Clinical impact of syndromic molecular point-of-care testing for gastrointestinal pathogens in adults hospitalised with suspected gastroenteritis (GastroPOC): a pragmatic, open-label, randomised controlled trial

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Summary

Background Single-occupancy isolation rooms are a finite resource in UK hospitals but are crucial in preventing transmission of infection. Patients with suspected gastroenteritis are nursed in single-occupancy rooms, but delays in laboratory testing lead to non-infectious patients remaining isolated for prolonged periods unnecessarily. Rapid molecular test panels for gastrointestinal pathogens have a run time of around 1 h but their clinical impact is unknown. We aimed to evaluate the clinical impact of syndromic molecular point-of-care testing (mPOCT) for gastrointestinal pathogens in adult patients presenting to hospital with suspected gastroenteritis on single-occupancy room use and a range of other outcome measures.

Methods In this pragmatic, open-label, randomised controlled trial, we enrolled adults hospitalised with suspected gastroenteritis in a large UK hospital. Patients were randomly allocated (1:1) to receive syndromic mPOCT of stool or rectal samples, or to routine clinical care (control) with laboratory testing. The primary outcome was the duration of time in single-occupancy rooms assessed on a modified intention-to-treat basis. Secondary outcomes included the time to results, time to de-isolation, antibiotic use, and safety outcomes. The study was registered with ISRCTN, ISRCTN88918395, and is complete.

Findings Between March 20, 2017 and March 17, 2020, from 455 patients assessed for eligibility, we enrolled 278 patients, 138 assigned to mPOCT (one withdrawal) and 140 to the control group. The duration (geometric mean) of single-occupancy room isolation was 1·8 days (95% CI 1·5–2·2) in the mPOCT group compared with 2·6 days (2·2–3·0) in the control group (exponentiated coefficient 0·70 [95% CI 0·56 to 0·87]; p=0·0017). The median (IQR) time to results was 1·7 h (1·5–2·0) for mPOCT and 44·7 h (21·2–66·1) for the control group (p<0·0001). Time to de-isolation was 0·6 days (0·3–1·8) in the mPOCT group compared with 2·2 days (1·2–3·2) in the control group, (p<0·0001). Antibiotics were given in 89 (65%) of 137 in the mPOCT group and 66 (47%) of 140 in the control group (p=0·0028). There were no differences between groups in length of hospital stay, or in safety outcomes including mortality, intensive care unit admission, or readmission to hospital.

Interpretation mPOCT for gastrointestinal pathogens in patients with suspected gastroenteritis returned results more rapidly than conventional testing and was associated with a reduction in single-occupancy room use. However, these benefits need to be balanced against a potential increase in antibiotic use.

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Introduction

Worldwide, diarrhoeal illness causes over 1·6 million deaths annually, and is the eighth most common cause of death.[1] Gastrointestinal illness accounts for over 1 million visits to emergency departments, and at least 130 000 hospital admissions, in England each year.[2,3] Diarrhoea can be caused by a wide range of gastrointestinal pathogens and also by many other illnesses and medications, and is therefore a non-specific symptom with a wide differential diagnosis.[2] Additionally, centralised laboratory testing of stool samples is associated with a long turnaround time to results.[4–7] Patients presenting to hospital with diarrhoea are routinely nursed in single-occupancy rooms (so-called side rooms, in the NHS) along with associated infection control measures. There are only about 40 000 single-occupancy rooms of about 111 000 acute hospital beds in the NHS in England and only around 1700 of these are dedicated isolation rooms.[8,9] The COVID-19 pandemic has put further pressure on this limited resource, therefore patients presenting with diarrhoea to hospital represent a diagnostic challenge, have delays in diagnosis, and stretch limited health-care resources.

Research in context

Evidence before this study

We searched PubMed, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, ClinicalTrials.gov, and the ISRCTN trial database for relevant published articles and ongoing trials assessing the clinical impact of molecular point-of-care testing for gastrointestinal pathogens in hospitalised adults. We used the search terms "point-of-care test*" OR "rapid PCR testing" OR "rapid molecular testing", AND "diarrhoea" OR "gastroenteritis". Word variations for British English or American English spellings were also searched. To widen the search, we also included the names of PCR panel manufacturers. We limited the search to studies published between Jan 1, 1980, and Oct 1, 2022, and also to articles in English. We excluded studies reporting only diagnostic test accuracy, studies in outpatients, studies enrolling patients presenting without gastrointestinal illness, studies using antigen-based tests, studies requiring endoscopy or ultrasound, studies assessing faecal occult blood testing, and studies only in children. Eight studies were identified that used rapid syndromic PCR for gastrointestinal pathogens in the laboratory, rather than at the point of care, and reported on the clinical impact beyond turnaround time of results. Only one study was a randomised controlled trial and the others were observational.
The randomised controlled trial was smaller than the study presented here and did not find any difference in isolation facility use or the narrow range of other clinical outcomes measured. Only one study (a small randomised controlled trial done in the emergency department) was identified that used syndromic PCR for gastrointestinal pathogens at the point of care; however, this study was terminated owing to the COVID-19 pandemic after including only 74 patients. This study showed an improvement in appropriate antibiotic prescriptions but did not report on isolation facility use. We found no systematic reviews evaluating the impact of molecular point-of-care testing for gastrointestinal pathogens.

Added value of this study

To our knowledge, this is the first large randomised controlled trial of molecular point-of-care testing of gastrointestinal pathogens in adults presenting to hospital, which evaluates the impact on isolation facility use in addition to other outcome measures.

Implications of all the available evidence

Routine molecular point-of-care testing for gastrointestinal pathogens by rectal swabs or stool samples in adults presenting to hospital with suspected gastroenteritis is associated with improved time to results and reduced time spent in single-occupancy isolation rooms by patients who are non-infectious, by accelerating the time to de-isolation from single-occupancy isolation rooms to bays. Use of mPOCT was also associated with increased antibiotic use and future studies are needed to evaluate this further.

Testing for gastrointestinal pathogens is further delayed by the need to wait for the patient to produce a stool sample, which is the standard sample type used for laboratory testing. However, rectal swabs have been shown to have broadly equivalent diagnostic performance compared with conventional stool samples for the molecular detection of gastrointestinal pathogens.[10–12] Additionally, the use of rectal swabs for diagnosis is supported by US guidelines when stool samples cannot be collected in a timely manner, and in European guidelines for *Clostridioides difficile* diagnosis.[13,14] Rectal swabs therefore provide an opportunity to expedite testing for gastrointestinal pathogens.

