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Karnataka Pediatric Journal

Editorial

Innovation – The way forward in Neonatology and Pediatrics

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India is rapidly progressing toward universalization of neonatal care and in many states is progressing towards the sustainable development goals of achieving neonatal mortality rate of 12 per 1000 live births and under –5 mortality to 25 deaths per 1000 live births.[1] As neonatal mortality falls as a result of public health measures technology needs to step in to accelerate the progress or maintain the tempo. Technology brings with it rapid innovative ideas which are likely to change health care delivery in many ways. This issue of Karnataka Pediatric Journal brings forth a sampling of many innovations in neonatal care which have been done in our country – hopefully stimulating readers to innovate many more.

Innovation can be in many domains. The easiest to understand for clinicians is innovation in clinical care. We present a slew of article by various clinicians who have done a lot of lateral thinking to develop – new instruments such as laryngoscope, breast milk pasteurizer, and a new phototherapy shield. There is an article by Agarwal, Kumar, and Gupta which reviews various low-cost innovations developed by this group. Clinicians need not be restricted to innovations in devices- as the emerging world of smartphones has given rise to many applications ("Apps") designed by and for doctors which makes clinical decision-making easier. In a cost-conscious country such as India financial innovation in healthcare is the need of the hour as detailed in an article by Kumar. Many a brilliant idea has died a natural death unless it is tempered by the fires of the marketplace. The article by Kumar and Sathasivam tells us the route to the market and the challenges and hurdles which it may face. The article by Ms. Sharma talks about patenting and intellectual property. The articles by Srinivas and Chaturvedi set the background and theoretical basis for innovation and give us an insight into the bio-design process. In all this issue attempts to set the stage for any possible "Edison or Edisons" who may be lurking in our midst. If you do have an innovative idea we hope this issue of the journal will help you to go about and develop it right till it helps children around the world.

Let me end by a quote from our beloved past President APJ Abdul Kalam who said –"Once your mind stretches to a new level it never goes back to its original dimension." We hope this issue of the journal will ignite the minds that innovation is possible and feasible in our country to all strata of the healthcare industry.

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Karnataka Pediatric Journal

Review Article

Genesis and evolution of KIMIE: New cost-effective indigenous human breast milk pasteurizer

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ABSTRACT

Natural mother's breast milk is the best food for all newborns, especially preterm babies. However, if mother's milk is unavailable or donor breast milk (DBM) is inadequate, DBM is the next best choice. Human milk pasteurizers are traditionally big, costly, and require special electrical and water connections, as well as need a large volume of water that is not recycled and an ongoing supply of disposable plastic bottles. Operation of these machines necessitates specialized training. The creation of Kimie, a compact, automated, and user-friendly human breast milk pasteurizer capable of pasteurizing small volumes of DBM, is described here. This system needs no special water plumbing, recycles water, and is reasonably priced.

Keywords: Human milk bank, Pasteurizer, Breast milk, Neonate

INTRODUCTION

Pasteurized donor breast milk (PDBM) is the next best feeding option for neonates when natural mother's breast milk (BM) is not available, insufficient, or contraindicated.[1,2]

GENESIS

A female baby (nick name KIMIE), B.W. 850 g, G.A. 27 weeks, was born to G4 P3 mother by vaginal delivery. By the 3rd day, while treated with moderate respiratory support and 30 ml/kg/day of expressed breast milk (EBM), the mother died unexpectedly. Since the other siblings were also premature, baby's father was familiar with prematurity related morbidities including NEC. He expressed a strong desire not to feed any formula. Various feeding options were discussed in detail. The level II NICU at Centinela Hospital (CH) did not have the tissue license (State of California) to use DBM obtained from a donor breast milk bank (DBMB). One nurse suggested of using another mother's EBM who had a premature baby born at 32 weeks GA. This lady was negative times two for HIV, RPR, and hepatitis B and was rubella immune. Her EBM was in excess, well tolerated by her son, and clinically, there was no suspicion for bacterial contamination. Although there was difference of opinion, there was consensus that the risk of developing NEC due to the use of formula was high as compared to the potential of acquiring bacterial or viral infection using raw donor breast milk (DBM). While use of unpasteurized DBM may be an accepted practice in other countries, there was no such precedence in the health-care system. There was a discussion among the NICU team, the hospital administrator, father of the baby,

and the potential BM donor. After extensive discussion and obtaining informed written consent by everyone, decision was made to use unpasteurized DBM milk.

After extensive search regarding availability of small breast milk pasteurizer (BMP), SafeGard used in the dairy industry was discovered [Figure 1].

An extensive search regarding the availability of a small BMP was performed. SafeGard used in the dairy industry was discovered [Figure 1]. While this pasteurizer uses the principle of holder pasteurization, cooling is performed manually using ice-cold water [Figure 2]. For the next 5 days, DBM pasteurized using SafeGard was fed. Subsequently, DBM obtained from the commercial DBMB was used till the baby was discharged.

Based on the basic design of the SafeGard, modified prototype was developed by Dr. Devaskar [Figure 2]. The concept was discussed with the chief of the biomedical engineering department at UCLA. While the idea to develop first prototype was introduced, it needed two engineers for at least 6 months needing initial investment of ~500,000 dollars was anticipated.

Thereafter, UD, VH, and SUK met with two engineers SW and AK. It was concluded to develop a portable human BMP capable of pasteurizing 300 ml during each cycle using the holder technique incorporating modern automated technology for heating, holding, and cooling [Figure 3].

Figure 1: SafeGard used in dairy industry.

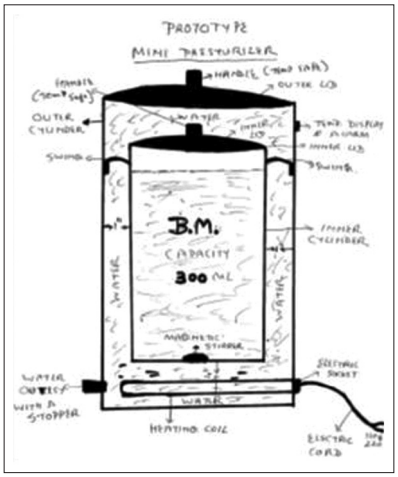

Figure 2: Prototype mini-pasteurizer.

EVOLUTION

It was discovered that within the existing pasteurizers used in human milk banks (e.g. Sterifeed, HSC, etc.), the plumbing is connected to a water supply for filling the chamber and a separate plumbing is required to empty the water. A submersible heater of very high power is employed. To distribute heat equally, they incorporate a water stirrer. Use of a submersible water heater was concerning due to a risk of electrical shock. In addition, the waste of enormous quantity, ~80 L, of water once every cycle was problematic. Numerous choices to manufacture a compact, portable, user- and eco-friendly, and cost-efficient device using modern technology were thought of. It was determined to use two separate water tanks, one for heating and one for cooling. Two totally different water pumps were connected to the respective tanks. During this closed-loop system, every pump propels water within the chamber that warms or cools DBM and water returns to its respective tank. The capability of heating and cooling tanks was arbitrarily decided to be 1750 and 2750 ml, respectively. Thus, only 4250 ml of water would be used and will be recycled. Other discussions included the technical and tubing design, the method of water circulate across the milk container, the components required and their placement, the

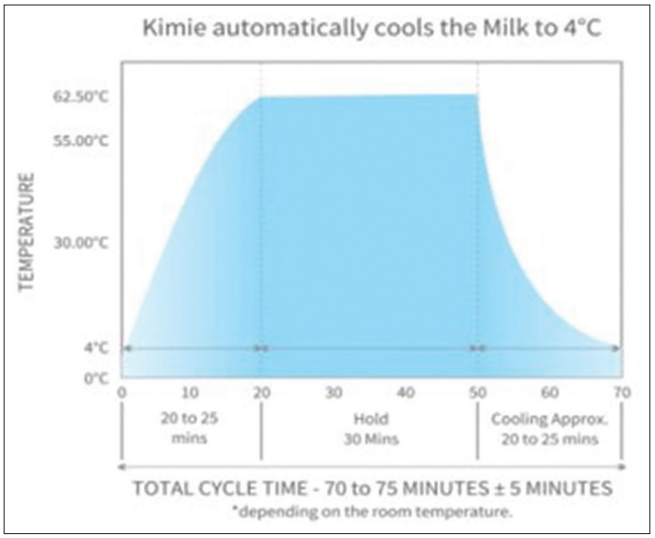

Figure 3: Holder technique.

kind of water pumps for heating and cooling, the specified flow rate, its sturdiness, the kind of heaters and their wattage, the sort of cooling mechanism (chiller) and their ability, the scale, and form of DBM container. The first prototype capable of pasteurizing 300 ml of EBM during each cycle was developed within 3 months [Figure 4]. Then, the second prototype was developed [Figure 5]. The major limitation of the prototypes was: They could pasteurize a single sample of 300 ml during each cycle. Finally, the third prototype able to pasteurizing five different EBM samples and a total of 500 ml were developed [Figure 6]. The information of the engineering and bacteriologic sterility information has been described [Table 1]. In short, to be eco-friendly, for easy cleaning and to be cost-effective, grade 304 stainless steel cylinders rather than the disposable plastic bottles were used. In this prototype, Perplex that's a better cloth as compared to plastic is used.

In 2018, Kimie obtained the ECU certificate of compliance (no 1810170911101) for a human milk pasteurizer and met standards EN 6060-1, EN 60601-1-2, and EN 60601-1-6 to illustrate conformity. In the USA, BM milk pasteurizer does not require FDA approval as it is considered a catering device. Kimie was imported to CH underneath commodity code 84198998.

Kimie [Figure 6] has been successfully used in several hospitals in India for more than 2½ years and at CH for >10 months. It was quickly recognized that there has been a need for production a system able to pasteurizing extra than 500 ml. Kimie [Figure 6] is the today's prototype able to pasteurizing 3000 ml during each cycle and has six different cylinders like Kimie-500. Selling price of Kimie-500 and Kimie-3000 is 5 and 8 lakh rupees, respectively.

Figure 4: Kimie 300 – first prototype.

Figure 5: Kimie 500 – second prototype.

Figure 6: Kimie 500 – third prototype.

DISCUSSION

The origins and evolution of a home-grown, compact, portable, fully automated, user-friendly, cost-effective BMP that uses modern technology, needs less space, has no special plumbing, and can recycle water are described in this paper. Stainless steel is preferred by regulatory agencies in the food industry for heating, cooling, and drying food because it avoids reactions between the food and the container. Safety, durability, corrosion resistance, non-absorbency, adequate weight and thickness to withstand repeated washing, a smooth, easy-to-clean surface, and resistance to pitting, chipping, crazing, scratching, and scoring are all requirements. As a result, stainless steel grade 304 bottles are used rather than plastic bottles.

The indications for using pasteurized BM have been listed in detail and are briefly discussed below.[3]

Premature infants

There is a growing trend to begin enteral feeding within few hours after birth and progress to full feeds as quickly

Table 1: Comparison of Kimie-500 vs Sterifeed (S-90) vs HSC (PAS 10002).

	Characteristic	KIMIE	Sterifeed	HSC
1.	Method of Pasteurisation	Holder	Holder	Holder
2.	Space Needed	10 sq ft	80 sq ft	120 sq ft
3.	Portability	Yes	No	No
4.	Pasteurization Capacity			
	Minimum:	10 ml	1000 ml	1000 ml
	Maximum:	500 ml	9000 ml	3000 ml
5.	Special Plumbing	No	Yes	Yes
6.	Special Electrical Connection	No	Yes	Yes
7	Electric Consumption-Watts	750	2800	> 3,500
8.	Time needed per cycle-minutes	70	120	180
9.	Water required and recycled	4.75 litres, yes.	85 litres, no.	80 litres, no .
10.	Cooling time (63 to 25* C)-minutes	2	10	10
11.	Operation	Fully Automatic	Fully Automatic	Fully Automatic
12.	Cooling mechanism	Inbuilt	Not inbuilt	Not inbuilt
13.	Sensor for milk temperature	Yes	Yes	Yes
14.	Sensor for water temperature	Yes	Yes	Yes
15.	Digital display in real time (Temperature and time)	Yes	Yes	Yes
16.	Noise Level	< 50 DbA	> 50 DbA	> 50 DbA
17.	Material used for the milk container and reused	Stainless steel, yes	Plastic, no	Plastic, no
18.	Auto drain	Yes	Yes	Yes
19.	Cycles / day	Several	Hard to use more than thrice	Hard to use more than thrice

as possible. The best feeding choice for a baby is his or her mother's EBM, which includes colostrum. Supplementing with PDBM is a safer choice when mother's EBM milk is unavailable, inadequate, or unsuitable.[1-5] DBM from another baby's mother can be collected, pasteurized, and frozen, or it can be pasteurized shortly after expression and used right away. This method would reduce the need for TPN and minimize the use of premature formula or DBM acquired from mothers who delivered their babies at full term.

Prevention of cytomegalovirus (CMV) transmission from the use of the natural mother's BM

A recent study reported an association between postnatal CMV infection and negative outcomes.[6] Pasteurization of BM can help to prevent CMV transmission since holder pasteurization eliminates the virus. Many times pasteurizing a baby's own mother's EBM is not feasible due to the lack of readily available pasteurization machines. It is easier to pasteurize the natural mother's BM to remove CMV now that Kimie is available. We have enrolled five babies born at <32 weeks of GA who have received own mother's EBM pasteurized using Kimie.

Prevention of CMV and HIV-1 transmission

Feeding accounts for half of mother-to-child transmission of HIV-1.[6,7] Coinfection with CMV in the BM is linked to an increased risk of HIV-1 transmission from mother to child after birth. In countries with limited resources, BM is still critical for infant survival. As a result, eliminating CMV and HIV-1 virus by pasteurizing mother's BM before ingestion will prevent vertical CMV and HIV-1 transmission. It should be possible to do so now that Kimie is available.

Prevention of CMV and other viral infection in immune-compromised infants

Severe combined immunodeficiency (SCID), 22q11 deletion syndrome (DiGeorge), CHARGE syndrome, VACTERL association, and ataxia telangiectasia are a few examples of primary immunodeficiencies.[6-11] It is not recommended to breastfeed or use PDBM to avoid viral transmission.[6-11] One baby was diagnosed with SCID at CH at the age of 9 days. He has been getting his own mother's BM, pasteurized with Kimie, for the past 10 months. Although awaiting the HSCT, he has remained CMV negative.

Prevention of COVID-19 transmission

In general, if the mother is COVID-19 positive at the time of birth, her baby will unlikely be colonized by the virus. Similarly, her BM tests negative for the virus at birth. However, if these women do not take the necessary precautions, the COVID-19 virus may infect their BM. Pasteurization of her EBM may be indicated in these circumstances, especially in the preterm baby. Holder pasteurization of milk has been shown to eliminate the COVID-19 virus in a recent study.[12]

CONCLUSION

Necessity breeds ingenuity, and disaster breeds opportunity. Kimie's development and evolution is an excellent example of clinicians and engineers collaborating. More partnerships like this are needed with the common aim of improving the health of neonates all over the world.

Declaration of patient consent

Institutional Review Board (IRB) permission obtained for the study.

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Conflicts of interest

There are no conflicts of interest.

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Review Article

Apps in Neonatology

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ABSTRACT

We all stand at the threshold of the digital era where mobile and digital health is going to be the norm. A number of apps are available on the iOS and android platforms for health workers in neonatology. In this article, we have compiled the information regarding various apps related to neonatology available for android and iOS mobile devices.

Keywords: Apps, Android, iOS, Neonatology, Digital

INTRODUCTION

mHealth is a quite fascinating new branch of health care which refers to the utilization of mobile and wireless devices to support health care.[1] The World Health Organization (WHO) recognizes mHealth as a form of eHealth with the potential to improve the delivery of health care in the world, especially in developing countries.[2] mHealth includes data collection and management, service delivery, health communication, and diagnostics. Applications or "apps" are programs which deliver health care-related information to health care workers in a coherent manner so that they can help in management of the patient. This review focusses on the application of these apps in the Indian work environment and makes no claim to be applicable to all set ups.

Many apps available are free but some have to be paid for [Tables 1 and 2]. These apps were searched for in Google Play Store and iOS platform using keywords such as apps in neonatology, neonatology, newborns, calculators in neonatology, apps in NICU, neonatal resuscitation, and apps for parents of preemies. We categorize these apps into three categories as follows. Point-of-care utility apps exist to assist in measurements for intubation, central line insertion, and drug and fluid calculations including parenteral nutrition. Some help in clinical management of jaundice, neonatal resuscitation, drug formularies, and standard treatment protocols. Educational apps are focused on examinations with practice materials, question banks, etc. Productivity apps are useful for the parents in monitoring the feeding, growth parameters, developmental milestones, as well as useful for trainees in maintaining their daily activities. In the tables, the available user ratings of individual app are mentioned [Tables 1 -3]. These are not exhaustive list of apps as there is constant evolution and innovations happening in the tech-world.

APPS RELATED TO POINT-OF-CARE UTILITY

Measurements and calculations

In emergency situations including resuscitation calculation of drug dosages, umbilical line measurements, endotracheal tube size, and depth of insertions are vital bits of data. Probably,

the best app is NeoMate which provides the size of endotracheal tube, dosage of medicines for rapid sequence intubation, the size and distance of insertion of UAC and UVC, and doses and preparation of vasopressors. It helps in IV fluid calculations and has neonatal transport check list. This app also gives the TOBY checklist and provides a centile calculator for follow-up of growth till corrected gestational age of 42 weeks. However, it does not provide total parenteral nutrition (TPN) or fluid deficit calculation. SANTA NICU is a similar app and scores over because it gives a target checklist for BP and HR. It has the following drawbacks. The app does not give the calculations for emergency drug infusions, neonatal transport checklist, TPN or fluid deficit calculation, growth chart, or cooling criteria. "Neonatology" is a paid app and has a free version called neonatology lite which only gives the ET size, UAC, UVC length, and doses of a few drugs. The paid version "Neonatology" provides a lot of other information except for anti-seizure treatment algorithm. Coombe Neonatal Guidelines provide information and protocols related to neonatal problems except seizure treatment protocol. These protocols are based on Coombe Women and Infants University Hospital Guidelines. "Neonatal Seizures causes and management" app contains details about causes, classification, diagnosis, management, and home care of seizures but it fails to provide drug doses and algorithmic management of neonatal seizures.

