

**Submission
No 72**

**INQUIRY INTO OFF-PROTOCOL PRESCRIBING OF
CHEMOTHERAPY IN NSW**

Name: Mr Garry Clarke

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21 October, 2016
The Hon Paul Green, MLC,
Chair,
Inquiry into off-protocol prescribing of chemotherapy in NSW,
Parliament House,
Macquarie Street,
SYDNEY. NSW 2000
Dear Mr Green,

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Please find following my submission to the above referenced inquiry.

I would like to thank the committee for this opportunity to provide information on this important subject and advise that if required I would be very happy to expand on the information and recommendations in my submission via first hand evidence at the committee hearings.

I would also like to apologise in advance for the length of my submission particularly for points b, c & d, of the terms of reference but in defence I hope the committee understands that I have tried to provide both information and convey a sense what it is like to be a patient or a carer and the sorts of complex issues and decisions that you face through the course of treating cancer or other complex disease.

With all due respect until you've been there yourself you cannot begin to imagine how complex life becomes when yourself or a loved one is diagnosed with cancer or other complex disease, I hope that by giving the committee a sense of what it's like at a personal level, the committee can then make recommendations on better support and management systems to ease the patient and the carers journey.

Thank you again.

Sincerely

Garry Clarke

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Recently on 'Anh's Brush With Fame' on the ABC, renowned neurosurgeon Charlie Teo joked that unlike others doctors could bury their mistakes, while to many viewers that was taken as a light hearted doctor joke to break the ice to many of us watching in NSW it was an all to chilling reminder that indeed in NSW doctors can and do bury their mistakes with in the vast majority of cases absolutely no consequences for having caused those deaths.

We might never know how many of Dr Grygiel's patient's lives were cut short as a result of his ability to depart significantly from recognised dosage practices and indeed it is not the job of this inquiry to determine that but what this inquiry must I believe do is get to the bottom of how Dr Grygiel or any other doctor's in the NSW health system can, despite all the protocols and procedures designed to prevent it, begin or continue questionable practices without being challenged by anyone in the health system.

That said, my wife was not a patient of Dr Grygiel and as such I am not able speak to the specifics of that particular case but what I can and have endeavoured to do with my submission is provide the committee with both an understanding of the underlying systemic failure that I believe is directly responsible for no one within the health system ringing alarm bells about Dr Grygiel's prescribing practices and more significantly the reforms that I am confident would ensure that no other patient in the NSW health system is harmed as a result of the failure of healthcare workers to ring the alarm bells when appropriate.

Before proceeding to the points from the terms of reference I would like to speak to in my submission I'd like to provide the committee with some background information on both myself and the circumstance that caused me to commit considerable resources to researching a subject that as fate would have may be of particular interest to this committee.

My background is in IT and in particular the research and design of systems combining software and process and procedural changes to improve business performance and outcomes, while my work has primarily been in the SME area I have had a long term interested in healthcare systems which has led to an understanding of the workings of the health system that is regarded by some within the system to be second to none.

In June 2013 my wife Rox was diagnosed with melanoma that had escaped the original site and found its way to the lymph nodes in her groin and abdomen. In January 2015 the melanoma was found in Rox's brain and liver. While the drugs she was using stopped the cancer in her liver they did little for the cancer in the brain and by January 2016 there was more melanoma in the brain, sadly on the 23rd of June 2016 my beautiful Rox lost her battle with a melanoma that we believed was totally avoidable.

While the details of Rox's case are outside the scope of this inquiry, it is our experience with the healthcare system subsequent to that diagnosis and my research into why there was a distinct disinterest in reporting doctor's questionable conduct or practices that I believe will of interest to the committee.

Term of Reference

- a) **The efficacy of electronic prescribing systems, and their capacity to stop or limit off protocol prescribing of chemotherapy,**

Over the years I have from time to time worked with chemists to integrate their prescribing systems with their point of sale systems, more recently and as part of Rox's treatment I had an opportunity to

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discuss with doctors drug treatments and the lack of and need for more advanced prescribing systems that allowed for better long term management of drug usage including the effectiveness of the drugs against trial results.

In preparation for this submission I have also discussed prescribing systems with a chemist and a senior IT person from the health system to ensure the information I provided on this point was current.

