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Can screening for Clostridioides difficile carriage help prevent disease?

Submission date
02/07/2026

Recruitment status
Not yet recruiting

Registration date
24/07/2026

Overall study status
Ongoing

Last Edited
24/07/2026

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Clostridioides difficile (often called C. difficile or C. diff) is a bacterium that can cause diarrhoea, particularly in people who are in hospital or who have recently taken antibiotics. While some people become unwell from C. diff, others carry the bacterium in their gut without having any symptoms. This is known as asymptomatic carriage.
People who carry C. diff may have a higher chance of developing an infection if they need antibiotics. This is because antibiotics can upset the normal balance of bacteria in the gut, allowing C. diff to grow and cause illness.
This study will look at whether testing patients to find out if they are carrying C. diff can help doctors make better decisions about antibiotic treatment. If a patient is found to be carrying C. diff, this information may encourage the healthcare team to choose antibiotics that are less likely to increase the risk of C. diff infection, where it is safe and appropriate to do so. The aim is to see whether this approach can reduce the number of people who go on to develop C. diff infection.

The main purpose of this study is to find out whether testing patients for C. diff and using the results to help doctors choose antibiotics can work as part of everyday care in a busy hospital. The study will also help us to:
• Find out how many patients carry C. diff without having symptoms.
• Understand whether people who carry C. diff are more likely to develop an infection.
• See whether knowing a patient's C. diff status changes the antibiotics that are prescribed.
• Assess whether this type of screening could become a practical part of routine hospital care in the future.
It is hoped that the results of this study will help improve the prevention of C. diff infection and support safer use of antibiotics for future patients.

Who can participate?
Any adult (aged 18 years or over) who is admitted to the Medical Assessment Unit and is able to understand the study and give their consent to take part may be invited to participate.

What does the study involve?
Participants will be asked to provide a stool sample so that it can be tested for C. diff. If

preferred, a rectal swab can be taken instead. A rectal swab involves gently inserting a small cotton swab just inside the back passage to collect a sample. It is a quick procedure and may be slightly uncomfortable, but should not be painful. Participants and the doctors looking after them will be told the result of your test.
If the test shows that the participant is carrying C. diff, some additional infection prevention measures may be put in place to reduce the chance of the bacteria spreading to other patients (washing hands with soap and water and using an apron and gloves as appropriate). The medical team may also use this information when making decisions about participants' antibiotic treatment, where appropriate, to help reduce their risk of developing a C. diff infection.
Taking part in the study will not affect any other aspect of participants' care, and all treatment decisions will continue to be made by the healthcare team looking after them.

What are the possible benefits and risks of participating?
What are the possible benefits?
The healthcare team will know whether the participant is carrying C. diff. This information may help them make decisions about their antibiotic treatment. Where it is safe and appropriate, they may choose antibiotics that are less likely to increase the risk of developing a C. diff infection.
It is also hoped that this study will help us learn how best to care for people who carry C. diff without symptoms. The results may help improve antibiotic prescribing and the prevention of C. diff infection for future patients.
However, there is no promise that taking part will provide a direct benefit to participants.

What are the possible risks?
There are very few risks associated with taking part. Providing a stool sample has no physical risks. If participants choose to have a rectal swab instead, the procedure may be briefly uncomfortable but should not be painful.
There is a small risk that knowing participants are carrying C. diff could influence treatment decisions in a way that is not helpful. To reduce this risk, healthcare staff involved in the study will receive guidance on how to use the test results, and all treatment decisions will continue to be made by the doctors responsible for their care. Doctors in the hospital are experienced in caring for patients who are known to carry C. diff, so this is not expected to be a significant risk. If their test shows that they are carrying C. diff, additional infection prevention measures may be put in place to help reduce the chance of the bacteria spreading to other patients.

Where is the study run from?
Public Health Wales in collaboration with Swansea Bay University Health Board.

When is the study starting and how long is it expected to run for?
August 2026 to December 2026.

Who is funding the study?
The Swansea Bay University Health Board, UK. Cepheid is supplying the test cartridges but is not responsible for the day-to-day running of the study or the care of participants.

