BIOMEDICAL INNOVATION MANUAL FOR MEDICAL STUDENTS

by

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THESIS

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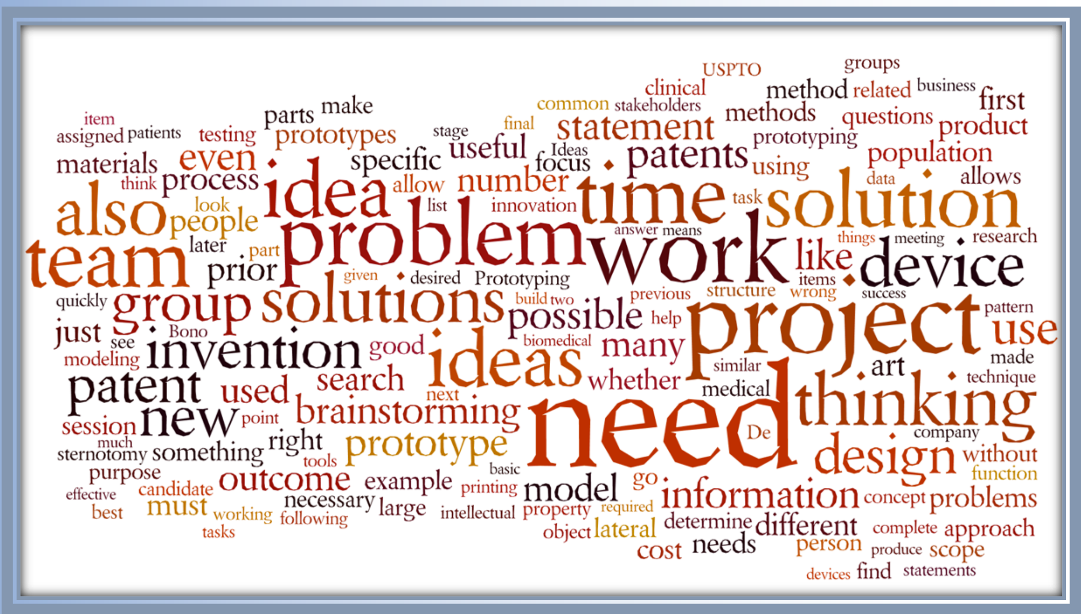
Biomedical Innovation Manual



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ABSTRACT

Biomedical Innovation Manual for Medical Students

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Background: *The UT Southwestern Biomedical Innovation program is modeled to a large degree after the Stanford Biodesign program. The program is based on the hypothesis that innovation can be learned, and it offers a step-by-step process which has been shown to result in successful new biomedical technologies. From a high level, the process involves starting with a broad list of needs in the healthcare sector, selecting a smaller number of these needs to focus on based upon criteria such as group capability, resources, and strategic fitness, devising a number of solutions to these needs, narrowing the number of solutions based upon feasibility, and then iteratively prototyping and testing the leading solution to develop a final working solution. The UT Southwestern Biomedical Innovation program hopes to encourage innovation at UT Southwestern Medical Center through the continued development of the Biomedical Innovation curriculum and organization.*

Objective: *Writing and distributing a primer on Biomedical Innovation to first year medical students will increase their confidence and competence as they embark on their first Biomedical Innovation projects.*

Methods: *Using Biodesign: The Process of Innovating Medical Technologies as a primary resource, an outline for a 10 chapter primer on medical device design for medical students was developed. Information from several primary resources and from local experts in medical technology development was collected and compiled into a short, accessible manual. Approaches and curricula from other medical schools were also incorporated. Efforts were made to introduce everything a medical student would need to know when embarking on her first medical technology design and development project.*

Results and Conclusions: *A 45 page introductory manual targeted at first year medical students learning how to perform their first biomedical innovation program was written. The manual covers topics such as clinical observation, project management, brainstorming, prototyping, patents, and pursuing FDA approval for a medical device. It presents each of these topics at a level appropriate for medical students and includes information relevant to students at UT Southwestern (e.g how to access prototyping resources on campus). The resulting manual will improve the resources available to UT Southwestern medical students interested in Biomedical Innovation and will increase the long-term stability of the Biomedical Innovation program by forming a more permanent body of institutional knowledge and standardizing the curriculum from year-to-year.*

TABLE OF CONTENTS

Chapter 1

Introduction to the Innovation Process

"I invented nothing new. I simply assembled into a car the discoveries of other men behind whom were centuries of work. Had I worked fifty, ten, or even five years before, I would have failed. So it is with every new thing. Progress happens when all the factors that make for it are ready, and then it is inevitable. To teach that a comparatively few men are responsible for the greatest forward steps of mankind is the worst sort of nonsense."

–Henry Ford

This chapter gives a brief overview of the process taught in Biomedical Innovation at UTSW. The method, which is derived from Stanford's Biodesign program[1], is based on the belief that innovation is a skill that can be taught and practiced. By breaking down the process into discrete steps, you will be able to learn a structured method for innovating new solutions to biomedical problems.

One method of innovation

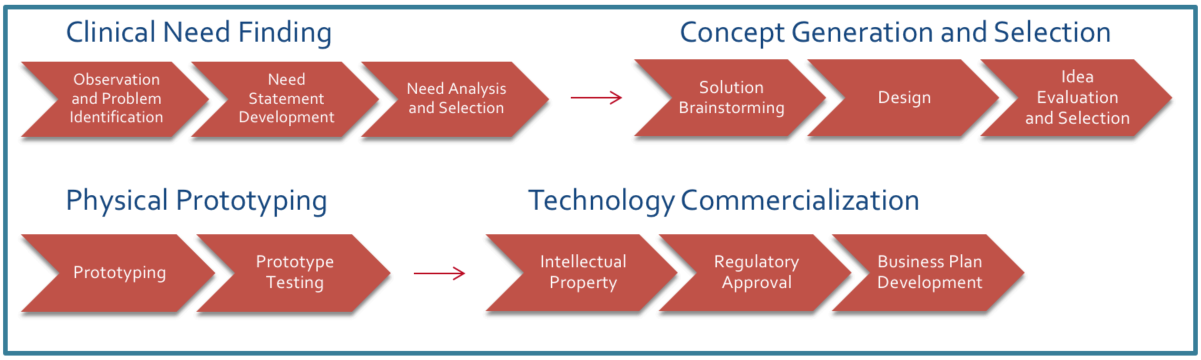

Figure 1. This diagram details the biomedical innovation process discussed in this manual.

Contained within this primer is a step-by-step method of innovation driven by the identification of problems and needs within the biomedical sphere. Solution generation itself is a late step in the process. Too often, new technologies are developed first and then an application is sought post hoc. When a solution is in search of a problem, it will often fail. Needs come first. Searching broadly, and accurately identifying a real need improves the chances that innovators' work will be high-impact and well received. Starting from a need has the inherent advantage of solving a problem that a large number of people are experiencing.

Identify a need to work on

The first step to finding a need to work on is finding a large number of needs you could work on. Needs can be found in many places. One place they can be derived from is first-hand experience in the field. When a need resonates with you personally it has the added benefit of personal passion and insight. Needs can also come from observing someone who is experiencing a problem. Often times, in the case of biomedical innovation, these needs are discovered by spending time at the hospital or in clinic. Needs can also be identified by interpreting economic data. Databases are available which track all manner of health-related data. The primary literature, especially quality and outcomes research, is another source of biomedical needs waiting for innovation.

Clarify the need

After a large number of needs are identified, it is necessary to choose one (or a few related ones) for your team to focus on. Needs should first be vetted to determine whether the need is a real one. This often necessitates research into the biological background of the need, the economics of the need, and the effect that the problem has on those involved. To clearly delineate the problem at hand, it is necessary to describe it as specifically as possible. This can be done using need statements. Need statements are a useful tool for thinking about the parameters of a need. They describe the root of the problem, the population affected, and the change in outcome that would be required to consider the need met and problem solved. They aid in thinking about the scope, mechanistic factors, and measurable desired changes in outcome of the need. They do not describe a solution to the need! They are solution independent. Once your team has determined the specific parameters of multiple needs, it is time to narrow down the list to a few candidates to carry on further in the process. This should be done strategically, thinking about the abilities and background of the team members, the resources available, the degree to which the problem is understood, the potential for real impact, and the market size and characteristics. The work put in at the need specification stage will pay itself back many times over, as a solution without a corresponding real and well-understood need is sure to fail.

Brainstorm solutions

Now, the fun part! Brainstorming is something you have likely been taught since you were in elementary school. Nevertheless, it is a skill you must practice to maintain your ability in it. There are many different techniques and strategies for brainstorming. The most important thing is that you and your team must strive to keep the realm of possible solutions as wide as possible. This is not the time to narrow down your solutions. That will come later. Brainstorming works best when it is semi-structured. This can be achieved in many ways which leverage the various aptitudes of your group. One way to increase the success of a brainstorming session is to ensure that all senses are used e.g. making a crude model of what you are thinking about allows the group to make use of kinesthetic reasoning. As another example, drawing your ideas can help visual learners brainstorm. Writing ideas on small cards and clustering them into similar groups on a board is another technique that may be useful.

Search the Prior Art

For several reasons, it is important to know what solutions already exist. One of the most obvious reasons is the disappointment that many students have suffered after working for months on a project only to find that their idea has already been tried and may even already be on the market. To research prior solutions it is best to start on the US Patent Office website to obtain the relevant product classification codes called CPC codes. Then these CPC codes can be searched on Google Patents. In this way, the team can search for relevant patents that have already been granted. These patents make up a large part of the prior art. Searching the prior art serves two main purposes: to determine novelty, avoiding later issues when pursuing intellectual property, and to clarify to the team what solutions are already in existence, thus spurring inventiveness to devise a solution beyond the current state of the art. Remember, however, that determining novelty is not easy, so don’t get discouraged if a patent for a similar idea already exists. The idea may still be patentable.

Prototype and Test

Prototyping is an indispensable tool for making fast progress toward either success or failure. It allows you to come down from the theoretical realm and hold something in your hands which will help you quickly realize if you are on the right track or if you need to go back to the drawing board. The utility of prototyping is to answer particular questions like how the device will function, what will the device be made out of, how will the user interact with the device, or will the functionality of the device be physically possible. It is important to keep in mind that a prototype is not and does not need to be a fully functioning model of the final product. Prototypes can help to test just one aspect of a device's functionality or even just to demonstrate how the final product will look.

The other utility of prototyping is that it allows early testing of concepts and solutions. Testing often begins with inanimate model systems to allow the collection of data indicating efficacy of the design. This is often referred to as bench testing. Bench testing of biomedical technologies can also include testing with tissue samples or animal cadavers and later in the development cycle, human cadaver testing. With some luck and a lot of hard work, first human clinical testing and clinical trials are possible after regulatory approval.

From concept to reality

One of the most common ways to put a new innovation to use is through technology commercialization. While the production and dissemination of technology without profit is possible, more often it is supported by either existing companies or by the formation of a company. The specifics of technology commercialization can vary, and there are many considerations leading up to this point such as filing for a provisional patent and pursuing regulatory approval. One common method of bringing a technology to market is to license the intellectual property to an existing company. This arrangement allows a medical technology company to pay the patent holders for the right to produce and sell the technology. It is also possible to partner with a company in the production and sale of a device or even to form a start-up company and contract out manufacture. The most obvious drawback of forming a start-up company is that as we are medical students, this would likely complicate our academic timelines. Nevertheless, it has been done. Regardless of whether this pursuit takes a central position in your future careers, our hope is that you will find that biomedical innovation a rewarding effort. Even if you do not invent the next big device, the skills you learn in the course will give you a new lens through which to see healthcare and allow you to think clearly about important clinical problems and how to solve them.