Effectively there are around 5 different prescribing systems in use in Australia today, they are very rudimentary in their capability with only 1 or 2 providing very limited capabilities to record prescribing protocols and none providing the ability to raise an alarm if the amount dispensed is outside the allowable dosages.

From discussions with health IT I understand that there is work being done in the health system around the development of software related to prescription management. While I believe that software will help identify if the drugs being prescribed in the hospital system have been dispensed and consumed, my thought is that while it is being touted as a way of identifying/preventing off protocol prescribing I have some reservations that it will be capable of delivering that outcome.

At the present time the only way an alarm can be raised is if the chemist dispensing the product thinks the dosage is incorrect and in the case of chemo drugs the factors contributing to the dosage decision are complex with none of them available to the chemist dispensing the drug.

In effect while oversight for drug dosages rests with the chemist the fact of the matter is that they do not have the information needed to provide the level of oversight required.

Recommendation

While I do not believe software in the foreseeable future would have the capacity to prevent adverse patient outcomes such as those that might occur due to off-protocol prescribing I do believe the current systems are not of a sufficient standard to take us into the future.

On that basis I would recommend that the committee give some thought to what could be done with prescribing software that also allowed for data capture and reporting around the actual use and effectiveness of drugs compared to the trial results for those drugs.

Term's of Reference

- b) the value of a potential new patient information sheet on dose adjustment for patients and caregivers information,**
- c) the process and systems around informed consent for all medical interventions, including chemotherapy,**
- d) the capacity of the NSW Health system to have all notifiable cancer patients in New South Wales overseen by a Multidisciplinary Cancer Care Teams, and if this may prevent off-protocol prescribing,**

I trust the committee will bear with me as I would like to respond to these three points in one.

Over the last six to seven years I have seen my father, Rox's mum and now Rox each face and then succumb to the respective cancers in each case the cancer, family support capability and indeed each patients approach to dealing with their cancer was unique and as such I think the committee needs to understand that what is going on at this point in a person's life is often vastly more complex than many have the ware with all to deal with.

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The other thing that the committee need to understand is that the circumstance is entirely fluid and can change rapidly, in fact as I found rapidly can be a matter of minutes for someone that looks otherwise fit and healthy.

That said and while I understand that this inquiry is looking at how to prevent off-protocol prescribing I would like to try and explain to the committee why it is not as simple as that by providing an example of where off-protocol prescribing was an entirely appropriate course of action to prevent the death of a patient but was denied in my opinion due to the pig ignorance of a senior doctor who when push came to shove bullied and intimidated a young doctor into abandoning a course of treatment that was the only way of saving the patient's life.

Let me paint the picture for you, Rox was a Jehovah's Witness (JW) who was strong in her faith and as such she would not have blood transfusion or accept transfusions of blood based products. I am not a JW but I absolutely respected Rox's faith and wishes so when she was critically ill and I needed to find ways of saving her life I had to be open to all the options.

At one stage in Rox's treatment the melanoma in her brain was bleeding badly and at the same time her blood counts had said her platelet levels were critically low, needless to say we had hit a point where, according to the blood tests, if Rox did not have a transfusion to increase her platelet levels she would die.

Rox had done well and ensured that at this time I had someone to call to find out what the options to a blood transfusion were, long and short of it was another young JW some years earlier faced exactly the same challenges as Rox, that young fellows life had been saved because the head of haematology recommended and off-protocol prescribed EPO, for those who are unaware an increased platelet count is a side effect of taking EPO.

Ultimately and despite all the evidence to support that in the context it was being used EPO was an entirely appropriate off-protocol course of treatment the head of haematology at the Mater refused to sign off on its use. The irony of that doctor's refusal to allow Rox to use EPO was that it was his immediate predecessor who'd pioneered the use of EPO for the JW with a low platelet count.

As you can see making this inquiry about stopping off-protocol prescribing of drugs will have unintended consequences because there is in fact a time in a patients treatment that off-protocol prescribing is entirely appropriate.

Because of this and I trust the committee agrees the remainder of my submission on these three points is primarily about better patient management and outcomes.

From experience the nature of cancer and for a number of complex diseases there are two treatment stages so to speak where the first stage is what I'll call maintenance and the second part critical care.

