BIOE 301 Project

The BIOE 301 project provides an opportunity for you to explore a public health problem and provide a detailed bioengineering solution. Working in teams of 2 to 4 students, you will complete two major project assignments:

- Propose a new technology to solve a health problem
- Present a mock design of the new technology and plans for a clinical trial to evaluate the technology

Each week you will turn in a smaller project task which will help your team to complete these two major assignments. **You should turn in the form on page 3 of this document with each project task.** We suggest that you read this entire document before beginning, and then review the document as you prepare each assignment.

Part One: Propose a new technology to address a public health issue within a regional context

In this part of the project, you will identify an important health problem, research the scope of the health problem and available technologic solutions, and specify limitations of current technologies which address the problem. Based on your research, you will propose a new technology to address the health problem, taking into account identified limitations. The major tasks of this part of the project are outlined below:

Task 1: Define a public health problem facing a particular country or region of the world. ***Due:*** _____
You may select your topic from a wide range of heath issues - you must simply demonstrate that the chosen issue significantly and adversely affects the lives of people in the country or region you have selected. Write a one-page (typed) summary of your disease including: Epidemiology (prevalence, incidence, etc…) in the region you have selected; Risk factors; Pathophysiology of the disease; Physical signs and symptoms.

Task 2: Evaluate available technology meant to address the health issue under consideration. ***Due:*** _____
Assess the actual effectiveness of current devices or strategies employed throughout the world. What are the usage constraints? Are current solutions available only to a limited population due to cost or other factors? Could alternate materials or approaches be used to reduce the overall cost? Is there another strategy/design that has never been tried? Write a one-page (typed) summary of: (1) Current methods for diagnosis and their constraints; are these available in the region you have selected? (2) Current treatments and their constraints; are these available in the region you have selected?

Task 3: Evaluate technology limitations in the selected country or region of the world. ***Due:*** _____
Assess the actual effectiveness of current devices or strategies employed in the selected country or region of the world. Of all current technologies available, which are feasible given the current resources in your selected part of the world? What investments is the health system in the region selected making to develop or implement new solutions? Are there other efforts from the private or public sectors to develop new solutions? Are there investments in basic or applied research? Are large clinical trials underway to test new solutions? What are the limitations of these approaches? Write a one-page (typed) summary of: (1) Current methods for diagnosis available in the country or region you have selected and their limitations; how does this compare to other parts of the world? (1) Current methods for treatment available in the country or region you have selected and their limitations; how does this compare to other parts of the world?

Task 4: Define design constraints that a solution to the health issue must satisfy. ***Due:*** _____
These should be quantitative measures that include both technical performance and economic constraints that a technology solution must address and satisfy. Examples of constraints that you might consider include: necessary educational level of primary user, necessary education level of patient/primary caregiver, detection limits of new screening/diagnostic methods, efficacy rates of new therapies, infrastructure requirements (e.g. electricity, support staff, laboratory services), cultural concerns, time demands (e.g. number of visits to clinic, recovery time), cost, and device size/portability. You should identify the performance capabilities and costs of existing solutions, as well as consider the preferred performance that new solutions should strive for. Turn in a one page (typed) table summarizing the design constraints of technology solutions that address the selected health issue. Each row in the table should correspond to a specific constraint (e.g. unit cost of device). Each column should correspond to each technology considered, one for each currently available solution assessed and one which represents the preferred performance of a new design.

Task 5: Propose a new technology to satisfy the design criteria specified in task 4. ***Due:*** _____

Your solution should provide an advantage compared to existing solutions. This could be either an improvement to an existing device or a completely new strategy. For example, if your project is to develop alternative TB therapies, you might propose an alternate drug delivery mechanism (e.g. patches, controlled-release injections, implantable devices, etc) that could be used to deliver 6 to 9 months of TB therapy without requiring frequent physician visits or daily drugs. Remember, improvements are not limited only to changes in device design, but may also include increasing availability of the device to health care workers in the field or decreasing the cost to manufacture and distribute a health technology. Turn in a one page summary of your new solution. The summary should include the following: (1) overview of your design, (2) scientific principles of the design, (3) expected benefits of the design, (4) potential risks associated with the design, (5) a determination of whether the design meets the constraints specified in Task 4, careful to justify trade-offs made between expected performance and cost.

Part Two: Present a design of the new technology and plans for a clinical trial to evaluate the technology.

In this part of the project, you will use the engineering design method to design a new solution to an important health problem. You will create a physical prototype of your design, outline a clinical trial to evaluate its performance, and present these to the class as part of a design review exercise.

