

Assessing the impact of rapid syndromic infection testing panel on diagnostic capacity and clinical and public health management in small island developing states

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ABSTRACT

Background: Many of the UK overseas territories (UKOTs) are small with limited microbiological diagnostic capacity for pathogens and antimicrobial resistance detection. The COVID-19 pandemic highlighted the vulnerability of these territories for the emergence of novel infections and antimicrobial resistance.

Objective: To describe the process and clinical implications of implementing rapid automated syndromic molecular diagnostics (RASM) in the UKOTs, evaluating the outcome in enhancing individual patient management, communicable disease control, and antimicrobial stewardship.

Methods: The UKOT program with its territory partners implemented RASM in March-May 2023, aiming to improve diagnostic capacity. Local laboratory staff were trained in the use of the diagnostics, and guidance was provided to clinicians for requesting tests. Syndromic diagnoses included enteric, respiratory, bloodstream, neurological infection, and antibiotic resistance mechanisms. Data on diagnostic capacity, turnaround times, and clinical impact were collected from records before and after the implementation of RASM.

Results: Turnaround time for results went from an average of 14 days to 1 day, and often much shorter (1 hour). The range of enteric, respiratory, and neurological pathogens was extended. Antibiotic resistance mechanisms could be detected for the first time. Previously undiagnosed conditions could now be identified rapidly at the microbiological level in the territory, allowing appropriate specific clinical management, infection prevention, improved antimicrobial stewardship, and rapid public health response.

Conclusion: Rapid microbiological diagnosis on-site transformed patient management, the timely investigation and management of outbreaks and clusters, accurate surveillance, and antimicrobial stewardship. Targeted RASM is likely to be cost-effective, reducing the requirement for highly trained scientific staff and expensive logistics around rapid transport to reference laboratories. Further cost analyses would be useful. This technology is simple to operate and maintain with little scope for user error. The speed of microbiological diagnosis for patient management and public health intervention was greatly enhanced.

INTRODUCTION

The COVID-19 pandemic highlighted the global inadequacy of infectious disease diagnostics and surveillance.¹ Small island populations, such as the UK Overseas Territories (UKOTs), faced significant vulnerability due to limited laboratory capabilities and the delay in obtaining diagnostic results from distant reference facilities². Small, remote, and isolated communities are highly vulnerable to the importation of infectious diseases and antibiotic resistance, largely due to inadequate laboratory diagnostics.^{3,4}

The lack of rapid on-site microbiology diagnostics makes appropriate rapid management of individual cases and clusters of infection a significant challenge. The UKOT programme funded by FCDO was set up during the Covid pandemic to support the UKOTs in public health and developing diagnostic capacity. During the pandemic, open platform PCR was set up in each of the UKOTs to detect COVID-19. Open platform PCR investigations require specialist technical skills, and these are not sustainable in some of the UKOTs where laboratory scientists are mostly generalists with a wide range of responsibilities in their laboratories. It is simply not possible to have the workforce capacity to have a broad open platform molecular laboratory with a wide range of diagnostic targets in each UKOT.

In 2022, at the end of the pandemic, the UKOT programme looked to alternative solutions for enhancing diagnostic range and capacity and developing an early warning system for infection within the territories. Previously any samples for complex investigation had to be sent to different reference laboratories around the world. The difficulty of transport logistics, cost, and turnaround times limited the efficacy of these reference services. Results would be received long after they served any clinical use. Furthermore, during periods of lockdown & travel restrictions such as those implemented during the COVID-19 pandemic, further reduction in flights and shipping traffic increased UKOT isolation and compounded logistic challenges, further emphasizing the need for within territory diagnostic resilience.

These circumstances highlighted the vulnerability of the small, isolated communities to infectious disease in terms of diagnostic capability and surveillance.³ To address this, the UKOT program developed and implemented a strategy to support syndromic infection diagnosis and enhance the range of diagnostic capacity locally. This strategy would reduce the dependence on specialized reference laboratories and the subsequent logistical

challenges related to transportation of samples and delays in receiving results.

The most appropriate commercial equipment to deliver this was the Biofire film array technology, based on ease of use, maintenance, and the range of targets in the syndromic panels. In addition, Cepheid GeneXpert technology was also considered for other important areas of diagnostic need, notably sexually transmitted diseases, HIV viral load, hepatitis serology, human papillomavirus, and tuberculosis. These technologies allowed non-specialist scientists to operate the equipment and deliver rapid investigation results in the territory. The UKOT programme sought the funding to purchase and implement these technologies and successfully achieved this by mid-2023.

