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A study exploring whether urgently required medication can be remotely issued from the REMEDY medicine machine in rural communities

Submission date
16/09/2025

Recruitment status
Recruiting

Registration date
14/10/2025

Overall study status
Ongoing

Last Edited
14/10/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

During the evening, overnight, and at weekends (known as the Out-of-Hours period) some people find it difficult to get medications prescribed by a doctor because local pharmacies (chemist shops) are closed, and patients may need to travel long distances or wait until the pharmacies open. This is a bigger problem for those people who cannot travel easily. If they can't start their medications quickly, minor health issues can turn into serious ones, which might need a hospital stay.

Being able to get a medication after a telephone consultation with a doctor during the evening, overnight or at weekends is important for people’s health and for avoiding the costs associated with delayed treatment when problems such as infections worsen. This is a big issue in Wales, especially rural areas where there may not be easy access to a pharmacy. We want to find out whether technology, in the form of a medication issuing machine (called REMEDY, for REmote MEdiction maDe easY) could help solve this problem. The machine operates similarly to a vending machine or parcel collection point, but there would be no charge to patients.

We plan to study REMEDY machines, which are being used by the North Wales GP Out of Hours service in Dolgellau and Holyhead, to address such challenges. If the doctor decides that a patient living in these areas needs a medication after speaking to them on the telephone, the doctor will use a REMEDY machine located near to the patient’s home to supply that medication. The patient would be given a code by the doctor which they would enter into the local REMEDY machine. The machine would then release their medication. We want to find out what will work well and what will not work well for patients and medical staff using this machine by watching and talking to them, as well as using information from the machine and routinely collected information held in the Out-of-Hours service records. We will also look at whether the machine provides value for money to the NHS.

Members of the public have already taken part in discussing the problems with getting medications during the Out-of-Hours period and have helped to develop the REMEDY machine. Going forward, members of the public will be invited to be part of groups giving advice to the REMEDY machine project and will help with writing patient facing materials and publications.

Who can participate?
1. Patients, parents, guardians, or carers who are prescribed medication via REMEDY after an Out-of-Hours consultation
2. NHS staff involved in implementing or using the machine (clinicians, pharmacy, admin, call centre staff)
3. Social care staff (e.g. care home staff) involved in obtaining Out-of-Hours medicines
4. Community members attending local engagement events
5. Regional and national stakeholders, including policy and professional representatives, with an interest in medicines access

What does the study involve?
1. Surveys: Automatically sent to patients/carers using REMEDY (≈200 target)
2. Interviews and focus groups: With patients, carers, NHS staff, pharmacy staff, social care staff, and stakeholders
3. Community events: Meetings in Dolgellau and Holyhead to gather local views
4, Ethnographic observations: Researcher attends Out-of-Hours call centres, meetings, and operational settings
5. Routinely collected data: Anonymised REMEDY machine logs, Adastra case records, Datix incident reports
6. Time-and-motion study: Logs completed by pharmacy staff involved in machine restocking and management

What are the possible benefits and risks of participating?
We hope that our study of how the REMEDY machine is used will provide an indication of whether it could help to provide medications quickly and safely when the local pharmacies are closed. We'll use the results of this study to help us develop the methods for a larger study looking at the use of the machine in different sites across Wales. We will also write a report, provide tools for organisations who want to use the REMEDY machine in the future, and information for policymakers and companies. We will share this so that patients, doctors, policymakers and companies can understand what works well and what does not work well about using the REMEDY machine.
Benefits: Helping test a new way of providing timely access to medicines in rural Wales; improving Out-of-Hours services and reducing treatment delays; contributing to evidence that may inform wider NHS adoption.
Risks: Possible inconvenience from completing surveys or interviews; possible distress if discussing negative experiences (support provided if needed); confidentiality risks – these have been minimised by anonymisation and secure data handling; there is minimal clinical risks as standard care pathways remain in place alongside REMEDY.