Task 6: Construct a prototype for an in class demonstration and design review. ***Due:*** _____

Your prototype does not need to actually function, but it should illustrate the scientific principles of the device as well as the ways in which it satisfies the design requirements. In constructing your prototype, we suggest that you use common household materials (plastic wrap, aluminum foil, cardboard, etc) to illustrate how the device would work. You are limited to a total materials cost of $10 and you will be asked to turn in receipts to verify that you satisfied this constraint.

Task 7: Design a clinical trial to evaluate the proposed technology. ***Due:*** _____

Turn in a design for a clinical trial. Specify the following: 1) the diagnostic/treatment standard of care and new technology to be compared; 2) the experimental group and control group; 3) participant inclusion and exclusion criteria; 4) desired primary and secondary outcomes; 5) the preferred p-value and power, with the rational for selection; and 6) the calculated necessary sample size, with the equation utilized.

Task 8: Write a research protocol for the clinical trial of the proposed technology. ***Due:*** _____

Turn in a research protocol, specifying: title of the research trial; name of the principal investigator(s); background, hypothesis, research questions, and project goals; research methods, design, and proposed statistical data analysis; human subject interactions, including source of participants, procedures for recruitment, and procedures for obtaining informed consent; potential risks and benefits to participants; and sites or agencies involved in the research. The information must be well organized and presented at the research participant's education level.

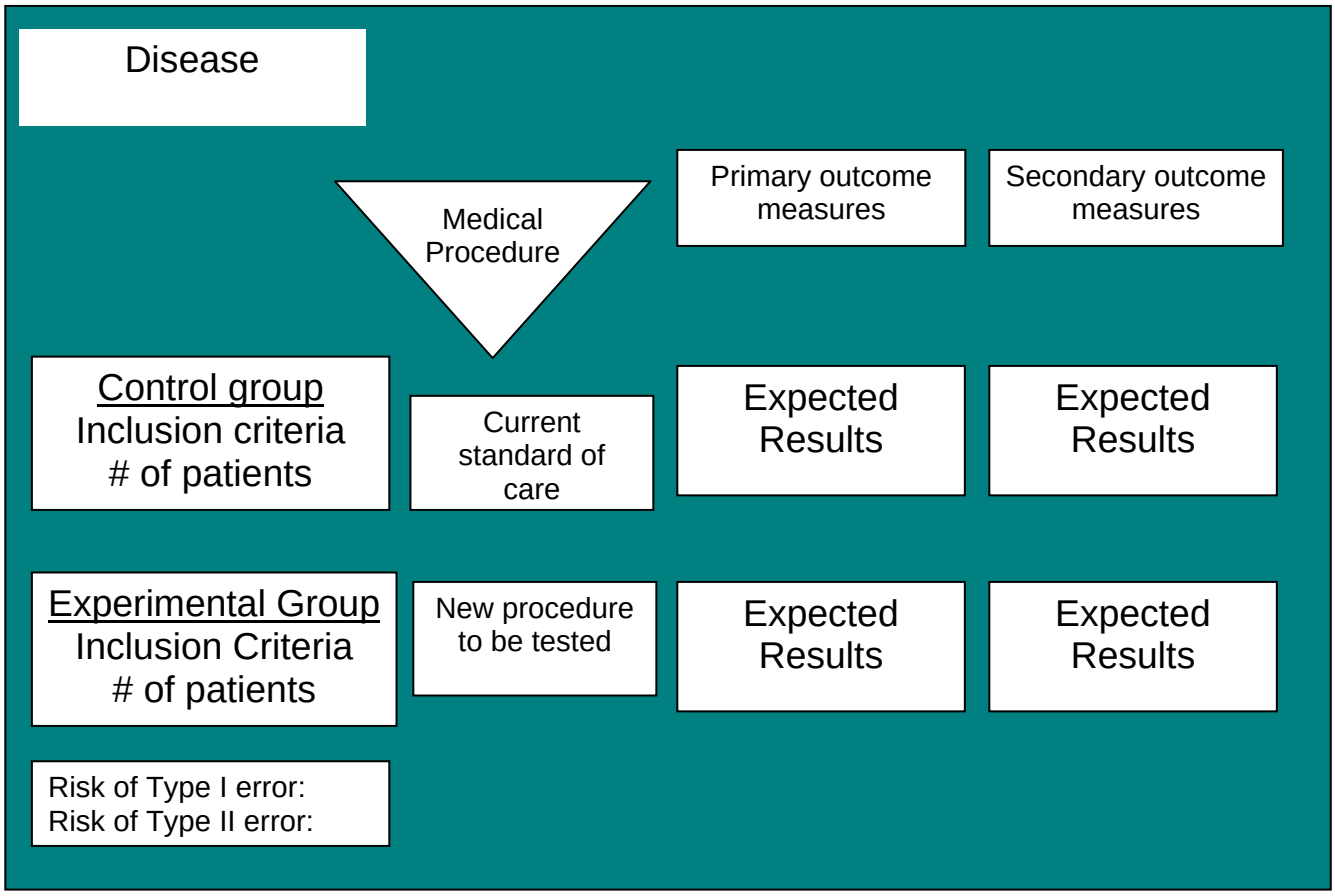
Task 9: Write an informed consent document for the clinical trial of the proposed technology. ***Due:*** _____

Turn in an informed consent document, specifying: the purpose of the study, the research procedure, risks and anticipated benefits to research participants, alternative procedures available to diagnose/treat the health condition, contact information for the principle investigator and the institutional review board, and the research participant's right to withdraw from the study at any time. The information must be well organized and presented at the research participant's education level.