The intervention was called Rapid Automated Syndromic Molecular Diagnostics (RASM) and involved a process that allowed for the detection of multiple infectious disease targets from a single sample, using a system operated by laboratory scientists with general training and not requiring specialist molecular scientist skills. For example, once a broad syndromic diagnosis was suspected in an individual patient, for example, respiratory tract infection, gastroenteritis, sepsis or meningitis/encephalitis, or if there was a disease outbreak (such as enteric, respiratory, or meningitis/encephalitis infection) a sample could be sent to the diagnostic laboratory and analyzed on a multi-target automated molecular PCR system to give a rapid result and facilitate timely clinical management.

This study describes the process and clinical implications of implementing RASM in the UKOTs, evaluating the outcome in terms of enhancement of clinical management, communicable disease control, and antimicrobial stewardship. The goal was to establish how RASM could support healthcare in small, resource-challenged territories by comparing before and after RASM implementation.

METHODS

Study setting

The UKOT program is part of the UK Health Security Agency (UKHSA) and has a specific remit and budget from the UK Foreign and Commonwealth Development Office (FCDO) to support health service development, particularly laboratory capacity for infectious disease and early recognition of outbreaks and emerging diseases in

the UKOTs. There are 14 UKOTs across the globe. Eight UKOTs were elected to be part of this study, four in the Caribbean region (Montserrat, Anguilla, Turks and Caicos Islands, Cayman Islands) and four in the Atlantic Ocean (Gibraltar, St Helena, Falkland Islands, and Ascension). The remaining six were not included; one because implementation was behind schedule, one because of data assimilation issues, and four because there was no laboratory. The UKOTs are anonymized in the results by region and number.

The UKOTs included in this study vary significantly, not least in population size from 800 (Ascension) to 68,000 (Cayman). They all have self-determining governance which includes responsibility for health services. Most of the UKOTs are small, remote and isolated and have limited workforce capacity. All these characteristics make it challenging to develop microbiology services that deliver timely and responsive results.

Study design

This was a pre- and post-intervention evaluation; the intervention was the Rapid Automated Syndromic Molecular Diagnostics (RASM). Anonymized laboratory data on diagnostic capacity, the range of investigations available, the pathogens detected, and numbers of key pathogens detected were collected pre and post-intervention from laboratory workbooks, laboratory information systems (if they existed) and surveillance data from public health records in the study sites. Patient notes were not reviewed by the research team. Local investigators submitted brief anonymized clinical details of cases where the rapid result had a significant clinical impact to help illustrate the use and advantages of RASM.

Target population

We included all diagnostic laboratories of the UKOTs. We consulted laboratory results from patients attending hospitals, community centres and primary care facilities. We sought information about enteric, respiratory, bloodstream or neurological infection testing during the pre- and post-implementation periods.

Pre-intervention (May 2022-April 2023)

1. Preparation for RASM investigations

The UKOT programme provided support for implementation, validation, and laboratory governance. The UKOT programme supervised the preparation for implementation of RASM through Biofire FilmArray TORCH equipment (Biomerieux [BIOFIRE® FILMARRAY® TORCH System](#)), reagents, and training to all UKOTs that requested the technology. Biofire was chosen because of the range of targets on the syndromic panels and the

simplicity of use (Table 1).

2. Baseline data collection pre- intervention

A survey was carried out in each laboratory in the participating study sites before implementation. We used a data collection sheet to gather information about the diagnostic capacity and range of pathogens that each laboratory was able to detect. We grouped these pathogens into broad categories similar to syndromic Biofire panels (Table 1), considering four categories for the pre-intervention survey: enteric pathogens, respiratory pathogens, bloodstream infections and key antimicrobial resistant mechanisms. For each category, we collected information about the laboratory capability to detect these pathogens, and if testing was available, the number and types of pathogens detected, the reported expected turnaround time (in days), and the nature and number of outbreaks detected by public health services.

3. Implementation of RASM

a. Service implementation: Biofire equipment was procured and delivered by May 2023. Service implementation took place between April and June 2023 and was achieved by on-site visits and on-line training. Biofire panels included in implementation were enteric (100), respiratory (100), neurological (10), and blood stream infections (50). The territories were encouraged to purchase further panels as required through regional suppliers. The infectious disease targets for these are listed in Table 1. The bloodstream infection panel also included targets for the detection of antimicrobial resistance genes.

