



Expecting perfection

THE PUBLIC HAS UNREALISTIC EXPECTATIONS OF PATHOLOGY'S ABILITY TO DELIVER PERFECT RESULTS, WRITES **BIANCA NOGRADY**.

One of the most spectacular errors in pathology history might indirectly be credited with claiming nearly 20 million lives. It's even more astounding to learn that the pathologist behind it was in fact the founding father of histopathology, Rudolph Virchow.

Virchow failed to diagnose German Emperor Friedrich III's laryngeal cancer until it was too late. The politically moderate and liberal Friedrich died in 1888 after ruling for just 99 days, and his militaristic son Wilhelm II inherited the throne, setting Europe on the path to the slaughter of World War I.

To err is human, even if you do happen to be a world expert in the field.

And at its heart, pathology is a very human practice, says Dr Stewart Bryant, President of the RCPA.

"If you're talking about anatomical pathology, it is a subjective interpretation of what the pathologist is seeing down the microscope," Dr Bryant says.

"It's a bit like a clinical diagnosis."

This means five experienced pathologists looking at the same biopsy may come up with five different interpretations.

"You might only know in five years time which of them was right."

The trouble is, there's a prevailing community perception that pathology is infallible. And this leaves the profession wide open to undue criticism when things go wrong.

Professor Anthony Leong, Medical Director of the Hunter Area Pathology Service and Professor of Anatomical Pathology at the University of Newcastle, writes that the use of the words 'test' and 'results' when referring to anatomical pathology diagnoses "inappropriately reinforces the public's misconception that the cognitive process of interpreting the features seen in a small piece of tissue is infallible" (*Pathology 2006*;38:490–7).

Overcoming this perception is no easy task, but Dr Bryant says it's a matter of reminding people that as with any human endeavour, there is a basic error rate.

So what exactly is an error in pathology? There's no universally accepted definition of 'error', but generally errors can be described according to who makes them, why they occur, when they occur and what impact they have on the patient.

Degrees of separation

To start with, it's important to realise that pathology errors aren't always made by pathologists.

"There are about 50 steps that happen between the time the biopsy is taken and the slides come to the pathologist, so things can go wrong at any of the steps in between," says Associate Professor Sanjiv Jain, anatomical pathologist and Director of Anatomical Pathology at ACT Pathology.

For example, a biopsy could be mislabelled as being from the colon instead of the stomach, or the wrong patient name or history could be put on the patient request form.

Samples can also be mislabelled after they arrive at the laboratory – the wrong specimen could be put into the cassette, or slides could be incorrectly labelled.

These sorts of patient identification errors can also be made by the pathologist, who may accidentally record a diagnosis on the wrong patient form.

Even after a diagnosis is correctly made for the right patient, things can go awry in the 'post-analytical' stage.

As Professor David Davies explains, the simple word 'no' can make a 180-degree difference.

"This happened with a fax system we were using," says Professor Davies, an anatomical pathologist at Sydney's Liverpool Hospital, and Joint Area Director of Pathology for Sydney South West Area Health Service.

"To be emphatic, the word 'no' was printed in capital letters, and the computer program failed to recognise characters of capital letters so the word just dropped out of this report."

Thankfully the glitch was spotted in time and corrected, but Professor Davies says the incident highlighted the need to look at the entire system in which anatomical pathology is practised.

Australian anatomical pathologists have, for many years now, adopted a range of processes to reduce the risk of errors.

- Professor Anthony Leong



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Grades of error

Finally, there are what Professor Jain calls interpretive errors, where the conclusion one pathologist reaches about a slide is different to what another pathologist might conclude.

“Within that context there are types and grades of errors,” he says.

“The worst grade of error is when a biopsy is benign and we call it malignant, or the biopsy is malignant and we call it benign.”

Several decades ago, a simple verdict of benign or malignant was all a pathologist was expected to deliver.

But these days, pathologists must extract far more information from a much smaller biopsy to help guide patient treatment, and many of these judgments are less black and white than ‘malignant versus benign’.

“With breast cancer, the diagnosis itself is not difficult – but that’s not the only diagnosis we give on breast cancer,” Professor Jain says.

“We talk about the type of breast cancer, the grade of breast cancer, we talk about whether breast cancer cells have gone into the blood vessels or whether the cancer has gone into the lymph nodes, we talk about whether the breast cancer has got oestrogen or progesterone receptors.”

Human impact

Ultimately, however, a major test of an error’s significance lies with its impact on the patient.

Professor Leong suggests one accepted approach to defining diagnostic error is to judge it by the impact on patient management (*Pathology* 2006;38:490–7).

A minor error may have absolutely no impact on management, or it could lead to minor morbidity, such as fever, where there is an impact, but hospitalisation or surgery is not required.

A more serious error could affect patient care enough to require

hospitalisation or surgical intervention, but without causing ‘major’ morbidity.

