THE USE OF POINT-OF-CARE BLOOD GAS ANALYSIS ON A SOUTH AFRICAN FIXED WING JET AIR AMBULANCE SERVICE

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DECLARATION

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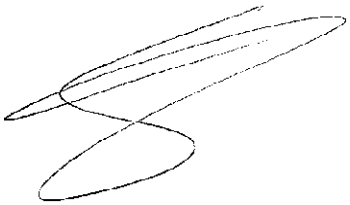
Signed 

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ABSTRACT

Background Point-of-care blood gas analysis is considered a standard of care in modern air ambulance operations by many professional organisations for clinical assessment and monitoring of patients. Instances where point-of-care blood gas analysis has identified clinically significant abnormalities which then led to clinical intervention are well documented and have been quantified previously in the air ambulance environment. However, results obtained from point-of-care blood gas analysis are not always required for patient care, nor do they always result in any clinical action on the part of the medical crew. Our question therefore related to the data for a Johannesburg based jet air ambulance service.

Methods By means of retrospective case reviews over a one year period, we reviewed the overall frequency of utilisation of point-of-care blood gas analysis on patient transportations within a Johannesburg based jet air ambulance service. We established how often point-of-care blood gas analysis yielded abnormal findings, and how frequently abnormalities detected by point-of-care blood gas analysis resulted in clinical interventions.

Results Point-of-care blood gas analysis was undertaken in 266 of 334 patients transported (79.6%). Abnormal findings were noted in 203 of the 338 blood gas analyses undertaken (60.1%). Patient age ($p=0.001$) and intubation status ($p=0.01$) were significant influences on number of analyses performed, while flight time was not significant ($p=0.07$). Clinical intervention followed in 65.5% of instances where abnormalities on blood gas analysis were noted and in 87.6% where clinical corrective intervention was assessed as being possible under prevailing conditions. Of all patients transported, some form of clinical intervention was undertaken following 39.3% of all blood gas analyses undertaken. This therapeutic yield evidenced is equivalent to 2.54 samples analysed per corrective clinical action evidenced. A costing analysis further revealed that this testing is relatively inexpensive per positive finding yielded and subsequent clinical actions.

Conclusions Abnormalities detected and subsequent clinical intervention using point-of-care blood gas analysis in this patient population was significant with a clinical yield of 39.3%. Since the costs are also not very high this modality is rightfully considered a minimum standard of care in air ambulance operations. These findings also support the notion that such testing should be carried out routinely on all patients irrespective of clinician interpretation of indication or need.

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LIST OF ABBREVIATIONS

BE	= Base Excess
BGA	= Blood Gas Analysis
CAMTS	= Commission on Accreditation of Medical Transport Systems
EURAMI	= European Air Medical Institute
F_iO_2	= Inspired Oxygen Fraction
Hb	= Haemoglobin
HCO_3^-	= Bicarbonate
HEMS	= Helicopter Emergency Medical Services
ICU	= Intensive Care Unit
K^+	= Potassium
Na^+	= Sodium
pO_2	= Partial Pressure Oxygen
pCO_2	= Partial Pressure Carbon Dioxide
POC	= Point of Care
POC BGA	= Point of Care Blood Gas Analysis
POCT	= Point of Care Testing
POCTRN	= Point-of-Care Technologies Research Network
USA	= United States of America
UN	= United Nations
ZAR	= South African Rand

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1 INTRODUCTION

1.1 Background

Point-of-care testing (POCT) has its origins in ancient times when practitioners utilized tasting of urine for the diagnosis of diabetes mellitus (1). Point-of-care testing in the modern sense, otherwise referred to as bedside or extra-laboratory testing, is achieved by utilising small bench top, hand held devices or test strips to measure various biochemical markers and values (2). Rapid provision of results at the point of care can result in better clinical decision making and improved patient outcomes. This testing is however occasionally perceived in general as expensive relative to standard laboratory testing in terms of producing a result. However, point-of care testing has wider operational, economic and patient care value (2). Moreover, it has been touted as a technological innovation that has the potential to improve patient care without in fact, increasing costs (3). Early studies showed that Point-of-care testing reduced time taken to make decisions dependant on blood results and could bring about faster changes in treatment for which time was critical (4). Improvements in process, such as a reduction in the time doctors waited for test results and the ability to make clinical decisions more quickly, did not seem to improve clinical outcome however (4). Point-of-care testing has more recently been shown to significantly reduce the length of stay in select paediatric patients in the emergency department setting – in one study reducing length of stay in the emergency department on average by 38.5 minutes (5). Length of stay in emergency departments has also been shown to be significantly decreased in chest pain patients with the use of point-of-care Troponin I testing by treating nurses (6).

Indeed, the application of these so-called point-of-care diagnostics and their application and utility has generated much research and debate. In April 2006 at Arlington, Virginia a workshop entitled “Improving Health Care Accessibility through Point-of-Care Technologies” was held, jointly sponsored by the National Institutes of Health (National Institute of Biomedical Imaging and Bioengineering and the National Heart, Lung and Blood Institute) and the National Science Foundation of the United States of America (USA) (7). The goal of this workshop which included both oral and poster presentations, was to bring together technology developers, researchers and clinicians to assess the technology developments required to advance point-of-care testing and to identify high-priority clinical problems that could benefit from a point-of-care testing approach (7). In response to recommendations from participants at this workshop, the *Point-of-Care Technologies Research Network* (POCTRN) was established (8). The POCTRN was created to drive the development of appropriate point-of-care diagnostic technologies through collaborative efforts that simultaneously merge scientific and technological capabilities with clinical requirements (8).

Point-of-care testing can be defined as patient specimens assayed at or near the patient with the assumption that results will be available immediately or within a very short timeframe to assist the clinician in rapid diagnosis and clinical intervention (9). The key aspects here are time and proximity to patient. In the true traditional sense, point-of-care testing refers to laboratory type specimen tests. However in more recent times, with development of new technologies, POCT has expanded to include portable ultrasound devices and even portable CT scanners (10).

Where no laboratory facilities exist in a given environment, point-of-care testing is by default the only option for specimen analysis – such as in the out-of-hospital Air Ambulance environment. In this context, the accessibility of a specimen analysis device is the issue, rather than speed of analysis although this does of course also apply. Point-of-care blood gas analysis (POC BGA) is considered a standard of care in modern Air Ambulance clinical assessment and monitoring of patients by many professional organisations including the Air Medical Physicians Association, Association of Air Medical Services and the Commission on Accreditation of Medical Transport Systems (11,12). However, there is no clear evidence at this point that POCT improves outcomes in the out-of-hospital transportation environment (13). These recommendations and standards, although certainly not in all aspects followed strict outcomes based evidence, have in fact followed the evolution of modern Air Ambulance operations. Critical patients are routinely moved from distant areas to regional centres of excellence for upgrade in medical care. Critically ill or injured patients require intensive care level management including ventilation, inotropic support and fluid management. Multiparameter monitoring is therefore required to properly manage the patient in a similar fashion to hospital intensive care units, including measurement of blood chemistry and gases using POCT technologies.

1.2 Medical Transportation & Air Ambulances

1.2.1 Introduction

Modern civilian medical transport systems have evolved over many years from the original military systems of days gone by. The first ever modern ambulance equivalent was probably used when Dominique Jean Larry, one of Napoleon's battle surgeons used a horse-drawn carriage to move patients from the battlefield to a field hospital (14,15). Since then we have

progressed significantly and have seen the introduction of rotary wing (helicopter) air ambulances in the Korean and Vietnam wars as a major pre-cursor to modern organised aero-medical systems. In the 1960's, military transport concepts and resources were applied to both trauma patients and neonates in the civilian setting (14,15). Modern transport systems were then further developed into what we have today, with advanced level of care ground and air ambulances the world over (14). Like transport, health care systems have been evolving over the years in an effort to improve care as well as optimise health care resources (14). Tertiary level health care has generally become centralised. The benefits of treating seriously ill patients at regional specialised centres have become recognised, and have developed into standard practice (14). It was further recognised that management of the most seriously ill patients in tertiary Intensive Care Units (ICU's) could actually improve their chances of survival (14-18). A means to move the most seriously ill from one centre to another was no longer optional. The need for rapid and safe transport of these critically ill or injured patients had become necessary. This need evolved and in many advanced centres resulted in the development of specialised transport teams for both ground and air ambulance systems (14).

1.2.2 Transport vehicle options

Three main types of transport vehicle exist for the patient today – road ambulance, fixed wing air ambulance, and rotor wing air ambulance.

The road ambulance is the most commonly used form of transport for the transfer of patients both between hospitals, as well as from the scene of an incident. They are generally readily available, and are geographically deployed to enable timeous access to different locations and hospitals (14). Two fundamental principles with regards road ambulances exist. Firstly, different road ambulances carry different types and level of equipment (14). And secondly, the

level of training and expertise of ambulance personnel varies widely (14). Both equipment levels and skill of personnel can vary from basic all the way through to advanced, with true mobile intensive care capability (14).

The utilisation of an aero-medical resource as opposed to a ground ambulance resource is a much debated area. Many different medical and governmental organisations globally have developed policies in this regard. One of the more evidence based, formalised approaches is probably that of the American College of Emergency Physicians and the National Association of Emergency Medical Services (EMS) Physicians (19,20). Air ambulance transportation is generally used when there is significant benefit in terms of time or medical resources to be gained when further distances for transport are needed. In general, air ambulances are equipped to a mobile intensive care level with appropriate staff. Rotor wing (helicopter) transport is appropriate for shorter distances, whereas fixed wing (aeroplane) transport would be more feasible for longer distances (14). Fixed wing aircraft are equipped with different types of engines. Whereas piston engines are not utilised on aero-medical aircraft in general, turboprop and jet engines are common. Jet and turboprop engines operate on the same physical principles, but jet engines produce thrust by expelling compressed gas, while turboprop engines produce thrust by rotating propellers attached to the engine (21). Jet aircraft are capably of flying at greater speed and altitude than turboprop aircraft. Aircraft cabins are either pressurised or non-pressurised. Pressurised cabins allow for the controlling of the internal cabin pressure relative to that of ambient external air pressure. In pressurised cabins, cabin pressure is kept at, near to or within comfortable physiological range compared to ground air pressure (22).

Rotor wing air ambulances offer direct facility to facility transportation – provided there are appropriate landing areas at each (14). As a rule of thumb, they are able to travel twice as fast as road ambulances, and do not have to negotiate traffic on the roads. The major disadvantages in this type of transportation are high noise levels, vibrations, air turbulence, temperature extremes and space and weight limitations (14). The cabin of the aircraft is also not pressurised, and these aircraft can only fly at lower altitudes. This combination of factors contributes to crew fatigue, dehydration, nausea and an inability to fully monitor or assess a patient clinically while in the air (14).

Fixed wing air ambulances offer transportation between appropriate air fields and airports, as determined by both the type of aircraft and actual available air fields or airports. Road transportation is then required between the hospitals and the air fields. As a rule of thumb, fixed wing air ambulances can travel between five and ten times as fast as a road ambulance. Disadvantages include space and weight constraints, air turbulence, vibrations, and noise. Temperatures within the aircraft can be relatively well controlled. Pressure changes with increasing altitude may offer a challenge in certain medical conditions. Even with pressurised aircraft, once at cruising altitude, the cabin pressure is seldom near that of ground level pressure. Cabins can be either pressurised or non-pressurised, however where the aircraft is a jet then the cabin is pressurised. Adverse effects on crew are similar to that experienced in rotor wing aircraft, but to a lesser degree. With the wide range of aircraft available, all these factors become more or less of an issue, depending on the aircraft utilised (14).

1.2.3 Equipment & staff

Various groups have evaluated equipment and medications available for inter-hospital transport of patients on board different ambulance vehicles (both road and air) (14,23,24). On-board medications for ICU level transportation may include drugs such as vasoactive agents, volume expanders and other intravenous fluids, sedatives, analgesics, paralytics, electrolyte supplements, antiarrhythmics, and anticonvulsants. Equipment on board an ICU level ambulance generally includes all equipment necessary for advanced airway maintenance and ventilatory support, invasive and non invasive hemodynamic monitoring, cardiac pacing and defibrillation, venous access, and the capacity for arterial blood gas or electrolyte analysis (14,23).

