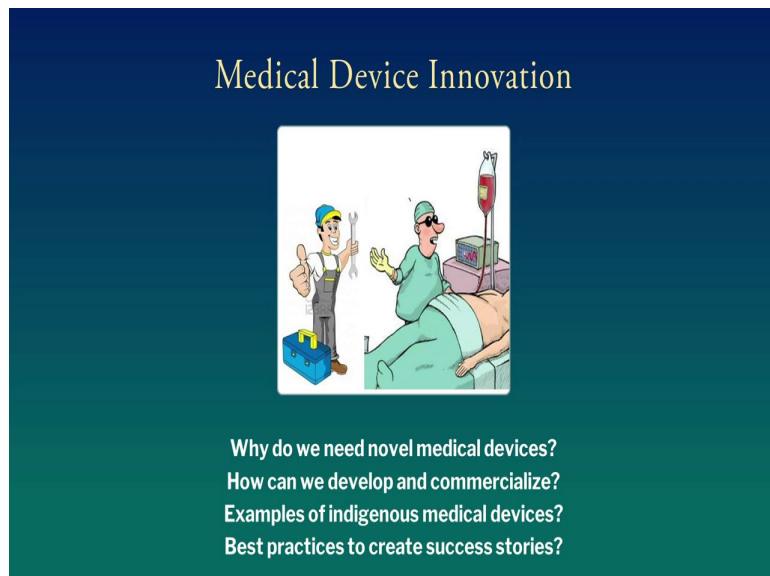


Design, Technology and Innovation
Prof. B. Ravi
IDC School of Design
Indian Institute Technology Bombay

Lecture-17
Systemic Approach to Biomed Innovations Part 1

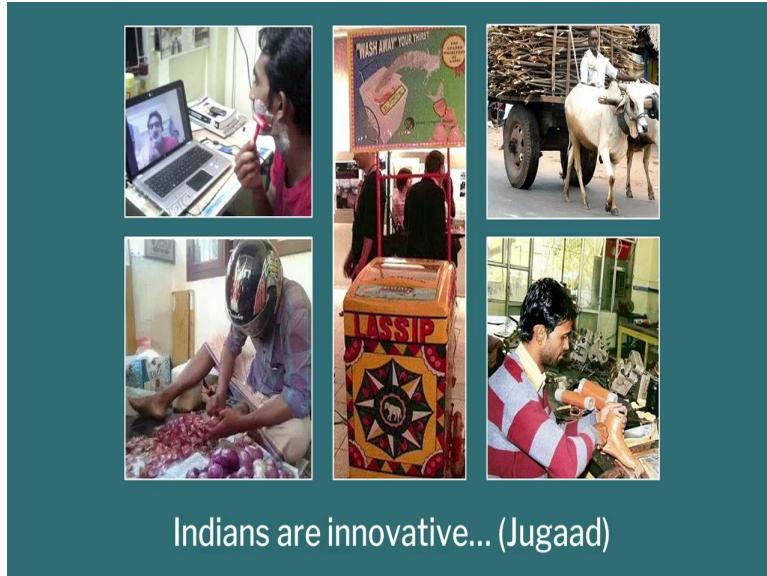
Welcome to this session. We are here to share our experience and some stories about medical device innovation.



In particular, we will answer 4 questions. Why do we need new medical devices? Number 1. Number 2: How can we develop and commercialize those devices? Specifically in an academic setting, students and faculty and so on. The third thing is: Are there any examples of indigenous medical devices which have actually reached the market? And fourth is: What are the best practices? Some tips to create many success stories in this field. These 4 we will answer.

Let me start with this slide which shows that Indians are innovative. You have to just go on to Google and say 'India and Jugaad'.

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And you will find many, many examples of Indians being very innovative. Whether it is shaving without a mirror, peeling onions without getting tears. Whether it is making *Lassi* in the washing machines or whether it is putting tractors as bullock carts. And one more innovation, which is the Jaipur leg. One Common Factor in all innovations is that there are no engineers involved. Even the first picture is the brother of an engineer, not an engineer.

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Indian market – Imported products

Electronics | Consumer Appliances | Defence | Industrial Machinery | Medical Devices



So if there are no engineers involved and there is a raw innovation capability in the Indian public, how come, that today when we go to market and look for some mass produced technology products, there is not a single Indian company to be looked to be found worldwide. We may find some Indian companies selling in India, but can you find Indian Products across the world?

Consumer goods, mobile phones, TV's, defence, transport, industrial machinery and medical devices? Very, very few. At this point of time we are just importing, importing and importing. The reasons for that are that it is not so easy to take an idea from a research lab into industry through the commercialization pathways.

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We say that there are 4 valleys of death. The first valley of death is just your idea in the head, putting it on the table in the form of a proof of concept. It could be just a plain paper and some threads and tubes, things like that. If you cross this value of the death, the next one is to create a prototype. That is also not so difficult to do in research labs because it is some 3D printing, maybe it is some PCB, maybe it is even a breadboard. You can do these things in labs these days.

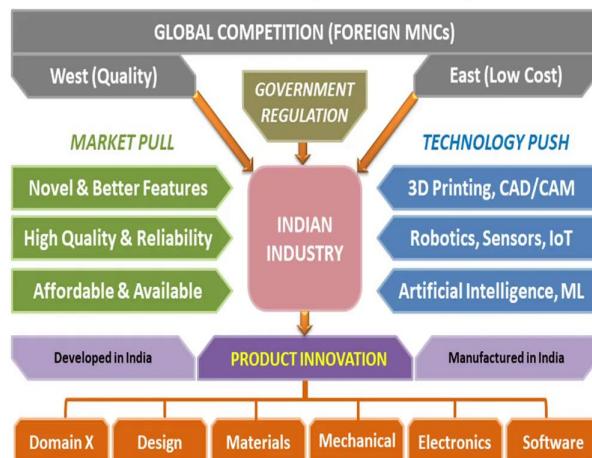
The problem is taking the prototype into the market through a product. Converting a prototype into a product is not easy. Neither academics know the game nor industries what should take a risk into that. Ok? There is a body of knowledge which is required to convert prototypes into a product which neither the academics nor the industry have. But if you somehow cross the third valley of death. The rest of the game is very well known to industries. How to get government permissions? How do you raise money? How to get land? Hire people, right equipment, distribution sales, they know the game.

Why is this not happening? One other reason is not happening is that academics think that if they got an idea, and maybe made a PoC (Proof of Concept), or maybe made a prototype, maybe wrote a paper or in the great case, published a patent, they think that the job is over. They think that half the job is over. It is not really so. Actually it is the other way around that idea generation is very easy. You and me can sit for the next half an hour and generate 30 ideas just like that, but taking ideas all the way to commercialization is actually very difficult.

Until academics realise the importance of commercialization, this is not going to happen. it is not even 10, 20, 30, 40, it is actually in the order of magnitude. You can build a prototype, PoC for a few thousand rupees, prototype for a few tens of thousands of rupees, and it keeps on growing 10 times and 10 times as you go to the next stages of the product life cycle. So, it is not easy, it is expensive.

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Indian Industry Landscape



Need a suitable and sustainable eco-system for indigenous product innovation!

So what is the status of the Indian industry today? I am sure reading papers that Indian industries are not doing so well. Sector after sector is either collapsing, or not doing very well, you must be hearing that. The reason is that at this point of time we are neither able to compete with the quality of western countries, nor can you compete with the Eastern countries: China, Vietnam, Thailand increasing. Even in Bangladesh, they are a much better manufacturers of textiles now, number 2, right after China. Ok?

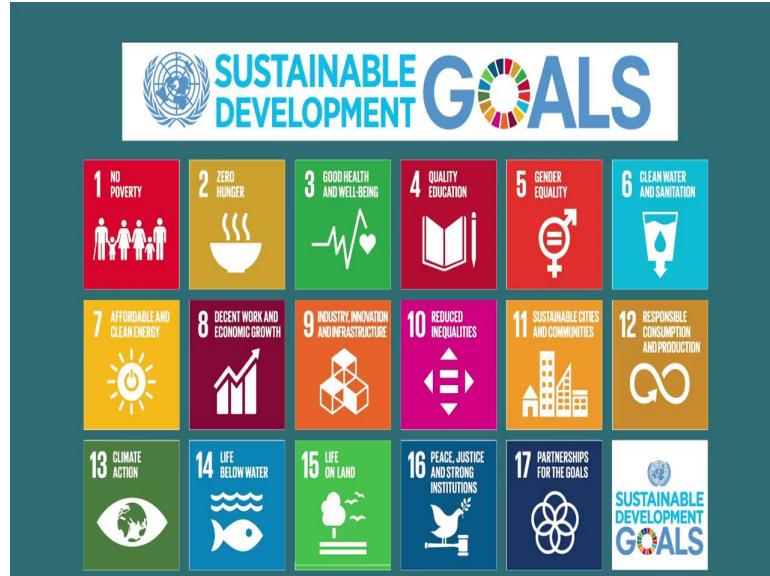
So we are not able to compete when it comes to cost because of the Eastern countries, and Government regulations is, of course, always a bottleneck. Although they are trying to do ease of business. So the only way to do so is innovation and there are some drivers there. Because customers are not loyal. Today you buy a Samsung phone, tomorrow you have some other company offering better features in less price. Are you going to be loyal to Samsung? Most probably not. Maybe there are some die hard fans of Apple but that's about it.

So, we can say that maybe we lost the game, but having said that there is a silver lining in the horizon, in the sense that there is this whole host of new technologies. Whether it is 3D printing, and CAD/CAM, whether it is sensors and the Internet of Things, whether it is medical imaging or imaging in general, image processing, artificial intelligence and machine learning, these are giving us a chance to rethink, reinvent products from scratch.

To give better features and better quality and lower cost and so on. So, the only way ahead actually is innovation. But please, as I keep mentioning all the time, innovation is not specifically a specific discipline. You cannot say that a product is mechanical or electrical or electronics and software, we need all the branches. And the domain discipline, if the product is for medical, we need doctors in the game. If the product is for agriculture, we need farmers in the room.

So we need to have domain expertise also. Ok, so having understood the whole reason for all that: Do we have the ecosystem for innovation in India this point of time? If not, how do you go about building the ecosystem? That is the question we want to answer.

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So, let me say that if you want to pick and choose which areas you want to start the innovation game rolling, to build the ecosystem, and young people actually have come up with consultation from all the countries and everyone else, politicians: Seeing the world at this point of time need to focus on 17 sustainable development goals. These actually give us a very good starting point, and a lot of young people are actually concerned and thinking about carriers in these domains.

If you think about these 17 SDG (Sustainable Development Goals) as a starting point, Where do we pick and choose? And I would like to say that, let us think about Healthcare as a starting point. Because ‘Healthcare’ and ‘Innovation’ and ‘Life on Land’ is 3 out of 17 and I will give 4 reasons for doing that.

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Reason number one is that, at this point of time medical devices are badly needed for taking care of both diagnosis and treatment of various diseases.

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Reason #1 – Healthcare is universal need

- 14,000 healthcare problems
- Require affordable devices to screen, diagnose, monitor, operate, treat and rehabilitate

How many diseases? 14,000 as per WHO (World Health Organisation). So you need a variety and an army of devices to diagnose, screen, monitor, treat, rehabilitate and assist patients.

