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A cost benefit analysis of the Luminex xTAG Gastrointestinal Pathogen Panel for detection of infectious gastroenteritis in hospitalised patients

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Summary *Objectives:* Recent advances in the laboratory detection of infectious diarrhoea allow more rapid and sensitive identification of infected patients. Several commercial multiplex molecular panels are now available and may have significant advantages over culture based techniques. Faster and more sensitive testing of hospitalised patients with suspected infectious gastroenteritis could result in significant efficiencies in the utilisation of isolation facilities, however few studies have examined this potential benefit. We studied the potential clinical and cost benefits of a commercially available molecular panel.
Methods: An eight-month parallel diagnostic study was conducted to measure potential economic benefits of testing hospitalised patients with the Luminex xTAG Gastrointestinal Pathogen Panel (GPP) compared with conventional laboratory testing (based on a combination of culture, microscopy and enzyme immunoassay). Laboratory testing costs and patient isolation costs were measured or estimated for 800 patients.
Results: Although costing an additional £22,283, use of GPP could enable a reduction in isolation time from 2202 to 1447 days, a saving of £66,765, which more than offsets the additional laboratory testing costs.
Conclusion: Syndromic testing of patients against a broad panel of organisms using a multiplex molecular panel can both improve detection rates and allow better laboratory workflow

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practices. Removing patients testing negative using this panel could result in significant patient isolation savings.

Introduction

Infectious gastroenteritis may be caused by a wide range of bacteria, viruses and parasites and may be difficult to differentiate from non-infectious causes.[1,2] It is a major burden to health services with associated socioeconomic costs estimated to be €345 million in The Netherlands,[3] A$343 million in Australia[4] and Can$ 3.7 billion in Canada.[5] There are an estimated 17 million cases of infectious intestinal disease in the UK annually,[6] however the true burden of infection is probably significantly underestimated. It is estimated that foodborne illness costs the UK economy £1.5 billion annually.[7]

Cases of suspected infectious diarrhoea presenting to or developing in hospitals and other health care facilities are usually isolated in single rooms, preferably with private bathroom, to reduce the risk of transmission. Since diarrhoea is a common symptom in hospitalised patients and isolation rooms are often a scare resource, clinicians must make pragmatic decisions regarding the use of these facilities whilst waiting for results of laboratory testing.

Current conventional testing may be selective, reliant on the clinician to choose the correct test, or may be sequential, testing for one pathogen at a time. This may create unnecessary delays or create inefficient laboratory workflows, which are wasteful of resources. Further inefficiencies may result from unnecessarily isolating patients who do not have infectious gastroenteritis. Additionally, infectious patients who are incorrectly diagnosed as non-infectious may be prematurely removed from isolation with the possibility of subsequent disease transmission.

Culture dependent testing of bacterial pathogens is slow, taking up to three days and may not be as sensitive as molecular based methods.[8–10] Multiplex molecular panels have recently become available commercially and have the potential to consolidate laboratory workflow, improve diagnostic accuracy and allow more efficient use of hospital resources.

We evaluated the healthcare economics of the Luminex xTAG® Gastrointestinal Pathogen Panel (GPP) compared to a range of conventional laboratory testing methods including culture and enzyme immunoassays. GPP is a multiplexed molecular test capable of simultaneously detecting adenovirus 40/41, rotavirus A, norovirus GI/GII, *Salmonella* spp., *Campylobacter* spp. (*Campylobacter jejuni*, *Campylobacter coli* and *Campylobacter lari*), *Shigella* spp., (*Shigella boydii*, *Shigella sonnei*, *Shigella flexneri* and *Shigella dysenteriae*), *Clostridium difficile*, enterotoxigenic *Escherichia coli* (ETEC), enterohaemorrhagic *E. coli* (EHEC), *E. coli* O157, *Yersinia enterocolitica*, *Vibrio cholera*, *Giardia lamblia*, *Entamoeba histolytica* and *Cryptosporidium* spp. (*Cryptosporidium parvum* and *Cryptosporidium hominis*). The assay uses the proprietary Luminex xTAG® technology and platform to detect multiple targets in the same sample.

