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TECHNOLOGY TRANSFER ASSISTANCE PROJECT BRINGS VA HEALTH CARE IDEAS TO LIFE

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Abstract

Clinicians and staff of the Department of Veterans Affairs Health Care System (VA), who provide services to veterans, have invented many devices and methods for improving veterans' lives. However, translating those inventions to the market has been a challenge due to limited collaboration between the clinical inventors and the scientists, researchers, and engineers who can produce the prototypes necessary for licensing the technology. The VA Technology Transfer Program office and the Human Engineering Research Laboratories, a research laboratory with experience with developing prototypes and licensing technology, jointly developed a program called the Technology Transfer Assistance Project (TTAP) to bridge the gap between clinical inventors and prototypes ready for licensing. This paper describes TTAP and provides examples of the first inventions that were developed or enhanced through TTAP.

Keywords

Technology transfer; Innovation; VA health care; Prototypes; Clinical

INTRODUCTION

Technology transfer is the process by which inventions and innovations are taken from idea, concept, and prototype to availability for sale and/or use to the public (1). This can occur in many ways. Some occur via licensing agreements from non-profit university research laboratories to established or start-up for-profit companies that market and sell the devices (1). However, not all inventions are conceived of in research laboratories that have the capabilities and funding to develop the ideas into a form that will entice for-profit companies to license the inventions (2,3). This is especially true in health care facilities, where the frontline workers and clinicians (i.e., doctors, nurses, and therapists) and health care recipients can have great ideas for new tools or processes to improve health care

delivery but do not have the resources to develop prototypes and test the inventions (4-6). Historically, these workers and clinicians have abandoned the idea of translating their ideas into products or services or have chosen to develop prototypes themselves to see their ideas brought to market, which can be very time consuming and costly (2). Without a prototype or data to demonstrate the usefulness of an invention, it is very difficult to 'sell' the idea to a company that will take the invention to market (1,7).

The Department of Veterans Affairs (VA) was in this situation a few years ago. From 2010 to 2019, the VA went from 170 invention disclosures and 19 issued patents to 733 invention disclosures and 61 issued patents (8). Also in 2019, the VA initiated 71 new licensing agreements. Some of the invention disclosures, patents, and licenses are jointly owned by affiliate universities and some are solely owned by the VA. Many invention disclosures come from VA clinicians, which makes them solely owned by the VA. The VA was having difficulty licensing those inventions to companies, largely because they did not have prototypes or data to demonstrate the usefulness of the inventions. This paper describes a new approach that was taken by the VA to increase the number of invention disclosures by VA employees successfully taken to market or translated into practice, where they could benefit both veterans and the general public.

Veterans Affairs Inventions

VA employees work with veterans every day and understand the needs of veterans and the common struggles and triumphs of these individuals. The VA employs more than 375,000 people, and this workforce includes some of our nation's most creative and innovative thinkers (9). The VA Technology Transfer Program (TTP) assesses discoveries and inventions by VA employees and aids in the technology transfer of the worthiest VA intellectual properties (IP) in order for the American public to benefit from VA inventions (8). This benefit is twofold: Americans enjoy the benefits of VA inventions as the technologies are commercialized, and the VA receives royalties that can be used for operations, thus saving taxpayer money. TTP was founded to ensure this creativity becomes fruitful for both our veterans and the entire country by assisting in the patenting and licensing of inventions made by VA employees.

TTP employs a bank of experts to evaluate each submitted invention disclosure. Historically, the number of invention disclosures made to TTP that have resulted in technology being brought to market has been low. This was attributed to not having physical prototypes or data to support the benefits of the inventions. TTP realized that there needed to be a process for further developing the ideas in the VA system so that companies would be more willing to license the technology. For assistance, TTP met with the leaders of the Human Engineering Research Laboratories (HERL), a VA research facility, to discuss how HERL and/or other research laboratories with physical prototyping capabilities within the VA could assist.

