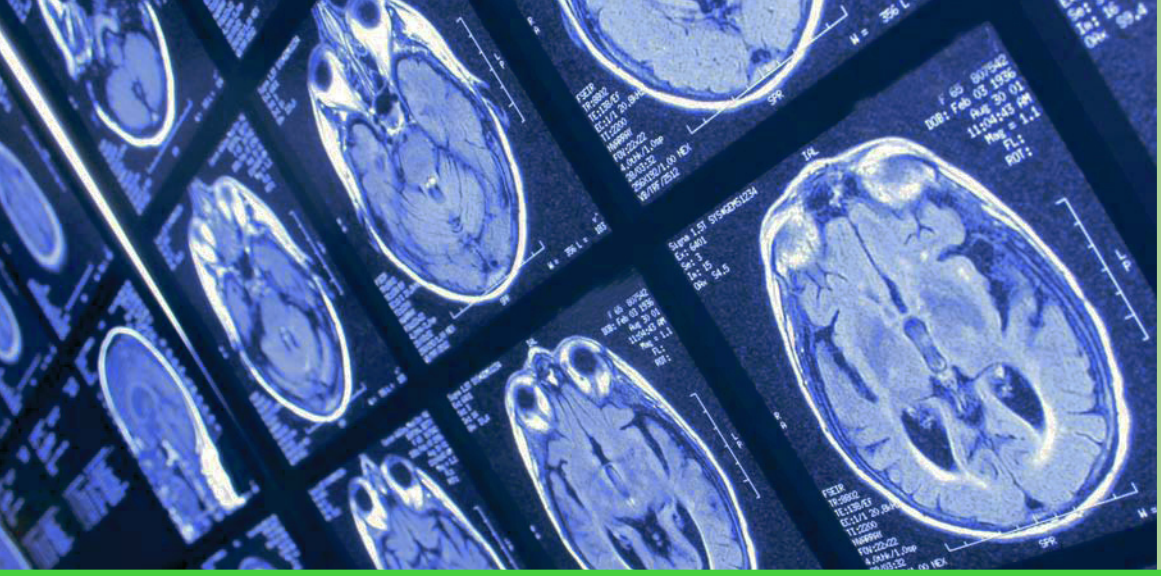

3.1 Ideation

One compelling medical need. Six knowledgeable participants with a range of backgrounds and experiences. Four empty whiteboards. 60 minutes. Plenty of candy. And a goal to develop 75 new ideas – one of which just may be the key to finally delivering a practical solution to a pressing medical need.

OBJECTIVES

- Understand the role of ideation in the context of the biodesign innovation process.
- Learn the basic methods of brainstorming and how to plan and execute a session.
- Consider other ideation approaches and tips that are specific to biomedical technology inventing.

"Ideation," which refers to the process of creating new concepts or ideas, is useful in the biodesign innovation process whenever new solutions are required to address well-defined needs. There are various approaches to ideation, developed for either individuals or groups. The most familiar of these is a form of group brainstorming in which participants are asked to suspend their instinct to criticize new ideas and open their minds to a rapid flow of creative possibilities. Other forms of ideation may take a more structured approach to generating ideas that allows for constructive conflict rather than minimizing it. Innovators may wish to experiment with different techniques in their efforts to come up with solutions to address their needs.

See ebiodesign.org for featured videos on ideation and brainstorming.

IDEATION FUNDAMENTALS

Since the time of Thomas Edison, the stereotypic picture of the invention process has been the "aha" moment – the burst of inspiration from the brilliant mind of the inventor that is portrayed by a light bulb flashing on. Edison himself, however, made it clear that inventing is a disciplined process that involves patience and hard work, saying, "None of my inventions came by accident. I see a worthwhile **need** to be met and I make trial after trial until it comes. What it boils down to is 1 percent inspiration and 99 percent perspiration."[1] Although he became an icon as an individual inventor, the key to Edison's productivity was that he developed a multidisciplinary *team* of innovators in his Menlo Park, New Jersey laboratory. He also knew that the *quantity* of ideas was important, that *prototyping* was an integral part of invention, and that the *failure* of many

potential solutions was inevitable – for example, the lab tried several thousand different filaments before finding a stable material for the first successful light bulb.[2]

Ideation in the medtech field

Invention of medical devices can be more involved and complex than invention in many other technology sectors. In contrast to the situation with many consumer products, healthcare typically involves multiple **stakeholders**, often with competing interests, as well as unique hurdles related to regulation and **reimbursement**. Against this backdrop, innovators may have an "aha" moment at some point, but it will likely come only after investing a lot of hard work and diligence. John Simpson, a pioneering medical device inventor and founder of multiple companies in the cardiovascular space, has a wry but insightful way of describing his inventing process:[3]

> *I know that there have been people who have had these visions and suddenly the design of a catheter pops into their mind and they make it that afternoon and then the following day they achieve enormous wealth. Every morning, I get up, I check my mind to see if it's in there and if it's not, then I go to work. And so far, I haven't missed a day of work yet.*

A few general guidelines related to ideation in the **medtech** field are worth emphasizing at the outset. First, it is important to understand that ideation calls for a mindset that is different from what is required at other stages of the biodesign innovation process. While critical filtering is necessary and important at other points in the process, it can be counterproductive when first considering solutions. Inventors need to open their minds to a creative flow of ideas, set aside their preconceived notions, and look beyond the solutions that they may have been consciously or subconsciously forming during needs screening. It is not important to get the solution completely "right" at this stage in the process. *The need for perfection is the enemy of ideation.*

A second main theme is the importance of cross-pollination in the ideation process. In medtech, abundant opportunities exist to look across specialties to adapt the technologies and approaches from one area to another. Acclarent, a company profiled in this text, is a case in point: it developed a new, minimally invasive approach to functional endoscopic sinus surgery to treat chronic sinusitis by adapting the equipment and procedures of coronary angioplasty that were originally developed for the heart. Medtech is rich with similar opportunities for cross-pollination – between different medical specialties; between physicians and engineers; and even between medical and non-medical technologies. Julio Palmaz, inventor of the balloon-expandable coronary stent, thought of the metal lattice approach when looking at the "chicken wire" used for masonry support.[4] Thomas Fogarty, one of today's most prolific medtech innovators, likes to walk the aisles of a hardware store to look at different materials and tools when he is struggling for new approaches to a medical need.[5]

A third general point is that ideation approaches can be applied at many different stages in the biodesign innovation process. For instance, ideation is particularly useful after the inventor has developed a **need specification** and is ready to begin thinking about different solution **concepts** to address the need. But there are many other circumstances that may be appropriate for this activity, including when an inventor or team is exploring a new or more specific direction for a solution (e.g., finding a delivery method to place a device in a particular spot) or when a team is refining its approach to an already accepted solution (e.g., exploring ways to modify the design of a device to improve its function). It can also be used to address different types of problems, including technical, clinical, or market-related challenges. In fact, solutions to many of the strategic issues that will need to be addressed later in the biodesign innovation process can be developed using an ideation approach.