Materials and methods

An eight-month parallel evaluation study was conducted at Guy's and St. Thomas' NHS Foundation Trust, a 1100 bed academic teaching hospital in central London between November 2011 and July 2012. This was designed to assess the feasibility, clinical utility and acceptability of using GPP to detect infectious gastroenteritis in unselected samples from hospitalised patients sent to our laboratory, and the findings are reported elsewhere.[11] The economics of a range of conventional testing methods (including selective culture, enzyme immunoassays and molecular testing, see Table 1.)[11] were compared with testing by GPP in terms of; diagnostic costs (the relative costs of the conventional and GPP methods) and patient isolation costs (the potential benefits of reducing time spent in isolation).

Protocol approval was obtained from the London City & East Research Ethics Committee. Patients admitted to hospital who developed diarrhoea and/or vomiting were placed in single rooms with private bathroom and kept in isolation until at least 48 h following return to normal bowel habit. Cross-transmission between hospitalised patients with gastrointestinal parasite infection is rare, so for the purposes of this study these patients were defined as having non-communicable gastroenteritis and standard infection control precautions were implemented. These patients were not required to remain in single room isolation in accordance with CDC guidelines.[12]

Clinicians investigated all cases of diarrhoea using a range of conventional testing methods according to their usual clinical practice and hospital infection control guidelines. Requesting bacterial culture on patients with hospital-associated diarrhoea is discouraged but not prevented. Infection control guidelines recommend that symptomatic patients (i.e. passage of 3 or more liquid stools within 24 h) considered likely to be infectious in aetiology (that is, without any other obvious causes such as medications or inflammatory bowel disease), should be placed in single rooms. Conventional testing was performed 7 days per week. Clinicians were unable to request a GPP test directly, instead; whenever a request for a conventional test was received, a GPP test was automatically triggered with the limitation that only one GPP test was performed per five-day period (defined as a single episode). Clinicians were advised to act on negative GPP results and remove the patient from isolation. For laboratory operational reasons, GPP samples were batched for testing commencing at 4pm Monday to Thursday with results available at 3pm the following day. On Fridays samples were tested earlier with results available on the evening of the same day or early Saturday morning. Samples received on Saturday and Sunday were not tested. Results were communicated electronically to requesting clinicians, with positive results telephoned out by an infectious diseases physician, as per the standard for conventional tests.

Table 1 Conventional testing methods, number of tests performed and associated costs.

Conventional test targets	Conventional test methods[a]	Number of initial tests performed	Number of repeat tests performed	Cost per test (£)[b]	Total costs (£)[b]
Clostridium difficile	Glutamate Dehydrogenase Enzyme Immunoassay (C. diff Chek-60; TechLab, Balcksburg, VA, USA) then GenXpert PCR (Cepheid, Sunnyvale, CA, USA)	513	58	26.05	14,875
Norovirus	Enzyme Immunoassay (Ridascreen 3rd generation assay; R-Biopharm, Darmstadt, Germany)	549	57	18.68	11,320
Adenovirus and Rotavirus	Combined immunochromatographic test (Ridaquick Rotavirus/Adenovirus combi; R-Biopharm, Darmstadt, Germany)	61	8	7	484
Campylobacter, Salmonella, Shigella, and *E. coli O:157*	Culture on selective and chromogenic agars followed by matrix-assisted laser desorption/ionization-time of flight mass spectrometry and/or basic serotyping	541	25	11.30	6396
Giardia, Entamoeba histolytica and *Cryptosporidium*	Light or fluorescent microscopy	80	4	10.53	885
Total		1744	152		33,960

[a] Full testing methodology in Halligan et al.
[b] Costs include all consumables, labour and overheads.