Where is the study run from?
The study is sponsored by Bangor University and run in collaboration with Betsi Cadwaladr University Health Board (BCUHB), North Wales Medical School (Bangor University), University of Aberdeen, University of Oxford, and Swansea University. The pilot machines are based in Dolgellau and Holyhead (North Wales).

When is the study starting and how long is it expected to run for?
April 2025 to March 2027

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Dr Rebecca Payne, rebecca.payne@bangor.ac.uk

Study website
https://www.bangor.ac.uk/north-wales-centre-for-primary-care-research/the-remedy-project

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
359070

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
REM2025

Study information

Scientific Title
A feasibility study to explore the introduction of a remotely controlled medication issuing machine during the out-of-hours period in rural and under-served areas of Wales: the REmote Medication maDe easY (REMEDY) study

Acronym
REMEDY

Study objectives
1. Explore how/whether Out-of-Hours clinicians use or don't use REMEDY to supply medications and identify any barriers or facilitators to use
2. Establish if fidelity to the intervention is maintained and whether workflows function as expected both for clinicians issuing medication and for patients, parents, guardians, or carers collecting from the machine
3. Explore how patients, parents, guardians, or carers respond to the option of using REMEDY when accessing care Out-of-Hours, including any decisions to decline this option
4. Establish whether patients, parents, guardians, or carers using REMEDY are willing to complete a feedback questionnaire to provide the user experience
5. Explore the acceptability of REMEDY to all stakeholders
6. Examine potential for, or actual, harms associated with REMEDY
7. Identify any modifications (if any) required to optimise REMEDY or the model of use within the NHS Wales Out-of-Hours service
8. Estimate the cost-effectiveness of implementing REMEDY, and the value of undertaking further research to establish effectiveness

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/09/2025, East Midlands – Nottingham 1 Research Ethics Committee (2 Redman Place, Stratford, Stratford, E20 1JQ, United Kingdom; +44 (0)2071048115; nottingham1.rec@hra.nhs.uk), ref: 359070

Study design
Mixed methods feasibility study

Primary study design
Observational

Secondary study design
Case study design using qualitative methods including interviews, focus groups, real world data and ethnography

Study setting(s)
Care home, Community, Medical and other records, Pharmacy, Other

Study type(s)
Other, Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Access to urgently required medication during the Out of Hours period following a telephone consultation with a primary care service

Interventions
This feasibility study uses a mixed-methods approach, combining qualitative and quantitative data collection to evaluate the implementation of a remotely controlled medication dispensing machine (REMEDY) in two rural Welsh communities: Dolgellau and Holyhead. The study is underpinned by Developmental Evaluation, allowing for real-time feedback and adaptation, and is structured using the Non-Adoption, Abandonment, Scale-Up, Spread and Sustainability (NASSS) framework to understand the complexities of introducing health technologies.

Participants will include patients, carers, NHS staff, community members, and stakeholders involved in or affected by the REMEDY system. Data collection will consist of patient surveys (sent automatically after machine use), semi-structured interviews, focus groups with care home staff, ethnographic observations, and analysis of routinely collected service data. Two community engagement events in each location will explore public views before and after implementation.

The qualitative data will be analysed thematically and mapped to NASSS domains, while quantitative data from surveys, machine logs, and clinical records will be analysed descriptively. A health economic analysis will estimate cost-effectiveness compared to usual care, using decision modelling and sensitivity analyses to inform the value of further research.

The study will be governed by an advisory group, frequent research team meetings, and ongoing public involvement. All data will be handled securely in line with GDPR and institutional policies.

Data analysis:
Qualitative data:
The analytical approach will be thematic analysis as described by Braun and Clarke within a constructivist paradigm. Data will be combined into an emerging narrative and refined as additional data sources are added as the study unfolds. Synthesis will be guided by the structure and methodology described in the NASSS framework paper to surface and explain the challenges and multiple forms of complexity that influences progress towards implementing and embedding use of the REMEDY machine in routine practice.

