Please answer the following essay questions:

1. **Read the posted background material on FMEA. What are some of the benefits of this approach to improving patient safety? What are some of the drawbacks?**

   In reading the background material on FMEA it is pointed out that the process is not new and is in practice in many industries. Its focus is centered on the identification of defects in products or processes. The same principles apply in a healthcare setting as well. Considering an example cited from the Institute for Healthcare Improvement website, the East Alabama Medical Center offered real data where their aim was to reduce the likelihood of occurrence, detection and the resulting severity (RPN) in their chemotherapy medication process. For context, the below examples will consider a single process of their larger aim. Let's consider the medical doctor's drug order. (East Alabama Medical Center Chemotherapy FMEA, 2003)

   The failure modes they listed in this process included:
   - Wrong Drug
   - Wrong dose or dose inappropriate for patient
   - Unclear number of doses or duration of therapy
   - Proper labs not ordered for outpatient prior to administration of chemo
   - Labs not ordered & dose given that should have been held
   - MD failed to order proper preparatory orders (I.e. hydration, anti-emetic)

   The majority of the above listed failure modes had very high severity scores. Most having the potential cause death or a serious adverse drug reaction (ADR). So given the consequences preventive measures to improve the process offer real and tangible benefits. Some might include:

   - *Improve reliability* – As the RPN's are calculated, the failure mode's with the highest score will quickly make evident opportunities that will have a greater impact on the process if improved. Patients will directly benefit because mistakes will reduce and they will suffer less from the consequences resulting from errors.
   - *Improve quality* – As more consistent and reliable results are achieved from focusing in on the highest impact problems of the process, the quality of the patient's care will improve because death or ADR and the possibility of both will go away or decrease. In addition patients will receive the correct medications and the symptom's they suffer with will be reduced through he natural benefits of the prescribed medications.
   - *Improve Safety* – The patient will naturally be subject to less risk through the process improvement as the potential for death or ADR decreases.
   - *Improve Efficiencies* – The correct orders would be issue and reduce time loss and monetary investment to correct errors.
   - *Improve Customer Satisfaction* – The patients and families of the patient would be happier when the medications needed were given and the health improved.

   Although there are benefits to applying FMEA in a healthcare setting, there are also drawbacks. In doing research I discovered an article that covered the potential pitfalls. Here are some extracted points (Marx, Slonim, 2003) :

   - Generally used on a local level without the benefit of multi-institutional experiences to help guide the model.
   - Individual healthcare institutions often limit their focus to their own safety problems and inadequacies. As a result, the institutions are concerned about allowing their data to become transparent to the public or other professionals because they may be exposing themselves to litigation or further public scrutiny. For example, if hospital X has had two serious events relating to child abduction in the last year, it may choose to improve the processes surrounding pediatric inpatient security in the institution using FMEA. However, even if it discovers important information that can assist other institutions and prevent duplication of effort, it is neither obliged nor is it likely to be interested in sharing that information publicly. Hence, patient safety interventions need to provide a broader view that takes into account the ideas and strategies of multiple institutions.
   - They do not assist the institution in prioritizing interventions based upon quantitative risk. If the members of the FMEA team inappropriately assess the risk associated with a particular process, the institution may expend considerable resources correcting a problem that, in fact, may have little to do with the risk of a recurrent event.

   In addition to the one's mentioned by this article, additional ones would to consider are:
   - Process is involved and requires the coordination of many resources across the institution or multi-institutional environment. The knowledge and expertise of processes is also spread out in the same manner.
   - This type of process can be expensive to those considering as it requires in depth analysis.
   - Benefits of the process are not realized over a short amount of time. Because of the involvement, the process would likely take a long time to implement.

2. **Using the Framingham LDL risk prediction equation from MedCalc3000 (available via Galter Library), what is the 10 year risk for developing coronary disease in a 37 year-old female patient who smokes with an LDL of 162, and HDL of 46, and blood pressure of 143/86?**

Med Calc 300 - Framingham 10 Year Coronary Risk Prediction by LDL

Fact	Actual Facts	Med Calc Answer	Point Value
Sex	Female	N/A	-4
Age	37	35 -39	2
LDL Cholesterol	162	>= 160 mg/dL	2
HDL Cholesterol	46	45-49 mg/dL	2
Blood Pressure (mm Hg)	143/86	sys 140-159 and dia < 100	2
Diabetes	N/A	No	0
Smoker	Yes	Yes	2

Result = 3% (2 - 3 points)

3. **What if the woman were 57 years old?**

Increasing the age elevates her estimated risk points by 11 where at a younger age there was actually a credited point value. It raises her overall 10 year risk score by 17%! Age is therefore an important factor.

