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Cancer Genetics Audit Group
NSW Health Pathology
&
CEO NSW Health Pathology

RE: Submission to audit on genomic services by NSWHP

In good faith and without prejudice I am offering this submission to the 'Audit of Cancer Genetics'. I address this letter to both the cancer genetics audit group as well as the CEO of NSW Health Pathology as I think it discusses significant issues of which the CEO and executive of NSWHP should be aware.

Despite significant investments, my belief is that genomic testing for somatic mutations in solid tumours within NSWHP is not currently fit for clinical purpose and is unlikely to be fit for purpose unless there is a profound reorganization and realignment. I believe that there has been a faulty structure and faulty patterns of behaviour in place in NSWHP that discourages best practice in somatic mutation testing in malignancies and has led to the disengagement of clinicians and pathologists in the LHDs.

I believe that the key structural flaws include:
i) The executive of NSWHP have sought advice from only a small group of scientists, essentially all from one centre. This has been to the exclusion of appropriately qualified medical pathologists who are in the best position to provide advice on somatic mutation testing in cancers and who, according to NPAAC and RCPA guidelines, should have on-site governance responsibility for this testing.

ii) Significant advice from multiple groups coming from outside this circle has been disregarded, and there has been an unwillingness to reconsider whether this small group of key decision makers have the qualifications, skills, and relationships within the various LHDs, to deliver tailored somatic mutation testing for solid malignancies.

iii) There has been an unwillingness to genuinely reassess advice, reconsider structures and alter practices in the face of repeated negative feedback and failures to meet expectations. In essence there has been an emphasis on 'being seen to be consultative' instead of being truly consultative.

iv) The choice of members of the genomics clinical stream; the disempowerment of members of this group so that there is no requirement for the small leadership team

to seek their advice; and the replacement of the promised 'external review' of genomic services by an 'internal audit' are examples of sacrificing actually being consultative for being seen to be consultative.

v) When shortcomings are highlighted and alternatives suggested, there has been a pattern of behaviour that, instead of fostering engagement, collaboration and participation, has led to alienation and disengagement of key potential partners at the different LHDs.

I will highlight examples of these faulty structures and patterns of behaviour. Then I would like to pose direct questions for the audit based on these seven points.

1. This 'audit' is quite different to the 'review' which was promised

On November 10 2020 I met with Deborah Willcox (CEO NSLHD), Roderick Clifton-Bligh, Angela Chou, Amanda Harris and Robert Lindeman to discuss the problems with somatic mutation testing for solid cancers. At that meeting Robert Lindeman accepted that there were problems with somatic mutation testing from RNS campus and that it had lost of the confidence of the clinicians on this campus. He indicated that he would commission a review by an external expert presumed to be someone from interstate. When there had been no movement on this, I met with Tracey McCosker, Robert Lindeman and Angela Chou on February 17 2021 to confirm that the promised review would be undertaken. At this meeting the CEO confirmed, very explicitly, that there would be an external review to address these issues but it had not yet been commissioned. The next communication I had on this issue was by email on March 22 when I was informed there would be an 'audit' – something with quite different implications and meaning. Furthermore rather than concentrating on whether somatic mutation testing should be performed on campus, the 'audit' was increased in scope to include many other matters and to de-emphasize the importance of structural review and renewal. I believe that this is an example of attempting to be 'seen to be consultative' instead of being consultative; or attempting to be seen to take stock and re-assess after a failure to meet expectations rather than to actually take stock and re-assess. This approach has contributed to the disengagement of those who were promised a review and increased their lack of faith in the ability of NSWHP to deliver structural change.

2. We were told that the consultant leading this review was to be external to NSWHP

There was an explicit agreement for an external and non-conflicted reviewer by the CEO of NSWHP. This has been replaced by a contractor with "previous knowledge of the genomic service in NSWHP". My understanding is that the contractor, Mr Brad Webb, worked as a "Consultant, Genomics Initiative, NSW Health Pathology Jan 2016 to Feb 2017"- ie: during the establishment of the current structure. I believe that he was intimately involved in approving and implementing the centralization of genomic services in Newcastle. To me this is very significant because the decision to centralize testing in Newcastle was intended to be the key part of the review. It also illustrates a pattern of behaviour of seeking advice from within a small group, essentially all of whom are from one centre. Furthermore I believe the contractor has had significant past and ongoing work relationships with key decision makers in NSWHP genomics. Indeed, I believe that the reviewer was involved in several