Although specific types or models of items of equipment will differ from place to place and system to system, the principle remains the same - equipment, disposables and medications are required to manage a patient to a level equivalent to an ICU (14). In the context of fixed wing jet air ambulance operations, this is the level of care referred to in this study.

Level of care not only refers to the equipment levels and specifications on board, but more importantly also refers to the qualifications, skills and experience of the staff in attendance. There are many different staffing configurations found globally. Different air ambulance operators make use of specialist medical doctors (in particular anaesthetists, intensivists and emergency physicians), generalist medical doctors, nurses, respiratory physicians, anaesthetic assistants/nurses, paramedics and other emergency care practitioners. The choice and combination of staffing is dependant on a number of factors, but is mainly local resource and

clinical requirement driven. Standard staffing configuration may be augmented with specialised staff for certain cases, for example specialised neonatal transfers.

1.2.4 Complications during transport

The transport of critically ill patients is not without risk. These risks will likely become even more prominent in the future, with the tendency towards centralising higher (tertiary) levels of health care increasing, for a number of reasons globally (14,25). Besides the medical risks during transportation, there is also the risk of accidents occurring. In a ground breaking survey in 2008, it was found that in the USA, an air medical crew member had a death rate that exceeded all other hazardous professions (164 deaths/100,000 workers) (26). This incidence rate made Helicopter Emergency Medical Services (HEMS) operations one of the most dangerous professions in the USA at that time (26).

In reviews of patient transports, some specific medical problems during transport have been identified in addition to many general problems (14,27): Blood pressure can be difficult to measure by automatic non-invasive methods or by auscultation and palpation due to vibrations, noise, and movements of the vehicle (ground or air ambulance); Hypotension can be exacerbated by movement and acceleration; Poor lighting can make assessment of ventilatory movements or subtle seizures difficult; Heating systems might not be adequate to prevent heat loss, especially from infants. Stretcher positioning can be limited due to reduced flexibility of stretchers, which would impact on patient positioning, which could pose a problem for example when trying to reduce intra-cranial pressure; Air turbulence, especially if extreme, can cause motion sickness in patient and crew, which can result in the crew's inability to monitor or care for the patient adequately.

Adverse medical events and patient morbidity during transport can be further described as either physiologic deterioration or equipment related (14,15,28). Physiological deterioration during transport has been reported as incidents of respiratory arrest or cyanosis, hypotension, cardiac arrest or arrhythmia, loss of consciousness, loss of brainstem reflexes, core temperature <34°C and hypoglycaemia (14,28). Reported equipment related events have included: occluded endotracheal tube, accidental tracheal extubation, loss of intravenous access, pulmonary aspiration, loss of patient monitoring, malfunction of ventilator and exhaustion of oxygen supply (14,28). Overall, shock and ventilatory problems appear to be the most common problems encountered during transport (14,28,29). Most of these problems are prevented when utilising specialised transfer and retrieval teams (14,15,28,30). Equipment and technical failures do occur, and whereas in the hospital setting there is in most instances the opportunity to acquire additional equipment from elsewhere, the transport environment is far more isolated from additional resources so that significant equipment failures can be catastrophic, unless additional backup equipment has been considered and is available (14).

1.3 Equipment & devices for point-of-care testing

Pre-hospital emergency medical transport has evolved from the simplest of transport methods to sophisticated, advanced life support mobile intensive care units. Indeed, medical transportation now extends over land, sea and air. As part of this development, individual items of medical and non-medical equipment have also evolved from minimalistic simple devices, to highly advanced pieces of equipment capable of providing in-hospital (or near in-hospital) quality of diagnostic, monitoring or therapeutic modalities and interventions.

Within the hospital environment, although not necessarily as dramatic, there has certainly been an evolution towards bringing certain diagnostic and treatment equipment items to the patient's bedside as opposed to moving the patient to an area of diagnostics or treatment. The development of bedside or point-of-care testing equipment has been the result. Indeed, point-of-care diagnostics have been suggested as something that can revolutionise the quality of care in the ICU (10). Point-of-care diagnostic devices include simple glucometers, dipsticks, ultrasound, X-ray and of course blood gas and electrolyte analysers. Other point-of-care diagnostics include specific biomarkers such as B-type natriuretic peptide, rapid access D-Dimer assays, and even novel ultra-rapid infectious disease diagnosis and antibiotic resistance methods (31).

Insofar as POCT for blood gases and electrolytes is concerned, there are a vast number of products available for this purpose (32). The i-STAT® (Abbott Laboratories, Abbott Park, Illinois, USA) is a portable handheld device that uses single use disposable test cartridges to perform a variety of diagnostic tests including cardiac markers, blood gases, chemistry and electrolytes, lactate, coagulation and haematology studies (33). The cartridges are smaller than a business card and incorporate advanced biosensor technology and microfluidics (33). Testing is performed by administering two drops of blood into the cartridge which is then closed and inserted into the analyser, with results available within a few minutes (33). (See Appendix E for examples of diagnostic tests available utilising the i-STAT® test cartridges). The i-STAT® has been shown to be equivalent to conventional laboratory blood gas analysers for blood gas analysis (34,35). The i-STAT® has also been shown to be clinically adequate compared to conventional laboratory analysis for electrolytes and other measurements (36).

1.4 Point-of-care testing in hospital

Point-of-care blood gas analysis has been validated in the hospital, Intensive Care Unit (ICU) and animal study settings compared to standard laboratory blood gas analysis and has been shown to be accurate and reliable (37,38,39). POC testing has also been shown to be effective and useful in the management of critical patients in the Emergency Department (ED) (4,40). In one particular study, POCT influenced treatment decisions in the ED in 14% of all patients seen (4). Results obtained from such POCT analyses can therefore be considered clinically appropriate and applicable. The principle benefit of course is that results are obtained in a rapid time frame at the "point-of-care" as opposed to waiting for results to be obtained from the hospital central laboratory, or nearby blood gas analysers in a side ward or similar. Studies have also shown significant and sustained cost savings when POCT replaces conventional laboratory testing in ICU's appropriately (35).

Certain devices such as glucometers have however shown significantly different values compared to laboratory values (41). Recent studies have also identified certain differences between POC blood analysis results and central laboratory analysis. In one series, using an ABL555 POC blood gas analyser, sodium values were shown to differ significantly, whereas potassium values were comparable to the laboratory findings (38). The differences in sodium values were however not considered clinically significant, and therefore the conclusions drawn were that clinical decisions and actions could reliably and safely be made using these results, in particular related to potassium values – a finding in keeping with findings of similar earlier studies evaluating other POC blood gas analysers (42,43). Discrepancies in pCO_2 values using the i-STAT® device have also been reported and found to be related to an incompatibility between the sampling syringes utilised in that particular hospital at the time, and the i-STAT® testing system (35).

A key factor that needs to be considered is that with POC testing, whole blood is being used, whereas with central laboratory testing, serum is analysed – the biomedical technologies and processes involved are different, and certainly one of the reasons put forward to explain some of the differences identified between POCT and central laboratory results (44). The problem is then really when POCT results are followed up with central laboratory results without consideration of potential differences or applying appropriate correction factors. Of course appropriate, compatible sampling methods and equipment is also a mandatory minimum requirement. Overall, POC testing in hospital is thus considered accurate and with safe clinical utility when used and understood correctly.

1.5 Point-of-care testing out-of-hospital

Many of the well-studied aspects of POCT relevant to hospital use can be transferred to the out-of-hospital setting. The key difference is of course the significantly different clinical environment, and there is literature available specifically regarding out-of-hospital POCT. Point-of-care blood gas analysis has been shown to be an accurate, rapid and reliable means of obtaining blood gas and electrolyte values in the out-of-hospital setting (45). Point-of-care blood gas analysis has been utilised in many different out-of-hospital settings from civilian ground and air ambulance operations to the austere military environment. Results obtained from these analyses were shown to be clinically equivalent to values obtained in the receiving hospital emergency department (46) or central laboratory control values (47,48). Furthermore, instances where point-of-care blood gas analyses have identified clinically significant abnormalities which then led to clinical intervention are well documented in the air ambulance environment (45).

From this same study series, some abnormal blood results were assessed as potentially life threatening, and could not have been identified without point-of-care blood gas analysis.

An early study reviewing the use of POCT using the i-STAT® portable analyser in a Helicopter Emergency Medical Service (HEMS) system in the USA compared the results obtained from POCT to those obtained using satellite or central laboratory equipment (47). There were no significant differences found between the POCT results and the laboratory results, except for blood glucose. The discrepancies in blood glucose were then attributed to the time delay in transport of the blood specimen tube to the laboratory for testing. Clinical interventions following as a direct result of POCT occurred in 18.5% of the patients where POCT was employed.

Similarly, in another early study, precision accuracy of the POCT device and comparison of results to laboratory values was undertaken in a ground ambulance system in the USA (46). The POCT device was found to be precise and reliable in the tests using control electrolytes for use in the pre-hospital environment of a moving ground ambulance. Similarly, comparison to laboratory findings showed high correlation values for the electrolytes analysed.

In a more recent small study evaluating the use of POCT in a ground ambulance system in Austria, emergency physicians involved in the study considered that the knowledge of blood gas variables were useful in 72% of patients treated and led to therapeutic intervention in 52% of all cases (49).

Six years of medical transportation cases were reviewed in another recent study (50). Medical team members reported subjectively that point-of-care testing provided a moderate to substantial improvement in the condition of 14% of patients while there was an uncertain or no improvement in 86%. Treatment decisions that were quantifiably directly linked to point-of-care testing results occurred in 30% of cases where point-of-care testing was employed. The authors noted further that certain normal results are however still clinically significant and are important in patient assessment. An example would be a normal blood gas post endotracheal intubation and initiation of mechanical ventilation. Interestingly, in this particular study, results revealed a relatively low rate of utilisation of point-of-care testing contrary to general concern for a high utilisation rate due to availability and ease of use.

Some potential limitations to the use of POCT in the out-of-hospital environment are environmental conditions. The operating temperature of the i-STAT® is from 15℃–30℃, and temperature insulated or controlled storage containers/bags for both the analyser and test cartridges are required (13). Test cartridges in fact require “fridge” storage conditions. This potential obstacle in certain environments is easily overcome by using appropriate transport containers/bags, and an air-conditioned cabin in an aircraft. If these are not achievable, then the use of the device will not be possible however.

As useful as the technology is, results obtained from POCT however are not always required for patient care, nor do they always result in any clinical action on the part of the medical crew. When instituted in a transport environment, although remote, POCT should ideally have real-time connectivity to receiving Emergency Departments, ICU’s as well as reference laboratories (13). Preferably, any POCT structure and system should ultimately be under the control of a

reference laboratory in some way (13). All factors considered, POCT is indeed a reliable and accurate investigative modality with established utility in the out-of-hospital setting.

1.6 Quality control in point-of-care testing

When overused or performed with poor quality, costs of POCT are unnecessarily escalated and risks to patients are increased (13). The environment of the air ambulance certainly lends itself to both of these possibilities, with a relatively uncontrolled environment and free access to POC testing. However, a good quality control system in place can minimise these risks by ensuring that results obtained are consistently accurate and reliable. A good quality control system should link in closely with a structured operating procedure regarding POCT to control and regulate its use within a system.

The disciplines of clinical chemistry and haematology have used well established statistical systems for quality control and assurance for many years (51). POCT analysers however appear to present laboratory and regulatory staff with ongoing quality control dilemmas and in fact do not fit within any traditional laboratory quality control system – certainly partly because these POCT devices were never designed to be used in laboratories, nor to be used by laboratory staff (51). These devices are intended for use in essentially uncontrolled (by laboratory standards at least) environments by clinicians. Alternative quality control systems therefore become a requirement, as traditional laboratory systems are too cumbersome and impractical for POCT devices (1).