References

1. Yock, Paul G., et al. *Biodesign the Process of Innovating Medical Technologies*. Cambridge University Press, 2015.

Chapter 2

Observation to Identify Clinical Problems

"In the field of observation, chance favors only the prepared mind."

–Louis Pasteur

Why are needs so important?

An accurate, well-vetted need gives you a target to shoot for when you are developing an innovative solution. It gives you something to measure your solution next to, allowing you to determine if you are on track. If you are off base on your need, the end solution will not be marketable. A need is just that: something people need!

Develop a mission statement and strategic focus

Before setting out to observe a clinical problem and identify a need, innovators must choose a focus. The most successful projects have a chosen focus which is closely related to the motivations, values, and competencies of the innovators. One way to come to a consensus as a team about what to focus on is to develop a mission statement. Each member should take an inventory of their values and their aspirations. A team's mission and focus should also take into account the strengths and weaknesses of its members and externalities such as the amount of time, money, and other resources available for the completion of the project. The mission statement does not need to be Pulitzer Prize-worthy, but it should serve as a decision-making tool when looking for healthcare needs to focus on.

Background research

The importance of background research before seeking to observe a need cannot be overstated. Once your team has identified a strategic focus, your next task is to build your knowledge of the topic. Having an outsider perspective is useful for solving problems in creative and innovative ways, but that does not mean you should have an outsider level of knowledge. Work to understand the mechanisms behind the topic, the physiology, the pathology, the way the need is currently addressed, the epidemiology, and the economic impact. This groundwork will help you interpret and understand what you are observing. That being said, beware of dogma and challenge assumptions rather than internalizing all of what you read as fact.

Checklist: familiarize yourself with these topics as they relate to your strategic focus

- ☐ Physiology
- ☐ Pathology
- ☐ Mechanism of problem
- ☐ Current Solutions
- ☐ Demographics of affected population
- ☐ Epidemiology
- ☐ Economics

Tools to identify problems

Ask

Conversations with the involved parties can go a long way. Listen for key phrases like "If only I had a way to…" While asking open-ended questions like "what is the biggest problem in your field that you think should be fixed" may seem like a good idea based on your medical training, this approach usually does not work. Physicians are often too close to the problems in their specialties to take a step back and see in an unbiased way what could be improved. Closed-ended questions like "what is the most common complication of this surgery" or "what do you think caused this problem" are more likely to lead in fruitful directions.

Observe

Observation is indispensable when it comes to finding problems to work on. It is the primary source of data; conversation, research, and surveys all depend on someone else to interpret the data and form an opinion. Often, people in the medical field become so accustomed to the work-arounds and patchwork solutions to problems that they may not even notice the solution is suboptimal. If you email a physician and ask what problem do you wish you could fix, the answer will be very different from the information you glean from direct observation. When observing in the clinical setting, it is important to behave like an anthropologist. The goal is to document as many relevant details of a clinical situation as possible without value judgment or editorializing. It is impossible to make observations in a clinical setting without causing a change in behavior of those being observed, however it is best to try to minimize the observer effect as best you can. Try to be "a fly on the wall". And above all else, remember that you are not trying to create a product. You are not trying to *solve* a problem. You are trying to *find* a problem through objective observation.

Research

To find a clinical need, innovators may also look at the primary literature, particularly quality and outcomes research. There is a desired outcome hidden in every quality article, and there is a problem in need of a solution in every article about a poor outcome. Sources of morbidity and mortality are clinical problems well suited to biomedical innovation projects. Publications from a systems perspective are also worthwhile. The goals of minimizing cost, reducing length of hospital stay, and allowing services to be delivered at a lower level of care are all worthy lenses through which to look at a clinical problem.

Surveys and focus groups can also lead to good patient oriented needs. The benefit of identifying a need through these methods is that you can be sure the most important stakeholder (patients) have been consulted. This sort of research will likely require an IRB.

Resources

GrandChallenges.org – Offers grants to groups who propose solutions to the global health and economic challenges that they have identified.

AHRQ – Agency for Healthcare Research and Quality (http://www.ahrq.gov/)

HCUP – Healthcare Cost and Utilization Project (https://www.hcup-us.ahrq.gov/)

MEPS – Medical Expenditure Panel Survey (http://meps.ahrq.gov/mepsweb/)

WHO – World Health Organization (http://www.who.int/en/)

References

1. Yock, Paul G., et al. *Biodesign the Process of Innovating Medical Technologies*. Cambridge University Press, 2015.

Chapter 3

Work with Need Statements

"A problem is simply the difference between what one has and what one wants"

–De Bono

Three Parts of a Need Statement: Problem, Population, Outcome

As discussed in Chapter 1, need statements are a useful tool for thinking about the specific parameters of a need. They describe the root of the problem, the population affected, and the change in outcome that would be required to consider the need met and problem solved. In need statement 1 in the box set off to the right, the problem is the wire breaking and the population is patients receiving a coronary artery bypass graft (CABG). The outcome is somewhat unclear, however. The target outcome could be not having the sternotomy wire break or it could be successfully closing the sternotomy. The first outcome focuses on a problem that happened during the surgery or recovery period—the wire broke. Not having the wire break is a device centered outcome. Taken to the extreme, this need statement could be solved by having extremely sturdy wires with impressive tensile strength. They may even be so strong that they tear through the relatively soft chondral cartilage of the sternum. This outcome would obviously not be desired. This goes to show that a patient centered outcome often makes more sense than a device centered outcome.

> **1:** "A way to close a sternotomy in coronary artery bypass graft (CABG) patients without the sternal wire breaking."

Need statement 2 (right) is an improved version of the original need statement. The problem is needing to close a sternotomy, the population is CABG patients, the outcome is that the sternotomy is closed in a quick secure way. This need statement targets an outcome that would be beneficial to patients. It also does not assume what device would be used to achieve the outcome, leaving plenty of room for creative solutions.

> **2:** "A way to close a CABG patient's sternotomy quickly and securely."

Dreaming even bigger, the need for a CABG or even a sternotomy could be challenged by writing a third need statement (right). This need statement identifies the population as people experiencing the problem of heart muscle ischemia and identifies the desired outcome as revascularization of the ischemic heart muscle without the requirement of a sternotomy. From these examples, it is clear that the way that a need statement is phrased has the power to drastically change the solutions that could be devised to solve the problem.

> **3:** "A way to revascularize heart muscle without the need for a sternotomy."

In this way, need statements can be thought of as tools to begin brainstorming solutions. Need statements must be specific about the problem, the population, and the desired outcome so that solutions which target these parameters can be devised. The worst thing that be done when writing need statements is to build the solution into the statement, thereby drastically narrowing the idea-space of possible solutions that can be devised.

Upscoping and Downscoping

When writing need statements, it can be useful to consider whether you are addressing the right population or whether there is a broader population experiencing the same problem. It can also help to consider whether the problem is part of a bigger root issue or whether instead, the need could be analyzed more clearly if the problem was restricted to a smaller subset of problems or populations. Biodesign teaches a technique for thinking systematically about the need statement scope in this way.[1] They call it upscoping and downscoping. Starting from an original need statement, the problem, population, and outcome can be either generalized or made more specific. In this way, the disease being targeted and the number and type of patients being targeted can be altered to allow exploration of which direction may be the most expeditious. Figure 1 shows an example of a need-scoping pyramid for the problem of herniated vertebral discs.

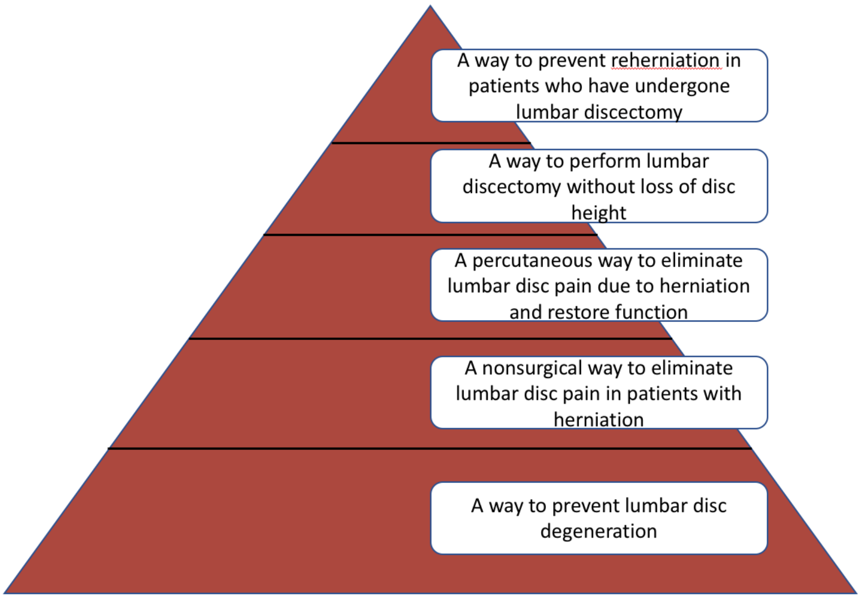

Figure 1. The problem of herniated discs can be narrowed to reherniation in patients who have already undergone discectomy. Alternatively, it can be generalized to prevention of disc degeneration in any patient.[2]

Templates of common need structures

To get started on brainstorming need statements here are some common need statement structures:

- A way to reduce the risk of (complication) after (specific surgical procedure)
- A way to (perform most direct goal of specific procedure) without using (expensive device/morbid technique)
- A way to perform (medical service) in (reduced level of care setting)
- A way to prevent (specific poor outcome) in (specific patient population)
- A way to (reduce patient negative experience/increase patient positive experience) during (specific procedure/exam/test)

References

1. Yock, Paul G., et al. *Biodesign the Process of Innovating Medical Technologies*. Cambridge University Press, 2015.
2. "Need Scoping Example 1." *YouTube*, Stanford Biodesign, 6 Feb. 2015, youtu.be/R5vNefHtSYg.

Chapter 4
Team Building and Resource Management

"Individual commitment to a group effort - that is what makes a team work, a company work, a society work, a civilization work."

— Vince Lombardi

Project management

Carefully planning and managing a project is crucial to its success. This process can be divided into three main parts: prepare, do, and follow through.[1] This is similar to the Quality Improvement idea of the PDSA (plan, do, study, act) cycle. First, in the preparation phase[1], the problem itself is defined, basic information is collected, and the plan is developed. What is causing the problem? What will the basic approach be? Is the approach feasible? What will be the value of fixing the problem? Is the benefit worth the effort? During this stage the basic plan is developed. One way to begin developing the plan is to ask the 5 W questions: who, what, when, where, why. Who will work on the project? What will each person do? Where will the project take place and what resources will be necessary? Why is this project worth doing—what will define success for the project? The more carefully your team can plan the project the easier it will be to complete it within scope, on time, and on budget. Later in this chapter, specific planning methods like a work breakdown structure and Gantt charts will be introduced.[1]

Next, your team gets going! This is the doing phase.[1] If your plan is detailed enough, it should be clear where to get started. Each team member should start working though each item they are assigned to in the schedule in the order it is supposed to be done. Regular check-ins will help the team stay in sync. It can be helpful to have one person assigned to compare the group's progress with what was planned so that they may call attention to any problems and anticipate any roadblocks ahead. As your team completes the work you have planned, it will become necessary to determine how to wrap up the project. This is the follow-through phase.[1] A fleshed-out idea is not a true stopping point. Depending on what your team defines as success, following though could mean different things. This could be completion of your Scholarly Activity, submission of a provisional patent application, or demonstration of a working prototype.

