INTERNATIONAL DESIGN CONFERENCE - DESIGN 2022
https://doi.org/10.1017/pds.2022.4

A Comparative Analysis of the Engineering Design and Lean Start-Up Innovation Methodologies

D. Karia [1], K. Shah [1,✉], K. Venkatesh [1], S. Acharya [2] and M. Arora [1]
[1] Indian Institute of Science, India, [2] Indian Institute of Technology Guwahati, India
✉ komalshah@iisc.ac.in

Abstract

Innovation is a key driver for product success. Engineering design and lean start-up are prominent innovation methodologies well accepted and widely used. There is a lack of availability of pragmatic reflections for innovators to put into practice. The paper addresses this need by undertaking a comparative analysis of the two methodologies, using three case studies of medical device innovation. Directions and insights on how innovators may employ one or both approaches at different stages of their innovation are presented.

Keywords: engineering design, lean start-up, innovation, design methodology, case study

1. Introduction

Innovation is a key driver for product success in today's competitive start-up ecosystem. Several methodologies, such as, systematic Engineering Design process (ED) by Pahl and Beitz (1996), and Lean Start-up (LS) by Blank (2006) have been widely used to foster innovation. While the "Lean" philosophy and its principles were first seen in the manufacturing world after the end of the second world war, recent attempts have extended its application to related fields, such as, engineered product design and entrepreneurship. LS - processes (Blank, 2006; Ries, 2011) centre on "customer development" and refinement of business hypotheses through customer interaction, whereas ED offers a "systematic approach" to address design problems through structured process, supported by appropriate design methods and tools, with a focus at the product end. The 'user-in-the-loop' approach to ED (Karia et al., 2019), extends on traditional ED and demonstrates the importance of engaging stakeholders at the end of each stage to validate, and modify, if necessary, the path of product design and development. Overall, both 'user-in-the-loop' approach to ED and LS have similar goals but employ different techniques to achieve them.

Extensive work has been done to understand methodological similarities and differences with LS, and some authors have highlighted the complementarity of LS and Design Thinking, whilst proposing that a larger benefit may be seen in their collective implementation (Hildenbrand and Meyer, 2012; Koen, 2015; Lichtenthaler, 2020; Mueller and Thoring, 2012). Others have built on this and put forth methods that leverage the strengths of both approaches, sometimes in combination with other approaches, such as (Dobrigkeit et al., 2019; Furr and Dyer, 2014; Gama et al., 2018; Hildenbrand and Meyer, 2012; de Paula and Araujo, 2016; Pease et al., 2014; Schelle et al, 2015; Ximenes et al., 2015). It may be argued that while Design Thinking is an activity-based approach, the systematic Engineering Design process proposed by Pahl and Beitz (1996) is a stage-based process, analogous to one other, with the common intent towards 'creative problem solving', and hence, has potential to compliment and bolster LS for product development. This paper presents a comparative analysis of the two methodologies - LS and 'user-in-the-loop' approach to ED, empirically founded on live cases, to explore the potential benefits of following each approach, subject to the objectives of the innovators, and how the two can be used in conjunction to leverage their strengths.

2. Literature Review

2.1. The Engineering Design (ED) and Lean Start-up (LS) methodologies:

Engineering Design (Figure 1) uses an iterative approach to develop a product in four stages, of which "Task Clarification", the first stage, is largely focussed on understanding the task at hand by collecting and interpreting information about product requirements, the context in which they must be fulfilled, relevant constraints and their relative importance. A specification in the form of a requirements list, which is the outcome of this stage, acts as the master source that informs the subsequent stages of the design process (Pahl and Beitz, 1996). Poor capture of requirements can result in significant business loss due to wasted time, wasted resources, and missed opportunities. The impact of these losses increases as more and more time elapses in the in the development process. As a result, several activities of the product development cycle require repetition to adequately fill the market gaps.

