Title

Determine the feasibility of a customizable Ultrasound gel phantom for production and distribution to the masses: A cheaper, realistic gel phantom will allow more accessibility and improved training for practitioners

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ISP Title: Determine the feasibility of a customizable Ultrasound gel phantom for production and distribution to the masses: A cheaper, realistic gel phantom will allow more accessibility and improved training for practitioners.

Background:
Simulation has become an integral part of learning new procedures and staying adept at skills already learned. Ultrasound (US) guided peripheral IV (PIV) needle insertion is a skill necessary for EM, Anesthesia, and general practice nurses and physicians. Medical schools, teaching hospitals, and community hospitals universally use simulation amongst their practitioners. Ultrasound POC use is increasing in Emergency Department (ED) and other hospital areas. Most institutions have formalized training to teach residents and nurses proper techniques for POC US use. Training models can vary from commercially available ones costing thousands of dollars to home-made ones that have a short life-span and suboptimal viewing characteristics.[1] Patient safety has been a driving force in changing medical training. “To Err is Human”, a landmark study published in 1999 estimated 3% of injuries to hospital patients are caused by medical errors, resulting in between 44,000-98,000 deaths per year. The traditional teaching mantra of “See one, Do one, Teach one” apprenticeship model has been replaced with proficiency-based teaching methods to improve physician training and patient safety.

Proficiency based teaching allows for four major advantages over traditional teaching methods: (1) improved patient safety as physicians can practice without harming others and help prepare for emergency situations. (2) People learn at different rates and a proficiency based model helps them to learn towards a common goal (3) uniformity in training (4) decreased costs from less mistakes, leading to shorter hospital stays and admissions (5) with more emphasis being placed on expediting patients in a safe manner, there is less time for practitioners to learn on patients. Simulation eliminates this need as it allows learners to spend the time they need to properly learn a particular procedure.[2]

Medical education has recently seen growth in the use of simulators and sim centers to help augment the teaching of clinical skills. Simulation has been defined as a situation in which a particular set of conditions is created artificially in order to study or experience something that is possible in real life; or a generic term that refers to the artificial representation of a real world process to achieve educational goals via experiential learning.[3] Simulators are defined as a device that enables the operator to reproduce or represent under test conditions phenomena likely to occur in actual performance.[4]

Ultrasound proficiency has been shown to improve by training with simulators prior to use on patients [5,6]. Improved training has led to increases in proficiency of both residents and even medical students. While the integration of US training has improved the quality of education, students are often limited in the availability and quality of models to practice on. US training models are most often held by an institution’s sim center, which gives the models out as needed for training. These models vary in price $450 for a simple gel block to well over $4000 for mannequins created to simulate the appearance of a human face or arm.[7] The large cost has led practitioners to create DIY kits, making gel molds from household items and sharing open-source instructions via the internet . Many of these DIY gel models require refrigeration,have a limited usable life before they become destroyed, and are labor-intensive. Still, because these models cost only a fraction of the cost of commercially-available ones, US practitioners are constantly seeking ways to improve the quality of DIY US models. For a DIY gel model to be useful, it must be: easy to make, accurately recreate the level of US quality found in commercially available products, be accessible to practice with, have a lifespan that allows for the time spent making the model to be worthwhile, customizable for a specific institutions particular needs, and produced at a cost point that makes the DIY model superior to buying a commercial model.[9.10,11]

Ballistic gel molds are actively being pursued as an alternative to buying commercially made US phantoms. Using CAD software a 3D design of the mold is created. Using a 3D printer, this drawing is then used to create a reproducible 3D mold. Heated ballistic gel is then poured into the mold, along with plastic tubes to simulate blood vessels and nerves. Once the gel cools, this allows for an ultrasound phantom with far greater durability then traditional DIY gelatin molds. Other advantages include: not having to deal with mold/fungus, a long shelf life, the ability to customize (using tubing for veins, etc.), and easy repair/reproducibility [9,12]. This type of computer assisted drawing and 3D printing to create ballistic gelatin molds has the potential to create significant cost savings.