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Reason #1 – Healthcare is universal need

- Indian Medical Device market:
 - Rs. 48,500 crore (US\$ 7 billion) 80% imported (Rs. 39,000 crore)
- Healthcare Expenditure:
 - India: 5% | USA: 18% of GDP
 - India: \$ 70 | USA: \$ 7500 / head / y

And what is the current scenario? The per capita expenditure on healthcare in India is less than 1% of that of the USA. And the USA is the world's, both, largest producer as well as consumer of medical devices. So even if you take a made in the USA device and give a 90% discount, it is still 10 times more expensive than what can be afforded by the average Indian population.

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Reason #2 – Significant social impact

Reason number 2 is that Healthcare has a great social impact.

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Reason #2 – Significant social impact

- Affordable Health
 - Cost per device
 - Cost per treatment
 - Cost per patient

If you can lower the cost of not just the device but cost of treatment or diagnosis to let us say, 1% and it is feasible. If you can, someone lower the cost for one person, it is a great opportunity to reach out to a large number of the population at the bottom of the Pyramid. Those who are specially unprivileged, if they fall sick, they lose 1 days wages. If one days income is not there, one days food is not there on the table. So, they cannot afford to fall sick. We need to make sure that they do not fall sick or are diagnosed time.

As per some reports Healthcare has become the largest employer in the USA already. And Healthcare startups are number 2 among all startups in India at this point of time, right after E-Commerce. Even in SINE (Society for Innovation and Entrepreneurship), IIT Bombay, now, out of 20 companies. Apparently half are Healthcare startups. So, startups are giving a lot of employment opportunities aswell.

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The third reason is that at this point of time there are fantastic funding avenues available from various Governments bodies apart from NGOs and the private sector.

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Reason #3 – Funding avenues and incubators

If you just take one Government arm itself which is BIRAC (Biotechnology Industry Research Assistance Council), which is an arm of the Department of Biotechnology, which is an arm of the Ministry of Science and Technology, just one arm of an arm, you may say one finger of the Government,

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Reason #3 – Funding avenues and incubators

- BIRAC

SIIP | SPARSH | SITARE | SRISTI-GYTI

BIG | SBIRI | BIPP | PACE | SEED | ACE

has so many schemes, I have listed only a few, including the famous BIG or Biotechnology Ignition Grant. A BIG grant of 50,000 rupees or 5 million rupees is given directly to an innovator or a startup company to start a company and take a product to market. Equity free, you can say, grant, and they are not going to take any shares in the company. It is a pure equity free grant.

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Reason #3 – Funding avenues and incubators

- 40 Bio-Incubators
- 20+80 Atal Incubators

And of course there are a large number of Bio-Incubators and Atal-Incubators where you can actually go and start this company.

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Bio-Chemistry
 Bio-Chemical
 Bio-Electronics
 Bio-Informatics
 Bio-Mimetics
 Bio-Materials
 Bio-Medical
 Bio-Mechanics
 Bio-Physics
 Bio-Statistics
Bio-Technology:
 Green(Agri)|Yellow(Food)
 Blue(Marine)|Brown(Dry)
 Gray(Toxic)|Dark(Military)



Reason #4 – Innovation driven by collaboration

Reason number 4 as I saved for the best which is: You cannot do innovation unless you do collaboration, and you cannot do collaboration unless you go out of your comfort zones. Ok? And at this point of time, bio combined with any domain, you cross bio with any domain, as you can see here, Bio-physics, Bio-electronics, Bio-materials and Bio-technology itself has several colours. Ok? Not only potential for research but also potential for practical applications.

And nothing like biomedical because if you want to collaborate and go out of comfort zones, the test of that is can you ask stupid questions to each other. You cannot have ego there. It is easier to let go of ego when you are trying to solve the problem of someone in pain or someone suffering. So, it is easy to collaborate in the Healthcare domain, coming across various disciplines because of this factor of social impact it has got.

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Let me come to what we are doing at BETIC (Biomedical Engineering and Technology Innovation Centre). So, BETIC is the lab inside IIT Bombay. It is a R&D project funded by the State Government of Maharashtra and Central Government of India, Department Science and Technology. And we started with a very simple thing.

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We said let us just bring the stakeholders together. What stakeholders? Doctors, researchers, entrepreneurs and Investors. These are the 4 critical stakeholders for medical device innovation and commercialization. Simply just we said, let us get them together and magic will start. So what we have inside the lab are several different small cells, you can say.

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Medical device innovation facilities - Virtual prototyping

We have one cell for generating ideas where the doctors meet us, we have one cell for doing CAD and simulation, one cell for doing plastic prototyping,

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one for electronics prototyping including electronics, CAD simulation and PCB milling,

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Medical device innovation facilities - Ti-alloy 3D Printing

and one for metal 3D printing. Plus we also have access to testing labs across IIT and so on. That is at IIT Bombay.

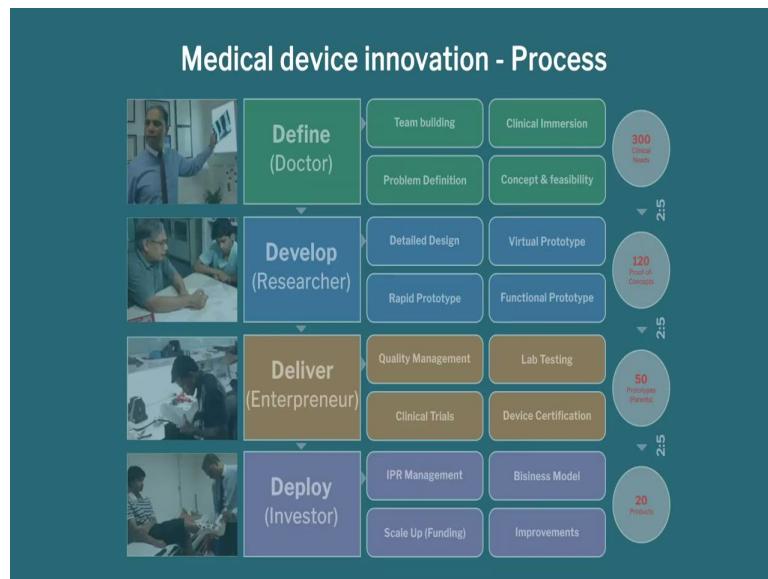
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But BITEC is also in other Institutions. One partner is VNIT (Visvesvaraya National Institute of Technology) Nagpur where they have tissue engineering facilities. You can 3D print materials which are bone-like substitutes and we can use them to fill gaps in the human body, especially bone gaps. We also have a BITEC cell in college of engineering Pune, where they are focusing on 3D printing and electronics. And we have a Gait Lab, where we have cameras on the ceiling and on the floor by which, when you walk we can capture 3D moments, which can be used to create, we can say, a stick diagram or Forced Model Diagram of the human body.

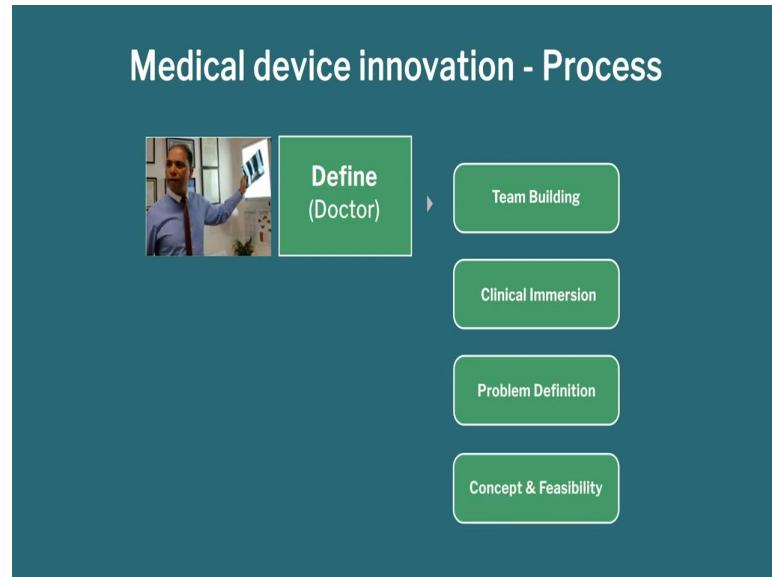
The way you walk is a signature of not only your skeletal problem, but also it is a signature of your neurological problem. The walking signature can tell the doctor what you are suffering from. So, we have the lab for doing that also.

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Then we have put a process in place for innovation, and this process if you can see has 4 major stages. Stage 1 is called ‘Define’, where doctors play a critical role. Stage 2 is called ‘Developed’ where researchers play a critical role. Stage 3 is called ‘Deliver’ a tested device where entrepreneurs play a role and Stage 4 is to ‘Deploy’ and practice, where investors are necessary. What we did was to divide each of the stages into 4 steps each so you have 16 steps.

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So the Define stage has 4 steps: Build a team, go and watch what is happening in hospitals, define the problem that you want to solve and then create a concept and then check the feasibility of the concept right at the early stages before you invest more effort and money into that.

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Then you get into the Development stage where you actually looking at the detailed design, Virtual CAD modelling, then Rapid Prototyping and Functional Prototyping.

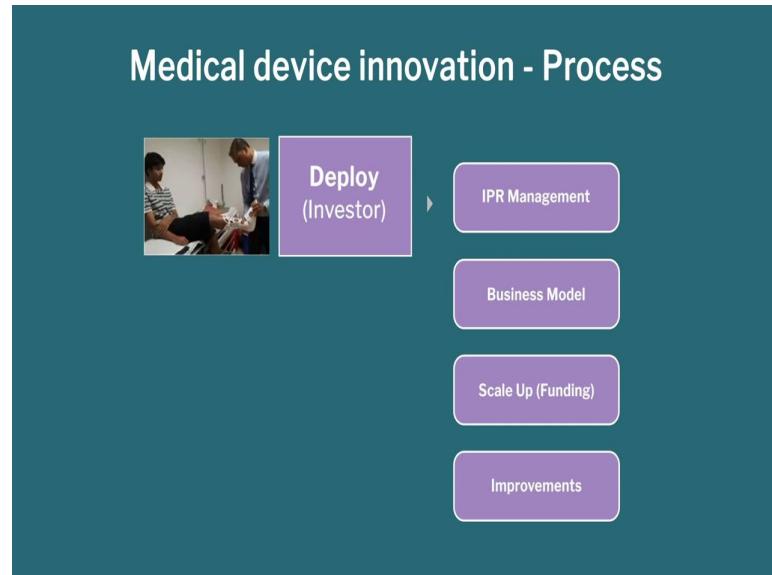
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Then we have a Delivery stage where testing has to come into picture. This is where most of the academics give up. They think that Development is over, they can file a patent or publish a paper, our job is over, someone will take it forward. Usually no one takes it forward. You are the mother and father of the idea, so it is your responsibility to nurture the child beyond. Testing is one critical phase like that. So, you have to actually figure out, how to test in the lab?

How to test it in the, how to manage the quality systems before you do testing? What standards do you have to follow? Then lab testing, the, clinical trials, preclinical trials, main clinical trials and finally certification of the device. Unless certification, you cannot go forward into manufacturing.

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Then the last stage comes where you have to Deploy the device into the market. So here we have the IPR (Intellectual Property Rights). You have your, you have to create a business model. How are you going to sell the product? Through what channels? What is your supply chain? Distribution channels all those things. And then you look at where do you get the funding for initial, and then scaling up, sustaining the activities and life is not over.

Once you have version 1 in the market, you go and build version 2 and version 3 and so on. No one brings a perfect product which is stable forever. Now, usually people say that the innovation game is very risky. Ok? If you have to start with 10 ideas, you go for 1 prototype, out of 10 prototypes 1 becomes the product, 10 products go to market 1 will make it big, breaking even, for 10 which break even 1 will make fantastic or huge profits.

