ORIGINAL RESEARCH

Development of a Mobile Laboratory for Sudden Onset Disasters

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ABSTRACT

Objectives: Clinical diagnostics in sudden onset disasters have historically been limited. We set out to design, implement, and evaluate a mobile diagnostic laboratory accompanying a type 2 emergency medical team (EMT) field hospital.

Methods: Available diagnostic platforms were reviewed and selected against in field need. Platforms included HemoCue301/WBC DIFF, i-STAT, BIOFIRE FILMARRAY multiplex rt-PCR, Olympus BX53 microscopy, ABO/Rh grouping, and specific rapid diagnostic tests. This equipment was trialed in Katherine, Australia, and Dili, Timor-Leste.

Results: During the initial deployment, an evaluation of FilmArray tests was successful using blood culture identification, gastrointestinal, and respiratory panels. HemoCue301 (n = 20) hemoglobin values were compared on Sysmex XN 550 (r = 0.94). HemoCue WBC DIFF had some variation, dependent on the cell, when compared with Sysmex XN 550 (r = 0.88-0.16). i-STAT showed nonsignificant differences against Vitros 250. Further evaluation of FilmArray in Dili, Timor-Leste, diagnosed 117 pathogens on 168 FilmArray pouches, including 25 separate organisms on blood culture and 4 separate cerebrospinal fluid pathogens.

Conclusion: This mobile laboratory represents a major advance in sudden onset disaster. Setup of the service was quick (< 24 hr) and transport to site rapid. Future deployment in fragmented health systems after sudden onset disasters with EMT2 will now allow broader diagnostic capability.

Key Words: diagnostics, disaster, infection, laboratory, mobile

Sudden onset disasters (SOD) occur with relative frequency in Asia and the Pacific. Between 2010 and 2014, there were 1446 events that could be deemed as "natural disasters.[1] Significantly, of all people affected by SOD between 1970 and 2014, 87% were located within Asia or the Pacific.[1]

The disease burden emanating from SOD is varied, including medical and surgical emergencies (Figure 1). Post-disaster outbreaks of communicable diseases have been widely reported (Figure 2).[2] Diagnostics that can provide basic biochemistry, hematology, and microbiology have the potential to significantly improve quality of care in these settings.[30-32] While medical teams and field hospitals have operated with limited diagnostics in the past, the availability of novel point-of-care technology offers the prospect of improved diagnostic precision in the field leading to both clinical and disease surveillance benefits.[33,34] Additionally, ABO/Rh grouping for whole "walking blood transfusion" requires screening of donors in accordance with World Health Organization (WHO) guidelines for what has been described as "damage control resuscitation."[35,36]

Australia's SOD regional medical response is provided by a WHO verified emergency medical team (EMT) type II field hospital.[35] This includes an emergency care unit (10 chairs, 12 stretchers), a 30-bed inpatient unit, 2 surgical theaters, medical, nursing, allied health staff, and logisticians. The field hospital must be operationally fully self-sufficient.

Current standards for diagnostics in the EMT type II field hospital are covered in the WHO guidelines[35] and include the need for equipment that can measure electrolytes, urea and creatinine, full blood count, blood gas analysis, cross matching, and a limited number of rapid tests, including those for human immunodeficiency virus (HIV), syphilis, and hepatitis B and C.

Historically, the provision of more complex testing in such field hospitals has been difficult.[37] Restrictions to regular laboratory processes include disruption of supply routes, difficulty with cold chains, and the use of fragile equipment in environmentally harsh conditions.[38] The average temperature and humidity in Southeast Asia ranges from 20-35 °C and 70-90%, respectively.