The design of the study was pragmatic in that it did not compare groups of patients tested with either conventional methods or GPP. Instead, both testing methods were performed in parallel so that diagnostic accuracy could be measured, this is reported elsewhere.[11] Consequently, it was not possible to infer that decisions on isolation of patients were made as a result of any testing pathway alone. Results from conventional and GPP testing became available at different times and these decisions would in reality have been influenced by the availability of both testing methods. Assumptions were made on the likely length of isolation for patients testing negative by GPP (based on actual turnaround time of the laboratory test plus local knowledge of the average time taken to deisolate patients after receipt of negative results), however this may have underestimated the potential economic savings attributable to GPP.

The analysis is written from the perspective of the NHS and does not consider costs associated with false positive and false negative results, treatment costs and treatment outcomes, the economic value of preventing outbreaks within hospital which result from failing to isolate when necessary, or preventing hospital admissions for gastroenteritis patients who did not require isolation.

The number of conventional tests performed, patient outcomes and the actual total number of isolation days per patient were measured. The Isolation costs under the conventional testing pathway are based on the actual patient isolation days observed during the study. Data were also collected for the GPP tests and results plus the estimated isolation time for each patient if the GPP results had been the sole source of reference for decision-making.

The economic analysis compares the actual cost of conventional testing and actual number of isolation days observed vs. the costs of GPP testing and theoretical number of isolation days based solely on GPP results. The costs of GPP testing include any confirmatory testing by conventional assays (i.e. costs of culture and antimicrobial sensitivity testing for *Campylobacter, Salmonella*, *Shigella* and *E. coli* O157 and costs of confirmatory toxin enzyme-immunoassay for *C. difficile*).

Patients with ongoing symptoms despite negative conventional tests were permitted to be re-tested by further conventional tests at the physician's discretion. Due to the improved sensitivity and negative predictive value of the GPP test, patients were permitted to be tested only once in any five day period.

Results

Isolation data

Patient tracking data were available for a total of 913 patient episodes, however 113 (14%) patients were not removed from isolation despite a negative GPP. This was due to a variety of reasons including colonisation with MRSA or other multi-drug resistant organisms, lack of alternative beds and dignity and safeguarding concerns. These patient episodes were not included in the isolation analysis since

the availability of either test results would not have affected their time in isolation.

Conventional testing pathway

Testing outcomes for patients tested using the conventional testing pathway and the simulated GPP pathway are summarised in Figs. 1 and 2.

Under the conventional testing pathway a total of 409 (51%) of symptomatic patients were isolated whist awaiting test results, of which 81 had one or more agents of infectious gastroenteritis detected. All of these patients had a communicable cause requiring continued isolation. A total of 328 of the isolated patients did not have an agent of infectious gastroenteritis detected; symptoms resolved in 314 of these patients and they were removed from isolation. Symptoms persisted in 14 of these patients and they were retested and alternative causes considered. In all but one case where norovirus was subsequently detected, no infectious cause of diarrhoea was identified.

Of the 391 patients who were not isolated, an agent of infectious gastroenteritis was detected in 20. Nineteen of these patients were infected with a communicable agent and were isolated and treated, the remaining patient had a non communicable cause and remained non-isolated. 371 of the non-isolated patients did not have an agent of infectious gastroenteritis detected; symptoms persisted in 42 of these patients and they were retested and alternative causes considered. Symptoms resolved in the remaining 329 patients. In total 409 patients were isolated for a total of 2116 days under the conventional testing pathway. See Table 2.

Simulated GPP testing pathway

Under the GPP testing pathway the same number of symptomatic patients were isolated (409), however detection rates were higher with 152 patients having an agent of infectious gastroenteritis detected (an increase of 37%). Of those, 141 had a communicable cause and were kept isolated. 257 of the isolated patients did not have an agent of infectious gastroenteritis detected; symptoms were assumed to have resolved in all of these patients and they were removed from isolation. Fig. 2 summarises the GPP testing pathway outcomes.

Of the 391 patients who were not isolated, an agent of infectious gastroenteritis was detected in 48, 40 of these were with a communicable agent and were isolated and treated; the remaining 8 patients had non-communicable causes and remained non-isolated. 343 of the non-isolated patients did not have an agent of infectious gastroenteritis detected and symptoms were assumed to have resolved.