Online calculators

MedCalc is a collection of online clinical calculators which includes APGAR score, Ballard score, fluids, TPN calculation, quick drip and quick IV, growth charts, and immunization related to neonatology.[3] MDCalc is a similar website which provides calculators for AaDo2, anion gap, ABG analysis, blood volume for partial exchange transfusions, QTc, and risk assessment for NNH.[4] Nicutools is a browser-based neonatal and infant calculators providing calculations of AaDO2, survival probability of extreme preterm neonates, diaphragmatic hernia, low flow O2 Fio2, glucose delivery, central lines, nitric oxide delivery, partial exchange transfusion, infusion calculation, as well as for EOS risk prediction. It also gives audit tool for nutrition and phlebotomy losses.[5] Calculators are also available in Up-to-date which includes neonatal jaundice assessment, APGAR score, fluid calculation, growth charts, GFR estimation, and QTc calculation.[6] Medscape is similar to Up-to-date in providing the calculators.[7] Pediatric Oncall provides calculators for Ballard score, Brue Resolved unexplained Events Criteria for Infants, Hyperbilirubinemia Risk Nomogram, Maternal-Fetal Hemorrhage Rh(D) Immune Globulin Dosage, Natural Porcine Surfactant, Phototherapy Nomogram, and Umbilical arterial line placement.[8]

Apps for neonatal jaundice

Probably, the most frequent use of apps is for the management of neonatal jaundice. "Phototherapy calculator" uses AAP guidelines whereas "Phototherapy" uses NICE guidelines for prediction of jaundice in newborns. Both of these are available in the android play store after payment of Rs. 250/- and Rs. 95/-. There are variety of applications available freely such as Biliapp (NICE), Bilirisk (AAP), Biliguru (NICE), Bilibaby (AAP), jaundice curve (AAP), Neonatal indirect hyperbilirubinemia (Emory university/ AAP guidelines). In Biliapp, bilirubin values should only be entered in mmol/L whereas in Biliguru, values can be entered in both mmol/L and mg/L. However, in Biliguru, the exact date and time of birth cannot be entered hence exact time hours have to be entered manually. Newborn weight loss/ weight gain calculator, though available only in kilograms/ grams, is a simple app to calculate weight loss/gain and percentage change in weight.

Sound and light in the NICU environment

"Noise meter" measures the sound level in decibels in NICU, however, there is a reported inaccuracy of =/− 10 dB. "Sound meter – Decibel meter and Noise meter" is an app available in play store to measure the sound level in and out of the NICU surroundings quite accurately and it is possible to save the recording. The cons of this app are it contains intrusive ads and cannot measure higher decibels. We find these apps useful to ensure that the noise level in the NICU is kept within the permissible limits as per our developmental supportive care norms.

Light measuring apps include Lux Light Meter Free, Lux meter (Light meter), Smart Luxmeter, and Illuminance: light Luxmeter. Light Meter measures the light level in lux units over a period of time. Smart Luxmeter measures the light level in lux and foot candle units. Lux light meter provides the light measurement values in lux units but it contains intrusive ads. We rarely use these apps. These apps DO NOT measure the output of phototherapy accurately and are NOT recommended for this use.

Fluid calculations and TPN

Fluid calculations are vital part as well as time consuming in a NICU, especially in very low birth weight infants as the chances of errors are high. All the applications are available freely. Neoliq is used for fluid and TPN calculations but amino acids and lipids are mixed with IV fluids. Hence, it would be difficult in usual settings as proteins and lipids are given separately in most NICUs as well as 50 ml syringes are used for infusions. Other applications available are "Neonatology fluid calculator," "NICU calculator," and "TPN." "Dextrose Calc and calories" is used only for calculation of dextrose

calories and GIR calculation, while "Newborn fluid therapy" is used for fluids and electrolyte calculation. Both are not used for TPN calculation.

Neonatal resuscitation

"NRP app" is based on NRP 7th edition AAP/AHA guidelines and it has illustrations with videos and posters that are easily understandable. "Neonatal Resuscitation" is a paid app provided by NHS Scotland for pediatricians, neonatologist, and NICU care nurses. Both the applications needed registration for initiation. eNRI is a free application designated for step-by-step approach during neonatal resuscitation based on the recent NRP guidelines. "LIFE: Neonatal Resuscitation Training" is a simulation training application but has only limited scenarios. "APGAR score" is an application to calculate the APGAR score in newborns immediately after birth. "NRP Vitals" is a neonatal monitor simulator application which displays heart rate, spo2, temperature, and timer and can be connected through Bluetooth/Wi-Fi to other mobile devices. SimMON is a simulator app which can be used to mimic a monitor during simulation exercises including neonatal resuscitation and ICU crash drills.

Interpreting arterial blood gases

Arterial blood gas interpretation has been made simple by an app called "Complete ABG." "Complete ABG" is a freely available application in IOS and android platforms that provides a handy tool for interpreting the printout of arterial blood gas report. It also has option of calculating the anion gap if the electrolyte values are fed in.

Drug doses

NeoMate and other apps provide dosages of drugs used in resuscitation. IBM Micromedex NeoFax is a comprehensive paid app which provides all the information as its printed version. DrugDoses is another paid app which mimics the drug dosage book published by the Royal Children's Hospital, Melbourne, Australia. It incorporates drug doses, pediatric calculators, and PICU guidelines. The Harriet Lane handbook is a paid app with even more features including photographs and illustrations, and is ideal for pediatric trainees. The British National Formulary also comes as a paid app. Depending on your budget and practice, it is worth subscribing to one of the apps.

EDUCATIONAL APPS

Learners guide from AIIMS WHO CC

A handy group of apps released by AIIMS is useful ready references for newborn care at the bedside in SCNUs. Applications provided by AIIMS WHO CC are free and includes "AIIMS WHO CC ENBC," "AIIMS WHO CC PTC," "AIIMS WHO CC STPs," "HBS ECSB," "Essential Newborn Care App," and covers essential newborn care, preterm care, and standard treatment protocols. The national neonatology forum has released an app "NNF CPG" which provides the latest recommendations January 2020 related to certain NICU treatment practices.

Learning echocardiography

TnECHO is an immensely popular learning tool which teaches functional echocardiography to the neonatal practitioner. It includes videos of probe position, 2D echo loops, color Doppler loops, and labeling of the various structures and is aimed at familiarizing neonatologists with basic echocardiography views and aiding self-directed learning. Echocardio is another app which provides pictures of various probe positions and the structure visualized. However, no videos are available. Echocalc is a free app for key echocardiographic calculators and reference tool for echocardiography. Echo UW app from the University of Wisconsin provides step-by-step instructions for performing a normal pediatric echocardiogram and uses video clips, images, and illustrations to aid in instruction.

Learning ultrasonogram

"Cranial Ultrasound" is a paid educational neonatal medical quiz app designed for medical student, doctors and healthcare professionals. This app solves over 50 real clinical cases and provides 250 high-quality images. "Ultrasound A2Z" provides very limited information about neonatal cranium. "NeoHead" is paid app in apple play store which provides interactive information on neurosonography. "iSonographer Ultimate Atlas" is a useful paid app which comprehensively covers reference ultrasound measurements of vascular and general ultrasound including echocardiography and USG of neonatal brain. Other apps useful for neonatal imaging includes "Radiology," "Pediatric Radiology," "Pediatric XR," "Pediatric Ultrasound," and "pedsMRI."

Atlas

"Clinical Pediatrics" is an app provides information about history, examination, spot diagnosis, X-rays, and CT scan. Most of the pictures, radiological images provided are related to neonates.

Neonatology books

Oxford Handbook of Neonatology provides bedside accessible practical advice to the treating clinician, however, the cost is high around Rs.3529/-. Essential Neonatal

Table 1: List of neonatology apps available on payment.

S. No.	Apps	Cost in Rs.	Uses	Remarks	Ratings (/5)
1.	Neonatology	300	Airway, intubation, emergency medications calculations, umbilical lines measurement	- Anti-seizure treatment not included - Gestation wise doses not mentioned	4.9
2.	Oxford handbook of neonatology	3529	- Bedside accessible - Delivers practical advice to the clinician	High cost (soft copy easily available)	Nil
3.	NICU Neonatal Intensive Care Unit test bank+4200 MCQ	170	Practice tests, study cards for nurses, students		Nil
4.	Neonatal Intensive Care Unit NICU	220	Practice tests, study notes, flash cards	Able to add own study notes and cards in the app	Nil
5.	NICU Neonatal Intensive Care Unit Exam Review app	170	Flash cards and study notes		Nil
6.	Phototherapy calculator	250	AAP Guidelines	Used in both micromol/L and mg/dl	3.6
7.	Phototherapy	95	NICE Guidelines	Used in both micromol/L and mg/dl	4.5
8.	Essential neonatal medicine 5 ed.	2500	Reference with calculators, high-resolution pictures	High cost	Nil
9.	Neonatal resuscitation	270	NHS Scotland	Registration must before use of the app	Nil
10.	Cranial ultrasound	60	Neonatal medical quiz app		Nil
11.	Neonatal formulary 7 ed.	5351	Drug use in pregnancy and the 1st year of life	High cost	Nil

Medicine 5 ed. is another paid app which provides quick reference to common neonatal problems, high-resolution pictures and has calculators for drug dosages. Drugs used during pregnancy and 1st year of life are available in Neonatal Formulary which costs Rs.5351/- [Table 1]. Pediatrics and Neonatology Book is a pocket manual which delivers concise evidence-based information, albeit it is available for 1-day free trial. Neodiagnosis is useful in providing quick link to relevant sites for over 700 neonatal diagnosis. Neonatal care contains two modules for basic and advance neonatal care which opens as separate pdf documents. IMNCI 2018 ed. is based on recent IMNCI guidelines and has illustrations with videos and posters. "Neonatal care and information" application provides information about basic newborn care, however, developmental aspects are not available. Gomella's Neonatology is an excellent pocket guide for treating common and rare neonatal problems. However, only limited content is available freely and needs upgradation for full content that costs very high.

Preparing for examinations

For nursing students and neonatal fellows, some apps help prepare for the examinations. "NICU Neonatal Intensive Care Unit Test Bank + 4200 MCQ," "Neonatal Intensive Care Unit NICU," and "NICU Neonatal Intensive Care Unit Exam Review App" are the paid apps and "NCA Neonatal care Academy," "NICU Neonatal Intensive Care Unit Test Bank Ltd.," "CCRN Neonatal Pocket Preparation," "Neonatal Nursing Review," and "Neonatology Intensive Care Unit for Learning and Exam" are the free apps used for students, nurses to learn neonatology through practice tests, study notes, and flash cards.

PRODUCTIVITY APPS

Log book for trainees

"My logs" is an app which functions as a log or notebook. No internet connection is required once the app is downloaded. Entries can be categorized; files can be attached and the log entries can be viewed in a list or calendar view.

Apps related to genetic diagnosis

"Genetics 4medics" is a free version with access to 50 genetic conditions, 50 clues, and 3 chromosomes in mapping. Paid version would give access to full resources including basic genetic concepts and gene teasers. "PediaGene: AAP Genetics Guide" is a one-stop app for a wealth of genetic screening information, patient care, and quick reference. "Face2Gene" app is designated solely for health-care professionals that facilitate comprehensive and precise genetic evaluations based on the phenotype.

Table 2: List of apps available for free.

S. No.	Apps	Uses	Remarks	Ratings (/5)
1.	Neomate	Checklists, calculations based on London NTS	Deficit calculations, electrolyte imbalance not included	Nil
2.	SANTA NICU	Southern Alberta Neonatal Transport App for airway, intubation, emergency medications calculations, umbilical lines measurement	Deficit calculations, electrolyte imbalance not included	Nil
3.	Neonatology lite	Airway, intubation, emergency medications calculations, umbilical lines measurement	Limited number of results compared to the paid neonatology version	3.6
4.	Coombe neonatal guidelines	Coombe women and infants university hospital guidelines	Anti-seizure treatment protocol not available	Nil
5.	Neonatal seizures causes and management	Contains details about causes, classification, diagnosis, management, home care of seizures	Drug doses and algorithm not mentioned in treatment	Nil
6.	Pediatrics and neonatology book	Pocket manual delivers concise, evidence-based information	Only 1 day free trial	4.4
7.	Neonatal illustrations	Provides illustrations and rare pathophysiology in neonatal medicine by Dr. Satyan Lakshminrushima	Cover limited topics	5
8.	Neodiagnosis	Quick link to relevant sites for over 700 neonatal diagnoses	Does not provide direct results	4.2
9.	AIIMS WHO CC ENBC	Learners guide for bedside newborn nursing by Dr. Ashok Deorari	Though videos can be downloaded, posters not downloadable	4.5
10.	AIIMS WHO CC PTC	Preterm care by Dr. Ashok Deorari	Needs registration	4.5
11.	AIIMS WHO CC STPs	Standard Treatment Protocols		4.3
12.	HBS ECSB	Essential Newborn care by Dr. Ashok Deorari AAP/WHO CC	Covers only the essential care	5
13.	Essential newborn care App	WHO current guidelines (AAP)	Covers only the essential care	4.6
14.	NNF CPG	January 2020 NNF CPG guidelines		5
15.	NCA neonatal care academy	Neonatal care topics by NATUS	Needs registration	4.8
16.	NICU neonatal intensive care unit test bank Ltd	Practice tests, study notes, flash cards	Upgradation required for more questions otherwise only limited questions	Nil
17.	CCRN neonatal pocket preparation	Practice tests for nurses	Upgradation required for more questions otherwise only limited questions	4.3
18.	Neonatal nursing review	Nurse examination style	Upgradation required for more questions otherwise only limited questions	Nil
19.	Neonatology intensive care unit for learning and exam	Practice tests, study notes, flash cards	Upgradation required for more questions otherwise only limited questions	Nil
20.	Neoliq	Neonatal parenteral nutrition solutions	Amino acids and lipids are mixed with IV fluids. Difficult in usual settings as 50 ml syringes are used for infusions	4.7
21.	Neonatology fluid calculator	Can be used separately for individual electrolyte calculation	Difficult to calculate TPN infusions	4.6
22	NICU calculator	Developed by Cleveland medical center	Need to enter the volume of TPN, fluids	Nil
23.	Total parenteral nutrition	Neonates/Pediatrics	Amino acids and lipids are mixed with IV fluids. Difficult in usual settings as 50 ml syringes are used for infusions	Nil
24.	Dextrose Calc	GIR and calories calculator	Not used for TPN calculation	4.9
25.	Newborn fluid therapy	Fluids and electrolytes calculation	Not used for TPN calculation	4.9

NTS: Neonatal transfer service, TPN: Total parenteral nutrition

Table 3: Miscellaneous apps.

S. No.	Apps	Uses	Remarks	Ratings (/5)
1.	NRI/eNRI	Neonatal resuscitation	NRP 7th edition	4.7
2.	Complete ABG	Assist nurses, students for interpreting ABG		3.6
3.	NRP App	NRP 7th edition - AAP/AHA guidelines	Illustrations with videos/poster Needs registration	4.3
4.	LIFE: Neonatal resuscitation training	Simulation training app	Limited scenarios	Nil
5.	NRP vitals	Neonate monitor simulator app; HR, Spo2, temperature, and timer	Respiratory rate not available	3.3
6.	APGAR score	Simple app for calculation of APGAR at birth		4.6
7.	Guide to NB care	Provides information about basic newborn care	Developmental aspects not available	Nil
8.	Neonatal care	Neonatal modules	Opens pdf document with two modules	4.8
9.	IMNCI 2018 ed.	Based on recent IMNCI guidelines	Illustration with videos/posters available	4
10.	Neonatal care and information	Provides information about basic newborn care	Developmental aspects not available	Nil
11.	Neonate	Canadian Neo learning resources	App is in development stage	Nil
12.	Gomella's neonatology	Pocket guide for treating common and rare neonatal problems	Only limited content available free. Upgradation needed for full content.	4.4
13.	IBM Micromedex NeoFax	Drug information, interactions, doses	Needs frequent updation	4
14.	Biliapp	NICE Guidelines	Only in mmol/L	4.3
15.	Biliguru	NICE Guidelines	Both in mg/dl and mmol/L. Option of entering exact time of birth and date not available so exact hours cannot be calculated on its own	4.5
16.	Bilibaby	AAP Guidelines; Available in mmol/L and mg/dl	Only for >35 weeks GA	3.9
17.	Bilirisk	AAP guidelines; available in mmol/L and mg/dl	Only for >35 weeks GA	4.3
18.	Jaundice curve	AAP guidelines	Only for >35 weeks GA; Graph is available, exact range is not marked	3.9
19.	Neonatal indirect hyperbilirubinemia	Emory university guidelines AAP guidelines	For GA>35 weeks	4.5
20.	Newborn baby weight loss/weight gain calculator	Simple app to calculate percentage of weight loss and weight gain	Only in kg/grams	4.4
21.	Sound meter – Decibel meter and Noise meter	Measures the sound level quite accurately and save the recording	Intrusive ads, cannot measure higher decibels	4.5
22.	Noise meter	Measures the volume of sounds	Inaccuracy +/− 10 dB	4.5
23.	Peekaboo ICU Preemies	App for parent of preemies. Contains information about prematurity, various organ systems, milestones, growth charts, nutrition logs, discharge	Technical issues related to growth chart	3.7
24.	My NICU newborn	Parent of preemies for tracking baby's progress, events, monitor feeding	No information about vaccination, growth charts, milestones	Nil
25.	Infant care	Feeding, growth, vaccination guide for parents	Does not provide information about neonatal jaundice	4.8

Apps for parents

Illustrative Neonatology by Prof. Satyan Lakshminrusimha is a free app aimed at neonatologists and parents and provides simple illustrations which can be used to understand neonatal diseases. "Peekaboo ICU preemies" is an app for parent of preemies which contains information about prematurity, growth of various organ systems, milestones, growth charts,

nutrition logs, and discharge. It is an excellent app except for a small technical glitch related to growth chart. "My NICU newborn" is a free app useful for parents whose babies are admitted in NICU for tracking baby's progress, events, and monitor feeding, however, there are no information available about vaccination, growth charts, and milestones. NICU companion helps by giving information about breathing support for babies and breastfeeding in the NICU. It helps hear stories from NICU families, see the equipment used to help babies breathe, use the feeding tracker, use the Kangaroo Care tracker. My preemie app is a pocket guide to parents of premature babies. It provides details about basics of preterm care, parenting, growth, development, feeding, equipment, complications, and management plan. In addition, it gives a diary of events, treasured moments, growth chart. "Infant care" gives information about feeding, growth, vaccination guide for parents except for neonatal jaundice. "Baby tracker – feeding, sleep and diaper" helps in tracking the feeding, sleep, and diapering for infants but the information cannot be shared which is overcome by another application, "Baby feeding tracker – newborn feeding and care" where both parents can update the information in the same profile using different devices. "Baby care week by week tips" provides limited information to the users about feeding, growth, and milestones. "Care for a newborn baby" application in android play store provides most newborn care from birth till development and available as a book format. This app could be of good help to new parents.

