identification of any pathway variations and proposals for any improvements if possible.
Deliverable 6	The creation and implementation of frameworks for potential integration with R&D partners and the future rising of Foreign Direct Investment.
Deliverable 7	The production of a CHC business model suitable for scaling across the North and sustainable for delivery in the NHS.

Table 2: Description of care pathways included for evaluation, by region.

Connected Health City (CHC) Region	Title of Care Pathway	Objectives of Care Pathway	Description of Care Pathway
Connected Yorkshire	Supporting community care and reducing demand on A&E services	• To link de-identified routine NHS data to describe a detailed profile of patient demand across both prehospital, primary care and hospital emergency and urgent care settings in Yorkshire.	To collect routine NHS data from a number of emergency and urgent care (EUC) providers and link the data to provide a coherent picture of EUC demand.
	Safer Prescribing for Frailty	• To reduce inappropriate polypharmacy for people with frailty.	To work with GPs to change behaviours related to deprescribing for older people with moderate or severe frailty as identified by electronic Frailty Index scores. This includes developing interventions using which apply evidenced tools to support deprescribing.
Greater Manchester	BRIT – Using data to tackle antibiotic resistance	• To provide the NHS and clinical care teams with better information on what is happening and who is getting antibiotics. • To assist in determining whether the use of antibiotics is reasonable given local resistance patterns to antibiotics	Analysis of patient records from GPs for effectiveness of antibiotic prescribing in general practices. This includes the development of a DataLab feeding back advanced analytics to clinical staff and policy makers and the evaluation of interventions to optimise prescribing.
	Using technology and data to improve the diagnosis and treatment of stroke	• Improve the recognition of stroke by paramedics to maximise the proportion of acute stroke patients taken directly to a specialist stroke centre for timely expert care and minimising the number of non-stroke patients entering the stroke pathway. • Provide timely and focused referral to neurosurgery for patients in Greater Manchester with stroke caused by a brain haemorrhage. • Ensure that all patients get all the right treatments that they need to reduce the risk of another stroke when they are discharged from hospital.	To improve stroke recognition by paramedics by linking ambulance data to data at Salford Royal; using primary and secondary care data to create a large cohort of stroke and TIA patients for creating a predictive model of patients who are at high risk of stroke; and using acute trust data to identify predictive factors of early deterioration and death.
North East North Cumbria	Predictive modelling for unplanned care	• To develop predictive modelling tools for unplanned care forecasting to support demand management and service planning in relevant health and social care services.	To produce statistical models that can be used by health/local authority/other analytics teams to produce daily forecasts up to six months in advance with the pertinent associated uncertainties and variations in urgent and emergency care.
	SILVER: Smart Interventions for Local Vulnerable Families	• To develop data sharing agreements to allow the linking of existing health data across multiple health agencies via one platform that provides recommendations to key workers.	To link data across multiple agencies including health (physical and mental), social care, criminal justice, housing and education to develop a more complete Learning Health System.
North West Coast	Development of a learning system for alcohol	• To be able to inform health professionals about local clinical care. • To define best care or treatments, implement and demonstrate benefits.	Improving the way information is collected, analysed and shared between agencies and service users to bring opportunities for news was to respond collectively.
	Development of a learning system for unplanned care	• To improve how data is used to enhance patient care admitted to hospital for emergency care.	Linking NHS data with social services data to improve the care pathway for patients with COPD and epilepsy.

Logic model

The Centre for Disease Control [9] framework for evaluation mentions 'logic models' as useful tools to help describe a programme or policy [9,10]. Logic models can be visualised as a sequential 'if-then' process[11]. This can be used as a basis for planning an evaluation strategy as it allows for the identification of the various steps that need to be fulfilled before one can expect to see the desired outcome from a programme or policy [12,13].

The evaluators have developed a logic model to assist in assessing the CHC programme against the seven deliverables (

Outcomes

If the CHC programme has accomplished its planned activities to the extent as planned, then it should have completed or demonstrated progression towards the following seven deliverables: establishment of data sharing strategy and agreements for each region; establishment and delivery of governance arrangements for the sharing and usage of data for each region; workforce arrangements optimised and CPD requirements identified; creation of Arks as analytical platforms; pathway analysis, variation assessment and improvements identifications; frameworks and integration with R&D partners; and the production of a business model suitable for scaling and sustainable for delivery in the NHS.

Impacts

The evaluators were asked by the funders to assess any potential impacts of the CHC programme. Short, medium and long term impacts were built into the impact sections of the logic model. Potential short term impacts include *'knowledge sharing between organisations'*, an *'iterative cycle of care pathway improvements'* in current CHC programme pathways is achieved and *'data action latency'* is further developed. Potential medium impacts of the CHC programme include: *'Generalisability of CHC approach in other care pathways'*, *'engagement of other organisations'* in the regions to further develop the CHC programme, and *'evaluation of care pathways'*. Potential long term impacts of the CHC programme include: *'tailored approach to local/individual circumstances'*, *'Reduction of costs in NHS'*, and *'improvements in patient outcomes'.*

). Logic modelling is a tool that can be useful in the development of monitoring and evaluation plans, identifying short, medium and long-term outcomes that are linked to key activities of a programme[14]. Throughout the first month of the evaluation, meetings were held with CHC staff from each of the different regions to gain an overview of the work being completed in relation to the CHC

programme deliverables. Information from these meetings was combined with a retrospective documentary review to formulate the logic model featuring input, output, outcome and impact stages. The logic model ensured that there was a consistent and systematic means in the design of the evaluation. This logic model is expected to change throughout the duration of the evaluation as data is gathered and other factors are found that have contributed to the CHC programme.

Inputs

Certain resources are needed to operationalise the CHC programme of work. These include the recruitment of staff, such as statisticians, clinicians, qualitative researchers and software engineers. Other resources included financial input and any infrastructure needed such as buildings, computers and software.

Outputs

If the CHC programme has access to the inputs then they can be used to accomplish the planned outputs. Outputs were divided into two distinct areas: activities and participation. Activities include the creation of Trusted Research Environments, putting in place regional and pathway governance arrangements, creating analytical platforms, identification of care pathways, patient and public involvement activities, creation of training workshops to enhance staff skills, processes for industry co-development and accessing data.

Participants included universities, NHS Trusts and industry as without their participation, the CHC programme would not be able to achieve its seven deliverables. These organisations have been determined as being separate to the staff inputs (from the inputs section of the logic model) that may come from these organisations. For example, a care pathway may employ a clinician to complete a range of activities; however, an NHS Trust may need to participate as part of the activities being driven by the CHC programme staff to ensure that a data sharing agreement can be used across a range of NHS organisations in one region.

Patients and members of the public were also key participants in the formulation and delivery of some CHC programme activities, such as the citizen's jury's and care pathway patient tools. A separate evaluation has been commissioned to fully assess the level of patient and public involvement in the CHC programme.

