What is the impact of a new service designed to improve communication about medicines between the hospital and the community when patients are discharged?

Submission date 20/10/2020	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 30/11/2020	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 22/03/2024	Condition category Other	Individual participant data

Plain English summary of protocol

Background and study aim:

This project is an evaluation of a new service that was introduced in NHS hospitals and surrounding GP surgeries and pharmacies in England in February 2019. The name of the service is electronic Transfers of Care Around Medicines (TCAM). The service consists of using an electronic system called PharmOutcomes[™], which sends a notification to the community pharmacy after the patient leaves the hospital. The service will affect medication use after patients leave the hospital, by reducing medication discrepancies (medication mismatching) in medication prescribing and dispensing between secondary and primary care, as both community pharmacy and the GP are quickly made aware of all details regarding patients' medication that the hospital wants them to have after they are sent home.

Our study aims to find out whether the TCAM service achieved its aims by studying its impact on medication safety.

Who can participate?

Clinical pharmacists working in general practices in the study Clinical Commission Group region will collect data to find out if the TCAM service improves safety. Clinical pharmacists employed and work at NHS acute hospital in England will collect electronic data which tells us how the TCAM service is used.

What does the study involve?

Our research seeks to understand how the TCAM service is used through the PharmOutcomes[™] system in community pharmacy (service 'Activity' study) and also the impact of the use of the TCAM service on medication 'safety' on reducing medication mismatches, time to medication checking and patient harm following hospital discharge to primary care.

For the 'activity' study, we are going to look at how often the referral service is used, and what additional services patients who are the subject of a referral receive from their community pharmacy. For the 'safety' study, we are going to find out if the service reduces the number of

medication mismatches patients had between the list of medications prescribed by their GP and what the hospital had listed in their discharge letter. Also, we are going to see if the service will affect how frequently harm that the patient may experience due to their medicines occurs. The data will be collected by looking at GP computer system records for things that happened in the past, both before and after the service was implemented.

What are the possible benefits and risks of participating? None

Where is the study run from?

1. The University of Manchester

2. Collaborating sites: Salford Royal NHS Foundation Trust (UK) and General Practices within Salford Clinical Commission Group.

When is the study starting and how long is it expected to run for? February 2020 to December 2020

Who is funding the study?

1. University of Manchester (UK)

2. This project is part of a PhD programme being funded by Kuwait Civil Service Commission

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 262688

ClinicalTrials.gov number Nil known

Secondary identifying numbers IRAS 262688

Study information

Scientific Title

Evaluation of medication discrepancies and adverse drug events following the transition from secondary to primary care before and after implementation of transfers of care around medicines service in NHS acute hospital and clinical commissioning group in England

Study objectives

This research evaluates the newly implemented electronic Transfer of Care Around Medicines (TCAM) service to pharmacy in an NHS acute hospital and surrounding Clinical Commissioning Group (CCG) in England. We aim to understand the extent of service utilisation 'activity' as well as the 'safety impact' of the use of the TCAM service to send discharge letters from hospital to community pharmacy on reducing medication discrepancies, time to medication reconciliation and adverse drug events following transition of care from secondary to primary care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 24/10/2019, Heath Research Authority (HRA) (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: none provided 2. The project was exempt from the University Research Ethics Committee (UREC) approval (University Research Ethics Committee 3, Research Governance, Ethics and Integrity 2nd Floor, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; +44 (0) 161 275 2206; research.ethics@manchester.ac.uk), ref: [2019-7048-10983]

Study design

Uncontrolled retrospective before and after study

Primary study design Other

Secondary study design

Study setting(s) GP practice

Study type(s) Other

Participant information sheet Not applicable (retrospective study)

Health condition(s) or problem(s) studied

Any medical condition

Interventions

This project is an evaluation of a newly implemented service that was introduced in NHS acute hospital and surrounding Clinical Commissioning Group (CCG) in England in February 2019. The name of the service is Transfers of Care Around Medicines (TCAM). The new service consists of using an electronic system called PharmOutcomes[™]. The service is designed to improve communication, reduce medicines waste, reduce medication discrepancies, and improve

monitoring and reporting of adverse drug reactions. The service is initially focused on patients with new or existing monitored dosage system (MDS) (also known as blister packs).

The PharmOutcomes[™] system was used by hospital pharmacists in the acute trust to send discharge notification to a patients' named community pharmacy when the patient leaves the hospital. This study evaluates the TCAM service, by studying utilization of the service through electronic referral 'activity', and by studying the impact of the TCAM on 'safety', specifically the rate and nature of medication discrepancies, and drug related harm post hospital discharge.