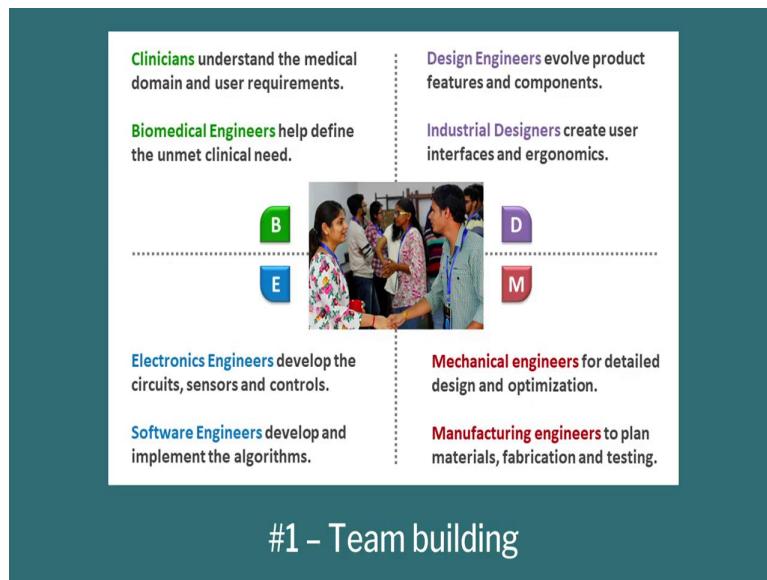
It is a 10,000 is to 1 success ratio. But be careful when people say that or you hear this type of statement. When we are talking about the idea stage I mentioned to you earlier that we can sit for 1 hour and can generate 100 years if you wish, now what is the cost per idea? Hardly anything. Maybe some tea and coffee. Out of 100 ideas we decide to take forward only one or two and that's a 90% failure rate. Does it sound like a good thing or a bad thing? It is a good thing. You have tried 100 with hardly any cost, throw away 98 and you are taking 2 forward.

So as you go forward in the life cycle of a product development, initially you can throw away a lot of ideas but it does not cost you anything or very little. But by the time we come to the final stages and the product is actually manufactured and put in the market, you better be very sure that it will break even at least, if not make you handsome profit. The actual success rate or actual failure rates are not as they say. The real cost of failure is not really that. Ok? If you do things in a systematic way.

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

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

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#1 – Team building

- *Clinicians* understand the medical domain and user requirements.
- *Biomedical Engineers* help define the unmet clinical need.

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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#1 – Team building

- *Electronics Engineers* develop the circuits, sensors and controls.
- *Software Engineers* develop and implement the algorithms.

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.

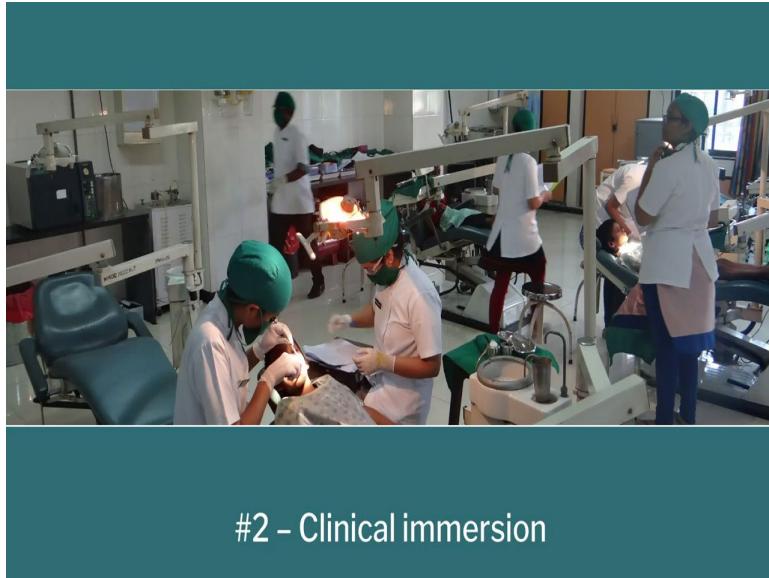
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#1 – Team building

- *Mechanical Engineers* for detailed design and optimization.
- *Manufacturing engineers* to plan materials, fabrication and testing.

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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#2 – Clinical immersion

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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#2 – Clinical immersion

- Prior permissions
- Patient consent/privacy

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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#2 – Clinical immersion

Devices used in treatment:

- Device selection
- Time | Skill | Variations

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 or 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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#3 – Problem definition

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

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#3 – Problem definition

- A well defined product is half-way to being designed

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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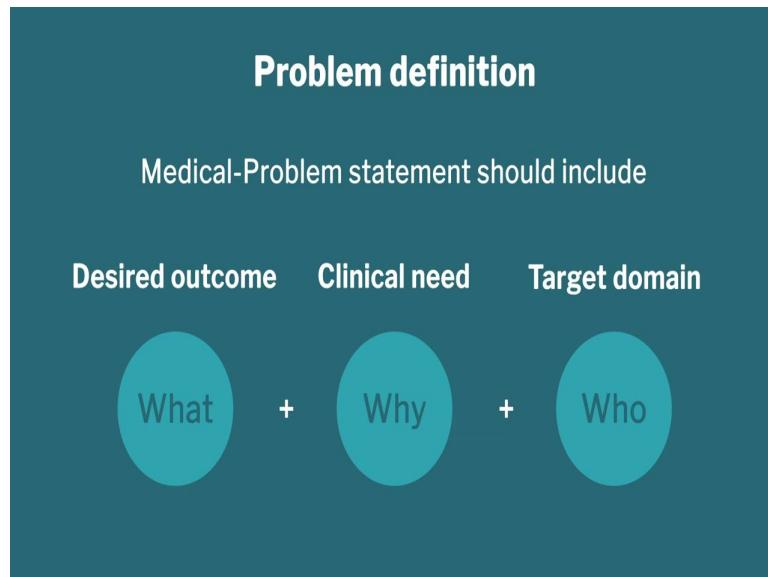
#3 – Problem definition

Clear statement of user need in minimum words:

- *Rule 1: Must not be vague (else difficult to evolve or evaluate ideas)*
- *Rule 2: Must not point to a solution (else radical new ideas get blocked)*
- *Rule 3: Go to the root cause (else wrong problems get solved)*

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.

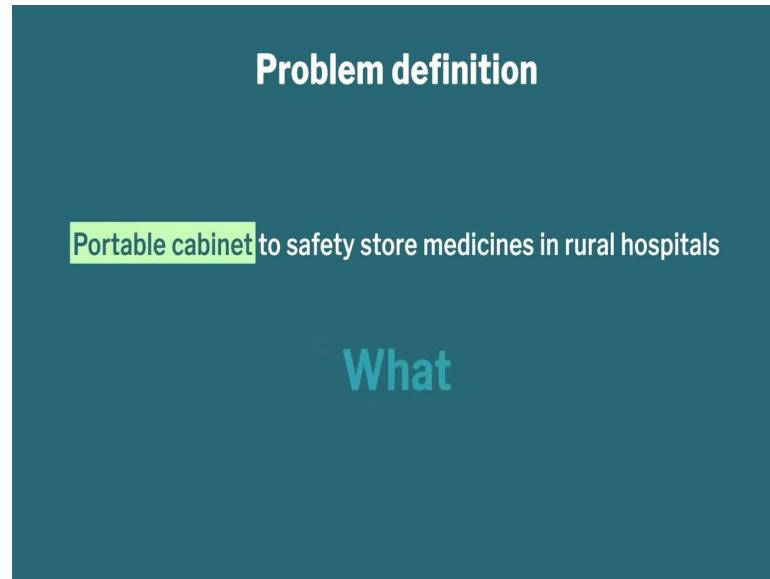
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In my opinion, a good problem definition must have 3 things. It must have a ‘Desired Outcome’ which is what you want. It must have some ‘Clinical Need’ because you also mentioned why you

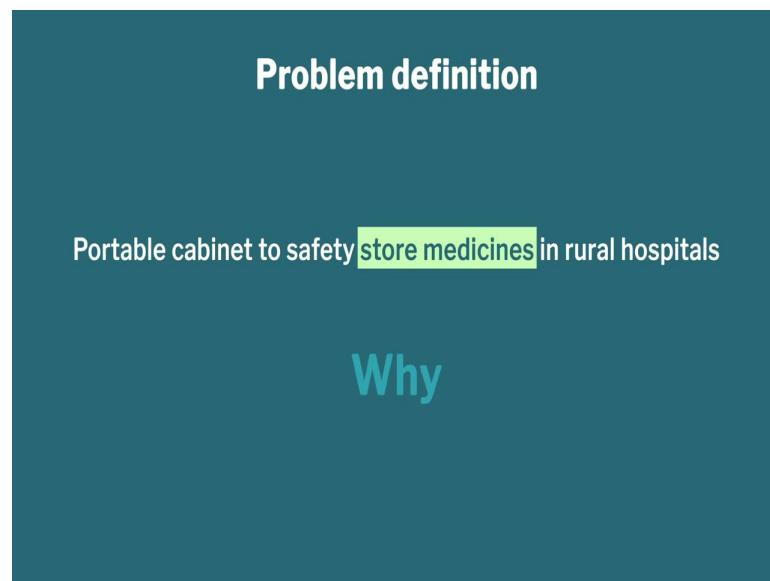
need that, and also in some way you define, who is the ‘Target Domain’, what it means is, who is that?

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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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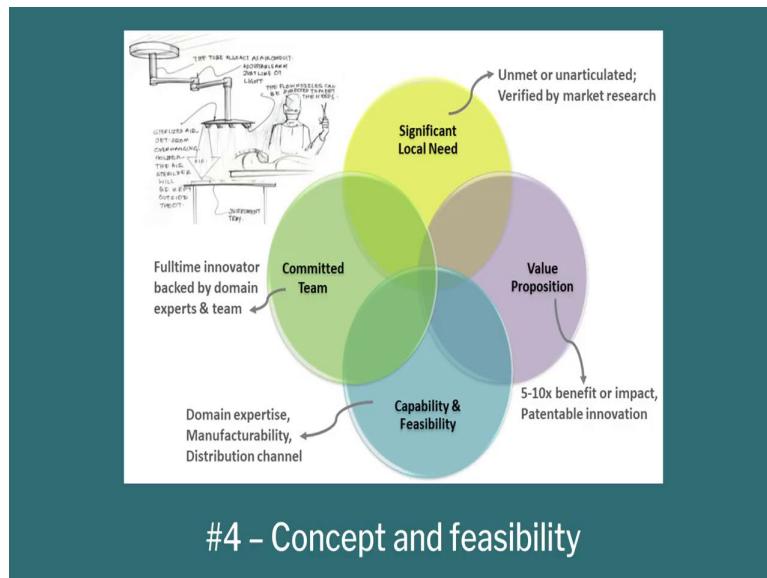


Why do I need it? To store medicines;

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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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Concept and feasibility

Significant local need

- Unmet & unarticulated: verified by market research

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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Concept and feasibility

Value proposition

- 5-10x benefit or impact, patentable innovation

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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Concept and feasibility

Capability & Feasibility

- Domain expertise,
Manufacturability,
distributional channel

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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Concept and feasibility

Committed team

- Full time innovator backed by
domain experts & team

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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#5 – Detailed design

- Overall structure
- For each component:
 - Geometry (features)
 - Material (properties)
- Component manufacture
- Product assembly

Now we go to the 'Develop' 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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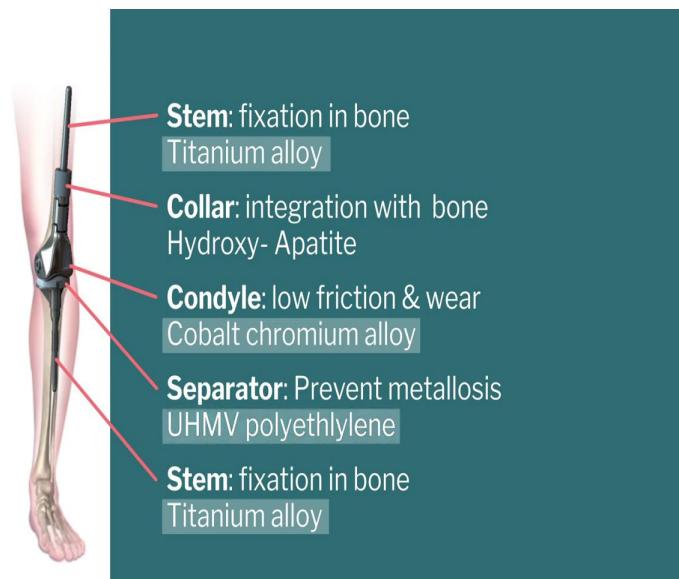
#5 – Detailed design

Separate component ?