Outcomes

If the CHC programme has accomplished its planned activities to the extent as planned, then it should have completed or demonstrated progression towards the following seven deliverables: establishment of data sharing strategy and agreements for each region; establishment and delivery of governance arrangements for the sharing and usage of data for each region; workforce arrangements optimised and CPD requirements identified; creation of Arks as analytical platforms; pathway analysis, variation assessment and improvements identifications; frameworks and integration with R&D partners; and the production of a business model suitable for scaling and sustainable for delivery in the NHS.

Impacts

The evaluators were asked by the funders to assess any potential impacts of the CHC programme. Short, medium and long term impacts were built into the impact sections of the logic model. Potential short term impacts include *'knowledge sharing between organisations'*, an *'iterative cycle of care pathway improvements'* in current CHC programme pathways is achieved and *'data action latency'* is further developed. Potential medium impacts of the CHC programme include: *'Generalisability of CHC approach in other care pathways'*, *'engagement of other organisations'* in the regions to further develop the CHC programme, and *'evaluation of care pathways'*. Potential long term impacts of the CHC programme include: *'tailored approach to local/individual circumstances'*, *'Reduction of costs in NHS'*, and *'improvements in patient outcomes'.*

Research methods

An evaluation can be described as a systematic process to assess the successes of a programme or intervention and the lessons learned [12,15]. It is based on evaluating a set of activities and formulating a judgement based on the evidence collected to increase the knowledge of programme or intervention for learning; informing the decision-making process for future programmes or interventions; and being accountable to stakeholders and donors[15].

This evaluation forms a distinct strand within the CHC programme of work, helping to assess progression towards delivery of the regional Arks and each care pathway, rather than a separate study focussed solely on the scientific understanding of learning healthcare systems. Furthermore, it

is important that this evaluation generates evidence to support decision-making within the CHC programme in the future, as well as evidence that assesses progression towards the seven programme deliverables to meet the needs of our funders.

In addition to the central CHC Hub that provides support to the overall programme, each of the CHC regions uses a variety of methods to create their own learning healthcare system. Furthermore, each of the eight care pathways within the CHC programme has a different focus with a variety of objectives. Other issues that needed to be taken into account was that at the start of the evaluation, the care pathways were at different points of delivery, with some still in the early development stages and others nearing completion for the first phase of care pathway delivery. Therefore, the data collection method needed to allow for these differences.

In formulating the research design of the evaluation, the following considerations were also adopted: first, the consideration of research ethics to ensure the informed consent and safety of all research participants and the management of confidential data. Second, it was important to ensure that all CHC staff from all regions had an opportunity to provide feedback through the evaluation. Third, to reduce potential interview and survey fatigue, a sufficiently in-depth methodology to meet the evaluation objectives was needed, but light touch where possible to avoid placing an undue burden on participants.

As a result, a mixed methods approach was deemed the most suitable approach to this evaluation. Utilising a mixed methods approach allows the evaluation to systematically combine and synthesise evidence from the eight care pathways, including a deeper investigation of each care pathway in order to gain a comprehensive understanding of the resources, processes, barriers and facilitators. Furthermore, because baseline data did not exist for all the pathways, utilising a range of data collection methods would ensure triangulation in order to increase the credibility and validity of the results. The evaluation will centre on three approaches to data collection: a documentary review, semi-structured interviews and an online survey. Ethical approval was granted by The University of Manchester Ethics Committee in May 2018 (Application reference: 2018-3923-6106).

Patient and Public Involvement

Whilst patients and members of the public are involved in the CHC programme, they were not involved in this evaluation. An evaluation solely dedicated to patients and public involvement has been commissioned separately.

Documentary review

A documentary review will be undertaken throughout the duration of the evaluation period. In doing so, we will be able to review pre-existing and new documentation to determine any differences between the proposed CHC pilot study and the actual programme of implementation. In doing so, the documentary review can highlight issues that can be missed through other means of data collection [16] and will assist in the formulation of semi-structured interview topic guides and the online survey.

To evaluate progress towards the CHC programme deliverables, documents from different time points in the project will be used to identify the structures and procedures used to deliver each care pathway, as well as the overall CHC programme. This will include monthly project reports, meeting documentation, internal evaluation reports, marketing materials and other project reports.

Online survey for CHC staff

As there are 210 members off staff working on the CHC programme, split across four regions in the North of England, it was felt that conducting an online survey that will be offered to all CHC staff to complete, was a practical approach to ensure all CHC staff had an opportunity to contribute to the evaluation. This is to gain a broad understanding of CHC staff experiences across the different pathways in relation to the CHC programme deliverables. The questions were developed using the logic model and CHC programme deliverables as a guide to ensure questions were relevant to the evaluation. The questionnaire will include the following sections:

- Approaches to creating regional learning health systems and pathways
- Challenges experienced and/or managed
- Unintended outputs from being involved on the CHC programme
- Recommendations for facilitating future learning health systems and pathways

The questionnaire has substantial sections for free text to all staff to describe their experiences in the CHC programme and care pathways in more detail. These sections will be transcribed for qualitative data analysis. A link to the questionnaire will be emailed to all 210 staff across the CHC programme. In addition to the online survey, staff can also request a paper-based copy of the survey, or to complete the survey over the telephone. Data from responses will be exported from the survey handler and securely stored in Microsoft Excel for initial data cleaning and then to SPSS for data analysis.

Semi-structured interviews

We will conduct semi-structured interviews with key CHC staff from all four regions, as well as the central CHC hub. The aim of the interview is to develop a clearer understanding of staff experiences in the design and delivery of the CHC programme and pathways. A topic guide was developed using the logic model and initial results from the documentary review as a framework in which to formulate interview questions. Key areas that would be explored during the interview include:

- The Learning Healthcare system
- CHC programme deliverables
- Using data in care pathways (such as information governance and data quality)
- Patient and public involvement within each region and pathway
- Creating a skilled workforce
- Working with industry

Using a semi-structured interview methodology would allow the researchers to explore emerging issues during the interview[17]. The interviews will take place at the place of work of the participant. All interviews will be audiotaped and transcribed verbatim. Transcribed data will be anonymised to remove any traceable information that could identify the respondent to the transcript (e.g. names of people or place names). Each respondent will be assigned a project code and this will be used in place of real names on all collected data. The 'project key code' linking project codes to identifiable respondent data will be kept electronically on a password protected secure server. Digital recordings of interviews will be stored on a password protected secure server, while hard copies of (anonymised) transcripts and field notes will be kept in a locked filing cabinet, in a locked room.

Analysis

Our data analysis utilises a thematic approach where we will triangulate the documentary review, survey and interview data to quantify progress towards the CHC programme deliverables. This is because no baseline data was collected for the CHC programme. Even though it is not possible to determine which pathways will provide data that will allow for a more sophisticated data analysis, where the data allows we will aim to measure cost reduction and improvements in patient deliverables for each pathway.

