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Can Smartphone Technology Improve Patient Care?

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A thesis submitted for the degree of Master of Science (Research) to The University of Glasgow

> Research conducted in the Department of Surgery Royal Alexandra Hospital Paisley

> > July 2014

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Summary

Introduction

The emergence of evidenced-based medicine (EBM) has led to an ever-increasing plethora of guidelines to follow in order to best deliver this high standard of care. Compliance with such guidelines remains sub-optimal and novel methods of guideline dissemination have become popular.

Two patient safety areas of major morbidity and, potentially, mortality for patients are venous thromboembolism (VTE) and sepsis. Prophylaxis is available to minimise risk of VTE and early resuscitation bundles for sepsis, such as Sepsis Six have become widely promoted. Both of these areas have local guidelines that should be followed but compliance is poor. At the start of this period of research Sepsis Six had not yet been rolled-out in the surgical department at the RAH, Paisley. This provided a golden opportunity to look at guideline dissemination for one area, using a variety of modalities.

Smartphone technology has become ubiquitous in the past few years. The reasons for this are examined and the role for smartphones, and their applications (apps) in delivering assistance to doctors involved in front-line care is discussed. Potential regulatory issues are reviewed

Aims

The aims of this thesis are:

To assess prevalence of smartphones in the doctor population in a three-site hospital board area and these doctors' attitudes to smartphone technology for clinical uses.

To design and implement novel apps for thromboprophylaxis and Sepsis Six as a supplemental modality for guideline dissemination.

To assess the impact of the introduction of these apps on guideline compliance, including assessing for fatiguing of interest.

Materials and Methods

A SurveyMonkey questionnaire was emailed to all 456 doctors across the three hospitals in the GGC Clyde sector asking about smartphone ownership and usage and their views on the roles of apps for clinical care.

Native smartphone apps were designed and developed for both iPhone and android platforms for both VTE prophylaxis and Sepsis Six. Once these had been field-tested, and pre-app audit of current guideline compliance undertaken they were manually deployed to the surgical junior doctors at the Royal Alexandra Hospital, Paisley. Concurrently, while the Sepsis Six app was being developed the concept of Sepsis Six was rolled out using standard posters, presentations and tutorials.

After each modality introduction for both VTE prophylaxis and Sepsis Six audit was undertaken both early, and some time later, to try and assess possible fatiguing of interest and compliance.

Results

There was a good response to the survey, revealing very high smartphone ownership levels at virtually 90%, with 100% ownership in doctors in the early years of training. Further analysis revealed that doctors in the middle of their training, rather than at either extreme, were the most likely to use a smartphone for clinical care. Doctors preferentially own iPhones rather than Android based smartphones which is out-of-keeping with worldwide, and indeed UK statistics, strongly favouring Android.

VTE prophylaxis at baseline audit was better than expected. This meant it was difficult to show any improvement on addition of the smartphone app. There were transient improvements in the correct prescribing of anti-embolic stockings however but generally results suggested that the app simply wasn't being used.

Sepsis bundle compliance at baseline was poor but slowly improved over the seven audit points. There were no sharp improvements in Sepsis Six bundle compliance to suggest that either the traditional methods or the app were particularly good at improving guideline compliance.

Conclusions

Electronic patient care is fast becoming universal and smartphone/ tablet technology will be at the forefront of this. Despite disappointing results here, the use of an app for more complex patient-specific guidelines is likely to become increasingly popular, as long as accuracy of the information provided by the app can be guaranteed.

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CD containing Android Virtual Device (AVD) loaded with DVT Prophylaxis and Sepsis Six apps.

Printout of instructions for installing AVD in emulator environment (included on CD as readme.txt)

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Dedication

I would like to dedicate this thesis to my husband, Andy, for his unwavering support and belief in me throughout this whole project; also to Mhairi for all the patience it's possible for a 2-year old to muster while asking "Is Mama writing her thesis, again?". The next exciting chapter of our lives is about to start.

Author's Declaration

I declare that the work contained within this thesis is my own, except where indicated below:

While the logic and design of the smartphone apps was mine, the expertise to turn this into the reality of a working app is beyond my area of expertise. Dr Andrew McCulloch provided his computer knowledge to translate the logic for both apps into code for both android and iPhone, leading to the apps you see today.

Data collection for one cycle of the thromboprophylaxis audit and the final two cycles of Sepsis Six was carried out by the junior doctors in the surgical receiving unit at the Royal Alexandra Hospital, Paisley. This was, in the case of thromboprophylaxis, in order to fulfil their need to perform audit for their own training. In the case of the Sepsis Six data collection, these final two cycles took place after I had left the Royal Alexandra Hospital.

E. Fiona Leitch

Presentations and Publications

Poster Presentations

"Sepsis 6: Initial experience of introduction of a smartphone app" Leitch EF, McCulloch AC, Blackhall V, Renwick A, Finn PJ April 2014 ASGBI 2014, Harrogate

"Sepsis 6: Does the novelty wear off?" Leitch EF, McCulloch AC, Blackhall V, Renwick A, Finn PJ April 2014 ASGBI 2014, Harrogate

"Smartphone technology - a potential modality for improving patient safety" EF Leitch, AC McCulloch, A Renwick, M Vella, K Rooney, PJ Finn April 2013 International Forum on Quality & Safety in Healthcare, London

"21st century surgery, the emerging role of smartphones in direct patient care" EF Leitch, AC McCulloch, A Renwick, M Vella, PJ Finn May 2013 ASGBI 2013, Glasgow

Commercial Apps

NHS Education for Scotland: NHS Scotland NEWS and Sepsis Screening Tool https://itunes.apple.com/gb/app/nhs-scotland-news-sepsisscreening/id657497806

Glossary

AES	Anti-embolism Stockings
AMU	Acute Medical Unit
API	Application Programming Interface
арр	Application; a software programme running on a smartphone
BSG	British Society of Gastroenterology
COPD	Chronic Obstructive Pulmonary Disease
DVT	Deep Vein Thrombosis
EBM	Evidence Based Medicine
ED	Emergency Department (aka Accident & Emergency)
FBC	Full Blood Count
FDA	Food and Drug Administration
Geofencing	A location-based service that sends messages to smartphone users who enter a defined geographic area.
GGC	Greater Glasgow and Clyde Health Board
GP	General Practitioner
GPS	Global Positioning System
IDE	Integrated Development Environment

iOS The operating system used on Apple iPhone and iPad

- LMWH Low Molecular Weight Heparin
- MAU Medical Assessment Unit
- MHRA Medicines and Healthcare Products Regulatory Agency
- NEWS National Early Warning Score
- NICE National Institute for Health and Care Excellence
- PE Pulmonary Embolism
- RAH Royal Alexandra Hospital, Paisley, Scotland
- SDK Software Development Kit
- SIGN Scottish Intercollegiate Guideline Network
- SIRS Systemic Inflammatory Response Syndrome
- SPSP Scottish Patient Safety Programme
- VTE Venous Thromboembolism

1 Introduction

1.1 Background

1.1.1 Guidelines in Medicine and Surgery

Provenance and Types of Guidelines

Healthcare guidelines have been described as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (2)

Over the past few years there has been increasing awareness of the importance of Evidence-Based Medicine (EBM) in patient care. In order to best deliver EBM to patients, guidelines and protocols have been developed to facilitate this - the most well-known bodies (in the United Kingdom) developing these being the Scottish Intercollegiate Guidelines Network (SIGN) (1) and the National Institute for Health and Care Excellence (NICE) (3). SIGN guidelines are developed by interested and respected clinicians and associated healthcare professionals across Scotland. They are updated every 3-7 years and each time a full systematic review of the existing literature is undertaken by the specialist panel.

These national guidelines grade their recommendations based on the quality and strength of the evidence reviewed. Therefore grade "A" recommendations are not more important than grade "D" ones, merely that the weight of evidence behind grade "A" is greater (Appendix 3).

Methods of guideline dissemination and barriers to compliance

Guidelines require dissemination in order to be used. Traditionally this has been via hard-copy: posters, hand-outs, journals; moving towards pocket hand-books; then to virtual platforms such as inter-and intra-net accessibility and, latterly, to mobile device technology (4).

It is logical that well-implemented healthcare-related guidelines should improve quality of patient care provided, by minimising procedural variation and promoting the provision of evidenced-based best practice. However, despite best efforts, compliance with and uptake of guidelines remains patchy (5), (6).

There has been much interest in motivators and barriers to compliance. Various factors have been identified that are barriers to guideline compliance and adherence (7). These include systems ambiguity (8), behavioural factors (9), (10), (11), institutional and environmental factors (12), (7), and guideline-related factors (13).

Systematic review has shown it is possible to change healthcare provider behaviour, with median absolute percentage improvement of about 10% in process-of-care indicators (14). This does not seem to be dependent on the modality of guideline dissemination but perhaps more on having a clear consensus from all senior clinicians, good leadership, and direct motivation for adherence to a specific set of guidelines (15).

1.1.2 Thromboprophylaxis

Context

Thrombosis is the formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system. A clot that forms in a leg vein is called a Deep Vein Thrombosis (DVT). If it breaks free and begins to travel around the body is known as an embolus; an embolus lodging in the lung circulation it is called a pulmonary embolism (PE). In general this process is known as venous thrombo-embolism (VTE).

The risk of VTE is significantly increased in patients who are hospitalised after trauma, surgery or immobilising medical illness. Many of these patients have an asymptomatic DVT, but others can suffer considerable morbidity and/or mortality. Successive studies have shown figures as high as 10% of hospital deaths (1% of all admissions) attributable to PE in the UK (16), and in 2009 the English Department of Health stated that PE caused more than 25,000

preventable deaths per year in England and Wales (17). More recently there has been work published suggesting that the rate of autopsy detected PE has substantially decreased and may be now in the region of 2% of hospital deaths (18). There are two possible interpretations of this significant drop in PE detection: firstly that thromboprophylaxis really is efficacious; secondly that patients are being mobilised sooner and being discharged earlier - meaning VTE is becoming a post-discharge problem, particularly as the risk of VTE exists for up to 90 days after admission. Either way, the importance of thromboprophylaxis cannot be emphasised enough.

Even non-fatal PE has major consequences, potentially giving rise to significant cardio-respiratory embarrassment acutely, as well as chronic pulmonary hypertension (19). The problem is not limited to the embolic component of the clot. Significant morbidity can affect up to 30% of patients after lower limb DVT. This post-thrombotic leg syndrome manifests as chronic leg pain, swelling and dermatitis and is a consequence of damage to the valves of the deep veins. Chronic venous leg ulcers can also occur in 2-10% of patients in the years following their DVT (20), (21), (22).

The crux of the problem, however, is that potentially fatal PE often results from an asymptomatic DVT (23); indeed up to 80% of patients may have a clinically silent DVT. On this basis, thromboprophylaxis is indicated for the majority of acutely admitted surgical and medical patients.

Methods of Thromboprophylaxis

Thromboprophylaxis can be undertaken using both mechanical and pharmacological methods

Pharmacological thromboprophylaxis

In recent years low-molecular weight heparin (LMWH) has emerged as the mostused pharmacological method of preventing VTE. This is given as a single subcutaneous bolus of 0.2 - 0.4 millilitres (volume depending on exact dose and brand of LMWH), once daily. Previously unfractionated heparin (UFH) was utilised but this had the significant drawbacks of being a continuous infusion,

and the requirement for regular blood test monitoring and dose adjustments depending on the results of these coagulation studies. Many studies (including a number of meta-analyses) over the past twenty years have compared LMWH against UFH. These have almost universally endorsed LMWH in preference to UFH both in terms of efficacy, ease of administration and monitoring, and side-effect profile (24), (25), (26), (27), (28).

Mechanical thromboprophylaxis

This can be provided simply, in the ward environment, by applying graduated compression stockings (also known as anti-embolism stockings (AES)), or in the operating theatre environment or critical care area using intermittent pneumatic compression (IPC).

AES can be knee- or thigh-length and require dimensions of a patient's leg to be measured and the correct size chosen. This service can be provided by all grades of healthcare staff, once they have been appropriately trained. AES have been well validated in their usefulness and even have their own Cochrane Review confirming their importance in VTE prevention (29). They are cheap to supply and have few side-effects - however by their very nature, they are contraindicated in patients in whom it would be detrimental to apply pressure to their legs - such as those with peripheral neuropathy or leg deformities.

IPC uses an inflatable sleeve that is wrapped around the lower leg and secured with Velcro. Tubing connects the sleeve to an air pump that forces air into the sleeve chambers, putting pressure on the soft tissues and forcing blood out of the peripheral deep veins and back towards the heart. Shortly thereafter air pumping ceases, air is allowed to exit the sleeve chambers and the deep veins can fill again. The cycle then repeats.

Overall recommendations

Across Scotland, SIGN 122 is the Gold standard guideline for both thromboprophylaxis and also treatment of VTE. This recommends:

- all patients admitted to hospital or presenting acutely to hospital should be individually assessed for risk of VTE and bleeding. The risks and benefits of prophylaxis should be discussed with the patient.
- the use of a risk assessment method checklist is recommended for this purpose). (see Appendix 2)
- the assessment should be repeated regularly and at least every 48 hours.

SIGN 122 also gives a Grade A recommendation that "Patients undergoing abdominal surgery who are at risk due to the procedure or personal risk factors should receive thromboprophylaxis with mechanical methods unless contraindicated and either subcutaneous LMWH, unfractionated heparin or fondaparinux" (16).

SIGN 122 was developed from many sources across many surgical sub-specialties (30), (31) including the 2004 Cochrane Review of thromboprophylaxis in colorectal surgery. This Cochrane review demonstrated that graduated compression stockings together with heparin provide optimal prophylaxis (32).

Available Guidelines

SIGN 122 was distilled into a flow-chart for the acute medical wards in 2011. This was incorporated directly into the Acute Medical Admissions Proforma in 2011 in order that it became a routine part of admission review and prescribing, as indicated. It was, however, quite convoluted and unwieldy (Appendix 2). It also was not utilised by the surgical directorate who, until late 2013 did not have any form of Acute Surgical Admissions Proforma. Instead, the Greater Glasgow & Clyde Health Board (GGC) thromboprophylaxis guidelines were available in the GGC Prescribing Handbook (updated yearly and given to all doctors at hospital induction as a hard copy), web-based guidelines on the intranet, and posters in the wards' doctors' rooms.

Guideline Compliance

Successive bi-annual audit cycles looking at thromboprophylaxis at RAH (in-house data, not externally presented or published) showed compliance of only 75% for this process, using the existing guideline modalities. These local results correlate with national recognition of incomplete implementation of the thromboprophylaxis recommendations (33), (34). Locally, barriers to use of the current modalities were reported as being due to inability to access the guidelines electronically due to lack of computers and the Handbook being to large to carry around and not being available in the most current version in clinical areas.

A review of the literature conducted by SIGN concluded that a passive approach to dissemination of these VTE guidelines was inadequate and an active approach was required to improve compliance (35). Novel approaches, such as electronic alerts were shown to improve guideline compliance and reduce the burden of VTE in a randomised study (36).

The summary recommendation from SIGN 122 to improve thromboprophylaxis guideline compliance is that "hospitals should adopt approaches which are likely to increase compliance with thromboprophylaxis guidelines and improve patient outcomes".

1.1.3 **Sepsis**

Pathophysiology of Sepsis

Sepsis results from activation of the systemic inflammatory response by infection (see Appendix 5). It was first defined in 1991, when the cascade from systemic inflammatory response syndrome (SIRS) to sepsis, severe sepsis and ultimately septic shock was first outlined at the American College of Chest Physicians /Society of Critical Care Medicine Consensus Conference (37). This strict definition of sepsis was revisited again in 2001 by these groups and confirmed as two or more features of SIRS plus infection (either confirmed or strongly suspected) (38), with infection being defined as "a pathological process caused by invasion of normally sterile tissue or fluid or body cavity by pathogenic or potentially pathogenic micro-organisms" (38).

Global Context

In the European Union it has been estimated that there are over 90 cases of severe sepsis per 100,000 people; in comparison, estimates are that only 58 people are affected by breast cancer per 100,000 (39). Mortality for severe sepsis is approximately 35% in developed countries, meaning the healthcare burden is significant and may result in up to 64,000 deaths yearly in the UK (40). Despite all of this, sepsis is frequently overlooked and its consequences underestimated. Recognised early, and with timely intervention, sepsis need not be fatal; however, left unchecked, the sepsis cascade can rapidly spiral towards septic shock. The longer the patient is untreated or sub-optimally treated, the slimmer the chance of survival - mortality from sepsis is estimated at 14%, with severe sepsis this rises to 44% and reaches 58% if septic shock is present.

Surviving Sepsis Campaign

In 2003, key members of the sepsis working parties from 1991 and 2001 met again and the "Surviving Sepsis" campaign was born (41). This aimed to identify and deliver a bundle of care to critically ill patients before they left the Emergency Department. This was slow to be implemented across the UK but updated guidelines published in 2008 were seized upon and strongly promoted nationwide There were two arms to the 2008 guidelines: a 6-hour (42). resuscitation bundle, aiming to reduce sepsis-induced hypoperfusion (Appendix 6), and a 24-hour "early goal-directed therapy" (EGDT) bundle, mainly involving interventions and monitoring in the intensive care setting, based on the work by Rivers et al (43). These EGDT bundles were all based on sound evidence but were over-complicated, quite labour-intensive to deliver and required specialist expertise for some tasks. Overall, it was difficult to achieve EGDT bundle compliance in an average non-specialist department (44). In a specialised unit, however, evaluation of implementation of the 6-hour resuscitation bundle did

show improvement in 28-day mortality, but uptake of and compliance with even these relatively straight-forward guidelines remained poor (45).

It was quickly appreciated that a different approach was needed - to make a rapid, reproducible management bundle that would be easy accessible to the inexperienced junior doctor on the front line. The existing sepsis guidelines were simplified and condensed, concentrating on the basics - leading to the development of Sepsis Six (46). Patient safety bodies have been quick to back this movement and it is now a key tenet of the Scottish Patient Safety Programme (SPSP) (47) with Government support and endorsement.

Identification of Sepsis

The pathway to a patient being identified as being septic is usually as follows:

- National Early Warning Score (NEWS) of >4 (Appendix 7) noted during observations taken by nursing staff
- If infection documented or likely, assessed for SIRS (Appendix 5)
- If SIRS ≥ 2 , sepsis is likely

On identification of a patient with sepsis, the following package Sepsis Six package should be delivered, ideally within one hour:

- Oxygen to achieve Saturations >94%, \leq 98% (Caution COPD)
- IV fluids (≥500ml/hr or 20ml/kg immediately, if organ dysfunction)
- Blood Cultures
- Intravenous antibiotics as per local guidelines
- Measure Lactate and FBC
- Accurate urine output and catheterise if organ dysfunction

Local Context

Sepsis Six was introduced across GGC from January 2012. At RAH this was initially just in the medical directorate for acute medical admissions. By August 2012 this had been firmly established and shown to be of clinical benefit but had yet to be rolled-out across the surgical directorate. This provided the perfect opportunity to look at the introduction of a new set of guidelines right from the outset (Time Zero).

Acute medical receiving at RAH is spearheaded by a team of Acute Physicians who support all SPSP activities but each have a mandate for one area. The introduction of Sepsis Six was instigated and managed by a newly appointed Acute Physician. He started by concentrating on implementing Sepsis Six in the Medical Assessment Unit (MAU) and the Acute Medical Unit (AMU). However, these units functioned in very distinct ways from each other.

Medical Assessment Unit

The MAU was open from 10:00-22:00hrs seven days a week, had a maximum capacity of eleven patients and had a higher than normal staffing ratio of senior nurses and several healthcare assistants. They took patients who had been referred by their General Practitioners (GPs). On arrival a patient was put straight into a cubicle, observations taken within five minutes and the history quickly re-visited. If the NEWS score was >5 and the senior nurse thought the patient had an infective pathology, the patient was scored for SIRS and the Sepsis Six pathway was triggered - a Sepsis Six sticker (Appendix 10) was placed in the patient's case sheet and an egg-timer was activated with a one-hour countdown. The Sepsis Six trolley was brought to the patient's cubicle: this contained all equipment required to deliver Sepsis Six. An intravenous cannula was placed immediately and blood withdrawn for standard bloods, blood cultures and a venous blood gas (for a lactate level). A 500ml bag of saline or Hartmann's solution was then connected up and run in over roughly thirty minutes. Simultaneously, oxygen was provided to the patient, if required, to ensure oxygen saturations were maintained at $\geq 94\%$. The nurse then had the patient reviewed by a junior doctor (who was resident in the MAU) who

confirmed (or refuted) the diagnosis of likely sepsis and, after determining the most likely source of infection, prescribed a first dose of intravenous antibiotics. This took merely a few minutes to be made up and was administered through the cannula. Bottles or shells were provided for the patient to pass urine into to measure the urine output non-invasively. If the patient's physiology suggested great cause for concern, a urinary catheter was placed into the bladder instead. In September 2012 the average time for this entire process was fifty-seven minutes and had fallen further to just twenty minutes by August 2013; well-within the recommended one hour for delivery of the Sepsis Six package.

Acute Medical Unit

The AMU was, in contrast, a standard medical receiving unit. It operated twenty-four hours a day and received all emergency admissions that came via the Emergency Department (ED), GP referrals outwith the hours operated by the MAU and GP referrals when the MAU was full. While it was appropriately staffed, it was a busy ward with high turnover of patients and many ill patients requiring a high level of nursing input. If a patient triggered a NEWS score of greater than 4 and infection thought likely, the Sepsis Six alert was triggered in the same way as in MAU. While an identical set of events, in the same speedy fashion, should have taken place as in MAU, this did not occur every time. Staff preoccupation (both nursing and medical) with other ill patients sometimes competed with new Sepsis Six triggering patients.

It was the AMU set-up that was most similar to that of the acute surgical receiving ward at RAH.

There were, however, a number of motivational strategies that the Acute Physician employed to keep his team focussed on delivering the Sepsis Six package in AMU within the recommended hour. These included a wallchart of fastest implementers per month, with a small prize for the fastest; daily peptalks to the AMU team and positive feedback to those completing within the hour. He also undertook weekly review of all patients who had triggered a NEWS of 4 or more to see if they should have received the Sepsis Six package and, if

they didn't, why this didn't happen and what could be done to improve the process.

Sepsis Six in Surgery

As of August 2012 the pathway for a surgical patient being admitted as an emergency was this:

All patients (GP and ED referrals) came via the ED, and were frequently seen in that department. When a bed became available, they were admitted to the acute surgical receiving unit. If they were thought to be septic, they had care implemented as directed by the admitting team. This usually consisted of intravenous fluids, antibiotics, blood cultures and possibly oxygen ± urinary output monitoring. Lactate was rarely measured.

There was definite scope to improve on the care being provided to patients with surgical sepsis and this coincided with the time that the Acute Physicians were keen to roll-out Sepsis Six to the surgical directorate.

1.2 Smartphone Technology

1.2.1 Smartphone Evolution and Ownership Trends

Mobile telephones have progressively evolved in terms of computing power and the functionality available as processor speed, power consumption, memory costs and display technology have all improved. The most significant telephonic innovation in recent time has been the smartphone. A smartphone is defined as "a mobile phone that includes advanced functionality beyond making phone calls and sending text messages" (48). Although the first device that could be regarded as a smartphone was released in 1994, functionality on early devices was limited. Initially these devices simply integrated Personal Digital Assistant (PDA) technology, including email, into a mobile telephone. Rapid evolution has resulted in today's smartphone allowing the user to also take and display photos, play videos, surf the Web and use third-party applications (apps). This ability to

run apps provides limitless functionality and is one of the main drivers for purchase.

There are currently four main platforms in the smartphone market: iPhone, Android, Blackberry and Windows. Of these, Blackberry was first to market in 1999 and enjoyed market dominance for many years, especially in the corporate sector. In terms of global sales, it has been very much eclipsed by the other platforms in recent years. One of the main reasons for this may be touch-screen technology, which was absent in most early smartphones. The first iPhone (Apple Inc, Cupertino, CA, USA) was released in 2007 and was massively successful, selling 6.1 million units in the first year. Most would regard this as the start of the smartphone revolution. Third party app support came in 2008 with Apple's iOS version 2 and the launch of the Apple App Store. This coincided with the release of the HTC Dream, the first smartphone using Android. Windows Phone, the consumer-targeted successor to the enterprise-orientated Windows Mobile, launched in 2010 with Windows Phone 7. All platforms and handsets have been through many incarnations, with functionality substantially increasing as a result.

Worldwide, in August 2012, Android was the most popular platform, generally having 60-65% market share to iPhone's 20-35%; this was true for the USA, UK and China. By May 2014, Android's market share had risen further to 83% in China (at the expense of iOS and all minority players, such as Windows), stayed static in the USA and UK (but virtually all UK Blackberry users had transferred to iOS, increasing Apple's market share) (49). Older platforms such as Symbian have almost no presence outwith developing economies.

It is estimated that there are currently more than 1 billion smartphones and tablets globally, with this number rapidly rising year-on-year. While the USA has been the market leader for many years, trends are changing and in 2012 the Chinese become the dominant smartphone market by volume, overtaking them (50). Europe has previously also lagged behind but growth in smartphone ownership here too continues to flourish.

Smartphone ownership among doctors in Europe rose sharply between 2010 and 2012. In 2010 EPG Health Media (Europe) Ltd conducted a survey of 240 doctors in Europe and 100 doctors in the USA. They then conducted a further survey on 2012 to assess interval change. While smartphone ownership has increased across both continents, it rose from 81 to 91% in the USA but from 44 to 81% in Europe; a significantly greater net increase in Europe.

A 2011 survey of medical students and Foundation doctors in one English health region revealed that almost 75% of their respondents owned a smartphone, with 68% of them owning an iPhone and 17% owning an Android-based smartphone (51). This is supported by a survey of iPhone usage in anaesthetists in 2010 (52), a survey of doctors in the US in 2011 (53), and London junior doctors in 2011 (54). It is therefore obvious that for any medically targeted smartphone app to be successful it must be available for both Android and iPhone. Given the relatively saturated smartphone market, this situation is unlikely to change significantly in the medium term.

1.2.2 3rd Party Applications

An "app" is a software application designed to run on mobile devices, such as smartphones and tablet computers. They can be downloaded via App Stores, which are usually specific to the operating system of the mobile device, such as the Apple App Store, Google Play (Android), Windows Phone Store, and BlackBerry App World. Consumers own varying numbers of apps but it is estimated that most have between twenty to thirty at any point in time, the most utilised of these being social media apps and games. A well-recognised phrase of the last few years is "there's an app for that" - recognising that smartphone and app technology have permeated every aspect of life in the 21st century.

1.2.3 Mobile Health Technology

The Global Observatory for eHealth (GOe) within the World Health Organization (WHO) defines mobile health (mHealth) as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices,

personal digital assistants (PDAs), and other wireless devices". mHealth utilises all functions of mobile technology: from the use of commonplace features such as voicemail and text messaging, to those functions involving wireless, Bluetooth and global positioning systems (GPS) technology.

Smartphone technology has galvanised the advances in mHealth. The 3G and wireless capability of smartphones allows individuals to access information and advice from anywhere at any time. They provide benefits over and above laptop computers - not just by way of their pocket-sized and thereby inherently portable nature - but also importantly utilising the GPS, sensor and camera functions - such as to provide the potential for teleconferencing or teleradiology at any point of the day or night.

Over the past five years the smartphone has been recognised as having revolutionary potential for the practice of medicine (55), (56), (57). Not only could the smartphone replace a pager, mobile telephone, PDA, pocket textbook and diary - all while being lightweight and very portable - it had mobile internet that could allow the viewing of education videos via youtube.com and mobile viewing of podcasts.

Much study has been undertaken into healthcare professionals' acceptance of and uptake of smartphone technology in the workplace (58), (59). Chen and Putzer's work in particular has shown that compatibility with existing technology in the workplace and knowing the device is secure and the functionality safe, were major predictors of adoption of smartphone technology. Pre-existing comfort and familiarity with smartphone technology is another positive predictor and this is naturally associated with seniority: older doctors and/or those less comfortable with newer technologies may be disadvantaged by these rapid advances in mHealth (60).

1.2.4 Healthcare Apps

Healthcare apps are now ubiquitous and come in myriad forms. They have tended to be targeted at either the healthcare professional or the healthcare consumer (patient), with by far the larger number of apps targeted at patients. By mid-2013 there were more than 23,000 healthcare Apps available for download, with an estimated 1,000 new healthcare apps being released every month (61). Of the currently available apps, over 7,000 were specifically designed for healthcare professionals; the remaining 16,000 were for patients. Those aimed at healthcare professionals had variable functionality, provenance and reliability and varied hugely in their aims - from simply being mobile guidelines, to performing calculations based on patient data, thereby providing clinical management advice.

Medical reference apps such as Epocrates (free, regularly updated pharmacologic reference), Medscape (free regularly updated diagnostic and management reference texts) and DynaMed (full medical reference app from EBSCO Publishing) are very popular and respected apps, used by doctors across the US and UK. These apps, however, while easily navigable, are not particularly interactive. Apps do exist that allow inputting of patient variables in order to generate a patient-specific recommendation. This smartphone-specific interactivity makes smartphones distinct from their traditional cousins - hardcopy textbooks. However, the obverse of this benefit is its risk: there is real potential for unintended outcomes. This is why app development has become such a minefield.

Apps have been evaluated for their potential benefit on performance and care provided, in a number of ways. These range from performance of advanced life support using the iResus app (62), to guiding students through prescribing emergency drug infusions to a critically ill child (63), to teaching neonatal intubation (64). Each of these studies concluded that smartphone technology conferred advantage over traditional teaching modalities, and should be explored further. Conversely, use of an app for assessment and management of stroke (65) was found to be slower than traditional paper methods, and an app for the general public to aid cardiopulmonary resuscitation again proved a

slower modality, but interestingly more accurate (66). An Australian group have suggested that these mixed findings may show that apps are more suitable for some tasks than others (67).

One of the most pressing concerns with the unprecedentedly rapid worldwide embrace of healthcare apps has been lack of consistent quality within them and unclear authorship and provenance (68), (69), (70), (71). Absence of declaration of medical professional involvement in content of apps has been noted and the need for doctors and other healthcare professionals have an important role to play in guiding app development has been widely expressed (72). If patients and healthcare professionals alike start to become reliant on apps to aid provision of care, it is paramount to ensure that only apps of the highest quality, reliability and safety are marketed.

1.2.5 Regulation

App regulation remains a minefield as regulation is only required for those Apps that are classified as a medical device. The US Food and Drug Administration (FDA) began drafting guidance on Apps several years ago, producing the first draft guidance in July 2011 (73).

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) had been following suit and by January 2013 had approved its first App, *Mersey Burns* (a tool to calculate burn area percentages and fluid requirements) (74).

In March 2014 the MHRA released a position statement (75). They compiled a list of words and phrases that they felt were associated with an App being a medical device :

• amplify, analysis, interpret, alarms, calculates, controls, converts, detects, diagnose, measures, monitors

There were certain on-going grey areas: "Software that provides general information but does not provide personalised advice, although it may be targeted to a particular user group, is unlikely to be considered a medical

device". However, "decision support or decision making software that applies some form of automated reasoning, such as a simple calculation, a decision support algorithm or a more complex series of calculations, e.g. dose calculations, symptom tracking, clinicians guides. These are the types of software most likely to fall within the scope of the medical devices directives."

If it is determined that an App meets the definition of a medical device, it requires to be regulated by MHRA as such. All medical devices need to be classified as they range from patient skin dressings (Class I, low risk) to implantable devices (Class III, high risk), and everything in between. Following classification, conformity of the device needs to be assessed - where manufacturers demonstrate that their devices meet the essential requirements of the Medical Devices Directive, by Class.

However, prior to 19/03/2014, and during the period of this research, the MHRA guidelines were simply for guidance, leaving it open to the developer's interpretation on what an App did and the level of patient risk associated with it as to whether it should be classified as a device or not.

The NHS itself is also attempting a degree of regulation and oversight over healthcare apps. In March 2013 the NHS England's Commissioning Board launched the Health Apps Library because they are "committed to improving outcomes for patients through the use of technology." All apps showcased on this website have been approved by a "clinical assurance team," of doctors and nurses and must come from "trusted sources of information, such as NHS Choices," (http://apps.nhs.uk/). Currently these apps in the NHS Apps Library are for healthcare consumers rather than providers, but emphasise the important contribution that apps now make the healthcare and how much smartphone technology has been embraced in recent years.

Overall, the feeling seems to be that app regulation is a positive move (76), but concerns from the US Congress that it may stifle mHealth innovation are acknowledged (77). Assuming app regulation is conducted with clarity and transparency, it is likely only be beneficial to patient care, rather than a hindrance.

It's not only app regulation for quality assurance that is a potential minefield, data protection and patient confidentiality must be considered. The Data Protection Act (1998) (78) details the principles of "good information handling" as well as the rights of a patient to know how their personal data is handled and the responsibilities of the individuals and organisations who utilise and process this data. The Information Commissioner's Office (ICO) has issued the Bring Your Own Device (BYOD) document in an attempt to clarify the responsibilities of the data controller and individuals if an organisation permits and/or individual healthcare professionals utilise patient data on personal devices BYOD (79).

1.2.6 Existing Guideline Apps

Thromboprophylaxis

Prior to the start of this research, there were two apps available on the Apple App Store relating to VTE prophylaxis.

- Thrombosis Guidelines app (London, Guy's and St Thomas')
 - o first released 14/7/11
 - This utilises the NICE guidelines for VTE treatment and prophylaxis
 (80)
 - Requires reference to several other pages within the main app to check for contraindications to AES and LMWH. Minimally interactive.
- Sanofi Clexane App
 - $\circ~$ Pre-dated the start of this research in August 2012
 - o Only available in French
 - \circ No longer available via the Apple App Store

SIGN 122 via SIGN app

Sepsis Six

At the time of starting this body of research, in August 2012, no Sepsis Six apps were available in the app stores for any platform.

The first Sepsis Six app became available to download in December 2012. This was marketed by the "Survive Sepsis" campaign and contained an interactive sepsis screening tool and an interactive "tick-sheet" for documenting completion of each element of the bundle. It also guided the user through the escalating cascade of severity of sepsis, ensuring that organ function was evaluated. Initial versions were not particularly user-friendly and updates during 2013 have improved on the original app.

A further Sepsis Six app was launched in January 2013 but was non-interactive and had limited functionality. Later that year the official NHS Scotland app was released in June 2013. There was significant collaboration at a design level between this project and the team developing that app.

Summary of available apps

No suitable apps were available at the start of this research project; hence novel apps for both thromboprophylaxis and Sepsis Six were designed and evaluated.

1.3 Hypothesis

Compliance with simple guidelines is likely to be unaffected by the introduction of an app but that an app for more complex guidelines may show an improvement in compliance.

Protocol-compliance fatigue is recognised as an issue, particularly in the closelyregulated world of today. Even if guideline compliance is improved with a novel modality, fatiguing of interest is likely with time
1.4 Aims

To assess prevalence of smartphones in the doctor population in a three-site hospital board area and these doctors' attitudes to smartphone technology for clinical uses.

To design and implement novel apps for thromboprophylaxis and Sepsis Six as a supplemental modality for guideline dissemination.

To assess the impact of the introduction of these apps on guideline compliance, including assessing for fatiguing of interest.

2 Materials and Methods

2.1 SurveyMonkey Questionnaire

2.1.1 Description of Service

The survey was created using the SurveyMonkey online tool (https://www.surveymonkey.com). SurveyMonkey is an extremely popular piece of online survey software. It allows customisation of survey questions, a link to the questionnaire to be created and then the questionnaire to be distributed via a chosen mailing list, with collection of responses in real time. Depending on requirements, a variety of options and packages are available, ranging from the free "Basic" package to the £779/year "Platinum" package.

The SurveyMonkey "Select" package was purchased at £24/month for a total of four months. This gave access to unlimited questions, up to 1000 responses per month, real-time results, skip-logic and downloadable and exportable results.

2.1.2 Identification of Recipients

It was decided that a suitably large subject population would be the cohort of doctors working in the Clyde sector of the Greater Glasgow & Clyde Health Board in August and September 2012. This included all doctors of all grades and specialties employed in secondary care across Clyde.

Email addresses for all doctors working across the three Clyde sites (Royal Alexandra Hospital, Paisley (RAH), Inverclyde Royal Hospital, Greenock (IRH) and Vale of Leven Hospital, Alexandria (VoL)) were obtained from the postgraduate administrators for RAH/VoL and IRH. In addition all departments were approached via the secretaries to see if any doctors had recently been appointed who were not on the lists received from the postgraduate administrators. This did indeed yield a further twenty doctors.

2.1.3 Survey Details

Information requested in the SurveyMonkey questionnaire included demographics, Smartphone ownership, Smartphone usage, App ownership and usage and feelings towards specific locally applicable guideline-based Apps. Full details of the questions posed and logic flow through the survey is listed in Appendix 1.

Emails inviting participation in this survey were sent on 23/08/2012 to all Consultants, Associate Specialists, Specialty Doctors, Specialty and Core Trainees (ST and CT), General Practice (GP) trainees, Locum Appointment for Training (LAT) / Locum Appointment for Service (LAS) doctors and first and second year Foundation Year (FY1 and 2) doctors across all specialties. The email included details of the research being undertaken, a brief resumé of the principal researcher and a link to the questionnaire on the SurveyMonkey website.

The first few respondents were very helpful as this identified hitherto unpredicted responses to the survey questions. Some smaller / niche specialties had not been included and there were glitches with the freetext boxes. Thankfully the survey link had been emailed out late at night and after a brief email correspondence with the first respondent, the survey was amended in real-time and all subsequent respondents able to access the fully satisfactory survey.

Two weeks after the initial email, on 04/09/2012, a follow-up email invitation was sent to all identified doctors. Three weeks following this, the survey was closed.

2.2 Ethics and Clinical Effectiveness

Ethical approval was applied for on 22/08/2012 to the Glasgow Research and Ethic Committee, via Dr Maureen Travers, Research Coordinator in the R&D Management Office at the Western Infirmary in Glasgow. The REC response on 02/11/2012 was that basically this was a comparison of audits, the development

and research aspect being in relation to the Apps and, as such, would not have to be dealt with by R&D.

The Clinical Effectiveness department for Greater Glasgow and Clyde (GGC) were notified of the project as they require oversight of all projects conducted in GGC.

2.3 Intellectual Property

Intellectual property (IP) rights grant creators or owners of a work certain controls over its use. The University of Glasgow does not automatically own intellectual property developed by a student, who will generally own the IP they develop during the course of their studies.

On this basis, the IP of the Apps themselves remained with the author. The actual guidelines used were widely available and reproduced in multiple formats already. Consent was applied for from the relevant local committees for Thromboprophylaxis and Sepsis, to use the definitive local guidelines for the Apps and this was freely granted.

2.4 App Design

2.4.1 Design Process

For both the DVT prophylaxis and Sepsis Six Apps an initial review was made of relevant apps currently available in each area for both the iPhone and Android platforms. An assessment was made as to the suitability of any Apps identified for use in this project. No apps identified met the specific requirements of this MSc project either in terms of functionality or user experience. This was kept under review at three monthly intervals.

Following review and consolidation of local and national guidelines in each area, a basic programme requirement was created to outline what the app should achieve and how this should be accomplished. Detailed programme flow and logic was designed and tested on paper to ensure that the resulting app would replicate the results of following existing forms of guideline delivery. This was refined to exploit the advantages of a smartphone platform and provide additional benefit over simply reproducing a piece of paper.

2.4.2 Governance

Advice was sought from the lead pharmacist for surgery on the legalities and potential repercussions of incorrect prescribing resulting directly from using one of the apps developed for this thesis. His concerns were as follows:

- Robust governance needed as the guidelines subtly, but not infrequently, changed in the GGC Handbook.
- The fact that a source of reference was being promoted other than those prescribed by hospital management was of concern. While junior doctors were perfectly able to download (and use) any apps they liked from an app store, promotion as part of this work changed responsibility.
- Responsibility for any errors would likely be shared between Author and User.
- Consider directing the User to local guidance for extremes of weight, as this varied across health boards at the time of conducting the study.
- Consider liaising with the Lead Haematologist and Thrombosis Committee in order to market the thromboprophylaxis app as endorsed by GGC.

2.4.3 Development Tools

Both iOS and Android applications were intentionally developed by Dr Andrew M^cCulloch as native apps with no reliance on internet access rather than as web based apps. This was due to the lack of Wi-Fi available in the hospital and limited internet access generally due to "black spots". iOS apps were developed using the latest version of Xcode on an Apple Mac computer. Android apps were developed using the Eclipse IDE with the Android SDK installed.

Although cross development tools exist that allow applications to be developed for both iOS and Android from a single codebase, there are limitations in this approach. As the size of the apps was anticipated to be small, it was decided to develop native apps for both platforms. Apps were initially developed for iOS with iterative refinements before a final version was ported to Android.

iOS

Xcode was used to develop the iOS application. This is an Integrated Development Environment (IDE) provided free of charge by Apple and is exclusive to OS X, the operating system on Apple Mac computers. A paid developer license is required in order to sign the application for deployment onto physical devices. The Xcode IDE comes with a simulator that allows testing of apps on currently supported hardware. Multiple versions of iOS can also be tested, provided these have already been installed on the development machine. Typically only the most recent version of iOS is available for installation, however. The Apple development documentation clearly indicates deprecated API calls and the earliest version of the operating system that supported functions are available on.

In part due to Apple's tight integration of software and hardware, there is rapid uptake of software updates. The majority of users will be running the latest major version, if not the latest point release, within a short period of its release. This greatly simplifies development of apps for iOS devices. iOS version 6 was released on September 19th 2012. Uptake of this in the last 11 days of September is shown in Figure 2-1 and in Figure 2-2 it can be seen that 60% of iPhones were running iOS6 in this period (81).

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Figure 2-1 - iOS 6 uptake after release



Figure 2-2 - iOS version distribution for iPhone October 2012

Android

The Eclipse IDE is developed and provided free of charge by the Eclipse Foundation. It is available for OS X, Windows and Linux operating systems and supports development for various languages and environments. Specific plugins

for the Android platform are provided free of charge by Google. This includes a simulator that can emulate the far more diverse range of devices running Android. These can be configured with any standard version of Android released to date. A number of device manufacturers, including Sony, customise the version of Android they deploy, which makes testing for all possible configurations more challenging. Unlike Apple, no fee or license is required to deploy apps to physical devices. A one time registration fee is required in order to distribute via the Google Play store.

The range of OS versions in current use with Android is far greater than with iOS due to the variety of device manufacturers involved and their integration with mobile phone operators. This is seen in Figure 2-3 which shows data from the Android developers' site maintained by Google. More than 50% of devices in November 2012 were running the Gingerbread version of the OS at API level 10, first released in February 2011. Version 4.1, Jellybean, has achieved only 2.7% penetrance since being released in July 2012.



Figure 2-3 - Android version distribution November 2012

2.4.4 Testing and Deployment

Given the timescales and potential regulatory hurdles involved, deployment of the apps to users was done manually, as a pilot, rather than via either the Apple App Store or Google Play. This was achieved by loading the source code for both versions of the app onto an Apple Mac with both Xcode and Eclipse installed and deploying directly onto users smartphones. Testing was initially carried out by loading the app onto a single iPad and taking notes whilst supervisors and select colleagues used the app. Once all were satisfied that the app was fit for purpose in terms of usability and its logic was robust and accurate, the app was ported from iOS to Android and then deployed onto subjects' smartphones. Any bugs or refinements required at this stage were fed back before the apps were updated and redeployed.

2.4.5 DVT App

First the DVT app asks the user to select the correct specialty before proceeding to highlight any risk factors for DVT in a scrolling list.

Carrier 🗢 1:56 PM	Carrier रु 1:57 PM 💼	Carrier 🗢 1:57 PM 💼
DVT Prophylaxis 👔	Kent Back DVT Risk Factors	K Back
Begin assessing your patient's DVT risk by	Acute surgical admissions with inflammatory or intra-abdominal condition	
selecting medical specialty and continue by selecting risk factors	Surgical procedure duration > 90 minutes or 60 minutes if lower limb	2 risk factors for DVT identified
	Critical care admission	Now assess the risk of bleeding
	Dehydration	
Madiaal Surgiaal Obstatria	Age >60 years	
Medical Surgical Obsterric	Obesity (BMI >30)	
	Active cancer or cancer treatment	
Begin	Known thrombo <mark>Next</mark>	Next

This is then repeated for bleeding risks and any contraindications to antiembolism stockings.



Renal function and weight are then input before a final screen gives advice on the appropriate dose of low molecular weight heparin. The ability to choose which low molecular weight heparin is used is provided.



On pressing the "Restart" button on the Result screen, the user is taken back to the DVT Prophylaxis home screen. This resets all values to the default ones as they are most commonly entered and minimises risk of using unusual and abnormal values left in from the last calculation.

2.4.6 Sepsis Six App

Following an initial start screen the user is asked to indicate what signs of systemic inflammation are present. If 2 or more are present, a red and yellow

'Sepsis' sign begins to flash at the bottom of the screen. Information pop-ups are provided to clarify the definition of altered mental state and that elevated glucose beyond 7.7mmol/L is primarily of relevance in non-diabetics.



Assuming that the criteria for sepsis are met, the user is taken on to the Sepsis Six screen where all 6 elements are listed. Clicking on one provides more detail and they can be scrolled through individually. The antibiotic screen had been configured to provide the antimicrobial prescribing guidance for Greater Glasgow & Clyde. The app has been programmed with an obsolescence date for these guidelines after which they will not be shown unless the app is updated. Should such an app enter routine use, subject to regulatory approval, these guidelines could be updated over the air. It would also be possible to provide antibiotic guidance specific to their location. This would require the cooperation of multiple health boards and could use GPS location and geofencing to ensure the correct antibiotic guidelines are provided.

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The next step in the app asks the user to assess for evidence of organ dysfunction. Information pop-ups are used to provide definitions of the various parameters such as hypotension and acidosis while keeping the interface uncluttered. If organ dysfunction is present the user now checks for septic shock.



Should septic shock be present the user is provided with a summary of the 6 hour resuscitation bundle defined by the Surviving Sepsis Campaign. The user is also encouraged to escalate the level of care the patient is receiving at this point. The end screen is a common exit point where the steps already taken are reiterated and the user is encouraged to regularly reassess the patient. This helps to remind the user that Sepsis Six is the start of a treatment pathway, not a complete treatment in itself.

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2.5 Audit of Guideline Compliance

2.5.1 Thromboprophylaxis

Baseline

An initial audit of current practice was carried out over a two week period in December 2012 in both the acute surgical receiving ward and the main general surgical ward. A snapshot of all patients in the receiving ward was conducted at the start of this cycle, as well as a snapshot of all patients in the general ward, ensuring any patients decanted from one to the other were omitted. The following week a further snapshot of the receiving ward was conducted, this timescale having allowed virtually all patients from the previous week's intake to have been discharged or moved on to other wards.

The existing audit datasheet in use at RAH prior to this body of research was produced to collect the data required by SPSP for their on-going national audit :

Ward	Room	CHI	Consultant	Clexane (mg)	eGFR <30	Platelets (150-400)	Contraindication	Reduced Dose	Ideal Dose

Unfortunately this proforma provided little useful analysable information and a new one was designed to collect more useful data.

The data collected about thromboprophylaxis prescribing and patient risk factors was as follows:

- Ward, Date of admission, Elective vs. Emergency admission, Reason for admission
- Demographics Age, Gender, Weight (kg), Height (m)
- Laboratory results eGFR, Platelets
- Medical/family history Thrombophilia? Previous VTE personally, or in first degree family member? Current significant major medical condition? Hormone treatment? Cancer in last 2 years, or active cancer?
- Bleeding risks Active bleeding? Already anticoagulated?
- Contraindications to AES PVD, Leg neuropathy, leg/foot ulcers, "tissue paper skin" of legs, major limb deformity, cellulitis/massive oedema
- Details regarding prescribing Was LMWH prescribed? Type? Dose? What was the correct dose? Was this the dose prescribed? Were AES prescribed? Were AES being worn? Should AES have been prescribed?
- Did the researcher need to change a prescription for safety? If so, how?

All data was collected as discretely as possible to try and maintain a singleblinded study. The purpose of this was to minimise contamination of the data at each audit cycle, in order to be able to attribute change to a specific intervention.

The elements of the dataset were collected from a variety of sources: the electronic Patient Management System (TrakCare) provided details of exact date and time of the patient departing the Emergency Department (ED). This was

used as a surrogate for arrival in the receiving ward as the time recorded in the medical and nursing notes for admission was on first contact with the patient during clerking-in. This provided an erroneously tardy time if the ward was busy. The nursing clerk-in and notes provided details of the type of admission, some details relating to the reason for admission (although this was sometimes a little simplistic), demographics and vital statistics for the patient, as well as documentation on skin quality and contraindications for AES. The medical notes were scrutinised for precise diagnosis/reason for this admission and past medical history, including that of cancer, PVD or bleeding risks/pre-existing anticoagulation. The electronic laboratory system was interrogated for results for platelet count and estimated Glomerular Filtration Rate (eGFR) The drug chart provided further information on pre-existing anticoagulation, hormone therapy and the details of what, if any, LMWH and/or AES were prescribed, and when.

Deployment of Thromboprophylaxis App

The concept of a thromboprophylaxis app using GGC guidelines was discussed with the lead for thromboprophylaxis at RAH, Dr Chris Foster (Consultant Acute Physician, Royal Alexandra Hospital) and, through him, the GGC Thrombosis committee. With Dr Foster having seen and used the app and happy with its logic and safety, and with the direct backing of the app by the surgical consultants at RAH, they gave their blessing to proceed with the app.

The thromboprophylaxis app was designed concurrently with the audit and revised and refined over the first few months of 2013. The app was deployed manually, over the space of a week, onto the smartphones of all doctors in the surgical department at RAH who were keen to try it. Simultaneously a poster promoting the existence of the thromboprophylaxis app was displayed in all clinical areas and junior doctors' offices (Appendix 9). To capitalise on enthusiasm that surrounded the novelty of having an app for standard prescribing tasks, the next audit cycle was started just ten days after the app was deployed to the last volunteer, at the end of April 2013.

A final audit cycle was undertaken three months later, in September 2013, to assess for "app fatigue". Again, this utilised the same dataset as before and was single-blinded.

2.5.2 Sepsis Six

The introduction of Sepsis Six to the surgical directorate was fully supported and, indeed, strongly encouraged by the Acute Physicians, Clinical Nurse Manager for Surgery and the Service Manager for General Surgery. Endorsement was given to proceed with this app project, in order to try to achieve the SPSP targets for sepsis that were currently unrecorded and, quite probably, unmet.

Time Zero

Given the absence of any data relating to the incidence and prevalence of sepsis in the acute surgical receiving unit at RAH, the initial phase of this research project was to audit this unknown area. This was an invaluable opportunity to conduct a true Time Zero review of the scope of the problem. It was felt that a two week period collecting data on all consecutive patients admitted to the acute receiving unit would provide a manageable, yet representative sample. Capturing all patients was the first challenge - to ensure veracious determination of prevalence of sepsis, an accurate denominator was required. From 08:00 Monday of the two-week cycle until 08:00 Monday, a fortnight later, all patients admitted through the surgical receiving ward, no matter how briefly, were included. To ensure no-one was missed, daily meticulous review of TrakCare for all patients who were recorded as admissions to the receiving ward was undertaken. Recording of the discharge destination for all patients who came through the ED was mandatory and all patients, even GP referrals, came through the ED. Once the name and unique patient identification number (CHI number) was known, the patient and their case notes were tracked down to their current ward for review.

The data required was collected from similar sources as utilised for the thromboprophylaxis arm of this research. For this Sepsis Six arm, it was paramount that date and time were recorded and, again, the most accurate

method of doing this was to use the surrogate of departure time from the ED (a corridor journey of fewer than five minutes). The medical notes were scrutinised for diagnosis and entries about possible Sepsis Six interventions, and the dates of any surgical procedures that might influence physiology, or indeed have been undertaken to achieve source control of infection; the NEWS charts in the patients' notes at the end of each bed provided information on physiological parameters at each point of recording, as well as the calculated NEWS score documented. The nursing notes provided dates (and times) of discharge as well as whether they had recognised a NEWS >4 and had taken appropriate action - such as triggering Sepsis Six, delivering the bundle elements they could, and informing the FY1 to urgently review the patient.

Time Limits for Completion of Each Element of Sepsis Six Bundle

Limits were set for completion of each Sepsis Six element where it had been instigated pre-trigger. Clearly the post-trigger limit was 60 minutes. After evaluation of the practicalities and weighting of each element, the following limits were set for analysis:

IV fluids - any time pre-trigger

Oxygen - any time pre-trigger

Blood cultures - up to 24 hours pre-trigger

Antibiotics - up to 12 hours pre-trigger

Lactate - up to 6 hours pre-trigger

Full blood count - up to 6 hours pre-trigger

Urinary catheter - any time pre-trigger

Introduction of Sepsis Six

Following the Time Zero audit, the concept of Sepsis Six was introduced and disseminated to all surgical doctors at the monthly departmental meeting on 07/11/2012. This involved a presentation detailing the prevalence of sepsis in the acute surgical patients - as evaluated from the Time Zero audit - and a succinct re-cap on the physiological changes that take place in a septic patient; this set the scene for why each element of the Sepsis Six bundle has its place in emergency resuscitation, and the relative impact on mortality per hour of delay for failure to implement each particular step. The existing RAH Sepsis Screening posters (from the Acute Physicians) and stickers (Appendix 10) were examined to ensure familiarity and understanding in how to use them. The critical importance of going that step further, once Sepsis Six had been delivered, of assessing the patient for organ dysfunction was also emphasised.

It was recognised by that buy-in and support from the nurses in the receiving ward was integral (to the point of paramount importance) to the adoption and integration of Sepsis Six into the ward environment. Between January and March 2013 small group sessions were held in Sister's office in the acute receiving ward, ensuring that virtually all nurses currently working in the ward could attend a session. A similar presentation (to that the doctors received) was given, tailored to them, about the importance, consequences and potential interventions of unchecked sepsis. These sessions were warmly received and the nurses very enthusiastic about a slight role-extension to permit delivery of some elements in an agreed protocolised fashion. It was agreed that, on identification of NEWS >4 the initiation of the oxygen and IV fluid components of Sepsis Six would be nurse-led. These are components that are relevant to anyone with deranged physiology, whatever the underlying cause. At the same time the ward Foundation Doctor would be paged to attend, assess the patient for presumed sepsis, and instigate the remaining parts of the bundle. The ward nurse would also place a Sepsis Six sticker in the medical notes, dated and timed at the point of sepsis recognition, and initial beside the elements they'd completed.

Sepsis Six Adjuncts

One of the key strategies that seemed to facilitate timely completion of the Sepsis Six bundle in MAU was the presence of the Sepsis Six trolley. This was a portable stand-alone unit with clearly labelled drawers, each containing supplies of equipment necessary to deliver each specific element of Sepsis Six (with the exception of intravenous antibiotics). It was clear that this would be of great importance in aiding implementation in the surgical receiving ward too. A thorough examination of the trolley and its contents was undertaken and potential areas the surgical trolley could reside in the receiving ward assessed. After in-depth consultation with the Ward Charge Nurse and evaluation of a number of potential units, it was decided that the best site would be next to the Resuscitation Trolley. The surgical Sepsis Six trolley was stocked with all necessary supplies and sundries, laid out in a logical sequence. All drawers and their contents clearly labelled and a laminated stock-check sheet compiled to aide restocking (Appendix 8). It was agreed that ensuring the trolley remained optimally stocked at all times was the responsibility of the ward nurses, just the same as the Resuscitation Trolley

Given that this was just the beginning of Sepsis Six in surgery, a conscious decision was made to utilise other existing resources that had worked well in medicine, namely the stickers to document completion of each element, and the posters (Appendix 10).

First Audit after Sepsis Six Introduction

Shortly following this introduction and briefing to all involved parties, the next audit cycle was conducted at the end of January 2013, again over a two week period and examining all consecutive patients admitted as emergencies. Precisely the same methods of data retrieval and parameters were used. A further two months later, compliance was re-audited in March 2013 to assess for potential fatigue, with identical methodology as the two preceding cycles.

Sepsis Six App

In May 2013 the Sepsis Six app was manually deployed, over the space of a week, onto the smartphones of all doctors in the surgical department at RAH who were keen to try it. Tutorials and guidance through all the functions of the app were provided. A short period of time was allowed to elapse following app deployment and then post-app audit was conducted at the end of June 2013, with a follow-up cycle in late July 2013 to assess for fatigue. Again, identical methods were used as in the previous cycles.

Back-to-Basics

In July an interim analysis of the results to date indicated that the Sepsis Six app wasn't improving guideline compliance to any significant degree. Despite all the strategies of information dissemination (including the novel smartphone app) so far, there was clearly more to do to raise its profile. A back-to-basics approach was decided upon, using high-visibility posters. The hope was that this would be visually prominent in all clinical areas and keep sepsis at the forefront of everyone's consciousness and daily priorities. The posters were designed and printed specifically for this research project, and were put up in every clinical area of the RAH surgical department during the first week of August.



Using identical audit methodology as all previous cycles, the first audit after the poster intervention took place in September 2013 and the final audit cycle for the whole Sepsis Six project in December 2013, as before, to assess for fatiguing of interest.

2.5.3 End of project focus group

During the last week of the academic year, just prior to the August changeover of all junior doctors, a focus group was held with six FY1 doctors to find out their thoughts and opinions on the two arms of the smartphone project. This consisted of a short anonymous paper questionnaire, with tick boxes for each of four areas. They could tick as many or as few responses as they felt applied to them. The information provided here fuelled the back-to-basics approach detailed above.

3 Results

3.1 Smartphone Survey

3.1.1 Response Rates

A total of 456 doctors were surveyed and a total of 201 (44.1%) responded - a pleasingly high response-rate for doctors. 126 of the final 201 who responded did so within 4 days of the survey being sent out. Responses had plateaued by day 10 (Figure 3-1). A second email on day 14 to prompt completion of the survey resulted in a further prompt response - 40 surveys completed within 72 hours.



Figure 3-1 – Cumulative responses to survey

258/456(56.6%) of those invited were male and 198 (43.4%) female. Of those who responded to the survey, 123/201 (61.2%) were male and 76 (37.8%) female; 2 (1.0%) declined to answer. Proportionately more men (123/258, 47.7%) elected to respond to the survey than women (76/198, 38.4%), based on the gender of those invited to participate.

Proportionately more consultants and specialty doctors (107/217, 49.3%) elected to respond to the survey than those in junior grades - based on the grade of those invited to participate (Table 3-1, Figure 3-2)

	FY1	FY2	CT/ST	Cons/SAS
Proportion of				
invited doctors	19/54	16/47	59/138	107/217
who responded	(35.2%)	(34.0%)	(42.8%)	(49.3%)
per grade (%)				· ·





Figure 3-2 – Responses by grade

Those responding to the survey were more likely to be under than over 40 years of age (121 under 40 versus 80 over 40 - Table 3-2).

Age	Number of doctors who replied by age (%) (n=201)
20-29	61 (30.3%)
30-39	60 (30.0%)
40-49	42 (21.4%)
50-59	30 (14.9%)
60+	5 (2.5%)
Declined to disclose	2 (1.0%)

Table 3-2 – Age of respondents

Both of the doctors who declined to disclose their age were Consultants.

3.1.2 Smartphone Ownership

180/201 (89.6%) owned a smartphone; 21/201 (10.4%) did not. There was no significant difference in ownership between males and females (p = 0.71, independent sample T-test). There was near universal ownership of a smartphone within training grade doctors, particularly at Core Trainee level and below. Other than GP trainees and specialty doctors who were underrepresented in the survey, the lowest percentage smartphone ownership was at consultant grade. However, there was no statistically significant between the grades (p=0.27 Chi-Square).

	Do yo	Total		
	Yes	No	% Yes	
Consultant	86	14	86%	100
ST3+	31	3	91%	34
Core Trainee	21	0	100%	21
FY1	19	0	100%	19
FY2	15	1	93.8%	16
GPST	3	1	75%	4
Specialty Doctor	5	2	71%	7
Total	180	21		201

Table 3-3 – Ownership of smartphones by grade





Figure 3-3 – Ownership of smartphones by grade

A clearer pattern of ownership emerges if we look at smartphone ownership by age (Figure 3-4). All respondents under the age of 30 owned a smartphone. There was a clear trend to decreasing smartphone ownership with increasing age that was statistically significant (p < 0.001, one-way ANOVA). This explains the trend seen with clinical grade as this correlates with increasing age.



Figure 3-4 – Ownership of smartphones by age

Levels of smartphone ownership were similar across all specialties (Table 3-4)with the exception of Obstetrics & Gynaecology where only 8 of 11 doctors (72.7%) owned a smartphone.

Specialty	Number of doctors who owned a smartphone by specialty (%) (n=201)
General medicine & medical specialties	53/58 (91.4%)
General surgery	26/29 (89.7%)
Orthopaedics	15/16 (93.8%)
Surgical subspecialties (ENT / urology/ ophthalmology etc)	8/9 (88.9%)
Anaesthetics / ITU	26/28 (92.9%)
Emergency medicine	16/16 (100%)
Obstetrics & Gynaecology	8/11 (72.7%)
Paediatrics	4/5 (80.0%)
Radiology	6/7 (85.7%)
Pathology / Laboratory medicine	4/6 (66.7%)
General Practice	7/8 (87.5%)
Psychiatry	7/8 (87.5%)

Table 3-4 – Ownership of smartphones by specialty

Of these 21 doctors who did not own a smartphone at the time of the survey, 17/21 (81.0%) would consider owning one in the future. The remaining 4/21 (19.0%) would not. Of these 4, 3 were male and 3 were Consultants, the other being an SAS. All were aged 40 or older.

The majority of respondents to the survey who owned a smartphone owned an iPhone (Table 3-5). A significant minority (21.7%) owned an Android-based smartphone. It is, therefore, clear that whilst an iOS-targeted app will reach over 70% of medics, Android support is essential. There is significant, usually tongue-in-cheek, rivalry between platforms that came through in some of the responses - Apple owners are referred to as iSheep or Fanboy, the corresponding "insult" being Fandroid. The once dominant market position of Blackberry is a thing of the past in general and our survey group had negligible ownership. It should be noted that the survey was conducted before the Windows Phone 7 gained any significant market share, hence the minimal numbers seen in the survey.

Smartphone Platform	No of doctors owning this phone (n=180)
iOS (iPhone)	131 (65.2%)
Android (Samsung, HTC, Sony)	36 (17.9%)
Blackberry	9 (4.5%)
Windows Phone 7	4 (2.0%)

Table 3-5 – Type of smartphone owned

3.1.3 Smartphone Usage and Ownership of Medical Apps

110/178 (61.8%) of doctors reported using their smartphone for patient care. However, of the 68 doctors who did not consider that they used their smartphone for patient care, 28 (41.2%) owned medical-related Apps and, of *these* 28 doctors, 9 (32.1%) used these Apps regularly - suggesting that they were in fact unconsciously using their smartphone for patient care. These doctors were distributed across the more senior grades (4 Cons/SAS doctors and 5 ST/CT doctors). Recoding these doctors gives a revised total of 119 (66.6%) doctors using their smartphone for patient care.

It was noticeably core and specialty trainees (44/55 (80.0%)) who were leading the way in using smartphones for patient care. There was a steady increase through the Foundation years in use of smartphones for this purpose - then a tailing off at consultant grade. This should not be taken to mean that consultants lose the ability to use smartphones. This is a single snapshot in time which highlights that the young are more eager adopters of new technology. The consultant grade spans three decades - from mid 30s to age 65 and beyond. We have already seen that smartphone ownership currently falls with age (Figure 3-4). Were this survey to be repeated in 10 years, we would likely see an increase in smartphone ownership among consultants as today's juniors' progress in their careers.

	FY1	FY2	CT/ST	Cons/SAS
Proportion of doctors who used a	6/18			
smartphone for pt	(33.3%)	8/15 (53.3%)	44/55 (80.0%)	61/90 (67.8%)
care, by grade				

Table 3-6 – Use of smartphones for patient care by grade

Type of usage of smartphone	No of doctors using this function
Generic smartphone functionality	
(Admin – phone/text, email, diary, notepad; Camera; Torch;	76
Map function; Calculator; Internet)	
Medical Apps	92
Logbook	9
Audit/data collection	4

 Table 3-7 – Patterns of smartphone app usage

Many doctors also reported that they used their smartphone to look up drug information or perform dose-calculations - either using an App or online tools/resources.

3.1.4 Receptiveness to Official Apps

164 of the 180 who responded to this question would be interested in apps specifically designed for patient care that used local or national guidelines. There was a strong expectation that apps developed by the local trust, or by national bodies, should be available free of charge. This is a reasonable position to take, particularly for permanent members of staff who are unlikely to change trusts with any degree of frequency. It would be more difficult to find agreement if apps and their development costs were trust-specific rather than via a national body such as NES.

23% of respondents would be comfortable paying £1.99 for an app (Table 3-8). Up to £5 would be acceptable for 4 respondents and 2 would pay up to £10.

	Number	Percent
Did not say	19	10.6%
£0.49	12	6.7%
£0.99	29	16.1%
£1.99	42	23.3%
Free	50	27.8%
Other (please specify)	28	15.6%

Table 3-8 – Price willing to pay for official apps

Significant interest was generated from several consultants in other specialties. This lead to collaboration with one of the obstetric trainees and his consultant and the addition of post-delivery DVT prophylaxis pathway to the DVT app being developed for this project. That was, however, not specifically tested within this project - this research was confined to general surgical inpatients.

There was also interest from one of the Emergency Department consultants who has involvement with an app used by the Emergency Medical Retrieval Service (EMRS). With the EMRS app patient data is securely stored on a remote server and transferred to mobile devices as required. This is an approach used by many apps, particularly when data must be synchronised across a number of devices. However, it the resources it requires included a server and the funding to maintain it, something only available to large bodies such as trusts or national bodies.

3.1.5 Concerns

126 of the 180 respondents who owned smartphones did not have any concerns about their usage in a clinical setting (Figure 3-5). The most commonly cited concern (32/180) was of the accuracy and reliability of apps. This included some concerns about how apps were to be kept up to date. This would suggest that apps developed or endorsed by regional or national would find more favour than those from small independent developers - the enthusiastic amateur. Confidentiality and appearing unprofessional were infrequently cited concerns (7/180 and 4/180 respectively). One comment was made that whilst there might be perceptions of being unprofessional at present, the increasing role of

technology in medicine means this will be seen as the norm and no different to a General Practitioner consulting a paper copy of the British National Formulary.

A further comment made by one survey respondent raised concerns over patchy mobile internet availability within hospitals. Mobile phone reception, particularly fast (3G/4G) data connections can be problematic within buildings. The prospect of allowing a large number of frequently changing devices access to a secure hospital Wi-Fi network is something that is likely to be unpalatable to local IT departments. This would be of importance where data needed to be pulled from, or pushed, to a remote server in order to allow the app to function.



Figure 3-5 – Concerns about clinical smartphone use

3.2 Thromboprophylaxis

The primary audit cycle was conducted in December 2012 pre-App. The thromboprophylaxis App was deployed in April 2013 and a post-App audit was

conducted in May 2013. A follow-up cycle was completed in September 2013 to assess for potential fatigue of interest.

3.2.1 Baseline Audit

116 patients were identified during this period, 101 of whom were emergency admissions. AES were indicated in 91 patients (91.4%)but were only applied correctly (indicated, prescribed and patient wearing them) in 34 (29.3%). AES not being prescribed where indicated, or not applied even when prescribed, were both common at 31% and 31.9% of the sample respectively (Table 3-9).

	Number	Percent
No error	34	29.3
Indicated, not prescribed	36	31.0
Prescribed, not applied	37	31.9
Not indicated but prescribed	4	3.4
On appropriately but not prescribed	5	4.3
Total	116	100.0

Table 3-9 – Accuracy of AES prescription (baseline)

The prescription of Low Molecular Weight Heparin did somewhat better. It was indicated in 104 of the 116 patients and prescribed correctly (or omitted if not indicated) in 100 patients. Of the remaining 16 patients, 10 had no LMWH prescribed where it was indicated and 6 had the wrong dose prescribed (Table 3-10).

	Number	Percent
No error	100	86.2
Indicated, not prescribed	10	8.6
Wrong dose	6	5.2
Total	116	100.0

Table 3-10 – Accuracy of LMWH prescription (baseline)

3.2.2 App Introduction (early)

84 patients were identified in this period, 76 being emergency admissions. AES were indicated in 76 patients (90.5%). They were applied correctly in 38

(45.2%). Failure to prescribe where indicated was common at 21/84 (25%) as was AES not being worn when prescribed (Table 3-11).

	Number	Percent
No error	40	47.6
Indicated, not prescribed	21	25.0
Prescribed, not applied	18	21.4
Not indicated but prescribed	2	2.4
On appropriately but not prescribed	3	3.6
Total	84	100.0

Table 3-11 – Accuracy of AES prescription (app early)

The prescription of LMWH was done well (Table 3-12). It was prescribed correctly in 70/84 patients (83.3%). It was not prescribed where indicated in 9 (10.7) and prescribed where not indicated in 2 patients (2.4%). The dose was incorrect in 3 patients.

	Number	Percent
No error	70	83.3
Indicated, not prescribed	9	10.7
Wrong dose	3	3.6
Not indicated but prescribed	2	2.4
Total	84	100.0

Table 3-12 – Accuracy of LMWH prescription (app early)

3.2.3 App Introduction (late)

Due to a change in ward staff during this final audit period, a small number of data points were missing. There were a total of 79 patients in this period, all of whom were emergency admissions. AES were only applied correctly in 23 patients (29.1%). AES were not prescribed where appropriate in 25 (32.9%) patients, and not applied where prescribed in 22 (27.8%) of patients (Table 3-13).

	Number	Percent
No error	23	29.1
Indicated, not prescribed	26	32.9
Prescribed, not applied	22	27.8
Not indicated but prescribed	1	1.3
Total	72	91.1
Missing	7	8.9

Table 3-13 – Accuracy of AES prescription (app late)

LMWH was prescribed correctly in 58(73.4%) of patients in this period. It was not prescribed where indicated in 8 (10.1%) and had an incorrect dose prescribed in 2 patients (2.5%) (Table 3-14).

	Number	Percent
No error	58	73.4
Indicated, not prescribed	8	10.1
Wrong dose	2	2.5
Total	68	86.1
Missing	11	13.9

Table 3-14 – Accuracy of LMWH prescription (app late)

3.2.4 Trends

Anti Embolism Stockings

With the introduction of the thromboprophylaxis app there was a significant increase in the proportion of AES prescribed and applied correctly as a binary result (29.3 vs. 47.6%), p = 0.02, Independent samples T-test. This improvement lost significance when baseline pre-app data was compared to the 2nd audit period post introduction (app-fatigue) (Figure 3-6). Missing data and a change in junior staff may be partly to blame in addition to a genuine app fatigue effect. The second audit period took place in April and June when the junior doctors most likely to be prescribing AES (FY1s) are fairly experienced and au fait with local protocols. In contrast, the third period assessed doctors 6-8 weeks into their job. This is a period when most will have settled in but still be relatively inexperienced.





Much of the missing data was documentation as to whether the AES were actually being worn. However, the proportion of patients in whom AES were indicated but not prescribed had risen to pre-app levels. Overall the type of error made in AES prescription remained similar across all three audit periods (Figure 3-7).







Low Molecular Weight Heparin

In contrast to AES, LMWH was prescribed very well, even at baseline. There was actually a small decrease in the percentage of LMWH prescribed correctly in the first pre-app audit period. This is shown in Figure 3-8 where the result is given as a binary yes/no as a percentage of all patients in that group.


Figure 3-8 – Correct prescription of LMWH across 3 periods as binary result

Over the three audit periods there was little variation in the proportions of the type of error being made in LMWH prescriptions (Table 3-15, Figure 3-9). These differences were not significant (p=0.48, Chi-Square).

		Audit period		
		Pre-App	App Introduced	App Fatigue
	Ν	100	70	58
None	%	86.2%	83.3%	85.3%
	Ν	10	9	8
Indicated, not prescribed	%	8.6%	10.7%	11.8%
	Ν	6	3	2
Wrong dose	%	5.2%	3.6%	2.9%
	Ν	0	2	0
Not indicated but prescribed	%	0.0%	2.4%	0.0%
Total	Ν	116	84	68

Table 3-15 – LMWH prescribing accuracy across 3 audit periods



Figure 3-9 – LMWH prescribing accuracy across 3 audit periods

Even with selection of the correct dose where one might expect improvement from an app that prompts for body weight and renal function, there was no significant improvement in dosing between any of the audit periods (p=0.38, one-way ANOVA). The performance in correctly reducing the LMWH dose is shown in Table 3-16.

This suggests that complacency in the prescription of LMWH is playing a hand. As LMWH is generally prescribed well without a smartphone app, prescribers may feel there is no need to consult such an app. This is perhaps true of LMWH prescription in medicine and surgery where dosing is simple, but may be less applicable in more complex situations such as obstetrics where dosing is more weight and intervention based.

		Dose	
		Correct	Wrong
	Pre-App	14	2
Audit Period	App	14	1
	App Fatigue	5	2
Total		33 5	

Table 3-16 – Number of patients with incorrect LMWH dose where reduced dose required

There were only 11 incorrect LMWH doses in total prescribed across the three periods (Table 3-17). The most common error was failure to reduce the dose of LMWH to take account of low body weight or renal impairment. This occurred in 5 of 38 cases (13.2%) where there should have been a dose reduction. The dose was unnecessarily reduced in 6 of 241 cases (2.5%). This may be due to several factors: previous guidelines in surgery have suggested a standard dose of 20mg enoxaparin (this has been revised to 40mg); uncertainty of renal function and the threshold for dose reduction (especially in borderline cases); and initial inaccurate assessment of patient weight (guesstimate).

			Dose	e
			Correct	Wrong
		Count	235	6
Reduced dose	No	% within Reduced dose LMWH required	97.5%	2.5%
LMWH required		Count	33	5
Yes	% within Reduced dose LMWH required	86.8%	13.2%	
		Count	268	11
Total		% within Reduced dose LMWH required	96.1%	3.9%

Table 3-17 – Accuracy of LMWH dosing regardless of what dose was indicated

3.3 Sepsis

3.3.1 Baseline Audit

Prior to this initial audit cycle no data existed as to the prevalence of sepsis in acute surgical patients at this institution. A primary aim was to evaluate this, as well as the actual numbers of patients being admitted weekly.

There were 181 admissions over a 2 week period (178 unique patients).

- 56 admissions with presumed or confirmed infection (31%)
- 22 admissions with pure inflammation (e.g. pancreatitis) (12%)

- 14 admissions with problems associated with advanced malignancy (8%)
- 89 "other" admissions (e.g. pain, colic, trauma) (49%)

15 of the 181 admissions scored \geq 5 on NEWS chart while in the acute receiving ward (8.3%) where the elevated NEWS score was thought secondary to infection. Of these only 13 (86.7%) had an SIRS score of \geq 2 i.e. fully met the definition of sepsis. The remaining 2 patients had a SIRS score of 1 each. One patient had a diagnosis of urinary sepsis, the other cholecystitis. Both had significantly elevated white cell counts.

Mean and median times for completion of each element are in Table 3-18. These include all cases where an element was done, not just those within the Sepsis Six time limits. Negative values indicate that an element was already completed prior to Sepsis Six being triggered by an elevated NEWS score. Percentage completion rates are for elements completed within the Sepsis Six constraints only.

	Median (mins)	Mean (mins)	% Completion
Oxygen	-45	-592.5	73.3%
IV Fluids	-180	-874.2	66.7%
Blood Cultures	-55	-238.8	26.7%
IV Antibiotics	-480	-749.3	66.7%
Lactate	-20	-6.7	13.3%
Full Blood Count	-60	-194.9	33.3%
Accurate Urine Output	-120	-885.6	40.0%

Table 3-18 – Element completion (baseline)

Boxplots for the time to complete each element are shown in Figure 3-10.



Figure 3-10 – Boxplot of time to element completion (baseline)

No patient had a complete Sepsis Six bundle delivered. The process was only formally documented in 1 patient which is, in part, explained by the fact that Sepsis Six had not been formally rolled out at this stage. Mean NEWS score at time of trigger was 6.6 and mean SSI score 2.5.

3.3.2 Sepsis Six Introduction (early)

A total of 13 of 181 patients activated the Sepsis Six protocol with an elevated NEWS score due to infection. The mean NEWS score for those that triggered was 5.6, and mean SSI score was 1.85. Only 2 of the 13 patients had the Sepsis Six process formally documented in casenotes. No patient had organ dysfunction formally assessed. No patient had a complete Sepsis Six package of care delivered.

	Median (mins)	Mean (mins)	% Completion
Oxygen	-200	-226.1	100%
IV Fluids	-545	-839.5	76.9%
Blood Cultures	17.5	-96.9	53.8%
IV Antibiotics	-485	-775.5	38.5%
Lactate	57.5	68.8	15.4%
Full Blood Count	-76	-21.6	38.5%
Accurate Urine Output	-395	-372.5	15.4%

Table 3-19 – Element completion (Sepsis6 early)



Figure 3-11 – Boxplot of time to element completion (Sepsis6 early)

3.3.3 Sepsis Six Introduction (late)

12 of 141 patients triggered Sepsis Six during this period. One patient with post endoscopic ultrasound pancreatitis triggered twice (2 consecutive days) and there were, therefore, 11 unique patients. Mean NEWS score at time of trigger was 6.6, mean SSI score 2.4. The Sepsis Six process was not formally documented in any case, although 1 patient did have formal documentation of assessment of organ dysfunction. No patient had a complete bundle delivered, although 1 patient who triggered on admission had all elements with the exception of blood cultures performed within 1 hour. No blood cultures were taken from this patient.

	Median (mins)	Mean (mins)	% Completion
Oxygen	10	6.6	58.3%
IV Fluids	2.5	30.5	75%
Blood Cultures	-82.5	-281.3	33.3%
IV Antibiotics	-400	-446.3	41.7%
Lactate	11	-34.5	33.3%
Full Blood Count	17.5	-52.4	58.3%
Accurate Urine Output	0	57.5	25.0%

Table 3-20 – Element completion (Sepsis6 late)



Figure 3-12 – Boxplot of time to element completion (Sepsis6 late)

3.3.4 App Introduction (early)

18 of 193 patients triggered Sepsis Six during this period. Mean NEWS score for these patients was 5.7, mean SSI score was 1.9. Only 1 patient had Sepsis Six documented in their notes but it was not this patient who was the sole patient so far to have a complete Sepsis Six bundle. No patients had formal assessment of organ dysfunction.

	Median (mins)	Mean (mins)	% Completion
Oxygen	9.5	-20	66.7%
IV Fluids	-162.5	-225.6	83.3%
Blood Cultures	-40	-108.3	33.3%
IV Antibiotics	-15	-98.9	50.0%
Lactate	-22.5	-102.5	44.4%
Full Blood Count	32	-73.9	55.6%
Accurate Urine Output	15	-62	38.9%

Table 3-21 – Element completion (App early)



Figure 3-13 – Boxplot of time to element completion (App early)

3.3.5 App Introduction (late)

14 of 175 patients triggered Sepsis Six. Of these 11 were unique - one patient with pyelonephritis triggered on days 0, 1 and 2, another patient with biliary

sepsis triggered on days 0 and 3. Mean NEWS score was 6.2 and mean SSI score 2.3. Sepsis Six was formally documented in 3 cases and 2 patients had a complete bundle delivered. Organ dysfunction was not formally assessed in any cases.

	Median (mins)	Mean (mins)	% Completion
Oxygen	-30	-231	71.4%
IV Fluids	-995	-1020	92.9%
Blood Cultures	-30	-266	57.1%
IV Antibiotics	-130	-490.1	35.7%
Lactate	-2.5	-76.7	42.9%
Full Blood Count	45	31.6	57.1%
Accurate Urine Output	-560	-716	35.7%

Table 3-22 – Element completion (app late)



Figure 3-14 – Boxplot of time to element completion (App late)

3.3.6 Poster Promotion (early)

9 of 159 patients triggered Sepsis Six during this period. Mean NEWS score was 7 and mean SSI score at trigger was 2.8. There was some form of Sepsis Six documentation in 3 patients. Organ dysfunction was formally assessed in 2 patients. There were no complete Sepsis Six bundles delivered.

	Median (mins)	Mean (mins)	% Completion
Oxygen	-50	-17.5	33.3%
IV Fluids	-240	-550.4	88.9%
Blood Cultures	55	-395.4	22.2%
IV Antibiotics	-45	-362.2	55.6%
Lactate	33	62.3	44.4%
Full Blood Count	30	-144.8	55.6%
Accurate Urine Output	-100	-71.7	22.2%

Table 3-23 – Element completion (Poster early)



Figure 3-15 – Boxplot of time to element completion (Poster early)

3.3.7 Poster Promotion (late)

Only 6 of 164 patients in this period triggered Sepsis Six. Mean NEWS score was 6.8, mean SSI score was 3. Sepsis Six was documented in 3 of the 6 patients and 4 had organ dysfunction assessed. Despite this seemingly impressive performance, only 1 patient had a full Sepsis Six bundle delivered.

	Median (mins)	Mean (mins)	% Completion
Oxygen	-184	-198	66.7%
IV Fluids	-152.5	-411.2	100%
Blood Cultures	-127.5	-127.5	33.3%
IV Antibiotics	-247.5	-553.7	66.7%
Lactate	22.5	111.3	50.0%
Full Blood Count	-182	-426.5	50%
Accurate Urine Output	-167	-353.4	83.3%

Table 3-24 – Element completion (Poster late)



Figure 3-16 – Boxplot of time to element completion (Poster late)

3.3.8 Trends

Time of admission and sepsis trigger

The majority of admissions either occurred outwith the normal 9am to 5pm working day (Table 3-25) or at weekends (Table 3-26). The time at which patients triggered was a little more balanced (Table 3-27, Table 3-28), although 2 periods ("Sepsis Six fatigue" and "App fatigue") had almost all of their triggers occur out of hours.

		Day / Night Admission		Total
		D	Ν	
	Pre-Sepsis Six	3	12	15
	Sepsis Six introduced	4	9	13
	Sepsis Six fatigue	2	10	12
Audit Period	App introduced	7	11	18
	App fatigue	4	10	14
	App + poster	3	6	9
	Poster fatigue	3	3	6
Total		26	61	87

Table 3-25 – Time of admission (day vs. night)

		Out of Hour	Out of Hours Admission	
		Ν	Y	
	Pre-Sepsis Six	1	14	15
	Sepsis Six introduced	4	9	13
	Sepsis Six fatigue	2	10	12
Audit Period	App introduced	3	15	18
	App fatigue	4	10	14
	App + poster	3	6	9
	Poster fatigue	2	4	6
Total		19	68	87

Table 3-26 – Time of admission (weekday daytime vs. overnight or weekend)

		Day / Nig	ht Trigger	Total
		D	Ν	
	Pre-Sepsis Six	7	8	15
	Sepsis Six introduced	6	7	13
Audit Period	Sepsis Six fatigue	1	11	12
	App introduced	11	7	18
	App fatigue	3	11	14
	App + poster	4	5	9
	Poster fatigue	3	3	6
Total		35	52	87

Table 3-27 – Time of trigger (day vs. night)

		Out of Hor	urs Trigger	Total
		Ν	Y	
	Pre-Sepsis Six	4	11	15
	Sepsis Six introduced	5	8	13
Audit Period	Sepsis Six fatigue	1	11	12
	App introduced	6	12	18
	App fatigue	3	11	14
	App + poster	4	5	9
	Poster fatigue	1	5	6
Total		24	63	87

Table 3-28 – Time of trigger (weekday daytime vs. overnight or weekend)

There was no significant difference in mean time to completion across the elements with the exception of the time between blood cultures and sepsis trigger. For an out of hours admission blood cultures were taken an average of 94.5 minutes prior to trigger. For an admission with normal hours during the week, they were obtained 180.4 minutes prior (p=0.11, Chi-square). As this is the only significant difference it may be due to chance but, if one bears in mind the significant delays from admission to triggering Sepsis Six, this actually suggests blood cultures are being taken more promptly as part of the standard process for daytime admissions. The level of staff availability between day and night is likely to be a factor here.

Admission to sepsis trigger

Time from admission to trigger was not significantly different between the audit periods (p=0.67, one-way ANOVA). Some outliers are seen in 3 of the audit periods but, in general, most patients who are going to trigger Sepsis Six do so within the first 36 hours of admission (Figure 3-17, Table 3-29).



Figure 3-17 – Boxplot of time from admission to sepsis trigger (minutes)

	Pre-	Sepsis6	Sepsis6	App	App	Poster	Poster
	Sepsis Six	(early)	(late)	(early)	(late)	(early)	(late)
Mean time to trigger (hours)	23.5	25.2	32.6	14.7	20.2	13.1	9.8

Table 3-29 – Mean time in hours from admission to sepsis trigger

Element Completion



The trends for completion of all elements of Sepsis Six are shown in Figure 3-18.

Figure 3-18 – Element completion over all audit periods

There is significant variation in element completion from one period to the next. Some, including IV fluids and measurement of lactate, do seem to have an upward trend. However no element showed a statistically significant difference between baseline and the final audit period (Table 3-30).

		Levene's Test for Equality of Variances		t-test for Equality of Mean		
		F	Sig.	t	df	Sig. (2- tailed)
02	Equal variances assumed	.50	.488	079	19	.938
02	Equal variances not assumed			073	8.05	.943
	Equal variances assumed	8.38	.009	-1.14	19	.270
IV Huids	Equal variances not assumed			-1.45	16.63	.165
	Equal variances assumed	.007	.933	08	19	.935
Blood cultures	Equal variances not assumed			08	9.24	.936
	Equal variances assumed	.003	.954	14	19	.890
Antibiotics	Equal variances not assumed			14	8.69	.895
	Equal variances assumed	.77	.390	-1.13	19	.274
Lactate valid	Equal variances not assumed			-1.05	8.16	.322
	Equal variances assumed	.12	.736	35	19	.728
FBC valid	Equal variances not assumed			35	9.21	.733
	Equal variances assumed	1.87	.188	-1.34	19	.195
Urine output	Equal variances not assumed			-1.44	10.88	.177

Table 3-30 – Element completion baseline versus poster (late) period

Small sample size will play a major factor. With so few cases of sepsis in the final 2 audit periods, to achieve statistical significance would be difficult. Anything doing so may well be spurious. The data collected as part of the Scottish Patient Safety Programme (SPSP) aims to record 20 cases per month to give a better chance of showing reliable trends. This is, of course, dependent on case incidence and ascertainment.

With median time to element completion, there is again no clear trend for any of the elements across any time periods (Figure 3-19). The majority of elements are being delivered in advance of the sepsis trigger throughout all periods. This is due to patients consistently not triggering Sepsis Six until many hours after admission. The lowest mean time from admission to trigger was 9.8 hours (Table 3-29). In 4 of the periods it was in excess of 20 hours. As many Sepsis Six elements comprise part of standard surgical care, one should expect that they should be instituted before crisis point is reached. Sepsis Six is poor at taking account of this and works best where the patient is already septic at hospital admission and one is starting with a clean sheet.



Figure 3-19 – Median time to element completion across all periods

3.3.9 Focus Group for Foundation Doctors - Feedback on Guidelines and App Research

In June 2013 a small focus group was held with six of the Foundation doctors who had worked in the surgical department between August 2012 and August 2013. It had become clear that the app was not the simple answer to the problem of guideline compliance that had been hoped for. This student wished to know what the barriers had been for this particular group of doctors.

A summary of their responses is below:

Sepsis Six

what stopped you following bepsis bix guidelines decurately:					
Didn't know they existed		Didn't think they applied to my patients			
Thought I knew them already	2	Couldn't be bothered			
No obvious penalty for non- compliance	1	Time pressure - no time to look things up	1		
Specifically told not to follow these guidelines		Guidelines not part of the culture of the ward	1		
Couldn't get help to fulfil all elements of package in <1 hour	4	Couldn't access the guidelines			

What stopped you following Sepsis Six guidelines accurately?

Specific comments:

- "I'd do it if a senior told me specifically"
- "If I knew there was a penalty for non-compliance I'd try harder"
- Need a better Sepsis Six trolley with everything fully-stocked and accessible, like in medicine.
- Desire for the ward nurses to tell them immediately that a patient has triggered NEWS >4 and that they've started the one hour egg-timer requirement of pressure to complete was repeatedly mentioned.

Did you use the Sepsis Six App: Y = 3 / N = 3

If Yes:	Comments
	1-3 = 1
How many times did you use it?	4-6 = 1
How many times and you use it?	7-10 = 1
	> 10 = 0
Did you like the App?	Y = 2, No answer = 1
Was it user-friendly?	Y = 2, No answer = 1
Would you use it again?	Y = 2, No answer = 1
Would you recommend it to a colleague?	Y = 2, No answer = 1
Any improvements you'd like to suggest?	

If No, why not?

No smartphone	No battery when I needed it	
No septic patients	Forgot App existed	1
No pockets on clothes so I don't carry my smartphone at work	Didn't want to use smartphone in presence of patient - in case thought unprofessional	
Management directive not to use smartphones in patient environment	Concern that seniors might think I'm skiving off if seen using smartphone at work	
Didn't think I needed to use it - knew guidelines already	Didn't get app uploaded	1

Thromboprophylaxis

What stopped you following thromboprophylaxis guidelines accurately?

Didn't know they existed		Didn't think they applied to my patients	
Thought I knew them already	4	Couldn't be bothered	
No obvious penalty for non-compliance		Time pressure - no time to look things up	2
Specifically told not to follow these guidelines		Guidelines not part of the culture of the ward	
Couldn't access the guidelines		Other:	

Did you use the thromboprophylaxis App:	Y = 5 / N = 1
If Yes:	Comments
	1-3 = 1
How many times did you use it?	4-6 = 2
now many times and you use it:	7-10 = 1
	> 10 = 1
Did you like the App?	Y = 5
Was it user-friendly?	Y = 5
Would you use it again?	Y = 4, Not sure = 1
Would you recommend it to a colleague?	Y = 4, No answer = 1
Any improvements you'd like to suggest?	No guidelines on extremes of weight - such as morbid obesity

If No, or not regularly, why not?

No smartphone		No battery when I needed it	
Never needed to prescribe LMWH or AES		Forgot App existed	1
No pockets on clothes so I don't carry my smartphone at work		Didn't want to use smartphone in presence of patient - in case thought unprofessional	2
Management directive not to use smartphones in patient environment	1	Concern that seniors might think I'm skiving off if seen using smartphone at work	2
Didn't think I needed to use it - knew guidelines already	1	Flowchart in medical proforma	1

4 Discussion

4.1 Implications of Results

4.1.1 Smartphone Ownership and Use for Healthcare

Smartphone ownership decreases with increasing age, especially over the age of fifty. As older consultants, less comfortable and familiar with smartphone technology, are gradually replaced by a more tech-literate younger generation this decline in ownership rates is likely to become less obvious. Although worldwide there is a distinct preference for android-based smartphone technology, this is much less pronounced in the medical fraternity and frequently the converse, compared with iPhone ownership. Compounding this is the unmistakeable brand-loyalty displayed by Apple customers. Other platforms are still very much minor players. This emphasises the need to support both android and iOS platforms with new software.

It was interesting to see the peak for those using smartphones for clinical care to be during the core and specialty trainee years, making them roughly 25-33 years of age. This highlights the appreciation that doctors at this stage in their training have about their level of knowledge and correlates with published data (53). It may also reflect the possibility that currently downloadable apps for doctors are aimed at those more senior than Foundation Doctors.

4.1.2 Thromboprophylaxis

The baseline audit revealed that, contrary to expectation and past experience, prescription of LMWH was already done well, leaving limited potential for the app to improve on this. The SPSP target for accurate LMWH prescription is 95% and RAH surgical department, at baseline, was approaching 90%. Despite this, the complacency issue seems to have prevented the app helping to reach this target.

AES prescribing and actual application of the stockings didn't change overall. Indeed, there was evidence to suggest that the app was not being used; AES were being prescribed for patients with clear contraindications. Similarly, dose reduction for low bodyweight or poor renal function (on admission) was not taking place. Interestingly, the obverse was also true for patients who had been transferred from the receiving ward to the general surgical ward; when renal function had recovered it took a long time for the for LMWH to be up-titrated on the prescription, potentially exposing the patient to greater VTE risk during that period (data not included in this body of work). Unfortunately the app would only avert this problem if it were used to calculate LMWH dose for every patient, every day.

It was gratifying to see a modest improvement in the correct prescribing and application of AES after initial introduction of the app, albeit this was an unsustained phenomenon. This makes it problematic to determine the contribution of the app to this result.

4.1.3 Sepsis Six

Out-of-hours triggering

The majority of Sepsis Six patients were triggering outwith standard working hours. Out-of-hours hospitals are run on considerably reduced staffing levels, especially covering the wards. This is likely to be a significant contributing reason behind failure to complete all elements in one hour, and may explain why the majority of doctors in the focus group reported a prime reason for not delivering a Sepsis Six bundle correctly was that they couldn't get help to fulfil all elements of package in less than one hour. Targeting of resources to this identified gap in service provision may be key to improvement.

It has become apparent that other health boards in Scotland operate very different methods of response to a Sepsis Six trigger. In the neighbouring hospitals of Ayrshire and Arran health board it is made clear at the annual hospital induction that non-compliance with Sepsis Six implementation will be taken very seriously, with repercussions for those involved. At any point of the

day and or night the duty ANP and the responsible FY1 are paged when a patient is recorded as having an elevated NEWS score >4. They are required to respond and review the patient within fifteen minutes and, if the patient is confirmed to be septic, institute the Sepsis Six bundle within the following forty-five minutes. The ANP also comes back within four hours to review the patient and check a repeat lactate level, to verify clinical improvement. Assessment of organ dysfunction, however, is not done so flawlessly. The Sepsis Six process, and the timings thereof, is strictly audited by the ANP team, with feedback given to departmental managers as well as the ward nurses and junior doctors about good, as well as poor, performance. Using these methods, Ayrshire and Arran routinely achieve >95% compliance, similar to the MAU at RAH.

During the period of research ANPs at RAH only covered the surgical wards overnight and at weekends. This was distinct to the medical wards where they had a twenty-four hour presence. If GGC were to employ the Ayrshire and Arran dual-pronged response to a Sepsis Six trigger, it is not unreasonable to anticipate a sharp improvement in Sepsis Six bundle compliance. This would, naturally, have cost implications that would have to be taken into consideration.

Differences between medical and surgical patients

Sepsis Six works well in the medical directorate as, at presentation, most patients with infection already manifest signs of systemic sepsis and the bundle of care can be delivered immediately, between the start of the egg timer and the buzzer alarming at sixty minutes. Analysis of the time from admission to time of trigger in these surgical patients revealed a median difference of approximately twenty-four hours. This serves to explain the seemingly preemptive antibiotics, fluids and blood tests in a lot of patients that were started for localised infection on admission but evolved into systemic sepsis thereafter.

The very different behaviour of medical and surgical patients suggests they should not be treated as a homogenous group of patients, and may be much better served being recognised as two distinct entities.

Complete Sepsis Six bundles

Despite Sepsis Six having been introduced almost a year previously, and despite the breadth of the modalities employed to try to encourage engagement, the frequency of bundle completion remained dismal. Some complete bundles were delivered following deployment of the app, but it is difficult to determine if this is primarily a success for the app or part of the on-going process of Sepsis Six integrating into the fabric of the surgical receiving ward.

Assessment of organ dysfunction

A total of eighty-seven patients were identified as being septic during the whole research project. Of these, only seven had documented evidence that they had been assessed for organ dysfunction, one patient being assessed following initial introduction of Sepsis Six and six following the "back-to-basics" poster campaign. It seems that while the concept of the one-hour resuscitation bundle has been slowly seeping into the fabric of the surgical receiving ward, the patients were not routinely being followed-up to determine if they had "simple" sepsis or whether they were potentially considerably more unwell. While an elevated lactate can help discriminate, assessment for organ dysfunction is vital to facilitate earlier recognition of the patient requiring early involvement of critical care personnel.

4.2 Barriers to App Usage by Junior Doctors

4.2.1 Confidentiality, security and public perception

The surgical junior doctors may have not wished to use these app in the clinical setting due to concerns about confidentiality and how they would be perceived by patients and other colleagues (although this was cited considerably more frequently at the Focus Group (2/6, 33%) than in the initial SurveyMonkey questionnaire (4/180, 2%). This is supported by work in Australia which found that the general public was "generally more accepting of the internet being used during clinical practice than apps" (67) as well as the Imperial College

microbiology team, when they devised and implemented their antibiotic prescribing app (54).

It was further suggested that Foundation doctors may not yet have got into the mindset of taking work home. They still differentiated into black and white what they did in each environment. Smartphones might be considered a "home" thing and not associated with work.

4.2.2 Accuracy of apps

The importance of the accuracy of the data contained in and results produced by a smartphone app cannot be emphasised enough. Although this was not detailed as a concern in the small focus group, it was highlighted by more senior respondents in the initial survey. Keeping apps updated with the most current guidelines and recommendations is a very real problem, particularly with native apps, as it relies on the user realising they have to regularly manually update the software and applications on each device they own (54).

4.2.3 Complacency

Fundamentally there were major complacency issues surrounding these seemingly simple algorithms, candidly confirmed in the focus group. Both VTE prophylaxis and Sepsis Six are major SPSP targets. Despite them being so important, the Foundation Doctors thought they knew the guidelines wellenough that, when pressed for time, it wasn't worth the effort to open an app to confirm this; this body of research would refute that notion.

The two year UK Foundation Programme takes doctors straight from Medical School and potentially as young as twenty two years of age. As new FY1s they have insight into their lack of knowledge and are receptive to new information. It is well recognised that this situation changes quickly and insight is lost disproportionate to expansion in knowledge. The apps were tested towards end of the FY1 year when many of the surgical doctors would have entered this second, recognised, phase of learning and this may have been a mitigating factor in both overall guideline compliance and app utilisation. By the time of entering

core and, particularly, specialty training doctors have entered a third phase of learning and know that they have some knowledge but are keen to expand it and they look for opportunities to do so.

4.2.4 Inaccurate NEWS recording

There were on-going issues with identification and documentation of correct NEWS score by the ward nurses. This was critical as, without identifying the potentially septic patients, care couldn't be delivered. Analysis of the NEWS charts (Appendix 7) revealed that documentation error was the greater problem; "dots" to mark parameters were not being marked accurately and values were being written in the wrong rows, mainly for oxygen saturations. The colour-coding is designed to assist the brain in calculating the total score. If abnormal values were erroneously being noted in a "white" area, they were not infrequently being missed and scored as 0, when potentially the score might have been 2, for example. It was also brought into standard practice that the nurses routinely perform bedside blood glucose measurement when the NEWS was >4, to permit proper sepsis screening.

This issue of incorrect appreciation of the severity of physiological derangement due to poor "totting up" of the individual elements of the NEWS score is well recognised. Attempts have been made to address this problem by providing an electronic solution: the NHS Education for Scotland (NES) working party released an iPhone app in June 2013 with NEWS calculation built in. Identification of deranged physiology led to advice to screen for sepsis and, if positive for the systemic inflammatory response, the user was taken into the Sepsis Six screen. The logic for this NES app was donated from this research project - as can be seen from the manifest similarity between the two apps.

4.2.5 Leadership and motivation

Williams et al (15) suggested that clear advice from a senior figure/group and direct motivation to adhere to guidelines was the most likely factor influencing compliance. The top-down, hands-on, highly visible and incentivised management style of the acute physicians at the RAH emulates this and is likely

to be the reason for markedly differing Sepsis Six bundle completion rates between MAU and surgery. This constant presence on the ward is not reproducible in a surgical environment with current consultant working patterns. If this is consistently shown to be the only factor likely to increase motivation and compliance, then it may be that working patterns need to be reconsidered.

One factor that has been proven to be beneficial in nursing infrastructure is having "champions" for various identified areas. At present a trained nurse or healthcare assistant is highlighted as a champion for issues such as pressure sores, hand hygiene, nutrition etc. The champion's role is to promote and encourage good practice and protocol compliance for their niche area, and act as a peer mentor and example of best practice to colleagues. There would certainly be a role for a Sepsis Six champion in the surgical wards at RAH. This would hopefully encourage nurses to recognise septic patients and be empowered to implement the Sepsis Six bundle and inform junior doctors to fulfil their elements in a timely fashion.

4.3 Commercial Apps Released During Study Period

4.3.1 Thromboprophylaxis

Four apps aimed at clinicians have been released since the start of this research project. They are all commercial projects, one of them only being available in Spain. This particular app, CLX Caprini, is produced by Sanofi and appears to be the successor to the French Clexane app. It was released in April 2013, and can be downloaded free-of-charge.

Of the other three apps, one costs £6.99 to download and was released in March 2014. It contains no mention of applying for, or indeed needing FDA/MHRA approval for the app, despite giving prescribing advice. This is in contrast to an app released in October 2013 that is free to download and contains a carefully worded disclaimer and makes no attempt to provide prescribing information.

4.3.2 Sepsis Six

The first Sepsis Six app became available to download in December 2012. This was marketed by the "Survive Sepsis" campaign and contained an interactive sepsis screening tool and an interactive "tick-sheet" for documenting completion of each element of the bundle. It also guided the user through the escalating cascade of severity of sepsis, ensuring that organ function was evaluated. Initial versions were not particularly user-friendly and updates during 2013 have improved on the original app.

The "Keep calm and do the Sepsis Six" app was launched in January 2013 but was non-interactive and had limited functionality, although it proved popular due to its moniker. Later that year the official NHS Scotland app was released in June 2013. There was significant collaboration at a design level between this project and the team developing that app.

4.4 Limitations of this project

A problem found to be unique to owners of android phones was that of having out-dated software. If they hadn't updated their operating system for several versions it proved impossible to deploy the app onto these smartphones. This situation simply wasn't encountered in iPhone users as uptake of each update is so rapid. Interestingly Charani et al found the very same problem (54).

The patient-safety topics of thromboprophylaxis and sepsis were perceived as too simple by many FY doctors to make them worthy of using an app for. This was despite clear evidence that there was room for improvement. This partial app adoption made it difficult to extract change related to app introduction from other potential sources for improvement.

Despite rigorous examination of all patient casenotes during the two-week audit cycles, there was overall a low number of septic patients in this project, especially in the last two audit cycles. This makes significance difficult to achieve or prove. The thromboprophylaxis project was slightly confounded by

the ubiquitous problem of missing data, although it did not prevent meaningful conclusions being drawn for most areas.

The annual junior doctor changeover took place during the first week of August 2013. Although the incoming FY1 doctors had spent six weeks shadowing during May 2013, and also spent the seven days prior to taking up post as supernumerary doctors on the wards, this was not the same cohort as the two preceding audit cycles. It had proved logistically impossible to undertake the final audit cycles prior to the changeover due to the sheer number of interventions that had taken place over the year, especially with two audit cycles after each intervention. To minimise the impact this might have on data collection, each app was deployed onto the smartphones of the incoming doctors while they were undertaking their shadowing period in order that they could be as familiar with using it as their outgoing counterparts.

4.5 Conclusions

With on-going developments and rapid progress towards a paperless society and healthcare being provided electronically, it is inevitable that the use of smartphone apps for direct patient care will become more familiar and, indeed, commonplace. Certainly doctors surveyed for this project have already embraced smartphone technology and indicated enthusiasm, in principle, for guideline apps such as those tested here.

As hypothesised, the addition of a smartphone app for relatively simple guidelines did not affect compliance rates but it proved impossible during this brief research period to test the hypothesis on a more complex set of guidelines. Fatigue was difficult to assess due to low numbers and conclusions relating to this cannot be drawn. While it is disappointing not to be able to prove the importance and benefit of smartphone apps for direct patient care they are likely to continue to be a growth market.

It is clear from the work undertaken here that basic principles of visible and omnipresent top-down leadership will always be required to support change, adoption of new ideas and sustained compliance with them.

4.6 Future Directions

4.6.1 Junior Doctor Education

It is clear that education of junior doctors on the wards is paramount to adherence with protocols. Formal, structured education sessions about both thromboprophylaxis and Sepsis 6, coupled with interactive tutored sessions about the apps, could be instituted at the start of each new cycle of junior doctors. These would emphasise the importance of these aspects of patient safety and the tools available to facilitate protocol compliance. It would be interesting and useful to conduct a full audit cycle both before and at the two points after this enhanced education session and see if a more focussed educational input would improve guideline compliance.

4.6.2 Electronic Patient Record

The initial phase of this project illustrated how ubiquitous smartphones are among doctors of all ages, particularly younger, more junior colleagues. It is time to capitalise on this and move resources to this medium and away from the antiquity of paper and standard computers. The future of secondary care is electronic and paper-free, with integrated patient observations, lab results, radiology and prescribing. Wholly electronic care provision already exists in some UK hospitals and more widely across North America, using secure tablets linked in to encrypted hospital Wi-Fi. Such a project is currently being trialled in the neighbouring Ayrshire and Arran health board.

The advent of the electronic patient record (EPR) and electronic prescribing should facilitate timely prescription of thromboprophylaxis, especially if safeguards are built in to prevent moving on from the VTE prophylaxis screen until either LMWH and AES have been prescribed or contraindications documented.

Medicines reconciliation forms (both paper-based and electronic) will play a role in encouraging appropriate prescribing of VTE prophylaxis. These are completed by junior medical staff and verified by a ward pharmacist, ensuring safe and

timely confirmation and prescription of medications already taken by the patient. Medicines reconciliation forms have already been built in to paperbased admissions proformas (see Chapter 1.1.2) and include а thromboprophylaxis section to ensure the admitting doctor is reminded of the importance of assessing risk and making an appropriate prescription. As discussed in Chapter 1, the current unwieldy nature of these paper-based thromboprophylaxis flow-charts inhibits compliance and hopefully moving to an electronic format will improve this problem.

4.6.3 Colorectal Polyp Surveillance App

An app to aid the calculation of correct surveillance interval for colorectal polyps is currently being developed. These polyps are pre-cancerous growths in the large bowel that can be detected visually during a colonoscopy. Once removed, the risk of malignant transformation to a bowel cancer is obviated. However, the risk of significant injury to the bowel is one in one thousand for a diagnostic colonoscopy, rising to one in fifty for removal of a large polyp. These two factors compete to determine the surveillance interval between tests, ensuring it remains as safe as possible while minimising the likelihood of an interval cancer. A useful benefit of ensuring the correct surveillance interval will be to decrease the waiting list for colonoscopy. The easy default position, if one is unsure, is to continue to survey patients ad infinitum, and more frequently than indicated, rather than risk missing a cancer. This is poor practice and detrimental to a service with finite resources.

An app is likely to be of great use and interest to those involved in polyp surveillance as national guidelines from the British Society of Gastroenterology (BSG) (82), while being practical, can bewilder the novice. This app will follow the BSG guidelines but use their algorithms to tailor a surveillance interval to a particular patient, taking into account their genetic predisposition (if known), size and number and histology of previous polyps, from all previous colonoscopies, as well as their age.

It is immediately evident that this app is quite different from the simple ones trialled in this project. The complexity of the decision-making will make a

supporting app enticing, particularly as it may permit streamlining of the process leading to appointment to follow-up colonoscopy. At present, nurse endoscopists can vet a patient direct to test, undertake the actual colonoscopy but then the decision-making regarding surveillance interval is deferred to a responsible consultant (either surgeon or gastroenterologist). If such an app as is proposed can be made to work, this will allow the endoscopist to calculate the appropriate surveillance interval at the end of the procedure, cutting out the consultant "middle-man" and any attendant delays appointment delays. It would also lend itself to the running of an autonomous nurse-led polyp clinic, where patients could be seen regarding their histopathology results, thereby relieving pressure of return appointments to the consultant-led colorectal clinic. These anticipated benefits would have a significant positive impact on the provision of surgical services.

Questions	Dropdown answers
What is your grade?	Consultant, Specialty Doctor/SG/AS,
	ST3-8/LAT3-8/SpR, CT/LAT1-2, FY1,
	FY2,
What is your gender?	Male, Female
What is your specialty?	Medical Specialties, General Surgery,
	Orthopaedics, Surgical Subspecialties
	(ENT/ophthalmology/urology),
	Psychiatry, Anaesthetics, Radiology,
	Emergency Medicine, Obstetrics &
	Gynaecology, Pathology/Laboratory
	Medicine, General Practice, Paediatrics
Which site do you work at most?	RAH, IRH, VoL
What age are you?	20-29, 30-39, 40-49, 50-59, 60 or older
Do you own a smartphone?	Yes, No
If NO - Although you don't own a	Yes, No, Don't know
smartphone now, would you consider	
using one in the future?	
What make of Smartphone do you use?	iPhone, Samsung, Nokia, HTC,
	Blackberry, LG, Sony,
Do you use your Smartphone for patient care?	Yes, No

In what way do you use your Smartphone for patient care?	(freetext)
Do you have any medical-related Smartphone Apps?	Yes, No
Which medical Apps do you own?	(freetext)
Do you use these medical Apps regularly?	Yes, No
Which are the medical Apps you use most regularly?	(freetext)
Does the price of Apps influence your decision about buying them?	Yes, No
Is there a maximum price you'd pay for a medical-related App?	FREE, £0.49, £0.99, £1.99, £4.99, £9.99, No maximum price threshold if App is "worth it"
Would you be interested in Apps specifically-designed for patient care that use local GGC and/or national guidelines?	Yes, No
What price would you be prepared to pay for such Apps?	FREE, £0.49, £0.99, £1.99, Other (please specify)
Appendix 2 Thromboprophylaxis risk assessment



Reproduced, courtesy of Dr C Foster, Lead Clinician for Thromboprophylaxis, RAH.

Appendix 3 Key to levels of evidence and grading of recommendations (1)

3.1 Levels of evidence

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a
	very low risk of bias
1+	Well conducted meta-analyses, systematic reviews, or RCTs with a low
	risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies
	High quality case control or cohort studies with a yery low risk of
	Fight quality case control of conort studies with a very low fisk of
	confounding or bias and a high probability that the relationship is
	causal
2	Well conducted case control or cohort studies with a low risk of
Δ+	well conducted case control of conort studies with a tow risk of
	confounding or bias and a moderate probability that the relationship
	IS CAUSAL
2-	Case control or cohort studies with a high risk of confounding or bias and
	a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

3.2 Grades of recommendation

А	At least one meta-analysis, systematic review, or RCT rated as 1++, and
	directly applicable to the target population;
	or
	A body of evidence consisting principally of studies rated as 1_* , directly
	applicable to the target population, and demonstrating overall
	consistency of results
В	A body of evidence including studies rated as 2_{++} , directly applicable to
	the target population, and demonstrating overall consistency of results;
	or
	Extrapolated evidence from studies rated as 1++ or 1+
	Extrapolated evidence from studies rated as 1++ or 1+
C	Extrapolated evidence from studies rated as 1++ or 1+ A body of evidence including studies rated as 2+, directly applicable to
С	Extrapolated evidence from studies rated as 1++ or 1+ A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results;
C	Extrapolated evidence from studies rated as 1++ or 1+ A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results;
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C	Extrapolated evidence from studies rated as 1++ or 1+ A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++ Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

Appendix 4 Sepsis Six data collection proforma

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Appendix 5 Systemic Inflammatory Response and Sepsis

5.1 SIRS

SIRS is considered to be present when patients have two or more of the following clinical findings (38):

- Body temperature > 38°C or < 36°C
- Heart rate > 90/min
- Hyperventilation evidenced by respiratory rate > 20/min, or PaCO₂ < 32 mmHg (4.3 kPa)
- White blood cell count > 12,000 cells/ μ L or < 4,000/ μ L

Levy's group also noted that two further features were frequently associated with septic patients. These features have since been incorporated into the list of criteria for diagnosis of SIRS, making a total of six (40):

- Acute confusion or reduced conscious level
- Blood glucose > 7.7mmol/L (unless diabetic)

5.2 Sepsis

SIRS plus documented or strongly suspected infection

5.3 Severe sepsis

Sepsis plus sepsis-induced organ dysfunction or tissue hypoperfusion (defined as infection-induced hypotension, elevated lactate, or oliguria. Abnormalities can also be seen in other parameters)

5.4 Septic shock

Severe sepsis with sepsis-induced hypotension that persists despite adequate fluid resuscitation - usually requiring inotropic or vasopressor support.

Sepsis-induced hypotension is defined as a systolic blood pressure (SBP) < 90mm Hg or mean arterial pressure (MAP) < 70mm Hg or a SBP decrease > 40mm Hg or less than two standard deviations below normal for age in the absence of other causes of hypotension.

In the 2012 update of the Surviving Sepsis Campaign (45), a distinction is made between septic shock (sepsis-induced hypotension which persists despite adequate fluid resuscitation) and sepsis-induced tissue hypoperfusion which adds elevated lactate and oliguria to hypotension as markers of sepsis severity.

Appendix 6 Surviving Sepsis Campaign Guidelines

6.1 The Surviving Sepsis Campaign 6-hour resuscitation bundle

- Measure serum lactate
- Obtain blood cultures prior to antibiotic administration
- From the time of presentation, broad-spectrum antibiotics to be given within 1 hour
- Source of infection to be identified and drained within 6 hours
- In the event of hypotension and/or lactate >4mmol/L (36mg/dl):
 - Deliver an initial minimum of 20 ml/kg of crystalloid (or colloid equivalent)
 - Give vasopressors for hypotension not responding to initial fluid resuscitation to maintain mean arterial pressure (MAP) > 65 mm Hg
- In the event of persistent arterial hypotension despite volume resuscitation (septic shock) and/or initial lactate >4 mmol/l (36 mg/dl):
 - \circ Achieve central venous pressure (CVP) of >8 mm Hg
 - Achieve central venous oxygen saturation (ScvO2) >70%

This was initially defined in 2008 (42) and subsequently updated in 2012 (45).

Appendix 7 National Early Warning Score

Source: www.rcplondon.ac.uk/resources/national-early-warning-score-news



Appendix 8 Sepsis Six box contents

Sepsis 6 Box

Oxygen items

General items

1x Egg Timer Sepsis 6 stickers 1x Gentamicin chart

Venpuncture and Venflon kit

<u>IV fluid kit</u> 2x IV giving sets (1 blood, 1 standard)

1x nasal cannulae with tubing

1x "trauma" oxygen mask

Dry swabs2x IV giving sets (1 blood, 1 standard)Mepore tape roll1x 500ml bag Compound Sodium LactateAlcoholic wipes for venepuncture2x 5ml Luer-tip syringes2x "Butterfly" needles – green or blue4x Venflons (1 pink, 2 green, 1 grey)1x Venflon Vacuette "green" adapter2x Venflon Vacuette "blue" needles2x Venflon dressingsVacutainer bottles (2x purple, 2x yellow, 2x pale blue, 2x pink)2x 10ml vials of 0.9% sodium chloride1x blood gas syringe1x "Octopus" IV set

Blood Culture and Antibiotics

1x microbiology form 1x dressing pack 2x pairs sterile gloves (1x size 6, 1x size 7) 1x 100ml bag 0.9% sodium chloride solution 2x yellow drug additive labels 1x set blood culture bottles 2x Vacutainer adapters for blood culture bottles 2x 20ml Luer-tip syringes 4x hypodermic needles (2x green, 2x white)

Appendix 9 Thromboprophylaxis App Poster for the Wards



Appendix 10 Pre-existing Sepsis Six Documentation

Look for Signs of Systemic Inflammation in <u>every</u> patient with an elevated NEWS(>4) OR where infection is likely



Sepsis Six poster utilised by the Acute Physicians at RAH from 2012.

Sepsis Six: Complete within <u>1 hour</u> of arrival in hospital
SIRS 🗆 Suspected bacteraemia 🗆 Suspected source
Time of arrival - ED MAU
1. Oxygen to achieve Saturations >94%, \leq 98% (Caution in COPD)
Time Initials Comment
2. IV fluids challenge Time Initials Comment
3. Blood Cultures
Time Initials Comment
4. Intravenous antibiotics as per local guidelines
Time Initials Comment
5. Measure Lactate .
Time Initials Comment/level
6. Consider catheterisation (if organ dysfunction apparent or poor urinary output)
Time Initials Comment
NameDesignationSignature

Sepsis Six sticker utilised by the Acute Physicians at RAH from 2012.

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