Welcome to this edition of the Communiqué in which we discuss the benefits and potential dangers of medical protocols. To illustrate this we include a case review of the death of a patient that occurred in part, due to the strict adherence of local protocols.

A clinical protocol is a rigid set of instructions for the investigation and management of a specific clinical scenario. The introduction of protocols into health care originated from the aviation industry. There, aircraft safety was dramatically improved as early as the 1930s through the systematic introduction of checklists and protocols.

The experience of the aviation industry exemplifies many of the benefits of a rigid, systematic approach. Firstly, protocols act as a checklist to ensure that important steps in management are not overlooked. Secondly, they allow for less experienced practitioners to manage patients in an appropriate way until more senior assistance is available. Thirdly, where there are several potential, equally valid management options, protocols create a consistency that gives all members of the clinical team greater familiarity with a particular approach, and so, reduces the risk of human error in the implementation of care. Fourthly, the rigid nature of protocols creates a very clear plan. It can also be printed and easily handed over between different shifts of treating doctors and nurses. The set instructions expedite the investigation and management processes, and the various components of the plan are clearly divided, and roles allocated to the treating team.

Unfortunately, the very strength of a protocol is its key limitation. Strict adherence and ongoing reliance on protocols can create a number of potential problems. Protocols are designed with a generic patient in mind and hence, may not be equally applicable or appropriate for every patient. The use of protocols may create a false sense of security and confidence in less experienced medical staff. This may lead them to overlook or ignore signs of deterioration and so fail to call for help. An inadvertent consequence is that reliance on protocols may detract from the overall development of clinical reasoning in junior medical staff.

The erosion of clinical or situational reasoning is an issue being faced by the heavily protocolised aviation industry. Protocollisation has reportedly eroded pilot expertise leading to de-skilling of pilots, to the extent that the US Federal Aviation Administration has issued a Safety Alert mandating pilots should gain more manual flying experience - this would be synonymous to practicing medicine without protocols.

This situation was highlighted in the Air France flight, AF447. In 2013, an A330 crashed into the Atlantic Ocean killing all 228 passengers and crew, after the air speed sensor iced-over. The pilots in this situation were likely task saturated, unable to respond appropriately to the dynamically changing situation, resulting in loss of situational awareness. Effectively, the pilots did the precise opposite to what should have been done given the available information.

Similarly, some academic and clinical commentators have suggested that heavy dependence on protocols among medical trainees have meant that they, “forget, or never learn to be a physician and make judgments”. The aviation industry has taught us the great potential for improving safety through the use of systems and checklists, perhaps it is now time that we also heed their warnings about over-reliance on such systems.

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EDITORIAL

We are delighted to announce the introduction of the Future Leaders Communiqué. We have designed this Communiqué for junior medical practitioners and any other recently graduated health professionals. Each issue is developed, written, reviewed and edited by a junior medical practitioner to ensure we have provided the relevant clinical context combined with accessible language and up-to-date expertise.

The Future Leaders Communiqué is an educational resource that aims to help you become better at what you want to do in clinical practice. Each guest editor is someone like you, a person who knows what it is like to start work for the first time in a healthcare system now, and not many years ago.

Our guest editor for this, our inaugural issue, is Dr Nicholas Lonergan who is in his third post-graduate year working at a large regional hospital. Nicholas’ professional interest is in Emergency Medicine and he puts the use of protocols, guidelines and checklists under the microscope. We are fortunate to have three expert commentators in this issue. Dr Mark Putland, a Fulbright scholar offers his views from an Emergency Medicine perspective, Dr Heather Buchan explains the role of the Australian Commission on Safety and Quality in Health Care and, Mr Slav Racunica, a former RAAF pilot provides unique insights from aviation that are relevant to both experienced and inexperienced health professionals.

Future Leaders Communiqué joins our two other educational resources to improve clinical care and patient safety. You may already be familiar with the Clinical Communiqué designed for senior medical practitioners and health professionals with a focus on patient safety in acute health care settings, and the Residential Aged Care Communiqué designed for professionals delivering care to older people and nursing home residents.