Human Engineering Research Laboratories

HERL is jointly supported through the University of Pittsburgh (Pitt) and the VA Pittsburgh Healthcare System (10). HERL conducts cutting-edge research and innovation in computer

and robotic manipulation and mobility appliances to assist veterans with disabilities such as spinal cord injury, upper and lower body disability, traumatic brain injury, and more. In creating technology and products to assist veterans with disabilities, HERL has partnered with the Innovation Institute at Pitt (UPII) for assistance in commercializing these products. Together they have experimented with the development of many educational programs, resources, and funding mechanisms to accelerate the progress of research from the lab to the market. Given the desire of HERL to be on the cutting edge of commercial translation, many of the newest UPII programs are piloted with the HERL team before they are transferred to the broader campus community and the Commonwealth of Pennsylvania (11).

HERL maintains an 11,000 square foot prototyping facility, utilizing state-of-the-art technology to support the design, fabrication, and other technical aspects of the rehabilitation and assistive technology research projects underway at HERL. The prototyping facility includes numerous production quality technologies for mechanical and electronic fabrication, including computer numerical control (CNC) milling, CNC turning, wire electrical discharge machining, water jet machines, CNC tube bending, welding, laser cutting, CNC press brake, additive manufacturing technologies, and laser-based printed circuit board fabrication.

Given TTP's success at finding and encouraging the creativity of VA employees to make inventions and HERL's success with the UPII at prototyping and commercializing its own inventions (12-30), starting a partnership between the organizations was determined to be a valuable opportunity (See Figure 1). Gains from the commercialization of products by VA inventors are expected to have a national and even international impact in the wide dissemination of new and improved technologies.

METHODS

The VA Technology Transfer Assistance Project (TTAP) is the name of this partnership. TTP collaborates directly with HERL, which supports TTP in the commercialization of some specific VA inventions (Flowchart in Figure 2). TTAP is funded through the VA Office of Research and Development (VA ORD) through the TTP office. Funds are allocated to the VA Pittsburgh Healthcare System (where HERL is located) from VA ORD. A portion of the funds are also contracted to Pitt for assistance from the UPII.

In practice, TTP examines each VA invention disclosure and refers inventions deemed feasible to license or otherwise commercialize to the TTAP program at HERL. TTAP staff initiate a meeting with the inventors, as well as the TTP technology transfer specialist, and conduct some preliminary market research to fully understand the problem being solved and the state of the art in the invention's domain. The statuses of the inventions have ranged from ideas written on a few sheets of paper to ideas that have already been highly researched and patented. Once all parties agree on the vision of the project, the staff working on TTAP at HERL use their design, engineering, and fabrication abilities and experience to create working prototypes. A participatory action design and engineering (PADE) process is used throughout to maximize the likelihood that the initial inventor's intent is met or exceeded (31). In most cases, the original invention is enhanced or expanded based on the

collaborative PADE process. Concept drawings, models, and prototypes are presented to the originating inventors and TTAP for evaluation through regular meetings. At each stage, the design, models, or prototypes are either refined if necessary, or the group collectively determines appropriate steps for evaluation and/or manufacturing.

The UPII also serves several roles in TTAP. UPII technology transfer specialists work with VA technology transfer specialists to help coordinate how best to pursue IP protection and licensing. UPII takes a lessor role when a TTAP project has IP secured through the VA prior to entering the TTAP pipeline. In some cases, other universities may have IP rights but have agreed to have the VA lead the technology transfer efforts. New IP is also sometimes created in this process. The new IP is owned jointly by the VA and Pitt, and the inventors include TTAP personnel working on the project as well as the original inventors.

TTAP also consults on pathways for commercialization by assisting in patent applications and licensing the invention to existing firms, spinning the invention off into a start-up corporation, or both. The short-term metrics for the success of TTAP are applications and awarding of IP, usable functional prototypes, and clinician feedback. The long-term metrics for the success of TTAP are licenses, products to market, and veterans served by the technology. The program has already met with significant short-term success and shows promise for long-term success.

RESULTS

In Year 1 of TTAP, progress has been swift. Projects that have been referred to TTAP include these five examples as well as others: Prosthetic Hook Mouse (US Patent Application No. 16/801,263), Heated Pulse Oximeter (US Patent No. US9795332B2), Thermal Fuse Cover (US Design Patent Application No. 29736993), Cord Caddy (US Patent No. USD834923S1), and STERI-TIP® Catheter (PCT Application No. PCT/US2019/012977). Short descriptions of these exemplar inventions, how they were further developed, and how TTAP assisted with the VA's COVID-19 response are described below.

