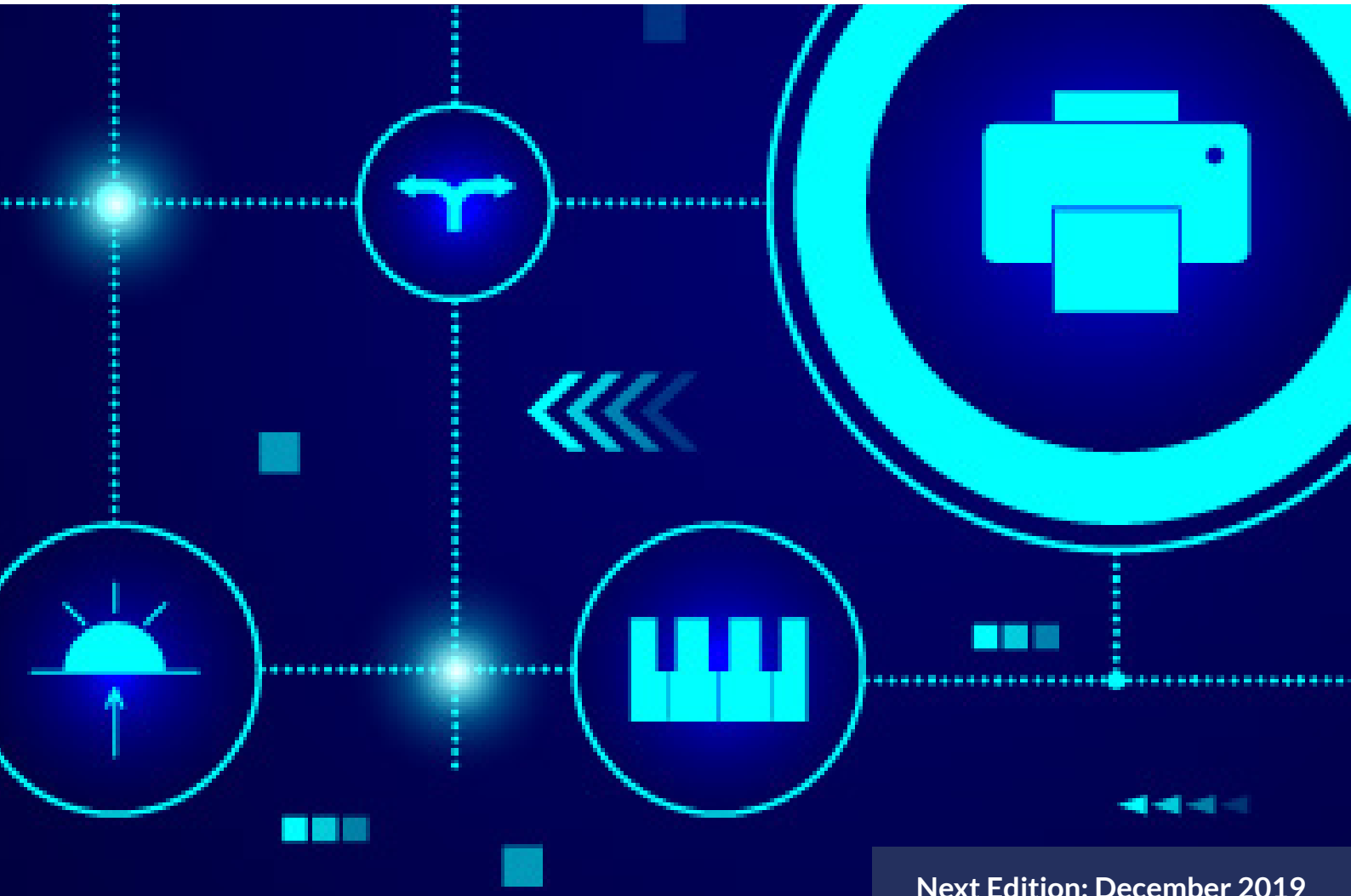
THE COMMUNIQUÉS

VOLUME 6. ISSUE 3.
SEPTEMBER 2019 Edition
ISSN 2204 - 0099

Clinical Communiqué



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Editorial

Dr Nicola Cunningham

Welcome to the third edition of the Clinical Communiqué for 2019. In this edition we present two cases - Baby AE and Mr M, where shortcomings in the interface between humans and technological systems slowed or distorted the transmission of information (diagnostic test results), contributing to their deaths. Our expert commentary, which has been jointly written by two leading researchers in the field of medical informatics and digital health, explores these shortcomings further, and offers sage advice on how to improve our communication systems. Technological advances in diagnostic testing only benefit our patients when there are robust systems in place for the delivery and receipt of those results.