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FIGURE 1

Disaster, Associated Pathology and Subsequent Testing Requirements

Disaster	Tsunami	Meteorological (Cyclone/Typhoon)	Flood	Geophysical (Earthquake, landslide)	Fire	Explosion
Clinical presentation	• Aspiration/near drowning • Fractures • Skin and soft tissue infection – high rates of MRO • Trauma • Contusion • Blood loss	• Penetrating and blunt trauma • Fracture • Blood loss • Insect borne arboviral illness • Contaminated water/diarrheal illness	• Aspiration/near drowning • Contaminated water/diarrheal illness • Skin soft tissue injuries (MRO) • Insect borne arboviral illness	• Crush injuries, hemorrhage, fractures, Infections – (MRO)	• Smoke inhalation, CO poisoning, burns	• Penetrating and blunt trauma, haemorrhage, burns, traumatic amputation, Infections (MRO)
Testing – Immediate	Electrolyte + pH Lactate Blood gas Hemoglobin ABO/Rh	Electrolyte + pH Lactate Hemoglobin ABO/Rh	Electrolyte + pH Lactate Hemoglobin ABO/Rh	Electrolyte + pH Lactate + Blood gas CK Hemoglobin ABO/Rh + X-ray	Electrolyte + pH Lactate + Blood gas CK Hemoglobin ABO/Rh + X-ray	ABO/Rh + Electrolytes Lactate Hemoglobin X-ray
Testing – Early	Microscopy / Gram stain / thick and thin smear White cell count differential Multiplex PCR BC / CSF analysis	Electrolytes White cell count Microscopy / Gram stain PCR for infectious agents WCC differential CXR	Electrolytes White cell count Microscopy / Gram stain PCR for infectious agents WCC differential CXR	Electrolytes White cell count Microscopy / Gram stain PCR for infectious agents WCC differential CXR	Microscopy / Gram stain / Multiplex PCR for wound infection WCC differential	HBV / HCV /Syphilis /HIV testing for transfusion support
Testing – Delayed	Arboviral testing, malaria, Leptospirosis, Diarrheal multiplex PCR screening	Dengue, malaria, Leptospirosis MRO Diarrhoeal illness screen	Dengue, malaria, Leptospirosis MRO Diarrhoeal illness screen	Multiplex PCR diarrheal screen Wound MRO testing	Burn infections (MRO)	Wound (MRO) testing

BC = blood culture; CSF = cerebrospinal fluid; MRO = multi-resistant organism; PCR = polymerase chain reaction.

This creates potential for variation in temperature sensitive equipment.[38]

Setup of EMT2 hospitals in austere environments must confront these issues. Equipment that does not require temperature regulation is desirable. Further, any laboratory requires an independent supply of electricity, water, and consumables. The laboratory must be adaptable to the disaster situation, mobile, robust, and reliable (see Table 1). With these requirements in mind, we designed a modular mobile laboratory and trialed its function using domestic and international deployments.