Prosthetic Hook Mouse

The prosthetic hook mouse is a computer mouse designed specifically for people who use prosthetic hooks, as the hooks make traditional mice unusable (Figure 3). Typically, people who use prosthetic hooks can only use keyboard shortcuts to control a computer, which can be slower than using a mouse. This device allows people with prosthetic hooks to use computers the same way as everyone else. It has been prototyped and is currently being evaluated by several individuals with upper limb amputations. While the VA's preference would be for a company to license the technology to sell the mouse to the general population, the VA recognizes that the market for this item is small yet very important. Currently, HERL is serving as the manufacturer for the VA to create around 100 units per year for distribution to veterans. TTAP devoted approximately six months and 750 person-hours to bring this project to its current stage.

Heated Pulse Oximeter

The heated pulse oximeter is an oxygen level and heart rate (pulse oximeter) probe that maintains a near-constant ideal temperature for several hours at the measurement site, resulting in a more accurate reading (Figure 4). This idea was conceived of by a VA respiratory therapist. Some conditions, such as peripheral vascular disease, Raynaud's Disease, and hypothermia or simply cold extremities, make using a standard pulse oximeter impractical because the blood vessels are pulled away from the skin, resulting in compromised accuracy or an unattainable reading. This can occur in long-term care of elderly people or in ambulances and intensive care units. The alternative is to take a blood sample from an artery and test the oxygen level with a blood gas machine, which is not always available. The ideated solution is to warm the extremity, which brings the blood vessel closer to the skin and allows an accurate reading to be obtained. The TTAP staff has prototyped this concept with various chemical reactions to make the heat level appropriate while maintaining it for multiple hours. The device is now ready for large-scale testing and has been licensed by a start-up company for manufacture. TTAP devoted approximately one and a half years and 1,000 person-hours to bring this project to its current stage.

Thermal Fuse Cover

The thermal fuse cover is a cover that clamps the thermal fuse on an oxygen line to the hose to prevent accidental removal and avert blowback in case of a fire (Figure 5). This problem was identified by a respiratory therapist and the VA regional director of the prosthetics and sensory aids service. Breathable oxygen systems have a thermal fuse placed in the lines under the cannula to prevent a potential fire in the system from blowing flames into the patient's nose and/or mouth and causing severe internal burns. However, VA patients who use oxygen for respiration assistance frequently and mistakenly disconnect the lines at the thermal fuse when switching oxygen systems (portable to home-based, and vice versa) and leave the fuse out of the lines. This device is a clamp, which makes removing the fuse more difficult by clamping it to the lines and requiring tools to disconnect it. However, since the hoses and components need to be replaced frequently (approximately once a month), the clamp needs to have the ability to be removed. Several iterations have been prototyped and tested by respiratory therapists using various securing mechanisms. The current iteration of the thermal fuse cover is being evaluated by several respiratory therapists. As the market for this item is modest—at several thousand units per year—yet inexpensive and very important, the VA is likely to find a manufacturer to create units for internal use unless an original equipment manufacturer adopts the improvement. TTAP devoted approximately six months and 500 person-hours to bring this project to its current stage.

Cord Caddy

The cord caddy is a single-application cord organizer for use during surgery (Figure 6). This idea was conceived of by a general surgeon. The standard of care currently has many cords, wires, and hoses that can become tangled or hang from the patient. The cord caddy helps to organize and hold the cords, thus decreasing stress and the potential for an error during surgery. It has been iteratively prototyped with various sizes and materials and is ready for testing during surgical simulation. It is also currently being marketed for licensing. TTAP

devoted approximately one and a half years and 1,000 person-hours to bring this project to its current stage.

STERI-TIP® Catheter

The STERI-TIP® Catheter is a lung probe that collects bodily fluids and avoids contamination from bacteria outside of the sample by using an endoscopic tip for placement control (Figure 7). The idea was conceived of by a pulmonologist. An existing process for obtaining a specimen sample from the lungs can cause the sample to become contaminated with bacteria residing along the route, for example, in the throat, nose, or mouth. This contamination can result in false results when diagnosing pneumonia and other conditions. The inventor realized that the probe needed to be controlled more effectively to have the end of the probe go exactly where it should without becoming contaminated along the way. A prototype of the probe with tip control has been created. The next steps are to conduct lab testing and identify sterilization techniques. The technology is currently being marketed for licensing. TTAP devoted approximately two years and 1,500 person-hours to bring this project to its current stage.