Equipment was accommodated in the main hospital laboratory for six participating territories. In two UKOTs the equipment was accommodated in a nearby separate public health laboratory. No additional equipment was required to support the automated equipment. Validation of the investigations was delivered during the implementation training.

b. Utilisation of tests: Frontline clinicians in community facilities and hospital and public health personnel were provided with a written guide and protocol on the appropriate clinical use of samples to be tested by RASM. The requesting decision was left to the clinician to ask for the test on clinical necessity. Once the test had been initiated in the laboratory, a result against all the targets in each panel was available within 90 minutes. Guidance recommended the RASM to be used on significantly unwell patients with:

- An enteric focus of infection (stool sample)
- A respiratory focus in infection (nasopharyngeal swab)
- A suspected neurological infection (CSF sample)
- Positive blood cultures

Post-intervention period (June 2023–May 2024)

A year after the implementation phase, we conducted, a post-intervention survey at the implementation sites. Similar to the pre-intervention period, we used a data collection sheet, to collect data about range of pathogens detected (number of pathogens detected and types of pathogens), the number of outbreaks detected, and reported turnaround times.

In addition to the quantitative data we collected, we also gathered examples of the impact of RASM on the clinical management of individual patients, and these findings were subsequently documented and presented in the form of case studies. Additionally, we collected information regarding the person, time, and location of detected outbreaks and presented it in brief epidemiological reports.

Data analysis

Although data was collected during both the pre-intervention and post-intervention periods, no hypothesis testing was conducted. Our analysis is purely descriptive. For each quantitative variable, we report the sums, and for turnaround time, we present the range, defined as the minimum time to the maximum time.

Ethical considerations

The UKHSA Research Ethics Governance Group (REGG) granted ethical approval for this evaluation (NR0374), alongside a separate study examining the behavioural aspects of novel diagnostic use. Basic clinical details were collected from laboratory requests and by discussion with clinicians or public health staff. Patient notes were not reviewed, and patient identity was not recorded. No identifiable patient information was included in the clinical vignettes.

RESULTS

Pre RASM Implementation

A summary of the results pre and post implementation are presented in Table 2.

1. Diagnostic capacity of laboratories in participating sites

Routine haematology and biochemistry were available in laboratories in all eight UKOTs. Six sites had microbiology services and were able to identify most bacterial pathogens within the limits of routine culture technology and carry out susceptibility testing. Two of the UKOTs had little or no phenotypic microbiology and were unable to provide bacteriology or susceptibility testing. Virology was extremely limited or absent in all 8 sites. Apart from Covid-19 testing, molecular diagnostics were being developed in three laboratories but were not present in the others.

2. Turnaround times

Bloodstream infections typically took 3-4 days to receive an isolate identification and antimicrobial susceptibility result pre-RASM. For blood cultures, processed by standard methods, results were available at different times. A Gram stain could be available soon after the blood culture signalled positive; culture would take 24-48 additional hours and then susceptibility testing a further 24 hours. For a CSF, microscopy was available soon after collection but culture and antimicrobial susceptibility testing could take 24-72 hours. Detection of respiratory and enteric pathogens were unavailable locally.

3. Surveillance

Several clusters or outbreaks of respiratory and enteric illness were suspected, but, as these could not be identified at the pathogen level, public health intervention was limited.

In the year before RASM implementation, three UKOTs identified respiratory infection outbreaks which were not caused by SARS Covid-19 (all UKOTs had implemented Covid testing capacity during the pandemic). The cause of these outbreaks was not determined but presumed to be influenza. Two of the UKOTs identified enteric infection outbreaks. The microbiological cause and source were not determined.

Four UKOTs were unable to detect key antimicrobial resistance (AMR) determinants – methicillin resistance, glycopeptide resistance, extended spectrum beta-lactamase (ESBL) production, and carbapenem resistance (CRE) (Table 2)

Post RASM implementation

1. Diagnostic capacity

Comparative data on the use and utility of RASM was available from eight UKOTs one year after implementation. All UKOTs were able to detect an expanded range of pathogens rapidly and on-site in all the syndromes covered by the RASM panels – respiratory, enteric, bloodstream infection, and neurological infections (Table 3).

