
Non-conformance, Complaint Reporting and Continuous Improvement

1. PURPOSE

The Royal Children's Hospital (RCH) is committed to the open and honest discussion of adverse events with patients, parents and carers.

The aim of this procedure is to define the process for detecting, evaluating, documenting and reporting non-conformances and complaints pertaining to the Haemopoietic Stem Cell Transplant (HSCT) Programme at the Children's Cancer Centre (CCC) of The Royal Children's Hospital (RCH).

Non-conformances include errors, accidents, suspected adverse events, complaints and biological product deviations which apply within the HSCT Programme.

This procedure also addresses the requirement that quality related problems including regulatory non-compliances, ideas for improvement and internal audit outcomes are documented, actioned and reviewed appropriately.

2. SCOPE

This procedure applies to all trained staff who are involved with the care and treatment of patients within the HSCT Programme.

3. RESPONSIBILITIES

All RCH staff are responsible for the identification, analysis, evaluation, treatment and reporting of non-conformances, complaints and ideas for improvement. They are also responsible for immediate remedial action commensurate with their level of qualification, training and authority.

It is the responsibility of the Nurse Unit Manager / Senior Staff member in the section to;

- Assess and ensure that appropriate and necessary immediate remedial actions have been completed.
- Evaluate the significance of the non-conformance or complaint and ensure the incident is reported via Riskman proposing any additional corrective and preventative actions.
- Where a complaint is not resolved, ensure it is referred to the Chair of the CCC Patient Care Committee.

It is the responsibility of the Quality Manager (QM) or equivalent to;

- Assess, refer and close out the non-conformance and complaints according to the HSCT Programme and RCH Policies and Procedures.
- Where the incident involves other areas, ensure that interface between relevant Departments is maintained.
- Ensure corrective and preventative actions have been implemented and are effective as assessed via Internal Audits (QS-P-004).
- Prepare regular reports (inclusive of root cause, risk and trend analyses where appropriate) for management review according to QS-P-006.
- Implement, maintain and ensure compliance to this procedure.

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It is the responsibility of the Head of the HSCT or delegate to review all non-conformance reports and complaints involving patients within the HSCT Programme.

It is the responsibility of the Director of the CCC or delegate to review all non-conformance reports and complaints associated with the CCC.

4. DEFINITIONS

Accidents and errors – Any unforeseen or unexpected deviations from applicable regulations, standards or established specifications.

Adverse event – Any unintended or unfavourable sign, symptom, abnormality, or condition temporally associated with an intervention that may or may not have causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.

Complaint – Any written, oral or electronic communication about a problem or negative feedback associated with patient care or a distributed cellular therapy product or a service related to the collection, processing, storage, distribution, or infusion of a cellular therapy product.

Biological product deviation – A deviation from applicable regulations, standards, or established specifications that relate to the prevention of communicable disease transmission or cellular therapy product contamination; or an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease or may lead to cellular therapy product contamination.

Improvement – Suggestions from staff and patients that may lead to enhancing overall operation and performance of the service. Improvements may also be the result of non-conformance and complaint reporting.

Non-conformance – Deviations from documented procedures.

Remedial Action – Immediate Action taken upon finding, or notified of a non-conformance or complaint. Remedial action resolves the immediate symptoms of the problem.

Corrective Action – Action taken to deal with the issues contributing to the root cause of the problem to ensure that it does not recur. Minor non-conformances may not require in depth corrective action to be taken, however in some instances this is necessary.

Preventative Action – Action taken to reduce the chances of the non-conformance or complaint re-occurring. Preventative action is pro-active rather than reactive.

Root Cause – The actual underlying root of the problem. There maybe more than one root cause for a non-conformance.

Risk Analysis – Calculating a risk rating according to Australian / New Zealand Standard AS / NZS 4360:2004, Risk Management.

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Trend Analysis- Monitoring the occurrence of incidents over time and in comparison with two or more time periods to identify underlying longer-term trends.

Objective Evidence – Unbiased proof relating to the non-conformance or complaint.

Riskman – The software system which allows RCH staff to fulfil non-conformance reporting responsibilities. This system is the means by which incidents are reported and managed.

5. EQUIPMENT AND SUPPLIES

Not applicable.

6. PROCEDURE

6.1 Immediate Remedial Action

6.1.1 Following identification of the non-conformance or complaint the staff member who has identified the problem should take appropriate immediate remedial action commensurate with their level of qualification, training and authority.

6.1.2 Significant incidents should be brought to the immediate attention of the Nurse Unit Manager / Senior Staff Member of the section.

