SERIOUS AND SENTINEL EVENTS

POLICY: Staff must report events that harm or have the potential to harm a patient. Appropriate response to Serious events includes a credible and thorough analysis and process improvement action plan to reduce the likelihood of reoccurrence of a similar event. All Sentinel events require a documented root cause analysis.

PROCEDURE:

1. Identification Of A Serious or Sentinel Event
   A. SERIOUS EVENT
      A Serious event is an unintended clinical event resulting from a variance from expected practice, procedure, or policy that leads to or has the potential (close call) to lead to serious patient harm. Serious events may involve the interaction of multiple services or a generalizable process or a system or have an extreme level of patient or parental concern.
      Note: Reviews of adverse events that relate solely to clinical profession judgment is to be done by departmental mechanisms.
   B. SENTINEL EVENT
      A Sentinel event is a Serious event that is reportable to JCAHO or the Washington State Department of Health (DOH).
      1) Appendix A lists adverse events reportable to DOH and DOH guidance.
      2) In addition, the following events are subject to review by JCAHO:
         a) The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition
         b) Unanticipated death of a full-term infant
         c) Patient discharged to the wrong family
         d) Radiation overdose involving prolonged fluoroscopy with cumulative dose more than 1500 rads to a single field
         e) Suicide of any patient receiving care, treatment, or services in a staffed around-the-clock setting or within 72 hours of discharge

2. Responsibilities
   A. LEADERSHIP
      The Chief Operating Officer and the Medical Director have primary responsibility for determining if a Sentinel event has occurred and initiating Children’s defined review process. They delegate operational responsibility to the Associate Medical Director of Quality Improvement, the Nurse Executive, the Administrator of Quality and People, and Patient Safety Manager.
   B. STAFF
      Any physician or staff shall immediately report information that reasonably suggests that a Serious event has occurred through the nursing or the medical chain of command (see “Chain of Command” policy and procedure). A report should be made via eFeedbackNOW or directly to QI Staff, Children’s or UW Risk Manager, or at nights or on weekends, to the Administrator-on-call. Notification should
include (1) a brief summary of the initial unit-based review specifying who, what, when, and where; (2) copies of any relevant portion of the medical record; and (3) a recommendation regarding scope of the review and members of the review team.

3. Immediate Response To Serious Event
If a Serious event occurs, follow-up by physicians and staff should include:

A. Document medical assessment of patient (by a physician or PNP or PA)
B. Save any involved devices (e.g., sequester drug stock, hold defective equipment, save syringes or vials or tubing)
C. Disclose to patient and legal representative (see “Disclosure of Unanticipated Outcomes/Communicating with Patients and Families to Reduce Risk” policy and procedure)
D. Document appropriately in medical records
E. Contact Clinical Engineering for medical device
F. Contact Building and Engineering for facility concern
G. Notify Risk Management
H. Support involved staff (“Critical Incident Stress Management” services are available by calling Psychosocial Intake Line ext. 7-2760 or page Social Work administrator-on-call)

4. Notification of Regulatory Agencies

A. JCAHO
The decision to submit a voluntary Sentinel Event Report to JCAHO rests with the Chief Operating Officer and the Medical Director or their designees. If so decided, they or their designees will make the initial as well as subsequent reports to JCAHO. They will serve as Children’s contact persons throughout the process. Reports will be made available without identifying the patient or the members of the medical care team.

1) LEGAL PROTECTION OF INFORMATION AND DOCUMENTS FROM DISCOVERABILITY AND ADMISSIBILITY
Children’s may, and upon request by JCAHO, shall disclose information to JCAHO in accordance with the sentinel event policy. The root cause analysis as well as other information and documents gathered as part of the review shall be deemed to reside within the hospital’s QI program and be afforded its associated legal protection from discoverability and admissibility. Use of JCAHO terminology such as “proximate cause” and “human error” is not to be interpreted as an admission of liability. Likewise, creation of a “corrective action plan” as part of a root cause analysis is not to be construed as evidence of previous substandard care.

B. WASHINGTON STATE DOH (eff. March 10, 1999; rev. June 7, 2006)

1) NOTIFICATION
The Chief Operating Officer and the Medical Director or their designees will provide the notification required by Department of Health within two administrative business days of confirming an event. They or their designees will serve as Children’s contact persons. Children’s confirms events through its quality improvement processes. Notification consists of a) hospital name, b) event number of event description from Appendix A
list, and c) date event occurred, and is made through one of the following means:

Telephone: 888-524-6257  
FAX: 360-236-2901  
Writing: Adverse Events  
P.O. Box 47852  
Olympia, WA 98504-7852

2) LEGAL PROTECTION OF INFORMATION AND DOCUMENTS FROM DISCOVERABILITY AND ADMISSIBILITY

The notification and related information are required to be confidentially maintained by the department per Public Disclosure Act, Chapter 42.17 RCW, RCW 70.41.150, 70.41.200, 70.41.210, and other applicable laws and regulations.

5. Root Cause Analysis and Action Plan for Sentinel Events

A. “ROOT CAUSE ANALYSIS” is a process improvement tool used to identify the most basic or causal factor(s) that underlie a Sentinel event. Characteristics of a credible and thorough analysis include:
   1) Primary focus on systems and processes, not individuals
   2) Progression from “special causes” to “common causes” in organizational processes
   3) Continues to ask “why” until no additional logical answer can be identified
   4) Identifies “risk points” and changes that could be made in systems and processes or redesigns or develops new systems or processes

B. SENTINEL EVENT QI REVIEW TEAM

The leadership (see Section 2.A) decides based on the nature and characteristics of the event on the scope of the QI review to be undertaken and appoints a team. Team members must sign a “QI Confidentiality Agreement” to encourage full and open discussion. The perceived level of risk to other patients determines the urgency of the review. The work products ordinarily include a “Root Cause Analysis” and an “Action Plan”. Any issue that may relate to competency of professional staff should be referred to the appropriate body.