Table 1. Targets available on the syndromic Biofire panels

RESPIRATORY PANEL	VIRUSES: • Adenovirus • Coronavirus 229E • Coronavirus HKU1 • Coronavirus NL63 • Coronavirus OC43 • Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) • Human Metapneumovirus • Human Rhinovirus/Enterovirus • Influenza A virus • Influenza A virus A/H1 • Influenza A virus A/H3 • Influenza A virus A/H1-2009 • Influenza B virus • Parainfluenza virus 1 • Parainfluenza virus 2 • Parainfluenza virus 3 • Parainfluenza virus 4 • Respiratory syncytial virus BACTERIA: • <i>Bordetella parapertussis</i> • <i>Bordetella pertussis</i> • <i>Chlamydia pneumoniae</i> • <i>Mycoplasma pneumoniae</i>
ENTERIC PANEL	VIRUSES: • Adenovirus F40/41 • Astrovirus • Norovirus GI/GII • Rotavirus A • Sapovirus (I, II, IV, and V) BACTERIA: • <i>Campylobacter</i> (<i>C. jejuni</i> / <i>C. coli</i> / <i>C. upsaliensis</i>) • <i>Clostridioides</i> (<i>Clostridium</i>) <i>difficile</i> (toxin A/B) • <i>Plesiomonas shigelloides</i> • <i>Salmonella</i> • <i>Yersinia enterocolitica</i> • <i>Vibrio</i> (<i>V. parahaemolyticus</i> / <i>V. vulnificus</i> / <i>V. cholerae</i>) DIARRHEAGENIC ESCHERICHIA COLI/SHIGELLA: • <i>Enteraggagative E. coli</i> (EAEC) • <i>Enteropathogenic E. coli</i> (EPEC) • <i>Enterotoxigenic E. coli</i> (ETEC) <i>lt/st</i> • <i>Shiga-like toxin-producing E. coli</i> (STEC) <i>stx1/stx2</i> ◦ <i>E. coli</i> O157 • <i>Shigella/Enteroinvasive E. coli</i> (EIEC) PARASITES: • <i>Cryptosporidium</i> • <i>Cyclospora cayetanensis</i> • <i>Entamoeba histolytica</i> • <i>Giardia lamblia</i>

Table 1. Targets available on the syndromic Biofire panels (continued)

BLOODSTREAM INFECTIONS	GRAM-NEGATIVE BACTERIA • <i>Acinetobacter calcoaceticus-baumannii</i> complex • <i>Bacteroides fragilis</i> • <i>Enterobacterales</i> • <i>Enterobacter cloacae</i> complex • <i>Escherichia coli</i> • <i>Klebsiella aerogenes</i> • <i>Klebsiella oxytoca</i> • <i>Klebsiella pneumoniae</i> group • <i>Proteus</i> spp. • <i>Salmonella</i> spp. • <i>Serratia marcescens</i> • <i>Haemophilus influenzae</i> • <i>Neisseria meningitidis</i> • <i>Pseudomonas aeruginosa</i> • <i>Stenotrophomonas maltophilia</i> GRAM-POSITIVE BACTERIA: • <i>Enterococcus faecalis</i> • <i>Enterococcus faecium</i> • <i>Listeria monocytogenes</i> • <i>Staphylococcus</i> spp. • <i>Staphylococcus aureus</i> • <i>Staphylococcus epidermidis</i> • <i>Staphylococcus lugdunensis</i> • <i>Streptococcus</i> spp. • <i>Streptococcus agalactiae</i> • <i>Streptococcus pneumoniae</i> • <i>Streptococcus pyogenes</i> YEAST: • <i>Candida albicans</i> • <i>Candida auris</i> • <i>Candida glabrata</i> • <i>Candida krusei</i> • <i>Candida parapsilosis</i> • <i>Candida tropicalis</i> • <i>Cryptococcus</i> (<i>C. neoformans</i>/<i>C. gattii</i>)
ANTIMICROBIAL RESISTANCE GENES	• Carbapenemases • IMP • KPC • OXA-48-like • NDM • VIM • Colistin Resistance • <i>mcr-1</i> • ESBL • CTX-M • Methicillin Resistance • <i>mecA/C</i> • <i>mecA/C</i> and MREJ (MRSA) • Vancomycin Resistance • <i>vanB</i> <i>vanA/B</i>

Table 1. Targets available on the syndromic Biofire panels (continued)

THE MENINGITIS/ ENCEPHALITIS PANEL	BACTERIA: • <i>Escherichia coli</i> K1 • <i>Haemophilus influenzae</i> • <i>Listeria monocytogenes</i> • <i>Neisseria meningitidis</i> • <i>Streptococcus agalactiae</i> • <i>Streptococcus pneumoniae</i> VIRUSES: • Cytomegalovirus (CMV) • Enterovirus (EV) • Herpes simplex virus 1 (HSV-1) • Herpes simplex virus 2 (HSV-2) • Human herpesvirus 6 (HHV-6) • Human parechovirus (HPeV) • Varicella zoster virus (VZV) YEAST: • <i>Cryptococcus (C. neoformans/C. gattii)</i>
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Table 3 shows the total number of investigations carried out for each syndromic category. It also shows the number of positive results by microbial diagnosis.