CONCLUSION

Various apps have come to the aid of neonatologist and trainees in emergency and bedside management of neonates. It is conceivable tele-medicine, e-medicine and mHealth will converge and smart equipment and monitors will interact with neonatal health-care providers in future.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Review Article

Grants, Funding, Awards and Recognition in Healthcare Innovation

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ABSTRACT

For an idea to be validated, prototyped and tested, adequate financial planning plays a major role in the long journey of the idea from the brains to the market. There are various ways of getting funds for the startup. The founders usually start with their own money from their savings or some borrowings from family and friends which is called bootstrapping and is very common and crucial, akin to doctors starting their own clinics and small nursing homes. As they start to grow, large funds are needed in the early stage to set the foot firm with the help of an angel investor/seed investor which is like starting a full-fledged hospital. The Venture capitalist comes in at a stage when the idea is proven and started with operations, early-stage customers and has a major potential to expand, just like when more branches of hospitals are planned. Private equity companies and investment banks are those who are keen to invest in companies who have proved themselves beyond doubt with strong leadership in the market and are looking for a major return on investment by making the company bigger, which is like planning a pan India network of the hospital chain. These investments happen multiple times or rounds at various stages of the company usually termed series A to series D or E and ultimately leading to the Initial Public Offering when it goes public from private holding. This funding journey is a well-planned effort quite specific to the investment stage, investor type, and their preferences. The recognition of the startups and their ideas plays a major role in them reaching to market and access to funding opportunities. The funding and national recognition from various govt. and private agencies such as BIRAC, FICCI, NASSCOM, Wellcome trust, and Villgro and international agencies such as CAMTech, Bill and Melinda gates foundation, Grand Challenges Canada, Stanford, and Harvard gives the much needed attention from the potential investors and is a major advantage which should be utilized well. Social media recognition plays a major role in recent times which has the potential to make an innovation "viral" and reach millions of customers and make relevant investors and govt. agencies notice, which can be a huge breakthrough for the company if the innovation has a social impact. We would like to make this article more practical, experiential, and contextual for better connect with pediatrician colleagues.

Keywords: Pitching, Healthcare grants, Healthcare Innovation funding, Healthcare innovation awards

PITCHING

Before dwelling about the grants, a brief about the most important tool of pitching the idea in the right way to the right person which gets the fund/grant approved. Having a brilliant idea is the first important step, the next is pitching[1] which is, to be able to present the idea and the business plan in a very effective way to the investor with all the essential aspects they are interested in, to help them decide to invest in your company. There are various types of pitching, of which the two of these are quite interesting:

Twitter/Twit pitch

Twitter/Twit pitch is to explain what you do in a tweet size byte (less than 280 characters/letters) like A new technology based healthcare company pitching: "we are the uber of healthcare, trying to solve the access in a very affordable way, all sitting at home via smartphones".

Elevator pitch

Elevator pitch means, to be able to explain about the problem you are solving, how innovative is your solution, the potential in market and the opportunity for the investor, all in under 1 min which is usually the time you get to pitch to an investor in case there is a chance meeting them while in an elevator. These are just to create curiosity for further discussions where you present the more detailed business pitch/investor pitch and seal the deals.

GRANTS

A grant[2] is an award, usually financial, given by one entity (typically a company, foundation, or government) to an individual or a company to facilitate a goal, or help company for the purpose for which grant is announced. For example: During the initial times of COVID pandemic, many govt. agencies announced grants for solutions targeted towards managing COVID diagnosis, affordable ventilators, monitoring of disease, etc. The biggest advantage is that there is no need to pay back the grant but it needs to be accounted for so that it's used for the intended purpose. But grants do not come easy. Writing a grant proposal itself is an art and you need to make sure you understand well about the purpose of the grant and alignment with the objectives of the grant and your company. Understanding the crucial factors that the agency is keen on and the impact your solution can create on the field are very important. In India, there are various government and private grant funding available specific for medical devices and healthcare related initiatives. Another way to get a grant is to participate in Hackathon[3] which is an event where people come together to solve problems. In health-care themed Hackathons there are people from diverse backgrounds of medical, engineering, design, business, etc., meet, with the healthcare experts pitching their pain points and the audience with varied expertise in different domains trying to understand the problem. They form teams with the clinician and brainstorm further to develop a proof-of-concept solution over the next 24 h or 48 h or a weeks' time and present it to the forum. The best problem to solve based on the impact it can create gets the prize in the form of a grant and other support. Ex: I (Dr. Gunda Srinivas) happen to participate in a multicity, pan India CAMTech 2016 Jugaadathon/Hackathon where I pitched about the problem of unsafe hand ambu-bagging practices in resource limited settings due to shortage of ventilators which I have witnessed in many healthcare setups. We created a team and developed a working prototype in 48 hrs and presented it to jury, for which our team was awarded national prize for an affordable, automated Ambu device solution. This device could be used as a standby ventilator instead of unsafe prolonged hand ambu bagging when there is non-availability of ventilators.[4]

A word about Incubators, these are organizations that support startups at their initial stages when they possess only an idea to bring to the marketplace, but no business model and support them to transition from innovative idea to reality. They typically provide the space to work, other support services such as connectivity, maintenance, and common facilities such as labs, makerspace, and workshops which can be used by all the startups being incubated there. The idea is to remove all possible hurdles and help the startups work and focus on their core idea and take it forward. This is like a doctor getting trained during the PG course.

Few examples of govt. and private grant schemes and incubators.[5] Many of them provide grant and incubation together.

Biotechnology Ignition Grant (BIG) scheme

Biotechnology Research Assistance Council (BIRAC) offers the BIG grant of up to INR 50,00,000/- for individuals or companies (not older than 3 years) for idea to proof of concept (PoC) generation stage.

AMTZ

Andhra Pradesh MedTech Zone Limited[6] (popularly known as AMTZ) is an enterprise under the Government of Andhra Pradesh, a 270 Acre zone, dedicated for Medical Device Manufacturing. AMTZ envisions to put India on the global map of high-end medical equipment production and make Funding and Awards in Healthcare Innovation. products affordable and accessible not only for India but for the world at large. They also provide incubation support to the startups.

Healthcare Technology Innovation Centre (HTIC)

HTIC[7] is part of IIT Madras – HTIC MedTech Incubator. The focus is to foster and stimulate MedTech innovators, aspiring entrepreneurs, and early-stage start-ups.

Startup India platform

Startup India[8] Hub is a one-stop platform for all stakeholders in the Startup ecosystem to interact amongst each other, exchange knowledge, and form successful partnerships in a highly dynamic environment. Startup India learning Program is an extensive 4-week free online entrepreneurship program to help entrepreneurs get their ideas and ventures to the next level through structured learning.

Centre for Cellular and Molecular Platforms (C-CAMP)

C-CAMP[9] is an initiative supported by the Department of Biotechnology, Govt. of India is an enabler or catalyst of cutting-edge research and innovation in the life sciences since 2009. They facilitate Bioscience Research and Entrepreneurship by providing Research, Development, Training and Services in state-of-the-art Technology Platforms. They provide grant funding and incubation support very specific to healthcare innovations. An example of a startup being incubated here working on neonatal solution: Sensivision, developing a comprehensive HIE management system with treatment, diagnosis and prognostication integrated on a single device. The product is currently in the final stages of prototyping.

NASSCOM Centre of Excellence for Internet of Things(IoT) and Artificial Intelligence(AI)

Centre of Excellence for IoT is a Digital India initiative led by Ministry of Electronics and Information Technology and NASSCOM.[10] It is the largest existing innovation platform for enabling IoT revolution through connected devices using emerging technologies such as Sensors, Big Data, Analytics, AI/Machine Learning, Augmented Reality/Virtual Reality and Robotics. Interesting examples of healthcare startups they are incubating are Cradlewise which is a start-up who have innovated an intelligent cradle which can soothe and bounce gently like the mother does while putting the baby to sleep and host of other features such as motion detection, remote monitoring, and music to help baby sleep well and the parents as well. Another interesting startup being incubated here is Doxper which is an intelligent prescription system with a smart pen and coded paper which can digitize the prescription as it is being written without need for using computer or mobile to type into it. All the records can be accessed through mobile app with the physician. The prescription paper is kept by the patients.

InnAccel

InnAccel[11] is another healthtech incubator based in Bangalore with myself (Dr. Jagdish Chaturvedi) having led as clinical director has co-invented 17 medical devices which are in various stages of development. Among them is an innovative CPAP device for neonates - SAANS which is a portable, infrastructure-independent, neonatal CPAP for short-term breathing support in RDS mainly during transport or as standby device. Another example is that of a Nasal foreign body extractor Noxeno which is a simple to use device and can be used by any pediatrician or physician with no training to extract nasal foreign bodies mainly in the anterior nasal cavity.

Tata social alpha, IKP eden, excubator, villgrow, and Unitus Seed Fund are few other Indian based incubators and grant providers.

CAMTech Innovation award, Bill and Melinda Gates foundation, and Grand Challenges Canada are international incubators and provide grants in significant amount.

FUNDING

"Funding"[12,13] refers to the money required to start and run a business. It is a financial investment in a company for product development, manufacturing, expansion, sales and marketing, office spaces, and inventory which is just like when we plan to start off a clinic or a hospital and list out the overall expenses. There are multiple sources of funding available for startups. However, the source of funding largely depends on the stage of the startup as depicted in [Figure 1].

Broadly there are three types of funds that can finance the company namely, Grants (as discussed earlier), Debt which are like loans and need to be returned back in stipulated time and Equity which means to give off a partial ownership of the company in return of the funds. In equity, there is no need to return the investment, the ownership value of the shares increases overtime due to the company's progress and fetches returns to the investors. Villgro, Avishkar, Unitus seed fund, Healthquad, etc., are specific healthcare focused investment firms.

Bootstrapping/Self-financing (Few lakhs)

It is relying on your own savings, borrowed from family or friends and initial revenue to operate and expand without any external investments. This is the first recourse or plan A. for most entrepreneurs as there is no pressure to pay back the funds or dilute control of your startup.

Angel Investor (25 Lakhs to 10 crores)

Angel investor is an individual with considerable wealth who assists new and small startups in the initial phase by providing them required funding or capital in return for a partial ownership in the company. They also bring in some relevant expertise, connects, and their network to make things happen fast. Ultimately, they gain only when the company gains.

Venture Capital(VC) (2 crores to 20 crores and can go upto 100 crores)

These are professionally managed investment funds that invest exclusively in high-growth startups. Each VC fund has its own investment thesis – preferred sectors, stage of startup, and funding amount – which should align with your startup.

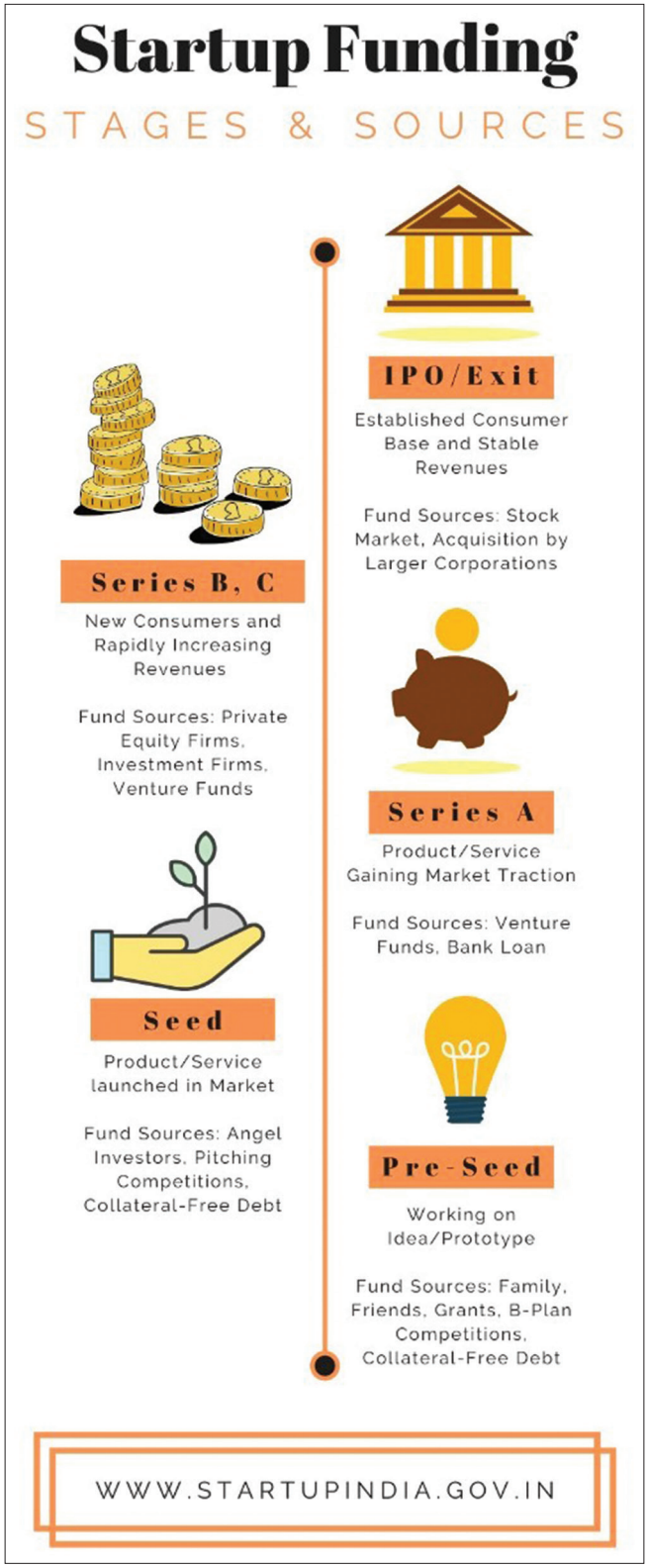

Figure 1: Various stages of a startup and funding sources.

VCs take startup equity in return for their investments and actively engage in mentorship of their investee startups.

Private Equity (100 cores onwards)

Private Equity (and investment banks) is designed for relatively mature companies that are beyond the "will this idea work?" phase and are onto the "how big can this possibly become in future?" phase. They operate massive funds that are more focused on smaller multiples than angel investors or venture capitalists, but more guaranteed returns because there is less risk involved in funding an already successful company.

STAGES OF STARTUPS

The above said type of investors come in at a specific stage of a startup as mentioned below, and the corresponding funding round is named in Series A, B, C, D, E.etc. A very buzz word among startups and dream of any startup is to be an Unicorn which means the valuation (current worth of an asset or a company) of a company has crossed $1 billion. Ex: There are 37 Indian Unicorns till now: [14] Flipkart, Swiggy, Zomato, Ola, Byju, Bigbasket, Oyo, etc.

Ideation/pre-seed Stage

This is the stage where you, the entrepreneur, has an idea and are working on bringing it to life. At this stage, the amount of funds needed is usually small. Bootstrapping and grant funding are the usual sources at this stage.

Validation stage/Seed stage

This is the stage where your startup has a prototype ready and you need to validate the potential demand for your startup's product/service. This is called conducting a "PoC," (Proof of Concept) after which comes the big market launch. Common funding sources utilized by startups in this stage are Incubators, govt. loan schemes, Angel investors or crowd funding. Very recently govt of India announced a 1000 crores seed fund for startups in the country. Hence, the opportunities are huge to be utilized well.

Early Traction/Series A stage

This is the stage where your startup's products or services have been launched in the market. Key performance indicators such as customer base, revenue, and app downloads become important at this stage. Funds are raised at this stage to further grow user base, product offerings, expand to new geographies, etc. Common funding sources utilized by startups in this stage are: Venture capital funds, Banks, and Venture debt funds.

Scaling/Series B and above stage

At this stage, the startup is experiencing a fast rate of market growth and increasing revenues. Common funding sources

utilized by startups in this stage are: Venture Capital and Private Equity firms.

Initial Public Offering (IPO)

IPO refers to the event where a startup lists on the stock market for the 1st time and leads the company in market from being private to public. Ex: Zomato, a food delivery startup which was founded in 2008 had around 21 rounds of funding till now and raised more than 2 billion $ with a recent IPO to raise another 1.5billion $ with the company's total valuation at more than 8 billion $ now !.

AWARDS AND RECOGNITION

Awards are a very important way of being recognized, which can bring in more awards and most importantly it motivates the team to achieve further. It brings various connects and reach to potential investors. Healthcare domain has off late become an exclusive domain of some investor firms.

HOW TO LEVERAGE THE AWARDS?

The most important aspect is that, when applying for awards, it has to be done at a specific stage where your solution has already been largely tested and making an impact. This helps because when it reaches more people, most of the questions are already answered and can impress upon the bigger investors. Awards mean the founders and core team coming into limelight and they all need to talk in alignment at various forums. Good number of investors might line up if the solution is disruptive and you need to assess the investors well for alignment with their intentions and company's vision/mission before going ahead with any of them.

THE AGE OF SOCIAL MEDIA RECOGNITION

In this new age of social media, a lot can be leveraged if you have a social media strategy to connect with people who will have potential investors as well. The way a startup portrays the award along with their uniqueness of solution can create quite a buzz and go "viral" over the social media especially if the solution connects with the mass and has potential to disrupt and is out of the box. Few examples are: Aum device, a silicone based voice prosthesis, innovated by an onco surgeon Dr. Vishal Rao from Bengaluru, that can help patients affected with throat cancer to regain voice.[15] It costs less than one hundred rupees and has been widely circulated, talked about over various social media platforms!

Another aspect is a good network among peers has a significant impact. In a study on social networking site LinkedIn, published in a journal,[16] it was found that:

- Founder connections are positively correlated with annual funds raised by a company. Social connectedness of founders is the best predictor of funds raised.
- The predictive validity or accuracy of the founders' social connectedness cue is 69% accuracy which is substantial compared to other investment decision-making models.

CONCLUSION

Irrespective of what problem you are solving, access to funding and building a very able core team is important. Appropriate funding and recognition at the right time can change the fate of the startup.