contentious decisions and discussions based on this centralized model. For example, I believe the reviewer was involved in a series of meetings with Cliff Meldrum and a pathologist at RPA discussing the same issue (about delivering molecular testing on campus at RPA as part of NSWHP). Given that we were told that the key issue to be addressed by this review is whether testing should be decentralized or delivered on campus at major hospitals, I believe this is inconsistent with an external review. Given that one of my major concerns is that advice has been sought primarily from a small group of people, all from one centre, the choice of this contractor with close ties to this centre is particularly troublesome to me.

3. There was poor engagement with senior pathologists and scientists from multiple campuses when the decision was made to centralize testing in Newcastle. This reflects a pattern of behaviour of seeking advice from a small group of people and not reconsidering this advice or accepting advice from elsewhere in the face of negative feedback and poor outcomes. The mechanisms for choosing this small leadership group have been opaque and not reconsidered after negative feedback.

To my knowledge no input was sought from anatomical pathologists at RNS when the Genomics Strategic Plan 2016-2018 was formulated. The NSLHD sees 25% of all new cancer diagnoses in the state and has two pathologists qualified to supervise molecular testing in cancers. Due to the unique patient mix and low smoking rates of the NSLHD, this area has the highest rate of so called ‘actionable mutations’ in lung cancer (more than 35%). These patients can only be treated in the context of advanced molecular testing and this site has a record of developing new targeted treatments in the setting of clinical trials. Furthermore, given the reputation for innovation in pathological testing of several pathologists and clinicians from this campus, most notably in the Australian Pancreatic Genome Initiative (the single biggest and most successful genomic project in Australian history), I do not understand why RNS pathologists were excluded from a leadership role (or in fact any role) in this project. I do not understand the selection process for inclusion in the small group of key decision makers in genomics policy. I would like to know the qualifications and experience of those tasked with selecting the key leadership positions in genomics within NSWHP including those who chose the first director of genomics. I would like to know if this group included a pathologist with qualifications in molecular pathology.

4. There has been a pattern of reporting of conversations and decisions with regard to molecular testing not being performed on campus at RNS that has led to a lack of trust.

After growing clinician dissatisfaction with somatic mutation testing for solid cancers for patients treated at RNS campus, on 19 December 2018 a meeting was held between myself, A/Prof Chou, the director of Cancer Services at RNS (Prof Stephen Clarke), the head of thoracic medicine (A/Prof Ben Harris), and the director of the Sydney Vital Translational Centre (Professor Alexander Engel). The CEO of NSWHP was expected to attend to represent NSWHP, but Cliff Meldrum and Robert Lindeman attended on her behalf. At that meeting, we were explicitly told by Cliff Meldrum and Robert Lindeman that it was not in their plan to allow somatic mutation testing at the RNS campus and this was not open for discussion despite our expressed beliefs and justifications that this is in the best interest of patient care. I subsequently met with the CEO on 24 January 2019 and 9 April 2019, where she

told me that this is not what Cliff Meldrum and Robert Lindeman had said at that meeting. I do not understand this apparent discrepancy.

5. There has not been a genuine effort to assess arguments and business cases for somatic mutation testing at RNSH campus despite an undertaking to do so.

After meeting with the CEO of NSWHP on 24 January 2019 and 9 April 2019, I was told that I could submit a business case for somatic mutation testing on campus at RNS. I explicitly clarified with the CEO, who confirmed, that there would be a genuine assessment of this business case. In fact, I remember alluding to a (perhaps?) cynical belief that sometimes clinicians are asked to submit business cases in an expectation that they would not follow through and this could be used to justify decisions that had already been made. I was reassured by the CEO that this was not the case, and that any business case would be appropriately reviewed.

Therefore, after much work over several months, A/Prof Angela Chou and I sent a fully budgeted discussion document and business case to Tracey McCosker, Robert Lindeman, and Cliff Meldrum by email on 18 June 2019. Two days later on 20 June 2019 we discussed this proposal by teleconference.