Our analysis strategy will also use an iterative process, whereby data collection and data analysis will be conducted concurrently. For data collected through our documentary review and interviews, a thematic analysis using our logic model as a framework will be used to assess progress against the CHC programme deliverables and to identify recommendations to support future programme decision-making. Descriptive analysis of the online survey data will also be used to inform actionable recommendations, which in turn will aid the future development and refinement of the CHC programme and care pathways. Each of the CHC regions will receive an evaluation report to further assist in the regional development of current and future pathways.

Concluding comments

Through this evaluation, a range of evidence will be collated and produced to support a series of evaluation judgements aimed at assessing the seven CHC programme deliverables. This will include a documentary review to identify how CHC programme deliverables were operationalised; an online survey to gain a broad understanding of CHC staff experiences in delivering each pathway; and semi-structured interviews with key programme staff will be used to gain a deeper understanding of key achievements and challenges. Using a three-pronged approach ensures triangulation and increases the validity, reliability and credibility of the results.

In planning this evaluation, we have utilised a logic model to guide the development of the data collection methods. Using a logic model, we have been able to initially identify and set out our short, medium and long-term impact measures that are linked to the CHC programme deliverables. We do not expect to be able to measure preciously all impact measures due the lack of baseline data, the different pathways in the CHC programme, the different stages of delivery of each pathway and the short time period of the evaluation. However, the data collected will allow us to assess progress made towards the CHC programme deliverables, as well as to determine the types of contributions made and challenges faced for each region in achieving these deliverables.

We have had to take a pragmatic approach to ensure the feasibility of completing the work within 10 months. Focusing the evaluation on eight care pathways allows for a systematic approach that will give an overview of the key achievements and challenges for each region, as well as the CHC programme overall. In addition, a key output of this evaluation was to assess progress towards the CHC programme deliverables. As a result of this, some aspects may be underexplored. However, as each pathway will be independently evaluated we are satisfied that this risk has been managed. Thus, in focusing the evaluation on the overall CHC programme deliverables, the evaluation will be

grounded in what the programme set out to do. This has the benefit of producing findings and recommendations that can be used in present and future CHC programme decision-making, as well as contributing to the wider discussion of learning healthcare systems

Declarations

Availability of data and materials:

This is study protocol. We will publish the results of the evaluation once this has been completed.

Competing interests:

There are no conflicts of interest declared.

Funding:

This study was part of Connected Health Cities which is a Northern Health Science Alliance (NHSA) led programme. It is funded by the U.K Department of Health and Social Care (DHSC) and delivered by a consortium of academic and NHS organisations across the North of England. NHSA and DHSC have no input into the evaluation to ensure this remains an independent piece of work.

Author Contributions:

SS developed the evaluation methodology and will carry out the data collection, transcribing and data analysis. SS wrote the manuscript with support from TvS. TvS contributed to the design of the evaluation methodology and supervised the evaluation implementation.

Acknowledgments

This study was part of Connected Health Cities which is a Northern Health Science Alliance (NHSA) led programme. It is funded by the U.K Department of Health and Social Care and delivered by a consortium of academic and NHS organisations across the north of England. The work uses data provided by patients and collected by the NHS as part of their care and support. The views expressed are those of the author(s) and not necessarily those of the NHSA, NHS or the Department of Health and Social Care. There are no conflicts of interest declared.

References

1 Chambers E, Farquharson C, Gumbley B, *et al.* A new settlement for health and social care. 2014. https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/Commission Final interactive.pdf (accessed March 7, 2018).

2 Murdoch TB, Detsky AS. The Inevitable Application of Big Data to Health Care. *JAMA* 2013; **309**: 1351.

3 Sacristán JA, Dilla T. No big data without small data: learning health care systems begin and end with the individual patient. *J Eval Clin Pract* 2015; **21**: 1014–7.

4 Roski J, Bo-Linn GW, Andrews TA. Creating Value In Health Care Through Big Data: Opportunities And Policy Implications. *Health Aff* 2014; **33**: 1115–22.

5 Schneeweiss S. Learning from Big Health Care Data. *N Engl J Med* 2014; **370**: 2161–3.

6 Guha S, Kumar S. Emergence of Big Data Research in Operations Management, Information Systems, and Healthcare: Past Contributions and Future Roadmap. *Prod Oper Manag* 2018; published online Jan 30. DOI:10.1111/poms.12833.

7 Institute of M. Integrating Research and Practice. Washington, D.C.: National Academies Press, 2015 DOI:10.17226/18945.

8 Friedman C, Wong A, Blumenthal D. Achieving a Nationwide Learning Health System. *pdfs.semanticscholar.org* 2010. https://pdfs.semanticscholar.org/80bf/b6259fc7f89bd19742b8a2d6bb5a7ae4a96f.pdf (accessed March 7, 2018).

9 CDC. CDC EVALUATION WORKING GROUP Summary of the Framework for Program Evaluation. 1999. http://www.cdc.gov/eval (accessed March 8, 2018).

10 CDC. Logic Models - Program Evaluation - CDC. 2018. https://www.cdc.gov/eval/logicmodels/index.htm (accessed March 8, 2018).

11 De Silva MJ, Breuer E, Lee L, *et al.* Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. *Trials* 2014; **15**: 267.

12 Blamey A, Mackenzie M. Theories of Change and Realistic Evaluation. *Evaluation* 2007; **13**: 439–55.

13 Moore G, Audrey S, Barker M, Bond L, Bmj CB-, 2015 U. Process evaluation of complex interventions: Medical Research Council guidance. *bmj.com* 2015. http://www.bmj.com/content/350/bmj.h1258 (accessed Feb 21, 2018).

14 Funnell S, Rogers P. Purposeful program theory: Effective use of theories of change and logic models. 2011 https://books.google.co.uk/books?hl=en&lr=&id=A9Iid1tcGwgC&oi=fnd&pg=PT10&dq=theories+of+change+in+evaluation&ots=ZrO0qoALoT&sig=SVWBdUIDQRHZtQvTw0_U4Ho-ER8 (accessed March 8, 2018).

15 Vedung E. Public policy and program evaluation. 2017 https://books.google.co.uk/books?hl=en&lr=&id=Kx0uDwAAQBAJ&oi=fnd&pg=PT17&dq=evaluation+defined&ots=GSOIpvMXnB&sig=S4B8P6LnIQplFzzUy9ZbG8RfLuQ (accessed March 9, 2018).

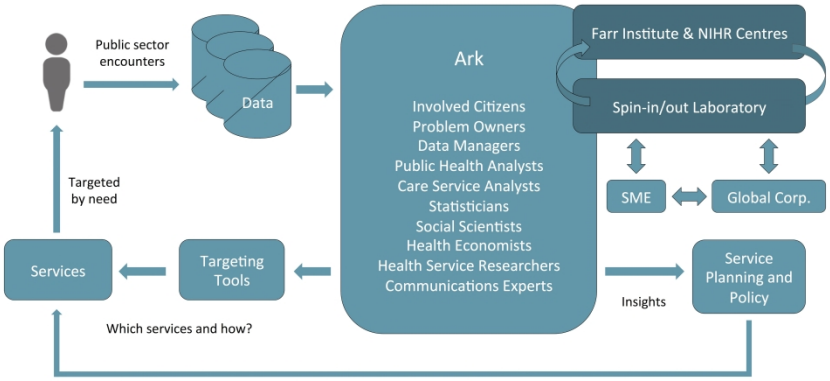
16 Creswell J, Creswell J. Research design: Qualitative, quantitative, and mixed methods approaches. 2017.

