Assistive Technology

Outcomes and Benefits

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Focused Issue: State of the Science for Technology Transfer

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Assistive Technology Outcomes and Benefits

State of the Science for Technology Transfer

Summer 2010 Focused Issue

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Assistive Technology Outcomes and Benefits (ATOB) is a collaborative peer-reviewed publication of the Assistive Technology Industry Association (ATIA) and the Special Education Assistive Technology (SEAT) Center at Illinois State University. *Delivering on the 'D' in R&D: Recommendations for Increasing Transfer Outcomes from Development Projects* is a special issue publication of ATOB, and is one of a series of topical publications on assistive technology issues.

Editing policies of this special issue are based on the *Publication Manual of the American Psychological Association* (5th ed.). The content presented herein does not reflect the position or policy of ATIA or the SEAT Center and no official endorsement should be inferred.

Assistive Technology Outcomes and Benefits

Editorial Policy

Assistive Technology Outcomes and Benefits is a peer-reviewed, cross-disability, transdisciplinary journal that publishes articles related to the *benefits* and *outcomes* of assistive technology (AT) across the lifespan. The journal's purposes are to (a) foster communication among vendors, AT Specialists, AT Consultants and other professionals that work in the field of AT, family members, and consumers with disabilities; (b) facilitate dialogue regarding effective AT practices; and (c) help practitioners, consumers, and family members advocate for effective AT practices.

Assistive Technology Outcomes and Benefits (ATOB) invites submission of manuscripts adhering to the format of the *Publication Manual of the American Psychological Association* (5th ed.) and which address a broad range of topics related to *outcomes and benefits* of AT devices and services. Manuscripts may include (a) findings of original scientific research, including group studies and single subject designs; (b) marketing research conducted relevant to specific devices having broad interest across disciplines and disabilities; (c) technical notes regarding AT product development findings; (d) qualitative studies, such as focus group and structured interview findings with consumers and their families regarding AT service delivery and associated outcomes and benefits; and (e) project/program descriptions in which AT outcomes and benefits have been documented.

ATOB will include a broad spectrum of papers on topics specifically dealing with AT outcomes and benefits issues, in (but NOT limited to) the following areas:

- Early Childhood and School-Age Populations
- Research and Product Development
- Outcomes Research
- Transitions
- Employment
- Innovative Program Descriptions
- Government Policy

Regardless of primary focus of any submission, primary consideration will be given by the journal to manuscripts presenting quantifiable results.

Types of articles that are appropriate include:

Applied/Clinical Research. This category includes original work presented with careful attention to experimental design, objective data analysis, and reference to the literature.

Case Studies. This category includes studies that involve only one or a few subjects or an informal protocol. Publication is justified if the results are potentially significant and have broad appeal to a cross-disciplinary audience.

Design. This category includes descriptions of conceptual or physical design of new AT models, techniques, or devices.

Marketing Research. This category includes industry-based research related to specific AT devices and/or services.

Project/Program Description. This category includes descriptions of grant projects, private foundation activities, institutes, and centers having specific goals, objectives, and outcomes related to AT outcomes and benefits.

In all categories, authors MUST include a section titled Outcomes and Benefits containing a discussion related to outcomes and benefits of the AT devices/services addressed in the article.

For specific manuscript preparation guidelines, contributors should refer to the Guidelines for Authors at http://atia.org/

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Innovative Program Descriptions
Government Policy
Research and Development
Low Incidence Populations

Submission Categories

Articles may be submitted under two categories—*Voices from the Field* and *Voices from the Industry.*

Voices from the Field

Articles submitted under this category should come from professionals who are involved in some aspect of AT service delivery with persons having disabilities, or from family members and/or consumers with disabilities.

Voices from the Industry

Articles submitted under this category should come from professionals involved in developing and marketing specific AT devices and services.

Within each of these two categories, authors have a range of options for the type of manuscript submitted. Regardless of the type of article submitted, primary consideration will be given by the journal to work that has *quantifiable results*.

Types of articles that are appropriate include:

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State of the Science on Technology Transfer

Cathy Bodine
Director, RERC for Advancing Cognitive Technologies
Focused Issue Editor

Stephen Bauer
Director, RERC on Technology Transfer

Howard P. Parette, Jr.
Executive Editor

The National Institute on Disability and Rehabilitation Research (NIDRR) is charged with developing, conducting research on, and transferring products to the commercial marketplace that have been developed by Rehabilitation Engineering Research Centers (RERCs). The difficulties inherent in this process are many. The need to remove barriers, improve processes, and successfully transfer usable technologies to the marketplace is critical. Persons with disabilities, their families, friends, and caregivers are waiting for the results of our research and development to reach them.

This ATOB Focused Issue--State of the Science on Technology Transfer--creates a much needed venue for both a robust dialogue and a platform for action. The lead author in each of the five papers in this issue is a senior member of the Rehabilitation Engineering Research Center on Technology Transfer (T^2RERC). Altogether, these authors have more than 60 years experience in technology transfer, AT development, and product commercialization. Each paper is accompanied by a content review prepared by a national expert.

The first paper, authored by Joseph P. Lane, is titled, "At the Confluence of Academic Research and Business Development – Merging Technology Transfer with Knowledge Translation to Deliver Value." This paper explores the continuing evolution of technology transfer practice. It is argued that linking technology transfer practice and knowledge translation will increase the relevance and impact of academic research on private sector development and production. Knowledge translation will also provide the government sector with critical evidence linking academic research to private sector development and commercialization and finally to the beneficial impacts on individuals with disabilities. The models, methods and measures presented in this paper have useful applications in other fields. The content review for the first paper is provided by Dr. John Westbrook, Director of the Southwest Educational Development Laboratory (SEDL).

The second paper, authored by Drs. Stephen Bauer and Sajay Arthanat, is titled, "SBIR and STTR Programs for Assistive Technology Development: Evaluation of Impact Using an ICF-Based Classification." This paper evaluates the impact of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs of five federal agencies (National Institutes of Health [NIH], National Science Foundation [NSF], U.S. Department of Education [USDE], U.S. Department of Agriculture [USDA], and Department of Transportation [DOT] on the development of assistive technology (AT). The study reviews more than 24,000 SBIR and STTR awards for the period 1996 through 2005. A classification

system based on the International Classification of Functioning, Disability, and Health framework, inclusion-exclusion criteria, and assignment rules were developed to support analysis. Findings include the classification and distribution of SBIR and STTR grants, grant number, type, phase and funding level by agency and year, cross-agency and temporal award and funding patterns, and concordance of these patterns to agency missions. The critical roles of the NIH and the NIDRR to AT product development are clarified. Content review is provided by Dr. Kevin Erler, President of Automatic Sync Technologies.

The third paper, authored by James A. Leahy and Joseph P. Lane, is titled "Knowledge from Research and Practice on the Barriers and Carriers to Successful Technology Transfer for Assistive Technology Devices." This paper outlines the critical barriers to brokering efforts between major U.S. university technology transfer offices and U.S. corporations. Barriers that impede technology transfer efforts span the research, development, and commercialization continuum. Carriers (or facilitators) and standard practices used to overcome these barriers in both the AT and mainstream markets are described. Over 14 years, using both the carriers and standard practices delineated in this paper, the authors successfully transferred new technologies and devices in the areas of AT and mainstream consumer products. Content review is provided by Jeffrey Dunbar, Director of Science, Technology Transfer, and Economic Outreach (STOR) at the State University of New York at Buffalo.

The fourth paper, authored by Dr. Vathsala I. Stone, Michelle Lockett, Douglas J. Usiak and Dr. Sajay Arthanat, is titled, "Beyond Technology Transfer: Quality of Life Impacts from R&D Outcomes." This paper presents methodology and findings from three product efficacy studies. Each study assessed the impact of three assistive technology products on consumers with disabilities in terms of perceived quality and value. The T^2RERC brokered the transfer of each technology and assisted manufacturers with post-transfer product development. The most successful product on all quality and value indicators was an automatic jar opener designed for consumers with limited hand function. Less successful was a computer software product, designed to facilitate mouse pointer use by persons with limited hand function or low vision; and a voice interactive thermostat, designed for persons with total or partial visual impairment. Few consumers were fully satisfied with the technical quality or usability of the latter two products. For each product, differences in the consumer perspective on product quality and value reflect differences in the use of evaluation during the product development process. A case is made for systematic and timely use of evaluation throughout the development process. The paper discusses key lessons learned with implications for product evaluation practice. Content review is provided by Dr. John Stone, Director of the Center for the International Rehabilitation Research Information and Exchange (CIRRIE).

The fifth and final paper, authored by Dr. Stephen Bauer and Jennifer Flagg, is titled, "Technology Transfer and Technology Transfer Intermediaries." This paper argues that a standard and comprehensive technology transfer model is needed to evaluate, compare, and provide oversight to technology transfer systems. The principle systems considered include U.S. federal laboratories, U.S. research universities, the RERCs, and SBIR programs. An earlier model delineated technology transfer activities, critical events, and the roles of stakeholders and resource providers. It is proposed to augment this model to address technology transfer dynamics (transfer efficiency, transfer

latency) and scale (micro-, macro-). The need for a standard model is demonstrated by showing gaps and inconsistencies, within and between research studies of major technology transfer systems. The appropriate role and philosophical perspective of technology transfer intermediaries is discussed. Examples pertinent to assistive technology industry illustrate important concepts and issues. Content review is provided by Pallavoor Vaidyanathan, Assistant Vice President for Research at the University of Central Florida.

State of the Science in Technology Transfer

At the Confluence of Academic Research and Business Development –

Merging Technology Transfer with Knowledge Translation to Deliver Value

Joseph P. Lane
University of Buffalo, SUNY

Abstract

The practice of technology transfer continues to evolve into a discipline. Efforts continue in the field of assistive technology (AT) to move technology-related prototypes, resulting from development in the academic sector, to product commercialization within the business sector. The article describes how technology transfer can be linked to knowledge translation. The results will increase the relevance of technology-oriented knowledge from upstream academic research to downstream development and production that involve both academic and business sectors. The linkage will provide the government sector with evidence with which stakeholders can apply research knowledge outputs to accomplish outcomes that achieve beneficial impacts for target populations of persons with disabilities. The resulting models, methods, and measures will also be useful to other fields of application.

Key words: Technology Transfer, Knowledge Translation, Assistive Technology, Research Development Production

Overview

The Application of Research and Development to Benefit Persons with Disabilities

In 2008, the State of the Science (SOS) for technology transfer (TT; Lane, 2003) was considering the changing relationships among the three economic sectors that are government, academia, and industry within the AT field of application. Historical relationships resulted from the field's heavy dependence on government support for research and development (R&D) and third-party payment, due to a dearth of market incentives for AT products and services. However, the market conditions are changing as the Baby Boom cohort ages. While the AT field has yet to achieve mainstream status, in the current transition phase companies are ready to consider AT within their seven- to 10-year product planning cycles. Now, more than ever, it is important that federally funded researchers and developers, in academic, government, and corporate laboratories, take into account how their work will (a) transfer to and through industry channels, and (b) benefit end customers.

This paper reviews how product development and TT can be reconciled and merged with the processes of scientific research and

knowledge innovation. The academic sector and the government sector, which fund the majority of research, are increasingly aware that the relevance of their results to the industrial sector and their customers is as important as the rigor of their methods. Federal funding agencies and the public expect more accountability on the part of funding recipients to deliver outcomes that impact the target audience. There is heightened expectation for a return on the investment of public funds. The term *knowledge translation* (KT) was coined to represent proactive strategies to communicate research findings to those in a position to put the findings into practice. KT tasks laboratory researchers with ensuring that the new knowledge they produce will be valued and applied by relevant knowledge users (e.g., other researchers, practitioners, policy makers, manufacturers, consumers). This makes KT a great match for TT. New program mandates and federal funding priorities are making this match explicit in practice.

Background

History of Technology and Disability in Government

The National Institute for Disability and Rehabilitation Research (NIDRR) operates out of the Offices for Special Education and Rehabilitative Services (OSERS) within the U.S. Dept. of Education (USDE). The institute manages research, development, education, and training programs related to the needs of persons with disabilities. In fact, NIDRR spends more on disability and rehabilitation than any other federal agency (Brandt & Pope, 1997).

Science and technology. Over the past 50 years, the intersection of scientific progress and empowerment of persons with disabilities generated opportunities for research in disability and technology (http://www.accessiblesociety.org/nidrr.htm). Breakthroughs in biomedical and technological sciences have changed the nature of work and community life. As these breakthroughs provide the potential for longer and more fulfilling lives for individuals with disabilities, they reinforce the second major development: successful independent living and civil rights advocacy by these individuals.

Medicine, technology, and rehabilitation. The field of medical rehabilitation adopted devices to assist patients with recovery and function as early as the Civil War. Advances in manipulation and mobility devices (e.g., wheelchair and prosthetics) moved from low-tech to high-tech throughout the 20th century. Devices to augment sensory limitations followed suit as computer-based technologies in optics, acoustics, and communications also advanced (Mann & Lane, 1995).

AT for independent living. The Independent Living Movement of the 1960s had repercussions for AT. People with disabilities who operated outside of the medical establishment reasoned that their products and services should be generated through the consumer market model rather than through the medical rehabilitation model. They wanted input into the products and services and the delivery systems through which they were acquired. Hence, the oft-quoted motto: "Nothing about me, without me."

The Rehabilitation Act of 1973. At the time of the Independent Living Movement, most federally sponsored research related to disability (a) was addressed by the field of rehabilitation medicine, (b) belonged under the umbrella of the medical model, and (c) was conducted by medically trained researchers sponsored by the NIH. These research programs operated under what the literature refers to as Mode 1 science in which pure, curiosity-driven exploration progresses

from theoretical to clinical, or applied, domains (Hessels & Van Lente, 2008).

Public pressure for federal support of studies that were more relevant to the needs of this constituent population, including issues beyond the medical model, prompted the Rehabilitation Act of 1973, a seminal piece of legislation. Among other things, this legislation and its subsequent amendments created NIDRR within the USDE. The language of the Rehabilitation Act of 1973–in response to the social pressures of the Independent Living Movement–was expressed in terms of Mode 2 science (http://www.ed.gov/policy/speced/reg/narrative.html).

NIDRR was charged with accomplishing dual outcomes to improve the quality of life for persons with disabilities by generating (a) conceptual discoveries through research and (b) tangible prototypes through development. This took place prior to the creation of the Small Business Innovation Research (SBIR) program, so the task of generating discoveries and prototypes fell to a new program designed to establish national centers of excellence.

These Rehabilitation Engineering Research Centers (RERCs) were modeled after the National Science Foundation's Engineering Research Centers, but with a focus on a single field of application, i.e., technology applied to the functional needs of persons with disabilities (Carnegie Mellon, the Robotics Institute, Quality of Life Technology Center, 2006) The USDE did eventually create an SBIR program with operational responsibility assigned to NIDRR (i.e., USDE, SBIR program). NIDRR maintains an academic focus through RERCs and an industry focus through SBIRs.

A cascade of empowerment legislation. Advocates equated the independent living philosophy with the civil rights agenda, sparking an array of federal legislation regarding disability rights. The advocacy continues. It has helped bring about periodic amendments to the Rehabilitation Act of 1973, Education for All Handicapped Children Act of 1975, the Technology-Related Assistance for Persons with Disabilities (Tech Act) of 1988, and the Americans with Disabilities (ADA) Act of 1990, the U.S. Supreme Court's Olmstead decision of 1999, and the New Freedom Initiative of 2001 (*Empowering Through the New Freedom Initiative*, 2001). Given the utility of technology-based devices to augment function for people with disabilities, most of these federal acts and decisions included language regarding such devices and services.

Assistive technology defined. The 1988 Tech Act legislation provided the first and only federal definition of AT devices. The definition, while carefully worded, has been misunderstood for years by various stakeholders, including consumers, manufacturers and clinicians. The Tech Act defined both devices and services associated with AT. As such, AT devices are defined thusly: "Any item, piece of equipment, or product system – whether acquired commercially off-the-shelf, modified or customized – that is used to increase, maintain or improve functional capabilities of individuals with disabilities" [29 U.S.C. §3(2)].

Federal definitions used the term *assistive technology* as an adjective and the terms *devices* and *services* as nouns. Since that time, general usage truncated these words into a single phrase. AT has come to refer to either devices *or* services, rather than a specific category of technology-based devices or service. However, technology is not a device. A technology is a form of know-how applied within a specific application. The adjective *assistive* is applied to provide a functional capability to people with a functional limitation within a tangible item, piece of equipment, or product system.

In the context of federally funded research and development activities, grantee research may generate knowledge that can be developed into new technologies (e.g., integrated circuits, storage devices, lasers), or knowledge that can be developed into new products (e.g., personal computer, DVD player, augmentative communication device; Christensen, 2003). Both forms of research and development–federal and grantee–are commonly understood to fall under the term TT, even though the former is actually focused on a technology outcome, while the latter is focused on a product outcome. The imprecise use of words within and across sectors will be shown later to be a barrier to effective communication, particularly in this context.

NIDRR's current mission and role. The creation of NIDRR as a federal research and development program addressing issues of health and function, but established outside of the NIH, demonstrated the government's commitment to supporting the direct application of scientifically derived knowledge to the area of disability and technology. The attributes of NIDRR's mission uniquely position it to address the confluence of research-based KT and development-based TT.

State of the Science in AT TT

In 2003, the RERC on Technology Transfer (T^2RERC) published an SOS in a special issue of the *Journal of Technology Transfer* (Lane, 2003). The SOS addressed neither the entire range of theories nor all facets of practice. Instead, it focused on a sub-set of TT practice concerned with research, development and commercialization of new (or improved) devices and services for people with disabilities: *assistive technology* devices and services.

Looking Ahead from the State of the Science in 2003

The 2003 SOS paper noted that technology transfer was evolving into a discipline. TT was characterized as under-developed because the models, methods, and metrics were not well documented, standardized, nor organized within a theoretical framework. Even the knowledge base underlying the practice was considered to be in the formative stages of development.

As part of the 2003 SOS conference process, conference participants responded to four questions. As a preamble to updates on progress in the intervening five years, those four questions and selected answers from conference participants are paraphrased as follows:

1. What steps are necessary for TT to evolve from a professional practice to an academic discipline?

Research must transform this 'ad hoc' process into something more systematic and rigorous to form the basis for an academic discipline such as knowledge management. TT researchers will probably require a combination of technical skills and applied transfer experience. Research, such as that underway at the T^2RERC, will directly benefit higher learning institutions. For most universities, transfer via formal license agreements is in its infancy, so efforts to study and understand the process will likely have substantial practical value to universities.

Forces driving practices to the level of academic disciplines include a confluence of social groups seeking solutions to unmet needs, practitioners seeking a theoretical framework for guidance, and researchers deciding that the underlying intellectual issues merit study. The field of evaluation grew into a discipline because researchers and practitioners from various fields realized they

had common needs and interests. They created affiliations based on this common bond.

Models of technology innovation management are evolving in concert with the latest models of organizational theory. TT is a complex outcome of cultural, market, technical and social forces. Illuminating the process will increase the likelihood of successful technology transfer in the future.

2. The T²RERC is operationalizing the elements of TT within a valid and reliable process model. What next steps are required to advance the field of technology transfer?

The T²RERC represents a holistic TT organization, which is rare, if not unprecedented. As the sponsor, NIDRR has provided a unique opportunity to study the process, develop and implement methods, and conduct work across the continuum of TT elements. The next step is to disseminate this information to the broader community of practitioners. However, the absence of an overarching model confines best-practices exchanges to one particular sector. Other sectors won't apply methods and tools until their validity is established.

The field could next expand the research agenda to include empirical testing and documentation of findings from models in practice, to replicate models validated in other fields and to conduct comparative studies of replicated models. Results of this research could be disseminated across disciplines to spread information about the value of the TT process and outcomes.

Literature on the management of innovation offers several models relevant to structuring TT as a formal process. Rigorous data on TT cases should be analyzed through each model to identify their shared and unique contributions to defining a formal process.

Continuing evaluation research is critical to establishing the validity of TT models because valid models are essential to developing the field. Best practices focus on targets and activities that maximize efficiency and effectiveness.

3. How can the T²RERC's activity further promote mainstream science and technology interest in the field of AT?

To increase federal laboratory involvement, statements of AT needs should be written in terminology that is accessible to scientists and technologists. Needs statements should also describe the benefits that will result from participation. Practitioners are fond of characterizing TT as a 'contact sport' because success requires close collaboration between people from different organizations and sectors. Creating direct linkages between the AT community and federal R&D facilities requires some official status. In other words, it should be a sanctioned activity in terms of advancement and reward in the participants' fields. It should include financial or professional incentives for federal employees who participate.

4. How can the T²RERC's TT models be implemented to facilitate TT in other industries?

The *supply push* model's market strategy could spark interest in technologies that would fill gaps between available technologies and unmet market needs that are known to product manufacturers. University research faculty members are entrepreneurs in the sense that the availability of funding shapes their research interests, but they are not entrepreneurial in a business sense. A strategic approach requires a TT *office* staff that explores the unmet needs of major product customers, matches available technologies to those needs, and then jointly approaches manufacturers to deliver products that incorporate advanced technologies.

The *demand pull* model requires a sufficient commitment to improve the state of technology supporting the features and functions of a particular product. It is important that programs addressing smaller industries demonstrate the cost effectiveness of a demand pull project and explain how that approach can be applied to other industries.

Demonstrating cost-effective success is the surest way to attract attention from other industries. The total direct cost of each technology commercialized through the SBIR program is $3.4 million (General Accounting Office, 1999). In comparison, each demand pull project costs about $250,000 and generates multiple commercialized technologies. Furthermore, because demand pull projects only target the highest priority needs of each industry, the resulting transfers are both successful and profitable.

Although the 2003 SOS discussion focused on the models, methods and measures of TT, the objective was to improve stakeholders' collective ability to take the outputs from academic research and development activities and apply them in industrial development and commercialization. The whole point of the funding, and of NIDRR's mission, was to generate useful new products and services to benefit persons with disabilities. The pertinent question is: How do we improve that process?

Advances in the SOS 2003-2008

During the five years since the 2003 SOS, the RERC on TT responded to these issues by expanding into a third form of transfer called *corporate collaboration*. In addition to pushing out innovations and pulling in market needs, this approach improves the accessibility and usability of new products that manufacturers have already initiated. These corporate collaborations gather input on product features and functions drawn from populations of people with varied levels of physical, sensory or cognitive impairment. By incorporating the needs of these neglected potential customers at the design stage, the eventual product is useful to a broader section of the marketplace. Just as OXO™ *Goodgrips* broadened the home market for utensils and tools, corporate collaboration is introducing trans-generational products to the marketplace. Mainstream brands like Black & Decker®, Kodak, Tupperware® and Whirlpool® are among the early beneficiaries of corporate collaboration TT. Sales of their products increased due to their improved accessibility and usability for users of all ages and all abilities.

Corporate collaboration reinforced Stephen Covey's philosophy to begin with the end in mind (Covey, 2004). Projects meant to achieve broad impacts in the marketplace should begin with partnerships with the capacity to deliver the end-result to the mainstream marketplace. Meanwhile, projects meant to benefit a subset of consumers should begin with partnerships that are capable of delivering the end-result to the intended beneficiaries. This lesson is equally relevant to the academic and business sectors. Curiosity-driven research conducted in the academic sector has an entrepreneurial element similar to that of exploratory development conducted by independent inventors in the business sector. The utility of both groups' results depends on initiators' knowledge of the current state of the practice and their ability to ensure that stakeholders will value their contributions. At a minimum, basic researchers have an audience of other researchers exploring the same topic; inventors may have an audience of family and friends.

Such local audiences are sufficient for researchers and inventors who are supported by locally obtained resources. However, it is different for those seeking support from venture capital groups or the federal

government. The federal government is increasingly interested in accountability among recipients of public funding. It asks the questions long posed by potential investors of private or public funds: What will be the return on that investment? What evidence will demonstrate that beneficial outcomes for stakeholders and beneficial impacts for society are likely?

Such scrutiny requires funding agencies and recipients alike to consider results before beginning a new project with federal support. Accountability standards are becoming stricter for industry development projects that intend to deliver tangible products. Further, the academic sector's standards, which once focused primarily on *rigor*, or research quality, are extending to ensure *relevance*, or the practical utility of the research findings. Balancing the twin standards of rigor and relevance, particularly for projects that combine both research and development methods, requires a new mindset among participants.

Conceptual linkages between TT and KT are becoming clearer. The strategy of linking the two processes may lead to integration of activities traditionally considered separate and distinct.

The following sections provide a brief review of TT followed by an overview of the models, methods, and measures of KT. It concludes with a strategy for integrating them into a single framework.

TT Overview

In the field of AT, there exists between the SOS for TT and the SOS for KT convergent, shared interests. The success of downstream technology transfer derived from development depends heavily on the quality of upstream technology-oriented innovations derived from research. Given the prior discussion of KT, and the relationship between research and development, discussion now turns to an overview of technology transfer concepts and constructs.

TT is a process of transforming an idea for the novel application of a technology into a viable product (Lane, 2003). The TT process arises from any of at least three initiating forces (Rothwell, 1992): (a) *technology supply push*, where new discoveries are offered to the field as opportunities to improve product features and functions; (b) *market demand pull*, where customers define unmet needs as opportunities for new products within specific markets; and (c) *corporate collaboration*, where internal corporate ideas for new products are refined through an iterative cycle of input and feedback from external stakeholders.

The transfer of knowledge into tangible forms is challenging as no path directly connects the source and target audience. Instead, the original discovery has to be transformed through a series of steps. Figure 1 illustrates this transformation through three critical events involving five stakeholder groups (Lane, 1999). The transformation encompasses all activity from the initial conception of an application of knowledge (Idea event), through its embodiment in tangible form (Prototype event) and out to commercial production (Product event). The entire TT process is preceded by various activities under the heading 'Research,' and is followed by various activities under the heading 'Production.' The majority of the TT process falls under the heading 'Development--hence, the Research, Development, Production (RDP) model.