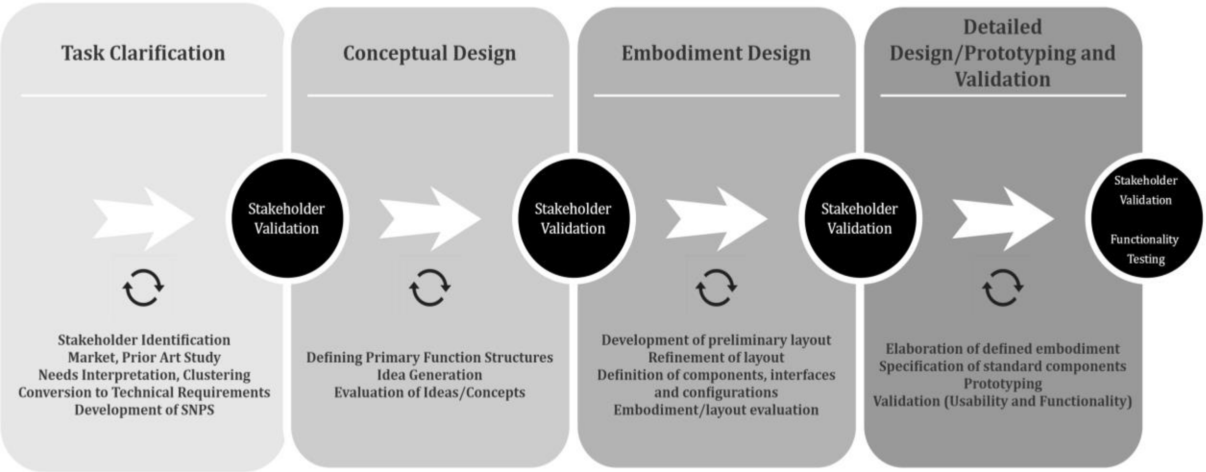

Figure 1. The 'user-in-the-loop' approach to engineering design (Karia et al., 2019)

These issues are directly addressed by "Customer Development", the corresponding first stage of the Lean Start-up methodology (Figure 2), which is highly focused on efficiency and market fit. It begins with an initial business idea, and multiple rounds of customer interview and data analysis are used for iterative formulation and testing of hypotheses, to learn if a problem is worth solving.

While ED attempts to identify and understand the needs and expectations of all relevant stakeholders, the LS methodology additionally focuses on finding the "earlyvangelist" - customers who are not only actively looking for an alternate solution but are displaying the strength of their need by engaging in, often self-discovered, makeshift ways of addressing it (Blank, 2006).

The next stage of ED is that of Conceptual Design, where the use of tools involving abstraction of essential problems, establishment of function structures and ideation techniques, such as, Brainstorming and Synectics, result in the specification of the principal solution, i.e., the concept. The largely open-ended nature of this stage allows one to explore and contemplate all the aspects of a problem and its potential solutions. In LS on the other hand, iterative testing of well-defined, falsifiable hypotheses about the business model, through a "get out of the building" approach (Blank and Dorf, 2012) seeks empirical evidence and converts them into objective learnings for customer validation.

The third stage of ED is that of Embodiment Design, where concepts are converted into a layout containing technical details, which is then tested for function, ergonomics, strength, aesthetics etc. These test results are used to optimize the layout, production, financing, manufacturing, and other plans of the design before taking it forward to the final stage of Detail design. This stage results in the generation of all final documents for production and manufacturing of the designed product (Pahl and Beitz, 1996).

https://doi.org/10.1017/pds.2022.4 Published online by Cambridge University Press

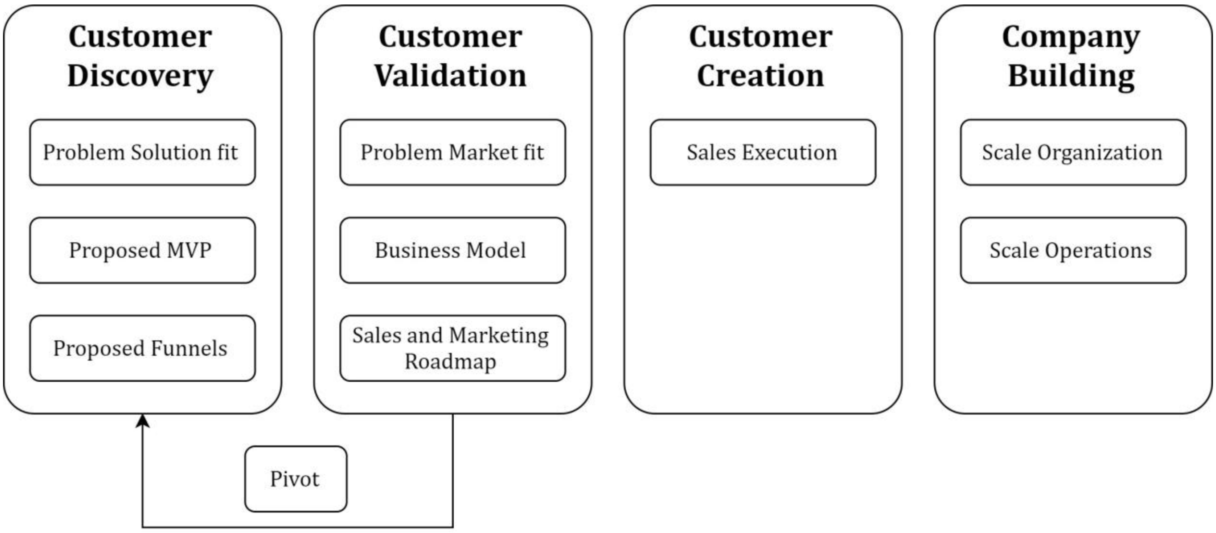

Figure 2. The lean start-up methodology adopted from Cooper and Vlaskovits (2010)