Associate Professor Farah Magrabi, an engineer by training, has conducted extensive research into the causes, consequences and outcomes of adverse events arising from digital technologies in health care. Professor Andrew Georgiou is a health and pathology informatics researcher who has published widely in quality and safety, outcomes measurement, and organisational communication. With particular reference to this edition, his work has included system specific issues in the communication of critical test results.

In a similar fashion, the inquest into the death of Mr M also demonstrates the merits of joint expertise when utilised in the form of concurrent expert evidence. This approach is sometimes adopted in coronial proceedings, where experts called by each party (or by the coroner) proffer their opinions after they have been given the opportunity to collectively discuss and consider the questions put to them. The group of experts are referred to as an expert conclave, and the provision of their concurrent evidence is also known as 'hot tubbing'. On the day of their evidence, the experts are presented with a list of questions and may be given time to formulate their answers in a private session before being heard by the court. The purpose is to allow a forum whereby experts can identify the issues at hand and reach common resolutions or address the basis for any disagreements. The coroner therefore has the benefit of exploring the opinions of experts who, not being constrained by an adversarial process, have freely and respectfully considered the views of their colleagues. This has the effect of refining the court's focus to the critically, and genuinely held points of difference in the evidence. Concurrent expert evidence has also been used in criminal and civil court hearings.

Thank you to all our readers for your ongoing support and the overwhelmingly positive feedback we have received since the launch of our new look and website. We look forward to sharing more coronial lessons and health care insights with you, well into the future.

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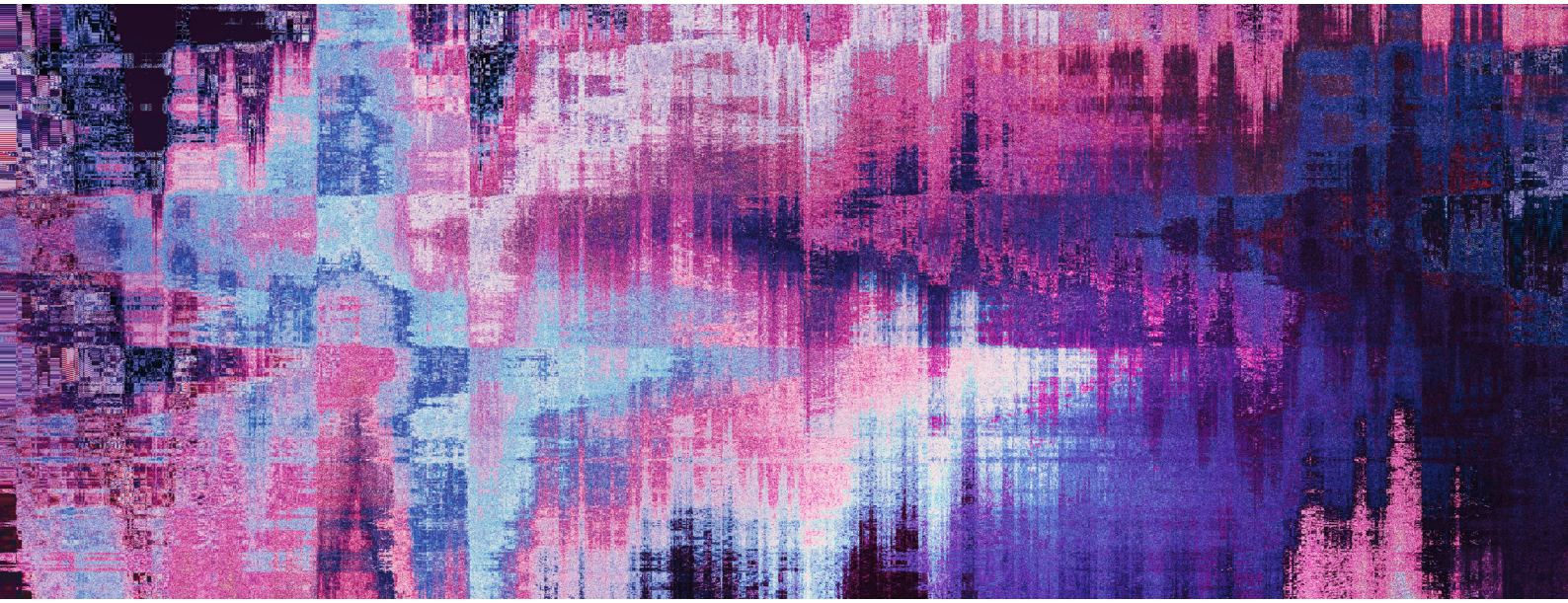