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Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

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Karnataka Pediatric Journal

Review Article

Neonatal innovations in resource-limited settings

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ABSTRACT

In the year 2000, Millennium Declaration was signed by the world leaders to reduce the under-5 mortality rate by two-thirds from the baseline figure in 1990. Millennium Development Goal 4 was replaced by the Sustainable Development Goal (SDG) in 2015. Reduction in the neonatal mortality, which accounts for majority of the deaths in children under the age of 5 years, was an imminent goal of SDG. Despite these initiatives, the current trends in neonatal mortality are far away from the expected targets. To curb the rate of neonatal mortality, the neonatal services are expanding in India at a rapid pace. To bridge the gap between the availability and accessibility to the health care technology between the developed and developing countries, the current focus is toward the development of low-cost and effective technological innovations in neonatal care and ensuring their patenting and effective publicity. This should facilitate the translation of innovations into mass production and availability for practice with significant effect in low- and middle-income countries. Generation of evidence will increase the acceptability of these innovations by demonstrating their benefit over the currently available technologies. Fortuitously, India has developed many innovations in the neonatal health care. However, majority of the neonatologists are still unaware of the existing technological solutions, and the ways to optimally utilize them. This review is, therefore, an attempt to recognize such low-cost, effective, and sustainable innovations done in the field of neonatology, over the past few decades.

Keywords: Cost effective, India, Innovation, Neonatology, Technology

INTRODUCTION

Globally, there is a rise in the neonatal mortality rate (NMR) from 40% of all child death's under-5 years age, in the year 1990 to 47% in the year 2019.[1] This suggests minimal or negligible advancement in the field of neonatal care over the past few years. Neonate and their mothers are the most vulnerable population, particularly in the low- and middle-income countries (LMICs). In India, the rate of decline of NMR is slower and lags behind the infant mortality and under-5 mortality rates. Recent data suggest that worldwide, India ranks the highest in NMR.[2]

In an attempt to curb the rate of neonatal mortality, the neonatal services are expanding in India at a rapid pace. Given the high cost involved in setting up a tertiary care neonatal intensive care unit (NICU), heterogeneity in the quality of care is imminent across the nation. To overcome this disparity and to bridge the gap between the availability and accessibility to the health-care technology between the developed and developing countries, the current focus is toward the development of low-cost and effective technological innovations in neonatal care. Fortuitously, India has recently witnessed many such innovations in the neonatal health care.

INNOVATION IN LMICs

Over the past few years, technology has leaped into the medical care to facilitate better and improvised management. However, these technological innovations are mainly limited to the industrialized world.[3] Due to the dearth of technology in the developing countries, a large majority of neonatal and maternal deaths occur in the underdeveloped/developing nations.

Recently, due to an increasing interest in global health, there is an increasing demand of technology "appropriate" for the resource-limited settings. The World Health Organization defines the "appropriate technology" as "scientifically valid, adapted to local needs, acceptable to both patient and health-care personnel and that can be utilized and maintained with resources the community or country can afford."[4]

However, majority of the neonatologists are still unaware of the existing technological solutions, and the ways to optimally utilize them. This review is, therefore, an attempt to recognize such low-cost, effective, and sustainable innovations done in the field of neonatology over the past few decades.

INNOVATIONS SO FAR!

The innovations done range from simple bedside medical devices to ventilation assisting devices. Many of these are available in public domain accessible to all, while others are available on other databases still requiring peer-review and scrutiny by practitioners. As there is no ready list of innovations developed in India in neonatology, the present paper is an effort to enlist the innovations, whose details could be obtained. In no way, it is a comprehensive or an updated list of the innovations. For the ease of understanding, these innovations have been grouped as those involved in patient care and others that are evolved to train the medical students.

Patient care

Respiratory care

Girisam Endotracheal and Auxiliary Tube Fixator

It was developed in the year 1995, as a safe, effective, and an atraumatic means of fixing endotracheal tube (ET), [Figure 1]. Conventional methods of fixing the ET are associated with an increased risk of facial abrasions with secondary nosocomial sepsis. This innovation ensures zero tube mobility and helps in reducing skin abrasion and sepsis. The innovation is under the process of patenting.

Warmidified oxygen

Dry or even humidified oxygen may not get warmed up by natural bodily mechanisms because of sickness, and hence may be less beneficial and even harmful. To overcome this concern, concept of Warmidified oxygen delivery was developed in the year 1996, using standalone humidifiers, to ensure both humidification and warmidification.

Water trap for humidified oxygen through oxygen hood

This was designed to tackle the problem of water dripping on baby's face from the oxygen hood, [Figure 2].

Split bubble continuous positive airway pressure (bCPAP)

To multiply the use of single bCPAP to two neonates, an attempt to split non-invasive respiratory support system was developed, Verma *et al*.[5] It used a T-piece splitter to split bCPAP. It is a technically simple, feasible, and reliable strategy tested in a simulation model.

Cardiovascular care

Head pulse oximetry

This pilot project was initiated in the year 2000 to address the fallacy of false oximetry readings, in the presence of poor perfusion or arm bandages. The available pulse oximeter probe was used for head pulse oximetry, [Figure 3].

Asepsis

Alcohol dispenser for hand disinfection

It was conceptualized in the year 1995, to reinforce hand disinfection in economic and feasible manner so that each

Figure 1: Girisam Endotracheal and Auxiliary Tube fixator.

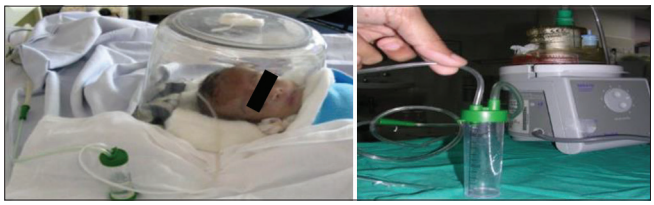

Figure 2: Water trap for humidified oxygen through oxygen hood.

neonatal bed could have a disposal plastic bottle filled with methyl spirit that could be hung, [Figure 4].

Aseptic intake output chart

This was developed in the year 1995, to provide intake output charts at bedside without compromising asepsis, this involved creating an assembly of sterile plastic board with autoclaved chart papers with disinfected pen, being hung on each bed, [Figure 5].

GAARIEP: Indian Innovation of caps and personal protective equipment

COVID-19 pandemic has brought an unprecedented crisis across the globe. There has been a shortage of adequate number of face masks and protective gears. To tackle this problem, protective gears were designed using the easily available materials in the NICU.[6]

Figure 3: Head pulse oximetry.

Figure 4: Alcohol dispenser for hand disinfection.

Jaundice management

Unavailability of effective phototherapy units poses an increased risk of kernicterus and double volume exchange transfusions. Efforts were made to use Isabgol husk to reduce the enterohepatic recirculation of bilirubin.

Routine neonate care

Heat shields for neonates

Commercially available heat shields are not only costly and also not freely available. [Figure 6] depicts free, easily available, disinfectable, disposable innovative alternatives of heat shields in neonates. It has been made by bleaching used radiograph films.

Incubator

Col Vishal Tewari, in the year 1996, designed a simple, light, disinfectable, non-battery or electricity operated incubator using cling wrap, humidifier, and air probe to warm micropremies, in an incubator-like environment using air mode, [Figure 7].

Transport incubator

A simple transport incubator was developed with a lightweight canopy, which could be carried easily. The

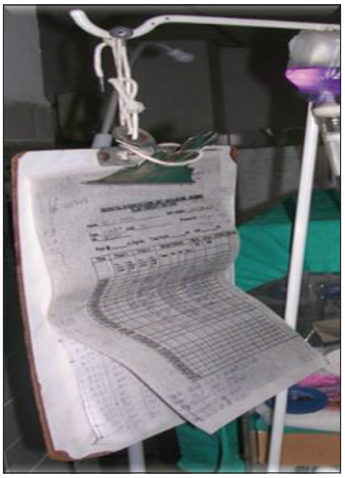

Figure 5: Aseptic intake output chart.

Figure 6: Heat shields for neonates.

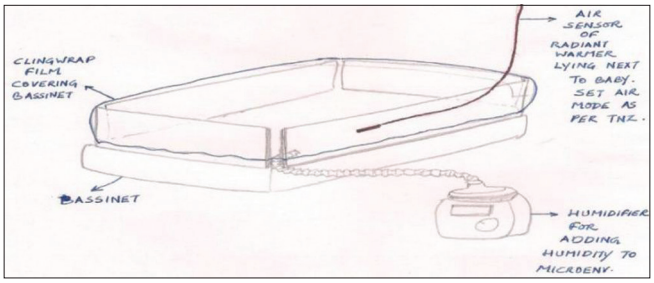

Figure 7: Open care converted as an incubator.

mechanism of heating involved an exothermic reaction producing chemical filled bags. This incubator remained appropriately warmed for 3–4 h and was easy to disinfect. This innovation won the best innovation award of NNF.

Girisuz syringe feeding T

To address the transition of feeding from gavage to nipple feeds, syringe feeding was conceptualized, as shown in [Figure 8].

Clinical volumetry

Used mucus traps were used as inexpensive/disposable volumetric collector device for various body fluids, [Figure 9].

Effects of musical intervention on vital parameters of neonates

Sounds of different frequencies from different sources example, Garbh-Sanskar music, female singing voice, classical instrumental music, and recorded human heart sounds with background of lullabies were played in NICU. Changes observed in vital parameters are depicted in the graph below, [Figure 10]. The graphs show encouraging stress reduction effects on vital parameters.

Training innovations

Various innovations act as simple affordable simulators to help acquire skills. Some of these are enumerated below:

1. "GirAash" Needle Cricothyrotomy trainer
2. Pericardiocentesis trainer
3. Peritoneal dialysis trainer
4. Girebu PICC Trainer
5. PICC insertion trainer
6. Intraosseous trainer
7. Umbilical vessels catheterization trainer
8. Suprapubic cystostomy trainer
9. Asvini formula for inotropes infusion calculation
10. Girish's Calf sign for early diagnosis of hemodynamically significant PDA

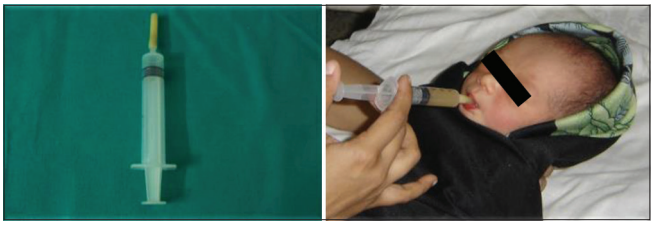

Figure 8: Syringe feeding.

Figure 9: Mucous trap for urinary volumetry.

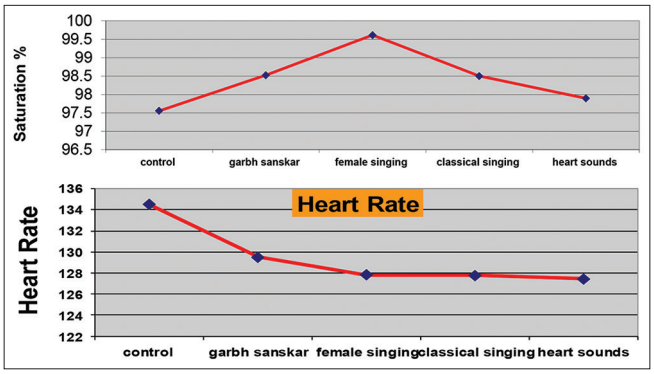

Figure 10: Effects of musical intervention on vital parameters of neonates.

11. Medical applications available on smartphones with cardiac sounds were used to take examination of UG and PG students
12. Ek Pahal: It is a 7 min human attributes developer program consisting of taking vows and practicing pranayama.

Limitations

Many of the innovations described above are yet to be published.

CONCLUSION – THE WAY FORWARD!

To decrease the neonatal mortality in LMIC countries, the most important and may be the only way ahead is to innovate and motivate the use of locally available resources as effective alternatives.

Creating evidence can contribute to increase in the acceptability of these innovations by demonstrating their benefit over the currently available technologies.

We believe that this article would serve the purpose of accelerating the rate of innovation diffusion/translation of the existing innovations of LMIC countries. It is also suggested that concerted facilitatory efforts must be made to help develop and propagate innovations. Some of the following methods are considered important.

a. Encouraging the formation of a nation-wide neonatal innovation registry
b. Inspiring and stimulating clinicians, or budding neonatologists to invent and/or innovate, by awarding or recognizing the innovators at various platforms
c. Inclusion of innovation and patents in the syllabi of medical and nursing education
d. Facilitating the process of patenting.

It is hoped that this article will serve as a catalyst in setting up a new script for innovations.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Karnataka Pediatric Journal

Review Article

Healthcare Innovation and Design Thinking

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ABSTRACT

The objective of this article is to bring awareness to the changing landscape of the healthcare ecosystem and the clinician's role with respect to medical devices, medical systems, technology, and processes involved in the system. Clinicians interact with them every day and have a huge implication for them directly, and to their patients indirectly. Clinicians are actively involved in clinical research which involves the knowledge and practice of the disease, diagnosis and management, etc. Recently, the role of non-clinical aspects such as medical devices, processes and systems of the healthcare ecosystem is gaining popularity. Hence, there is potential to explore this aspect of the healthcare delivery system to redesign and innovate for improving clinical outcomes. To achieve this, the clinicians need to understand these systems from a perspective that will help them to identify the problems and develop innovative solutions. Just like the clinical research is systematic and methodical, the improvement of the medical systems is also methodical to a large extent. This includes concepts and techniques that are quite fresh and new to a clinician who probably has never been exposed to these in their medical careers. These general principles of Innovation and Design thinking applied to other domains have yielded fantastic results and for the same to be applied in the medical domain, the role of the practicing clinician is central. As clinicians, we have always practiced innovation at some point of time in our career when we would have faced a resource crunch and were compelled to save the children and hence have tried to innovate on the devices, processes, etc., in our own way and has worked many a times. To generate many such solutions at large scale, the whole process needs to be methodical and systematic so that the solutions developed are safe and consistent at all times. Such a solution can be scaled up and made to reach across such setups where it is needed and there can be a measurable improvement in efficiency, quality, effectiveness, or economics of patient care delivery on a large scale.

Keywords: Healthcare innovation, Healthcare design thinking, Health system innovation, Medical innovations

WHAT IS CREATIVITY AND INNOVATION?

Creativity[1] is the ability to transcend traditional ways of thinking or acting, and to develop new, original ideas, methods, or objects. This ability comes from perception of the world in new ways, understanding hidden subtle patterns and make connections between seemingly unrelated things which lead to a new set of ideas and solutions.[2]

Innovation means to develop a new solution or introduction of new things/methods to solve any problem. It is the practical application of creativity that adds value to a product or service. Creativity is the basis of innovation.

Some other related terms to innovation are:

Invention[3] means creating something that has never been made before, or the process of creating something that has never been made before.

Jugaad is a very common Hindi word, meaning a cheap, improvised but effective solution to a problem inspite of limited resources born out of human ingenuity and cleverness. It can also be called a hack in terms of solving problems.

We need innovation in healthcare as well to solve old existing and new age problems, primarily to improve user (patient in healthcare domain) experience, clinical outcomes, and to make the care delivery more economical.

TYPES OF INNOVATION

Innovation[4] can be classified in various ways like, for example: We have various classifications of cerebral palsy by etiology, topography, etc.

Let's highlight a few types to get a glimpse of how it can be extrapolated into the healthcare domain.

Based on the novelty of the solution and the impact it can create on the market, four types of innovation are described in Figure 1:

Incremental Innovation

a. Constantly improving the existing products and services to add value.
b. It mainly focuses on reducing the shortcomings in design, adding new features, comfort, reducing costs or building next generation products.
c. This is short lived and of low impact, but helps the company to stay relevant.

Ex: Next series of BMW cars, new mechanical ventilators with better user interface and safety features. newer compact phototherapy devices, newer infant warmers with better efficiency.

Architectural Innovation

a. Modifying the existing products to suit to an entirely new user segment of market
b. It refers to changing the overall design of a product by putting existing components together in new ways
c. This innovation occurs in the short to medium term.

Ex: Sony Walkman, Desktop photocopiers, pre-operative practice using 3D models to shorten surgeries. high flow nasal cannula oxygen delivery systems in NICU, PICU.

Disruptive Innovation

a. First coined by well-known expert Clayton Christensen in one of his bestseller Innovator's Dilemma, it is a very novel solution, concept, product, or a service that transform expensive, complex and sophisticated solutions into ones that are simpler, more convenient and affordable.
b. It happens when new technologies and products are created to serve an existing market.
c. This type of innovation is usually enabled by advent of new technology as an effective and economical alternative to what is already existing in the market. Disruptive innovation mostly originates at the lower end of the market segment; however, as the maturity of the technology increases, it eventually displaces established market leaders.
d. This innovation occurs in the medium to long term.

Ex: Peer-to-peer travel platforms-Airbnb, Digital photography, Point-of-care Ultrasound (POCUS) bringing compact bedside USG to intensivists and ER physicians, Telemedicine coupled with remote patient monitoring and smartphone-based devices as diagnostics.

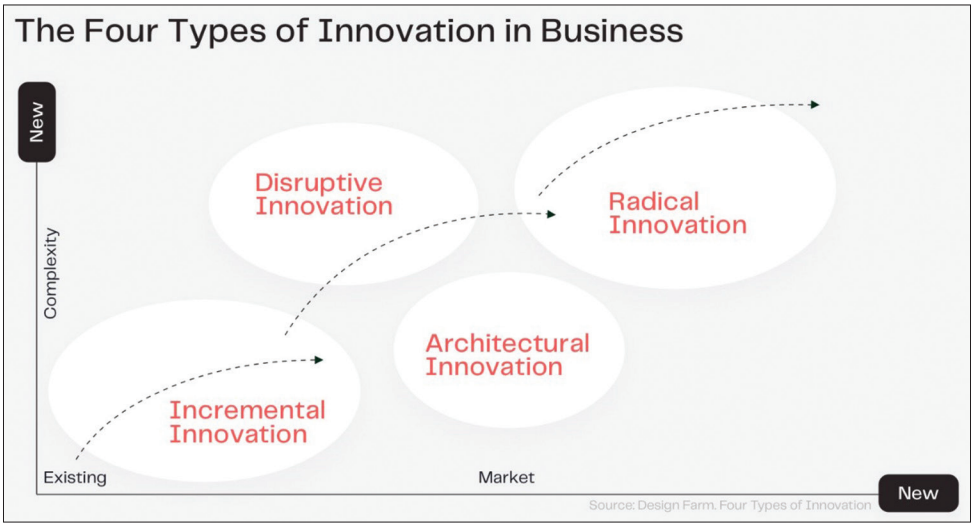

Figure 1: Types of innovation.

Radical Innovation

a. When an organization applies new technology to a new market.
b. This type of innovation happens when a new product, process, or service with high technological advancement has a high market impact and eventually replaces an existing provider.
c. This innovation occurs in the long-term.