- Functionality?
- Movement?
- Properties?
- Manufacturability?

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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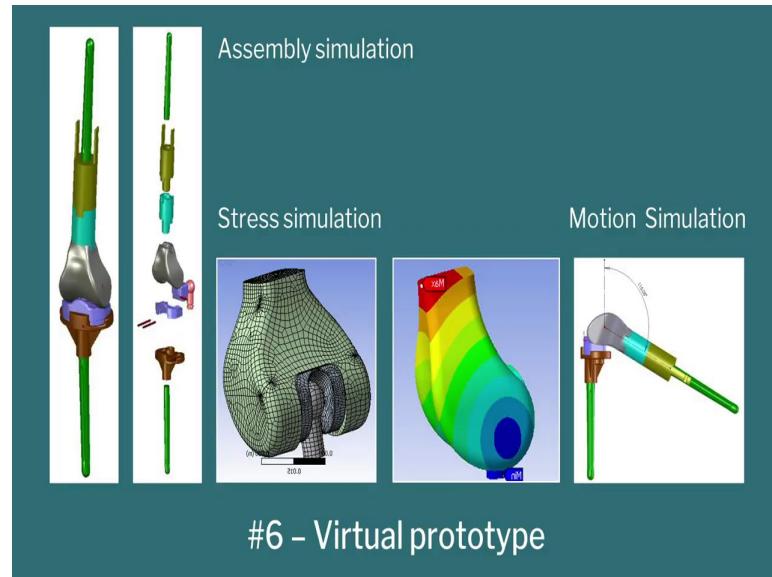
Let me take an example here. This is a process for children with bone cancer. Ok, you can see that there are several components there. You have the condyle in the middle on which the kneecap or patella will glide. Then you have the collar kind of thing, which gives an extension because someone's tumor 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?

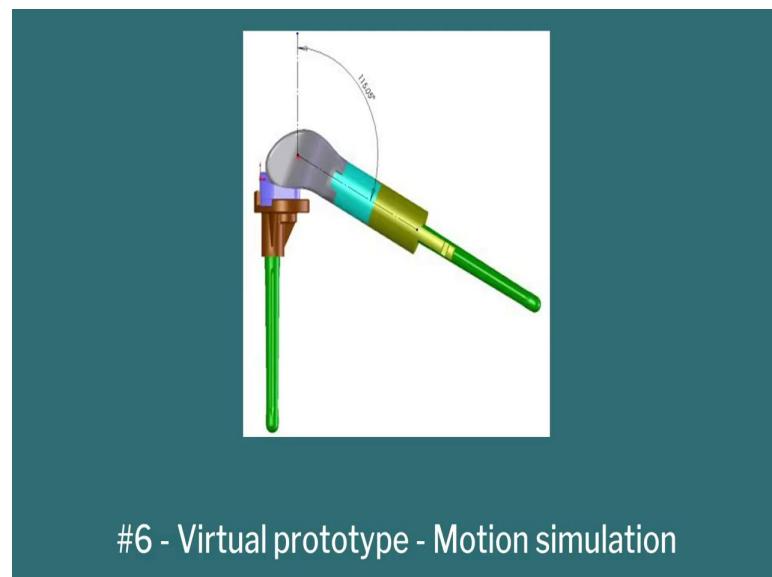
So this showed you how you decide about the various components and decide about the material and geometry component based upon the functionality and properties.

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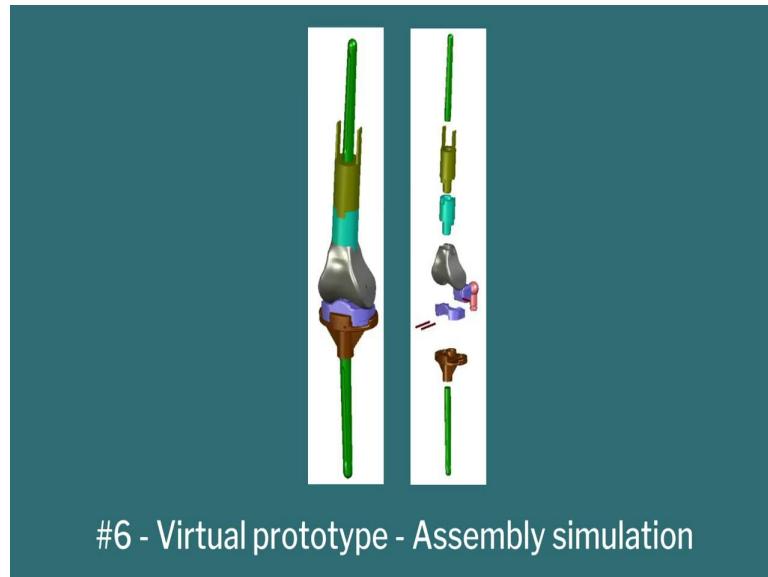
Then you are going to detailed design. We are actually going into the dimensioning, the actual shape, the actual features and thanks to CAD today it is very easy to visualise, model and visualise that. But CAD also allows you to do few other things. Using CAD you actually can give the movement. You can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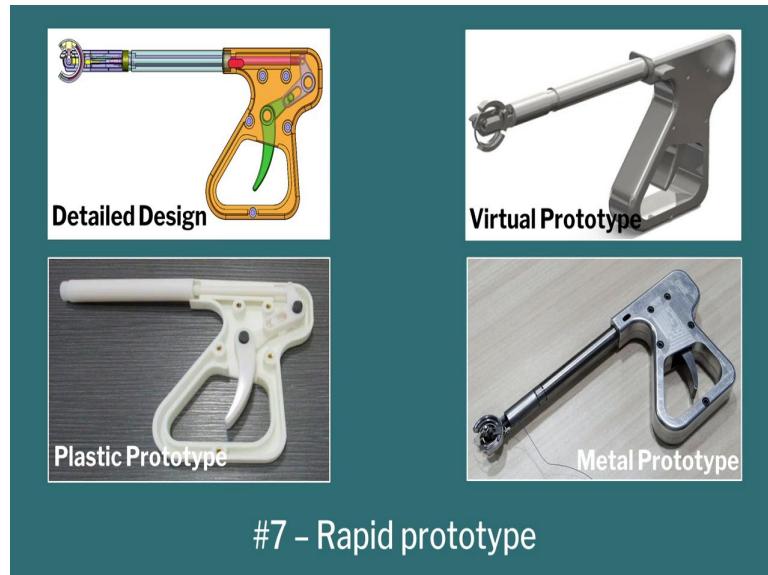


We can also do Assembly Sequencing. You can see what sequence to assemble or disassemble. Disassemble for maintenance let us say. And with all these things, in an additional software called FEA or Finite Element Method, you can actually simulate the loads on the components and how the component will 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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#8 – Functional prototype

Check compatibility:
between part requirements and process
capabilities to ensure high manufacturability =
desired quality + low cost

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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#8 – Functional prototype

Design for Manufacturability:
Iteratively modify geometry, material &
tolerances to optimize manufacturability

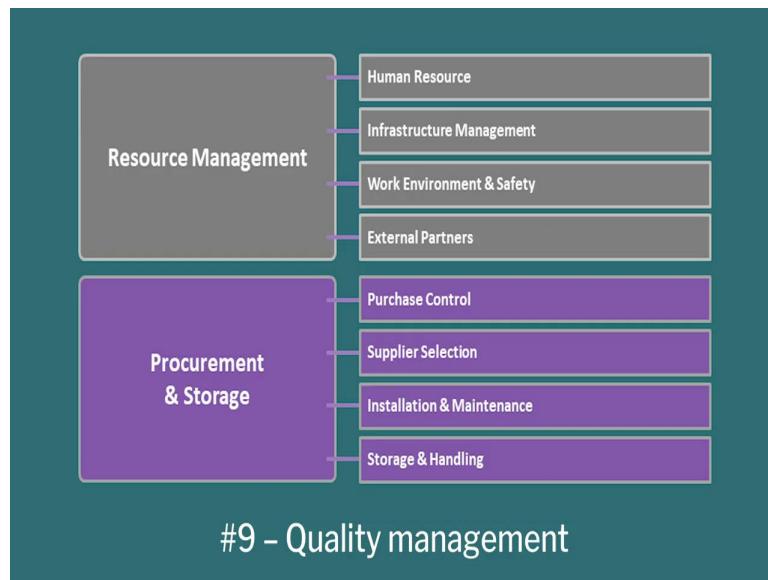
So, you cannot get that, you change your process or change your geometry or change your material, and that is a cyclic process. So, function prototyping although it is just two here, it is actually a challenging job.

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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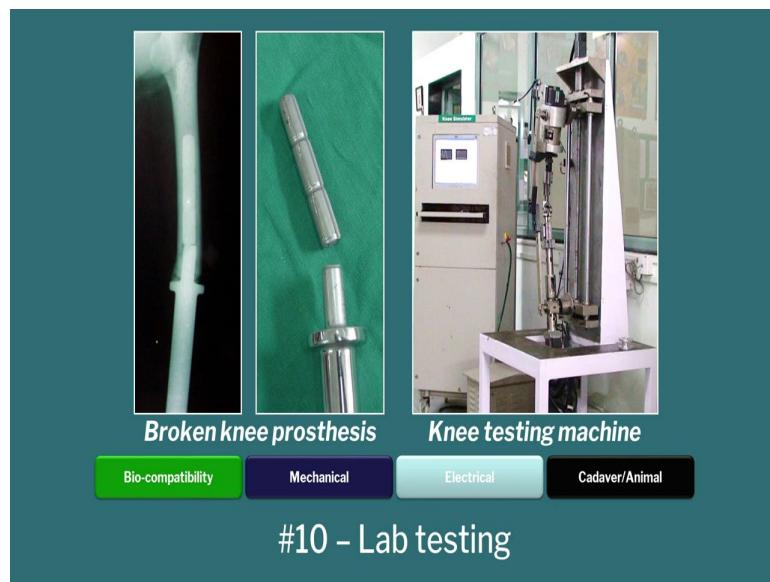


So what typically in medical device development you do is, you look at various headings of departments you can say.