Finally, it is important to realize that ideation is part of an iterative or cyclic approach. New information and new circumstances crop up at all stages of the innovation process and may require the team to go back into ideation mode. There is an especially important feedback loop between prototyping and ideation: good **prototypes** provide powerful stimuli for new ideas.

A guide to brainstorming

As noted, there are a number of different ideation techniques and a fair amount of controversy about which of these are most effective.[6] For example, some studies suggest that individuals can generate more ideas more rapidly on their own versus in a group.[7] The counterpoint to this view is that group ideation may provide ideas that have more potential for success because they tap into the motivation and capabilities of the team that will be responsible for carrying the concepts forward.[8] Another source of controversy is related to the issue of constructive conflict versus uncritical acceptance of ideas as a guiding principle for group **brainstorming** (more about this later). In the end, as with many other steps in the biodesign innovation process, innovators should experiment with different methods and evolve toward the approach that they personally find most productive and fulfilling.

Framing the question

No matter which approach to ideation an individual or team pursues, an essential first step is to identify the core questions that need to be answered. In the biodesign innovation process, this framing of questions should be based on the need specification – in particular, the core **need statement** and **need criteria** (see 2.5 Needs Selection). In order to transition from the need specification to a more actionable process of ideation, it is useful to employ a tool from design thinking called "How Might We" (HMW) questions.[9] The basic idea is to convert the need statement and criteria into a set of focused questions to jumpstart the ideation process using the format "How might we . . .?" for each question (see the Working Example on this topic). Typically, there will be at least several of these HMWs for a given need. The HMWs should probe different areas based on the different components of the need statement (problem, population, outcome) and/or the most important need criteria. Developing the HMWs is really a first step in the ideation process itself and it lends itself well to some of the approaches outlined in the remainder of this chapter. In particular, it is a useful approach to helping the team shift from focusing on needs to thinking about solutions. To apply the technique, team members should generate a number of HMW questions and then select the handful among them that seem most promising or inviting for full-fledged ideation. As a next step, the team could schedule a series of brainstorming session focused on each question and use the HMWs as a prompt to get the creative process going.

Working Example
Generating "how might we" questions

Consider a hypothetical need statement related to the problem of atrial fibrillation: *a way to identify the onset and duration of atrial fibrillation in patients with recurrent AF in order improve the expediency and efficiency of physician visits.* Suppose the must-have need criteria for this need statement are:

- Easy to implement at home or on the road.
- Comfortable and unobtrusive.
- Sensitivity greater than 90 percent and specificity greater than 80 percent.
- Can be read/deciphered in any physician office.

Based on this information, some sample HMW questions could be:

- *HMW make a tiny recorder that the patient will not even notice?* This could be a good start to a brainstorm. There are likely some fun (if impractical) solutions that would come up in ideation.
- *HMW record a heart rhythm at home without touching the patient?* This is a "stretch" question that carries a challenge to consider some blue-sky opportunities.
- *HMW use a cell phone to record rhythm?* This could be a more practical field for ideation, leading to thoughts about ubiquitous technologies that could be "borrowed" for this purpose.
- *HMW employ online resources to read the EKG for the doctor/nurse?* This focuses on another component of the problem: how the information is transmitted to the physician.

FIGURE 3.1.1
A relaxed space for a company brainstorm (courtesy of Cordis Corporation).

Although HMW questions can be a fruitful way to initiate ideation and move a team into a "solution mindset," innovators should be cautious not to let this approach limit the range of ideas they ultimately consider. For instance, in the Working Example, using a cell phone to record heart rhythm is only one way to measure heart rate at home or on the road. After "warming up" on this approach, the team should be sure to explore other potential solutions as ideation progresses.

The "classic" approach to team brainstorming

Many of the core concepts behind what we now think of as brainstorming – and in fact the term "brainstorming" itself – originated with the work of an advertising executive from Buffalo, NY named Alex Osborn. Osborn outlined a basic set of ground rules that anticipated much of what we now recognize as brainstorming (though the methods have continued to evolve over time through research and practice in both university programs and commercial design firms).[10] Currently, the most widely recognized list of rules for brainstorming (outlined in the Working Example) comes from the design and innovation firm IDEO. A more detailed treatment can be found in *The Art of Innovation*, by Tom Kelley, IDEO's general manager.[11] (Other references are listed in the online Getting Started section for this chapter.)

Working Example
IDEO's seven rules for effective brainstorming

1. **Defer judgment** – Don't dismiss any ideas.
2. **Encourage wild ideas** – Think "outside the box."
3. **Build on the ideas of others** – No "buts," only "ands."
4. **Go for quantity** – Aim for 100 ideas in 60 minutes!
5. **One conversation at a time** – Let people have their say.
6. **Stay focused on the topic** – Keep the discussion on target.
7. **Be visual** – Take advantage of your space. Use objects and toys to stimulate ideas.

1. Defer judgment Deferring judgment is perhaps the most counterintuitive and difficult to follow of all the brainstorming rules. The point is to suspend any critical thoughts or commentary until later in the innovation process (well after the brainstorming session). The purpose of brainstorming is to open up both individual creativity and the group's creative process. One good way to make this happen is to accept any new idea – even those suggestions that seem at first to be impractical or silly – and move on quickly to the next concept.

Learning to defer judgment can be challenging. If some of the participants in a brainstorming session are new to the process, it is especially important to explain this first rule and to practice it with an informal warm-up. Another effective way to make sure that this first rule is followed is to be careful when selecting participants for the brainstorm. There are certain people who are extremely valuable as critics and will be essential later in the biodesign innovation process (e.g., during concept screening), but they do not belong in an early-stage

brainstorming session because they may negatively affect the flow of creative ideas.

