Design, Technology and Innovation
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Lecture-18
Systemic Approach to Biomed Innovations Part 2

So let us go into those 16 steps one by one. Step number one was to form a team and I mentioned that the team has to be multidisciplinary. What disciplines do you need in a medical device innovation? I would say 4 critical disciplines.

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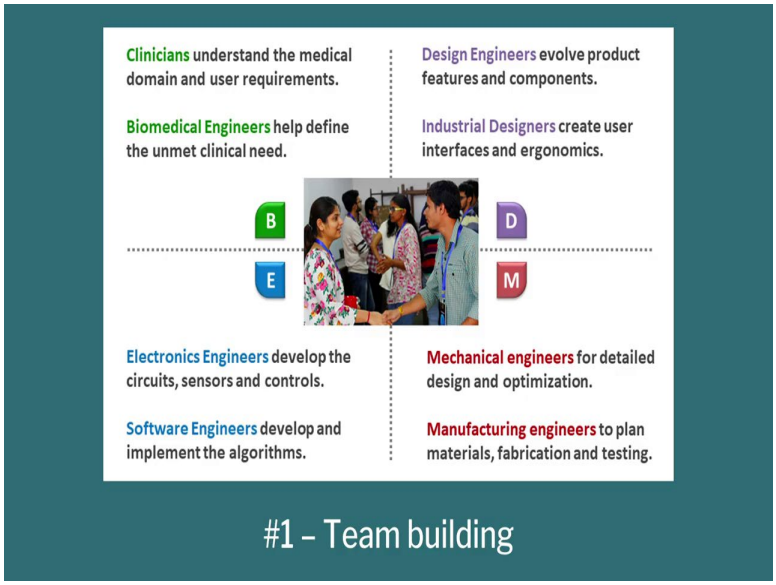

That should be one person in the team who knows Bio.

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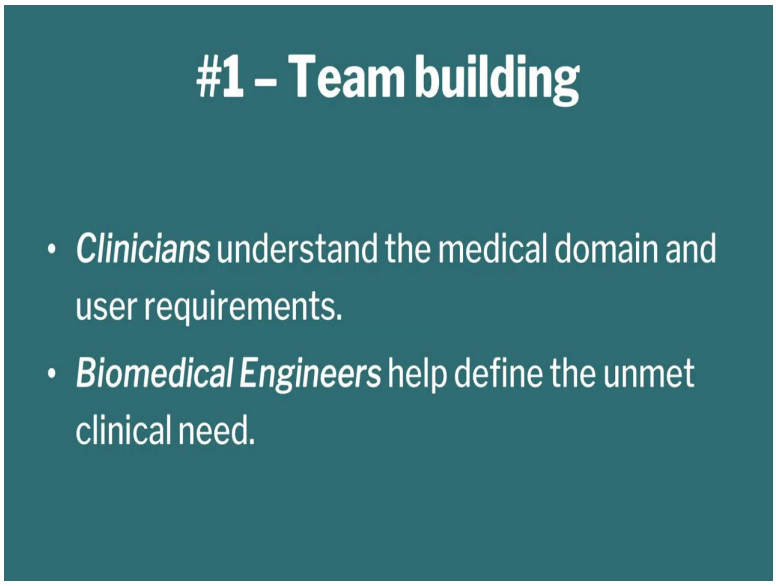

It could be a doctor, it could be a Biomedical engineer. Or some who knows human anatomy. Number 2 you need is a creative person, a designer, industrial designer, product designer, creative designer. Ok?

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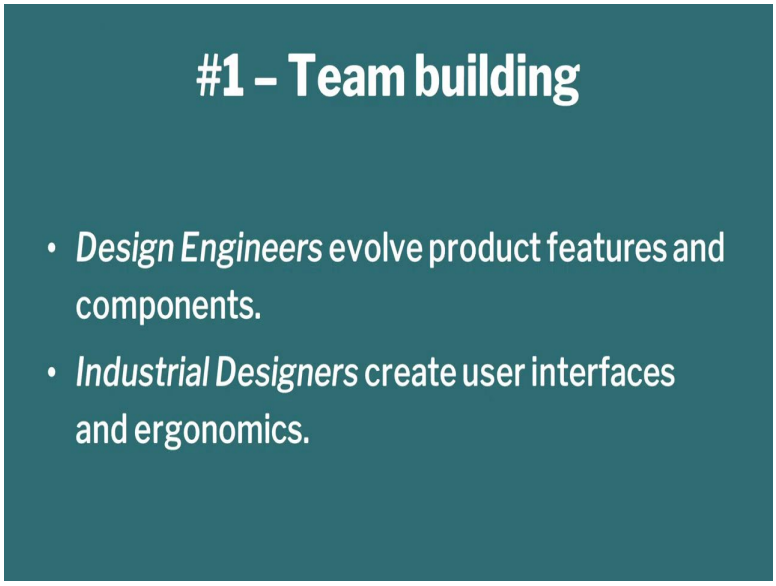

If nothing else works, an architect is fine. Anyone who has a creative mind set, who can make and look and visualise ideas and sketch them.

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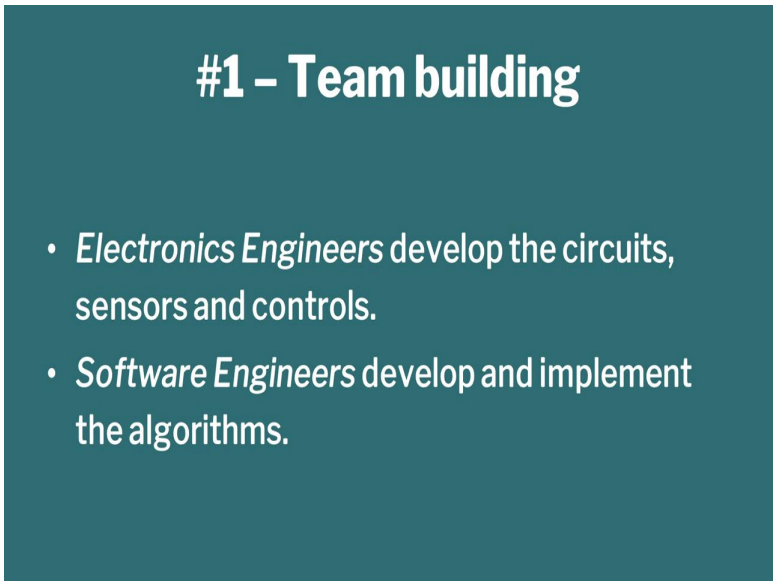

The third we need is electronics. E which is Electronics. With electronics I mean a group of people: electronics, electrical, computer science, software, IT. All this I would group as E, because if you do not have E, you cannot use what I told you earlier, those great new technologies, all of which need electronic and software capabilities. And the fourth one is mechanical, but M also stands for mechanical, manufacturing, materials and so on.

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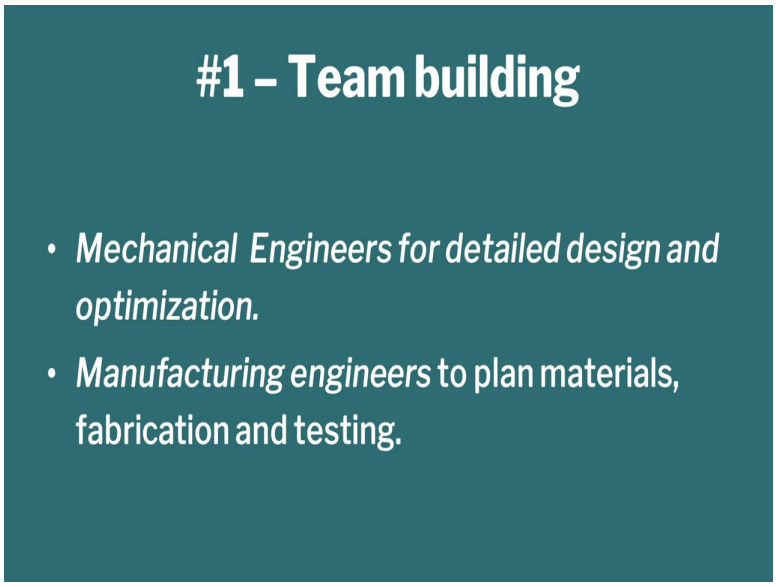

And you need these people in the room, because they are the ones who will give physical shape to the thing and can actually get it manufactured. So these 4 are absolutely critical four elements of a team, of a medical device innovation.

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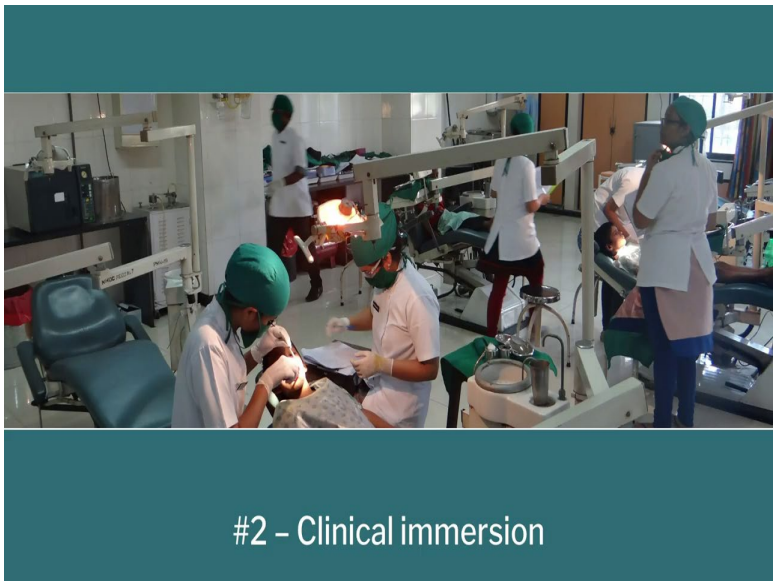

Set number two is Clinical Immersion, ok? You cannot sit here and create a medical device and go into a hospital and tell the doctor, 'Here is a nice, new, great device. Start using it'. There is a good chance that they will laugh at you because you never did your homework. What is the problem that they really want you to solve? Is there an already existing solution? What is the real pain point? So you need to go to hospital, talk to a doctor, and watch those procedures. Ok?

