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Lost in Transit: Implications and Insights for Making Medical Task Trainer Prototypes with an Open Source Hardware Paradigm

D. N. Ege ✉, M. Auflem and M. Steinert

Norwegian University of Science and Technology, Norway
✉ danieneg@stud.ntnu.no

Abstract

This paper presents an open-source novel intravenous cannulation task trainer developed during the Covid-19 pandemic for unsupervised clinical skill practice. Multiple user errors were uncovered when observing 13 registered nurses using the task trainer during a two-hour unsupervised skill training session. These insights raise the question of how OSH needs to share more than just device descriptions and assembly instructions- as designs are being shared only in its current state of an ongoing project, sharing insights, user errors and test results should be encouraged and prioritized.

Keywords: open source design, prototyping, medical task trainer, healthcare design, prototype testing

1. Introduction

With the Covid-19 pandemic requiring remote working, virtual training, and education, we are witnessing increased initiatives that transfer product development from professionals to the public through the emergence of Open-Source Hardware (OSH). These initiatives are sparked by the ease of sharing information and digital blueprints online and the growing accessibility of distributed manufacturing equipment such as 3D printers (Bonvoisin et al., 2017; Boujut, 2019). OSH is based on the open-source principles that originated for software (Open Source Initiative, 2007) and transfer these to tangible artifacts, machines, and devices whose design has been released so that anyone can make, modify, distribute, and use them (Balka and Herstatt, 2011). This transformation is not straightforward, as while software can be displayed and shared online without specific tools, physical objects need to be described through more complex constructs (Bonvoisin and Boujut, 2015), such as CAD models and assembly guides. Still, recent efforts of openly sharing hardware designs and projects for free allow for more collaboration with others with similar needs and increase the speed of innovation (Daniel K. and Peter J., 2012). OSH enables designs and product solutions to be distributed instantly by relying on people's ability to manufacture and assemble equipment/products/hardware themselves. It has given researchers access to expensive test equipment for a fraction of the cost (Pearce, 2014). The medical technology sector also calls for more OSH tools to reduce costs and democratize access to new technology (Linde and Kunkler, 2015). Examples exist of OSH solutions for this sector, including Open Source CT scanners, infusion pumps, and prostheses (Niezen, Eslambolchilar, and Thimbleby, 2016).
Given this context, we consider a case of a novel intravenous cannulation task trainer developed during the Covid- 19 pandemic. Throughout this development project, prototypes were used to probe an ambiguous solution space (Gerstenberg et al., 2015) to learn as quickly as possible (Lauff, Kotys-

Schwartz, and Rentschler 2018) and validate assumptions (Lim et al., 2008; Menold et al., 2017). Users were consulted from the initial phases to uncover current task trainers' needs and pain points (Sutcliffe and Sawyer 2013). Sufficient fidelity and realism were captured by continuously testing prototypes with expert users, as suggested by Ege et al. (2021), while mitigating the risk of severe obstacles later in the project (Thomke and Reinertsen 1998; Takeuchi and Nonaka 1986). Intentional and reflective prototypes were built and tested with users to explore specific dimensions of the concept (Houde and Hill, 1997) and to elicit experts' tacit knowledge at an early stage of development, as previously demonstrated by Auflem et al. (2019) and Ege et al. (2020). Prototypes were developed through design-build-test cycles, as described by Gerstenberg et al. (2015), driving the development as new insights and knowledge got revealed.

The case presented in this paper showcase both the development journey of an IV cannulation trainer, the deployment of this trainer in structured user testing, and the obtained insights and implications for utilizing this device in unsupervised training scenarios as an OSH design. The case exemplifies and highlights the importance of structured user-testing and user-centered design mindset when providing OSH healthcare training solutions. By showcasing the prototyping journey of this case project, we aim to exemplify user-centered and prototype-driven development of medical training equipment. Moreso, we show how to effectively deploy prototypes with users to gain valuable insights for further development, and for sharing insights in the context of OSH solutions. By piloting the concept, the authors observed several procedural errors performed by users. Without testing, these errors and other interactions would not have been identified. By the insights presented we raise the question of how OSH needs to share more than just device descriptions and assembly instructions- as designs are being shared only in its current state of an ongoing project, sharing insights, user errors, and test results should be encouraged and prioritized.

