San Gabriel Valley Medical Center

PATIENT SAFETY PROGRAM
Failure Mode, Effects & Analysis (FMEA)
Failure Mode Process Description
Updated: 5-13-02

Process to be Assessed:	Management of macrosomic infants Effective nursing interventions in the assessment and anticipation of complications related to macrosomia Note: Process description presumes accurate and timely documentation of patient care.			
Process Scope Boundaries:	Patient presentation on LDRP unit through vaginal deliver of viable infant or initiation of cesarean section procedure			
Essential Process Steps	Process Sub-Steps	Critical Sub-Processes	Potential Failure Mode	RPN*
ASSESSMENT PHASE				
Patient enters LDRP unit	(Patients arrive through ED or are pre-admitted)	Video-intercom provides access to unit	Failure of controlled access notification device	A
Visual assessment of patient	Inquiry re due date & reason presenting	Translator needed for non-English speaking patients	Lack of access to patient information due to no available translator	B
		Prenatal care essential to accurate knowledge of due date	Lack of information due to absence of/or limited prenatal care	C
	Inquiry re physician name	Patient's identification of physician presumes prenatal care received	Lack of information due to absence of/or limited prenatal care	D
	Inquiry re pregnancy history *	Patient awareness of membrane status	Patient may not distinguish fluid leak from incontinence	E
		Accurate patient communication of pregnancy history (gravida, gestation, prior birth weights, maternal weight gain)	Lack of information due to absence of/or limited prenatal care	F
Physical assessment	Patient provided gown & assigned bed	RN assigns labor room and registers patient as outpatient	Inadequate labor beds due to census	G
	External fetal monitor placed	Multiple gestation may require multiple monitors (Note: All monitors have twin capabilities.)	Inadequate number of monitors available due to census	H
	Contractions monitored		Inadequate number of monitors available due to census	I
	Vital signs taken		Inadequate number of BP monitors available due to census	J

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	Blood sugar evaluated if diabetes reported by patient	Patient awareness of diabetes presumes prenatal care	Lack of information due to absence of/or limited prenatal care	K
	Inquiry to patient re last MD appointment, last ultrasound, hypertension, any physician referrals, current medications and awareness of placental position	Accurate patient history presumes prenatal care	Lack of information due to absence of/or limited prenatal care	L
Assessment: Patient in active labor?	Yes: Admit patient as inpatient	Admit patient to LDRP room	Inadequate LDRP beds due to census	M
	No: Observe patient minimum 2 hours	Continuous monitoring of fetal heart rate an d contractions, pain level	Incompetent nursing assessment of patient physical status and FM strip	N
Assessment: Patient bleeding?	Yes: Defer vaginal exam Determine extent of bleeding Call physician	Extensive bleeding may indicate needed for minimally invasive vaginal examination in order to provide adequate information to physician	Failure to accurately assess extent of bleeding	O
	No: Complete visual and physical (vaginal) exam		Failure to utilize collaborative efforts of care team to assure accurate patient assessment	P
Initiate standing MD orders	If no prenatal care, patient assigned to ED on-call OB	If patient newly assigned to MD, physician may come in to exam patient or order ultrasound (inc. gestation, estimated fetal weight, placental presentation, amniotic fluid index.	Failure to reach on-call obstetrician	Q

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	Order routine lab tests		Failure to order baseline lab tests results in incomplete or delayed patient assessment	R
	If no prenatal care, order expanded lab tests to include Hepatitis, toxicology screen and Rebella		Failure to order baseline lab tests results in incomplete or delayed patient assessment	S
	Continue to monitor fetal heart rate	If monitoring inadequate, RN applies internal fetal electrode if membranes are ruptured.	Failure to recognize inadequate monitoring strip	T
	Continue to monitor contractions	If monitoring inadequate, RN applies internal fetal electrode if membranes are ruptured.	Failure to recognize inadequate monitoring strip	U
	Assess pain (1 – 10 pain scale)	Patient's subjective assessment of own pain.	Patient refusal of medication	V
Contact physician for ultrasound order	Ultrasound order request by RN due to suspected macrosomia based on known past delivery history.	Effective communication of assessment outcome	Failure of MD to order ultrasound	W
			Delayed completion of ultrasound or radiologist's report	X
			Failure to communicate ultrasound result to MD	Y
Assessment: Probability of macrosomic infant?	Yes: Contact physician	Observed slow progress in first stage of labor	Failure to recognize lack of descent, dilation and inadequate contractions	Z