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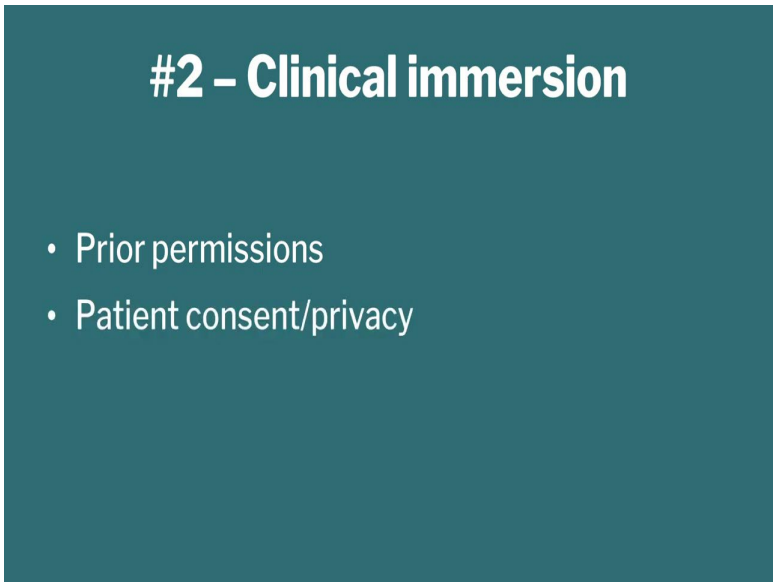

And please, these should be done with great care. You have to take prior permission. You cannot just walk in and say I want to meet you. I want to see you treating patients. Patient data is important, patient privacy is important, so take care of those things. What are you, when you go to hospitals and watch the doctors doing either diagnosis or treatment, look at what devices they are using.

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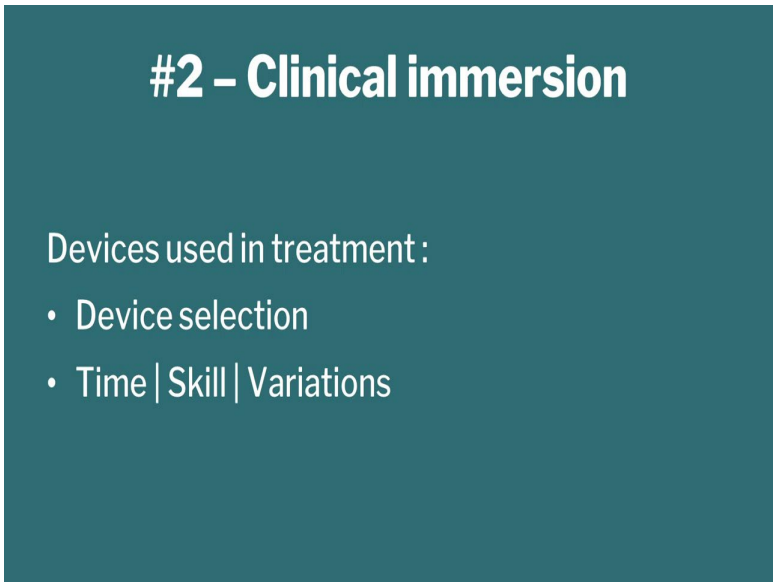

If you are going to multiple Hospitals, you see if they are using the same device or different devices. Is there a difference in the time taken for treatment of diagnosis? The skill level of a doctor? What are the variations of patients and other complications? etc. This you must watch very carefully.

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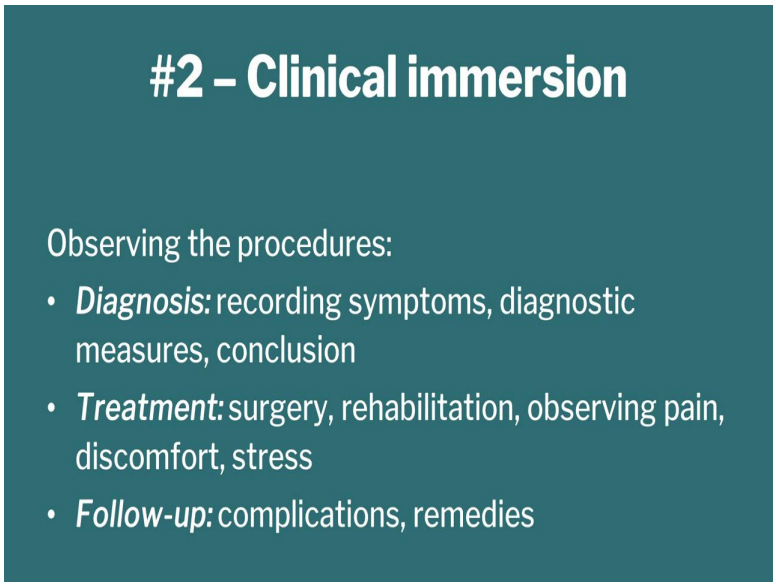

You look at all procedures, diagnosis and treatment including follow up, see what is happening. What has happened to the patient? Are they comfortable or not comfortable? Are they having pain? Is the doctor having trouble? All those you have to observe carefully.

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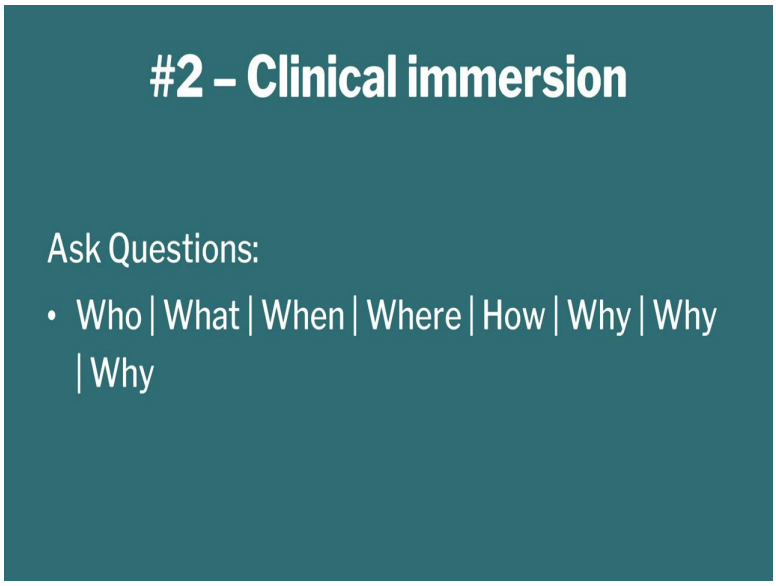

And then ask questions. If you notice something funny here, what is funny here? 'Why' is there 3 times. Why is 'why' 3 times? because the doctor may say that I am having, I need a device for like this, do like this, if you just go ahead along and start developing that device, you may miss out some great opportunity. If you do not ask the question why. Ask a doctor why, and he may say, 'I need a device to treat this complication'.

Then you can ask the doctor why this complication is happening and he may say, 'Maybe because of this reason'. And you may finally find that solving this root cause is better than solving or creating a duplicate device at a lower cost, 'which is what most doctors want, 'Can you make a cheaper version of the existing device'. If you get a cheaper version, you may reduce cost maybe halfway, maybe one third. You can never bring it on to 1%.

But we ask 'Why' multiple times and go to the root cause, you may be able to do the treatment or diagnosis at 100th cost. It is possible and I will show you an example of that anyway.

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So what we say is that whatever you want to do, define your problem as early as possible,

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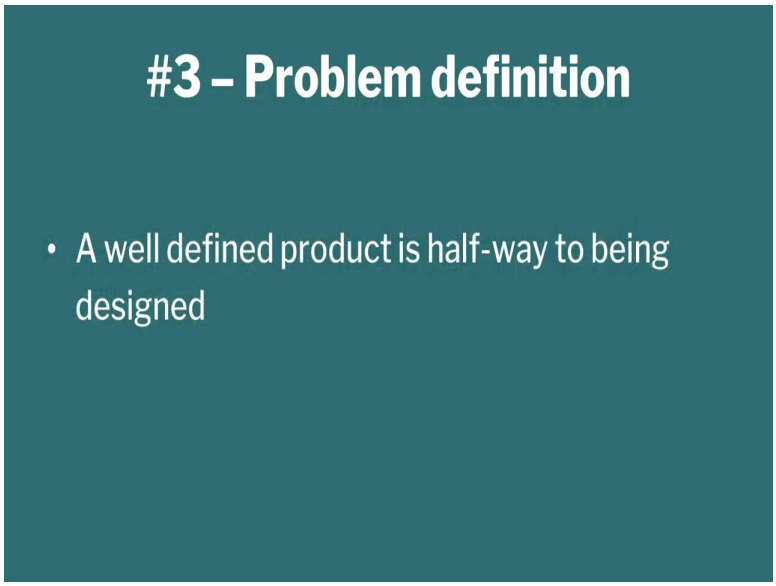

in as few words as possible. We typically say that 10 words is a good target or less than 10 words. But it must satisfy three criterias as far as we are concerned in the medical domain.