In both stages I found that there seemed to be little or no co-ordination of what was going on, it was like everywhere you were shunted you started again and told the same old story time and time again, every time you told the story the fear was did I tell these guys what they needed to know, have I forgotten something, have I wasted their time telling them things they don't need to know.

You can't begin to imagine how stressful this is to both patients and carers particularly when you know how much money has been wasted on software such as the EHealth system which was supposed to provide this functionality.

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To help the committee understand the two care stages I'd like to provide the committee with information about things Rox and I experienced in the health system that I think both highlight some of the issues and the positive care outcomes that could be applied more broadly to ensure that the patient and their careers are better informed and that above all else the focus of clinicians is on optimal care outcomes.

I'll start with the maintenance process.

As I said lots of very complex things going on for cancer patients and more often than not the time a patient actually spends with the doctor can be a blur. When Rox and I first started going to the melanoma unit that blur was made a lot easier because a visit to the unit had a couple of parts.

The first part was with the doctor, be it the surgeon or the oncologist and the second part was with a very senior nurse who clearly had had extensive experience with melanoma.

It was this second meeting that things got done, appointments were made reports followed up, what was going on with the disease and treatment was explained more clearly and in a language that was targeted to your capabilities and when needed there was always the shoulder to cry on before you put your smile back on to face the world and whatever lie ahead.

Above all else we felt that this meeting was a form of oversight that helped to make us feel confident that the treatment course the doctor was recommending was appropriate at that stage of Rox's disease, while for reasons I'll come to later in my submission I know these people would never have actually spoken out publicly if they did not consider the treatment was appropriate I do feel confident that they would have warned us in some way.

Towards the end of Rox's time the Melanoma unit got a new head, with all due respect a lot of money was wasted on landscape photographs, and our second appointment with the nursing staff was cut.

No one actually told us the patient and career what was going on and needless to say the quality of Rox's and no doubt a lot of other patients care declined dramatically as a result of this service being removed.

While it was claimed that the doctor would fill this role in place of the specialist nurses the fact of the matter was the doctor was not equipped to provide the quality of support required.

Ultimately what concerns me most is that the decision to remove the service was not about good patient care outcomes it was about, just like the expensive pictures, stroking the ego of a doctor by removing what I'm sure they saw (because we saw it that way) as a point of oversight of their treatment.

With the benefit of hindsight I realise now that the role that those people played was that they in consultation with us managed Rox's treatment and without them we were left to make decisions about Rox's treatment that we really did not have the information or capacity to make.

To help the committee understand just how specialist that role is, as things got more difficult for Rox and I to know if we were making the right decisions we approached our GP to see if he could help manage Rox's care, he apologised profusely but correctly pointed out that he did not have the expertise needed to advise us with confidence so responsibility for managing Rox's treatment fell on us.

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While I will never know because the service had been withdrawn but I can't help but wonder if we had had the benefit of their input through a time we needed it most in Rox's treatment if Rox would still be here today.

I'll Turn now to critical care.

By critical care I mean those times where the patient is hospitalised due to a major issue that has arisen.

In brief I'd like to touch on 2 critical care experiences Rox and I had in the last few months of her life that had circumstances been different could well have cost Rox her life.

The first instance Rox had a slow bleed in her brain that it was decided to take her for surgery to remove the melanoma. Rox had been at the Mater for a number of days before the surgery and had continued to take her regular medication which included an aspirin a day as a result of a stroke she'd had while recovering from an earlier melanoma surgery.

I kick myself for not having made the connection earlier but Rox had been moved to and was being prepared for surgery when it dawned on me that no one had bothered to think to put an end to the aspirin which with the benefit of hindsight also should have been stopped the moment Rox was diagnosed with melanoma of the brain but that is another story.

In any event had I not raised the alarm when I did Rox would have been on the operating table before they discovered her blood had no clotting ability.

The point I'm making here is that I am not the expert, we pay our medical professionals a lot of money to NOT make that kind of simple error and yet the fact is errors of this kind are not isolated and people die in our health system because of it and no one speaks up to report it.

The second incident for Rox, she had gone to hospital as scans had revealed there was an issue with what was happening with the cancer in her brain, during the MRI Rox had another bleed on the brain and as a consequence Rox had a major seizure.

In the period after the seizure and dealing with everything else around Rox's care I became concerned because of the lack of forward planning, in effect Rox's treatment was management by crisis with no actual planning for what to do if and when particular things occur.