Case #1 Informing the delivery

Case Number
COR 2014 2294 Vic

Case Précis Author
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i. Clinical Summary

Baby AE was an infant born at 41 weeks gestation following an uncomplicated pregnancy with a normal morphology ultrasound at 20 weeks. Baby AE's mother was admitted to hospital when her labour commenced and her membranes spontaneously ruptured soon after. The maternal observations recorded in hospital were normal, and the liquor was described as pink. Initially the attending midwife assessed the foetal heart rate (FHR) by intermittent auscultation. The readings were normal with a baseline of 110-160 beats per minute (bpm) and no audible decelerations.

Several hours later the midwife detected a rising baseline FHR and an audible deceleration, findings that may be associated with foetal compromise. Baby AE's mother had been pushing with contractions for approximately two hours with no progress in the descent of Baby AE's head. The obstetric registrar who was called to assist then performed a vaginal examination and applied a foetal scalp electrode attached to a cardiotocography (CTG) to enable continuous FHR monitoring. Full dilation of the cervix was confirmed by vaginal examination.

An hour later a decision was made in consultation with the on-call obstetric consultant for a trial of instrumental delivery in theatre. This was because there was still no progression in the descent of Baby AE's head despite active maternal pushing, and meconium liquor had been observed.

After two attempts of vacuum extraction suction, the foetal head was delivered with the application of forceps. It was noted that the umbilical cord was tight around Baby AE's neck and there was thick meconium. Shoulder dystocia was recognised with foetal head retraction into the perineum. McRoberts manoeuvre (flexion and abduction of the maternal hips), posterior arm delivery, and rotational manoeuvres, were all attempted before Baby AE was successfully delivered.

There was a three-minute delay between delivering the head and the body of baby AE. The paediatric registrar immediately assessed baby AE as being in poor condition, covered in meconium, with no heart rate or breathing effort. Intubation and cardiopulmonary resuscitation (CPR) were performed. A heart beat was first heard at six minutes of life.

At 19 minutes, Baby AE's heart rate was 100 bpm and CPR was stopped. At 40 minutes of life, Baby AE's heart rate had increased to 140 bpm but there was no spontaneous breathing or movements.

Despite ongoing resuscitation, peripheral perfusion remained poor and Baby AE had increasing oxygen requirements. The impression was that Baby AE had severe hypoxic-ischaemic encephalopathy. At approximately six hours of life, Baby AE became bradycardic and hypoxic, and CPR was re-commenced. Baby AE's pupils were fixed and dilated, there was no gag or suck reflex, no spontaneous movements and no audible heart rate. Resuscitation was ceased after a discussion between the medical staff and the family.

ii. Pathology

At autopsy, the forensic pathologist observed that Baby AE weighed 4.42kg which is above the 97% centile for a 41-week baby. The cause of death was described as perinatal asphyxia. In addition, the forensic pathologist identified features of in-utero brain ischaemia, meconium and amniotic fluid aspiration, chorioamnionitis, and foetal thrombotic vasculopathy. In combination, they resulted in Baby AE being physiologically compromised and less able to withstand a complicated delivery.

iii. Investigation

The Coroners Prevention Unit (CPU) reviewed the circumstances surrounding Baby AE's death. Statements were obtained from the staff involved in Baby AE's care.

An independent expert opinion from an obstetrician was also sought as part the CPU investigation. The overall view was that Baby AE had received appropriate care. The timeline to delivery, the decision to perform a trial of instrumental delivery, and the management of the shoulder dystocia were all reasonable in the given circumstances.

The CPU noted that AE's mother had a family history of diabetes mellitus and therefore had been tested for gestational diabetes mellitus (GDM) at 18 and 28 weeks' gestation. There are three measures in the results of an oral glucose tolerance test (GTT): a fasting plasma glucose level, a plasma glucose level at 60 minutes, and a further plasma glucose level at 120 minutes. The oral GTT results for Baby AE's mother were normal at 18 weeks but the 120-minute glucose level was abnormal at 28 weeks. Therefore, Baby AE's mother should have been diagnosed with GDM however this did not occur for a number of different reasons.