Syndromic molecular test platforms for the detection of gastrointestinal pathogens are highly accurate, test for a comprehensive range of pathogens, and selected platforms are easy to use so-called sample-to-answer type platforms, with a run time of about 1 h. These have the potential to be deployed as near-patient or point-of-care tests in acute care areas.[6,15–17] Because some syndromic molecular panels test comprehensively for gastrointestinal pathogens in a single test, negative test results can lead to confident de-isolation decisions. The use of rectal swabs combined with syndromic molecular point-of-care tests (mPOCTs) might therefore reduce the delays associated with laboratory testing, and lead to improved use of single-occupancy rooms in patients presenting to hospital with diarrhoea. Other potential benefits include improved diagnosis and treatment of patients with diarrhoea through increased pathogen detection, although the detection of pathogens by molecular testing might not always represent the cause of the patient's illness and concern exists around the potential for overtreatment of colonising or non-pathogenic organisms.[18]

The UK's National Institute for Health and Care Excellence diagnostic assessment programme has previously reviewed molecular panels for gastrointestinal pathogens and identified key research priorities for assessing the impact of their use. Suggested outcome measures included length of time in a single-occupancy room, length of hospital stay, and change of treatment as a result of testing.[19]

We aimed to address this evidence gap by doing a pragmatic, randomised controlled trial of mPOCT for gastrointestinal pathogens on stool samples or rectal swabs in adult patients presenting to hospital with suspected gastroenteritis and evaluating the clinical impact on single-occupancy room use, antibiotic use, and a range of other outcome measures.

Methods

Study design

We did a single-centre, pragmatic, open-label, parallel group, randomised controlled trial (GastroPOC). Patients

were recruited from the acute medicine unit (AMU), acute surgical unit (ASU), emergency department, and other acute clinical areas within Southampton General Hospital, a large acute teaching hospital in the UK. The hospital serves a secondary care population of 650 000 people, and is run by University Hospital Southampton NHS Foundation Trust, which was the trial sponsor.

The study was approved by the West Midlands—Solihull Research Ethics Committee (REC) on Jan 9, 2017 (reference 16/WM/0515). The study protocol was amended once (REC approved on June 19, 2018) to change the study from a pilot to a full study, increase the sample size from 200 to 300 participants, allow 3 years for participant recruitment, and add additional patient de-isolation measures as secondary outcome measures. The study protocol is available online and in the appendix.[20]

Participants

Patients were eligible if they had an acute diarrhoeal illness or vomiting of up to 14 days duration, were at least 18 years old, had capacity to provide informed written consent, were able to adhere to study procedures, and were located in the emergency department, AMU, ASU, or inpatient ward. Patients had to be recruited within 48 h of first triage in the emergency department, or within 48 h of arrival in the AMU, ASU, or inpatient ward if they were admitted directly from the community. Acute diarrhoeal illness was defined as having three or more loose stools for a least 1 day. Patients were excluded if a palliative approach was being taken by the treating clinicians, they were previously included in the study and were re-presenting within 30 days after hospital discharge, or they declined to give a stool sample or rectal swab. All participants gave written informed consent.

Randomisation and masking

Patient–participants were consecutively assigned a unique participant identification number by study staff who then used the internet-based randomisation service Sealed Envelope, which uses random permuted blocks of sizes 4, 6, and 8, to generate the allocation sequence, and assigned the participants (1:1) to either the intervention group or control group. Data analysts and statisticians were masked to group allocation. Owing to the nature of the intervention, research staff, participants, and the clinical teams were not masked to group allocation.

Procedures

Patients randomly allocated to the intervention group had a stool sample or rectal swab obtained (both in Carey-Blair media, Remel, Thermo Fisher Scientific, KS, USA, and FecalSwab, Copan, Brescia, Italy) and analysed immediately by means of the FilmArray Gastrointestinal Panel (BioFire Diagnostics, bioMérieux, Salt Lake City, UT, USA) at the point of care. Clinical staff caring for the patient, and the hospital infection control team, were informed of the mPOCT result directly. The FilmArray testing units were located in dedicated areas within the AMU and ASU. If a rectal swab was obtained, a subsequent stool sample was obtained whenever possible. The mPOCT analysers were operated by members of the research team.

Patients randomly assigned to receive routine clinical care (control group) had stool testing done by standard laboratory testing at the discretion of the clinical team. In addition, all patients in the control group also had a stool sample or rectal swab taken (into Carey-Blair media) and frozen at –80°C, and subsequently analysed by means of the FilmArray Gastrointestinal Panel (at least 30 days after collection) to allow direct comparison for pathogens not detected by routine clinical care.

The FilmArray Gastrointestinal Panel gives a result in about 60 min and detects 22 pathogens: bacteria; *Campylobacter* (*jejuni*, *coli*, and *upsaliensis*), *Clostridioides difficile* (toxin A or B), *Plesiomonas shigelloides*, *Salmonella* spp, *Yersinia enterocolitica*, *Vibrio* (*parahaemolyticus*, *vulnificus*, and *cholerae*); the diarrhoeagenic *Escherichia coli–Shigella* spp; enteroaggregative *E coli* (EAEC), enteropathogenic *E coli* (EPEC), enterotoxigenic *E coli*, Shiga-like toxin-producing *E coli* (STEC) *stx1–stx2*, *E coli* O157, and *Shigella* spp–enteroinvasive *E coli* (EIEC); parasites; *Cryptosporidium* spp, *Cyclospora cayetanensis*, *Entamoeba histolytica*, and *Giardia lamblia*; and viruses; adenovirus F40/41, astrovirus, norovirus GI/GII, rotavirus A, and sapovirus (I, II, IV, and V).[16]

The on-site microbiology laboratory used various diagnostic methods for the detection of gastrointestinal pathogens including culture for *Salmonella* spp, *Shigella* spp, *Campylobacter* spp, and *E coli* O157; the EntericBio PCR system (Serosep, Annacotty, Ireland and Crawley, UK) for bacterial pathogens (*Salmonella* spp, *Shigella* spp, *Campylobacter* spp, verotoxigenic *E coli*, plus *Cryptosporidium* spp and *Giardia* spp), *Clostridioides difficile* (in addition to toxin detection by enzyme immunoassay), and separate norovirus GI/GII PCR; microscopy for ova, cysts and parasites; and antigen testing for adenovirus and rotavirus (bioNexia Rota-Adeno, bioMérieux, Marcy-l'Étoile, France).