17 Flick U. An introduction to qualitative research. 2014 https://books.google.co.uk/books?hl=en&lr=&id=HB-VAgAAQBAJ&oi=fnd&pg=PP1&ots=kDp20OmXXl&sig=Ksfl5hN6o4FEGN5vXI-j-C_ClEw (accessed Feb 19, 2018).

Figure Legends:

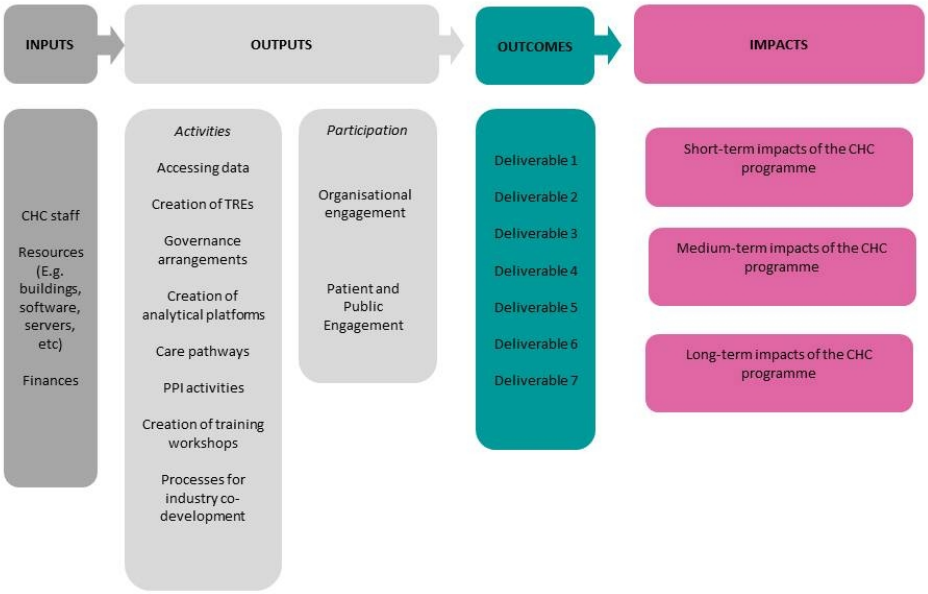
Figure 1: Connected Health City: Ark-enhanced Information Flows

Figure 2: Logic Model for the Connected Cities (CHC) Pilot Study Evaluation



Connected Health City: Ark-enhanced Information Flows

2500x1766mm (72 x 72 DPI)



Logic Model for the Connected Health Cities (CHC) Programme Evaluation

81x60mm (300 x 300 DPI)

BMJ Open

An evaluation protocol of the implementation of a learning healthcare system in clinical practice: the Connected Health Cities programme in the North of England

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-025484.R2
Article Type:	Protocol
Date Submitted by the Author:	29-Mar-2019
Complete List of Authors:	Steels, Stephanie; University of Manchester, School of Health Sciences van Staa, Tjeerd; University of Manchester, School of Health Sciences; Utrecht University
Primary Subject Heading:	Health informatics
Secondary Subject Heading:	Evidence based practice, Health services research, Research methods
Keywords:	Evaluation, learning healthcare system, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

An evaluation protocol of the implementation of a learning healthcare system in clinical practice: the Connected Health Cities programme in the North of England

Stephanie Steels[1], Tjeerd Pieter van Staa[1,2]

[1]Health e-Research Centre, Farr Institute, School of Health Sciences, Faculty of Biology, Medicine and Health, the University of Manchester, Oxford Road, Manchester, M13 9PL, UK2

[2]Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Utrecht, the Netherlands

Corresponding author: Stephanie.Steels@manchester.ac.uk

Word count (article): 4118

Number of tables: 2

Number of figures: 2

Abstract

Introduction: The 'learning healthcare system' (LHS) has been proposed to deliver better outcomes for patients and communities by analysing routinely captured health information and feeding back results to clinical staff. This approach is piloted in the Connected Health Cities (CHC) programme in four regions in the North of England. This article describes the protocol of the evaluation of this programme.

Methods and analysis: In designing this evaluation, we have had to take a pragmatic approach to ensure the feasibility of completing the work within one year. Furthermore, we have designed the evaluation in such a way as to be able to capture differences in how each of the CHC regions uses a variety of methods to create their own learning healthcare system. A mixed methods approach has been adopted for this evaluation due the scale and complexities of the pilot study. A documentary review will identify how CHC pilot study deliverables were operationalised. To gain a broad understanding of CHC staff experiences, an online survey will be offered to all staff to complete. Semi-structured interviews with key programme staff will be used to gain a deeper understanding of key achievements, as well as how challenges have been overcome or managed. Our data analysis will triangulate the documentary review, survey and interview data. A thematic analysis using our logic model as a framework will also be used to assess progress against the CHC programme deliverables and to identify recommendations to support future programme decision-making.

Ethics and Dissemination: Ethical approval was granted by The University of Manchester Ethics Committee on the 24th May 2018 (Application reference: 2018-3923-6106). The results will be actively disseminated through peer-reviewed journals, conference presentations, social media, the internet and various stakeholder/patient and public engagement activities.

Key words: Evaluation; protocol; learning healthcare system;

Article Summary

Strengths and limitations

- This study will represent the largest evaluation ever conducted to examine the barriers, facilitators and lessons learned for creating and piloting learning healthcare systems in four regions in the North of England.

- The use of a mixed methods approach will mitigate the risk of not having baseline outcome measures at the start of the pilot study period, as well as the risk of sampling, recruitment and participation bias.

- The use of purposive sample, while based on access to the subject group most appropriate for taking part in this study, will elevate the risk of self-selection bias.

Background

The U.K is experiencing rapid changes to its population: an ageing population, increased life expectancy and changing patterns of chronic diseases have led to an increased demand in health and social care services [1]. At the same time, the amount of health data being digitally collected and stored is vast and expanding rapidly [2], whilst the technology and analytic tools needed to analyse large datasets has also been developed [3]. Therefore, there is the potential for utilising routinely collected health data to drive forward improvements in health outcomes [4–6].

The Connected Health Cities (CHC) (https://www.connectedhealthcities.org/) programme is a U.K government-funded programme that aims to create learning healthcare systems across the North of England. A learning healthcare system is defined by the Institute of Medicine (IOM)[7] as a system which:

"science, informatics, incentives, and culture are aligned for continuous improvement and innovation […] with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."

