ST VINCENT'S
HEALTH AUSTRALIA

Purpose of Paper

To report findings in regards to dosing of Carboplatin in Head and Neck cancer patients.

Scope

47 head and neck cancer patients treated with Carboplatin 100mg doses were investigated. Only those with Dr Gallagher as treating surgeon were investigated. Cases reviewed had Carboplatin 100mg treatment initiated between the dates January 2012 and April 2015.

Background

- In question for these patients is the prescription of a standard dose of Carboplatin, generally 100 mg. One patient reviewed was prescribed 180 mg.
- The best practice dosing regimen as defined by the Cancer Institute NSW in the EviQ treatment guidelines is calculated from the "Area under the Curve" (AUC).
- The AUC is a function of the patient's age, gender, weight, and renal function.
- Carboplatin dosage regimens for head and neck cancer include:
    - 1.5 x AUC in definitive chemo-radiation for patients with low probability of surgical cure, including unresectable tumours
    - 2 x AUC for post-operative chemo-radiation for patients with locally advanced disease.
- The only mention of 100 found in a treatment regimen is Cisplatin at 100 mg/ m^2 recommended for three weekly chemo-radiation or in TPF induction.
- No changes to the protocol for Carboplatin prescribing have been made since EviQ commenced in 2010.
- Indications for a reduction in dose of Carboplatin would normally include haematological toxicity (neutropaenia, thrombocytopaenia), renal impairment, and ototoxicity.
- The processes in place cancer services at SVH (prior to the 'go-live' of electronic prescribing via the EMR MOSAIQ in August 2015) for use of EviQ protocols were to: print and retain the protocol in the patients file and the treating medical officer prescribes the protocol on the flow chart (paper medication chart for chemotherapy).

Review undertaken

- An attempt was made to obtain and review the medical record for the 47 patients identified with head and neck cancer who had received Carboplatin, and a treating surgeon of Dr Gallagher.
- Of most importance to the review was the treatment protocol and flow chart. These are the sources that contain the dose given, patient age, gender, weight, and renal function.
- No flow chart was viewed in 7 of 47 patients. Comment is not made on these patients as patient's weight and dose given is unknown.
- No protocol was viewed in 15 of 47 patients. If the protocol were taken as 1.5 x AUC (lowest dose by protocol):
    - All patients were still under-dosed by between 17 mg and 125 mg
- Both the treatment protocol and flow chart were viewed in 25 of 47 patients:
    - 7 of 25 had a protocol dose of 1.5 x AUC

locally advanced

adjuvant setting

- 18 of 25 had a protocol dose of 2 x AUC
- One patient (IS) was given a dose of 180 mg (his protocol was 1.5 x AUC) - under-dosed between 2 and 25 mg; IS is excluded from the comments below
- The remaining 24/25 patients were given the dose of 100 mg, regardless of the protocol
- All patients were under-dosed, between 10 mg and 200 mg per dose assuming 1
- An extensive review of the notes looking for indications for a reduction in dose was only undertaken for the original 5 patients with known recurrence. Of these, one patient (WK) had documented otalgia in the notes from 2011. His chemotherapy was initiated in May 2014.

Summary

- 47 relevant patients were identified for review.
- No flow chart was obtained in 7 of 47 patients.
- 39 of these 40 patients reviewed received the standard dosing of 100 mg Carboplatin.
- 1 of the 40 patients reviewed received dosing of 180 mg Carboplatin.
- All patients were under dosed by between 2 mg and 200 mg.

Report by Dr. P. Savage (Medical governance/administration trainee)

a trainee??

why did they have a trainee do their internal inquiry?

92.2 95.2.