The actual days observed in isolation for the 191 patients with communicable infectious gastroenteritis

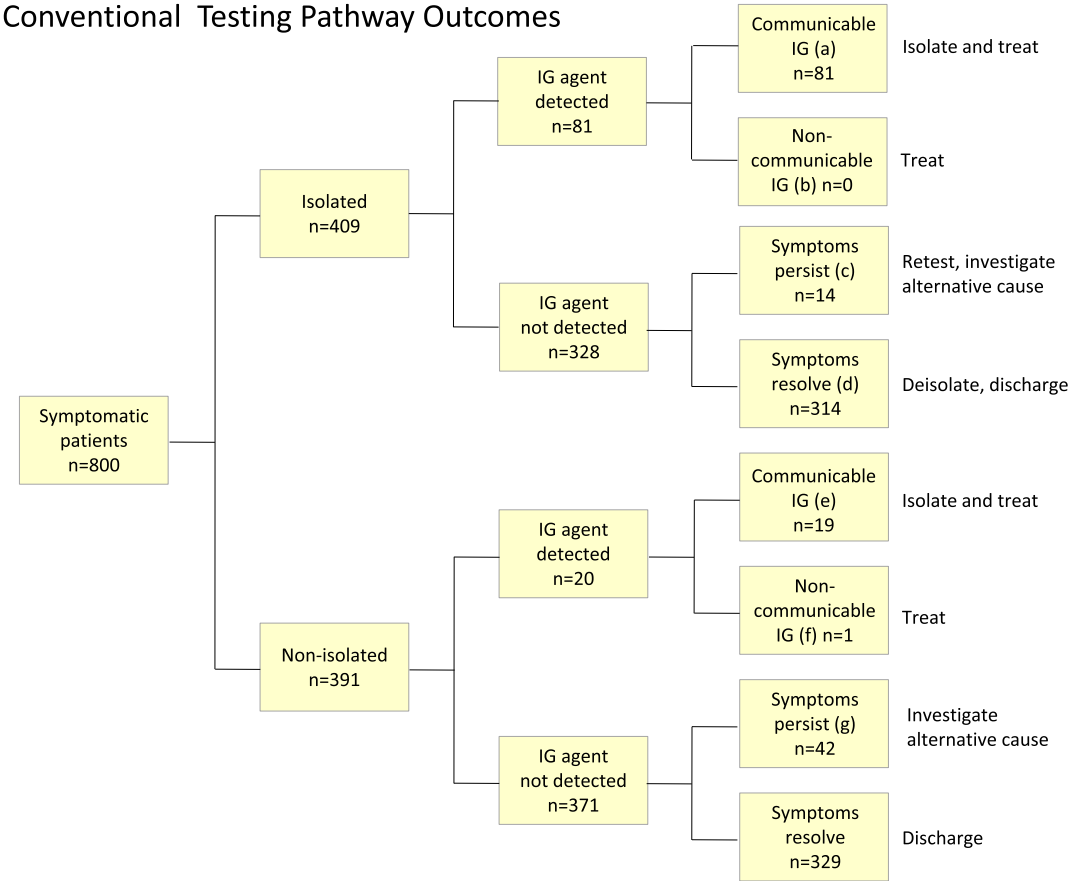

Figure 1 Outcomes under the conventional testing pathway. [1]Infection with *Giardia*, *Cryptosporidium* or *Entamoeba histolytica* were considered non communicable infections and patients were not isolated.

