1. Full description

Adverse event, critical incident, serious issue, and near miss procedure

2. Preamble

Medical practitioners working in Australia have responsibilities for managing adverse events, critical incidents, near misses, and ‘serious issues’. These responsibilities include appropriate reporting and the reviewing of what occurred in relation to these events. Medical practitioners’ responsibilities extend to complying with statutory reporting requirements, which includes the mandatory reporting requirements under the Health Practitioner Regulation National Law Act 2009 (Medical Board of Australia, accessed 22/12/16).

The key documents cited in this procedure are not congruent; referring to a number of related or alternate terms. The RACGP’s (2015) Accreditation Management Agreement with Murray City Country Coast (MCCC) GP Training refers to the World Health Organisation’s (2009) definitions of adverse events, critical incidents, and near misses; whilst ACRRM (2016) use the overarching term, ‘serious issues’.

MCCC is required to report ‘critical incidents’ and ‘serious issues’ to the respective general practice Colleges as they occur and has some additional annual reporting requirements in the relation to the RACGP (see the requirements of the Accreditation Annual Report). MCCC can only fulfil its obligations if stakeholders, especially employees in MCCC’s accredited training posts and registrars enrolled in the Australian General Practice Training (AGPT) program act in accordance with their aforementioned responsibilities.

3. Purpose

The aim of this procedure is to:

1. Provide definitions of adverse events, critical incidents, near misses, and serious issues.
2. Clarify who to notify and how to notify when an adverse event, critical incident or serious issue occurs. (Near misses that occur in training posts should be documented in the practice’s clinical risk management system.)
4. Ensure that adverse events, critical incidents, and serious issues are investigated, documented and reporting obligations are met.
4. Scope of this policy

The definitions employed by the RACGP in their key documents primarily focus on the safety and well-being of patients. The RACGP (2015) acknowledge that a number of clinical errors and mistakes can occur during the training of a registrar and expect the vast majority will be dealt with at the training post. Only those that are significant and result in a serious adverse outcome need to be reported to MCCC.

ACRRM’s definition of a serious issue has an overlapping focus on the safety and well-being of patients, but additionally includes activities and events involving all employees in a training post and the actions of MCCC’s employees.

In a personal communication to MCCC (10/05/16), the RACGP gave an expanded definition of a ‘critical incident (see Appendix A), which mirrors ACRRM’s broad scope.

Although registrars’ practice in relation to the health and well-being of patients is at the heart of this policy, the Colleges’ guidance and definitions bring the actions of training posts’ employees and MCCC’s employees under its remit. Although events that relate to patients are relatively clearly defined; behaviours related to other domains are more ambiguous.

If a stakeholder of the training program is unclear from the given definitions as to whether an ‘incident’ is serious enough to be reported using this procedure, he or she should seek advice from the Director of Medical Education and Training or the Chief Executive Officer.

5. Definitions

Adverse event:

1. An injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalization or disability at the time of discharge from medical care, or both.
2. An undesired patient outcome that may or may not be the result of an error.
3. An event or omission arising during clinical care and causing physical or psychological injury to a patient.
4. A negative consequence of care that results in unintended injury or illness which may or may not have been preventable.
5. An injury that was caused by medical management and that results in measurable disability.
6. An untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.

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*One significant extension occurs in the WHO’s definition of an adverse event, which includes, “An untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization”.*
7. Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other facility. Adverse events may result from acts of commission or omission.

8. An undesirable event occurring in the course of medical care that produces a measurable change in patient status.

9. An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

10. An injury resulting from a medical intervention and not due to the underlying condition of the patient.

11. An unexpected and undesired incident directly associated with the care or services provided to the patient.


**Critical incident:** An incident resulting in serious harm... to the patient... when there is an evident need for immediate investigation and response (WHO, p.2009, p.111).

**Critical incident reporting:** The identification of preventable incidents (i.e., occurrences that could have led, or did lead, to an undesirable outcome) reported by personnel directly involved in the process in question at the time the event was discovered. Incident reports may target events in any or all of three basic categories: adverse events, no harm events, and near misses. (WHO, 2009, p.112)

**Near miss:**

1. An event that almost happened or an event that did happen but no one knows about. If the person involved in the near miss does not come forward, no one may ever know it occurred.