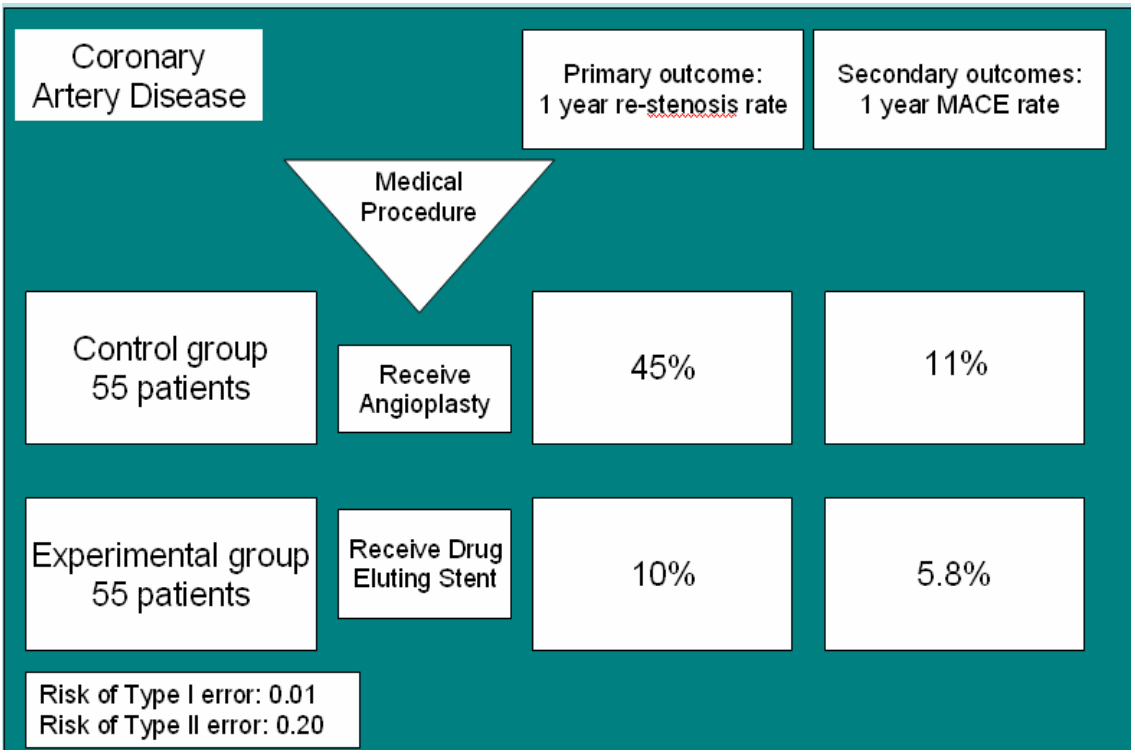
Task 10: Present your prototype & plans for clinical trials of the proposed technology. ***Due:*** _____

The audience for your presentation will be a scientific review panel from the World Health Organization. The panel will review the proposed designs and decide which efforts will receive funding to move into the development phase. Therefore, you must convince the panel of the severity of the problem as well as the efficacy of the proposed design. You should be prepared for 5 minutes of Q&A from the review panel following your 30 minute presentation.

To design a clinical trial, you must be able to fill out all the information in the diagram below. Use this template as a guide to help you design your trial.