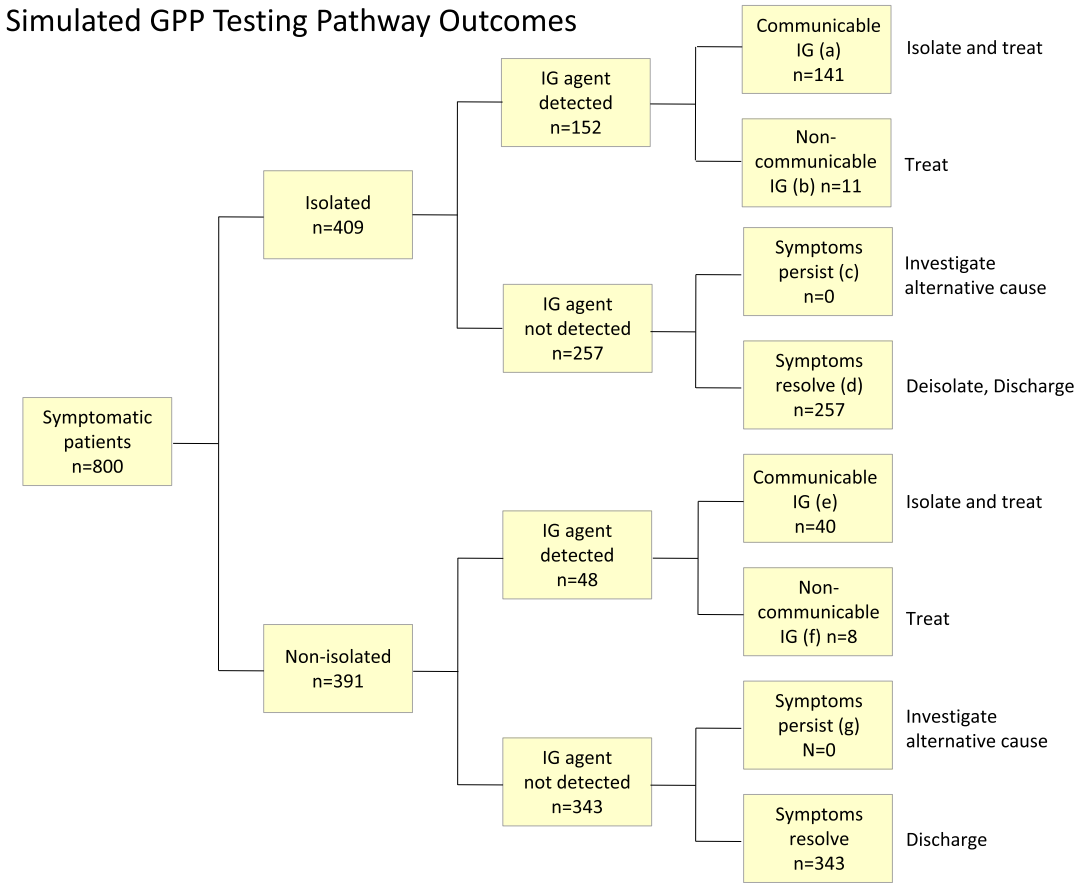

Figure 2 Outcomes under the simulated GPP testing pathway. [1]Infection with *Giardia*, *Cryptosporidium* or *Entamoeba histolytica* were considered non communicable infections and patients were not isolated.

were 691. Each of the 11 patients who had non-communicable infectious gastroenteritis was assumed to spend 2 days in isolation before being removed (a total of 22 days for this group).

Similarly patients who were presumptively isolated but did not have an agent of infectious gastroenteritis detected were assumed to spend 2 days each in isolation before being removed (a total of 257 patients and 514 isolation days). The 40 patients with communicable infectious gastroenteritis but who were not presumptively isolated were subsequently moved into isolation; this was a total of 220 days.

The total isolation time for the GPP testing pathway was 1447 days, 755 days less than the conventional testing

Table 2 Patient isolation data under the conventional and simulated GPP testing pathways.

Patient status	Conventional testing pathway		GPP testing pathway	
	Total patients	Actual observed isolation days	Total patients	Actual observed or estimated isolation days
Communicable IG, patient isolated (a)	81	446	141	691
Non-communicable IG[a] detected, patient isolated (b)	0	0	11	22[c]
IG not detected, patient isolated (c + d)	328	1703	257	514[c]
Communicable IG detected, patient not isolated (e)	19	0	40	220
Non-communicable IG[a] detected, patient not isolated (f)	1	0	8	0
IG not detected, patient not isolated (g + h)	371[b]	53	343	0
Total (a to h)	800	2202	800	1447

IG = infectious gastroenteritis.