Firstly, when the details for the test request were submitted into the laboratory computer system, the patient was not registered as being pregnant. This caused the result to have the wrong reference intervals.

Secondly, the pathology laboratory was in the process of introducing a new computer system at the time of the 28-week GTT. The system code that was used to order her test was not configured for the entry of results from three glucose samples. Her fasting results were entered and correctly communicated by the pathology service, but her 60 and 120-minute glucose test results were missed in the patient report file because these were set as optional fields in the computer system.

Thirdly, there was a 'computer transfer error' at the hospital which resulted in the abnormal GTT result only being uploaded onto the hospital's pathology computer system approximately three months after the birth of Baby AE. In addition to the technological limitations, the treating medical staff failed to make proactive enquiries to determine the results of the 28-week GTT.

In addition to the technological limitations, the treating medical staff failed to make proactive enquiries to determine the results of the 28-week GTT.

Although Baby AE's birth weight was above the 97th centile, Baby AE's mother had normal fundal height measurements during her pregnancy. The coroner heard that clinical estimation of foetal weight is unreliable. Without the diagnosis of GDM there was no reason for the medical staff to anticipate a macrosomic (large for gestational age) baby.

iv. Coroner's Findings

The coroner made a finding without inquest that the missed diagnosis of GDM in Baby AE's mother was the main contributing factor to Baby AE's death from perinatal asphyxia. GDM is associated with an increased risk of macrosomia, shoulder dystocia and late stillbirth. If the diagnosis had

been made, antenatal care would have likely included input from a dietician and diabetes educator, careful monitoring of blood sugar levels, and an additional ultrasound late in pregnancy. Labour management would have likely been very different also, with a heightened awareness of the risks. There would have been increased vigilance with possible induction of labour prior to term, continuous CTG monitoring during labour, and potentially a decision to proceed to caesarean section instead of trialling an instrumental delivery.

The coroner found that Baby AE's death could have been prevented if the diagnosis of gestational diabetes had been made.

The failure was both a system error on the part of the pathology service, and failure of the hospital medical staff to follow up blood results.

Changes have since been implemented both at the hospital and at the pathology centre. Following their internal review of Baby AE's death, the hospital introduced an improvement project that highlights the responsibilities of the clinician ordering a test to follow up the complete results.

The pathology centre corrected their system error so that all three results of a GTT must be entered into the patient report file. They also commenced more general, widely applicable risk minimisation procedures to prevent similar technological errors arising in the future.

v. Author's Comments

In health care, much of what we do as clinicians is heavily dependent on technology. Although we often rely on computer software to deliver results of investigations, and bring abnormalities to our attention, technological systems are not immune to error. Results always need to be interpreted with the clinical context in mind, and despite significant advancements in healthcare informatics, it remains the responsibility of the treating healthcare providers to ensure this occurs.

In this case, data collection at the point of admission, such as a checklist for mandatory results, would have offered a clinician-led opportunity to ensure that technological and systematic steps up to that point were accurate. This case demonstrates the importance of clinicians being involved in IT changes and highlighting what is needed of the system to safeguard the processes of follow up and interpretation of patients' results.

Although we often rely on computer software to deliver results of investigations, and bring abnormalities to our attention, technological systems are not immune to error.

vi. Keywords

Obstetric, technology, error, gestational diabetes mellitus, results

Case #2 Getting all the fax

Case Number
COR 2015 5857 Vic

Case Précis Author
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i. Clinical Summary

Mr M was a 58 year old male, otherwise well, who was married with two daughters. He was a civil engineer working at a regional centre and staying in a hotel away from his family while he worked.

After a week of general symptoms including weight loss, fevers, a sore throat and loss of appetite, Mr M presented to a regional hospital, where he was diagnosed with Hodgkin's lymphoma. He was transferred to a major metropolitan hospital where the diagnosis was confirmed and he was commenced on chemotherapy with ABVD (adriamycin, bleomycin, vinclastine, dacarbazine).

As he tolerated the chemotherapy well, he was discharged back to his hotel the next day. He was referred to Dr R, a haematologist, who agreed to oversee ongoing chemotherapy at the regional hospital. Dr R visited once a month, and it was not uncommon for him to manage chemotherapy at the regional site as an outreach service.