Who is the main contact?
1. Dr Brendan Healy, Principal Investigator, brendan.healy@wales.nhs.uk
2. Personal Assistant Team, SwanseaMicrobiologyPATeam@wales.nhs.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
354961

Central Portfolio Management System (CPMS)
74202

Study information

Scientific Title
A pilot study to determining the feasibility of screening of hospital patients on admission for asymptomatic C. difficile in order to act to reduce subsequent disease incidence

Study objectives
Primary Objective:
1. To assess the feasibility of carrying out C. difficile screening of admissions to an acute medical admissions unit.

Secondary Objectives:
1. To estimate the temporal carriage rate (prevalence) in patients admitted to the medical admission units of MH.
2. To estimate the rate of C. difficile disease development (incidence) among previously asymptomatic C. difficile carriers.
3. To assess whether results from carriage can be successfully communicated to the clinical teams and determine if it results in enhanced contact precautions for those individuals (use of appropriate PPE (apron and gloves), using soap for hand hygiene).
4. To assess whether identification of carriage has any impact on prescribing. The notes of carriers will be reviewed for evidence of any impact on prescribing decisions and rate of initiation of broad spectrum antibiotics (Clindamycin, ciprofloxacin (quinolones), cephalosporins, co-amoxiclav (4C's), Tazocin and Meropenem) will be compared between carriers and non carriers.

5. To determine level of relatedness between the screening identified C. difficile isolates and current and historic cases using WGS data.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/01/2026, Wales Research Ethics Committee 3 (Health and Care Research Wales Floor 4, Crown Building Cathays Park, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC3@wales.nhs.uk), ref: 25/WA/0354

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Diagnostic, Prevention

Study type(s)
Prevention, Screening

Health condition(s) or problem(s) studied
Acceptability of screening for C. difficile

Interventions
Overview:
The study will be undertaken in the Medical Admission Units in Morriston Hospital. Screening all consenting adults (aged ≥18 years) admitted to the acute admission units in Morriston Hospital who do not, at the time of admission, have diarrhoea (defined as Bristol stool chart >4). The bacteria (i.e. germ) we will be screening for is Clostridioides difficile (a.k.a C. difficile or C. diff). If a patient has been confirmed to be carrying C. difficile, a simple intervention flagging the carriage status to clinical teams caring for patients and triggering increased scrutiny of antibiotic prescribing will be piloted. This is a similar approach to that adopted in national policies regarding Carbapenemase-producing Enterobacteriaceae (i.e. CPE).

Screening for C. difficile:
A faecal sample or rectal swab will be collected from patients as soon as practically possible after admission to the ward. Only one screening sample per patient will be required. Patients will be able to opt out of the screening. Patients who lack the capacity to consent will be excluded from the study, and a sample will not be collected.

Patients will be provided with patient information sheets prior to verbal consent. Verbal consent will be obtained from the patients on the admission units prior to sample collection. The clinical staff responsible for providing care to the patients will ask the patients if they are willing to provide a faecal sample to identify C. difficile carriage. Patients will be required to complete a section of the patient information sheet confirming their verbal consent.

Sample collection will be carried out using standard clinical procedures (these are used for similar microbiological screening e.g. CPE). Where rectal samples are collected, this will be done by trained clinical health care staff employed on the wards. Samples will be processed via existing Public Health Wales microbiology testing procedures, and results will be entered into patients' notes and recorded within existing laboratory and patient data management systems (as per standard practice).

Laboratory test results from screening will be uploaded to existing electronic patient records (ICNET/LIMS/Welsh Clinical Portal). These are routinely visible to clinicians caring for the patient; this will include the patient's GP. The GP will not directly be informed of study enrollment. However, they will be able to see the electronic test record. The samples will be labelled as screening swabs to identify these samples, and results will contain an automated response indicating the context in which the test was taken. A member of the site infection prevention and control team will have responsibility for alerting the ward staff of carriage and to trigger the subsequent response; this individual will have existing access to all microbiology tests carried out on these patients.