2. Background

Nurses are expected to apply cognitive, psychomotor, and procedural skills when performing essential medical procedures in clinical environments. Intravenous (IV) cannulation is such an essential skill, in which a cannula is placed inside a vein to provide venous access to treat various types of patients, sample blood, and administer fluids in acutely or critically ill patients (Jones et al. 2014). Intravenous cannulation is among the most common procedures nurses face, and most of all hospitalized patients undergo it (Devenny et al., 2018). Generally, educators use medical task trainers or fellow students for teaching IV cannulation skills. Several task trainers for practicing IV cannulation exist on the market, ranging from full-size human mannequins to small, wearable pads to simulate cannulation, injections, and blood tests. These, to different degrees, embody both physical and visual attributes of the human arm to facilitate realistic motor skill training without the risk of infections and injuries associated with practicing on fellow students.

Jacobson and Winslow (2005) found that almost a quarter of all IV insertion attempts were unsuccessful. Nurses needed two and even three shots before correctly placing the cannula in a vein. This low success rate can be critical in acute situations where patients rely on quick access to medicine and blood (Witting 2012). Experienced nurses show significantly higher success rates than those less skilled (Jacobson and Winslow 2005), indicating a need for easily accessible equipment for skill training. Available commercial training equipment can provide equivalent procedural skill training to training using fellow students, without the percutaneous and infectious risk involved in practicing on peers (Jones et al. 2014). However, these task trainers are both often expensive and tedious to use and maintain. Even though they are available to educational institutions, they are not widely available or used by practicing health care professionals. Furthermore, with the Covid- 19 pandemic requiring remote working, virtual training, and education, the availability of skill training equipment has decreased for medical students alike.

As a response to the COVID-19 pandemic, designs for medical personal protective equipment PPE, ventilators and oxygenation were shared in various communities (Mora, Duarte, and Ratti 2020). Furthermore, medical training equipment is also being shared and published free online, such as intubation task trainers made using low-cost materials and 3D printers (Park et al. 2019; Tasnim, Parikh, and Naik 2020) that simplify access to task training equipment. Because of postponed and canceled clinical skill exercises, the demand for self-directed learning in healthcare education has increased. Open-source solutions for practicing procedures have therefore been made available, and several tasks are now being taught through self-directed learning. For instance, Gieswein et al. (2021) developed low-fidelity simulation models from household items for medical students to make themselves to practice essential procedural skills without access to the high-fidelity training equipment in a simulation center traditionally used. These skills included central venous catheterization and emergency airway management.

3. Development of an open-source IV cannulation task trainer

In response to the highlighted challenges with IV cannulation training, the authors have developed a novel task trainer concept for use in medical education and the repetition of skill training (Figure 3). In the preliminary design phases, expert users, in this case, registered nurses, were consulted to uncover needs and functional requirements. Initial requirements included a realistic feel and look, as well as easy use and maintenance. The task trainer must also simulate blood flashback, in which blood fills a chamber in the back of the cannula when correctly placed in a vein. Issenberg et al. (1999) argue that medical training equipment needs to provide users with feedback, allow repetitive practice, integrate with the curriculum, and simulate clinical variation. These factors also influenced the design of the final concept.

Initial prototypes, illustrated in Figure 1, were made to elicit expert users' tacit knowledge quickly as a primary bounding object between designer and practitioner. A latex glove (Prototype 1) with thin-walled tubes glued to the inside was presented to expert users to observe their interaction with a wearable task trainer. Prototype 2 informed material selection and tactile and visual realism of the eventual final design. It showed that a silicone skin and thin silicone tubing could recreate parts of the tactile sensation of inserting a cannula in a patient's vein but lacked the possibility of veins to move more freely under the skin. Prototype 3 addressed this by stretching silicone over a sponge with silicone tubing laying free underneath. Iterating on this concept, Prototype 4 implemented a 3D printed case. Prototype 5 improved this design before it was optimized for 3D printing and simpler manufacturing in the final design.