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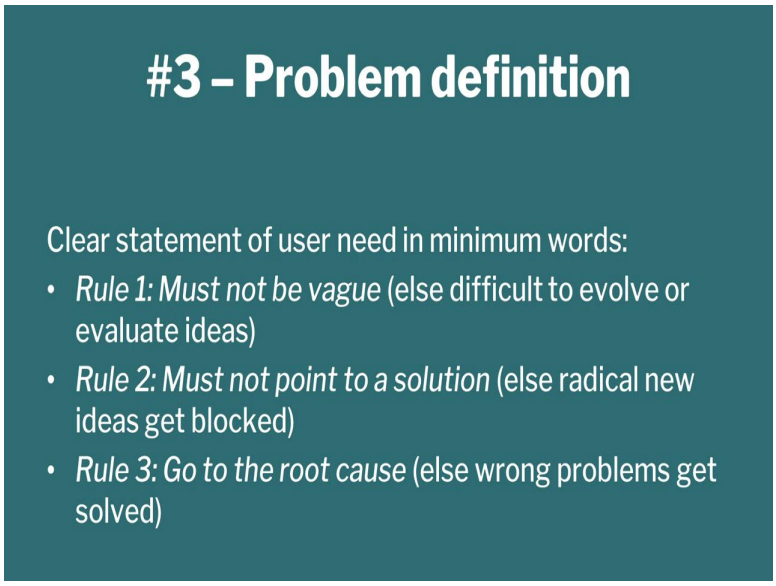

Number 1 is: It should not be vague. Ok? It must always, if you make it vague it is very difficult to evaluate or find out if the idea is good or bad. So the idea must be very clear. Number 2: It must not point to a solution. You cannot say treat this thing using ultrasound. You cannot tell this: How to solve the problem. Tell us what the problem is, do not tell us how to solve the problem in the problem definition. Number 3: By asking 'Why' multiple times, go to the root cause. So, let me give an example of what it, how it should be.

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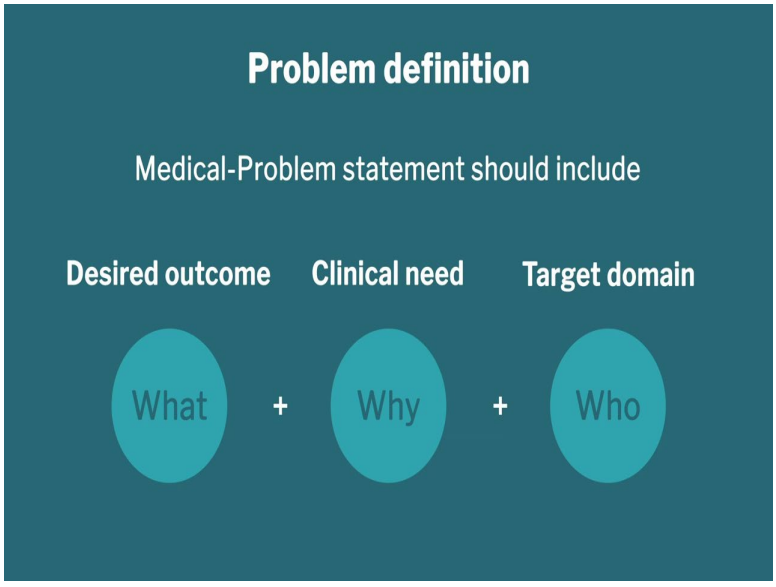

In my opinion, a good problem definition must have 3 things. It must have a 'Desired Outcome' which is what you want. It must have some 'Clinical Need' because you also mentioned why you

need that, and also in some way you define, who is the 'Target Domain', what it means is, who is that?

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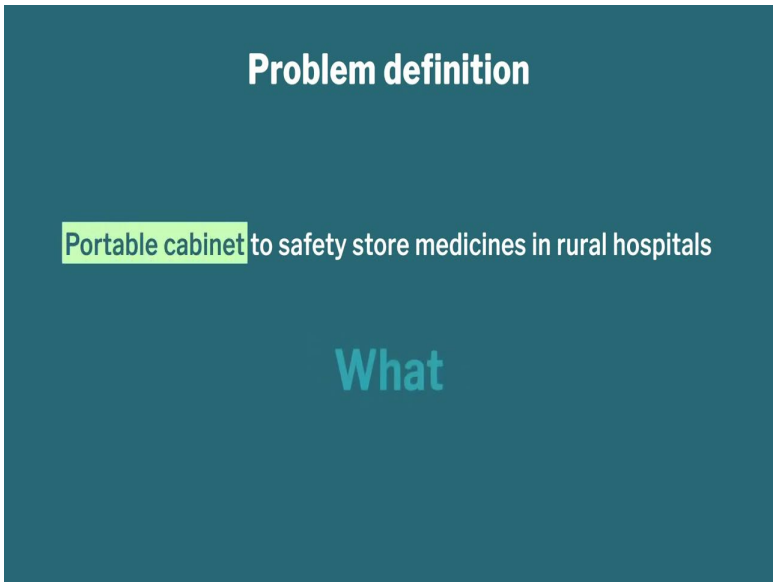

An example, if you say: I want a portable cabinet to safely store medicines in rural hospitals, it has taken care of the 3 things. What I want is a portable cabinet that is my Desired Outcome.

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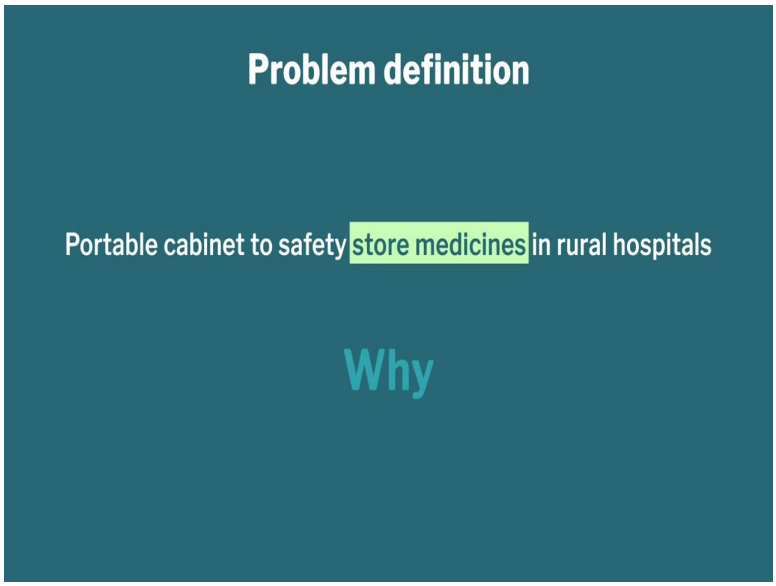

Why do I need it? To store medicines;

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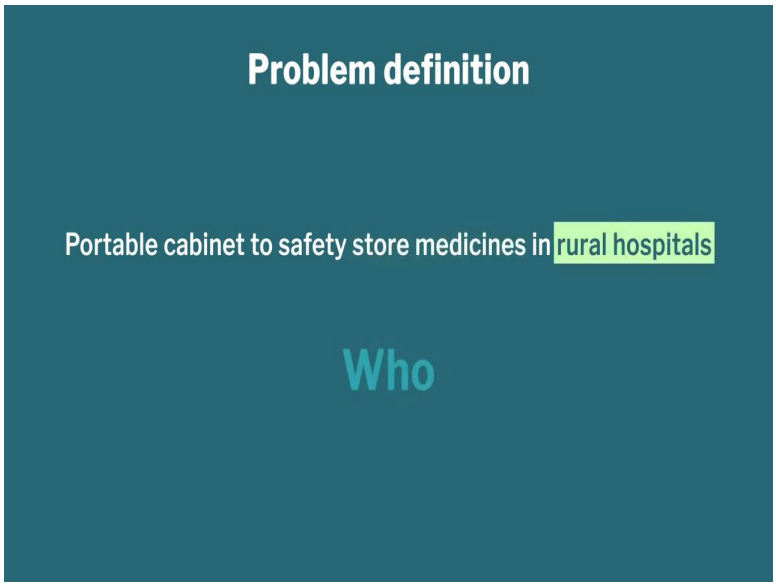

And for whom it is meant? Rural hospitals. This is a reasonably good example of a well defined problem statement.

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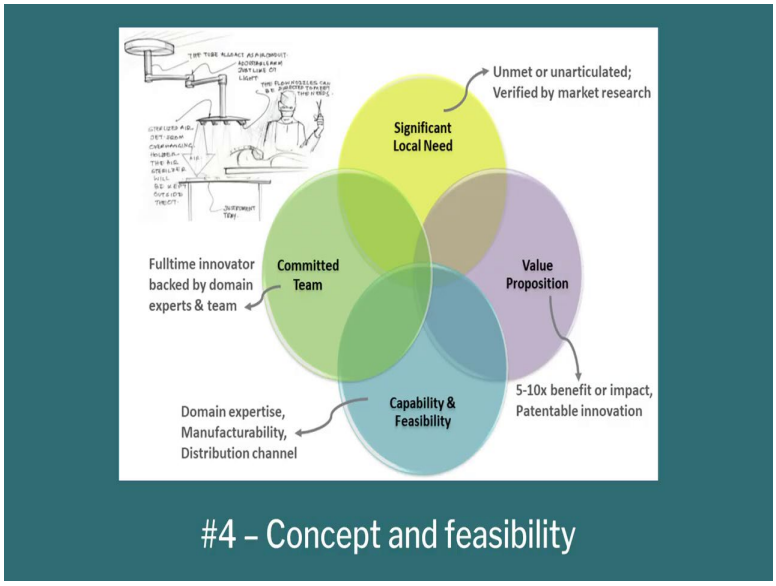

Step number 4: Concept and feasibility. The issue many times with engineers is that they fall in love with an idea. You generate a concept and somehow you latch onto that, and your mind blanks out to anything else that may be out there which may be better than that. Ok? So what we say is, do not fall in love, be very clinical about it and pass it through 4 filters. I have 4 filters.

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Filter Number 1, is there is significant local market requirement for that. If there is no market for that, why are you doing this project?