2. Turnaround times

Results for blood cultures (identifying isolate and resistance mechanism) were available within 90 minutes of the blood culture signalling positive. Subsequent antibiotic susceptibility testing was carried out phenotypically and would take 24-48 hours. Results for respiratory, enteric pathogens and CSF samples were available within 90 minutes.

3. Clinical and public health outcomes

Three themes were considered: public interventions during disease outbreaks, antibiotic stewardship in clinical management and management of severe infections.

a. Public health intervention in disease outbreaks

- i. **Community respiratory infection cluster:** A cluster of cases with acute respiratory illness. Patients were clinically stable, and hospital

Case 1: Sepsis. A patient was admitted to the hospital with suspected biliary sepsis. The initial management plan included commencing an empirical penicillin-based antibiotic and beta lactamase production inhibiting properties with broad spectrum coverage. Blood cultures collected on admission provided a result in 8 hours showing Gram-negative rods. Blood was subcultured but also run on the RASM bloodstream infection panel. The result was available in 90 minutes; *Klebsiella* species was identified producing extended spectrum beta lactamase.

admission was not required except for one infant who required observation overnight. There was public health concern that this may be a new wave of Covid-19. Nasopharyngeal swabs were processed on the RASM respiratory panel within 90 minutes identifying the pathogen as Metapneumovirus. As a result, antibiotics were not required for patients.

- ii. **Community enteric outbreak:** More than 10 cases were affected with acute diarrhoea. One patient with comorbidities was admitted to hospital with dehydration. Stool samples were sent to the laboratory from the hospitalized patient. Results from the RASM enteric panel identified *Salmonella* sp. food poisoning type in 90 minutes while results from phenotypic microbiology were available two days later. Public health control was implemented rapidly.

b. Antibiotic stewardship and clinical management

This indicated resistance to the original empirical antibiotic leading to change to a more appropriate antibiotic choice. The ability to identify the pathogen within 90 minutes compared to two days pre implementation of the RASM is likely to have improved the clinical outcome.

Case 2: Meningitis. A patient was diagnosed with suspected meningitis and empirical antibiotics and antivirals commenced to treat possible bacterial and viral

pathogens. The concern was a diagnosis of meningococcal meningitis which would necessitate antibiotic prophylaxis for close contacts. Lumbar puncture and CSF microscopy demonstrated meningeal inflammation with a raised cerebrospinal white count. CSF was analysed on RASM neurological panel. At 40 minutes, *Streptococcus pneumoniae* was detected. Antibiotics were rationalized and antiviral treatment discontinued given that that bacterial cause was identified. Antibiotic prophylaxis was not necessary since meningococcal meningitis was confirmed.

Case 3: Cholera. A traveller in the region returned to his home territory and admitted to hospital with watery diarrhoea, vomiting, and collapse from dehydration. A stool sample was sent for RASM enteric panel with a result available in 90 minutes. *Vibrio cholerae* O1 was detected. The territory cholera plan was rapidly implemented, a public health incident group was called, and public health measures to prevent further spread and investigate other possible cases were implemented rapidly.

Case 4. Suspected Middle Eastern Respiratory Syndrome (MERS). Prior to the implementation of RASM, a patient returned from Hajj with cough, fever, shortness of breath. The diagnosis was suspected MERS and empirical antibiotics were commenced. The sample was sent via courier plane to the UK where a negative result was available after six days. Post implementation of the RASM, a patient presented with fever, runny nose, chest tightness and possible contact with someone who was diagnosed with MERS. COVID-19 test was negative. The sample was tested using the RASM panel which provided positive result within three hours of arrival at hospital for Respiratory Syncytial Virus, Rhinovirus/Enterovirus and negative for MERS. Antibiotics were not prescribed based on the pathogens identified.

DISCUSSION

Rapid Automated Syndromic Molecular (RASM) diagnostics has been transformative for most UKOT laboratories that lacked the technology, workforce, and diagnostic capacity to identify a broad range of pathogens. Low-resource settings are disproportionately burdened by infectious diseases and antimicrobial resistance.^{1,2} Accurate microbiological diagnosis is essential for appropriate

individual patient management and effect public health control of infection incidents, clusters, and outbreaks.^{3,4,8} Without a clear diagnosis, clinical management is at best a guess, there is a waste of resources, there is inappropriate use of antibiotics and public health control relies on intuition alone.^{8,9} Failure to deliver a clear diagnosis contributes to morbidity and mortality.¹⁰

The recent SARS-COVID-19 - pandemic has highlighted the need for early warning systems to detect emerging infection and its spread¹, and RASM has extended this capacity in a way that was previously impossible. While the pandemic and encroaching AMR have highlighted, like never before, the necessity for improving diagnostic capacity, it is not enough to simply supply equipment and reagents. Laboratory governance has to be at the heart of such developments,^{2,3} and consequently, the UKOT programme worked closely with UKOT laboratories to implement and validate the technology and support the development of guidance for the most appropriate clinical use of the novel technology. The Biofire Torch system was chosen for delivering RASM because of its range of targets, supporting validation research^{5,6,7} and simplicity of use.