When designing a quality control system consideration needs to be given to the type of POCT device being used. These fall into three broad categories, namely (i) “laboratory type,” (ii) “cartridge based” and (iii) “strip based” instruments (51). It is also therefore useful to think of POCT as a system with an “analyser” component and a “cartridge/strip” component (51). Quality control processes can then be applied to each of these components, and also broadly to the system as a whole.

An electronic quality control system is one in which the electronics of the particular device are tested, but without any testing of the reagents. This system relies on a prior established fact that reagents are stable from the time of manufacture to the time of use, provided proper storage conditions were adhered to (1). This approach was found to facilitate the performance and management of POCT as it eliminated the need for frequent liquid quality control (1). This is the system in place for most, if not all electronic analysers with cartridge reagent components, as in the i-STAT® analyser.

Automatic quality control is a system in which liquid quality control is automatically performed by the individual instrument without the need for operator intervention (1). This could be a system utilised in a bench top analyser for example, but not for the average portable POCT device. Then in addition, some devices have automatic lock-out functions when quality control has not been performed, failures have been detected, or expired reagent cartridges are attempted to be used (1).

Irrespective of the type of system employed in a particular device, an established quality control procedure should be in place to ensure correct application of the system. This would include training of staff and the institution of manufacturer recommended quality control practices and routines (51). Well established and instituted training, operating procedures and quality control practices will combine to form a true POCT system that can be relied on by clinicians for rapid, accurate and reliable information.

1.7 Study aims & objectives

Point-of-care testing has indeed become well established within both the in-hospital as well as out-of-hospital environments. The question addressed in this study was therefore, within a Johannesburg based jet air ambulance service, how often point-of-care blood gas analysis yielded abnormal findings. Secondly, how frequently did point-of-care blood gas analysis result in clinical interventions? Finally, the overall frequency of utilisation of point-of-care blood gas analysis on air ambulance missions was established.

Specific objectives were:

1. To determine the frequency that point-of-care blood gas analysis was undertaken, identified abnormalities and resulted in medical crew action in a specific air ambulance service in a one year period.
2. To describe demographics and clinical characteristics in patients where blood gas analysis was undertaken.
3. To describe the logistical characteristics of air ambulance missions where blood gas analysis was undertaken.

4. To determine the frequency of abnormalities identified in the blood gas variables that were pre-selected.
5. To describe the clinical actions taken by medical flight crew following the identification of abnormal blood gas variables.

2 MATERIALS & METHODS

2.1 Overview

All medical transportation cases undertaken over the 2010 calendar year period for a Johannesburg based South African jet air ambulance service were reviewed in a retrospective descriptive study. Air ambulance medical evacuation and transportation missions were identified and extracted from all medical transportation cases, while all other non-air ambulance cases such as commercial medically escorted repatriations were excluded from the data collection. The air ambulance medical evacuations were then reviewed, by means of a retrospective review of the clinical flight notes and patient records.

2.2 Ethics

Ethics approval and clearance for research was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (clearance certificate number M110108, see Appendix A and Appendix B). Permission was obtained from the identified air ambulance service to undertake this review of patient records (see Appendix C).

2.3 Site of study

Johannesburg, South Africa – Air Rescue Africa, an independent private fixed wing air ambulance service, with dedicated air ambulance configured jet aircraft. Air Rescue Africa is a fully owned subsidiary and dedicated air ambulance service provider to International SOS Assistance (Pty) Ltd with offices in Midrand, South Africa.

International SOS is a global medical and security services assistance company, supporting a diverse range of industries and corporations from biotechnology and financial to large oil and gas, mining and construction companies (52). International SOS helps corporations manage the health and security risks facing their international travellers and expatriates through their 27 alarm centres, 33 International SOS clinics, and approximately 73,000 medical, security and logistics providers worldwide (52).

As one of these service providers to International SOS, Air Rescue Africa operates three dedicated jet air ambulance aircraft from their base at Lanseria International Airport. These jet aircraft (two Lear Jet 35A's and one Falcon 10) are permanently configured as air ambulances equipped with powered Lifeport™ stretcher systems, and modern mobile intensive care equipment, including on board point-of-care diagnostics capability (53). Air Rescue Africa holds current accreditations with the European Air Medical Institute (EURAMI) and the Commission on Accreditation of Medical Transport Systems (CAMTS) (54,55). The point-of-care blood analyser utilized by Air Rescue Africa is the i-STAT® blood gas analyser which is standard equipment and available for use on every air ambulance flight. Manufacturer specified routine maintenance, calibration and quality control of these devices is undertaken consistently to ensure correct operation on all air ambulance flights. The staffing utilised by Air Rescue Africa is that of a generalist medical doctor with experience in emergency medicine, intensive care and transportation, paired with either an ICU/Emergency trained nurse or advanced life support paramedic. The staffing is therefore to a mobile intensive care level, capable of the utilisation and interpretation of POC blood analysis on each and every mission undertaken. In addition, medical staff is trained on the correct use of the device including calibration, testing, care of cartridges, and use of the device for POCT of blood samples.

Air Rescue Africa operates predominantly in sub-Saharan Africa, evacuating patients into Johannesburg South Africa from its base of aircraft operations at Lanseria International Airport. Lanseria International Airport is situated to the north-west of Johannesburg located within close proximity to Johannesburg and Pretoria hospitals to where patients are taken following the air ambulance flight by ground ambulance and subsequently admitted for in-patient care (see Figure 1).

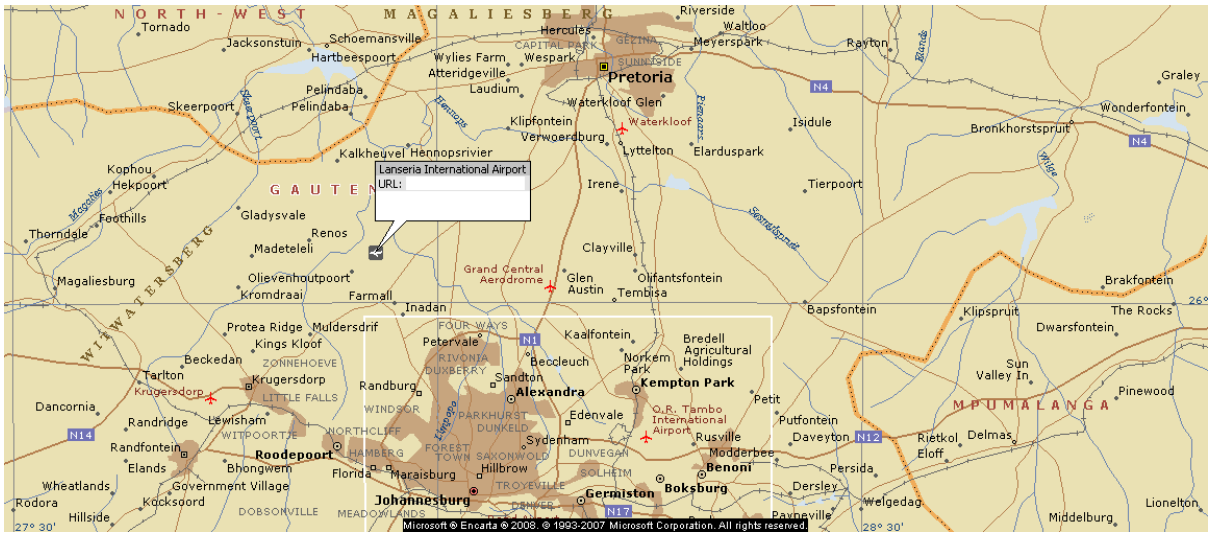

Figure 1 Location of Lanseria International Airport.

Map showing the Location of Lanseria International Airport, in proximity to Pretoria and Johannesburg. (Microsoft® Encarta® 2008)

2.4 Study population & sampling

All clinical patient records of patients transported by the above air ambulance service during the study period of one calendar year were reviewed (see Appendix D for an example of the standard patient report form utilised). Only patient records of patients transported by air ambulance were reviewed. Patients transported by commercial carrier or other means besides air ambulance, were excluded from review. These different mission types were identified by the routing and aircraft details that were recorded in the medical flight notes. 334 cases over the

one calendar year period of 2010 were reviewed. Where the results of point-of-care blood gas analysis were not available in the flight records (illegible or omitted from the records or the printed results were not attached to the flight records) these patient records were recorded as blood gas not done.

2.5 Measuring tool or instrument

A case review sheet was designed and utilised which incorporated a checklist, yes/no answers and place for additional detailed information when required. A data number was assigned per case reviewed and a cross-reference spreadsheet utilised to link patient flight record to data number, to ensure there was no duplication of individual case reviews. Once case and data numbers had been assigned, the cross-reference sheet was kept separate to data collection sheets, to maintain case anonymity.

2.6 Data collection

Manual review of clinical case notes was undertaken with appropriate recording of data on the case review sheet. This review was undertaken by the researcher who is a medical doctor experienced in aero-medical evacuation and emergency medicine. There was no reference on the case review sheet to the particular case notes reviewed, which ensured anonymity and patient confidentiality. To avoid repeated review of individual case notes, an inconspicuous mark was made on the left lower corner of the front page of the clinical case notes. In addition, a note was made on the cross-reference spreadsheet when a case review was completed.

Cases where point-of-care blood gas analysis was utilised were then identified. These were identified by the results of blood gas analysis, or reference to the undertaking thereof being noted in clinical flight notes and/or the printed copies of these results attached to the clinical flight notes.

Each set of blood gas analysis results were then reviewed to identify abnormalities. This was achieved by review of the results, comparing them to a pre-defined set of standard reference normal values for the point-of-care blood analysis device in use (i-STAT®) and the specific test cartridges utilised (see Appendix E). The selected pre-defined values that were specifically compared were (from i-STAT® test cartridges EG6, EG7 and CG4): pH, partial pressure of oxygen (PO_2) (mmHg), partial pressure of carbon dioxide (PCO_2) (mmHg), standard bicarbonate (HCO_3) (mmol/l) Base Excess (BE), oxygen saturation of haemoglobin (SO_2) (%) Sodium (Na^+) (mmol/l), Potassium (K^+) (mmol/l), Haemoglobin (Hb) (g/dL) and lactate (mmol/l).

Whenever an abnormal result was identified, evidence of a subsequent follow up action to address the blood gas abnormality by the medical flight crew was sought. This was accomplished by a review of the clinical case notes, specifically looking at time of blood gas analysis, treatment plans, medications given, changes to ventilation parameters, changes to intravenous infusion regimens or any other action deemed to address the identified abnormality.

Additional information gathered and recorded regarding blood sampling included time of sampling, location of sampling (hospital, airport tarmac, aircraft in flight), site of sampling (arterial venipuncture, indwelling arterial line, venous venipuncture), analyser failures and poor

or unclear medical records. Further data extracted from the flight medical records included patient demographics age, sex, nationality (expatriate or local national), intubation status (intubated or not intubated), medical diagnosis category as defined by the researcher, destination of flight, flying times and re-fuelling stop requirements.

Medical diagnosis categories were defined by the researcher and based on generic surgical versus medical approaches to categorisation. The categories devised were then tailored according to the most common diagnosis categories identified from all the diagnoses. This categorisation was done retrospectively following gathering of all the patient diagnoses, to enable a reasonable number of common categories to be created for this particular patient population, as opposed to creating a large number of categories prospectively for which there may or may not have been any diagnoses found to fall within any of the categories. The diagnosis categories finally defined were: medical (other), medical (cardiac), medical (malaria), medical (neuro), surgical, trauma (other), trauma (head/spinal injury), congenital, and obstetrics/gynaecological. The congenital diagnosis category refers to infants with congenital (almost exclusively cardiac) birth defects.

2.7 Data analysis

Microsoft® Office Excel ®2007 and Statistica™ 10.0 statistical package were utilised for data entry and analysis respectively. Pearson Chi-squared and Mann-Whitney U tests for non-parametric data were applied to appropriate data sets to determine statistical significance where possible. Where statistical testing for significance was not possible, percentages and proportions as descriptive data were reviewed.

