Pharmaceutical Failure Mode and Effects Analysis
Chantix® (varenicline)

· **Step 1:**

Describe how the intended product will be procured and used, from acquisition through administration.

  Who will prescribe the drug and for what type of patient?
  Physicians/PAs will prescribe the drug for smoking cessation.

  Where will the drug be stored?
  It will be stored in the inpatient and outpatient pharmacies.

  Who will prepare and dispense it?
  It will be prepared by a pharmacy technician and dispensed by a pharmacist.

  How will it be administered?
  It will be administered orally by the patient (outpatient) or by the nurse (inpatient).

· **Step 2:**

Identify potential failure modes (how and where systems and processes may fail) while considering how the product will be used.

  Could the drug be mistaken for another similarly packaged product?
  Yes – they are small white or blue oval tablets in Pfizer bottles.

  Does the label clearly express the strength or concentration?
  Yes. Strengths are also imprinted on the tablets.

  Does the name sound or look like another drug on the formulary?
  They are small white or blue oval tablets in Pfizer bottles.

  Are dosing parameters complex?
  No.

  Is the administration process error prone?
  No.
· Step 3:

Once failure modes have been identified, determine the likelihood of making a mistake and the potential consequences of an error.

What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate? A higher dose may cause increased nausea.

· Step 4:

Identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

A second check is in place between the prescriber and a pharmacist.
A second check is in place between the pharmacy technician and a pharmacist.
A second check is in place between the pharmacy and nursing.

· Step 5:

If failure modes could cause errors with significant consequences, what actions could be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences? (A few examples include: using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders).

Set default ordering parameters in Epic for inpatient use.

Administration Information:

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?
Nausea.

Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care?
None.