Friedman[8] describes a common cycle process that can be found in all learning healthcare systems. This is characterised by five steps divided between an afferent and efferent side [8]:

Afferent side:

1. Assemble the data from various sources
2. Use a range of analysis on the data
3. Interpret the findings

Efferent side:

4. Feed the findings back into the system in many formats
5. Change practice

Building on this notion of a learning healthcare system, a Connected Health City (CHC) is a civic partnership in which health and care services, science, technology and work culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as a by-product of delivering care. At the centre of a CHC is a secure information system called an 'Ark' which will provide a trustworthy, regional combinatorial innovation centre for health and social care data analysis, providing timely and actionable information for the care of the population it serves (see Figure 1).

This protocol describes the design of the evaluation of the CHC programme which aims to answer the following objectives:

1. To evaluate progression and early impact of each CHC region against seven Department of Health and Social Care deliverables.
2. To identify the benefits, additionality and added value of the CHC programme.
3. To identify the challenges of implementing a Learning Healthcare System in four regions in the North of England and how these have been overcome.
4. To assess the level of input required from staff, resources and approvals (such as information governance) to create each regional Ark and care pathway.

The outline of this paper is as follows: first, we provide a summary of the overall CHC programme, outlining the deliverables for the programme and pilot study, as well as the eight pathways that have been chosen for inclusion in the evaluation. Then we describe the analytical framework that underpins the evaluation, discussing the formulation of a logic model and programme deliverables. Next, we discuss the logic model and the issues that needed to be considered in formulating the research design. Next, we present a summary of the three data collection methodologies to be used in our evaluation: the documentary review, questionnaire for all CHC staff and a semi-structured interview. This is followed by a description of how we will analyse the data collected. Finally, our concluding remarks summarise the key issues and approaches used in our evaluation.

Design of Connected Health Cities Programme

The Connected Health Cities (CHC) programme is a Northern Health Science Alliance (NHSA) led programme delivered by a consortium of academics and NHS organisations, including NHS Trusts and Clinical Commissioning Groups (CCGs), across the North of England. It is being funded by the Department of Health and Social Care (DHSC) to assist in the delivery of the U.K government's commitment to reducing healthcare need, reducing inequalities and constructing the 'Northern Powerhouse'. The CHC programme covers four regions: Greater Manchester, Yorkshire, North West Coast and North East and North Cumbria. Each region has been tasked with establishing a LHS, using patient data to create and test innovative solutions for a variety of clinical pathways. This also includes the development of a central development hub to oversee the overall programme of work in relation to seven deliverables (Table 1): establishment of data sharing strategy and agreements for each region; establishment and delivery of governance arrangements for the sharing and usage of data for each region; workforce arrangements optimised and CPD requirements identified;

creation of Arks as analytical platforms; pathway analysis, variation assessment and improvements identifications; frameworks and integration with R&D partners; and the production of a business model suitable for scaling and sustainable for delivery in the NHS.

The CHC programme has over sixteen different care pathways in the process of delivery. However, whilst the number of pathways varies for each region, the CHC programme was tasked with developing at least two pathways per region. Our funders requested that eight care pathways were included as part of the evaluation process. Table 2 shows the four CHC regions in relation to the eight care pathways with a brief overview of the work undertaken for each pathway. The eight pathways included in this evaluation were selected to showcase the types of data that could be analysed to inform the pathways of a range of health issues.

Table 1: The Connected Health City (CHC) Programme deliverables

Deliverable	Description of deliverable
Deliverable 1	The establishment of data sharing strategies and data sharing agreements for each CHC region.
Deliverable 2	The establishment and delivery of governance arrangement for the sharing and usage of data for each CHC region, across the North and the U.K.
Deliverable 3	The optimisation of Ark workforce arrangements, including the identification of long term CPD requirements the establishment of new skill bases.
Deliverable 4	The creation of the Ark as an analytical platform for investigating linked data.
Deliverable 5	The analysis of eight care pathways, identification of any pathway variations and proposals for any improvements if possible.
Deliverable 6	The creation and implementation of frameworks for potential integration with R&D partners and the future rising of Foreign Direct Investment.
Deliverable 7	The production of a CHC business model suitable for scaling across the North and sustainable for delivery in the NHS.

Table 2: Description of care pathways included for evaluation, by region.

Connected Health City (CHC) Region	Title of Care Pathway	Objectives of Care Pathway	Description of Care Pathway
Connected Yorkshire	Supporting community care and reducing demand on A&E services	• To link de-identified routine NHS data to describe a detailed profile of patient demand across both prehospital, primary care and hospital emergency and urgent care settings in Yorkshire.	To collect routine NHS data from a number of emergency and urgent care (EUC) providers and link the data to provide a coherent picture of EUC demand.
	Safer Prescribing for Frailty	• To reduce inappropriate polypharmacy for people with frailty.	To work with GPs to change behaviours related to deprescribing for older people with moderate or severe frailty as identified by electronic Frailty Index scores. This includes developing interventions using which apply evidenced tools to support deprescribing.
Greater Manchester	BRIT – Using data to tackle antibiotic resistance	• To provide the NHS and clinical care teams with better information on what is happening and who is getting antibiotics. • To assist in determining whether the use of antibiotics is reasonable given local resistance patterns to antibiotics	Analysis of patient records from GPs for effectiveness of antibiotic prescribing in general practices. This includes the development of a DataLab feeding back advanced analytics to clinical staff and policy makers and the evaluation of interventions to optimise prescribing.
	Using technology and data to improve the diagnosis and treatment of stroke	• Improve the recognition of stroke by paramedics to maximise the proportion of acute stroke patients taken directly to a specialist stroke centre for timely expert care and minimising the number of non-stroke patients entering the stroke pathway. • Provide timely and focused referral to neurosurgery for patients in Greater Manchester with stroke caused by a brain haemorrhage. • Ensure that all patients get all the right treatments that they need to reduce the risk of another stroke when they are discharged from hospital.	To improve stroke recognition by paramedics by linking ambulance data to data at Salford Royal; using primary and secondary care data to create a large cohort of stroke and TIA patients for creating a predictive model of patients who are at high risk of stroke; and using acute trust data to identify predictive factors of early deterioration and death.
North East North Cumbria	Predictive modelling for unplanned care	• To develop predictive modelling tools for unplanned care forecasting to support demand management and service planning in relevant health and social care services.	To produce statistical models that can be used by health/local authority/other analytics teams to produce daily forecasts up to six months in advance with the pertinent associated uncertainties and variations in urgent and emergency care.
	SILVER: Smart Interventions for Local Vulnerable Families	• To develop data sharing agreements to allow the linking of existing health data across multiple health agencies via one platform that provides recommendations to key workers.	To link data across multiple agencies including health (physical and mental), social care, criminal justice, housing and education to develop a more complete Learning Health System.
North West Coast	Development of a learning system for alcohol	• To be able to inform health professionals about local clinical care. • To define best care or treatments, implement and demonstrate benefits.	Improving the way information is collected, analysed and shared between agencies and service users to bring opportunities for news was to respond collectively.
	Development of a learning system for unplanned care	• To improve how data is used to enhance patient care admitted to hospital for emergency care.	Linking NHS data with social services data to improve the care pathway for patients with COPD and epilepsy.