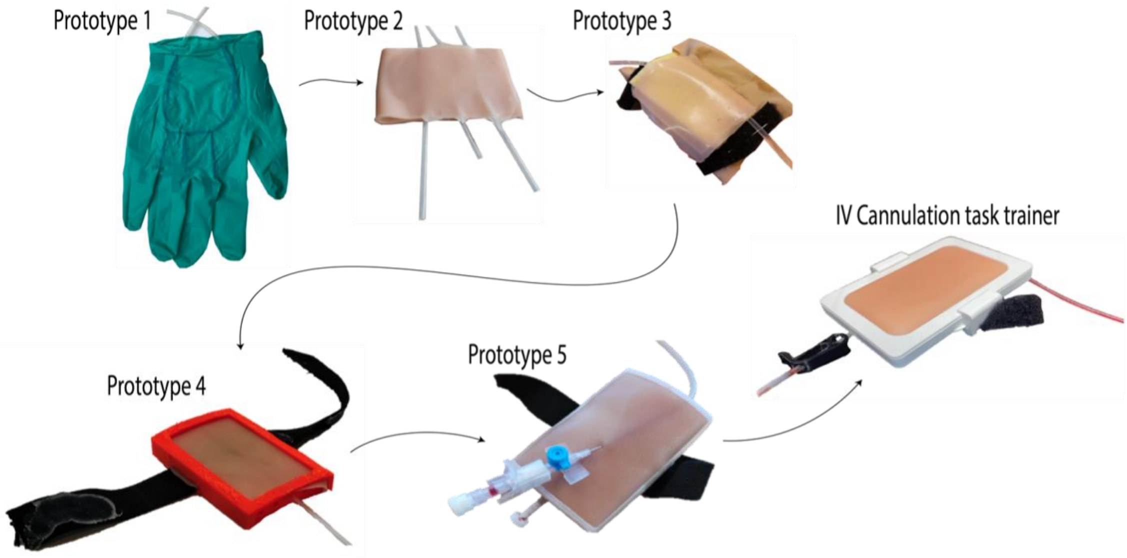

Figure 1. Iterative prototyping journey

Figure 2 show and describe all the components of the final IV task trainer concept. The 3D- printed case consists of a top and bottom part that snaps together to keep all components in place. Depending on the training scenario, a clamp and flexible strap make it possible to attach the task trainer to someone's hand, arm, or leg with Velcro. The case is 120mm by 80mm, with an opening of 100mm by 60mm for the skin and vein to be palpated and a cannula inserted. Tabs in the corners of the top part stretch the skin, while openings at the front and back allow a silicone tube to move freely back and forth. The silicone skin is made from Smooth-On Ecoflex 30 platinum cure silicone with skin color. Cotton fabric that was laser cut to shape and embedded during casting gives the perimeter of the skin

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reinforcement. A casting mold made from acrylic sheets has a faux leather bottom that provides the silicone with skin texture and more realistic looks. Soft silicone tubing represents veins. The tube has an outer diameter of 4 mm and a wall thickness of 0,5 mm. The veins are filled with artificial blood and pressurized by an external reservoir (Figure 3) hung at a variable height (40 cm to 70 cm) to simulate different blood pressures. A 3D printed hose clamp is attached to the opposite end of the tube to make the system pressurized. When pierced by a cannula, blood fills the chamber in the back, indicating blood flashback. When it starts to leak after repeated use, the vein can be pulled thru the task trainer, and the clamp moved up. Used tubing can simply be cut off and thrown away, eliminating the need for flushing and washing after use as with traditional equipment. Filling the remaining of the task trainer is an 8 mm thick high-density melamine foam. A channel is cut in the foam for the vein. Changing the shape and size of this channel influences the palpability of the vein and how much it is allowed to roll, allowing for clinical variation and difficulty during exercise.