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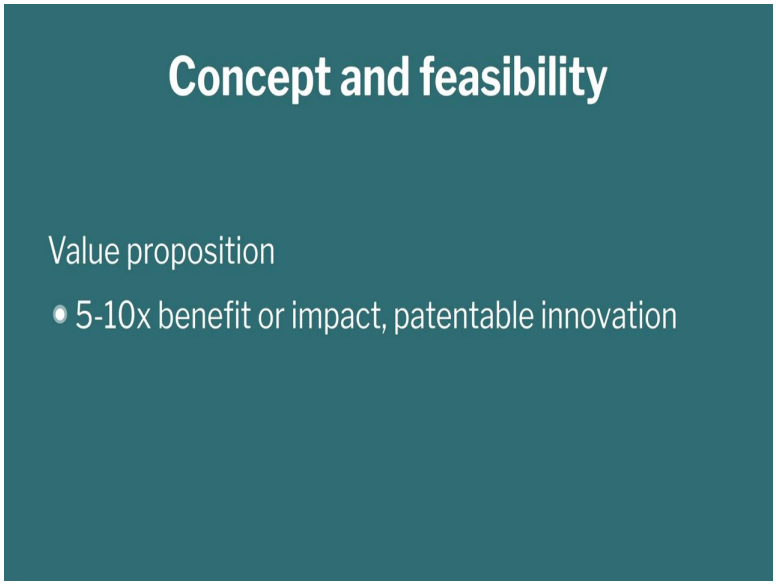

Number (Filter) 2: Have a value proposition: the feasibility of doing something much greater, not 10%, 20% improvement, that is not worth it. Ok? Can I make it 10 times, 20 times better, faster, easier or less expensive.

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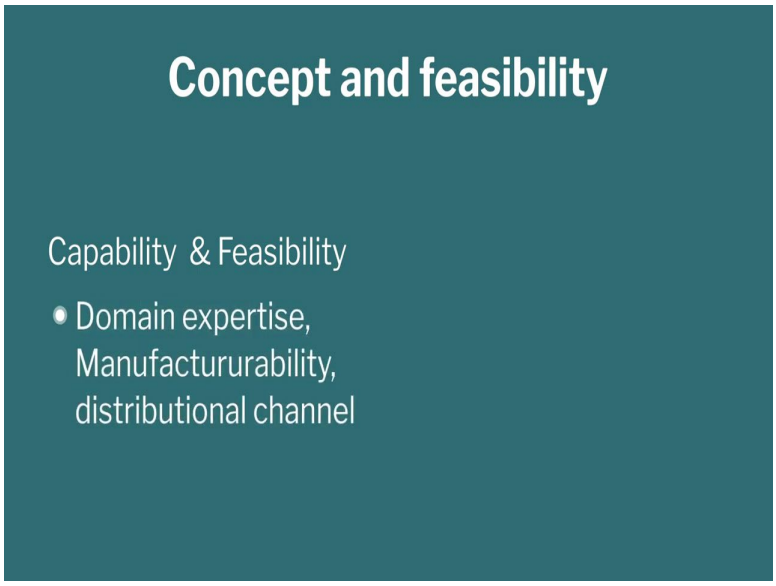

The third thing is: Capability of doing so. If you do not have the right kind of materials and skills and equipment and so on, you cannot do that and expertise. There is no point starting something which will take the next 20 years to develop. Because by 20 years everything will change anyway, so no point in doing something, which takes so much time. So, do with your capabilities what you can put a market in the next 2, 3, 4 years maximum.

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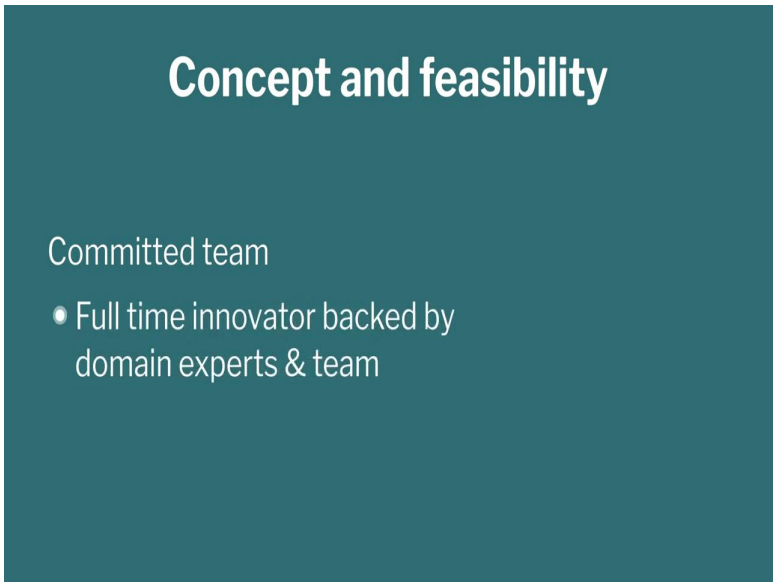

But the 4th one is: The full time commitment of the innovator as well as stakeholders. In the medical domain, we have doctors many times coming to us and they say that, ‘There is a great problem. Why don't you solve that?’ We ask the doctors usually, ‘Sir, will you give us one hour time every week? Either you come to our lab, and give us feedback or we will come to your hospital

and tell us how we are doing'. If a doctor cannot spend 1 hour per week. There is no way we can commit to developing the device because in medical devices clinical inputs are absolutely critical. Ok?

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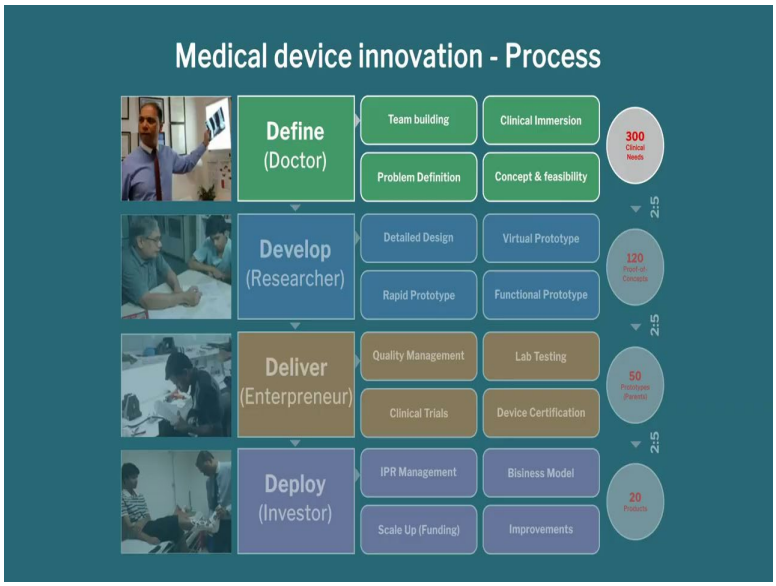

Now, going to step number 5, we have done the first four steps which is to do with the Define stage of the project.

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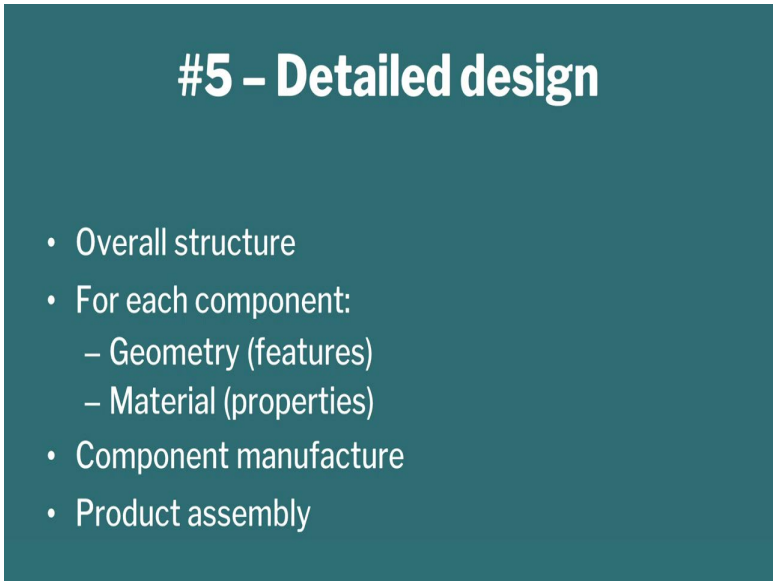

Now we go to the 'Develope' stage of the project. So very quickly, Detailed design means you are looking at the overall structure, what are the components into the structure, for each component, what should be the material, what should be the geometry. Geometry means the functionality and

the features and material means what properties I want from that particular component. If I want a transparent component, obviously, materials have to be chosen accordingly. And then you worry about manufacturing and assembly.

When do we make different components? Why cannot we have the whole product be a single piece? Why do we need multiple pieces? It could be for three or four reasons. You make different pieces when there is a, by function you need that.

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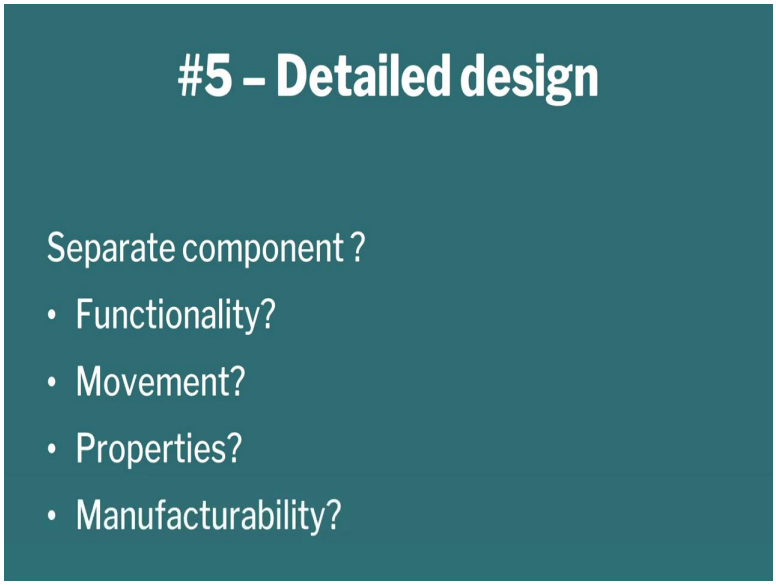

Or there is a movement with respect to each other. Then it is made of different pieces. Or you may need different properties, like I just mentioned just now, transparency property. Or from a manufacturing point of view you have to make it separate and assemble it then also you may need to have separate components.