[a] Infections with *Giardia*, *Cryptosporidium* or *Entamoeba histolytica* were considered non-communicable and patient isolation was not required.

[b] 42 patients with ongoing symptoms were assumed to be remain in isolation with a total isolation time of 53 days.

[c] Estimated total isolation days cased on total isolation duration of 2 days per patient.

pathway. Table 2 summarises the isolation days under the GPP testing pathway.

Testing results and costs

Performance characteristics of the GPP were not taken into consideration in this study and all GPP tests were assumed to be 100% accurate, this may not be the case, however several studies have reported improved detection rates using GPP[11,13,14] and other commercially available molecular panels.[15–17]

GPP identified an additional 81 patients with infectious gastroenteritis compared with conventional testing, including 21 patients who had not been presumptively isolated.

A total of 1744 initial tests and 152 repeat tests were performed at a cost of £33,960. With unrestricted access to all conventional tests, clinicians ordered a mean of 4.5 tests per patient episode, which includes repeated testing for the same pathogen(s), which occurred for 7% of patients overall. Only one GPP test was permitted per five-day patient episode. The cost of a GPP test was £68.88. Confirmatory testing was also costed for culture and antimicrobial susceptibility testing of *Campylobacter*, *Salmonella*, *Shigella* and *E. coli* O157 (£11.30 per test) and confirmatory toxin A/B testing for *C. difficile* positives (£12.50 per test). This resulted in a total testing cost of £56,243 for all 800 patient episodes.

Table 1 summarises the total number of conventional tests performed and their associated costs, calculated using an activity based costing algorithm and including all equipment, consumables, labour and overheads.

Cost benefit analysis

The incremental cost of providing and servicing the additional space with single beds in single room isolation compared to open wards was estimated at £88.43/day.[18] A reduction in the number of days a patient spends in isolation results in an economic saving and increases capacity for other infectious patients. The GPP testing pathway resulted in the potential to save 755 isolation days at a cost of £66,765.

The overall costs for laboratory testing of patients using GPP (£56,243) was more than that of conventional testing costs (£33,960). However, the reduction in isolation costs (1447 days for GPP testing pathway vs. 2202 days for the conventional testing pathway) generated savings of £66,765 for the GPP testing pathway, which offset the additional laboratory testing costs and produced an overall cost saving of £44,482. The economic analysis of both testing pathways are summarised in Table 3.

Sensitivity analysis

Since the economic benefit of the GPP test is contingent on removing patients testing negative from isolation, any change in the isolation time will affect the cost benefit analysis. A sensitivity analysis around the time spent in isolation was conducted, varying the time spent from one to three days, in increments of half a day. In all cases there was a net saving under the GPP testing pathway. Table 4 shows how the time in isolation affects the economic benefit of using the GPP testing pathway.

Table 3 Economic analysis of conventional and GPP testing pathways.

Conventional testing pathway	
Total number of isolation days	2202
Total isolation costs	£194,723
Total laboratory testing costs	£33,960
Total costs	£228,683
GPP testing pathway	
Total number of isolation days	1447
Total isolation costs	£127,958
Total GPP laboratory testing costs	£55,104
Total confirmatory testing costs[a]	£1139
Total laboratory testing costs	£56,243
Total costs	£184,201
Difference (GPP testing pathway − conventional testing pathway)	
Total number of isolation days	−755
Total isolation costs	−£66,765
Total laboratory testing costs	£22,283
Total costs	**£−44,482**

[a] Includes confirmatory culture and antimicrobial susceptibility testing for 51 samples positive by GPP for *Campylobacter*, *Salmonella*, *Shigella* and *E. coli* O157 (£11.30 per test) plus confirmatory toxin A/B enzyme-immunoassay for 45 samples positive by GPP for *C. difficile* (£12.50 per test).