The following key variables were evaluated:

1. The frequency that point-of-care blood gas analysis was undertaken, identified abnormalities, and resulted in medical crew action/clinical intervention.
2. Number of abnormalities identified for each of the pre-selected blood gas variables.
3. Number of occasions of clinical actions undertaken, and the numbers within each different category of clinical action.
4. Number of intubated vs non-intubated patients where blood gas analysis was undertaken.
5. Site of sampling (venous or arterial via stab or indwelling arterial line).
6. Frequency of analyser failures.
7. Duration of air ambulance missions and flying times where blood gas analysis was undertaken.
8. Regional destinations (Region defined as per the United Nations (53))
9. Physical location that blood gas analysis was undertaken (hospital, airport tarmac, or aircraft in flight).

2.8 Study limitations & sources of bias

Certain clinical interventions are not always possible during air ambulance missions. Therefore, medical flight crew are not always able to correct certain abnormalities. These scenarios include for example a significantly low Haemoglobin, where transfusion of blood products would normally be considered, however blood products are rarely available during flight. In these cases, “no action taken” was recorded, however it does not necessarily accurately reflect the fact that action would have been taken if it were possible to do so. Consideration of whether it was indeed possible to undertake a clinical intervention was therefore considered and included in the data collection and analysis.

Poorly documented case notes, where clear indication of either analysis or undertaking of blood gas was not evident. Where this was found, the principle of “not documented not done” was applied. Where notes were adequate, but the attached printed results were missing or illegible, and no duplication of the results written up in the case notes, the blood gas analysis results obtained were considered “unknown” and neither normal or abnormal assigned. In addition, where incomplete clinical notes were made and treatments given were not accurately recorded even if they were in fact undertaken, the approach of “not recorded, not done” was taken. Clinical flight notes that did not reflect treatment given were counted as no action taken.

Specific detailed clinical patient data for example vital signs, clinical risk or severity scores, and trends or responses following treatment were not recorded. Thus assessment of outcome, either immediate or long term, was not possible. Review of other accompanying case/mission documentation was not undertaken, thus anything not recorded in the actual clinical case notes could not be reviewed. Instances of cartridge or analyser failure recorded in an incident report but not recorded in the clinical case notes were therefore not identified.

3 RESULTS

A total of 334 air ambulance patient transport cases were reviewed. In 266 (79.6%) of these patients, point-of-care blood gas analysis (POC BGA) was undertaken.

3.1 Patient demographics

A total of 334 patients were transported including 260 male and 74 female patients with a median age of 48 years. Table 1 and Figure 2 show data for patient age. Age of patient was found to be a significant factor related to the undertaking of POC BGA (Mann-Whitney U test Z-adjusted=3.296, p=0.001), see Figure 3. Patients were classified into eight diagnosis categories namely medical (other), medical (malaria), medical (neuro), surgical, trauma (other), trauma (head/spinal injury), congenital and obstetrics/gynaecological. Table 2 and Figure 4 present diagnosis categories for patients evacuated numerically and graphically. Cardiac cases (93%), Medical (Neuro) (89.1%) and Medical (Malaria) (88.5%) cases are listed as the categories of patients in whom POCT was undertaken at the highest frequencies, above the overall average for the entire patient population of 79.6%. In contrast, only 20% of patients in the congenital diagnosis category had POCT undertaken.

Further factors associated with POCT that were evaluated were patient nationality (only distinguishing between local national or expatriate within country of evacuation origin) and intubation status. In total 79 patients were local nationals in their home country, while 255 patients were expatriate workers or travellers. Of the 334 patients transported, 37 (11.08%) were intubated while 297 (88.92%) were not intubated. Patient nationality, sex (male or female) and numbers of intubated patients transported are shown in Table 3. Where nationality and sex

of patient were not significant, intubation status of the patient was found to be a significant factor influencing the undertaking of POC BGA (Pearson Chi square, X^2=5.738544, p=0.01660).

Table 1 Patient Age & POCT performed

	Number of Patients	Minimum Age (years)	Maximum Age (years)	Median (years)
POCT performed	266 (79.6%)	0.1	86	50
POCT not performed	68 (20.4%)	0.06	90	40.5
All Patients	**334**	**0.06**	**90**	**48**

Table listing age data for patients in either POCT performed or not performed groups with totals for the whole patient population reflected in the bottom row. Ages are in years with percentage of population in parentheses for number of patients in each group. POCT = Point of Care Testing. SD = Standard Deviation from the mean.

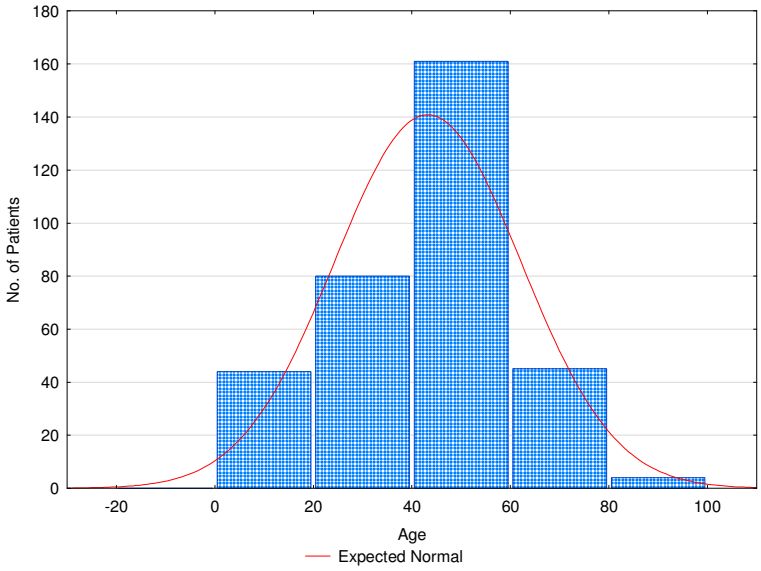

Figure 2 Distribution of Patient Ages (in years)

Bar graph distribution of patient ages in 20 year age group categories. Number of patients are represented on the Y-axis, with age category (in 20 year age group categories) on the X-axis. Expected normal distribution for ages in the population is line plotted over the bar graph to illustrate the non-normal distribution of ages.

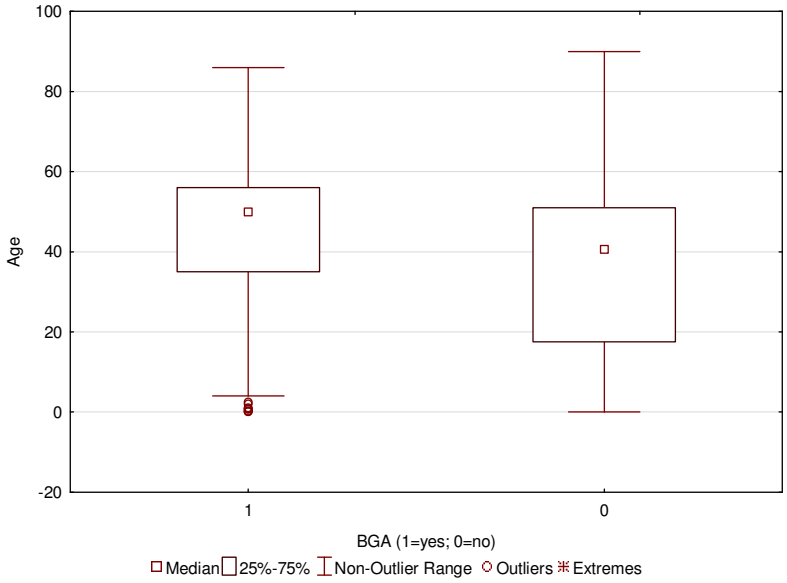

Figure 3 Patient Age vs Blood Gas Analysis undertaken.

Box-plot of patient ages in BGA undertaken (1) or BGA not undertaken (0) groups. Patient age is represented on the Y-axis, with BGA group on the X-axis. Age of patient was found to be significant with reference to BGA being undertaken. (Mann-Whitney U test Z-adjusted=3.296, p=0.001). BGA = Blood Gas Analysis.

Table 2 Diagnosis Categories of Patients

Diagnosis Category	No. of Patients (%)	BGA done	BGA not done
Medical (Other)	87 (26%)	65 (74.7%)	22 (24.3%)
Medical (Cardiac)	57 (17.1%)	53 (93%)	4 (7%)
Medical (Malaria)	26 (7.8%)	23 (88.5%)	3 (11.5%)
Medical (Neuro)	55 (16.5%)	49 (89.1%)	6 (10.9%)
Surgical	21 (6.3%)	15 (71.4%)	6 (28.6%)
Trauma (other)	51 (15.3%)	37 (72.5%)	14 (27.5%)
Trauma (Head/Spinal Injury)	22 (6.6%)	16 (72.7%)	6 (27.3%)
Congenital	5 (1.5%)	1 (20%)	4 (80%)
Obstetrics/Gynaecological	10 (3%)	7 (70%)	3 (30%)
Total	**334**	**266**	**68**

Diagnosis categories of patients listed with corresponding numbers of patients in each diagnosis category within the entire patient population, with percentages in parentheses. Numbers of patients in which POCT was undertaken or not undertaken within each diagnosis category is then listed, with percentage within diagnosis category in parentheses. BGA = Blood Gas Analysis.

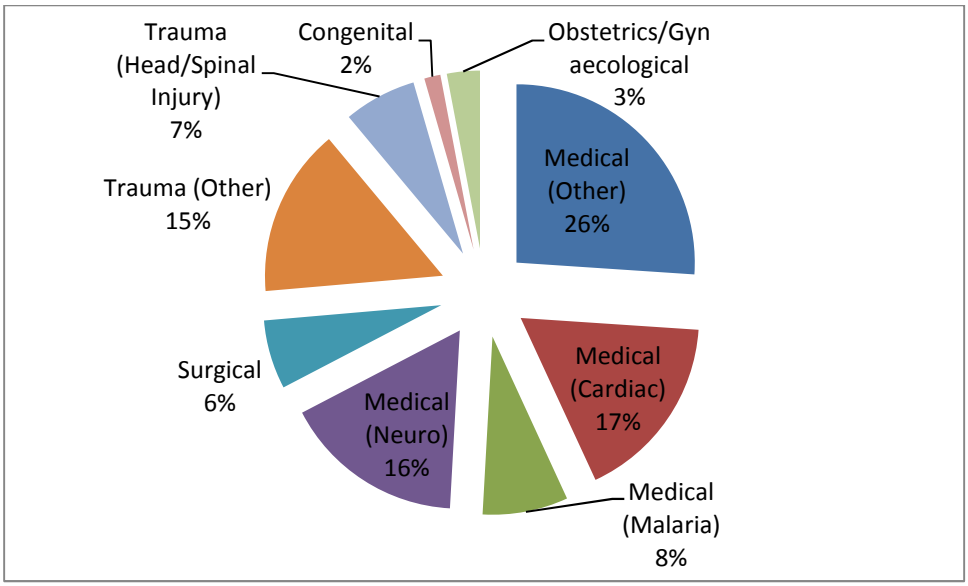

Figure 4 Diagnosis Category of Patients Transported

Pie-chart showing the proportions of patients in each diagnosis category within the entire population of patients transported. Figures stated are percentages of the entire patient population for each individual diagnosis category.

Table 3 Patient Intubation Status, Nationality & Sex with BGA performed

Intubation Status		**BGA**		**Nationality**		**BGA**		**Sex**		**BGA**	
Intubated	37 (11.08%)	Done	**35* (94.59%)**	Expatriate	255 (76.35%)	Done	204 (80%)	Male	260 (77.84%)	Done	204 (78.46%)
		Not done	2 (5.41%)			Not done	51 (20%)			Not done	56 (21.54%)
Not Intubated	297 (88.92%)	Done	231 (77.77%)	Local National	79 (23.65%)	Done	62 (78.48 %)	Female	74 (22.16%)	Done	62 (83.78%)
		Not done	66 (22.22%)			Not done	17 (21.52 %)			Not done	12 (16.22%)
Total	**334**				**334**				**334**		

Table listing patient intubation status, nationality and sex grouped by BGA analysis performed or not performed. Patient intubation status was found to be a significant factor influencing whether BGA was undertaken (X^2=5.738544, p=0.0166*). Percentages are in parentheses. BGA = Blood Gas Analysis.