Logic model

The Centre for Disease Control [9] framework for evaluation mentions 'logic models' as useful tools to help describe a programme or policy [9,10]. Logic models can be visualised as a sequential 'if-then' process[11]. This can be used as a basis for planning an evaluation strategy as it allows for the identification of the various steps that need to be fulfilled before one can expect to see the desired outcome from a programme or policy [12,13].

The evaluators have developed a logic model to assist in assessing the CHC programme against the seven deliverables (

Outcomes

If the CHC programme has accomplished its planned activities to the extent as planned, then it should have completed or demonstrated progression towards the following seven deliverables: establishment of data sharing strategy and agreements for each region; establishment and delivery of governance arrangements for the sharing and usage of data for each region; workforce arrangements optimised and CPD requirements identified; creation of Arks as analytical platforms; pathway analysis, variation assessment and improvements identifications; frameworks and integration with R&D partners; and the production of a business model suitable for scaling and sustainable for delivery in the NHS.

Impacts

The evaluators were asked by the funders to assess any potential impacts of the CHC programme. Short, medium and long term impacts were built into the impact sections of the logic model. Potential short term impacts include *'knowledge sharing between organisations'*, an *'iterative cycle of care pathway improvements'* in current CHC programme pathways is achieved and *'data action latency'* is further developed. Potential medium impacts of the CHC programme include: *'Generalisability of CHC approach in other care pathways'*, *'engagement of other organisations'* in the regions to further develop the CHC programme, and *'evaluation of care pathways'*. Potential long term impacts of the CHC programme include: *'tailored approach to local/individual circumstances'*, *'Reduction of costs in NHS'*, and *'improvements in patient outcomes'.*

). Logic modelling is a tool that can be useful in the development of monitoring and evaluation plans, identifying short, medium and long-term outcomes that are linked to key activities of a programme[14]. Throughout the first month of the evaluation, meetings were held with CHC staff from each of the different regions to gain an overview of the work being completed in relation to the CHC

programme deliverables. Information from these meetings was combined with a retrospective documentary review to formulate the logic model featuring input, output, outcome and impact stages. The logic model ensured that there was a consistent and systematic means in the design of the evaluation. This logic model is expected to change throughout the duration of the evaluation as data is gathered and other factors are found that have contributed to the CHC programme.

Inputs

Certain resources are needed to operationalise the CHC programme of work. These include the recruitment of staff, such as statisticians, clinicians, qualitative researchers and software engineers. Other resources included financial input and any infrastructure needed such as buildings, computers and software.

Outputs

If the CHC programme has access to the inputs then they can be used to accomplish the planned outputs. Outputs were divided into two distinct areas: activities and participation. Activities include the creation of Trusted Research Environments, putting in place regional and pathway governance arrangements, creating analytical platforms, identification of care pathways, patient and public involvement activities, creation of training workshops to enhance staff skills, processes for industry co-development and accessing data.

Participants included universities, NHS Trusts and industry as without their participation, the CHC programme would not be able to achieve its seven deliverables. These organisations have been determined as being separate to the staff inputs (from the inputs section of the logic model) that may come from these organisations. For example, a care pathway may employ a clinician to complete a range of activities; however, an NHS Trust may need to participate as part of the activities being driven by the CHC programme staff to ensure that a data sharing agreement can be used across a range of NHS organisations in one region.

Patients and members of the public were also key participants in the formulation and delivery of some CHC programme activities, such as the citizen's jury's and care pathway patient tools. A separate evaluation has been commissioned to fully assess the level of patient and public involvement in the CHC programme.

Outcomes

If the CHC programme has accomplished its planned activities to the extent as planned, then it should have completed or demonstrated progression towards the following seven deliverables: establishment of data sharing strategy and agreements for each region; establishment and delivery of governance arrangements for the sharing and usage of data for each region; workforce arrangements optimised and CPD requirements identified; creation of Arks as analytical platforms; pathway analysis, variation assessment and improvements identifications; frameworks and integration with R&D partners; and the production of a business model suitable for scaling and sustainable for delivery in the NHS.

Impacts

The evaluators were asked by the funders to assess any potential impacts of the CHC programme. Short, medium and long term impacts were built into the impact sections of the logic model. Potential short term impacts include *'knowledge sharing between organisations'*, an *'iterative cycle of care pathway improvements'* in current CHC programme pathways is achieved and *'data action latency'* is further developed. Potential medium impacts of the CHC programme include: *'Generalisability of CHC approach in other care pathways'*, *'engagement of other organisations'* in the regions to further develop the CHC programme, and *'evaluation of care pathways'*. Potential long term impacts of the CHC programme include: *'tailored approach to local/individual circumstances'*, *'Reduction of costs in NHS'*, and *'improvements in patient outcomes'.*

Research methods

An evaluation can be described as a systematic process to assess the successes of a programme or intervention and the lessons learned [12,15]. It is based on evaluating a set of activities and formulating a judgement based on the evidence collected to increase the knowledge of programme or intervention for learning; informing the decision-making process for future programmes or interventions; and being accountable to stakeholders and donors[15].

This evaluation forms a distinct strand within the CHC programme of work, helping to assess progression towards delivery of the regional Arks and each care pathway, rather than a separate study focussed solely on the scientific understanding of learning healthcare systems. Furthermore, it is important that this evaluation generates evidence to support decision-making within the CHC

programme in the future, as well as evidence that assesses progression towards the seven programme deliverables to meet the needs of our funders.

In addition to the central CHC Hub that provides support to the overall programme, each of the CHC regions uses a variety of methods to create their own learning healthcare system. Furthermore, each of the eight care pathways within the CHC programme has a different focus with a variety of objectives. Other issues that needed to be taken into account was that at the start of the evaluation, the care pathways were at different points of delivery, with some still in the early development stages and others nearing completion for the first phase of care pathway delivery. Therefore, the data collection method needed to allow for these differences.

In formulating the research design of the evaluation, the following considerations were also adopted: first, the consideration of research ethics to ensure the informed consent and safety of all research participants and the management of confidential data. Second, it was important to ensure that all CHC staff from all regions had an opportunity to provide feedback through the evaluation. Third, to reduce potential interview and survey fatigue, a sufficiently in-depth methodology to meet the evaluation objectives was needed, but light touch where possible to avoid placing an undue burden on participants.

As a result, a mixed methods approach was deemed the most suitable approach to this evaluation. Utilising a mixed methods approach allows the evaluation to systematically combine and synthesise evidence from the eight care pathways, including a deeper investigation of each care pathway in order to gain a comprehensive understanding of the resources, processes, barriers and facilitators. Furthermore, because baseline data did not exist for all the pathways, utilising a range of data collection methods would ensure triangulation in order to increase the credibility and validity of the results. The evaluation will centre on three approaches to data collection: a documentary review, semi-structured interviews and an online survey. Ethical approval was granted by The University of Manchester Ethics Committee in May 2018 (Application reference: 2018-3923-6106).