In contrast, LS advocates the iterative development and testing of a Minimum Viable Product (MVP) which, according to Ries (2011), is "that version of the product that enables a full turn of the Build-Measure-Learn loop with a minimum amount of effort and the least amount of development time"; before making market-oriented, informed decisions about pursuing or pivoting the business model. In the following steps of LS, the details of design, production, manufacturing, etc. are finalised, and various means are used to create market demand, and eventually for business scale up (Ries, 2011).

2.2. Research gaps and objective

Each methodology is well supported by an active community of proponents. These communities have specific goals which are aligned in certain aspects. However, they often tend to operate in silos, with little interchange of potential ideas.

Further, there is a lack in the availability of practical guidelines illustrating comparisons amongst methodologies, in a usable manner during design. Such an exercise would reinforce theoretical deductions and could potentially identify nuances that may not be otherwise visible.

Thus, the objective of this paper is to address this need by undertaking a comparative analysis of the 'user-in-the-loop' approach to ED and LS methodologies using three case studies.

3. Research methodology and approach

Three medical devices under development at the Indian Institute of Science were chosen for the study. These devices have the common objective of addressing an unmet clinical need within resource constrained settings, and the study authors have worked on them as part of a larger research group. This common objective and design team is the basis for selection of these projects.

Subsequent to selection of the case studies, a set of criteria were derived from literature (Hildenbrand and Meyer, 2012; Lichtenthaler, 2020; Mueller and Thoring, 2012) which serve as the basis of comparison. These criteria broadly include the general goals and specific focus of both methods, the approaches, specific process steps, as well as the respective outcomes. Results and more detailed descriptions of both strategies are provided in the two following sections. The workflow undertaken for this paper is summarized in Figure 3.

While case study 1 (CS1) began with a problem brief of insulin pumps being unaffordable in the Indian market, multiple other problems were identified and prioritized. Stakeholders were not clearly identified prior to interviews, and their understanding only evolved as further interactions/interviews were conducted. More importantly there was no presumption of what the possible solution/concept to address these problems might be (Karia et al., 2019).

https://doi.org/10.1017/pds.2022.4 Published online by Cambridge University Press

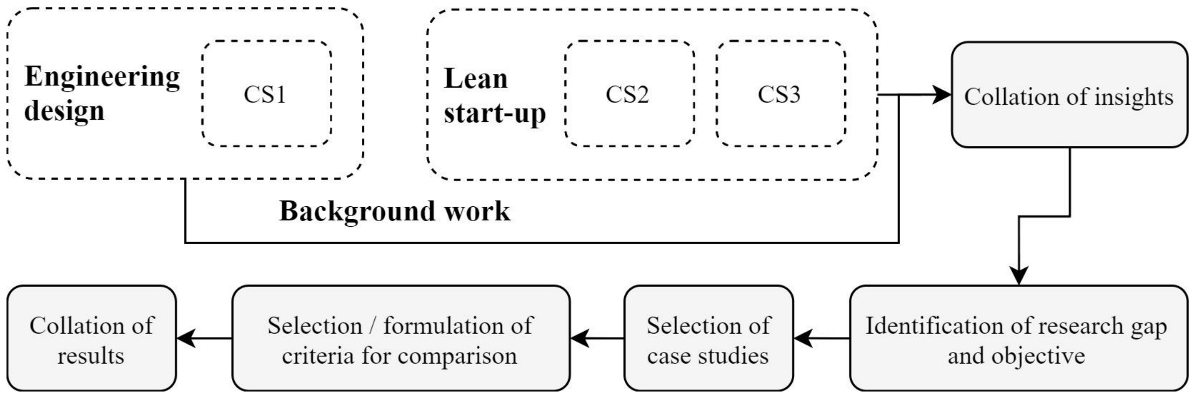

Figure 3. Workflow undertaken for the study

LS begins with customer discovery wherein a problem and a possible solution must be pre-defined. Once hypotheses related to this are iteratively validated, an MVP is developed which must again be iteratively validated (Blank, 2006). Case studies 2 and 3, (CS2) and (CS3) respectively, began with an identified problem and a pre-conceived notion of what might be a solution to address it.
A summary and the methodology adopted for development are provided in the section below:

3.1. Case study 1 (CS1) - An affordable insulin pump for type-1 diabetic patients

Despite being the gold-standard for management of type 1 diabetes mellitus, adoption of insulin pumps is sparse in resource constrained settings like India because of their prohibitive prices. Yog-i is a novel, affordable insulin pump, which costs a fraction of commercially available devices.
The project has adopted a user-in-the-loop approach to ED (Karia et al., 2019). It began with multiple stakeholder interviews, discussions, and empathy exercises. At the end of each design stage, stakeholders were consulted and based on their feedback, course corrections, if necessary, were undertaken. Conceptually, multiple ideas were brainstormed, leading to development of several prototypes and a novel mechanism that allows for significant cost reduction. Delivery accuracy (by volume) of initial prototypes were not clinically acceptable. This was iteratively addressed via minor modifications to the mechanism. The current prototype, however, is larger than commercially available pumps, which is attributed to limitations of additive manufacturing as a prototyping method. The group did not have an in-depth understanding of the LS approach prior to undertaking this design exercise, making them unbiased towards a particular approach.

3.2. Case study 2 (CS2) - Meraki: A portable pelvic floor exerciser for women with urinary incontinence

Pelvic floor muscle exercise is often the frontline treatment for urinary incontinence in women, but it is difficult to identify and isolate these deep-seated muscles in order to perform the exercises correctly. For women who can identify these muscles, the prescribed routine is taxing. Meraki is a novel system that addresses these issues by allowing patients to perform the exercises correctly, anytime, anywhere.
The project developed around an initial idea of a ‘portable, wearable, pelvic floor muscle exerciser’, and adopted the LS-based approach in the design process. Several in-depth discussions led to the identification of customer segments whose pain could be addressed via the conceptualized device. For each customer segment, the archetype was identified, attributes listed, and journey maps created. Several hypotheses, covering various sections of the BMC, were generated, and tested in 102 problem interviews. The business idea underwent several iterations, until the "earlyvangelists" were identified, and a "problem-solution fit" (Blank and Dorf, 2012) was reached. Currently, the team is building the MVP for testing in subsequent stages, with the goal of achieving a "product-market fit" (Blank and Dorf, 2012).

https://doi.org/10.1017/pds.2022.4 Published online by Cambridge University Press

3.3. Case study 3 (CS3) - Dhwani: A holistic rehabilitation solution for children with hearing impairment

Hearing impairment impedes the normal development of speech and language skills in children. The standard of care for such children involves providing appropriate amplification devices (external/implanted) followed by speech and language therapy. Regular adherence to therapy requires considerable time commitment by the parent/caretaker and is a financial burden due to cost of therapy sessions coupled with possible loss of wages for parents/caretakers. Dhwani is a holistic rehabilitation solution, wherein a smartphone application facilitates home-based therapy for children with hearing impairment (Nambiar et al., 2018) (Karia et al., 2019).

It began with a broad problem brief provided by a clinician. Preliminary interviews with stakeholders helped identify critical problems within the ecosystem: prohibitive costs, and a dearth of qualified speech therapists in resource-constrained settings. While these interviews also provided some understanding of the stakeholders, several other aspects were unclear to the team. These included price-points which would be affordable, methods to reach out to parents/caretakers among other items. LS was then adopted at this stage and a pathway similar to CS2 followed. A total of 108 interviews were conducted to develop, test, and validate the generated hypotheses. A set of earlyvangelists were identified for subsequent interactions. An MVP was developed for each sub-system, which were then evaluated by these earlyvangelists (Venkatesh et al., 2021). Feedback and insights received were used to modifications prior to a pilot clinical investigation.

4. Analysis

The results of the study are summarized criteria-wise: a descriptive comparison followed by a one-on-one comparison provided in Table 1. The following criteria have been found appropriate:

Hypothesis testing (Mueller and Thoring, 2012; Lichtenthaler, 2020); Iteration (Hildenbrand and Meyer, 2012; Mueller and Thoring, 2012); Ideation, Business Model, Prototype testing (Hildenbrand and Meyer, 2012; Mueller and Thoring, 2012; Lichtenthaler, 2020); Qualitative and Quantitative methods, Adaption of deployments, Solution focus, and Final output (Mueller and Thoring, 2012);Emphasis (Hildenbrand and Meyer, 2012; Lichtenthaler, 2020).

It is important to acknowledge here that practice of any innovation methodology involves multiple intangible elements such as the experience and make of the team, mindset, timeframes involved etc. While the effect of such variables cannot be negated, it has been possibly minimized by selection of a common team and design objective (medical devices for resource constrained settings).