Anthony Schembri

From: Gabrielle Prest
Sent: Tuesday, 23 February 2016 08:11
To: Anthony Schembri; Chris Conn
Cc: Brett Gardiner
Subject: RE: RIB and RiskMan Chemotherapy Under-dose Request

No, we acted/started the investigation on the basis of the information provided to Brett verbally.
At the time I was aware of reference to one but we've never seen evidence of it – none of the relevant people (those of us who would expect to receive it) received it automatically.
It was an oversight not to do it retrospectively
Gabrielle

From: Anthony Schembri
Sent: Monday, 22 February 2016 7:58 PM
To: Gabrielle Prest; Chris Conn
Cc: Brett Gardiner
Subject: RE: RIB and RiskMan Chemotherapy Under-dose Request

Hi,
Are you able to advise why a riskman notification wasn't made?
A

From: Phillip Broughton
Sent: Monday, 22 February 2016 7:44
To: Anthony Schembri
Subject: RIB and RiskMan Chemotherapy Under-dose Request

Hi Anthony,

Following your request, I contacted Gabrielle Prest and Carlie Tighe to obtain copies of the RIB and RiskMan entries.

I have been advised that there was no formal RIB completed, however a draft RIB (attached and incomplete) was completed at the time time a Matter for Information was completed (dated 7 August 2015), notifying of the incident. I believe that the information that was used in the draft RIB was used for the Matter for Information. A clinical governance decision was made that a RIB was not required and the Matter for Information was sufficient. I was unable to obtain any information as to who made this decision and / or the grounds behind it.

I have also been advised that a RiskMan entry was not completed for this matter. Again, upon my questioning, I was unable to ascertain why this was the case.

Regards,

Phillip Broughton
Executive Officer and Manager of Corporate Governance

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Executive Officer and Manager of Corporate Governance

St Vincent's Hospital

Minutes
Cancer and Immunology Program Clinical Governance Committee, Wednesday 4th July, 1230 - 1330

Chair: Professor Allan Spigelman **Deputy Chair:** Ashley O'Rourke **Membership:** Prof A Spigelman, Mr A O'Rourke, Ms S Francis, Mr J McAllister, Ms D How-Chow, Mrs A Fisher, Ms L Nolan, Ms M Bramwell, Ms K Storer, Ms G Beardsworth, Ms L Lynagh, Mr G Harvey, Ms M Rule, Ms S Ball, Mr D Behan, Ms L Davis, Mr R Fielden, Ms A Nolan, Ms A Horne, Ms S Kyle, Ms A Green, Ms A McLaughlin, Ms C Dolan, Ms F Hammond, Ms S Flynn, Dr D Dalley, Dr T Dodds, Dr R Jagavkar, Ms J Contemplacion, Ms A Polizios, E Lavie, Dr A Carr, Ms C Macks, Ms L Byrne, Ms T Melocco

Attendees: Prof A Spigelman, Mr A O'Rourke, Ms S Francis, Ms D How-Chow, Ms A Fisher, Ms L Nolan , Ms S Kyle, Ms C Dolan, Ms F Hammond, Ms S Flynn, Dr D Dalley, Dr R Jagavkar, Ms A Polizois, Ms C Macks, Ms E Lavie, Mr G Harvey, Ms L Byrne

1. **Apologies :** L Nolan, A O'Rourke, Z Potgeiter, B Cottam, S Levak, M Rule, C Dolan, Mr J McAllister, Dr T Dodds, T Melocco

2. **Confirmation of the Minutes of the previous meeting held on 9th May 2012.**

3. **Business arising**

3.1 Items from action log due:
- See updated action log.

4.1 **Patient Focus** – N/A

4.2 **Patient Feedback (Compliments/Complaints)**
- Bree/Glenn to feedback about patient complaint on X9S regarding cleanliness of bathrooms as raised by Tony Dodds.
- Standardised report being finalised with Anthony Marsh.

5. **Patient Safety**

5.1 SAC1 & 2 Report PSQC
- No SAC 1 or SAC 2 for the month of June for the Program

5.2 Incident reports
- Nil

5.3 RCA recommendations status update
- Ongoing work on the database which will lead to an improved report structure.

5.4 Reports Deteriorating Patient in HOAC/IBAC/The Kinghorn Cancer Centre (TKCC)
- PACE and code blue progressing well. Due to start week commencing 16th July.
- RMO TKCC –The process of contacting a HOAC registrar in the event of PACE/Code Blue in TKCC. TKCC RMO responsibility to decide who to call or roster system? Meeting with David, Linzi, Sally and John Rihari-Thomas to be organised.