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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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#10 – Lab testing

- To establish ‘reasonable evidence of safety’ before human clinical trials

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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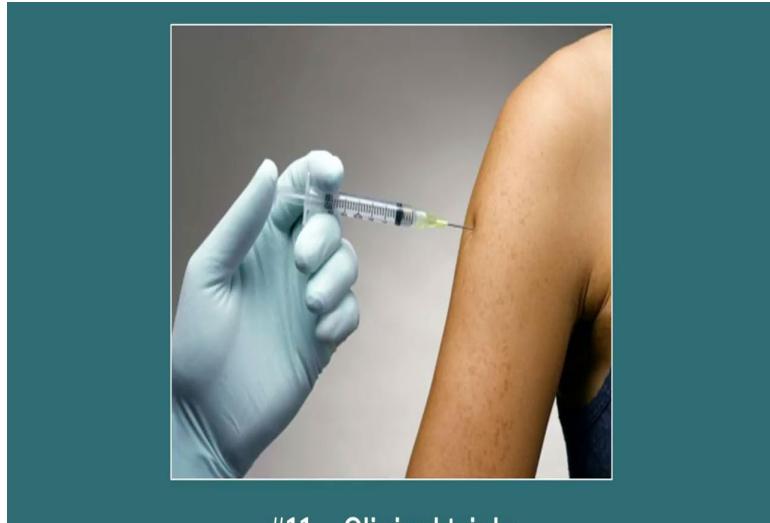


Knee testing machine

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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#11 – Clinical trials

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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#11 – Clinical trials

- Prove device safety and efficacy
- On pre-determined number of volunteers after their consent
- Tightly controlled and monitored by regulatory authorities.

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.

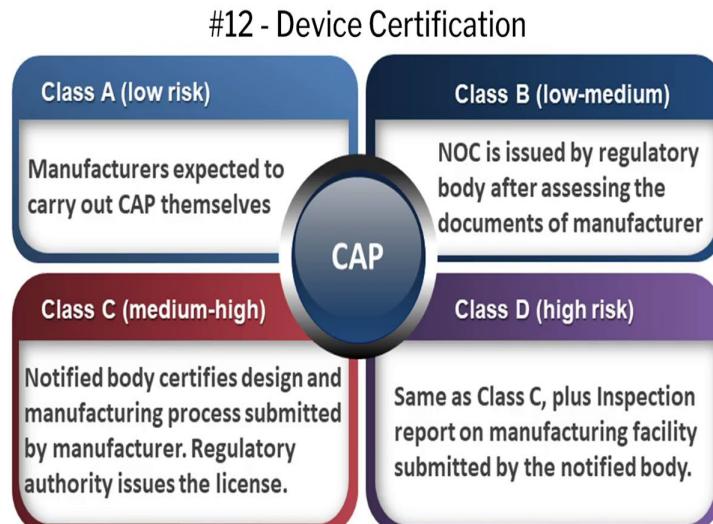
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#12 – Device Certification

- Conformity Assessment Procedure by notified bodies of government.
- Audit of product dossier, quality management and manufacturing sites.

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.



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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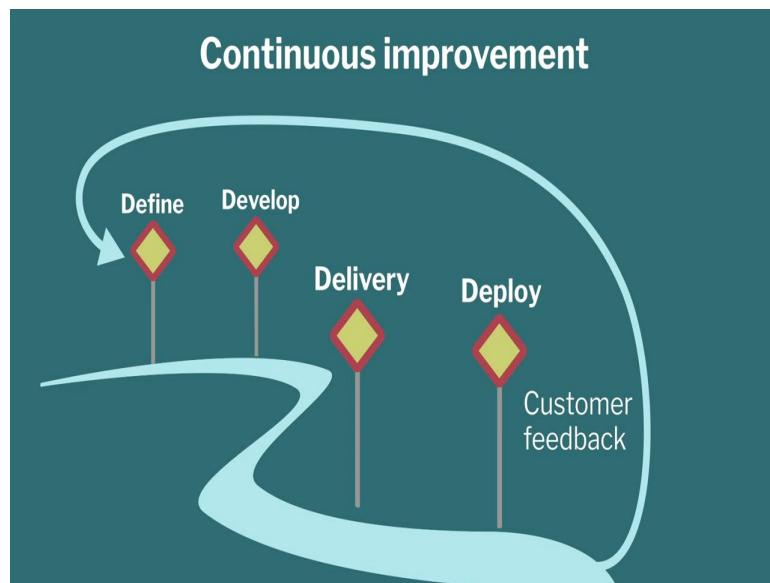
One is to establish a minimum viable product which can be actually sold in the market. Typically, this you have to fund it yourself, out of your own personal, family, friends and whatever. If you are working in a lab, and the lab has a project, maybe the projects can fund that. Second thing is you want 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.

Design, Technology and Innovation
Prof. B. Ravi
IDC School of Design
Indian Institute Technology Bombay

Lecture-19
Systemic Approach to Biomed Innovations Part 3

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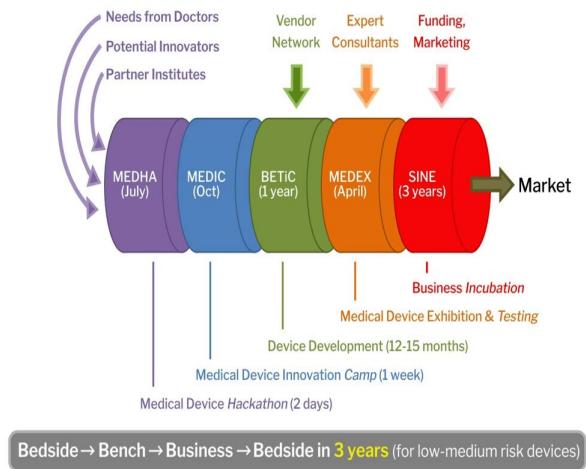
Medical device innovation – Role of clinicians

One thing I want to highlight is that in all the steps, right from defining to deploying, the role of doctors is very critical. In fact, call it as Bedside to Bench to Business to Bedside, because you are identifying the need of the bedside of a patient. Developing a solution on the bench side which is engineering, but then unless you go to business you cannot deploy it, but it goes back to bedside again.

So, Bedside to Bench to Business to Bedside is a cycle for a medical device innovation. In every step doctors had to be consulted and without them you cannot succeed. Ideally multiple doctors. So what I am going to share now with you is the pipeline or the process by which we are able to do the innovation, put the resources together, and take it all the way from bedside to bedside again.

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Medical device innovation – Funnel



It starts from MEDHA which is a Medical Device Hackathon. What you do is, the whole year we keep getting doctors saying, ‘Solve this problem, solve that problem’, so we make a list of those problems. We also get a lot of applications from students or working professionals saying, ‘we want to try this area out’. And third is, we have several institutions who want to initiate or start a medical device innovation cluster. So what we do is we put all the three things together and we organise a series of hackathons called as Medical Device Hackathons, which is a two day affair.

Starts on a Saturday morning and ends on a Sunday evening. And we bring those institutions, we do it some other place and those people who wanted to work in this field and doctors who said we want to take up some problems. We bring all of them together, and typically we do it in May, June, July, August months, and those who after doing that, some of the working professionals or winners of those events, MEDHA events, especially those who want to take, go forward, one more step forward. They want to equip themselves with the right kind of skills and contacts and so on.

We bring them to what is called a Medical Device Innovation Camp or MEDIC. We typically do it in the end September or early October. And this is a one week affair. So we start on a, let us say Friday evening, and of course it is a Friday morning, Friday, Saturday, Sunday, Monday, Tuesday, it goes for 5 days and five days and four nights, ok? Usually we have people not sleeping on the fourth night because they are trying to push the whole thing.

But many times it happens that people start, start losing sleep from day 1 itself. And those who withstand that training and pressure and are able to build something in 5 days 4 Nights, we usually invite them, or they usually come by themselves for a fellowship in BETIC. This is a one year fellowship, it usually sometimes extended it for one and half years, but in one to one and a half years, they are supposed to develop a complete medical device, test it in the lab, may be even preliminary testing in a good hospital and go to the next step which is put it in an exhibition. Medical Device Expo, MEDEX, Ok? So we organise our own MEDEX twice in a year.

But you also put in other exhibitions organised by our Government or private organisations. Now, exhibition what happens is, when people are coming in and saying, ‘Hey, I like this device. What does it do? Can I get it? Can I buy this? Or some distributors would like to partner with you or some doctor says, ‘This is fantastic, I want to talk about it or test it’. Then you start getting the validation that what you have done is something very nice.

And that is the stage when you go to the next step which is to actually start a company. What is happening is many young people start a company, then you start developing a device, then they are pivoting that is changing the Design or Market or Customers, Ok? Then trying to find partners and by that time they run out of money, Ok? Then you end up giving a lot of equity to private companies or venture funding. So it is not a, we feel a better way is to do as much as possible before.

And once you start a company, you should be able to start selling in year 1. Not developing, developing for 2 to 3 years. So typically what we say is from Bedside to Bench to Business to Bedside. We should be able to traverse the entire pathway in 3 years time for a low risk device.



Mumbai, July 2017

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Mumbai, Aug 2018

So these are pictures of the hackathons that we have done, Medical device hackathons in different places.

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Pune, July 2017

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Pune, July 2019

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Nagpur, Aug 2018

They are in Bombay, Pune, Nagpur, Kolhapur, Wardha different places. We have done about 11 of those. And then we also do medical device innovation camp. The first one we did in IIT Bombay in 2015. Then we cycled it to Pune and Nagpur. Came back to IIT Bombay last year and this year also we did it in IIT Bombay. And these are all teams of 4 people. Every team has a doctor, a designer, a mechanical/electronics engineer.

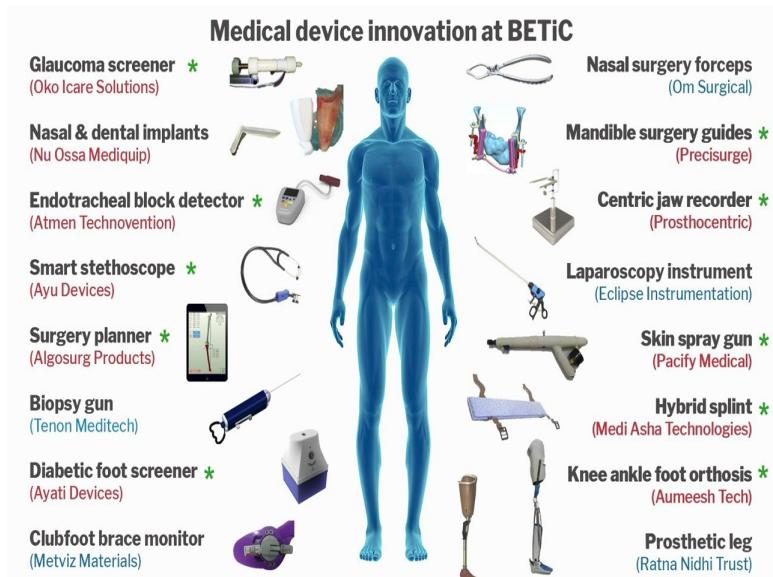
that these people wanted to actually work on devices through the night. And finally, we have a spotlight on the last day where they actually present their ideas. What they have done in 4 days and 4 nights to a jury, a room full of hundred members, top doctors and industry people, investors and so on. And usually it is a game changing life changing experience for everyone.

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So people who are working in BTech over the last 2 years, this is the current team. They all have come from previous MEDHA and MEDIC like that. So either they attend that or participate in that, they won the things. And they usually leave their current jobs and then come and join because they think this is the, they want to make a contribution, make a difference to medical device innovation.