Outcomes

The primary outcome measure was the duration of time in a single-occupancy room (known as a side room in the National Health Service [NHS]). This was chosen because single-occupancy rooms are a finite hospital resource and vital for preventing transmissions of infection between patients, and was suggested by the National Institute for Health and Care Excellence diagnostic assessment programme review of this technology as detailed in the introduction.[19] The duration of time in a side room was measured for the whole of the admission to hospital, regardless of the time of gastrointestinal pathogen testing.

	Molecular point-of-care testing group (n=137)	Control group (n=140)
Demographics		
Age, years	56 (35-70)	57 (36-70)
Age >65 years	45 (33%)	50 (36%)
Female sex	68 (50%)	69 (49%)
Male sex	69 (50%)	71 (51%)
Ethnicity		
White British	124 (91%)	126 (90%)
White other	7 (5%)	5 (4%)
African Caribbean	1 (1%)	2 (1%)
Black African	1 (1%)	0
Chinese	1 (1%)	0
Indian, Pakistani, or Bangladeshi	2 (1%)	4 (3%)
Other	1 (1%)	3 (2%)
Gastrointestinal pathogen risk factors		
Health-care worker	7 (5%)	7 (5%)
Foreign travel within 14 days	12 (9%)	10 (7%)
Contact with someone with diarrhoea	19 (14%)	12 (9%)
Antibiotic use within 30 days	27 (20%)	31 (22%)
Residential or nursing home resident	1 (1%)	2 (1%)
Comorbidity		
Cardiovascular disease	31 (23%)	31 (22%)
Hypertension	37 (27%)	32 (23%)
Respiratory disease	28 (20%)	28 (20%)
Chronic kidney disease	11 (8%)	12 (9%)
Diabetes	20 (15%)	19 (14%)
Active malignancy	3 (2%)	4 (3%)
Immunocompromised	29 (21%)	35 (25%)
Inflammatory bowel disease	36 (26%)	38 (27%)

(Table 1 continues in next column)

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	Molecular point-of-care testing group (n=137)	Control group (n=140)
Symptoms		
Fever	78 (57%)	72 (51%)
Vomiting	74 (54%)	79 (56%)
Abdominal pain	105 (77%)	112 (81%)*
Blood in stool	28 (20%)	48 (34%)
Diarrhoea	137 (100%)	140 (100%)
Duration of diarrhoea, days	4 (2-6)†	4 (2-5)
Frequency of diarrhoeal stool		
<5 per day	44 (32%)	31 (22%)
5 to 10 per day	48 (35%)	50 (36%)
>10 per day	42 (31%)	57 (41%)
Increased stoma output	3 (2%)	2 (1%)
Observations at admission		
Heart rate, beats/min	88 (76–103)‡	91 (80–104)*
Systolic blood pressure, mmHg	126 (112–140)‡	126 (111–139)
Diastolic blood pressure, mmHg	70 (64–80)‡	72 (65–82)
Temperature, °C	36·7 (36·3–37·3)§	36·6 (36·2–37·1)*
Temperature ≥38·0°C	15 (11%)§	14 (10%)*
Respiratory rate, breaths/min	18 (16–20)¶	18 (16–20)
Oxygen saturations, %	97 (96–98)§	98 (96–99)
Other		
Time from admission to recruitment, h	17·2 (11·4–22·5)	17·0 (10·5–21·1)
Isolated in a single-occupancy room at recruitment	130 (95%)	132 (94%)

Data are n (%) or median (IQR) unless specified otherwise. *n=139. †n=136. ‡n=135. §n=134. ¶n=132 (data availability).

Table 1: **Baseline characteristics**

Secondary outcome measures were duration of time in a side room for patients who were pathogen positive (days), duration of time in a side room for patients who were pathogen negative (days), proportion of patients isolated in a side room, proportion of patients who were pathogen positive isolated in a side room, proportion of patients who were pathogen negative isolated in a side room, proportion of patients who were pathogen negative de-isolated, proportion of patients who were pathogen positive de-isolated, time to de-isolation in patients who were pathogen negative (days), proportion of patients treated with antibiotics, duration of antibiotics (days), duration of hospitalisation (days), proportion of patients with a pathogen detected, proportion of patients with a bacterial pathogen detected, proportion of patients with missed diagnoses, concordance between results obtained from rectal swab and stool culture, and time from sampling to availability of results (hours). Safety outcome measures included intensive care unit admissions, 30-day mortality, and re-presentation (without admission) and readmission to hospital. Patient satisfaction scores and other medication use were exploratory outcomes and are not reported here. Complications including acute kidney injury and the time to treatment with antibiotics were planned as outcome measures but data were unobtainable. Time to patient isolation was a planned outcome but was not analysed as almost all patients were isolated at enrolment (table 1). Where appropriate, all outcomes were measured until discharge from hospital or the first 30 days of hospitalisation, whichever was shorter; however, antibiotic duration included what the patient was discharged with. Serious adverse events were reported to the sponsor.

For the post-hoc additional secondary outcome analysis of inappropriate antibiotic use, antibiotic prescriptions were reviewed by two independent infectious diseases physician researchers, with any disagreements adjudicated by a third infectious diseases researcher. Appropriateness was based on a retrospective assessment regarding the clinical relevance of the pathogens detected, the use of antibiotics recommended by national

and international guidelines, and on pathogen detection from FilmArray Gastrointestinal Panel testing used either as mPOCT or retrospectively done on frozen samples in the control group, in addition to pathogens detected by routine laboratory testing where this was done.[13,21] Antibiotics not active against *Clostridioides difficile* and prescribed for gastrointestinal illness when *C difficile* was detected and deemed to be causing disease were termed inappropriate. Antibiotics given for gastrointestinal illness when no pathogen or only a viral pathogen was detected were deemed inappropriate.