Our notes of this teleconference attended by, A/Prof Chou, Cliff Meldrum and Tracey McCosker on 20 June 2019 are informative and were circulated to all attendees at the time. They read as follows:

"During the meeting we discussed the first draft of our business proposal to introduce Molecular Testing at RNSH, which was emailed to you both prior to the meeting. As discussed, the needs of our treating physicians and patients at RNSH are:
1. Provide molecular testing for current Medicare rebatable items (EGFR, ALK, ROS1, RAS, BRAF)
2. Provided comprehensive large panel gene testing (161 genes) for oncogenic drivers in rare and recurrent cancers to match patients to clinical trials.
3. To support ongoing and future clinical trials on our campus for which a comprehensive large panel gene testing is required.

From our discussion these are the views from us and NSWHP:
1. You have both addressed that we will not be permitted to perform molecular testing using next-generation sequencing technique on this campus.
2. Cliff confirmed that the only type of molecular testing that might be considered by NSWHP is using real-time PCR method on the Idylla platform that covers only medicare rebatable items and does not meet the needs of this campus.
3. We indicated that the 'position statement' provided by Cliff does not seem to reflect current practice. For example, the position statement indicated that Illumina Focus Tumour Panel and Archer VariantPlex Solid Tumour Panel are currently performed on RNSH cases, whereas our experience is that it is being performed on the Sequenom platform.
4. Tracy discussed that the goals of NSWHP is to only have next-generation sequencing facility in a few sites such as John Hunter and RPAH to make the tests more affordable and sustainable. As discussed by Cliff at the meeting and on his position statement, the Archer VariantPlex Solid Tumour assay (61 genes) is the solution that is endorsed by NSWHP and will be used second line for non-urgent cases. This solution does not cover the needs of our campus which require the

detection of complex genomic variation such as gene 'fusions' that are important drivers in rare cancers. In addition, Archer is a very expensive solution and we queried about the 'sustainability and affordability' of this for NSWHP.
5. We want it recorded that we think the Archer Comprehensive Solid tumour Kit which includes the VariantPlex panel and FusionPlex panel would be suitable for our needs, but we do not think it will be delivered in a timely or cost effective manner.
6. We indicated that we would not be professionally comfortable with 'remotely supervising' molecular testing performed on a campus remote from where we work."

That is, we believe that the offer to submit a business case made prior to this meeting was not made in good faith as a binding and final decision had in fact already been made. We believe that subsequently there was not a genuine attempt to reassess our business case after this meeting. Of note, Cliff Meldrum met me on 25 November 2019 (1pm to 2pm) in my office at RNS to tell me that this proposal for somatic mutation testing was unsuccessful, but did not leave an email or written notification of his decision or reasons for his decision (despite a specific request to do so). This is significant because my understanding is that he may have subsequently stated that we had not submitted a business case in 2019. In any case, to me this is an example of an attempting to be seen to reassess the structure (in this case by offering us the opportunity to submit a business case) but not actually reassessing the structure.

6. Having been told categorically that we would not be permitted to perform broad panel somatic mutation testing for cancers on RNS campus within NSWHP we began to build a collaboration involving multiple clinicians and key personnel from the NSLHD to perform molecular testing on RNS campus separate to NSWHP. Subsequent events have given the appearance of a deliberate effort on behalf of members of the NSWHP genomics working group to undermine innovation and further contributed to poor trust.
When it became clear in 2019 that NSWHP would not accept (or even consider) broad panel somatic mutation testing on campus at RNS, we then developed and submitted a new and separate business case for somatic mutation testing to be based not in NSWHP but in the NSLHD. This model was fully funded and structured entirely external to NSWHP and the business case was submitted to the NSLHD (not to NSWHP). My understanding is that this business case was inadvertently sent from the NSLHD to NSWHP for comment. This was an error for which the NSLHD executive has apologized. This business case (which by then was close to 12 months old) was subsequently circulated to members of the genomics working group without the knowledge of the authors. I have not been provided with the comments, and can only speculate on what they may be. However I believe that comments were then made to the NSLHD on the business case that may be misleading and I seek clarification. For example, I have been told that these included a comment that no business case had previously been submitted to NSWHP (a statement that is in direct conflict with discussion point 5 above). I have also been told that these comments included a statement that there would be inadequate supervision on campus at RNS as this site only has two appropriate qualified pathologists (Prof Gill and A/Prof Chou). If this statement was made, I consider it disingenuous because there are no pathologists who are appropriately qualified to supervise somatic mutation testing of solid cancers on site at John Hunter Hospital which appears to be the preferred location for the testing by the NSWHP genomics working group.