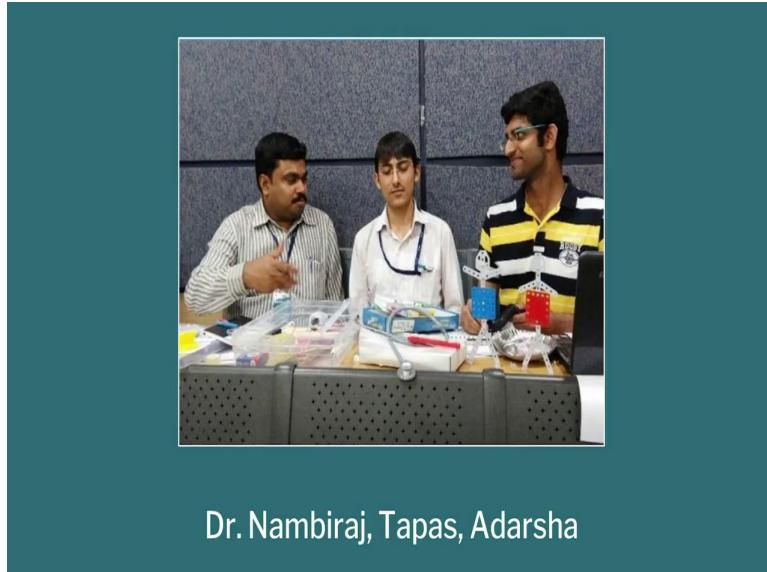
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What they have done in the last 4, 5 years is amazing, about 16-20 products. You look at diagnosis, monitoring, screening devices, surgical instruments, your assistive rehabilitation devices. You literally head to toe has happened in BETiC in the last four years. And within, among them, if you have noticed, the red ones are the startup companies. There are 10 startup companies. And then there are blue ones, (which) are licensed to Indian industry. Some companies come in and agree to manufacture it and we will transfer technology to them.

Now you also see green stars. The green star is the Biotechnology Ignition Grant, or BIG Grant of 5 million rupees. 10 times Betic people have won that. Plus there are 5 more companies started by BETiC innovators, which are not in this list. So, total 15 startup companies and 5 licensed to industry. So, 20 you can say is a high impact of BETiC.

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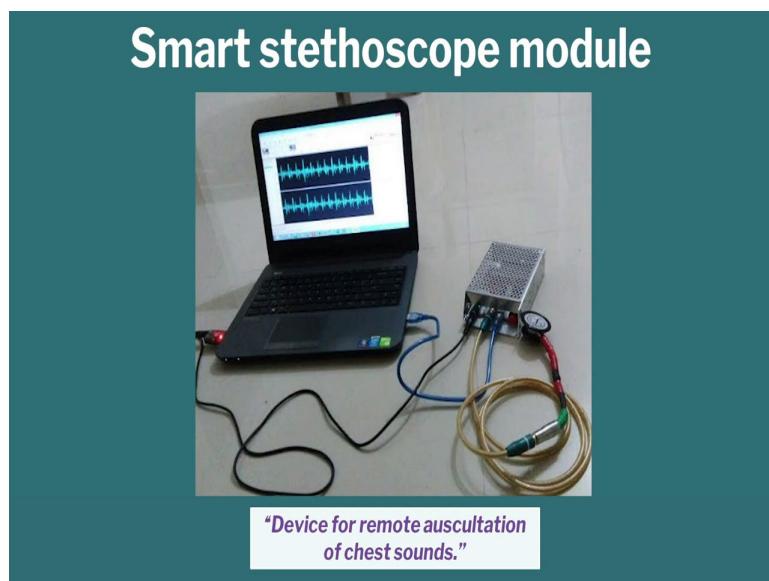


Dr. Nambiraj, Tapas, Adarsha

So let me give you two of the stories out of this.

The first story is the story of Tapas and Adarsha, who joined hands, at that point with a rural hospital doctor called Dr. Nambiraj. So these three were participants in MEDIC 2015. They all got together for the first time, when the doctor said that, ‘When I put a stethoscope on the chest of a patient in my rural hospital and I hear an unusual sound, I do not know whether it is an emergency or not. Should I send the patient immediately to a city hospital or a district hospital or not? I wish I could somehow send the sound to my friend in Pune or Nagpur or Mumbai and get a second opinion. Remote auscultation’.

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Auscultation means hearing the chest sounds, remote means hearing the sounds of a patient who is not in front of you, Ok? So can you believe that in 4 days and 4 nights these people built a prototype and Tapas was in the audience, put a stethoscope on his chest, Adharsha was on the stage and a loudspeaker, you could hear Tapas's heartbeat. So they won the competition, MEDIC competition but instead of going back to their companies, they were both working at that point of time, a few months later, they resigned from their jobs, came to IIT and said we want to take it up full-time, Ok?

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Discussions at Hinduja Hospital

And so we put them in touch with hospitals, Fortis hospital, Hinduja hospital and so on. Within a years time they developed a proper prototype which is self-contained, ok?

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And they developed the electronic circuitry for that, to enhance sound, cancel noise. And they can record it using an output to a mobile device and of course you can transmit through mobile to someone else. So now the audio file can become part of the health record and you can see they can start doing the analytics. They can now start distinguishing between unusual heart sounds, a murmur or unusual lung sounds let say, a veeze or a cough. Ok.

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Biotechnology Ignition Grant, 2017

They filed a patent, they continued to work with the doctors, they applied for the BIG Grant, the won the Grant in 2017. Right after they started a company.

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Smart stethoscope module



Shegaon Camp, 2018

Last year in December, 2018 December, they went to a rural camp where they had to screen a lot of patients for chest and heart sound and, within one year of starting a company, they had sold more than 500 units of the device. Various companies, doctors, hospitals, telemedicine companies, rural Primary Health Care Centres and so on. They are now outgoing and very strong.

(Video Start Time: 09:21)

(Video End Time: 9:31)

So this video shows you that, how they got together, how they worked together, developed the product, then took it to market as a startup company. What difference they are making, all this they are showing.

Let me tell you one more story like that. This is a story of multiple innovators, I am telling.

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Diabetic foot screening device



Amit Maurya



Dr. Rajani

It started from one student called Amit Maurya, a Mechanical Engineer student and Dr. Rajini is the Director of Centre for Human Movement Science in MGM hospital in Navi Mumbai. So, she said that many patients come to her with what is called as Diabetic Foot Neuropathy. Now diabetes, you know, is affecting, like, 60 million people in India. In that order, more than that. And apparently 10% of them will develop what is called Diabetic Foot Neuropathy.

What it means is that the nerves and the blood vessels in the foot are now damaged, they do not work. So when one steps on a stone or damages your foot in some way, you do not feel the pain because the nerves are damaged, but it will not heal either because now this blood supply is not there.

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So eventually infection becomes gangrene, gets infected and eventually the foot's are amputated.

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Diabetic foot screening device

- 4% of diabetic patients: foot ulcer One amputation every 30 seconds
- “Diabetic Foot Infection: An Indian Scenario” Rastogi & Bhansali, J. Foot & Ankle Surgery, 2016

And apparently at this point of time, every 30 second someone's foot is being amputated. It could be a toe, it could be the entire leg. And remember that every half of the diabetics are in India only, or at least one third are in India. So, every minute or every 2 minutes someone's leg is being amputated because of diabetic complications. Now it is still not making it to newspapers, but it will become big headlines before you know it, ok? So the doctor told us that this is important, and we said, ‘Ok, let us start doing something to prevent the amputations, by predicting that this patient is susceptible to Diabetic Foot Neuropathic condition and so a device to save the patients.

There are devices but they are cumbersome, they take time, they are subjective, it depends on the patients and doctors opinion. So we wanted to make something which is objective, scientifically works by itself.

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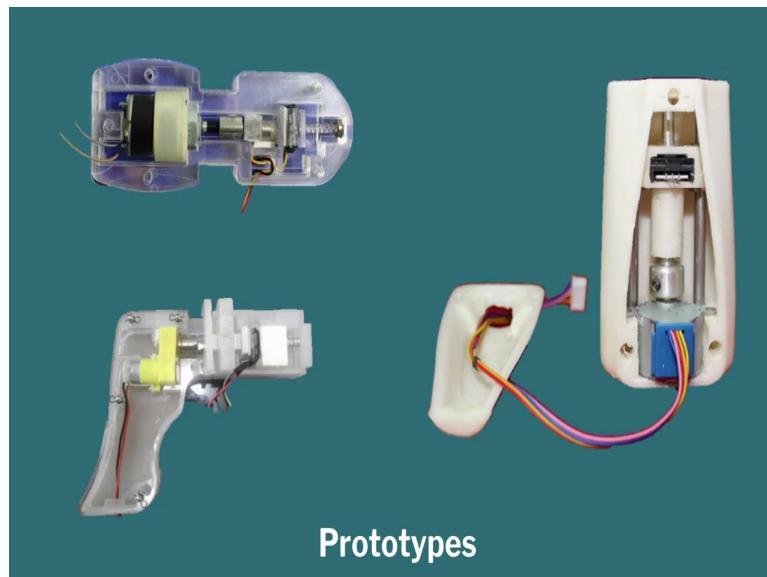


Indian Patent Filed: 'Device for measuring mechanical properties of a body part'
1431/MUM/2015

Prototype demo in First Feet Clinic

So, we created the first version of that, went to some hospitals and demonstrated that. The doctors gave a lot of feedback.

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And you have version 2 and 3 and 4 and you can see, each version is different. And this student left and he joined some other startup company.

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Then we got someone else called Nishanth Kathpal, who is an electrical engineering graduate of IIT Bombay. And he took the project forward. Devised and developed a much more comprehensive, much more smarter, much more faster, device. Ok.

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He added more functionality to do the whole thing.

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Diabetic foot screening device



"This will be the first indigenous device to combine all parameters for objective assessment (of diabetic foot)."

Dr. Sanjay Vaidya, Diabetologist

And eventually he also applied for the BIG Grant and won the award and started a company called Ayati devices.

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Launch of AYATI devices at IIT Bombay by
Padma Vibhushan Dr. Anil Kakodkar &
Director of IIT B. Prof. Subhasis Chaudhury

(Video Start Time: 12:01)

(Video End Time: 12:44)

(Video Start Time: 12:51)

(Video End Time: 13:03)

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So, STIMU stands for Stiffness Measurement Unit.

(Video Start Time: 13:02)

(Video End Time: 13:37)

What we found is that instead of looking at just the touch and temperature sensation, what is what doctors do, we actually send a probe to find how hard or soft the tissue is? And apparently, the tissue stiffness has a very high correlation with possible diabetic foot. The entire foot can be scanned. You have special points where you can see where they have high points, that is where you need to probe and see whether that it is susceptible to diabetic for the doctor.

The whole thing can be done in a fraction of the time of what it takes by normal way of doing. And the patient can stand, does not need to be lying down and all. And he has 2 versions. 1 is a home unit, which can be used by patients or by lets say, GP's, General Practitioner Doctors and one for let us say Diabetologist or diabetes specialist. So a lot of advantages for the whole thing and this technology is now going forward to be a start-up company.

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Knee ankle foot orthosis



Anish Karma

The next story I want to share with you is the story of Anish Karma, and he is a polio victim himself, and he said that when polio victims either have to place a hand (on their leg) to prevent buckling or they wear what is called a caliper, technical name is Knee Ankle Foot Orthosis or KAFO, Ok?