The proportion of patients with bacterial gastroenteritis treated with antibiotics, and the proportion of patients without bacterial gastroenteritis treated with antibiotics were originally planned as secondary outcome measures. After review, these data were instead analysed post hoc as antibiotic use by clinical diagnosis and according to individual pathogens detected, owing to the complexities caused by pathogen co-detection and other factors.

Hospital infection control policy would permit immediate de-isolation on the basis of test results. The research team members had no influence over decisions relating to de-isolation, antibiotic management, or other clinical or patient-flow decisions.

Statistical analysis

The initial phase of this study was designed as an internal pilot study so as to derive data to inform the sample size of the full study. After recruiting 100 patients (50 per group) we generated data on the duration of single-occupancy room use and withdrawal rate, allowing us to calculate the sample size on the basis of primary outcome. 141 patients per group were required to provide 90% power, at a 0·05 significance level, to detect a 1-day reduction in the mean duration of single-occupancy room use, from 3 to 2 days (with a variance of 6·7 days). We considered this reduction significant from an institutional and economical perspective. Allowing for an approximately 5% withdrawal rate, we aimed to recruit 150 patients per group (300 in total).

The trial design framework was superiority. Analysis was by intention to treat. Statistical analyses were done by a trial statistician independent from the study team who was masked to group allocation. The use of multiple imputation was planned should missing data exceed 5% for the primary outcome or for key secondary outcomes, but was not needed as missing data were below this threshold. There were no missing data for the primary outcome and missing data were less than 1% overall.

Descriptive statistics were used to summarise baseline demographic and clinical variables. For continuous variables, the mean and SD was used for normally distributed data. For non-normally distributed data, the median and IQR were calculated. Categorical or binary variables were summarised as frequency and percentage of total.

The primary outcome was compared between groups by means of Student's *t* test. The distribution of time in a single-occupancy room was right-skewed (appendix p 2), and log-transformation of this variable was found to yield a normal distribution. This was verified by means of the Sharpiro-Wilk and skewness and kurtosis tests. A multiple regression model with a range of explanatory variables (age, sex, presence of inflammatory bowel disease, duration of diarrhoea, time from admission to recruitment, and whether a pathogen was detected) was used to estimate the effects of these key variables on the primary outcome of (log transformed) time in a single-occupancy room. This model also included an interaction term in order to investigate whether the relationship between time in a single-occupancy room and intervention group differed depending on pathogen status.

For secondary outcomes, we compared the intervention and control groups for equality of proportions by means of the two-sample test of proportions for binary data by means of the Z test. For continuous data, we used the appropriate regression model. Time-to-event analysis data were compared by means of the log-rank test. No differences were expected between the sexes and therefore no analyses were done disaggregated by sex. All

See Online for appendix

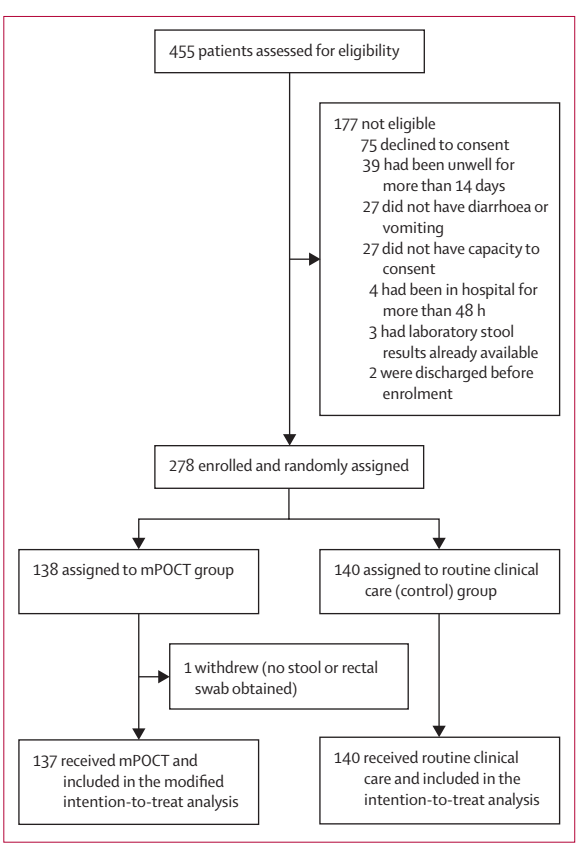

Figure 1: **Trial profile**
mPOCT=molecular point-of-care testing.

	Molecular point-of-care testing group (n=137)	Control group (n=140)	Exponentiated coefficient comparing mPOCT with control*
All patients, days	1·8 (1·5–2·2)	2·6 (2·2–3·0)	0·70 (0·56–0·87), p=0·0017
Patients with pathogen detected, days	2·8 (2·1–3·5)	2·9 (2·2–3·9)	0·94 (0·64–1·39), p=0·76
Patients with no pathogen detected, days	1·3 (1·0–1·6)	2·5 (2·1–2·9)	0·51 (0·39–0·67), p<0·0001

Data are geometric mean (95% CI). Time in a side room log-transformed for analysis. Pathogen testing in the control group was by laboratory testing. *The interpretation of the exponentiated coefficient is that the time in a single-occupancy room was reduced by 30% in the intervention group (100 × [1 – 0·70]) for all patients.

Table 2: **Duration of time in single-occupancy rooms for all patients, and by pathogen detection status**