Recognizing what problems practitioners are facing in making gel models and what deficiencies in training they hope to address are the first steps to making a better US model. In analyzing what attributes centers look for in a model for US guided needle procedures, we hope to determine how to produce an easy-to-make, realistic, low-cost gel model. With this information we hope to be able to make recommendations to practitioners and simulation centers so they can create and customize US models to their specific needs at a low cost.

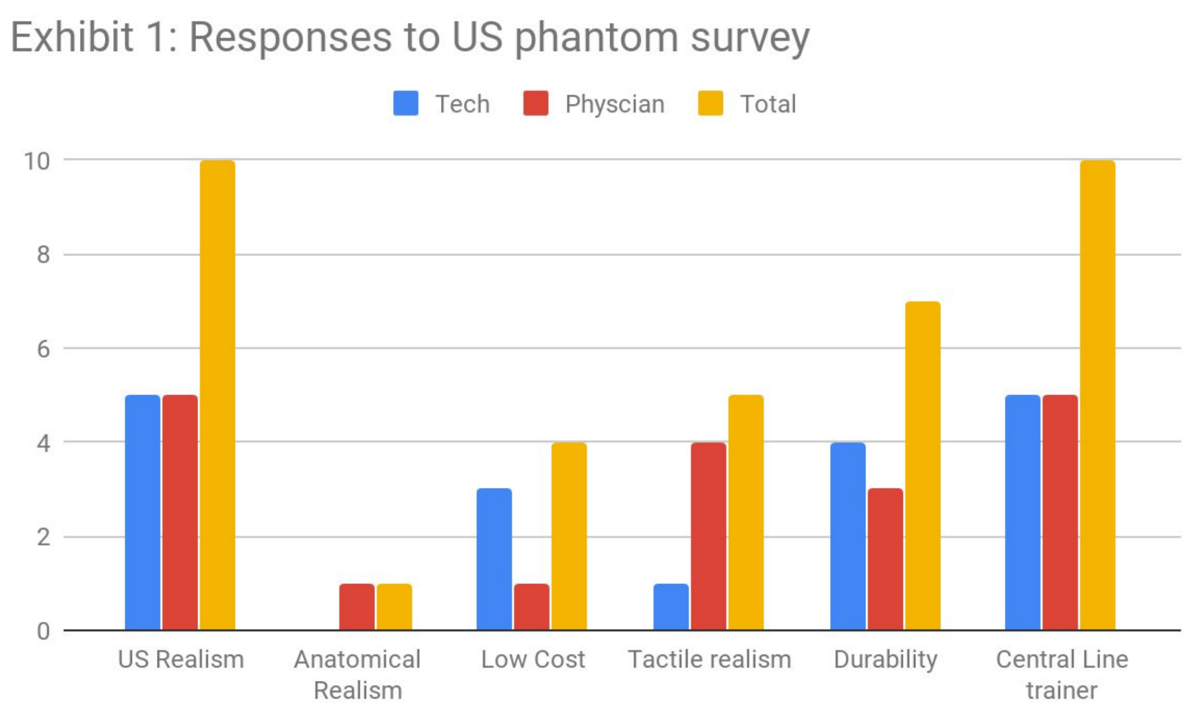
Methods:

The goals stated above were the foundation for the research. Research through a review of scholarly journals to provided background, and primary research through contacting Simulation Center directors, Ultrasound department heads, and physicians engaged in training operators in US guided needle procedures. A metaindex search through Lexus Nexus of “DIY” “Ultrasound trainer” “Ultrasound phantom” “gel” from 2014 to present produced 98 articles. Each article was thoroughly read and critiqued, with specific focus on the methodology and discussion of each study. Interviews with relevant personnel were documented and the findings analyzed in a quantitative manner (Exhibit 1). Throughout the designated time frame, we actively working with the Simulation Center to share the results of our findings and incorporate them into curricular reform.