2. Encourage wild ideas When brainstorming, participants should do more than suspend their critical filters. They should actually practice thinking in new and creative ways to generate ideas that are true outliers, meaning that they are different enough to offer the possibility of a real breakthrough. Fun (or even silly) ideas serve an important purpose in that they can stimulate collective creativity by building a connection to something far removed from the current conversation. This, in turn, can lead to new inspirations. As one former member of the IDEO team shared informally, "Great ideas hide right behind the goofy ones."[12] In an effective brainstorming session there is a rhythm or momentum that builds up, and this can be stimulated by group members offering far-fetched ideas. Additionally, wild ideas help keep the energy in the session upbeat and thought-provoking, which is essential to the creative process (see Figure 3.1.2).

3. Build on the ideas of others Building on the ideas of others means leveraging one idea as a foundation from which to make another suggestion. The power of this method is seen as one participant's idea stimulates other participants to come up with solution enhancements, novel connections, and even new ideas they would not have thought of otherwise.

One technique for helping participants with this behavior is to encourage them to explicitly say the words, "Building on [this person's] idea, what if …." This approach acknowledges the contribution of the individual with a preceding idea, while also offering a way to enhance or improve it without being critical. This works especially well in brainstorming sessions that include participants across different functional areas or disciplines.

4. Go for quantity A successful brainstorming session builds a flow that breaks through the usual inhibitions of a group. One way to achieve this desired effect is to set a target goal for the group to create a large number of concepts without regard to how "good" the ideas are. A typical brainstorming session lasts for about an hour (more than 90 minutes of intense brainstorming can be exhausting and unproductive). Within this timeframe, a team might expect at least 60 new ideas to be generated, with a "stretch" goal of 100 or more. Clearly, developing so many ideas within such a short period of time requires the group to move quickly from idea to idea rather than dwelling on any single suggestion.

FIGURE 3.1.2
A playful warm-up to a brainstorm helps to jumpstart the flow of wild ideas (by Steve Castillo, courtesy of the Stanford Graduate School of Business).

5. One conversation at a time The critical concept underlying this rule is that listening can be as important as talking during the creative process. Enforcing this rule usually falls to the facilitator (see below), although each participant should help keep the group focused on one discussion. As with all of the brainstorming rules, the need for one conversation at a time should be established as an expectation going into the session so that the facilitator has an accepted, non-threatening basis for holding people accountable to the rule if a problem arises. It can be helpful to have the brainstorming rules posted in the room, both as a reminder for everyone and to make it a little bit easier for someone with a concern to point to the rule and say, "Remember: one conversation at a time."

6. Stay focused on the topic Even the most disciplined participants may have a tendency to let their conversations "wander" in a brainstorming session. While these digressions sometimes result in valuable ideas and information, they tend to have a negative effect on both the productivity and the flow of the meeting. To help a group stay focused, try to avoid distractions, side conversations, real-time analysis, and filtering of ideas (which comes later). One useful strategy to minimize the occurrence of these distractions is to have a special flip chart or section of a whiteboard where unrelated suggestions or questions can be set aside until another time (this is sometimes called the "parking lot"). If the momentum of the meeting begins to slow down, the facilitator should try to jump to a new area of brainstorming within the general topic of the session. If the meeting is seriously stalling, the group should consider taking a short break or stopping altogether for the day.

Keep in mind that wild ideas are not digressions, but valuable components of the brainstorming process (even though they may seem somewhat off-topic at the time). However, there is no clear rule for distinguishing one from the other. As a result, the facilitator and participants should not get too concerned about policing this distinction. Remember that brainstorming is an iterative process. If a brainstorming area is important, it will be worth conducting more than one session. With this approach, today's digression may turn into tomorrow's great idea.

7. Be visual Being visual begins with the physical space in which brainstorming occurs. It is useful to have blackboards, whiteboards, large flip pads, sticky notes and/or other means of drawing and writing that encourage an open, fast, and unlimited flow of ideas. Everyone needs to be able to see what is being written and it is useful not to have to erase or cover up pages (that is, have a lot of space to write). It is typical to have a scribe – sometimes two, if the idea flow is rapid – to make sure that all ideas are captured and made visible to participants throughout the session. Another approach is to have everyone write down their own ideas and then take turns briefly presenting them to the group as they post them in the space. Giving everyone a pen and paper can help ensure that people do not forget their ideas, and it can also help ensure that one person talks at a time. When documenting, encourage people to use as few words as possible to describe the idea clearly. Catchy labels or "headlines" are helpful, as long as everyone will remember what they mean.

Cartoon-like doodles can increase the speed and economy of communication. The point is not to create great art, but to stimulate the flow of ideas. This is similar to the game "Pictionary" in which players must use drawings (not words) to help their team guess a word, saying, or concept. It is not the most skilled artist who wins, but rather the player who can most quickly use rudimentary drawings to communicate critical information.

Another strategy for making a brainstorming session more visual is to make various artifacts available (toys and props) since they can be useful in prompting new connections and inspiring insights. Simple props, such as blocks, pipe cleaners, clay, balls, tubes, or Lego, can be used to help create an interactive and fertile mood during the session. They also can be used to visually stimulate ideas and demonstrate three-dimensional (3D) concepts. Tape and staplers help support the assembly of more complex (although still quick and crude) mock-ups. As an example, in one brainstorming session focused on addressing common problems with traditional otolaryngology tools, a whiteboard marker taped to a film canister became the key prop for stimulating ideation (see Figure 3.1.3).[13] Miming, role playing, or physically

FIGURE 3.1.3
A quick prototype from a brainstorm session led to a breakthrough in conceptualizing a new ENT dissection tool (courtesy of IDEO).

simulating the use of a device can also be a good way to express a 3D concept to others, in order to provide rapid understanding and provoke new ideas.

Tracking ideas as the number reaches 100 or more can be challenging, but keeping the ideas visually displayed in the working space is important. A typical brainstorm can fill multiple whiteboards or flip chart pages, so be prepared with plenty of space for capturing ideas. Planning the spatial locations where ideas will be written down (or where notes are placed) in the room is also important for staying oriented and organized, and should be given careful thought prior to the session. It is often useful to cluster ideas into different "regions" of the room if they seem to be related (sticky notes can be particularly convenient when it comes to clustering ideas). Showing a flow of ideas (i.e., one idea building on the other) with arrows is a different way to increase the visual aspects of a brainstorming session. Another simple strategy is to number all ideas as they are generated so that they can be quickly and easily referred to when building on previous concepts. Some groups like to use computer-based concept maps (see 3.2 Initial Concept Selection) as a way of tracking ideation in real time during a brainstorming session.