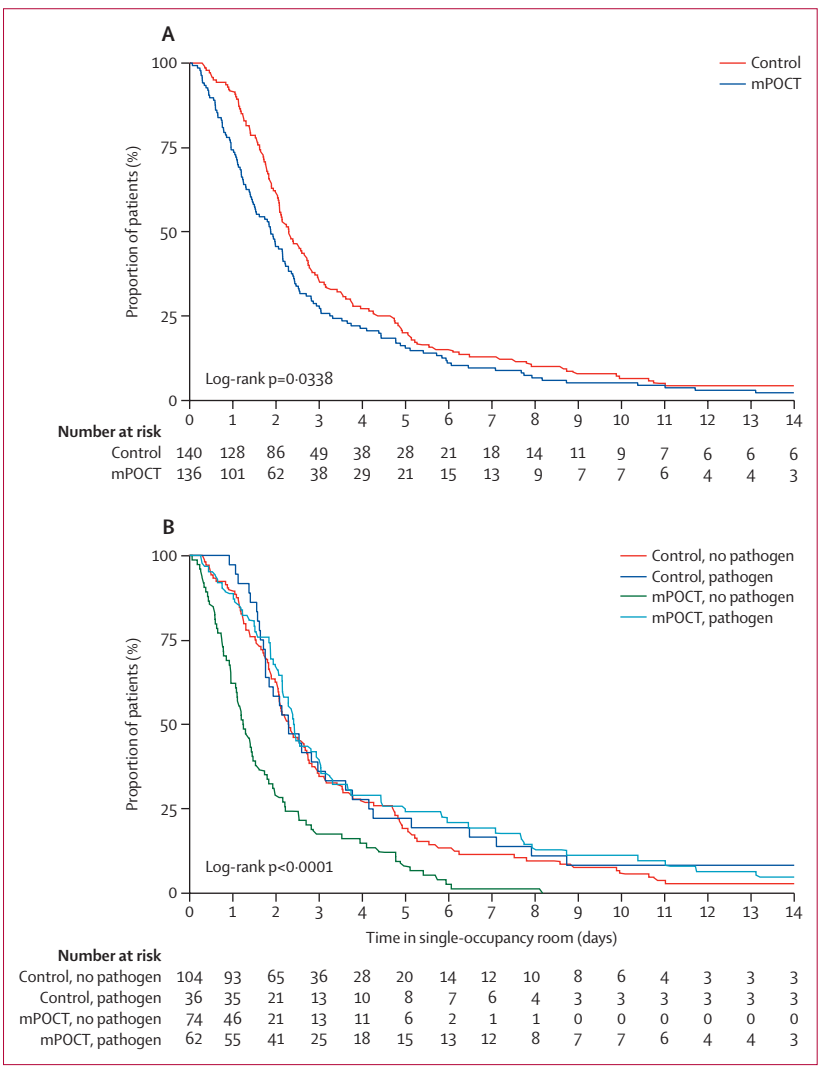

Figure 2: **Time-to-event analyses showing time in a single-occupancy room for mPOCT group and control groups (A) and mPOCT group and control groups, by pathogen detection (B)**
mPOCT=molecular point-of-care testing.

analyses were done by means of Prism version 9.4.1 (and Stata version 17.0. No data monitoring committee was used, as this trial was considered to be of low risk of adverse outcomes at the trial design stage. The study was prospectively registered on an international trials database, ISRCTN88918395.

Role of the funding source
The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results
Between March 20, 2017, and March 17, 2020, 455 patients were assessed for eligibility, and 278 were enrolled and randomly assigned to either the mPOCT group (n=138) or to routine clinical care group (n=140). One patient randomly assigned to the intervention group did not receive the intervention (as they could not produce a stool sample and declined a rectal swab) and so was withdrawn from the study leaving 137 and 140 in the modified intention-to-treat analysis. Although the desired number of recruited participants was not achieved (150 per group), because of resource constraints due to the COVID-19 pandemic, the study recruitment period could not be extended. The trial profile is shown in figure 1. Baseline characteristics for all patients are shown in table 1 and were well matched between the groups. 130 (95%) of 137 patients in the mPOCT group and 132 (94%) of 140 patients in the control group were isolated in single-occupancy rooms at the time of study enrolment. 136 (99%) of 137 patients in the mPOCT group and 140 (100%) of 140 patients in the control group were isolated at any time during their admission.

The duration (geometric mean) of time in a single-occupancy room in the mPOCT group was 1·8 days (95% CI 1·5–2·2) compared with 2·6 days (2·2–3·0) in the control group (exponentiated coefficient 0·70 [95% CI 0·56–0·87], p=0·0017, table 2). The interpretation of the exponentiated coefficient is that the time in a single-occupancy room was reduced by 30% overall in the intervention group (100×[1–0·70]). The difference between the groups for the primary outcome remained significant when adjusting for multiple covariates (appendix p 3).

Patients with no pathogen detected had a shorter duration of time in a single-occupancy room in the mPOCT group, 1·3 days (1·0–1·6), compared with the control group, 2·5 days (2·1–2·9; exponentiated coefficient 0·51 [95% CI 0·39–0·67]; p<0·0001, table 2). There was no difference in the duration of time in a single-occupancy room between the groups in patients who had a pathogen detected, 2·8 days (2·1–3·5), in the mPOCT group compared with 2·9 days (2·2–3·9) in the control group (exponentiated coefficient 0·94 [95% CI 0·64–1·39]; p=0·76). Time-to-event analyses further show that patients in the mPOCT group had a shorter time in single-occupancy isolation rooms, that de-isolation occurred promptly after mPOCT, and that patients in the mPOCT group with no pathogen detected

were the reason for the shorter duration of time in isolation between the groups overall (figure 2).

The median time from study enrolment to results being available to clinicians was 1·7 h (1·5 to 2·0) in the mPOCT group and 44·7 h (21·2 to 66·1) in the control group (difference of –43·9 [95% CI –49·3 to –38·4]; p<0·0001, table 3).

A higher proportion of patients in the mPOCT group were de-isolated (moved from single-occupancy room accommodation to a shared bay area) during their hospitalisation compared with the control group, 58 (43%) of 136 versus 38 (27%) of 140 (difference of 16% [95% CI 4 to 27]; p=0·0069, table 3). Patients with no pathogen detected were more likely to be de-isolated during their hospital stay in the mPOCT group than in the control group, 54 (73%) of 74 versus 35 (34%) of 104 (difference of 39% [95% CI 26 to 53]; p<0·0001) whereas there was no difference between the groups in patients with a pathogen detected, four (6%) of 62 versus three (8%) of 36 (difference of –2% [95% CI –13 to 9]; p=0·73).

The median time from study enrolment to de-isolation was 0·6 (0·3 to 1·8) days in the mPOCT group compared with 2·2 days (1·2 to 3·2) in the control group (difference –1·5 (95% CI –2·2 to –0·8); p<0·0001). This difference in time to de-isolation was again because of patients with no pathogen detected in the mPOCT group compared with the control group, 0·6 days (0·3 to 1·3) compared with 2·2 days (1·2 to 3·2) (difference of –1·6 [–2·2 to –0·9]; p<0·0001) and there was no difference in time to de-isolation in patients with pathogens detected (p=1·0).