Phone interviews were conducted using a premade survey (Appendix 1) produced with help from physicians at UCSD [9,10,11]. Ultrasound trained physicians, sim center technicians, and sim center operations directors were interviewed over the phone during the course of the project. All interviews were conducted by myself during the time period of June 2018-September 2018. Interviews lasted between 10-30 minutes. 5 Emergency Medicine physicians and 5 ultrasound/Sim center technicians and operations directors were interviewed. Additional interviews were conducted with individuals developing ballistic gel mold US trainers as well as individuals working to develop a cost-efficient method of producing ballistic gel mold trainers.

Results

Responses to questions have been broken up into “total” as well as “sim center” vs “physician” answers as shown in Exhibit 1.



All respondents cited **US realism as the most important** or tied for the most important quality in an ultrasound phantom.

Low cost: 3/5 staff, ⅕ physicians. Low cost” was hard to define by both physicians and staff. As “low” is a relative term, interviewees had to give their best estimate of what they believed quantifies as a low cost for the purposes of an ultrasound phantom. Amongst the interviewees that were able to give an answer, respondents stated $100-200 would be a low cost solution to commercially available phantoms. As an ancillary question, participants were asked about their concern for a central line trainer insert to which **all staff (5/5) and ⅘ physicians** were concerned about cost of Central Line inserts , which currently are $1000+. Positive respondents stated the if central line inserts could be manufactured in-house there could be significant cost savings for their respective institutions.

Tactile realism was denoted as an important characteristic by **1/5 staff, 4/5 physicians**. Defined as realism regarding how inserting an IV feels to touch with the phantom trainer as compared to inserting a peripheral IV into a patient.

Anatomical realism: ⅕ staff, 0/5 physicians. An overall consensus amongst interviewees appears to be that anatomical realism is not a necessary attribute for PIV US phantoms.

Durability:⅘ staff, ⅗ physicians. Consensus amongst all (5/5) of the staff interviewed that commercially bought PIV US trainers last 1-2 years or approximately 200 pokes.

Budget: Only two interviewees could speak to the budget they worked with. Those values ranged from “unlimited” to 200k for US budget.

At the end of the conversation, participants were given the freedom to talk about other areas they believed to be of concern for peripheral IV phantoms not specifically covered in the survey. Answers in this free-text section included:
-Timing of classes needed be taught using PIV phantoms
-limit in how many different types of trainers can be used.
-Purchasing: Multiple departments to buy new equipment vs a central purchaser
-Use of volunteers
-Sharing of information with other institutions.
- Kits, replacement parts, trash, etc from different systems can make teaching with multiple systems overbearing.

Limitations

This study has a number of important limitations. Most importantly, the survey was given to a very limited number of respondents (10). Amongst the respondents, I had interacted with all of physicians and all of the simulation center staff participants were part of the UC system. There is ample concern for selection bias.

The study looked at a limited number of physicians, and a limited number of simulation center staff for the survey. Part of the problem here lies in the design of the project. We did not understand there would be a difference in the expertise/needs/functions of staff physicians vs the simulation staff in regards to the PIV US phantoms before the start of this project. The overall flaw in the design was not understanding how decisions are made in acquiring US phantoms. Before the project began, the assumption had been that a physician in charge of Ultrasound training evaluates the necessary training equipment and then makes a purchasing decision. Throughout the course of the interviews it became apparent this was a completely erroneous assumption. Purchasing pathways varied between all institutions [15,16,19,20,21]. In some cases a physician was able to determine what got purchased. In other cases, the simulation center determined what would be purchased and how to allocate resources to different departments. In yet another case, the simulation center had a minimal budget of its own and instead resources were from various departments to the simulation center when a department had a particular need. A mixture of simulation center staff and physicians were interviewed for the project, giving different perspectives on what attributes were necessary for a trainer. Before the project began, our assumption was to interview only physicians as they are the ones responsible for using US in patient care (and to supervise nurses and staff). As this project deals with the training of US practitioners it became apparent the perspectives of both the Simulation Center staff and the physicians were necessary. US phantoms are often used to train hundreds of residents over the course of a year. The staff are more involved in the purchase, upkeep, and running of classes, while the physicians will be on hand to directly observe how well the students are able to apply what is learned in simulation to real-life scenarios. In a perfect scenario, It would have been helpful to have been able to talk to sim center staff and physicians at each of the hospitals. This would have given insight into whether certain answers were influenced by institution or if there is a true split between the needs of physicians and Sim center staff.