Whether and how to use computers and the Internet during a brainstorm depends on the participants and purpose of the session. Online connectivity can be useful to quickly pull up images, search through devices, and watch procedure videos, but the opportunity for distraction and breaking the rhythm of the session is obviously quite high. In general, it is probably best to avoid the Internet while brainstorming unless someone has been designated as the online searcher and has had the chance to prepare ahead of time.

It is not necessary to have a space specifically designed for brainstorming (see Figure 3.1.4) – productive sessions have been conducted in nearly every type of space using flips pads, whiteboards, or sticky notes on the walls. Once the session is underway, check in to confirm whether or not the space and configuration is working for the group. If not, it may be worthwhile to interrupt the session and try a different approach. It is also a good practice to change venues for different brainstorming sessions – go to another room or building, someone's living room, or an inspiring outdoor space. A fresh location may bring a new spark and some new associations into the group's ideation process.

Special considerations for medtech brainstorming

Before identifying participants and a facilitator for a brainstorming session, it is important for the individual or group hosting the session to clearly define the topic to be addressed. For medtech brainstorming, the need specification (see 2.5 Needs Selection) generally should be used as a starting point for defining the scope of the meeting. The idea is to address the core problem

FIGURE 3.1.4
An immersion room designed for brainstorming offers the fun of being able to write directly on the walls! But almost any space can be made effective for ideation with a little advanced preparation (by Anne Knudsen, courtesy of the Stanford Graduate School of Business).

outlined in the need statement while leaving enough room for participants to be able get creative and think beyond existing solutions. Accordingly, the topic for a given session should not be too broad or too restrictive.[14] In practice, it is not always easy to dial in the right "focal zone" in advance of the session, but it is possible to avoid major errors. For example, "reducing the pain and disability of arthritis" is too general a topic to provide traction in a brainstorm, but a session on "slowing or reversing the progression of early cartilage deterioration in the knee" has a good chance at being productive. If the given problem is particularly broad in scope, consider dividing it into multiple topics that can be addressed through a series of brainstorming sessions (e.g., one session on ways to address key aspects of the disease state, another in identifying gaps in the treatment landscape). Sessions can also be divided up according to potential engineering solution sets (e.g., electrical, mechanical, chemical, biologic) or potential business models (disposable, reusable, implantable, capital equipment, etc.). Good topic choices come with practice. Do not worry too much about the topic at first; remember, the group can always schedule another brainstorming session with a different focus or even make a change in the middle of a session when the focus becomes clearer.

Selecting participants Choosing the team for medtech brainstorming can be a challenge, given that domain experts in the medical device field are typically physicians and engineers who, by training, can be reflexively critical when it comes to new ideas (including their own). Medical training is based on the maxim of "doing no harm." The deeply ingrained value of avoiding damage to patients tends to make many experts in the field conservative when it comes to innovation or change. This factor is influential enough that an inventor or team may want to think carefully whether or not to invite experts in the problem area to participate in the brainstorming session, particularly early in the biodesign innovation process. Again, guidance from these physicians and engineers may be more appropriate later in the process, when screening and improving ideas become the focus.

A related challenge with involving experts who are currently active in the field is that they may be disproportionately focused on near-term improvements that can make their work safer or more efficacious. For example, some physicians will be full of good ideas for the next generation of a device (one to two years in the future). However, they may not have spent as much time thinking about breakthrough concepts or radical new ideas that will revolutionize a practice area in the long

term (a 10- to 20-year vision). Similarly, executives, managers, and engineers within medical device firms may have a wealth of knowledge to share in the brainstorming process, but bring with them certain preferences or **biases** based on the products their companies are investing in and/or currently marketing.

Among all these cautions about the "expert problem" in brainstorming, it is important to mention that there are many exceptions to this profile – that is, there are many wonderfully innovative physicians, engineers, and executives who have no trouble whatsoever contributing to freewheeling brainstorms. Finding these individuals can supercharge a brainstorming session and lead to impressive results.

With or without domain experts, it can be helpful to include participants with little or no medical expertise, but who bring a unique perspective, or whose background can cross-pollinate the brainstorming session. For example, in addition to one or two physicians with relevant clinical experience in a practice area, it may be useful to invite specialists from other areas unrelated to the one in which the need exists. The contributions of these individuals are often based on technologies or procedures they know from their own fields. Similarly, it is helpful to include different types of engineers in the process (e.g., mechanical, electrical, and chemical engineers). It can also be useful to involve a "maker" in the group – an expert at prototyping devices who can conceptualize how a device might look and perhaps make a quick mock-up in the session.

In developing the list of participants to invite to a brainstorming session, try to anticipate different areas that potentially will come into play in designing and developing a solution (of course, this can be hard to do since it is impossible to predict exactly where the solution will lie). It is also important to find people who understand the field of interest and existing technologies, but equally essential that they have the ability see past their own knowledge and biases so as not to steer the group toward a particular type of solution. For example, if a team is brainstorming new solutions for visualizing the gastrointestinal (GI) tract, which is currently performed using an endoscope, it may want to enlist cross-functional representation from individuals who understand fluids, light, electronics, displays, optics, and the mechanics of scopes. In finding a person with an understanding of endoscope mechanics, the group should target someone with an open mind and the ability to think beyond the known mechanics of today's endoscopes to fruitfully brainstorm new solutions for visualizing the GI tract.

In the same example, it could be helpful to include physicians from the clinical area in which the scope would be used, as well as experts who could represent how other body corridors are assessed (e.g., catheters for blood vessels). The team should not overlook the possibility of including "non-technical" individuals within the group, too. Business people from various functional backgrounds (finance, operations, marketing, sales) can all make strong contributions to the creative process, particularly since they may overlook (or overcome) conventional practices entrenched in the status quo. In the Stanford Biodesign course several years ago, one device concept that went forward to form a start-up company was proposed by an MBA with a finance background as he brainstormed with two PhD engineers and a cardiologist.