4.1. Approach:

The traditional approach to ED, while being highly iterative only provides for stakeholder interaction in the initial stage of task clarification and hereon, are largely excluded in the subsequent development (Pahl and Beitz, 1996). CS1 adopted the 'user in the loop' approach to ED which included engagement of stakeholders at the end of each stage. The approach allowed for validation/reorientation of the product development direction at critical junctures (Karia et al., 2019). A stakeholder analysis was also done to deepen the team's understanding of each stakeholder.

LS with its business model centric approach is focused on customers (Blank, 2006). The initial phases of the methodology use several tools to understand potential customers. Their archetypes (end user, buyer, influencer, recommender, saboteur, etc.) are identified, attributes listed and the role and importance of each customer in the overall ecosystem is understood (Blank and Dorf, 2012). In both CS2 and CS3, these activities were followed by the identification of earlyvangelists.

4.2. Iteration vs. Pivot:

The ED process is an iterative one, in that the outcomes after each stage are analysed against the initially defined, expected outcomes and several steps of the process are repeated until a satisfactory end point is reached (Pahl and Beitz, 1996). The 'user in the loop' approach to ED adopted in CS1 made it possible for the team to receive user feedback on the outcomes after each stage and iterate accordingly (Karia et al., 2019).

https://doi.org/10.1017/pds.2022.4 Published online by Cambridge University Press

The LS process is also cyclic in nature, in that it uses the "build-measure-learn" loop (Reis, 2011), which involves iterative building of the MVP, testing of hypotheses and refining of the business model. However, the LS process also emphasizes the importance of "pivoting" or making structural course corrections when it is seen that a significant change is required to align the business model to market needs (Blank and Dorf, 2012).

In CS2, identification of pharmaceutical companies as the top potential competitor led to revision of the business model to include an appropriate differentiating factor, and re-positioning within the same market. In CS3, customer discovery resulted in the identification of a new customer segment (speech therapists), and their corresponding value propositions. Attempts to meet this value proposition led the team to pivot and include a "response system" as part of the intervention.

Table 1. Comparative analysis of process outcomes

Criteria	ED exemplified by CS1	LS exemplified by CS2, CS3
Hypothesis testing	No explicit formulation of a hypotheses. Design output tested against test cases derived from requirements Within CS1, perceived needs were interpreted, clustered (stakeholder requirements) and converted into technical requirements by means of quantitative tools. Test cases were derived from this, against which the design output was evaluated. This allows for closed loop traceability, which is particularly important for medical devices to ensure patient safety (Ward et al., 2003).	The use of coherent and falsifiable hypotheses about relevant variables is central to the process. All hypotheses are tested and have implications for decisions. Both CS2 and CS3 involved iterative formulation and testing of hypotheses, primarily about who the potential customer is, what the proposed benefits are and why the customer will choose them, based on the initial business idea. In CS3, leap-of-faith assumptions related to design constraints of MVP and business viability of the product were formulated and tested. The test output was used to refine both the hypotheses and the business idea.
Iteration	Longer iteration cycles, undertaken after some concepts/preliminary prototypes are available. An example of this in CS1 is a change in embodiment of the pump triggered by stakeholder feedback in the embodiment design stage (Pahl and Beitz, 1996). This could have potentially been identified earlier if each assumption within the process was subjected to validation.	Shorter iteration cycles. Hypotheses are tested and modified rapidly. In CS2 and CS3, customer interviews were used as the primary mode of hypothesis testing. The implementation was quick and inexpensive, resulting in an efficient cycle for fast feedback. For example, the identification of earlyvangelists and of the importance of the role of clinicians, in the initial stages of the design process in CS2 and CS3 respectively, helped in the timely course correction of the path for product development.
Ideation	Structured tools for concept generation are available to the innovator. Primary functions that the device must fulfil were defined, and ideas to achieve each of those functions were conceptualised using tools such as brainstorming, synectics and trigger words. These were collated in a morphological matrix to generate multiple device concepts (Pahl and Beitz, 1996).	Ideation is not a part of the process. The process begins with an initial business idea, which may have been developed systematically, outside of the framework, or may simply refer to a vision of the start-up. This idea is then tested for alignment with the market and may change during the process (Mueller and Thoring, 2012).

https://doi.org/10.1017/pds.2022.4 Published online by Cambridge University Press