Recruit a team

Innovation is a team sport, and the best teams are those composed of individuals from a large array of backgrounds. Having people from different fields of training with different areas of expertise on your team leads to more creative solutions as a result of a sort of cross-pollination of disciplines. Not only that, but also the project will often be so complex that one person cannot know how to do each part of it from beginning to end. The single person who is an expert in healthcare, engineering, communication, intellectual property, and business is a rare beast. As you build a team, it can be useful to take note of your team's body of expertise as well as its deficiencies related to the task at hand. It's much faster to recruit an expert than it is to try to become one yourself.

Communication

As you work on your project, your team will need to communicate both with each other and externally. Communication styles within the team are highly dependent upon team needs and it is useful to establish early on with the team what method of communication they prefer. That being said, there are some best practices. While it may be possible to complete a project using Google Drive and never meeting in person, a team which meets in person and uses some methods of organization is much more likely to succeed.

There are also suggested best practices for communicating with entities outside of the team. Innovators might need to communicate with physician mentors, heads of departments within the campus, local companies, or regulatory bodies. It is often best to select one person from the group to communicate with each entity. This way, misunderstandings and mixed messages are kept to a minimum as the single point of communication can allow the group to present a unified message. More than one person on the team can be in charge of communication with different stakeholders, but there should be only one point of contact on an entity-by-entity basis.

Organization

When it comes to group projects, it is important to remember that not all work will be done in a group setting. Tasks should be broken up and assigned to individuals as action items with a due date. One effective way to do this is to maintain an action item list which is accessible by everyone in the group at any time. There are several apps which could be used for this. Todoist can be used in this way but the free version does not include group coordination. Wunderlist is a free app which is accessible on the computer on a webpage or on a mobile device which is effective for this use.

Meetings

Meetings allow the group to come together, give each other updates and exchange information, and decide what to do next and how to do it. A meeting should have a defined purpose, and only those who are necessary to achieve the purpose should be invited to attend. The duration should be appropriate for the task at hand and should allow time for a quick summary and review of new action items, tasks to be done before the next meeting. At regularly scheduled team meetings, time can also be allowed for review of previous action items before the meeting starts.

When planning a meeting, notify the attendees of the time, place, duration, and any special requirements of things to bring or work to do ahead of time. Meetings often run more smoothly if an agenda is sent out 1 day in advance. The agenda should contain the time, place, purpose, and a list of topics for discussion. This can also serve as the meeting reminder.
Someone should be assigned to take notes at each meeting. The most important items to record are any decisions made or new action items that came from the meeting. Attendance may also be taken. These minutes should be sent to everyone involved by the next day.

Time, Money, and Scope: The Triple Constraint

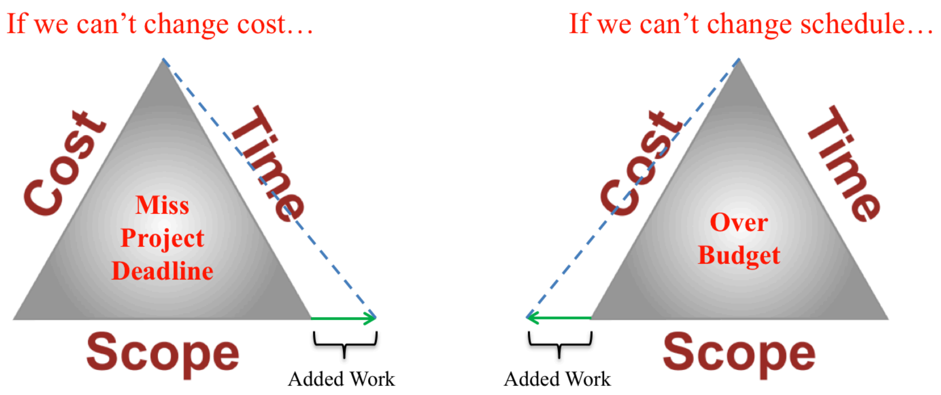

Figure 1. The triple constraint model of time, cost, and scope encourages innovators to think about the secondary effects of their project management decisions.[2]

One useful way of thinking about a project is with the triple constraint of time, cost, and scope (Figure 1). If the scope is increased, the time it takes to complete the project will likely increase. Alternatively, the budget of the project can increase to absorb the increased scope without increasing the project timeline. For example, more people can be hired to work on the project or more project items can be contracted out. There exist many project management techniques to get a handle on this triple constraint. Typically, one of these constraints will serve as the main driver—the parameter that will be minimized or focused on when planning the project. For example, many projects have budgetary constraints which cannot be exceeded or have a hard deadline.

As you go forward, you will need to define the requirements of your project, develop a strategy to meet the technical, budgetary, and schedule constraints, and keep track of your progress as you go along. The following techniques will help you do each of these things in a systematic way.

Planning Using Work Breakdown Structure

A work breakdown structure is a method of breaking your project down into bite sized tasks so that all of the required work has been identified and can be anticipated. This is often done as a parent-task/child-task outline as shown below. Start from a basic statement of the project goal and then work to develop a more specific description of what the project will produce. This description is the scope. Once you have defined the scope, work from the top down and subdivide the project into smaller and smaller activities. The lowest level should be discrete work items that will be assigned to individual members of the team. They should be broken down enough that they don't make sense to further subdivide, but not broken down to the point that the tasks are disjointed. They should also follow the 100% rule: with each subdivision, work can neither be gained nor lost. In other words there can be no overlap or duplicate tasks in the chart. For similar reasons, it is important that one and only one person be assigned to each task because unassigned tasks or tasks with multiple responsible parties are often neglected. Don't forget to add project management and document/presentation preparation to the work breakdown! A tool worth checking out is www.wbstool.com which allows you to make a work breakdown quite quickly.

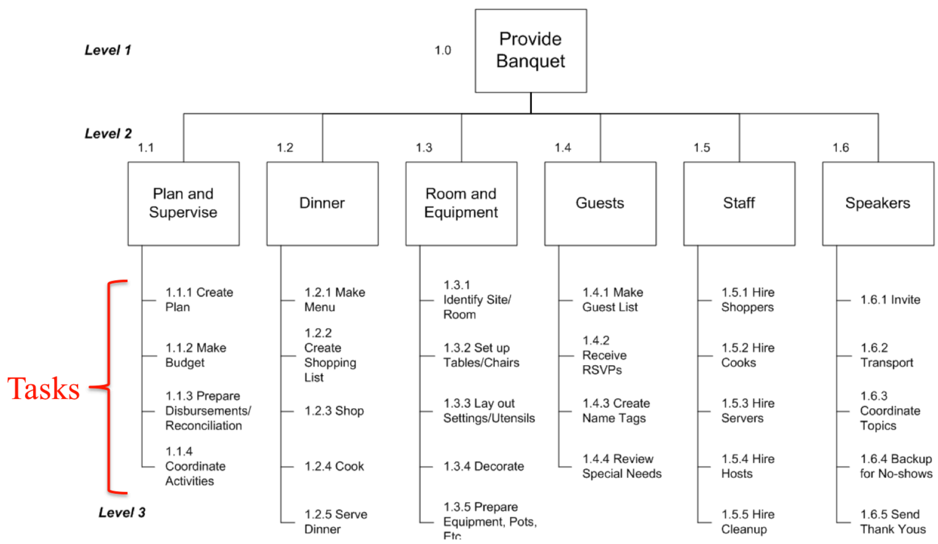

Figure 2. This example work breakdown structure has three levels. The third level contains individual tasks that could be assigned to a team member. If all of the individual tasks are completed, then the entire event will be achieved with success.[2]

Develop a Schedule

The work breakdown structure your team makes can be used to address the next aspect of the triple constraint: time. Each item on the lowest level of the work breakdown can be assigned an anticipated duration. This duration will be an estimation based on what information is available at the time. As the project goes on it will become easier to make accurate estimations once your team has a better idea of how long each task may take. At the beginning it is necessary just to make an educated guess—you may be surprised how close you are to the truth. It is best to make time estimates in person-hours rather than in terms of days or weeks from start to finish because additional people working on a task will alter the absolute duration but the number of person-hours will remain unchanged.[1] Kemp suggests including a high and a low estimate of the time needed for each task.

Once you have an estimation of the time each subtask on your WBS will take, you can begin to schedule that work. As you begin to schedule the work it is important to note the dependencies of each item, paying special attention to which items cannot be started until another is finished and thus must be done in sequence. In the hosting a banquet example from Figure 2, many of the sub-tasks are ordered in a logical way due to their dependencies (e.g. set up the tables before laying out the table settings/utensils).

A common method of project scheduling is the Gantt chart[4] in which time is set on the horizontal axis and horizontal bars are drawn in sequence or parallel for each project work item which is listed on the left. An example Gantt chart from the free software *Gantt Project* is shown in Figure 3. Something to pay particular attention to is the critical path, the sequence of tasks that must be done in series to complete the project. The critical path will set the overall time needed to complete the project. Other tasks which can be done in parallel are part of the **non**-critical path. They can be done at any time and are of variable importance to the final product. The team can be flexible about when non-critical path tasks are done and what resources they are allotted. Also good to include in the Gantt chart are milestones like due dates, presentations, etc. As the project goes on, the true progress can be compared to what was planned in the baseline Gantt chart. This makes it easy to spot if any aspect of the project is lagging behind.

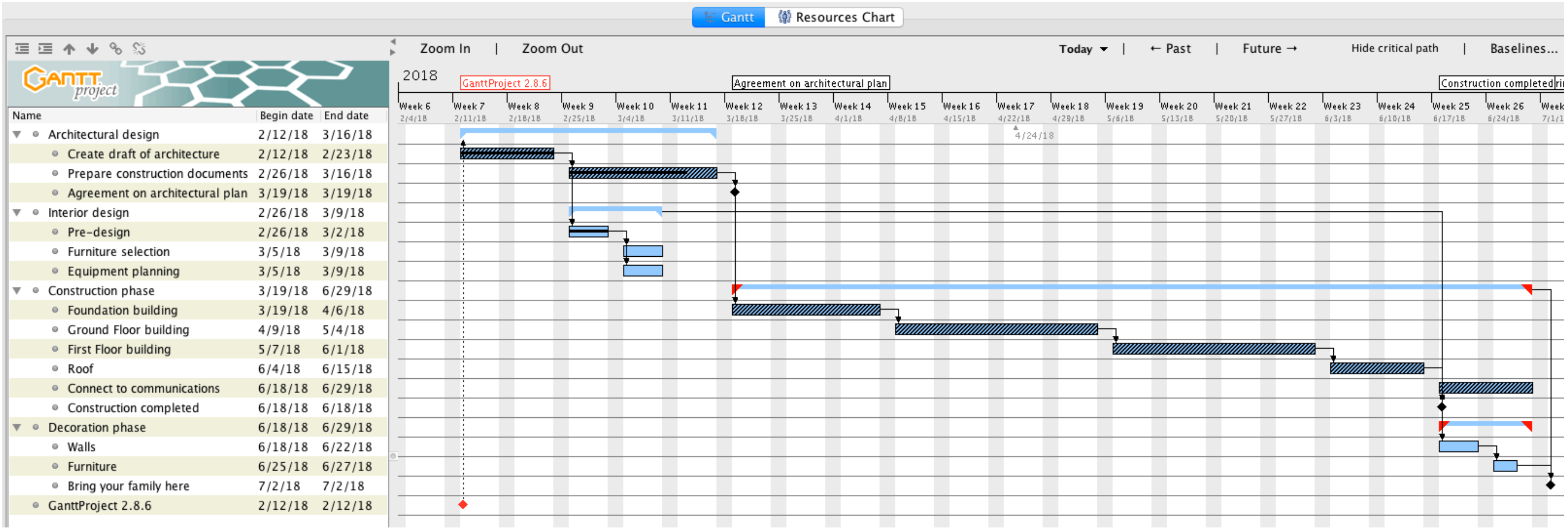

Figure 3. This is an example Gantt chart created in the free software, *Gantt Project*. Each of the tasks required in building a house are listed on the left. They were likely generated using a work breakdown structure. They are organized according to logical groupings such as architectural design and construction. Each of the subtasks is plotted on the time chart according to how long they are predicted to take given the work, resources, and man-hours available. Tasks highlighted in darker blue are part of the critical path, and as such, they have to be done in sequence. They define the total duration of the project. Things like interior design and decoration can occur simultaneously with other tasks so long as the tasks they are contingent on are completed. Thus, they are not part of the critical path.

