Pharmaceutical Failure Mode and Effects Analysis
Raltegravir (Isentress)

· **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?
An Infectious Diseases Faculty or Fellow will prescribe this medication for patients with HIV who have previous treatment experience.

Where will the drug be stored?
It will be stored in the Inpatient Pharmacy at room temperature.

Who will prepare and dispense it?
Prescriptions will be prepared by pharmacy technicians and dispensed by pharmacists.

How will it be administered?
Raltegravir is administered orally twice a day with or without food.

· **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?
Isentress is available in a white Merck bottle containing 60 tablets.

Does the label clearly express the strength or concentration?
Yes – the bottle is clearly marked as 400 mg.

Does the name sound or look like another drug on the formulary?
“Raltegravir” may sound like other antiretrovirals such as ritonavir.

Are dosing parameters complex?
No – the dosing regimen is 400 mg orally twice daily.

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? The most common side effects are diarrhea and 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.

There is a double check between the physician and the pharmacy and again 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).

The multiple double-checks between disciplines should be effective in catching potential errors.

**Administration Information:**

What are the most common side effects that Nursing should be aware of to ensure proper monitoring?
Diarrhea, nausea, and headache.

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