Another limitation is all of the simulation center technicians, and the majority of the physicians, who participated in the study were part of the UC system. This was helpful as the basis of the project was to help guide production of a phantom produced within the UC system, but there is no comparison to how other sim center technicians operate. In the future it would be helpful to incentivize other simulation centers outside of the UC and part of other consortiums to participate in the study.

Another limitation in the survey questions regarded depreciation. Respondents were asked how they depreciate PIV US phantoms but most did not believe this was a relevant question as they use depreciation to account for more expensive models. Hard to depreciate peripheral access vascular trainers when the initial cost is so little. Given these trainers are disposable items, the question of depreciation is wrapped up within durability, and generally replaced every two years.

The study was also limited as many of the questions asked had been referenced in many articles, but never properly defined. For example “low cost” appeared in every result for our metaindex search, but the actual dollar range for low cost was never defined. The same applies to durability and other factors investigated in this study. For the purposes of the study, participants were asked what they believed to be “low cost” in regards to a PIV trainer, but there is no basis of comparison to other studies. In a similar manner, “durability” is often listed in other studies as an important quality for DIY PIV phantoms, but what defines durability is seldom if ever defined. While these ambiguous terms have attempted to be defined in this paper, they can fluctuate from person to person in how they are interpreted.

The ability for a PIV US phantom to be cost-effective is a central question asked in this study, but regardless of the cost of the phantom, the budget of the Simulation Center/Dept has to be taken into consideration. Most (8/10) of the participants had no knowledge of the budget they had to work with and the two respondents who did have knowledge gave widely divergent answers. In order to holistically understand how a simulation center views the cost effectiveness of DIY phantoms vs commercially bought products, it would be helpful to understand their overall budgeting for phantoms and depreciation of equipment. A study in the future may focus solely on contacting Simulation Center Directors and ascertaining what the average budget they have to work is, how much they allocate for replaceable equipment, and what would be the most cost-effective DIY model to work on in order to truly help their bottom line.

Discussion
All interviewees agreed one of the most important qualities was insuring the PIV trainer reproduced ultrasound realism. A notable divergence was how the two groups rated cost and tactile realism. ⅗ staff and ⅕ physicians were concerned with low cost, whereas ⅕ staff and ⅘ physicians were concerned with tactile realism [10,11,13,14,15,16,17,18,19,21,22]. This disparity may be due to differences in how SimCenter/Ultrasound simulation staff see the ultimate goal of PIV training. Sim Center staff are concerned with teaching large volumes of students: med school, general residency trainees, and advanced procedures for certain specialties (EM, Anesthesia, etc.). Techs/sim center staff are mainly concerned with teaching general US PIV skills to a great many number of students. Physicians deal with residents and nurses who are in their specialty. The issues they see center on their chosen specialty: pediatric ICU nurses needing more training for placing IVs in newborns, EM residents needing more realistic training to put IVs in obese patients, etc. The situations physicians are concerned to get better training in affect a very select group of practitioners [10,11,13,14,17].

This helps us answer the question of *What level of difficulty are Sim Centers wanting to recreate in their models?*
Sim Centers are concerned with being able to recreate simple procedures for a large number of practitioners to gain expertise on. Difficult procedures are more speciality specific. Practitioners have a particular set of parameters they are looking to recreate, and this may not translate into something that can be readily reproducible [10-13,16,21]. There are still limitations on the level of realism an ultrasound phantom can recreate.