This study was a pre and post intervention study that described the process and outcomes for establishing a Rapid Automated Syndromic Molecular panel in eight UKOTs. The study assessed the impact of the intervention on diagnostic capacity, turnaround times and clinical outcomes. Key findings are discussed.

Key benefits

The advantages of RASM have been clear, ensuring improved clinical outcomes for individual patients, biosecurity, and response capabilities for public health and infection control teams. Individual patient management can be compromised unless there is a clear microbiological diagnosis. Antibiotic resistant infections increase morbidity and mortality.^{9,10} With a rapid diagnosis, the most appropriate antibiotics can be administered quickly, or antibiotics stopped quickly if they are not indicated (antibiotic rationalisation).¹¹ Early diagnosis has supported antimicrobial stewardship and probably helps to limit resistance selection. Early diagnosis also supported appropriate infection prevention intervention within healthcare settings.¹²

Table 2: Summary of laboratory capacity pre- and post-RASM implementation in the 8 UKOTs

Diagnostic Capability	Caribbean 1	Caribbean 2	Caribbean 3	Caribbean 4	Atlantic 1	Atlantic 2	Atlantic 3	Atlantic 4
Respiratory pathogen detection	Not available	Limited bacteriology and virology	Limited bacteriology, no virology	Limited bacteriology, no virology	Limited bacteriology, no virology	Limited bacteriology, no virology	Limited bacteriology and virology	Not available
	Detection of 22 targets on respiratory panel for common viruses and bacteria. Turnaround time 90 minutes.							
Enteric pathogen	Not available	Limited bacteriology. TAT 48 hours	Limited bacteriology. TAT 48 hours	Limited bacteriology. TAT 48 hours	Limited bacteriology. TAT 48 hours	Limited bacteriology. TAT 48 hours	Limited bacteriology. TAT 48 hours	Not available
	Detection of 21 targets on enteric panel. Turnaround time 90 minutes.							
Antimicrobial Susceptibility test	Limited	Phenotypic	Phenotypic	Phenotypic	Phenotypic	Phenotypic	Phenotypic	Not available
	Detection of 10 key AMR targets. Turnaround time 90 minutes.							
Turnaround time for blood cultures	2-5 days	2-5 days	2-5 days	2-5 days	2-5 days	2-5 days	2-5 days	Not available
	Detection of 32 common bloodstream infection pathogens + 10 AMR targets from blood culture positive bottles. Turnaround time 90 minutes from blood culture signalling positive.							
Turnaround time for sending away reference tests	2-4 weeks	2-4 weeks	2-4 weeks	2-4 weeks	4-8 weeks	2-4 weeks	2-4 weeks	4-8 weeks
Outbreaks of enteric infection managed by PH	2 3	1 2	2 3	0 1	0 1	0	2	0
Outbreak of respiratory infection managed by PH	1 1	0 1	0 1	0 2	1 2	0 1	1 1	1 0

TAT- turnaround time, AMR - antimicrobial resistance, PH - Public health

Pre RASM	
Post RASM	

Table 3. RASM usage and pathogen detection in the 8 UKOTs

	Caribbean 1	Caribbean 2	Caribbean 3	Caribbean 4	Atlantic 1	Atlantic 2	Atlantic 3	Atlantic 4
Total tests used	65	400	95	81	97	46	480	28
Respiratory panel	37	400	29	26	46	28	292	20
Bloodstream panel	5	0	30	24	24	5	0	8
GI panel	22	0	36	31	22	14	96	0
Neuro panel	1	0	0	0	5	1	0	0
RESPIRATORY PANEL								
Human Rhinovirus	18	81	2	1	4	1	49	6
Inf A (H1N1) pdm09		65	1	6	4	2		3
Influenza A H3	2	12			1	2		
Influenza A	1	2						17
Influenza B		13			1			
Parainfluenza 1		5					3	
Parainfluenza 2		2	1					
Parainfluenza 3		8			1		7	
Parainfluenza 4		2						
Coronavirus NL64	1							
Coronavirus OC43		14			1	2	3	
Coronavirus 229E		4		1			1	
Coronavirus HKU1		1					1	
Coronavirus NL63		4					2	
Acute respiratory syndrome coronavirus 2 (sars-Cov-2)	1	72	1	1		2	24	
RSV	4	5				1	3	
Adenovirus	2	9	1				20	1
Human metapneumovirus		7		1	3	2	6	