Mr M tolerated three further doses of chemotherapy well, under the guidance of Dr R, and it appeared he was improving clinically. However, it was acknowledged that Mr M had "high risk disease", which carried a lower chance of cure.

In order to track the progress of the Hodgkin's lymphoma, Dr R referred Mr M for a positron emission tomography (PET) scan. The referral was faxed from "Fax Number A", with a return address for "Dr R at Clinic A". The scan was requested for the purposes of "restaging" the Hodgkin's lymphoma, which was effectively a routine request.

Specifically, Dr R was not investigating for, or actively concerned about, chemotherapy toxicity.

The PET scan occurred on a Wednesday, and was reported the same day by Dr X, a nuclear medicine physician. It showed *'widespread uptake of the tracer within both lung fields, possibly related to bleomycin toxicity or opportunistic infection.'* The extent of the uptake was an extremely unusual and an unexpected finding.

For reasons that were unclear, the PET report was sent the next day to "Fax Number B" (instead of "Fax Number A") and posted to "Dr R at Clinic B". There was no record of the facsimile being received at "Fax Number B". Importantly, the unusual and unexpected findings of the PET scan were not communicated verbally to Dr R.

When Mr M presented for his 5th dose of chemotherapy on Friday, two days after the scan, he was seen by an intern who noted a five-day history of a dry cough and sore throat. He was not clinically unwell though - and had minor blood tests abnormalities that were consistent with his disease.

Due to his visiting schedule, Dr R was not present for the administration of the 5th dose of chemotherapy. This was not unusual as the schedule had been pre-planned, and Mr M had tolerated the previous doses. Furthermore, neither Dr R, nor the intern, nor the regional hospital were aware of the results of the PET scan at that stage.

Over the weekend, Mr M became progressively short of breath. He visited his family and told them he *'felt as if his whole body was on fire'* and he appeared to have difficulty breathing and walking. He called Dr R's rooms on Monday to report he was not feeling well and was advised to present to the local hospital. Later that evening, Dr R opened mail containing the results of the PET scan. Although this finding was unexpected and potentially serious, Dr R did not contact Mr M as he had assumed that Mr M had presented to the local hospital and that the hospital had receipt of the results already and would call him about Mr M's presentation.

Unfortunately, Mr M was found deceased in his hotel room the next morning.

ii. Pathology

Following an autopsy on Mr M, the pathologist recorded the cause of death as complications of chemotherapy related to Hodgkin's lymphoma. He found reactive pneumocytes and interstitial fibrosis and considered that severe and rapid onset bleomycin toxicity had contributed significantly to Mr M's death.

iii. Investigation

The coroner held an inquest to investigate concerns about the adequacy of communication of abnormal test results between Dr X, the reporting physician, and Dr R, the treating haematologist. The coroner called to inquest the two specialists involved in the case, and also heard evidence from four additional specialists in the fields of medical imaging and haematology, who gave their evidence concurrently as an expert conclave.

Dr R explained that he was not expecting any abnormal results in the PET scan, and specifically it was not done for the purposes of looking for bleomycin toxicity. Instead the scan was being used to stage Mr M's response to the disease. Indeed, it was not a mandatory test before the next dose of chemotherapy. Furthermore, ongoing treatment - including the decision to withhold chemotherapy - would normally be guided by clinical signs and symptoms. Finally, although pneumonitis from bleomycin has been described, it is very rare and difficult to treat.

Dr X explained that she had also expected that faxed and mailed copies of the result would be both received and acted upon by Dr R in a timely manner. There was no indication on the referral as to when the next dose of chemotherapy was due to be given. She was not aware that it was due two days later nor that Dr R would not review the PET result prior.

The expert conclave agreed that the result was potentially *'quite'* or *'very'* significant and Dr X was entitled to expect that Dr R would follow up the result before further treatment. They also agreed that the results warranted timely communication but could not reach consensus about whether facsimile was sufficient or direct communication by telephone was also needed.

The conclave responded that electronic distribution of results with confirmation of receipt should be routine.

The coroner invited the expert conclave to recommend ways to improve systems for communication of diagnostic results in the future. The conclave responded that electronic distribution of results with confirmation of receipt should be routine. The conclave was also invited to consider the formulation of specific criteria or *'words'* that would indicate those results requiring direct communication at the time of reporting. The conclave suggested the matter be referred to the relevant colleges to consider further. A final option put to the conclave by the coroner was the routine distribution of results to patients as well as their doctors.

