



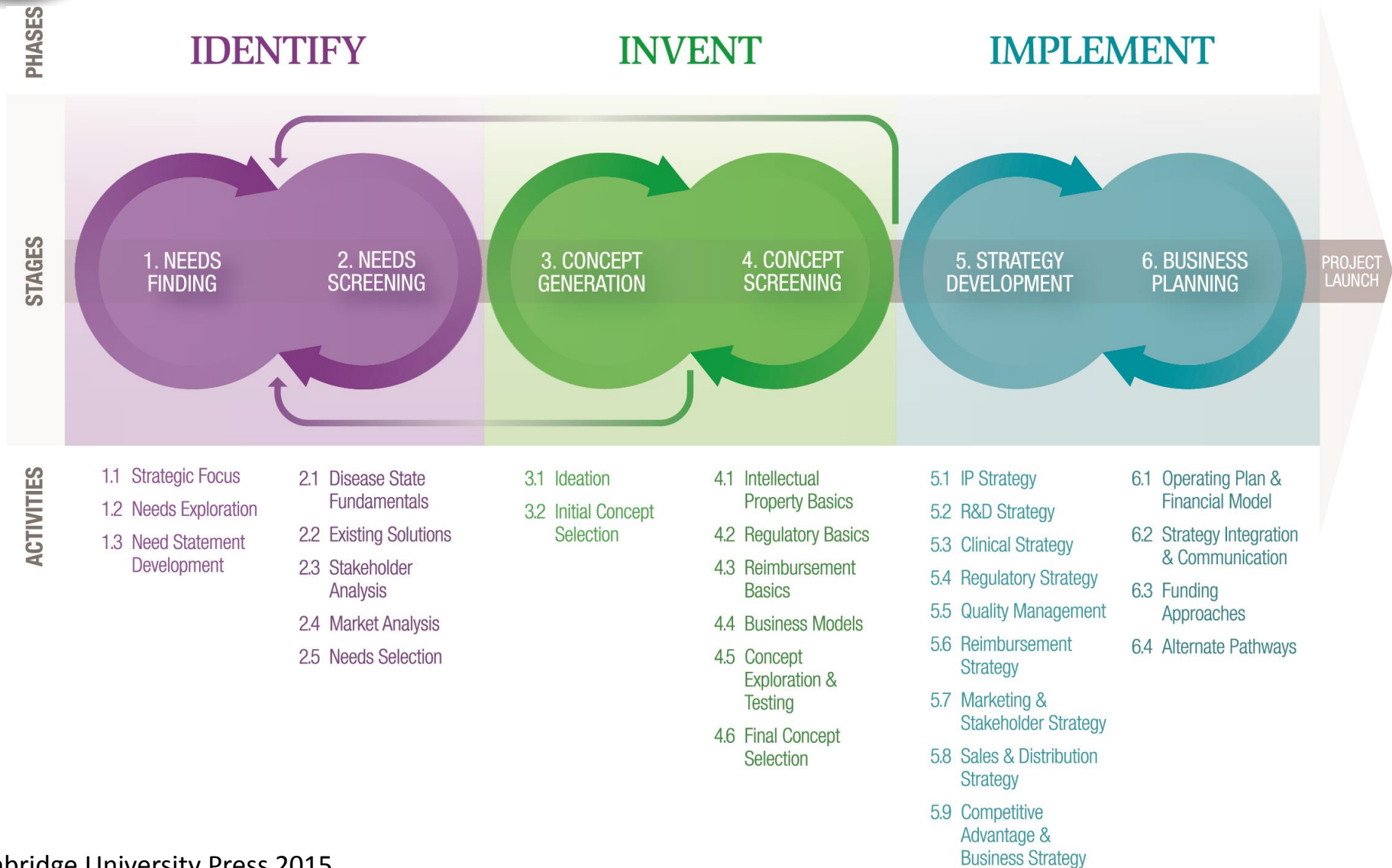
Medical Devices and Diagnostics in Global Health: Enabling Technology with Innovative Business Models

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Innovations in Devices/Diagnostics Panel, EPPICon, March 28th 2015



Biodesign Process





Technologies developed by India Biodesign

Fellows 2012 (Gastroenterology) and 2011 (Pediatric)



Variseal - a breakthrough in the (short-term) emergent management of Upper GI variceal bleed

Jagdish, Jonathan, Siraj, Siddhartha

A revolutionary way of looking at temporary and immediate management of upper GI variceal bleed for patients who don't have immediate access to hospitals with endoscopy facilities. Currently, bench-top testing on ex-vivo animal tissue has been successfully done.

BioScoop - a safer and simple semi-automatic device for liver biopsies

Jagdish, Jonathan, Siraj, Siddhartha



BioScoop is a semi-automatic biopsy device based on needle aspiration biopsy technology, which has a much lower chances of post-procedure bleeding. The device not just reduces the skill for the procedure, but also improves the sample quality for evaluation. The prototype has been tested ex vivo with good results.



Parasafe - an innovative device to standardize the process of paracentesis for all healthcare facilities

Jagdish, Jonathan, Siraj, Siddhartha

About 20% of all cirrhotic patients will need abdominal Paracentesis - draining of peritoneal fluid. Most will need it upto twice a week till liver transplant. Parasafe is a comprehensive package which provides all necessary products for the entire procedure in a market where no dedicated kit exists at all. Product is already tested and ready to be licensed.

Noxeno - A simple and effective device to remove posterior impacted foreign bodies for children

Jagdish, Jonathan, Siraj, Siddhartha



Foreign body impaction in the nose is a common problem for kids upto 5 years of age, yet no dedicated device currently exists in India which facilitates their extraction. Noxeno reduces the skill required for the procedure as well as trauma to the child, making it an ideal device for all general practitioners and pediatricians.



Neobreathe - Neonatal resuscitation: Beyond the urban elite.

Avijit Bansal, Ayesha Choudhary

Every year 900,000 newborns die of asphyxia in the absence of effective resuscitation. NeoBreathe is the world's first integrated newborn resuscitation solution that enables providers at all levels to save lives of newborns, with unique features. It enables a single operator do deliver artificial breaths as well as chest compressions.

Fellows and Interns 2008 - 2012



Consume - a new standard of care for the short term management of fecal incontinence

Nishith Chasmawala, Amit K Sharma, Dr Sandeep Singh

Fecal incontinence, the inability to control the release of stool, has a prevalence of 10 - 58% and its global market is valued at more than \$4 billion. Consume is a low cost, highly efficacious device for all stool types and is indicated for non-ambulatory patients across all care facilities.

Sohum - low cost device to screen neonates for hearing defects in resource constrained places

Nitin Sisodia, Pragun Goyal, Mayank Kumar



A device to detect early hearing loss can save the child from speech disorder, impaired communication skills and possibly mental illness and unemployment. Sohumi is a non-invasive safe device based on advanced brainstem response acquisition technology in an appropriate way for the new born.



Intraosseous (IO) Device - a device to access intramedullary space of long bones to administer fluids and drugs during emergency

Jayant Karve, Srinivas Kiran Jaggu, Dr Sandeep Singh

IO access is the best alternative to difficult intravenous access during emergency. However, it has its own unique challenges. The calcified bones of adults make the procedure extremely difficult. This device provides a simple, cost effective, quick way to gain IO access in all age group of patients.

Relligo - A novel, low cost device for pre-hospital care in trauma patients

Darshan Nayak, Pulin Raje



There is a strong possibility of aggravating lower limb injury after a road traffic accident while transporting the patient to the hospital. Relligo is a simple and cost effective device what will be used to temporarily immobilize the lower limbs of the patients for up to 6 hr till definitive care is provided.



BreathClear - a device to dislodge mucus from respiratory tract of patients with Chronic Obstructive Pulmonary Disease (COPD)

Soniakshi Pandey, Vishal Agale

In India upto 10% of adult population is affected by Chronic obstructive pulmonary disease. The main aim of BreathClear is to help the moderate and severely affected COPD patients in home settings to loosen the respiratory secretions deposited in the peripheral airway and strengthen respiratory muscles.

Fellows and Interns 2008 - 2012



Handy - simplifying hand hygiene in hospitals with improved accessibility and functionality

Aanan Khurma, Neeraj Josmatiya

Handy is a smart wearable device, designed to motivate health-care professionals (HCP) to comply with prescribed hand-hygiene practices thus helping to reduce any infections spread through hands. Handy can be worn on the waist of the user over any kind of attire with the help of a belt.

Uthishtami - an uplift device to help elderly rise independently from a sitting position

Deepali Chandratre, Sneha Venkat



Uthishtami is an extremely lightweight, portable, collapsible and easy to carry assistive device for the elderly to help them rise from sitting position. When folded, it can be easily carried along as a simple hand-held bag. The prototype of the product is done and initial testing has also been done.



Sharps - a cost effective way to manage sharps in healthcare settings

Sonakshi Pandey, Vishal Agale

A better way to organize and manage surgical sharps in the operation theatre so as to reduce incidence of needle sharp injuries. It's a sustainable product made of medical grade paper, its compact design when packaged is easy to transport and store.

iWe - a transillumination device for peripheral Vein detection in pediatric patients.

Vishal Agale, Megha Agrawal, Ramakant Beesetty, Chandni Kobra



Difficulty in detection can lead to failure in successful IV cannulization in pediatric patients because of collapsed veins. This device is based on transillumination principle and is easy to use at any anatomical location.



TransferLife - a simpler way to transfer non ambulatory patients from one bed to another

Mansi Agarwal, Shitij Malhotra, Pooja Singh

TransferLife is the next generation of medical bed sheets to transfer patients between lateral surfaces in the hospital. This disposable fabric based solution, requires only one to two care providers and reduces transfer time to half. The global market for such devices is estimated at USD 2.1 billion.

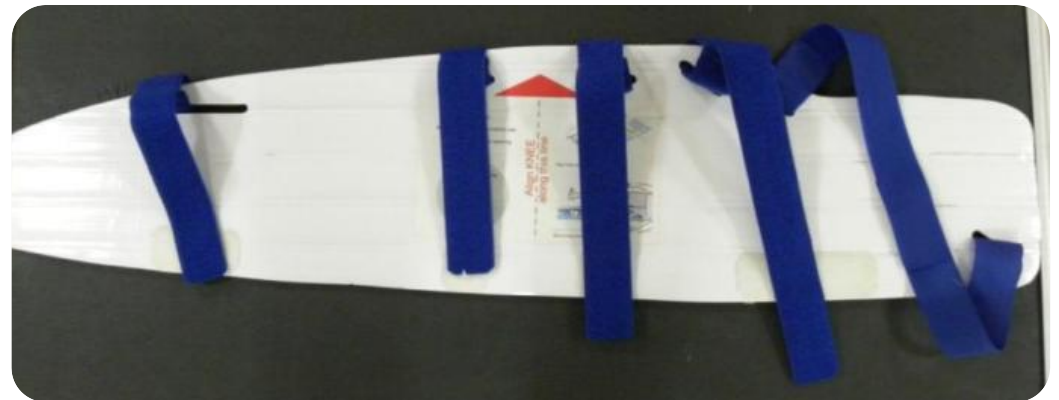
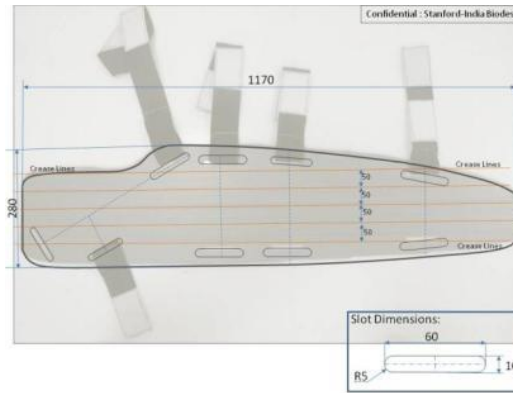


15 Million

Road traffic accidents (RTAs) annually in India

Need: A better way to temporarily immobilize lower limbs in trauma patients

Solution: A Disposable Splint for the Masses





Value Chain in Global Health: PATH





Uterine Balloon Tamponade



http://www.path.org/publications/files/TS_update_bt.pdf

- **Need:** 14 million cases of Postpartum hemorrhage (PPH) occur each year; 25% of the maternal deaths due to PPH
- Current solutions (oxytocin, bimanual uterine massage, surgery) are partially effective or not accessible
- **Innovation:** A balloon inserted into the uterus and slowly filled with water to stop the bleeding stops, reducing the need for surgery or stabilizing for transport
- **Lab to Market:** Initial prototypes by MGH based on off-the-shelf condom tested in Ghana, South Sudan, and Kenya. UBT is now part of WHO guidelines for PPH management. PATH partnering with a manufacturing partner in South Africa to develop a next-gen UBT.



Woman's Condom



http://www.path.org/projects/womans_condom.php

- **Need:** A female condom gives women control over their contraceptive needs
- **User-centered design:** inputs from couples in Khon Kaen, Thailand; Cuernavaca, Mexico; Durban, South Africa; and Seattle, United States throughout the design process
- **Innovation:** Better material, softer anchors, ease of insertion
- **Lab to Market:** testing across several countries, manufacturing knowhow transferred to China partner, WHO approval being sought, new marketing and distribution approaches being tested

Research & Design

Product Development

Evidence for Approval/Reg

Market Introduction

Scale Up



Additional Slides



Lesson 1: Needs Finding

- India is heterogeneous
- Broad on-the-ground clinical immersion critical to fully understand needs
 - North, South, East and West
 - Urban vs. rural
 - Government vs. private
 - All socioeconomic classes
- Helpful if those doing needs finding are the inventors
- Essential to have those who understand culture and language



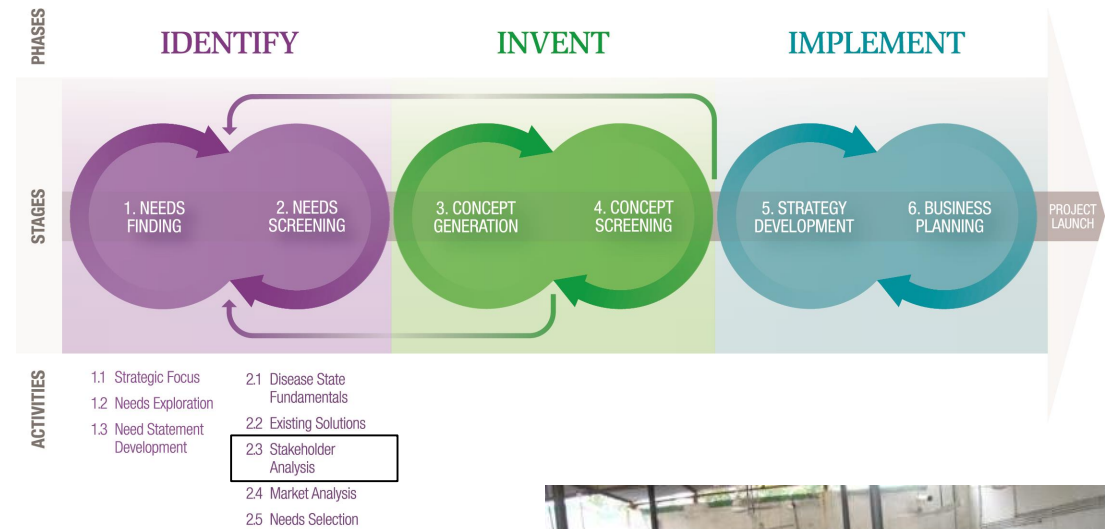


Lesson 2: Needs Screening

Stakeholder analysis is essential

- Physicians
- Other healthcare providers
- Patients
- Patients' families
- Distributors
- Hospital administrators

Stakeholder analysis informs the business model

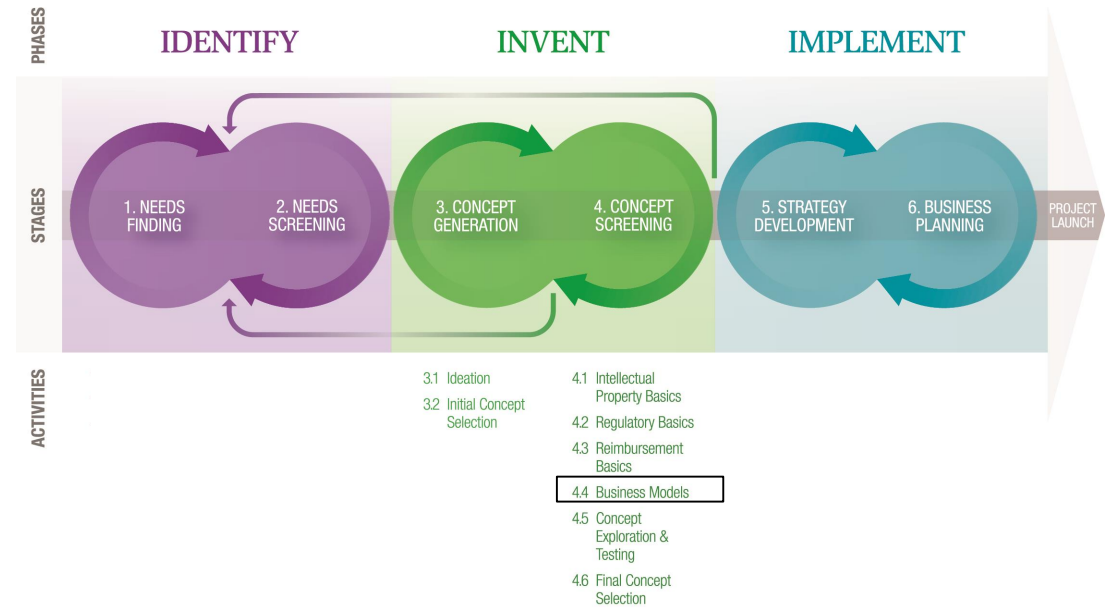




Lesson 3: Business Models

Business model innovation will likely be required:

- Creative financing models
- Creative means of educating/training providers
- Creating awareness and desire to treat among patients

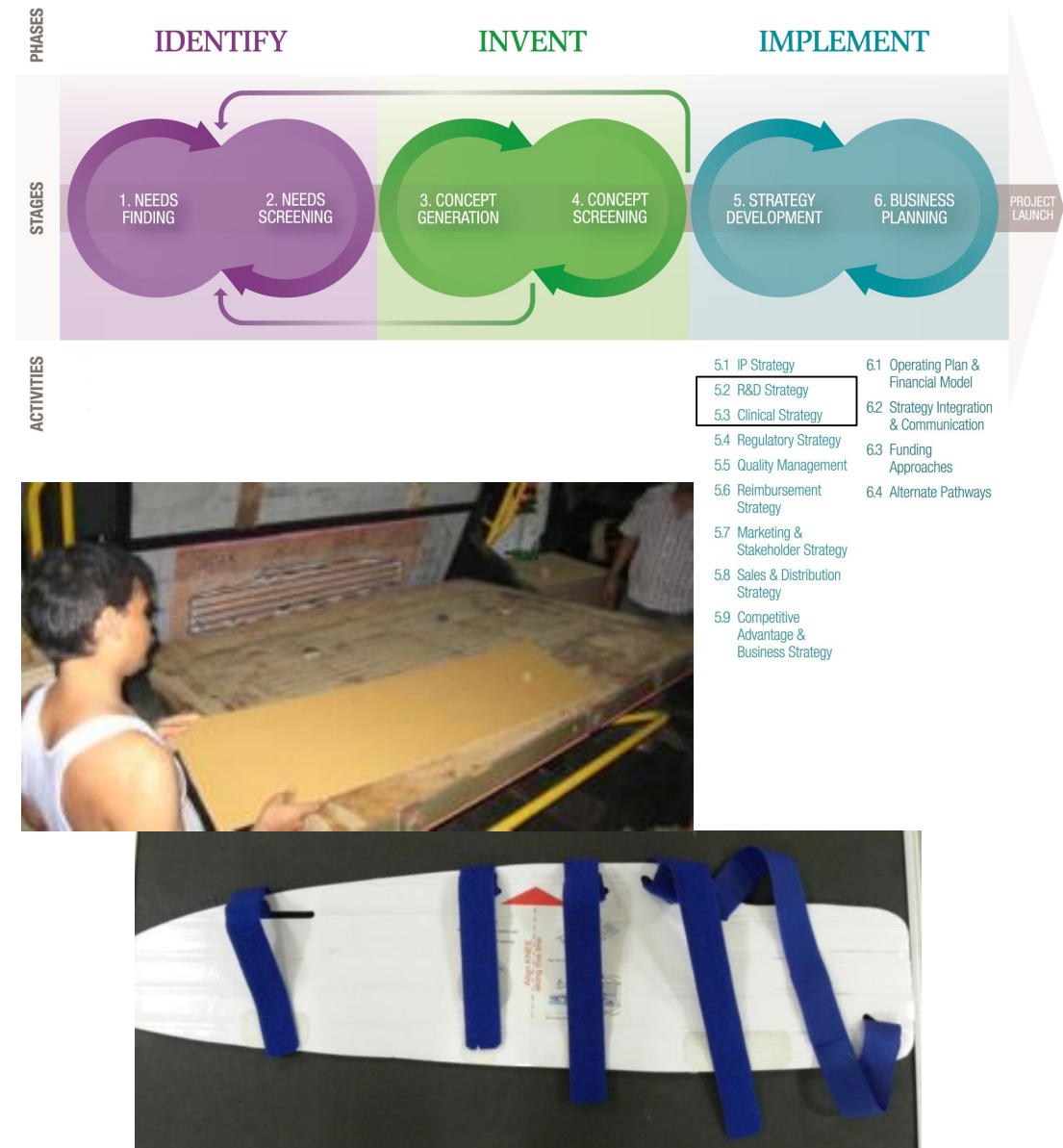




Lesson 4: Development & Testing

Essential to understand:

- Available manufacturing methods
- Quality and reliability of supply chain
- Ability to hire suitable employees with relevant experience
- Challenges in performing animal and human studies in country





Lesson 5: Commercialization/Scaling

- Mentorship in med tech generally scarce in India
- Commercialization partners highly desired