Quantitative data:
Data from the surveys will be cleaned by checking for outliers and out of range entries. Quantitative data will also be collated from routine operational data supplied by the implementation team. Analyses of quantitative data will include descriptive statistics (e.g., frequencies, percentages, means and standard deviations/medians and interquartile ranges).

Health economic analysis:
An economic analysis of REMEDY machines will be conducted using standard methods of decision analytic modelling, based on the most robust data available, and reported according to the CHEERS statement. Cost-effectiveness will be estimated from the perspective of the NHS and Personal Social Services in line with NICE guidance and based on an economic model that considers health outcomes, resource use, costs and health utilities to estimate the incremental cost per quality-adjusted life year (QALY) gained. The model structure will be developed in consultation with clinical experts to ensure it reflects a reasonable simplification of the context of care in the NHS. A Discrete Event Simulation may be necessary.

The model will compare workflows including REMEDY machines with current practice and will consider patient proximity to pharmacies using geospatial data, community pharmacy opening times, and patient access to public and private transport. The decision analytic model will evaluate costs and outcomes over the lifetime of hypothetical patient cohorts: costs and benefits in future years will be discounted at an annual rate of 3.5% and varied between 0% and 6% in sensitivity analysis. Results from the model will be reported as incremental cost per QALY gained (ICERs) and compared with the NICE threshold range of £20,000 to £30,000 per QALY. Uncertainties in all parameter inputs will be accounted for in the analysis by including parametric distributions for each point estimate. This will enable probabilistic sensitivity analyses to be performed based on sampling from distributions using Monte Carlo simulation. Uncertainty in cost-effectiveness will be represented by cost-effectiveness acceptability curves (CEACs).

We will conduct a value of information analysis to inform future research priorities and the design of a definitive study of the clinical effectiveness of REMEDY machines. The expected value of perfect information (EVPI) and the expected value of perfect parameter information (EVPPI) will be calculated on both per-patient and population levels using the Sheffield Accelerated Value of Information (SAVI) approximation to facilitate computation effort. The EVPI for a decision problem must exceed the cost of research to make additional investigation worthwhile. It places an upper value on conducting further research overall (EVPI) or a specific area of information (EVPPI). If relatively small values are obtained for EVPI and EVPPI then this may suggest that no further research is necessary or required to obtain more precise estimates for specific parameters.

Intervention Type
Other

Primary outcome measure
1. Feasibility & Acceptability
1.1. Proportion of patients, parents, guardians, or carers completing the survey measured using automatically texted Microsoft Forms survey sent via the REMEDY machine software (machine usage logs used to track completion rates) at all patient uses of the machine during the 18-month data collection period (Sept 2025 – Mar 2027)
1.2. Patient/carer reported ease of use of REMEDY measured using patient and carer survey (closed Likert-scale and free-text questions on usability and accessibility) at each machine use throughout the 18-month data collection period, with analysis at mid-study and end-of-study

1.3. Willingness to participate in interviews or provide feedback measured using proportion of survey respondents indicating consent to a follow-up interview in the final survey question at time of survey completion (continuous throughout study period)
1.4. Acceptability of REMEDY to staff (clinical, pharmacy, administrative) and stakeholders measured using semi-structured interviews with Out-of-Hours clinicians, pharmacy, and administrative staff (≈10 participants), pharmacy stakeholder interviews (≈10), and regional /national stakeholder interviews analysed thematically using the NASSS framework at mid-implementation (≈6 months post-launch (pharmacy and external stakeholders) and mid- post-implementation (staff regularly using the machine)