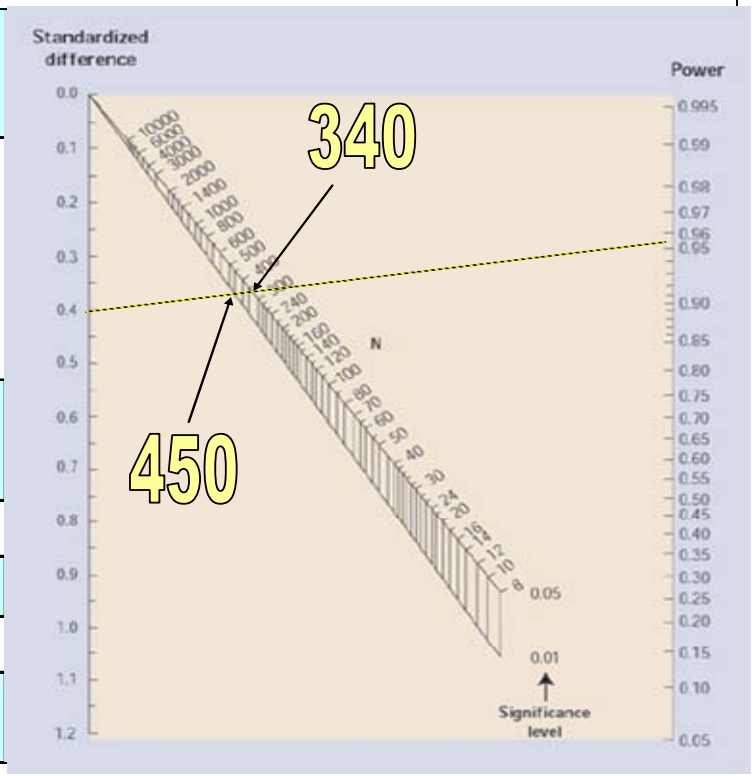
For Example: Angioplasty vs. Drug Eluting Stent



To calculate sample size for a clinical trial, you can use a calculator like the one shown below (and in Homework 14). Note the recommendations regarding type I & type II error and how they impact the p-value and the power.

Let's take, for example, a technology such as a new effective vaccine for lung cancer. Let's say that the expected outcome of the standard of care is 70% of people with end stage lung cancer die, then P1 will be 0.7. You design a vaccine for lung cancer which has the expected outcome of a death rate of 50%, so P2 is 0.5. We are trying to detect an expected difference of 20%.

Expected outcome of the control group (P1)	0.7
Expected outcome of the treatment group (P2)	0.5
Type I error (p value) *	0.05
Power (1-beta) **	0.95
Standardized Difference	0.408



Using the resulting standardized difference and power, draw a line on the graph to connect these two points. Where that line intersects with the sample size line, gives you the number of people you need for your trial. Therefore, a sample size of about 340 people would be needed for a significance level of 0.05, and about 450 people for a level of 0.01.

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Type I error occurs when we mistakenly conclude that there is a difference beween the two groups when in reality there is no difference. If we use .05, there is a 5% chance of a type I error.

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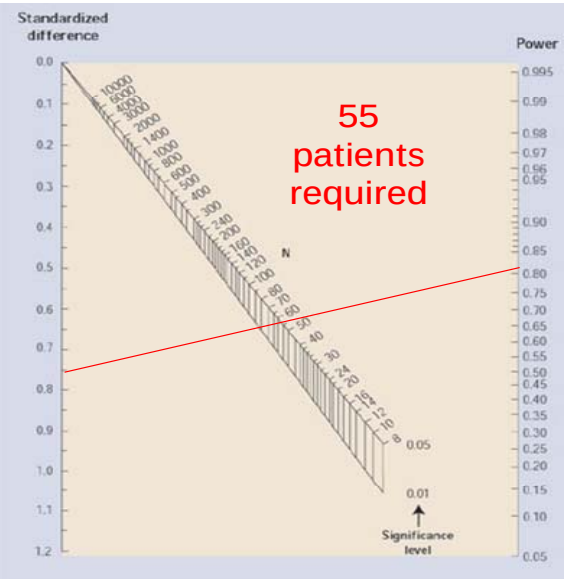
Type II error occurs when we mistakenly conclude that there is not a difference between the two groups when in reality a difference exits. Power is the probability of not having a type II error. Usually, a power of 80% - 90% and a p value of 0.05-0.01 is used in clinical research.

For Example: Angioplasty vs. Drug Eluting Stent

- Treatment group:
  - Receive stent
- Control group:
  - Get angioplasty
- Primary Outcome:
  - 1 year restenosis rate
- Expected Outcomes:
  - Stent: 10%
  - Angioplasty: 45%
- Error rates:
  - p = .05
  - Beta = 0.2



Project Assignment Submission Coversheet

Group Members:

Name:_____ e-mail:_____

Name:_____ e-mail:_____

Name:_____ e-mail:_____

Name:_____ e-mail:_____

General Health Topic:_____

Check the item being submitted

Part One: **Grade**

- ☐ Task 1 – define a public health problem _____
- ☐ Task 2 – evaluate a current technology _____
- ☐ Task 3 – evaluate technology limitations _____
- ☐ Task 4 – define design constraints _____
- ☐ Task 5 – propose a new technology _____

Part Two:

- ☐ Task 6 – construct a prototype (receipts for construction materials attached below) _____
- ☐ Task 7 – design a clinical trial _____
- ☐ Task 8 – write a research protocol _____
- ☐ Task 9 – write an informed consent _____
- ☐ Task 10 – present your prototype and clinical trial plan _____