Make a Project Budget

The final aspect of the triple constraint is the cost. It is often calculated after the scope and time are estimated and if the cost is deemed to be too high, the scope and project timing are addressed to allow cost reduction.[2] The two main drivers of project cost are people's time and the materials that will be needed to perform the project. To estimate the cost of people's time, assign a dollar value to an hour of each person's time. What is the opportunity cost for them to spend an hour working on the project instead of doing something else? The dollar per hour rate multiplied by the anticipated work hours for each person will give the total cost. As before a high and a low estimate can be made. The materials cost is the other main contributor. This is usually quantified using a bill of materials or BoM. The BoM is an itemized spreadsheet of each material that will be needed, where it will be sourced, how many are needed, and how much it will cost.[2] Some materials will be consumed when they are used (e.g. plastic 3D printing filament) while others will be a one-time cost (e.g. the 3D printer itself). Some expenses will be incidental, such as maintenance of tools, travel to meetings, etc.

Bill of Materials						
Item	**Material**	**Qty.**	**Specifications**	**Vender Information**	**Model No.**	**Price**
2" STD C10200 HD OFHC Copper Pipe	Copper	3	ID: 2.063", OD: 2.375", Length: 80.0", Weight: 85 lbs	Farmer's Copper Ltd.	102P02000STD-HD	$262.00 ea.
2" STD Cast Bronze Threaded Coupling	Bronze	1	ID: 2.375", Length: 4"	Farmer's Copper Ltd.	BRZF02000CPLG-3100	$38.00 ea.
3" Schedule 40 PVC DWV Pipe	PVC	1	ID: 3.000", Length: 72"	Lowes	PVC-04300-0600	$9.38 ea.
Pipe Insulation, Self Seal	Elastomer	1	ID: 2.375", Length: 72", Temp Range: -56 to 104 C, R Factor: 2.7	Grainger	1WYF7	$22.07 ea.

Figure 4. The bill of materials is an itemization of all materials needed for the project, their prices, and details about them.[2]

Plan the Work and Work the Plan

Ideally, performing all of this preliminary work of planning will be useful because it will allow the group to simulate the course of the project and anticipate problems. As the project continues, the person assigned to managing the project can compare the project status to what the plan predicted and encourage the group to respond accordingly. Of course with open-ended projects such as this, it can be difficult to envision what work will be required ahead of time. Part of project management is assessing the project status at any given time and adjusting the plan accordingly.

References

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3. Horine, Greg. *Project Management: Absolute Beginner's Guide*. Que, 2017.
4. Clark, Wallace. *The Gantt Chart: A Working Tool of Management*. The Ronald Press Company, 1922.

Chapter 5

Brainstorm Ideas

"More and more, creativity is coming to be valued as the essential ingredient in change and in progress. It is coming to be valued above knowledge and above technique since both these are becoming so accessible. In order to be able to use creativity one must rid it of this aura of mystique and regard it as a way of using the mind—a way of handling information."

—De Bono

Lateral Thinking

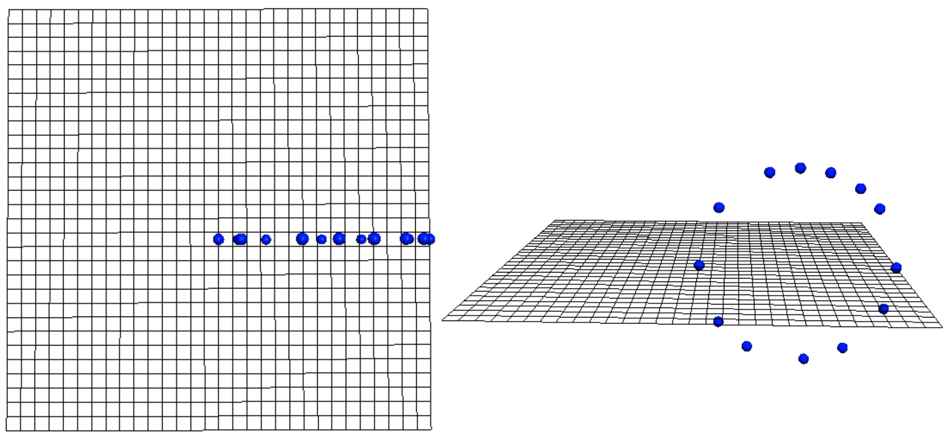

Figure 1. Vertical thinking would recognize the collection of data on the left as a line. In lateral thinking, all angles are explored, allowing the true circular shape of the data to be discovered.

De Bono describes the mind as a passive pattern-recognizing machine. He conceptualizes the mind as receiving a stream of sequenced information and sorting each piece of information into a pattern as it comes. He identifies most of the logical thinking that we have been taught in school as vertical thinking (Figure 1), in which each new piece of information is assessed in light of previous information and the established pattern. As information continues to come in, the pattern builds upon itself—tending to a state in which the body of information is as organized as possible. But in terms of organization this state is only a local maximum (to borrow a term from the mathematics of optimization) (Figure 2). If a new piece of information arrives which does not fit the pattern, we are in trouble. There may be other alternative patterns or arrangements which are more organized, but to achieve them, the established pattern must be broken, torn apart, and rearranged. He advocates for a different kind of reasoning, which he calls lateral thinking, to allow the global maximum (Figure 2) of a more encompassing patterning of ideas to be found.[1]

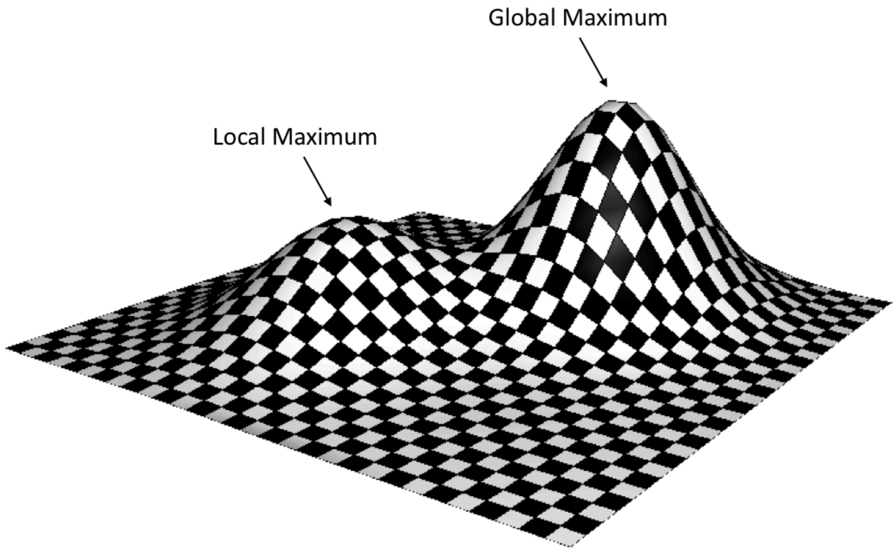

Figure 2. Following a certain pattern and only making incremental improvements within it leads to a local maximum. A better concept may exist upon a wider search for a global maximum.

Lateral thinking is a generative process, while vertical thinking is a selective process. In vertical thinking, new ideas are produced only until a promising idea is identified at which point idea generation ceases and the promising approach is selected and carried through to its logical conclusion. In lateral thinking, a promising idea is noted but then the thinker moves on to generate more ideas, one of which may be even more effective. Lateral thinking prevents the mind from getting 'stuck in a rut'. It offers an opportunity to collect a large number of ideas, no matter how probable or improbable, before moving on to pursue any one of them. De Bono even advocates for the temporary suspension of disbelief while lateral thinking. He suggests that lateral thinking should allow ideas to be entertained without proof and even ideas that could be proven wrong, citing the possibility that an improbable idea may be later proven correct in a different reference frame. De Bono claims that "the purpose of thinking is not to be right, but to be effective… Being right means being right all the time. Being effective means being right only at the end." In vertical thinking, validity is assessed at every step of the process and many ideas are excluded on the way to selecting an answer. In lateral thinking, invalid arrangements of information are allowed, recognizing that they may lead to a perfectly valid and novel restructuring of the information. Thus there is an idea exploration period in which the logical rigor to which we are accustomed is ignored, followed by an idea assessment period in which the raw material of these ideas is sifted through to see what stands up to logical assessment. This two-phase process is very effective for brainstorming, design, and other creative processes.

Examples of Lateral Thinking

One of the most basic assumptions of lateral thinking is that there are multiple ways of looking at something. A concrete example of this is the act of producing a certain number (say, 20) alternative descriptions of the same thing. In lateral thinking the purpose is to find as many approaches as possible, so it is the quantity of alternatives that is most important rather than the quality of each idea. Limiting oneself to good and valid descriptions would make it nearly impossible to produce an arbitrarily large number of descriptions. In lateral thinking, validity should be ignored for the sake of variety so that the most diverse possible set of ideas is created. Particularly good ideas can be noted and returned to after the initial generative phase.

Five Whys

A major technique of lateral thinking is to challenge assumptions relating to the problem. Consider which dimensions are not constrained or are only implicitly constrained. Some of the constraints, explicit or implicit, may not be valid. One technique to begin thinking like this is the game of serial whys. For any given rule, assumption, or fact, ask “why?”. For the given explanation ask “why?” again. Continuing in this way will reveal not only the root of each constraint but also its possible arbitrary nature. As De Bono puts it, “It is historical continuity that maintains most assumptions—not a repeated assessment of their validity.”[1]

Fractionation and Reversal

Fractionation and reversal are slightly more abstract examples of lateral thinking.

Fractionation consists of breaking a problem into lots of parts or fractionating it. The tendency is to break a problem into well defined parts. For example, when asked to brainstorm new ideas for an engine, a group may break it down into pistons, cylinders, and a crank shaft, but these parts are defined by the solution of a modern engine and any recombination of them is bound to fit that same pattern. In order to break out of the dominant pattern, the engine must be fractionated into parts which do not force the way in which they are put together. Thus a fractionation of an engine could be: convert energy to motion, change direction of forces, chemical energy, potential energy, mechanical energy, heat, turning, pushing. These fractions both overlap and do not completely describe an engine, but once the fractions have been generated, they can be recombined to yield a much larger number of different engine designs. The fractions can be used to build a new idea from the ground up, hopefully avoiding the dominant pattern.

Reversal is a way of looking at a situation from a new perspective by inverting, negating, upending or reversing roles in a situation and reassessing the resulting combination. This is sort of like looking at a situation like it is a Russian reversal joke e.g. ‘In the United States, you break the law; in Soviet Russia, law breaks you.’ Another example, given in De Bono’s book relates a story of a shepherd with a large flock traveling along a narrow road with tall embankments. A man in a car drives up and asks him to move his sheep to one side so that he can pass quickly as he is in a hurry. The shepherd refuses because he is worried the man will hit one of the sheep with his car. Instead, the shepherd asks the man to stop on the road and allow him to guide his sheep back the way they came until they are all behind the car, allowing the man in his car to be beyond the sheep without putting them at risk.[1] Reversal and fractionation may not result in a functional new idea but they may shed new light on the problem.