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		Assessment of intensity of labor	Failure to recognize lack of descent, dilation and inadequate contractions	AA
	No: Continue to monitor labor	Assessment of staffing/census	Inability to anticipate future admissions	BB
		Assessment of OR availability	Inadequate Env. Serv. support for operating room turn-around	CC
Communications of macrosomic indications to MD	Accurate communication & documentation of observed macrosomic indications	Assertive request by nurse for specific physician intervention by clinically credible nurse	Failure to effectively communicate patient assessment and needed intervention	DD
ASSESSMENT PHASE CONCLUDED				
MACROSOMIC DELIVERY INTERVENTION PHASE				
Continuous Assessment: Patient progressing?	Yes: Continue to monitor labor through delviery	Continuous assessment of fetal heart rate	Failure to recognize fetal heart rate changes	EE
		Monitoring of maternal vital signs	Failure to observe vital sign changes	FF
	No: No dilation or fetal descent , schedule surgery	Assessment of intensity of labor	Failure to recognize failure to progress	GG
		Assessment of staffing/census	Inability to anticipate future admissions	HH

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		Assessment of OR availability	Inadequate Env. Serv. support for operating room turn-around	II
		Assertive request by nurse for specific physician intervention by clinically credible nurse	Failure to effectively communicate patient assessment and needed intervention	JJ
Continuous Assessment: Patient descending?	Yes: Continue to monitor labor through delivery	Continuous assessment of fetal heart rate	Failure to recognize fetal heart rate changes	KK
		Monitoring of maternal vital signs	Failure to observe vital sign changes	LL
	No: A) Possible physician mgmt by - Pitocin - Vacuum - Shoulder dystocia protocol	Administration of pitocin consistent with protocol	Failure to effectively titrate Pitocin	MM
		Vacuum application consistent with protocol	Excessive use of vacuum pressure or duration	NN
		Anticipation of utilization of McRobert's maneuver at delivery	Inadequate assistance from other team members essential to deliver intervention	OO
		Assistance requested from NICU team	Inadequate resuscitative support upon delivery	PP
	B) Schedule surgery	Notification to anesthesiologist and assistant surgeon	Delay in surgery due to no available anesthesiologist or assistant	QQ
	C) Lack of MD orders or intervention	Assertive request by nurse for plan of care for stable patient who is not progressing	Failure to effectively communicate patient need for immediate intervention	RR

Continuous Assessment: Fetal distress?	Notify physician	Specific request by nurse for surgical intervention	Failure to effectively communicate patient need for immediate intervention	SS
		Utilization of chain of command physician reluctance to commence surgery	Failure to initiate chain of command	TT
		OR prepared	Delay due to OR unavailable	UU
		Anesthesiologist notified	Delay due to participation current case	VV
		NICU team notified	Delay due to NICU census or acuity	WW
Cesarean –section initiated	Physician arrives for surgery	Surgery initiated within 30 minutes	(See above)	

* RPN Risk Potential Number determined in subsequent document

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Identify potential failures for each component step in process (Complete this analysis page for each process step)	Identify potential outcome of failure to patient	On a scale of 1-10 (10= highly likely), identify the likelihood of this failure actually occurring. Example: 1 = Remote probability 5 = Moderate probability 10 = Very high probability	On a scale of 1-10 (10= worst potential failure outcome), identify the potential severity of the consequences of this failure. Example: 1 = Very minor outcome 5 = Moderate outcome 10 = Very severe outcome	On a scale of 1-10 (1 = failure easily discovered under normal circumstances), identify the potential difficulty of discovery of failure. Example: 1 = Certain detection 5 = Possible detection 10 = Cannot detect	RPN = Freq. x Sev. x Detect.
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San Gabriel Valley Medical Center

