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Accessing medicines at end-of-life: an evaluation of service provision

Submission date
29/01/2018

Recruitment status
No longer recruiting

Registration date
02/02/2018

Overall study status
Completed

Last Edited
17/03/2023

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

Patients and carers are recommending that finding ways of effectively managing medicines at the end of life should be a priority for research. Experience from recent studies, and from talking with patients and carers, showed problems in getting the right prescriptions, at the right time, and from an accessible health care professional. They experienced problems with obtaining GP prescriptions and medicines from local pharmacies, getting hold of medicines outside of normal NHS hours can be very difficult, and confusion about how and who to get their medicines from. Our recent research also suggests that patients and carers need more information when medicines are first prescribed and supplied. Currently, accessing medicines (i.e. prescription, dispensing and information-giving processes) can cause patients and carers extra work and worry. These problems may also lead to under- or over-use of medicines, poor control of symptoms and avoidable use of NHS services. Some difficulties accessing medicines are related to the services that GPs provide. But there is also some evidence to suggest that what nurses do could be better: e.g. fewer than expected have trained to prescribe medicines. It has also been suggested that pharmacists could play more of a role in helping patients access end of life medicines. There are also new end of life services that might help with access, e.g. 24 hour services. However, none of these issues have been researched systematically, in-depth or on a large scale. The aim of this study is to provide an evaluation of patient and carer access to medicines at the end-of-life within the context of models of service delivery.

Who can participate?

This study includes GPs, nurses, pharmacists and end of life patients.

What does the study involve?

This study looks at services designed to help people access medicines in their last year of life and is split into phases. The first phase of the study fully reviews previous research to check what is already known and what the gaps and key issues are. Then, an on-line survey of approximately 200 each of GPs, nurses and pharmacists who provide care to patients at the end of life in the community is conducted. This survey is used to analyse their current practice and what needs to change to improve prescribing, supplying and giving information to patients about medicines. In the next phase the study, six different types of end of life services, including new or novel services, are evaluated in detail, using each one as a case study. In each type, 10 patients and

carers are asked to keep a log of their experiences of accessing medicines and then undergo interviews initially face-to-face, and then over the telephone four and eight weeks later. Health professionals involved in prescribing, supplying and giving information about their medicines are also interviews. In each case study, patient pathways to accessing medicines are mapped out by looking at a sample of 40 patients' records to analyse what medicines were prescribed, by whom, when, how often and what services were used. This helps to identify problems and where actions could be taken to improve services. The costs and outcomes for each type of service are also analysed. In the next phase of the study, a sample of 20-30 community pharmacists and a sample of companies that make and distribute medicines to pharmacies are interviewed over the phone to understand the "medicines supply chain" and why disconnections happen. Finally, after analysing the data, up to 40 people with interest and expertise in end of life medicines are invited to a workshop to debate our findings and make recommendations for policy, practice and future research.

What are the possible benefits and risks of participating?
It is not anticipated that there will be any direct benefits or risks from taking part in the study, other than those benefits associated with knowingly contributing to scientific knowledge through participation in research.

Where is the study run from?
This study is being run by University of Southampton (UK).

When is the study starting and how long is it expected to run for?
January 2018 to November 2020 (updated 13/04/2021, previously: July 2020)

Who is funding the study?
Health Services and Delivery Research Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Integrated Research Application System (IRAS)
231837

Protocol serial number
IRAS 231837, IRAS 253133, HS & DR 16/52/23

Study information

Scientific Title
Accessing medicines at end-of-life: a multi-stakeholder, mixed method evaluation of service provision

Acronym
ActMed

Study objectives
Study aim:
The aim of this study is provide an evaluation of patient and carer access to medicines at end-of-life within the context of models of service delivery.

Objectives:
1. To produce a critical overview of existing research on experiences and outcomes of medicines access within EoL models of service delivery, through a systematic literature review (Phase 1).
2. To undertake a large scale survey to evaluate EoL care professionals' current practices, identify factors influencing professionals' contributions, the potential of the community-based nurse and pharmacist workforce to improve patient access to medicines at EoL, and provide an overview of current models of service delivery (Phase 2)
3. To evaluate and compare patient and carer experience of medicines access within models of EoL service delivery, including those featuring innovations in care, and to investigate their integration and sustainability through undertaking mixed methods case studies of practice (Phase 3)
4. To estimate the cost-effectiveness of service models (Phase 3)
5. To map patient 'access to medicines pathways' at EoL, including time-lines of problems, decisions, actions and use of services (Phase 3)
6. To identify barriers and facilitators to maximising the contribution of the nurse and pharmacist workforce to medicines access at EoL (Phases 2 & 3)
7. To interview community pharmacists and wholesalers and distributors to evaluate supply chain processes and identify challenges in providing access to EoL medicines (Phase 4)
8. To convene an expert consensus-building workshop to review study findings and generate recommendations on key characteristics of EoL service delivery that result in responsive, person-centred, coordinated medicines access, together with identification of factors that will embed and sustain characteristics in routine practice (Phase 5)
9. To use the expert consensus workshop to identify models to evaluate in a follow on study, comparing the effectiveness and cost-effectiveness of service delivery models (Phase 5)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 31/01/2020:
Phase 2 approved 26/06/2018, Health Research Authority, IRAS ref: 231837
Phase 3 and 4 approved 06/02/2019, amendment approved 09/07/2019, Health Research Authority, IRAS ref: 253133, REC ref: 18/SC/0675