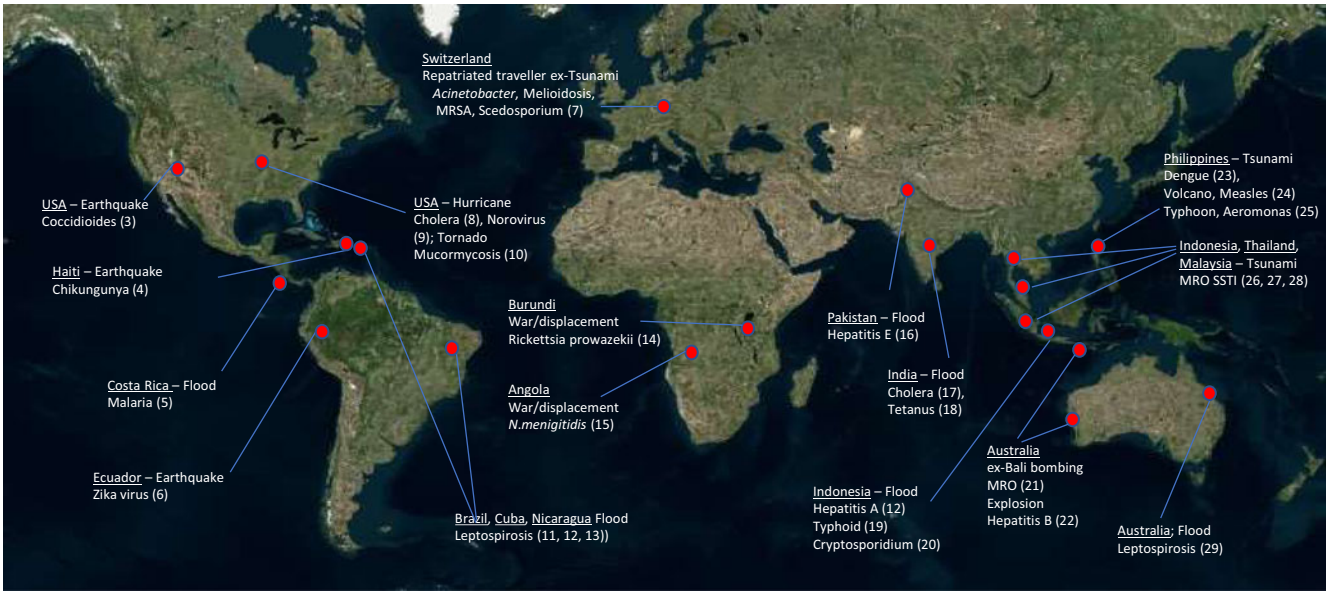
METHODS

A number of device platforms were assembled after consultation with field experienced personnel and a review of the literature (Table 2). Parameters required for selection were portability, adaptability, ease of consumable supply, and simplicity of quality control (QC) performance. Standard operating procedures (SOPs) were designed for each platform. A programmatic approach to sample collection, delivery, and processing was created. This was based on operation by 1 senior microbiology trained scientist (as would mimic an infield deployment). All plans incorporated pre-analytical and post-analytical sample processing requirements (based on ISO15189). Stringent screening, drawing, labeling, and issuing standards were enlisted for blood grouping. All non-analytical processes were designed specifically for EMT2 in a SOD environment.[39] A review of rapid diagnostic tests (RDT) was performed and SOD field applicable lateral flow tests chosen for hepatitis B, C, syphilis, HIV, leptospirosis, dengue, and malaria (Table 2). A selection of malaria RDT was based on best operation for *Plasmodium falciparum* and *Plasmodium vivax* in the Southeast Asian/Pacific region (as per WHO product testing of malaria RDTs: round 6).[40] The BIOFIRE FILMARRAY multiplex real-time (rt) polymerase chain reaction (PCR) system was maintained in an external quality assurance program prior to deployment to ensure correct functionality.

The National Critical Care and Trauma Response Centre's (NCCTRC) modular mobile laboratory was trialed in 2 locations. The first was a remote hospital in Katherine, Northern

FIGURE 2

Communicable infections post SOD



* MRO – Multi-resistant organisms; MRSA – Methicillin resistant *Staphylococcal aureus*

Territory (NT), Australia, for 12 days. This hospital is a 60-bed facility located 320 km from the nearest referral center. BIOFIRE® FILMARRAY® multiplex rt-PCR (BioFire Diagnostics, bioMérieux, Salt Lake City, Utah, USA), iSTAT (Abbott, Princeton, New Jersey, USA), Hemo Cue301, HemoCueWBC DIFF (A Quest Diagnostic Company, Sweden), and the BX53 – Olympus upright microscope were used on pre-collected patient samples by a single microbiology trained staff member. Reproducibility of those systems was tested against accredited validated platforms, including VITROS® 4600 (Ortho-Clinical Diagnostics, Inc., Rochester, NY), Sysmex XN 550 (Sysmex Corporation, Kobe, Japan), and traditional culture-dependent techniques, which included VITEK® 2 (bioMérieux, Marcy l'Étoile, France), VITEK® MS matrix assisted laser desorption ionization time-of-flight (MALDI-TOF) mass spectrometry (bioMérieux, Marcy l'Étoile, France), and where necessary specific in-house PCR at Royal Darwin Hospital, Australia. Blood cultures were performed using both BacT/ALERT® (bioMérieux, Marcy l'Étoile, France) and BACTEC™ (BD, Franklin Lakes, New Jersey, USA) culture media.

TABLE 1

Key Features of the Mobile Laboratory Unit for SOD

Simple operation
Transportable – deployable to remote locations via aircraft, vehicles, personnel carriage
Minimal dependence on cold chain
Availability of key tests – blood grouping, clinical chemistry, hematology, basic microbiology
Reliable internal quality control systems
Quality assurance system adaptable to numerous deployments
Robust data information management system adaptable to disaster/ patient care model
Adaptable delivery dependent on disaster – modular concept
Logistics of consumable supply sound

The second deployment involved transport of the microbiology module to Dili, Timor-Leste, for operation of the FilmArray system within a national referral laboratory for 84 days by a series of pre-trained Timorese scientists. Training on platform loading, operation, and troubleshooting was completed over 1 day at deployment. This module was embedded within a laboratory with limited microbiology services. Initiation of a blood culture and cerebrospinal fluid (CSF) service occurred for the first time for the local national hospital, Hospital Nacional Guido Valadares (HNGV). FilmArray gastrointestinal and respiratory multiplex panels supplemented pre-existing stool microscopy and influenza testing, respectively. Positive CSF and blood culture samples were run against the corresponding FilmArray panel and concurrently cultured using an on-site incubator and traditional bench top microbiology identification techniques, including API® analytical profile index (bioMérieux, Marcy l'Etoile, France).

All staff involved were trained on biosafety operations prior to use and deployment. Personnel protective equipment (PPE) and biosafety and biosecurity management protocols

were implemented for Risk Group 2 organisms. All organisms considered possible Risk Group 3[41] and above were to be isolated and transferred with International Air Transport Association (IATA) Category A packaging for further testing. A special note was made for samples that were thought likely to be containing *Mycobacterium tuberculosis*. Given the risk to laboratory staff, all high-risk samples were required to be handled in the HEPA filtered film isolator only, and no aerosolization procedures were allowed. QC, necessary for all laboratory diagnostics, occurred on deployment with previously identified organisms for FilmArray, and microscopy. ABO/Rh reagents required strict pre-deployment and in field QC to ensure no diagnostic failures. HemoCue and i-STAT required liquid pre-deployment QC and infield internal QC; however, QC of each RDT batch occurred prior to deployment, not in the field, given the logistics of positive control supply of these infectious agents to a remote site.

During both trials, equipment used uninterruptible power supply (UPS) protected power from the site of deployment rather than generator driven sine wave power as would be provided in a typical disaster scenario. Both sites had temperature and humidity control available, and this was used. Atmosphere control in SOD deployments occurs in a 32-foot Alaska Shelter™ with floor and insulated lining. It has its own environmental control unit and is thermostatically regulated down to 23 °C.

With all equipment assembled, the space required was approximately 3 m x 2.5 m for adequate sample flow (see Table 2 for further details of platforms). Initial costs for laboratory equipment deployment were approximately US $95 000. Ongoing procurement of consumables was estimated at between US $2000 and US $10 000 per deployment (dependent on size and length of period in use).

Ethical approval was obtained from the Cabinet of Quality Control and Ministry of Health for Timor-Leste and the Menzies School of Health and Research (Darwin, NT, Australia), HREC Ref: 2017-2838.

RESULTS

Deployment of all modules to the domestic site (Katherine) was by a single vehicle. Setup at the site was rapid with QC on all platforms started within 2 hours of arrival.

Over the 12-day Australian deployment, 11 FilmArray multiplex rt-PCR pouches were used, including 4 blood culture, 4 gastrointestinal, and 3 respiratory pouches. These detected a total of 9 pathogens with 3 pouches being negative and 1 panel detecting 2 pathogens concurrently. All results were confirmed with approved validated testing platforms, including VITEK 2, VITEKMS, and API. One blood culture sample required a transfer to Royal Darwin Hospital for confirmation as *Burkholderia pseudomallei* – a pathogen not included on the FilmArray panel. There were 20 HemoCue301 tests performed, all displaying non-clinically significant differences on each parameter when compared with Sysmex XN 550 ($r = 0.94$). HemoCueWBC DIFF did display some differences on each WBC parameter when compared with Sysmex XN 550. Pearson's correlation coefficient showed variable effect dependent on the parameter in question (neutrophils $r = 0.88$, lymphocytes $r = 0.49$, monocytes $r = 0.16$, eosinophils $r = 0.70$, basophils $r = 0.16$). One sample failed HemoCueWBC DIFF testing and had abnormal film results requiring a detailed BX-53 microscopy review. This case was later diagnosed as chronic lymphocytic leukemia. iSTAT tests were run in parallel against Vitros 250 showing non-clinically significant differences for CHEM4 ($n = 10$), CG8 ($n = 10$), and TnI ($n = 5$) cards. Pearson's correlation coefficient for Na^+, K^+, and creatinine were 0.93, 0.95, and 0.99, respectively.

The iSTAT and HemoCue devices fail to perform at high ambient temperatures. The trial at 30 °C caused a machine error requiring the platforms to be reset and cooled for operation at a lower temperature. This is in keeping with known product specifications. The FilmArray and microscopy were not evaluated at these ambient air temperatures and instead were used in a temperature-controlled environment that would mimic the NCCTRC EMT2 Alaska Shelter™.

Deployment to the National Laboratory in Dili, Timor-Leste, occurred on a commercial flight as standard luggage allowance and was operational within 24 hours of arrival. After passing QC, 168 FilmArray pouches were run successfully, with 117 pathogens identified over the period. This included positive blood culture specimens using Oxoid media bottles[59] (Oxoid, Basingstoke, UK) plus an accompanying SIGNAL trigger system,[60] CSF, respiratory (nasopharyngeal swabs), and stool samples. All samples were run through corresponding FilmArray multiplex panels. Culture was performed concurrently on blood culture and CSF samples with verification of 92% of culturable organisms using standard bench top tests and API. See Table 3 for further details of organisms isolated.

Safety protocols were audited, and no safety events occurred. The incorporation of SOPs was deemed adequate for the field location, with no major adjustments needed. Malfunctioning rt-PCR runs occurred, with 5 due to power failures (despite functional uninterrupted power supply (UPS), as power delays were persistent not allowing for adequate charging), a further 5 "software errors," and two pouches that failed to demonstrate vacuum sealing. All samples from failed tests were re-run with normal performance of the assay.

DISCUSSION

Previous use of rapid diagnostics for the NCCTRC was limited.[61] Development of this modular mobile laboratory represents a significant improved diagnostic capability, with an opportunity to impact on patient care. We have shown that

TABLE 2

NCCTRC Mobile Modular Laboratory

Device (environmental limitations)	Wt	Consumable/Panel Required	Tested	Cold Chain Required	Time to Result	Sensitivity and Specificity (Sn/Sp) % Correlation Coefficient (r)	Country Ref
iSTAT (Venous samples: 18-30°C) 90% humidity (maximum)	650 g	CG4, CHEM8, TnI	Na^+, K^+, Cl^-, anion gap, glucose, urea, TnI, creatinine, HCO3, pH, BE, PCO^2, PO^2, lactate	Yes (2-week limit at room temp)	<5 min	Slope coefficient (Sodium 1.18 / potassium 1.0 / Chloride 1.0 Creatinine 1.04)	Australia[42]
HemoCue301 (Venous/capillary samples in EDTA: 18-30°C) (Capillary samples from finger stick: 18-25°C)	500 g	Hemoglobin pipette	Hb	No	10 sec	(27.9/99.4) (Pearson correlation coefficient r = 0.75 p < 0.001)	Netherlands[43]
HemoCueWBC (Venous/capillary samples in EDTA: 18-30°C Capillary samples from finger stick: 18-25°C)	1.3 kg	Combined neutrophil, lymphocyte, monocyte, eosinophil, basophil pipette	Neutrophil eosinophil monocyte lymphocyte basophil	No	5 min	Slope coefficient Neutrophil r = 1.03 (0.96-1.13) Lymphocyte r = 0.89 (0.75-1.00) Monocyte r = 0.52 Eosinophil r = 2.50 (1.00-5.33)	Australia[42] Australia[44]
BioFire FilmArray **multiplex rt-PCR** (operation 15-30°C)	9 kg	Blood culture identification (BCID) panel, meningitis-encephalitis (ME) panel, respiratory panel, gastrointestinal panel	See https://www.biofiredx.com/ for full diagnostic list	No	60-90 min	– BCID (98.1%/99.9%) – Respiratory (84.5% %/100%) – GI (94.5-100%/97.1%) – ME [CSF] (85.7-100%/ 99.2%) # *BioFire Diagnostics data on file sensitivity/specifity* (**BCID** 98.1%/99.9%, **Respiratory** 97.1%/99.3%, **GI** 98.5%/99.2%, **ME** [CSF] 94.2%/99.8%)	USA[45] USA[46] USA[47] USA[48]
Microscopy BX53 + Camera (Tele-microbiology) (Ambient temp 5 - 40°C - relative humidity restrictions - 80 % at 31°C / 70 % at 34°C / 50 % relative humidity at 40°C)	21 kg	Gram, mAFB, Giemsa, and QuikDiff stains, glass slides, coverslips, etc.	Bacterial, parasitic and fungal stain. Blood film review and platelet count.	No	Variable	Performance specifications dependent on microscopist and level of training	
Blood bank fridge - AcuTemp Ax 56L	66 kg	Storage of whole blood product	Regular internal QC	Yes	–	–	–
Biosafety – HEPA filtered isolator	1.8 kg	HEPA filtered flexible isolator	RG2 loading	No	–	–	–
Malaria Store at 1 - 40°C	< 1 kg	CareStart (G0131)	Pf (HRP2)/ Pv/ Po/ Pm (LDH)	No	20 min	(89.6/98.2)	China-Myanmar[49]
Dengue Store at 1 - 30°C	< 1 kg	SD Dengue Duo	NS1 / IgM / IgG	No	15 min	(82-87/92-100)	French Guiana[50]