3.2 Flight logistics

Three hundred and thirty four flights (334) were undertaken over the one year study period. The median flight time was 3.3 hours with the greatest number of flights of 3-4 hours duration. Figure 5 and Table 4 provide flight time (with patient) data on the 334 flights performed over the calendar year. Flight time with patient was not significant in influencing when POC BGA was undertaken (Mann-Whitney U test Z adjusted 1.789, p=0.0736).

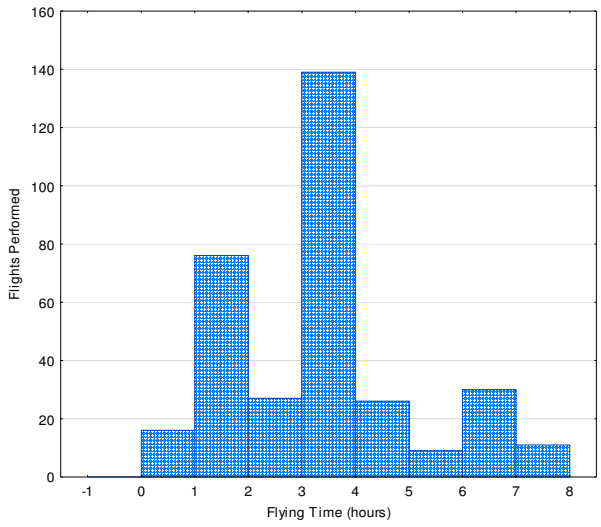

Figure 5 Distribution of Flight Times (hours)

Bar Graph of number of flights on Y-axis, with one-hour category of flight time (with patient) in hours on the X-axis.

Table 4 Flying Times (with patient)

	Number of Flights	Minimum Flight Time (hours)	Maximum Flight Time (hours)	Mean (hours)	SD (hours)
Without Technical Stop	261	0.5	4.6	2.7	0.97
With Technical Stop	73	2.5	8.0	5.9	1.31
All Flights	**334**	**0.5**	**8**	**3.42**	**1.70**

Table listing flight time data (with patient) in hours for flights grouped by technical stop requirement. Technical stops would be required most frequently for aircraft refuelling purposes, and occasionally for customs entry and exit purposes into and out of countries of patient pick-up. SD = Standard Deviation from the mean.

3.3 Regional distribution of flights

Regions from where patients were evacuated from (or in a small number of cases repatriated to) are shown in Table 5, with Figure 6 as a visual reference to African regions as defined by the United Nations (53). 79% of all flights were out of Southern and Eastern Africa.

Table 5 Regional Destinations of flights conducted

Region	Number of Flights (%)
Southern Africa	134 (40%)
East Africa	130 (39%)
Central Africa	30 (9%)
West Africa	33 (10%)
North Africa	0
Islands	7 (2%)
Total	**334**

Table with number of flights conducted per regional destination. Percentages per region of the total flights conducted are in parentheses. Regions were as defined by the United Nations, with Madagascar being included into East Africa, while other Indian Ocean islands were grouped into the "Islands" region.

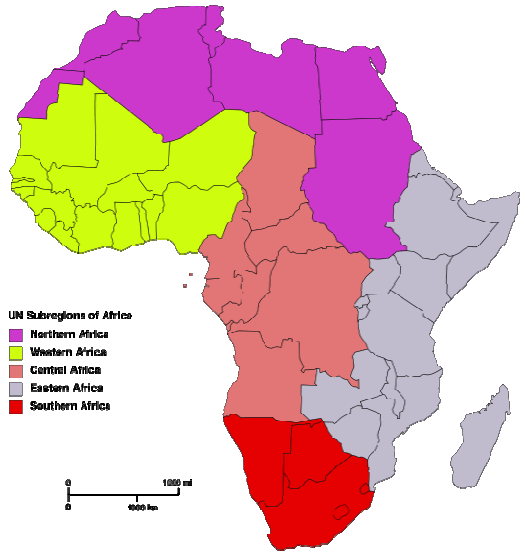

Figure 6 United Nations Subregions of Africa

Map of Africa with subregions as defined by the United Nations in different colours for each region.

(From: http://goafrica.about.com/od/africatraveltips/ig/Maps-of-Africa/Regional-Map-of-Africa-.htm)

3.4 Blood gas analysis results

POC BGA was undertaken in 266 patients (see Table 1) and resulted in a total of 338 samples from the 334 patients transported by Air Ambulance (see Table 6 and Table 7). These 338 samples refer to successful sample analysis, and exclude any failed sampling attempts. In certain POCT episodes, more than one test cartridge was utilised to achieve testing for all required parameters. This resulted in a total of 534 cartridges being used, where 208 were $CG4^+$ cartridges, 178 were $EG6^+$ cartridges and 142 were $CG7^+$, while there were 6 unknown cartridges used. There were a total number of three reported i-Stat analyser failures identified from the clinical flight notes reviewed.

Table 6 shows number of POCT samplings undertaken via either venous or arterial venipuncture, or via indwelling arterial line. Each type of sampling techniques is then grouped according to location/setting in which the sampling took place. Hospital and airport tarmac (pre-flight) sampling accounted for 28.99% and 49.7% of all sampling respectively, while in-flight sampling accounted for 21.3% of all POCT. Of the total samples, arterial sampling accounted for 52.3%, venous for 45.3%, while 2.4% were either arterial or venous (undetermined) (see Figure 7). Proportionately, arterial sampling occurred more frequently than venous sampling in the hospital and in-flight settings. Arterial sampling accounted for 58.2% of samples at hospital, and 75% of samples in-flight. In contrast, venous sampling accounted for 58.9% of samples in the airport tarmac setting.

Table 6 Location undertaken & sampling site of BGA

Location	Site	No. of samples
Hospital	Venous	38 (38.8%)
	Arterial	49 (50%)
	Indwelling A-line	8 (8.2%)
	Unknown	3 (3%)
		98 (28.99%)
Airport tarmac	Venous	99 (58.9%)
	Arterial	65 (32.7%)
	Indwelling A-line	1 (0.6%)
	Unknown	3 (1.8%)
		168 (49.7%)
In Flight	Venous	16 (22.2%)
	Arterial	40 (55.6%)
	Indwelling A-line	14 (19.4%)
	Unknown	2 (2.8%)
		72 (21.3%)
		338

Table listing number of POCT samples per geographical location (hospital, airport tarmac or in flight). Site/type of sample taken (arterial stab, venous, or via indwelling arterial catheter) is then listed for each location. The far right column lists total numbers of site/type of samples for all POCT sampling. BGA = Blood Gas Analysis. POCT = Point of Care Testing.

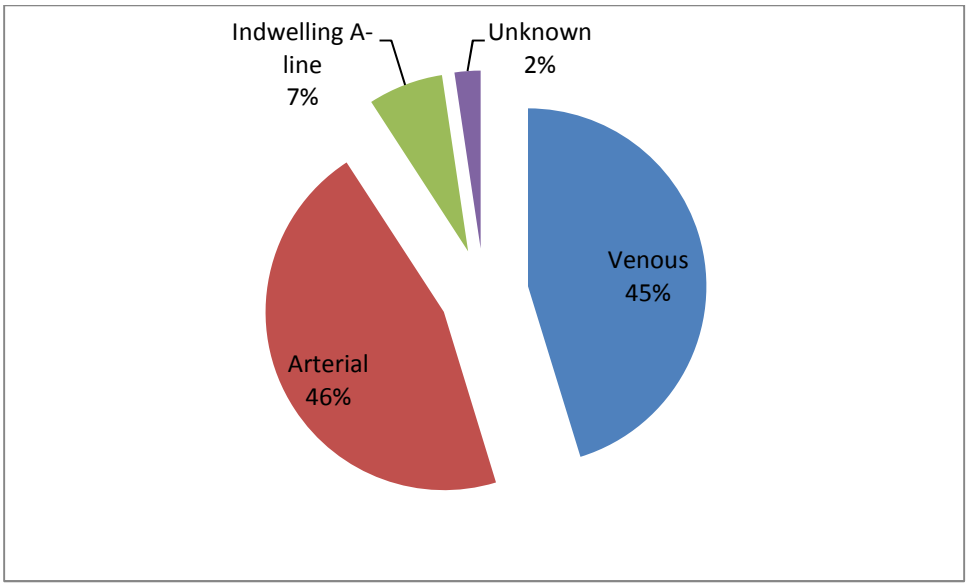

Figure 7 Site of POCT Blood Sampling

Pie-chart depicting total percentages for all blood sampling sites of POCT for all geographical locations (hospital, airport tarmac or in flight). Figures stated are percentages of all blood samples taken for each individual site of sampling. POCT = Point of Care Testing.

Two hundred and three (203) out of 338 samples tested (60.1%) identified an abnormality in at least one of the variables tested (see Table 7). Therefore for every 1.67 samples analysed an abnormality was detected. Of the 203 abnormal results identified, some form of corrective action followed in 133 instances – that is, an action was evidenced for every 1.53 abnormal POCT results (65.5%). Overall a corrective action was taken following every 2.54 POCT performed. The therapeutic yield found was therefore 39.3%.

Table 7 BGA performed, abnormal findings & corrective action evidenced

BGA	No. of Patients	BGA Result	No. of Findings	Corrective Action	No. of events	Corrective Action for Abnormality		Corrective Action	
Undertaken	266 (79.6%)	Abnormal	203 (60.1%)	Taken	133 (65.5%)	Possible	145 (71.4%)	Taken	127 (87.6%)
								Not taken	18 (12.4%)
Not undertaken	68 (20.4%)	Normal	135 (39.9%)	Not taken	70 (34.5%)	Not possible	58 (28.6%)		N/A
Total Pts	**334**	**Total BGA**	**338**	**Total AbN BGA**	**203**		**203**		

Table listing stepwise progression of numbers of instances from left to right columns of (1) BGA undertaken or not; (2) if BGA done, then whether normal or abnormal; (3) if abnormal then whether corrective action evidenced or not; (4) whether corrective action actually possible or not; and (5) if corrective action possible, was corrective action taken. BGA = Blood Gas Analysis. AbN = Abnormal.

Table 8 shows the number of abnormalities of specific blood gas variables identified with percentages in both the abnormal findings POCT group as well as the total number of POCT undertaken. Of all samples analysed, pCO_2 was the most frequently identified abnormality found in 28.1% of all samples and in 46.8% of abnormal samples. Frequencies for pO_2 and pH showed similar lesser values, while Na^+ was found to be abnormal the least number of times in all samples at 2.1%.

Table 8 Abnormalities in Blood Gas variables identified

Blood Gas variable	No. of abnormalities detected	% of 203 abnormal samples	% of all 338 samples
pH	90	44.3%	26.6%
pO_2	94	46.3%	27.8%
pCO_2	95	46.8%	28.1%
HCO_3^-	68	33.5%	20.1%
BE	78	38.4%	23.1%
Hb	76	37.4%	22.5%
K^+	62	30.5%	18.3%
Na^+	7	3.4%	2.1%
Lactate	25	12.3%	7.4%

Table listing Blood Gas variables reviewed and number of abnormal findings for each variable. Percentages of the number of abnormalities of each variable are then listed first as a percentage of the abnormal POCT identified, and then as a percentage of the total number of POCT undertaken. POCT = Point of Care Testing.