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Failure of controlled access notification device	A	No patient access to unit	1	1	1	1
Lack of access to patient information due to no available translator	B	Lack of patient history and accurate pain assessment or effective patient instruction	3	3	1	9
Lack of information due to absence of/or limited prenatal care	C	Lack of accurate patient information essential to safe delivery	3	8	1	24
Lack of information due to absence of/or limited prenatal care	D	Lack of accurate patient information essential to safe delivery	3	8	1	24
Patient may not distinguish fluid leak from incontinence	E	Delay in accurate patient assessment	1	2	1	2
Lack of information due to absence of/or limited prenatal care	F	Lack of accurate patient information essential to safe delivery	3	8	1	24
Inadequate labor beds due to census	G	Delay in accurate patient assessment	3	3	1	9

San Gabriel Valley Medical Center

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Inadequate number of monitors available due to census	H	Delay in accurate patient assessment	3	5	1	15
Inadequate number of monitors available due to census	I	Delay in accurate patient assessment	3	5	1	15
Inadequate number of BP monitors available due to census	J	Delay in accurate patient assessment	1	1	1	1
Lack of information due to absence of/or limited prenatal care	K	Lack of accurate patient information essential to safe delivery	3	8	1	24
Lack of information due to absence of/or limited prenatal care	L	Lack of accurate patient information essential to safe delivery	3	8	1	24
Inadequate LDRP beds due to census	M	Delay in accurate patient assessment	3	3	1	9
Incompetent nursing assessment of patient physical status and fetal monitoring strip	N	Delay in essential nursing interventions	1	10	7	70
Failure to accurately assess extent of bleeding	O	Delay in essential nursing interventions	1	10	2	20

RNFMEA1

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Failure to utilize collaborative efforts of care team to assure accurate patient assessment	P	Delay in essential nursing interventions	1	7	2	14
Failure to reach on-call obstetrician	Q	Delay in essential nursing interventions	1	3	1	3
Failure to order baseline lab tests results in incomplete or delayed patient assessment	R	Lack of accurate patient information essential to safe delivery	2	2	1	4
Failure to order baseline lab tests results in incomplete or delayed patient assessment	S	Lack of accurate patient information essential to safe delivery	2	2	1	4
Failure to recognize inadequate monitoring strip	T	Delay in essential nursing interventions	1	10	1	10
Failure to recognize inadequate monitoring strip	U	Delay in essential nursing interventions	1	10	1	10
Patient refusal of medication	V	Inadequate pain relief	2	3	1	6

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Failure of MD to order ultrasound	W	Lack of accurate patient information essential to safe delivery	1	5	1	5
Delayed completion of ultrasound or radiologist's report	X	Delay in essential physician interventions	2	3	1	6
Failure to communicate ultrasound result to MD	Y	Delay in essential physician interventions	1	3	1	3
Failure to recognize lack of descent, dilation and inadequate contractions	Z	Delay in essential physician interventions	1	3	1	3
Failure to recognize lack of descent, dilation and inadequate contractions	AA	Delay in essential physician interventions	1	3	1	3
Inability to anticipate future admissions	BB	Delay in essential physician interventions	8	2	1	16
Inadequate Env. Serv. support for operating room turn-around	CC	Delay in essential physician interventions	3	1	1	3
Failure to effectively communicate patient assessment and needed intervention	DD	Delay in essential physician interventions	2	5	1	10

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Failure to recognize fetal heart rate changes	EE	Delay in essential physician interventions	2	3	1	6
Failure to observe vital sign changes	FF	Delay in essential nursing interventions	3	3	2	18
Failure to recognize failure to progress	GG	Delay in essential nursing interventions	2	2	2	8
Inability to anticipate future admissions	HH	Delay in essential physician interventions	2	5	1	10
Inadequate Env. Serv. support for operating room turn-around	II	Delay in essential physician interventions	3	1	1	3
Failure to effectively communicate patient assessment and needed intervention	JJ	Delay in essential physician interventions	2	3	1	6
Failure to recognize fetal heart rate changes	KK	Delay in essential physician interventions	2	4	1	6
Failure to observe vital sign changes	LL	Delay in essential physician interventions	2	4	1	6
Failure to effectively titrate Pitocin	MM	Continued ineffective labor	2	2	1	4
Excessive use of vacuum pressure or duration	NN	Delivery trauma to infant	1	8	1	8