Suspension of Judgement

What all of these lateral thinking techniques have in common is that they rely in the suspension of judgment. A wrong idea at some stage may lead to a right idea later on. For this reason, is important not to discount an idea or approach because it does not seem relevant, valid, or correct. When working in a group to generate ideas, one of the worst things one can do is not share an idea because of doubt in the validity of one's own thinking process. A wrong idea shared and digested is more useful than if it were struck down before being uttered. The idea may echo off of another person's conscious and trigger a great and valid idea. It is just as important not to condemn or refuse to accept someone else's idea if it seems wrong. In lateral thinking, do not rush to judge or evaluate ideas. Explore how each idea can be useful. Even wrong ideas can aid thinking. The longer an idea is in circulation, the more it can offer for the development of new ideas. We all have an ingrained habit of forcing an idea in the direction of logic. Instead, follow an idea in the direction it is leading to see what you may find there.

Brainstorming

Brainstorming is something that we have done since our early schooling, yet it almost seems as though we get worse at it as we go through school. It is a process that requires creative and open thinking and discourse rather than calculated analysis and debate. The purpose of brainstorming is to quickly explore the idea space and to document these ideas so that they can then be assessed later. There is no one right way to hold a brainstorming session. One way to frame a brainstorming session is to convert a need statement to a set of questions of the format "How might we ___?". Asking 'how' allows group members to begin imagining a variety of approaches to achieve the end goal. The group could also approach a brainstorming session as a "painstorming" session. Similar to the age old stand-up comedian joke set up "You know what I hate about ___?", the group brings up all the things that cause the problem's current solution to be a pain and then go about devising ways to avoid these pains. Brain storming usually requires a facilitator who both enforces brainstorming good practices and keeps the session moving. Having a scribe to document each idea in an organized way is also indispensible.

Rules of brainstorming

The following rules of brainstorming are adapted from those suggested by IDEO Lab:

- Defer judgement

    - Don't dismiss any ideas at this stage. It is not the time to say "that won't work because…"
- Encourage wild ideas
- Build on ideas of others
    - Drawing on one of the cardinal rules of improv theater, try to make your first reaction be phrases like "yes, and…" or "what if" rather than "but…"
- Stay on topic but think broadly
- One conversation at a time
- Use all your senses
    - Draw what you are thinking of
    - Use post-its to organize and reorganize
    - Make mind-maps
    - Build a quick and dirty model that can be held and touched
- Quantity is important
- DOCUMENT
    - Give each idea a number so that it can be referred to later

Ways brainstorming can go wrong

- Facilitator does all the talking or rigidly determines who talks and when
- Ideas are immediately assessed after being articulated or even worse—ideas are assessed *before* being articulated and are never shared
- Keeping ideas separate and not allowing mixing of the good parts of two ideas
- People talking over each other or having side conversations
- Ideas are not recorded and are soon forgotten
- Premature attachment to one idea

Design Session

Agree on the need statement the team will be creating designs for and then assign each member to create a visual design (sketch, model, etc) on their own time when they can think deeply and concentrate. Set a time to reconvene and present and discuss each design as a group.

1. Resist the temptation to judge the design's methods, function, or effectiveness.
2. Resist the temptation to choose a preferred method or front-runner to allow all designs to prosper at this point.
3. Encourage variety of solutions and note the multiplicity of means for achieving an end.
4. Look beyond the specifics of the design to see the intention of the designer.
5. Note the critical features and non-critical features.
6. Question design decisions to understand the designer's thought process.
7. Recognize assumptions and challenge them.

References

1. Bono, Edward De. *Lateral Thinking: Creativity Step by Step*. Perennial Library, 2015.

Chapter 6

Stakeholder Analysis: Investigate the Broader Context

Taking people into account

Your project begins and ends with people. As discussed in previous chapters, the need you are working on should be something experienced by real people. Real people will be the ones who adopt or reject your solution. The need and solution may affect patients themselves or patients' families. It could also affect the experience of the healthcare team whether that be doctors, nurses, physician assistants, medical assistants, nurse practitioners, etc. The list of people (and entities) directly or indirectly affected by a solution does not stop there. The solution would likely also affect funding organizations such as insurance providers, public payers, private payers, or humanitarian aid groups. Groups like government officials and hospital leadership will also be affected by the solution. In addition, they will also have the power to determine the future use of the solution. This power should also be taken into account. Together, these groups of people and these entities are the stakeholders of the project. In stakeholder analysis, innovators systematically examine the direct and indirect motivations of each group involved in the delivery of care.

Each stakeholder has the power to drive or inhibit adoption of healthcare products and services. Systematically analyzing the different perspectives of each stakeholder allows innovators to anticipate potential conflicts and resistance to adoption. Starting stakeholder analysis early in the design process can increase the chances of success by guiding design, development, and implementation decisions.

Systematically identify stakeholders

Stakeholder analysis begins with identifying who the stakeholders are. The two major methods for doing this are cycle of care analysis and flow of money analysis.[1] In cycle of care analysis, stakeholders are identified by tracking a patient through the healthcare system all the way from experiencing first symptoms, to traveling to the hospital, to emergency room triage and intake, to diagnosis, to treatment or referral, and finally to ongoing care and follow-up. For example, if your team is looking at the need for a simpler way to diagnose a broken arm, the team would first think about the cycle of care for that healthcare problem. 1) The patient suffers a fall and subsequent injury. 2) The patient's family member helps them and perhaps gives a bag of ice and some ibuprofen to the patient before driving them to the emergency department. 3) At the emergency department a triage nurse asks for the chief complaint and performs an intake. A medical assistant may take the patient's vitals. 4) The patient is transferred to a room in the emergency department by a nurse. 5) A physician assistant or physician obtains a history and performs a physical exam. 6) The provider orders x-rays of the arm. 7) A radiology technician takes images of the patient's arm. 8) The radiologist reads the images and diagnoses a non-displaced fracture. 9) A medical assistant places a temporary splint on the arm. 10) A physician or physician assistant explains the injury to the patient and family and gives them the phone number of an orthopedic surgeon to call. 11) The family member calls the orthopedic surgeon's office the following day and speaks with an office coordinator. They schedule an outpatient appointment to be seen by the orthopedic surgeon. As you can see, a patient's cycle of care consists of many interactions of varying duration and intensity. Each of the people involved in the cycle of care can be considered a stakeholder as each one has different motivations, requirements, and interests.

Flow of money analysis looks at the healthcare interaction from a different angle: the direct and indirect financing of a healthcare event. Flow of money analysis focuses on who pays for services and procedures related to the diagnosis and treatment of a disease. To a large extent, healthcare is economically driven and analysis of those who have a financial stake related to a healthcare need gives insight into who the decision makers are when it comes to diagnosing and treating a disease. Sometimes the financial relationship is simple and a patient pays out of pocket directly to a physician for a service or procedure. Often, however, intermediaries are involved. Patients may have private or public insurance. Public insurance is funded through taxes. Private insurance may be paid for by patients or by their employers. After performing a service, a physician my bill an insurer themselves or the facility at which the physician works may interface with third-party payers like insurance companies. The patient may also be charged an out-of-pocket copay. Each of these stakeholders can affect the way in which healthcare is delivered. Reimbursement for a service or procedure may be affected by policies of insurers. Patients may choose not to receive a service after weighing the financial cost and health benefits. Facilities may also enact policies affecting patient care after their own financial analysis. Tracking the flow of money in a healthcare event allows innovators to systematically anticipate and address each stakeholder's financial concerns related to the healthcare need.

Systematically analyze stakeholders

Now that the major stakeholders have been identified, take the time to think about how your solution would affect each stakeholder. What barriers might cause a stakeholder to resist adoption of the solution? What improvements might drive adoption? How would the solution benefit them? How might it harm them? What do you think the group's reaction would be to the solution? Are there any unintended consequences you can foresee? Would conflicts of interest arise? Do any of the groups have interests that would conflict with the goals of the project? One way to organize this analysis is in table format as shown in Figure 1.

Need: Way to perform emergency intubations under visual guidance at low cost.			
Stakeholder	Benefit	Harm	Reaction
Patient	Faster intubations Reduce tracheotomies	May not be reliable	Open to adoption
Family	Help loved one	Harm loved one	Cautious adoption
Doctors	Save time	Incr. malpractice exposure	Resist adoption
Mid-levels	Increase number/complexity of intubations performed	May be beyond their abilities to rectify failure	Adopt
Hospital Admin.	May reduce costs	Malpractice liability	Mixed: worry of malpractice, but acknowledge time and money savings

FDA		Public outcry if shown not to be safe	May be cautious about approval

Figure 1. Example stakeholder analysis table with each entity as a row and columns answering the above questions.

Just as your project has the ability to affect the stakeholders, the stakeholders can also influence your project. Who might oppose adoption of your solution? What influence does each stakeholder have? What skills and resources do the stakeholders have available to aid in the success of the project? To what extent should each stakeholder be involved in the project? These sorts of questions are worth considering because they may encourage you to consult with other groups to guide your solution design. Innovators may also develop mutually beneficial relationships with stakeholders, thus increasing the chances of success.

References

1. Yock, Paul G., et al. *Biodesign the Process of Innovating Medical Technologies*. Cambridge University Press, 2015.

Chapter 7

Evaluate Ideas

Process the raw material from a brainstorming session

As explained before, there should be no critical analysis during an idea generating session. Brainstorming only works if judgment is withheld, allowing all sorts of ideas to flow forth freely. At a later date, it is important to do something with the raw material that was generated during a brainstorming session. Innovators can reconvene the following day or some time later for an evaluation session. In an evaluation session, the group is looking for ideas that will be immediately useful without need for alteration, Ideas that will offer new ways of considering the problem, new directions for further investigation, and ideas which could be tested quickly and cheaply. Ideas which have been tried already should be noted. Ideas which are ridiculous or flat out wrong should not be immediately dismissed, but should be interrogated for what generalizable truth they contain as they may point the group toward a more reasonable approach. As you can tell, this process is not just potato sorting, tossing ideas into the good pile and the bad pile. The object is to extract and distill as much good as possible from the previous brainstorming session, and it requires manipulating and developing these ideas during the session.[1]

Concept Clustering

After all of the brainstorming ideas have been processed, you should have a list of well fleshed out ideas and concepts. Each concept should be a specific and detailed solution to the problem rather than just a general approach. During this stage each concept will be assessed on its concrete merits so it should not be a nebulous, fuzzy idea. To facilitate discussion, each concept should be given a short, unique, explicit name e.g intravascular filter or drug eluting mesh. This name will help all team members remain on the same page about which idea is being discussed. The Biodesign book introduces a technique of concept clustering which allows the team to look for gaps, biases, and possible synergies among their candidate solutions.[2] Concept clustering consists of creating families of concepts according to specific differentiating categories. This can be done by writing each concept's name on a post-it or

3x5 card and sorting them into groups. Alternatively, a concept map can be drawn on a whiteboard with the problem statement in the middle and each concept cluster branching off in a hierarchical organization. Examples of categories to use are anatomical area, mechanism of action, type of engineering required, feasibility, funding required, and appeal to stakeholders. Performing this task may lead to other solutions in overlooked categories or reveal that the candidate solutions were biased in a particular direction unnecessarily. Once this task is complete the candidate solution list should be relatively thorough and quite long. The following section will discuss methods for paring down this list to promising solutions which will be carried forward.