Med Calc 300 - Framingham 10 Year Coronary Risk Prediction by LDL

Fact	Actual Facts	Med Calc Answer	Point Value
Sex	Female	N/A	-4
Age	57	35 -39	2
LDL Cholesterol	162	>= 160 mg/dL	2
HDL Cholesterol	46	45-49 mg/dL	2
Blood Pressure (mm Hg)	143/86	sys 140-159 and dia < 100	2
Diabetes	N/A	No	0
Smoker	Yes	Yes	2

Result = 20% (14 points)

4. **If the 57 year-old woman asks you (her physician) for a test to see if she has coronary disease, how do you answer her?**

As noted in the notes for this pre-test in Med Calc, age is a prominent determinant of the CHD risk score. On average, the scores are higher in older persons and thus is more specific to younger ages. The notes suggest that relative estimates where comparison with low risk individuals can prove to be more useful than taking the absolute estimates with older persons. (MedCalc 3000 Medical Calculator, 2010)

In following the recommendation of the noted points, as her physician, I would concur with her request for a test and would recommend a highly sensitive test which would rule out the diagnosis given a negative result from that test. I would also take into account her family history of heart disease and consider her activity level. These would help weigh in on the decision. Equally important would be the specificity of the test. Knowing the limitations of the pre-test, it would be important to test further to see if the patient was identified as a false positive (FP) in the pre-test. A more specific test would rule in the disease given a positive result. So having a test that is as sensitive and specific as possible would be ideal. That is to say one with a high test efficiency (sum of sensitivity and specificity / 2). Choosing an Electrocardiogram, Echocardiogram, Nuclear Scanning or Angiography that fit both needs would be the test to perform. Given the evasive nature of an Angiography and Nuclear Scanning, a stress test or Electrocardiogram would probably

be a better place to start.

5. **You decide to perform a stress echocardiogram exam with a sensitivity of 85% and a specificity of 95% on the 57 year-old woman. Please draw a 2 x 2 chart demonstrating this scenario like the examples we reviewed in class. Use her Framingham risk score as her pre-test probability of disease.**

				Disease (20)		No Disease (80)
PPV	= TP / (TP + FP) = 17/21 = 81%	+	TP	17	FP	4
NPV	= TN / (TN + FN) = 76 / 79 = 96%	-	FN	3	TN	76

Sensitivity (Sn) = 0.85 (TP / (TP + FN)

Specificity (Sp) = 0.95 (TN / (TN + FP)

TP	= P (C/D) = .95 x 20 = 17
FN	= P(-C/D) = .15 x 20 = 3
TN	= P(-C/-D) = .95 x 80 = 76
FP	= P(C/-D) = .05 x 80 = 4

Test Efficiency	= (Sn + Sp / 2) = (1.8 /2) = 90%
Prevalence	= .2 (Provided)

FNR	= 1 - Sn = 1 - .85 = .15 of 15%
FPR	= 1 - Sp = 1 - .95 = .05 or 5%

PLR	= Sn/ (1 - Sp) = 0.85 / 0.05 = 17
NLR	= 1-Sn / Sp = 0.15/0.95 = .1579

Pre-Test Probability	= Prevalence = 20%
Pre-Test Odds	= Pre-Test Prob / (1 - Pre-Test Prob) = 0.2 / 0.8 = 25%
Post-Test Odds	= Pre-test Odds x Likelihood Ratio = .25 x 17 = 4.25
Post-Test Probability	= Post-Test Odds / (1 + Post-Test odds) = 4.25 / 5.25 = .8095

6. **Using concepts of PPV and NPV, please answer the following questions:**

   a) **What is the probability your patient does not have CAD despite a positive test?**

   The False Positive Rate (FPR) indicates this probability and can be calculated by taking 1 – Specificity.

   1 - .95 = 5%

   b) **What is the probability your patient still has CAD despite a negative test?**

   The False Negative Rate (FNR) indicates this probability and can be calculated by taking 1 – Sensitivity.

   1 - .85 = 15%

References

East Alabama Medical Center Chemotherapy FMEA. (2003). Retrieved July 22, 2010 from Institute for Healthcare Improvement, ihi.org: http://www.ihi.org/ihi/workspace/tools/fmea/processdetaildatareport.aspx?toolid=1&scenarioid=2&type=2.

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