Previous ethics approval:
Request for approval for Phase 2 submitted to Faculty of Health Sciences Ethics Committee 26.01.2018
Request for approval of Phase 3 to be made in May 2018 to HRA
Request for approval of Phase 4 to be made in October 2018 to HRA
Not provided at time of registration

Study design
Mixed methods design

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
End-of-life care

Interventions
Phase 1: This phase consists of a systematic review of research evaluating medicines access experiences, influences and outcomes within EoL service delivery models.

Phase 2: This phase includes sending on-line questionnaire surveys to GPs, nurses and pharmacists providing community-based EoL care. These are sent to GPs (n≥200), community-based clinical nurse specialists (n≥200), community nurses (n≥200) and community pharmacists (n≥200) to identify current practices in facilitating EoL medicines access, barriers and facilitators to improving access, and identification of models of service provision for Phase 3 evaluation. Data analysis is doing using descriptive and inferential statistics.

Phase 3: This phase consists of evaluative case studies (n=6) of medicines access experiences within different service delivery models. The unit of analysis is the service delivery model. Within each case, mixed methods are conducted which include 10 patient / carer medicines access logs and interviews (study entry and at 4 and 8 weeks), case note review of 40 patient records, health care professional interviews, and an economic evaluation. Logs are analysed using descriptive statistics and visual display techniques. Patient / carer interview data is audio-recorded, fully transcribed and analysed using Framework Analysis. Health care professional interviews are audio-recorded, fully transcribed and analysed using Framework Analysis. Annotated time-lines aree constructed from patient records for each patient with decisions, action points, services used, information accessed, to understand medicines access processes and identify points that would benefit from action. From patient records, the main pathways and healthcare resources used therein are identified, and use sources e.g. NHS Reference costs and the Personal Social Services Research Unit cost report to cost these pathways. Method and data source triangulation are undertaken within each case and cross-case comparison will be used for theory-building.

Phase 4: This phase consists of interviews with pharmacists and pharmaceutical companies. Telephone interviews are conducted with 20-30 community pharmacists, and a national sample of key pharmaceutical wholesaler distribution companies (n=10) to illuminate the supply chain and barriers and facilitators to the effective supply of EoL medicines to patients and carers. Data is analysed using Framework Analysis (9).

Phase 5: An expert consensus-building workshop, to critically review and refine the study's preliminary findings and recommendations. Sample participants are EoL experts (n=40) including national policy leads (for service & workforce development), commissioners, EoL regional leads, patients, carers and health care professionals. With the study team, experts generate policy, service delivery, practice and future research recommendations based on identification of: a) features of service delivery models that facilitate optimum access to medicines at EoL b) the mechanisms required to lever change and embed best models in routine practice.

Intervention Type
Behavioural

Primary outcome(s)
1. Identification of gaps in service provision and deficits in care experienced by patients and carers is assessed using a systematic review of literature (Phase 1), questionnaire survey (Phase 2), patient logs, patient and health care professional interviews, data on service use from patient records within evaluative case studies (Phase 3), and interviews with community pharmacists and pharmaceutical wholesalers and distributors
2. Models of good practice of EoL in service delivery is assessed using a systematic review of literature (Phase 1), questionnaire survey (Phase 2), patient logs, patient and health care professional interviews, data on service use from patient records within evaluative case studies (Phase 3), and interviews with community pharmacists and pharmaceutical wholesalers and distributors

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
27/11/2020

Eligibility

Key inclusion criteria
Phase 2:
1. GPs
2. Community-based palliative care clinical nurse specialists
3. Community nurses
4. Community pharmacists

Phase 3:
Purposively selected 3 service delivery models in the north of England and 3 in the south, using a sampling frame derived from Phase 2 respondent EoL service models and informed by logic models.

Phase 5:
Purposive and snowball sampling will be used to identify national experts, including EoL policy, service delivery, professional, and education leads at the Department of Health, NHS England, Health Education England, Royal College of Nursing, Royal College of General Practitioners, Royal Pharmaceutical Society, Health Education England workforce development leads, Clinical Commissioning Group leads for EoL, EoL and Non-Medical Prescribing programme leads from HEIs, charity representatives e.g. Marie Curie, Macmillan Cancer Care, pharmaceutical wholesaler representatives, and key EoL health care professionals. Our PPI co-applicant and Advisory Group PPI members will represent EoL informal carer perspectives.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Those who do not fit the inclusion criteria.

Date of first enrolment
01/06/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
Southampton
United Kingdom
S017 1BJ

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2021	13/08/2021	Yes	No
Results article	online survey results	24/09/2020	13/08/2021	Yes	No
Results article		01/07/2022	17/03/2023	Yes	No
HRA research summary			28/06/2023	No	No

Other publications	systematic review	28/03/2021	13/08/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		16/04/2019	08/08/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes