Usability Engineering
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Module - 12
Lecture - 39
Contextual Enquiry - Case study

Welcome everyone to module 12 of Usability Engineering course. My name is Neelarnab Dutta. I am a research scholar at Department of Design IIT, Guwahati. In this lecture we will discuss about a case study on Contextual Enquiry where a medical device has been developed out of a efficient contextual enquiry process. And the intent of this class is to go through a various activities and strategies that has been adopted as a part of efficient contextual enquiry process.

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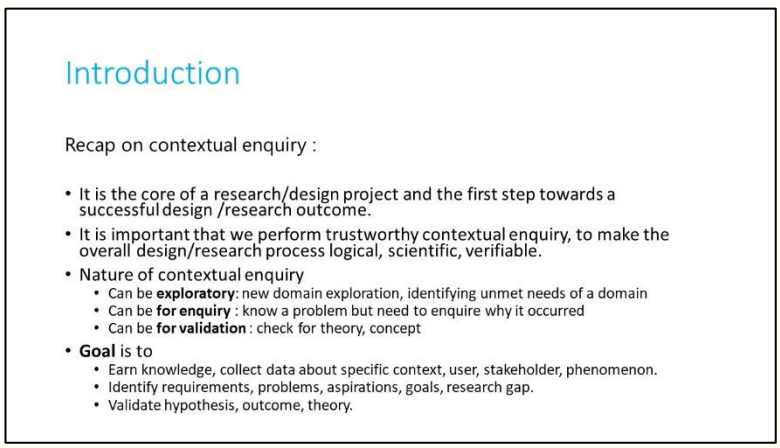

So, let me first give a brief recap of what we have learned in the last class. So, contextual enquiry is the core of a research and design project and it is the first step towards a successful design and research outcome. So, it is very much necessary that we do efficient contextual enquiry to get a good product outcome. So, it is important that we perform trustworthy contextual enquiry to make the overall design and research process logical, scientific and verifiable.

However, depending upon the nature of the product or requirement contextual enquiry can be exploratory. For example, if we are working in a new domain a designer working in a new

domain may not have past experience from where he can guess problems or unmet needs. So, for him it is completely exploratory in nature.

Similarly, there can be contextual enquiry where the problem is known, but there has to be in enquiry why it occurs, what are the cause and effect of this particular incident. So, that fall under enquiry category. And, the third category can be theoretical validation or concept validation when a designer or researcher have to validate something.

However, the ultimate goal of a contextual enquiry process is to earn knowledge, collect data about specific context, user, know who are the users, stakeholders and what phenomena are involved. Contextual enquiry process also leads to realization of requirements, problems, user aspirations, goals, and research gap. And also, it can be used to validate hypothesis, outcome and theory that has been generated by designer or researcher.

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So, this is the case study I was talking about which is design of a wound healing technology. It was part of a Biodesign i-fellowship program at AIIMS, New Delhi. So, this was a flagship program initially started as Stanford Biodesign program and since it was a International program multidiscipline team was formed and people from various countries and disciplines joined together. In the batch of 2016, 4 Indian fellows and 4 international fellows were joined

together to collaborate as a team in this particular project.

So, this case study is about the journey experienced, activities performed as a part of contextual enquiry process in identifying unmet clinical need from Indian setting. So, here is a disclaimer I want to mention. So, this lecture is free from any intellectual property contents generated out of the Biodesign fellowship program. It only showcases generic contents for educational purpose only.

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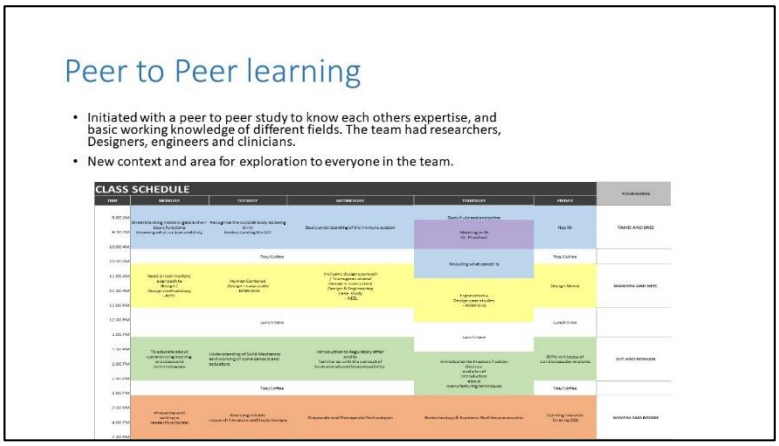

The process which I was referring to start with a peer to peer learning in 2016. Since all of us from various background so, it is important that we learn each other's expertise, we know the domains little bit of domain knowledge needs to be there among us so that later we can work together as a team.

Initially classes were scheduled where each team member has to teach the others about their expertise, their knowledge, about their field, their work pipe line etcetera. However, for all of them the context was new because it was a clinical context and the clinicians that are part of this fellowship are either Japanese there was a Japanese doctor involved and there is a nurse from Australia and they do not have any idea about Indian healthcare system and the context. And the rest of the team members were like designers, researchers, engineers, they never

have any exposure in a clinical setting. So, it was new for everyone.

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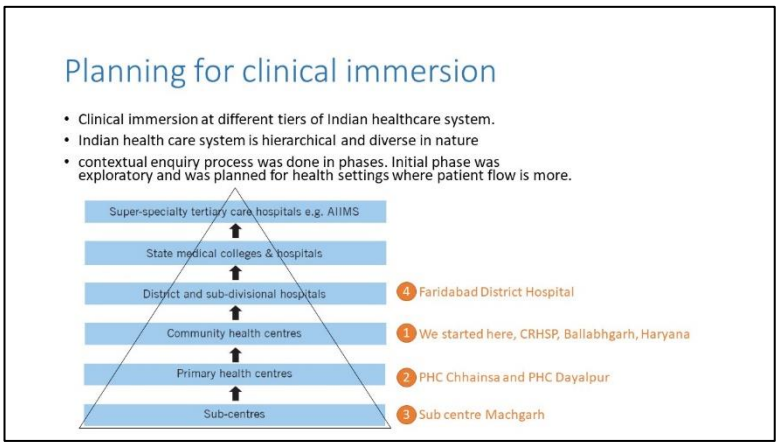

But, at the very initial phase there was a planning for clinical immersion. So, the clinical immersion was the first phase of contextual enquiry and it was planned to do field study at various tiers of Indian healthcare system. If we look into Indian healthcare system it is hierarchical in nature and also very diverse.

We have state of the art healthcare facilities at tertiary care hospitals like AIIMS and at very resource and constraint settings we have primary health centre sub centres like that, but the entire system is hierarchical in nature. So, at the very bottom we have sub centres and there are multiple sub centres under a primary health centre.

Similarly, there are multiple primary health centre under a community health centre and there are above community health centre, there are District hospitals, then there are State medical colleges and hospitals and at very top we have the super speciality tertiary care hospitals like AIIMS, Apollo etcetera.

The contextual enquiry process was done in phases and the initial phase was quite exploratory

for all of us and was planned for health settings where patient flow was more. We started at community health centre Ballabhgarh and then we decided to move below go below at PHCs and sub centres and later we thought of coming back to district hospitals.

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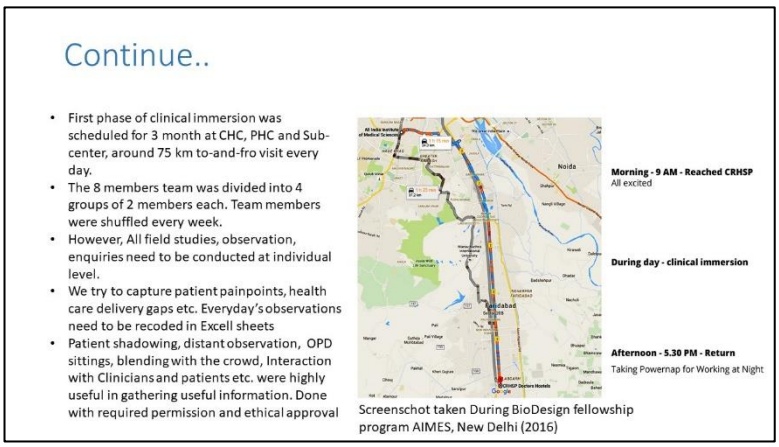

This is how it started the clinical immersion phase. The first clinical immersion phase was planned for 3 months and we are located almost 35 kilometre away from the location where the community health centre and PHCs and sub centres were located. And for us every day it was almost 2 – 3-hour journey and we need to move around to 75 kilometre every day.

And, the all the 8 members team were divided into 4 groups of 2 members and the teams team members were shuffled every week within the team. However, all the field studies, observation, enquiries need to be conducted at individual level. So, we used to take our own notebooks, cameras where we can take picture if it is possible. So, we used to conduct our own enquiries in the health care settings.

What we tried to capture was patient pain points, healthcare delivery gaps etcetera. However, at the very beginning we were not aware of Indian healthcare system and whatever data we

have collected are not very much appropriate in all way. What we did was everyday observations we recorded in a excel sheet after coming back from our clinical immersion.

Different contextual enquiry techniques have been used. So, we used patient shadowing, distant observation, OPD sittings, then we tried to blend with the crowd and tried to ask patients what are their conditions, then we also tried to interact with clinician and patients to know about their pain points why they are there and we tried to extract useful information.

And, all of these are done through required permission and ethical approval. And, here I want to mention one thing that it we are not allowed to take videography or photography in those clinical settings because it was considered ethically not correct. So, we have to depend lot on our observations and shadowing techniques.

Shadowing means you follow a patient without knowing him without the aware of that patient know that you were following and try to observe his activities, his pain points and also try to listen what he described in front of a doctor in OPD sitting.
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So, during the first phase of clinical immersion we visited various health care facilities like a

antenatal care ANC, paediatrics department, Ayush, postnatal care, wards, child delivery, emergency, operation theatre, PMR, ophthalmology, dentist, obstetrician gynaecology, orthopaedics, ENT. So, these are various departments we have visited and we tried to capture as many as data every day.

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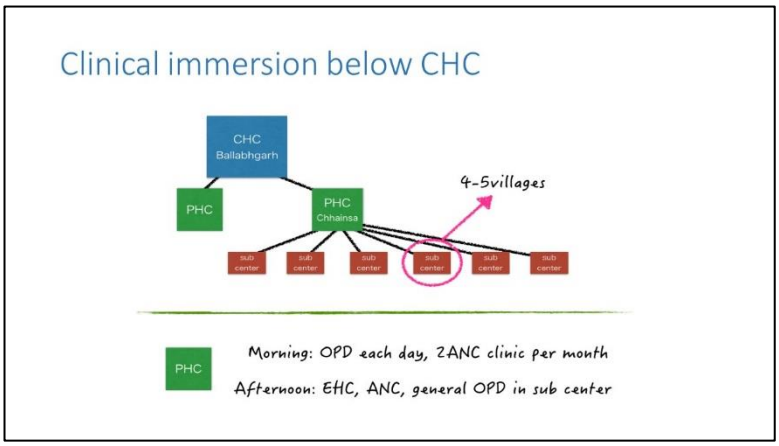

And, next we try to capture information down the CHC setting. So, this is the hierarchy how the health care setting in India exist. So, under CHCs there are PHCs and under every PHC there are many sub centres and each sub centre can cover at least 4 to 5 villages and patient there.

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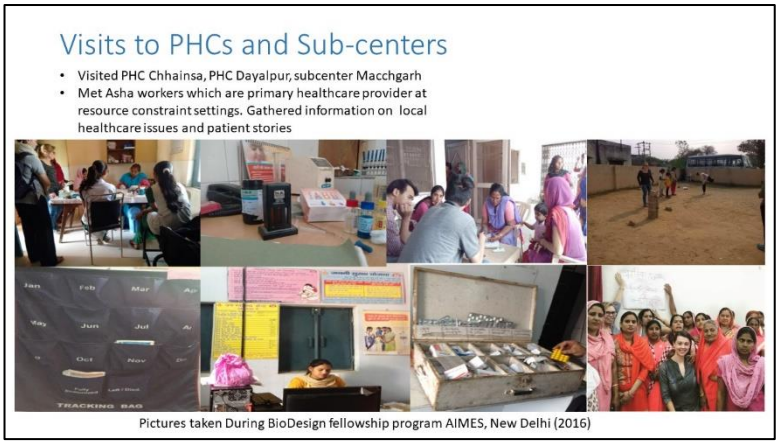

We visited PHCs very much closely located to the community health centre Ballabhgarh, they were PHC Chhainsa and Dayalpur and also, we visited sub centre Macchgarh. We also met very low-level health care provider Asha worker and try to gather information about regional healthcare issues and patient stories.

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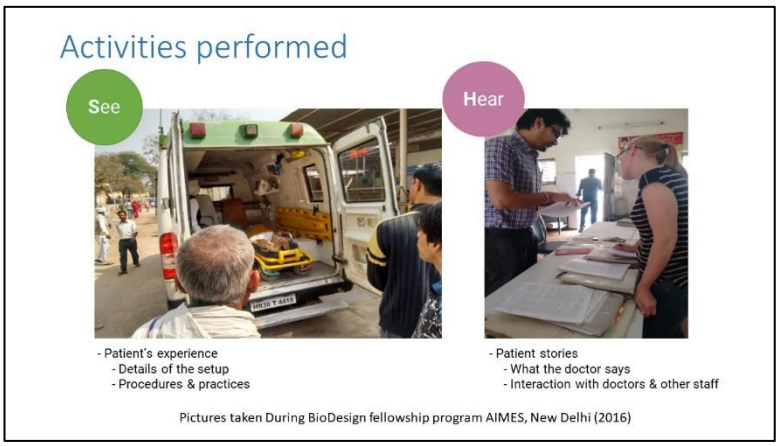

So, these are some of the activities that we used to perform during that three-month clinical

immersion. So, we used to see observe various patient pain points, we tried to see procedures, practices and we try to hear what the patient says, what the doctors say about the situation.

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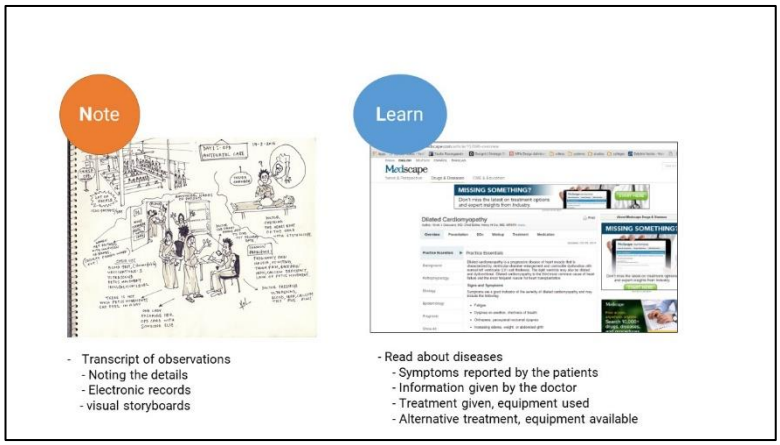

And, then we used to take note of all of this information individually either by noting in a notebook or by electronic record and also we tried to create some visual storyboards where we try to recreate the scenario with some sketches. And, after we returned back from our clinical immersion we used to learn what we have heard in the observations by internet searching and by reading various research articles etcetera.

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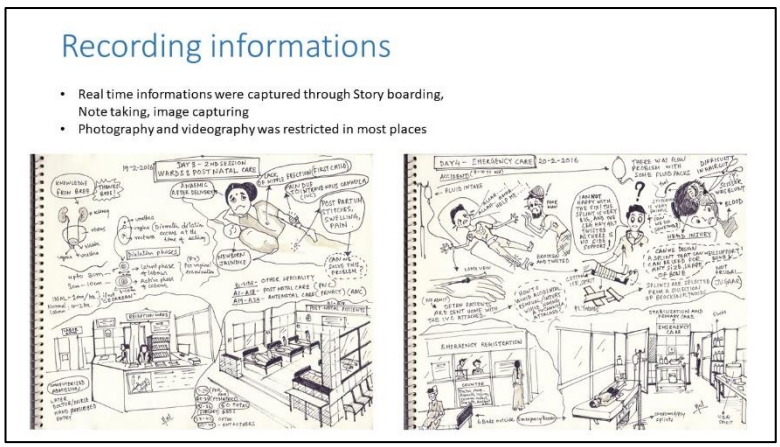

So, these are some of the evidences that we have collected. These are some of the techniques how we captured the day to day observations through a story boarding. Photography and videography, I already told that it was not allowed in most places. So, for those places we need to only rely on our personal note taking capabilities.

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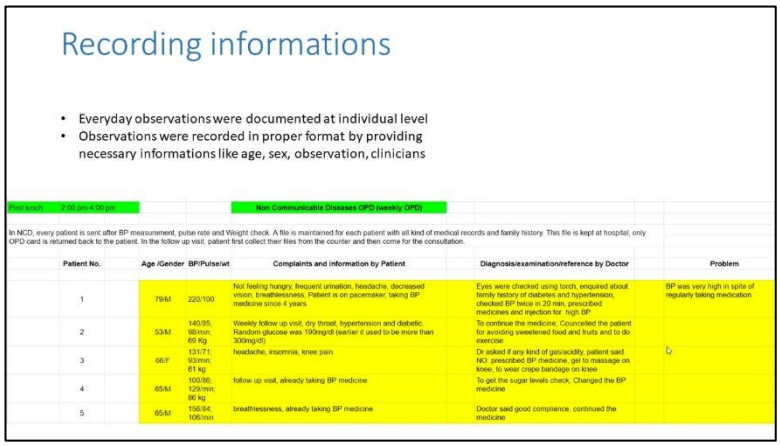

So, how we recorded our information? So, everyday observations were documented at individual level and observations were recorded in proper format by providing necessary information like age, sex, observation, clinician feedback etcetera. And, this is done at individual levels, each of the fellows have their own sheets.

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Example observation sheet 1

PHC	Title	Observation	Problem	Incident
[redacted]	Thyroid Tumor FNA Edema Injection	【Thyroid1】 The plump woman coming to the outpatient office is 61 years old. She has suffered HT, and has been going to a private hospital in order to take BP medicine. In these days she felt head ache and whole body swelling, so she went to the private hospital and complained about it. Then the doctor told her that she must be hypothyroidism. The doctor gave her thyroid hormone. She took the thyroid hormone neatly, but stopped taking antihypertensive drug by her judgment. It is because that she doesn't know if taking both medicines is good or not. Today she felt headache and anxiety. The private hospital has holiday today, so she came to the PHC. She looks like very restless, and she also complained about her sleepless and her fatigue with crying. The BP test indicated 150. The doctor assessed the reason of hypertension is not only stopping medicines but also generalized edema. The doctor directed her to get furosemide injection. But an internship tried to inject furosemide into her arm, she was too bloated to be found her blood vessel. At the end another doctor injected it into her back of the hand, and she cried out in pain.	・Low compliance of medicine ========== ・Some patients give up taking their medicines by their own judgment. ・It is very dangerous for patients to give up taking thyroid hormone suddenly. ・Some patients don't understand how to take medicine. ・Some thyroid disease patients don't take thyroid ultrasound examinations. ・It is difficult for medical staff to inject into patient's arm having severe edema.	Hypothyroidism occurring in 1 out of 2640 neonates with the worldwide average value of 1 in 3600 ba In childhood too, hypothyroidism can occur. In a Mumbai, out of 800 children with thyroid disease hypothyroidism. Among adult people, the prevalence of hypothyr The prevalence of subclinical hypothyroidism wa the value being 9.4%. In women, the prevalence when compared with men, in whom the prevalen

So, here is an example of another such observation sheet.

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Example observation sheet 2

LOCATION	OBSERVATIONS	Symptoms	PROBLEMS	GENERAL INFO	Inclu
	Patient Flow (Antenatal OPD-Monday to Wednesday)				
Ballabhgarh ANC 17-19/2/26 wednesday-Friday	1. Patients are seated on the waiting area. 2. Names of the patient are called out by a "gyu" through a microphone 3. The patients are handed 2 pieces of paper. One is blue in colour (antenatal) and the other is white which is the OPD card which cost 2 rupees 4. The patients then wait in this narrow "alley" which is about 2m in width and about 3m in length and wait to get into any on the 5 consultation rooms 5. Inside the room there is a small table for the doctor to put the forms and an x-ray viewer/illuminator mounted on the wall. There is also a consultation bed along with some chairs 6. Consultation time varies from 2 to 7 mins. 7. Dependig on the patient presentation the doctor takes the next appropriate action. 8. High risk patients are referred to an obstrician		Systematic issue		
Ballabhgarh ANC 17-19/2/26 wednesday-Friday	It was observed that doctors use a mobile app on their phone to calculate or estimate the due date (EDD) and gestational age. The estimated due date (EDD or EDC) is the date that spontaneous onset of labour is expected to occur. The due date may be estimated by adding 280 days (9 months and 7 days) to the first day of the last menstrual period (LMP). Use of the LMP to establish the due date may overestimate the duration of the pregnancy, and can be subject to an error of more than 2 weeks.		Need "smart phone" for the app to run.	A simple method to calculate the due date is to add seven days to the date of the first day of your last period, then add nine months. For example, If the first day of your last period was 1 February, add seven days (8 February) then add nine months, for a due date of 8 November	Pregnant women are about 280 days after period (LMP). Only 4 only 70% deliver with even when the date
	It was observed that doctors use a mobile app on their phone to		"Most" doctors rely on the use of a	A simple method to calculate the due date is to add	Pregnant women are

So, these are from someone else.

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Analysis of 1st phase contextual enquiry data

- Team discussion to analyze similarity in observation (Investigator triangulation)
- Identification of Disease or clinical condition, cause and clinical presentation, healthcare delivery issues and problems

Pictures taken During BioDesign fellowship program AIMES, New Delhi (2016)

So, by that time we ended the first phase of clinical immersion and it was time for us to analyse the data the initial from the initial enquiry. So, what we did was we did a team discussion to analyse the similarities in observation. So, this was part of a investigator triangulation strategy that I have discussed in the last lecture that this is this can be a strategy to make a contextual enquiry process more trustworthy.

So, what we did that whatever observations we have in common and whatever problems we identified in common are considered finally, for discussion and for recording. So, we identified disease states, clinical condition, cause and clinical presentation etcetera and various health care disease and issues and problems.

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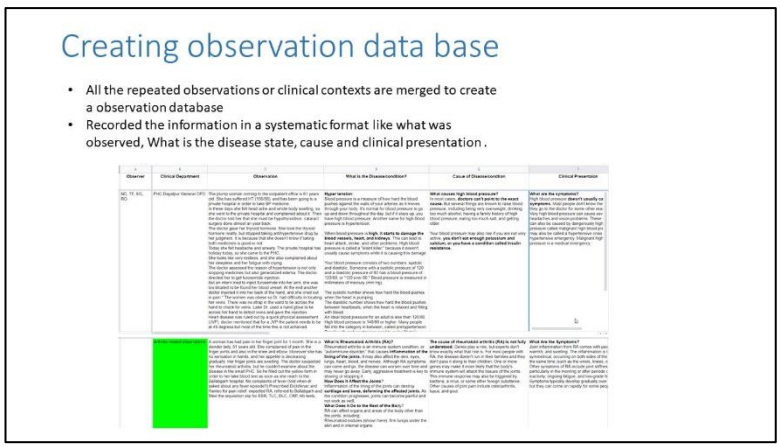

So, finally, what we did we have around eight such observation sheets and we have to prepare one central database where all the common observation has to be recorded. So, all the repeated observations or clinical contexts were merged to create an observation database. They we recorded the information in a systematic format like what we observed, what are the disease states, what are the cause and clinical presentation like that way.

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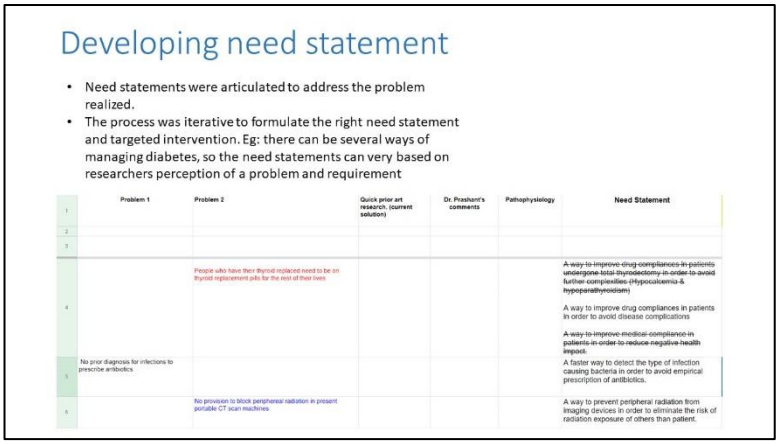

So, next job was to develop a need statement. Now, need statement have to be articulated to address the problem realized and it was a iterative process where multiple need statements were formed for target intervention. And, the reason why multiple need statements have to be formed because there can be intervention at various level and based on what we perceived as a problem and what we thought as a intervention.

So, for example, there can be several ways of managing diabetes. So, the need statement can vary based on the researcher's perception of a problem and requirements. One can think of monitoring blood glucose early, one can think of managing blood sugar early, one can think of preventing the blood sugar at a very early stage.

So, from the problem we have realized we can actually go after various need statements, but we have to rank these need statements based on what is already there and what is not there, where the unmet need lies that needs to be realized.

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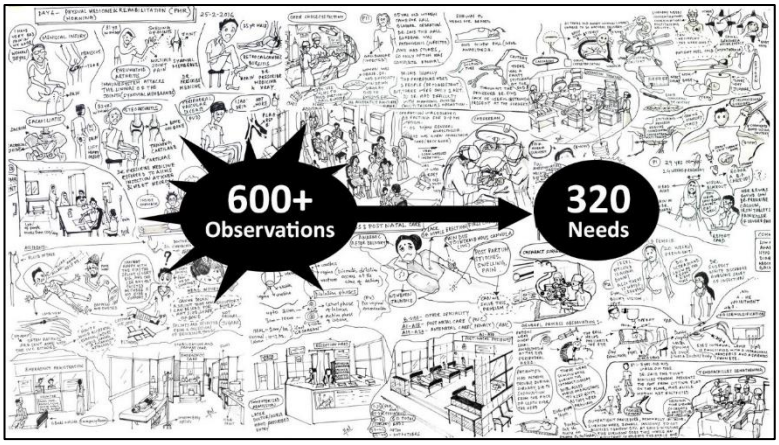

So, by the end of this first phase of clinical immersion we end up with 600 plus observations and out of that we have generated around 320 needs.

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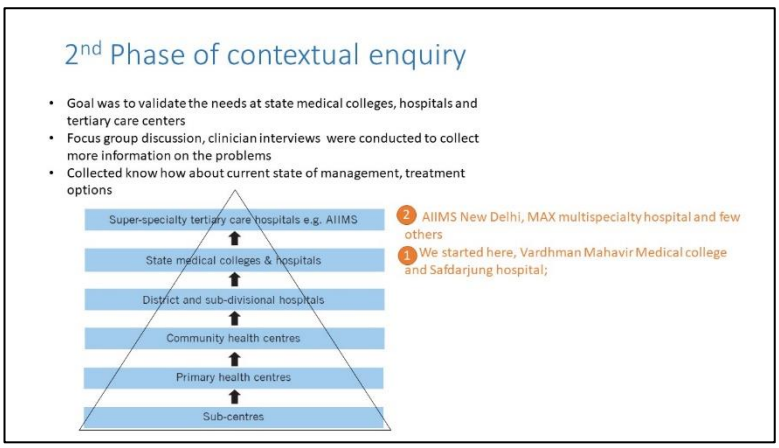

So, next was the second phase of contextual enquiry. The goal of this particular phase was to validate these 320 needs in Indian settings whether they also exist in higher level health care settings like in district hospitals or at tertiary care hospitals.

We also thought of doing focus group discussion and conducted clinical interviews to understand the problem and validate these needs. We collected data on current state of disease management and treatment options. So, we initiated with Vardhman Mahavir Medical College and Safdarjung hospital in New Delhi and first tried to gather information from the doctors, nurses, the clinician there.

And, then we moved to higher tertiary care hospitals like AIIMS, MAX multispecialty hospital to know about the advance treatment options available there and what kind of patients come there.

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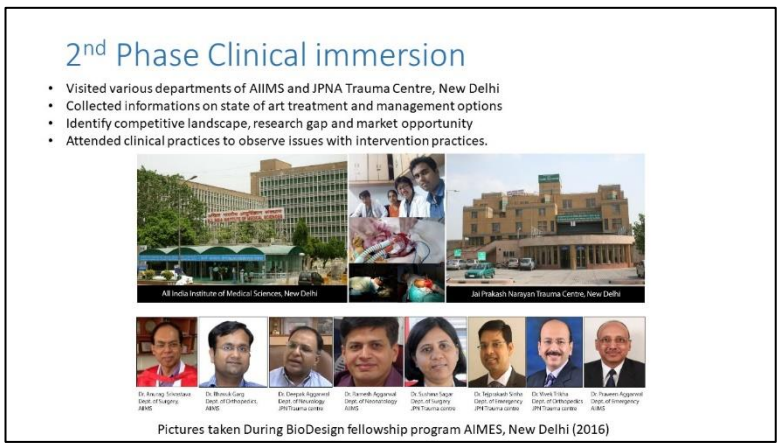

So, we visited departments at AIIMS as a part of our 2nd phase of clinical immersion and also JPNA Trauma Centre which is for emergency purpose.

We collected information on state-of-the-art treatment and management options and identify competitive landscape by knowing what kind of instruments and devices currently they are using to solve or to give treatment options. We also look for market opportunity where there is a device gap, where there is a need for intervention all these things we tried to gather by doing this 2nd phase of clinical immersion.

We also attended clinical practices like surgeries under the guidance of doctors and try to see

is there any kind of issues in terms of intervention practices. So, this was done as a part of 2nd phase of clinical immersion.

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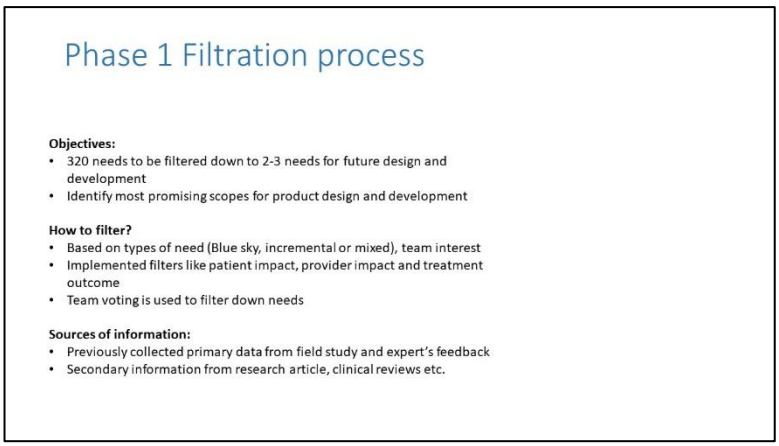

And then comes the filtration process. So, by the end of our 2nd phase of clinical immersion we already have around 320 needs. However, these 320 needs; needs to be filtered down to 2 to 3 needs for future design and development. Our goal is also to identify the most promising scopes for product design and development.

So, how we conducted this filter was a challenge initially, but later we get to know about it. So, based on types of need like whether the need is a blue sky, incremented or mixed. So, the blue sky means nothing has been done so far and it is a completely grey area where nobody has worked on so far. So, those kind of needs we try to eliminate, then there are incremental needs where already there is a base where researchers are working and then on top of that you are trying to go forward and do some new interventions.

So, those falls under incremental and we targeted for those and there are also mixed needs those also we targeted. Basically, we selected those needs which are incremental in nature and

also mixed in nature. Then also there is a filter for team interest, the team has to have the interest to proceed with the process of developing certain product. Other filters we have implemented where patient impact by knowing what are the incidents and prevalence of a particular disease states.

How a intervention can impact the society all those things we have considered, then provider impact what is the current state of the clinicians, how they are practicing, whether a new intervention will help them to adapt to the new devices or the intervention you are bringing. Then also based on treatment outcome you want to filter down those needs. Team voting is used to filter down those needs. Again, this is a point of investigator triangulation where a team voting is considered to select and filter particular needs.

The sources of information were the previously collected primary data that were part of field study and expert feedback. And, the secondary information was from research article, clinical reviews etcetera.

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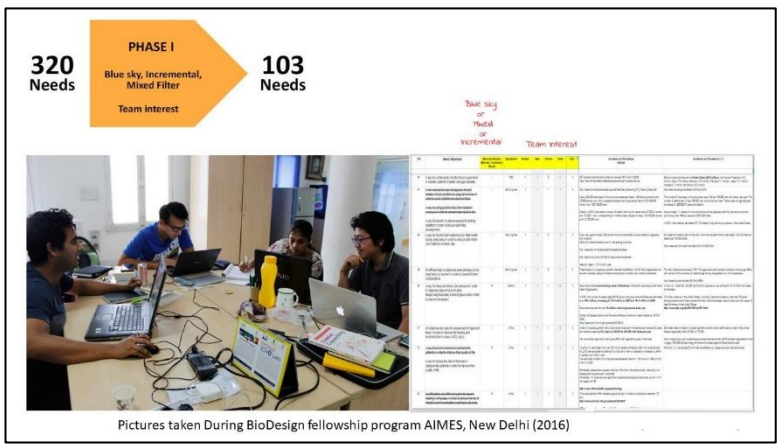

Pictures taken During BioDesign fellowship program AIMES, New Delhi (2016)

This is how we filtered down the 320 needs to 103 needs at first level at phase I of filtration process we considered the need type like blue sky, incremental or mixed and also, we choose team interest.

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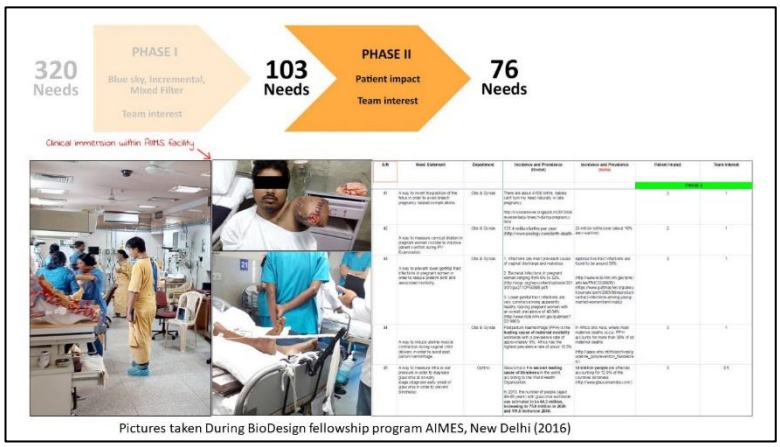

Pictures taken During BioDesign fellowship program AIMES, New Delhi (2016)

In the IInd phase of filtration we considered patient impact and team interest and we filtered down to 76 needs.

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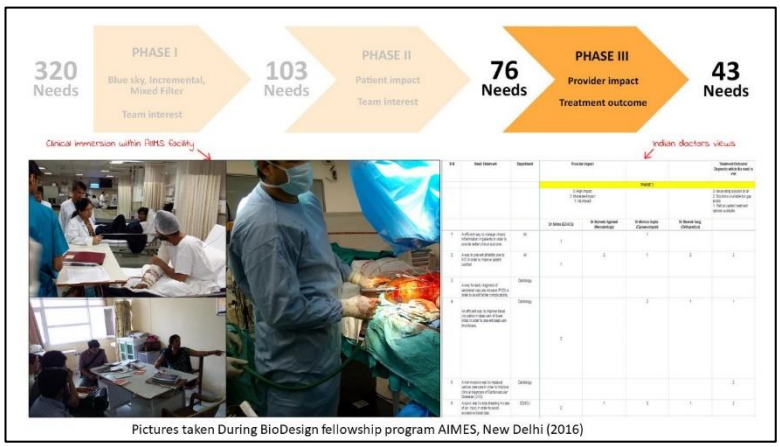

Pictures taken During BioDesign fellowship program AIMES, New Delhi (2016)

And, in the IIIrd phase of need filtration we considered provider impact and treatment option

and finally, we arrive at 43 needs as our top needs for Indian setting.

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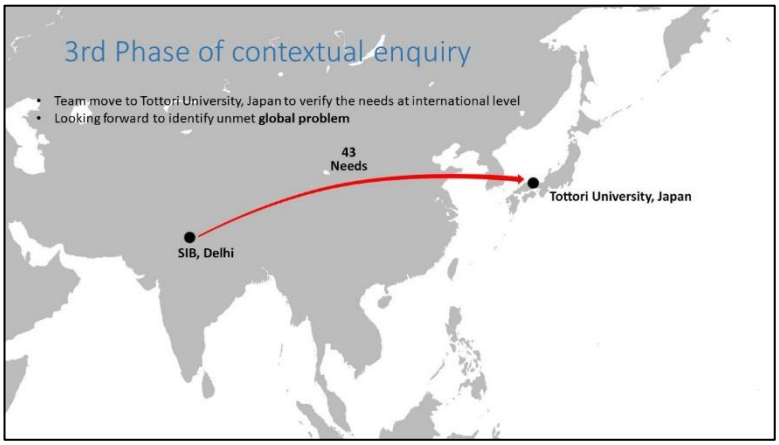

Then comes the 3rd phase of contextual enquiry. In this phase, we are trying to validate whether these needs also exist in a international at the international level, whether the developed countries also have the same issues or clinical unmet needs.

So, we as a team separated and one of the team of 4 members we move to Tottori University, Japan and we looking forward to identify unmet global problem there.

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So, this is School of Medicine, Tottori University where we have visited.

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This is Tottori School of Engineering.

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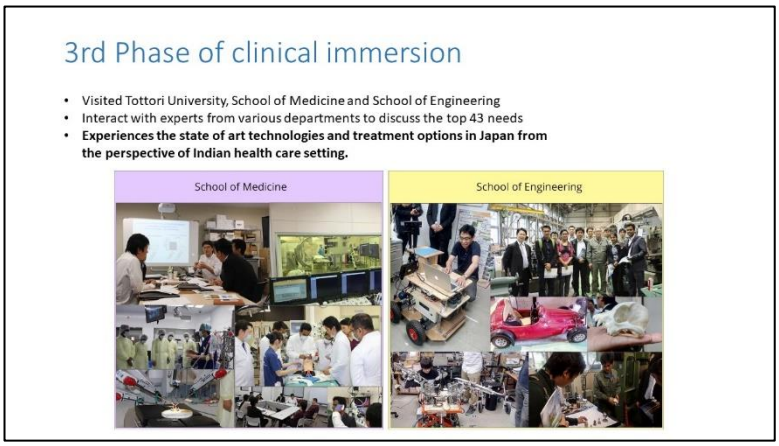

And, then we conducted the 3rd phase of clinical immersion in Japan. So, we visited Tottori University and School of Medicine and interact with experts from various department there to discuss our top 43 needs.

We also experience the state of art technologies and treatment options in Japan from robotic

surgery to autonomous diagnostics facilities etcetera and we tried to compare how these are different from Indian setting.

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The top 37 needs that we brought from India mainly fall under four categories in Japan, in Japanese health care setting. Those were emergency, ENT, orthopaedics and internal medicine. And, we took expert opinion to discuss about these issues and tried to compare the health care setting differences between India and Japan.

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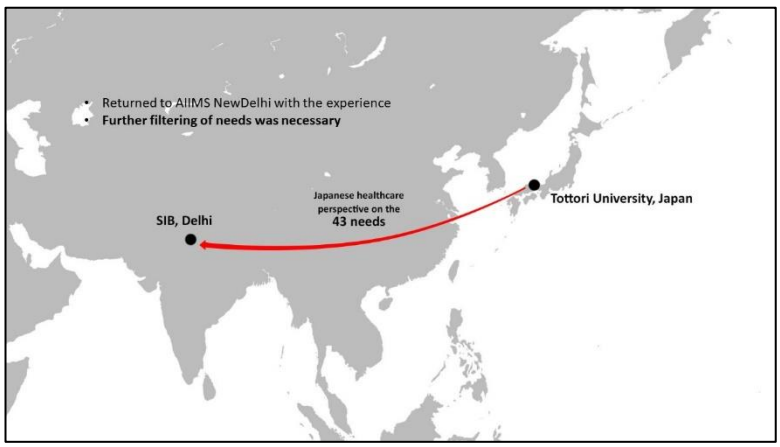

After this study and know how about the state of these needs in a developed country we returned back with 43 needs and it was required for us to further filtering these 43 needs to something workable.

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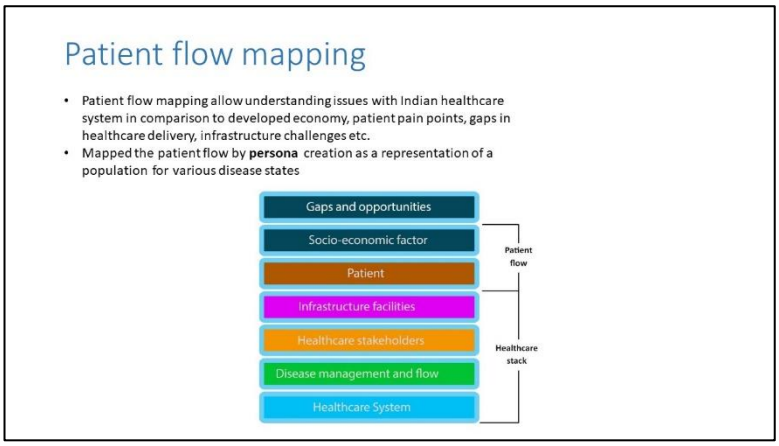

So, next thing we did after coming back from Japan was patient flow mapping. So, patient flow mapping is a process where you try to map the patient journey. You try to create a persona that represents a population for various disease states, you try to understand the issues in Indian healthcare system in comparison to developed economy and try to see what are patient pain points and gaps in health care facility and infrastructure.

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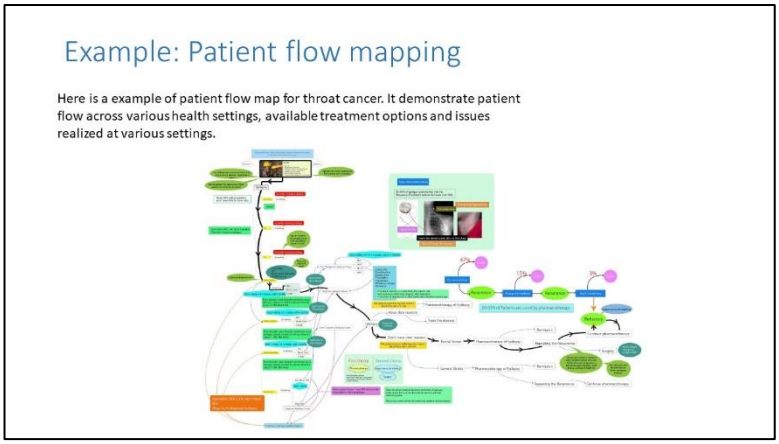

So, here is an example of patient flow map for throat cancer which is one of our need. So, it demonstrates patient flow across various health care setting from CHCs, PHCs to district hospital to AIIMS and it demonstrate what kind of pain points patient encounter in the process of getting good treatment and what are treatment options available, are there any gaps in terms of availability or accessibility of health care intervention in particular setting.

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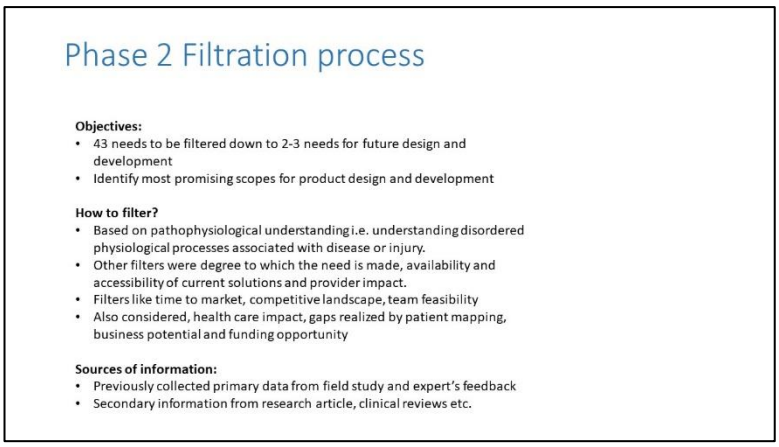


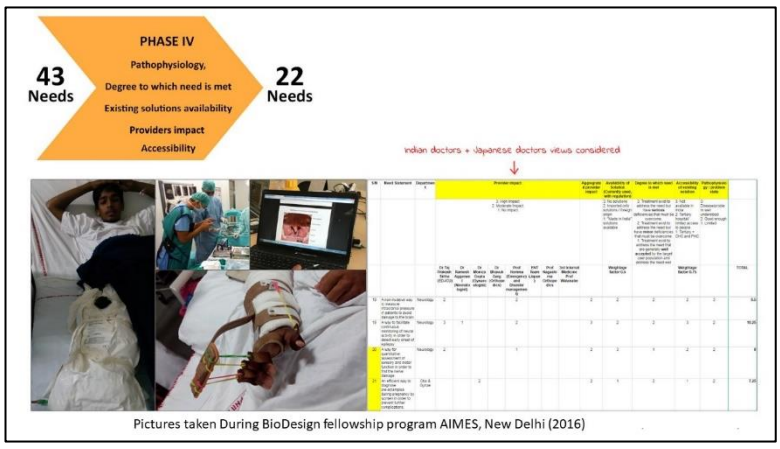
So, this was very helpful for us and then with this kind of study we then proceed further for our phase 2 of filtration process. The objective was to filter down the top 43 needs to something like 2 and 3 needs for future design and development. We also try to identify some needs those are very promising for future product design and development.

So, this time the filtration process that we choose was based on filters like pathological understanding that is understanding the disordered physiological process associate with certain disease or injury. So, for that we need to refer various clinical articles, reviews and expert feedback. The other filters were degree to which the need is made, availability and accessibility of current solution and provider impact.

Filters like time to market, competitive landscape and team feasibility was also considered. We also considered health care impact, gap realized by passion mapping, business potential and funding opportunity because the ultimate goal of this particular fellowship was an entrepreneurial journey.

So, we need to consider those needs which have a bigger scope for

commercialization. (Refer Slide Time: 23:33)



Pictures taken During BioDesign fellowship program AIMES, New Delhi (2016)

In the phase IV of filtration process we filtered down 43 needs based on pathophysiological understanding, degree to which needs we are met, existing solution availability, provider impact and accessibility and we arrive at 22 needs.

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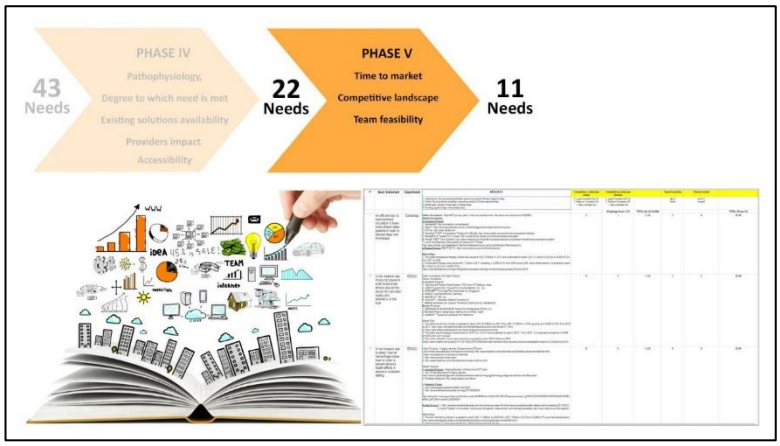

Similarly, in phase V, we consider time to market, competitive landscape, team feasibility again to arrive at 11 needs. Now, by that time we actually also started understanding the various technologies as a part of solution, so that later we can filter down our needs based on technological availability and team feasibility.

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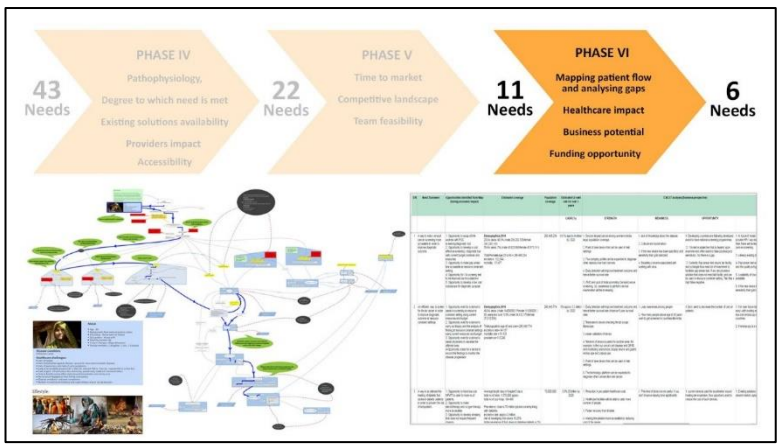

At phase VI which was the final filtration phases we arrive at top 6 needs which were based on patient flow mapping and various analysis we did on top of that and by considering health care impact, the business potential and the funding opportunity.

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So, later by the end of a year of contextual enquiry we finally, selected 3 top need areas based on rigorous technological assessment and team discussion. So, the 3 need areas were cancer screening, neurological monitoring and wound management. Now, these are areas, but exact need statements are not disclosed here.

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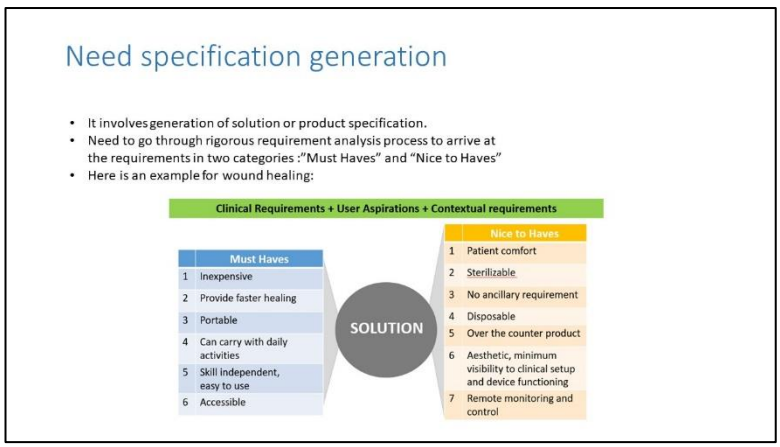

So, soon after we arrive at our need areas and final needs we have generated need specifications which are very similar to product specification that we do as a part of user centric design process. So, this needs rigorous requirement analysis to arrive at requirements in two categories; those which are must have and those which are nice to have.

So, we here give priorities to clinical requirements and those requirements comes under must haves and other requirements like user aspiration, contextual requirements we put it as nice to haves. Here is an example for wound healing.

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So, that is the end of the contextual enquiry process that we did as a part of the fellowship till the end of 2017. In 2017, January we co-founded a company called Inochi care private limited and where we chose wound management area to proceed for an entrepreneurial journey. So, I was part of the design and development team.

And, we have gone through an 18 month period for product development and process to arrive at this final product which is a beta prototype.

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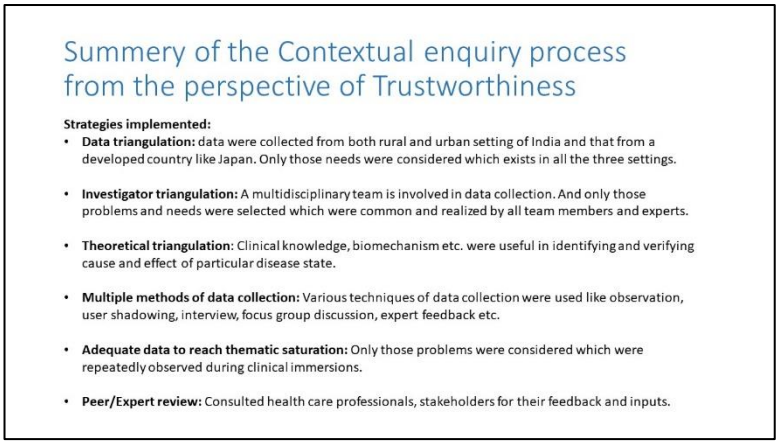

So, this is the final summary of today's class which is how contextual enquiry we look into it from the perspective of trustworthiness. If we look into the process what are these various strategies implemented we find that we have used some of these strategies that I have discussed you earlier in the previous class.

For example: data triangulation. In the contextual enquiry phase, we collected data from both rural and urban setting of India and that from a developed country like Japan also. So, there is a geographical variation of data collection and only those needs were considered which exist in all the three settings – low resource settings, the urban setting and a developed country setting.

Then there was a strategy like investigation triangulation. A multidisciplinary team was involved in data collection and only those problems and needs were selected which were common and realized by all team members and experts. There is the complete validation that the contextual enquiry data we have collected were free from any kind of biases.

Then there was a theoretical triangulation like clinical knowledge, bio mechanism, existing disease states were already informed to us. Also, we studied those to actually realize for certain issues, to realize what are the cause and effect of these particular disease states. So, those were for us as theoretical evidence for choosing particular need area.

Then the other strategy also we have considered is multiple methods of data collection. Various techniques of data collection were used like observation, user shadowing, interview, focus group discussion, expert feedback. So, this way we maximize the variation from the user, the stakeholder's input and we can conclude that the inputs we got from various stakeholder and users are trustworthy.

Also, we adopted this strategy like adequate data to reach thematic saturation. Only those problems were considered which were repeatedly observed during our clinical immersion. Certain problems which occur only 1 or 2 times we never considered those as a part of a problem or clinical that needs a clinical intervention.

And, also we considered peer and expert review. We consulted healthcare professional, stakeholders for their feedback and input.

So, that is the end of this lecture. I hope you learn a lot about contextual enquiry process and how it can be made trustworthy.

Thank you.