Choosing a facilitator The facilitator's job is to run the session, enforce the rules of brainstorming, and make sure the process works smoothly. Facilitators need to be able to stimulate ideas, prevent lingering too long on any one idea, and move the group in fresh directions when idea generation lags (see Figure 3.1.5). Often, it is best to have facilitators refrain from being participants so that they can be completely focused on managing the effectiveness of the session.

Especially for new inventors and teams, it may be helpful to avoid positioning an expert clinician or engineer as the session leader as these individuals may naturally wind up in an authority position within the group, which could stifle less experienced participants from sharing ideas. Depending on the dynamics of the team, the participants, and the topic, having a neutral third party act as facilitator of the session can be effective. The facilitator must, of course, understand the area well enough to effectively navigate the participants' contributions and stimulate their thinking. However, it is

FIGURE 3.1.5
A skilled facilitator can help make a brainstorming session productive and fun (by Steve Castillo, courtesy of the Stanford Graduate School of Business).

equally important for the facilitator to have the ability to keep the session balanced and well-paced, and serve as a referee regarding adherence to the brainstorming rules.

Although the model of one facilitator per brainstorm is a good starting point, the team may want to consider other alternatives. It can be useful to switch facilitators during the course of a brainstorm to keep the session fresh, to use the talents of the facilitator as a participant, or to make other adjustments in response to a change in the group dynamic that becomes obvious during the session. The point is to stay alert regarding the effectiveness of the session and be flexible about the facilitator's role.

In advance of the session Once participants and a facilitator have been chosen, the individual or group hosting the brainstorming session should think about what background information can be provided before the session to aid the idea generation process. For brainstorming sessions focused on creating solutions to needs, usually the need specification can be the foundation of this background information (see chapter 2.5). A disease-state fundamentals report (see chapter 2.1), an overview of existing solutions (see chapter 2.2), or other data relevant to the creation of the need specification may also be provided. However, the aim is to achieve a balance between offering ample information for effective brainstorming without constraining creativity by restrictive framing of background information about the need itself. This is another reason to mix in participants who are not specific experts in the medical or technical areas under consideration.

Medical props As mentioned, it is useful to make props available to participants in a brainstorm. For medtech sessions, consider having a few real medical tools among the generic blocks and Lego on hand in the brainstorming room. Simple instruments – clamps, retractors, trocars, basic balloon catheters, etc. – can be mixed in with the other artifacts since they can be useful in quickly conveying a concept or inspiring a connection to a new idea (see Figure 3.1.6).

Anatomical drawings and models are other tools that can be useful in a medical-related brainstorming session, as long as the discussion does not get bogged down in detail. Many companies sell large anatomical charts of the different organ systems that are both helpful and visually stimulating. Simple pictures or drawings of a particular operation or procedure can also help motivate ideas. Even better are 3D models of the human anatomy (or portions directly related to the brainstorm focus area,

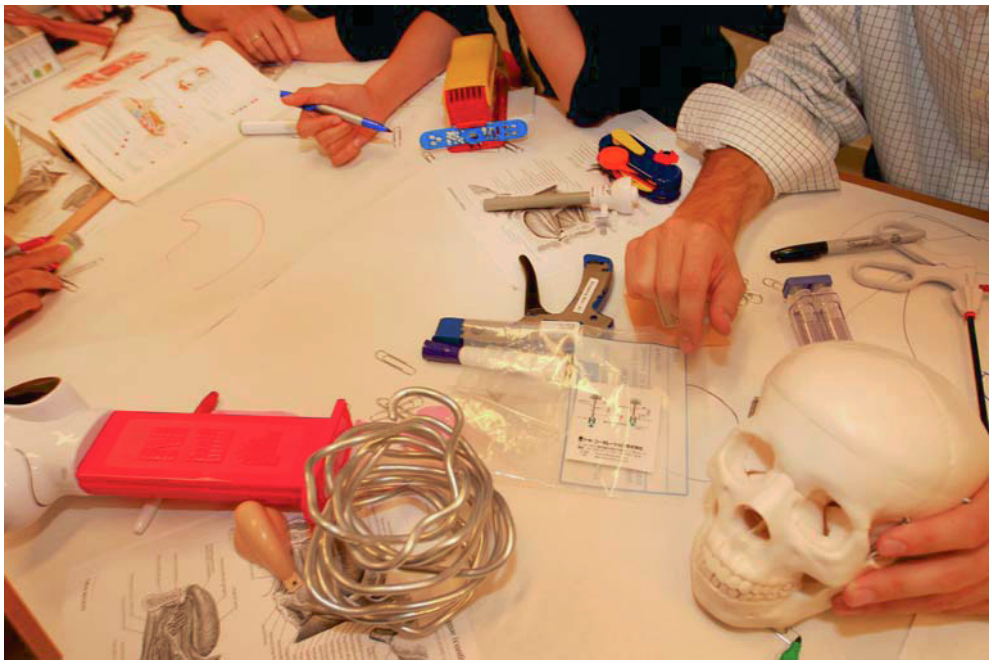

FIGURE 3.1.6
Medtech brainstorming tools – a creative jumble of anatomy aids, devices and toys (by Anne Knudsen, courtesy of the Stanford Graduate School of Business).

e.g., the GI tract, the heart, the skeleton). These plastic models are typically expensive, but can be purchased online or borrowed from a medical school or specialty practice office. Brainstorming with actual tissue parts is another idea to consider, especially when the physical characteristics of the organ are important to understanding the need and developing potential solutions (e.g., looking at a pig stomach when exploring GI needs – see case example). Just be sure to understand the bio-safety regulations in the chosen setting if any actual tissues will be brought to the session.

Innovators should also think beyond the medical arena for props and gadgets that can be useful in stimulating ideas during medical ideation. For example, one physician noted how he had got inspiration for new surgical tools from devices as diverse as bicycle components and ponytail clamps. At IDEO, the professional designers maintain a collection of interesting devices and toys with different mechanisms. As Tom Kelley described, "The complex and extremely reliable mechanisms of rock-climbing camalots or the simple mechanism of a Japanese folding razor can get people thinking in new ways as they hold the those items in their hands." Think creatively about materials and parts that might make a fruitful addition to the ideation process and make a variety of tools available to participants.