5.5 Infection Control
- Data presented. Doctors performing well.

6. **Improvement Programs/Projects**

6.1 Project update: Patient Allocation HOAC – see presentation attached..

7. **Clinical Governance**

7.1 Clinical Policy & Procedures/Guidelines/Clinical Pathways/ Forms
- Database is being updated and should be able to report at the next meeting how many policies and procedures are actually out of date.

7.2 Clinical Unit/Department Morbidity& Mortality Report
- Receipt of Department reports confirmed.

7.3 Health Round Table
- New report is now available. Sally to send to Allan the report to decipher Program responsibility.

7.4 Risk Register(6 monthly)
- Work in progress.

8. **Other business (raised by Program committee members)**

8.1 Chemotherapy administration
- Chemotherapy being administered outside of HOAC.
- Report being finalised by the director of Pharmacy. Ashley to meet with Terry to discuss issues and concerns once this report is available.
- Michele Rule has a database of who is accredited for chemotherapy administration in the Hospital.
- Discuss chemotherapy administration protocols at our next protocol meeting.
- Dianne How-Chow to meet with Cancer Care Coordinators to facilitate a collaborative effort with response to the chemotherapy administration protocol for patients with HCC.

- **Committees**
  - SVH Patient Safety & Quality Committee Verbal Update
    - No outstanding issues for the program.
- **Date of Next Meeting:** To be advised

H&N_Chemotherapy Critical Incident Action Register Aug-Nov 2015

Action	Lead	Date	Completed	Comments
General	*Ngaire Buchanan*			
Instigate modified IMT	NB			
Inform CEO & CMO	NB		✓	
SVHA DCEO & GCEO Chair	AS		✓	
Sisters	NB		✓	
Ministry & NSW Cancer	RG		✓	
Identify expert in H&N _ Chemotherapy Treatment	RG		✓	
Legal Advise _ TMF				
Confirm timing of activation for patient contact				
Identify other stakeholders	MtL			
Confirm principles of approach				
Do no harm				
Patient contact process fully complete before activated				
Researched/evidenced based approach				
Open disclosure approach				
Ethnicity & Cultural requirements taken into account				
Media on hold until patients informed				
Clinical / Patient risk Assessment	*Richard Gallagher*			
Confirm - adverse results x Chemotherapy treatment Plan	RG		✓	
Review all H&N patients who have received Chemo under the current	RG / Paul		✓	
Review non H&N patients treatment plan	GP /TM / CM		✓	confirmed with Pharmacy Dept Head and Senior Oncology
Confirm treatment plan appropriateness for the non H&N pts	GP		✓	
Service Provision	*Richard Gallagher*			
Patients being treated now to have plan reviewed	✓			Through peer group at H&N MDT
Confirm number and changes required				
Communication plan refer to Communication section				
New patients treatment to be in line with NSW Cancer pathway				
Communications	*David Faktor*			
Separate out national & local response requirements	DF			
Briefing of identified stakeholders	DF			
Media approach	DF			
Key Themes	DF			
National comms links	DF			
Spokespeople	DF			
Identify and brief	DF			
B[illegible]rvice staff	GP			
I[illegible] staff briefing	BG			
B[illegible]ferring LHD's	AS			
Sign off from Clinical / Ethics and National as required	NB			
Patient Contact	*Brett Gardiner*			
Overall approach to patients	CC			
List of patient contact requirements				
Patient status (clinical)				
Support requirements				
Review of clinical / checklist of patient information req'd				
Patient contact team				
Consultant / SW / Senior nurse identified and briefed				
Standardised call sheet				
Individualised approach				
Information sheet				
Patient script and sign off with SMO's				
Prep of team / briefing packs				
Pt & GP letters and pack				
Prepare Q&A				
Identify dates involved				
Forms for collecting patient information				
0800 (national) line				
Statement / Script prepared				
Flowchart for 0800 i.E. if impacted pt rings on 0800				
Collection of live Dura (as above)				
Team rosters and times / Facilities				
FAQ's for Hot line				
Quality Control				
QA for:	CC			
Internal consistency				
Communication plan				
Clinicians				
[illegible]ture				
[illegible]nal approach				
QA patient contact lists				
Sign off with NSW MoH & SVHA				
Comms plan, Action register, patient contact process				
Recovery Plan				
Review (RCA) of event	BG		✓	
Communications plan to reassure patients and referrers	DF			
Debriefing of IMT and associated members	NB			
				All Rxs EviQ bsed or otherwise non-EviQ protocol committee to be convened for rv
Alert system process in place for treatments outside of pathways in pl	GP		✓	
Appreciation to the teams				
Social Support for impacted families	ML			
Review redundancy required for future proofing similar events	GP			a/a