TABLE 2

Continued

Device (environmental limitations)	Wt	Consumable/Panel Required	Tested	Cold Chain Required	Time to Result	Sensitivity and Specificity (Sn/Sp) % Correlation Coefficient (r)	Country Ref
Leptospirosis	< 1 kg	Standard Diagnostics, Yongin, South Korea	IgM	No	15-20 min	(72.7/71.2) (26.7/94.8)	India[51] Laos[52]
Store at 1 - 30°C							
HIV	< 1 kg	Alere Determine	p24 Ag, gp41 Ab	No	20 min	(87/100)	Australia[53]
Store at 1 to 30°C							
Syphilis	< 1 kg	Chembio	RPR / TPPA	No	25 min	TPPA (89 / 98.3) RPR > 1:8 (95.3 / 62.2)	Australia[54] Australia[55]
Store at 2 to 30°C							
Hepatitis B	< 1 kg	Alere Determine	HBsAg	No	20 min	(88.5/100)	The Gambia[56]
Store at 2 to 30°C							
Hepatitis C	< 1 kg	SD Bioline (Standard Diagnostics)	HCV Ab	No	20 min	(78.8/100)	South Korea[57]
Store at 2 to 30°C							
Anti-RhD/A/B grouping monoclonal	< 1 kg	Epiclone Anti-A, Anti-B, Anti-D (IgM/IgG)	ABO/Rh antigens	Yes	< 15 min	(100/100)	Malaysia[58]

mAFB = modified acid-fast bacilli; Pf = Plasmodium falciparum; Pm = Plasmodium malariae; Po = Plasmodium ovale; Pv = Plasmodium vivax; RG – Risk Group.
# Data on File, BioFire Diagnostics (https://www.biofiredx.com/ [accessed 10/03/2019])

the ability to make a reliable and moderately complex diagnosis is now available to an EMT2 unit while attending an SOD.

Adaptability and transportability were a major focus in design. Feasibility of modular deployment of this laboratory means that certain equipment can be sent depending on the support necessary. Setup of the service is quick (< 24 hours), and transport to the site can be rapid. Training for most platforms was straightforward for scientists, and performance was largely consistent in both domestic and international settings. A trained microbiology scientist is deemed necessary for operation, including maintenance of equipment, the skilled microscopy work, and ongoing quality assurance and QC. An interpretation of results requires a background in the basics of microbiology and blood grouping to avoid errors. Use of all modules concurrently is possible for 1 microbiology-trained senior scientist trained in blood grouping; however, the basic operation of i-STAT and HemoCue equipment can be operated by adequately trained nursing staff, lessening the workload on scientists and enabling rapid turnaround times of results.

Infectious diseases can cause significant morbidity and mortality in SODs. This is limited to not only communicable disease spread, but also soft tissue infections, which can be limb- and life-threatening. Antibiotic resistance is now well established in the environment in many Southeast Asian locations.[62] This was seen in data reviewed by Uçkay et al., where repatriated travelers post natural disasters were found to have highly resistant organisms present (including but not restricted to) Enterobacteriaceae, *Aeromonas* spp., *Pseudomonas aeruginosa*, *Acinetobacter* spp., and *Burkholderia pseudomallei*.[8] Use of our current diagnostics can lead to more accurate treatment and directed antibiotic use for many of these.[8]

Currently, disease surveillance in SODs is syndromic and based on presentation features only. This is achieved using data collection tools such as the Surveillance for Post Extreme Emergencies and Disasters (SPEED).[63] Supplementation of this information with PCR-based infectious disease diagnostics could enhance disease surveillance in SODs. For many communicable causes of gastroenteritis, on-site PCR will allow for early intervention and limitation of spread by infection control procedures.[12]

Transfusion support is also enabled by this laboratory. Rapid blood ABO/Rh grouping with bloodborne virus (BBV) screening allows for a whole blood transfusion expanding capability of surgical and obstetric management options. Current trauma resuscitation guidelines recommend a balanced component therapy (1:1:1) of packed red cells, fresh frozen plasma, and apheresed platelets for massive transfusion. The logistics of stored component therapy, particularly for platelets, can preclude this in the austere environment. The use of whole blood transfusion is well established as a therapeutic

TABLE 3

BioFire FilmArray Multiplex PCR Results

(No. Positive/Tested)	Panel Used With Organisms Positively Identified	Confirmatory Result From Culture and Traditional Microbiology Workup
Australia (Katherine) 12 Days		
3/4	**Blood Culture Panel**	
	– *E. faecalis*	– *E. faecalis - (VITEK 2 confirmed)*
	– *H. influenzae*	– *H. influenzae - (VITEK 2 confirmed)*
	– *K. pneumoniae*	– *K. pneumoniae - (VITEK 2 confirmed)*
	One Gram negative organism failed to identify on BioFire	– *B. pseudomallei (In-house PCR confirmation primer site - Type 3 secretion system)*
3/4	**Gastrointestinal Panel**	
	– *Campylobacter*	– *Campylobacter spp. (culture confirmed)*
	– *Salmonella*	– *Salmonella spp. (culture confirmed)*
	– *Giardia*	– *Giardia (Antigen positive)*
1/3	**Respiratory Panel**	
	– *Chlamydia pneumoniae* + *Rhinovirus*	– *Chlamydia IgA serological positive*
Timor-Leste (Dili) 84 Days		
117/168	**Panel Used With Organisms Positively Identified**	**Confirmatory Result From Culture and Traditional Microbiology Workup**
	Blood Culture Identification Panel	
	– *P. aeruginosa*	– *P. aeruginosa (API confirmed)*
	– *S. aureus*	– *S. aureus (Latex confirmed)*
	– *E. coli*	– *E. coli (API confirmed)*
	– *S. pneumoniae*	– *S. pneumoniae (optochin sensitive)*
	– *S. pyogenes*	– *S. pyogenes (Group A confirmed)*
	– *Enterococcus spp.*	– *Enterococcus spp.*
	Meningitis-Encephalitis Panel	
	– Cryptococcus	– Cryptococcus – *(culture confirmed)*
	– *H. influenzae*	– *H. influenzae – (culture confirmed)*
	– *S. pneumoniae*	– *S. pneumoniae - (culture confirmed optochin sensitive)*
	– Enterovirus	→ HHV6, EV not confirmed due to lack of alternative microbiological testing method in Timor-Leste
	– HHV6	
	Respiratory Panel	
	Adenovirus, Coronavirus, Rhinovirus, Influenza A, Influenza A/H1-2009, Influenza A/H3, Influenza B, Parainfluenza 3, RSV, *Mycoplasma pneumoniae*	Not confirmed due to lack of alternative microbiological testing method in Timor-Leste
	Gastrointestinal Panel	
	Campylobacter spp. C. difficile P. shigelloides, Salmonella spp., V.cholerae, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st, Shiga-like toxin-producing E. coli (STEC), Shigella/Enteroinvasive E. coli (EIEC), Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus, Cryptosporidium, E. histolytica, G.lamblia	Not confirmed due to lack of alternative microbiological testing method in Timor-Leste

option in many low- and middle-income countries (LMICs),[36] is used in humanitarian actions by non-governmental organizations such as the International committee of the Red Cross (ICRC),[64] and has been used extensively in military conflicts since World War I.[65-67] While not a US Food and Drug Administration approved therapy, they provide a lifesaving management option for massive exsanguination in the restricted field hospital environment that adequately supplies coagulation factors, hemoglobin, and platelets. There are data on successful outcomes in Afghanistan and Iraq,[67] and a pilot study of early whole blood in trauma has been reported in the United States.[68] The risks of use of whole blood, like any transfusion, should be weighed against the benefits. A relative risk of transmission of infectious agents is dependent on the prevalence in the community in question. A retrospective review of whole blood transfusion products in Iraq by the US military found very few (0.11%) transmissible agents present in any of the units donated.[64]

Electrolyte and blood differential analysis can give valuable information in the setting of crush injuries (which requires close potassium monitoring) and blood loss, or large electrolyte imbalances. The lack of renal replacement therapy on deployment would require careful monitoring of creatinine to detect any renal impairment arising from crush injury or overwhelming sepsis. The growing burden of non-communicable diseases, including type 2 diabetes, its vascular complications, as well as ischemic heart disease are well known in the Pacific and

Southeast Asian regions.[64] Rise in this baseline prevalence means that the monitoring of troponin, creatinine, and blood glucose is necessary, widening the scope of electrolytes needed by a mobile laboratory.

The availability of electrolyte and acid base assessment is reported to have proven useful in previous disaster events.[69] The i-STAT platform was limited by the failure of cartridges at ambient temperature (requiring cold chain if > 2 weeks storage). Alternative options include the epoc® microfluidic blood analysis system (Epocal Inc., Ottawa, Ontario, Canada), which uses room temperature stored cartridges but has similar environmental limitations to platform use. Previous use has shown linearity when compared with both iSTAT and larger biochemistry analyzers in controlled environments.[70]

Biosafety against potential infectious agents requires thought and prior planning in any laboratory work. *Mycobacterium tuberculosis* is a bacterium known to cause laboratory acquired infections and can be present in a variety of specimens.[71] This as well as other agents deemed high risk are classified by the internationally known Risk Group classification.[41] In our region, this includes (but is not limited to) Risk Group 3: *Mycobacterium tuberculosis*, *Brucella* spp., *Burkholderia pseudomallei*, *Neisseria meningitidis*, dimorphic fungi; and Risk Group 4 viruses: Hendra and Nipah. Amplifying the inoculum load with use of blood culture exponentially increases transmission risk and hence requires adequate biosafety cabinet/isolator use with HEPA filtration. Any agent in Risk Group 3 or above cannot be managed in this current laboratory and requires transfer via an internationally specified IATA Category A logistics team, if further testing is deemed necessary. Trained scientists are required to know how to identify and avoid further spread of these agents early in the diagnostic process concurrently avoiding all aerosolizing activities. Any use of laboratory equipment without prior planning for these agents risks spread and laboratory staff health.[71]

Diagnostic errors can also risk patient health. Most diagnostic errors occur in the steps leading up to the sample analysis (pre-analytical) or in the post-analytical period of result transfer and interpretation.[72] Limitations in pre-analytical and post-analytical collection and processing were controlled in our study with protocols based on international standards and the integrity of sample flow and detailed documentation.[39] Failures in this area are well described in ABO/Rh testing with mismatching of details and samples leading to catastrophic life-ending events (transfusion incompatibility).[72] Efforts were employed to ensure that this is avoided, with a strict "hemovigilance" pathway implemented that must be followed at all times.

Elements of this mobile laboratory can also prove useful in Australia. With a broad range of diagnostics, it can serve to provide service where an established laboratory may not be functional due to an SOD. The mobile laboratory is capable of temporarily providing rapid on-site results that would have been available pre-disaster at many Australian hospital sites.

There are limitations. These must be understood when considering the use of platforms for near patient testing. Portability can come at the expense of greater analytical imprecision.[42] As our results show, there is lack of correlation with known gold standards on the biochemistry and hematology platforms. Further environmental limitations have been described previously.[38] Many sites within Asia and the Pacific have high ambient temperatures with high humidity. This is a current limitation to the functional capabilities of at least 3 of the platforms in this lab – see Table 2.[38] Both of these issues mean use and interpretation needs to be tempered against the possibility of false negatives, false positives, and differences that may or may not be clinically relevant. Given the inherent individual variation of each of these platforms, adequate external QCs are needed and further verification of the result (if available) should be sought. Limitations to RDTs are already well documented.[40] Malaria rapid test kits do not currently provide adequate diagnostic's capability for *Plasmodium knowlesi* (a potentially deadly malaria present in some locations in Southeast Asia) and lowered sensitivity for *Plasmodium malariae* and *ovale*. For this reason, microscopy is still necessary.

Further limitations are due to the requirement for constant power. Electricity requirements for the FilmArray rt-PCR instrument and accompanying laptop include an input voltage 90-264 VAC and input current 10 A. Power supply from the EMT2 field hospital is via a UPS connected to a Genset 22KVa 3 phase diesel generator. Microscopy BX53 requires 12 V for a 100-W lamp illumination and 240 V for digital camera/monitor function and is connected to this same supply. A critical Genset power failure would restrict the use of much of the axillary laboratory setup but still allow for rapid test, iSTAT, and HemoCue use. The iSTAT operation has versatile power requirements but limitations at high ambient temperatures (requires T < 30 °C). Similarly, optimal thermocycling for multiplex rt-PCR requires a temperature-controlled environment with operation between 15-30 °C and 20-80% humidity. This is available in the NCCTRC's EMT2 designed climate-controlled facility, but this may not be available to all EMT2 teams.

These trials did not test the suitability of the ABO/Rh whole blood transfusion techniques, as there was little role for this at either location. Neither were the RDT/lateral flow assays assessed in field. These have been assessed previously (as per Table 2) and are known also to have variable sensitivity and specificity dependent on the assay in use.

With the acknowledgment of these caveats, this laboratory is seen as a major advance that can help in the diagnosis and management of patients in SODs. Ongoing horizon scanning to detect and evaluate new platforms that may be more suitable to the SOD environment is important.

CONCLUSION

The development of this mobile laboratory represents a significant increase in diagnostic capability for AUSMAT health assets deploying post-SOD. This will likely translate into more accurate care for future patients. This development of individual diagnostic modules allows customization to individual SODs. It is portable, intuitive to learn, and validated on 2 separate high-fidelity trial deployments. It is anticipated that future diagnostic possibilities will continue to expand with the development of novel, potentially more accurate and portable platforms.

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Author Contribution

IM, KM, DR, and NC designed laboratory modules; IM, NC, and JF designed and reviewed the studies; IM, DPS, DR, JF, RWB, and NC drafted and reviewed the manuscript.

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Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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