Sugar, caffeine, and brainstorming endorphins It is part of brainstorming ritual to provide participants with candy, cookies, and cola to help ensure a high energy level. Whether or not a medtech group thinks a metabolic "buzz" is desirable (or healthy!), it can certainly help create a positive, engaging, and upbeat environment. The props and the set-up all contribute to the right tone and feeling for the session. It can also be a good idea for the facilitator to encourage participants at the outset of the meeting by pointing out that the attendees have been chosen for their talent and creativity, and conveying that it is an honor to have been invited. The positive reinforcement of ideas also goes a long way and can be helpful as the group is just getting going.

Managing the session It is essential to be clear with participants that the brainstorming session will require 60 to 90 minutes of uninterrupted attention. Physicians are especially vulnerable to being phoned or texted by the hospital. If possible, get them when they are not on call or are able to "sign out" to someone else during the session. It is appropriate to ask participants to turn off

their communication devices during the meeting. If an important interruption occurs, the participant should leave the session to take the call. The idea is to focus on the topic, avoid interruptions, and maintain the momentum that the group has built.

At the beginning of the session, invest a few minutes in doing some kind of quick warm-up exercise (the design thinkers call this "stoking"[15]). This is particularly valuable when dealing with participants who are new to the brainstorming process. An unrelated ice breaker can help in making this transition. Finding an "easy" medical-related exercise that participants should be relatively familiar with can be an effective way to get started. For example, the facilitator might ask the group to come up with as many suggestions as possible within two minutes for improving a hospital bed. By making it clear that s/he is looking for creative and even wacky suggestions delivered at a rapid rate, the facilitator can bring the group up to brainstorming speed without spending too much time on a warm-up. Another approach is to coax a warm-up need from the group. Ask a simple question like, "What was the most irritating technical problem you had today?" Make a quick list of responses on the whiteboard and then choose the one that seems to resonate most with the group. Dedicate just a few minutes to coming up with solutions, with the facilitator encouraging the group to think of quick, interesting, and goofy responses. Some groups may appreciate a non-medical warm-up. Try brainstorming a topic such as "How could you prove there is life on Mars?" Another strategy is to watch a short video, for example, with a far-out science fiction scene full of cool inventions. It can also be good to get participants up and out of their chairs for a short game. For instance, for a round of "category, category, out!" the facilitator asks participants to line up, names a category (breakfast cereals, vegetables, animals, car manufacturers, etc.), and then points at each person in rapid succession, skipping around the group. Each player has to name something in the category. If someone cannot, everyone yells "out!" and that player sits out for the next round.[16] The point of stoking is to briefly engage everyone, build a rhythm of rapid responses, and have some fun!

One of the most challenging issues for both the facilitator and the group can be dealing with the spectrum of personality types among participants. One of the criticisms of the classic brainstorming approach is that it is designed for extroverts and creates an environment that can be difficult for introverts (who may be equally or more creative).[17] If the facilitator discovers that there is a reticent or quiet member or two in the group, it is important to be encouraging but not heavy-handed in inviting participation. It is absolutely not the case that everyone in a brainstorm must contribute equally – in fact, one of the best ways to kill ideation is to "cold call" on participants to make sure everyone is getting equal say.

On the other end of the spectrum is the overbearing, controlling, or dominating participant. Here the facilitator, joined by any brave members of the group, needs to help direct this participant toward a more positive contribution. The brainstorming rules generally provide a useful framework for making these suggestions. If this is not successful, the facilitator might choose to declare a break and speak to the participant privately.

A less extreme version of this same issue is a brainstorming session in which there is a hierarchy of participants. This problem can arise in business or academic settings and requires both a skilled facilitator and the willingness of the group to overcome. Different cultural contexts can also lead to this particular challenges. For example, in reflecting on his experience brainstorming in India, Consure Medical co-founder Amit Sharma remarked, "Not everyone will speak up with the same frequency. For instance, sometimes the more experienced, senior people think that their ideas should be given more weight compared to the other people in the room. And the other people may defer to those who are more senior and experienced. The emphasis on the true merit of the ideas can occasionally be missing." Here the challenge for the moderator is considerable, requiring a blend of deep cultural knowledge and leadership skills.

Capturing the results It is essential to capture and preserve the results of every brainstorm with as much accuracy and richness as possible. If large paper or sticky notes have been used, these should be gathered

up and saved. It is worth paying attention to the spatial order in collecting them, because remembering where a particular note was physically made in the room may aid more detailed recollection later on. If a follow-on brainstorm is conducted, it can be useful to place the sheets back in the position they were in at the end of the first session. When whiteboards are used, digital photographs of the boards are convenient. The photos can be projected later for a second session and are also easy to archive electronically. It is important that some method of recording is performed immediately at the end of the brainstorm, even if that requires the brute force method of simply copying down the output of the session. Again, it is most useful to do this in a way that is spatially close to the original organization. Remember to include any numbering scheme that was used in the session. Further recommendations for collecting and organizing the results of a brainstorm are presented in 3.2 Initial Concept Selection.

In capturing the results of a brainstorm it is important to assess whether all of the solutions are sufficiently well thought out to potentially take forward into concept screening and prototype development, or whether one or more ideas may still be too general and in need of further brainstorming. For instance, the idea to "capture a clot in the blood vessel" is representative of a general approach that is not yet actionable as a potential solution. In comparison, the idea to "use a stent with integrated mesh to a capture clot in carotid artery" is far more concrete. Of course, not all general concepts will yield workable solutions. It is a matter of judgment to decide whether the team should invest in additional brainstorming on the approach, or whether to set aside the general concept and move on.

Intellectual property ownership Brainstorming creates new ideas, and new ideas are the heart of new intellectual property (IP – see 4.1 Intellectual Property Basics). The inventor or team needs to be clear with the members of a brainstorming group regarding the implications of their participation in the session with respect to IP. If the participants are all from the same company or university, the ownership of an important idea may stay within that organization (and, thus, ownership is relatively uncomplicated). If the team employs a facilitator or other participants who are not part of the company or university, it may be reasonable to ask them to sign a non-disclosure agreement (see chapter 4.1).