Ex: Electric vehicles, SpaceX developing reusable vehicles for space travel, 3D printing of bones in maxillofacial and orthopedic surgeries, Artificial Intelligence applied to healthcare data for disease epidemiology and prognostication, drones in healthcare, genome sequencing for disease management, etc.

Based on where exactly the innovation happens, innovations can also be classified as:

Product Innovation

There are improvements in performance characteristics and features of the products or devices.

Ex: Introduction of ultrasound technology, infrared vein finder, embrace warmer bags for newborn babies, etc.

Process Innovation

There is an implementation of a new or significantly improved research process, production, or delivery method.

Ex: The COVID vaccine innovation[5] developed by many companies was possible because of a change in the methodology/process of figuring out the right vaccine component like mRNA, mass producing it for millions in short time, The whole process to deliver the vaccine using the Co-WIN technology platform in India, healthcare simulation used to train medical and paramedical personnel.

Technology Innovation

This is where a new technology is being applied may be with a new product as well to solve problems in various domains.

Ex: The telemedicine system, virtual reality application in rehabilitation, application of 3D printing technology to printing bones, prosthesis, tissues, etc.,

Business model Innovation

Business model is nothing but a plan for the successful operation of a business, identifying sources of revenue, the intended customer base, products, and details of financing. This type of innovation is the easiest in terms of the resources required to implement it, but most complicated since it involves a deeper understanding of the customer (a patient in our case) to what exactly they need/want/would love to have but nobody understood them well till now. Here, a new business model is innovated with a fundamental change in how a company delivers value to its customers.

Ex: Pristyn care clinics which are chain of surgical clinics who rent the operation theaters (OTs) in less busy hospitals at nominal cost. They utilize this capacity and add their expertise in insurance, equipment, surgery and patient care practices, providing surgical services with same standard of care to patients without building any of hospitals or OTs. They intend to be better than corporate hospitals but 40% cheaper, Uber in transport, Swiggy in food delivery, and AirBnb in hospitality are all examples of newer disruptive business models.

CLINICIANS AND HEALTH SYSTEMS

Current health systems

Now that we understand what innovation means, let's see how the healthcare domain operates. The clinicians and paramedical personnel are the main people involved in the care delivery with people of other domain expertise supporting the system. Clinicians are the important stakeholders who understand the ground reality and the pain points of the system. But the paradox is, clinicians are largely not involved in the designing or setting up of such systems. Clinicians have come to accept that the systems work in the way they work including the ingrained problems in them and continue to work with those problems or inefficiencies during the care delivery. They are unaware that, these are problems that can be solved with newer technologies and hence a status quo is maintained. To put it in a medical perspective, If you can't identify a symptom or not aware of the diagnostic criteria, how can you diagnose a disease? This might not change unless either the clinician develops a new perspective to understand the system or the system is handled by others who can work closely with the clinicians and have the capability to solve them. Conventionally, clinicians' primary responsibility has been patient care and anything else is not given much importance. Clinicians are very much involved in clinical research which includes the disease management, protocols, patient outcomes, and related aspects. However, what about the other parts of the care delivery such as the medical devices, existing processes, adoption of newer technologies, business models, and patient engagement which also impact patient care although indirectly? The clinicians are not formally trained in these aspects and hence not aware of how to handle these issues. They largely end up handing over these responsibilities to people of other domains who are not aware of the practical pain points and hence unable to improve them in an efficient way. These non-clinicians might develop some newer devices, implement newer systems, etc., which might not suit the clinical needs or might not be adopted well, usually ending up as failures.

The Innovative Clinician

Humans in general are innovative in nature but is not expressed unless pushed or they happen to work in adverse/resource limited settings/scenarios. This applies to clinicians as well. For example: In the management of respiratory distress syndrome (RDS) in newborns, when the standard continuous positive airway pressure (CPAP) devices were not widely available, we have at many instances designed and assembled a simple bubble CPAP system using the urine collection bag and tubings connected to a T-piece and oxygen supply. This has worked reasonably well in the management of the RDS in term and preterm newborns and many would agree with it.[6,7] Another example is the use of styrofoam boxes as baby warmers especially for preterm/LBW babies in home setting, PHCs, during transport.[8]

Now, what if a clinician applies their innovative potential in solving other problems of the system? It is easier said than done because, in earlier scenarios, a clinician is able to solve clinical problems as he has in-depth knowledge. He knows what is needed to deliver that specific intervention either with an available device or could ingeniously assemble from commonly available resources of which he has prior knowledge of. Hence, he will not be able to innovate if his understanding of the problem is poor/biased, prior knowledge of such resources is limited or his way of thinking is not suitable to identify the problem at all at first stage. This is the exact scenario of the clinician's current inability to handle other aspects of the healthcare ecosystem. Examples like a simple appointment system, digital tools in the management of chronic diseases, many new medical devices playing a significant role in healthcare ecosystem, are being designed by the incumbent non-clinicians.

PATTERNED THINKING- SCHEMAS

Schemas

Humans naturally develop defined patterns of thinking modeled on daily, repetitive activities, and commonly accessed knowledge. These assist us in quickly applying the same actions and knowledge repeatedly in similar or familiar situations. These patterns of thinking are often referred to as schemas,[9] which are organized sets of information and relationships between things, actions, and thoughts that are stimulated and initiated in the human mind when we encounter some common environmental stimuli.

Advantages

We as clinicians also have schemas or so-called spinal reflexes which help us to identify common set of symptoms, disease patterns, clinical signs, and assist in implementing the disease management schemas fast without taking much time. In a way, the schemas help us to be efficient and save time and energy for more complex acts.

Limitations

Schemas also have the potential to stop us from accessing or developing new ways of seeing, perceiving, understanding, and solving problems. We need to understand when schemas do not work and need to develop a different way of perceiving things. As long as the patients respond well clinically and there is no other complex underlying condition missed by the initial diagnostic schemas, they work well. Our higher centers kick in when there is some deviation in clinical course and that is when we start to deeply analyze the clinical scenario again. These schemas or patterned thinking prevent us from diagnosing a complex condition or understanding a complex problem. In particular, experts and specialists rely on their solid thought patterns, and it can be very challenging and difficult for experts to start questioning their knowledge, or schemas.

To illustrate the limitations of schemas, take this for example: Some years ago, an incident occurred where a truck driver tried to pass the truck under a low bridge. But he failed, and the truck got stuck firmly under the bridge causing massive traffic jams, which resulted in emergency personnel, engineers, firelighters, and truck drivers gathering to devise and negotiate various solutions for dislodging the trapped vehicle. Emergency workers were debating whether to dismantle parts of the truck or chip away some part of the bridge. Each spoke of a solution which fitted within his or her respective level of expertise. A boy walking by and witnessing the intense debate looked at the truck, at the bridge, then looked at the road and said nonchalantly, "*Why not just let the air out of the tyres*?" to the absolute amazement of all the specialists and experts trying to solve the problem. When the solution was tested, the driver was able to drive away the truck with ease. The story symbolizes the struggles we face where oftentimes the most obvious solutions are hardest to come by because of the self-imposed constraints we work within. Time has come for clinicians to breakout of these schemas and think fresh.

DESIGN THINKING

Design thinking[9] is basically the way a designer would think while designing a product by being in the user's position and empathizing with user on what exactly they would feel, need, and like. Some of the world's leading brands such as Apple, Google, Samsung, and GE, have rapidly adopted the Design thinking approach, and is also being taught at leading universities around the world, including the Stanford, Harvard and MIT. "*Design is not just what it looks like and*

feels like. Design is how it works." quotes Steve Jobs, founder of Apple Inc.

Design thinking is a repetitive process in which we seek to understand the people (users of the end product/service), challenge our existing assumptions, and redefine problems in an attempt to identify alternative strategies and all possible solutions in an unbiased manner. These solutions might not be instantly apparent with our initial level of understanding/schemas. It revolves around a deep interest in developing an understanding of the people for whom we are designing the products or services. It helps us to observe and develop empathy with the target user. It helps us in the process of questioning: questioning the problems, assumptions, and implications without bias.

Design thinking is extremely useful in tackling problems that are ill defined or unknown like that of healthcare, by

a. Understanding the user (patient in our case) and re-framing the problem in human-centric ways.
b. Creating many ideas in brainstorming (focused, repetitive, and iterative process) sessions.
c. Adopting a hands-on approach in prototyping (sketching, creating working models, and mock runs).
d. Testing and trying out the concepts and ideas.

All variants of Design thinking embody the same principles, which were first described by Nobel Prize laureate Herbert Simon in The Sciences of the Artificial in 1969. Let's discuss the 5-phase model proposed by the Hasso-Plattner Institute of Design at Stanford, which is also known as d.school which is shown in Figure 2:[10]

Design thinking is often referred to as "*outside the box*" thinking, as designers are attempting to develop new ways of thinking that do not abide by the dominant or more common problem-solving methods. It is not only to find the right solutions but also the ability to ask the right questions as well.

Empathize

To connect with the users and understand the problem from a user perspective in real sense which might include spending focused time with them, being the user themselves and observing to understand what exactly they go through and understand the problem inside out.

Define

To define your users' needs, their problems, and your insights very clearly and in detail is very crucial. "Five Whys" approach (asking 'Why?' 5 times in a sequence) is used to get to the root cause which might be a good way to understand a problem, it is like the conventional history taking for any symptom to get to the probable diagnosis. Most important of all, is that the process is repetitive and expansive. Define clear problem statements as the outcome. Do not think of the solutions in this stage.

Ideate

Goal is to ideate by challenging assumptions and create ideas for innovative solutions, as many as possible in an unbiased manner. Designers resist the temptation to jump immediately to a solution to the stated problem. Brainstorming is the key to engage collaborative, multi-disciplinary teams to apply their perspectives, skills, personalities, and thinking styles of many to solve multifaceted problems. Only then will they

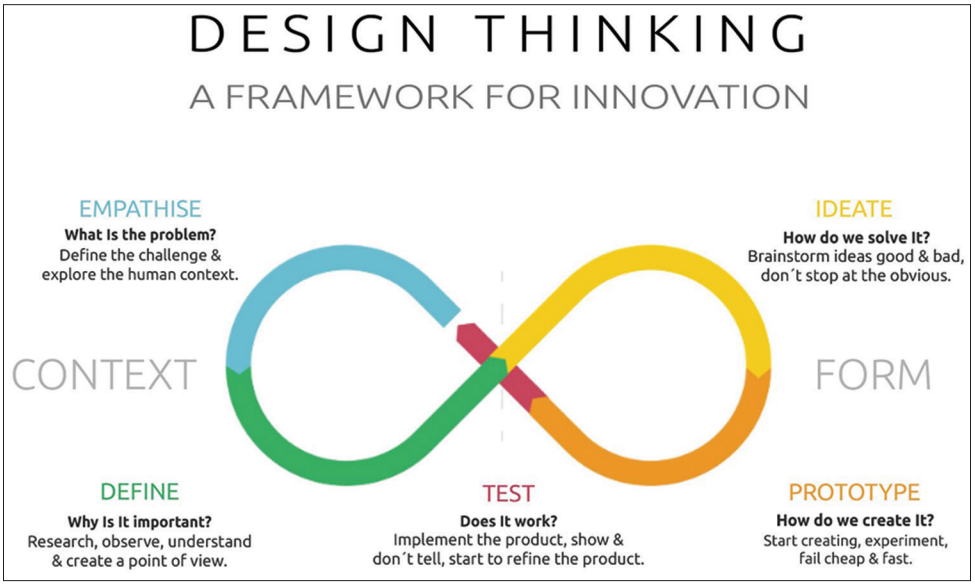

Figure 2: 5 Steps of design thinking.

finally converge upon their solutions. This is the essence of "Design Thinking."

Prototype

Start creating some rough working models of product solutions using commonly available resources or doing a mock run of new process to understand how they might perform in real world.

Test

Very crucial is to test the solutions with the prototypes and get feedback and again repeat the process. This continues with assessing whether you could find answers to the questions you asked, ideate, and brainstorm solutions again.

DESIGN THINKING AND HEALTHCARE

Design thinking tries to empathize with human beings and involves ambiguous or inherently subjective concepts such as emotions, needs, motivations, and drivers of behaviours. This is very much true to the healthcare domain as well. The end users are the patients who are distressed and all they need is the support to get better. Healthcare domain has a lot to gain from design thinking. Well known physicians of the past have always preached us to see the patient and understand them as a whole that was probably design thinking applied to patients and all the clinical knowledge we have today is the result of that way of thinking.

Design thinking can be applied in two ways in healthcare

a. To solve the problems of the healthcare delivery system helping the clinician perform better using better devices, processes, and efficient systems.
b. To help patients as well, by designing products around them to make them part of the care delivery process such as chronic care apps, rehabilitation devices, and self-monitoring wearables etc.

The challenge today is that, design thinking needs to be applied by the clinician himself to the care delivery systems because, it would be impractical for the existing design thinkers to learn medicine, let them gain clinical experience and later apply it. Instead, the clinicians who face the problems can be taught design thinking approach. This article is all about sensitization to that need and develop such a newer approach which can enable us to see our systems with the design thinking glasses. It might happen that a design thinking clinician might start pointing out many critical problems in the system which can always be solved once identified. Some examples of applied design thinking in healthcare are:

1. Health-care simulations systems for better training and preparedness to reduce errors and improve preparedness and management.
2. Redesigning MRI console with theme of an adventure trip that excited kids rather than scare them and reducing the need to sedate or delay the scans at Pittsburg hospital.[11]
3. Designing the Pediatric Emergency Unit at Aster RV hospital, JP Nagar, Bangalore with the theme of a train (outside and inside) with a colorful ambience and distraction systems to reduce the fear, anxiety associated with visits to emergency rooms and make it a better experience to children and parents as well.
4. The number entry system on infusion pumps became more user centric with application of design thinking. A study found that 1000, 100, and 50 were most commonly used numbers but entry of these numbers was cumbersome in existing pumps until this study helped to understand the user, who is primarily the nurse at bedside.[12]
5. Peripheral intra venous (IV) line fixation using splints increased the life-span of the IV line.[13]

CONCLUSION AND THE WAY FORWARD

1. It is time to organize more events for the clinicians to get to understand design thinking in-depth, through workshops, active discussions, and hands-on experiences.
2. Multidisciplinary/cross domain interaction needs to be encouraged so that clinicians get exposed to various newer technologies, perspectives, and potential solutions that can be applied in the clinical domain.
3. Appropriate validation for safety standards and consistency is a must through suitable clinical trials before commercializing or propagating it.
4. Collaborate with technical domains, institutions, and work together to co-create solutions as a team.

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Declaration of patient consent

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There are no conflicts of interest.

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Review Article

Innovation in business model and finances in pediatrics

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ABSTRACT

Innovation is something original, more effective, and, as a consequence, new, that "breaks into" the market or society, by development and implementation of a new product, process, or service, with the aim of improving efficiency, effectiveness, or competitive advantage. Entrepreneurship, by contrast, is applying the innovation to bring the ideas to life. It is a social invention, which lets people do what they could not previously do. Health-care delivery is a complex subject, which determines whether a government succeeds in improving the health of the nation or not. In this article, we will be talking on the innovations – specifically financial innovations as applicable to neonatal care, pregnancy care, and pediatrics – as this can make a huge impact on our everyday life.

Keywords: Innovations, Entrepreneurship, Financial, Newborn screening

Health care is a basic need of a human being, but still universal health care is not available in most countries. Sweden has provided universal health coverage for legal residents since 1955,[1] Sweden spending 9.2% of gross domestic product (GDP) on health care in 2008, as compared to the Organization for Economic Cooperation and Development an average of 8.9, and 16.6% of the GDP by the United States of America (USA).[2] India spending 0.9% of GDP is nowhere near providing universal health-care needs of the country.[3] It is not going to improve in the near future despite anyone's efforts with only 3.7% of the population paying the income tax! Hence, most Indians depend on private health care to fulfill their needs, which needs a lot of innovation to ensure universal health care is affordable to everyone. Since health-care costs are the biggest expenditure for the common man – private health care becomes unaffordable most of the time and it increases the population to start being suspicious of private health care due to lack of transparency.

Innovation is something original, more effective, and, as a consequence, new, that "breaks into" the market or society, by development and implementation of a new product, process, or service, with the aim of improving efficiency, effectiveness, or competitive advantage. Innovation and entrepreneurship are two closely related words used in the business world. Entrepreneurship, by contrast, is applying the innovation to bring the ideas to life. It is a social invention, which lets people do what they could not previously do.

Health-care delivery is a complex subject. Health-care delivery determines whether a government succeeds in improving the health of the nation or not. In this article, we will be talking on the innovations in a business model – specifically financial innovations as applicable to neonatal care, pregnancy care, and pediatrics – as this can make a huge impact on our everyday life.

Pregnancy and childbirth are fraught with danger for most families – as traditionally, the girls side is supposed to bear the bills for the childbirth and the cost could be unknown leaving the families

sometimes with unexpected expenses and also outcome. In India, it continued to remain like that for most families – some were comparing it to a wedding! Due to the uncertain nature of the finances involved in labor, delivery, and recovery, some people dread going to the private hospitals with the unknown. In some cultures, it is even negotiated to be part of the dowry – at the time of marriage. Moreover, some women may develop few known complications, minor or major infections, which along with the baby's needs – like the possible need for phototherapy or if the baby were to be born premature or has any other diseases requiring treatment – can lead to unknown financial burden on the family/ies.

We conceived "the concept of Cloudnine"' – It's an English idiom meaning a state of perfect happiness, a feeling of well-being or elation – for a mother and baby hospital, as we felt the need to have a separate mother and baby hospital to separate illnesses – as we believed in the concept of pregnancy being a WELLNESS and not an ILLNESS.[4] But what we realized is that parents were going through a lot of stress – because of the uncertainty of the finances involved for the labor and delivery. Hence, among other things we did, we also felt the joyous moment should not be spoilt with the unnecessary financial issues. We created delivery packages – for both normal delivery and cesarean sections – taking into account all possible charges – doctors (obstetrician, pediatrician, and, if required, anesthetist in case of epidural pain relief for normal deliveries and for cesarean sections), consumables used, drugs commonly used, and the hospital charges – this was a comprehensive charge – with no need of the husband or the family dashing down to the pharmacy or other places every time something was required, to get the medicines or other consumables to be "bought" and given to the doctor or the nurse concerned, as used to happen in all the hospitals. This changed the way the prospective parents enjoyed their birthing process – as even before they got admitted, they knew what they were in for. They were left in peace to enjoy their newborn with no worries of dashing down here and there. They did not have to have the unknowns – how they can arrange the finances, whether they can afford this hospital or the doctor or not – were able to make a judicious decision. This led to many other hospitals following suit – the result is that it is not stressful anymore for most families as they could choose the hospital according to their needs and finances.

