CLINICAL EXCELLENCE COMMISSION

Our Ref: D12/9042-1

30 August 2012

Professor Debora Picone AM
Chief Executive Officer
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
SYDNEY NSW 2001

Final Report of the Open Disclosure Review Committee in response to the recommendations of the NSW Ombudsman

Dear Professor Picone

Please find enclosed the response from NSW Health Local Health Districts,Special Health Networks and the Clinical Excellence Commission to the Draft Framework for Open Disclosure. Representatives from the Ministry of Health, the CEC and numerous LHDs and SHNs also provided feedback at a meeting in Sydney in early August.

Concerns have been expressed about the following issues;

1. The status of a Framework vs a Standard and the degree of agreement with the document prior to its publication
2. The length and complexity of the document
3. The dilemma of providing disclosure when an event is discovered some time after its occurrence and the limited reference to this in the document
4. The need to adequately consider and address the challenges faced by clinicians in performing this process
5. Difficult interface with insurers and legal advisors, especially in relation to covering costs ex gratia
6. The need to provide more guidance around the legal issues
7. A concern about adequately addressing the training requirements and providing appropriate advisory back-up

The feedback comments are attached. We look forward to working with you to finalise the document and oversee its implementation in NSW.

Yours sincerely

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DCG Feedback – Draft Open Disclosure Framework

Local Health District / Agency	Response by	Response Details
Clinical Excellence Commission	**Clinical Governance Unit**	**General Comments:** 1. The document is very detailed (especially section B) and appears to me more than a framework. Should it be re-named a guideline? Section B is too detailed and should be included in a training package. 2. Is the document too long? I think it may be. Section B could be part of a training module. 3. 1.3 involving insurers in policy development may be tricky. For NSW Public health it would be TMF and I am not sure how supportive they really are. 4. 4.4.3 – there may be times (rare) when OD could be harmful to the mental health patient's condition. Advice of the treating clinician should be sought. 5. 5.1 – Sometimes it is necessary (due to regulation) to report the clinician to the relevant registration authority. This is not included here. 6. 5.2.1 – Sometimes the patient or family do not want the treating clinician involved in the OD. They should have a say who comes. 7. 5.3 – Not all states allow apologies, do they? 8. 9.1 – do we really need to include suggested wording for a low level initial meeting. Not much about high level initial meeting which is very important to set up for on-going disclosure. This is more important than the low level disclosure. 9. 11.1 – Open Disclosure plan – I have no experience with a formal plan but have discussed future meetings etc. Will a written plan make the process too formal? 10. 13 Closure may often be protracted, especially if there is a Coroner's inquest occurring. Contact after final OD may go on for many months with intermittent contact. This doesn't come out in the Framework. 11. Appendix 2 0 Measures of Open Disclosure – difficult to measure these processes, especially outcomes. Sometimes all the correct processes occur but the family may still be unhappy with what happened. They may understand what happened but not accept it. Alternatively OD processes may be lacking but the family is happy to have had a discussion. Not sure any of the measures are really helpful. I don't think we should use the term "satisfaction" in this context.
CEC	Patient Based Care	• Approaches relating to 'Patient considerations/communication/engagement' need to incorporate the recommendations/findings of Rick Iedema's 100 Patient Stories Study (ACSQHC) • The need for timely resolution for the patient/family needs to be emphasized