The Communiqués contain narrative case reports about lessons learned from coroners’ investigations into preventable deaths. They are published free, distributed electronically every quarter, and use cases from local, interstate, and international jurisdictions to explore the challenges that clinicians face every day in providing clinical care.

Future Leaders Communiqué is made possible through the support of the Victorian Institute of Forensic Medicine, Monash University, La Trobe University, Department of Health and Human Services, Victorian Managed Insurance Authority, and the Postgraduate Medical Council of Victoria. It is an initiative that has been achieved thanks to the enormous generosity of the contributing junior medical staff, editorial team and expert commentators.

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ACKNOWLEDGEMENTS
This initiative has been made possible by collaboration with the Department of Forensic Medicine (DFM), Monash University, Victorian Institute of Forensic Medicine (VIFM) and Victorian Managed Insurance Authority (VMIA), La Trobe University, Dementia Training Centres, Department of Health and Human Services Ageing and Aged Care Branch, and the Postgraduate Medical Council of Victoria.

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DISCLAIMER
All cases that are discussed in the Future Leaders Communiqué are public documents. A document becomes public once the coronial investigation process has been completed and the case is closed. We have made every attempt to ensure that individuals and organizations are de-identified. The views and conclusions are those of the authors and do not necessarily represent those of the individual Coroner, the Coroners Court, Department of Health, Department of Forensic Medicine, Victorian Institute of Forensic Medicine or Monash University. If you would like to examine the case in greater detail, please contact us and we will provide the relevant website for the Coroners Court jurisdiction.

FEEDBACK
The editorial team is keen to receive feedback about this communication especially in relation to changes in clinical practice. Please email your comments, questions and suggestions to: flc@vifmcommuniques.org

FREE SUBSCRIPTION
The Department of Forensic Medicine Monash University and the Victorian Institute of Forensic Medicine will publish the Future Leaders Communiqué on a quarterly basis. Subscription is free of charge and will be sent electronically to your preferred email address. If you would like to subscribe to the Future Leaders Communiqué, please go to: www.vifmcommuniques.org/subscribe
Case Number: 20/2012 SA

Case Précis Author: Dr. Nicholas Lonergan MBBS, BMedSci (Emergency Registrar)

**CLINICAL SUMMARY**

Mr S was a 64 year old farmer who was thrown from his horse at approximately 5pm on a weekday in December 2009. He was transported to a tertiary hospital via helicopter where a CT scan of his abdomen and pelvis revealed a comminuted right pelvic fracture, with the whole of the acetabulum shattered, and a small retroperitoneal haematoma. His haemoglobin was 126g/L and he was deemed haemodynamically stable by the admitting orthopaedic registrar.

On ward round the following day, the orthopaedic team reviewed Mr S and anticoagulation was requested ‘as per pelvic protocol’. The prescribing intern felt ‘quite anxious’ as she had never seen or used this protocol before. The ward pharmacist was enlisted and checked the protocol and calculations. Enoxaparin 100mg twice daily was prescribed to start in 48 hours as per protocol. The following 48 hours were uneventful and the anticoagulant was administered as charted.

On the afternoon of the next day, Mr S clinically deteriorated. A HMO or registrar was not called to review the patient despite family concerns that he was “extremely pale, perspiring profusely…clammy, his skin smelt acidic…was very agitated”.

That evening, Mr S suffered an asystolic cardiac arrest and was successfully resuscitated after 20 minutes of downtime. His post-arrest CT showed a retroperitoneal haematoma extending 13.5cm in the sagittal plane and 8cm in the coronal plane. A blush of contrast was also seen indicating that he was actively bleeding at the time of the CT scan. Mr S failed to recover and died in the intensive care unit.

**PATHOLOGY**

An autopsy was conducted which found the cause of death to be “hypoxic-ischaemic encephalopathy complicating cardiac arrest due to retroperitoneal and pelvic haemorrhage complicating pelvic fractures”.

**INVESTIGATION**

The death was reported to the coroner. Witness statements were obtained from the treating team, including medical and nursing staff, and two expert witnesses were called.

One expert testimony during the inquest was obtained from an Intensive Care Specialist with extensive clinical and research experience in anticoagulation. His expert testimony was highly critical of the anticoagulation protocol at the hospital and found that the protocol for pelvic fractures was flawed, with “[no] literature supporting such a dose in this setting”.

In his opinion the therapeutic dose of enoxaparin which was given to Mr S, contributed to the fatal bleed. However, the expert noted that the intern who prescribed the anticoagulation had applied and followed the local protocol correctly. The hospital was accepting that the protocol was flawed and it was subsequently updated to reflect correct practice.

**CORONER’S FINDINGS**

The coroner concluded that the cause of bleeding was most likely from the branch of the right internal iliac artery that was severed by a migrating bony fragment. This movement was to be expected given the severity of comminuted pelvic fracture.

The dose of enoxaparin which was prescribed to Mr S probably contributed to the fatal bleed.

There was no criticism of the intern who had followed the hospital protocol, however the coroner and the expert witness were critical of the flawed ‘pelvic protocol’.

**AUTHOR’S COMMENTS**

Blindly following protocols without evaluation or an understanding of the underlying assumptions that contributed to protocol development may result in significant patient morbidity and mortality. In this case, the intern who prescribed the therapeutic dose of enoxaparin correctly enlisted support due to her inexperience with using the protocol. However, the appropriateness of prescribing therapeutic anticoagulation in the setting of a significant pelvic fracture was not considered, rather the protocol was followed without question by both the intern and pharmacist.

It may be difficult for doctors, especially junior doctors, to analyse a protocol and determine whether it would be safely and/or appropriately applied to the situation in front of them. This may be due to inexperience, lack of clinical knowledge, or lack of clinical support by senior colleagues. Protocols need to facilitate discussion, review, reflection, and if appropriate, non-compliance if indicated. For this reason, it is essential that doctors, at any level, retain the ability to think and be supported through appropriately crafted protocols.

**KEYWORDS**

Anticoagulation, trauma, protocol, pelvic fracture, haemorrhage
PROBLEMS WITH PROTOCOLS

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With the benefit of hindsight, full anticoagulation of patients with comminuted pelvic fractures and associated haematoma seems poorly formulated. Full anticoagulation of all pelvic fracture patients is a significantly more aggressive approach to thromboprophylaxis than its used currently however, the science in this area remains unsettled. In any case, for the sake of examining the use of protocols in modern medicine we can assume that in this case the protocol contributed to the death of the patient.

The origins of protocols may be traced beyond the medical world to theories of management that arose out of the mechanisation of industry during the industrial revolution. Early in the 20th century the Scientific Management movement developed, which saw workers as another part of the machinery of production, to be engineered for optimal performance.

In the period after WWII the growing cadres of middle managers led to the development of Decision Making Theory. This aimed to improve the decision making of these managers by limiting their options and by having them consider information and make decisions in a structured and formulaic fashion. From this school developed standard operating procedures, algorithms and protocols.

At that time, the idea that a professional field like medicine would be managed in the way that corporate middle managers were managed would have been inconceivable. In recent decades however, several factors have led to the proliferation of these tools in medicine. Health care has become much more complex. Hospitals have evolved from charity institutions to organisations providing a service for payment (whether through taxation, insurance or direct payment). The patients’ rights movement has developed as an offshoot of the civil rights movements of the mid-20th century.

Consequently, expectations have developed amongst the users and regulators of teaching hospitals that patients will receive from the junior medical staff the same level of care as would have been delivered by the consultant. In fact, the care delivered by a given consultant is increasingly expected to be of the same standard that would have been delivered by a national or world expert in the field. Consultants are significantly more involved in the day-to-day clinical care in teaching hospitals now than they were even two decades ago, however, they are not able to provide directly all the care delivered in the hospital.

In an attempt to extend the reach of the consultant, junior medical staff are increasingly expected to follow protocols and guidelines developed by their consultants, or developed externally and approved for use by their consultants.

Problems occur when:
- The protocol is poorly conceived in the first place and gives bad direction,
- The protocol is poorly worded and is open to misinterpretation,
- The protocol fails to cover specifically all possible clinical scenarios, so that junior staff are left to make their own interpretations.

The question of whether this case represents a poorly conceived protocol or a failure of the notion of protocols altogether is difficult to answer. It is tempting to invoke “common sense” or “clinical judgement of junior doctors” as factors which might have mitigated the increase in consultant engagement in public hospital care over recent decades. To my knowledge this hypothesis has not been tested and the absence. With the pressure on all in healthcare to increase productivity there is the risk that experienced medical staff are being made busy elsewhere while their juniors are left to follow protocols and guidelines in their absence. To my knowledge this hypothesis has not been tested and the increase in consultant engagement in public hospital care over recent decades would suggest that it is unlikely to be the case.

A subtler negative effect of the use of guidelines, protocols and algorithms is that by extending the reach of the consultant they may allow more work to be done in the consultant’s absence. With the pressure on all in health care to increase productivity there is the risk that experienced medical staff are being made busy elsewhere while their juniors are left to follow protocols and guidelines in their absence. To my knowledge this hypothesis has not been tested and the increase in consultant engagement in public hospital care over recent decades would suggest that it is unlikely to be the case.

Ultimately, the demands on the health care system for productivity, quality and accountability mean that decision support and decision management strategies will remain important features of our work. Just as consultant advice is only as good as the consultant giving it, these tools are only as good as the people and processes behind their creation.
Local organisational protocols describe the steps taken in the care of a patient. They provide a way of implementing evidence and evidence-based guidelines by describing what should be done for patients, when, where and by whom at a local level. The aim in standardising practice in this way is to reduce undesirable variation in the treatment of patients and improve the quality of care. The responsibility to ensure that protocols meet these aims rests with both the healthcare organisations and the clinicians who work within the organisations.

The effectiveness of a protocol in improving care outcomes is dependent on the quality of the protocol, the way in which it is integrated into organisational systems and the way in which the protocol is applied in practice.

It also reinforces the need for ongoing clinical assessment of patients and, of ensuring the care provided is appropriate to manage the needs and potential risks for each individual.

This case identifies a range of issues concerning one hospital protocol dealing with provision of anticoagulation to patients - the content of the protocol itself, the information, training and supervision provided to junior staff about protocols in use in the hospital, and the monitoring of care provided. It also reinforces the need for ongoing clinical assessment of patients and, of ensuring the care provided is appropriate to manage the needs and potential risks for each individual.

In Australia, all acute health services and day procedure centres are required to meet National Safety and Quality Health Service (NSQHS) Standards. The first of these ten Standards outlines the general and overarching requirement for organisations to have integrated governance systems to maintain and improve the reliability and quality of patient care and outcomes. The Standard also specifies that healthcare organisations promote clinical practice that is evidence based and effective. There is an explicit requirement for use of appropriate clinical guidelines and pathways that are supported by the best available evidence, and for routine monitoring and evaluation of their use.

Poor protocols that are misunderstood or misinterpreted will not lead to good outcomes. Senior clinicians and managers are responsible for ensuring that their organisations develop sound protocols that are well integrated into care systems. A clinical protocol should clearly state its purpose and the patient groups it covers, and should specify care that is consistent with the evidence of benefit in these groups of patients. Actions that need to be taken to mitigate any potential harms or risks associated with care should be explicitly stated. The use of protocols should be included in the orientation of clinical staff and the expectation of good supervision of junior staff should apply regardless of whether protocols are in use or not. Monitoring of the use of the protocol is important so that potential problems with the protocol itself, or how it is being applied in practice can be identified. Clinical staff need to remain aware that, as with guidelines, use of a protocol does not replace the need for thoughtful assessment of a patient's clinical condition and response to treatment.

This case also highlights how the absence of protocols can adversely affect patient care and outcomes. Failure to recognise and respond to clinical deterioration is a major contributor to adverse events and outcomes for patients in hospitals.

Avoidable deaths are tragedies for everyone concerned. While the judgment and actions of individual clinicians will always be key to avoiding potentially preventable deaths the culture, policies and protocols established within organisations are also critically important.

FURTHER READING


Australian Commission on Safety and Quality in Health Care (ACSQHC), (September 2011). National Safety and Quality Health Service Standards, ASQHC, Sydney.
Checklist use originated in 1934 in response to a failed test flight of the Boeing model 299 (later to become the B17) bomber where in spite of a highly experienced crew operating the aircraft, a basic procedural step of unlocking the elevator flight surface was omitted. The aircraft stalled and crashed which cast dispersions on the integrity of the aircraft's design and brought Boeing to the edge of bankruptcy. At the time the aircraft was dubbed "too much for any man to fly", however subsequent insight refined the issue as "too complex for any one man's memory". Out of necessity the checklist was born and the B17 bombers flew over 1.8 million nautical miles without incident.

The pilot's checklist is a step-by-step procedure executed by the pilot (and often involving the co-pilot and other members of the crew) by which each critical system and function is checked and verified to be correct for the aircraft's current disposition. Checklists are designed to be a standard foundation for verifying aircraft configuration. They act as a buffer against any reduction in the flight crew's psychological and physical condition by providing convenient sequences of motor and eye movements. A secondary effect is to improve flight deck teamwork by enhancing cross-checking of actions and using a proscribed procedural framework to promote a shared mental model between crew members. Countless lives have been saved by this simple yet very effective tool.

The improper use, or the non-use, of the checklist by flight crews is often cited as the probable cause or at least a contributing factor to aircraft accidents. A recent example was the loss of a Boeing 737 operated by Helios where problems with communication and training, misinterpretation of a dual purpose aural warning horn, and lack of critical actions being expeditiously performed, were implicated. The correct checklist actions for decompression, by memory or otherwise, were never accomplished before the crew were incapacitated. All souls on board perished.

In aviation, there is clear differentiation between normal operations and non-normal operations with philosophies that govern checklist use in both circumstances. Non-normal (or non-routine) operations infer a deviation from normal aircraft operating states or external environmental influences. Boeing gives guidance on the use and most importantly, the limitations of checklist use:

"While every attempt is made to supply needed non–normal checklists, it is not possible to develop checklists for all conceivable situations. ....the captain must assess the situation and use good judgment to determine the safest course of action. ....In some multiple failure situations, the flight crew may need to combine the elements of more than one checklist. ...At the Captain's discretion, deviation from a checklist can be needed..."

Checklist incorporation into the medical sphere has been a valuable tool for both education and human factors error management. In 2009 the World Health Organization issued a 'Surgical Safety Checklist' as well as an implementation manual to assist with its inception. The instructions are clear as to the purpose and use of the checklist - a direct comparison to the aviation checklist.

THE CHECKLIST AS A SYSTEM

A checklist is not an end in itself, but is a single component of a robust system, be it industrial, aviation or medical. Whether we choose to acknowledge our inherent weaknesses as humans or not, checklists originated and have evolved in response to a need to learn from systemic errors and accidents. As proposed by James Reason in 1990, and quickly adopted by the wider community, the ‘Swiss Cheese’ model incorporates the checklist as a layer of systemic risk management. It recognises that in any system there are inherent weaknesses in every layer that need to be ameliorated with multiple methods of defence, of which a checklist is but one.