Qualitative methods	Strong focus. Multiple tools are available to the innovator, particularly for developing a thorough understanding of the stakeholders involved. A diverse set of stakeholders (patients, endocrinologists etc.) were identified initially in the task clarification stage. Understanding of these stakeholders was developed and refined using tools such as persona development, journey mapping, among others. This thorough understanding allowed identification of requirements which may not have been explicit by mere interviews/observations.	Not a strong focus. Qualitative methods are often used to gain an initial understanding and generate hypotheses which are subsequently validated via other techniques. Within CS2 and CS3, for a better understanding of each customer segment, user personas, journey maps (current and envisaged scenarios) and customer jobs-pains-gains charts were created. Ecosystem mapping was useful for understanding the network and various interconnections of the stakeholders involved. Further, the generation of the initial set of hypotheses and customer interviews for testing them, both used qualitative methods.
Quantitative methods	Strong focus on objective development. Availability of multiple such tools allows for the same. Within CS1, conversion of interpreted needs into technical requirements was done using competitive benchmarking and the house of quality (Pahl and Beitz, 1996) methodology.	Strong focus on objective outcomes as a measure of validation of the business idea. Within CS2, success criteria were defined for the test of each hypothesis and acceptable evidence was required to be empirical in nature. Within CS3, quantitative methods were further employed for usability tests to improve specific design elements.
Business model	Not an explicit focus. A limited set of business aspects were looked at during the task clarification stage. These include the total available market, growth rate, competing insulin pumps available among other items.	Strong foundational focus. Process revolves around validating the various elements of the business model. In CS2, the initial business idea was mapped onto the Business Model Canvas (BMC), which was then used as a tool, for enabling a meaningful transformation of the initial idea, throughout the process until a Problem-Solution Fit (Blank and Dorf, 2012) was obtained. The same was used further to the stage of a Product-Market Fit (Blank and Dorf, 2012) in the case of CS3.
Adaption of deployments	Limited tools available. Interpretation depends on multiple tacit elements such as the designer's experience, empathy exercises undertaken etc. Within CS1, user needs collected were interpreted and clustered based on an understanding gained by the authors.	Multiple tools available, to be employed during customer interaction, for the derivation, interpretation, and refinement of hypotheses. In both CS2 and CS3, the Five Whys Method (Ries, 2011) was used to understand the core aspects of the various concerns, attitudes and viewpoints expressed by the customer. This understanding was used to refine the hypotheses at each step.

https://doi.org/10.1017/pds.2022.4 Published online by Cambridge University Press

Prototype testing	Undertaken for a proof-of-concept (PoC) or prototype of the device, which attempts to test whether requirements are being met/addressed. Within CS1, multiple concepts brainstormed for each function structure were evaluated with a PoC. Once a concept was derived via the morphological chart, a prototype device was developed for testing with the relevant stakeholders.	Undertaken for an MVP, which attempts to test technical specifications as well as business-related hypotheses. The MVP can take multiple forms, which include video demonstrations, hardware prototypes etc. Within CS3, MVPs were built and tested for each sub-system. Learnings from each test were used to improve subsequent iterations. Demonstration videos, wireframes of the application design and digital mock-ups were used for testing. The team is currently testing the response system of the device with earlyvangelists.
Emphasis	The conceptual design stage is focused on novelty of outcomes that can address the identified function structures. The device being affordable for the target stakeholders was an important requirement for CS1. When the reasons for the prohibitive cost of commercially available devices was understood, concepts were brainstormed that could potentially address these constraints.	Focused on market differentiation and positioning. In CS2, it was seen that a large section of the identified earlyvangelists were using pharmacotherapy as a treatment solution. On understanding their reason for using the same, the team was able to identify pharmaceutical companies as their top competitors and accordingly develop a strategy of 'differentiation and positioning' for the target market.
Solution focus	Strives for solution neutrality in the task clarification stage Requirements derived in this stage culminate into the formulation of a solution neutral problem statement (SNPS) (Pahl and Beitz, 1996) which serves as an input to the conceptual design stage. As the name suggests, this statement must succinctly summarise the key problem being addressed via the design exercise, while being agnostic to the solutions for the same.	Highly dependent on the solution. LS revolves around the validation of a solution, which was available before the process began. Iterative testing of hypotheses and refinement of the business model results in iterations of the solution itself. This allows for better alignment with the market.
Final output	Tested prototype CS1 has undergone multiple cycles of prototype building and is currently undergoing in-vitro testing prior to a pilot clinical investigation.	Viable business concept for an innovative start-up The final envisaged output for both CS2 and CS3 is a start-up. However, at the current point in time, CS2 has achieved problem-solution fit, whereas CS3 has achieved problem-market fit and requires further work for MVP building and testing.