Simulation techs unanimously agreed PIV training was very cyclical, with a peak as new residency classes began in June/July [14,15,18-20]. Centers have to accomodate large classes of new physicians and conduct IV/ultrasound training during their orientation or first weeks of residency. This “surge” in training requires many PIV trainers to be on hand so there are an acceptable number of students per trainer. Commercially bought PIV trainers were exclusively used by all but one site. Even the one site that used self-made PIV trainers stated they needed to use commercial PIV trainers during this June-July surge as the commercial trainers are much more durable than DIY trainers. This surge in training calls for two recommendations:

1.When new PIV trainers are ordered, there should be enough to cover this surge in training during the summer months.

2. If a DIY trainer is being developed, it behooves the makers to have the phantom ready for student use by June. This allows for feedback on the construction of the phantom through a large sample size of incoming residents. It also allows facilitators to make a direct comparison of the newly made phantoms with the well-known durable commercially bought phantoms.

Low cost: 4/10 interviewees were concerned about a PIV being “low cost”. Amongst the interviewees concerned about PIV cost, there was rough consensus in buying a DIY/3D printed ballistic gel mold if the price point can be dropped to the sub $150 mark, assuming the level of realism and durability can be maintained. Given that an off the shelf PIV trainers sells for around $300 they are not seen a major budgetary issue. Producing a PIV trainer in house requires time and resources from physicians or Sim Center technicians which is relatively limited. It is an easier matter for most facilities to simply purchase new PIV trainers through a commercial manufacturer than take the time to constantly be melting down and rebuilding PIV trainers. Respondents stated the June/July timeframe of training new residents was extremely busy and instructors would be hard pressed to find time to melt down and “refurbish” ballistic gel mold PIV trainers [14,15,18-20].

Entailed in the issue of low cost is durability. This was understandably more of a concern to the staff members (⅘) who and all agreed trainers last 2 years or approximately 200 pokes. This information is useful in further discussions of PIV US trainers as it allows us to actively compare between DIY/ballistic gel mold models and commercially available ones. An important consideration in the durability of ballistic gel models is the number of pokes before the model needs to be melted and reformed. Staff members discussed how during peak training sessions in June-July ballistic gel molds may need to be melted down on days between classes [15,18]. This may be impossible staff members having limited time. Other options include keeping extra ballistic gel mold phantoms on hand so they could be “rotated through” without having to melt down or keeping commercially available durable phantoms on hand to accommodate the large class sizes and volume.

While only 4/10 respondents were concerned with a PIV phantom being “low cost”, all interviewees expressed an interest in being able to recreate the gel insert for a Central line trainer [10,11,12,13,14,15,16,17,18,19,20]. Central line trainers are much more expensive, running $1000+ for a new gel insert that often only lasts one residency class training year. Compared to a PIV trainer which lasts 2-3 years of residency training classes, and costs a third the price, central line trainers are a significant perishable line item for a simulation center’s balance sheet [14,15,16,17,18,19,20]. A central line trainer is more complicated to build than a standard peripheral IV trainer, but the basic concept remains the same: a gel insert is put into a mannequin central line trainer and then students are able to use ultrasound to insert a needle into the vena cava. UCSD is currently working on producing a central line trainer from ballistic gel and 3D modeling. Given the level of interest amongst all the UCs and out of state institutions, producing ballistic gel mold central line inserts has the potential to generate significant cost savings.

All (5/5) of the staff members interviewed were interested in fostering greater ties between the UC ultrasound simulation departments [14,15,16,17,18,19,20]. Interviewees expressed frustration with current procurement methods and lack of knowledge between different models and types. Departments will often continue to reorder a phantom they feel has defects because there is more of a risk in trying a new replacement product that fails when used in a teaching session. Having a centralized database between UC systems would help when making purchasing decisions. Respondents would list suppliers and producers that they have used. They will be able to give explanations on why they made purchasing decisions and then rating what they buy. Allowing for more cross-talk may also increase purchasing power, as institutions may order the same item in bulk from a manufacturer and have more influence as it will be a single large order vs multiple smaller orders.