COVID-19 Response

Because of the relationships and resources established through the TTAP program, there were strong ties between the VA research and the VA clinical communities. This facilitated the rapid communication and coordination of VA leadership, clinicians, and researchers to help rapidly address the needs of veterans in response to the COVID-19 pandemic. As a result, HERL was able to work with VA clinicians to rapidly respond to the need for personal protective equipment and to produce swabs for testing (Figure 8). The relationships established through TTAP were essential for bringing all of the necessary experts together to work collaboratively to rapidly respond to emergent needs. For example, over 2,000 swabs were able to be produced per day with a safe and reliable testing, cleaning, sterilizing, and packaging program.

DISCUSSION

Many organizations have identified the concepts of human-centered design (32-34) and PADE (35-38) to be effective means to develop innovations. These concepts involve integrating the end-users and other stakeholders into the design process to ensure that nothing is overlooked that would cause the device to not work as intended and that the end-users will maximally benefit from the use of the device. TTAP is essentially a form of that concept in which the end-users or stakeholders create a concept or idea and then work with engineers and innovation partners at HERL to see the ideas developed, improved, prototyped, and tested.

The TTAP program is a model for how partnerships can work to support worthwhile health care inventions that can fall through the cracks without the optimal combination of resources. Many of the inventors of the TTAP projects are not scientists or engineers but are clinicians who have identified challenges that they face while trying to provide the best health care possible. They know what they need but do not necessarily have the resources

or knowledge to bring the idea to reality. While this is a demonstration project in the VA, it could be replicated in many other health care facilities around the country. Many health care systems are partnered with universities that likely have engineering schools or research laboratories, which could aid in developing the ideas of clinicians into high-quality functional prototypes that demonstrate the usefulness of the ideas and could potentially improve health care (39). The university and/or health care system technology transfer office would then have more evidence and data to present to patent examiners and potential licensers, leading to greater success of the device making it to market and/or improving health care.

The exact impacts of TTAP have not been measured yet, as the partnership is only in the second year. One of the innovations has been licensed, and several others are undergoing review by potential licensees. Some of the inventions may require further iterations, and some may require more lab or clinical tests to quantify the usefulness and benefits for the devices. However, the projects and concepts are clearly in a better position to be licensed, as there are now drawings, specifications, bills of materials, and functional prototypes for a company to examine, allowing them to understand the concept better than a simple description of the idea would permit (1,7). Licensing can take several months or years, so it is anticipated that more licensing agreements will occur within the next one to two years.

CONCLUSION

Many good health care inventions and innovations come from clinicians (doctors, nurses, therapists, etc.). However, there generally is not a technology transfer process that includes the ability to prototype and test inventions in many health care systems, especially in regard to demonstrating the validity and safety of invention. TTAP is allowing the VA to prototype inventions made by VA clinicians in an attempt to make the technologies available to assist veterans and the public. Other health care facilities could follow similar procedures by partnering with research and engineering laboratories and schools to work with their clinician innovators and enhance the likelihood of seeing their inventions make it into practice.

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Figure 1.

The Natural Fit Pushrims manufactured by Permobil and distributed globally have helped hundreds of thousands of wheelchair users to avoid devastating injuries and illnesses. Here a veteran is pictured using them on the cover of the *The Patriot*, the Fisher House Foundation magazine (2020, Volume 11, No.1)

Figure 2.
Flowchart of work process for TTAP.

Figure 3.
Image of prosthetic hook mouse.

Figure 4.
Image of heated pulse oximeter prototype.

Figure 5.
Image of thermal fuse cover prototype.

Figure 6.
Image of cord caddy prototype.

Figure 7.
STERI-TIP® Catheter.

Figure 8. Swabs for virus testing after being sterilized and packaged. Swabs were fabricated using a selective laser sintering (SLS) three-dimensional printer.