At its worst, a mistake could lead to loss of an organ, limb or even life.

These most serious errors tend to involve a change in categorisation – the most obvious being from benign to malignant or vice versa.

Community consternation

Thankfully, serious errors are rare, occurring in approximately 0.5–1% of cases. But unfortunately, this distinction between major and minor errors is not always obvious to outside observers, as happened during the recent media frenzy over an inquiry into the work of NSW pathologist Dr Farid Zaer.

The inquiry was initiated after concerns were raised about Dr Zaer’s quality of work during his time as a solo pathologist in Tamworth and later as one of three pathologists in a laboratory in Wollongong.



“In pathology, there’s nobody that goes around and says ‘you’ve looked at 50 biopsies today, you’re not going to do any more’.”

- Professor David Davies

The review of 7432 tests in Tamworth found ‘minor diagnostic variations’, with no impact on patient management, in 30.27% of cases, and significant diagnostic variation in 2.92% of cases.

However, among those 217 significant diagnostic variations, only 38 cases – 0.51% of the total case load reviewed – were assessed to have potential clinical impact – well within what is considered an acceptable error rate.

The experience highlighted that the majority of people do not realise or accept that errors do occur in pathology, Professor Leong says.

“The managers were not aware of what was an acceptable error rate, so they thought you should have a perfect zero-error rate.

“Obviously the pathology community has not educated the public and the media and the administrators to the fact that this is a cognitive interpretation, and there are obvious errors inherent in the process.

“If God did not accept errors he would have made us all perfect.”

No-one has yet established baseline error rates for Australia, so there is no accepted benchmark point for the public, management and the pathology profession.

“While we may simply embrace the American rates... our conditions are different,” Professor Leong says.

“Error rates need to vary, as pathologists practise under different

conditions – alone, in groups, as specialists or as general trained pathologists.”

Dr Bryant agrees that researching baseline error rates would help establish what is a reasonable level of proficiency for pathologists, but says it would be a complex and massive undertaking.

“To actually get enough data in and stratify according to complexity of diagnosis would be an enormous task,” he says.

Pressures on pathologists

Apart from defining baseline error rates, the issue of the impact of workload on error is another unresolved question. This problem is being exacerbated by the workforce crisis in pathology.

The Zaer case also drew attention to the overwhelming workload many pathologists handle due to isolation and lack of back-up. The pathologist in question had examined 7432 biopsies in just 13 months – 70% more than the UK Royal College of Pathologists’ recommended annual case load of no more than 4000 biopsies. (Australia does not have a recommended equivalent case load but the UK recommendations are accepted here.)

Professor Davies suggests pathology could benefit from a similar approach to that taken by the airline industry in terms of managing workload, where pilots must have ‘time out’ after so many hours of flying time.

“In pathology, there’s nobody that goes around and says ‘you’ve looked at 50 biopsies today, you’re not going to do any more’.”

Dr Zaer was also working alone in Tamworth – a scenario the UK College advises against. Anatomical pathology is by necessity a very collegiate activity, Dr Bryant argues.

“Most pathologists work in groups or teams, and it’s very common if pathologists find something that they

think is a bit different or funny, they will walk next door and ask a colleague,” he says.

In particularly tricky cases, a group of pathologists might gather to discuss the case to reach a team consensus or even refer the case to a national or international expert.

“It’s a matter of the pathologist knowing what they don’t know, and having a back-up system,” Dr Bryant says.

Unfortunately, the pathology workforce crisis means there will inevitably be pathologists in rural and regional areas working alone and under pressure.

These solo practitioners are also expected to be a jack-of-all-trades, Professor Leong says.

“Just because the rubric ‘pathologist’ is used, this man probably had to run chemistry, microbiology, haematology and also do anatomical pathology on the side.”

More importantly, he was expected to diagnose a range of materials that would sometimes require the highly specialised expertise found only in larger pathology practices.