Team Members	
Anthony Schembri - CEO	AS
Ngaire Buchanan COO - **Lead Incident Control**	NB
TBC - **Lead Technical Advisory Group (TAG)**	
Richard Gallaher Cancer Director - **Clinical Lead**	RG
Margaret Lazar - Allied Health Director	ML
Brett Gardiner - DCG & CMO	BG
David Faktor - **Communications**	DF
Gabrielle Prest - Clinical Stream Manager	GP
Majid Shahi - Acting Clinical Sream Manager	MS
Terry Melocco - Chief Pharmacist	TM
Chris Conn- Patient safey & Quality	CC
Carlie Tighe - Patient safety & Quality	CT
Linzi Nolan - NUM Nelune	LN
Matt Larkin - Emergency Response Manager	MtL

Unposted Incident - Edit 1

St Vincents Mater Health

Incident ID: 151838

This is a confidential report, please dispose of in an appropriate and secure manner ie. by shredding. Failure to ensure the destruction of records may lead to the unauthorised release of sensitive information

Incident Details

Incident Involved: Non-individual
Surname: [redacted] under Dr Grygiel
Street:
Suburb/City:
Postcode: Country:

Dates

Incident Date: 29 February 2012 Incident Time: 13:30
Notification Date: 29 February 2012
Date Closed:

Notification Details

Summary: Patient treatment schedule not completed by a consultant, wrong dose entered into chemotherapy schedule
Details: Patient treatment schedule not completed by a consultant, wrong dose entered into chemotherapy schedule
Reporter's Name: [redacted] Reporter's Position: Registered Nurse
Contact Phone:
Reporter's Site: Reporter's Location:
Seen By: Seen By Name:
Treatment Given: None
Action(s) Taken:
Investigations/Findings:
Investigated By:
Controls Implemented:
Control Hierarchy :
Was Restraint Used?: No
Seclusion?: No
Coroner Notified: No
Autopsy performed: No
Next Of Kin Notified: No
Outcome:
Sentinel:

Personnel Involved

Person #1: no personel involved Person #1 Position:
Person #2: none Person #2 Position:

Restraint

Type of restraint used:
Reason For Restraint:
Approved by Medical Officer?: No Approved by Medical Officer/General Practitioner:
Medication administered in the 2hrs prior to restraint:
Medication administered during the restraint:
Injuries Sustained (Restraint): No

Prior to restraint episode was the risk assessment for:

Aggression(Restraint):
Absconding(Restraint):
Self harm (Restraint):
Prior to restraint episode was the risk assessment for Sexual Safety:
Prior to restraint episode was the risk assessment for Suicide:
Prior to restraint episode was the risk assessment for Harm from Others:
Preventative Strategies (Restraint):

Prior History (Restraint, Aggression): No
Prior History (Restraint, Absconding): No
Prior History (Restraint, Self Harm): No
Prior History (Restraint, Sexual Safety): No
Prior History (Restraint, For Suicide): No
Prior History (Restraint, Harm from Others): No