Hon. Jack Snelling
SA Minister for Health

Cc David Swan CEO SA Health,
Prof Peter Bardy, Clinical Director of Cancer Services, Central Adelaide Local Health Network
Tracey Doherty, A/Head SA Cancer Services.

Re: Chemotherapy under-dosing incident,

Cancer Voices SA is shocked and concerned by the report of the significant system 'error' of under-dosing 10 cancer patients **by 50%** of the standard treatment chemotherapy dose.
See Appendix A, The Advertiser, 1st August 2015 newspaper report revealing these details.

Cancer Voices purpose is about "**good systems, not just good luck!"**. We **seek answers, to explain how these errors could have occurred , and what can be done to ensure similar errors never happen again**? We also propose some actions we would like to happen, following from this.

Our Questions regarding the error(s) causing this chemotherapy under-dosing are:

1. How did the under-dosing error occur?
2. Why wasn't the 'typo' picked up in 'quality assurance' checking when any changes are made to treatment protocols? (We assume there are 'quality assurance' procedures? Surely global changes can't be made to treatment protocols without cross-checks?)
3. Why didn't any staff notice or query the change? (There should have been all sorts of other signals – surely nurses routinely dispensing chemotherapy protocols like this should have noticed and raised an alarm, or pharmacists noticed a change in the ordering or amount of unused 'stock' of this chemotherapy agent? If not, why not? What are the barriers to health service staff raising an alarm if they notice something of concern?)
4. Was it "good luck' rather than good systems when an 'alert pharmacist' responded to the dose prescribed from clinical knowledge/ memory of an experienced clinician?
5. What is/ has being done to ensure similar errors don't occur again?
6. Could there be 'typos' in the protocols for other cancer treatments? Who authorizes release of verified protocols?
7. Why wasn't Open Disclosure practiced to inform the public of the error and its correction, rather than being revealed by The Advertiser 6 months later? Transparency builds trust.
8. How can we restore public confidence that effective quality and safety systems are in place?

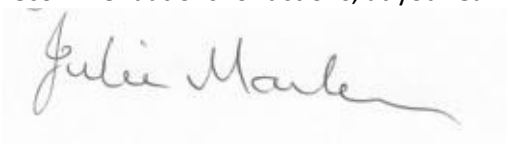
We must question why the health system is not applying the learnings from previous 'incidents', and investing in a culture of safety, quality and accuracy in all aspects of hospital systems. We refer to the previous radiotherapy under-dosing errors revealed in July 2008 (The SA Dept of Health revealed that 869 cancer patients received a radiotherapy dose up to 5% less than prescribed during a 2 year period, July 2004-2006.) and chemotherapy overdosing errors revealed in December 2008 (SA Dept of Health reveal that 11 patients at the Womens and Childrens Hospital received an overdose of chemotherapy drug *Etoposide phosphate*.). See Appendix B and C.

Cancer Voices SA wish to contribute constructively to solutions. Our representatives have actively and constructively contributed at executive committee levels since 2008, yet we only heard of this incident via the media?

What **Cancer Voices SA want to happen –**

1. **Obtain answers to our questions regarding this chemotherapy under-dosing incident, with the opportunity to discuss issues and implications around this.**
2. **Incorporate Safety and Quality measures in the standards for clinical cancer care.** For example, provide every patient with EviQ chemotherapy Patient Information about their treatment protocol (See Appendix D). EviQ is a recognised national repository of current chemo protocols and resources. **Help patients to be partners in managing their own care.**
3. **Ensure full transparent reporting and monitoring of the review and outcomes of this incident.**
4. **Ensure full implementation of Open Disclosure policies.**
5. **Ensure peak-body consumer representation is embedded at all levels, as full members, in all areas to achieve improvements around cancer treatment, care, services, policy, safety, quality, monitoring, research, teaching.**
6. **Ensure we all learn from this incident** - and ensure lessons from errors occurring elsewhere are heeded and incorporated into quality assurance checks. We need integrated systems of monitoring, audits and 'cross-checks' to prevent or catch errors or 'near miss errors' as well as **identify and report on 'error prone' areas or processes** that require attention.

We look forward to a response to our questions and opportunity to discuss our concerns and recommendations for actions, at your earliest opportunity.



Julie Marker
Chair, on behalf of the
Cancer Voices SA Executive Team,

3 August 2015

Cancer Voices SA is **'raising a voice for South Australians affected by cancer'** through **advocacy, involvement, awareness and information**. We represent people with all types and stage of cancers across all ages, social circumstances, gender and locality. Our focus is on wellness and not just illness. We are an **independent**, not-for-profit, **100% volunteer organisation**, formed in 2007. Cancer Voices SA is a member of Cancer Voices Australia, the Australian Cancer Consumer Network, Health Consumers Alliance SA and Consumers Health Forum of Australia.

We aim to be representative, responsive and respectful of the diversity of our grassroots members, their backgrounds and experiences, and we try hard to hear those views. We have regular engagement and interaction via our websites (**www.cancervoicessa.org.au** and www.cvsacyclingteam.org.au), events, social media (Twitter @CVSAinfo , FaceBook – CancerVoicesSA, YouTube), and physical activity initiatives (cycling, walking).

Appendix A – How 'typo' denied cancer patients full treatment at Adelaide's two major hospitals

PENNY DEBELLE, THE ADVERTISER, JULY 31, 2015 10:34PM

http://www.adelaidenow.com.au/news/south-australia/how-typo-denied-cancer-patients-full-treatment-at-adelaides-two-major-hospitals/story-fni6uo1m-1227465565297

TEN seriously ill cancer patients at Adelaide's two major hospitals have had their hopes for a cure compromised because of a typographical error that halved their chemotherapy dose.

The patients, with acute myeloid leukaemia, were admitted to the RAH and Flinders Medical Centre last year for intensive chemo — but received half the dose recommended for optimal treatment.

SA Health Minister Jack Snelling apologised on Friday for the mistake, telling *The Advertiser*: "We are very sorry."

"Incidents such as this are incredibly rare when you consider the thousands of people who deal with our health system every single day," Mr Snelling said.

At least one patient, a man aged in his 60s who relapsed in March, has reached a confidential settlement with the RAH.

He was in remission from last November but was called in early this year after worrying blood results. He is gravely ill and is receiving treatment but has lost hope for a cure, which was a potential outcome from his initial treatment.

Legal sources said the family of the man had been left tormented by the thought of what might have been if he had received the treatment to which he was entitled.

The dosing error continued for six months and affected the second and third rounds of chemotherapy given to new patients diagnosed with a potentially fatal cancer, which attacks the blood and bone marrow.

It occurred because half the recommended amount of chemotherapy — one dose a day instead of two — was wrongly entered into the internal system that stores treatment protocols and is relied on by doctors and pharmacists.

Professor Peter Bardy, clinical director of cancer services for the Central Adelaide Local Health Network, confirmed the underdosing of the drug Cytarabine and blamed it on a typographical error.

He said all 10 patients had been notified of the mistake, which was in the system undetected from July 2014 until January this year.

"We have apologised for the distress this error has caused them and their families," Professor Bardy said.

He said each patient was assessed to determine if any further treatment was required in light of them receiving less than the intended chemotherapy dose.

The Advertiser has learned through legal sources that the error came to light in January when a senior clinician wrote a script for the correct dose from her clinical knowledge and sent it to the pharmacy.

An alert pharmacist contacted her to say she had ordered twice the recommended amount. When she double-checked, the error was revealed.

Mr Snelling said yesterday the problem that led to it happening in the first place had been rectified. Professor Bardy confirmed the mistake was "a typographical error" and said all hospital database protocols had been reviewed for accuracy since it was discovered.

"We have put in additional measures to ensure this error does not happen again," he said.

"This includes more stringent reviews of the protocols from senior clinicians and pharmacists to ensure accuracy before the protocols are made available to staff."

The Advertiser understands the mistake was blamed by a senior clinician on a data entry error that occurred after the correct amount of chemotherapy had been prescribed.

The lesser amount appears to have been missed by specialists who countersigned the protocol before it was approved, and by practising specialists who administered the drug over six months.

The impact of the half-dose on patients with acute myeloid leukaemia is unknown but has caused distress to the patients and families of those already facing serious illness.

Legal arguments for compensation in relation to acute myeloid leukaemia are difficult to prove because of the high rate of relapse with the disease.

The Government refused to comment on whether there had been other applications for compensation.

Appendix B

Radiotherapy Under Dosing Incident (July 2008)

The SA Dept of Health revealed that 869 cancer patients received a radiotherapy dose up to 5% less than prescribed during a 2 year period, July 2004-2006.