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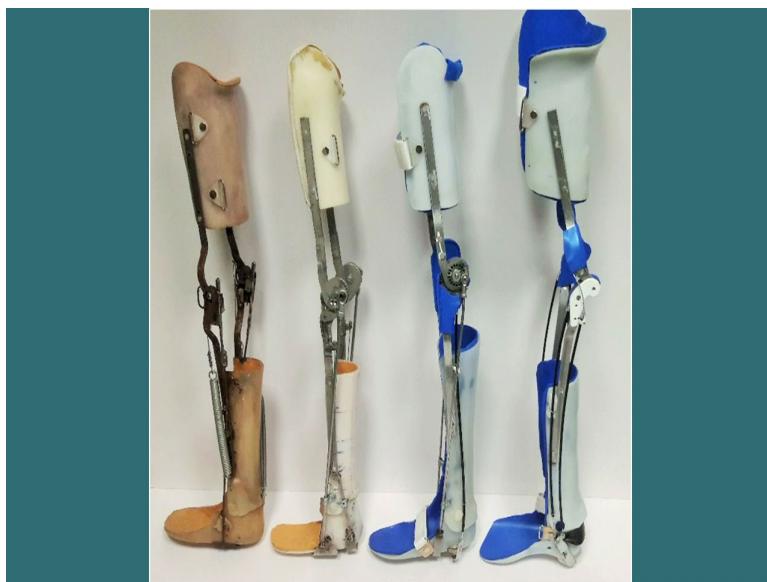


Now KAFO comes in only two versions mostly. You have one low end version which is supplied free of cost to Government hospitals, which is rigid, Ok. For sitting you have to unhook the whole thing and it will dangle and you can sit down. But you cannot, even that sitting thing is only 90°, you cannot squat on the floor. You cannot cycle with that. Whereas the high end devices cost you lakhs of rupees, millions of rupees.

And those have electronics and power packs and hydraulics and so on. So if something goes wrong, you cannot use it anymore. What this man said is, ‘Can I have something in between, something which makes me walk a little more naturally, like with a knee joint and so on, and lightweight and give support, but not expensive like the high end device. So he would go to, he took free calipers from a government hospital but started going to local cycle shops, started doing welding and modifying saying that, I just, and he is not even an engineer.

He has not even passed his college exam. So he started innovating himself, eventually got in touch with BETiC. We invented him over here.

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And you can see from version 1, he has progressed to version 2 and 3 and 4, far more aesthetic, far more functional, far lighter weight, easier to manufacture, Ok? It won't tear clothes and we are putting now, some more covering to the whole thing and so on. Now it is progressing to a stage where we can commercialise that.

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Knee ankle foot orthosis



Dr. Rajani

And that is the stage where he also got in touch with Dr. Rajni again, so using the Gait lab which we already have. He walked on the platform and we are seeing whether it is closer to a normal human gait or not.

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Remember this the first time he is wearing his own calipers. And remember he is walking without putting his hand and he is walking more naturally, he is not like, leg is not rigid leg. Although you can see that there is a little bit of not a natural walk but he will get there eventually.

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Then he started winning awards. Lot of awards in handicapped category, design category and he also recently got BIG award and that money has now gone to start his company, which is called Aumeesh Technologies.

(Video Start Time: 16:15)

And this is again a bit of video of how the functionality of the whole thing. As you can see he is able to not only walk, he is able to squat. Look at the angle, almost close to 0 degrees. He is able to walk and eventually you will see him even cycling. So, the patient is an innovator and the innovator became the entrepreneur now. That is the story of Anish Khan Karma.

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Orthopedic hybrid plaster splint



“Cost-effective first-aid kit to immobilize injured limb”

Dr. Ashish Ranade
Consultant Orthopedic Surgeon, Deenanath
Mangeshkar Hospital

The next story I pickup is a student from College of Engineering Pune, CoEP, and the local doctor, Dr. Ashish Ranade, he said that, ‘When children break their bones in the school, you usually put a splint to immobilize that until they go to hospital. But imagine that happening on a highway or in a farm.

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Plaster, fiberglass, prefab splits have issues

So we have to immobilize the hand until you go to a hospital and then they will put a plaster. So you need something in between before you put a plaster. That could be for even for a few hours or for a few days. How do you solve the problem? So what he came up with is that he said, ‘I will make a hybrid splint’.

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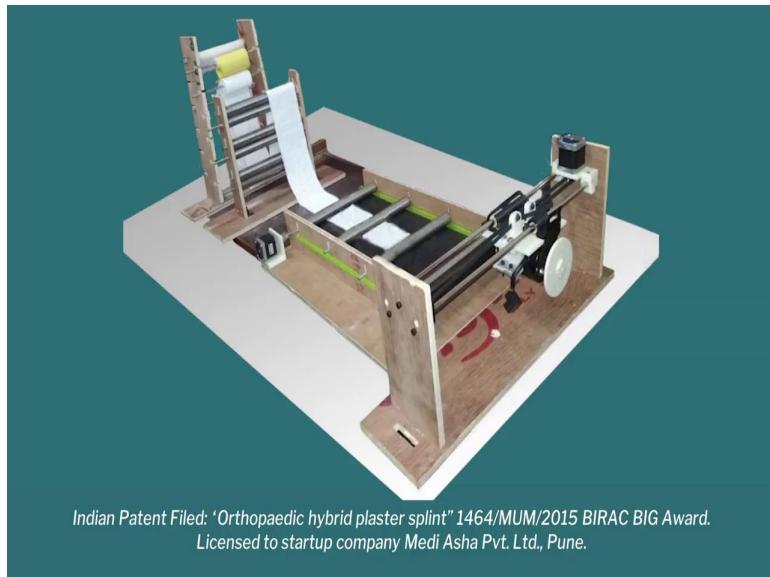
Prototype demo by Mayur Sanas

It is made of a combination of materials: paper and plastic and tissue and cotton and so on, and you dipped in water, you shape it around the zone where the fracture is there and within minutes it becomes rigid or hard in the air. So it becomes like a splint and you can now go to hospital. It will hold your hand until you go to hospital.

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Again he has gotten very good responses from potential partners, distributors and so on. One distributor is actually speaking to them as we speak to take it all over the country. He is looking at designing machines to make it rapidly, at low cost. So, imagine that it can be deployed in every hospital, every school, every sports facility, wherever there is a possibility of fracture occurring.

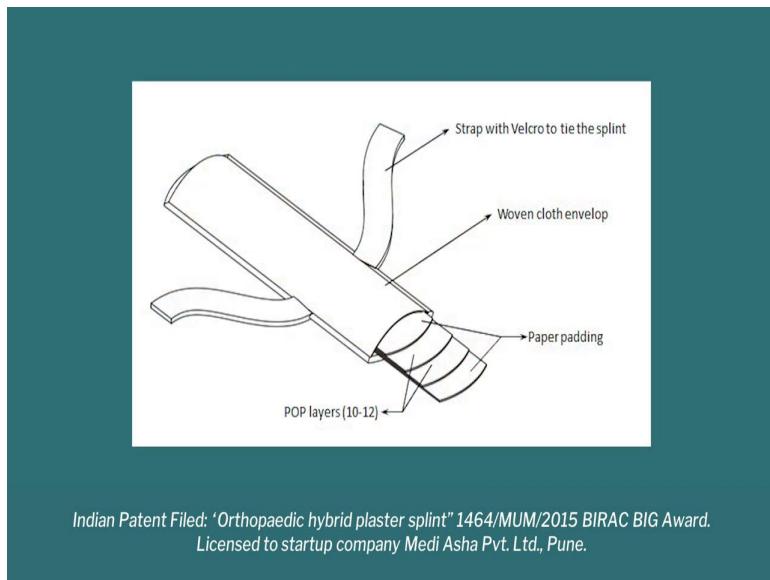
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Indian Patent Filed: 'Orthopaedic hybrid plaster splint' 1464/MUM/2015 BIRAC BIG Award.
Licensed to startup company Medi Asha Pvt. Ltd., Pune.

He also got a BIG award. He also filed his patent and a patent is licenced to his own company, which is called as Medi Asha company.

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Indian Patent Filed: 'Orthopaedic hybrid plaster splint' 1464/MUM/2015 BIRAC BIG Award.
Licensed to startup company Medi Asha Pvt. Ltd., Pune.

Two more stories I will tell you which one of them is an instrument. I have been talking about diagnosis and treatment and assistive devices, but what about surgical instruments.

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Flexible laparoscopy instrument



“Reusable laparoscopic instrument with additional degree of freedom to reach occluded organs with ease.”

Dr. Suresh Deshpande with Sritam Rout

This is one story of Sritam who is from IIT, who later on went to Johns Hopkins and now is in a US company, but when he was here for 2 years, he worked with one doctor called Dr. Suresh Deshpande. Suresh Deshpandey has trained thousands of laparoscopic surgeries. Laparoscopic surgery is that if you have anything in your abdomen, could be appendicitis or gallbladder or kidney problem, whatever, instead of making a big cut they can just send an instrument through the navel, small cut. And through the instrument they can do surgeries.

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Clinical immersion

Now, because now you are not doing with your hand you are only holding a handle and the surgery is happening at the end part of the handle, imagine that. At the end part there is only 1 degree of moment. It can either grasp it or cut it. But what if you want to suture? Not possible, very difficult.

So what the doctor said is, ‘Can you give me a wrist at the end of the instrument? Can you make the instrument have more degrees of freedom?’

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Paper prototype

So, Sritam started with that. Initially it was a paper concept, literally. And then 3D printed concept then metal prototypes.

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Metal prototype

(Video Start Time: 20:04)

(Video End Time: 20:23)

And making these metal parts was a big nightmare for us. Very fine metal parts, and the doctor said, 'I should be able to sterilize equipment again and again and reuse that'. And sterilizing means you cannot have wires, the wire will become loose. So all are rigid links and how we develop that is a mystery. Development and manufacturing is a big challenge and fortunately a company came forward called Eclipse Instrumentation in Thane, and they said that, 'We were looking for something like this to commercialise and take it forward'.

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So they licenced the technology. We have given the whole details, the drawings, the bill of materials. How to make it? All the training for them. We have helped them to make the first few batches of the parts and then they are gearing up for mass production and marketing of the device. So this is one more example of an instrument.

One last example perhaps I want to give is a biopsy gun. Whenever there is a tumor in the body, you want to know whether the tumor is benign or malignant. Ok.

And so what you do is the tumor is somewhere inside the body, somewhere inside, you want to, you cannot, you want to take a sample to test it. If it is malignant and you remove the entire tumor but benign you can leave it on. Generally the body will take care of itself.

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Adjustable biopsy gun



“Reusable Biopsy Gun with size and length adjustment of sample”

Dr. Manish Agarwal
and Shivam Mittal



Now you need a sample of the tissue. That is done using what is called a biopsy gun. You send a needle inside the body and it will suck out or cut out a piece of tissue, bring it out safely and put it under a microscope to check whether it is malignant or benign. Now the thing is the existing device is for single use. You use the device, get the sample and throw the instrument out and bill something 3000 or 5000 rupees to the patient. What doctor said is, ‘Why am I wasting the instrument? Why cannot I reuse the instrument? Why can't I just throw the needle and the needle can be made for just 100 or 200 rupees’.

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CAD Model

So he started on the journey. He made the first device. They can see how the design is changing through the CAD model to Physical, first prototype, second prototype, third prototype. Made more easy, more economic, more easy to adjust, handle all those things.