Even in a situation where all participants are from the same entity, recognize that each participant may become an inventor as a result of ideas discussed in the session and that ownership should be decided in a fair and equitable manner. It is impossible to give specific guidance on how to do this, as each situation is unique. In practice, it will only be clear later in the biodesign innovation process whether an idea coming from a brainstorm session will move forward into a **patent**. Basically, as described in chapter 4.1, an inventor is someone who materially contributes to one or more claims of a patent. In some cases it will be clear that a single individual from the group came up with the key concept that was patentable, while in other cases it will be some combination of individuals or the whole group. One way to clarify this from the outset is to jot down the initials of the key contributor(s) alongside the idea, in real time, as the concepts are generated. The disadvantage of this approach is that the participants may get distracted by concerns about which ideas they do or do not "own." A more subtle method is to ask each participant in the session to use different colored sticky notes so that ideas can easily be linked to individuals. Ultimately, it is the responsibility of the team leader (the person or people responsible for driving the project) to make a determination of IP ownership in consultation with the group's members. It is, of course, best to clarify who is an inventor and what his/her relative contribution is, as early as possible in the patent filing process.

The case example demonstrates how all of these considerations come together in planning and executing a medtech brainstorming session.

Other approaches to ideation

Although classic brainstorming may be the most popular form of ideation being taught at universities, schools, and corporations around the world as the core of "design thinking," it is certainly not the only effective technique for generating concepts.

FROM THE FIELD A TEAM IN THE STANFORD BIODESIGN PROGRAM

Brainstorming early concepts in the obesity space

As part of a biodesign innovation course, Darin Buxbaum, a first-year Stanford MBA student, and his team collaborated to address the need for *a less invasive way to help morbidly obese people lose weight*. In addition to Buxbaum, who had a business background in the medical device field, the team included one postgraduate resident who had completed a rotation in general surgery and was working on a specialty in plastic surgery, two students pursuing master's degrees in bioengineering with a specialty in biomaterials, and a PhD student in bioengineering with a background in mechanical engineering (see Figure 3.1.7).

After investigating the disease state of morbid obesity, understanding the current solution landscape, performing stakeholder and market analyses, and developing a need specification, the team was ready to begin the process of concept generation. "The need was so big to begin with," recalled Buxbaum, "that we agreed to focus our first brainstorming session on coming up with broad mechanisms for losing weight, like increasing energy expenditure or reducing caloric intake. And then we would devote a session to exploring the categories that seemed to be the most promising."

All of the team members were relatively new to brainstorming, so they decided to bring in an outside facilitator to lead the first session. "When we were first getting together, there was no formal organization," noted Buxbaum. "Bringing in an outside facilitator helped impose some structure on the brainstorm – there was a designated facilitator and everyone else on the team was an equal contributor." With limited funds at their disposal during this early stage, the team called in a favor with a friend who worked at a design firm, asking him to lead the session. However, according to Buxbaum, it would have been worth paying a junior design consultant to facilitate based on the value they extracted from the role. Because the chosen facilitator was a personal friend, they did not ask the individual to sign a non-disclosure agreement. However, Buxbaum advised other teams to be more cautious. "You just never know who's going to be the one to come up with something really interesting in this kind of session," he said.

FIGURE 3.1.7
Buxbaum (standing by laptop) and his team at an early brainstorming session (by Anne Knudsen, courtesy of the Stanford Graduate School of Business).

The facilitator started the session by leading a couple of short, fast-paced warm-up exercises to get the team going, for example asking the participants to name as many different animals as they could in one minute. "This is something we would have completely glossed over if we hadn't used a facilitator," commented Buxbaum. "But it really helped people get used to the approach of throwing out ideas as fast as they could and building on the ideas of others."

Where the facilitator really demonstrated value, however, was in helping the group manage a team member who had difficulty allowing for wild and crazy ideas without passing judgment. According to Buxbaum, "Any time a really far-fetched idea would be thrown out like, 'Let's put a black hole in the stomach,' this person would say, 'That's not possible.' He complained about any idea that wasn't physically feasible. In the end, he shut down and stopped giving suggestions. It was really frustrating for the team, and must have been painfully frustrating for him. If it wasn't for the facilitator, we probably would have had a team argument about what we should and shouldn't be able to brainstorm." However, the facilitator was able to mediate the situation, enforce the rules, and keep the session going. Over time, the problematic team member grew increasingly comfortable with the brainstorming approach. "In subsequent sessions, he loosened up and eventually came up with some of our most creative ideas," noted Buxbaum. In later sessions, the team was able to facilitate the brainstorms on its own. "The norms became so ingrained in us that we were able to self-police," he said.

Because the team members came from a diversity of backgrounds, they decided that some advance preparation was required to get everyone up to speed before each session. "One of the things we worked incredibly hard on was looking at the mechanisms by which the human body works," said Buxbaum. "The physician on our team would create a presentation before each meeting and teach us everything about the relevant anatomy. For instance, if we wanted to talk about mechanical ways for making people eat less, he went over all the different parts of the stomach and how they interact. One time before a session, he presented the entire gastrointestinal system, how the chemical pathways work, and how the hormones are released to stimulate satiety. Having that depth of knowledge led to some really neat ideas. For example, one of our more interesting concepts was to put a stent in the intestines where it would elute fatty acids to activate a hormonal pathway to make people feel full and slow down the entire digestive tract." However, Buxbaum admitted that the concept of advance preparation could be taken too far. "One way that we may have over-prepared was to look at IP early in the process. While it seemed like a good idea to understand what concepts were already being worked on, this may have actually clouded our judgment and put unnecessary constraints on our thinking," he said.

Another technique that proved to be invaluable to the team was using drawings, crude prototypes, and medical props during the sessions, including pig stomachs in a few sessions (see Figure 3.1.8). In fact, Buxbaum credited one of the team's major breakthroughs to its use of the stomachs in a brainstorming session: "We were playing with a pig stomach in one of our meetings, literally just manipulating

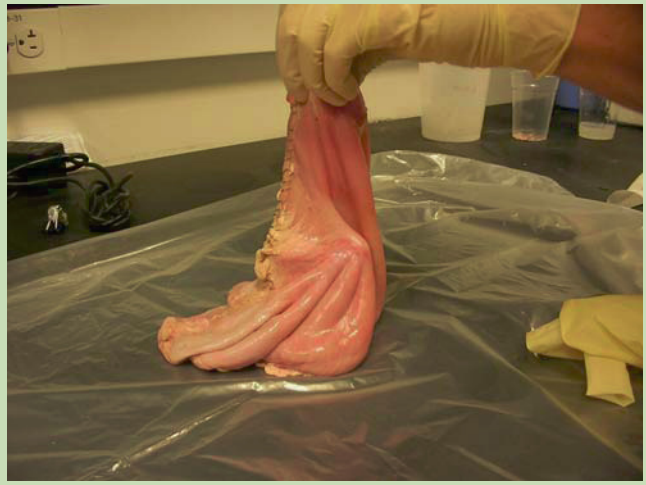

FIGURE 3.1.8
Having a pig stomach available in the brainstorm provided the key insight for the team's invention (courtesy of Jennifer Blundo, Darin Buxbaum, Charles Hsu, Ivan Tzetanov, and Fan Zhang).