There was also no knowledge about the importance of newborn screening and the need for this in 2005.[5] Hence, we created an educational session in antenatal classes – explained to the prospective parents – what is newborn screening and why it is important. We explained that no baby can be examined for any biochemical or metabolic abnormality by any pediatrician, however experienced he/she may be – they can only do so for any physical abnormality – and biochemical or metabolic abnormality (though rare) can happen to any baby, and does not necessarily depend on any prior family history. We produced leaflets to this effect and made these available. We created a small additional package for this – and offered to the parents – and for those who declined we got them to sign a "consent for not consenting to these tests – with the declaration, that they have read and understood the importance of newborn screening but still they would like to decline" and this made the acceptance of the newborn screening close to 100%. Now 15 years down the line, this has become a routine practice in many hospitals, especially in Bangalore and across India. With this, we have eliminated preventable causes of mental retardation like congenital hypothyroidism and also identified and treated many metabolic diseases, who would have otherwise become statistics.

Premature babies had remained a taboo for most parents and obstetricians. No one wanted to take the risk and no one wanted to take a chance with the survival and possible developmental problems with the premature babies.

At Cloudnine, we introduced the concept of transparency and packages for the care of preterm babies too. Based on the data we had, we prepared a chart showing survival and morbidity chances for various gestational ages of prematurity – which was a welcome relief for both the obstetricians and the prospective parents – and the financial packages were an incentive to know how much they are in for – else they could choose other ways of caring for their babies – if they could not afford – like crowd funding. With this, we increased the number of premature babies being catered to and increased their intact survival too – as the obstetricians turned optimistic and catered for the pregnancy better with all the relevant antenatal modalities of treatment. For example – we had Neonatal Intensive Care Unit packages of 16 lakh rupees for 24 and 25 weekers, and 10–12 lakhs rupees for 28 weekers and so on.

Vaccination soon after birth was not done by most hospitals to keep the cost down and parents were being asked to come few days later for the same – and many parents realized that childbirth is not the end of their financial woes. It continued after that. Hence, we designed vaccination packages for both compulsory and optional vaccines for the 1st year – giving them an overview and also discounts if they were to book the whole package together – so that they are aware of what is involved and what is not. This uncertainty of the financial burden taken off from their shoulders was a big thing for many parents.

Pregnancy is a "fixed" term of 40 weeks or popularly known to the common man as an event of 9 months. During these 9 months, the World Association of Perinatal Medicine has issued guidelines as to how many visits are expected for a pregnant woman – during the antenatal period, how many

blood tests and how many ultrasound scans. We arrived at the charges incurred for these along with the consultations – and discounted the whole charge by 20% – for those who book the whole 9 months' antenatal package – so that they are aware of what is in store for them – and also they can avail the discount – this way – most prospective parents – need not "wait" every time they came to see their obstetrician – nor for the blood tests nor the scans – as they knew when to expect what and could also plan their finances. This gave the prospective parents such independence and liberty to enjoy their parenthood – that we made their life easier – especially for the working parents with limited income/time to worry about all these.

Among other things, we did this innovation in financial models – for various things related to both baby and mother care, including antenatal packages – the plan was simple – calculate the charges incurred for the duration as a whole, discount it by 20–30% as it improves the cash flow for the hospital, if parents book them in advance, and for parents it gives the confidence knowing how much they are expected to spend. With this – they can enjoy parenthood better than before. This financial independence is something very important for every family irrespective of the procedure or the treatment planned – as health care is one of the most "hidden" expense lists for most Indians or for that matter most Asians.

Packages in health care can be designed with what is involved – doctors charges, hospital charges, consumables, medication charges, taxes involved, and any other relevant charges – like investigations for that particular problem – once the total cost is worked out – one could give an incentive for people who pay the whole "expected packages" in advance – this not only improving the cash flow of the hospital, it also allows the hospital to "plan" their admissions/bed capacity – to make efficiency even better. It also helps for transparency. In addition to these financial innovations, we allowed husbands to be part of the delivery process – be it a normal delivery or a cesarean section – and this helped increase the transparency and accountability, trust for them on the doctors and private health-care facilities – though this is not the place to elaborate much on that. For the common man, knowing what is in store for them is so much relief than the unknown. Hence, everyone is a winner with the financial packages and the innovation has revolutionized the maternal and neonatal industry in a big way – a small step in the long road ahead to improve the health-care delivery in India.

Despite the innovation in the financial area, obstacles persist. It takes a lot of effort for minimal innovations in financial models, as these have to be accepted by the insurance companies, who look at these under an electron microscope before approving – and customers verify this – thinking that there is a "catch" somewhere – in view of their history. But once the insurance companies are convinced, which they did eventually after a year or so – this became the norm.

There are other areas where financial innovations can happen in private health care. Private health care accounts for 80% of the needs of the country in India.[6,7] As a group, private health care should be focused on getting themselves tax efficient, tax rebatable for all goods related to health – that way the cost of healthcare can come down. Private health care can also innovate many other financial areas – like instead of buying expensive equipment or buy under loan – they can lease them – which covers the cost of buying, maintenance (annual maintenance contracts and costs – popularly known as AMC). The government should give financial incentives to the manufacturers for lending the equipment – and also simplify the depreciation costs – which will go a long way. In addition, the consumables – could be supplied to the hospitals by the companies directly without the middle men – and the expensive consumables could be ordered 2 days before the need – thus reducing the cost of paying for it by the private health care and the cash flow – which, in turn, reduces the cost to the consumer.

The tele-consultation – which got approved during the pandemic by the Government of India and the Medical Council of India – was long overdue. In a country as big or bigger than all the European countries united together with regional difficulties in access to health-care facilities – telemedicine is the need of the hour. With telemedicine, the cost of health care can come down significantly as the unnecessary travel by the patient, avoiding the long queues in the hospital and crowded lobbies – will go a long way in increasing productivity and choice of the health-care provider to the consumer. Furthermore, people can take a second opinion for various issues they may have without much difficulty. Irrespective of their location, people will have access to their trusted doctor – which eventually reduces further doctor/patient frictions or medicolegal problems.

Overall, health-care delivery is a complex system[8] – but financial innovations in reducing hospital charges and increasing transparency will go a long way in making private health care being accepted as a friendly alternative rather than as a foe.

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Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

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Karnataka Pediatric Journal

Original Article

Giggles: An indigenous new eye covering device used during neonatal phototherapy

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ABSTRACT

Objectives: Phototherapy (PT) is commonly used for neonates with indirect hyperbilirubinemia. Dislodgment and inability for spontaneous eye opening are few shortcomings with the traditionally used eye covering devices in neonates while under PT. The study objective was to describe the development of an invention for eye protection in neonatal PT. This invention aims to develop and improvised means that are comfortable for the baby.

Materials and Methods: The present descriptive study was conducted in level III NICU.

Results: The invention consists of an eye protector model (Giggles) for use during the neonate's PT, allowing lesser dislodgements and ophthalmic complications with better esthetics.

Conclusion: The device is easy to use, and appropriate for neonates, causing no discomfort, and its safety has been proved through radiance tests.

Keywords: Phototherapy, Neonate, Eye covering, Giggles

INTRODUCTION

Phototherapy (PT) is commonly used for more than six decades for treating neonates with hyperbilirubinemia. About 14 million babies worldwide are treated annually with PT. In some patients, PT is needed for more than 5 days. Because of the potential for retinal damage, it is a standard practice to cover both eyes with an eye covering device (ECD).[1] Most of the currently available ECD are tight bands made out of some kind of fabric which prevents the neonate from opening the eye lids [Figure 1]. This tight eye closure is a source of irritation and discomfort for the baby.[2] Forced eye closure can lead to conjunctivitis or keratitis.[3] Displacement of the ECD is a common occurrence needing frequent adjustments and re-applications. Unintentional displacement of these ECD on both the nostrils can lead to life threatening apnea.[4] ECD made out of fabric are not reusable. Finally, they are not aesthetic [Figure 1]. Therefore, a need for developing better ECD was recognized.

MATERIALS AND METHODS

The primary design requirements for the new ECD named Giggles were defined: Eliminate forced eye closure, use non-fabric material, it should be soft, light weight, non-allergic, reusable, and easy to apply with an appropriate fitting.

Figure 1: Traditionally used eye covering.

Figure 2: Giggles eye covering.

After considering several options including polycarbonate and several elastomers, silicone was considered to be the best material. Silicone, being a non-reactive material, is commonly used in other medical devices. It is soft, flexible, affordable, and easy to wash or sterilize thus suitable for multiple use. The silicone used in making giggles has passed the opacity test, both, before and after exposure to blue light. The approved silicone has passed the test for *in vivo* bio-compatibility as per ISO-10993.

Head circumference of many neonates was measured before arriving at the appropriate size for the ECD. The dome like structure of the ECD provides space for eye lid opening [Figure 2]. They are flanked with flat rims to give the ECD a comfortable landing around the eyes. The depth of the bubble and a good fit around the head was of major consideration. Finally, it was decided to use multiple slit bands for easy adjustment. The width of the slit had to undergo several alterations to ensure ease of application. A mushroom button, where the band gets fixed to the eye-piece, was positioned close to the eyes to eliminate discomfort when the baby turns his head.

RESULTS

An IRB approved randomized control trial comparing giggles (study group) versus commonly used ECD (control) is being conducted at DMH. To date, we have enrolled 52 patients. Preliminary results of the interim analysis are very encouraging favoring use of giggles.

DISCUSSION

Concerns with the use of currently available eve covering devices on newborns receiving phototherapy include the possibility of eye and periorbital skin irritation, corneal abrasion, and infection. Giggles' one-of-a-kind design should not be associated with these complications. The Giggles ECD is simple and user friendly. The newly developed Giggle ECD we describe provides a convenient and cost effective means of eye protection, and it may be especially useful in busy and understaffed newborn wards and NICU where continuous careful eye-care of infants receiving phototherapy may be impossible.

CONCLUSION

We have developed a new ECD for use during neonatal PT. Giggles is more comfortable allowing the baby to open his eyes, fits better, is safe and hygienic, is easy to apply and clean, reusable, and esthetic. While waiting for the final results of the clinical trial, we believe giggles will be a significant improvement in the ECD used during neonatal PT.

Declaration of patient consent

Institutional Review Board (IRB) permission obtained for the study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Karnataka Pediatric Journal

Original Article

Neonatal intubation: Can we make it better? A journey from ideation to intellectual property rights

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ABSTRACT

Objectives: Neonatal intubation is regarded as one of the elite skills a medical professional; particularly a pediatrician could aspire to master. More the practice, the skill gets refined so that the success rate improves. However, it is not uncommon even for most experienced professional to fail in an intubation attempt. Why does it happen? Is there a solution? This article discusses the journey from ideation to intellectual property rights.

Materials and Methods: Observational study followed by Randomised control study.

Results: Reduction in the pressure exerted on upper jaw during intubation from 455 to 80 KPa and decrease in blocked visual area from 38.5 to 12%.

Conclusion: Appropriate design modification of neonatal laryngoscope is potentially more safe and easy to use.

Keywords: Neonatal intubation, NOBL scope, Innovation

INTRODUCTION

Neonatal intubation is regarded as one of the elite skills a medical professional; particularly a pediatrician could aspire to master. More the practice, the skill gets refined so that the success rate improves.[1] However, it is not uncommon even for most experienced professional to fail in an intubation attempt. Why does it happen? Is there a solution?

Many of the intubation attempts result in trauma to the upper jaw of the neonates. Unfortunately, these are rarely documented and reported in any scientific platform.[2,3] How big is this trauma? Can this be avoided?

Problem statement

It is often difficult to intubate neonates particularly if they are tiny premature babies. We can look at this problem in two different ways.

The most common approach would be to accept the limitation of individual's skill, given the difficult anatomy they have to deal with. This approach leads to elimination of any opportunity to find a solution.

The second and an unusual approach would be to deny the limitation of individual's skill and explore the limitation of other associated factors involved in neonatal intubation. The second approach is

unfortunately non-intuitive and remains unexplored in a niche. This article is the narration of how the second approach was successful in finding a solution for the stated problem.

History of neonatal laryngoscope

1878 – William MacEwan attempted adult intubation using his finger as guide. A direct laryngoscope was developed by Alfred Kirstein in 1895 which improved the technique of adult intubation compared to finger guided approach. It was in 1914 McGill developed Speculum laryngoscope which is the forerunner of modern laryngoscope. As the pediatric care improved, the McGill blade was modified in its size to suit children by 1940. A curved speculum blade was introduced for children by Macintosh in 1943. Significant change in the design of laryngoscope keeping in mind small infants was done by Miller in 1946 by introducing a straight blade. All these modifications hinged on changing either the size or the curvature of the blade without substantially altering its design.[4] The smaller ones are used in neonatal practice.

MATERIALS AND METHODS

Ideation

Neonatal intubation is difficult primarily because the neonatal airway anatomy considerably differs from that of adults and older children. There was no laryngoscope specifically designed for use in neonates. This formed the seed for ideation.

Ideation primarily is a creative mental process of developing a thought pattern and a plan sequence to solve a problem. Ideation is not just limited to formation of an idea but also act on it further until proof of concept is demonstrated.

Designing a new laryngoscope exclusively for neonates started with the study of the mismatch between the neonatal airway anatomy and the design of the laryngoscope in use. On studying the mismatch, two important design flaws became evident [Figure 1].

a. The size of the blade-Hinge complex was too big resulting in blocking the vision of the operator
b. The lateral flange on the intraoral portion of the blade, which is designed to restrain tongue on to a side during intubation in adults, is not useful in neonates. Added to this, the space available for intubation substantially decreases and also result in traumatizing the alveolar margin of the upper jaw.

Path ahead

As there was no scientific literature substantiating the above findings, a robust study had to be designed, conducted, and published to educate the scientific community. Following this, a new laryngoscope had to be designed which essentially eliminated the two design flaws noted.

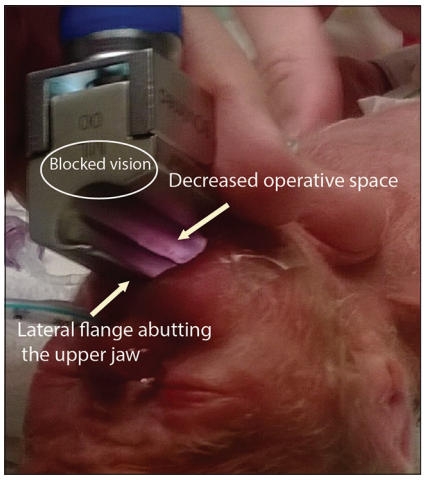

Figure 1: Design flaws associated with conventional pediatric laryngoscope.

Background study

A study was designed and conducted to measure the inadvertent force exerted on the upper jaw of the neonate (Mannikin) during intubation.[5] A pressure sensitive film was taped to the upper jaw of the Mannikin and the volunteers were requested to intubate. The force applied on the upper jaw resulted in the color change in the film which could be quantified using the graph provided by the manufacturer. Thirty volunteers with various levels of experience in neonatal care participated in the study and a total of 90 attempts were analyzed.

RESULTS 1

Overall pressure applied (Mean [SD]) over the upper jaw was 568 (78) Kilo pascals. This was more than twice the pressure that is shown to cause permanent tissue injury in animal models (around 250 KPa). There was no significant difference between the pressure exerted by frequent intubators (>6 intubation in a year) and less frequent intubators (<6 intubations per year).

In the same study, we also noted that 48% of the area of mouth was occupied by the laryngoscope hinge which blocked the vision (data unpublished).

Several take away message form this study was:

a. Our observation of lateral flange traumatizing the upper jaw was true and significant
b. This was prevalent among all experience categories of health-care professionals
c. Higher experience in neonatal intubation did not eliminate this harm
d. Nearly half of the area (Mouth) was blocked by the hinge of the laryngoscope blade which decreased both the area of operation and vision.

Overall, we could conclude that there is lot to do with the design of laryngoscope than the individual expertise.

NOBL scope

Neonatal offset blade laryngoscope for potentially safe intubation in neonates.

Design of the NOBL scope

Initial study bolstered the argument of laryngoscope design being one of the main contributors for difficulty in neonatal intubation and hence fixing that was an important step forward.

The new design obviously focused on eliminating the bulky hinge of the laryngoscope blade and the lateral flange. This necessitated that the blade to nearly float in the oral cavity by anchoring it at a distant point. After couple of designs and re designs, a blade which was offset from the handle was designed. [Figure 2] shows the illustration and a 3 D printed non-functional model of NOBL scope.

Description

The new laryngoscope [Figure 3] has a novel design featuring the handle being offset from the blade by a horizontal element. The thick bulky hinge lock is eliminated from the line of vision to enhance the visibility of the larynx.

The new device has a handle which houses battery, toggle switch and a LED light source. The handle has a specifically designed locking system for the blade which actuates when the blade is aligned and turned in anticlockwise direction.

The blade has a small hub which serves as the handle lock. The hub is separated from the intraoral portion of the blade by a horizontal element which anatomically curves at 90 degrees twice and leads to the handle. The hub and the offset element have an optical fiber running inside its center. The tip of the optic fiber terminates at the end of the curved offset element on to a lens which throws the light into the oral cavity. The intra oral portion of the blade is a flat element which has a gentle curve on the longitudinal axis to enhance the area or the operating field. The length and width of the blade vary to suit the size of the oral cavity. The typical size currently designed is 50 × 10, 75 × 15, 100 × 20 mm (Length × Breadth). This corresponds to 00, 0, and 1 sized blade currently in use. The newly designed NOBL scope was subjected to scientific study for proving its worth.

Proof of concept study

We conducted a randomized control trial on manikin comparing the conventional Miller blade laryngoscope with our new NOBL scope.[6] 20 volunteers with various levels of experience in neonatal care participated in the study.

The objectives were, primarily to compare the pressure exerted on the upper lip of the mannequin between pediatric laryngoscope and NOBL scope and to compare the area of vision between pediatric laryngoscope and NOBL scope. Secondary objectives were to compare the area of pressure impression and time taken for intubation between pediatric laryngoscope and NOBL scope.