Table 9 lists the types of corrective action undertaken in response to abnormal findings. The most common clinical corrective action undertaken in 25% of cases was initiation or changes to ventilatory support. Administration of medications and intravenous fluid therapy were the next most frequent interventions at 22% and 21% respectively. From Table 7, one can see that corrective action was taken on 133 occasions, while in Table 9 the total number of occasions of all clinical actions undertaken exceeds this number. This is due to a combination of different actions being undertaken in 40% of occasions.

Table 9 Corrective Clinical Action undertaken

Clinical Action	No. of Occasions undertaken
Transfusion of Blood Products	10 (5%)
Medications administered (Bolus or Infusion)	47 (22%)
Intravenous Fluid Administration	45 (21%)
Oxygen Administration	32 (15%)
Ventilatory Support or changes	54 (25%)
General Supportive Treatment	29 (13%)
Combination of actions	54 (40%)

Table listing categories of clinical action and the number of occasions on which each was identified to have taken place following an abnormal POC BGA finding. Total number of occasions each action was identified is represented, together with the percentage of that category within all actions undertaken in parentheses. The number of occasions where more than one category of clinical action was undertaken following a single abnormal POCT result, was counted as "combination of actions" and is listed in addition to the separate actions in the bottom row.

4 DISCUSSION

4.1 Summary of results

Of the 334 patients transported by air ambulance, a total of 266 patients (79.6%) had POC BGA undertaken as part of their clinical assessment. In these 266 patients, a total of 338 blood samples were taken for analysis including initial and follow up POCT. Age and intubation status of patients were found to be significant determinants of whether POCT was undertaken. Total flying time and sex of patient were however not significant determinants of POCT being undertaken. A total of 203 abnormal blood gas results were identified (60.1%) out of these 338 samples analysed. Corrective clinical action for abnormal results found was noted following 133 of the 203 abnormal blood gas results (65.5%). Of these 203 abnormal blood gas results, it was established that corrective clinical action for the abnormality identified was possible in 145 cases (71.4%). Where corrective action was in fact possible, it was subsequently undertaken following an abnormal finding in 127 (87.6%) cases. Taking all 338 POC BGA into account, a clinical action followed every 2.54 POC BGA undertaken, (133 actions following 338 samples). Therapeutic yield for POCT in this study was thus 39.3%. The most common corrective actions noted were ventilatory support or changes (25%), administration of medications (22%), and administration of intravenous fluids (21%). Any combination of corrective actions occurred in 40% of cases. These actions do appear to reflect the specific abnormalities noted and corrective actions clinically possible. The most common abnormal blood gas variable noted was pCO_2 (46.8%) followed by pO_2 (46.3%) and pH (44.3%) as the next most commonly found abnormal blood gas variables.

4.2 Patient demographics

A total of 334 patients were transported in the one calendar year period reviewed. Of these patients 79 (23.65%) were local nationals in the country of pickup, while 255 (76.35%) were expatriates. 260 (77.84%) patients were male, while 74 (22.16%) patients were female (see Table 3). This bias towards expatriates and males is very likely related directly to the client base and service offerings of the international medical assistance company for which the air ambulance service investigated is a provider (52,53). These clients are large multinational mining, construction and oil and gas corporations (52) who have a business need to deploy technically skilled expatriate professionals and managers to take care of their international operations in sub-Saharan Africa. As a rule, males are most likely preferred to go to remote foreign countries under potentially less than savoury conditions. These corporations who then follow a modern “duty-of-care” approach (52) to their employees will prefer to have seriously ill or injured staff reviewed and managed in medical circumstances and environment approximating those to which the employee is accustomed to in their home country. Duty-of-care is defined as a requirement that a person or organisation act towards others with watchfulness, attention, caution and prudence that a reasonable person in the circumstances would; if a person or organisation’s actions do not meet this standard of care, then the acts are considered negligent (57). Johannesburg, South Africa is in many circumstances a regional centre of excellence for medical care in this context in sub-Saharan Africa for expatriate workers.

Patient nationality and sex were not found to influence the undertaking of POCT. POCT was undertaken in 266 (79.6%), while not undertaken in 68 (20.4%) of the 334 patients in total. Analysis of patient nationality showed similar figures for POCT. 204 (80%) of the 255 expatriate patients had POCT undertaken compared to 62 (78.48%) of the 79 local national patients.

Similarly, there were no differences in POCT utilisation between males and females, 78.46% vs.83.78% respectively. These figures reflect that factors other than nationality and sex played a role in the decision to undertake POC BGA by the medical crew. Certainly this is a finding that would have been expected, and if it were to have been found to be a significant factor, then in depth analysis around the diagnosis and clinical status of patients in these groups would have been required to provide further explanation.

For the one calendar year reviewed, the median age of patient within the total of 334 patients was 48 years (see Table 1 and Figure 2). Again, these averages probably reflect the type of worker employed by these multinational corporations in the sub-Saharan region in a similar fashion to how sex of patient was surmised to be accounted for. It is likely that this age group represents a well-experienced and senior yet not necessarily the most senior or aged of a group of employees. This postulation is based on the technical expertise required, but also a requirement for the individuals with this expertise to be willing to travel, and be in a position to work away from home. Thus the average age of patient in this population studied is likely to fit in with these requirements.

Table 1 and Figure 3 show the distribution of patient age versus POCT undertaken or not undertaken. Patient age was found to be a factor influencing the undertaking of POCT. The median age of 50 years for POCT undertaken does appear to mirror that of the total patient population of 48 years, which makes intuitive sense. Statistical difference between the two groups however requires further discussion. There is a marginally greater range of ages for which POCT is not undertaken (0.06 years – 90 years), compared to a relatively smaller range for the group where POCT is undertaken (0.1 years – 86 years). It can be reasoned from these

results that the significantly younger patients had a smaller chance that POCT would be undertaken. This is a feasible argument, in that clinicians are indeed far more circumspect in general when it comes to undertaking blood sampling in the very young or the very old. In the younger patients POCT would be reserved for the more seriously ill patient where this investigation is considered as absolutely required. Where this is not the case, POCT would be avoided in the interests of keeping the patient calm and avoiding inflicting unnecessary suffering on the young patient. This concept may be responsible for only one in five patients (20%) in the congenital diagnosis category having POCT undertaken (see Table 2).

The patient's intubation status was found to be a statistically significant influencing factor for POCT to be undertaken. In the group of patients who were not intubated, 231 (77.77%) of the 297 patients in this group had POCT undertaken – in keeping with the proportions for the entire patient population of 79.6% (discussed above). However, intubated patients had a much greater POCT utilisation (94.59%). This finding is not surprising, as one would expect these types of investigations to be undertaken routinely in intubated patients. This finding is also in keeping with further results showing common abnormalities detected, as well as corrective clinical actions undertaken, reflecting abnormalities and actions closely linked to respiratory and ventilatory function and management – discussed in sections to follow.

Diagnosis categories for all patients transported are listed in Table 2. Cardiac cases are listed as the category of patients in whom POCT was undertaken at the highest frequency with 93% of these patients having POC BGA done. This is above the overall average for the patient population of 79.6%. Other diagnosis categories with higher than population average POCT frequency were Medical (Malaria) (88.5%) and Medical (Neuro) (89.1%). These figures are

likely to represent patients in whom POCT was deemed potentially more useful by medical staff due to the nature of the pathology and potential abnormalities predicted. In contrast, only 20% of congenital diagnosis category patients had POCT undertaken, most likely due to their age and the medical staff's intention to avoid unnecessary invasive interventions. This is also reflected in the data reviewing patient age and POCT, already discussed. Cases were not reviewed for categories of clinical seriousness, so this influence on decision to undertake POCT was not assessed.

4.3 Flight logistics & regions

Table 4 provides flight time (with patient) data on the 334 flights performed over the calendar year. Figure 5 shows the distribution of flight times and visually illustrates the flight times listed in Table 4. Average (mean) flight time with patient was 3.42 hours, with the shortest flight being 30 minutes, and the longest flight 8 hours inclusive of a one hour refuelling stop. Refuelling or customs clearance technical stops were required in 73 cases. Flight time with patient was found not to be significant in influencing when POC BGA was undertaken (Mann-Whitney U test Z adjusted 1.789, p=0.0736).

Since flight time as an independent factor did not influence the medical team's decision to utilize POCT, the logical conclusion that follows is that this decision was based on other factors. However it is also clear that the non-clinical factors analysed (patient sex and flying time) have not influenced the utilization of POCT. Therefore clinical or other factors (although not specifically reviewed in detail) must have influenced these decisions on the part of the medical flight crew. It was shown that age of patient had indeed influenced whether POCT was undertaken. Intubation status has already been discussed as a significant factor in the

utilization of POCT. Clinical diagnosis category will be discussed in a later section. Detailed clinical information was not in the scope of this study, so objective debate beyond intubation status and diagnosis category cannot be engaged within this paper unfortunately. However, that this present study has been able to show that the non-clinical aspects of patient demographics and flight logistics did not influence the use of POCT is certainly both reassuring and significant from a clinicians perspective.

Southern and Eastern Africa were the most common destinations of origin of patients flown into Johannesburg (see Table 5) accounting for 264 (79%) of all flights. It is reasonable to argue that this dominance of patients flown out of these regions as opposed to others is related primarily to South Africa as a regional centre of medical excellence for referral of patients out of Southern and Eastern Africa. Whereas a European destination as the nearest centre of medical excellence may be considered more appropriate from western, northern and northern central Africa. Regional destination was not analysed separately with reference to any influence on POCT, as flying time was utilised and was more appropriate for this purpose.

4.4 Blood gas analysis results

POCT was undertaken in 266 patients and resulted in a total of 338 successfully analysed samples from the 334 patients transported (see Table 1 and Table 7). This is equivalent to 79.6% of all patients transported having POCT undertaken at an average of 1.27 samplings per patient where POCT was employed. This number is very similar to a small study reviewing a doctor based ground ambulance service in Austria which showed 1.19 samplings per patient where POCT was undertaken (49). This Austrian study did not however report on the total patient population and the percentage of patients where POCT was undertaken, which in this

present study was 79.6%. Analysis of reported figures from a large six year study in a combined ground and air ambulance system in the USA (50) showed that only 26.8% of the total patient population had POCT undertaken, a significantly lower number than in the present study. The investigators did report however that 66% of POCT was undertaken in patients graded "critical" and although specific numbers were not reported, it is reasonable to deduce that the lower frequency of usage of POCT could be related to lower numbers of patients in which POCT was deemed to be a useful part of patient assessment. Our analysis did not include review of initial patient clinical data beyond clinical diagnosis category and intubation status. Therefore we are unable to quantify these variables to take a view on grading the patients clinically in terms of severity of illness. However, it can be surmised that the patient population transported in this present study had a higher percentage of "critical" cases which lead to a significantly higher rate of use of POCT.

4.4.1 Analyser & cartridge failures

These 338 samples above refer to successful sample analysis. There were a total number of three reported i-STAT® analyser failures (0.01%), and no reported cartridge failures. Previously up to 7% of testing has been reported to be compromised by failures, comprising 55% cartridge failures, 42% operator errors and 3% analyser failures (50). Since our study was of a retrospective design, accurate analysis of errors was not possible, as the only evidence of error identified was if specific note was made thereof in the clinical notes, or the failed message print out from the i-STAT® was attached to the notes. A separate review of cartridges purchased, disposed of (if expired) and utilised over the calendar year period was also not undertaken, which would have been a useful cross-reference for cartridge usage and errors. Air Ambulance equipment failure incident reports were also not reviewed together with clinical records to identify failures not recorded in clinical notes. Thus what can be reported on is a very low

recording in clinical notes of analyser failures, which is not likely to be due to a true low failure rate, but rather to the non-reporting of such in clinical notes. This would certainly be appropriate, unless a failure had clinical consequence which the treating doctor wished to record in the patient record. However this leads to further legal liability and ethical debate, which although interesting and worthy of discussion is beyond the scope of this paper. No comment on actual cartridge or analyser failure rates can therefore be objectively commented on in the present study.

4.4.2 Site and location of sampling

Anatomical site and geographic location of blood sampling are summarised in Table 6. Only 21.3% of all POCT was done in flight. The remainder (78.7%) of the POCT undertaken was either at the referring hospital or at the airport of patient collection. These should be reviewed in the context of the operation of the air ambulance service regarding patient collection. Patient collections occur either at the bedside in the referring hospital, or on the tarmac at the airport. All POCT at hospital or on the tarmac can therefore be considered pre-flight and as part of patient assessment and preparation for the flight itself. The same is not true in the context of preparation for transport, as some of the POCT done on the tarmac was part of the transport process when the patient was collected from the bedside at the hospital. When analysing the data with regards to number of “initial” patient assessment POCT versus “follow-up” POCT, 266 (78.7%) of samples were initial assessment samples, while 72 (21.3%) of POCT was as follow up. These figures are very close to other studies where 77% of testing was reported as pre-transport (50). The practice of comprehensive pre-transport assessment and patient preparation is also reflected in these high numbers of pre-transport POC BGA samples. Appropriate patient preparation for flight is especially important for longer duration transports. Here, a high proportion of POCT utilised in the pre-transport phase is related to the average

flight time with patient of 3.42 hours for all flights undertaken. These transport timelines with patient are considered fairly long and thus thorough pre-transport assessment and preparation is both justified and necessary (11).

Blood samples were drawn from either peripheral venous sites or arterial sites via direct venipuncture or indwelling arterial catheter (see Table 6). In 2.4% of cases it was unclear as to the site of sampling. Arterial blood sampling accounted for 52.4% while venous sampling for 45.3% of POCT blood samples. Of the total samples, arterial sampling via direct venipuncture comprised of 45.6%, while 6.8% was via indwelling arterial catheter. While venous blood samples are adequate to assess blood electrolytes, an arterial sample is required for appropriate analysis and assessment of blood gases for review of oxygenation and ventilation status. The slightly greater proportion of arterial vs venous samples taken could therefore reflect the requirements of the treating doctor in terms of information required for particular patient assessment. Of interest is how the in-flight proportions are dramatically different from the pre-flight phase of POCT. For the hospital and airport tarmac phases combined (i.e. pre-flight), venous sampling accounted for 51.5%, while arterial accounted for 46.2% of samples, where 2.3% where from an undetermined site. In flight however, arterial sampling and analysis was heavily favoured, being utilised in 75% of POCT. Since in-flight sampling was almost exclusively utilised for follow-up purposes, these figures are likely to represent the greater need for follow-up analysis related to blood gases as opposed to electrolytes. This is also borne out when reviewing the specific abnormalities detected, and the follow up clinical actions, to be discussed below.

4.4.3 Abnormalities identified & clinical actions

Of the 338 samples from 266 patients where POCT was employed, 203 samples analysed identified an abnormality in at least one of the variables tested (see Table 7). Therefore, 60.1% of POCT samples analysed detected an abnormality. And also, for every 1.67 samples analysed an abnormality was detected. Of the 203 abnormal results identified, some form of corrective action followed in 133 instances, or 65.5% of the time. This is equivalent to a clinical action following every 1.53 abnormal POC BGA.

Further breakdown from the abnormal POCT results into categories of clinical action being either possible or not possible revealed interesting findings. Corrective clinical action was assessed to have been possible following 145 (71.4%) of the 203 abnormal POCT results. In the remaining 58 (28.6%) corrective action was noted not to have been possible. On 21 of these occasions (36%) this was noted to be as a consequence of blood products not being available on the aircraft for that particular flight. In the remaining cases, clinical action not being possible was attributed to no specific interventions available to address the abnormality. However the clinical notes review and data collection were not structured in a way to specifically address this issue, so no detailed objective comment on this aspect, besides the availability of blood products can be offered.

Where clinical action was in fact assessed to have been possible following an abnormal POCT result (145 cases out of 203 abnormal), clinical action followed in 87.6% of cases. In the 12.4% of cases where clinical action was possible, but not carried out, a large proportion of these were attributed to clinically assessed insignificant degrees of abnormality or in some cases the lack of clinical action was unexplained.

Table 8 shows the number of abnormalities of specific blood gas variables identified. The highest numbers of abnormalities noted were in the blood gas variables pCO_2, pO_2 and pH. This would suggest that arterial sampling should be preferred over venous sampling as a standard approach, even when these are not necessarily the variables of interest initially. However, the marginal dominance of arterial sampling undertaken compared to venous could be a contributing factor to this finding. The abnormal electrolyte findings for potassium (K^+) reveal that K^+ was found to be abnormal in 30.5% of the 203 abnormal samples, and in 18.3% of all samples analysed. Abnormal K^+ levels can certainly be lethal, thus identification and correction of this abnormality is vital. These findings reinforce the value and necessity of measured K^+ as part of routine patient assessment in this setting.

The abnormalities noted above are also in agreement with the clinical actions undertaken where ventilatory support or changes were the most common clinical action noted as 25% of all corrective clinical actions undertaken. Medications administered was the second most frequent clinical intervention at 22%. Previously reported corrective clinical actions have included adjustments to mechanical ventilation being required in 30% and adjustments of F_iO_2 specifically in 45% of patients based on results of POCT in transports of critically ill paediatric patients (45) – a figure similar although indeed greater than findings in this present study. The greater numbers are certainly related to the clinical severity of illness in the paediatric transport review compared to patients transported in this current study, whom were from a more “general” patient population. This of course is speculative and intuitive, as the clinical severity of cases was not reviewed in the present study.

Table 9 lists the further types of corrective action undertaken in response to abnormal findings. It is evident from the preceding comments and inspection and comparison of Table 8 and Table 9 that findings and actions cover multiple different simultaneous abnormalities and consequent clinical actions. This eye-ball review is then confirmed by 40% of occasions of clinical actions having required a combination of different types of action.

4.4.4 Therapeutic yield

Taking all 338 POC BGA into account, a clinical action followed every 2.54 POC BGA undertaken, (133 actions following 338 samples). As a percentage, this equates to an action undertaken following blood gas analysis in 39.3% of POCT events. Therapeutic yield for POCT in this study was thus 39.3%. Other studies show therapeutic yields of 30% and 52% (49,50) which appears therefore to place our findings on a similar level to previous findings. Subjective questionnaire based findings have previously reported treating doctors to have found the results of POCT to be useful in 72% of cases (49). In another descriptive study, interviewing the attending doctor following the inter hospital transport of critically ill children, it was shown that results of POCT influenced treatment in 76.5% of all samples (45). This number is significantly higher than our findings, and it is most likely related to the paediatric patients in this study being critically ill in almost all instances.

Although our study did not assess the opinions of treating doctors specifically, we did show that 79.6% of patients had POCT revealing abnormalities in 60.1% of these cases. It is not only abnormal results that are useful, but indeed confirmation of normal findings that are also useful to the attending clinician. It is therefore reasonable to argue that POCT was useful in this

present study in a range between 47.8% (60.1% of 79.6%) up to 79.6% of all patients evaluated and transported.

In conclusion, these findings show frequent usage of POCT, followed by frequent detection of abnormalities and resultant clinical actions, with an overall therapeutic yield of 39.3%. Thus it would certainly be reasonable to suggest that within this air ambulance service, that POCT be instituted as mandatory for all patients. Arterial sampling as a standard technique rather than venous sampling could also well be a further consideration. Further evaluation of patient outcomes would be of significant value in determining the true utility of POCT in this setting.

4.5 Costing analysis

A total of 534 i-STAT® test cartridges were used, which included 208 $CG4^+$ cartridges, 178 $EC6^+$ cartridges and 142 $CG7^+$ cartridges. There were 6 unknown cartridges used. As some variables included in one cartridge are not included in others, it is sometimes necessary to utilise two cartridges per POCT occasion. Thus across all POCT events the average number used per POCT was 1.58 cartridges. The costs of all the aforementioned cartridges to the air ambulance service are equivalent at ZAR83.67 per cartridge. Therefore the cost of cartridges per POCT undertaken was ZAR132.20. There were a total of 203 abnormal POC BGA sample results identified from all samples analysed, translating to a cost therefore of ZAR220.10 per abnormal sample result. Similarly, from the 133 corrective clinical actions noted following POCT, the cost per clinical action (or cost of therapeutic yield) was ZAR335.90. In the context of the costs involved in other diagnostic investigations, this is certainly not expensive.

It must be noted however that the above are only the costs of the i-STAT® test cartridges. And further, that the number of discarded failed cartridges was not possible to establish in this study design, so there were certainly a small number of additional cartridges that should be considered in this analysis. Additional costs would also include the heparinised syringes, hypodermic needles, alcohol swabs, gauze and any other disposable items required to undertake the sampling. These costs would be relatively small compared to the cost of the test cartridges. The capital expense of the i-STAT® analyser (approximately ZAR65,000.00) should also be considered. However, this particular expense could be considered as part of the general capital operating costs, and for the purposes of understanding individual POCT occasions, be excluded. Finally, costs of i-STAT® test cartridges and other disposable items utilised for training purposes should also be included in an analysis of true costs of POCT within any particular system.

4.6 Limitations

In addition to issues already raised in preceding sections, some general comments are worth noting at this point. Since this was a retrospective review of clinical case notes, certain aspects related to POCT could not be accurately evaluated. Failure rates for analyser and cartridges are very likely to be much higher than the three identified reported failures. Failure rate is an important aspect in POCT that could not be assessed in this study. A greater positive finding in terms of numbers of abnormalities detected could well have been elicited if all variables measured were assessed. By design, a certain subset of blood gas variables was pre-chosen, and therefore other variables that may have been measured were not evaluated. A prospective design taking these issues into account would be a solution.

Review and analysis of clinical parameters utilising scoring systems and the like would have been useful in providing analysis and commentary on the influence of patient clinical status on attending medical personnel's use of POCT. It is quite likely that a correlation between clinical severity and use of POCT would be found.

No means to distinguish between clinical actions undertaken as a direct result of information obtained from POCT or those undertaken as a result of other clinical assessment or combination of assessment variables and methods was possible. For the purposes of this study, the design was such that it assumed actions intended to correct an abnormality were undertaken as a consequence of being provided with that information from POCT, and not by any other means such as clinical examination or clinician intuition and analysis. Thus, the figures related to clinical actions and final therapeutic yield are certainly not conservative, and could be lower in practice if these factors had been analysed. A prospective study design including a questionnaire based process to evaluate the clinicians decision process would be a good option to evaluate and understand this particular aspect.

Finally, no review of clinical investigation and intervention would be complete without a review of clinical outcomes. Further study and review of clinical progression and outcome within the system studied would be of great value in this regard.

5 CONCLUSIONS

5.1 Summary

Point-of-care testing when used appropriately has the potential to improve patient outcomes. However, when overused or performed with poor quality, costs are unnecessarily escalated and risks to patients are increased (13). The environment of the air ambulance certainly lends itself to both of these possibilities, with a relatively uncontrolled environment and free access to POC testing. However, with a good quality control and training system in place, together with prudent decision making on the part of the medical team, these risks can be minimised. Certainly, POCT is considered a standard of care in modern Air Ambulance clinical assessment and monitoring of patients by many professional organisations (11).

Point-of-care testing carried out in 79.6% of the population in this study showed 60.1% of the POCT samples to have at least one abnormal value. Clinical intervention followed in 65.5% of instances where abnormalities on blood gas analysis were noted and in 87.6% where clinical corrective intervention was assessed as actually being possible. Patient age and intubation status were significant influences on number of analyses performed, while flight time was not significant. Overall the therapeutic yield for all blood gas analyses undertaken and follow up clinical action evidenced was 39.3%. Thus these results are similar to findings in other previous studies on POCT in different transport systems. The costs of i-STAT® sample cartridges utilised were calculated at ZAR132.20 per POCT undertaken, ZAR 220.10 per abnormality detected, and ZAR 335.90 per clinical action executed.