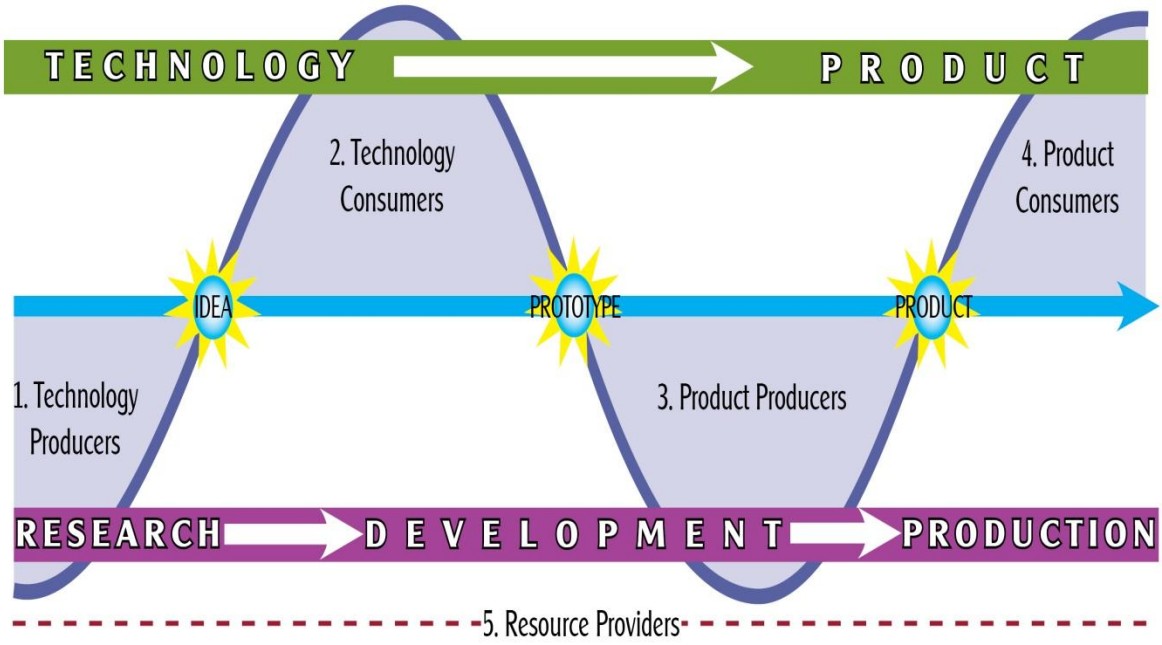

Figure 1. A composite model of technology transfer elements.

It is important to note that the five Stakeholder groups involved in the TT process overlap with the set of five User categories involved in the KT process. Manufacturers and Brokers-Users--are directly engaged as stakeholders under the 'Technology Consumers' and 'Product Producers' headings. The User category, Other Researchers, typically engages in the preceding Research section, called 'Technology Producer' stakeholders. The User categories Clinician/Practitioner and Consumer are typically engaged in the subsequent Commercialization section, called 'Product Consumer' stakeholders. However, representatives from all User categories may provide input throughout the Development process. User categories Brokers and Public Policy are each part of the 'Resource Providers' stakeholder group.

Figure 1 demonstrates how research-based knowledge about various technologies and their possible applications culminates in the *idea event*–the articulation of a specific application of a specific technology. Development activity ensues to transform the idea into the first tangible and functional form–the *prototype event*. The prototype demonstrates that the application idea is feasible in a practical form. Further development ensues, turning the prototype into a set of designs and specifications for a product. The first copy of the final design to roll off the assembly line is the *product event*. TT practices focus on the area in the process between the idea event and the product event. This area of development is where the conceptual value of knowledge under the control of the research innovator is transferred to manufacturers' control where its value takes product form and becomes tangible.

Development activity progresses through a sequence of focused activities called steps. The Product Development Managers Association (PDMA) recently published the second edition of a textbook, along with a three-volume toolbook series, characterizing the contents of any new product development process (Belliveau, Griffin, & Somermeyer, 2007; Kahn, Castellion, & Griffin, 2005). The author extracted and ordered a series of 20

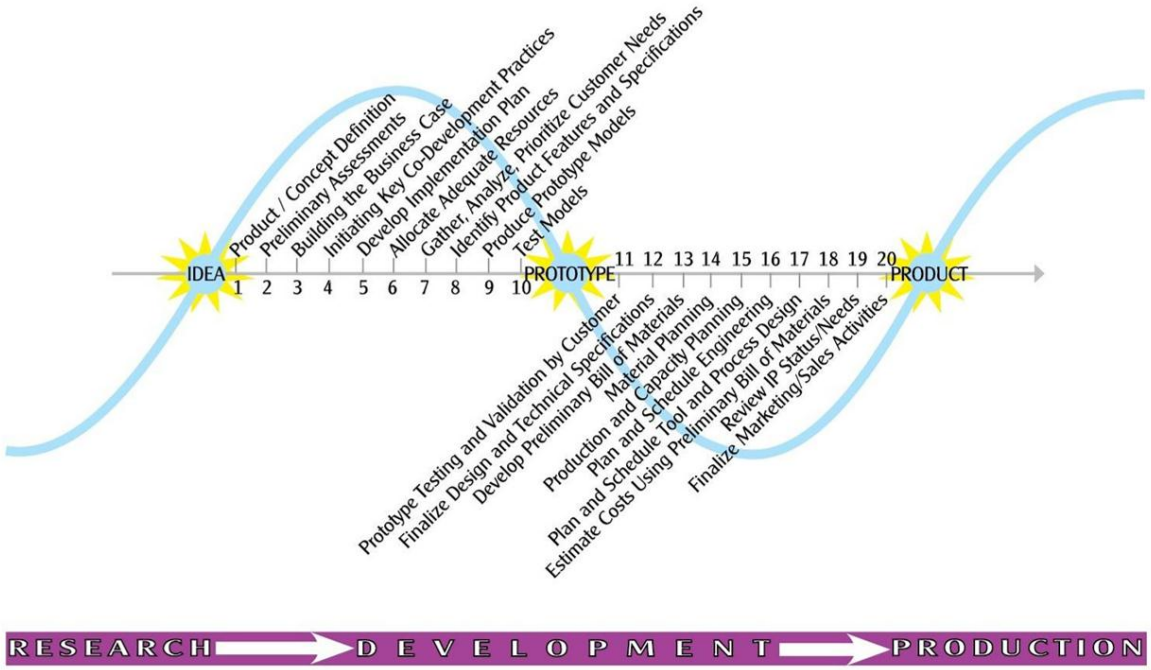

Figure 2. The PDMA 20-step product development process.

steps that represent the minimum range of activities required to advance a project from the idea event to the product event. A chart of these steps was compared with another framework in the literature to verify their order and content (PHAE Group, n.d.). Overlaying these 20 steps on the technology transfer figure resulted in the map shown in Figure 2.

Management science literature studies the practices required to accomplish these 20 steps. The literature is also a resource for identifying and categorizing any barriers to progress and ways to avoid or overcome those barriers. Figure 2 shows the 20-step development process as linking research to production. This corresponds to the definition of KT as encompassing all steps between the creation of new knowledge and its application to yield beneficial outcomes for society (Canadian Institutes of Health Research, n.d.). Each step in the product development sequence has its own input, process, and output tasks. The fundamental work of creating an operational model of KT, in the context of the operational model of technology, will occur at these levels of steps and tasks.

KT Overview

Origins of KT

KT is the bridge between research discovery and societal impact (Graham, 2007). The knowledge production system–particularly in the area of health research–is adopting KT theory and practice as a means to increase knowledge utilization. This includes efforts to increase the impact on society of technology-based knowledge via new products and services.

Canadian Institutes of Health Research (CIHR). The CIHR was created in 2000 with a mandate for "the creation of new knowledge and its translation into improved health care for Canadians, more effective health services and products…" (CIHR Research Act, 2000, p. 7). The CIHR generated immediate international interest by coining the term KT.

While CIHR's definition of KT continues to evolve, the institute currently defines it thusly: "Knowledge translation is a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of [citizens], provide more effective health services and products and strengthen the health care system" (CIHR, n.d.).

The CIHR's first KT model overlaid a traditional linear model of research progression, running from idea conception to contribution to the global knowledge base (CIHR, 2008). The opportunities to apply KT within the standard cycle of scholarly activity were indicated in six places (see Figure 3).

Within the CIHR model, two knowledge-translation opportunities (KT_1, KT_2) fall within the research process itself. Researchers, therefore, could increase translation opportunities by involving stakeholders in the design and research. This principle was previously espoused under the title 'Participatory Action Research' (see discussion of KT-related concepts below; Whyte, 1991).

The CIHR overlay shows that opportunities to practice KT did not end at their contribution to the global state of knowledge. The researcher had two options for moving the knowledge to potential user groups. Both are conceptual in nature, which is appropriate given that researchers are not expected to apply their findings.

One option, KT_3, involves knowledge dissemination. The traditional dissemination path for research outputs involves sharing new knowledge with other researchers in the same field through the journals and conferences established for that very purpose. The KT_3 approach expands dissemination to

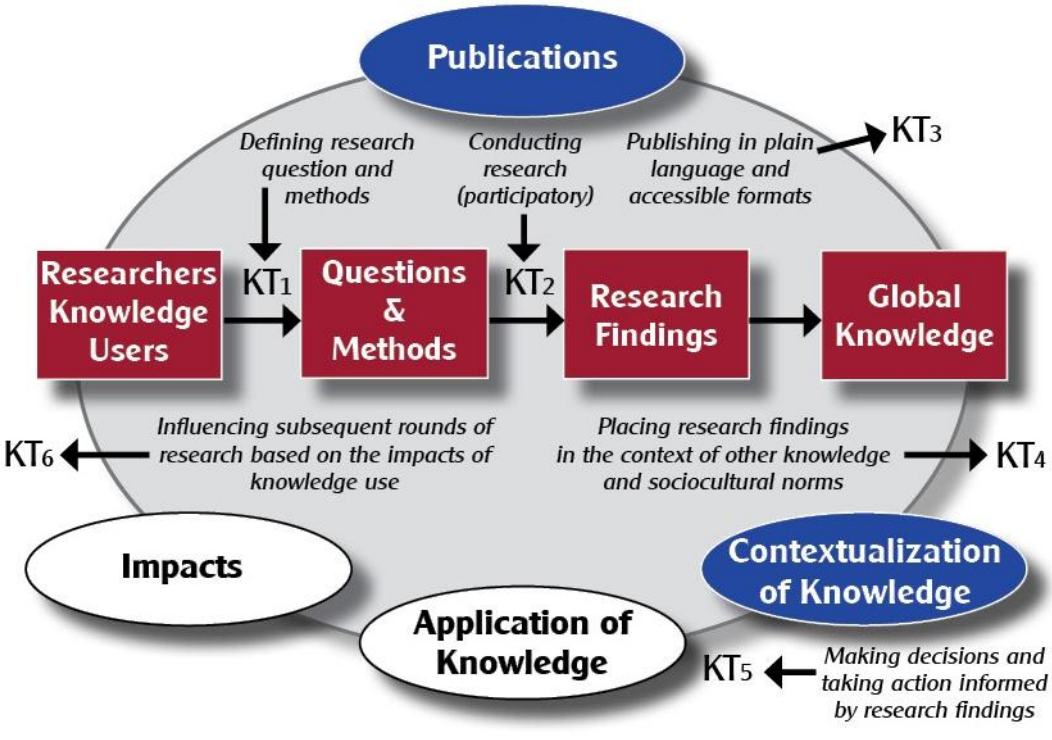

Figure 3. CIHR model of KT.

other target audiences. Doing so requires tailoring the form and content to that audience, which assumes a researcher will devote time and attention to understanding that audience's needs and interests. One might convey this distinction by modifying the diagram so that there are multiple arcing lines between the Global Knowledge box and the Publications oval, thus signifying multiple dissemination paths.

The other option, KT_4, involves knowledge contextualization. Science has limited experience with contextualization, as the traditional role calls for objectivity characterized by an independence from context (see discussion of Mode 1 vs. Mode 2 science). The KT_4 approach requires researchers to become involved with various stakeholders, at least to the extent that they help stakeholders apply the knowledge. The diagram could be altered in a similar fashion to show multiple arcs between the Global Knowledge box and the Contextualization oval, given that knowledge can likely be applied to a variety of contexts. Two shaded ovals in Figure 3--labeled 'Publication' and 'Contextualization of Knowledge'--are the options for the application of new knowledge which are directly available to the researcher as the knowledge producer. The two ovals labeled 'Application of Knowledge' and 'Impacts' require actions by some external stakeholders as the knowledge users, who are beyond the direct control of the knowledge producer. This point is expanded in Figure 4 below.

The two options available to knowledge producers for communicating any new discoveries both require them to operate outside their traditional academic networks. The CIHR calls the KT_1 and KT_2 approaches *integrated KT* because they engage stakeholders from the inception of the research project and involve them in all phases. The familiarity that comes with early involvement simplifies the later dissemination and contextualization. CIHR calls the KT_3 and KT_4 approaches 'End of Grant KT' because the researcher creates a plan to share research findings with the appropriate target audiences but only after the work is completed. The end of the grant approach requires an assumption regarding the actual utility of knowledge outputs to the target audiences, which can only be validated once potential users apply the knowledge.

Opportunities KT_1 through KT_4 were largely investigator-initiated, although any group of stakeholders could approach a researcher about establishing such a relationship. The final opportunity, KT_6, falls within the same conceptual mode, where the researcher examines the evidence of impacts and consequences, and applies them to future research. KT_5 differs from the others in that it represents instrumental rather than conceptual activity (see discussion of forms of use below). Research-based decisions and actions can take many forms. The remainder of this paper will focus on decisions and actions related to knowledge outputs about technologies in the context of accomplishing TT outcomes.

The Application of Knowledge oval within the CIHR diagram represents an extensive, complex range of activities. It is important to note that researchers are not compelled to independently perform the full range. However, if they conducted sponsored research that comes with an expectation of public benefit, they should know enough about the entire process to ensure they facilitate progress through to beneficial impacts. Likewise, they should do nothing to hinder that progress by other stakeholders.

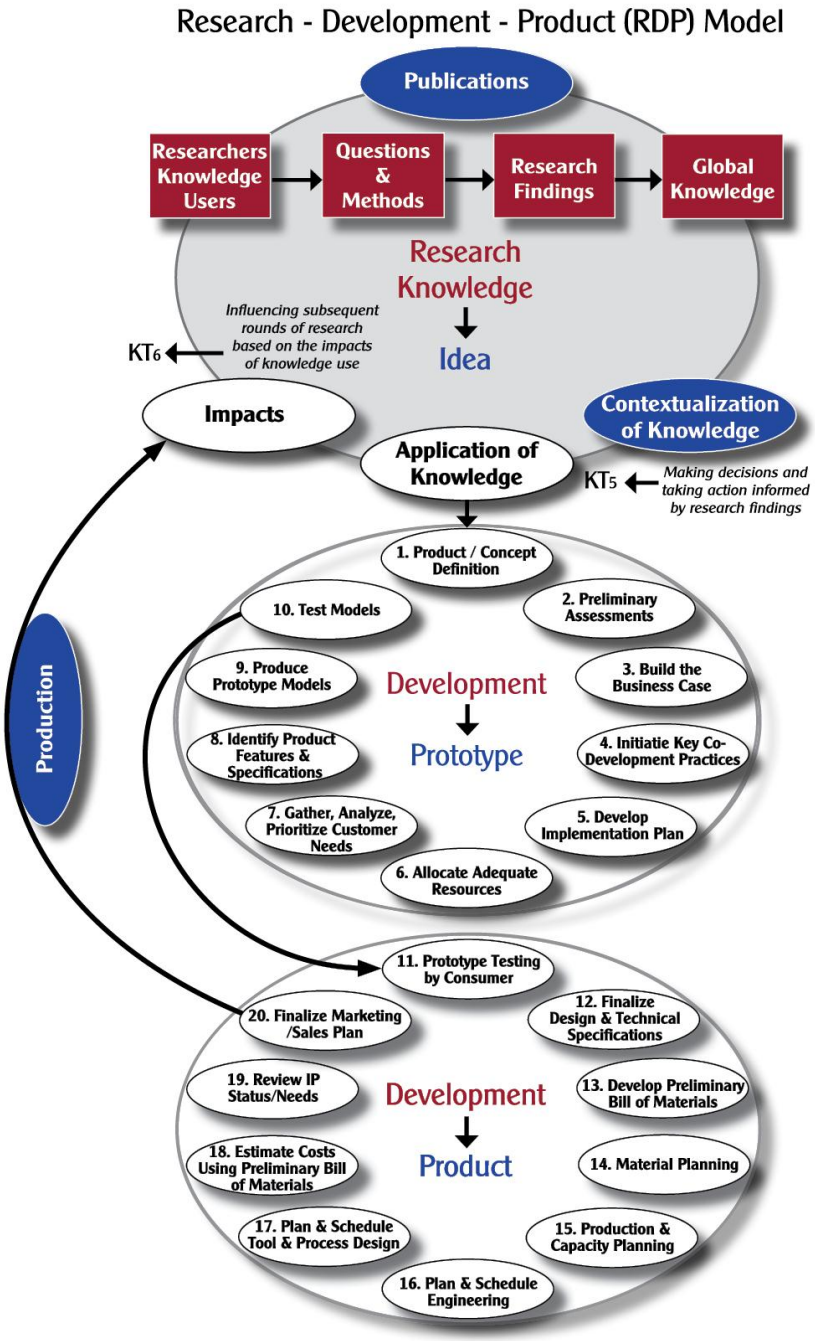

Figure 4. RDP model.

This paper provides additional details to illustrate the extensive and complex range of activities that must occur to bridge research to impact by adding two additional cycles of activity to the CIHR's original diagram in Figure 3. In Figure 4 these two additional cycles represent the 'Action' portion of the TT process, which follows a knowledge user's decision to acquire and apply the research-based knowledge in the tangible form of a product. Figure 4 shows these two linked cycles as white ovals to link them to the white ovals from Figure 3. The RDP model also adds one additional shaded oval labeled

'Production' to represent the replication of the new product or service in their final form. The final form is what reaches the intended beneficiaries and what actually generates the impacts suggested in the last white oval under the CIHR model. This extended diagram is called the Research/Development/ Production (RDP) model, because it expands the Application of Research Knowledge oval into a Prototype Development cycle and a Product Development cycle.

The traditional scholar may believe that the majority of the effort is accomplished once new knowledge is generated through research methods. However, the RDP model shows how much 'end-of-grant' effort is required to transform conceptual knowledge into a tangible product or service. The scholar's success at enlisting other stakeholders to conduct this additional work is directly related to the perceived utility and value of the eventual outcome to these same stakeholders. The transition from conceptual knowledge requires the communication of benefits to target audiences requires the methods reflected in the KT model. Meanwhile instrumental application, in the form of devices or services, requires the methods listed in the RDP model. The latter is described in terms of product development steps in the context of the TT model.

Other KT definitions. The CIHR is not the only organization to define KT (Graham et al., 2006). European governments are pursuing similar strategies. The U.K. Medical Research Council (2007) held a workshop on 'Accelerating the Translation of Medical Research,' which articulated a need for "cultural change within the research community and recognition that translation of research findings and communicating findings to research users was part of a researcher's role." The Netherlands Organization for Health Research and Development recently published a guide to Knowledge Synthesis to promote the use of knowledge in policy and practice (Bos & Van Kammen, 2007).

These international efforts focus on moving knowledge from the production system to the user system for public benefit. The shared focus on beneficial impacts means that KT in word must be matched by KT in deed. In response to this heightened focus on action, the CIHR is implementing the Knowledge to Action (KTA) model, described in detail below. These models show how the KT concept applies to the traditional research paradigm. KT's models, methods and measures are still evolving, as are its relationships to the traditional development paradigm.

Related Activities in the U.S. Federal Government

NIH roadmap for medical research. The NIH Roadmap for Medical Research (National Institutes of Health, 2008) was implemented in 2002. The process involved identifying major opportunities to advance biomedical research and address major gaps in the knowledge base that no single NIH institute could address alone. Instead, the NIH would address these opportunities and gaps at the institute level in conjunction with government, academic and private sectors. The purpose is to accelerate advances in medical research at a scope of complexity and scale of application to profoundly impact the health and welfare of humanity and society.

The NIH roadmap process identified three themes relevant to KT for TT:

1. *New pathways to discovery*. This intends to create a better 'toolbox,' including access to technologies, databases and other resources that are more sensitive, more robust and more easily adaptable to researchers' individual needs.

2. *Research teams of the future*. This encourages scientists and scientific institutions to test alternative models for conducting research, including: interdisciplinary research that links the physical and biological sciences, high-risk and high-return investigations and public-private partnerships that accelerate the movement of research discoveries "from bench to bedside."
3. *Re-engineering the clinical research enterprise*. This accelerates the transformation of research discoveries into drugs, treatments, interventions, and devices. The results are to simultaneously support evidence-based practices and improve the knowledge base.

The NIH roadmap indicates how the academic research sector strives to balance the rigor of Mode 1 science with the relevance of Mode 2 science. The role of Mode 1 science is well established, as are the underlying models, methods and measures and the peer-review standards by which scholarship is valued in academia. Science conducted within the context of application, or Mode 2 science, brings a different set of constructs and expectations (Nowotny, Scott, & Gibbons, 2001). Three examples include that applied science (a) is holistic rather than reductionist, requiring interdisciplinary approaches to complex issues (Giacomini, 2004); (b) requires collaborations with non-academic stakeholders and even target users' audiences to ensure relevance (Denis & Lomas, 2003); and (c) holds that discoveries are a means to the end of knowledge use in practice or policy (Canadian Health Services Foundation, 2000).

Mode 2 science is not readily or easily valued under traditional Mode 1 standards, but it is more readily embraced by the relevant stakeholders and by the general public (Phaneuf, Lomas, McCutcheon, Church, & Wilson, 2007). The NIH Office of Behavioral and Social Sciences Research succinctly framed the problem and solution on behalf of the basic (Mode 1) and applied (Mode 2) science funding through all of the NIH institutes (U.S. Department of Health and Human Services, 2007): "How can we strengthen the science of dissemination and the dissemination of the science of behavior change?" (p. 5).

In 2000, the same year the CIHR was established in Canada, the U.S. Agency for Healthcare Research and Quality established the "Translating Research into Practice Initiative" because:

> Translation of research findings . . . remains a substantial obstacle to improving the quality of care. Up to two decades may pass before the findings of original research become part of routine clinical practice. [This] initiative focuses on implementation techniques and factors associated with successfully translating research findings into diverse applied settings. (Agency for Healthcare Research and Quality [AHRQ], 2001, para 1)

The sectors, organizations and individuals responsible for improving our quality of life seem united on the importance of increasing the translation and utilization of research by knowledge user groups as a means to increase the beneficial impacts of this work.

OSERS/NIDRR principles and practices. In the early 1990s, NIDRR's new leadership was appointed from the community of persons with disabilities. The director of NIDRR and her supervising director of OSERS were both consumers, as well as advocates, for their respective constituents. Thus, they witnessed and experienced the lack of engagement between researchers and the public, which was particularly irksome in programs designed to address the needs of people with disabilities. Having grown up in the

Independent Living Movement, these leaders approached the federal government determined to increase the research culture's responsiveness to their constituents.

The changes were couched in several principles and practices. NIDRR had sponsored national centers of excellence on technology evaluation and TT since the 1980s. However, from the early 1990s onward, NIDRR focused these centers' work on moving technology discoveries and prototype inventions to the marketplace. At the same time, NIDDR introduced the principle of participatory action research by encouraging all grantees to integrate people with disabilities into each phase of their research and development. The NIDRR established another national center in the mid-1990s to increase grantee focus on knowledge dissemination and utilization activities. Recognizing that KT encompasses these dissemination and utilization activities, NIDRR recently redefined that center's mission to address all aspects of KT (National Center for the Dissemination of Disability Research, n.d.).

Converging interests in knowledge production systems. As noted previously, government is increasingly interested in boosting societal return from its investment in research. Society has a say in the role of science--at least in the portion of science sponsored by a publicly funded government. One example is the recent debate over federal support of stem cell research. However, the role of science in society appears to be changing at an even more fundamental level. The traditional paradigm of scientific research is theoretical, discovery-oriented and curiosity-driven (Mode 1; Knorr-Cetina, 1999).

Tensions between Mode 1 and Mode 2. A recent paper by Kitson and Bisby (2008) recounts an interdisciplinary body of literature, which articulates fundamental change in society's perception of research and knowledge production. To wit, Mode 1 science and its practitioners are increasingly challenged to engage in Mode 2 research or at least collaborate with Mode 2 researchers (Kitson & Bisby).

Supporting evidence comes from three sources: (a) public policy that steers scientific research priorities toward programmatic, relevant, collaborative and cost-effective projects (e.g., Human Genome Project); (b) funding allocations that are driven by the commercial potential of new discoveries rather than as contributions to the public knowledge base (e.g., patent protection and licensing revenues); and (c) increasing accountability of science to society in terms of resource management, project deliverables and measurable benefits (e.g., Nowotny et al., 2003; Office of Management and Budgets' Program Assessment Rating Tool).

The point is not to consider the relative merits or possible synergy between Mode 1 and Mode 2 science, nor to debate the role of science in society. The interplay of government, industry and academia has been studied intently (Bransomb & Keller, 1998). The point is to ground NIDRR's current problem within the context of the current social expectations facing all science--particularly publicly funded projects. All science is being held accountable in various new ways. The Mode 2 science designed for application--such as that conducted by NIDRR's technology grantees--is logically subjected to the most intense scrutiny at the formative and summative levels. Given the national and even international nature of this social shift, NIDRR had the luxury of seeking possible solutions to its problem in work already underway elsewhere.

By definition, Mode 2 science should demonstrate evidence of science-based knowledge applied within some context

external to the production of that knowledge. Application requires action by actors. Action requires actors to expend resources on that application task. All resource allocation decisions represent commitments from actors to accomplish a course of action, presumably to receive personal or professional reward. Researchers and their funding agencies must ensure that knowledge outputs will be applied by stakeholders, who will otherwise question the purpose of the research. Once applied, the knowledge should generate positive impacts for the intended beneficiaries and possibly for unintended beneficiaries. Of growing concern to NIDRR and to government research sponsors globally is the need to increase the diffusion of knowledge produced by knowledge producers and to thereby increase the outcomes generated by knowledge users.

In summary, now that federal agencies in Canada, America and elsewhere are looking to apply sponsored research outputs whenever and however possible, the early NIDRR practices are coalescing around this KT concept. This focus opens new conceptual frontiers for NIDRR, their grantees and all stakeholders involved in the field of AT.

Theories of KT

A *theory* is a systematic rendering of ideas, concepts or principles along with the causal or associational relationships among them (Jacobson, 2007). The literature claims that no satisfactory overarching theory for KT exists in the health sciences. An established KT theory is essential for designing testable and likely useful interventions, but none of the models in organizational innovation (Grol, Wensing, & Eccles, 2005), nor in social science literature (Weiss, 1979), appear to offer a solution. Instead, some authors call for combining multiple theories from various disciplines to address the range of practice settings into which research findings must be translated. They liken theories to maps which are specific to a geographic area--the more specific the map (theory), the more useful for negotiating the terrain (context). A range of theories from multiple disciplines is required to address user categories at all the levels and types of use (Estabrooks, Thompson, Lovely, & Hofmeyer, 2006).