Concept Selection

Starting with the need statement, develop a need specification enumerating and detailing all of the requirements for a solution to that need. This specification includes must-have criteria and nice-but-not-necessary criteria. These criteria can now be used to assess candidate solutions. First, the must-have criteria can be used to screen the large number of solutions. If a solution does not meet all of the must-have criteria, it is out. Then, to distinguish between the remaining viable ideas a more careful approach is needed. When selecting which solution to carry forward, innovators may want to begin thinking about the relative merits of each idea in terms of intellectual property, regulatory, reimbursement, and business models. This is a good time to consult with experts in the fields related to your candidate solutions whether that be physicians, nurses, patients, engineers, scientists, or business people. After more information is obtained, individual solutions can be formally compared, allowing your group to select which candidate solutions to carry forward.

Decision Matrix

A decision matrix is a relatively simple tool for evaluating ideas which uses a spreadsheet to numerically compare ideas based on defined criteria. Because the differences between ideas can be aggregated into a single score, it lends itself not only to comparing ideas but also to selecting one or a few best ideas. Step by step directions for building a decision matrix can be seen below.

1. List each idea as a row.
2. List each assessment criterion as a column.
3. Decide the relative weight of how important each assessment criterion is.
4. For each assessment criterion, go down the column and assign a score for how well each idea meets that criterion.
5. To calculate the total score, go along each row multiplying the scores by their weight percent and add all of these together.

Relative Weight	1	2	1	4	2	10
Weight %	10%	20%	10%	40%	20%	100%
Option	**Attribute 1**	**Attribute 2**	**Attribute 3**	**Attribute 4**	**Attribute 5**	**Score**
Option A	8					1
Option B						0
Option C						0
Option D						0
Option E						0

Figure 1. This chart gives an example of the necessary items for creating a decision matrix on spreadsheet software like Excel or Google Spreadsheets. The Weight % is calculated by dividing the relative weight by the total of all the relative weights and multiplying by 100.

Dot Voting

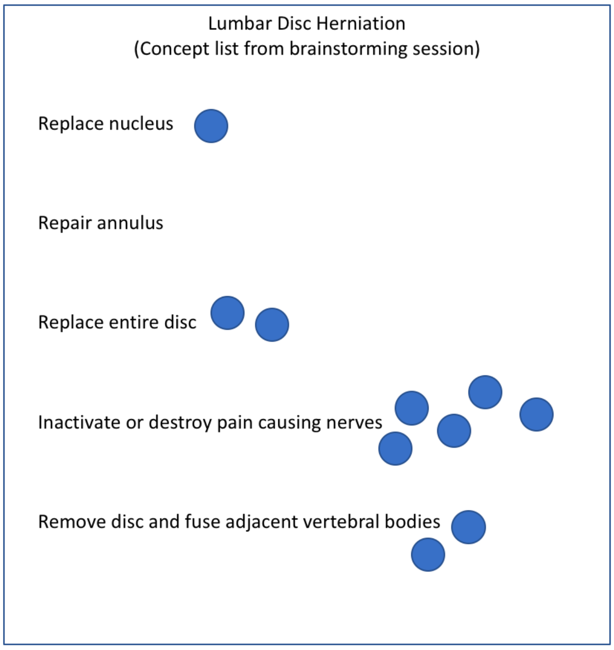

Figure 2. Teammates use blue dots to vote on which solution concept they think would be the best to develop going forward.

After screening and systematic assessment, your team will likely be left with a small number of leading solutions. Once the number of candidate solutions has been narrowed down, it will become necessary to select just one to carry forward at least for now. Dot voting is a way for each team member to anonymously vote on which solution(s) they prefer. In dot voting, each team member is given a few dots (these can be stickers, post-its, paper with tape on it) and the candidate solutions are written on a board. Everyone is allowed to go to the board at the same time and anonymously put dots next to the solution they prefer most (Figure 2). They may put more than one dot by a solution if desired. The solution with the most dots next to it after all the dots are placed is the winner.

References

1. Bono, Edward De. *Lateral Thinking: Creativity Step by Step*. Perennial Library, 2015.
2. Yock, Paul G., et al. *Biodesign the Process of Innovating Medical Technologies*. Cambridge University Press, 2015.

Chapter 8

Prototyping

"If a picture is worth a thousand words then a prototype is worth a thousand pictures."

–IDEO Labs

The utility of prototyping is to answer questions

A prototype is a model which makes the theoretical aspects of a device physical, observable, and even testable. A prototype can embody an entire device or just part of it. Prototypes can range from entirely non-functional to a fully functional first iteration of a device. The purpose of prototypes is to answer specific questions. An early prototype can be a nonfunctional item that answers how something will look or a more functional item which shows how it will work to use. A prototype can also serve as proof of concept, showing whether the most difficult to achieve functionality of the design is indeed possible but not going into detail on the more run-of-the-mill parts. Another use for prototypes is to guide manufacturing decisions such as what materials and manufacturing processes should be used for each part and what the maximum production cost can be before the device becomes uneconomical. Prototyping allows design teams to work out most of the kinks in a product during the development stage so that they are not unpleasantly surprised after the product is in production.[1]

Prototype uses

- Idea exploration
- User testing
- Appearance
- Physical Testing
- Design verification
- Technical performance testing
- Safety standards testing

Start fast, cheap, and easy

Early on in the prototyping process, it makes sense to use cheap, lightweight, easy to handle materials because the design is in its infancy. Your team may determine that they need to go back to the drawing board after this first prototype and start over. It would be a shame to have spent 8 hours creating a virtual model in CAD and another 12 hours printing the first prototype only to find that you overlooked something. An early prototype can be made of foam core, modeling clay, balsa wood, polystyrene foam, or other easily manipulated cheap materials.[1] These materials have the added benefit of allowing the prototype to be altered dynamically, adding, removing, and rearranging parts of it as the group explores and interrogates the first physical embodiment of their idea.

Iterate

The famous design firm IDEO is quoted as saying "fail often to succeed sooner", meaning that a design group will arrive at a successful design more quickly if they have a low barrier to trying out their ideas, assessing them often, and returning to the design phase if the idea isn't working.[1] In the realm of prototyping this translates to making many iterations of a design, recognizing the flaws and successes in previous prototypes and creating an improved design in the subsequent iteration.

A structured prototyping method

The prototyping needs of each project will be unique, however there are several published strategies for how to approach the problem. The book *Prototyping and Modelmaking for Product Design* suggests breaking the design problem into smaller, more focused prototyping tasks or functional blocks.[1] Some of the functional blocks will be novel and perhaps difficult to anticipate how they will be solved. This is where innovators should focus their prototyping efforts. Prototyping solutions to each of these blocks will aid in design development and understanding. In his book, Halgrimsson introduces the concept of fidelity which is basically the degree of detail of a model or how closely it represents the intended final product.[1] Early prototypes should be low fidelity, meaning that they may not exactly represent the product, but are more likely to be quick and dirty studies of the basic nature of the design or even just parts of the design. The two major types of prototypes are looks-like prototypes and works-like prototypes. Looks-like prototypes are low-fidelity prototypes which do not function that are made to demonstrate just the physical structure and layout of an invention. Figure 1 shows an example of a looks-like prototype. They are made with light weight, easy to work with materials to quickly arrive at a candidate design. Works-like prototypes are also relatively low-fidelity at first but they include working parts to prototype the core functionality of the product. Works-like prototypes are often meant to be handled, so they are made with more durable materials. They may not perform the complete function of the invention, but they demonstrate one or more functional characteristics which the designers want to test out. Figure 2 shows an example of a works-like prototype of an electronic device.

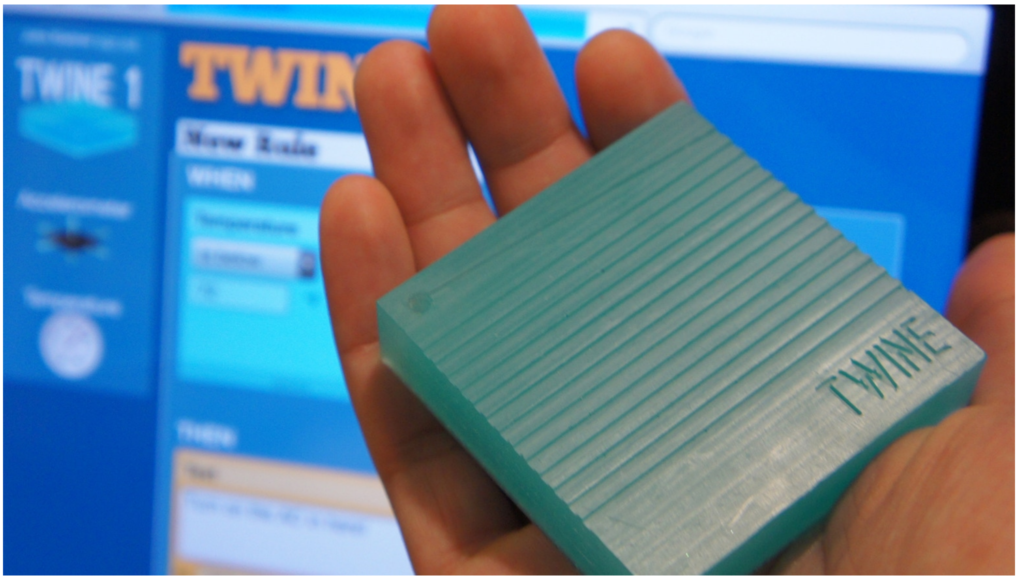

Figure 1. This looks-like prototype of Supermechanical's Twine internet connected sensor is a cast polyeurethane block made to resemble the intended final product.[6]

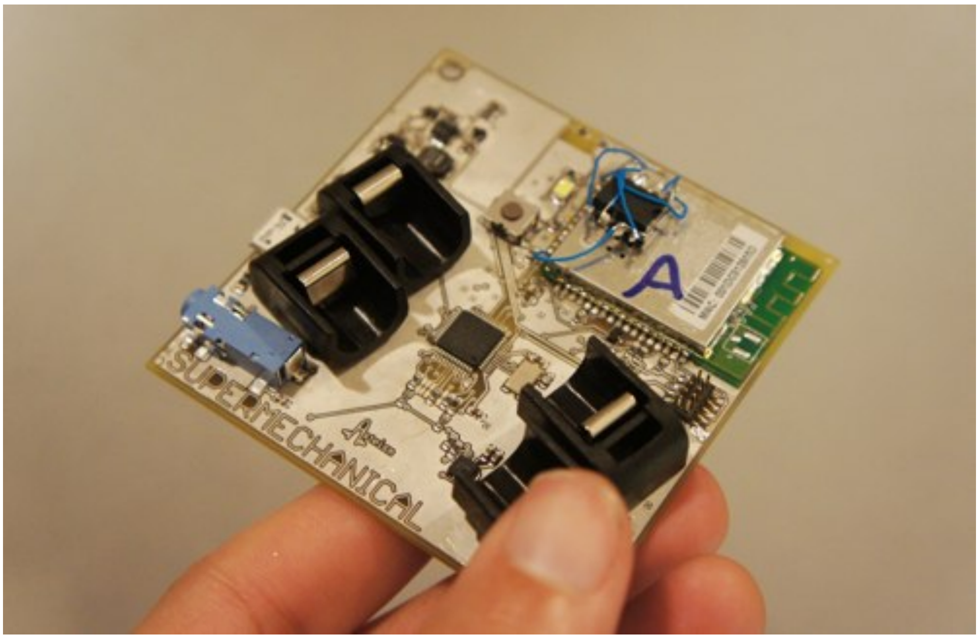

Figure 2. This works-like prototype of Twine is a small production run printed circuit board with all of the necessary electronic components for the prototype to function.[7]

The first step to building a prototype is to sketch the idea in 2D. Consider the purpose of the prototype during this phase. Is it a works-like prototype or a looks-like prototype? The prototyping materials and degree of detail will depend on its intended use. If being used to explore the functional characteristics of the design it will need to be a sturdy prototype since it will be handled often, but it may not need to include all of the details and form of the final product. If the prototype will serve as a demonstration of how the final product will look, care must be taken to create an accurate model with good craftsmanship, especially of the exterior forms and surfaces. Functionality and sturdiness may be secondary considerations at this stage. 2D sketches can be drawn by hand or in applications like Adobe Illustrator or CoreDRAW. AutoCAD, Rhinoceros, and SolidWorks can be use for both 2D sketches and 3D renderings. 2D sketches can be used as templates for production of the model if using modeling materials like paper, foam, or modeling clay. If you are planning to use 3D printing or CNC machining to create your 3D model, 2D sketches will be used to produce 3D CAD files.