Expanding on this idea is to have the various UCs collaborate more in the production of phantoms [14,15,16,17,18,19,20]. Each UC has subject matter experts in differing specialties. These specialities could be utilized in the production of new phantoms and training equipment. For example, UCSF has a former special effects artist who has experience shaping and making models by hand, UCLA has a technician skilled in 3D modeling and production, while UC Davis has expertise creating low cost DIY models for all of their training. This also allows for departments to know what others are working on and eliminate a doubling up of efforts. For example, UCSD may be working on a ballistic gel trainer central line insert while UC Davis has developed a working pump to recreate arterial blood flow. Combining these efforts could potentially save the cost of buying a trainer costing thousands of dollars. Increasing communication between the Ultrasound/Simulation departments of the UCs will allow for a greater dissemination of knowledge and the ability to tap into the diverse expertise of subject matter experts.

-Based upon the research, what recommendations can we make about manufacturing ballistic gels and 3D printing for US guided PIV training?

In order to understand the market a 3D printed ballistic gel mold US PIV trainer we must consider how the commercially available products are currently a very small line item in a simulation department's budget. The market is not all institutions who using phantoms for US guided PIV, but only that small subset that sees commercially available phantoms as an expensive line item. Given the durability and minimal impact PIV phantoms have on a Sim Center or Ultrasound department's budget, it seems unlikely that developing a 3D ballistic gel phantom will gain much traction amongst most institutions. However, within the market of institutions using PIV US phantoms, there is a smaller subset that has the manpower and time to experiment with phantoms. Institutions that have the manpower to melt down and recast a ballistic gel mold PIV US phantom would be the target market UCSD.

Given the relative low cost of PIV US phantoms, there does not appear to be overwhelming support for an in house ballistic gel 3D printed phantom. Creating in house ballistic gel mold phantoms is prohibitively time consuming and expensive in small scales. Institutions can download the mold design and print it out or pay to have the mold sent to them, then create ballistic gel molds very easily. Creating a 3D mold to use for one institution's purposes can be prohibitively cost-expensive. In order to achieve even small-scale economies of scale, 20-30 phantoms need to be ordered [17]. This is far too many phantoms for any single institution to have a need for.

For more specialized US phantoms that are requested by physicians to practice and teach advanced procedures (pediatric, criss-crossing veins, obese) the degree of specialization makes it infeasible to mass produce specialized trainers at this time. The specialization requested by different physicians varies greatly between institutions and between physicians. In order to better understand the particular needs of these specializations we suggest a follow-on survey to determine if there are commonalities amongst physicians: e.g. survey a group of critical care doctors, NICU physicians, geriatric, etc.

As mentioned earlier, In order for a 3D printer ballistic gel mold phantom to be produced economically, a large number of phantoms must be ordered. A preliminary study[20]showed that if phantoms were ordered on the scale of 30 at a time, they could be bought for around $60/phantom, and an order total of ~$1800 (depending on the cost of the PIV phantom, this cost could be much less or greater. A working model at UCSD as of the time of this publication had been produced for ~$20). This is above what a typical replacement for commercially bought ultrasound PIV trainers would cost. In order to mitigate this cost, the UC system is in a unique position to take advantage of economies of scale. By having each UC agree to spend a set dollar amount towards phantom/simulation development, it will allow for the production of phantom trainers. $2500 from the combined UCs will give ample starting capital for this fund, and allow for experimentation in developing an US trainer. By having each UC give a yearly commitment to this fund, every school will have "skin in the game". This incentivizes each participant to actively work towards the group's goals, and to share information and expertise in the hopes of making a better product that all institutions will share. While a PIV US trainer is not high on a priority list, the UC consortium could instead look to develop a central line trainer for in house use.