The roadmap analogy seems apt and can be expanded. Maps are most useful when one knows the starting point and the intended destination. Advance knowledge of the terrain and identifiable landmarks help to keep a journey on course and on time. In this context, it is important to identify and synthesize the KT models most relevant to accomplishing technology transfer outcomes, and to refine the KT concepts in operational terms appropriate for TT. This includes refining the KT methods in operational terms.

The two major landmarks on this particular map are the domains of the Knowledge Production System (KPS) and the Knowledge Utilization System (KUS). Both the KPS and KUS operate at the levels of individuals, organizations and sectors. Recent literature emphasizes the importance of exploring utilization at the multiple levels of each system: "These levels of analysis influence each other and cannot be disassociated" (Belkhodja, Amara, Landry, & Ouimet, 2007, p. 380).

Knowledge Production System

The knowledge production system consists of elements operating at the sector, organization, and individual levels. Although KT originated outside the U.S., the examples here focus on U.S. organizations for domestic readers.

Sector. This level includes government, industry, academic and civic sectors, each representing groups of organizations, their inter-relationships and the societal context. The government level includes all publicly

sponsored agencies conducting research and development. This sector includes all cabinet-level departments (e.g., Education, Health, Commerce), related agencies (e.g., NSF, NASA) and the network of mission-oriented government laboratories. They all sponsor intramural research and development.

Organization. At this level, sector-level entities sponsor extramural research and development through subsidiary organizations (e.g., NIDRR, NIH, NIST). Sponsoring organizations interact with the sponsored programs at the organizational level (e.g., universities, corporations). Each organization encompasses all internal personnel, resources and capabilities.

Individual. The sponsored activity at this level is conducted through grants, contracts or cooperative agreements conducted by individual project directors as technology grantees. NIDRR's technology grantees in the three selected technology areas are a sub-set of all NIDRR grantees as noted above.

Knowledge Utilization System

The sector, organization, and individual levels of knowledge users are also described using U.S. examples.

Sector. The societal sectors of civil, government, industry and academia all contribute to the quality of life for people in general. Also, at this level, the health-related components of each sector are particularly concerned with the quality of life for persons with disabilities.

Organization. In each sector there exist organizations that focus on health and function as it relates to people with disabilities. For example, the Assistive Technology Industry Association represents manufacturers of products for use by people with sensory or cognitive impairments. Meanwhile the American Association for Homecare represents manufacturers of technology-based devices that are acquired through third-party reimbursement (e.g., wheelchairs, respirators, prosthetics). Professional associations exist for physical, occupational, speech and respiratory therapy. Consumer associations have been instrumental in enacting empowerment legislation that emphasizes quality of life for persons with disabilities.

Individual. NIDRR staff recently published an article describing four categories of knowledge users (the first four in the list below) at the individual level (Sherwood & Melia, 2007). The author adds two additional categories of knowledge users (the final pair in the list below), which are particularly relevant to the field of AT. Here is a listing of the six categories:

1. *Other Researchers*--The academic structure encourages knowledge exchange through publications, conferences and collaboration.
2. *Practitioners, Clinicians*--These are physicians and nurses, for example, who are subjects for much KT research, as well as therapists, counselors and rehabilitation engineers.
3. *Policy Makers*--These public- and private-agency representatives apply evidence-based knowledge to establish programs, protocols and reimbursement levels.
4. *People with Disabilities*--Members of this category use knowledge to manage their own access to products and services, as well as to advocate for change.
5. *Manufacturers, Suppliers*--This category includes original equipment manufacturers (OEMs) and value added retailers (VARs) who perform the production, distribution,

marketing, sales and support of devices and services after TT occurs.

6. *Brokers*--These are typical legal, marketing or technical professionals who protect, disclose, market and sell rights to use innovations created by others. Universities operate technology transfer offices (TTO); federal laboratories operate offices of research and technology administration (ORTA); and corporations contract with law firms.

Knowledge User categories are described only in terms of those with direct relationships to the field of AT. A parallel set of potential Knowledge Users with indirect relationships to the field also exists. For example, Other Researchers in the field of robotics identified, adapted and used research discoveries generated by the research on prosthetics and orthotics. They applied discoveries regarding the biomechanics of a 'shape-and-roll' artificial foot to the gait of robots. In this case, knowledge users from outside the AT field actively sought and used knowledge that was generated and disseminated only within the AT field. The indirect relationships are too numerous to recount here, but their presence is a reminder that knowledge users are not restricted to those participating directly in any particular field of application.

Three KT theories--called *meta-narratives*--explain how the KPS and the KUS systems interact (Greenhalgh, Robert, Macfarlane, Bate, Kyriakidou, & Peacock, 2005):

Meta-Narrative 1: Spreading beneficial ideas through practice networks. This theory follows the sociological explanation underlying the diffusion of innovations. Useful new knowledge is interjected into a social system and gains influence through personal and organizational contacts. The key is that the network is comprised of practitioners so all have a vested interest in applying new tools or techniques through a peer-to-peer process. This is an emergent, ecological paradigm particularly appropriate for naturally occurring social networks.

Meta-Narrative 2: Evidence-based methods and practices that are delivered to practitioners. This is called *rationalistic theory* because management identifies demonstrably superior approaches in the external environment then mandates adoption of the new approach to the internal organization. The logic follows that any innovation is adopted with alacrity for the simple reason that the evidence shows it to be superior. This is an organizational-management paradigm most appropriate for hierarchical systems where rewards follow compliance.

Meta-Narrative 3: Knowledge utilization as an organizational capability. This theory operates independent of external factors because the form and function of knowledge is assumed to change as it moves between organizations and across intra-organizational levels. The knowledge in its external or transitory forms is less important than how the knowledge moves within an organization and supports organizational functions.

All three meta-narratives address the context of knowledge use and the intent of the users, who reside within the individual knowledge users and their organizations (Estabrooks, 1999). Understanding content and intent requires the KPS to examine the KUS to understand the: (a) circumstances and contexts in which new knowledge could be applied, and (b) values of target audiences, which will shape their perceptions of knowledge utility.

Despite the three levels at which KPS and KUS operate, these theories suggest that successful application of KT requires producers to thoroughly understand users at the micro-level of individual adopters.

Models of Knowledge Communication that Inform KT

A *model* represents a theory or a set of concepts and their underlying relational structures (Jacobson, 2007). The conversion and communication of knowledge from one system to another has been modeled in the literature under many terms. Here are four: *innovation diffusion*, *knowledge transfer*, *knowledge use* and *research knowledge utilization* (Bzdel, Wither, & Graham, 2004).

Diffusion of innovations. Some scholars view the *diffusion of innovations* as the closest thing the field of KT has to a reference theory (Estabrooks et al., 2006). Diffusion research began in the field of rural sociology with a study of how the use of hybrid seed corn (an innovation) migrated to Iowa farmers (Ryan & Gross, 1943). The results of this and subsequent sociological studies showed that innovations are communicated through social networks over time and that the rate of adoption typically follows an s-curve. The s-curve results from variations in the speed at which members of the social network adopt or decline the innovation. Users typically fall into five adopter categories derived by laying off standard deviations from the average time of adoption: (a) Innovators (2.5%); (b) Early Adopters (13.5%); (c) Early Majority (34%); (d) Late Majority (34%); (e) Laggards (16%) (Rogers, 1995).

Knowledge transfer. This model considers a variety of methods for communicating knowledge from a source to a target audience. The primary methods are dissemination or education and or training. It means more than publication. Dissemination includes efforts to synthesize research findings and tailor the resulting message to an intended target audience. These steps are deemed necessary as many potential users are not trained to critically appraise and apply research findings (Lomas, 1993). The methods may be applied individually or in combinations. Studies indicate that knowledge transfer methods offer modest to moderate improvements in knowledge implementation when applied as single interventions, although the relative effectiveness of each strategy varies with the circumstances surrounding application (Grimshaw et al., 2004).

One of the only studies on this topic evaluated changes in knowledge and practice among health care workers (Heinemann, Roth, Rychlik, Pe, King, & Clumpner, 2003). The study found that clinicians with the least knowledge are the least likely to cooperate with an education/training program. Of course, their attitudes may determine their low knowledge levels. Clinicians' pre-training knowledge levels, and their readiness to change, are key indicators of the need to put successful knowledge transfer into practice.

The concept 'readiness to change' is a topic of research (Dalton & Gottlieb, 2003). Much of the work focuses on changing the behaviors of patients or clients, who risk suffering serious consequences from their current behaviors (e.g., risk of stroke; Miller & Spilker, 2003); substance abuse (Prochaska & D'Clemente, 1993); and inappropriate behaviors (Rosenbaum, Frankes, & Jaffe, 1983). Despite seemingly high motivations to change, high incentives from current behaviors create resistance to change. Contrast this to *readiness to change* in situations where motivations for change and incentives to resist change are both fairly low. It may be difficult to motivate change when the expected results hardly overcome the inertia of habit.

The Concerns-Based Adoption model (CBAM) is a well established conceptual framework that describes, explains, and predicts probable behaviors in the change process. Its design encourages modifications that fit individual situations (Hall & Hord, 2006).

The three principal diagnostic dimensions of the CBAM are: (a) stages of concern (i.e., seven different reactions that people experience when they implement a new program); (b) levels of use (i.e., behaviors people develop as they become more familiar with, and more skilled in, using an innovation); and (c) innovation configurations (i.e., people adapt innovations differently depending on their situations).

Knowledge use. Conceptual models of knowledge use are as varied as the fields, actors and contexts in which the use occurs. Three basic dimensions of knowledge use models are identified (Dunn, 1983): (a) composition, i.e., distinguishing between individual use for decision-making, and collective use for edification; (b) expected effects, i.e., may be individual or collective but expected effects differ by whether use changes the user's understanding of a situation or changes a user's behavior in response to a situation; and (c) scope, i.e., concerns the processes involved in use in terms of their generality such as a heuristic, or specificity, in terms of protocols or guidelines.

Any combination of these three dimensions can define knowledge use, as when decision-based actions are specific, individual and behavioral. These three dimensions are foundational and remain apparent even in the more refined constructs that follow.

Research Knowledge Utilization

The use of research knowledge is treated as a specific form of knowledge use. In research knowledge use, empirical findings from one or more studies combine to substantiate a decision, intervention or policy (Estabrooks, 1999). Analysis of the potential public benefits from social science research defined three forms of research knowledge use (Weiss, 1979):

1. *Knowledge-driven* use--This is a linear process where basis research results are identified as relevant to a public need. These results are tested for applicability. If the results demonstrate applicability, an appropriate device or service is created and applied. This model represents the Cascade model (Mode 1) of science and therefore represents the operating premise of most university-based technology transfer offices (Tornatzky, Waugaman, & Gray, 2002). The outputs from research are viewed as contributions to the global knowledge base, while applications are secondary outcomes.
2. *Problem-solving use*--This is the opposite circumstance. In problem-solving use, a public need for information initiates the design and conduct of a research study. This is another linear process where a lack of information prompts research and the resulting knowledge is applied. This model represents the Applied model (Mode 2) of science. It is the operating premise of most contract research and the mission-oriented Federal Laboratory Consortium for TT (FLC). People who rely on this model expect research to be problem-driven, and they criticize Mode 1 science that fails to demonstrate social relevance.
3. *Interactive use*--This is a non-linear network of relationships between knowledge producers, user and intermediaries. Existing research-based knowledge is viewed as one input to public issues. It may be combined with newly commissioned research on a given topic. *Interactive use* generates the

greatest tensions between Mode 1 and Mode 2 science.

Taken together, the four preceding models, diffusion of innovations, knowledge transfer, knowledge use, and research knowledge utilization, represent a historical progression (maturation) with respect to knowledge valuation and use over time (Landry, Amara, & Lamari, 2001). They represent the formative stages of KT model development, which is discussed in the next section.

KT Models

This KT overview has described CIHR's role in establishing the field of knowledge translation and articulating KT's first model. As a health research organization, CIHR first drew lessons from, and applied the KT model to, biomedical contexts where the producer and user systems were already closely linked (Sudsawad, 2007). Physicians and nurses working in medical facilities operate within tightly scheduled, highly regimented and thoroughly documented environments. Implementing KT systems to change practices within these closed environments (or systems) is somewhat akin to working within a controlled laboratory. For researchers, it's an ideal setting in which to pre-test, introduce interventions and post-test. Changes in attitudes, behaviors and clinical outcomes are fairly strong indicators of the intervention's effectiveness.

New drug development involves collaboration among academic, corporate and government laboratories. These entities work together to rapidly move discoveries to the marketplace. This was another situation with near-laboratory conditions in which interventions could be tested.

These conditions led to the creation and exploration of numerous models, including the Stetler, PARiHS, Ottawa, 10 Stage, and Knowledge to Action model (Kitson & Bisby, 2008). These models share many important elements. The models differ more on emphasis than on content. They have collectively contributed to the creation of the KTA (Graham et al., 2006). The CIHR focuses on the KTA model. Given CIHR's leadership in the field, the SOS also focuses on the KTA model (Tetroe, 2008).

Focusing on the KTA model is appropriate for linking KT to TT as they relate to generating AT outcomes and impacts. Manufacturers and practitioners or clinicians are the primary audience for the transfer of technology-based products and services. KT is a process for introducing the core value--the innovation--into the context of the target audience's own value systems. The need to translate knowledge from one value system to another may happen between sectors. NIDRR, for example, expects manufacturers to transform research findings into new products, or it expects practitioners and clinicians to agree to use, or recommend, a particular product or service.

As noted above in CIHR's KT model, the application of contextualized knowledge to generate outcomes is intended to result in beneficial impacts on target populations. Getting from knowledge to impact requires decisions, resources and action, ideally in partnership with target-audience representatives. The Knowledge to Action model imparts the focus on action and is highly relevant to AT where the standard industry practices of TT and new product (or service) development and delivery must be applied to generate the desired impacts for intended beneficiaries.

The Knowledge to Action (KTA) Model

The premise of the KTA model is that KT deals with three inter-related issues: (a) making users aware of knowledge and

facilitating their use of it, (b) closing the gap between what we know and what we do, (c) moving knowledge into action.

The KTA model (see Figure 5) depicts these issues as three components of knowledge creation (funnel) and knowledge application (cycle) systems (Graham et al., 2006; Graham & Tetroe, 2007).

Integrated KT Versus End-of-Grant KT

KT can be initiated anywhere along the research continuum. Initiating KT at the earliest stages of idea inception is called *integrated KT*. Initiating KT after research outputs are generated is called *end-of-grant KT*. The KTA model is applicable under either the *integrated KT* or the *end-of-grant KT* situations. Because KT is relatively new to the U.S., domestic researchers are not expected to have applied KT at the inception of their projects. Thus the discussion here will focus on the end-of-grant perspective.

KT is a process for considering the needs and values of knowledge users. The research knowledge can be tailored at the end-of-grant

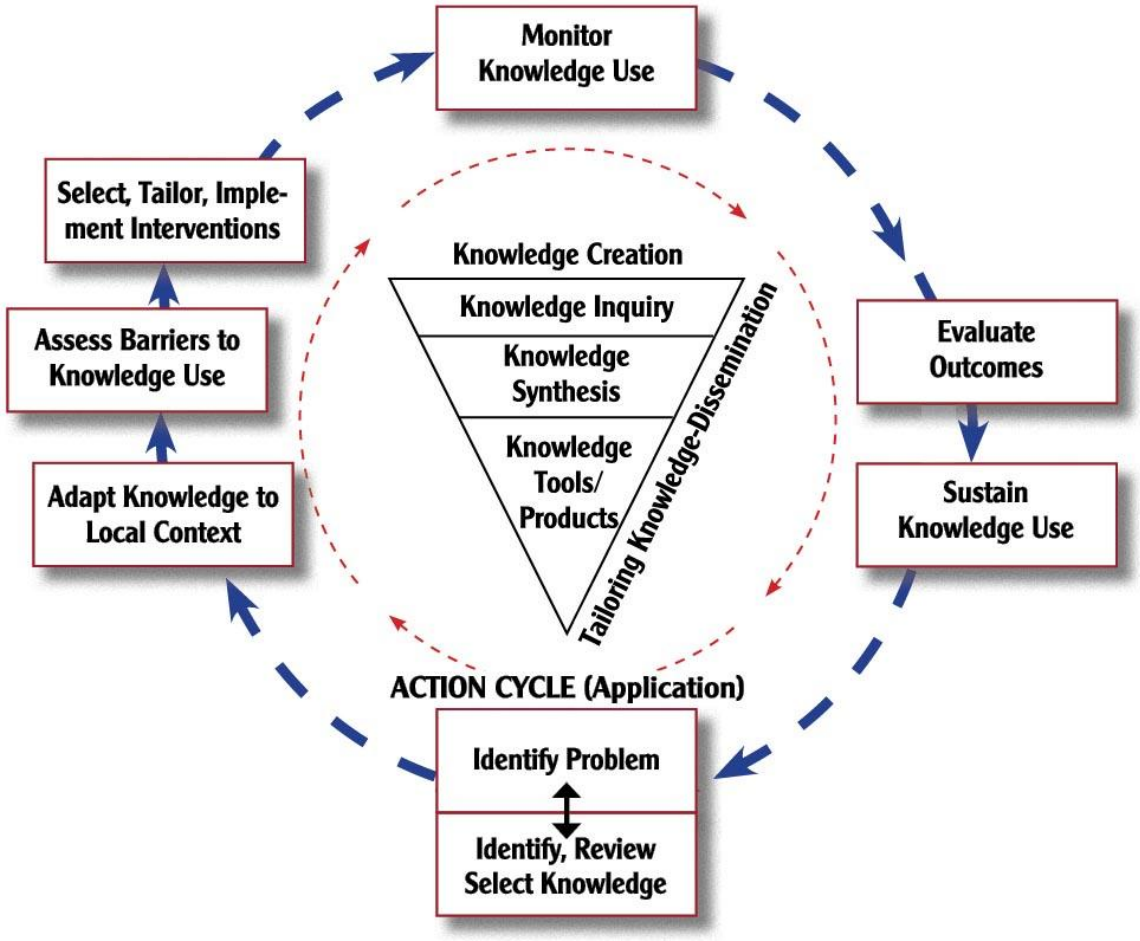

Figure 5. Knowledge to action model.

stage for optimal communication with those knowledge users. Better yet, knowledge users' needs and values can be built directly into the research design at the conception of the new project. The parallels between the KT and TT processes are readily observable. In terms of model, method and likelihood of success, supply-push technology transfer is equivalent to end-of-grant knowledge translation, while demand-pull TT is equivalent to beginning-of-grant KT. The general rule holds that incorporating the needs and values of the intended users at the beginning is much more efficient and effective than engaging them after completing the work.

Recent syntheses of KT literature indicate that new interventions should implement multi-method strategies, including passive dissemination and training as well as active demonstration and technical assistance to include (Kitson & Bisby, 2008; Sudsawad, 2007): (a) diffusion--researcher-push and collaborative tailoring (researcher push; user pull); (b) conference presentations and peer-reviewed publications (open-access policy); (c) non-peer-reviewed publications; (d) Web site postings; (e) end-of-grant report to funders and summary briefings to stakeholders; (f) educational sessions with patients, practitioners and or policy makers; (g) engaging end users in developing and executing dissemination or implementation plan; (h) commercialization efforts; tools creation; and (i) media engagement; use of knowledge brokers.

Reconciling Concepts/Definitions for KT and TT

Key concepts and definitions found in the literature focus on the verbs (e.g., translate, transfer, disseminate, diffuse, implement, utilize), rather than the nouns (e.g., knowledge, innovation). That is, the focus is on the transaction rather than on the object. In KT, the object is the knowledge product generated by the research activity, whether in conceptual or tangible form. In KT for TT, the knowledge product can be either conceptual or tangible at the knowledge producer's output stage. But it becomes tangible within a product or service at the knowledge user's outcome stage. The tangible product or service creates a beneficial impact within the target population. Given the transition from conceptual to tangible form, the utility, or value, of the knowledge object within the context of the intended beneficiaries becomes a critical success factor for achieving eventual impacts.

Knowledge as Innovation

The KT literature contains little mention of the inherent value of the knowledge object itself. Value is comprised of both internal rigor (merit) and external relevance (worth). Few explicit definitions of the innovation exist. It appears that most attention focuses on the functional attributes of the knowledge rather than the inherent value of the knowledge. Two definitions are

> "An idea, practice or object that is perceived as new by an individual. . .If the idea seems new to the individual, it is an innovation" (Rogers, 1995, p. 11).

> ". . .A novel set of behaviors, routines and ways of working that are directed at improving. . ." (Greenhalgh, Robert, MacFarlane, Bate, & Kyriakidou, 2004, p. 582).

Greenhalgh et al. (2004) note that assuming the inherent value of a knowledge object under study is both a convenience and a dilemma. It is a convenience in that it permits KT models to hold constant the 'innovation value,' and it allows studies to focus on the transactional attributes of the knowledge, such as: (a) *How* the knowledge object's value might

be perceived by potential users depending on their motivations for utilization (e.g., instrumental, conceptual, symbolic; Lavis, Robertson, Woodside, McLeod, & Abelson, 2003); (b) *Which* attributes of the knowledge object offer value within the user's context (e.g., relative advantage; Meyers, Sivakumar, & Nakata, 1999), compatibility (Foy, MacLennan, Grimshaw, Penny, Campbell, & Grol, 2002), complexity and face validity (Denis, Hebert, Langley, Lozeau, & Trottier, 2002), and trial use and task issues (Yetton, Sharma, & Southon, 1999); (c) *Which* user attributes might influence their ability to perceive, adapt and apply the value of the knowledge object (e.g., education, motivation, structure; Savory, 2006); and (d) *Which* levels of the organization are involved in making decisions about use of the knowledge object (e.g., individual, organization, sector, system).

However, the assumption of inherent value of a knowledge object is also a dilemma because without any standard criteria for 'innovativeness,' one cannot reliably attribute variance in transaction outcomes to the many other explanatory factors proposed. Some authors hint at this dilemma. They suggest that successful diffusion requires extra attention to the validity and reliability of the knowledge output, because this inherent value to others is the core building block upon which KT efforts will be constructed (Carlisle, 2004).

Indeed, the assumption that scientific research findings in the context of practice are naturally innovative has not been tested: "To use Rogers' model in health requires us to assume that the innovation in classic diffusion theory is equivalent to scientific research finding in the context of practice, an assumption that has not been rigorously tested" (Estabrooks et al., 2006, p. 29).

The field of KT could resolve this dilemma by adopting an existing, well-established convention for determining a knowledge output's innovativeness. The U.S. Patent and Trademark Office (USPTO) has a clear definition. Based on three criteria (listed here and defined below), it serves as the basis for granting an individual's claim of innovative knowledge: (a) novelty, (b) non-obviousness, and (c) utility (Ohio State University, Office of Research, n.d.).

The patent system recognizes that the three criteria may be assessed subjectively or objectively. A knowledge creator may subjectively believe that all three criteria are met. The patent application process provides an opportunity for an objective review of these criteria. The process revolves around the concept of a claim, the articulation of what an individual believes he or she is adding to the knowledge base. In a patent application, the claim is written in the first person singular: "I claim the following . . ."

The individual's claims are then reviewed objectively within the USPTO system.

The *novelty* criterion is the most straightforward in the patent system. It is based on a search of key words and related terms in prior patent claims.

Non-obviousness criteria considers one's ability to make the claim based on familiarity with the existing knowledge base–the prior art. This is important for determining ownership over the innovation, but it is not relevant to the potential users.

Utility criteria involve an extrapolation from claims of novelty to the application of the same claims in practice. The utility criteria include the feasibility of making the innovation work in reality (the basis for rejecting many claims of innovation in the categories of alchemy and perpetual motion machines).

By adopting a modified standard for innovativeness, every KT study could begin by stating the inherent value of the knowledge claim: *What knowledge is claimed and on what basis is it determined to be novel, feasible and useful?* The presence of actual innovativeness is critical to validating any KT model. If an attempt to diffuse knowledge fails, is the failure attributable to the diffusion process or the utility and value of the knowledge itself? Were users correct to reject the knowledge, or were they incapable of adapting useful knowledge to their own circumstances? Verifying the presence of innovation helps clarify such interpretations.

Here is an example of why innovation requires a standard definition. In the above summary of diffusion of innovation research, innovation was defined subjectively. In 1995, Dr. Rogers wrote that one Iowa farmer was classified pejoratively as a 'laggard' for rejecting all forms of chemicals (e.g., weed control, fertilizers, insecticide, feeds), which were perceived as innovations. The laggards say chemicals harm songbirds, earthworms, and other aspects of the natural environment.

Dr. Rogers said, "I have come to understand that the organic farmer respondent in Iowa may actually have been the most innovative individual in my study" (Rogers, 1995, p. 425). A standard definition of *innovation* may have included this farmer's concerns in the criteria and perhaps changed the study's conclusions.

Under the *integrated* KT approach, participants in the KTA model would first identify a problem then search for knowledge to address the problem. In the case of integrated KT, the knowledge would be critically appraised to determine its validity and usefulness for a particular problem (Graham et al., 2006). Under the end-of-grant KT approach, KTA participants cannot identify a specific problem a priori. Instead, the participants must consider the validity and utility of the new knowledge for as many potential applications as possible at the three levels of use and across the six user categories. Participants must assess the inherent value of each new scholarly knowledge object in the context of future applications by knowledge users. For example, the form of a knowledge object can be depicted in a series of stages with value and utility to users increasing along a value chain (object, data, information, knowledge, wisdom; McInerney & Day, 2007).

To the extent that KT literature has considered the inherent value of knowledge objects, the definitions have encompassed both subjective and objective perspectives on innovation value. Here is a four-point scale for assessing innovations:

- *Grade A Innovations*–Subjective (looks new or useful) and objective (is new or useful)
- *Grade B Innovations*–Subjective but not objective--false positive
- *Grade C Innovations*–Not subjective but is objective--false negative
- *Grade F Innovations*–Not subjective or objective

Grade A innovations will be defined as representing true value within a knowledge output. Grade A innovations demonstrate all three applicant criteria: novelty, feasibility and utility.

Grade B innovations may be fairly common among research outputs given that a peer review may focus on the originality of the research design or the gap addressed in the literature. Being novel does not always imply being useful to others. Most 'garage inventions' are Grade B. The inventor as creator subjectively bestows utility and value on something, which, objectively, has none.

Attempts to diffuse Grade B innovations will prove fruitless as the absence of utility is

exposed. However, because of their appearance of value, Grade B innovations may be even more wasteful than Grade F innovations.

Grade F innovations are not innovative in any way. Few waste time and effort on diffusing them. It bears noting that integrated knowledge translation would have given researchers information that led to abandonment of the work at an early stage.