		• Hollow apologies without an expression of empathy are over-rated (stresses need for this to be lead by experienced & trained clinician) • Closure – 13.1.1 refers to feedback to the patient about "information about what has been and will be done to avoid recurrence of the adverse event, and how these improvements will be monitored" (last dot point) This is very 'one way' and not really about engagement – needs to incorporate giving patient/family the opportunity to recommend systems improvements in response to an incident. **13.1 Key components of closure** **13.1.1 Communication** When the investigation is complete, provide feedback to the patient through face-to-face interview or equivalent (e.g. videoconference), and in writing. The interview and document will include: • details of the incident, including the clinical facts and other relevant facts • the patient's concerns or complaints • an apology or expression of regret (including the word 'sorry') for the harm suffered • a summary of the factors contributing to the adverse event • information about what has been and will be done to avoid recurrence of the adverse event, and how these improvements will be monitored. - enabling patients/family to articulate their questions and views about the incident - guidance about how best to do this - more guidance about how these questions and views are brought to bear on how the incident is understood, reported and investigated - ensuring alignment the OD Framework with the ACSQHC Standards 1 & 2 promoting consumer involvement
Ambulance Service NSW (ASNSW)		Ambulance does not have any issues with the content of the draft document.
Hunter New England (HNE)		Document Title: Australian Open Disclosure Framework Section, Part B: Open disclosure practice; Page 36 Key considerations and actions – point 1: A statement here about recording the lower level response in the patient's medical record would be beneficial. Overall easy to read, however is very long so most clinicians will not read this length of document proactively but may want to use it if faced with an open disclosure incident as a reference document. An exec summary would be useful to summarise key information points. The issue of potentially avoidance incidents found during death audits needs consideration. Should open disclosure be performed at time at the audit (noting that the relatives are coping with funeral/grief) or should a review be conducted immediately and then open disclosure performed if adverse findings, which are considered to impact on the death of the person, found on review. Document Title: Open Disclosure Standard **Section 7.7; Page 13** Footnote refers to FOI Act. In NSW, this has been replaced by Government Information Public Access Act (GIPAA)

		Section 7.8; Page 14 Rather than obtain consent from a patient regarding release of their personal health information, our business process is to inform the patient about use and disclosure options by providing a copy of the NSW Health Information Privacy leaflet in accordance with NSW Privacy law. **Section 11.2; Page 22** Should the health care record also document the following:- • Any acknowledgement expressed by the health care provider that an adverse event has occurred; • Any acknowledgement of regret expressed by a health care provider Statements by the patient or their authorised representative expressing dissatisfaction with the incident or subsequent actions. **Section** 2.3.1 Near misses; **Page** 15 Should not instigate near misses in open disclosures **Section 2.5** Adverse events occurring in other places; **Page** 16 Difficult commencing open disclosure when the event occurred in another place **Part B 4.3 Out of pocket expenses** Concern as to how much out of pocket expenses should be paid Policy should be developed by the CGU not individual facilities Short guide excellent resource
		Section 5 Staff considerations ; Page 24 In relation to training all of the components that have been identified need to be considered - I do not believe this can be done by purely a online package, it needs to have a robust face to face component, taking into account all of the human emotions involved in this very sensitive issue. It also need to be remembered in rural areas that often the person who does the open disclosure is well recognised by the community and is very much part of these communities and dealing with an adverse effect in rural communities is challenging, there has to be a much more intensive effort put into skilling up clinicians and mangers in their communication skills giving them strategies in dealing with families in these circumstances There also needs to be a much more cohesive recognition by organisations of the impact of the events on the clinicians in involved, in the main clinicians and managers do not come to work to harm patients, but also they must be held professionally accountable for the care they have provided. This is often a difficult balance. **Section: Overall** This is an excellent document BUT implementing in rural areas and rural hospitals would pose significant challenges, the senior clinicians are often VMOs with significant engagement policies