Another question to be answered in this project was how best to market the phantom technologies being developed at UCSD.

1. Share instructions for how to develop US phantoms freely.
   The market for DIY PIV trainers remains relatively small given that most institutions are able to buy and replace commercially available trainers without a thought as to how it effects their overall budget. Were UCSD to sell a ballistic gel mold PIV trainer of comparable durability and quality to commercially available products, a marketing campaign would have to be undertaken to make the public aware of the new product. Furthermore, many institutions may prefer the durability of the commercial products as they can simply replace vs having to spend the manpower to melt and recast the ballistic gel products. However, those institutions that are willing to melt down and recast the mold as necessary may move exclusively to ballistic gel molds. There is an initial hurdle to overcome in training and manpower to have the resources necessary to use reusable

gel trainers. Once this hurdle is overcome, institutions are incentivized to only use reusable trainers as (a) they have the staff necessary (b) institutions want to limit the amount of different models they use since staff members must be trained on each model, and repair/replacement varies from model to model.

2. Sell the mold only
   Because 3D modeling technology and expertise is not common at most hospitals and teaching institutions, if demand presents itself, on a limited basis UCSD can sell molds that have already been produced phantom with a markup from cost to cover time and expenses. I suggest only selling the computer designed mold vs the completed product (ultrasound phantom that has been formed in the mold). This narrows the market to those institutions who are willing to melt down and recast the trainers as they get used. The option to allow customers to send in used trainers to UCSD in order to be remelted and reformed (for a cost) seems time-consuming for the Sim Center staff and most likely not a cost-effective option.
3. Be poised to benefit from interest in Central Line trainers
   Unlinke PIV US phantoms, inserts for central line trainers have a short life span (1year, 100 pokes) and are a higher ticket item ($1000+). Should current efforts at UCSD continue to be successful in creating a central line trainer is similar in quality to commercially available products, efforts should be made to distribute the trainer to institutions in the UC consortium. As the hurdle cost for developing a central line trainer has already been absorbed by UCSD, efforts should be made to distribute the technology to other the other UC members. Absorbing the marginal cost of producing more ballistic gel inserts ($20-30[9]) UCSD can introduce their system to a friendly market who can give actionable feedback. Having consortium members report back on the quality of the central line molds will give UCSD valuable information for further improvements and publication of work. Should the program want to expand, we suggest using an area-centric approach in order to minimize problems encountered dealing solely through email or phone. Approach community hospitals in San Diego and Riverside counties and expand outwards from there.

Appendix 1: Ultrasound questionnaire

1. Do you have a peripheral access ultrasound vascular trainer? Which ones?
    a. Approximately how many hours per month is a peripheral ultrasound vascular access trainer used? / how many learner hours is spent using it? # learners x hours booked?

2. How important are the following characteristics to you:
    a. Low cost
    b. Tactile realism
        i. Feel for needle placement
        ii. Resistance to needle insertion
        iii. Small caliber veins
        iv. Veins that roll
        v. Veins that cross
        vi. Veins in close proximity to one another
    c. Anatomical realism
    d. US realism
    e. Phantom is easily made/reproducible with materials that are readily available
    f. Phantom is simple and easy to use. Minimal instruction is required to operate the phantom
    g. Ability to increase difficulty of phantom trainer
    h. Other attribute not listed above

3. What is the budget you work with for US phantoms?
    a. How many different models do you ideally have to work with?
    b. What is the price range you look for in a phantom.
    c. What is your overall yearly budget?
        i. how many $ of your budget is set aside annually for new equipment purchases? Of that, how much would you reasonably spend on peripheral US vascular access trainers? Based on current requests or utilization, what is the ideal number you would have?
    d. Do you purchase ready made phantoms or make your own?
        i. On average, how long does it take to create the phantoms?
        ii. What is the most laborious part?
        iii. Do you often recreate the same phantoms?
        iv. Would it be beneficial if you could outsource any part of the construction?
4. Other

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