2. A deviation from best practice in health care delivery that would have led to unwanted harm to the patient or to the mission of the organization, but was prevented through planned or unplanned actions.

3. An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.

4. Any process variation which did not affect an outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.

5. A situation in which a medical error could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention.

6. An error of commission or omission that could have harmed the patient, but serious harm did not occur as a result of chance... prevention... or mitigation.

7. An event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient.

8. Unexpected or unplanned events in the provision of care that could have, but did not, lead to harm, loss or damage.


**Reasonable belief:**

A term commonly used in regulatory legislation to denote the threshold test for action, such as an obligation to report. A reasonable belief is formed by an objective consideration of all relevant matters (including matters of opinion).

**Serious issues:**

Training Organisations are required to report to ACRRM:

- An error by a registrar or supervisor that is suspected to have caused death or significant injury to a patient.
MCCC may amend and vary this procedure from time to time.
8. Procedure

From this point forward adverse events, critical incidents, and serious issues will all be covered by the term ‘incident’ for ease of reading.

Registrars

1. An ‘incident’ related to a registrar may be noticed by the registrar him or herself or by a member of the supervisory team. If noticed by the registrar, he or she must notify his or her supervisor and the practice manager of the ‘incident’. An ‘incident’ detected by any member of the supervisory team should be reported to the lead supervisor, who will notify the registrar.

2. The registrar should report the ‘incident’ to his/her Medical Indemnity provider.

3. If desired, the registrar can also discuss the incident with a Registrar Education and Practice Support (REAPS) Coordinator, Registrar Liaison Officer, his or her Training Advisor, or the Pastoral and Learning Support (PALS) Medical Educator.

4. The MCCC Adverse event, critical incident, and serious issue reporting form (Appendix C) should be completed and submitted to the relevant Regional Head of Education as soon as practicable following the ‘incident’. In meeting this timely reporting requirement, it is expected that this form is submitted within 10 business days of the incident. The form must be counter-signed off by the registrar’s supervisor.

5. The ‘incident’ should also be recorded in the practice’s clinical risk management system.

6. Details of the ‘incident’ will be entered into MCCC’s Incidents Register by the Executive Project Officer. The following fields of the Incidents Register are to be entered at this stage: Registrar, Region, Training Post/Practice, Supervisor(s), Registrar’s Training Stage (e.g. GPT1/PRRT1), RACGP/ACRRM, Date of Incident, Nature of Incident, and Date of Incident Report to MCCC.

7. The Regional Head of Education will review the ‘incident’ with MCCC’s Director of Medical Education and Training in order to determine whether any further action should be taken (e.g. further investigation by named person). The date of this review will be entered in MCCC’s Incidents Register.

8. The Regional Head of Education notifies the registrar and supervisor of the outcome of the review, even if no further action is deemed necessary.

9. If the ‘incident’ is deemed serious enough to report to the respective College, the Director of Medical Education and Training is responsible for ensuring that this happens. If the ‘incident’ relates to a registrar registered with ACRRM, the ACRRM College’s Serious issues reporting form (Appendix B) must be completed and sent to the ACRRM Director of Training at DOT@acrrm.org.au. Notification to RACGP can be made using RACGP RTO Critical Incident / Adverse Event Report form (Appendix D).

10. If judged appropriate, a notification will be made to AHPRA (Australian Health Practitioner Regulation Agency) and/or the respective College.

11. The Regional Head of Education will ensure that any relevant details of the incident are discussed by the appropriate Medical Educator Group, so that suitable support is given to the registrar and agreed actions are implemented (e.g. an intervention from the Pastoral and Learning Support Team). Outcomes of this discussion and the support offered will be documented.
Preamble

Although a registrar has a named lead general practice supervisor, the supervision of registrars typically takes place under the umbrella of a supervisory team (i.e. includes other doctors, nurses, allied health professionals and administration staff who work within the training post). Should a member of the supervisory team be involved in an ‘incident’, details of the incident must be reported to MCCC, so that the training post can be confirmed as providing a safe practice environment that supports high quality training.