Grade C innovations can be mistaken for something that is already known--called competency traps (Martins & Kambi, 1999). Grade C innovations are worth diffusing because if the subjective barriers are overcome, the innovation will deliver utility and value to the users.

Studies of the effectiveness of KT for diffusion, uptake and use should control for the quality of the subject 'innovation.' Of course, a lack of sensitivity within this preliminary four-point scale is limiting. Theoretically, the minimum threshold for a Grade A score is value for any of the six user categories, at any of the three organizational levels, in any of the three forms of use. Some knowledge outputs may achieve the minimal threshold while others may represent utility and value across multiple categories of users, at multiple levels and in multiple forms. Clarifying these variables and establishing valid metrics for innovations will be an important area of research.

Types of Knowledge Use

As mentioned above, any assessment of knowledge value has to consider all three ways in which users might apply knowledge, as each represents a different perspective on the knowledge value. The literature recognizes three types of knowledge utilization: *instrumental*, *conceptual*, and *symbolic* (Huberman, 1994): (a) *instrumental* utilization is the direct application of research, typically in a tangible and material form, such as a clinical protocol, measurement instrument, or device; (b) *conceptual* utilization changes awareness, perspective or conceptualization but does not result in direct, tangible action; and (c) *symbolic* utilization applies research in support of a previously established position or to accomplish a desired outcome. There is no direct application nor is there any lasting impact on the user. The research findings are a means to an end.

One author created a scale to measure the three levels of utilization and found that a complex activity, operating at all three levels, can be measured with relatively simple questions (Estabrooks, 1999). Studies of knowledge use should take into account these variables within the parameters of the six categories of potential users.

KT Capabilities of User Organizations

With value (innovativeness) of new knowledge outputs from the *knowledge production system* established, attention turns to establishing the capabilities of the *knowledge value system* to uptake and use of these innovations. Literature describes technology-related KT capabilities of user categories at the organization level as being comprised of five components (Savory, 2006):

1. *Absorptive capability*--The organization's technological capability depends on its ability to recognize, assimilate and apply knowledge from outside the organization (Cohen & Levinthal, 1990). A prerequisite is a prior path of learning in the relevant domain. Scientific research is the relevant domain of most NIDRR grantees; few have a prior learning path in the product development domain. The applicant's utilization program will help close the gap in prior learning.

2. *Combinative capability*--Once absorbed, new knowledge must be integrated and reconfigured with the existing knowledge base in novel ways (Kogut & Zander, 1992). The absorbed knowledge must be codified in a new context before it can be applied. This codification process is similar to linguistic translation and involves abstracting the original knowledge, codifying it in the new context and diffusing the original knowledge even beyond the original context (Boisot, 1998).
3. *Transformational capability*--The ability to transform conceptual knowledge into a tangible product that meets a valid need. This ability requires an organization to learn at three different levels or loops (Boisot, 1998; Leonard, 1995): (a) single-loop learning represents an organization's core competence; (b) double-loop learning coordinates and uses a combination of resources; and (c) triple-loop learning is the ability to adapt to changing circumstances; it is the process of learning to learn.
4. *Dynamic capability*--The prior three capabilities describe characteristics of knowledge use within a static context: how it imports and implements external knowledge then integrates that knowledge--through experimentation and prototyping--to solve technological problems. Dynamic capability represents the organization's ability to hold the knowledge application on course while the contextual environment is in a state of flux (Leonard, 1995).
5. *Innovation capability*--The presence of all of these other capabilities collectively constitute an organization's ability to survive by generating novel, feasible and useful products and services for its customer base. Such innovation requires a direct and continuous

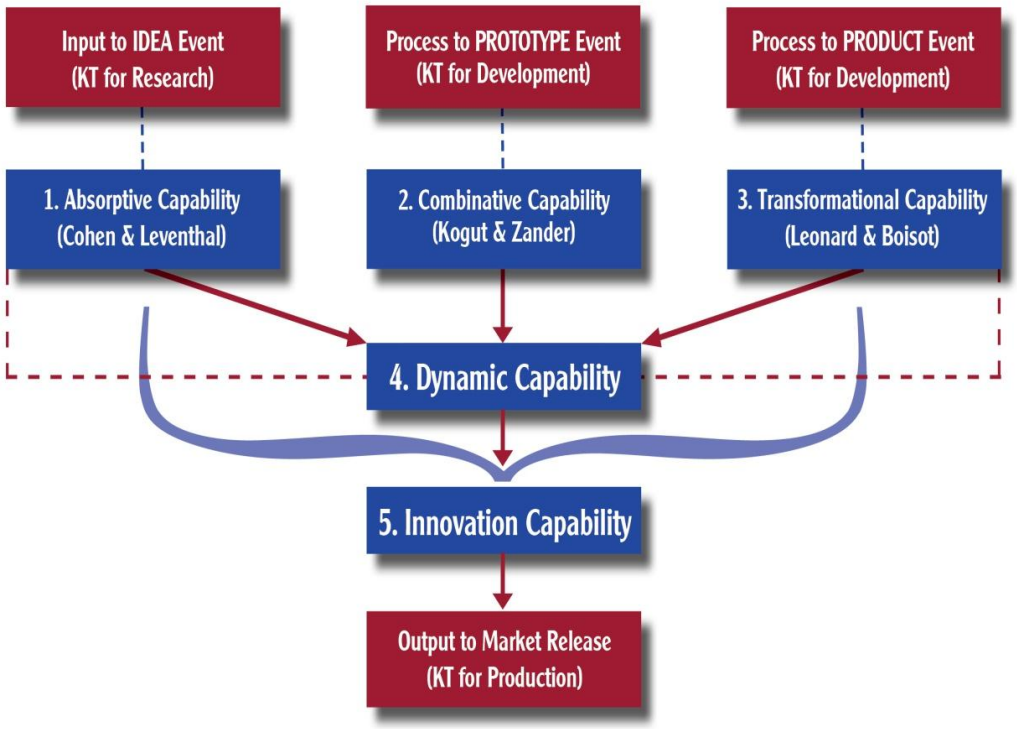

Figure 6. The role of organizational KT capabilities in advancing TT.

Table 1
Create Awareness or Facilitate Use

Attributes to Create Awareness	Attributes to Facilitate Use
The source or originator of message	Influential person as the prime source, reinforced by messages about value of change from multiple internal and external channels.
Channel used to communicate message	Personalized interaction as the channel, with message presented in user-friendly formats, language and style, and repeated over time.
The content of the message	Message grounded in local experience and setting to show it is feasible, adaptable for trial.
Characteristics of the audience	Opinion leader as the initial audience and candidate for early adoption, representing the local need to consider the change.
The setting where the message is received	Local, informal settings where users can test concept and weigh risk to incentives and risk of disincentives.

interplay of KT between knowledge producers and users, and of TT between product producers and consumers.

Figure 6 shows how the five organizational competencies developed through KT practices contribute to an organization's ability to move ideas into tangible product or service forms.

Facilitating Knowledge Use Through KT

The espoused contribution of KT is to facilitate the use of research-based knowledge by target audiences. Sponsored programs may generate innovative outputs, identify target audiences, anticipate various forms of use and even deliver the knowledge through multiple approaches. All are necessary but collectively they are insufficient to make use happen.

Several authors addressed the facilitation of knowledge use in ways that informed the applicant's strategic model and tactical methods. This literature is summarized here then referenced within each aspect of the research, development and utilization project.

One perspective relevant to facilitating knowledge use asserts that diffusion, dissemination and implementation are related phases. They form a process of increasingly active communication reflecting more focused intent. Each subsequent phase depends on the success of its predecessor (Lomas, 1993). Knowledge producers who shift from diffusion to dissemination have changed their intent toward communication outcomes, reflected in changed behavior from passive to active.

However, evidence shows that this shift on the part of the producer is insufficient to prompt knowledge users to shift their intent and behavior from passive awareness of the knowledge to its active use. The successful transmission of knowledge from producer to

potential user can only pre-dispose the user to change behavior by raising awareness about the opportunity to change. Even tailored dissemination only predisposes and is not sufficient to prompt action (Green & Eriksen, 1988).

The RERC on Technology Transfer has verified these findings through repeated examples. Decisions and actions to apply (implement) knowledge come from the attitudes and behaviors of the user. No matter whether one leads a horse to water, as the saying goes, a lack of follow-through by users is a reminder that one can't necessarily make the horse drink.

What triggers action to implement an innovation from the user's perspective? The field of marketing has long focused on tools and techniques to prompt action by targeted consumers. Literature on persuasive communication distinguishes between a set of five general attributes that influence any audience's awareness of new knowledge (Table 1 left side), and a set of five specific attributes that contribute to shifting user intent--prompting action (Table 1 right side; Lomas, 1993; Winkler, Lohr, & Brook, 1985).

A second concept relevant to facilitating knowledge use is *knowledge boundaries*. Knowledge boundaries lie at the point of intersection between the flow of knowledge to users, and the reception of knowledge by users (Carlisle, 2004). Knowledge boundaries exist in three progressively complex types, representing three increasingly complex processes. Moves toward greater complexity still require the less complex capacities (see Table 2).

KTA Model – Knowledge Creation Funnel and Application Action Cycle

The prior discussion of the KTA model focused on the new innovation outputs generated by the knowledge production system. Now attention turns to outcomes and impacts that require action on the part of the Knowledge User System (KUS). Achieving these outcomes and impacts through knowledge utilization by the KUS requires an operational version of the KTA model.

Table 3 shows how the steps in the KTA Knowledge Creation Funnel and Action Cycles (column 1) intersect with key concepts from the KT and TT literature (column 2). These key concepts from KT and TT still

Table 2
Knowledge Boundary Type and Process

Knowledge Boundary Type	Knowledge Boundary Process
Syntactic – Information processing model with a common lexicon to cross the boundary.	*Transfer* – The common lexicon requires stable conditions and is destabilized by novel information.
Semantic – Community-of-practice model where novel information is reconciled through shared meanings or shared mechanisms.	*Translation* – Interpretation required to maintain effective communication. Revealed barriers require carriers.
Pragmatic – Creative abrasion model where novelty generates competing interests that must be resolved via negotiation.	*Transformation* – Create new knowledge by integrating existing knowledge *at stake* along with the value of the innovation.

Table 3
Integrating KT and TT to Facilitate Knowledge Utilization

KTA Knowledge Creation Funnel	*Key KT Concepts*	*Required Integration of KT & TT in Operational Terms*	*Strategies to Facilitate Utilization*
Identify stakeholders and establish shared understanding of KT process.	Knowledge Production System and Knowledge Utilization System; KT & TT models.	Synthesize KT knowledge within KTA model; then reconcile with TT model, methods and measures.	Source of message – send expert message through professional organization.
KTA Steps in Action Cycle	*Key KT Concepts*	*Required Integration of KT & TT in Operational Terms*	*Strategies to Facilitate Utilization*
1) Identify knowledge need (integrated KT) or validate knowledge value (end-of-grant KT).	Research-based knowledge outputs. New knowledge = innovation?	Validate Grade A innovations from technology-related research projects.	Content of the message – true innovation with value to members.
2) Placing useful knowledge in specific context of problem.	Knowledge diffusion, transfer, utilization; five organizational capabilities for use.	Profile value systems of targeted knowledge user categories.	Audience characteristics – opinion leader via organization.
3) Assess barriers and identify carriers to overcome them.	Three levels – individual, organization and sector; transactional attributes of user and knowledge.	Identify specific barriers and carriers for innovations in context of targeted users in each category.	Opinion leader; local setting and norms; feasible, flexible, testable.
4) Tailor intervention to known barriers and target audiences.	Diffusion, syntactic, transfer. Dissemination, semantic, translation. Implementation, pragmatic, transformation.	Create communication vehicles tailored to each target audience for delivery through multiple modes.	Channel used – user-friendly message delivered via multiple channels over extended time.
5) Monitor and measure knowledge utilization	Three types of knowledge use – instrumental, conceptual and strategic.	Pre- and post-tests of users; and or secondary source evidence of utilization.	Recognize need for change, value knowledge as change agent.
6) Determine the impact of use and assess costs involved.	Cost-benefit to KPS and to KUS, as well as value to targeted beneficiaries.	Calculate cost of KT intervention and benefits of outcomes and impacts.	Mid-Term: Collect quantitative and qualitative evidence of value.
7) Sustaining knowledge use: Recapitulates steps 4-7.	New area of KT interest: Literature on public policy and systems change.	Use cost-benefit results to promote movement from end-of-grant KT to integrated KT.	Long-Term: Generate more evidence of value; promote KT change to KPS system.

require additional integration (column 3) before they can be applied in operational terms to facilitate knowledge use (column 4). To facilitate use, the operational model cannot stop with the Knowledge Creation Funnel. Instead, the KTA's Steps in the Action Cycle must also be expressed in operational terms applied by the knowledge users. The established models, methods and measures of

technology transfer offer such operational terms.

Table 3 can also be taken to consider the relationships between existing theories (column 2), existing models (column 1), and new methods (column 3), and how they all might converge to facilitate the desired outcome of knowledge utilization by target audiences (column 4). From this perspective, columns 1, 2, and 4 refer to the current SOS. Column 3 represents the emerging research agenda in relation to integrating TT with KT.

For example, the third column in Table 3 suggests that integrating KT and TT in operational terms was important in creating an operational KT model. One approach would be to create a parallel linear model from the circular Knowledge to Action model, which could be based on the PDMA's linear TT model involving these 20 steps. Such a linear model should consider the dynamic aspects of the KTA model. However, the linearity would permit model builders to identify analogous activities along the KTA and PDMA models. These analogous activities may occur at different points in the progression through the respective models, but the established TT tools and products for conducting the activity may be readily converted into tools and products to conduct the KT activity.

Exploring the TT stages in greater detail would help determine the viability of such a crosswalk from TT to KT models. Within the CIHR KT model (Figure 3), the KT_5 decision point initiates the application of knowledge in a tangible form, through the 20-step development process where research discoveries transform into product outcomes. Development activity occurring between the creation of new knowledge and its release as a product in the marketplace involves two phases, *prototype development* and *product development*.

1. *Prototype development*--In business terms, this phase involves a reduction to practice. Prototype development determines the invention's feasibility in the form of the envisioned product. The process consumes the first 10 steps in Figure 2, culminating in a final prototype (Bowling Green State University, 1997).
2. *Product development*--The prototype can only become a product if a manufacturer decides to invest the necessary resources to transform the prototype into a set of designs and specifications representing a new product. The product development phase consumes the second 10 steps in Figure 2, culminating in the first unit of a produced product.

The decision to actually manufacture and release a new product into the marketplace involves an entirely different and additional cycle of activities and practices called *production*, as indicated in Figure 2. This production cycle occurs beyond the *product* event so its details fall outside the scope of the initial KT and TT model crosswalk. It is important to note that the innovation process continues after the product reaches the marketplace because actual use drives continued product innovation (Howells, 2004). For example, product users identify gaps or misconceptions in the original expectations for product use. The process of use also identifies novel applications for the technology. So, long-term efforts to build parallel models would eventually also have to address analogies in the production cycle as well.

Subsequent to the product's market release, acquisition and use by targeted beneficiaries generates impacts on individuals, their communities and on society. These impacts

lead discussion back to the CIHR KT model (Figure 3) where the *impacts* oval in the bottom left represents these consequences from acquisition and use. The *impact* stage precipitates the final KT opportunity: KT_6--influencing subsequent rounds of research based on the impacts of knowledge use.

At that point, the cycle of research, development and production may repeat (see Figure 4, RDP model). This is the dynamic nature of technology-related innovations. Having an operational KT model for research, linked to the existing operational TT model for development and production, would provide a meta-model for technology-related innovations. There is precedent for such a meta-model, most notably in times of national crisis such as World War II and the Space Race. In such instances, government united academia and industry to create innovative technologies through research. These technologies translated into tangible products in response to clearly defined national needs.

Implementing KT Processes to Accomplish TT Outcomes

The KT process is designed to communicate the value of conceptual knowledge, while the TT process is designed to transform this value into tangible outcomes. The AT field needs to link both processes to increase the outcome yields from technology grantees as demonstrated by new or improved products in the marketplace.

The frameworks for KT and for TT discussed up to this point can now all be linked to illustrate the full transformation of knowledge from the idea for the application of knowledge in the mind of the researcher, through to the impact of new product outcomes on the intended beneficiaries. The initial research discovery sparks an idea for an application. That idea then becomes a tangible proof-of-concept prototype via Phase I development activity (Steps 1-10), and is then refined into a product under Phase II development activity (Steps 11-20). The resulting product is released into the marketplace where it benefits the target users. These target beneficiaries then generate quality of life, economic, and social impacts.

This entire process between the initial *idea* input and eventual impacts from the *product* outcome is represented by Figure 7. From left to right, Figure 7 begins with the *KT Application of Knowledge*, which corresponds to the first white oval on the bottom of the CIHR KT model in Figure 1, where some action follows the decision to apply the new knowledge in a tangible form--the *idea* event.

Figure 7 proceeds through the 20 steps of

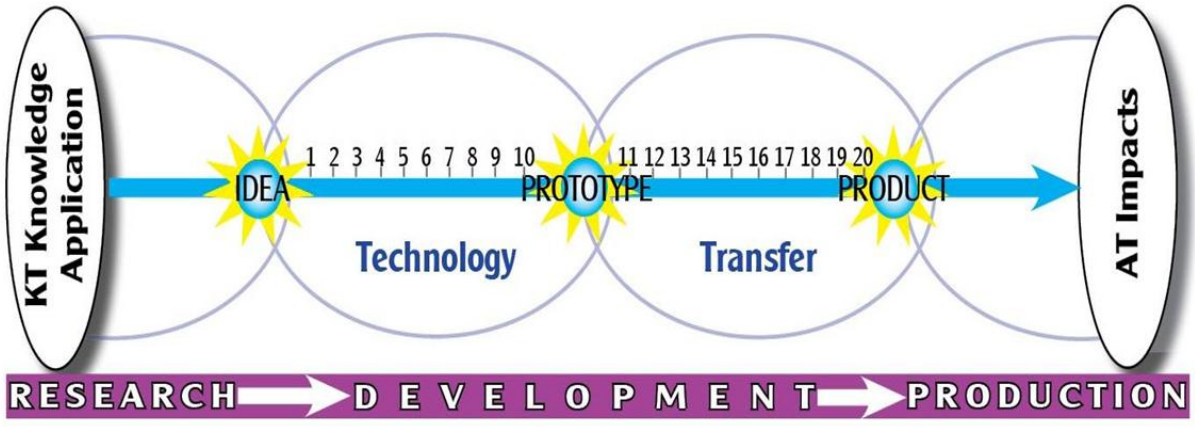

Figure 7. From KT input to TT impacts.

product development. The first 10 steps to *prototype* event are typically performed by NIDRR technology grantees. Some grantees--a few RERC entrepreneurs and many SBIR enterprises--continue with steps 11 through 20. This moves them away from corporate partnerships and toward becoming manufacturers themselves. In other instances, grantees stop internal work at the prototype event and create formal partnerships with corporate manufacturers to achieve the product event.

Figure 7 shows the product event, which is followed by all the commercialization activity. The far right side concludes with the second white oval labeled as *AT Impacts*, which corresponds to second white oval at the bottom left in the Figure 1 CIHR KT model, where impacts result from the application of knowledge. Figure 7 is a reference diagram for SOS discussion regarding the transformation of knowledge outputs into product outcomes.

The SOS Q&A for 2008-2013

The SOS progresses with knowledge drawn from research and from practice. The four questions from 2003 are revisited here with a view toward the next steps in progress.

1. What steps are necessary for technology transfer to evolve from a professional practice to an academic discipline?

The evolution from practice to discipline will be advanced by linking the theory and practice of KT to the models, methods and metrics of TT. This addresses concerns about the ad hoc nature of the process and generates needed understanding of how and why transfers occur between knowledge producers and knowledge users. The government and public demand that research contributes to societal needs is precisely the impetus to move from art to science. KT arose from a complex mix of forces to contribute to the management of technology innovations. Indeed, the prior discussion illustrated the interdependence between processes, previously treated as the purview of independent sectors.

2. The T²RERC is operationalizing the elements of TT within a valid and reliable process model. What next steps are required to advance the field of TT?

With an operational TT process established, the next step is to crosswalk its components to create an operational model of knowledge translation. Then, applying the operational KT model in practice for the field of AT will establish its validity along with its potential for application in other fields of practice. Combining existing evidence from research with new evidence from application will generate a more formal process, and establish the approaches considered to represent best practices.

3. How can the T²RERC's activity further promote mainstream science and technology interest in the field of AT?

Active efforts to engage stakeholders in the translation of knowledge about technology-related needs in the field of AT, and about the potential utility of AT knowledge for application in other fields, is a core activity of the KT for TT approaches to increased outcomes and impacts. Integrated KT involves an articulation of benefits for both the knowledge producer and the knowledge user, including both professional and personal incentives for collaboration across fields of application and economic sectors.

4. How can the T²RERC's technology transfer models be implemented to facilitate TT in other industries?

KT represents the scholarly entrepreneurialism of the academic sector, while TT represents the monetary entrepreneurialism of the industrial sector.

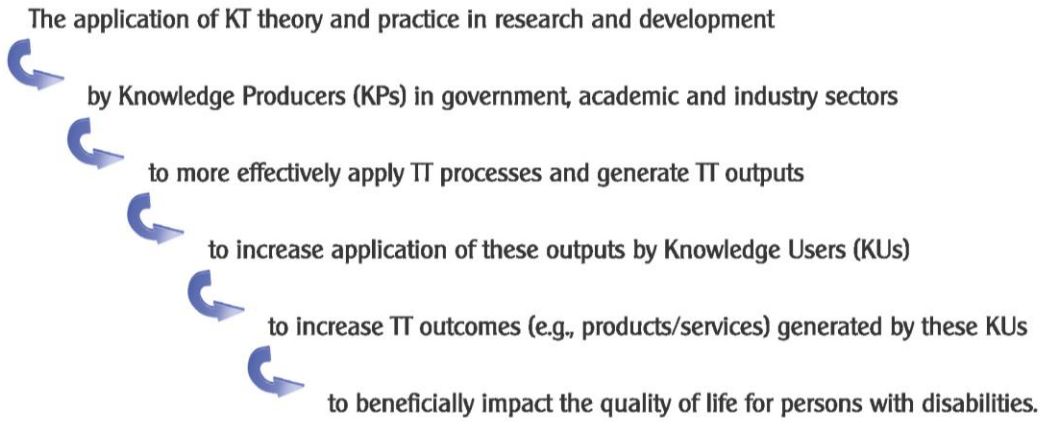

*Figure 8.*The Knowledge Translation for Technology Transfer Cascade.

The convergence of these two processes will improve researchers' abilities to see and plan for the downstream applications of their knowledge outputs. At the same time, it will improve the manufacturers' abilities to identify and evaluate the potential contributions of new knowledge to gaps in their product and service offerings. Testing the KT for TT model through intervention studies will provide the cost-benefit analysis necessary to make sound decisions regarding the future application of this model by the government, academic and business sectors.

In summary, *KT* for *TT* can be abbreviated as shown in Figure 8.

The field of AT can advance if KT strategies are used to communicate this model to knowledge producers and if KT strategies are used to communicate their innovative knowledge outputs to knowledge users. The integration of KT and TT models--and the broader integration of research, development and production activities--is the next critical contribution to the state of the science, the state of the practice and the state of the art.

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SBIR and STTR Programs for Assistive Technology Device Development: Evaluation of Impact Using an ICF-based Classification

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Abstract

The purpose of this paper was to evaluate the impact of Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) grant programs of 5 federal agencies National Institutes of Health (NIH), National Science Foundation (NSF), U.S. Department of Education (USDE), U.S. Department of Agriculture (USDA), and Department of Transportation (DOT) on the development of assistive technology (AT) devices using an International Classification of Functioning, Disability and Health (ICF)-based framework

SBIR and STTR awards were reviewed for the period 1996 through 2005. An ICF-based classification system, inclusion-exclusion criteria and assignment heuristics was developed. Awards were classified in reference to ICF components: *Body Structures and Functions, Activity, Participation* (separated in this system from *Activity*) and *Contextual Factors*, and further classified within each component. More than 24,000 SBIR and STTR, Phase I and Phase II grants were reviewed. Findings include the distribution of SBIR and STTR grants for assistive technology device (ATD) development, by component and category (of the ICF-based classification system); awards and funding by agency and year; cross-agency and temporal funding patterns; and concordance of funding patterns to agency missions. The authors concluded that the NIH and the USDE are the key SBIR funders for ATD development. The ICF-based classification scheme successfully differentiated agency award portfolios at both the component and category levels. The NIH is the key STTR funder for ATD development however the STTR program is relatively underutilized by ATD manufacturers. The USDE had the smallest SBIR program, yet was second in importance as an SBIR funder only to the NIH. The USDE mission is focused on addressing the needs of people with disabilities. No other agency mission had an analogous focus.

Introduction

People with disabilities use assistive technology devices (ATD) to enhance their levels of independence and to participate in activities of daily living, education, employment, recreation, and community living. Historically, many AT products have lagged behind mainstream products in terms of functionality, performance, quality, availability and cost. The ATD market landscape is dominated by niche markets and served by small manufacturers. Even within a specific disability market, customer diversity further reduces business opportunity as a

driver for innovation. In general, additionally, innovation by most small manufacturers is constrained by limited financial, technical, or infrastructural capacities. To help overcome these challenges, some ATD manufacturers rely on Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) grants that are administrated and funded by certain large federal agencies.

SBIR and STTR programs fund small ATD manufacturers to conduct applied research and development activities with the intended outcome being the commercialization of new and improved products. SBIR and STTR funding is especially important for ATD manufacturers who develop products for small markets unlikely to attract investment capital. Studies conducted by the General Accounting Office (GAO) have concluded that the SBIR and STTR programs provide tremendous impetus for high-risk research, product development, and economic growth (GAO/T-RCED-98-218, 1998; GAO/T-RCED-99-198, 1999; GAO-05-861T, 2005). However, use of these programs by ATD manufacturers and the impact of SBIR and STTR programs on ATD development and commercialization is unstudied and unknown.