Data collection to evaluate how the TCAM service is used through the PharmOutcomes[™] system in community pharmacy (service 'Activity' study) will be via looking at how often the referral service is used, and what additional services patients who are the subject of a referral receive from their community pharmacy. This data will be extracted by one pharmacist in the hospital and sent securely to the research team for analysis.

For the 'safety' study, we are going to find out if the service reduces the number of medication discrepancies and adverse drug events patients had, before and after the service was Implemented. The data will be collected retrospectively by clinical pharmacists at general practices. This will be followed by an expert panel meeting to assess the severity and causality of adverse drug events identified.

Intervention Type

Other

Primary outcome measure

Measured before and after the introduction of the TCAM intervention:

1. Prevalence of medication discrepancies, and adverse drug events using data gathered pseudonymously from primary care electronic health records by general practice clinical pharmacists

2. Class of medications involved, patient gender and age group involved associated with medication discrepancies measured using data from health records

3. Presence, preventability (ADEs) and potential/actual severity of identified medication discrepancies and adverse drug events using review by an expert panel

4. Factors associated with increased risk of medication discrepancies and adverse drug events measured using data from health records:

4.1. Patient factors: patients age, gender, hospital discharge diagnosis

4.2. Medication factors: medication group, medicine dose, and medicine formulation

4.3. Service factors: time to complete medication reconciliation

5. Time to identification of discrepancies using medication reconciliation (or equivalent) entry data gathered pseudonymously from electronic health records by general practice clinical pharmacists

6. Number of referrals, nature of the referrals and outcome of the referrals (i.e. activity in community pharmacy post-hospital discharge) including accepted, completed and rejected referral rates, and any reasons for rejections by community pharmacy using a mixed-method approach to analyse anonymised patient referral data via PharmOutcomes[™]

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/02/2020

Eligibility

Key inclusion criteria

The study did not involve recruiting participants, the inclusion criteria for is for eligible patient records for retrospective screening by general practice pharmacists.

'Safety' impact study data:

- 1. Age of 18 years or above
- 2. Discharged from in-patient hospital stay at NHS acute hospital in England
- 3. Staying at least 24 hours in hospital
- 4. Patients are prescribed at least 1 regular medication

5. Patients must be registered to one of the 20 named general practices involved in the project, located within the study Clinical Commissioning Group

6. Patient discharged on new or recurrent Monitored Dosage System (MDS) during a predefined 6-month period before and after the TCAM service went live

TCAM service utilisation 'Activity' data:

7. All patient discharged and referred via the TCAM service from March 2019 - February 2020

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex Both

Target number of participants 638

Total final enrolment 594

Key exclusion criteria

The study did not involve recruiting participants, the exclusion criteria are for patient records for retrospective screening stage by general practice-based pharmacists.

1. Patients discharged from an inpatient hospital stay from a hospital other than the proposed hospital

- 2. Patient stays less than 24 hours in NHS acute hospital in England
- 3. Discharged with no MDS

4. Patients who had a planned hospital admission including, e.g. dialysis, day-case surgery, chemotherapy or transfusion-related: as they are a specific group of patients which limits the

generalisability of the data

5. Patients without a mediation reconciliation or equivalent data in the general practice computer system, to extract data from

Date of first enrolment 01/02/2020

Date of final enrolment 30/12/2020

Locations

Countries of recruitment England

United Kingdom

Study participating centre University of Manchester Oxford Road Manchester United Kingdom M13 9PT

Sponsor information

Organisation University of Manchester

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Funder(s)

Funder type University/education

Funder Name University of Manchester

Alternative Name(s) The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Funder Name

This project is part of a PhD programme being funded by Kuwait Civil Service Commission

Results and Publications

Publication and dissemination plan

1. The findings identified from this study will be submitted as one or more chapters of a PhD thesis at The University of Manchester (expected submission late 2021)

 The team also plan to disseminate any findings in professional and academic conferences (expected during 2021) and publish them in academic peer reviewed journals (expected 2021)
 The findings identified from this study will also be shared with the participating NHS hospital and Clinical Commissioning Group (CCG), to help inform the ongoing development of this intervention to improve medication safety in transition of care

4. Where identified as appropriate, the research team may use a mixed method approach to combine data generated from this study with qualitative data collected from a study evaluating the perception of the TCAM service from the point of view of healthcare providers including pharmacists, physicians as well as patients/carers who have received the service

Intention to publish date

01/09/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of ethical approval.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/10/2023	22/03/2024	Yes	No