As this was very foreign to me and because I was concerned something might happen to Rox while the doctors were working out what to do for her I had a lengthy discussion with Rox's treating doctor about forward treatment planning and the need to adopt IT based "Agile" management methodologies.

While the young doctor was reluctant at first, from working with me to treat Rox over the next 5 weeks or so I believe he had become a convert to more forward planning and "Agile" management methodologies in patient care.

This brings me back to off-protocol prescribing and senior clinicians bullying and intimidating young colleagues.

This same young doctor, I also felt enormously sorry for because I had asked him to continually question and present to the haematologist that refused to sign off on the off-protocol prescribing of EPO for Rox, evidence to support that the decision to use EPO was entirely appropriate. I would off

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thought it was Rox's oncologists job to do that but no it falls to juniors who are easy prey for doctors who engage in questionable practices.

The young doctor did his best because he knew that if push came to shove it was the only treatment that could save Rox if she needed it but the haematologist held his line and became increasingly agitated at his ruling being questioned, when it became clear the consequences of pushing it were too great I dropped it then lived in this horrible horrible place for the next 36 hrs hoping and praying that Rox's platelet count came up because if it didn't I knew there was nothing we could do because the haematologist said NO.

Bottom line no one doctor should have this power over life and death particularly when that power can and is so easily misused.

Recommendations

As I said the subject at hand is vastly more complex than I think the majority of people realise and as such I do not believe a simple information sheet or series of sheets could ever possibly deal with all the variabilities that people with cancer and other complex diseases face with their treatment decisions.

Ultimately pieces of paper fail because they provide no oversight at a time where oversight should be a priority.

For this reason I hope the committee would consider a structure that in broad terms combines a "Patient Manager" based on the role played by the senior nurses at the melanoma unit and a multi-discipline team.

Under this structure rather than treatment decisions being left to an individual specialist the specialist would just be one member of the team making decisions about matters such as the appropriateness off-protocol prescribing or other treatment options. An important aspect of this change would be to adopt through the role of a patient manager a whole of patient approach rather than the current structure which is very siloistic.

In effect the manager becomes the go to man who co-ordinates and distributes relevant info to the appropriate person. IE they'd be the ones to make sure that things like aspirin stop when they are supposed to.

While clearly there would need to be a more rigorous investigation of how that structure might work I do believe that if implemented correctly this structure would deliver vastly superior patient outcomes than are being achieved today.

That said these changes would represent a significant departure from what is standard practice by doctors and as such I would expect a fight from doctors who I believe will be vehemently opposed to any changes that would put their decisions under greater scrutiny.

In addition to structural changes to patient care and disease/treatment management approaches I would also recommend a substantial review of the EHealth system as the functionality it should provide is core to achieving better patient outcomes.

In its current form the software is all but useless because it has no way of getting the patient information it needs from doctors practice management software, this deficiencies needs to be addressed with great urgency.

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As part of the review of the EHealth software I would strongly recommend consideration of tight integration with prescribing software and Business Intelligence capabilities to establish metrics and benchmarks that can be used to gauge performance of clinicians, treatment options and post-trial drug performance.

In addition to this capability the software design must also be capable of identifying and alerting for risks such like we encountered with the use of aspirin both after the brain melanoma was diagnosed and when they were prepping Rox for brain surgery.

Term of Reference

- e) **St Vincent's Hospital capability to comply with relevant NSW Health Policy Directives and Guidelines, particularly Open Disclosure Policy (PD2014_028) and Incident Management Policy (PD2014_004),**

I am not able to comment on this aspect of the terms of reference as it applies to St Vincent's because Rox was not a patient at St Vincent's hospital.

Term of Reference

- f) **the NSW Health Code of Conduct and specific programmes within NSW Health and St Vincent's Hospital, in relation to staff raising concerns about the practice of clinicians, and other breaches of the Code of Conduct**

Now we get to the \$64000 question of how, for so many years, across so many different hospitals, and clearly through how many hundreds of hospital staff hands was a doctor able to depart so substantially from standard practices and yet no one, despite the requirements of codes of conduct and other NSW health policy and procedures that require them to do so, spoke up and raised the alarm?

