NEVADA FERTILITY CENTER

PATIENT SAFETY PROGRAM

Purpose and Description of PSP

Nevada Fertility Center has implemented a Patient Safety Program to focus on the prevention and reduction of medical incidents and adverse events. This program has been approved and overseen by the Governing Board, and enforced by the Administrator/Director of the surgery center.

The surgery center staff understands and demonstrates that in order to improve existing processes, healthcare providers must constantly examine and monitor clinical outcomes with a systematic, concurrent approach. The surgery center staff is dedicated to providing all patients with the highest quality and efficiency of clinical services and thereby implements a consistent process for the identification, reporting, analysis, and prevention of adverse incidents/events/occurrences.

For purposes of the Patient Safety Program, the definition of an adverse incident/event/occurrence at a minimum includes the following:

I. An unexpected incident during a healthcare encounter involving patient death or serious physical or psychological injury or illness, including loss of limb or function that is unrelated to the natural course of the patient's illness or underlying condition.

II. Variations in processes for which a recurrence carries a significant chance of a serious adverse outcome.

III. Events involving medical negligence, breeches in administrative procedures, or others causing a negative impact on a patient even if death or loss of limb and/or function does not occur. This includes reactions to drugs and materials.

IV. Sources of identifiable problems include, but are not limited to:

   A. Unacceptable or unexpected results of on-going monitoring of care, such as complications, hospital transfers, malpractice cases, lack of follow-up on abnormal test results, radiology film re-takes, prescribing errors for medications, specific diagnoses, and so forth.

Event/Occurrence reports

At the surgery center, any adverse incident/event/occurrence that affects a patient, provider, employee, or visitor will be documented on an Event Report Form as soon as it is identified. Such situations may include but not limited to: accidents, injury, malfunction of equipment, errors in carrying out a physician's order, or any unusual situation.

For purposes of this PSP, the definition of an adverse incident/event/occurrence at a minimum includes the following:

I. An unexpected incident during a healthcare encounter involving patient death or serious physical or psychological injury or illness, including loss of limb or function that is unrelated to the natural course of the patient's illness or underlying condition. (see Event Report Form for specific items)

II. Variations in processes for which a recurrence carries a significant chance of a serious adverse outcome.

III. Events involving medical negligence, breeches in administrative procedures, or others causing a negative impact on a patient even if death or loss of limb and/or function does not occur. This includes reactions to drugs and materials.

Procedures

Reporting/Documentation:

I. The Event Report Form should be initiated as soon as the occurrence has been identified and completed by the person who was involved in, witnessed, or discovered the occurrence.

III. Failure to report an occurrence may result in disciplinary action by the surgery center.

IV. When a patient is involved, the examining or attending physician must complete the report and return it to the Nurse Manager.

V. All reports of occurrences will be reviewed by the Nurse Manager, Medical Director and Administrator/Director as soon as possible. The Administrator/Director compiles statistics and other pertinent information from Event Reports which is then forwarded to the Governing Board.

VI. All incident/event/occurrence data collected of shall become a permanent part of the Governing Board data.

VII. All data analyzed and reported to the Governing Board shall be documented in meeting minutes of said committees.

VIII. Any event that involves medical negligence, breeches in administrative procedures, or others causing a negative impact on a patient even if death or loss of limb and/or function does not occur, will be reviewed by a"root cause analysis" tool which is a tool used to identify causal factors which may be identified in order to prevent the event from occurring again.

(See attached documents)

Analysis/Prevention:

I. The following steps should occur once the event/occurrence report is reviewed by the Nurse Manager, Medical Director, and Administrator/Director (as appropriate):

A. A thorough investigation and analysis is performed to determine possible underlying causes which may demonstrate a variation in performance.

B. The analysis should result in the identification of potential improvements for processes or systems that would likely decrease such future incidents or determine that no such improvement opportunities exist.

C. All reports of adverse events should be reported and handled through established channels in the organization and as described in this PSP.

D. Action plans should be developed for identifying organizational strategies for reducing the risk of similar future incidents. This plan includes the involvement

of individuals responsible for implementation, oversight, time frames, pilot testing (when needed), and strategies to measure action effectiveness.

E. All of the above information should be reported to the Governing Board for review.

F. Follow-up activity will be performed to determine the outcome and bring closure to any reported incident.

G. Follow-up activity will be communicated to staff through staff meetings.

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Event Report *(Confidential-Not a Part of Medical Record)*

Incident Date ___/___/___ Time _____am/ pm

Day of Week _____

Patient Visitor Male Female

Admitting Diagnosis _____

Procedure _____

_____

Brief Description (*attach additional page, if needed)*

_____

Patient Family Aware of Accident - Yes No
Location of Event

_____

TYPE OF EVENT (*Circle only the one that most applies)*

A: Falls

Slip/Fall Found on Floor Other:

_____

B: Medication Variance

Contraindicated Omission of dose Wrong patient Wrong time

Extra dose Wrong dose Wrong route Wrong drug

Confirmed adverse drug reaction Wrong IV solution

C: Treatment or Procedure Variance

Consent/Not documented Complication following procedure
Surgical count/retained FB Consent/Different procedure performed
Cancellation/after induction of anesthesia Unscheduled return to OR/within 72 hours
Delayed Inability to complete procedure/with complications
Unplanned Hospital transfer Delayed/while under anesthesia
Received unplanned blood/products Procedure/not ordered Procedure/omitted
Surgical count/unresolved