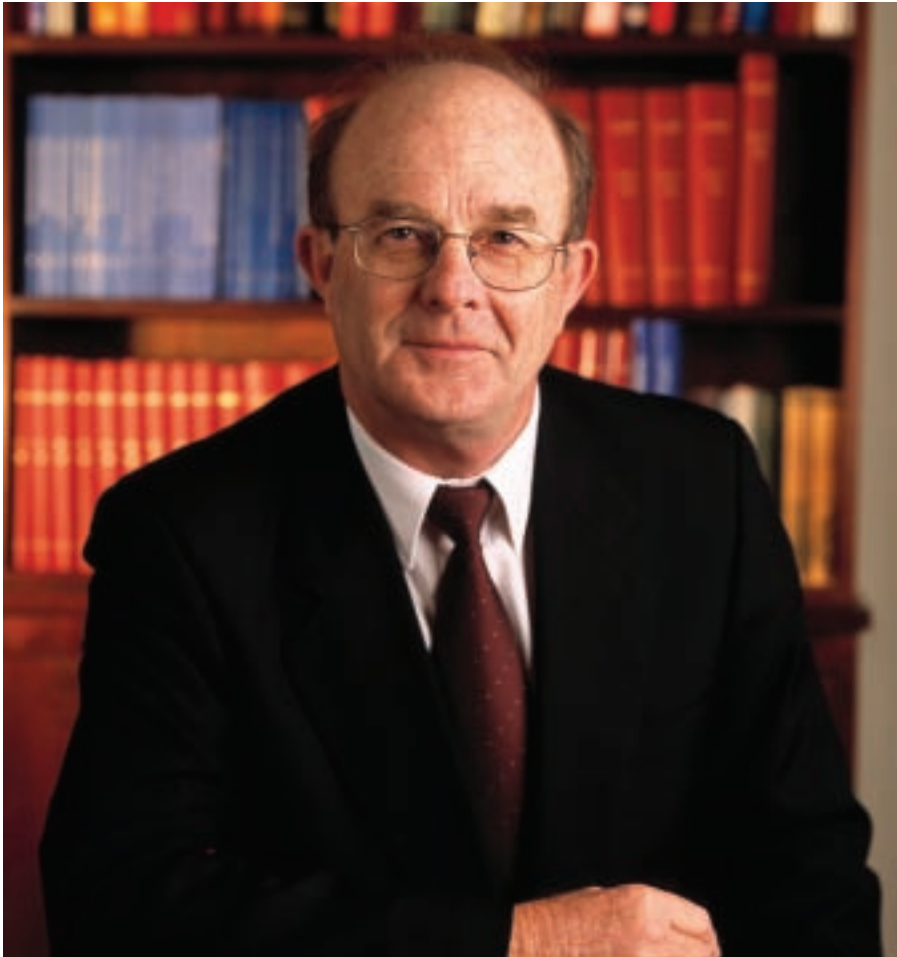
The shortage of pathologists is unlikely to be solved in the near future, despite continued lobbying of governments to provide adequate training positions. This raises the question of what other steps can be taken to reduce the risk of errors. While considerable effort is being made in laboratories around Australia to reduce errors, there’s no doubt Australia is already far ahead of the game, with a consistently and uniformly high standard of pathology practice.

But Dr Bryant says it’s important not to rest on our laurels.

“I think we’ve achieved a very high standard – as good as it gets in the Western world – but we have to make sure it doesn’t deteriorate.”

KEPT IN CHECK: METHODS PATHOLOGISTS USE TO MINIMISE ERROR

- Clinicopathological meetings where biopsies are reviewed
- External quality assurance programs
- Internal clinical audit
- Continuing medical education



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Keeping errors in check

Professor Leong says Australian anatomical pathologists have, for many years now, adopted a range of processes to reduce the risk of errors. One is the conduct of clinicopathological meetings with multidisciplinary teams, where biopsies are reviewed by expert pathologists independently in the context of the individual patient’s presentation.

There are also external and internal quality assurance programs, and the active participation in on-going professional continuing education.

One approach to reducing error that is working well for ACT Pathology is the internal clinical audit, which is performed to varying degrees in hospitals across the country.

As part of its audit process, ACT Pathology holds weekly histology quality assurance meetings with consultants and registrars, conducts a weekly audit of all breast-screening cases, and performs

directed reviews of particular organ or cancer-type biopsies. The lab also launched a Histology Practice Improvement project in 2005, which aims to decrease non-pathologist-generated errors and improve laboratory efficiency. Professor Jain, who designed the audit program, says it has helped keep errors at ACT Pathology in check.

“It keeps on reminding us that we are still fallible and we make errors, so that makes us more vigilant as we do our work,” he says.

The audit allows him to take action in a situation where a pathologist is making more errors of knowledge. It also encourages staff to sit down together and review practices.

“It stops people being defensive about their diagnosis, and they are able to share knowledge and problems with each other,” he says. “It helps to standardise processes in the laboratory.”

Audits also help reduce the risk of what Professor Jain calls ‘slips’ – the errors that

occur simply because of a lapse in concentration. These errors can be made by even the most experienced and focused pathologists, although Professor Jain says people are less likely to make slips when there’s a good chance their work will be subject to a random review.

So in defence of Rudolph Virchow’s catastrophic nineteenth-century misdiagnosis, the biopsy sample may have been of poor quality, it may have been mislabelled, or Virchow may have simply experienced a lapse in concentration.

Professor Davies also points out that laryngeal biopsies are notoriously difficult.

As he puts it: “Those of us who are more self-critical say ‘there but for the grace of God go I’.”

Besides, had the laryngeal tumour been diagnosed in time, the surgery would just as likely have killed Emperor Friedrich as the cancer. . 🔥