When a positive asymptomatic carrier of C. difficile is identified, the ward will be made aware, thus facilitating a high level of infection prevention vigilance around the patient. This will involve a highlight sticker on the patient's notes and other patient documentation to allow nursing staff to ensure optimal infection prevention steps are taken throughout the patient's hospital stay. This may include, for example, the use of dedicated commodes or lavatories, strict adherence to hand hygiene and appropriate cleaning of the patient environment (in line with best standard practice)-measures designed to reduce the risk of progression from C. difficile carriage to disease. The alert will be continued for the full length of the patient hospital episode.

C. difficile isolates will be stored for future epidemiological comparison with other UK isolated strains. This will use Whole Genome Sequencing (WGS).

Outcomes:
This is a feasibility pilot to determine the acceptability of the intervention to patients and to hospital staff and the feasibility of delivering the intervention in a clinical setting. The key outcome measures will be the proportion of admitted patients who are screened and the rate of C. difficile carriage. The study is not designed to detect an impact on C. difficile incidence (i.e. transmission in the hospital setting); however, data on symptomatic cases within the study sites will be collected to inform future study of the intervention, including future comparison of phylogenetic information obtained from whole-genome sequencing of symptomatic and asymptomatic isolates.

Intervention Type
Other

Primary outcome(s)
1. Feasibility: the proportion of admitted patients who are screened measured using data collected from electronic patient records at the end of the study

Key secondary outcome(s)
1. Patient-related characteristics: Proportion for whom sample collection was not possible for reasons other than the patient declining measured using information collected by the study team based on results from those enrolled at the end of the study

2. Patient-related characteristics: The prevalence of asymptomatic C. difficile carriage in the admitted patient cohort measured using the number of positive screens versus the total number screened at the end of the study

3. Patient-related characteristics: The number and percentage of patients who develop diarrhoea within 28 days of admission measured using data collected from clinical notes and stool specimens sent at the end of the study

4. Patient-related characteristics: The number and percentage of patients who develop laboratory-confirmed C. difficile infection measured using data collected from lab results at the end of the study

5. Patient-related characteristics: Death measured using data from the clinical portal at the end of the study

6. Organism-related characteristics: Genetic strain of C. difficile isolate measured using genomics-specific visualisation tools to determine the level of relatedness between the C. difficile isolates from both asymptomatic and symptomatic cases within the study site and period at the end of the study

7. Antibiotic prescription-related characteristics: The rate of broad-spectrum antibiotic use (Clindamycin, ciprofloxacin (quinolones), cephalosporins, co-amoxiclav (4C's), Tazocin and Meropenem) will be compared between carriers and a non-carrier age-matched population measured using data from the electronic prescribing system at the end of the study

8. Antibiotic prescription-related characteristics: Proportion of those prescribed antibiotics within 28 days of admission measured using data from the electronic prescribing system at the end of the study

9. Infection prevention outcomes: The rate of implementation of the use of an apron, gloves and hand washing with soap and water in MAU patients who would otherwise have been managed without these interventions measured using data collected by study personnel through inpatient and notes review at the end of the study

10. Infection prevention outcomes: The speed of isolation following onset of diarrhoea in carriers vs non-carriers measured using data from the hospital bed data system at the end of the study

Completion date
03/12/2026

Eligibility

Key inclusion criteria

1. All patients aged ≥18 years admitted to the acute admission units in the study site who do not, at the time of admission,
have diarrhoea (defined as Bristol stool chart >4)
2. Willing to provide a faecal sample or rectal swab on the basis of a verbal consent process.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients who decline screening
2. Patients who have diarrhoea on admission to Morriston Hospital
3. Aged under 18 years old
4. Patients without the capacity to provide verbal consent
5. Other clinical emergency issues that require precedence over study inclusion

Date of first enrolment
03/08/2026

Date of final enrolment
03/12/2026

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea

Wales
SA6 6NL

Sponsor information

Organisation
Public Health Wales

ROR
https://ror.org/00265c946

Funder(s)

Funder type
Government

Funder Name
Cepheid

Alternative Name(s)
Cepheid Inc

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available