RESULTS 2

The frequency of pressure indentation on the maxilla was reduced by 45% with NOBL scope. The median (IQR) pressure exerted on the upper jaw with the conventional laryngoscope was 455 KPa (350–526) and that with NOBL scope was 80 KPa (0–134). The area of pressure indentation and time taken to

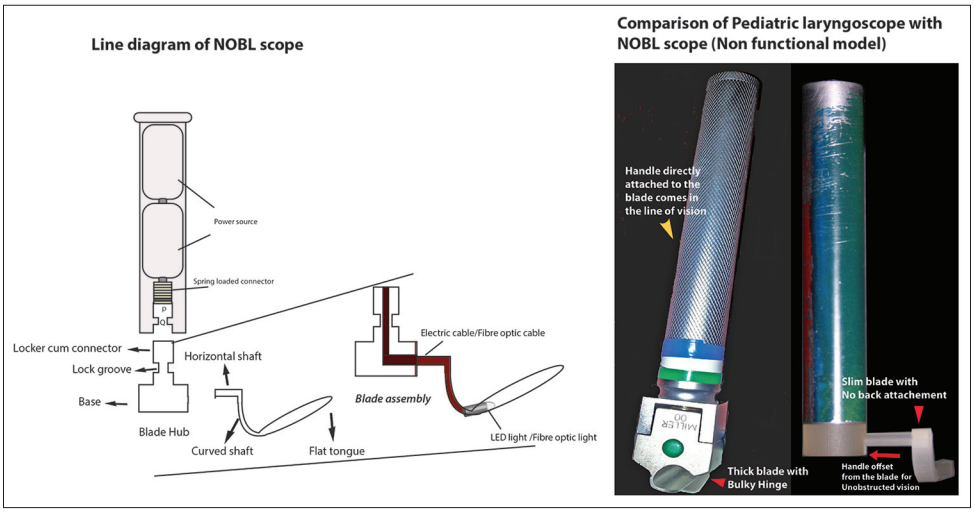

Figure 2: NOBL Scope – Illustration and comparison with conventional laryngoscope.

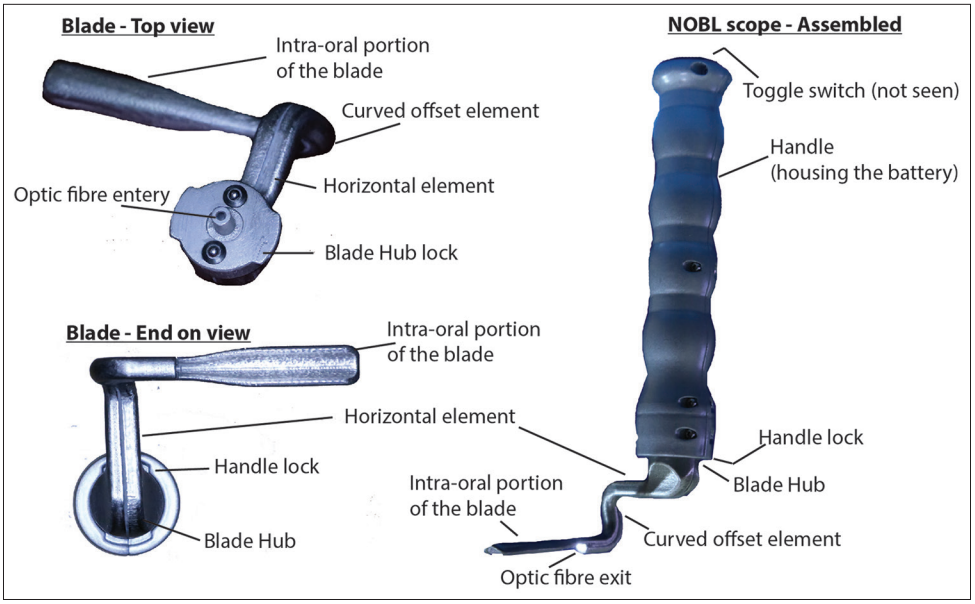

Figure 3: Functional NOBL scope – parts.

intubate was significantly lower with the NOBL scope. We used photographic technique to measure the area of vision blocked while intubating. The area of vision blocked by conventional laryngoscope was 38.5% of the oral orifice compared to 12% with the NOBL scope [Figure 4]. About 95% of the participants agreed NOBL scope was easy to use.

We had faced several challenges during the execution of the project. It was the diligent work of couple of engineers which made the design on the paper a reality as a product. Getting the unusual design manufactured was a huge challenge which was addressed using 3D print technology. Measuring the surface pressure on the manikin was another challenge. We used the pressure sensor films by Fujifilm to measure the pressures with appropriate experimental setup. The project was funded by Ontario Center of excellence, Canada.

DISCUSSION

Advances in the neonatal care have led to use of miniaturized adult laryngoscope in tiniest neonates. The pediatric and neonatologist community have endured the challenges these adopted laryngoscopes have thrown at us due to lack of purpose designed laryngoscope. Even the recent advances in video laryngoscopy have not improved the success rate of routine neonatal intubation.[7]

Conventional neonatal laryngoscope results in significant failure rate particularly among less experienced health-care providers.[1] It also results in trauma to the alveolar margin of the neonate leading to permanent damage to the dentition in future.[8-10] Our own study showed that the traumatic force exerted on the upper jaw during intubation was twice higher than the force determined

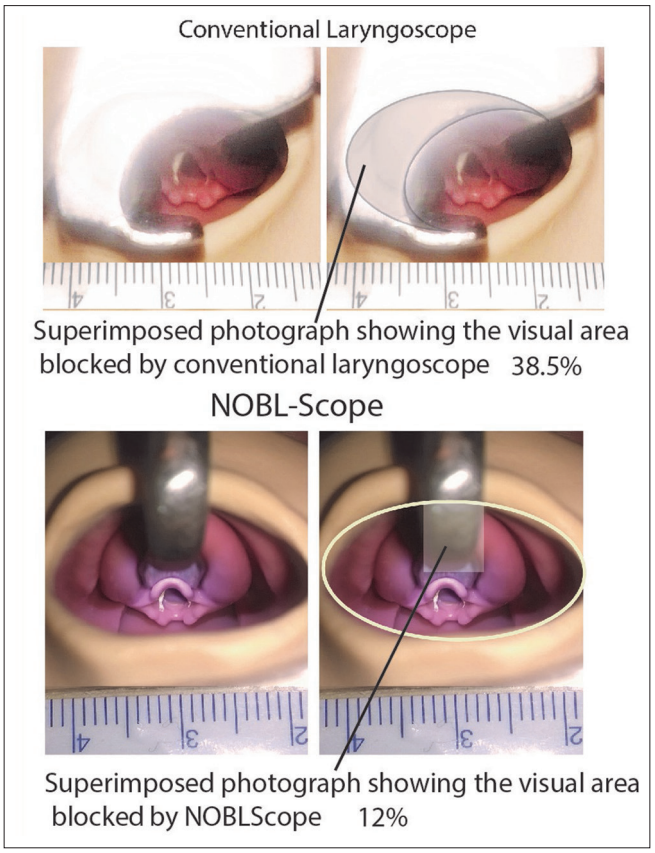

Figure 4: Comparison of vision blocked by conventional pediatric laryngoscope and NOBL scope.

to cause permanent histological damage in the animal models. The visual area is decreased by 38.5 to 48% depending on the oral cavity thus making the procedure difficult.

The new purpose designed NOBL scope do not have the hinge lock or the lateral flange seen in the traditional laryngoscope blade. The handle is attached to the blade at a distance away from the oral cavity and hence the visual area is significantly increased. The curved design of the horizontal offset element ensures the traumatic force exerted on the upper jaw is significantly reduced. Clinical study on cadaver is underway following which data on clinical safety will be available.

Intellectual property rights: It is especially important aspect of any innovation. The novelty has to be noted and certified by the appropriate agency so that the inventor can claim his/her achievement for either economical or career benefit.

NOBL scope is patented under the author's name in United States patent office. Patent No US 10,327,628, B2 date June 25, 2019.

Parting thoughts

Innovation is an inherent strength in every individual. It is the enlightenment of one's own strength in problem solving. Many innovations which make our day-to-day life easier do so without much of fanfare. Hence, every scientific individual should embark on innovation for the progress of the science.

CONCLUSION

Neonatal intubation – can we make it better? Yes, we can!!

Declaration of patient consent

Institutional Review Board (IRB) permission obtained for the study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Karnataka Pediatric Journal

Original Article

MedTech Innovation using a structured Biodesign process: Barriers and Opportunities

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ABSTRACT

Objectives: Medical Technology (MedTech) can be defined as the application of science to develop solutions to health problems. It also includes devices, processes and existing systems in the healthcare ecosystem. Biodesign process is the tried and tested methodology of identifying the unmet clinical needs and solving the problems of the healthcare ecosystem by applying science and technology. Hence, biodesign process is nothing but a process of developing systematic MedTech Innovations. Just like there is clinical research for disease and all its aspects like etiology, management etc, the systematic process of identifying problems and finding solutions in healthcare ecosystem is termed biodesign process. The starting point in this whole process is to define the right problem, figuring out all the possible solutions, zeroing on to the right solution and see that it solves the problem efficiently. But ultimately, did that solve the problem? At the first instance, was there a problem at all? These are the questions that arise during the course and biodesign process has the answers to all these questions. This process allows the innovator to ask the right questions and find the right answers in the best possible way, so that any of the time and effort of the team are not futile. The biodesign process established by the Stanford biodesign program gave the basic understanding of the process, which was modified to the Indian healthcare ecosystem to identify relevant problems and innovate suitable solutions.

Materials and Methods: Multidisciplinary teams went through clinical immersions, figured out various crucial needs, validated their understanding with subject experts, brainstormed about the new strategies/solutions/approaches, and then did the prototyping of these solutions.

Results: 71 detailed observations made overall of which 52 critical and unmet clinical problem statements with significant negative impact on patient outcome were obtained.

Conclusion: A structured biodesign process with active role of the clinician at every stage gives better insights into the unmet clinical needs in the healthcare ecosystem.

Keywords: Biodesign process, Health innovation, Stanford biodesign process, AIM program, Pediatric innovation

INTRODUCTION

Approximately 75% of all the medical equipment and diagnostic devices that are being used in India are imported from many of the developed countries, which makes healthcare costly. This has proven to be a bottleneck as witnessed in the current COVID crisis as well when there was a sudden increase in the need of many such devices to be deployed across the healthcare delivery ecosystem at a rapid pace. Furthermore, many a times, they are not adapted to the needs of India's unique healthcare ecosystem which include the healthcare provider's approach to care, variable sourcing needs, and who exactly reimburses the cost of healthcare delivery. Hence, currently, there is a dire need to indigenously develop medical technologies to fulfill the specific needs of our unique Indian healthcare ecosystem. Few current relevant examples are the oxygen generating plants, oxygen concentrators, ventilators, etc.

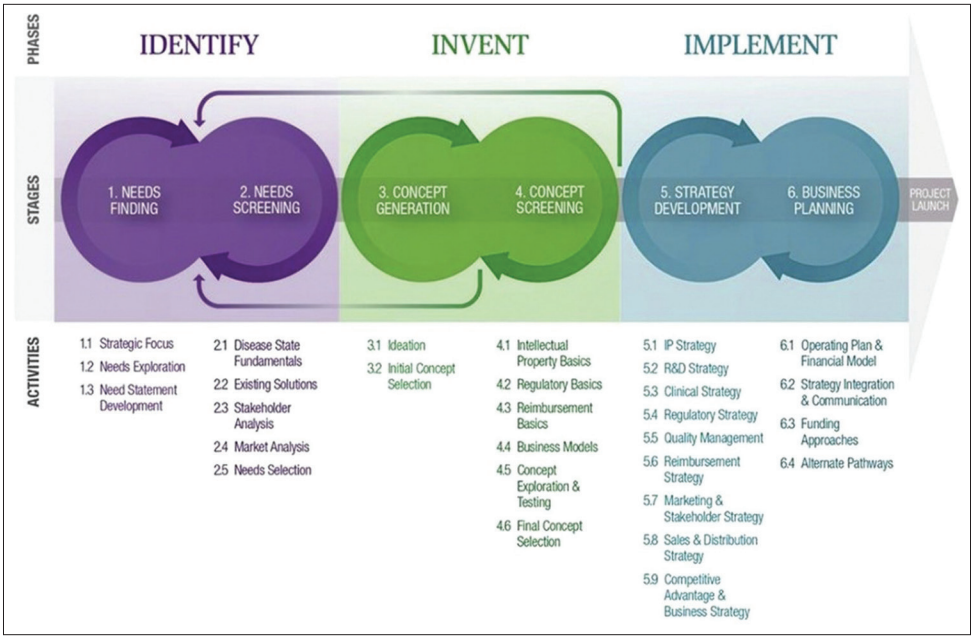

Figure 1: An infographic of the three phases of biodesign process is shown here as elaborated by Stanford biodesign.

Overview of the biodesign process

Biodesign is the systematic process of innovation in healthcare systems/medical technologies. Innovation in healthcare systems is usually thought to be discovery driven where scientific research at various laboratories, universities, pharma, and biotech leads breakthroughs leading to further developments. This is the typical top-down model or the laboratory to bedside pattern. Over the last decade, there has been a major shift in this approach to a more practical bottom-up model. A deeper focus on innovation based on our unique needs has emerged as a sustainable model for medical product development, specific to India, particularly in the domain of biomedical technology (medical devices and diagnostics). Influenced by the advent of design thinking (design thinking has been dealt with in article titled "Healthcare Innovation and Design thinking" of this issue) across industries and new age organizations alike, innovators have started to focus more on having a deeper understanding of the ground level practical clinical needs as the critical starting point of the process to innovate in this domain.[2] The mantra for this biodesign process is that "a well-characterized/structured need is the DNA of a great invention."[3]

The Stanford biodesign process

The implementation of the biodesign process started from the Stanford Biodesign program[2,4] of the well-known Stanford University through Stanford Byers Center for biodesign which began in 2001 with a primary focus to train leaders in Biomedical Innovation. The differentiating feature of this process is the priority on needs identification through clinical observations, a formal selection process, researching and characterizing needs through structured filtering process before beginning the process of inventing. The teams involved typically spend 3–5 months performing need identification and characterization before they even start thinking of a solution. The Stanford Biodesign process has 3 phases with 6 stages with various activities happening in each stage [Figure 1].

Phase of Identification

This is the phase where the unmet needs are first identified that are later clinically validated. A multidisciplinary team composed of an engineer, a product designer, a business graduate, and interestingly, a doctor who is a critical part of such teams, carryout clinical observations inside a hospital at bedside, in a specific focus area or a problematic domain of hospital such as OPD, procedure room, and laboratory for a period of 6–8 weeks. The team shadows/follows doctors, paramedical staff, and patients during this period, and keenly observes the activities between health-care personnel and patients including interactions, procedures, and the overall care provided. This is termed as clinical immersion. The team is informed to note down all the observations including seemingly efficient processes and also inefficient practices and poor health outcomes without any bias. After systematically documenting the observations for around 6–8 weeks, the team brainstorms to categorize and sort the observations using a defined process to filter out the not so relevant ones.

Once a critical need is identified, a structured document containing a set of all the needs criteria is compiled. This so-called "needs criteria" essentially is a list of must-haves and nice-to-haves in the proposed solution, which actually are the objective parameters that are expected to be satisfied from the prospective solution.

Phase of Invention

During this phase of invention, the team brainstorm all possible ways in which the need/problem can be addressed/solved. This brainstorming session focusses on generating a large set of ideas that build cumulatively on each other. The problem statements to work on are selected based on satisfying these needs criteria initially outlined in the need specification document. In the next phase, the teams focus on the constant prototyping and validation with stakeholders.

Phase of Implementation

This stage includes evaluation of the intellectual property issues, regulatory compliances, validating the stakeholders, and strategy to adopt in marketing and also includes the plan for manufacturing process, operations, and finance. The preclinical and clinical testing of the prototype is also taken into account.

As an example of the practical application of Stanford Biodesign program in cardiology was, solving the unmet clinical need of the "detection of potential arrhythmias in non-hospitalized patients." With a team led by cardiologist as part of the biodesign program, the top solution that filtered out was a long term (up to 14 days), water resistant, disposable patch-based monitor to identify cardiac arrhythmias. This cardiologist eventually formed a start-up and licensed the technology from Stanford, following which their team developed a complete solution, which included a cloud-based algorithm and robust supporting services. The device is currently commercially available [Figure 2]. To date, the device has been used on nearly 500,000 patients, and several publications have documented the clinical and economic utility of the approach. This device is an example of a successful medical device initially conceived by a fellowship group in the Stanford Biodesign Program. It is currently commercially available in the United States and Europe.[5]

Figure 2: A novel single-use, 14-day cardiac event monitor.

Indian specific Biodesign process

The Affordable Innovation in MedTech (AIM) Program[2] is based on my (Dr. Jagdish Chaturvedi) experience with the Stanford biodesign program. There were some lacunae felt when being applied to the Indian medical ecosystem and as my role as clinical director at InnAccel, an Indian medical technology acceleration company, an improvised version of the Stanford Biodesign program was conceived with few modifications to suit our problems and solutions needed. This was the AIM program. The important additions/modifications were as follows:

a. Involvement of working clinicians as clinical team members.
b. Collection of larger amount of data (in terms of frequency and criticality), focused on negative outcomes.
c. The use of pre-calibrated filters designed to bring out needs with substantial market size which can be solved by moderately complex solutions.

I (Dr. Gunda Srinivas) would like to explain the importance of the need to find out the right clinical problem and document it appropriately as well with a simple example here.[6]

A good need should address a clear and well-defined problem

A *clinical problem* is an undesirable situation that leads to a negative outcome. A *need* is the requirement to solve the problem and avoid the negative outcome. For example: "*A faster way to restore blood/fluid volume to normal levels in children (under the age of 5) who are brought to the casualty/Emergency department in a state of severe dehydration, in order to prevent hypovolemic shock*." This is a need which all the pediatricians can connect well and this statement clearly defines what the solution should focus *on what?* – Faster restoration of blood volume; *for whom?* – Under 5 children; *where?* – In the casualty; and *why?* – To prevent hypovolemic shock. The problem being addressed is the delayed restoration of intravascular volume in children with dehydration which is common due to difficult IV access. Let's see the same clinical problem, if not constructed well or poorly observed and not documented in a structured manner. It would be something like this "*A better way to manage dehydration in children*" which is a poorly defined need. It does not provide any direction or clarity toward generation of a solution. In this case, there can be many ways to make the management of dehydration better which could be identifying levels of dehydration, preventing dehydration altogether, restoring hydration quickly, or by preventing hypovolemic shock which is the actual need here. Therefore, there is a possibility for the

team to focus on an approach that may not be ideal to solve or might delay the process by deviating from the actual need.