The Rehabilitation Engineering Research Center on Technology Transfer (T2RERC) based at the University at Buffalo conducted a public policy project that examined federal agencies and programs that support research activities that impact AT development. This paper focuses on five federal SBIR programs and two federal STTR programs that are developing a broad spectrum of ATDs. To accommodate the great diversity of ATDs, associate ATD development with industry segments, and assess the impact of the SBIR and STTR programs on ATD development, an ATD classification system was developed based upon the International Classification of Functioning, Disability and Health (World Health Organization, 2001). Expected outcomes from this effort are multifold:

1. Study findings will facilitate further research and analysis. These findings will include on a yearly and aggregate basis: company-level award data (companies receiving awards, number of awards received, funding per award, types of ATDs funded); agency-level award data (number of awards, funding levels, ATD award portfolios); interagency comparisons of award data (award number, funding levels, ATD award portfolios); and inter-program (SBIR v. STTR) comparisons at the company and agency levels.
2. Study findings will guide ATD manufacturers to the most appropriate SBIR and STTR funding sources. In turn, these resources will facilitate the development of high-risk, high-need ATDs.
3. Study findings will allow federal agencies to compare and optimize the makeup and foci of their SBIR and STTR grant portfolios. In particular, the findings will reduce portfolio similarities, accentuate portfolio differences, and allow appraisal of SBIR and STTR programs with regard to mission fulfillment.
4. Study findings may guide policy leaders (in state and federal legislative bodies). In turn, policy leaders set government priorities, establish program mandates, and evaluate program performance.
5. Study findings will inform disability advocates wishing to evaluate government programs. In particular, advocates will be able to compare and contrast the impact of different programs on IWDs.
6. Finally, the ICF-based classification system should have many additional

applications in the domains of policy and disability research. Formal validation of the ICF-based classification system was planned for Spring, 2009.

This paper begins with a detailed background of SBIR and STTR programs with the intent of informing small business ATD manufacturers. Reports suggest that about 13% of ATD manufacturers initiate and seek funding from SBIR and STTR programs (U.S. Department. of Commerce, 2003). Subsequently, existing government reports appraising the impact of SBIR and STTR programs are systematically reviewed to provide a context for the current research effort. The methodology section introduces the ICF model and ICF-based classification system and describes the data collection protocols. The results section includes a classification and analysis of grant awards and funding for the five SBIR and two STTR programs over the period 1996 through 2005. The concluding sections include data interpretation and comparisons, implications and future work.

Background

In 2003, the U.S. Department of Commerce, Bureau of Industry and Security (BIS) published the *Technology Assessment of the Assistive Technology Industry*. The BIS developed a survey for domestic businesses involved in the design, testing, research, development, manufacture and distribution of ATDs. An opportunistic sample comprised of 359 AT product companies completed the survey and only 10 of these companies did not qualify as small businesses. Among many important findings, only 52 (14%) of these companies had applied for SBIR funding during the period 1997 to 1999. None of the companies noted applying for STTR awards (U.S. Department of Commerce). In January 2008, the Assistive Technology Industry Association was comprised of 130 members. For the period 1996 to 2005 only 16 (13%) of these ATIA members *had received* one or more SBIR awards from the NIH, NSF, USDE, DOT or the USDA (Bauer & Flagg, 2008). These results suggest that most ATD manufacturers were either unaware of, or uninterested (for unknown reasons), in competing for SBIR or STTR funding. For this reason, the background section of this article includes substantial detail and references for both programs.

The SBIR program was established under the Small Business Innovation Development Act of 1982 (P.L., 97-219); it was reauthorized until September 30, 2000, by the Small Business Technology Transfer Act (P.L. 102-564), and reauthorized again until September 30, 2008, by the Small Business Reauthorization Act of 2000 (P.L. 106-554). The current embodiment of this law will be referred to as the 'SBIR Act.' The SBIR Act (Public Law 97-219) requires that large federal agencies with extramural research budgets of at least $100 million set aside 2.5% of these funds for grants to small U.S. businesses. The expressed purpose of the SBIR Act is to stimulate technological innovation in the private sector, increase the role of small businesses in meeting federal research and development needs, and to increase private sector commercialization of innovations derived from federally supported research and development efforts. The act also encourages the participation, by women-owned and socially disadvantaged small business firms.

Table 1
Typical SBIR Phases.

• **Phase I** awards are up to 6 months duration at up to $100K. Phase I activities typically establish the technical feasibility of a *proof-of-concept prototype*. The small business must complete at least of two-thirds the Phase I award. Subcontractors can complete up to one-third of the award and their participation is often encouraged. Upon concluding Phase I, a final report is required, summarizing progress toward stated Phase I objectives.
• **Phase II** awards are up to 2 years long and up to $750,000 total. Only Phase I award winners can apply for Phase II funding and applications must be accompanied by the Phase I final report. Phase II activity typically supports development of a proof-of-product and demonstrates commercial potential. The small business must complete at least 50% of the Phase II award while subcontractors can complete up to 50% of the award.
• **Phase III** has indefinite duration and is unfunded. A successful Phase III outcome is a new or improved technology or commercial product. Phase III is the 'proof of the pudding' in terms of program performance and return-on-investment, however participating manufacturers are not required to report Phase III outcomes. This creates difficulties for agencies and other entities charged with program oversight.

Source: U.S. Small Business Administration. (n.d.). *Office of Technology SBIR/STTR.* Retrieved January 20, 2009, from http://www.sba.gov/aboutsba/sbaprograms/sbir/index.html

The second of these objectives "to use small business to meet federal research and development needs" [§2(b)(2)] has special significance. Each federal agency's mission is distinct, and the research and development sponsored by these agencies to address 'mission-driven needs' should be expected to vary accordingly. In practice, some SBIR programs will be more relevant to ATD manufacturers than others.

The basic requirements for participation in an SBIR program are: (a) U.S. business, (b) U.S. owned (≥51%) and operated, (c) principle investigator is employed by business, (d) business has less than 500 employees, and (d) business is a for-profit entity. In fact, almost all U.S. ATD manufacturers qualify as small businesses (U.S. Department of Commerce, 2003). There is variation across federal agencies, but SBIR programs typically have three phases and similar funding levels and grant periods. Typical SBIR phases are summarized in Table 1.

Many SBIR grants result in patentable intellectual property (inventions). Small businesses generally retain title to these patents. In turn, the invention is the basis for, or incorporated into, new and improved products, tools, and services that meet private sector needs. The small business must grant the federal government a non-transferable license to practice the invention. In turn, the federal government may ask other public or private entities (e.g., a private subcontractor) to practice the invention on its behalf. Non-transferrable licenses are one of the principle mechanisms through which SBIR programs address an agency's 'mission critical needs.'

At least 11 federal agencies currently have SBIR programs including the Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services (NIH, n.d.), Homeland Security, Transportation, Environmental Protection Agency, and National Aeronautics and Space Administration (NASA), and NSF. Each agency sets the goals and objectives for its SBIR programs, administrates its program and

must report yearly performance data to the Department of Commerce, Small Business Administration (SBA). In turn the SBA produces annual reports with aggregate information on SBIR and STTR program activities. While informative, SBA annual reports offer few specifics on the technologies developed or products commercialized (GAO/T-RCED-99-198, 1999; GAO-07-38, 2006).

SBIR programs are broadly classified as being acquisition- or non-acquisition-based. Acquisition-based SBIR programs are employed to develop technologies for an agency's own use. In effect, the federal agency is the primary market for technologies developed through acquisition-based SBIR programs. Acquisition-based SBIR programs typically employ tightly constrained solicitations, giving small businesses little leeway regarding the scope and purpose of research efforts. Examples of federal agencies with acquisition-based SBIR programs include: the Department of Defense, sectors of the Department of Energy, and NASA.

Non-acquisition-based SBIR programs are employed to develop technologies for the *private sector*. Non-acquisition-based SBIR programs typically employ solicitations with broadly stated requirements, giving small businesses great leeway regarding the scope and purpose of research efforts. Examples of federal agencies with non-acquisition-based programs include: the Departments of Agriculture, Education, Transportation and sectors of the Department of Energy, as well as NIH; and NSF. While this study focuses on non-acquisition-based SBIR and STTR programs, it is reasonable to assume that some acquisition-based programs (e.g. NASA) play a significant role in ATD development.

The STTR program, roughly one-tenth the size of the SBIR program, was established under the Small Business Technology Transfer Development Act of 1992 (Title II, Public Law 102-564) and subsequently reauthorized in 1997 and 2002. The STTR legislation requires large federal agencies to set aside 0.3% of their extramural budget for their STTR programs. The STTR and SBIR programs have similar missions with mostly minor differences. The STTR program also has three phases. Nominally, Phase I is funded at $75,000 for up to 9 months, and Phase II at $500,000 for up to 2 years, while Phase III is unfunded. The STTR principle investigator may be affiliated with a U.S. university (or other non-profit entity) or U.S. manufacturer. In Phase I, the university can complete up to two-thirds of work while a small business can complete up to one-third of the work. In Phase II, the small business can complete up to one half of the work. Accounting for program size, it is unknown whether ATD manufacturers prefer SBIR and STTR programs. If there is a preference, the reasons for this preference have not been explored.

In addition to annual reports, the SBA records yearly SBIR and STTR awards across all agencies in the Tech-Net database. Collected data for Phase I and Phase II awards include the proposal title and abstract, company name and address, principle investigator and contact information, grant number, phase, amount and awarding agency, and the start and end dates for the award. The Tech-Net database was intended to be the central cross-agency repository for SBIR records dating from the inception of the SBIR legislation. The Tech-Net database is in principle an excellent concept and public resource. However, GAO studies have criticized the quality and completeness of Tech-Net records (GAO-07-38, 2006).

Starting in the late 1990s some federal agencies (e.g., DOT, USDA) created their own databases to house SBIR and STTR program data. Other agencies (e.g., NIH,

NSF, and USDE) maintained parallel, independent databases starting from the inception of their respective SBIR and STTR programs.

Problem Statement

All federal agencies compile aggregate performance statistics for their SBIR and STTR programs on a yearly basis. These statistics typically include: (a) the number of Phase I applicants, (b) the number of Phase I awardees, (c) the number of Phase II applicants, (d) the number of Phase II awardees, (e) total Phase I funding, and (f) total Phase II funding. These statistics form the basis for most GAO and annual SBA reports but provide neither details on industry segments, manufacturers, and technologies, nor on products that are being developed. The SBA Tech-Net database and agency SBIR and STTR databases do include details on the manufacturers being funded and research abstracts. However, analysis of these databases is hindered by the lack of a universal classification system for industry segments and product types. Two federal agencies, the National Research Council (NRC) and NIH, recently evaluated and reported on the merits of key SBIR programs. These reports were reviewed in detail in order to gain insight on ATD development.

Starting in 2003 the NRC began publishing studies on large SBIR programs and, in 2007, the NRC published a summative study of the five largest SBIR programs (DOD, NIH, DOE, NASA, and NSF) comprising more than 96% of all SBIR expenditures (Wessner, 2007a-d, 2008a-b). No similar large studies have been published for the STTR programs, nor have studies been published for smaller SBIR programs such as those run by the USDE, DOT, or USDA.

Section 108 of The Small Business Reauthorization Act of 2000 requires that the NRC conduct comprehensive studies of federal agencies with SBIR budgets exceeding $50 million. Five agencies, in rank order of their SBIR program outlays, met these criteria in 2000: DOD, NIH, NASA, DOE, and NSF. The overall goal for these NRC studies was to determine how the SBIR program has stimulated technological innovation and used small businesses to meet federal research and development needs. The NRC study is summarized in Table 2.

Overall, the NRC study results suggest that SBIR programs are a critical and effective resource for small businesses developing and commercializing high-risk products. Two study findings are immediately relevant to ATD manufacturers. In 2003, 2005, and 2006 NIH and NSF funded the majority of Phase I SBIR applicants, and a large portion of NIH and NSF Phase I awards went to first-time applicants. The NIH (n.d.) and NSF (n.d.) mission statements have no apparent bias for or against the development of technologies benefiting individuals with disabilities. Assuming an absence of bias, NIH and NSF should be preferred funding sources for ATD development. It is also unclear whether the absence of a barrier-to-entry for first-time applicants applies similarly for ATD manufacturers.

For those ATD manufacturers considering SBIR funding for product development, the NRC study shows a recent downward trend in the number of Phase I awards and a parallel upward trend in both the size and number of Phase II awards. Stated another way, Phase I awards have become more competitive and a Phase I award-winner is more likely to win a larger Phase II award. As a consequence, more SBIR funding is being focused on fewer manufacturers. At completion of a Phase I grant, manufacturers have typically completed a *proof-of-concept prototype*. At completion of a Phase II grant, manufacturers have typically made significant progress toward a *proof-of-*

Table 2
NRC Study of the Five Largest SBIR Programs

Report	National Research Council (2007)
Federal Agencies Reviewed	• Agencies listed in the rank order of their SBIR programs: Department of Defense, National Institutes of Health, Department of Energy, National Aeronautics and Space Administration, and the National Science Foundation
Goals & Objectives	To examine the role of SBIR programs in technological innovation and their benefits to small businesses to meet federal research and development needs by: • Clarifying the quality of research conducted • Economic benefits achieved • Non-economic benefits achieved • Trends in SBIR funding allocation from 1983 to 2000 • Agency procurement of technologies developed with Phase II funding • Recommendations
Method	Survey • Respondents: 1,916 small businesses • Sampling: Stratified random sampling, targeting 20% of small businesses receiving Phase II awards from each of the five SBIR programs. Study achieved a 42% response rate (1,916 of 4,523 firms contacted). • Inclusion Criteria: Any firms receiving one or more Phase II awards for the period 1992 to 2001
Key Findings	• In 2003, 2004, and 2005, NIH funded 23%, 19%, and 18% of Phase I applicants. For the same years, NSF funded 21%, 17% and 14% of Phase I applicants. A downward trend in the percentage of funded Phase I applicants and an upward trend in the percentage of funded Phase II applicants (along with increased award size) was noted for these years. • For the period 2000 to 2005, about 62% of NIH Phase I awards went to first time applicants. • For the period 1996 to 2003, about 53% of NSF Phase I awards went to first time applicants. • 43% of respondents received additional non-SBIR investment averaging about $1.54 million. • 78% of respondents reported that obtaining Phase I and Phase II SBIR funding was the key to obtaining further non-SBIR investment. • 54% of small businesses receiving a Phase II award reported receiving at least one additional related Phase I SBIR award, and 40% received at least one related Phase II award. • 47% of Phase II awards led to commercial products, 19% expected to culminate in commercial products, while 5% of the projects were still ongoing. • Respondents reported that product development would definitely (38%) or probably (33%) not have been initiated without SBIR funding. Only 13% of respondents would have initiated product development without SBIR funding. • 5% received royalties for technologies developed with SBIR funding.
Conclusions	• The pool of small businesses funded by SBIR programs is dynamic with a low 'barrier-to-entry' for first-time applicants. • SBIR programs are a critical and effective resource for small businesses to develop and commercialize high-risk products. • SBIR programs have excellent commercialization and licensing outcomes.
Limitations	• Study did not identify or classify technologies developed or licensed, products commercialized, or participating firms. • Firms receiving multiple Phase II awards were more likely to complete the NRC survey. • Firms receiving multiple Phase II awards were underrepresented in the sample.

Source: Wessner, C. W. (Ed.). (2007d). *An assessment of the Small Business Innovation Research Program.* Washington, DC: National Research Council.

product. In effect, large SBIR programs have shifted their investments from exploratory Phase I activities to more commercial Phase II activities. The NRC study found that manufacturers successful in receiving Phase II awards are likely to attract follow-on funding from non-SBIR sources such as angel investors and venture capitalists. Follow-on

funding is critical to resource-constrained small businesses since development costs typically escalate greatly as an innovation progresses from proof-of-concept to proof-of-product. It is unclear how the shift of agency investment from Phase I to Phase II impacts ATD manufacturers, or whether ATD manufacturers winning Phase II awards similarly attract follow on funding. For example, agencies might award fewer Phase I grants and proportionately more or larger Phase II grants. However, would it be necessary for these agencies to narrow their funding priorities and would (currently funded) AT fall under these priorities?

The NRC study found that across the five agencies, at least 47% and at most 71% of Phase II awards led or will lead to commercial products. It is unclear if this outstanding record for commercialization is also found for ATD manufacturers. The reasons for any such deviation should it be found is also unknown. Moreover, several respondents reported that product development *would definitely* (38%) or *probably not* (33%) have been initiated without SBIR funding. As a fundamental barrier to analysis, the NRC study does not identify or classify participating companies, industry segments, technologies developed, or products commercialized. As a consequence, it is impossible to ascertain the impact of SBIR funding on ATD development.

In 2003, the NIH published a comprehensive self-study of their SBIR program. The methodology and findings from this study are presented in Table 3 in a similar format as that of the NRC. In congruence with the NRC findings, the conclusion of the NIH study was that the SBIR program provides a crucial impetus for small business manufacturers in technology development.

In corroboration with the NRC study findings, NIH SBIR awardees showed a strong ability to receive additional SBIR and non-SBIR funding for further development of their core technology. NIH awardees reported generating 'revenue' of $821 million through product sales and technology licensing. These revenues include: follow-on funding from angel investors and venture capitalists, additional SBIR grants that extend work completed under the initial SBIR grants, license royalties from patented technologies developed under the SBIR grants, and revenues from the sale of commercial products. NIH Phase II awardees reported additional benefits related to obtaining SBIR funding included the creation of new knowledge, scientific publications, knowledge dissemination, and networking opportunities.

In contrast to the NRC study, the NIH study did employ an ad hoc classification system (see Figure 3) to support the analysis of its SBIR program's impact on industry and market segments. The classification scheme does provide insights regarding large-scale NIH investments in technology and product development. The classification scheme does not however, provide insights regarding ATD development in ATD industry segments. This is not unexpected since development of ATDs is unlikely to account for more than a low percentage of the total NIH SBIR funding.

In a review of SBIR program research, including GAO reports, SBA annual reports, NRC studies, and the NIH study, a few observations can be made. First, none of these reports or studies focused on ATDs, ATD manufacturers or industry segments. Second, where classification schemes have been employed, they are irrelevant to ATD development. The current study is focused on ATD development supported by SBIR and STTR funding. A detailed and comprehensive classification scheme for ATDs and ATD industry segments is needed to carry out

Table 3
NRC Study of the NIH SBIR Program

Report	National Institute of Health (2003)[1]
Federal Agencies Reviewed	• National Institutes of Health
Goals & Objectives	• G1: Evaluate the extent to which NIH SBIR awardees stimulate technological innovation, meet federal R&D needs and commercialize innovations supported through SBIR awards • G2: Comply with statutes and regulations requiring assessments of federal programs to demonstrate their contribution to the nation's economic well-being • G3: Test the feasibility of using an evaluation framework as the analytic basis for a dynamic project monitoring system
Method	• Survey (alternative formats) • Inclusion/Exclusion: 1052 firms receiving a NIH Phase II SBIR award from 1992 to 2001 • Sampling: 768 firms (95% of firms receiving one or more Phase II awards) • Used classification system described in the *Industry* and *Market* segments
Key Findings	• 73% of awardees commercialized 670 new or improved products, processes, usages, and/or services • Respondents produced 2,203 technical articles, 666 patents, 2,850 conference presentations, 453 copyrights, 252 awards, and 322 trademarks • 52% (399) of respondents received additional Phase I or Phase II awards related to the continued development and exploitation of their core technology. • 37% (291) of respondents also obtained non-SBIR funding related to the continued development and exploitation of their core technology. • NIH invested $551million in the firms receiving Phase II awards • Respondent firms generated $821M in revenues from sales and licensing. Many other technologies were in a pre-commercial stage • 64% of respondents would not have pursued product development without SBIR funding • Respondents also thought that SBIR awards impacted pursuit of high-risk ideas (87%), personnel hiring (87%), raising additional capital (44%), and fostering partnerships (70%)
Conclusions	• First comprehensive review of NIH SBIR program • Basis established for systematic collection and analysis of NIH SBIR program outcomes • NIH has made significant contributions to the three goals and objectives (G1, G2 and G3)
Limitations	• Analysis does not reflect costs and revenue generation of non-extent firms and non-respondents • No reason to believe that the industry and market framework used for classification and analysis would generalize to other agencies (e.g. DOD, DOE, NASA) or programs (e.g. STTR)

Source: National Institutes of Health. (2003). *National survey to evaluate the NIH SBIR*

analysis across the SBIR and STTR programs under consideration.

The Technology Related Assistance for Individuals with Disabilities Act (Tech Act) of 1988 (P.L. 100-407) as amended in 1994, defined an ATD as "any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve the functional capabilities of individuals with disabilities" [§3(1)]. This definition places some constraints on the meaning of an ATD but does not establish a classification system.

The International Classification of Functioning, Disability and Health (ICF) was endorsed by the Fifty-Fourth World Health Assembly for international use in 2001 and "provides a unified and standard language and framework for the description of health and

health-related states" (World Health Organization [WHO], 2001, p.3). The ICF model is comprehensive, systematic, and detailed. It provides an excellent framework upon which to build a comprehensive classification scheme for ATDs.

Five non-acquisition-based SBIR programs and two acquisition-based STTR programs are considered in the current study. Among the five federal agencies supporting these programs, we will find that the NIH, USDE, and NSF SBIR programs are the dominant funding sources for ATD development. NIH and NSF have been evaluated in large agency self-studies and NRC studies. However, as a small federal agency, the Small Business Reauthorization Act of 2000 does not require the USDE to receive a comprehensive evaluation by the National Research Council and no other comprehensive studies of the USDE SBIR program have been done. A review of the USDE SBIR program web pages reveals that in 2003 and 2004, USDE funded 9% and 11% of Phase I SBIR applicants, or at roughly half the funding rate of NIH and NSF SBIR applicants. In addition, from 2000 through 2004, the USDE funded no more than 56 Phase I SBIR grants (2002), and 17 Phase II SBIR grants (2003). Total SBIR funding never exceeded $3.1 million (2004; U.S. Department of Education, n.d.). A simple comparison of scale between the USDE SBIR program and the NSF and NIH SBIR programs might suggest that these programs should provide far more support for ATD development. However, the NIDRR exercises significant influence on USDE SBIR solicitations.

The NIDRR mission is:

> to generate new knowledge and promote its effective use to improve the abilities of people with disabilities to perform activities of their choice in the community, and also to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities. (National Institute on Disability and Rehabilitation Research, n.d.)

In contrast, the NIH and NSF missions do not place a special emphasis on meeting the needs of people with disabilities through the development of ATDs and products (NIH mission statement, NSF mission statement). Of the five agencies studied, only the NIH and the NSF have STTR programs. The Small Business Technology Transfer Reauthorization Act of 2001 does not mandate that large STTR programs should be reviewed in a manner analogous to Section 108 of the SBIR Act. As a consequence, performance data on STTR programs is limited to small studies undertaken by the Congressional General Accountability Office and the Department of Commerce Small Business Administration. As noted for SBIR programs, GAO and SBA reports do not support detailed analysis.

Research Objectives

This study has three research objectives:

1. Identify the Phase I and Phase II SBIR (for five agencies) and STTR (for two agencies) awards and funding for ATD development for the period 1996 through 2005. Classify the awards and funding using an ICF-based taxonomy.
2. Evaluate Phase I and Phase II SBIR and STTR awards and funding on a yearly and aggregate basis by: (a) types of ATDs funded (component and category); (b) agencies (number of awards, funding levels and award portfolios); (c) inter-agency comparisons (award numbers, funding levels and award portfolios); and (d)

inter-program comparisons (SBIR and STTR programs) and trends.

3. Interpret data and draw conclusions regarding SBIR and STTR award and funding trends for companies, agencies, across-agencies, across programs and across-technology domains (industry segments). Analysis will especially include longitudinal trends and a comparison of award portfolios.

Method

Methods address four principle issues. These issues are: (a) gathering of SBIR and STTR award data, (b) construction of an ICF-based classification system, (c) inclusion and exclusion criteria for ATDs, and (d) and assignment heuristics to place ATDs into the ICF-based classification system.

Gathering SBIR and STTR Award Data.

SBIR and STTR awards from NIH, NSF, USDE, USDA, and DOT were reviewed for the period 1996 through 2005. Agency databases were the primary sources for award data (Table 4). For each award the following information was entered into a Microsoft Access® database: award title, year, type (SBIR, STTR), Phase (I, II), amount, and abstract; principle investigator, organization name and address; and funding agency.

There is some variation in how SBIR and STTR award data is documented by the agencies studied. NIH maintains two complementary databases. The NIH CRISP database contains all the needed data except award funding which must be found in the NIH SBIR/STTR Award database or SBA Tech-Net. NIH tracks yearly Phase II sub-awards with unique award numbers and sub-awards. As a consequence, NIH award, and

Table 4
SBIR and STTR Databases

Database	URL
1. DOT, Volpe Library SBIR Awards (1999-present)	http://www.volpe.dot.gov/sbir/previous.html
2. NIH, *CRISP* (Computer Retrieval of Information on Scientific Projects, 1983-present)	http://crisp.cit.nih.gov/
3. NIH, SBIR/STTR Award Data (1996-present)	http://grants.nih.gov/grants/funding/award_data.htm
4. NSF, Award Search (1983-present)	http://www.nsf.gov/eng/sbir/
5. Small Business Administration, Tech-*Net* (1983-present)	http://technet.sba.gov/
6. USDA, SBIR Awards (2002-present)	http://www.csrees.usda.gov/funding/sbir/sbir_abstracts.html
7. USDE, Historical SBIR Database (1983-2000)	http://www.ed.gov/programs/sbir/database.html
8. USDE, Recent SBIR Awards (2001-present)	http://www.ed.gov/programs/sbir/awards.html

Table 5
ICF Model

Part	Components	Domain Examples	Levels (Codes)
I: Functioning & Disability	Body Functions	Global Mental Functions	b110*-b199*
		…	…
		Functions of the Skin	b810*-b899*
	Body Structures	Structures of the Nervous System	s110*-s199*
		…	…
		Skin & Related Structures	s810*-s899*
	Activities & Participation	Learning & Applying Knowledge	d110*-d199*
		…	…
		Community, Social and Civic Life	d910*-d999*
II: Contextual Factors	Environmental Factors	Products & Technology (Assistive Technologies)	e110*-e199*
		…	…
		Services, Systems, Policies	e510*-e599*
	Personal Factors	N/A	N/A

(* indicates further coding levels)

funding data must be carefully aggregated.

The USDE Historical Awards Database records are complete for the period 1996 through 2000. For 2001 to 2005, the USDE Recent SBIR Awards database records include only the award title, principle investigator and organization. Information lacking in the USDE Recent SBIR Awards database was obtained from SBA Tech-Net.

The NSF maintained complete award records since the inception of its SBIR and STTR programs through 2007. In 2008, NSF shifted award record-keeping entirely over to SBA Tech-Net. USDA and DOT established SBIR award databases in 2002 and 1999 respectively. Both databases are easy to use and contain complete records (for our purposes). Prior to establishing these databases, SBA Tech-Net served as the primary data source for USDA and DOT awards.

Three search heuristics were followed to ensure that collected award data was substantially complete and accurate: if an (a) investigator received a Phase II ATDs award, then databases are searched until the corresponding Phase I award was identified; (b) investigator received a Phase I or Phase II award, then databases are searched for other awards using this investigator's name as the keyword; and (c) organization received a Phase I or Phase II award, then databases are searched for other awards using the organization's name as the keyword.