Table 3: RASM usage and pathogen detection in the 8 UKOTs (continued)

	Caribbean 1	Caribbean 2	Caribbean 3	Caribbean 4	Atlantic 1	Atlantic 2	Atlantic 3	Atlantic 4
<i>Bordetella pertussis</i>							4	
<i>Bordetella parapertussis</i>		1			1			
<i>Mycoplasma pneumoniae</i>		2	1				13	
<i>Strep. pneumoniae</i>							1	
<i>Chlamydia pneumoniae</i>							1	
<i>H. influenza</i>							2	
<i>Moraxella catarrhalis</i>							1	
<i>Other Gram negs</i>							2	
<i>Pseudomonas sp</i>							3	
BLOODSTREAM PANEL								
<i>Staph. epidermidis</i>	1			4	4			
<i>Staphylococcus sp.</i>	1			7		1		
<i>Staph. aureus</i>			1	3	3			
<i>MRSA</i>								
<i>Streptococcus Group B</i>						1		
<i>Streptococcus sp.</i>					1	1		
<i>Enterococcus faecalis</i>				1				
<i>Esch. coli</i>			1	1	4			
<i>Esch. coli CTX-M</i>				1				
<i>E. coli NDM</i>				1				
<i>Klebsiella pneumoniae</i>			1		2	1		

Table 3: RASM usage and pathogen detection in the 8 UKOTs (continued)

	Caribbean 1	Caribbean 2	Caribbean 3	Caribbean 4	Atlantic 1	Atlantic 2	Atlantic 3	Atlantic 4
<i>Klebsiella pneumoniae</i> (CTX-M gene)					1			
<i>Klebsiella pneumoniae</i> (OXA-48-like)				1	1			
<i>Klebsiella aerogenes</i>								
<i>Klebsiella oxytoca</i>					1			
<i>Pseudomonas aeruginosa</i>			1	1	1			
<i>Serratia marcescens</i>					1			
<i>Enterobacter cloacae</i>				1	1			
<i>Haemophilus influenzae</i>					1			
<i>Bacteroides fragilis</i>					1			
<i>Acinetobacter baumannii</i>				1				
<i>Candida tropicalis</i>				1				
GI PANEL								
<i>Salmonella</i>	2		1	9	1		4	
<i>Shigella sp</i>			1					
<i>Vibrio cholerae</i>	2		1					
<i>Vibrio sp.</i>				1		1	2	
<i>Campylobacter sp.</i>				6	5	1	5	
<i>Pleisiomonas shigelloides</i>			1					
STEC			1					
EPEC	8		1	4	3	1	5	
EAEC	3		1	2	2		7	
ETEC			1			1	2	

Table 3: RASM usage and pathogen detection in the 8 UKOTs (continued)

	Caribbean 1	Caribbean 2	Caribbean 3	Caribbean 4	Atlantic 1	Atlantic 2	Atlantic 3	Atlantic 4
<i>E. coli</i> O157			1		1			
Astrovirus	2						1	
Rotavirus							1	
Norovirus			1		5		1	
Sapovirus				6	1		1	
Adenovirus F40/41			1				1	
<i>Cryptosporidium</i>			2					
<i>Giardia lamblia</i>			1	1		1	2	
<i>Clostridium</i> <i>difficile</i> toxin A/B					1		5	
NEURO PANEL								
<i>Strep pneumoniae</i>							1	
<i>Haem. influenzae</i>						1	1	
HSV							1	
Enterovirus							1	
CMV							3	
VZV							1	

Syndromic diagnosis has allowed early public health intervention of respiratory and enteric clusters and outbreaks for the first time and has improved the accuracy and quality of surveillance. This is exemplified by the clinical vignettes. In the respiratory cluster, RASM enabled early exclusion of Covid-19, identified the pathogen, metapneumovirus, supported the decision not to use antibiotics which were unnecessary in the treatment of viral infection. In the enteric outbreak vignette, the pathogen, salmonella, was identified in several patients quickly, helping to confirm a point source outbreak, and supporting the most appropriate treatment of those affected.