Breakeven analysis

The breakeven analysis is designed to indicate the degree to which savings in isolation days need to be achieved to cover the additional GPP diagnostic costs. The breakeven analysis converts the incremental cost of GPP diagnosis into the equivalent number of isolation days that would need to be reduced for the net economic outcome to be £0, i.e. the costs equal the savings. The analysis found that the overall breakeven point associated with implementing GPP is a reduction of 252 isolation days (11.4%). See Table 5.

Discussion

Despite significant additional laboratory testing costs, the GPP testing pathway could result in overall savings due to a significant reduction in isolation days required (a reduction of 755 days at a saving of £66,765) over the course of this study). The overall saving under the GPP testing pathway was £44,482.

These savings are dependent upon being able to remove patients with negative GPP tests from isolation. The turnaround time of the GPP test must therefore be faster than the turnaround time for conventional testing. This was measured in our previous study, which found the median turnaround time for conventional testing ranged from 17.3 to 66.5 h and the median GPP turnaround time to be 41.8 h.[11] Others have reported faster turnaround times for the GPP test,[14] however it is not clear if sample collection

Table 4 Sensitivity analysis. The time in isolation was altered from one to three days in increments of half a day to estimate the overall effect on isolation savings.

Isolation days	3.0 days	2.5 days	2.0 days	1.5 days	1.0 days
Total isolation days GPP testing pathway	1715	1581	1447	1313	1179
Total isolation cost under GPP testing pathway	£151,602	£139,754	£127,944	£116,057	£104,209
Total laboratory testing costs for GPP	£56,243	£56,243	£56,243	£56,243	£56,243
Total costs for GPP testing pathway	£207,845	£195,997	£184,187	£172,300	£160,452
Total costs for conventional testing pathway	£228,661	£228,661	£228,661	£228,661	£228,661
Net savings using GPP testing pathway	£20,816	£32,664	£44,474	£56,361	£68,209

Table 5 Break-even analysis of the GPP testing pathway.

Cost of GPP laboratory testing	£56,243
Cost of conventional laboratory testing	£33,960
Additional cost of GPP laboratory testing	£22,283
Equivalent days in isolation at £88.43 per day	252
Total isolation days under conventional testing pathway	2202
Percentage reduction in isolation days needed to break-even	11.4%

and transportation time were included in the total turnaround time in this study. These measurements are essential to include when assessing the potential clinical impact. The economic benefit of using the GPP testing pathway was maintained even if the average time in isolation was increased to three days.

Molecular testing may not be able to completely replace conventional culture based testing, since it does not yield antimicrobial susceptibility data. Positive tests should be confirmed with culture, which also provides valuable epidemiological information for public health purposes e.g. strain typing.

Our study did not attempt to measure the risk of transmitting an undetected pathogen in those patients removed from isolation after receiving a negative GPP test. Sapovirus and astrovirus are not included on the GPP panel yet have been implicated in several hospital outbreaks.[19–21] Ultimately clinicians and other decision makers must have clinical confidence in the diagnostics that laboratories provide, in order to make individual patient management decisions. A trusted and highly accurate test may ultimately reduce unnecessary repeat testing of patients.

In our institution samples submitted from hospitalised patients represent just over 30% of the total samples submitted to our laboratory. The remaining samples originate from outpatient clinics and local general practitioners, and the advantage in terms of cost-effectiveness may be more limited in this group.

A significant limitation of the study was the parallel testing design, thus it was not possible to measure isolation times resulting from either conventional tests or GPP alone. In all likelihood the measures were a composite of both GPP and conventional tests (since some conventional tests had a shorter and others a longer turnaround time that GPP).

In addition to the outlined potential economic benefits, and the previously described improved sensitivity and turnaround times compared with some conventional testing methods, there is also the potential to consolidate laboratory workflow, allowing a single specimen to be tested for multiple targets.

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