There was no difference in the length of hospital stay between the mPOCT group and the control group, 3·3 days (2·1 to 7·9) versus 3·0 days (2·0 to 7·1) (difference of 0·3 [95% CI –0·7 to 1·3]; p=0·55) and there were no differences between groups in mortality, intensive care unit admission, re-presentation to hospital (without admission), or readmission to hospital (table 3).

A higher proportion of patients had pathogens detected in the mPOCT group, 62 (45%) of 137 patients, compared with the control group (with laboratory testing), 36 (26%) of 140 (difference of 20% [95% CI 9 to 31]; p=0·0007; table 3). *Campylobacter* spp was the most frequently detected pathogen in both groups (appendix p 4). mPOCT detected a greater number of pathogens (71 detections versus 36) and range of pathogens (14 different pathogens versus ten), compared with the control group. In addition, co-detection of pathogens was also more common in the mPOCT group and involved detection of EPEC in all cases (appendix p 4). The details of pathogens detected in the control group by retrospective testing of frozen stored samples by means of the FilmArray Gastrointestinal Panel are shown in the appendix (p 5). 30 (21%) of 140 patients were found to have had at least one pathogen that was not detected via routine clinical care, including: *Campylobacter* spp (five detections), norovirus (five), EPEC (11), *C difficile* (four), and *Shigella* spp–EIEC (two).

	Molecular point-of-care testing group (n=137)	Control group (n=140)	Absolute difference (95% CI)	p value
All patients				
Samples tested	137 (100%)	117 (84%)	16% (10 to 23)	<0·0001
Rectal swab	55 (40%)	0	..	<0·0001
Stool	78 (57%)	117/117 (100%)	..	..
Both	4 (3%)	0	..	..
Time from study enrolment to results, hours	1·7 (1·5 to 2·0)*	44·7 (21·2 to 66·1)†	–43·9 (–49·3 to –38·4)	<0·0001
Isolated in single-occupancy room accommodation‡	136 (99%)	140 (100%)	–0·7% (–2 to 0·7)	0·31
De-isolated§	58/136 (43%)	38 (27%)	16% (4 to 27)	0·0069
Time from enrolment to de-isolation, days	0·6 (0·3 to 1·8)	2·2 (1·2 to 3·2)	–1·5 (–2·2 to –0·8)	<0·0001
Length of hospital stay, days	3·3 (2·1 to 7·9)	3·0 (2·0 to 7·1)	0·3 (–0·7 to 1·3)	0·55
Patients with pathogens detected	62 (45%)	36 (26%)	20% (9 to 31)	0·0007
De-isolated	4/62 (6%)	3/36 (8%)	–2% (–13 to 9)	0·73
Time from enrolment to de-isolation, days	7·5 (2·6 to 15·6)	1·3 (1·0 to 30·0)	..	1·0
Length of hospital stay, days	2·6 (1·8 to 5·9)	2·4 (1·9 to 4·9)	0·2 (–1·1 to 1·5)	0·79
Patients with no pathogen detected	75 (55%)	104 (74%)	20% (9 to 31)	0·0007
De-isolated	54/74 (73%)¶	35/104 (34%)	39% (26 to 53)	<0·0001
Time from enrolment to de-isolation, days	0·6 (0·3 to 1·3)	2·2 (1·2 to 3·2)	–1·6 (–2·2 to –0·9)	<0·0001
Length of hospital stay, days	4·5 (2·6 to 9·1)	3·3 (2·1 to 7·6)	1·2 (–0·5 to 3·0)	0·16
Safety outcomes for all patients‖				
Intensive care unit admission	3 (2%)	4 (3%)	–0·7% (–4 to 3)	0·72
Died in hospital	1 (1%)	4 (3%)	–2% (–5 to 1)	0·18
Died within 30 days enrolment	1 (1%)	3 (2%)	–1% (–4 to 1)	0·32
Re-presented to hospital within 30 days	4 (3%)	7 (5%)	–2% (–7 to 3)	0·38
Readmitted within 30 days	14 (10%)	10 (7%)	3% (–4 to 10)	0·36

Data are n (%), n/N (%), or median (IQR) unless specified otherwise. *n=133. †n=114 (data availability). ‡At any time during hospital stay. §Moved from single accommodation room to a bay. ¶There was one patient who was never isolated in this group, therefore n=74 rather than n=75; all other patients were isolated at some point during their admission. ‖No other adverse events or serious adverse events were reported.

***Table* 3: Key secondary outcomes**

89 (65%) of 137 patients in the mPOCT group received an antibiotic at any point in their hospitalisation compared with 66 (47%) of 140 patients in the control group (difference of 18% [95% CI 6 to 29]; p=0·0028, table 4). Patients with a final diagnosis of gastroenteritis were more frequently treated with antibiotics in the mPOCT group, 45 (65%) of 69 versus 40 (48%) of 83 in the control group (p=0·049). Antibiotic treatment of *Campylobacter* spp and EPEC was more common in the mPOCT group, although EPEC was frequently co-detected with other pathogens (including *Campylobacter* spp; appendix p 6).

	Molecular point-of-care testing group (n=137)	Control group (n=140)	Absolute difference (95% CI)	p value
Antibiotics received	89 (65%)	66 (47%)	18% (6 to 29)	0·0028
Number of agents used per patient	2 (1 to 3)	2 (1 to 3)	0 (−0·9 to 0·9)	1·0
Duration of all antibiotics, days	5·0 (2·0 to 8·3)	5·4 (1·9 to 7·3)	−0·4 (−2·1 to 1·3)	0·63
Received intravenous antibiotics	53 (39%)	46 (33%)	6% (−5 to 17)	0·31
Duration of intravenous antibiotics, days	2·1 (0·1 to 5·0)	2·0 (0·6 to 4·9)	0·1 (−1·9 to 2·0)	0·93
Received inappropriate antibiotics	34/89 (38%)	35/66 (53%)	−15% (−31 to 0·9)	0·066
Duration of inappropriate antibiotics, days	0·5 (0·04 to 1·8)	4·2 (0·7 to 6·5)	−3·7 (−5·6 to −1·9)	0·0002

Data are n (%), n/N (%), or median (IQR).