The RACGP (2013) Standards for general practices require practice teams to demonstrate how they “monitor, identify and report near misses and mistakes in clinical care” and “identify deviations from standard clinical practice that may result in patient harm” (p.70). MCCC’s accredited training posts are therefore expected to have a documented clinical risk management system in place, so that all members of the practice team know who and how to notify when an ‘incident’ occurs. Given that MCCC only places registrars in practices that have been accredited by Australian General Practice Accreditation Limited (AGPAL) or GPA ACCREDITATION plus, MCCC assumes that there is a clinical risk management system in place.

1. It is expected that any ‘incident’ involving training post employees who are part of a registrar’s supervisory team will be documented in the practice’s clinical risk management system.
2. Details of the ‘incident’ should be submitted to the relevant Regional Head of Education as soon as practicable following the ‘incident’. (Near misses involving members of the supervisory team do not need to be reported to MCCC, although they should be documented in the training post’s clinical risk management system.) Given that practices do not have a uniform clinical risk management system, a practice can choose the written format by which it notifies the Regional Head of Education.
3. The Regional Head of Education will review the ‘incident’ with MCCC’s Director of Medical Education and Training in order to determine whether any further action should be taken (e.g. further investigation by named person).
4. The Regional Head of Education notifies the training post’s contact person of the outcome of the review, even if no further action is deemed necessary.
5. If the ‘incident’ is deemed serious enough to report to the respective College, the Director of Medical Education and Training is responsible for ensuring that this happens. If the ‘incident’ relates to a registrar registered with ACRRM, the ACRRM College’s Serious issues reporting form (Appendix B) must be completed and sent to the ACRRM Director of Training at DOT@acrmm.org.au. Notification to RACGP can be made using RACGP RTO Critical Incident / Adverse Event Report form (Appendix D).
6. The Regional Head of Education will ensure that agreed actions arising from the review are implemented.

7. Documentation related to the ‘incident’ will be kept on the training post’s (re-)accreditation file. ‘Incident’ details will be entered in MCCC’s Incidents Register, as described in the subsection 8.1 of this Procedure.

MCCC employees

Preamble

‘Incidents’ involving MCCC employees (Medical Educators and Administrative staff) that are covered by this procedure are likely to be extremely rare. Nonetheless, the definitions provided by the Colleges refer to MCCC’s employees, (e.g. actions of an MCCC employee likely to bring ACRRM into disrepute).

1. In the first instance the employee must notify his or her line manager of the ‘incident. (For Medical Educators this will likely be a Regional Head of Education or the Director of Medical Education and Training.)

2. The line manager should choose the appropriate pathway to review the ‘incident’ with the appropriate senior manager (i.e. The Chief Executive Officer, Chief Operations Officer, or the Director of Medical Education and Training).

3. The senior manager will ensure that the ‘incident’ is reviewed by MCCC’s Executive in order to determine whether any further action should be taken, which is likely to include a review of the employee’s performance and conduct.

4. The relevant senior manager notifies the employee and his or her line manager of the outcome of the review, even if no further action is deemed necessary.

5. If the ‘incident’ is deemed serious enough to report to the respective College, the Chief Executive Officer is responsible for ensuring that this happens. If the ‘incident’ relates to ACRRM, the ACRRM College’s Serious issues reporting form (Appendix B) must be completed and sent to the ACRRM Director of Training at DOT@acrrm.org.au. Notification to RACGP can be made using RACGP RTO Critical Incident / Adverse Event Report form (Appendix D).

6. Documentation related to the ‘incident’ will be kept in the employee’s personnel file.

7. The following fields will be filled in MCCC’s Incidents Register: Incident, Support, Notification and Status. Details of the Affected Practice/Staff will only be entered when applicable, e.g. when the action of a Medical Educator led to an incident at a training post/practice.