The first heuristic ensures that no Phase I award is missed given that a Phase II award has been recorded. The second and third heuristics assume that investigators and companies that obtain SBIR or STTR funding to develop ATDs will be inclined to seek further SBIR or STTR funding. The second and third heuristics also provide a means to find Phase II awards subsequent to recording a Phase I award. Finally, all award data, component and category assignments were reviewed by at least two study personnel.

ICF-Based ATD Classification System.

The ICF is a model that classifies individuals across various levels of health, health-related outcomes, and functioning by use of a

standard set of terminologies and classification scheme. Applying the model to evaluate SBIR and STTR programs aligns with one of the fundamental uses of this multipurpose tool, which is to "to permit comparison of data across health care disciplines, services and time" (WHO, 2001, p. 5). As a social policy tool, application of the ICF model provides a basis to evaluate the design and implementation of these programs at the federal level. The overall ICF is sufficiently structured, detailed and logical to provide a framework upon which to construct a comprehensive and intuitively appealing ATD classification.

The ICF is an extensible, hierarchical classification scheme composed of parts, components, domains, and levels (see Table 5). Part I: Functioning and Disability is comprised of two components: Body Functions and Structures (BFS), and Activities and Participation (AP). Part II: Contextual Factors is also comprised of two components: Environmental Factors, and Personal Factors. The ICF classification further expands upon the first three components. BFS AP and Environmental Factors (EF). Each component is divided into domains, and domains are further divided into levels with corresponding classification codes.

The ICF framework assigns all ATDs under Part II: Context, Environment (component), Products and Technologies (domain) and 14 levels, corresponding to different types of ATDs. Table 6 illustrates the assignment of ATDs under the ICF framework.

Disability and Health (Short Version). Geneva: World Health Organization, p. 3.

ATDs are classified within the ICF as *Products & Technology* under the contextual component. However, ATDs can easily be related to all ICF Part I chapters and domains to

Table 6
Classification of ATDs in ICF as Products and Technology

Part	Component	Domain	Levels	Codes
Contextual Factors	Environmental Factors	Products and Technology	Products or substances for personal consumption	e110
			Products and technology for personal use in daily living	e115
			Products and technology for personal indoor and outdoor mobility and transportation	e120
			Products and technology for communication	e125
			Products and technology for education	e130
			Products and technology for employment	e135
			Products and technology for culture, recreation and sport	e140
			Products and technology for the practice of religion and spirituality	e145
			Design, construction and building products and technology of buildings for public use	e150
			Design, construction and building products and technology of buildings for private use	e155
			Products and technology for land development	e160
			Assets	e165
			Products and technology, other specified	e198
			Products and technology, unspecified	e199

Source: World Health Organization. (2001). *ICF: International Classification of Functioning,*

encompass and distinguish diverse ATDs and ATD industries. Simply stated, the idea of the proposed classification is not to map or 'mold' the ICF classification to fit the ATD industry, but to classify the segments of the ATD industry to the ICF components and domains. It must also be noted that although ATD impact the entire span of the ICF framework, the purpose of the classification is to categorize ATD industry segments by their functionality and specific relevance to the ICF components and domains.

ATD categories were assigned to the ICF components of BFS, AP, and EF based on the conceptual definition of these components. ATD categories were exclusively assigned to the Activity component and Participation component considering a fundamental distinction in their conceptual definition-'activity' being "the execution of a task or action by an individual, while participation being the fulfillment of roles by "involvement in a life situation" (WHO, 2001, p. 10). The fourteen ICF levels under Part II: Contextual Factors, EF component were retained as an ATD category, *Contextual ATD*. A rarely used ATD category 'other' was added under each of the four 'components' Body Functions and Body Structures, Activities, Participation, and Environmental Factors.

The following are the definitions of the ATD categories based on their conceptual relevance to the ICF components. The classification was formulated using descriptors that defined the ATD categories as listed in Table 7.

ATD for body function and structure. This is any technology that is implanted in an individual's body (intrinsic), with a permanent configuration (*fixed*), used to fulfill many or all life roles (*pervasive*), across many or all contexts (*pervasive*). For example, cochlear implants, hip replacements, and cardiac pacemakers are implanted in the individual, closely configured to the individual, to support many or all roles, and in many or all contexts.

ATD for activity. This is any technology that is external to but accompanies the individual (*extrinsic*), with single or multiple configurations (*customizable*), used to perform particular activities, to accomplish many or all life roles (*pervasive*), and in many or all contexts (*pervasive*). Examples include hearing aids, Braille note-takers, and power wheelchairs, and which are external to but accompany the individual, and are customized for individual use to support many roles in many contexts.

ATD for participation. This includes any technology encountered in particular environments (*environmental*), that is configurable for individuals with similar functional abilities (*group*) to accomplish specific life roles (situational), and in specific contexts (*situational*). Examples include screen reader software, personal lifts, and assistive listening systems encountered in particular environments, which meet the needs of individuals with similar abilities for specific

Table 7
AT Classification Rules

ICF Component	Descriptors			
	Integration	Customization	Context(s)	Role(s)
Body Structure & Function	*Intrinsic*	*Fixed*	*Pervasive*	*Pervasive*
Activities	*Extrinsic*	*Customizable*	*Pervasive*	*Pervasive*
Participation	*Environmental*	*Group*	*Situational*	*Situational*
Contextual	*Societal*	*Cross-Group*	*Facilitator*	*Facilitator*

Table 8
ICF-Based Classification Scheme: Body Functions & Structure

ICF Domains	ATD Categories
Mental functions; Structures of the nervous system	Cognition
Sensory functions; The eye, ear and related structures	Sensory (Hearing and Vision)
Voice and Speech functions; Structures involved in voice and speech	Communication
Functions of the cardiovascular, hematological, immunological and respiratory systems; Structures of the cardiovascular, hematological, immunological and respiratory systems	Cardiovascular and Respiratory Health
Functions of the digestive, metabolic and endocrine functions; Structures related to the digestive, metabolic and endocrine functions	Digestive System
Genitourinary and reproductive functions; Structures related to genitourinary and reproductive functions	Genitourinary System
Neuro-musculoskeletal and movement related functions; Structures related to movement	Neuromuscular System
Products and technology, other unspecified	Other

roles in specific contexts.

Contextual ATD. This is any technology, service or tool (*societal*), for individuals with similar or dissimilar abilities (*cross-group*), that increases the use, function, or availability of ATD across roles and/or contexts (*facilitator*). An example would include an online database used to locate ATD for individuals with diverse functional abilities, and used in various roles and contexts.

The ICF-based classification scheme used in the current study is summarized in Tables 8-

Table 9
ICF-Based Classification Scheme: Activities

ICF Domains	ATD Categories
Learning and applying knowledge	Cognition
General tasks and demands: Self care; Community, social and civic life	Independent Living; Health
Communication; Interpersonal interactions and relationships	Communication; Sensory (Hearing and Vision)
Mobility	Mobility and Seating; Prosthetics and Orthotics
Major life areas	Education; Employment
Products and technology, other unspecified	Other

11. There are 13 ATD categories under BFS; 14 ATD categories under Activities; 14 ATD categories under Participation; and 14 ATD categories under EF. The ICF-based classification is comprehensive in that all ICF codes are mapped onto ATD categories. This mapping can be found on the T²RERC Public Policy webpage (Public Policy, RERC on Technology Transfer, n.d.).

Inclusion-Exclusion Criteria

When classifying SBIR and STTR awards, inclusion-exclusion criteria are first applied to distinguish ATD from non-ATD. According to the 2004 Tech Act, assistive technology is "any item, piece of equipment or product system acquired commercially off the shelf, modified, or customized used to increase, maintain, or improve functional capabilities of people with disabilities" [§3(4)]. According to the (1990) Americans with Disabilities Act the term disability means, with respect to an individual (a) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (b) a record of such an impairment; or (c) being regarded as having such impairment [§12102 (1)]. Our understanding of the concepts of major life activities and disability continues to evolve under a series of Supreme Court rulings (National Council on Disability, 2003). Inclusion and exclusion criteria are summarized below.

Inclusion criteria. This is any item, piece of equipment or product system used to increase, maintain, or improve functional capabilities. The item, piece of equipment or product system should be used by an individual with a physical or mental impairment that substantially limits one or more of the major life activities on a permanent or intermittent basis.

Exclusion criteria. This is any item, piece of equipment or product system used primarily to treat, diagnose or rehabilitate an injury, illness, or exposure or to protect or maintain the health or well-being of people without disabilities. Examples of excluded technology include diagnostic or screening tools, and exercise equipment and splints worn to promote healing as opposed to facilitate function.

Classification Assignment Heuristics

Once an award is included, each technology is then assigned to a component and a

Table 10
ICF-Based Classification Scheme: Participation

ICF Domains	ATD Categories
Learning and applying knowledge	Cognition
General tasks and demands: Self care; Community, social and civic life	Independent Living; Health
Communication; Interpersonal interactions and relationships	Communication; Sensory (Hearing and Vision)
Mobility	Mobility and Seating; Prosthetics and Orthotics
Major life areas	Education; Employment
Products and technology, other unspecified	Other

corresponding domain. A set of heuristics for assignment of ATD to classification categories was adopted to ensure that each technology is assigned uniquely to one classification category.

1. In selecting a category, the order of precedence for technology assignment is disability > context > role. For example, a technology for children with *blindness* for use in an *educational setting* would be assigned to the *Activity Component* and *Sensory (blind)* category as opposed to the *Context Componen*t and *Education* category.
2. In selecting a category, when a technology serves two or more disabilities, assignment is based upon context. For example, a technology for individuals with *blindness* or *cognitive impairment* for use in a *vocational setting* would be assigned to the *Participation Component* and *Employment* category.
3. In selecting a category, when a technology has relevance to two or more categories under a component and the assignment cannot be made using rules 1 or 2, the technology is assigned to 'Other.' For example, an electrode technology used to produce neural stimulation in the brain for *cognitive* and *motor impairments* would not be assigned to the *Body Function and Structure Component* and *Cognitive* category or the *Neuromuscular* category, but instead would assigned to the *Other* category.

Table 11
ICF-Based Classification Scheme: Environmental Factors

ICF Domains	ATD Categories
Products or substances for personal consumption	Consumption
Products and technology for personal use in daily living	Independent Living
Products and technology for personal indoor and outdoor mobility and transportation	Mobility
Products and technology for communication	Communication
Products and technology for education	Education
Products and technology for employment	Employment
Products and technology for culture, recreation and sport	Recreation
Products and technology for the practice of religion and spirituality	Religion
Design, construction and building products and technology of buildings for public use	Public Building Access
Design, construction and building products and technology of buildings for private use	Private Building Access
Products and technology for land development	Lands
Assets	Financial
Products and technology, other unspecified	Other

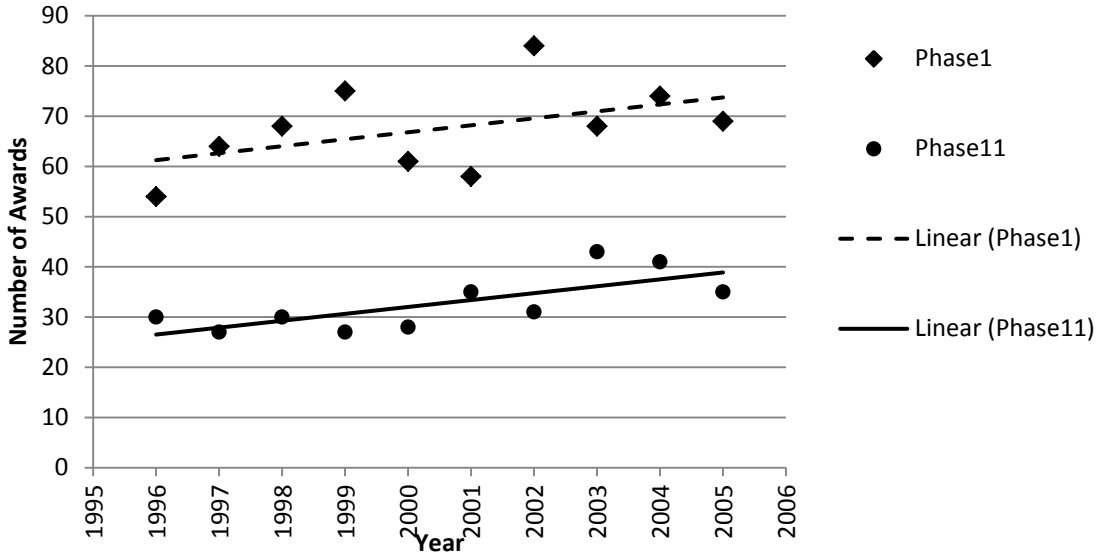

Figure 1. SBIR Phase I and Phase II awards for ATD development (1996-2005).

Results

For the 10-year period 1996 through 2005, more than 22,354 SBIR grant abstracts (16,764 Phase I; 5,590 Phase II) and more 1,717 STTR grant abstracts (1,453 Phase I; 264 Phase II) were reviewed. The SBIR and STTR grant records were found in eight federal databases (see Table 12). Awards meeting the inclusion criteria for ATD were classified using the ICF-based taxonomy.

In the Microsoft® Access© database, yearly NIH Phase I sub-contracts (for the same Phase I award) were aggregated into single Phase I awards. Yearly NIH Phase II sub-contracts (for the same Phase II award) were similarly treated. Rare NSF Phase Ia, IIa, or IIb awards were aggregated with the corresponding NSF Phase I or Phase II award. A Phase I award from one agency

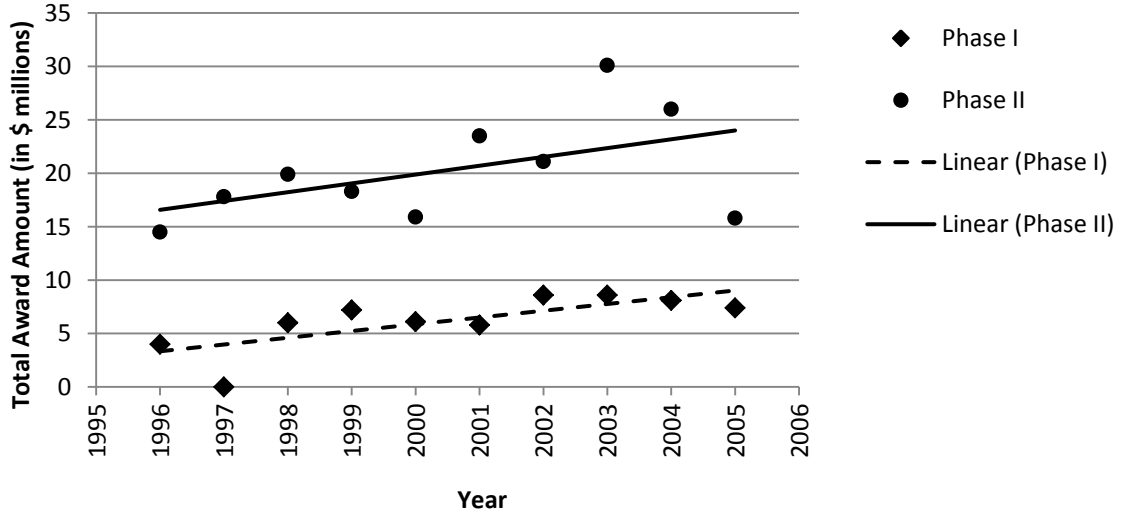

Figure 2. SBIR Phase I and Phase II funding for ATD development (1996-2005).

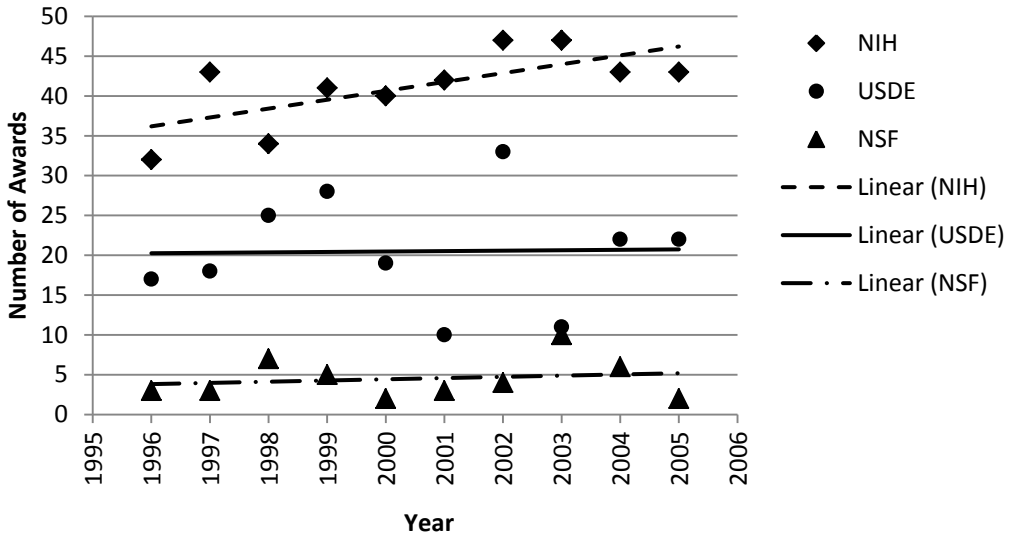

Figure 3. Number of Phase I SBIR awards by agency for ATD development (1996-2005).

followed by a Phase II award from another agency was counted against each agency's numbers and amounts.

All data including award year, number of awards, type of award (SBIR, STTR), Phase (I, II) and grant size pertain specifically to SBIR and STTR grants to small businesses for the purpose of ATD development and commercialization.

SBIR Award Data

From 1996 through 2005, five federal agencies (NIH, USDE, NSF, USDA, and DOT) awarded 675 SBIR Phase I and 329 SBIR Phase II grants to small businesses supporting the development of ATDs. The total value of SBIR Phase I grants and SBIR Phase II grants was $68.3 million and $202.2 million respectively. For these agencies, SBIR Phase I and Phase II grants for ATD development constituted 4.0% of all SBIR Phase I grants (675 of 16,764) and 5.9% all SBIR Phase II grants (329 of 5,590) respectively. The number of Phase I and Phase II awards generally grew from 1996 through 2005 (see Figure 2).

Funding of SBIR Phase I and Phase II grants for ATD development included $68.3 million for all Phase I SBIR grants and $202.2 million

Table 12
Awards and Funding for ATD Development by Agency and by Year (1996-2005)

SBIR Awards	Federal Agency				
	NIH	USDE	NSF	USDA	DOT
N Phase I Grants	414	206	46	8	4
Phase I Funding	$46.0 M	$12.04 M	$4.0 M	0.42 M	$0.4M
M Phase I Award	$114.08 K	$64. K	$109.6K	$70K	$100K
N Phase II Grants	220	83	20	6	0
Phase II Funding	$162 M	$ 26.2 M	$11.6M	$2.2M	$0.0M
M Phase II Award	$754.6 K	$320.1 K	$580.0K	$366.7K	$0.0K

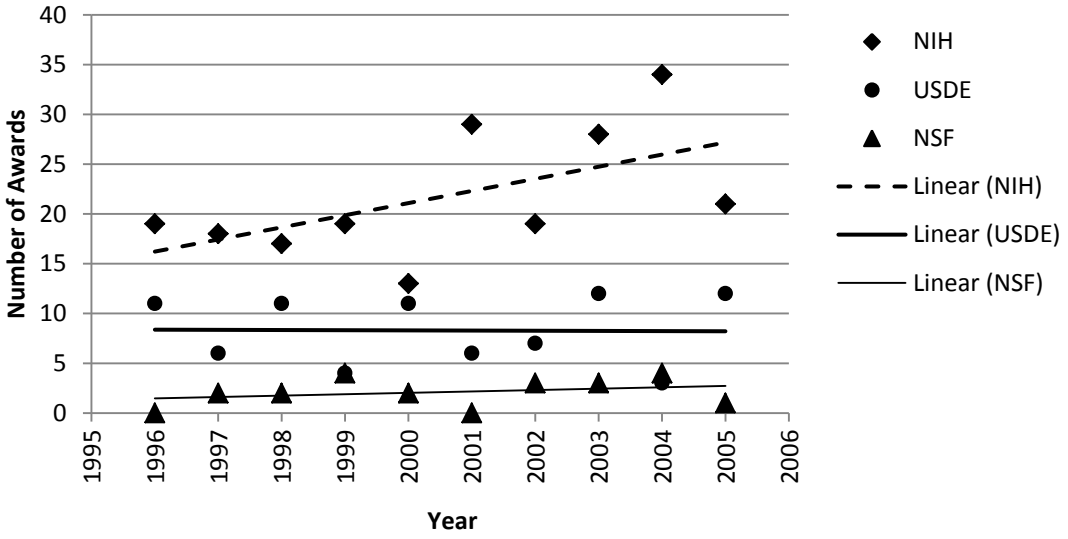

Figure 4. Number of Phase II SBIR awards by agency for ATD development (1996-2005).

for all SBIR Phase II grant. A small downturn in SBIR Phase I funding after 2002 and a sharp downturn in SBIR Phase II funding after 2003 may be taking place (Figure 3).

From 1996 through 2005, three federal agencies (NIH, USDE, and NSF) dominated in both the number of awards and total funding while USDA and DOT played minor roles (see Table 12). Across the five agencies studied, Phase I SBIR awards ($63.2 million) accounted for about 24% of all SBIR funding ($265.2 million). Phase II SBIR awards ($202 million) account for about 76% of all SBIR funding.

NIH, USDE, and NSF differ greatly in the average funding per grant. From 1996 to 2005, the ratio for NIH to USDE SBIR Phase I awards is 1.78 ($114.1 thousand/$64.9 thousand), while the ratio for NIH to USDE SBIR Phase II awards is 2.4 ($754.6 thousand/$320.1 thousand). The ratio for total NIH to NSF SBIR Phase I awards is

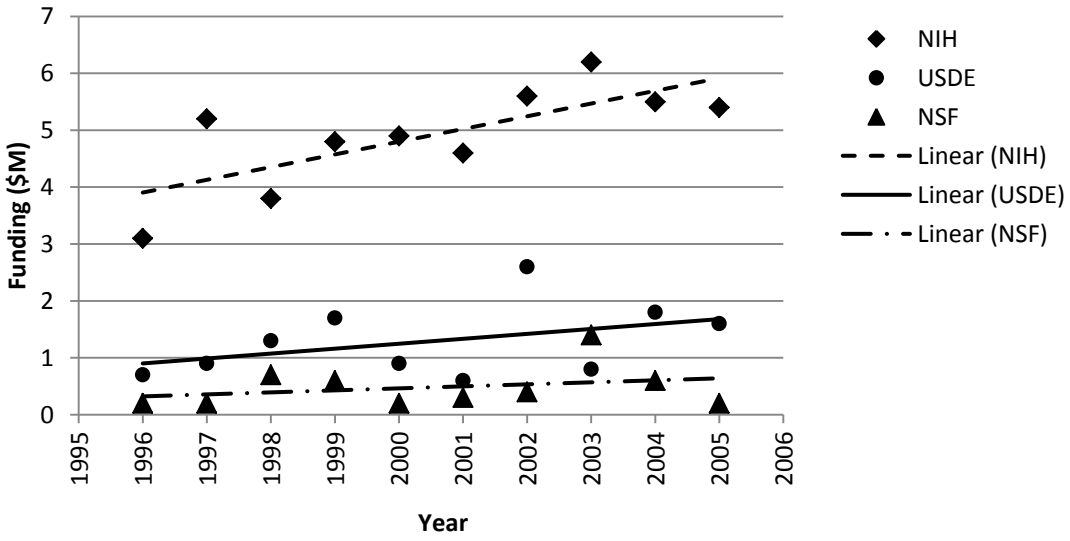

Figure 5. Phase I SBIR funding by agency and year for ATD development (1996-2005).

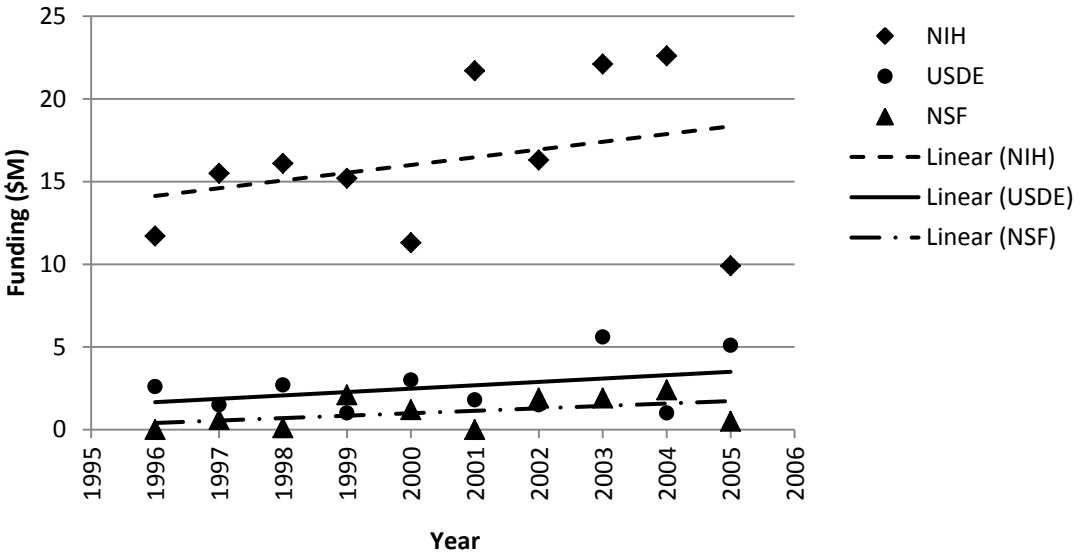

Figure 6. Phase II SBIR funding by agency and year for ATD development (1996-2005).

1.04 ($114.08 thousand/$109.6 thousand), while the ratio for NIH to NSF SBIR Phase II awards is 1.3 ($754.6 thousand/$580.0 thousand).

Phase I SBIR grants are typically used to demonstrate a 'proof of concept' for an innovative product or technology prototype. Across the five agencies studied, from 2003 to 2005 small ATD businesses received 68, 74, and 69 Phase I SBIR grants totaling $8.6 million, $8.1 million, and $7.4 million respectively (see Figure 4).

Phase II grants are typically used to establish commercial viability and to initiate development of a 'proof of product.' Across the five agencies studied, from 2003 to 2005 small businesses received a total of 43, 41, and 35 Phase II SBIR awards worth $30.05 million, $26.0 million, and $15.8 million respectively. The large drop in 2005 Phase II SBIR funding reflects a drop in the number of NIH awards from 34 (2004) to 21 (2005) and NSF awards from 4 (2004) to 1 (2005). An increase in the number of USDE awards from 3 (2004) to 12 (2005) could not compensate for these losses (see Figure 5).