The remote, isolated situation of many UKOTs makes them vulnerable to imported high consequence infection.² High consequence infections are those that are highly pathogenic (e.g. cholera, viral haemorrhagic fever, MERS)

and/or those infections that spread rapidly.¹³ These may include highly resistant microbes such as Carbapenemase-producing bacteria, for which effective antibiotic treatment may be unavailable. The ability to be able to detect these pathogens and resistance mechanisms quickly is crucial for effective patient and public health management and to prevent spread in small vulnerable communities.

In the clinical vignettes, the early diagnosis of cholera enabled appropriate isolation, prevention of spread, investigation of contacts and appropriate patient management. It allowed early investigation of risk factors, sources of infection and routes of transmission. The last vignette shows the importance of improving turnaround time in detecting high consequence infection. The first patient with suspected MERS required isolation for 6 days before the virus could be excluded. The costs of couriering

a sample to an overseas reference lab, public health monitoring of contacts and isolating the patient for so long were high. In the second suspected MERS patient, the diagnosis was excluded by RASM within three hours of admission and permitted an immediate scaling down of resource intensive interventions.

The advantages of RASM in patient management are exemplified by the vignettes on sepsis and meningitis. In the septic patient infected with an extended spectrum beta lactamase- producing organism, the empirical antibiotic treatment would have been ineffective. Ineffective early treatment of sepsis is associated with higher morbidity and mortality.¹⁰ RASM allowed rapid identification of the causative organism and the resistance mechanism, permitted change of antibiotic to an appropriate agent. In the case of meningitis, early identification of the pathogen as a pneumococcus, for which prophylaxis is not required, rather than a meningococcus, for which prophylaxis is indicated, ensured that the patient was appropriately treated quickly and also prevented unnecessary use of prophylactic antibiotics. RASM has proved a useful tool in antimicrobial stewardship.¹⁴

Challenges with implementation

Implementation of this diagnostic equipment was challenging to some of the UKOTs based on their remoteness, supply chains and logistics, but it was successfully achieved through commercial lines of procurement and through the support of UK Crown Agents. Training of staff in use of the equipment was achieved by a combination of face-to face and online training by UKOT staff and the manufacturer. RASM proved to be transformative for several UKOT laboratories that lacked the technology, workforce, and diagnostic capacity to identify a broad range of pathogens. It has also provided the UKOTs the ability to diagnose infection quickly, a key advantage in the management of individual patients and controlling infection.

This study has not carried out a cost-effectiveness analysis. Molecular diagnostics, including RASM, are costly and the consumables must be purchased and be available with an adequate shelf life in a timely way. Procurement and supply lines for consumables can be complex in remote territories. These are all limitations for implementation of RASM but they are the same limitations as for any diagnostic technology. Nevertheless, targeted RASM is likely to be cost-effective for the UKOTs in comparison with the alternative costs of developing multiple diagnostic platforms with associated highly

trained, specialist scientific staff, cost of transport of samples to reference facilities, cost of delayed public health or infection control intervention, prolonged isolation of patients, cost of collateral damage from inappropriate antimicrobials.¹⁵ The clinical vignettes illustrate this well. Health ministries should be aware that the financing of rapid diagnostics is likely to be highly cost-effective.^{4,15}

CONCLUSION

It is difficult to manage outbreaks and provide the best treatment for patients without good diagnostic data.⁸ Surveillance of infectious disease and antibiotic resistance has to date been limited across the UKOTs. Antibiotic resistance across the Caribbean region is likely to be high and forecast to be increasing, contributing to higher morbidity and mortality.¹⁶ Early detection of major antibiotic resistance mechanisms is therefore essential. RASM has proved an essential tool in improving the quality of both of these and supporting antimicrobial stewardship.

The syndromic diagnostic model can be developed further. Certain regions, especially the Caribbean, are susceptible to outbreaks because of increasing global travel, tourism and major events. Before and since the COVID-19 pandemic the Caribbean has suffered epidemics of Zika, dengue, and chikungunya.¹⁷ Many other emerging and vector borne diseases could have major consequences for the UKOTs.¹⁸ Some UKOTs are at the crossroads of shipping lanes and have had incidents of potential introduction of high-consequence infections. Without rapid diagnostics, the risk to public health is significant. While current syndromic panels are unable to detect many causes of high consequence infection or emerging global diseases, the UKOT programme is working with all the territories to increase the range of diagnostic capability in this area of global infection, especially for vector borne disease and viral haemorrhagic fever, by similar RASM technology. The programme strategy is to deliver local rapid diagnostics for most emerging and high-consequence infection within the next two years.

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