5. Discussion

This paper analyses three case studies of products developed with the 'user in the loop' approach of ED and LS methodology, based on criteria identified across literature to assess the suitability of each methodology. Through the comparative analysis, it is found that ED is unsuitable for start-ups, wherein optimal use of resources is critical for survival, as it lacks effective tools to evaluate the commercialization potential of the unmet needs identified. However, once a need is identified and established, structured ideation techniques in ED can generate novel concepts and can provide for methods to translate selected concepts to prototypes. However, such prototypes only allow for limited functional/user testing. In contrast, LS is found suitable for resource-constrained environments because it saves the entrepreneur prototyping costs, prior to receiving validation from a customer/stakeholder. While concept generation and prototype development does not fall within the ambit of the LS approach, it does allow for testing a product/business hypothesis via an MVP, without the need for a functional prototype. Shorter iteration cycles of LS further reinforce this suitability. In summary, this work has

https://doi.org/10.1017/pds.2022.4 Published online by Cambridge University Press

provided a comparative understanding for innovators beyond the theoretical outlines presented in available literature for employing ED and LS approaches. Emphasis has been laid on the specific tools, implementation used in each methodology, with any benefit/limitation accordingly highlighted. This could potentially help innovators gain a comprehensive understanding of the methodologies and their respective nuances.

Multiple avenues of interchanging specific tools and processes between the two methodologies to leverage their respective strengths have been identified. Such a hybrid-approach, drawing from elements of ED and LS, has been detailed by Shah et. Al. (2019) for the task clarification stage and beckons the opportunity to detail out subsequent stages in the future. Similar approaches are also available in literature, wherein a combination of LS with Design Thinking (Furr and Dyer, 2014; Hildenbrand and Meyer, 2012), and Scrum (Dobrigkeit et al., 2019) have been proposed. While these hybrid methodologies may have their inherent benefits, adopting them in a team is restrictive in terms of training requirements (Furr and Dyer, 2014). An immediate, pragmatic adoption approach could be to evaluate the nature of the project beforehand and select a primary methodology, with certain external tools adopted as required, subject to the existing skillset of the team and the nature of the product being developed. As a generalization, beginning with need identification via ED and subsequent adoption of hypothesis and MVP testing tools from LS, for the task clarification and conceptual design stages is recommended.

A limitation of this work noted is, that the understanding gained by the authors in CS1 may have affected execution of the other two case studies. As an example, formulation of hypotheses is akin to formulating requirements, in that both have overlapping characteristics; clear, concise, testable (Blank and Dorf, 2012; Cespedes et al., 2012; Ward et al., 2003). This prior practice with an innovation methodology (i.e., ED) may have overshadowed some potential shortcomings of LS. Effects of these tacit elements need to be further investigated. The scope of this study is also limited to a comparative analysis of the two methodologies and does not evaluate the effectiveness of each, which warrants an empirical study.

Acknowledgement

We acknowledge the funding from: (i) the Indian Council of Medical Research (ICMR) as part of the IMPRINT program of the Ministry of Human Resource Development, Government of India, and BIRAC, Department of Biotechnology, Government of India, as part of the BIG program for CS1, (ii) NSTEDB, PMU-SINE, and IKP EDEN as part of the NIDHI-PRAYAS program for CS2, and (iii) BIRAC, Department of Biotechnology, Government of India, as part of the PACE program for CS3. We would also like to thank members of the Gopalakrishnan-Deshpande Centre for Innovation and Entrepreneurship, IIT Madras for their courses and programs on the LS methodology, and C-CAMP for their mentorship and support as funding partners for CS1.

References

Blank, S. G. (2006), *The Four Steps to the Epiphany: Successful Strategies for Products that Win*, Foster City, Calif.: Cafepress.com

Blank, S. G. and Dorf, B. (2012), *The Startup Owner's Manual: The Step-by-Step Guide for Building a Great Company*, Pescadero, CA: K&S Ranch Publishers.

Cespedes, F. V., Eisenmann, T. and Blank, S. G. (2012), "Customer discovery and validation for entrepreneurs", *Harvard Business School Entrepreneurial Management Case*, 812 - 097.

Christensen, C. M. and Raynor, M. E. (2003), *The Innovator's Solution: Creating and Sustaining Successful Growth*, Boston, MA: Harvard Business Review Press.

Cooper, B. and Vlaskovits, P. (2010), *The Entrepreneur's Guide to Customer Development: A "cheat sheet" to The Four Steps to the Epiphany*, CustDev.

Dobrigkeit, F., Paula, D. and Uflacker, M. (2019), "InnoDev: A software development methodology integrating design thinking, scrum and lean startup", *Design Thinking Research*, pp. 199-227, Springer, Cham. https://doi.org/10.1007/978-3-319-97082-0_11

Furr, N. and Dyer, J. (2014), *The Innovator's Method: Bringing the Lean Start-up into your Organization*, Harvard Business Review Press.