Results show that POCT yielded a high percentage of abnormal results within the patient population and resulted in a high number of clinical actions undertaken as a result. Since the costs have been shown not to be very high, this modality is rightfully considered a minimum standard of care in Air Ambulance operations. These findings support the notion that point-of-care blood gas analysis and testing should be carried out routinely on all patients, irrespective of the attending clinician's interpretation of the clinical indication or need thereof. Further, that arterial sampling in preference to venous sampling can also be recommended.

5.2 Recommendations

A careful review of available test cartridges to identify (if possible) a single cartridge with appropriate combinations of the most common abnormal variables and essentially required variables would not only potentially reduce costs, but also standardise the usage of POCT. Further study, specifically in the sub-Saharan African setting, could include the undertaking of a prospective study evaluating the clinical status of patients undergoing POCT, including a questionnaire administered to attending air medical crew to evaluate the decision making process and perceived utility of POCT. A follow up study designed around using POCT in all patients transported with similar objectives would then add further insights. Of significant value to include in these studies would be the evaluation of the change in clinical status of patients following POCT and clinical interventions following testing with the objective to quantify the clinical benefits and outcomes following POCT. The evaluation of all parameters tested, instead of the review of a pre-defined set of variables should also reveal additional abnormalities identified using POCT.

Together with further studies and evidence, the findings from this present study can certainly form part of an evidence base, if not potentially independently, to promote the use of POCT in all patients transported via air ambulance in the sub-Saharan African setting, as standard practice guidelines.

APPENDIX A: Ethics Clearance Certificate

M110108M110108

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Steven Lunt

CLEARANCE CERTIFICATE	**M110108**
PROJECT	The Use of Point-of-Care Blood Gas Analysis on a South Africa Jet Air Ambulance Service
INVESTIGATORS	Dr Steven Lunt.
DEPARTMENT Medicine	Department of Family Medicine/Emergency
DATE CONSIDERED	28/01/2011
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 28/01/2011 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Roger Dickerson

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX B: WITS Approval of Title Letter

Faculty of Health Sciences
Medical School, 7 York Road, Parktown, 2193
Fax: (011) 717-2119
Tel: (011) 717-2745

Reference: Ms Tania Van Leeve
E-mail: tania.vanleeve@wits.ac.za
03 May 2011
Person No: 9200129E
PAG

Dr SE Lunt
P O Box 13024
DOWERGLEN
1612
South Africa

Dear Dr Lunt

Master of Science in Medicine (Emergency Medicine): Approval of Title

We have pleasure in advising that your proposal entitled "*The use of point-of-care blood gas analysis on a South African Fixed Wing Jet Air Ambulance service*" has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

APPENDIX C: Intl SOS Letter of Permission

20 October 2009

Dr SE Lunt
PO Box 13024
Dowerglen
1612

Dear Steven

Access to Patient Flight Medical Forms

I refer to your communication of 1 October 2009.

Your request has been considered, and I can confirm that such has been approved. Please note that the usual confidentiality of information rules will apply, with no mention of confidential patient or client details being allowed.

Kind regards

Dr F Lamond
Regional Medical Director
International SOS
Southern Africa

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J.A. Jacobsz, L. Sabourin(French) T.V. van Stryp (Managing)

APPENDIX D: Air Rescue Africa Patient Report Form

Air Rescue Africa
Tel:- +27 11 541 1100
Fax:- +27 86 554 3884

Pre-flight evaluation Page 1

Date:_____ Case Number:_____
Patient:_____ Sex: M F Age:_____ Wt:_____
Aircraft Type and Registration:_____
Routing and Destination:_____
Crew 1:_____ Crew 2:_____ Crew 3:_____
Medical Hx:_____

Medications:_____

Allergies:_____
Hx of Presenting Condition:_____

ATD Base:_____ ATA Destination:_____ ATD Destination:_____ ATA Base:_____

General Assessment

Primary Survey

A_____
B_____
C_____
D_____

Secondary Survey

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Secondary Survey Cont. Page 2

Date:	Pt:	Case No:

Provisional Diagnosis:

Medications

Time	Medication	Dose	Route	Sign

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In-flight monitoring		Altitude							Cabin Alt								Page 3
	Date:	Pt:							Case No:								
	Time:																
Vital Signs	B.P. ^ v	220															
		200															
	H.R. ●	180															
		160															
		140															
		120															
		100															
		80															
		60															
		40															
	MAP																
	ECG Rhythm																
	R.R.																
	ET CO_2																
	FI O_2																
	O_2 Saturation %																
	Temp °C																
	Dextrose																
	CVP / IBP																
Airway Management	ETT cm Teeth																
	ETT Cuff Pressure																
	A/E																
	Vent rate																
	Vent mode																
	Tidal Vol																
	Min Vol																
	PEEP																
	Peak Airway Pressure																
	IE Ratio																
Neurovascular Assessment	Pupils (L)																
	(R)																
	Eye Opening																
	Verbal																
	Motor																
	Mot/Sen Arm L/R																
	Mot/Sen Leg L/R																
	Pulses/Perfusion Arm L/R																
	Pulses/Perfusion Leg L/R																
	Pain	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Infusions																	
	Incubator Temp																
	Foetal HR																

Air Rescue Africa
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Fax:- +27 11 541 1058

In-flight record

Page 4

Date: Pt: Case No:

IV Fluids / Infusions

Infusions	Concentration	Vol	Ml/Hr	Dose	Time Started

Time	Site	Gauge	IV Fluid	Vol Up	Rate	Total Volume Infused

Intake / Output

Time	PO	IV	Total	Time	Urine	NGT	Blood/Stool	Total
	Intake over _____ hours				Output over _____ hours			

Transport Notes

Handover

Date: Time:

Patients Vitals: BP HR RR SpO2

Temp HGT

Neuro Status: E M V = /15 Motor Sens Prop

Valuables:

Valuables handed over to:

Medical Crew: Signature: Signature:

Receiving facility:

Doctor: RN:

Signature: Signature:

APPENDIX E: i-STAT® Reference Ranges

CARTRIDGE AND TEST INFORMATION

i-STAT sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT Portable Clinical Analyzer and the i-STAT 1 Analyzer* for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

CARTRIDGE SPECIFICATIONS

Shelf Life:

Refrigerated at 2 to 8°C (35 to 46°F) until expiration date.

Refer to the cartridge box for room temperature storage requirements.

Preparation for Use:

Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Sample Type:

Fresh whole blood from arterial, venous, or skin punctures

(Note: Skin puncture is NOT a recommended sample type for ACT, cTnI, CK-MB, or BNP testing.)

cTnI and CK-MB cartridges require the use of heparinized whole blood or plasma, or non-heparinized whole blood tested within one minute of patient draw.

BNP cartridges require the use of EDTA whole blood or plasma samples.

Sample Volume:

17µL, 20µL, 40µL, 65µL, or 95µL depending on cartridge type.

Test Timing:

Immediately after collection

- Samples for the measurement of ACT, PT/INR and Lactate

Within 3 minutes after collection

- Samples collected in capillary tubes, both with and without anticoagulant
- Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant

Within 10 minutes after collection

- Samples collected with anticoagulant for the measurement of pH, PCO_2, PO_2, TCO_2 and iCa. Maintain anaerobic conditions. Remix before filling cartridge.

Within 30 minutes after collection

- Samples collected with anticoagulant for the measure of Sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, and BNP. Remix thoroughly before testing.

Abbott Point of Care

Art: 714258-00M Rev. Date: 25-Mar-10

* The cTnI, CK-MB, and BNP cartridges can only be used with the i-STAT 1 analyzer bearing the i symbol. The CHEM8+ cartridge can only be used with the i-STAT 1 analyzer.

Analysis Time:

- ACT cartridge: to detection of end point - up to 1000 seconds (16.7 min.)
- PT/INR cartridge: to detection of end point – up to 300 seconds (5 min.)
- cTnI and BNP cartridges: 600 seconds (10 min.)
- CK-MB cartridge: 300 seconds (5 min.)
- Other cartridges: typically 130 to 200 seconds

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which measure ionized calcium	• Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Without anticoagulant • With balanced heparin anticoagulant	• Not recommended • Not recommended for blood gas analysis; arterial specimens are preferred.
Cartridges which perform ACT	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Not recommended
Cartridges which perform PT/ INR	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Recommended
Cartridges which perform Troponin I or CK-MB	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw.	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw. • Samples should not be used unless the blood collection tube is filled at least half full.	• Not recommended	• Not recommended

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which perform BNP	• With EDTA anticoagulant. • Syringes must be plastic.	• With EDTA anticoagulant. • Tubes must be plastic. • Samples should not be used unless the blood collection tube is filled at least half full.	• Not recommended	• Not recommended
All other cartridges	• Without anticoagulant • With lithium, sodium, or balanced heparin anticoagulant	• Without anticoagulant • With lithium or sodium heparin anticoagulant	• Without anticoagulant • With balanced heparin anticoagulant • With sodium or lithium heparin if labeled for the measurement of electrolytes	• While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred. • Not recommended for blood gas analysis; arterial specimens are preferred.

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, i-STAT recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

EXPECTED VALUES

Measured:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3

Measured: (cont.)

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115
pH		6.50 – 8.20	7.35 – 7.45	7.31 – 7.41
PCO_2	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
TCO_2 (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
PO_2	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	mmol/L mg/dL	0.25 – 2.50 1.0 – 10.0	1.12 – 1.32 4.5 – 5.3	1.12 – 1.32 4.5 – 5.3
Urea Nitrogen/BUN **Urea**	mg/dL mmol/L mg/dL g/L	3 – 140 1 – 50 6 – 300 0.06 – 3.00	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56
Hematocrit/Hct	%PCV Fraction	10 – 75 0.10 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / ^{Celite}ACT	seconds	50 – 1000	74 – 125 (Prewrm) 84 – 139 (Nonwrm)	74 – 125 (Prewrm) 84 – 139 (Nonwrm)
The range from 80 - 1000 seconds has been verified through method comparison studies.				
Kaolin Activated Clotting Time / ^{Kaolin}ACT	seconds	50 – 1000	74 – 137 (Prewrm) 82 – 152 (Nonwrm)	74 – 137 (Prewrm) 82 – 152 (Nonwrm)
The range from 77 - 1000 seconds has been verified through method comparison studies.				
Prothrombin Time / PT	INR	0.9 – 8.0		
Performance characteristics have not been established for INRs above 6.0.				
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.00		0.00 – 0.03* 0.00 – 0.08**
Performance characteristics have not been established for cTnI values above 35.00 ng/mL. ** Represents the 0 to 97.5% range of results.* *** Represents the 0 to 99% range of results.*				
Creatine Kinase MB / CK-MB	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5***
****Represents the 0 to 95% range of results.*				
B-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#
# Represents the 0 to 95% range of results.				

Calculated:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Hemoglobin/Hb	g/dL	3.4 – 25.5	12 – 17	12 – 17
	g/L	34 – 255	120 – 170	120 – 170
	mmol/L	2.1 – 15.8	7 – 11	7 – 11
TCO_2 (on all cartridges but the CHEM8+)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO_2	%	N/A	95 – 98	

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT $^{EC}8^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO_2
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO_2*
HCO_3*
BE*
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT 6+ (65µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{EC}4^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT $^{E}3^{+}$ (65µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT G (65µL)
Glucose (Glu)

i-STAT CREA (65µL)
Creatinine (Crea)

i-STAT $^{EG}7^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{EG}6^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT $^{G}3^{+}$ (95µL)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT $^{CG}4^{+}$ (95µL)
pH
PCO_2
PO_2
Lactate
TCO_2*
HCO_3*
BE*
sO_2*

*Calculated

i-STAT $^{CG}8^{+}$ (95µL)
Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT ^{Celite}ACT (40µL)
Celite® ACT

i-STAT ^{Kaolin}ACT (40µL)
Kaolin ACT

i-STAT PT/INR (20µL)
Prothrombin Time

i-STAT cTnI (17 µL)
Troponin I

i-STAT CK-MB (17µL)
Creatine Kinase MB

i-STAT BNP (17µL)
B-type Natriuretic Peptide

i-STAT CHEM8+ (95µL)
Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO_2
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

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