Model making can be divided into two major processes: additive modeling and subtractive modeling. Subtractive modeling is to start with a large chunk of material and to remove parts of it until what is left is your model. This is like whittling a piece of balsa wood to produce a model of a car. Marble sculptors and CNC routers work by subtractive modeling. Additive modeling is to produce your model by building it up piece by piece. Clay sculptors and 3D printers work by additive modeling. Additive manufacturing allows the creation of many simpler geometric parts which are then combined to create the final model. Because of its speed and adaptability additive manufacturing is usually more effective. For looks-like prototypes additive manufacturing allows the finishing (sanding, painting, etc) of each part individually before they are combined. It also lends itself to rearranging of individual parts to try new ideas. For works-like prototypes, hardware like hinges, springs, clasps, and electronics will likely need to be incorporated to give the model its mechanical and electrical functions.

Prototyping tools

Prototyping and Modelmaking for Product Design goes in to substantial detail about many common prototyping tools. It discusses basic hand tools, power tools, and machine shop tools and briefly goes over common uses and major considerations when using them. I am not sure how useful reproducing that discussion here will be, so I will just be covering 3D printing in this manual. 3D printing is an additive manufacturing technique in which a three dimensional computer model of an object is used as instructions for a machine to build that object layer by layer. There are many different 3D CAD (computer aided design) programs, some of which are free and some of which require a license. Availability and ease of use will likely determine which you may want to use. The file type that 3D printers understand is STL, so a 3D CAD file must be converted to STL before attempting to 3D print it. The STL format approximates a surface using tessellated triangles. Depending on the size of each triangle a curved surface will look more or less blocky. The object in Figure 3 is rendered in relatively high detail with a large number of triangles.

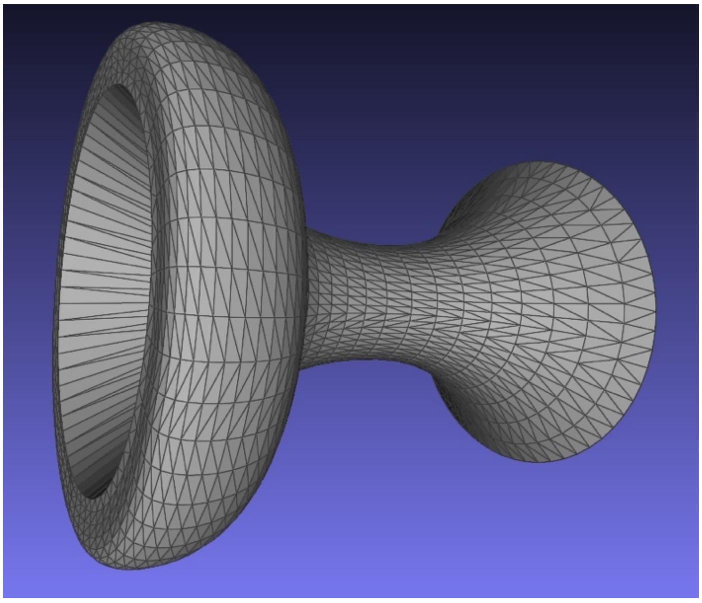

Figure 3. This is an example of a 3D image in STL format with its surface rendered as tessellated triangles.[2]

Another consideration when planning a 3D print is that the structure needs to be stable at all times when it is being printed. Because 3D printers build the object layer by later, they can only build upon a previous layer or the floor of the printer surface. Parts cannot be floating in the air as they form; they must be laid down on some form of supporting structure whether that is part of the object itself or support structure added specifically for the practicalities of printing. Support structures should be placed wherever there is not already any structure between part of the object and the floor of the printer. If the angle of the overhang is less than 45 degrees, a support may not be necessary. Depending on the details of your object, it may make sense to print it in a different orientation than you would expect as this may reduce the number of supports needed. Luckily, as shown in Figure 4, many 3D printing programs can determine for you where supports should be placed.

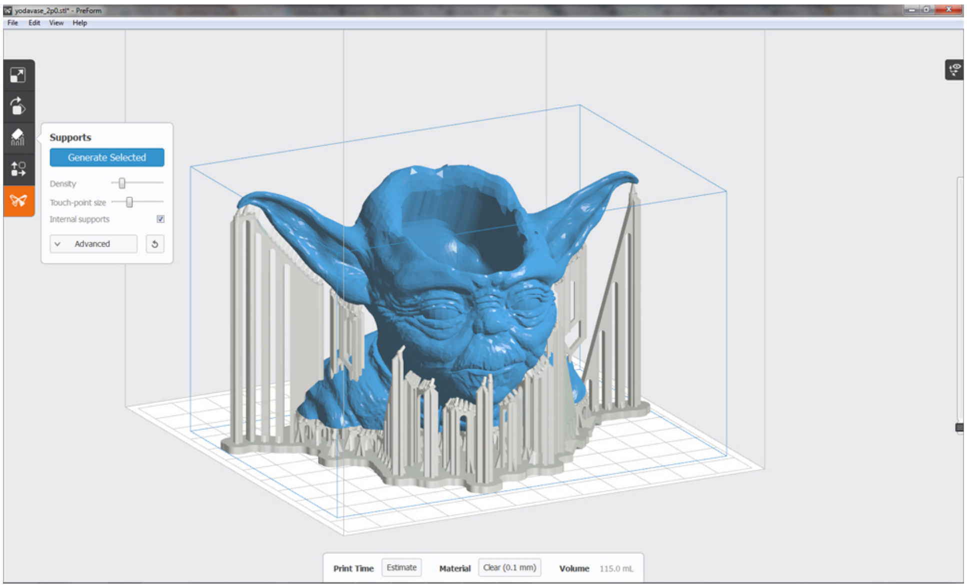

Figure 4. Many 3D printing software packages can automatically generate support structures. In this screenshot, a blogger on 3Dprintingforbeginners.com has imported a yoda vase STL file to a program called PreForm. The menu in the top left shows the sliders to control support density and size of the points at which the supports touch the object—the only two inputs the program required to yield a printable object.[3]

Resources at UTSW

The UTSW Makerspace is located in the K building. It offers basic hand tools, sewing equipment, electronics equipment, and some machine shop tools (e.g. drill press, bandsaw, etc). There is also space to store project materials. There are two 3D printers available for student use on campus, a Lulzbot Taz 5 fused deposition modeling printer (Figure 5) in the library and FormLabs Form 2 (Figure 6) stereolithography printer in the makerspace. If additional resources are needed, the Dallas Maker Space in Farmer's Branch is a great resource in terms of both equipment and expertise. Starving students can obtain a month-to-month membership for $35 per month at the time of writing this.

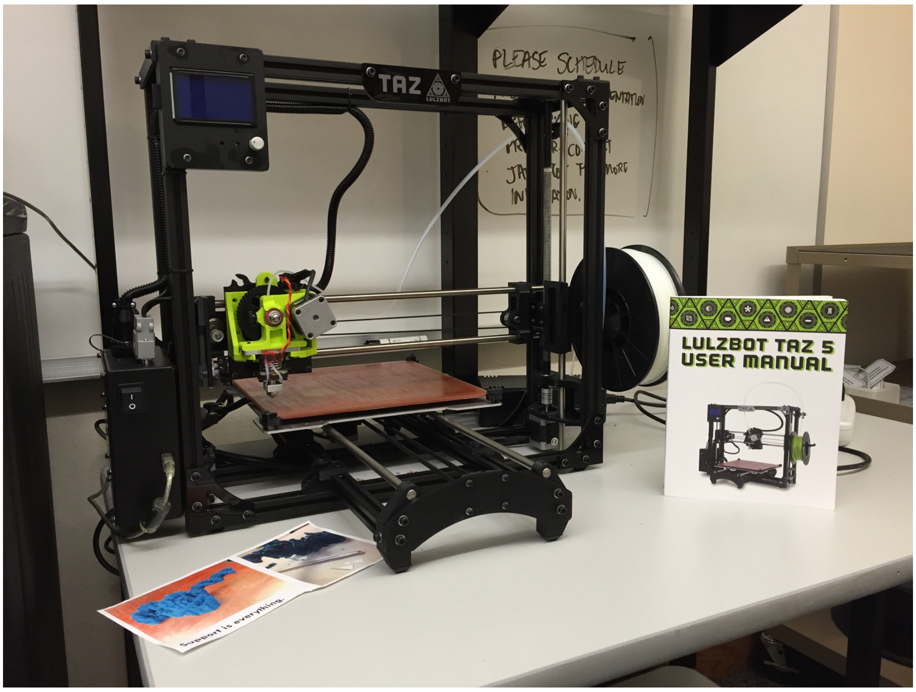

Figure 5. The library offers a FDM printer for student use. This type of printer fuses bits of plastic filament to build up the 3D printed object.

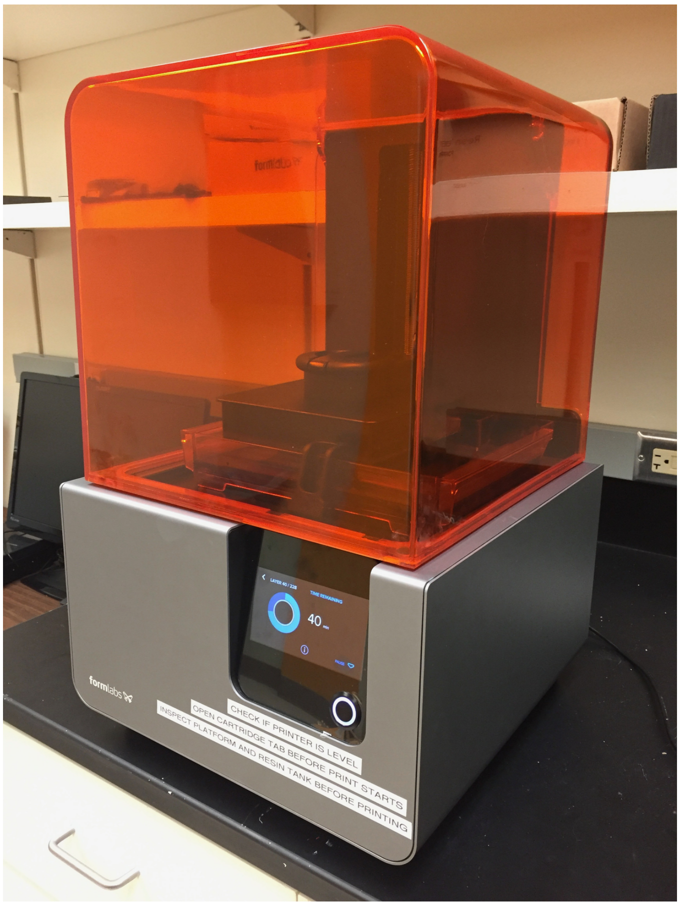

Figure 6. The UTSW Makerspace includes an SLS printer. This type of printer uses UV light and a photopolymer which is fused by a radical reaction to build up the 3D printed object.