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And again one more company called Tenon Meditech in Pune, they came forward and said that, 'We want to licence the device and we want to do mass production'. They were already looking for developing something like that. Fortunately, we had developed already. So they joined hands and whatever we developed, we gave to them and after that they are modifying it slightly more with our help only and then it will be ready for mass production and marketing.

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So as you can see these stories are part of a larger Canvas of doctors working with engineers. And these are all our happy pictures. Most pictures will have doctors and engineers and some pictures will have patients also. The MEDEX exhibition. Exhibition is very, very important for us. It is an acid test to know whether this device should be commercialized or not. Final acid test. Put on an exhibition, all stakeholders, distributors, doctors, patients, possible patients, investors, all are coming there.

If they show a lot of interest then you know that it is time to start a company and we have done 15-20 of our own exhibitions and we have put in exhibitions of other organisations.

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Medical Devices & Innovators - Media Coverage



And exhibition will also mean press coverage. So we have had press coverage in all the major national mainstream media and also on social media. We have online media, we have TED Talks, we have things like Forbes India, Business Outlook. So we have covered fairly well. What it does is that, one it gives an incentive to the innovator himself or herself, which is like an incentive. It is like they feel good that, 'Ok I have done something which is valuable and interesting to the society'.

Number 2 is, it attracts potential partners, doctors, investors, distributors and so on. In fact the first order for the Stethoscope came from an IAS Officer in Gujarat who read the article in Business Outlook or Forbes magazine, and he read that and made a phone call saying that, 'I heard about it.

Can you come for a demonstration?' So we get contacts through, sometimes through media outreach like that, so it is very valuable to have a media presence in a nice way.

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And also the stories of the medical devices innovated at BETiC, 16 stories of them, along with 16 steps which I talked to you about, those 16 steps, all illustrated by 16 stories are there in this book called The Essence of Medical Device Innovation. And also the best practices of every step, I mentioned to you that we have standard operating procedures, we have forms, we have records, all these things are now being captured in what is called an ISO 13485. It is like ISO 9001 for medical devices. Far more difficult than ISO 9001, but we finally got a certificate for BETiC.

We got the verification, surveillance audit was also done successfully, so we are now authorised to develop medical devices. And what the certificate means is that we are doing it in a systematic manner. Anytime anyone wants any detail, there is a written record of how we have done, what we have done and why we have done something.

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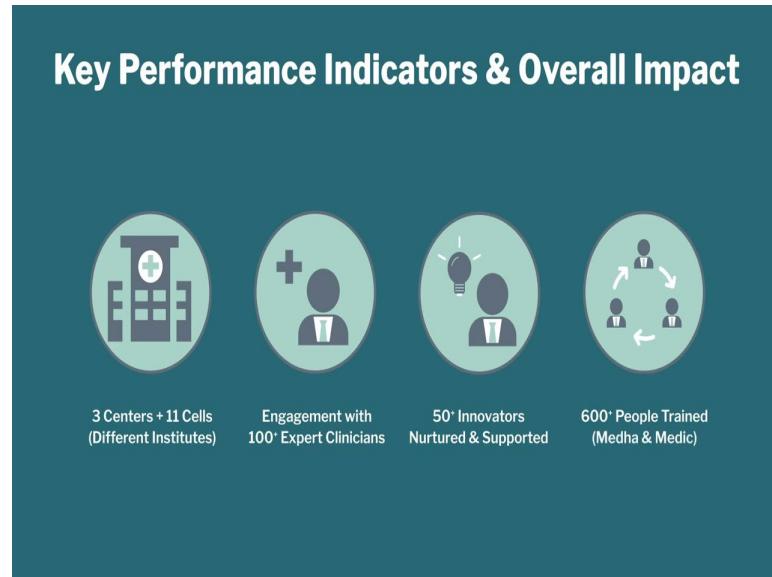


Medical device innovation network

And today BETiC is no longer one centre in one place. We, as I mentioned to you earlier, BETiC was earlier established in three places, immediately after IIT Bombay, VNIT Nagpur and College of Engineering Pune. But right after that in the last 3 years. We have had four more engineering colleges, K J Somaiya College in Mumbai, MIT Arts and Design Technology University in Pune, Symbiosis International University in Pune, G H Raisoni College Nagpur, these 4 also set up their own self sufficient BETiC cells.

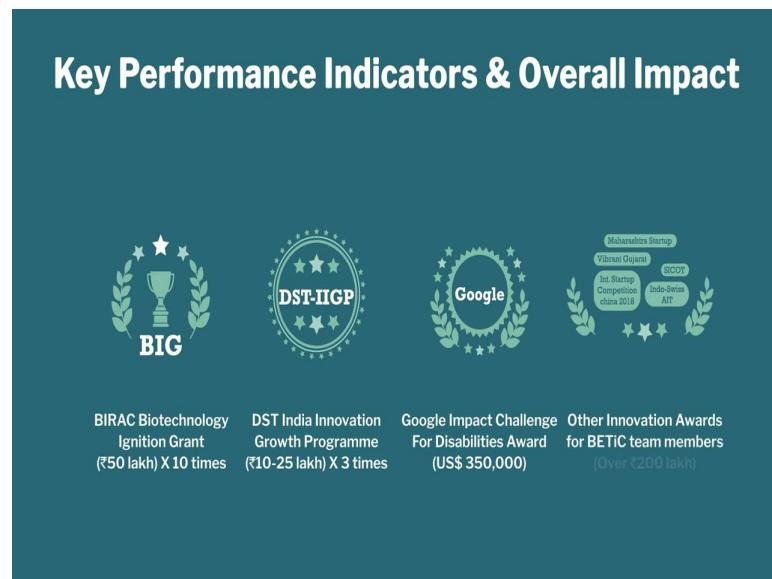
We also have now 5, 6 hospitals. Plus we have an agreement with SINE, IIT Bombay, Venture Centre in Pune, An agreement or arrangements so that these innovators can start companies in these incubators. And various Governments also take our help to create the Innovation and Entrepreneurship ecosystem in those things.

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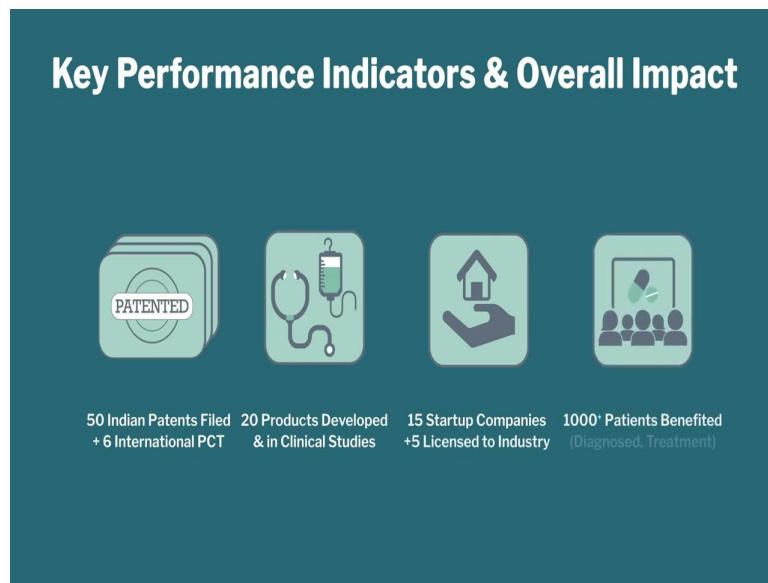
So, if you look at the overall summary of what we have achieved so far, we have now 14, 15 centres, we have more than hundred doctors who have continuously engaged with us. More than 50 innovators who have gone through the process, BETiC fellows who have invented something. Many of them have either licensed the technology to a company or to their own startup company and therefore we have like a startup company. More than 600, 700 people trained through MEDHA and MEDIC, so they now know medical innovation.

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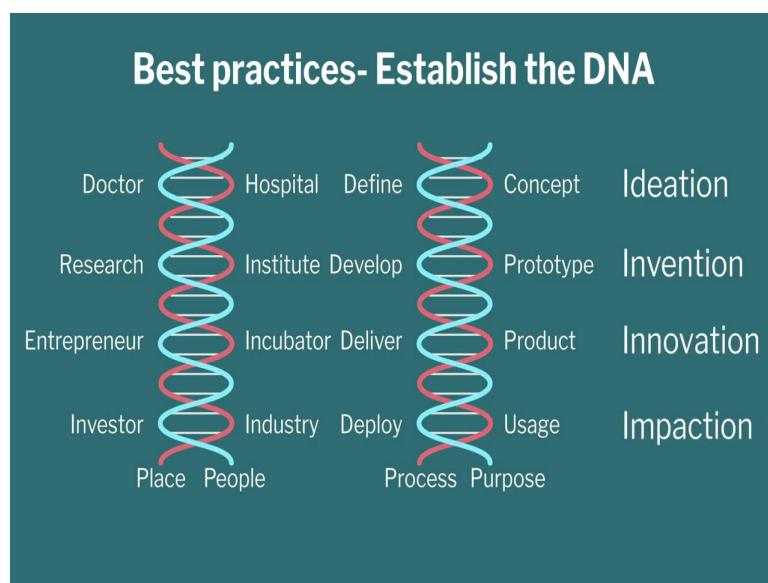
BIG awards (was granted) 10 times. Similarly, there is another big award called DST Lockheed Martin, India Innovation Growth Program gold medal, that we got 3 or 4 times. And then Google Challenge award and many other awards which are not even counted, but that is not a happy thing.

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The real happiness comes from the fact that we have a technology created and IPR rights secured, patents filed, 50 patents filed and 6 filed internationally, 20 products developed, 15 startups and 5 licenced to industry and more than 1000 patients, and this number is going very rapidly now, who have been touched and benefited by these devices. So the question now is: How did it happen? What is a secret ingredient or secret sauce for the whole thing? When people ask these questions we try to boil down to something which is easily understandable and implementable also.

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research in an institute and so on. And then the two other strands are the process strand: Define, Develop, Deliver, Deploy. And then the purpose or the outcome strand which is: The first one is concept, second stage is prototype, third stage is where you get a product and the fourth stage is where you get an application of the product in the market, usage. We call this as Ideation, Invention, Innovation and Impaction axis.

Ok that is the DNA of the medical device innovation ecosystem as implemented in Betic. The other secret sauce is that we need to create the right kind of a facility. One is hardware, equipment. You need prototyping in plastic and metal and electronics and software, that definitely you will need. And ideally if it's certified, ISO 13485 or ISO 9001, it is great because your systems are in place.

Second layer is about the people in the centers. You definitely need people of different disciplines and branches, because innovation requires collaboration between different disciplines, I have been telling you that, so you need that. And ideally visitors and faculty and experts and technicians, all coming in, you need all kinds of expertise for that. But the most important thing is a culture part of it, and I want to highlight once again that innovation is driven by collaboration. Collaboration means going out of your comfort zone. And that means reduced ego. That is possible when you focus on the end user which is a patient in this case.

A patient in suffering, a patient in pain, if you keep that in your laser focus, that laser focus gives you the energy to go out of the comfort zone and do something wonderful.

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I will end with this last slide by saying that finally if you want the right results in life, it is applicable to anything of course, but if you want the right results in life, you have to put in the right action. Right action comes with the right vision. Vision is a very dicey thing, very difficult to grasp. But the easier way to understand is that, if you have the right intentions, you will automatically have the right vision. If you have the right vision, automatically you will have the right action. If you have done these three things right, you do not have to worry about results in any case. Life will be ok. Thank you very much.