The conclave unanimously rejected the proposition, emphasising the need for an "interpretive filter". They acknowledged however, that in certain scenarios, direct communication of results to the patient may be a reasonable next step.

iv. Coroner's Findings

The coroner found that there were shortfalls in both Dr R's and Dr X's management. Once the PET scan was performed, there existed an onus on both the reporting and referring clinicians to ensure that the abnormal results were acted upon in a timely manner. If the result had been telephoned through to Dr R on the Wednesday, the chemotherapy would not have been given to Mr M on Friday. Once the result had been seen by Dr R the following Monday evening, there was an expectation that he make reasonable attempts to contact Mr M, his family, and the hospital to ensure the results were acted upon urgently. Although it was probable that the bleomycin toxicity was not reversible, avoiding further exposure was Mr M's only chance of survival. He also lost the opportunity to have a more comfortable death surrounded by loved ones.

The coroner cited the *Royal Australian and New Zealand College of Radiology Standards of Practice for Diagnostic and Interventional Radiology*, which recommends the provision of nuclear medicine reports meet the requirements of the *Australian Association of Nuclear Medicine Specialists Standards*. That is, reports are to be provided *'within 24 hours'*, or communicated directly to the referrer if there are *'urgent or unexpected findings'*. The coroner recommended that the Royal Australian and New Zealand College of Radiologists, the Australian Association of Nuclear Medicine Specialists, and the Royal Australasian College of physicians work on a collaborative set of Standards dedicated to systems for the communication of imaging results. These standards would ideally explicitly specify expectations of the roles and responsibilities of both the referrer and the reporter –particularly with respect to communication of urgent and unexpected results. The coroner highlighted that *'good medical care demands not only a collaborative approach between health professionals, but individual responsibility for patient welfare'*.

In this case, there were a series of delays in the communication of unexpected and abnormal results, from a routine test.

The coroner also recommended urgent phasing out of *'fax transmission'* of results, which was described as *'antiquated'* in the era of email.

v. Author's Comments

Chemotherapeutic agents are known to have toxic side effects; however, this case is not about chemotherapy toxicity. Instead it is about communication of abnormal or unexpected results in a timely manner, in order to prevent harm to the patient.

In this case, there were a series of delays in the communication of unexpected and abnormal results, from a routine test. The coroner found that the onus rested jointly on both the referrer and the reporter to make sure that the test results were delivered and received.

Many clinicians working within the public health sector will be all too familiar with the types of delays in communication observed in this case, possibly even to the point of resigned complacency. Some clinicians may have also been involved in cases where significant test results were missed – perhaps due to workload, delegation to junior medical staff, incorrect contact details, or simply human error.

The effect of human factors can be mitigated by systemic changes that serve to *'close the loop'* on communication. Electronic mail (including *'read receipts'*) is currently the most effective way to achieve this, particularly due to the immediacy of delivery and trackability. It is no longer reasonable to rely on communication of important medical results by facsimile. Rather, direct clinician communication, usually via a telephone call or face-to-face discussion, followed up by written communication, ensures that the message delivered is the message received.

It is not a fail-safe process - but it is currently the best workable option that we have.

vi. Keywords

Communication, radiology, imaging, chemotherapy, results, facsimile

Expert Commentary
Digital health – keeping patients safe

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Diagnostic testing (pathology and medical imaging) plays a major role in the diagnosis, prevention and treatment of disease, and consequently is critically important for the safe and effective delivery of health care.[1] Diagnostic error can be defined as the failure to: a) establish an accurate and timely explanation of the patient's health problem(s); or b) communicate that explanation to the patient.[2] It is a major patient safety hazard, accounting for 6% to 17% of hospital adverse events.[2] One of the biggest contributors to diagnostic error is the failure to follow-up on test results – identified by the World Health Organization, World Alliance for Patient Safety as a priority patient safety area.[3]

The importance of the safe and effective communication of test results was tragically confirmed by the two cases presented in this edition. One of the cases involved the death of Baby AE from perinatal asphyxia. Baby AE's mother was suffering from gestational diabetes mellitus which remained undiagnosed because the abnormal result of a 28-week Glucose Tolerance Test was not communicated to the responsible clinicians, and therefore not followed up. Had the mother been appropriately diagnosed she would likely have been the recipient of a different level of monitoring, care and delivery. The coroner concluded that the failure to diagnose Baby AE's mother was due to both a system error on the part of the pathology service for failing to communicate the results onto her file; and a failure of the health care provider to follow up on the outstanding test results.