- Ashleigh Moore on RAH radiation under dosage - ABC Radio
- Hospital radiation bungle widens - ABC Radio 11 August 2008
- More Patients in radiation bungle - ABC Radio 12 August 2008

The independent Delaney Review into the Royal Adelaide Hospital radiotherapy under-dosing incident made 14 recommendations for system changes to address issues identified during the investigation. (Find the report at SA Department of Health - Delaney Review, Sep 2008)

Cancer Voices SA Executive demanded action and raised consumer concerns over the incident at a range of levels including with the media, the Chief Executive of SA Department of Health and Professor Delaney.

The ABC Stateline program presented the 'Cancer Bungle' story on 15 August 2008, featuring interviews with Cancer Voices SA Executive Ashleigh Moore and Dept of Health Chief Executive, Dr Tony Sherbon.

Stateline SA, ABC TV - www.youtube.com.au/cancervoicessa

Eleven Kids In Chemotherapy Overdose (4 Dec 08)

Cancer Voices SA responded to the media release from SA Dept of Health, revealing that 11 patients at the Womens and Childrens Hospital received an overdose of chemotherapy drug *Etoposide phosphate*.

- ABC News
- SA Gov News

Appendix C

Cancer Voices SA draws reference to the

- Key Review Findings and Recommendations of the 2009 **Communio Report on the Review of SA Cancer Services** (following the radiotherapy and Etoposide incidents),
- Clinical Oncological Society of Australia 'Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy (2008) .
- SA Health Standards for Chemotherapy Services in South Australia (2010) and
- SA Health Open Disclosure Policy Directive (2014)

While progress has been made towards improved safety and quality of services flowing from these reviews and guidelines, not all recommendations are yet in place.

A further element overlooked in all these documents is 'partnering with consumers'.

Partnering with consumers: national standards and lessons from other countries

Stephen D Gill and Melinda Gill | Med J Aust 2015; 203 (3): 134-136.

Appendix D - Example of EviQ Chemotherapy Patient Information Sheet; information like this may have helped prevent the under-dosing error.

https://www.eviq.org.au/Protocol/tabid/66/categoryid/434/id/1453/Acute+Myeloid+Leukaemia+HAM+(Cytarabine+and+Mitozantrone)+.aspx

Chemotherapy Patient Information

Acute Myeloid Leukaemia (AML)

Name of Treatment: HAM
Drug(s): High-dose (H) Cytarabine (A) and Mitozantrone (M)

The aim of this leaflet is to help to inform you, and those that are close to you, about the side effects that may occur with this treatment.

Your treatment

Day(s)	Drug(s)	How is it given?	How long will it take?
1 to 3	**Cytarabine** *(sye-tara-been)*	By a drip into a vein TWICE a day	About 3 hours
3, 4 and 5	**Mitozantrone** *(my-tow-zan-trone)*	By a drip into a vein	About 5 to 10 minutes

- this treatment cycle may be given up to two times. Your doctor will advise you of the number of treatments you will have
- to have this treatment you will need to have a central or a PICC line inserted. Your doctor will decide what line will best suit you
- you will need to have a blood test before each treatment to check that your blood count has returned to normal. If your blood count is too low it may be necessary to delay your next treatment until your blood count has returned to normal. You will be told when to have these blood tests
- you will be given eye drops to help prevent sore eyes. You will start using the eye drops the day before you have your chemotherapy and will finish using the eye drops at least 72 hours after your last infusion of chemotherapy

Important Information

If you:

- **become unwell**
- **develop chills, shivers or shakes**
- **develop a temperature of 38°C or above**
- **feel short of breath**

Go to your nearest hospital emergency department immediately

During treatment let your nurse know immediately if you develop :-

- redness, soreness or pain around the injection site
- skin rash, itching, fever, shivers, dizziness, breathlessness or any other symptoms
- feel drowsy, sleepy, have any difficulty walking in a straight line or if you feel agitated

At home it is important to :-

- take your medications as prescribed by your doctor, including your anti-sickness medications, even if you do not feel sick at the time
- attend to your mouth care after each meal and before you go to bed
- for 2 days after treatment drink at least 8 to 10 glasses of fluid and empty your bladder frequently
- tell your doctor if you develop any numbness or tingling in your fingers or toes
- tell your doctor if you notice you are bruising easily or develop any bleeding around your gums or other minor bleeding
- tell your doctor or nurse if you have trouble with you balance feel light headed or confused

If you have any questions or concerns about your treatment and the side effects, please contact your treating team

Daytime contact.....

After hours contact.....