Gama, K., Castor, F., Alessio, P., Neves, A., Araujo, C., Formiga, R., Soares-Neto, F., and Oliveira, H. (2018), "Combining challenge-based learning and design thinking to teach mobile app development", *IEEE Frontiers in Education Conference (FIE)*, Vol, 1, pp. 1 - 5. DOI:10.1109/FIE.2018.8658447

Hildenbrand, T. and Meyer, J. (2012), "Intertwining lean and design thinking: software product development from empathy to shipment", *Software for people*, pp. 217 - 237, Springer, Berlin, Heidelberg. DOI 10.1007/978-3-642-31371-4_13

Karia, D., Nambiar, R. S. and Arora, M. (2019), "An affordable insulin pump for type-1 diabetic patients: a case study of user-in-the-loop approach to engineering design", *Proceedings of the 22nd International Conference on Engineering Design (ICED19)*, Vol. 1, No. 1, pp. 847 - 856, Cambridge University Press. DOI:10.1017/dsi.2019.89

Karia D., Nambiar, R. S., Maurya, A.P., Ramesh A., Arora M., Application of waterfall design process in designing of a holistic system for children with hearing impairment in resource-constrained settings, in International Conference on Research into Design, Jan 2019

Koen, P. (2015), "Lean startup in large enterprises using human-centered design thinking: a new approach for developing transformational and disruptive innovations", *Howe School Research Paper*, 2015 - 46.

Lichtenthaler, U. (2020), "Agile innovation: the complementarity of design thinking and lean startup", *International Journal of Service Science, Management, Engineering, and Technology*, Vol. 11 (1), pp. 157 - 167. DOI: 10.4018/IJSSMET.2020010110

Mueller, R. M. and Thoring, K. (2012), "Design thinking vs. lean startup: a comparison of two user-driven innovation strategies", *Leading through design*, 151, pp. 91 - 106.

Nambiar, R., Karia, D., Venkatesh, K., Ramesh, A., Thattankandy, A., Nair, S., Maurya, A. P., Ramesh, A. and Arora, M. (2018), "A holistic approach to the design of hearing aids for children with hearing impairment in resource constraint settings", *IEEE Global Humanitarian Technology Conference (GHTC)*, pp. 1 - 7. DOI: 10.1109/GHTC.2018.8601903

Osterwalder, A. and Pigneur, Y. (2010), *Business Model Generation: A Handbook for Visionaries, Game Changers, and Challengers*, John Wiley & Sons.

Pahl, G. and Beitz, W. (1996), *Engineering Design: A Systematic Approach*, Springer, Berlin. http://dx.doi.org/10.1007/978-1-4471-3581-4

de Paula, D. F. O. and Araujo, C. C. (2016), "Pet empires: combining design thinking, lean startup and agile to learn from failure and develop a successful game in an undergraduate environment", *International Conference on Human-Computer Interaction*, pp. 30-34, Springer, Cham. https://doi.org/10.1007/978-3-319-40548-3_5

Pease, J. F., Dean, J. H. and Bossuyt, D. L. V. (2014), "Toward a market-based lean startup product design method for the developing world", *Proceedings of the ASME 2014 International Design Engineering Technical Conferences & Computers and Information in Engineering Conference*, Vol. 46315, p. V02AT03A045. https://doi.org/10.1115/DETC2014-34150

Ries, E (2011), *The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful Businesses*, Currency

Schelle, K. J., Gubenko, E., Kreymer, R., Naranjo, C. G., Tetteroo, D. and Soute, I. A. C. (2015), "Increasing engagement in workshops: designing a toolkit using lean design thinking", *Proceedings of the Multimedia*, Interaction, Design and Innovation, pp. 1 - 8. https://doi.org/10.1145/2814464.2814481

Shah, K and Arora, M (2021) Requirements Capture and Validation: Adopting the Lean Approach for Task Clarification. In: 8th International Conference on Research into Design, 7-10 Jan 2021, pp. 733-744.

Venkatesh, K., Karia, D., Jayaprakash, S., Nair, R., Manalel L., A. Ramesh and Arora, M. (2021). Design of Response Channels to Augment Speech and Language Rehabilitation in Children with Hearing Impairment. 10.1115/DMD2021-1028. In Proceedings of the 2021 Design of Medical Devices Conference, 12-15 April 2021.

Ward, J., Shefelbine, S. and Clarkson, P. J. (2003), "Requirements capture for medical device design", *Proceedings of ICED 03, the 14th International Conference on Engineering Design*, Stockholm, pp. 65-66.

Ximenes, B. H., Alves, I. N. and Araujo, C. C. (2015), "Software project management combining agile, lean startup and design thinking", *Design, User Experience, and Usability: Design Discourse, Lecture Notes in Computer Science*, Vol. 9186, Springer, Cham. https://doi.org/10.1007/978-3-319-20886-2_34