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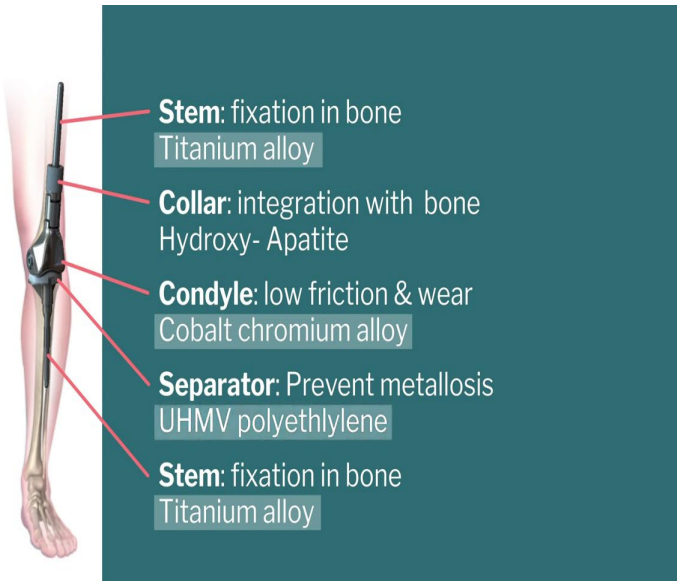

Let me take an example here. This is a process for children with bone cancer. Ok, you can see that there are several components there. You have the condyle in the middle on which the kneecap or patella will glide. Then you have the collar kind of thing, which gives an extension because someone's tumor may be big or small, so you put the extension pieces to cover the gap. Then you have a stem, both upper stem and lower stem which goes into the bone. You drill a hole and the stem goes into the bone.

And then you have a separator. A white piece is a separator, because you do not want metal to metal rubbing that creates metal particles and metallosis, blood poisoning. So, you want to prevent that by putting a plastic in between. Now once you know the functionality of each of the pieces, now you know they have to be separated because there is a movement, or because by function you want to separate, or you want a buy compatibility which then goes into the bone, you know you need different materials.

And thereby you choose materials accordingly. So when you have, you need a high biocompatibility, the stem going into the bone and I want the bone to grip the stem, then you go for titanium alloy. Where you have movement, and you want an extremely mirror surface finish because you want a very low coefficient of friction, you go for cobalt chromium molybdenum. That you want a polymer to separate the tools metal particle, so you go for not an ordinary polymer, it has to be Ultra High Molecular Weight polymer. Ok?

So this showed you how you decide about the various components and decide about the material and geometry component based upon the functionality and properties.

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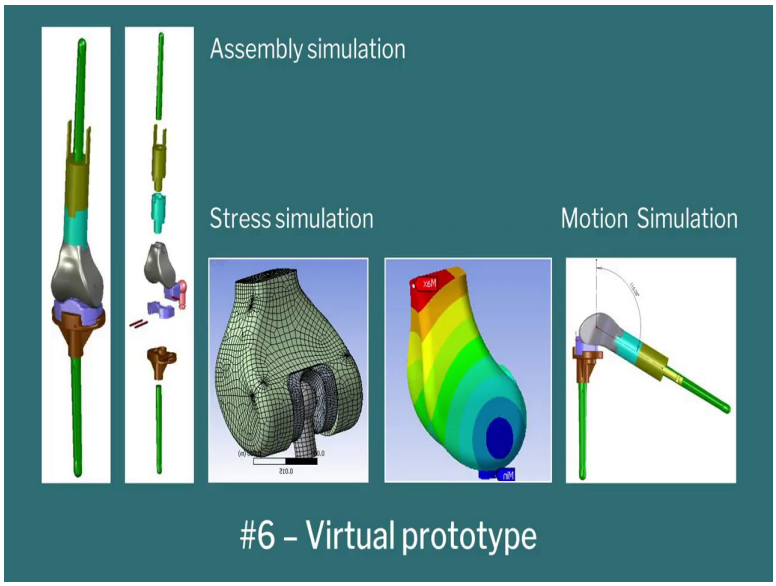

Then you are going to detailed design. We are actually going into the dimensioning, the actual shape, the actual features and thanks to CAD today it is very easy to visualise, model and visualise that. But CAD also allows you to do few other things. Using CAD you actually can give the movement. You can see how it is going to move. Are any parts going to hit each other or hinder each other.

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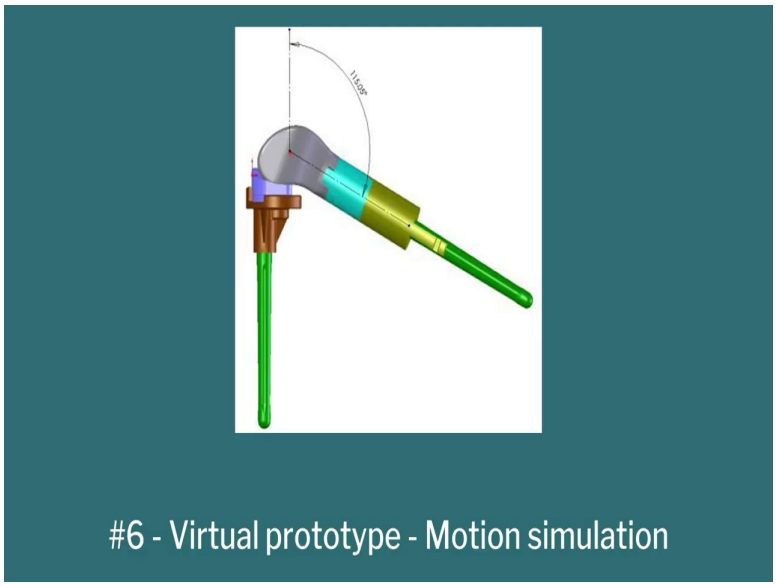

So, we can do motion analysis or kinematic analysis.

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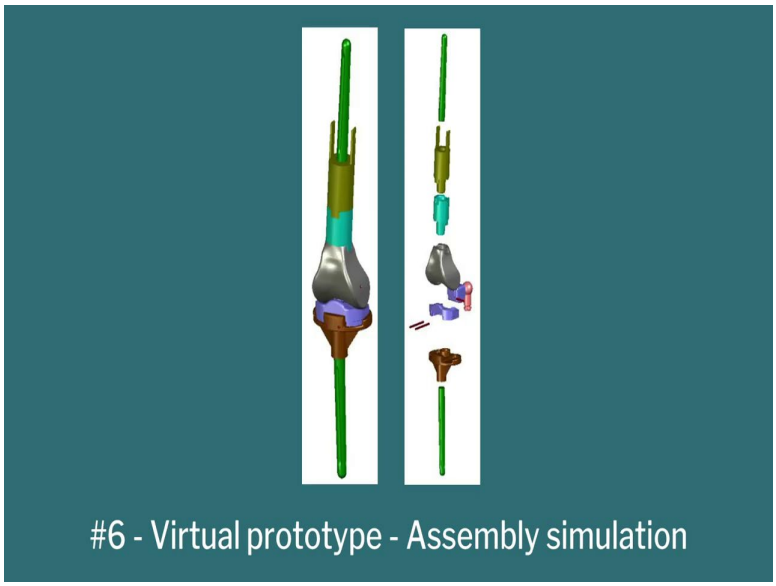

We can also do Assembly Sequencing. You can see what sequence to assemble or disassemble. Disassemble for maintenance let us say. And with all these things, in an additional software called FEA or Finite Element Method, you can actually simulate the loads on the components and how the component will be stressed. Stresses and strains.

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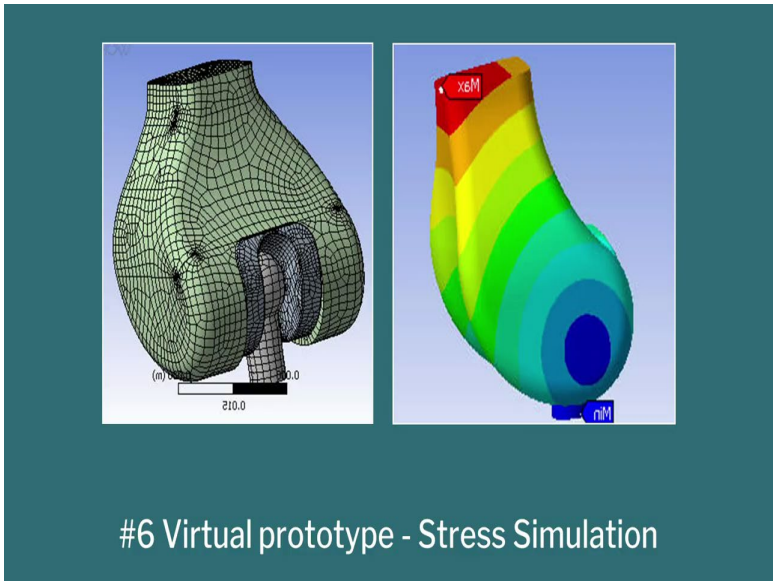

The colour coding will tell you that red means you have high stress. Blue means you have low stress. Where high stress is there you add material, where you have low stress you remove material and so on.