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Inadequate assistance from other team members essential to deliver intervention	OO	Delivery trauma to infant	1	8	1	8
Inadequate resuscitative support upon delivery	PP	Delivery trauma to infant due to delayed resuscitation	1	10	1	10
Delay in surgery due to no available anesthesiologist or assistant	QQ	Delay in essential physician interventions	1	3	1	3
Failure to effectively communicate patient need for immediate intervention	RR	Delay in essential physician interventions	2	10	3	60
Failure to effectively communicate patient need for immediate intervention	SS	Delay in essential physician interventions	2	10	3	60
Failure to initiate chain of command	TT	Delivery trauma to infant	6	8	7	336
Delay due to OR unavailable	UU	Delay in essential physician interventions	1	8	1	8
Delay due to participation current case	VV	Delay in essential physician interventions	1	2	1	2

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Delay due to NICU census or acuity	WW	Delay in essential nursing interventions	1	2	1	2

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Critical Failure Mode		Proximate Causes	Root Cause	Remedial Action or Current Controls	Implementation & Measurement	Action Assigned	Date Due	Status/Comments
List root causes with highest RPN	RPN	Brainstorm possible causes. Assessment & Observation Communication Competency Education & Training Environment Equipment Info. Availability Medication Issues Security Staffing Supervision Tech Support	Identify probable or critical causes	Describe action to be taken to "error proof" process	Describe pilot test and measurement preliminary to final implementation	Identify responsible party	Identify completion date	
Failure to initiate chain of command	336 TT	Competency Communication skills Education & training Perceived Historical Lack of Supervisor Support	Perceived historical lack of supervisory support	Remedial Action: LDRP/Postpartum chain of command call sequence to be revised to be initiated by call to one of two unit supervisors for assistance in triage of needed action. On-call schedule to be published.	• Chain of command phone numbers to be published on card to attach to ID badge • Supervisor s on-call schedule posted • Pilot July 1 through Sept. 30,2002 to be monitored via log of all calls to supervisor and subsequent disposition . Logto be compared to reported perinatal events during same peirod.			

RNFMEA1

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Competency of nursing assessment of patient physical status and fetal monitoring strip	70 N	Artifact strip may result in inaccurate assessment External monitor placement may result in artifact strip Staffing/Census/Acuity	Inadequate integrated nursing assessment skills	Current Control: Current requirements document verification of nursing fetal monitoring competencies annually with completion of advanced fetal monitoring class at 2 year intervals. Adjunctive Remedial Action: Monthly LDRP staff strip reviews with physician educator to be reinitiated July 2002.	• Monitor for initiation of monthly strip reviews July 2002. • Survey LDRP staff September 2002 for perceived assessment of benefit			

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Failure to effectively communicate need for immediate intervention	60 RR SS	Communications skills Perceptions of prior physician interactions	Communication skills	Remedial Action: Education module to be developed by supervisors to include principles of effective communication to physicians and role playing of those themes. Content to include reiteration of 4 essential components of communi-cation & documentation of MD contacts: • Change/Condition precipitating call • What was communicated to MD • What request made of MD • MD response Rubber stamp for use in narrative nursing notes listing 4 critical communications points above to be implemented to structure charting.	• Education to be implemented July 2002 • Rubber stamp to be implemented on education • Chain of command reference (laminated card described above) to include 4 essential communication components and to be distributed at July education session • Pilot July 1 through Sept. 30,2002 to be monitored through use of stamp in nursing notes as compared to supervisor call log.			

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Lack of patient assessment information due to absence of/or limited prenatal care	24 C D F K L	Absence of prenatal care Patient records unavailable Inadequate nursing assessment	Adequacy of nursing assessment sufficient to elicit absent prenatal information.	LDRP nursing assessment tool to be revised to include queries to patient which would elicit patient information predictive of macrosomia in the absence of complete prenatal history.	• Nursing assessment tool to be revised by 7-01-02. • Revised tool to be piloted from July 1 through Aug. 30,2002 chart review to compare documented utilization of revised assessment with occurrence of perinatal events related to macrosomia during the same time period.			