As I said earlier in my submission this is a subject I have researched extensively over the last 3 years and based on that research I can say unequivocally the one reason staff in the NSW health system never ever raise concerns about the practice of Doctors is FEAR!

To put it bluntly at the present time the fear of the consequence of raising concerns about a doctors questionable practices is by far and away greater than the fear of the consequence of not raising a concern.

Lets face it, questioning a doctors practice's will destroy a career but not reporting a doctor that is killing his patients through poor practices gets you a reprimand. While it would be nice to think that altruism would rise to the fore the fact is it does not because ultimately doing the right thing does not pay the bills.

Before I provide more details on the systemic failure that my research has revealed is behind the fear I'd like to provide the committee with some examples of the experience's Rox and I have had in trying to ensure the doctor that we believe is responsible for Rox's death was taken out of the system.

My primary purpose for providing this information is because I believe the committee needs to understand that the issue of healthcare workers not reporting questionable conduct by doctors is widespread, has been going on for many years and has as a result created a ticking time bomb of adverse patient outcomes because doctors who should have been removed from the system have not.

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Bottom line Rox was passionate that the doctor who had left her with a terminal illness didn't do to anyone else what he'd done to her so at every opportunity in the health system we raised our concerns regarding the doctors conduct because we believed health system staff had an obligation to raise our concerns with higher authorities.

In many cases the specialists or health workers that dismissed or ignored our concerns had often provided another piece of information that confirmed in our minds that Rox's doctor's departure from standard practice was directly responsible for her illness.

Bottom line speaking to healthcare workers about your concerns about a doctors questionable practices is like speaking to a brick wall.

Unfortunately for Rox this lack of interest in speaking up is not limited to the hospital system because as it turns out, Rox's GP had a suspicion there was a problem with the dermatologist because he had not been receiving reports following Rox's visits but did nothing about it. I can assure you his apology that with the benefit of hindsight he wished he'd warned us earlier was of no comfort.

In any event Rox passed away and never saw justice for what had been done to her because no one in the college of Dermatologists was prepared to write the report that's now needed to get a doctor to court for his negligence.

From what Rox's lawyers told us the closest they came to getting a report was that one NSW dermatologist was so concerned about what had happened to Rox that while he would not write a report about his 'friends' negligence he did agree to write the questions Rox's lawyers would need to put to a dermatologist to get a report that confirmed negligence.

Ultimately not one dermatologist in Australia or the United Kingdom was prepared to write that report.

This brings me back to the fear that is behind healthcare workers refusal to speak up when they see or hear of a doctors questionable practices.

Based on my research that fear has one source and that is the ease with which a vexatious doctor who has had their judgement question can use a combination of the health care complaints process and a campaign of Chinese whispers within their college to destroy the career of those who dared to call into question their competence.

I am not alone in the view that the health care complaints process is being abused to both cover up negligence and stifle good patient outcomes and in fact the same Dr Charlie Teo who was making light of doctors burying mistakes is one of the most vocal advocates of the need for a Royal Commission into the bullying and intimidation and other abuses of the health care complaints process by unscrupulous and often incompetent doctors.

In addition to Charlie and I there is also the Health Professionals Australia Reform Association who have been actively pursuing this matter for some time.

In their efforts to bring about the much needed reforms, prior to the 2016 federal election they were successful in lobbying Senator Xenophon to establish a senate inquiry into the health care complaints process and as I understand it the HPARA is also cooperating with the ACCC in the investigation of activities within the regulation and administration of health professionals. This includes organisations

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such as AHPRA and the Colleges and individual health professionals who may have misused the systems of the regulator and administration.

That said and rather than repeat my earlier comments regarding my experience with doctors inappropriate conduct when their authority is questioned I'd like to provide the committee with information on how the extent of the systemic failure of the healthcare complaints process has created a ticking time bomb of adverse patient outcomes that I trust the committee agrees must not be ignored.

Through our research we identified that due to the systemic failure of the health care complaints process not only were doctors questionable practices not the subject of alarms but more significantly that, known negligent doctors are regularly identified but then with absolute callous disregard returned to their practices, often in both the public and private health systems, with no remedial training and more significantly no warning to the employers or other patients of the negligent Doctor.