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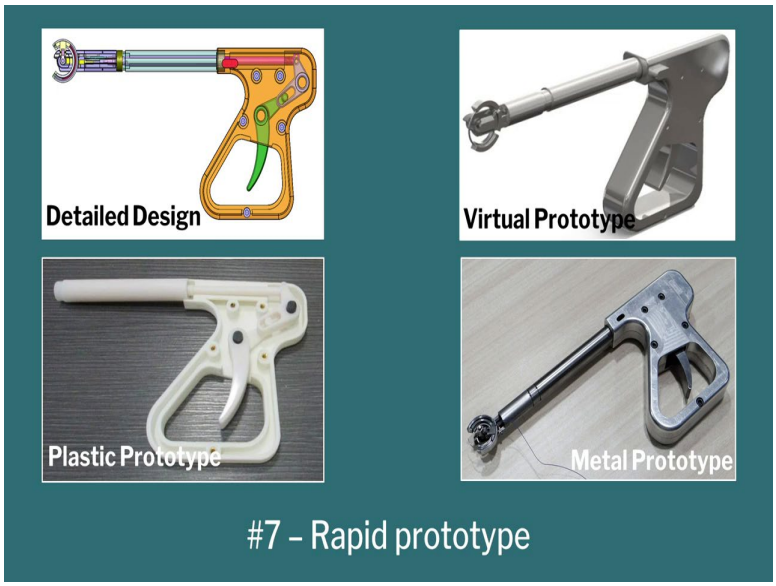

And then you come onto the physical plane, which is you create a physical prototype.

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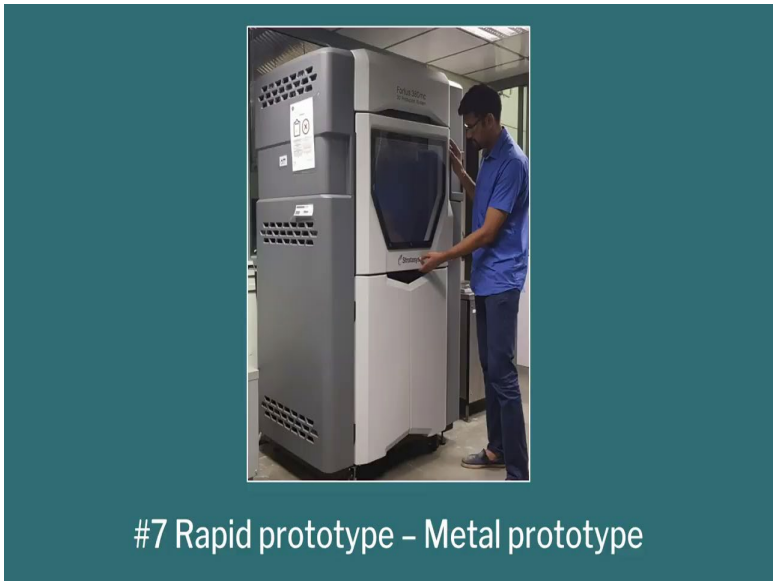

Thanks to 3D printers and multi material 3D printers, like the one you see there, it is now possible to build very accurate physical replicas from the CAD models directly, ok? Of course you have support structures which you have to remove, but you plan very well, you will have minimum support structures and you can create an assembly model from 3D printed parts. It can take some loads, but don't expect it to take real life loads.

It is great to check the form and fit, to some extent the function also. Not to loadings, but at least some basic loading functions also you can try. So form check, fit check and partial functionality check can be done by 3D printed models. Then you go into the functional prototype, which is the actual materials which you want to use. Whether it is Steel, Cobalt Chromium or Titanium or any other specific materials, industrial plastics.

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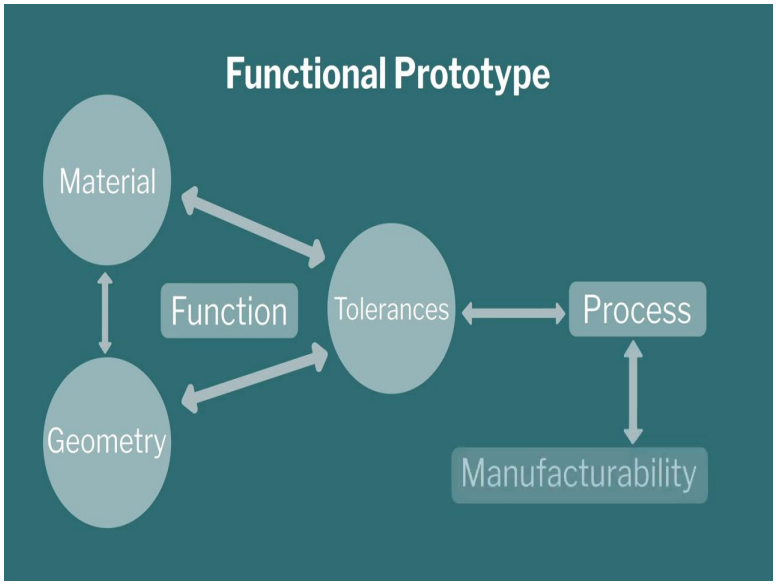

So, what ends up having is, you have some function in mind. You create some geometry and material and tolerances. Based upon these three, you decide a manufacturing process. So process determines manufacturability.

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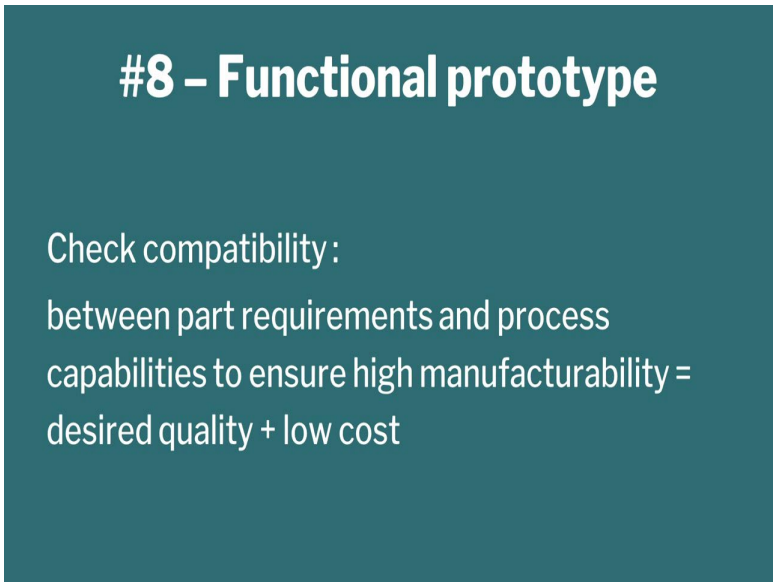

Manufacturability in a very simple sense is: How easy it is to get the desired quality at the least possible cost.

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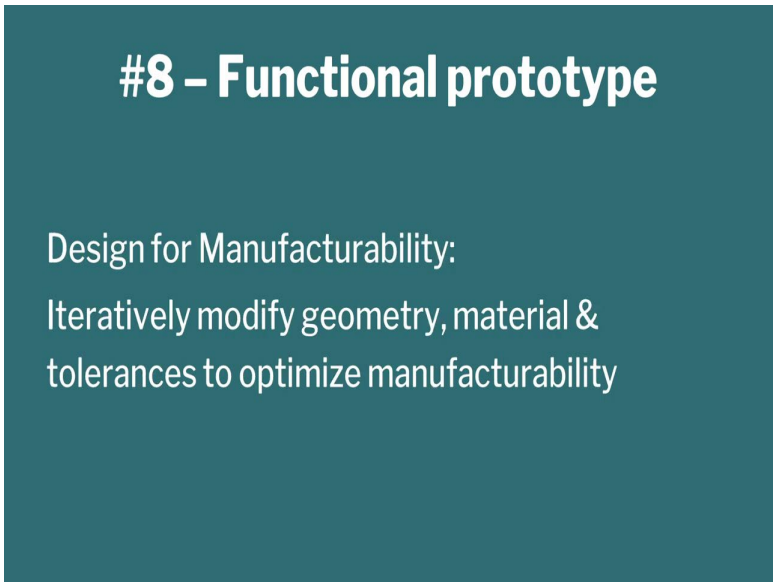

So, you cannot get that, you change your process or change your geometry or change your material, and that is a cyclic process. So, function prototyping although it is just two here, it is actually a challenging job.

Step number 9 is about quality. You cannot, you cannot do an innovation game unless you think about quality and quality management.

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And if you have a quality management system in process, what it means in real life is that you have standard operating procedures, you have some forms, you fill up the forms, someone checks the forms, signs and it becomes a record. Supposing tomorrow something goes wrong and you want to trace back saying, 'What is the reason for that?', if you have not maintained any documentation, how will you figure it out? You need to know: What material was used for that batch? Who made the, who manufactured the part? Who expected the part? You want to look at all the history of the part. That is not possible unless you maintain records.

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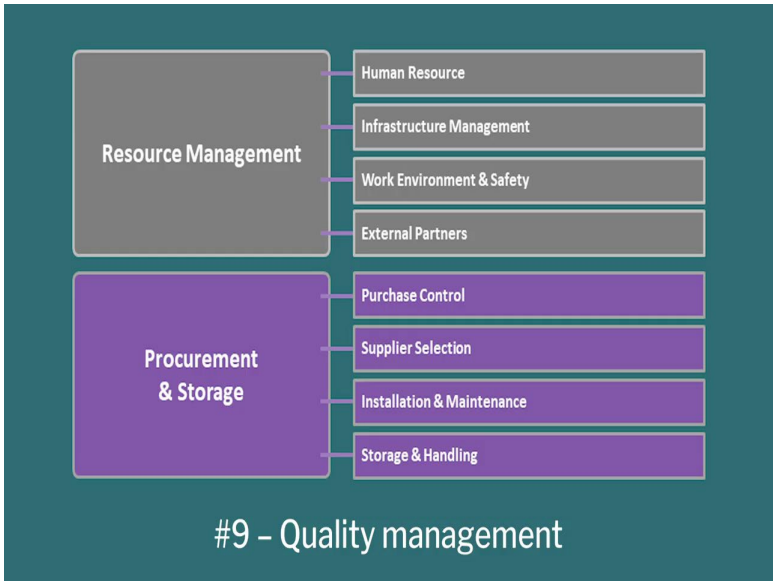

So what typically in medical device development you do is, you look at various headings of departments you can say.