The following year, Mr M died from complications of chemotherapy for the treatment of Hodgkin's lymphoma. The coroner found Mr M may have survived if the results of a Positron Emission Tomography (PET) scan indicating he was suffering from toxicity due to his chemotherapy, had been correctly conveyed to the treating doctor. The results of the PET scan had been faxed but not received. The coroner's finding highlighted the importance of effective communication that encompass not only the method of information delivery (e.g., problems associated with faxes) but also the responsibilities related to the review of results, pointedly asking if hospitals are dedicating the time and resources for clinicians to ensure that results are received and read. The coroner also flagged the potential for results in many cases to be distributed to patients as an added protection against the possibility of significant results going missing.

The terrible consequences of the two cases are not a new phenomenon. In 2012, the Clinical Excellence Commission (CEC) in New South Wales reported that 11% (3/27) of clinical incidents resulting in a serious outcome (e.g., patient death), and 32% (24/75) of clinical incidents with major patient-related consequences, were related to problems with test follow-up.[4] Every day between 41% and 100% of patients leave hospital with at least one test pending at discharge, influenced in part by pressure to reduce length of stay.[5,6,] Approximately 30% to 40% of finalised test results pending at discharge are likely to change patients' management, so timely follow-up is vital to ensure diagnosis and treatment are not delayed.[7]

The tragic circumstances surrounding the deaths of Baby AE and Mr M demonstrate the patient care process is not a single undertaking but a multi-layered series of tasks involving many people across different components of the healthcare spectrum.[8] It follows therefore that the provision of safe care must engage all stakeholders (including patients) to arrive at effective decisions about who needs to receive the results of tests,[9] and how and when the results are acknowledged and acted upon.[10]

The cases also draw attention to the role that information (relating to patient-specific factors and biomedical knowledge) plays in the provision of our complex healthcare system. It goes without saying that the information of our modern medicine system is large in volume and diversity.[11] Strategies to improve test result follow-up should include the use of health information technology (IT) for the communication of test results using automated result notifications to the appropriate clinician responsible for a patient's care.[12] These IT-focused solutions come with their own risks with the potential to harm patients on a large-scale,[13], [14] so they need to be supplemented by initiatives to establish guidelines and recommendations for successful implementation, quality improvement and evaluation.[10], [15-19]

Health services need to pay particular attention to system transitions. These are often the times of high risk because this is when new hazards and errors are most likely to be introduced by how the systems are implemented and configured.[20] Transitions include the switch from paper to electronic systems including hybrid records when the transition from paper to electronic is partial, as well as routine system updates and software patches. The hazards associated with partial implementation need to be identified and managed for improved safety. Lack of systems for electronic reporting of test results (e.g. pathology, imaging) and letters means that paper documents need to be scanned and filed into electronic record systems by administrative staff; this is also akin to operating a hybrid system. Many such problems with managing test results and letters may not be solely an IT issue but involve local systems to make sure that the right test results and letters are filed for the right patient and go to the right clinician.

Well-managed IT can enhance access to such documents and provide audit trails.

Human factors issues also need attention as system use errors are an important contributor to patient harm.[20] User errors can be reduced by making the user interface of software more intuitive, by designing out error-prone features and enhancing integration with clinical workflow. Another approach is to incorporate specific requirements for safe use of IT into existing programs for staff orientation. At an individual level, the ongoing vigilance of users can be highly effective in preventing IT-related incidents from turning into adverse events with harm to patients.[21]

Finally, the lessons from the deaths of Baby AE and Mr M highlight the need to establish patients, their families and loved ones as collaborators in the care process. The *Australian Charter of Healthcare Rights* outlines patient expectations in relation to the right to access, safety, respect, communication, participation, privacy and comment in all Australian health settings, including diagnostic services.[22] To this end, patient involvement in the care process must involve shared information (enabling patients to read, comment on and share in decisions about their care) and timely and meaningful communication (enabling patients to receive, send and comprehend the information required). Such approaches may well be the best way that the health system can address the lessons from the tragic failure in care that was provided to Baby AE and Mr M.

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Acknowledgements

This initiative has been made possible by collaboration with Monash University, the Victorian Institute of Forensic Medicine, 'The Communiques Australia Inc' and funding from the Victorian Managed Insurance Authority.