A good need should not create a bias toward any particular solution

The purpose of a well-defined need statement is to provide a direction for the generation of a solution, but not the solution in itself. Consider the same example: "*A faster way to give IV fluids in children with dehydration*" very specifically and narrowly means a solution focused on delivering fluids in intravenous route only. Here, the invention team will be biased on thinking about solutions which are all directed toward giving fluids in intravenous route. Whereas in the rephrased need statement – "*A faster way to restore blood/fluid volume to normal levels in children under 5 who are brought to casualty/ER in a state of dehydration, to prevent hypovolemic shock*." Here, restoring of blood/fluid volume can be done through Intravenous administration, through oral administration, intradermal, subcutaneous, or intraosseous routes as well. This need statement focuses on the outcome that fluid volume must be restored but does not direct how the volume must be restored. This allows the inventing team to explore all possibilities for solving the need which can be validated by the clinician in the team later.

A study was conducted at St. Johns Medical College Hospital, Bengaluru, to test the effectiveness of using such a structured process for MedTech innovation in neonatal and pediatric domain.

MATERIALS AND METHODS

A well-designed and structured process was used to chalk out unmet clinical needs, wherein multidisciplinary teams went through clinical immersions, figured out various crucial needs, validated their understanding with subject experts, brainstormed about the new strategies/solutions/approaches, and then did the prototyping of these solutions, as shown in [Figure 3]. In the first stage, a multidisciplinary team carried out simple clinical observations at bedside in a specific focus area of hospital. The team followed doctors, paramedical staff, and patients as well and keenly observed the care provided, in an unbiased manner. The team was instructed to note all observations including the inefficient practices and poor health outcomes. Then, the members of the team understood the critical and exact needs after performing deep dive into the keen observations made their indications and implications. Following this step, based on various factors such as clinical implication of the need and its criticality, frequency of the negative outcomes, and the market potential of the proposed solution, the team filtered out the various needs collected in the previous step. Once the critical need was figured out, the team then brainstormed various possible methods in which the problem could be solved without any bias. The intention of these brainstorming sessions was to generate as many number of high-quality ideas and solutions as possible to solve the critical problem. Finally, the team prototyped the most relevant solutions and validated their work with clinicians. A start-up was planned after this stage if the critical need and the suggested solution seemed to be sustainable in all ways at this point as well so that the solution is brought to the market and scaled up.

Criteria for selection of a strategic focus area

Around 20% of the world's pediatric mortality happens in India. Under 5 children's mortality in highest income quantile is 1.78 lakh/year in contrast to the lowest income quantile which is almost 3 times more at 5.3 lakh/year![6] There is a huge difference in mortality rates of various states of India. Kerala's under-5 mortality rate is 14/1000 live births whereas Madhya Pradesh has 92/1000 live births.[7-9] These startling facts pushed us to undertake the clinical need analysis in the domain of child and newborn health.

Team composition

Around six clinical immersion sessions were carried out in a tertiary care hospital setup, and during these immersions, we had two biomedical engineers spending around 6 weeks

Figure 3: A well-defined and structured process in MedTech innovation.

shadowing and observing the doctors and paramedical staff in the department of pediatrics. The intended goal of this unique activity of clinical immersion was to identify clinical needs and genuine problems that the clinicians face, which could be later on taken up by the health technology startups grown indigenously and solve them at large scale.

RESULTS

Outcome of 2 months of clinical immersion

Outcome was quite interesting, with 71 detailed observations made overall. From this set of observations, 52 critical and unmet clinical problem statements with significant negative impact on patient outcome were obtained. The members of the team then worked up to identify the fundamentals of the disease state involved for better understanding, current treatment and management options, challenges with the current management, potential market size, business competitors in the market, regulatory clearances and requirements needed, and business models that would sustain and reimbursement methods. All the teams then worked on the need/problem statements that were documented during the initial phase of clinical immersion. This was done by applying four rounds of appropriate filters after discussion with treating pediatricians and the administration of the hospital, including the parents as well who are also the important stakeholders in the ecosystem, as shown in [Figure 4].

Strong motivation and personal interest are also key roles in determining the critical needs which would be pursued further, as shown in [Figure 5].

DISCUSSION

This article is all about various unmet clinical needs of our unique Indian healthcare ecosystem and the ways to solve them using a well-defined and structured biodesign process. The main advantage and strength of this method were the right identification of multiple critical needs using the clinical immersion process in the shortest possible time period.

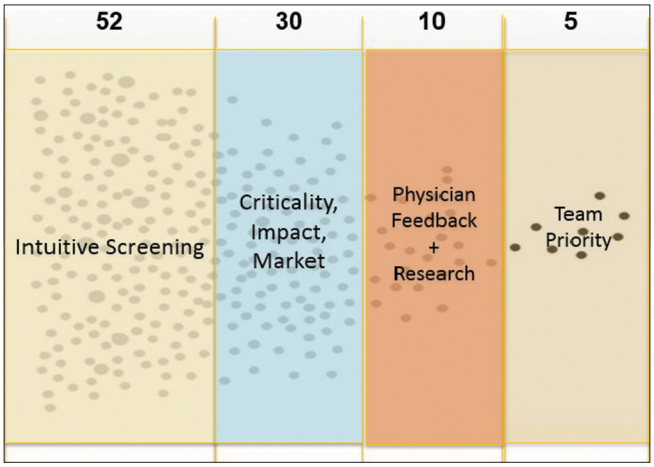

Figure 4: A graphical representation of the key steps in the filtering process.

The principal barrier while using this method was the absence of a dedicated physician as part of the team which led to a number of challenges later in the process. This caused suboptimal understanding, misunderstanding, and misinterpretation of the core clinical and medical concepts such as pathophysiology of the disease and their fundamentals at a very crucial stage. A dedicated clinician as part of the team serves as a domain-specific knowledge expert during clinical immersions, helping non-clinical members to understand simple medical terminologies, relevant basic anatomy, and pathophysiological processes of the disease. He can also help during brainstorming and guide the team in selecting the appropriate possible solutions. We were forced to spend extra amount of time for extensive research and understanding by talking to various external clinicians in addition to the time spent in clinical immersion due to lack of dedicated clinician in the team.

The next challenge was an inherent sceptical attitude in the health-care ecosystem about the non-medical team members such as the engineers and salesman of the team. Many of the doctors and nurses that we met in hospitals as part of the clinical immersion became very conscious of our presence and were worried that our team was assessing their performance and monitoring their activities to report the negative aspects to the management. A dedicated clinician in the team can always build the rapport with the doctors and nurses and explain the intentions behind our keen observations and break the ice. Finally, without a dedicated clinician, it was very cumbersome to make sense of the observations and also to understand which procedures are the most critical without frequently asking the clinician in the hospital which was not preferable most of the times.

This crucial study activity depicts the importance of a pre-planned, well-structured multidisciplinary team for more effective clinical immersions with a motivated physician as an integral part of the team, bridging the gap, and guiding the team in right path. This whole activity is augmented by the presence of biomedical engineers, designers, and people unrelated to the medical systems in the team, who can look at the scenario with an unbiased and fresh perspective for better understanding and better solutions.

This might not be possible with the doctors alone, as they might get adapted and biased due to constantly working in the same setting for a long time and unfamiliar with the available technologies and systems to solve these problems. This is very crucial for the success of the end product which might be a medical device or a service that needs to fit

	Need
1	A fast, reliable way for clinicians to measure bilirubin levels in order to provide timely and optimal phototherapy treatment
2	A way to assess the maximum amount of positive pressure tolerable by an individual neonates' lungs in order to provide effective ventilation and prevent the occurrence of pneumothorax
3	A reliable way to immediately detect pneumothorax in in the NICU in order to provide timely, lifesaving treatment
4	An easier way to safely deliver nutrition and antibiotics to hospitalized neonates in order to prevent vein damage, cyanosis, and infection
5	A more effective way to provide suction in ambulances or clinics without electricity or a main suction line in order to decrease the risk of infection and asphyxia.

Figure 5: Some of the critical needs that were identified following a structured biodesign innovation process.

seamlessly into the existing clinical workflow of clinicians or paramedical staff.

Spending many hours inside a hospital at bedside observing the doctors, nursing staff, and patients give a better understanding to the engineers, designers about various practical aspects of design, size, and orientation for the devices they would be designing. Ex: Nurse might have only one hand freely available while performing a specific procedure when handling children, or devices aimed toward children require specific considerations in size, positioning in ICU, bedside, etc. When the whole team is together in the clinical space, it allows more opportunities for each team member to better understand the user who might be a nurse, doctor, administrator, or the patient himself. Our experiences say that these deeper understandings and clinical insights can definitely motivate the various team members to continue to develop products and services in scenarios where others would have easily considered as not feasible. Thomas Fogarty, an internationally recognized surgeon, inventor, and entrepreneur noted, "Innovators tend to go out and ask doctors what they want rather than observe what they need. When you talk to physicians, as well as others involved in the delivery of care, you need to learn the difference between what they say and what they want, and what they would be willing to pay for, and what they actually do."

MedTech innovation is a well-structured process that requires multidisciplinary team with collaboration across various domains. For this process to be successful, it requires complete commitment, dedication, and coordination among all team members. After initial challenges during our immersion stage, we spent couple of weeks getting to know more about the clinicians in the hospital and the department we were observing in, and attempted to recruit them to join our team for better understanding and coordination. The process went on smoothly once we had developed a good rapport with the doctors and nurses. Fortunately, we were able to course correct during mid-immersion, but we highly recommend each team to start the immersion with a multidisciplinary team, complete with dedicated clinicians, engineers, designers, etc., to effectively utilize the advantage of creative collaboration.

CONCLUSION

a. This structured biodesign process when employed to develop a new medical device or define a new process is highly effective in defining and innovate in the strategic clinical focus area which is essential to figure out the right problem for the appropriate solution.
b. Limited involvement by the clinicians in initial stages and the sceptical attitude of the doctors and nurses in hospital about the engineers were some practical challenges in the process. This proves the crucial and irreplaceable role of the clinicians not only at the very important stage of the needs assessment but also at every stage of the biodesign process.
c. The clinician has a new role that has emerged out of the biodesign process and all these can be managed by continuing in the clinical domain and at the same time being part of a multidisciplinary team to innovate that saves lives too.

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We acknowledge our teachers, mentors, patients, and families who have given all these insights, learning, and newer opportunities to further our learning.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

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Karnataka Pediatric Journal

Letter to Editor

Lift the lip: Screening tool for health care professionals

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Sir,

Early childhood caries continues to be a highly prevalent global disease of public health importance in children under the age of 6 years.[1] Various guidelines states child should visit a dentist within 6 months of eruption of the first primary tooth and no later than 12 months of age.[2] But the compliance of this dictum is poor even in developed countries like UK. The Royal College of Surgeons of England press release media release shows that 80% of 1–2-year-olds and 60% of children aged one to four did not visit an NHS dentist in 2016–17.[3] In India, common age for the first dental visit was 4–6 years.[4]

A timely first visit to the dental office creates oral health awareness among parents and caregivers. It can have long-term benefits for the child and should be an integral part of pediatric health care. Pediatricians and other healthcare professionals examine infants several times from birth to adulthood.[5] Therefore "Lift the Lip" can be an oral health screening tool used to detect the early signs of dental diseases.[6] By performing "Lift the Lip" Program for all the patients, any health care professionals can identify white lines or spots on the tooth, brown spots at the gumline, broken teeth, cavities, and halitosis. If this simple quick screening is done on a consistent basis, pediatricians can identify the dental conditions and inform the parents to treat it before it becomes serious. The morbidity associated with ECC can be reduced to large extend. Therefore, it is imperative that "Lift the lip" diagnostic tool has to be emphasized to the healthcare professionals through their specialist organizations and also by conducting continuing education programs.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Karnataka Pediatric Journal

Journal Review

KPJ journal watch: Innovations in neonatology

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Source: McCullough LB, Coverdale JH, Chervenak FA. Professional integrity in maternal–fetal innovation and research: an essential component of perinatal medicine. Journal of Perinatal Medicine. 2021 May 19.

Clinical innovation and research on maternal-fetal interventions have become an essential subject for the development of perinatal medicine. In this paper, the authors present an ethical argument that the professional virtue of integrity should guide perinatal investigators. Leaders in perinatal medicine should create and sustain an organizational culture of professional integrity in fetal centers, where perinatal innovation and research should be conducted. The authors identify the implications of both intellectual and moral integrity for innovation, research, prospective oversight, the role of equipoise in randomized clinical trials, and organizational leadership to ensure that perinatal innovation and research are conducted with professional integrity.

Source: Palmer KR, Tanner M, Davies-Tuck M, Rindt A, Papacostas K, Giles ML, Brown K, Diamandis H, Fradkin R, Stewart AE, Rolnik DL. Widespread implementation of a low-cost telehealth service in the delivery of antenatal care during the COVID-19 pandemic: an interrupted time-series analysis. The Lancet. 2021 Jul 3;398(10294):41-52.

Little evidence is available on the use of telehealth for antenatal care. In response to the COVID-19 pandemic, the authors developed and implemented a new antenatal care schedule integrating telehealth across all models of pregnancy care. Telehealth integrated antenatal care enabled the reduction of in-person consultations by 50% without compromising pregnancy outcomes. This innovative care model can help to minimize in-person interactions during the COVID-19 pandemic, but should also be considered in post-pandemic health-care models. This innovation can be expected to increase the quality of antenatal care by leading to the detection of more maternal and fetal problems.

Source: Jagarapu J, Savani RC. Development and Implementation of a Teleneonatology Program: Opportunities and Challenges. InSeminars in Perinatology 2021 Apr 7 (p. 151428). WB Saunders.

Teleneonatology, encompassing all telemedicine applications in neonatal medicine, is evolving with innovative applications for use in all aspects of neonatal care. In this review, the authors discuss the key components of and a framework for the development, implementation, and evaluation of a program based on existing literature and their own program. They also review some important barriers to implementation and potential solutions. Let's hope that this review will serve as a guide for those seeking to develop and implement other new teleneonatology programs.

Source: Pangratz-Fuehrer S, Genzel-Boroviczény O, Bodensohn WE, Eisenburger R, Scharpenack J, Geyer PE, Müller-Reif JB, van Hagen N, Müller AM, Jensen MK, Klein C.

Cohort profile: the MUNICH Preterm and Term Clinical study (MUNICH-PreTCl), a neonatal birth cohort with focus on prenatal and postnatal determinants of infant and childhood morbidity. BMJ open. 2021 Jun 1;11(6):e050652.

To uncover pathological processes contributing to infant/childhood morbidity and mortality, establishment of the MUNICH-PreTCl birth cohort was done. Comprehensive medical information of healthy and sick newborns and their families were obtained, along with infant blood samples for proteomic analysis. Via MUNICH-PreTCl, researchers seek mechanism-based biomarkers in infant health and disease to deliver more accurate diagnostic and predictive information for disease prevention. Particularly, they focused on risk factors for pregnancy complications, family history of genetically influenced health conditions such as diabetes and pediatric long-term health. From the Perinatal Center at the LMU University Hospital, Munich, recruitment of a total of 662 infants was done, 44% of these were female (36% in preterm and 46% in term). Participation was accepted by 90% of the approached families. Over 450 data points were collected per child–parent set, (family history, demographics, pregnancy, birth, and daily follow-ups throughout hospitalization) and 841 blood samples were obtained longitudinally. For the questionnaire, the completion rates for medical examinations and blood samples were 100% and 95%. Along with the use of medical registries, the correlation of large clinical datasets with proteomic phenotypes, will allow future evaluation aiming to determine mechanisms of disorders in a systems biology perspective.

Source: Glass HC, Soul JS, Chang T, Wusthoff CJ, Chu CJ, Massey SL, Abend NS, Lemmon M, Thomas C, Numis AL, Guillet R. Safety of Early Discontinuation of Antiseizure Medication After Acute Symptomatic Neonatal Seizures. JAMA neurology. 2021 May 24.

In the field of epilepsy treatment, we are often caught between the proverbial rock and hard place: our seizure medications can cause harm but so can seizures. The authors provide important and robust evidence to address this contentious issue. Their data from 9 American Neonatal Seizure Registry centers suggest that prolonged antiseizure medication (ASM) treatment is unnecessary for most neonates and support routine discontinuation of ASMs after resolution of acute symptomatic neonatal seizures before hospital discharge. This is a welcome finding and probably will become a practice changing recommendation.

Source: Rosenstein MG, Chang SC, Sakowski C, Markow C, Teleki S, Lang L, Logan J, Cape V, Main EK. Hospital quality improvement interventions, statewide policy initiatives, and rates of cesarean delivery for nulliparous, term, singleton, vertex births in California. JAMA. 2021 Apr 27;325(16):1631-9.

An estimated 4 million births occur each year in the US, and almost 1 in 3 births involve cesarean delivery. The national rate of cesarean delivery steadily increased from 20.7% in 1996 to 32.8% in 2010, and for the past decade, this rate has remained largely unchanged. Although cesarean delivery can be lifesaving for both the mother and neonate, the increase in cesarean delivery rates has not been associated with any demonstrable improvements in maternal or neonatal morbidity or mortality. Because of these procedure rates, obstetric leaders and organizations have highlighted the importance of addressing cesarean delivery, especially among low-risk births. The rates of cesarean delivery decreased over time in the setting of the implementation of an innovative, coordinated hospital-level collaborative, and statewide initiatives designed to support vaginal birth. This is the need of the hour initiative that needs to be replicated across the LMICs in general and India in particular.

Source: Baker H, Pilarski N, Hodgetts VA, Morris RK. Comparison of visual and computerized antenatal cardiotocography in the prevention of perinatal morbidity and mortality. A systematic review and meta-analysis. European Journal of Obstetrics and Gynecology and Reproductive Biology. 2021 Jun 4.

Two methods — visual (vCTG) or computerized (cCTG) Antenatal cardiotocography (CTG) — are used to monitor fetal well-being. Researchers conducted this systematic review with the aim to update an earlier Cochrane review comparing the effects of both approaches on maternal and fetal outcomes. In addition, they sought for studies not included in the Cochrane review. Searching MEDLINE, EMBASE, CINAHL, and MIDIRS databases up to February 2021, they identified three RCTs and three NRS for inclusion. Outcomes revealed a non-significant reduction in perinatal mortality with cCTG. Although cCTG was not linked with clear reduction in perinatal mortality and morbidity, it is objective and may decrease time spent in hospital and further investigations for women.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflict of interest

There are no conflict of interest.

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