Table 4: **Antibiotic use**

Of patients receiving antibiotics, there was no difference in the proportion of patients who received inappropriate antibiotics, 34 (38%) of 89 in the mPOCT group versus 35 (53%) of 66 in the control group (difference of –15% [95% CI –31 to 0·9]; p=0·066), however patients in the mPOCT group received a shorter median duration of inappropriate antibiotics compared with the control group, 0·5 days (0·04 to 1·8) compared with 4·2 days (0·7 to 6·5; difference –3·7 [95% CI –5·6 to –1·9], p=0·0002; table 4). Further details of inappropriate antibiotic use and the antibiotic agents used are shown in the appendix (pp 7–8). Empirical use of broad-spectrum intravenous antibiotics (eg, cefuroxime and metronidazole) was common in patients with gastroenteritis including in those patients subsequently testing positive for *Campylobacter* spp, and in patients without pathogens detected. The patients in the mPOCT group and the control group had similar proportions of different categories of final diagnoses on the basis of discharge International Statistical Classification of Diseases and Related Health Problems 10th revision codes (appendix p 9).

There was high concordance in pathogens detected between paired rectal swabs and stool samples collected at the same time and tested on the FilmArray Gastrointestinal Panel, with rectal swabs having a negative predictive value of 91% (95% CI 80 to 97; appendix p 9). Five (56%) of nine discordant rectal swabs occurred in samples with multiple pathogen detections (appendix p 9).

Discussion

In this study, routine syndromic molecular point-of-care testing for gastrointestinal pathogens in adults hospitalised with suspected gastroenteritis led to a faster time to results, identified more pathogens, and reduced the duration of single-occupancy isolation room use, compared to routine clinical care with conventional laboratory testing. The reduced time in single-occupancy rooms was driven by pathogen-negative patients being appropriately de-isolated a day and half earlier in the course of their hospitalisation.

Single-occupancy isolation rooms are a limited resource in the UK NHS, and many other health-care systems, and most hospital beds are located in shared bays.[22] Around 130 000 hospital admissions for potentially infectious diarrhoeal illnesses occur in England each year.[3] This study suggests that a molecular point-of-care testing strategy for these patients could reduce unnecessary single-occupancy room use and overall decrease use by around 30% (ie, around 40 000 single-occupancy rooms saved per year), therefore improving patient flow and operational capacity within NHS hospitals.

Overall antibiotic use was higher in the mPOCT group compared with the control group, which is potentially concerning for overtreatment of colonising organisms including *C difficile* owing to increased detection. Our data show that increased antibiotic use was due to a higher proportion of patients with gastroenteritis in the mPOCT group receiving antibiotics, including those with *Campylobacter* spp and EPEC but not *C difficile*. Not all patients with *Campylobacter* spp require antibiotics and so the impact of this increase in treatment is difficult to ascertain. Similarly, most of the patients with EPEC who were treated with antibiotics were co-infected with another pathogen (most frequently *Campylobacter* spp) and so the likely impact of this is unclear.

Inappropriate antibiotic use was very common in both groups, with broad spectrum antibiotics commonly being given empirically, probably representing diagnostic uncertainty at the point of admission and before results were available. The duration of inappropriate antibiotics was reduced by almost 4 days in the mPOCT group, showing that clinicians acted on mPOCT results by switching to appropriate agents on the basis of pathogen detected or by stopping antibiotics, representing a powerful antibiotic stewardship intervention. Use of mPOCT even earlier in the patient pathway might overcome this issue and could lead to even greater clinical benefits and true pathogen-directed therapy.

A single small previous study has shown that use of mPOCT in the emergency department was associated with improvements in pathogen-directed antibiotic use but did not evaluate impact on infection control measures.[23] The only randomised controlled trial of laboratory-based molecular testing in hospitalised adults enrolled around half the number of patients in our study and found no difference in isolation facility use or other clinical outcomes, which is unsurprising given the delays in obtaining laboratory results compared with mPOCT.[24] In addition, in a randomised controlled trial in children in Botswana, a test-and-treat strategy with rapid molecular laboratory testing was not associated with improved outcomes, although this study was significantly underpowered.[25] That there was no difference in the length of hospital stay or other clinical outcome measures between groups in our study might suggest that other factors, such as age and comorbidity, are more important

determinants, although it is important to note that our study was not powered specifically to evaluate these endpoints. In our study, about a quarter of participants were patients with known inflammatory bowel disease (IBD) and studies of mPOCT use in IBD rapid access clinics with outcome measures including admission avoidance, antibiotic and steroid use are now warranted.

The concordance of pathogen detection in rectal swabs and stool samples tested on the FilmArray platform was high and similar to previously reported studies.[10–12] In particular, the negative predictive value of rectal swabs was high in this study, suggesting that routine rectal swab use in clinical practice is reasonable and can safely facilitate rapid diagnosis, as its use is likely to negate the significant delays associated with obtaining a stool sample.

Patients in the mPOCT group had more pathogens detected than those in the control group. The reasons for this are multifactorial. First, all patients in the mPOCT group were tested for gastrointestinal pathogens, whereas only 84% were tested in the control group as stool samples were not always sent for laboratory testing. This is likely to be due to the inability of some patients to produce stool samples when requested and the inability to use rectal swabs to overcome this as part of routine diagnostic testing. Second, it is due to the wider range of pathogens detectable on the syndromic molecular panel compared with laboratory testing, including pathogens that the in-house laboratory methods did not test for (for example EPEC). Third, it was due to patients in the mPOCT group always being tested for all pathogens (ie, syndromic approach), whereas patients in the control group were often tested for only one type of pathogen (ie, bacterial, viral, parasitic, or *C difficile*) depending on the clinical details provided to the laboratory. The retrospective testing of patients in the control group by use of the FilmArray Gastrointestinal Panel allowed an objective assessment of pathogens not detected by the processes of routine clinical care and showed frequent missed detections of pathogens, including norovirus, *Campylobacter* spp, and *C difficile*. Finally, the increased detection of pathogens in the mPOCT group might also reflect the greater sensitivity of molecular methods compared with the culture or antigen-based testing that were sometimes used in the control group.