Patient and Public Involvement

Whilst patients and members of the public are involved in the CHC programme, they were not involved in this evaluation. An evaluation solely dedicated to patients and public involvement has been commissioned separately.

Documentary review

A documentary review will be undertaken throughout the duration of the evaluation period. In doing so, we will be able to review pre-existing and new documentation to determine any differences between the proposed CHC pilot study and the actual programme of implementation. In doing so, the documentary review can highlight issues that can be missed through other means of data collection [16] and will assist in the formulation of semi-structured interview topic guides and the online survey.

To evaluate progress towards the CHC programme deliverables, documents from different time points in the project will be used to identify the structures and procedures used to deliver each care pathway, as well as the overall CHC programme. This will include monthly project reports, meeting documentation, internal evaluation reports, marketing materials and other project reports.

Online survey for CHC staff

As there are 210 members off staff working on the CHC programme, split across four regions in the North of England, it was felt that conducting an online survey that will be offered to all CHC staff to complete, was a practical approach to ensure all CHC staff had an opportunity to contribute to the evaluation. This is to gain a broad understanding of CHC staff experiences across the different pathways in relation to the CHC programme deliverables. The questions were developed using the logic model and CHC programme deliverables as a guide to ensure questions were relevant to the evaluation. The questionnaire will include the following sections:

- Approaches to creating regional learning health systems and pathways
- Challenges experienced and/or managed
- Unintended outputs from being involved on the CHC programme
- Recommendations for facilitating future learning health systems and pathways

The questionnaire has substantial sections for free text to all staff to describe their experiences in the CHC programme and care pathways in more detail. These sections will be transcribed for qualitative data analysis. A link to the questionnaire will be emailed to all 210 staff across the CHC programme. In addition to the online survey, staff can also request a paper-based copy of the survey, or to complete the survey over the telephone. Data from responses will be exported from the survey handler and securely stored in Microsoft Excel for initial data cleaning and then to SPSS for data analysis.

Semi-structured interviews

We will conduct semi-structured interviews with key CHC staff from all four regions, as well as the central CHC hub. The aim of the interview is to develop a clearer understanding of staff experiences in the design and delivery of the CHC programme and pathways. A topic guide was developed using the logic model and initial results from the documentary review as a framework in which to formulate interview questions. Key areas that would be explored during the interview include:

- The Learning Healthcare system
- CHC programme deliverables
- Using data in care pathways (such as information governance and data quality)
- Patient and public involvement within each region and pathway
- Creating a skilled workforce
- Working with industry

Using a semi-structured interview methodology would allow the researchers to explore emerging issues during the interview[17]. The interviews will take place at the place of work of the participant. All interviews will be audiotaped and transcribed verbatim. Transcribed data will be anonymised to remove any traceable information that could identify the respondent to the transcript (e.g. names of people or place names). Each respondent will be assigned a project code and this will be used in place of real names on all collected data. The 'project key code' linking project codes to identifiable respondent data will be kept electronically on a password protected secure server. Digital recordings of interviews will be stored on a password protected secure server, while hard copies of (anonymised) transcripts and field notes will be kept in a locked filing cabinet, in a locked room.

Analysis

Our data analysis utilises a thematic approach where we will triangulate the documentary review, survey and interview data to quantify progress towards the CHC programme deliverables. This is because no baseline data was collected for the CHC programme. Even though it is not possible to determine which pathways will provide data that will allow for a more sophisticated data analysis, where the data allows we will aim to measure cost reduction and improvements in patient deliverables for each pathway.

Our analysis strategy will also use an iterative process, whereby data collection and data analysis will be conducted concurrently. For data collected through our documentary review and interviews, a thematic analysis using our logic model as a framework will be used to assess progress against the CHC programme deliverables and to identify recommendations to support future programme decision-making. Descriptive analysis of the online survey data will also be used to inform actionable recommendations, which in turn will aid the future development and refinement of the CHC programme and care pathways. Each of the CHC regions will receive an evaluation report to further assist in the regional development of current and future pathways.

Concluding comments

Through this evaluation, a range of evidence will be collated and produced to support a series of evaluation judgements aimed at assessing the seven CHC programme deliverables. This will include a documentary review to identify how CHC programme deliverables were operationalised; an online survey to gain a broad understanding of CHC staff experiences in delivering each pathway; and semi-structured interviews with key programme staff will be used to gain a deeper understanding of key achievements and challenges. Using a three-pronged approach ensures triangulation and increases the validity, reliability and credibility of the results.

In planning this evaluation, we have utilised a logic model to guide the development of the data collection methods. Using a logic model, we have been able to initially identify and set out our short, medium and long-term impact measures that are linked to the CHC programme deliverables. We do not expect to be able to measure preciously all impact measures due the lack of baseline data, the different pathways in the CHC programme, the different stages of delivery of each pathway and the short time period of the evaluation. However, the data collected will allow us to assess progress made towards the CHC programme deliverables, as well as to determine the types of contributions made and challenges faced for each region in achieving these deliverables. Any future evaluations that consider both the costs of implementation, as well as patient and public involvement, which will assist in determining the feasibility of converting the CHC programme becoming a sustainable model across the U.K is dependent on the funder.

We have had to take a pragmatic approach to ensure the feasibility of completing the work within 10 months. Focusing the evaluation on eight care pathways allows for a systematic approach that will give an overview of the key achievements and challenges for each region, as well as the CHC programme overall. In addition, a key output of this evaluation was to assess progress towards the

CHC programme deliverables. As a result of this, some aspects may be underexplored. However, as each pathway will be independently evaluated we are satisfied that this risk has been managed. Thus, in focusing the evaluation on the overall CHC programme deliverables, the evaluation will be grounded in what the programme set out to do. This has the benefit of producing findings and recommendations that can be used in present and future CHC programme decision-making, as well as contributing to the wider discussion of learning healthcare systems.

Declarations

Availability of data and materials:

This is study protocol. We will publish the results of the evaluation once this has been completed.

Competing interests:

There are no conflicts of interest declared.

Funding:

This study was part of Connected Health Cities which is a Northern Health Science Alliance (NHSA) led programme. It is funded by the U.K Department of Health and Social Care (DHSC) and delivered by a consortium of academic and NHS organisations across the North of England. NHSA and DHSC have no input into the evaluation to ensure this remains an independent piece of work.

Author Contributions:

SS developed the evaluation methodology and will carry out the data collection, transcribing and data analysis. SS wrote the manuscript with support from TvS. TvS contributed to the design of the evaluation methodology and supervised the evaluation implementation.

Acknowledgments

This study was part of Connected Health Cities which is a Northern Health Science Alliance (NHSA) led programme. It is funded by the U.K Department of Health and Social Care and delivered by a consortium of academic and NHS organisations across the north of England. The work uses data provided by patients and collected by the NHS as part of their care and support. The views expressed are those of the author(s) and not necessarily those of the NHSA, NHS or the Department of Health and Social Care. There are no conflicts of interest declared.

