Pharmaceutical Failure Mode and Effects Analysis
Samsca - Tolvaptan

· **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 will prescribe Samsca for hypervolemic and euvolemic hyponatremia including patients with heart failure, cirrhosis, and SIADH.

Where will the drug be stored?
The drug will be stored in the Pharmacy Storeroom and in the Central Pharmacy.

Who will prepare and dispense it?
Pharmacy technicians will prepare the drug. Pharmacists will dispense the drug.

How will it be administered?
The drug is administered orally.

· **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?
The 15 mg tablet is triangular and is marked with “OTSUKA 15”. The 30 mg tablet is circular and is marked with “OTSUKA 30”. Both are blue and are available in blister packs.

Does the label clearly express the strength or concentration?
Unknown.

Does the name sound or look like another drug on the formulary?
Sound alike: Conivaptan

Are dosing parameters complex?
No. Dosing is 15 mg or 30 mg once daily orally.

Is the administration process error prone?
Initiation or re-initiation of Samsca must occur in a hospital where serum sodium can be monitored. Do not administer to patients requiring urgent intervention to raise serum sodium acutely. Do not use in patients who are unable to sense or respond appropriately to thirst. Do not use in patients with hypovolemic
hyponatremia. Do not use with strong CYP 3A4 inhibitors. Do not administer to patients who are anuric as no benefit is expected.

**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? Too rapid correction of serum sodium can cause serious neurololgic sequelae such as osmotic demyelination resulting in dysartria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. Samsca therapy induces copious aquareisis which is normally partially offset by fluid intake. Dehydration and hypovolemia can occur especially in potentially volume-depleted patients receiving diuretics or those who are fluid restricted.

**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 the pharmacist. A second check is in place between pharmacy and nursing. Nurses use two patient identifiers prior to administration of medications.

**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).

Ordering parameters can be defaulted in Epic. An order set can be developed in Epic to ensure that proper labs are ordered for monitoring the patient.

**Administration Information:**

What are the most common side effects that Nursing should be aware of to ensure proper monitoring? Side effects: Dry mouth 28%, thirst 35%, pollakiuria or polyuria 25%

Do NOT fluid restrict in the first 24 hours.

Do not use in patients who are unable to sense or to respond appropriately to thirst.
Do not administer to patients who are anuric.
Do not use with strong CYP3A inhibitors such as ketoconazole, clarithromycin, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin.
Do not administer to patients requiring urgent intervention to raise serum sodium acutely.

**Is there any associated laboratory monitoring that Nursing should be aware of to ensure proper patient care?**
Monitor serum sodium and volume status.
Monitor serum potassium in patients with potassium >5 mEq/L or drugs known to increase potassium.