Although the increased detection of pathogens might improve diagnosis and management of patients with gastroenteritis, the higher sensitivity of molecular testing compared with traditional laboratory methods might also result in detection of low amounts of genetic material found in stools from past infection or asymptomatic carriage. This might lead to over-diagnosis of some pathogens, particularly of *C difficile,* for which detection by PCR alone often represents carriage. Similarly, some targets on molecular panels such as EPEC and EAEC are not always pathogenic and their detection might be unrelated to patients' illnesses. Both of these situations have the potential to result in unnecessary antibiotic treatment and, as discussed, highlight the importance of integrating robust diagnostic and antibiotic stewardship when introducing new molecular tests such as gastrointestinal panels.

Despite the increased pathogen detection by mPOCT, a higher proportion of patients were de-isolated during their hospitalisation in the mPOCT group than the control group. This suggests that the rapid turnaround time of results and subsequent rapid de-isolation of patients who do not have infectious diarrhoea more than offsets the effect of increased pathogen detection by mPOCT on single-occupancy room use. However, the increased frequency of pathogen detection by molecular testing has the potential to increase the use of single-occupancy rooms in institutions where patients hospitalised with diarrhoea are not routinely isolated. The use of a finite number of single-occupancy rooms for isolation of patients with COVID-19, influenza, and other contagious diseases could therefore be further pressured by the introduction of molecular gastrointestinal testing, although this might be managed by pragmatic infection control policies and skilled coordination of patient flow.

To our knowledge, this is the first randomised controlled trial to evaluate the clinical impacts of molecular point-of-care testing for gastrointestinal pathogens on isolation facility use in addition to a wide range of other clinically relevant outcomes. The study recruited standard adult medical patients presenting to hospital over a 3-year period, limiting bias from any gastrointestinal pathogen outbreaks or epidemics. Other strengths of the study include the pragmatic trial design (ie, comparison with routine clinical care) and broad inclusion criteria. Therefore, the study results are likely to be generalisable to other UK and international centres.

The limitations of the study include that it was a single-centre non-blinded study, and that we could not extend study recruitment to obtain the original target sample size because of the COVID-19 pandemic. Despite this, our achieved sample size was able to detect clinically significant differences between the groups for both the primary and for several key secondary outcome measures. The patient, clinical teams, and researchers could not be masked to group allocation and intervention results, as it was required that these groups be informed of the mPOCT results to evaluate the effects of these results on patient management. Adjudicating antibiotic appropriateness is prone to subjectivity and so might potentially introduce bias despite prescriptions being compared with guideline-based advice. Furthermore, antibiotic treatment guidelines are based on pathogen detection by traditional diagnostic methods rather than highly sensitive molecular testing, and do not consider the potential that detection represents non-pathogenic colonisation rather than infection, therefore, our

adjudication of appropriateness might unduly favour molecular testing. The FilmArray system is not marketed as a point-of-care test platform and is not Clinical Laboratory Improvement Amendments-waived in the US for this purpose. A health economic analysis is needed to understand the cost implications of mPOCT implementation. Although molecular panel tests are more expensive than conventional laboratory testing, these costs are likely to be offset by the improvements seen in isolation facility use as this might improve patient flow and operational capacity in hospital, and potentially prevent nosocomial outbreaks.

The use of molecular point-of-care testing for respiratory viruses including SARS-CoV-2 in hospital pathways now has a robust evidence base, and has been associated with improvements in antibiotic use, length of stay, patient flow through the hospital, and isolation facility use.[26–29] Many NHS hospital trusts and hospitals internationally have now developed POCT or a near-patient testing infrastructure to allow rapid molecular SARS-CoV-2 testing.[29–30] Therefore widespread implementation of gastrointestinal pathogen detection at the point of care might be feasible. Although the optimal delivery model for mPOCT services will depend on the circumstances of individual institutions, all such services must be embedded within a comprehensive quality management system provided by local pathology services in order to ensure the accuracy and reliability of results.

In conclusion, molecular point-of-care testing for gastrointestinal pathogens on stool and rectal swabs in adults hospitalised with suspected gastroenteritis was associated with a faster time to results and reduced the unnecessary use of single-occupancy isolation rooms. This is likely to have a significant impact on hospital infection control capacity and patient flow though acute areas. mPOCT was also associated with the detection of more pathogens and an increase in antibiotic use. Although the duration of inappropriate antibiotics appears reduced, the overall increase in antibiotic use has an unclear effect on clinical outcome and is potentially concerning from an antimicrobial stewardship perspective. Further studies are needed to examine the effects of mPOCT on antibiotic use and clinical outcomes in greater detail.

Contributors

TWC reviewed the medical literature, conceived of and designed the study, oversaw the conduct of the study, collected data, interpreted results, and wrote the manuscript. NJB reviewed the medical literature, participated in the trial design, recruited patients, generated and collected data, interpreted results, and drafted and wrote the manuscript. KRB reviewed the medical literature, participated in the trial design, recruited patients, and generated and collected data. AKM recruited patients, and generated and collected data. ART and LS-N generated and collected data. MG and JRFC participated in the trial design and assisted with study oversight. HEM designed the statistical analysis plan and analysed the data. All authors contributed to, reviewed, and approved the final manuscript and had final responsibility for the decision to submit for publication. TWC and NJB accessed and verified the data for this study.

Declaration of interests

TWC has received speaker fees, honoraria, travel reimbursement, and equipment and consumables at discount or free of charge for purposes independent of research, outside of this submitted study, from BioFire Diagnostics–bioMérieux and QIAGEN. He has received consultancy fees from BioFire Diagnostics–bioMérieux, Cepheid, Roche, Janssen, Synairgen, Randox Laboratories, IP Pragmatics, and Cidara therapeutics; has received speaker fees or honoraria from Janssen, Sanofi, and Medscape; has received honoraria for participation in advisory boards from Cepheid, Roche, Janssen, Seqirus, Sanofi, and Shionogi; is a member of an independent data monitoring committee for a trial sponsored by Roche; owns Synairgen stock; has acted as the UK chief investigator for a study sponsored by Janssen; was supported by a National Institute for Health Research (NIHR) post-doctoral fellowship (grant number PDF 2016-09-061); has received grant funding via an NIHR AMR research infrastructure award; andhas received grant funding from the Norwegian Research Council for the CAPNOR randomised controlled trial. NJB is supported by the NIHR Clinical Lecturer programme. KRB is supported by the NIHR Academic Clinical Fellow programme. All other authors declare no competing interests.

Data sharing

All deidentified participant data analysed and presented in this study are available from the corresponding author following publication, on reasonable request.

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