The inference in systemic checklist use is that a system will take responsibility for the design, implementation, and ongoing evolution of the procedures. To support the systemic layers, the organisation should have a strong culture of teaching, reporting, and learning from incidents.
The organisation must have processes that incorporate incident lessons, allowing behaviour modification to facilitate error rate reduction, and integrate checklist and procedural modification.

**INDIVIDUAL USE OF CHECKLISTS**

The risk inherent in a systemic approach to error management with checklist use is individual reaction. Without proper training and supervision in checklist use and the limitations of the procedures covered, an individual can become overly reliant on ‘the system’. This can result in an abrogation of personal responsibility from the individual to the organisation that is represented.

A checklist is thus not an end in itself, nor a prompt for action but a valuable tool within an effective individual decision-making model. An example of a decision-making model is:

- **C** - Clarify the problem
- **L** - Look for ideas and input and share information
- **E** - Evaluate different solutions
- **A** - Act on your decision
- **R** - Review performance

The checklist is best used after evaluation of a scenario has led to a diagnosis of the problem, be it medical or material. The checklist is then part of the implementation phase. However, an oft ignored part of any robust decision-making model is a continual reappraisal of actual versus expected outcomes.

In the context of a flight where a crew comes together and remains together until the flight is complete, re-evaluation is confined to the team that experiences any issue. However, this is not the case in the context of a hospital where one party can make the diagnosis, another person can implement the checklist and/or procedural actions, and a third party can assume responsibility for expected outcomes. The onus is upon both the system and the individuals to ensure common mental models of any situation are established and passed onto relieving staff.

Most importantly, as an individual working in a complex and dynamic environment, there will always be situations presented outside the scope of normal and non-normal procedures/protocols, checklists and experience.

In those cases, the actions will be guided by experience and analysis, sometimes in a short period of time, that will require reversion to the basic maxims of medicine/aviation.

This may include applying a combination of more than one checklist, or deviating from the checklist entirely for a specific reason.

In aviation some basic maxims to revert to are:

- **Aviate** - fly the aircraft, don’t crash trying to reprogram a computer.
- **Navigate** - keep situational awareness of your condition as well as projecting into and processing the environment around you (weather, terrain, hostile airspace).
- **Communicate** - talk, succinctly to your crew, and any agencies that you believe can assist you with your predicament.

And more recently as increasing levels of automation become prevalent:

- **Manage**.

**SUMMARY**

Checklists can be useful for both individual and systemic error reduction. The starting point on the journey will be the acknowledgement that to err is part of the human condition and that the aim is always to ensure the best possible outcome for both passenger and patient.

**FURTHER READING**


**COMMENTS FROM OUR PEERS**

“The coroner’s report of this case makes a good point about considering the applicability of medical protocols. It reminds me that when following protocols I should always have the patient’s specific circumstance in mind.”

“The expert commentaries raise this same point that protocols should exist to generate discussion and it is a starting point for management and it is worthwhile discussing appropriateness with more senior medical staff. This would include expressing any hesitations or concerns I might have.”

“Protocols are helpful, however if you are unsure, unfamiliar or uncomfortable with what the protocol requires you to do, it is important to ask someone more senior for advice.”

“Anti-coagulation is important for inpatients to prevent VTE, however it is important to think about the harm it may cause to the individual patient before prescribing it – both at therapeutic and prophylactic doses.”

“When a family are concerned that their relative has deteriorated or changed, it is important to review their relative has deteriorated or changed.”
The Clinical Communiqué is an electronic publication containing narrative case reports about clinical lessons learned from patient deaths that have been investigated by the coroners’ court.

Next Edition: December 2016

The Residential Aged Care Communiqué is an electronic publication containing narrative case reports about lessons learned from coroners’ investigations into preventable deaths in Residential Aged Care settings.

Next Edition: February 2017

The Future Leaders Communiqué is an electronic publication containing narrative case reports about lessons learned from coroners’ investigations into preventable deaths. These articles are written by healthcare graduates with a fresh take on current matters.

Next Edition: January 2017