6.1.3 Significant incidents requiring urgent input by the Head of HSCT Programme or Director of CCC or delegate(s) should be communicated to them directly.

6.1.4 Where applicable and in accordance with RCH Organisational Policies and Procedures, the RCH Clinical Quality and Safety Unit may be notified.

6.2 Reporting the Non-Conformance or Complaint

6.2.1 Ideally the non-conformance or complaint should be reported immediately following appropriate remedial action by the staff member who identified the problem. If this is not the case, the Nurse Unit Manager / Senior Staff member of the section must ensure the non-conformance or complaint is reported as soon as reasonably possible.

6.2.2 Riskman is the software system used by the RCH staff to fulfil non-conformance and complaint reporting. It is available on the RCH intranet.

6.2.3 Go to the RCH Intranet and click on the Riskman On-Line icon. If you have not got a Login, create your Login (Username and Password) as prompted.

6.2.4 The Help icon gives you access to;

- Forgotten password.
- Contact with the RCH Clinical Quality and Safety Unit.
- Riskman help (Incident Entry Guide).

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6.2.5 Complete details as prompted (refer to the on-line Riskman Incident Entry Guide as required). Once you have completed details, ensure to include direct Nurse Unit Manager(s) / Senior Staff member(s) in the distribution list for notification of the non-conformance or complaint.

6.2.6 Remember to preserve and inform the Nurse Unit Manager / Senior Staff Member of any objective evidence relating to the non-conformance or complaint. This evidence maybe required for subsequent root cause analysis and resolution.

6.3 Follow-up of the Non-Conformance or Complaint

6.3.1 On notification of an incident via Riskman, the Nurse Unit Manager / Senior Staff member ensure that appropriate remedial action was completed.

6.3.2 Nurse Unit Manager / Senior Staff member then completes fields and includes any proposed additional corrective and preventative actions, nominating who is responsible for the task and where feasible, possible closeout date.

6.3.3 Once the journal entry is complete, ensure that direct line Manager(s) and Quality Manager or delegates are included in the distribution list for notification of the non-conformance or complaint.

6.4 Close-out of the Non-Conformance

6.4.1 The Quality Manager or delegate will review the non-conformance or complaint and may suggest additional corrective and preventative action as appropriate and in consultation with the Nurse Unit Manager / Senior Staff Member.

6.4.2 Effectiveness of the corrective and / or preventative action may be assessed by internal audit as deemed by the Quality Manager or delegate.

6.4.3 The Quality Manager will prepare root cause, risk and trend analyses in consultation with and as instructed by the Head of the HSCT Programme, Director of the CCC or the Chair of the CCC Patient Care Committee. These reports will be prepared using Riskman report modules and according to;

- Root Cause Analysis Education Modules. Department of Human Services Victoria. 2006.
- AS / NZS 4360 Risk Management. Australian / New Zealand Standard. 2004.

6.4.4 Non-conformance and complaint reports, analyses and internal audit reports pertaining to HSCT Programme will be presented for management review at a;

- Local Level - HSCT Multidisciplinary Meeting,
- Unit Level – CCC Patient Care Committee,
- and Organisational Level – RCH Quality and Improvement Committee.

6.4.5 The Chair of either of these committees may further instigate an External Independent Audit and Review in accordance with RCH Policies and Procedures.

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6.5 Resolution of Complaint

6.5.1 If the complaint was not resolved, the incident is referred to the Chair of the CCC Patient Care Committee.

6.5.2 The complaint is resolved by the committee according to Organisational Policies and Procedures.

7. ENDPOINT

Not applicable.

8. ATTACHMENTS

Consumer Complaint Management Toolbox. CCC Patient Care Committee.

9. REFERENCES

9.1 Risk Management Policy – Clinical. Royal Children's Hospital Policies and Procedures Manual. Policy Number: RCH0322. Version0. 2004.

9.2 Open Disclosure Policy. Royal Children's Hospital Policies and Procedures Manual. Policy Number: RCH0330. Version0. 2004.

9.3 Risk Policy. Royal Children's Hospital Policies and Procedures Manual. Policy Number: RCH0364. Version0. 2005.

9.4 Complaints Policy. Royal Children's Hospital Policies and Procedures Manual. Policy Number: RCH0258. Version: 2. 2003.

9.5 Root Cause Analysis Education Modules. Department of Human Services Victoria. 2006.

9.6 AS / NZS 4360 Risk Management. Australian / New Zealand Standard. 2004.

9.7 International Standards for Cellular Therapy Product Collection, Processing and Administration. FACT-JACIE. Fourth Edition. July 2008.