Monitoring and reporting of ‘incidents’

MCCC is required to report ‘incidents’ to the respective general practice Colleges as they occur. In addition, MCCC must provide the RACGP with a list of all the ‘incidents’ that occurred in a calendar year in its Accreditation Annual Report. The primary motivation for this exercise is for individuals and the organisation to maximise the learning for these ‘incidents’, especially to avoid their recurrence.

In order to keep an accurate ongoing record of ‘incidents’ and to ensure that this procedure is followed, MCCC has an Adverse event, critical incident, and serious issue handling officer.

Regardless of whether ‘incidents’ involving registrars, training post employees who are part of a registrar’s supervisory team, or MCCC employees are reported to the Colleges, all ‘incidents’ that are reported to MCCC should be forwarded to the Adverse event, critical incident, and serious issue handling officer. In the case of registrars, the requisite documentation is the MCCC’s Adverse event, critical incident, and serious issue reporting form (Appendix C), signed by the Director of Medical Medical.
Education and Training and/or Regional Head of Education. For ‘other training post employees’ and MCCC employees the documentation may take a variety of forms.

The Adverse event, critical incident, and serious issue handling officer will provide the collated information to the Manager Education Quality by February 1st each year. This is to ensure that personal and organisational learning occurs in relation to all the ‘incidents’, regardless of judgements about their severity. The Manager Education Quality will review the previous year’s ‘incidents’ and provide a report to the author of the RACGP’s Accreditation Annual Report.

9. Additional information

- ACRRM Serious issues reporting form
- National Health Practitioner Regulation National Law 2009
- Guidelines for Mandatory Notification (Medical Board)
- Critical Incident Reporting Form
- Health Practitioner Regulation National Law Act 2009 (the National Law)
- Medical Board of Australia. (accessed 22/12/16) Good Medical Practice: A code of conduct for Doctors in Australia
- Registrar Complaint and Appeals Procedure
- Registrar Safety Procedure
- Registrar in Difficulty Procedure
- Registrar Agreement
- RACGP Accreditation Management Agreement
- RACGP Critical incident / adverse event report
- RACGP (2103) Standards for general practices (4th Edition)
- RACGP (2015) Vocational Training Standards Supervision and Training Agreement
- Royal Australian College of General Practitioners (2013) Vocational Standards. East Melbourne: The Royal Australian College of General Practitioners

10. Document History

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<thead>
<tr>
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<th>Summary of changes</th>
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<tr>
<td>2.0</td>
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<tr>
<td>3.0</td>
<td>Revision/correction of section numbering and typographical errors</td>
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<tr>
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<td>Change “doctor” to medical practitioner – section 2</td>
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<td>Addition of expected timeframe – paragraph 8.1.4</td>
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<td>Addition of paragraphs 8.1.6, 8.1.13, 8.1.14, 8.3.7</td>
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MCCC may amend and vary this procedure from time to time.
Appendix A

RACGP e-mail communication 10/05/16

A critical incident may be defined as any event which causes disruption to an organisation, creates significant danger or risk where registrars, supervisors, practice staff, RTO staff or patients feel unsafe, vulnerable or under stress.

A critical incident need not be a dramatic event: usually it is an incident which has significance for the individual or organisation. It is an incident which in some way has had a significant impact on personal, professional or organisational operations/activity.

In the clinical setting, a critical incident might include:

- A medical emergency
- A difficult situation in which the individual was ill prepared.
- A communication problem (e.g. with a patient or colleague)
- Activity that increased awareness, or challenged understanding of social justice issues
- An incident involving conflict, hostility, aggression or criticism
- An interaction with a patient which may have resulted or did result in a problematic or difficult situation requiring third party intervention
- Confrontation with a patient, staff member or colleague where the individual felt threatened, pressured or vulnerable.

Critical incidents may relate to issues of communication, knowledge, treatment, culture, relationships, emotions or beliefs.

With respect to RACGP requirements the reporting of a critical incident is held to an incident that is or is likely to have a major adverse effect upon the wellbeing/reputation/security of an individual and/or organisation.

The notification is to the RACGP General Manager Education Services or in the case of what has been deemed a major incident, the RACGP CEO.
Serious issues reporting form

Purpose

This form is to be used when reporting a serious issue to ACRRM.