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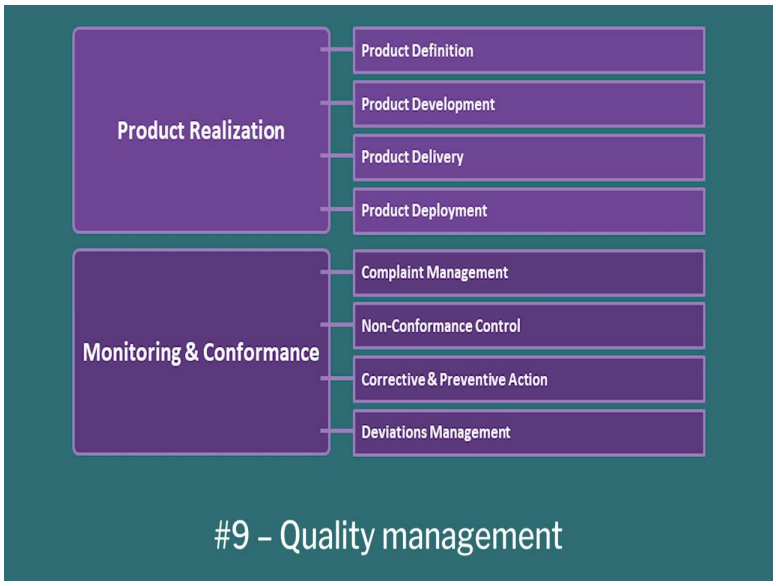

And for each Department to create a certain set of Standard Operating Procedure or SOP. Those become forms and records and so on.

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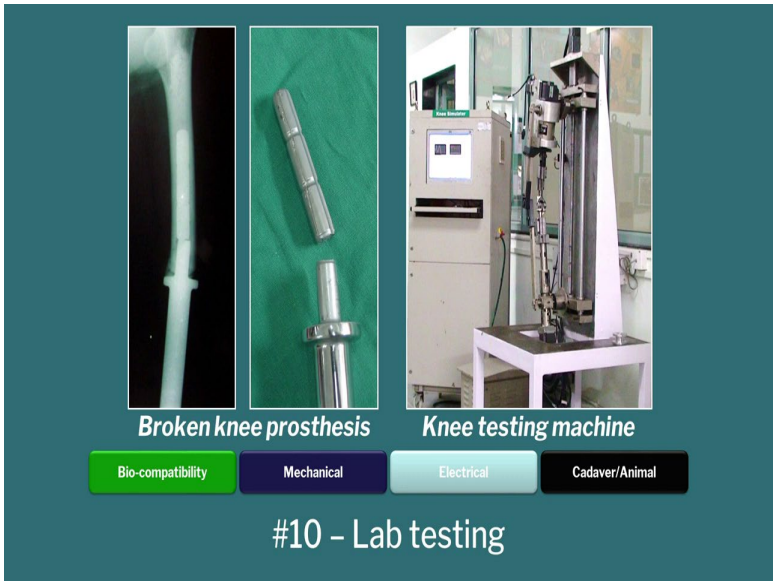

Then, we will go to step number 10, which is your testing in the lab first. Obviously you do not want to put the medical devices in hospitals before you test in the labs first. You do not take a chance.

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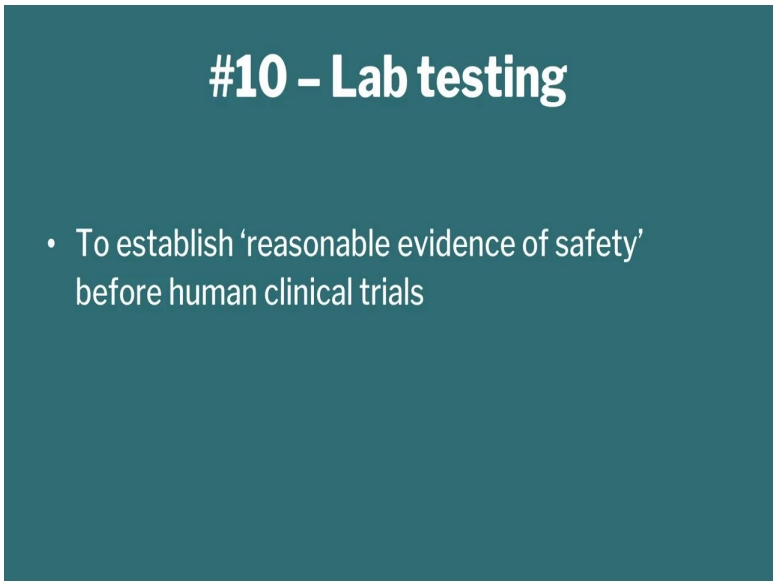

What it means is that you want to establish a reasonable evidence of safety. There is no guarantee that even after lab testing it will be perfectly fine in the real world. At least you have some reasonable level of safety, ok? And so you subject it to various kinds of tests. You have what is called a biocompatibility test, especially if you are using a new material, OK? Or a new composition of a material. You changed slightly composition or the composition of structure changed because of the manufacturing process, you will have to check for what is called as biocompatibility, ok?

Essentially it means toxicity testing, skin sensitivity testing, it should not cause cancer. So these are all tested in the laboratories.

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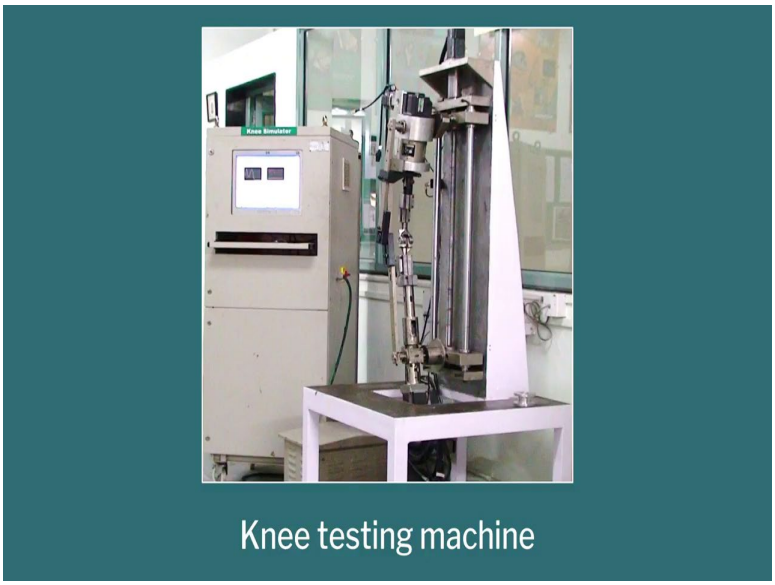

Other than that you also test for mechanical, which is, it should not break, it should not bend, it should not collapse and all that. Mechanical testing also includes that when you drop it, it should not fracture. It also could also mean that if you put it through water jets it should not leak. You also have to make sure that the device will not stop functioning because of some electromagnetic fields or power fluctuations, nor the device will cause disturbance to other devices in the room.

In either way, you have to test it for electromagnetic compatibility and electromagnetic interference. And finally if it pass all the things, you can also try it on dead animals for which the regulations are not that strict, but real animal testing is very highly regulated and controlled. It is only done in specific institutions without permission. But it is possible to do animal trials for certain classes of products. You need not test everything on animals, only those which go into human body that you may need to test on animals.

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After you do all those things, then it's the time for the human related trials. You actually try the device on human patients, but not unsuspecting patients.

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You have to make sure you have criteria for inclusion and exclusions. What kind of patients will try the device? Number 1. Number 2, you will look at Consent forms. The patient should be informed that it is a new device, and why should he/she try the device unless it is better than the existing devices. And if anything goes wrong he/she should have insurance. And if you say everything goes wrong, you say we will give the current best standard treatment back to you, which is we will put him/her back on their feet anyway. So you take care of your patient's safety at any cost.

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So safety is one part of thing and number 2, why you are doing clinical trials is to look at the efficacy of the device. Is it really functioning the way you are promising the way it will function? Better? Faster? Easier? Whatever it is.

Besides these, there are two more things. Specially, if it is a diagnostic device, you also worry about what is called Sensitivity and Specificity. If you are trying to screen or diagnose a person for disease, you want to make sure that there are No False Negatives.

If someone has a disease, the device must be able to catch the person with the disease. No false negative. It says that disease is not there but the disease is there, then it is a risky part. Similarly is also specificity. If someone does not have a disease, the device should not say that he has a disease. That is false positive. Then he will go for unnecessary treatment. We do not want that either. So this is your four criteria or four basic thumb rules for human clinical trials.

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Then, you are getting into the 12th step which is your Certification. Most academics give up by this stage. Certification is a long procedure. You have to submit a lot of documentation to say that you have done all this design properly, testing properly, in the lab, biocompatibility, all the tests, and maybe animal trials, human trials and all the results of that. Then the Government will say that, 'Ok fine. Looks like it is safe and efficient. Now you go ahead and manufacture it'. License to Manufacture and Market is what is implied by this Licensing.

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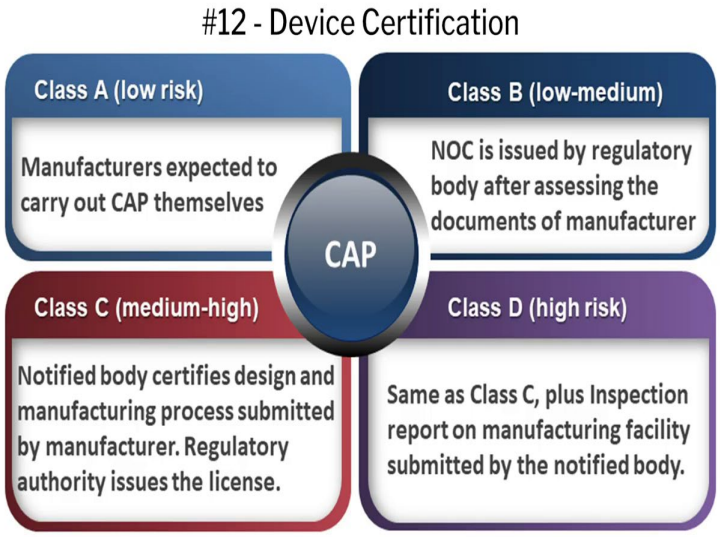

Now licensing depends on the class of the device. If you have a low risk device, regulations are not very strict as long as you are doing basic, good practices of safety and cleanliness and quality

management system and all that, Government will not come in the way. Maybe you should, still for safety, should go and say, 'Please give a No Objection Certificate', NOC.