C. PLANNING AND IMPLEMENTING IMPROVEMENTS

1) The leadership (see Section 2.A) reviews all cases and presents select reviews to the Quality Improvement Steering Committee (QISC) for discussion. The QISC has the following choices:
   a) Accept the action plan
   b) Modify the action plan
   c) Request further review

Selected reviews and action plans that relate to medical staff policies, procedures, or oversight are sent to the MEC for approval and policy implementation. Some may be sent to the Hospital Steering Committee (HSC) for comment and policy development.
2) The QI staff monitor the action plans including the policy completion process and the measurement and monitoring tools that are used to assure compliance and successful process improvement.

6. Resources

A. JCAHO Office of Quality Monitoring “Sentinel Event Hotline” number (630)-792-3700 (Mon.-Fri. 8:30 a.m.-5 p.m. Central Time)
B. Website at http://jcaho.org/sentinel


7. Information Management
The QI office maintains Sentinel and Serious event files in the eFeedbackNOW electronic database. Data are analyzed periodically for trends and other pertinent information as part of the hospital-wide PI plan.

8. Confidentiality
The statement of confidentiality of information for Children’s PI Program applies to this Sentinel and Serious event subpart. Materials generated for QI review are not subject to subpoena or discovery proceedings or introduction into evidence pursuant to sections 4.24.250 and 70.41.200 of the Revised Code of Washington. See “Confidential and Protected QI Information and Documents” policy and procedure.

Submitted by: 
Reviewed by: 
Revised by: Quality Improvement Steering Committee; Medical Executive Committee; QI Coaches and Workgroup (Ed Marcuse, MD, Chair)
Revised by (05/06): Jill Langle, Patient Safety Manager; Ann Nakamoto, Quality Improvement; Ed Marcuse, MD, Associate Medical Director of Quality Improvement

APPROVED BY: 
Rich Molteni, MD 06/06/2006
Chair, MEC Date

Susan Heath
Nurse Executive
Pat Hagan
Chief Operating Officer

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Additional Key Words: Patient Safety; FMEA; Notification; NPSG; HB 2292; Medical Malpractice and Patient Safety Bill; Sentinel Event; WAC 246.320.145
### Appendix A

**List of the 27 Reportable Adverse Events**

*From the NQF Serious Reportable Events in Healthcare, 2002 Consensus Report*

<table>
<thead>
<tr>
<th>ADVERSE EVENT</th>
<th>DOH GUIDANCE</th>
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<tbody>
<tr>
<td>1. Surgery performed on the wrong body part</td>
<td>Defined as a surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose existence precludes obtaining informed consent. Surgery includes endoscopies &amp; other invasive procedures.</td>
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<tr>
<td>2. Surgery performed on the wrong patient.</td>
<td>Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies &amp; other invasive procedures.</td>
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<tr>
<td>3. Wrong surgical procedure performed on a patient.</td>
<td>Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose existence precludes obtaining informed consent. Surgery includes endoscopies &amp; other invasive procedures.</td>
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<td>4. Retention of a foreign object in a patient after surgery or other procedure.</td>
<td>Excludes objects intentionally implanted as part of a planned intervention &amp; objects present prior to surgery that were intentionally retained.</td>
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<td>5. Intraoperative or immediately post-operative death in an ASA Class 1 patient.</td>
<td>Includes all ASA Class 1 patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means with 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.</td>
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<td>6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.</td>
<td>Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.</td>
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<td>7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended.</td>
<td>Includes but not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.</td>
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<td>8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.</td>
<td>Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</td>
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<td>9. Infant discharged to wrong person.</td>
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<td>10. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours.</td>
<td>Excludes events involving competent adults.</td>
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<td>11. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility.</td>
<td>Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.</td>
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<td>12. Patient death or serious disability associated with a medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration).</td>
<td>Excludes reasonable differences in clinical judgment on drug selection and dose.</td>
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<td><strong>13.</strong></td>
<td>Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.</td>
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<td><strong>14.</strong></td>
<td>Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility. Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.</td>
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<tr>
<td><strong>15.</strong></td>
<td>Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.</td>
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<td><strong>16.</strong></td>
<td>Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia neonates. Hyperbilirubinemia is defined as bilirubin levels &gt; 30mg/dl. Neonates refers to the first 28 days of life.</td>
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<td><strong>17.</strong></td>
<td>Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility. Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.</td>
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<td><strong>18.</strong></td>
<td>Patient death or serious disability due to spinal manipulative therapy.</td>
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<tr>
<td><strong>19.</strong></td>
<td>Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility. Excludes events involving planned treatments such as electric countershock.</td>
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<td><strong>20.</strong></td>
<td>Any incident in which a line designed for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.</td>
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<td><strong>21.</strong></td>
<td>Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.</td>
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<td><strong>22.</strong></td>
<td>Patient death associated with a fall while being cared for in a healthcare facility.</td>
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<tr>
<td><strong>23.</strong></td>
<td>Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.</td>
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<td><strong>24.</strong></td>
<td>Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</td>
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<td><strong>25.</strong></td>
<td>Abduction of a patient of any age.</td>
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<td><strong>26.</strong></td>
<td>Sexual assault on a patient within or on the grounds of a healthcare facility.</td>
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<tr>
<td><strong>27.</strong></td>
<td>Death or significant injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of a healthcare facility.</td>
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