References

1 Chambers E, Farquharson C, Gumbley B, *et al.* A new settlement for health and social care. 2014. https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/Commission Final interactive.pdf (accessed March 7, 2018).

2 Murdoch TB, Detsky AS. The Inevitable Application of Big Data to Health Care. *JAMA* 2013; **309**: 1351.

3 Sacristán JA, Dilla T. No big data without small data: learning health care systems begin and end with the individual patient. *J Eval Clin Pract* 2015; **21**: 1014–7.

4 Roski J, Bo-Linn GW, Andrews TA. Creating Value In Health Care Through Big Data: Opportunities And Policy Implications. *Health Aff* 2014; **33**: 1115–22.

5 Schneeweiss S. Learning from Big Health Care Data. *N Engl J Med* 2014; **370**: 2161–3.

6 Guha S, Kumar S. Emergence of Big Data Research in Operations Management, Information Systems, and Healthcare: Past Contributions and Future Roadmap. *Prod Oper Manag* 2018; published online Jan 30. DOI:10.1111/poms.12833.

7 Institute of M. Integrating Research and Practice. Washington, D.C.: National Academies Press, 2015 DOI:10.17226/18945.

8 Friedman C, Wong A, Blumenthal D. Achieving a Nationwide Learning Health System. *pdfs.semanticscholar.org* 2010. https://pdfs.semanticscholar.org/80bf/b6259fc7f89bd19742b8a2d6bb5a7ae4a96f.pdf (accessed March 7, 2018).

9 CDC. CDC EVALUATION WORKING GROUP Summary of the Framework for Program Evaluation. 1999. http://www.cdc.gov/eval (accessed March 8, 2018).

10 CDC. Logic Models - Program Evaluation - CDC. 2018. https://www.cdc.gov/eval/logicmodels/index.htm (accessed March 8, 2018).

11 De Silva MJ, Breuer E, Lee L, *et al.* Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. *Trials* 2014; **15**: 267.

12 Blamey A, Mackenzie M. Theories of Change and Realistic Evaluation. *Evaluation* 2007; **13**: 439–55.

13 Moore G, Audrey S, Barker M, Bond L, Bmj CB-, 2015 U. Process evaluation of complex interventions: Medical Research Council guidance. *bmj.com* 2015. http://www.bmj.com/content/350/bmj.h1258 (accessed Feb 21, 2018).

14 Funnell S, Rogers P. Purposeful program theory: Effective use of theories of change and logic models. 2011 https://books.google.co.uk/books?hl=en&lr=&id=A9Iid1tcGwgC&oi=fnd&pg=PT10&dq=theories+of+change+in+evaluation&ots=ZrO0qoALoT&sig=SVWBdUIDQRHZtQvTw0_U4Ho-ER8 (accessed March 8, 2018).

15 Vedung E. Public policy and program evaluation. 2017 https://books.google.co.uk/books?hl=en&lr=&id=Kx0uDwAAQBAJ&oi=fnd&pg=PT17&dq=evaluation+defined&ots=GSOIpvMXnB&sig=S4B8P6LnIQplFzzUy9ZbG8RfLuQ (accessed March 9, 2018).

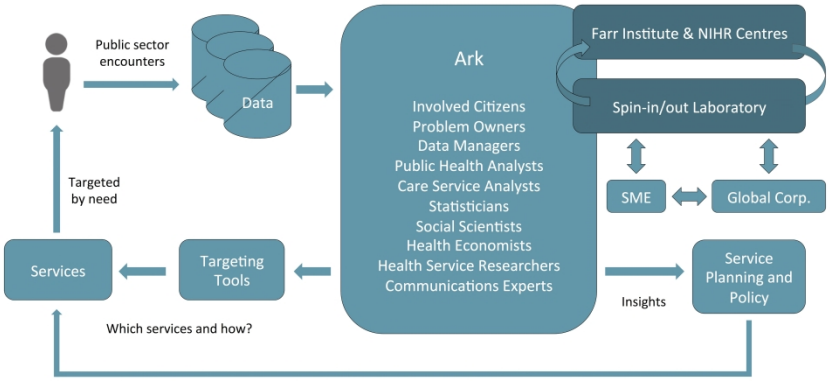
16 Creswell J, Creswell J. Research design: Qualitative, quantitative, and mixed methods approaches. 2017.

17 Flick U. An introduction to qualitative research. 2014 https://books.google.co.uk/books?hl=en&lr=&id=HB-VAgAAQBAJ&oi=fnd&pg=PP1&ots=kDp20OmXXl&sig=Ksfl5hN6o4FEGN5vXI-j-C_ClEw (accessed Feb 19, 2018).

Figure Legends:

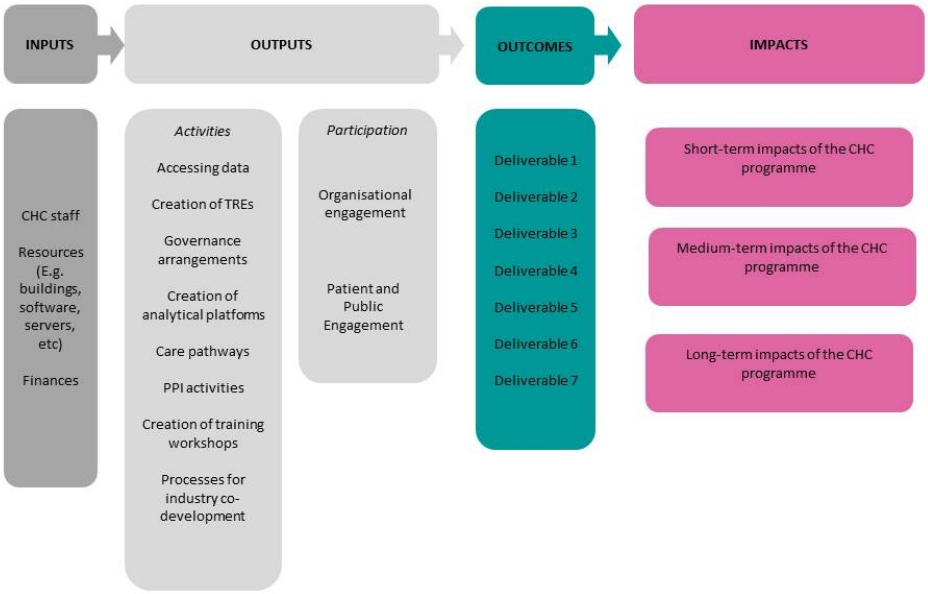
Figure 1: Connected Health City: Ark-enhanced Information Flows

Figure 2: Logic Model for the Connected Cities (CHC) Pilot Study Evaluation



Connected Health City: Ark-enhanced Information Flows

2500x1766mm (72 x 72 DPI)



Logic Model for the Connected Health Cities (CHC) Programme Evaluation

81x60mm (300 x 300 DPI)