That is also for the class B, which is low to medium risk. But when it comes to medium to high and high risk devices, then its procedures are far most stricter. It also specifies: Where are you doing? What is the manufacturing process? Your quality checks in the manufacturing processes? Your site plan? Who are your neighbouring manufacturers? If right next to your site there is someone else who is producing poisonous or toxins. Then you don't want to be manufacturing in this site either. So, your neighbouring sites also come into consideration when you have to get a license for manufacturing.

So these are all done and for class division which is high risk, like implants, the Government will not touch, they will actually send an Inspector to see that what you saying on paper is, actually true in reality. So, all this put together, if you pass the whole thing then you get your device certification for manufacturing and market.

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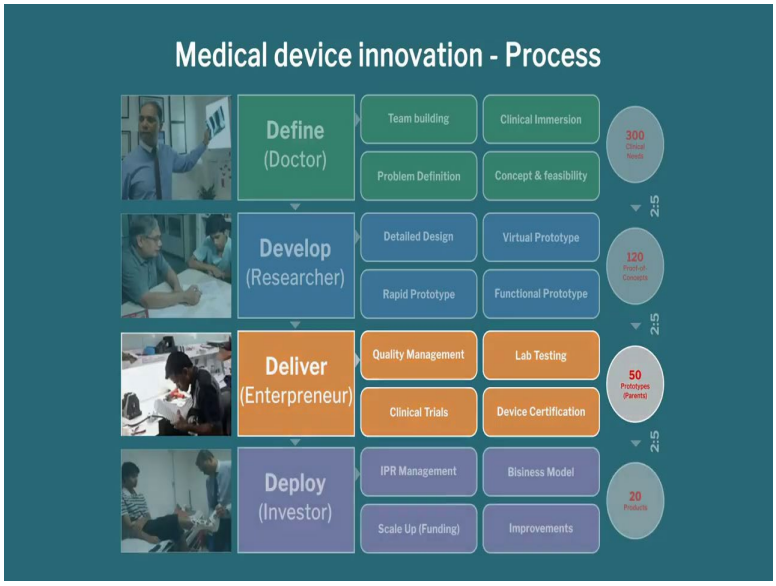

Now you go to the last stage of the life cycle. The last stage is Deploy, which is putting the device into the practical Hospitals. So here is where you need to give a right to yourself and exclude others from manufacturing and copying your device. That is what we get from Intellectual Property Rights, primary of which is patent.

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#13 – Intellectual property rights

Patent

Exclusive right granted to an inventor in exchange for public disclosure of an invention

Criteria for patentability:
1. **Novel** – not publicly known
2. **Useful** – practical application
3. **Non-obvious** to others

What is a patent? It is an exclusive right given by the Government of a particular country, to a manufacturer in that country so that only that manufacturer can manufacture and sell it legally. And other manufacturers sell it, that is illegal. And they can be taken to court. But what do you give in return to the Government is a full disclosure of the innovation. You describe in great detail, how your device works? What are the components? How do they work with each other? Entire drawing, explanation you give it and file it, and it is publicly available.

You may get scared. I am giving away all my knowledge to the public, but because it is given and then the right patent is given to you, even if it is in the public, no one can copy it. If someone copies exactly you can take the person to court and ask for damages.
But what can be patented? only those ideas which are novel, those ideas which are useful and non obvious. You cannot say that, draw something and say that this is, I want to file a patent for that.

If someone else also can come up with a similar idea very easily, it is an obvious idea. So obvious ideas cannot be patented. Combinations of A and B do not become a C and C becomes a patent, that is not possible. They are all obvious things. So, Novel, useful and non obvious, and patenting is not a simple thing, it is a long process. Until recently it would take 8 to 10 years to get a patent in India ok. Now they are reducing the cycle time 4-5 years, hopefully it will come down 2 to 3 years in the next few years.

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The two major steps in the patenting as far as innovators are concerned. The first thing is to file a provisional patent. The moment you have a reasonably clear idea about your innovation and you have a sketch and drawing and you can explain that, you file a provisional patent. Then you have one whole year in your hands to change the drawings and file what is called as a complete specification along with claims. You claim that this is my innovation.

This, you know, this feature is my innovation. So you have one whole year to change the thing, because do not delay the thing. The moment you think you have a good idea, someone else may also file the patent, who knows. You think you are new, someone else may also be thinking of the same idea at the same time. Ok?

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So, filing provisional patents, filing complete specifications are two critical steps for an innovator. Rest of the things are usually taken care of by the lawyer. Even patent drafting is done by a lawyer but in consultation with you. Rest of the thing, filing fees, chasing the thing and hearing and publication, all that the patent attorneys will take care of. Again Business model is a big area and you can spend a whole semester in multiple courses or we can go and do an IAM or an MBA to learn business modeling.

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All you need to worry about is four things. Number 1: You worry about what it is you are offering to customers? Is it a product? Is it a service? Is it a product, or a one time product or is it a product on a multiple times? Or is it a lease? Number 2: Who are the customers? In the medical domain, who is the customer? Customers can be different from the user. Users can be doctors or a patient or a family member. The customer is the one who is paying for the device.

The paying could be either by the patient, or by the hospital, or by insurance agency, or by Government. So that is the customer. Or Hospitals are also maybe buying, once in a while large equipment. And then you have a supply chain and distribution channel. And of course as a startup you always have options. You can say, you can take a technology yourself, license it to yourself and you start a company yourself, great.

Or you may say we will license the technology to some other company or if you are very benevolent, you say, 'Ok, I will put my design on the open source, let anyone copy'. There is also one more option: You can give it to a 'for profit' or 'not for profit' company. We can give it to an NGO, which will supply the products, manufacturer, supplier, zero cost or very low cost to the end users.

Now last but one is Funding. People have tried to look at the causes or failures of innovation companies. And they found that the failures could be for many reasons, but the top three reasons

which come up is: One is that the team is not so strong. The team, complementary skills, or leadership, or maybe size of the team, whatever, team dynamics is one major cause of failure specially in India. Reason number 2 is that: Product-market fit. And we have been telling all from the beginning: if you are solving the wrong problem, or you develop something and you think people should just, everyone should buy this one, but no one is buying it, which means something is wrong.

What you thought people would buy, they are not buying it, it means the product and market fit is not good. But a third reason for failure is: Lack of funds. Exactly the time that you want to go and expand a company or buy some equipment and hire some people, you have zero cash left. And then, you have no option but to wind it down. So typically you need money for four stages of the company.

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One is to establish a minimum viable product which can be actually sold in the market. Typically, this you have to fund it yourself, out of your own personal, family, friends and whatever. If you are working in a lab, and the lab has a project, maybe the projects can fund that. Second thing is you want to establish a minimum viable market. You would actually go and sell that to territories, target customers or users. Ok? Then you know, 'OK, it is selling. People are talking about it'.

And what do they like, what they do not like about it. A minimum viable market. If you have funds yourself and you can bootstrap, nothing like it. Otherwise, you can go towards what is called Angel Funds. Private, it could be private people or the Government, also has got several arms of the Government which is giving angel funding to you.

The Third thing is to establish a suitable business entity. We actually want to start a company, hire a space, hire people, hire furniture, hire equipment, basic things. That needs money, a few million rupees typical. Now there if you do not have funds yourself or the Government or something like that, then you look at what is called as, there are many resources, I'm just giving one one example here, Venture Funding is one source of it.

And once you start selling and it is doing fine and all that, but now you want to go International, or you now want to now start, add one more manufacturing plant or four more manufacturing plants, put distributors in all the states or across the world, you need a large amount of money. Your profit margins are not sufficient to expand like that. Then you have to go to some other sources of funding. There are many other sources again. You can do IPO, or you can go for Private Equity or you can go for Mergers Acquisitions, several examples are like that.

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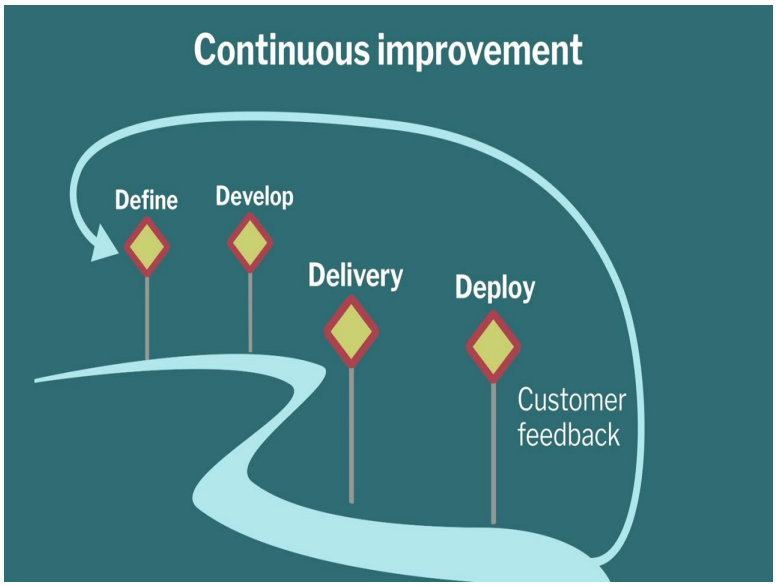

So, this slide was to, just to give a hint of the need for funding, and stages of funding and some examples of fundings in each stage. The last step is continuous improvement. Life never stops at

version 1. You have defined an unmet need. Developed a novel solution. Delivered and tested the product and Deployed in the market. Great, but life does not stop there. Usually when we deploy in the market, you have customer feedback coming in, or complaints, or suggestions and that gives you seed for going back to defining a new product, for new version and life continues like that.