it while we were thinking, and it just flopped into the right geometry. We never would have imagined that the stomach could take this particular shape unless we had a real piece of tissue in front of us." Acquiring the pig stomach was an adventure in itself. First the team tried a traditional butcher shop. "They made a really big deal about it," remembered Buxbaum. "They said they would have to call the place where they got their meat and convince them to stop the line, pull out the stomach, inspect it, and package it for us. They charged us $30 and it took about two weeks for us to get it." He continued: "In the meantime, a couple of our team members happened to be at a Chinese grocery and saw a whole stack of pig stomachs for $1.99." These stomachs ended up working just as well, at much lower cost and greater convenience to the team.

In total, the team held approximately 12 brainstorming sessions that typically ranged from 60 to 120 minutes. "Usually, we wouldn't go longer than 90 minutes," said Buxbaum. "Our longest session was probably two hours but that was pretty draining. If we went over our time limit, we would table the process and pick it up in another session." In these sessions, the team's goal was to generate two to three ideas a minute, sometimes walking out with as many as 200 ideas from a single meeting.

Reflecting back on the process, he noted, "We have a lot of fond memories of brainstorming. It was a real coming together for the team." In fact, Buxbaum recommended using brainstorming as a technique for fueling progress beyond concept generation. "Whenever you're dealing with an undefined space, brainstorming can really help you fill it out. Our team didn't brainstorm to figure out how to design the device. To our detriment, we sat around tables at coffee shops or in people's living rooms instead. The space wasn't as good and we didn't use all the rules. As a result, our ideas weren't as creative and we didn't get anywhere near the same quality."

One alternate approach focuses on constructive conflict as a mechanism for stimulating effective ideation. This more critical or debate-oriented style of ideation sidesteps the cardinal rule of brainstorming to suspend judgment. Yet, it has been shown in some situations to produce an advantage in creative output when compared to traditional brainstorming.[18] Proponents for this approach assert that dissent opens the mind, allowing for a broader consideration of different possibilities. They also believe that competition can be effective in stimulating creativity.[19] However, there are some important conditions to making this approach work. As one professor summarized, "Whenever you're fighting about ideas ... it's important that you're engaging in the 'right fight,' criticizing another person's ideas and not the person himself. This type of conflict, what researchers call 'intellectual' or 'task' conflict, must be done in an atmosphere of mutual respect and must be based on the factual information available."[20]

Team members at The Foundry, a successful medical technology incubator in Menlo Park, California, have embraced the creative conflict approach. As managing partner Mark Deem explained, "When we brainstorm at The Foundry, we feel comfortable challenging each other. We've been together a long time – we trust each other and we respect the different perspectives each of us brings. So we're not afraid to mix it up a bit. There *are* bad ideas and wrong assumptions, and when we're in a brainstorm, we challenge those. Not, 'that's a stupid idea,' but 'that's not going to work because of this.' So it's about being factual, not critical."

Another variation on ideation seeks to take advantage of the deep knowledge of one or more experts by abandoning the "horizontal" or non-hierarchical philosophy of traditional brainstorming. In particular, medical device companies often use a format where they invite in a physician key opinion leader (**KOL**) to visit the company and participate in a group ideation session. While this type of facilitated discussion may draw on many of the same aspects of the brainstorming process described in this chapter (e.g., having different types of people from engineering, sales and marketing, etc. in attendance), it

differs in one important way. The purpose of these working sessions is usually to "uncork" the expert's mind and stimulate interesting ideas. Unlike a brainstorming session in which all participants are encouraged to contribute more equally, in these situations the group is asymmetrical, with the expert's ideas being given the most attention. Despite this important distinction, the presence of the group and the upbeat, thought-provoking nature of the interaction can help stimulate powerful ideas.

A substantially different approach to ideation is represented by the TRIZ method. Developed by a Soviet inventor (Genrich Altshuller) and his colleagues from the 1940s through 1980s, TRIZ advocates a highly structured, pattern-driven approach to generating solutions (the acronym is Russian for the Theory of Inventive Problem Solving). Like brainstorming, it is meant to create a leap forward in ideation, especially when there is some form of barrier or blockage impeding progress. However, TRIZ does not rely on the collective intuition of the team. Instead, the core philosophy is that it is possible to tap into ideas from other inventions, particularly those in other industries, to find solutions to the current need or problem. In short, "Somebody someplace has already solved this problem (or one very similar to it) …. Creativity involves finding that solution and adapting it to this particular problem."[21]

To help innovators tap into the solutions of other inventors, the TRIZ creators analyzed three million patents to identify the "contradictions" or trade-offs that they believe are at the root of most problems. These can be engineering trade-offs (e.g., in order to provide more diagnostic functionality in a pacemaker, the complexity increases and battery life decreases) or physical contradictions (e.g., in order to create a lower catheter profile, thinner balloon material is required, which means the balloon will rupture more easily after inflation). They then codified common problem-solution patterns into 40 Principles of Problem Solving, which are available in a knowledgebase along with a collection of tools for applying them in a structured way.[22] Importantly, the TRIZ approach may be particularly useful when ideation is applied to concept exploration and testing.

A final note on ideation

Consistent across all approaches to ideation is the fact that the process of coming up with new solutions to fundamental problems is a challenging one. Even professionals in design firms who routinely brainstorm with their expert colleagues continue to develop and learn new techniques to help them more effectively address the challenges of this work. These experts also point out that there is an important element of "staying in shape" for ideation, both for the individual and the team. Like other forms of creative and intellectual activity, practicing the skill helps maintain a level of ongoing fitness for the undertaking.

Online Resources

Visit www.ebiodesign.org/3.1 for more content, including:

Activities and links for "Getting Started"

- Understand basic ideation and/or brainstorming concepts
- Define the topic
- Identify participants
- Choose a facilitator
- Prepare for the session
- Conduct the session and capture output

Videos on ideation and brainstorming

CREDITS

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