2. Safety
2.1. Reported adverse outcomes or challenges (patient survey, interviews) measured using patient/carer survey items on adverse outcomes or difficulties using the REMEDY machine, supplemented by patient and staff interviews at ongoing collection throughout 18-month period with interim (≈9 months) and final analysis
2.2. Examples of harm or near-misses (from interviews, Datix logs, ethnographic observations) measured using triangulation of Datix incident reports, Adastra case records, semi-structured staff and patient interviews, and ethnographic field notes from Out-of-Hours call centres and implementation meetings at continuous monitoring throughout implementation and steady-state operation, with periodic review at implementation meetings
2.3. Fidelity of workflows — whether REMEDY was used as intended by clinicians and patients measured using linkage of REMEDY machine logs, Adastra case records, and ethnographic observations to determine correct workflow and use patterns at continuous data capture during implementation, with analyses at mid-study and end-of-study

3. Implementation & Workflow
3.1. How clinicians decide to use or not use REMEDY measured using semi-structured interviews with GPOOH and 111 National Clinical Support Hub staff, supported by ethnographic observation of call-centre workflows and implementation meetings at implementation and steady-state phases across the 18-month data collection period
3.2. Impact on Out-of-Hours workflows (from staff interviews, observations) measured using staff interviews, ethnographic observation of Out-of-Hours and pharmacy operations, and a time-and-motion study with pharmacy staff at mid-implementation and steady-state (approx. 12 months after launch)
3.3. Barriers and facilitators to adoption measured using synthesis of qualitative data from staff, patient, stakeholder interviews, community events, and ethnographic field notes analysed using the NASSS framework at interim (mid-study) and final data analysis stages

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2025

Completion date
31/03/2027

Eligibility

Key inclusion criteria

1. Patients, parents, guardians, or carers, who have been allocated medication via the machine
2. Community members who choose to take part in community engagement events
3. NHS Staff who have been involved in the implementation or use of the machine
4. Stakeholders with an interest in getting urgently required medication to patients will be eligible. These will include representatives from Welsh government, the Royal Pharmaceutical Society, Community Pharmacy Wales, the Royal College of GPs, and British Medical Association
5. Industry representatives involved in developing and/or distributing the machine

Participant type(s)
Patient, Carer, Service user

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
350

Key exclusion criteria
1. NHS staff who have not been involved in the project
2. Stakeholders who are not involved with, or able to influence, the provision of urgently required medication
3. Patients, parents, guardians, or carers who do not consent to participate

Date of first enrolment
01/10/2025

Date of final enrolment
01/03/2027

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd

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Sponsor type
University/education

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ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study will be disseminated through:
1. National networks: Welsh OOH Forum, Scottish OOH National Operations Group, Urgent Health UK network.
2. European research group: EUROOHNET (European Out-of-Hours).
3. Project website: REMEDY project website.

Planned outputs:
1. Case study report – to inform design of a future definitive study, including an implementation toolkit and data collection instruments for future multisite evaluations.
2. Planned publication in a peer reviewed journal
3. Briefing papers
4. For industry: summarising issues and recommendations, shared with manufacturers /distributors + industry webinar.
5. For policy makers: short report for policy dissemination via professional networks.
6. Public newsletters & presentations – to Llais and RCGP patient group in 2025 (sharing early insights), plus regular newsletters for participants and All-Wales OOH Forum staff.
7. Media engagement – with BCUHB and Oxford University communications teams.
8. All outputs will also be hosted on the REMEDY project website, and participants will be signposted there in information sheets.

Intention to publish date
21/03/2028

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 sensitive and identifiable nature of patient and staff data, and the restrictions of NHS information governance. Participants have not consented to their data being shared outside the research team. Anonymised excerpts supporting the findings may be available in publications, and further access requests can be considered on a case-by-case basis subject to appropriate data sharing agreements

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 0.1		19/09/2025	No	No
Other files			19/09/2025	No	No
Participant information sheet	version 4 version 3	17/09/2025	19/09/2025	No	Yes

Participant information sheet		17/09/2025	19/09/2025	No	Yes
Participant information sheet	version 4	17/09/2025	19/09/2025	No	Yes
Participant information sheet	version 3	17/09/2025	19/09/2025	No	Yes
Participant information sheet	version 3	17/09/2025	19/09/2025	No	Yes
Protocol file	version 10	04/09/2025	19/09/2025	No	No