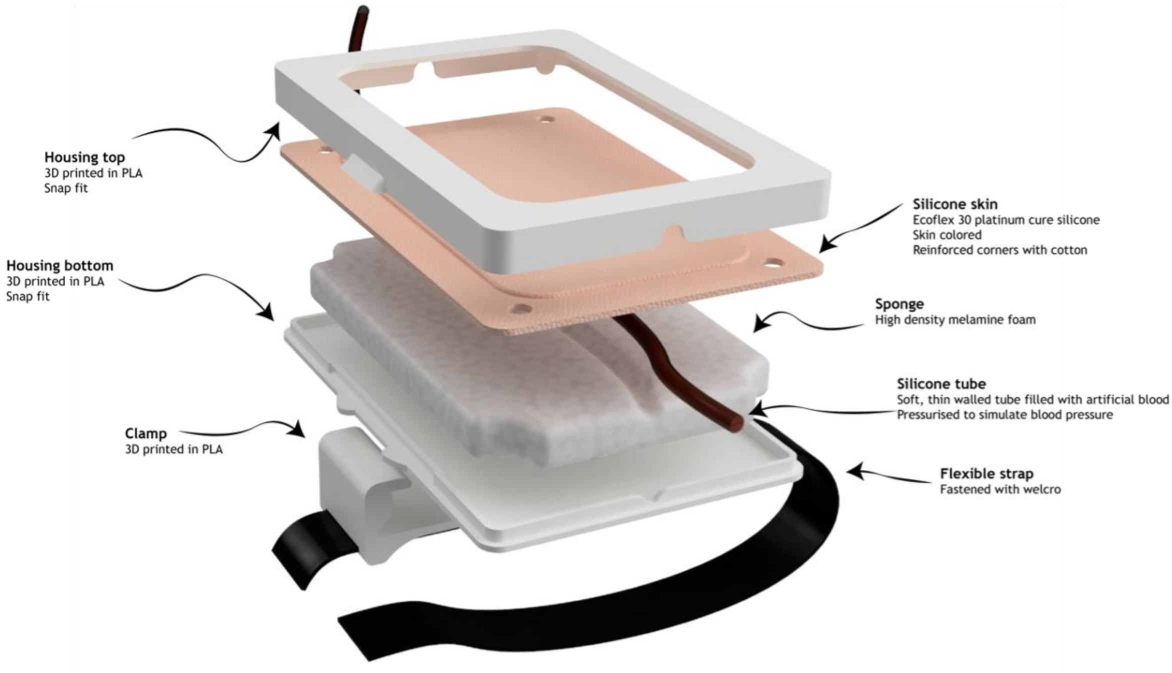

Figure 2. Exploded view of the conceptual prototype

Figure 3. Variable stand with artificial blood

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To maximize the availability of OSH, it should use readily available materials and components or custom components that anyone can easily manufacture. Therefore, the conceptual prototype presented in this paper can be manufactured using a 3D printer, laser cutter, and readily available materials. The case can be printed without support structures, minimizing sources of error during printing. To make the skin, silicone moulding was simplified by a laser-cut mould. The rest of the components can be supplied from well-equipped hardware stores or online. The final design combines the functional requirements elicited in the initial stage of development while being in line with the Open Source Hardware Associations best practices ("Best Practices for Open Source Hardware 1.0," n.d.)

4. Method

We want to observe how the task trainer prototype is used in a realistic scenario, in which nurses practice IV cannulation skills in an unsupervised group setting. To capture realistic interactions and potential errors during use, thirteen nurses and two nursing students participated in a practice session for IV cannulation in their workplace. The session lasted 2 hours. Participants were placed in pairs and practiced IV cannulation on each other with the task trainer. During the session, participants were observed and filmed to capture their interactions with the task trainer. The number of attempts each participant needed to insert the cannula correctly was counted.

Figure 4. Task trainer in use during the training session.

5. Results

Thirteen nurses and two students used on average 3,2 attempts (SD= 2,57) to correctly insert the IV cannula in the task trainer's vein. However, half of the participants used two or fewer attempts. The histogram in Figure 5 shows how many participants used the same number of attempts.

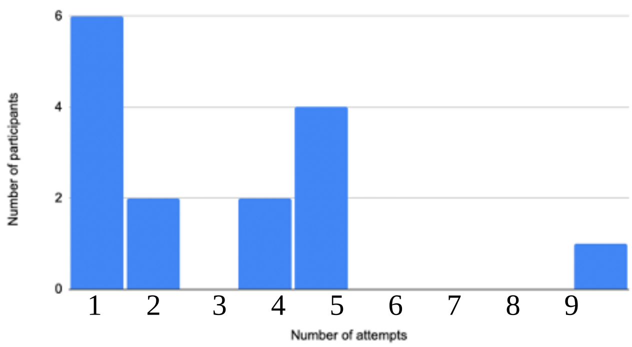

Figure 5. Histogram showing how many attempts participants used

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After the training session, an experienced nurse assisted in a video review to determine user errors and procedural mistakes. Figure 6 illustrates some of the user errors that were observed. In A, the needle was inserted far into the task trainer without receiving blood flashback. Instead of pulling the needle out and trying again, the participant further inserted the needle, which would cause excessive pain on an actual patient. B depicts a participant touching the insertion site while the needle is inserted, which significantly increases the risk of infection. In C, a participant that missed the vein moves the needle around under the skin, causing excessive pain to the patient. D shows a participant stopping blood flow while removing the needle by pressing directly on top of the catheter. The nurse should instead put pressure further up to decrease infection risk and pain for the patient. E shows how a participant left the entire needle inside the vein instead of pulling it out. This would likely perforate the vein and lead to a hematoma on an actual patient. Whereas the first 5 cases show procedural mistakes, F shows how one participant managed to simplify the procedure using the prototype's case as a guide. The vein lies perpendicular to the case, so this participant could perfectly insert the needle in the vein by using the case as a guide and sliding the catheter against it. Most of the participants were also observed touching the vein after cleaning it with alcohol, increasing the risk of infection. Several participants also used the same needle multiple times when missing the vein, which can lead to parts of the cannula breaking inside the patient's vein.