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Chapter 9
Intellectual Property

Intellectual Property: trademarks, copyrights, trade secrets and patents

Intellectual property (IP) is a general term for intangible property rights that are awarded in exchange for disclosure of the results of creative intellectual effort. There are four main types of IP: patents, trademarks, copyrights, and trade secrets.[1] Patents protect utilitarian inventions such as hardware, devices, and biotechnology, while copyrights protect artistic compositions such as a book, music, or even software.[1] Likely, the most relevant IP construct for your group is the patent, however, trade secrets may also be relevant. Trade secrets are things like production methods, formulas, business plans, or sets of data. It is not necessary to officially register a trade secret. Simply by taking efforts to keep information secret (non-disclosure agreements, password protection, etc) the information can be considered a trade secret. In this way, trade secrets can serve to protect information until patent applications are filed.[1]

As Siva Vaidhyanathan succinctly defines it in his book, *Intellectual Property: A Very Short Introduction*, "a patent is a state-granted limited monopoly".[2] The main function of patents is to serve as protection against imitators. In exchange for disclosure, the inventor is granted an enforceable protection against other competitors using her ideas for a finite amount of time. This is thought to offer an incentive to develop a product commercially as it gives the inventor a temporary competitive advantage.

Patents

There are three types of patents: utility patents, plant patents, and design patents. Utility patents are what we will focus on here. They protect any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.[1] This protection also includes software algorithms, business methods and even therapeutic processes.[2] A utility patent describes the necessary elements of an invention in enough detail that someone with skill in the field would be able to reproduce the invention. Applying for patents can be expensive, so a strategy must be devised about which aspects of a new invention should be patented to offer the greatest competitive protection. The decision about which designs, functions, configurations, or methods to protect depends greatly on the business strategy and competitor landscape. Before applying for a patent, the invention does not need to be 100% worked out, however. Many inventors delay pursuit of a patent because they mistakenly believe that they have to have a working prototype or at least a well-established design of their invention before filing. Because patents are worded to claim as broad a scope of invention as possible, it is often not necessary to have a prototype or exact knowledge of how the invention will work so long as the essential characteristics are established.[1]

Prior Art

An invention must be both novel and non-obvious in order to receive a patent. To determine novelty, one must look at the prior art. The prior art is the body of publicly available information (patent or otherwise) related to your invention. This includes any published writing (including but not limited to patents), any U.S. patent, any relevant invention itself whether described or just in physical existence, and any public or commercial use, sale, or knowledge of the invention more than one year prior to the application filing date.[3] This means that a patent application is not valid if there is a previous patent describing the invention. It also means that a patent application is not valid if the invention is currently in public use even if it isn't patented.

Perform a prior art search

While the prior art includes much more than just patents, the US and European patent databases are a convenient place to start a search. The United States Patent and Trademark Office (USPTO) groups patents according to a class and subclass system. There are over 100,000 different classes and subclasses. While this may sound boring, it can be a powerful tool to find patents related to your invention. We all know how to search for keywords and are likely even pretty ok at using Boolean search terms, but these results will only be what you ask for and you don't always know what to ask. Tapping in to the way the USPTO structurally organizes their patents allows you to see similarities between patents the way that a USPTO patent examiner would.[3] You can see all of these classes in the Manual of Classification on the USPTO website. The US patent office and European patent office recently agreed to use a harmonized (i.e. shared) classification scheme called CPC. It's probably better to use this system in your research than the US system.

The USPTO suggests a seven step strategy for a preliminary search of US patents, but it's overly complicated and their database tools are straight out of the '90s.[4] The USPTO website is pretty good for navigating through the Manual of Classification, but I would suggest using Google Patents to do your keyword searching and actual patent retrieval. Here's how I would approach it:

1. Brainstorm terms to describe your invention based on purpose, composition, and use.
2. Use the USPTO search box to search the following "CPC scheme (your keyword)". Collect a list of classifications that you think might be relevant.
3. Go to Google Patents and enter a CPC classification into the first box. The format of how you type it in has to be just right. The whole thing should be run together and all the forward slashes should be kept. No additional forward slashes should be added e.g. A61B5/02028. Consider adding a keyword or two in the second search box.
4. Use the window to the right to see what CPCs came up and who the most common inventors and companies are.
5. Download relevant patents.

A word on novelty

As discussed previously, your invention must be novel in order to be awarded a patent. In this case novelty means that there is no *single* prior art item which describes *all* of your invention's key elements.[3] When searching the prior art, you will likely find inventions that perform similar functions, rely on similar a theoretical basis, or are made from similar materials or in a similar way. Ways you can distinguish your new device include physical differences, combinatorial differences, and new uses. David Hitchcock in *Patent Searching Made Easy* suggests the following systematic approach:[3]

1. Analyze your invention for elements

2. Analyze the prior art references you have for elements
3. Compare the elements of each prior art reference to those of your invention
4. If no single prior art reference contains all of the same elements as your invention used in the same way for the same purpose then your invention is novel.

The author of *Patents Demystified* argues against performing a prior art search given that the chances of having missed something which the patent examiner will find in the prior art are high and the time and cost associated with a thorough search rival, and can even exceed, that of just submitting the patent application.[1] He also warns inventors against attempting to interpret the prior art that they have found in their search, citing the risk of prematurely discounting their invention as unpatentable. He suggests that inventors bring the results of their prior art search to a patent attorney for a couple hours of review and an additional professional search. His book is an approachable and interesting read which goes through the considerations of finding a patent attorney, preparing and submitting a patent, and corresponding with the USPTO.

IP at UTSW

At UTSW the Office of Technology Development handles all things relating to intellectual property for the institution. They encourage prospective inventors to consult with them about their ideas regardless of what stage of development they are in. Inventors start by submitting an intellectual property questionnaire describing their invention.[6] This allows the Office of Technology Development to begin a preliminary prior art search and to evaluate the invention to determine whether to develop and execute an intellectual property and commercialization strategy. The UT system policy gives inventors 50% ownership of any successfully pursued intellectual property.[5] It should also be known that according to the UT system, intellectual property belongs to students if it was developed by students during a course, an extracurricular activity, or during their own time using campus resources paid for by their tuition. If the student was paid to do the work or collaborated with an employee to develop the intellectual property, this rule does not apply.[7] The UT Southwestern policy differs, however, stating that intellectual property developed by students is assigned to the Board of

Regents.[5]

One of the barriers to pursuing intellectual property for students and faculty at an academic institution is the inability to see how it will fit with other career plans. Licensing is an alternative to developing a business complete with manufacturing and marketing capabilities to commercialize an invention. It is a contract with another company allowing them the right to produce and sell the invention in exchange for an ongoing payment or a single time payment.[1] Universities and Medical Centers like UTSW often opt to go this route as the intention is usually not to create a new business surrounding an invention. Patenting UTSW inventions and licensing those patents to existing companies is one of the missions of Office of Technology Development.

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Chapter 10

Regulatory Process

Introduction

Medical devices are regulated by the FDA. They are separated into three classes based on risk. Each of the three classes of devices requires a different level of regulatory testing and review. The FDA scrutinizes new devices for both effectiveness and safety. When the FDA approves a device, it is approved for a particular indication, meaning that it has been shown to be effective for treating or diagnosing a particular disease. The FDA does not exercise control on how doctors use a particular device, however. As a result, a device can be used for a number of of indications whether they have been individually approved by the FDA or not. This rough guide should get you started in the right direction for pursuing FDA approval for your device.

Classify your device

The FDA has established classifications for 1,700+ types of devices. Subsets of these classifications are owned by 16 different panels, each corresponding to a different medical specialty. Each of the generic device classifications is sorted into one of three regulatory classes stratified by risk.

Before setting out to classify your device, the first question to answer is whether it is a medical device at all. According to the FDA, a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component or accessory which is either a) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease or, b) intended to affect the structure or any function of the body of man or other animals.[1]

The next step is to define the intended use of the device. What is the clinical condition being diagnosed or treated? Who is the intended patient population? What is the method and site of use? Who will use the device?

There are three classes of medical devices based on the risk associated with the device. Class I is the lowest risk. Class I devices are generally exempt from premarket review but subject to post-market general controls. This means that Class I devices must be registered with the FDA, branded appropriately, and manufactured properly but many do not need to pursue FDA approval.[2] Class II corresponds to moderate risk. Class II devices are subject to premarket 510(k) approval in addition to post-market general controls and special controls. An example of a Class II device is an endoscope. Special controls for class II devices include things like performance standards and post-market safety surveillance. Class III is the highest risk. These devices are subject to premarket approval and post-market general controls and special controls. Special controls for class III devices include evidence of safety and efficacy from clinical trials.

The initial goals for innovators when beginning to think about regulatory approval are 1) to determine which Product Classification Regulation number their device falls under, 2) to determine which risk class their device falls under, and 3) to determine which panel will likely review their submission. The easiest way to do this is to compare the device to those devices that have already been reviewed by the FDA. Predicate devices can be found on the FDA Product Classification Database.[3] Start by searching for related device classifications by keyword.

Key data contained by the FDA Product Classification Database:

- Regulation Number
    - Defines a set of related devices e.g retractor, patient gown, etc
- Product Code
- Intended Use
- Classification
    - Class I, II, or III depending on risk level of device
- Premarket Requirements
- GMP Requirements
- Recognized Standards

- Third Party Testing
- Problems related to the device

Regulatory Pathways

There are three major pathways to regulatory approval, each of which differs by difficulty, cost, and time required. These three pathways are application submission for substantial equivalence through a 510(k), premarket approval (PMA), and device exemption. Device exemption is the simplest pathway to the market. The majority of class I devices (about 75%) are eligible for exemption and thus can be marketed without FDA clearance.

If there is an already approved device that is substantially equivalent (a predicate device), then innovators can pursue FDA approval through a pathway called the 510(k) premarket submission. To determine if a device is substantially equivalent, answer the following question: Is the device for the same intended use? If the intended use is different, then the devices are not substantially equivalent. Do the technological characteristics raise different questions of safety and effectiveness? If they do, then the device is not substantially equivalent. If there are no new or different questions of safety and effectiveness, then the next step is to review the proposed premarket testing scientific methods. If the methods are acceptable, then the device will need to be tested according to these methods. About 90% of the time, testing on animal models and bench testing is sufficient.[4] If the resulting data demonstrate substantial equivalence then FDA approval can be pursued by submitting a 510(k).[2] Most Class II devices are cleared through this pathway. Class II devices without a predicate device must pursue De Novo 510(k) clearance, a process with typically includes more substantial clinical data collection.[4]

The premarket approval (PMA) pathway is somewhat more onerous. It is required for devices that are Class III and for some Class II devices including those which have no predicate device. The major difference lies in the amount of scientific evidence of safety and efficacy required for approval. Typically, a randomized controlled clinical trial is required.[4]

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AUTHOR VITAE

Tim Sotman was born in Fort Worth, Texas in 1991 where he grew up tinkering with anything he could get his hands on. At University of Texas Austin, Tim studied Chemistry in the Dean's Scholars Honors Program. Tim got his start in technology and design working at Supermechanical, an Austin based startup company. At Supermechanical, Tim helped organize the first production run of the Twine internet connected sensor and wrote the code that powers the temperature and vibration sensors. In medical school at University of Texas Southwestern, Tim collaborated with several classmates and faculty members to develop the Biomedical Innovation Program. Following his graduation from medical school, Tim will continue his medical training at Beth Israel Deaconess Hospital in Boston, Massachusetts where he will specialize in Radiology. Tim hopes to continue teaching and innovating throughout his career.