To a large extent how that was facilitated can be traced back to the collapse of the doctors professional indemnity insurance schemes back in 2002 where the response of the medical profession and government was twofold;

- at a federal level doctors insurance premiums would be subsidised & high cost "Payouts" would be shared 50/50 with the fed govt and insurers
- In NSW the Carr Govt introduced tort law reforms that exceeded those proposed by David Ipp (from the review John Howard initiated), in effect the reforms are bias and substantially disadvantage plaintiffs and more significantly they are wide open to abuse by unscrupulous doctors and medical colleges intent on protecting their reputation above all else.

While it was argued at the time that corporate governance issues within the insurers was the cause of the collapse I believe that the real cause of the collapse was the high number and high cost of claims resulting from again I believe a number of known negligent doctors being continually returned to the system with no remedial training to repeatedly offend IE harm their patients.

In my opinion it was the failure of the process in 2002 to look at what could be done to eliminate negligent doctors (through better training) from the system that has laid the foundation for doctors to engage in questionable practices at will and with total disregard for the consequences on unsuspecting patients.

Ideally yes the Health Care Complaints Commission should deal with this but the fact is the vast majority of medical negligence cases go nowhere near the HCCC. The three key reasons for this are that;

1. You are advised by everyone and sundry – government departments, police, etc etc – that it's a civil matter that you need to see a lawyer for so most people never know of the existence of the health care complaints commission
2. Even if you did know about the two different processes you must follow if you want both compensation for the negligence and to ensure the doctor did not harm anyone else, the fact is you must endure two process's which are completely separate, lengthy and arduous at a time your also fighting for your life so like it or not only the compensation path is followed
3. And finally if you are successful in obtaining compensation for the doctors negligence you are then forced to sign a non-disclosure agreement which while you are told it prevents you from talking to anyone about the case is not actually legally binding under section 98 of the health

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care complaint act, so while they could they don't because they are either too sick/deceased or are scared of losing their compensation or to be quit frank simply deliberately deceived

Bottom line when you realise how messed up the whole health care complaints process is, its no wonder people within the system are afraid to speak up and why doctors get away with engaging in questionable practices that are costing patients their lives.

Before making my recommendations around this point I'd like to take a moment to point out is that in addition to the human cost of doctors departing from acceptable practices, there can and is very often a massive and also totally avoidable financial cost to the health system.

To put that in perspective in addition to costing Rox 40+ years of her life, the actual financial cost's of care over three years resulting from her doctors failure to follow recognised practices was conservatively \$320K in medication costs and again conservative \$250K in scans, surgery's, blood tests hospital stays, palliative caring and so on.

Given the overall costs we can no longer afford to turn a blind eye to doctors departing from standard practices without any oversight and without putting too fine a point on it the only way to do that is ensure that those who speak out are protected by removing the opportunities for abuse that exist with the current health care complaints process.

Recommendations

I cannot overemphasise the need for the development of software that will better record patient information and allow for the capture of information that will facilitate the production of reports that will help to identify both clinicians and drugs/treatment options that are not meeting minimum performance standards.

I also cannot overemphasise the need for a complete overhaul of the Health Care complaints process including existing tort laws round medical negligence with a view to achieving the following sorts of outcomes;

- That the current separate and distinct two part system (HCCC & Civil action) be replaced with a 1 stop approach IE HCCC
- That a review process be implemented to determine if the claim is vexatious or if the metrics of the case are within acceptable standards
- Once its been determined that a matter requires investigation, that a process and structure similar to the existing HCCC investigation and review process be followed
- The final outcome of the investigation & review is to determine if the doctor was negligent or not
- The HCCC will make orders regarding any remedial training that might be required or in the event of a serious case if the doctor is allowed to continue practicing or referred to the DPP for prosecution
- The findings are open to appeal
- Evidence from the review process is to be made available to any related proceedings determining the compensation payable to the victim
- At the completion of the process, if there is a finding of negligence then all existing patients of the doctor would be notified immediately and a public record detailing the negligence & disciplinary or remedial action taken must made available

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The final overarching recommendation I would make is that the broader issues identified by this inquiry be referred to a commission of enquiry similar to the one run by Margaret Cunneen into the catholic church as it is my view that the protection of negligent doctors by the medical profession is as repugnant as the lengths the churches went to to protect paedophile clergy and in the same way as those who protected paedophiles need to be held to account so to do the doctors and others who've protected negligent doctors.