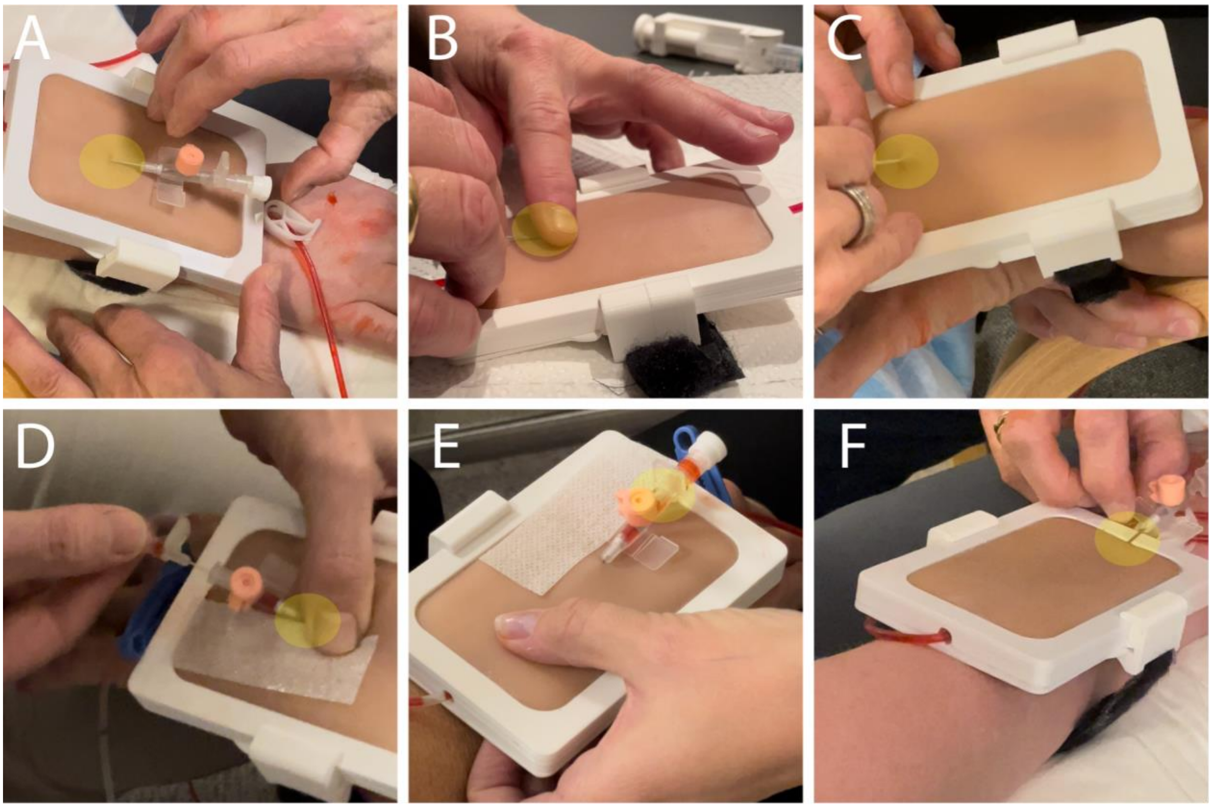

Figure 6. User errors with a yellow circle indicating the mistake. A: needle inserted too far, B: touching insertion site, C: needle moved around under the skin, D: pressure applied on top of the catheter, E: needle not pulled out, F: prototype case used a guide to align the needle with the vein.