Other:_____
_____

D: Infection

Infection days post op _____
Pneumonia days post op _____
Confirmed Physician Post op phone call Other:
_____

E: Equipment

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Defective Electrical Shock Improper Use of Equipment

Electrical Problem Equipment unavailable Malfunction

Other:

_____

Lot # _____ Model # _____

Manufacturer _____ Serial # _____

F: Other

Fire/Thermal Patient complaint Loss/theft/damaged property
Exposure/biohazard or chemical
Inclement weather Patient abuse Security issue
Other: _____
Explanation:

_____

G: Medical Treatment

Not Applicable Offered Refused Obtained Referred for further treatment
Emergency Room
Physician: _____
Notified Date: _____ Time: _____

Address_____

H: Nature of Injury

Abrasion / Bruise / Contusion Skin irritation Electric Shock Burn
Sprain/Strain Hemorrhage Phlebitis Wound disruption
Cardiopulmonary arrest IV infiltration Respiratory impairment
Death/at facility Death/within 72 hours

I: Related Factors *(Circle all that apply)*

Refused orders Unexpected movement Floor wet/obstructed
Unable to follow orders Enter Name of Computer System Here impaired Side rails down
Bed position hi/lo
Visitor assisting patient Horseplay/rowdiness Language barrier
Medical/surgical condition Call light not in reach Safety Device use improperly
Employee did not follow procedure

Security Level

Level 1 Event is not related to illness or injury/no apparent injury
Level 2 Occurrence that causes temporary illness or injury, whether or not physician/nurse/other practitioner interventions required
Level 3 Injury with potential for complications/follow up required by physician/nurse

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Level 4 Major injuries; occurrence is potentially life threatening, immediate physician/nurse/other practitioner interventions required

Level 5 Occurrence resulting in death within 72 hours

Witness

Name_____ **Address**

_____

Phone _____ **City/State**

_____

Employee Preparing Report

Name _____ **Date/Time**

_____

Title _____

Risk Management/ MEC or Physician/Administrator

_____

_____

Signature **Date/Time received**

Explain investigation/follow-up/corrective action taken:

_____

_____

_____

_____

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ROOT CAUSE ANALYSIS AND ACTION PLAN

I. In this section, "root cause analysis" means the process that identifies basic or causal factors underlying a variation in performance leading to an event.

A. Focuses primarily on systems and processes;

B. Progresses from special causes in clinical processes to common causes in organizational processes; and

C. Identifies potential improvements in processes or systems.

D. Utilize the Root Cause Analysis Evaluation Tool to ensure all elements of Root Cause Analysis are addressed.

II. Not later than the 45th day after an ambulatory surgery center becomes aware of the occurrence of an event, the center shall:

A. Conduct a root cause analysis of the event; and

B. Develop an action plan that identifies strategies to reduce the risk of a similar event occurring in the future.

(See attached document)

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ROOT CAUSE ANALYSIS EVALUATION TOOL

ELEMENTS	GUIDELINES	MET	NOT MET
Multidisciplinary Team	Participants listed by name and title. Some participants should have knowledge of the processes or systems being analyzed.		
Description of Event	Includes details of the event, date, day of week, and time event occurred; includes area/service involved and timeline if appropriate. Addresses whether a similar even occurred in the past, and looks at previous outcomes, as applicable, to determine if actions were effective.		
Flow diagram or Cause and Effect Diagram Used	Identifies which type of diagram was used and whether the diagram reflects the process as it actually worked (or did not work) at the time of events; or, if the diagram indicates the process as it should work		
Analysis of All Available Resources	Demonstrates that the team looked at all medical records, policies and procedures, maintenance logs, committee minutes, etc. as necessary to identify all factors relevant to the event. All pertinent staff were interviewed.		
Analysis of Cause and Effect Through:			
Analysis of Human Factors	Includes communication, training, competencies, staffing and fatigue/scheduling		
Analysis of Equipment and Environment	Includes availability of equipment, performance and maintenance of equipment, and identification of uncontrollable environmental factors.		
Identification of Risks and Possible contributing Factors	Includes possible obstacles to identifying, reporting and responding to risks. Identifies if risks or contributing factors to this adverse event continue to exist at the time of the Root Cause Analysis, or if all risks and contributing factors were immediately eliminated.		
Analysis of Related Processes and Systems	Identifies if risks or contributing factors may affect other areas/processes in the facility.		
Clearly Identified Root Causes and Contributing Factors	Clearly shows cause and effect		
	Is specific and accurate, does not use negative and vague words		
	Identifies the preceding causes of human errors, identifying systems issues, and avoiding blame		
	Identifies the preceding causes of relevant procedural violations, contrasting normal operating procedures versus ideal (i.e., per P&P)		
	Action plans are specific, are clearly related to the root causes and contributing factors, and include ways		

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Action Statement(s) Appropriate	to address system improvement.		
	Action plans include the job title of the person who will be responsible for implementing and monitoring the actions.		
Outcome Measures	Must be specific and quantifiable with defined numerators, denominators and thresholds. Should be realistic and achievable, and include any physical/operational changes that will be required.		
	Must measure the impact on the root cause or contributing factor, and the effectiveness of the actions.		
	Must define a reasonable time frame for implementation & monitoring		
Leadership concurrence	Must demonstrate that the corrective actions planned were approved by leadership or other approval authority		
Relevant Literature Reviewed	Root Cause Analysis includes a description of the literature reviewed.		