Phase I SBIR award trends are shown in Figure 6. As expected, NIH clearly dominates SBIR Phase I funding after 1995.

Phase II SBIR award trends are shown in Figure 7. A precipitous drop in NIH Phase II SBIR funding occurs from 2004 (about $23.5 million) to 2005 (about $9.9 million).

Table 12
Ratio of Phase II / Phase I Awards

SBIR Awards	Federal Agencies					
	Total	NIH	USDE	NSF	USDA	DOT
N Phase I	606	369	184	43	6	4
N Phase II	272	177	69	20	6	0
Phase II / Phase1 Ratio	0.45	0.48	0.38	0.45	1	0.00

Table 13
Number of Phase I and Phase II SBIR Awards by ICF Component and Agency

ICF Component	Federal Agencies					
	Total	NIH	USDE	NSF	USDA	DOT
	Phase I/II	I/II	I/II	I/II	I/II	I/II
BFS	100/44	92/40	3/2	5/2	0/0	0/0
Activity	152/73	113/63	29/9	9/0	1/1	0/0
Participation	350/183	180/102	138/60	27/18	4/3	1/0
Context	75/31	28/16	36/12	5/1	3/2	3/0
Totals	678/331	414/221	206/83	46/21	8/6	4/0

We have seen that USDE Phase II SBIR grants are significantly smaller than NIH and NSF Phase II SBIR grants. Another important consideration for small businesses is the likelihood of winning a Phase II award subsequent to winning a Phase I award. NIH has the highest ratio of Phase II winners to Phase I winners (Table 12). On average, an NIH SBIR Phase I award winner was 1.3 and 1.2 times more likely to win a subsequent Phase II award than a USDE or NSF SBIR Phase I award winner.

Almost all SBIR Phase II grants are awarded one year after the corresponding SBIR Phase I grant. In Table 12, SBIR Phase I grants are totaled from 1996 through 2004 and SBIR Phase II grants are totaled from 1997 through 2005. For these timeframes, the ratio of Phase II to Phase I award winners for NIH is 52.7% (218/414), for NSF is 45.6% (20/46) and for USDE is 40.8% (84/206).

The distribution of Phase I and Phase II SBIR awards was further broken down by agency and component (see Table 13). The component level ratios of Phase II to Phase I award winners were BFS 44% (44/100), *Activity* 48.0% (73/152), *Participation* 52.6% (184/350), and *Context* 41.3% (31/75). Across agencies, Phase I SBIR awards funded the development of ATD for BFS 14.7% (100/678), *Activities* 22.4% (152/678), *Participation* 51.6% (350/678) and *Context* 11.1% (75/678). By agency, Phase I SBIR awards were distributed NIH 61.1% (414/678), USDE 30.4% (206/678), NSF 6.8% (46/678), USDA 1.2% (8/678), and DOT 0.6% [4/678]. Similarly, Phase II SBIR awards were distributed NIH 66.8% (223/334), USDE 25.1% (83/331), NSF 6.3% (21/331), USDA 1.8% (6/331), and DOT 0.0% (0/331).

The percentage of Phase I SBIR awards by ICF component and agency is given in Table 14. The NIH funding pattern is *Participation* (44%) > *Activity* (27%) > BFS (22%) > Context (7%). The NSF has a similar pattern of *Participation* (59%) > *Activity* (20%) > BFS

Table 14
Percent of Phase I Awards by ICF Component and Agency

ICF Component	Federal Agencies					
	Total	NIH	USDE	NSF	USDA	DOT
BFS	0.15	0.22	0.01	0.11	0.00	0.00
Activity	0.22	0.27	0.14	0.20	0.13	0.00
Participation	0.52	0.44	0.67	0.59	0.5	0.25
Context	0.11	0.07	0.17	0.11	0.38	0.75

Table 15
SBIR Phase I & Phase II Awards by Agency and by BFS Domain.

Body Function & Structure	Federal Agencies					
	Total	NIH	NSF I / II	USDE	DOT	USDA
	Phase I / II	I / II		I / II	I / II	I / II
Cognition	7/2	5/1	1/0	1/1	0	0
Communication	2/1	2/1	0	0	0	0
Cardiovascular & Respiratory	27/16	26/15	0	1/1	0	0
Digestive	2/1	2/1	0	0	0	0
Genitourinary	9/3	9/3	0	0	0	0
Neuro-Musculoskeletal	18/4	17/4	1/0	0	0	0
Sensory (Blind)	2/0	2/0	0	0	0	0
Sensory (Deaf)	7/3	7/3	0	0	0	0
Sensory (Impaired Hearing)	2/1	2/1	0	0	0	0
Sensory (Impaired Vision)	2/2	2/2	0	0	0	0
Other	22/11	18/9	3/2	1/0	0	0
Total	100/44	92/40	5/2	3/2	0/0	0/0

(11%) = *Context* (11%). The USDE has a significantly different funding pattern of *Participation* (67%) > *Context* (17%) > *Activity* (14%) > *Body Function and Structure* (1%). Presumably component level funding patterns are signatures of each agency's mission.

Similar agency funding patterns (e.g., NIH, NSF) may still be differentiated at the category level. In Tables 15 through 18 SBIR awards are classified under one of four ICF components and further sub-classified into categories. There were a total of 100 Phase I awards and 44 Phase II awards for the development of ATD for *Body Function and Structure* (Table 15). NIH funded 92% (92/100) of Phase I awards and 91% (40/44) of Phase II awards with USDE and NSF making minor contributions.

Categories accounting for 67% (67/100) of all Phase I SBIR awards were cardiovascular-respiratory 27% (27/100), "other" 22% (22/100) and neuro-musculoskeletal 18% (18/100). 20 of twenty-two "other" Phase I SBIR awards funded the development of electrode technology with applications across multiple categories (e.g. sensory [*], cognitive, CVR, DE, GU, and NMS).

There were a total of 152 Phase I SBIR awards and 76 Phase II SBIR awards for the development of ATD for *Activity* (see Table 16). NIH is the dominant funding source with 74% (113/152) of Phase I SBIR awards and 84% (64/76) of Phase II SBIR awards. Of lesser importance, USDE and NSF provided 19% (29/152) and 6% (9/152) of Phase I awards and 13% (10/76) and 1% (1/76) of Phase II awards.

Categories accounting for 65% (98/152) of all Phase I SBIR awards were mobility 27% (41/152), prosthesis 24% (37/152) and communication 13% (20/152). The USDE is a significant Phase I and Phase II funding source for mobility products 26.8% (11/41) and 24% (5/21) respectively. Finally, 0% (0/10) of NSF Phase I SBIR awardees were successful in winning a Phase II SBIR award.

There were a total of 350 Phase I SBIR awards and 180 Phase II SBIR awards for the development of ATD for *Participation* (see

Table 17). Categories accounting for 73% (254/347) of all Phase I SBIR awards were deaf 17% (60/350), cognitive 26% (91/350), blind 14%(49/350), health 14%(49/350), and access 12.1% (43/347). NIH and USDE dominate funding with 51% (180/350) and 39.7% (139/350) of Phase I SBIR awards and 56% (101/180) and 32.7% (59/180) of Phase II SBIR awards respectively. Of lesser importance, NSF provided 7.7% (27/350) of Phase I SBIR awards and 9.4% (17/180) of Phase II SBIR awards.

NIH and USDE funding patterns have apparent differences at the category level. NIH and USDE categories with at least 10 Phase I SBIR awards are listed in descending rank order with uncommon components bolded.

- NIH: **health** (42), cognitive (51), deaf (23), blind (15), **mobility** (11), **hearing** (11), **vision** (10), other (0)
- USDE: cognitive (37), deaf (33), blind (25), other (0), **employment** (13), **education** (13)

NIH is the primary funding source for the development of products for Participation in health management, mobility, hearing, and vision. USDE is the primary funding source for the development of products for *Participation* in education and employment. Jointly, NIH and USDE are primary funding sources for the development of *Participation* based products for cognitive impairment, deafness, access, and blindness

There were a total of 75 Phase I SBIR awards and 31 Phase II SBIR awards for the development of ATDs for *Context* (see Table 18). USDE and NIH dominate funding with 48% (36/75) and 37.33% (28/75) of Phase I SBIR awards and 39% (12/31) and 48% (15/31) of Phase II SBIR awards respectively. Categories accounting for 81% (63/77) of all Phase I SBIR awards were communication 18.67% (14/75), other 18.67% (14/75), mobility 14.66% (11/75), education 14.67%

Table 16
SBIR Phase I (II) Awards by Agency and by Activity Categories

Activity	Federal Agencies					
	Total Phase I/ II	NIH I/ II	NSF I/ II	USDE I/ II	DOT I/ II	USDA I/ II
Cognition	9/4	5/3	0	4/1	0	0
Communication	20/8	17/6	0	3/2	0	0
Education	0	0	0	0	0	0
Employment	0	0	0	0	0	0
Health	2/2	2/ 2	0	0	0	0
Independent Living	0	0	0	0	0	0
Mobility and Seating	41/21	29/16	2/0	11/5	0	0
Prosthetics and Orthotics	37/15	28/14	5/0	4/1	0	0
Sensory (Blind)	12/3	7/3	2/0	3/0	0	0
Sensory (Deaf)	3/2	1/1	0	1/0	0	1/1
Sensory (Impaired Hearing)	12/7	11/7	1/0	0	0	0
Sensory (Impaired Vision)	16/11	13/11	0	3/ 0	0	0
Other	0/0	0/0	0	0	0	0
Total	152/73	113/63	10/0	29/9	0/0	1/1

(11/75), and employment 14.67% (11/75).

NIH and USDE funding patterns have apparent differences at the category level. NIH and USDE categories with at least 10 Phase I SBIR awards are listed in descending rank order with uncommon components bolded.

- USDE: **employment** (10), **education** (9), other (7)
- NIH: **communication** (10), **mobility** (7), other (5)

The USDE is the primary funding source for the development of Context-based products for employment and education. NIH is the primary funding source for the development of Context-based products for communication and mobility. Jointly, NIH and USDE are primary funding sources for the development of Context-based products for 'other.' Other includes awards that cannot readily be matched to a single Context/Environment description.

STTR Award Data

Of the five agencies studied, only NIH and NSF have STTR programs. Relative to their SBIR programs NIH and NSF provide few STTR awards for the development of ATDs. For both agencies, 1996 through 2005 there were a total of 29 Phase I STTR grants (see Table 19) with funding of $3.1 million and 10 Phase II STTR grants with funding of $5.7 million were identified (see Table 20).

For all components, the number of Phase I and Phase II STTR awards is very small relative to Phase I and Phase II SBIR awards. Almost half (13/29) of all Phase I STTR grants and half (5/10) of all Phase II STTR grants were for the development of ATDs for *Participation*.

The NIH and NSF STTR programs constitute 0.3% of their respective extramural research budgets. The NIH, NSF, USDE, DOT and

Table 17
SBIR Phase I (II) Awards by Agency and by Participation Categories

Participation	Federal Agencies					
	Total Phase I/II	NIH I/II	NSF I/II	USDE I/II	DOT I/II	USDA I/II
Cognition	91/41	51/22	3/2	37/17	0	0
Communication	11/5	5/3	3/0	3/0	0	0
Education	25/19	7/8	3/2	15/9	0	0
Employment	14/5	1/1	0	13/4	0	0
Health	49/34	42/30	2/1	4/2	0	1/1
Independent Living	6/4	3/3	0	1/0	0	2/1
Sensory (Blind)	49/27	15/9	9/5	25/13	0	0
Sensory (Deaf)	60/23	23/8	4/3	33/12	0	0
Sensory (Impaired Hearing)	17/10	11/6	2/2	4/2	0	0
Sensory (Impaired Vision)	13/7	10/7	1/0	2/0	0	0
Mobility and Seating	13/3	11/3	0	1/0	1/0	0
Prosthetics and Orthotics	1/1	1/1	0	0	0	0
Other	1/1	0/5	0/0	0/1	0	1/0
Total	350/180	180/101	27/17	138/59	1/0	4/3

Table 18
SBIR Phase I (II) Awards by Agency and by Context Categories

Context	Federal Agencies					
	Total	NIH	NSF	USDE	DOT	USDA
Private Building Access	1/1	1/1	0	0	0	0
Public Building Access	2/1	1/1	1/0	0	0	0
Communication	15/8	10/6	1/0	4/2	0	0
Consumption	0	0	0	0	0	0
Independent Living	2/0	1/0	0	1/0	0	0
Education	11/4	2/1	0	9/3	0	0
Employment	11/4	0	1/1	10/3	0	0
Financial	0	0	0	0	0	0
Lands	8/5	1/2	0	3/1	1/0	3/2
Mobility	11/3	7/2	0	2/1	2/0	0
Recreation	1/0	1/0	0	0	0	0
Religion	0	0	0	0	0	0
Other	14/5	5/3	2/0	7/2	0	0
Total	75/31	28/15	5/1	36/12	3/0	3/2

USDA SBIR programs constitute 2.5% of their respective extramural research budgets. For all years of this study, STTR Phase I and Phase II grants are normally smaller than corresponding SBIR Phase I and Phase II grants (see Table 21). Naively we would expect eight or fewer SBIR Phase I (Phase II) grants for ATD development for each STTR Phase I (Phase II) grant. Instead there are 23.2 (675/29) Phase I SBIR grants for each Phase I STTR grant and 22.7 (227/10) Phase II SBIR grants for each Phase II STTR grant.

Discussion

SBIR and STTR programs should be ideal funding sources for product development by small ATD manufacturers. A 2003 Department of Commerce study found that only 52 (13%) of 349 small ATD manufacturers participating in the study had submitted one or more SBIR proposals during the period 1997-1999. The DOC study employed opportunistic sampling and many types of ATD manufacturer (with respect to the ICF-based classification system) were underrepresented. Roughly one in eight Phase I SBIR proposals are funded, so the DOC findings suggest that very few small ATD manufacturers may compete for and win SBIR and STTR grants.

Table 19
STTR Phase I Awards by Component

STTR	Year										
Phase I	96	97	98	99	00	01	02	03	04	05	Totals
BFS	0	0	1	0	2	1	1	0	1	0	6
Activity	1	0	1	0	0	1	0	2	2	1	8
Participation	1	2	0	0	0	2	1	1	2	4	13
Context	0	0	0	0	1	0	0	0	1	0	2
Total	2	2	2	0	3	4	2	3	6	5	29

Table 20
STTR Phase II Awards by Component

STTR Phase II	Year										
	96	97	98	99	00	01	02	03	04	05	Totals
BFS	1	0	0	0	0	0	2	0	0	0	3
Activity	0	1	0	0	0	0	1	0	0	0	2
Participation	0	0	0	1	0	1	0	2	1	0	5
Context	0	0	0	0	0	0	0	0	0	0	0
Total	1	1	0	1	0	1	3	2	1	0	10

For the five agencies and timeframes considered, this current study establishes that the NIH and the USDE are the predominant sources of SBIR funding for ATD development. The NIH is the leading STTR funding source for ATD development. Across the five agencies studies, funding for ATD development constituted about 4.0% of all Phase I SBIR funding and 5.9% of all Phase II SBIR funding. At the component level, the NIH is the leading funder of ATD development for *BFS*, *Activity*, and *Participation*. The USDE is the leading funder for ATD development for *Context* and a secondary, but important, funding source for ATD development for *Activity* and *Participation*. The NSF (not the USDE) is (a minor), but secondary, funding source for ATD development for *BFS* and is the tertiary funding source for ATD development corresponding to the other three components. The DOT and the USDA provide little funding for ATD development. However, at the category level, these agencies may still have an important funding role. For example, the USDA was the only SBIR funder for ATD development for the Context component and public lands category.

The current study could not have been done without defining inclusion and exclusion criteria for ATDs, a detailed and comprehensive classification system for assistive technology, and assignment heuristics. The Assistive Technology Act and the Americans with Disabilities Act were used to define the inclusion and exclusion criteria. The International Classification System of Functioning, Disability and Health provided the framework for the ATD classification system. Assignment heuristics are based upon an ATD's integration, customization, role, and context of use. Using these assignment heuristics each SBIR and STTR award could

Table 21
Comparison of STTR and SBIR Awards by Phase

Program/Phase	Year										
	96	97	98	99	00	01	02	03	04	05	Totals
SBIR/Phase I	54	64	68	75	61	58	84	68	74	69	675
STTR/Phase I	2	2	2	0	3	4	2	3	6	5	29
Phase I Ratio	.037	.031	.029	0	.049	.069	.024	.044	.081	.072	.043
SBIR Phase II	29	27	30	27	28	35	31	43	40	35	325
STTR Phase II	0	1	0	1	0	1	3	2	2	0	10
Phase II Ratio	0	.037	0	.037	0	.029	.097	.047	.050	0	.031

be placed (in principle) into a unique component and category. The ICF-based classification system while not perfect (e.g., the "other" category though rarely used was required for each component) is a major outcome of the current study.

SBIR and STTR programs are subject to federal oversight by the U.S. DOC SBA and the U.S. Congress's General Accountability Office (GAO). SBIR programs have also been the subject of large studies by the National Academies of Science as required by the Small Business Innovation Research Act. However, the SBA and GAO reports, and NAS studies provide no information pertaining to ATD small businesses use of the SBIR and STTR programs or ATD development with SBIR or STTR support. The current paper reports the only large, systematic study of SBIR and STTR support for ATD development.

The Small Business Innovation Research Act (P.L. 97-219) requires (since 1997) that large federal agencies set aside 2.5% (2.0% in 1996) of their extramural research budgets for grants to small businesses. The Small Business Technology Transfer Act (P.L. 102-564) requires that large federal agencies set aside 0.3% of their extramural research budgets for grants to range of collaborations that include universities, research hospitals, and other entities in partnership with small business. For the period and agencies studied, total SBIR funding was $270.2 million and total STTR funding was $8.8 million.

Over the period and agencies studied, ATD manufacturers received 675 Phase I awards and 329 Phase II SBIR awards and 29 Phase I and 10 Phase II STTR awards. Across the five agencies studied for 2003 to 2005, the three most recent years of this study, ATD small businesses averaged 70 SBIR Phase I awards per year and 40 SBIR Phase II awards per year. Data collected in the NRC study suggest that about half of small businesses receiving a Phase II awards ultimately commercialize a product. Assuming that these results can be extended to Phase II SBIR grants that support ATD development and commercialization then these five programs supported the commercialization of about 20 products per year (Wessner, 2007d).

Five non-acquisition-based SBIR programs (NIH, USDE, NSF, DOT, and USDA) and two non-acquisition STTR programs (NIH, NSF) were evaluated. The NIH and NSF have the second- and fifth-largest SBIR programs. We conjecture that non-acquisition-based SBIR and STTR programs are more likely to fund ATD development (products that satisfy a market need) than acquisition-based SBIR and STTR programs (products that satisfy agency needs that are unlikely to involve ATDs). This conjecture should be validated (or refuted) in future studies.

Among the five agencies studied, the USDE has the smallest SBIR program, much smaller than the NIH or NSF SBIR programs and smaller than, but roughly comparable to, the USDA and DOT SBIR programs. For example, in 2005 these agencies had outlays for ATD development through their SBIR programs of $15.3 million (NIH), $0.7 million (NSF), $6.7 million (USDE), $1.2 million (USDA), and $0 million (DOT). Nonetheless, the USDE is second only to the NIH in terms of the total number and funding for Phase I and Phase II SBIR awards. This can reasonably be explained as an alignment between the USDE/NIDRR mission statement (with its focus on meeting the needs of individuals with disabilities) and the USDE/NIDRR mission statement. The mission statements for the four other agencies lack such a focus.

During the study period, Phase I SBIR awards (about 60%) amounting to $46 million came from the NIH. Phase I SBIR awards (about 30%) amounting to $12 million came from

the USDE. The majority of Phase II grants (about 68%) amounting to $162 million came from the NIH. A significant portion of Phase II grants (about 23%) amounting to $26 million came from the USDE. Accounting for over 90% of Phase I and Phase II SBIR grants and funding, the NIH and the USDE are critical SBIR sources of funding for ATD development. Any diminishment of SBIR funding by either agency is likely to have a large and negative impact on ATD development.

Approximately 51% (estimating the number of out-year Phase II SBIR awards) of Phase I awardees were successful in winning a Phase II grant. For ATD manufacturers successful in winning both a Phase I and Phase II SBIR grants, 53% of the Phase II grants occurred one year subsequent to the Phase I award, while 47% of the Phase II grants occurred two or more years after the Phase I grant.

At the component level for SBIR Phase I awards, the NIH is the primary funder for ATD development. Across the four components, NIH provided 61.06% (414/678 awards) of all Phase I SBIR awards. The NIH is an especially important funder for *Body Function & Structure* at 92% (92/100 awards) and *Activity* at 74.3% (113/152 awards). The NIH at 51.4% (180/350 awards) and the USDE at 39.4% (138/350 awards) are (roughly) co-leading funders for *Participation*. The USDE at 48.0% (36/75 awards) and the NIH at 37.3% (28/75 awards) are (roughly) co-leading funders for *Context*. The USDE is not important as a SBIR Phase I funder for *Body Function and Structure* at 3% (3/100 awards). The NSF is the second-most important Phase I SBIR funder for *Body Function & Structure* at 5% (5/100 awards) and the third-most important funder for *Activity* at 5.9% (9/152 awards) and *Participation* at 7.7% (27/350 awards). On face, the ICF-based classification system and assignment heuristics differentiated agency portfolios at the component level.

At the category level, 66.3% (61/92) of NIH Phase I SBIR awards for *Body Function and Structure* were cardiovascular and respiratory (26), other (18), or neuro-musculoskeletal (17). The eight remaining *BF&S* categories included the remaining NIH Phase I SBIR awards totaling 34% (31/92). The NIH and the USDE Phase I SBIR funding patterns for *Participation* at the category level show both similarities and differences. For similarities, the NIH and the USDE have at least 10 awards for the categories cognitive, deaf, other, and blind. For differences, the NIH and the USDE have at least 10 awards for the categories health, vision, mobility, and hearing. On face, the ICF classification system and assignment heuristics differentiated the NIH and the USDE portfolios at the category level.

ATD development through the NIH and the NSF, SBIR, and STTR programs was compared. On face, the STTR programs had too few awards (29 Phase I, 10 Phase II) to warrant examination at the category level. At the component level, there are 23.27 (675/29) Phase I SBIR grants for each Phase I STTR grant and 32.5 (325/10) Phase II SBIR grants for each Phase II STTR grant. These ratios are much lower than one might (naively) expect based upon the relative size (8.1:1) of the SBIR and STTR programs. Additional research is needed to determine why the STTR program is a relatively underutilized funding source for ATD development. Possible explanations range from barriers that deter ATD small businesses from pursuing STTR funding, to barriers that deter STTR programs from awarding grants to ATD small business applicants.

The current study has a number of limitations. The inclusion/exclusion criteria, classification system, and assignment heuristics should

uniquely classify all ATD-related awards and this was not always the case. For example, implantable electrodes were necessarily placed into the *Body Function and Structure* component and "other" category because these electrodes had applications in two or more categories. Across the four components, 37 ATD Phase I and 17 ATD Phase II SBIR awards were placed into an "other" category constituting 5.5% of all Phase I and 5.1% Phase II awards classified.

There are many applications for the ICF-based classification system. More work must be done to ensure that the classification system is valid and reliable. Applications include documenting ATD transferred from the federal laboratory system to the private sector via cooperative research and development agreements, license agreements and material transfer agreements (as required by the Stevenson-Wydler Act of 1980). A second application is the classification of ATDs transferred from U.S. universities to the private sector via license agreements and related mechanisms.

The current study lays the groundwork for future research. Issues to resolve by this research include: Why do so few ATD small businesses use the SBIR and STTR programs? For those ATD small businesses using SBIR and STTR programs, what is the rate of success obtaining follow-on funding, obtaining additional SBIR and STTR grants, and commercializing products? How do these rates compare to overall SBIR and STTR program rates? Why is the STTR program particularly underused by ATD manufacturers? What barriers hinder the use of the SBIR and STTR programs by ATD manufacturers? What can be done by the federal government, federal agencies, ATD manufacturers, and other entities (such as ATIA) to reduce barriers and encourage participation by ATD manufacturers? How do funding trends evolve and what implication does this have for ATD product development?

Conclusion

This study evaluated SBIR and STTR funding portfolios pertaining to ATD development and commercialization. To facilitate analysis, an ICF-based classification system was developed and employed throughout this study. Analysis included SBIR and STTR awards by agency, type, phase, year, funding level, agency mission, cross-agency comparisons, and longitudinal trends. Five non-acquisition-based SBIR programs (NIH, NSF, USDE, USDA, and DOT) and two non-acquisition-based STTR programs (NIH and NSF) were evaluated for the period 1996-2005. No similar or related study of ATD development with SBIR and STTR funding has been conducted.

Ultimately, federal public policy makers have the authority to set funding priorities for federal agencies, and to determine whether allocations for ATD development (4.0% of Phase I SBIR and 5.9% of Phase II SBIR grant dollars) and portfolio mix (at the component and category levels) are consistent with national priorities and interests.

This study and earlier studies by the National Research Council suggest that public policy makers lack critical data and constructs necessary to evaluate current SBIR and STTR programs, and to provide oversight and guidance to the agencies managing these programs. It is reasonable to expect that federal oversight is especially problematic for large, complex SBIR and STTR programs (especially DOD, NIH, DOE, NASA, and NSF). Lacking strong oversight, federal agencies are free to establish priorities and develop award portfolios independent of (not necessarily at odds with) national priorities and interests.

For federal policy makers to provide effective oversight, at least four issues must be addressed. First, a single, universal classification system must be developed. This classification system should have sufficient breadth, detail, clarity, reliability, intuitive appeal, ease of learning, and ease of use to reasonably distinguish or aggregate, (somehow) dissimilar or similar product types. The ICF-based classification system developed in this study along with its inclusion and exclusion criteria and assignment rules could serve as a model for this broader classification system. The authors recognize the challenge of such an undertaking but believe that this step is critical.

Second, all federal agencies must be required to use this classification system when stating their missions and priorities, describing award portfolios and when reporting grants and grant outcomes. By doing so, federal policy makers and federal agencies (interactively) can compare, contrast and adjust agency priorities and portfolios to better address national priorities and interests. Adjustment of agency priorities and portfolios might reduce funding redundancies and inadequacies and improve the overall effectiveness of the SBIR and STTR programs across agencies. By reviewing agency funding allocations, priorities, and portfolios, small businesses will know which SBIR and STTR programs are the most suitable funding sources.