6. Discussion

This paper describes how prototypes can be leveraged to uncover user errors through user interaction in realistic, ecologically valid scenarios. In this case, new needs and requirements arose because of the observed user errors. All participants were able to insert the cannula in a vein, indicating that the task trainer can, in fact, be used to practice IV cannulation. However, the observed user errors, both regarding the clinical procedure and use can affect the learning outcome of using the task trainer unsupervised. By learning a procedure wrong from the start, it is harder to correct it later. We,

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therefore, argue that emphasis should be put on mitigating such user errors during the design process. As shown in this paper, testing a conceptual task trainer can help discover potential user errors. This should arguably be done as early as possible so that it is possible to address them, either by design changes or by also providing user instructions. When designing training equipment emulating the human body, an inherent trade-off the designers need to address is realism and foolproof design. If the aim is to make a task trainer as realistic as possible, it needs to allow for the same mistakes that can be done on actual patients, such as the procedural errors witnessed in this study, but can at the same time allow for learning errors. The solution might be to focus more on user feedback to reduce improper use. Other OSH devices, such as open-source 3D printers, use sensors and self-calibration to mitigate user errors. Using smart sensor systems or machine vision could mitigate specific errors of the task trainer we are presenting but would increase the complexity significantly.

The development project presented here exemplifies how prototyping can be used for learning and knowledge generation. Prototypes are used actively to elicit critical functionalities to make the product function as intended and sufficiently. In this case, it concerns both building, testing, and iterating on concepts and learning about their potentials and pitfalls. A critical notion to make is how to convey this information, the tangible insights obtained through development, to mitigate sources of user error, both in the context of assembly and use. We argue that the development of OSH is more than sharing of technical blueprints. There is a need for detailed instructions and testing of design in context to reveal sources of error extending beyond the technical capabilities of the hardware itself. We also need to consider the intended end user and how we address the user when developing OSH solutions. Providing sufficient assembly instructions and making sure people can assemble and use the device is quite simple. Understanding how the product will be used/altered/interacted with is more ambiguous. Compared to traditional prototype testing and evaluation, designers lose control of this situation. As exemplified in this paper, a solution might be to observe how users interact with a device in an unsupervised setting. Then, insight and observations can be used to address this uncertainty.

While current OSH research has focused on the availability of manufacturing tools, sharing practices, and licensing, there is a lack of research and best practices regarding the development process and sharing of knowledge generated throughout development. In this paper, we consider an IV-cannulation trainer prototype, which was developed using an iterative development framework. Prototypes were developed through design-build-test cycles, driving the development as new insights and knowledge got revealed. A prototype to evaluate the concept potential was tested in the context of unsupervised cannulation skill training, thus revealing areas for improvement and sources of wrong learning for end-users. Hence, we exemplify how the design and build stages of hardware development should be shared and results from testing and evaluation of the shared designs.

As OSH facilitates new product designs to be shared, built, tested, re-designed and re-distributed, we emphasize the importance of sharing more than merely technical blueprints and building instructions. We argue that this is especially important when distributing open hardware designs, as opposed to in a conventional new product development process, because its unknown who and in what state the design is going to be used in. Considering designs being shared is only the current state of an ongoing project, sharing insights, user errors, and test results should be encouraged. This way, new designs could be shared with the assurance that they function as intended and thus mitigate sources of error both considering assembly and of end-use. Alternatively, novel designs could be shared before being tested, re-designed, and thus improved by other researchers and developers to mitigate the risk of not meeting the targeted requirements. Further research is necessary to determine effective knowledge transfer of OSH designs. As the transfer of tacit knowledge trough physical artefacts is challenging to obtain given physical distance and virtual sharing of ideas, sharing development stories, experiences of manufacturing and deploying the designs could be valuable. Moreover, this could be critical given use-cases (such as the one presented in this paper) where critical learning outcome could be affected by premature design choices and designs not sufficiently tested.

7. Conclusion

With the Covid-19 pandemic requiring remote working, virtual training, and education, we are witnessing an increase in initiatives that transfer product development from professionals to the public

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through the emergence of Open-Source Hardware. Open-Source designs grant access to tangible artifacts by relying on people's ability to manufacture and assemble these themselves. Because of postponed and canceled clinical skill exercises, open-source solutions for practicing procedures have been made available, and several tasks are now being taught through self-directed learning. We, however, question how this affects the learning outcome of task training. We consider a case of a novel intravenous cannulation task trainer developed during the Covid- 19 pandemic. The task trainer is designed as an Open-source device for unsupervised clinical skill practice. Multiple user errors were uncovered by observing 13 registered nurses and two students using this task trainer during a two-hour unsupervised skill training session. Without user testing, these errors and other interactions might not have been identified. These insights raise the question of how OSH needs to share more than just device descriptions and assembly instructions- as designs are being shared only in its current state of an ongoing project, sharing insights, user errors, and test results should be encouraged. Therefore, we argue that the insights and learning from an iterative design process should be shared on the same basis as final hardware designs to take full advantage of OSH's potential.

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