Of note, this business case including modelling on billing contracted clinical trials and research work at above scheduled fee and using this money to subsidize non-billable cases (which could not otherwise be able to be tested). This is only achievable because of the international academic reputations of the key clinicians and pathologists at RNS campus and the ability to run this work on site at this campus. We emphasized that all medicare eligible and routine clinical diagnostic work would be billed at the scheduled fee. We believe this business case was unfairly criticized and it was in some way implied that we would be requesting above scheduled fees for clinical diagnostic work.

7. The current structure of NSWHP genomics without an on-site pathologist for somatic mutation testing for solid cancers performed in Newcastle is not in keeping with the NPAAC guidelines and by continuing this structure until the next NATA assessment, NSWHP gives the impression of disregarding these guidelines. Furthermore there has not been open disclosure of the status of molecular testing in Newcastle as being performed in a category B laboratory. I believe that structurally there has been a consistent bias against medical pathologist supervision of laboratories.

The NPAAC Tier 3A document 'Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)' outlines requirements for governance and supervision of molecular testing laboratories. For a GX laboratory there must be at least one full time equivalent, in aggregate, onsite Pathologist with the relevant Scope of Practice for each pathology test offered by the Laboratory. My understanding of the NPAAC guidelines is that category B laboratories with this scope of practice cannot be supervised remotely. For reference an official document on interpreting NPAAC guidelines is attached. On this question, this document states:

"*Q: Can a pathologist with a specific scope of practice supervise testing with their scope of practice if they are situated at a GX laboratory and testing is performed at a distant Category G or B laboratory?*

No. Any risk based assessment of supervision arrangements would dictate that the supervising pathologist be at the site where testing is conducted, in this example, at the other G or B laboratory."

Conclusion

In summary, I believe there has been a very significant disengagement between the strategic decision makers responsible for genomics testing in NSWHP and the patients and clinical teams delivering care at this campus. This has led to a repertoire of genetic testing which is not matched to patient needs on individual campuses; turn-around times and testing expectations that are discordant with clinical needs; a lack of flexibility to adjust to a changing clinical landscape, insufficient knowledge base and engagement to tailor testing in response to local clinical needs, a bias against innovation, and alienation of key onsite clinicians and pathologists with the skills to deliver state of the art testing.

The CEO and leadership team of NSWHP have outsourced key decisions (as well as this this review/audit) to a small group of individuals who were selected in an opaque manner and essentially all based in one centre. As a result there has been a structural bias towards basing testing in this one centre, at the exclusion of other

centres including RNS, despite a failure to meet expectations and the inability to recruit an appropriately qualified molecular pathologist. The same structural flaw has led to the inability and unwillingness to reassess key decisions after significant expenses were incurred and key expectations not met.

For many years I believe I have offered assistance and advice to those interested in molecular testing in NSWHP in good faith. Unfortunately my input has been rejected, not always in a transparent and straightforward manner as detailed above. I do not believe NSWHP will be able to deliver genomic testing in a truly patient centred and responsive manner without very significant structural change. In view of the decision to not follow through with the agreed upon 'external review' but instead to replace it with an 'internal audit', I now doubt that NSWHP is genuinely willing to consider structural change. I honestly hope that I am incorrect as I am deeply and passionately committed to state of the art pathology testing in the public system in NSW.

I therefore seek written answers to the questions below. Ideally these answers should be provided as part of this audit/review. If this is thought inappropriate by the reviewer or CEO, I would be happy if the answers were provided separately by the CEO or an appropriate delegate on her behalf:

Questions from Point 1
i) Why has a 'review' been replaced with an 'audit'? If the terms are interchangeable, why has it been emphasized at various meetings that this is not a 'review' but an 'audit'?
ii) Did the CEO of NSWHP over-rule Dr Lindeman's decision to offer a review and instead replace it with an audit?