		Section 3.3 Disclosing multiple incidents or large-scale harm (or potential harm) to multiple individuals or the general public is out of scope of the Framework. Healthcare services are advised to have procedures in place to expedite decision-making in the event of multiple or large- scale incidents, and assess each situation promptly with legal counsel and public relations departments. I think that excluding advice on large-scale disclosure warrants reconsideration as we demonstrated that applying open disclosure principles widely to a group of people commonly affected by an adverse event meant that we were able to implement optimal patient care protocols. It might be useful to include in our submission back to the Commission our view and a copy of our peer-reviewed publication about how we were able to achieve this. Please see attached: R Aldrich P Finlayson K Hill M Sullivan 2012 "Look back and talk openly: responding to and communicating about the risk of large- scale error in pathology diagnoses". International Journal for Quality in Health Care 24 (2):135-143 (first published online January 10, 2012; doi:10.1093/intqhc/mzr084) **Section 3.6.1; Page 19** I think the blanket statement "it is important to obtain legal advice in each case" will hinder and slow down the open disclosure process and is not necessary. Consideration should be given to amending this section to recommend legal advice be obtained where local policies and procedures do not provide information relating to relevant legal considerations and/or the clinician is unclear as to their legal position- or something of that nature. **Section 4.3; Page 21** I think the important recommendation here is that this only be considered with the appropriate legal advice and in consultation with the organisation's insurer. This point needs emphasising- we have had issues locally with this and has led to circumstances where a clear agreement as to the extent of costs that will be covered has not been established. **Appendix 1; Table: Part 3** Gather information should also include seeking clarification of legal considerations and obligations where the team is unclear or the health service's policy is silent on these aspects. **Appendix 2 Section 2a** Legal Professional Privilege: Consider adding text relating to the test for LPP- that is documents for which LPP is claimed do not need to have been solely created for the purpose of seeking legal advice, i.e. it may have been created for more than one purpose however obtaining legal advice must be the dominant purpose for LPP to apply.

		In relation to implied waiver of LPP where the client has disclosed the communication/document- I think it would assist understanding of this principle if examples are provided.
Illawarra Shoalhaven (ISLHD)		**General Comments** The document focuses on incidents being identified in real time and the duty to disclose. However, we have learnt from experience that sometimes an incident or episode of harm has been identified through review processes well after the patient and carers have left us. What is our duty in these cases where there is a significant time delay from the incident to the review and therefore open disclosure? The evaluation report and guide do not appear to address this scenario and does not provide a timeframe for when retrospective OD is appropriate. This is one of our most problematic scenarios and is one where additional guidance would be appreciated.
		It is a very thorough document with good coverage of challenges to providing open disclosure and addressing gaps in current NSW policy. **Training and Education requirements** The determination of who owns/ is responsible for the training – CGUs, the whole LHD, and Ministry of Health. The LHD will need to consider a model of ownership of OD training, and timeframe for developing OD Officers. The implications from the OD framework include the need to training and education programs for clinicians and particularly those staff (such as medical officers) who will be involved in delivering open disclosure. Training should include clear guidelines on communication issues. For example, what and how much should be said / how apologies should be worded to ensure transparency and openness but also to protect staff from potential liability. Training should also address readiness for repercussions to staff from patient / family in response to open disclosure (e.g. Hostility and anger, blame, high levels of grief etc). **Organisational support for staff involved in incidents and open disclosure** The framework raises issues for organisations in terms of identifying and providing support to staff involved in incidents and OD (e.g. Defusing opportunity, time off work, EAP etc).
Nepean Blue Mountains (NBM)		It is worth noting that it is a very comprehensive framework. The issue for NBMLHD relates to how we operationalise

Southern NSW (SNSW)		**Section 2.6.1; Page 16** Nominating a support person – will require Admission clerk education, changes to admission forms and will need clarification as will be seen as 'next of kin' **Section 5.2.1; Page 25** Clinicians involved with adverse events be given the option of being included in the open disclosure- is this wise? Additional support will be needed for the clinician for the meeting, may result in more legal ramifications if not handled well. Would need very skilled people leading the session **Section 5.2.2; Page 25** There has been a strong reliance on CGU to lead the open disclosure process, to the extent, that people involved in the RCA process which is covered by 'privilege' have been part of the open disclosure meeting- concerns here from a legal point of view. **Section Open Disclosure practice – Part B; Page 33** High level open disclosure education is paramount and is not well addressed nor supported locally or from a State perspective. **Practice** is needed -role play required, scenarios developed and evaluations undertaken to skill up facility leaders in OD **Section 14.1 Maintaining documentation; Page 44** Standardisation is required for OD reporting formats and check lists as very difficult to write into a medical record and cover all of the OD meeting with a family. Should the terminology/language used by the family be used in this documentation?