Policy

Training Organisations are required to report to ACRRM:

- An error by a registrar or supervisor that is suspected to have caused death or significant injury to a patient
- Criminal activity or suspected criminal activity by a registrar, supervisor or teaching post
- An event (including illness) that significantly affects a registrar’s ability to train
- Any actions by a registrar, supervisor, or employee of a training organisation likely to bring the College into disrepute
- Any material change with the training organisation that has the capacity to affect the delivery of ACRRM training in accordance with standards.

Details of serious issue

Please indicate what the incident relates to:

- Registrar
- Accredited Teaching Post
- Accredited Supervisor
- Accredited Training Organisation
- Other (if other, please detail below)

Name of person/organisation involved: ___________________________________

Date issue occurred: __/__/____

Brief description of serious issue:
Appendix B (continued)

Please describe what actions have been taken:

Who has this issue been reported to:
Name: ____________________________________
Position Title: ______________________________
Organisation: ______________________________

Please outline the next steps to be taken:

Reported to ACRRM by:
Name: ____________________________________
Position Title: ______________________________
Contact details: ____________________________

Completed forms to be sent ACRRM Director of Training at DOT@acrrm.org.au
Appendix C: MCCC Adverse event, critical incident, and serious issue reporting form

In the form below, ‘incident’ can refer to an adverse event, critical incident, or serious issue as defined in ED 028 Adverse Event, Critical Incident, Serious Issue and Near Miss Procedure

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<th>Registrar Name:</th>
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<th>What is the ‘incident’?</th>
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<th>Why is the ‘incident’ significant (i.e. adverse, critical or serious)?</th>
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<th>Who is involved?</th>
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<th>What factors led to this ‘incident’?</th>
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<th>How was the ‘incident’ handled?</th>
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3 Adapted from: [www.gp-training.net/cme/appraisal/docs/sigevent.doc](http://www.gp-training.net/cme/appraisal/docs/sigevent.doc)
How could it have been handled differently?

What action needs to be taken as a result of this ‘incident’?

What lessons can be learnt for future reference?

Registrar Signature: □ □ □ □ Date: ______

Supervisor Signature: □ □ □ □ Date: ______

Review of incident by Regional Head of Education and Director of Medical Education and Training. List the outcomes and actions arising from the review of this ‘incident’.

DMET Signature: □ □ □ □ Date: ______

Or RHE

Please email completed form to your region below:

Metro West: mw@mccc.com.au
North East: ne@mccc.com.au
North West: nw@mccc.com.au
South West: sw@mccc.com.au

FOR OFFICE USE ONLY: This form must be forwarded to the relevant RHE and copied to the Critical Incident Handling Officer.
## Significant Event Analysis (source www.rcgp.org.uk)

The guidance that follows is intended to guide participants through a review of an ‘incident’. The text retains the language of ‘significant event analysis’

### Recommendations in facilitating the structured analysis of a significant event:

1. **What happened?**
   - Collate and record as much factual information as possible about the event including, for example, what happened, when and where, what was the outcome and who was involved.
   - Record the thoughts and opinions of those involved, including patients and relatives if appropriate, and attempt to form an accurate impression of what happened.

2. **Why did it happen?**
   - Ensure the main reasons why the event occurred are fully established and recorded, e.g. was it a failure in a practice system or a failure to adhere to a protocol?
   - Establish the underlying or contributory reasons as to why the event occurred e.g. why was there a failure in a practice system or adherence to a protocol?

3. **What has been learned?**
   - Agree and record the main learning issues for the practice team or individual members of the team.
   - Ensure that insight into the event has been established by the practice team or the individual members of the team.
   - Ensure that insight into the event has been established by the practice team or the individuals concerned.

4. **What has been changed?**
   - Agree and implement appropriate action in order to minimise the chances of the event recurring, where change is considered to be relevant.
   - Monitor the implementation of any change introduced.
Appendix D: RACGP RTO Critical Incident / Adverse Event Report

Click here to access the form for RACGP