Questions from Point 2
i) Is the decision to engage this consultant who previously advised about the structure of molecular testing being centralized in Newcastle and has advised NSWHP about several contentious issues related to genomic testing in keeping with the explicit undertaking to commission an external review?
ii) In the opinion of the executive of NSWHP, in view of this past involvement, is the consultant conflicted and/or 'external' in the true meaning of the words?
iii) In the opinion of the consultant, is the consultant conflicted? If not, is the consultant 'external' in the true meaning of the word?
iv) Did the CEO of NSWHP choose the contractor to lead this review and reassess this decision when I indicated that myself and others did not believe the reviewer was independent or external in the true meanings of the words?

Questions from point 3
i) Why has no RNS based anatomical pathologist been asked to join the NSWHP genomics working group at establishment of subsequently?
ii) What was the basis for excluding RNS as a site for genomic testing at the establishment of the NSWHP genomic testing plan given the unique skill sets and experience of the clinicians and pathologists and patient mix of this area?
iii) Who advised on the selection of the small leadership group for genomics, including the first director of genomics Dr Cliff Meldrum, and what are their

qualifications and experience in somatic molecular testing in carcinomas in the clinical setting?
iv) If it were a pathologist without qualifications and experience in molecular testing is this considered working outside of scope of practice?

Questions from point 4
i) Did Cliff Meldrum and Robert Lindeman explicitly rule out performing somatic mutation testing for cancers at the meeting on 19 December 2018?
ii) If so, is this approach in keeping with a broadly consultative and patient based strategy that should be being continually reassessed?
iii) If they did not rule out such testing, why are the other attendees at that meeting, including myself, under this impression?

Questions from point 5
i) Was the offer to submit a business case to NSWHP for assessment in early 2019 (subsequently submitted 18 June 2019) made after there had been a firm decision not to allow somatic mutation testing of malignancies at RNS campus? That is, was the offer to submit a business case for somatic mutation testing on campus at RNS made with the knowledge that there was no reasonable expectation that it would be considered or could be successful?
ii) Was the business case and discussion document that was submitted 18 June 2019 and discussed 20 June 2019 by teleconference actually reviewed by the NSWHP genomics working group in 2019 as promised (or did this occur in 2020 only after a similar business case was submitted to the NSLHD)?
iii) Did Cliff Meldrum meet with me on 25 November 2019 and tell me the business case was unsuccessful and that there would be no possibility of doing somatic mutation testing on campus at RNS?

Questions from point 6
i) Can I be provided with a full copy of the comments made by the NSWHP genomics working group on the business case that I submitted to the NSLHD in 2020?
ii) When they were asked to consider the business case for NSLHD based testing in 2020, were members of the genomic working group told that RNS pathologists had submitted a business case to NSWHP for somatic molecular testing on RNS campus in 2019 (which I assumed they had not previously seen)?
iii) Was this business case criticized due to poor supervision on the basis that there were 'only' two pathologists qualified to supervise testing in full knowledge that there are no pathologists qualified to supervise molecular testing of somatic mutations in solid tumours on campus at Newcastle?
iv) Was this business case criticized under a misapprehension that there was a plan to bill above the scheduled fee for clinical diagnostic work? Does the NSWHP genomics working group acknowledge that internationally recognized pathologists and clinicians at RNS campus, including national leaders in clinical trials, are able to attract testing for clinical trials performed at this campus and that this can be used to subsidize other work?

Questions from point 7
i) Are the current arrangements for supervision of somatic mutation testing centralized in Newcastle in keeping with NPAAC and RCPA guidelines?
ii) If they are considered to be in breach, do the NSWHP executive endorse operating in breach of these guidelines when alternate structures that would satisfy these guidelines have been proposed?
iii) NSWHP seems to have endorsed a structure for genomics testing where the director of genomics and senior leadership and decision makers are not medically qualified pathologists. Does NSWHP wish to pursue a structure where a pathologist is not in practice the actual clinical director and key decision maker for genomic services?
iv) Is it appropriate and safe for somatic mutation testing of solid organ malignancies not to be directly supervised by a pathologists with qualifications in both anatomical pathology and molecular pathology?
v) Have there been statements made on behalf of the executive and/or members of the genomics working group that they do not accept the RCPA/NPAAC guidelines describing the appropriate qualifications and on-site attendance required to supervise somatic mutation testing of cancers?

Sincerely,

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&
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