Third, all small businesses receiving an SBIR or STTR grant (Phase I or Phase II) must be required to report Phase III (commercialization) outcomes. The NRC SBIR program studies provide a useful breakdown for 'types' of revenue generation. Establishing return on investment is critical for properly 'sizing' the SBIR and STTR programs. Commercialization outcomes mapped against the classification system would further guide federal public policy decisions and agency level program management.

Fourth, all SBIR and STTR performance data must be available from one entity through a single online web interface and database. The logical candidate for this entity is the U.S. DOC, Small Business Administration. The logical tool for the online web interface and database is an enhanced version of TechNet. All agencies must collect the same information and provide this information in a timely manner to the SBA (or equivalent). Currently, SBIR and STTR program outcomes are placed in distributed, partially redundant databases; include disparate, incomplete and dated information; and are accessed through search engines with inconsistent functionality. Lack of access to complete and consistent SBIR and STTR program outcomes creates a huge barrier to federal oversight, agency management, and academic research.

The current Small Business Innovation Research Act (P.L. 106-554) expired March 20, 2009 and Congress is now funding SBIR programs under a continuing resolution while house and senate business committees try to compromise their differences. Important issues to be resolved include: (a) the percentage of extramural funding allocated to SBIR programs, (b) small business ownership (by venture capitalists, by other U.S. companies); (c) recommended Phase I and Phase II grant size; and (d) funding allocation between Phase I and Phase II (SBIR Insider Newsletter, 2009).

With many details omitted, increasing total funding available through SBIR programs will (in principle) benefit ATD small businesses. Most ATD small businesses are not (and are not likely to be) owned by venture capitalists or to be subsidiaries of other U.S. companies. As a consequence, broadening the definition of 'small business owner' in either manner is

likely to increase competition for SBIR funding to the disadvantage of ATD small businesses.

Current Phase I grants are too small to substantially underwrite technology development and product commercialization activities. However, Phase II grants can have a major impact on the outcome of development and commercialization activities. It is reasonable to conjecture that larger Phase II grants would allow small businesses to take on greater risk and increase the rate of successful commercialization. However, ATD small businesses with promising Phase I outcomes are more likely to be rewarded with a Phase II award. The optimal balance between the size and allocation of Phase I and Phase II awards is not readily apparent at this time.

The current study provides a basis for future research. Such research might include: commercialization rates and revenue generation by ATD small businesses developing ATDs with SBIR and STTR funding; use (to include barriers and facilitators) of SBIR and STTR programs by small ATD businesses; the economic impact of SBIR and STTR funding (on the small ATD business, for the broader society); and the extension of all studies to acquisition-based SBIR and STTR programs. Finally, the impact of (particularly the changes to) the reauthorized SBIR Act on ATD development should be subject to study.

Study results will be broadly available to public policy makers, SBIR and STTR program managers, academics, small businesses and consumer advocates through the online peer-reviewed journal, Assistive Technology Outcomes and Benefits and abstracted and linked from the National Rehabilitation Information Center (n.d.). Finally, results will be shared with the Interagency Committee on Disability Research (ICDR), a leadership forum for federal agencies (Interagency Committee on Disability Research, n.d.).

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Knowledge from Research and Practice on the Barriers and Carriers to Successful Technology Transfer for Assistive Technology Devices

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Abstract

Historically, the assistive technology (AT) industry is made up of small to medium size companies serving relatively small markets with products characterized as 'niche' or 'orphan' products. Presenting opportunities to AT companies that are created by outside sources is difficult. Presenting such opportunities to companies serving larger markets is even more difficult. In both cases, transferring new or improved products is fraught with barriers.

This paper outlines the critical barriers to brokering efforts between major U.S. university technology transfer offices and U.S. corporations. This paper also identifies the corresponding carriers, or facilitators, and standard practices that are employed to overcome these barriers in both the AT and mainstream markets. The barriers identified in this paper will span the research, development, and commercialization continuum for technology transfer. Over the past 14 years, by using the carriers and standard practices delineated in this paper, the authors have successfully transferred new technologies and devices in the areas of AT and mainstream consumer products.

Key words: Barriers, Carriers, Facilitators, Technology Transfer, Assistive Technology, University-based Research, Technology Transfer Office

Background

Modeling the Technology Transfer Process

When an entity attempts to shift control and responsibility for a prototype invention to another entity, it engages in a process commonly referred to as technology transfer (TT). Definitions of TT vary widely. In order to provide common ground for dialogue, and for action within the field of AT, we created and published a generic model that characterized the key elements of the TT process (i.e., initiating transfer forces, critical events and stakeholder groups) and linked these elements within an overall process (Lane, 1999). This generic model (Figure 1 below) is intended for application within the context of any specific program.

In the context of this generic model, TT should be viewed and treated as a single broad process that encompasses multiple elements. The elements comprising TT are routinely viewed as disparate activities, but it is more constructive to treat them as stages of a continuous process from technology discovery through product consumption. Technologies enable a product's features and functions. For example, the manufacturer of a non-stick frying pan incorporates multiple technologies (e.g., metals, ceramics, plastics, and bonding agents), while the consumer only buys one product (e.g., a frying pan with the desired non-stick feature; Camp & Sexton, 1992).

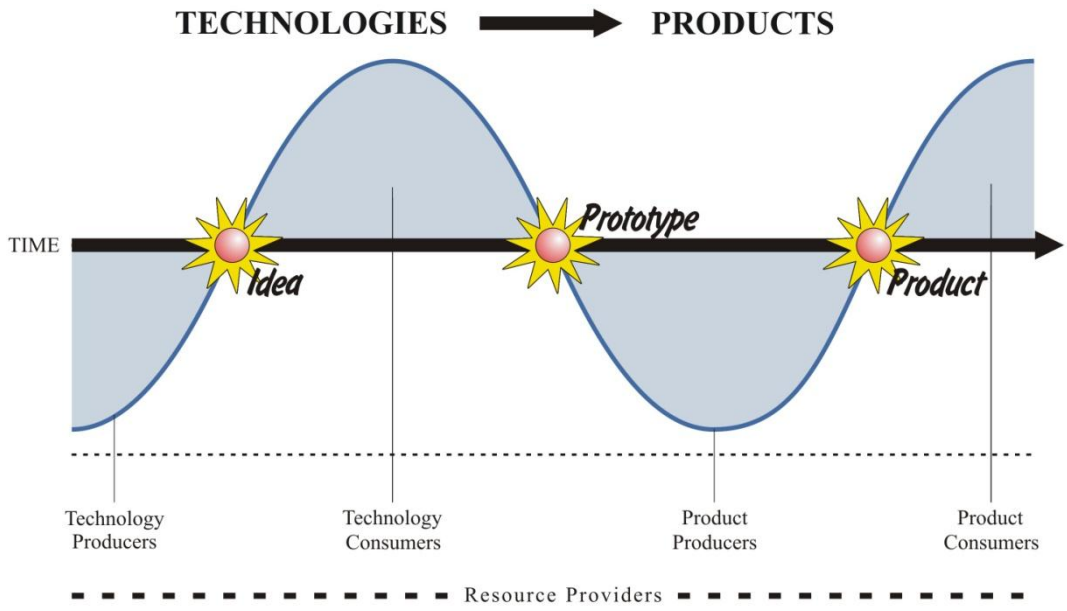

Figure 1. Generic model of the TT process.

TT commences by one of two initiating forces. Forces at either the technology discovery end or the product consumption end can initiate TT.

A *supply push* TT is initiated through an effort to apply a technology's utility within a new product. Otherwise put, the technology is *pushed* toward the marketplace to address an assumed, unsatisfied demand (Paul, 1987). For example, an elderly person may struggle to rise from a wheelchair because he or she struggles to engage the wheel locks. In an effort to solve this problem, a therapist prototyped a device that automatically engaged the wheel locks as the elderly person rose from the wheelchair. The device was effective, so the inventor sought a broader commercial market for the invention through license or sale. In this example, the inventor collaborated with the authors to improve and license this device to a corporation within the wheelchair industry. This is a classic case of supply push transfer in that an invention designed for limited application is assumed to be applicable to a larger population, without a validated expression of the market's need for the perceived solution. It is a gamble that may prove right or wrong.

Demand pull TTs, on the other hand, are initiated in response to a validated market demand for a product feature or function. Companies may seek a solution to a problem articulated by their customers (Von Hippel, 1986). The authors, for example, determined that power wheelchair manufacturers, and people with mobility impairments, considered the battery charging process to be inefficient. Once the market articulated demand for an improved battery charging process, we identified a device in the automobile industry that met the demand. Within six months the authors brokered a transfer agreement between the device and five wheelchair companies.

Another source of demand pull activity is evident in technology requests from manufacturers, or National Aeronautics and Space Administration (NASA) specifications, which circulate through the Small Business Innovation Research (SBIR) program because

they are market problems seeking a technology solution.

In some cases, breakthrough technologies (e.g., telephone, integrated circuits) enter the market through supply push activities. Subsequently, demand pull forces expand those applications. Identifying the initiating force as either supply push or as demand pull helps validate the transfer opportunity, estimate market value, and assess the likelihood of future success.

Within the generic model, all technology transfer projects pass through three critical events. These critical events, which are listed and defined below, represent the transformation from core technology to commercial product (Rogers, 1995).

The *idea event* is the conceptual awareness that an existing technology might be applicable in a new field. The idea event involves no tangible development. Take, for example, an engineer who asserts that a transfer of composite materials used in aircrafts could improve consumer goods by reducing weight while increasing strength and flexibility.

The *prototype event* occurs when a working model demonstrates that the idea functions as expected in an actual application, where, in legal parlance, the idea is 'reduced to practice.' When bicycle and wheelchair frames that are formed from composite materials pass basic performance tests, a prototype event has occurred.

The transition from feasible prototype to market product is the crux of technology transfer. For the transition to take place, a manufacturer, or *product producer* (see Figure 1), must decide to invest in product development (Krishnan & Ulrich, 2001). They make this decision based on their assessments of the technology created by a *technology producer*. This decision is required whether the prototype is developed inside or outside a company. From a manufacturer's perspective, assessing the prototype's commercial viability includes internal manufacturing capabilities, sales and marketing expertise, and product planning horizons (Day & Shoemaker, 2000). Beyond that, the manufacturer's involvement requires successful negotiation of intellectual property, financial compensation, and agreement on due diligence terms between the manufacturer and prototype developer (Gutterman & Erlich, 1997). Problems in any area will likely result in project termination. Manufacturers maintain an especially low rejection threshold for external projects.

The *product event* takes place when the first production-quality unit leaves the assembly line for the marketplace. In our example, the proliferation of bicycle and wheelchair frames made from composite materials--along with limb braces, tennis rackets, and golf club shafts--demonstrates the range of *product events* that can result from an initial idea event. It also shows the power of one technology to enhance the lives of people with and without disabilities.

The product event represents the culmination of an arduous journey through the product development 'valley of death,' a series of gaps that must be bridged to achieve success (Rosenau, 1996). Specifically, the transition from prototype to product requires bridging three crucial gaps: the (a) *funding gap* between government and commercial support; (b) *value gap* between academic knowledge and market potential; and (c) *information gap* between technologists and marketers (Hartman & Lakatos, 1998). Successfully bridging all three gaps leads to the challenges of product introduction. Product introduction encompasses production, distribution, sales, marketing, and support activities (Jolly, 1997). Each of these must be considered in the developer's earliest transfer plans because

manufacturers will consider the costs of these activities in their transfer decision.

As a TT broker, the authors focus on the portion of the TT process between the prototype event and the product event--the aforementioned valley of death. This focus makes the manufacturers (technology consumers/product producers) in Figure 1 the most critical stakeholder group and, therefore, our primary target population. Manufacturers are critical as they are uniquely positioned to turn a prototype into a commercial product. They are also pivotal to the roles of other stakeholders (Scadden, 1987). Manufacturers rely mostly on *product consumers*, including people with disabilities, to be customers for their products. To a lesser extent, manufacturers rely on *technology producers* for innovations in core technologies. For small markets like AT, manufacturers also need support from resource providers like federal agencies, which fund development projects, regulate new products, or set reimbursement levels. All of these stakeholders, therefore, are considered target populations, with manufacturers in a pivotal role.

However, in order to successfully transfer commercial products to the marketplace, the authors must also consider the implications of early work on the remaining elements of the technology transfer process. No matter how great the need, or whose need, not all prototypes culminate in products with value to the AT marketplace. Market failures can often be traced back to activity preceding the prototype event. Improper assumptions about ideas, incorrect information about markets, interpersonal conflicts, or the trajectory of parallel research that makes current work obsolete, can all lead to market failure. Early decisions, or actions, by any stakeholder group may have grave consequences later in the process.

In general, TT is clearly more business-oriented than academic-oriented. Intellectual criteria that make a project interesting in the context of an academic model are subordinate to economic criteria, which require a project to be sound and profitable in the framework of a business model. Even when a product is supported by a sound business plan, the champion of the product faces a major hurdle simply by virtue of coming from outside the targeted partner corporation.

External product submissions to companies must compete against internal product initiatives which are supported by internal corporate champions. These internal initiatives already have corporate time and money invested based on prior management decisions to proceed. The internal champions possess the experience necessary to: (a) navigate the corporate product development cycle, (b) overcome barriers, and (c) satisfactorily answer questions and address concerns from a company's internal managers. Few companies have slack resources available to support new projects. Instead, companies must weigh the merits of competing opportunities and then invest in the most compelling option.

Companies are generally risk-averse and, thus, conservative when investing internal resources on research and development. They tend to focus on refinements to existing products that are proven commodities with established market positions. It is safer and easier to invest in expanding market share for a profitable product than it is to justify the expense of fulfilling an unmet need in the marketplace with a new, unproven product. In the current environment, truly novel ideas are left to start-up companies. Established firms prefer to wait and will pay a premium to acquire a successful new product or company rather than make the risk investment themselves.

Eliminating or minimizing barriers to commercialization perceived by licensing companies is of the utmost importance to the successful transfer, licensing, and production of new inventions. It is much easier for a corporation to refuse an external invention than to accept it. A refusal requires neither licensing nor any expenditures of time or capital in research and development, marketing analysis, and consumer testing. The external inventor who hopes to initiate the product development cycle must overcome this corporate inertia.

Modeling the Product Development Process

For the purpose of this paper, discussion of barriers, carriers, and standard practices should be considered in the context of TT processes at federally funded (U.S.) programs at universities where prototype development is followed by TT to corporations for product development.

The Product Development Managers Association (PDMA) has published a series of textbooks on the product development process. We have extracted from this literature 20 steps--from the idea to product stages--which, when followed, ensure successful product development. Each step has input and output processes, which advance an idea from its conception to a successful product in the marketplace. There are 10 steps from the idea to prototype stage and 10 more steps from the *prototype* to *product* stage. PDMA's product development process is based on the assumption that one entity, a company, performs all 20 steps (see Figure 2).

However, in TT at universities, the initial product development process is performed by a university researcher. This process ceases when the prototype is developed. From there, a university's TT office (TTO) handles the invention's licensing and subsequent handoff to a company that completes the product development process.

The barriers, carriers, and standard practices discussed in this paper are the same, in some

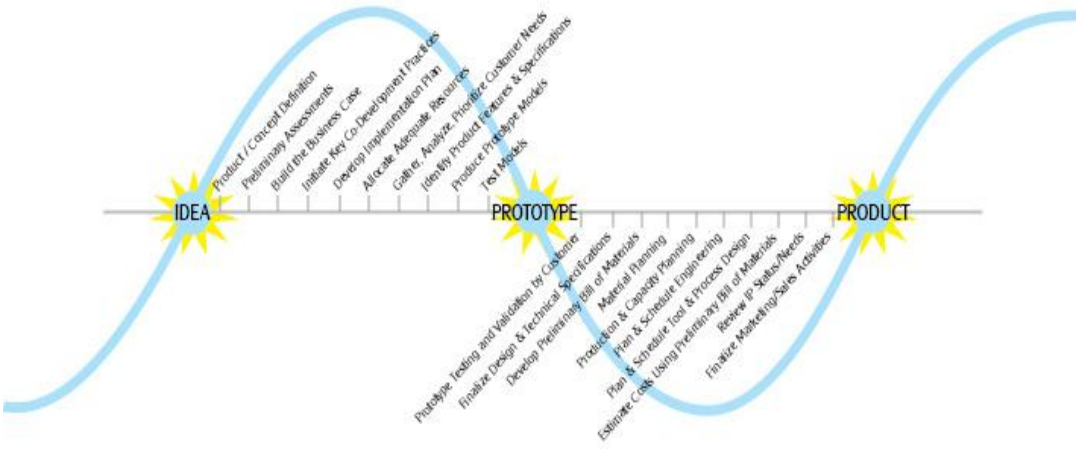

Figure 2. Development literature shows 20 steps from *idea* to *product*.

cases, as those encountered in standard new product development processes by corporations. However, because a university attempts to license a prototype invention to a company, the barriers, carriers, and standard practices are unique to university research communities and to universities attempting to license prototypes.

Figure 2 shows the three critical events of TT and the PDMA's 20 steps between the idea event for the application of an enabling technology to the product event resulting in a commercial product that is ready for production and market introduction. This paper describes and discusses barriers to progress in each of the critical events as well as carriers that will circumvent or dissolve those barriers.

Barriers and Carriers Prior to the Idea Critical Event

Our discussion begins with the 'valley' that precedes the idea critical event. Barriers to successful TT of an invention spring up at the earliest stages of research, even before a researcher develops an invention. If a researcher or inventor fails to meticulously consider and address these early barriers, the future product may fail downstream.

At this stage, the researcher knows of an unmet consumer need for a technology or a product. But at this point, the researcher is uncertain of exactly what to develop. He or she applies for a grant from a funding agency to do research to develop a technology that the researcher hopes will address the unmet need and become a usable product for consumers. Even at this stage, potential barriers that go unaddressed will lead to project failure.

Barriers to Achieving a Valid Idea Critical Event

Failure to allocate an adequate amount of researcher's time. Here, if a researcher allocates only minimal time to the research project, for example, 5%-10% full-time effort, practically speaking, the project won't receive enough attention to succeed (Lane, 2008).

Failure to allocate adequate resources. A researcher may allocate insufficient lab and financial resources to the project. If only one member of a research team works on a project, the future of the project is already in jeopardy. Similarly, if that individual leaves the team, it's possible that the team's remaining members would let the project fall by the wayside.

Carriers that Can Nullify Barriers Prior to the Idea Stage

Granting agencies or universities should see to it that federally funded investigators who perform research have allocated a substantial minimum amount of time to a research project. Generally, very low full-time effort allocation of a researcher's time (5%-10%) results in project failure (Lane, 2008).

Allocation of adequate resources includes staff, facility, and consumer involvement time. While researchers may understand their laboratory and staff needs, researchers who fail to allocate sufficient financial resources to a consumer component of research (i.e., focus groups, surveys, etc.) may remain unaware of the full range of consumers' needs, wants, and desires for a product solution. Researchers may incorrectly make assumptions about what is good for, necessary to, and desired by end consumers (Cooper, 1999).

Projects should be seeded with the efforts and interests of multiple researchers. Multiple investigators should contribute significant full-time effort. By this approach, a project

can survive the departure of any single researcher (Lane, 2008).

Barriers and Carriers Between Idea and Prototype Critical Events

By now, a researcher has received federal funding and university backing. For research to result in invention, innovation, and, eventually, a viable commercial product, product development literature shows that certain carriers and standard practices should be performed by the research team at this early stage. Failure to navigate potential barriers here significantly inhibits the project's potential for success.

Barriers to Progressing to the Prototype Critical Event

Lack of preliminary assessment. Lack of due diligence by an inventor or research team could result in duplication of research and thus only minor or incremental improvements to technology and products that are already in the commercial marketplace. If the research team lacks awareness of the industry, of which technologies are being developed into commercial products, and of regulatory or business perspectives (i.e., device reimbursement issues, government accessibility regulations [such as those contained in Section 508 of the Rehabilitation Act], or the relocation of manufacturer production facilities overseas), their research will fail to lead to a development outcome of a product in the commercial marketplace.

Failure to build the business case. AT markets are historically small. Unless research generates technology that can be used across markets, the cost of the technology will stunt its early acceptance and use by consumers. If the overall goal of a research project is to impact the lives of consumers now, then awareness of the costs of technology is paramount. A decade ago the cost of the voice chips used in voice-interactive products was prohibitive, which delayed the arrival of many voice-operated products to the market. Today, as more product applications have appeared, and the technology to produce voice chips has become cheaper, the cost of voice-interactive products has decreased. These products are now viable commercially. Similarly, researchers may believe themselves to be experts in terms of both the technologies and products that are currently available as well as consumers' needs. Therefore they will not perform due diligence requirements on an industry. They will also fail to assess consumer needs in detail.

Carriers that Would Nullify Potential Barriers Between Idea and Prototype Stages

Perform preliminary assessments. Researchers should perform an extensive search of regulatory standards and competing technology and products to verify that their research will meet an existing need or solve a problem. Options include searching similar technologies, products, and patents. Researchers should contact industry associations in their areas of research to track current developments from manufacturing and regulatory standpoints.

Build the business case. Researchers should explore the technology costs and applications. Retailers and professionals may be visited to learn how individuals presently address the relevant function or need through products currently in the market. Inventors must also recognize that consumers sometimes prefer a technology-free option. Also, researchers need to constantly search for disruptive technologies as this may negatively affect the acceptance and adoption of their work.

Barriers and Carriers Between the Prototype and Product Critical Event

The remainder of this paper focuses on technology transfer at U.S. federally funded

programs where prototype creation occurs at universities with subsequent technology transfer to corporations for product development. Universities operate technology transfer offices (TTO) to ensure compliance with all institutional and federal regulations concerning intellectual property, such as the Bayh-Dole, Patent and Trademark Act Amendments of 1980. Research performed by university employees, on or off premises, and specifically all research performed on university property, utilizing university facilities that leads to an invention by a university employee must be disclosed to the university's TTO. For inventions that result from federal funding, the TTO discloses the invention to the funding sponsor and determines if either the TTO or the sponsor elects to lay claim to the invention.

Potential Barriers Between Prototype and Product Stages

A university invention may meet a number of barriers on its path towards commercialization.

1. If researchers fail to communicate with the appropriate office at their university, the TTO may be unaware of a new federally funded grant being awarded to its university. The TTO, therefore, may be unaware of its duties and responsibilities under the new grant.
2. Unknowing or uninformed researchers may not make timely disclosures to the TTO, thus the TTO will not preliminarily search patent-related artwork. Thus the TTO may or may not proceed with intellectual property protection (patent) for the invention. Consequently, an inventor may not be the first to file for a patent on his or her invention. This may delay licensing or may result in failure to license the invention at all.
3. Inventors under pressure to publish research results, may, through their publications, publicly disclose their work, inadvertently activating a one-year time bar for filing patent application for the invention. For example, a researcher publicly disclosed his work on a thermostat with voice feedback. Unfortunately the researcher never filed for a patent on his work in the year following its public disclosure. Because his work had entered the public domain, no thermostat company could exclusively own the intellectual property rights to the concept. Thus, no company would invest in bringing the concept to fruition in the marketplace.
4. When universities retain claims to inventions, the institutions may include them among inventions that it passively solicits potential licensees for. In this case, the invention would not be shopped actively and may never be licensed.
5. Assuming the TTO finds a potential licensing company, the TTO may be unaware of the lower royalty rates (ranging from 3% to 8% for non-software items) associated with AT products (due to much lower sales volume) and may ask for too high of a return. This can mean the invention won't be licensed.
6. In some cases, inventors' main goal is to publish their work, not bring an invention to the marketplace. Due to the inventor's lack of interest and assistance, companies may forego licensing the invention.
7. The inventor may provide inadequate information to the TTO, thus hindering the intellectual property protection and licensing of the invention.
8. The eventual licensing of a prototype can be stalled by a university TTO's reluctance, skepticism, and

complacency in signing off on agreements, including a non-disclosure agreement.
9. An inventor may not actually have proof-of-concept for the prototype of his invention. In this case, licensing the invention will be most difficult.
10. If a university researcher proceeds without significant consumer input, the invention can be void of design functions and features that would enable its licensing and success in the marketplace.
11. In licensing negotiations, the inventor may delay sending the functioning prototype to the licensing company for evaluation. This delay may kill a potential licensing deal as companies cannot wait indefinitely this information. Companies interested in new product development may search for other opportunities. In the meantime, the invention may be rendered obsolete.
12. If an inventor's prototype does not function the way that potential licensing companies were led to believe by the TTO, it can negate a licensing company's interest.
13. In the eyes of consumers and licensing companies, a prototype may seem unfinished, thus negating the potential licensing to a company. This applies to companies that may lack the financial wherewithal to redesign a prototype into a product.
14. When inventors send prototypes to potential licensing companies, they may need to answer technical questions. Delays or non-responsiveness on the part of inventors may stifle licensing opportunities.
15. The TTO may fail to identify the correct corporate personnel to contact for licensing an invention, a possibility given that, in AT companies, that role may be filled by multiple people, though it's unclear who the true decision-maker is.
16. Due to triaging, both internal and external, of new inventions, corporate personnel may not respond to a university TTO's licensing inquiries.
17. Due to turnover of corporate personnel at a potential licensing company, the TTO representative may have to forge new working relationships with new personnel, or seek a different licensing partner.
18. Delays in agreements on terms between inventors and licensees can mean that timely inventions miss their windows of opportunity. During the delay, the licensing company may decide to focus on a different invention or technology.
19. Incorrect licensing terminology (e.g., the inaccurate use of 'Universal Design' [UD] instead of 'Transgenerational Design' [TD]) may inadvertently disinterest a company.
20. In presenting to potential licensing companies, TTOs may fail to provide enough information or may incorrectly format the information.

Carriers that Nullify Barriers Between Prototype and Product Events

The following are carriers and standard practices that can nullify the potential barriers noted above. The numbers listed with the carrier and standard practice correspond to the potential barriers above.

With the receipt of a new federal grant, a university's TTO office needs to be brought up to date as soon as the initial granting agency's site visit and prior to the actual financial award. The funded researcher and funding agency are responsible for ensuring that university TTO is aware of its commercialization duties and associated responsibilities under the new federal grant.

Time should be spent outlining both the researcher's development projects and the nature of the associated responsibilities a university's TTO should anticipate in terms of representing and licensing any resultant invention.

Having initiated a relationship between the researcher and his or her university TTO at the time of the grant award, the researcher should be made aware of the need for timely invention disclosures to the university TTO. This awareness and training should be continually reinforced by the university's TTO through faculty and researcher training programs.

TTO training programs for researchers and or inventors should clarify guidelines regarding the topics of intellectual property protection and public disclosure of the work.

Grant-generating entities, like the National Science Foundation, U.S. Department of Education, and National Institutes of Health, should make the university TTO aware of its expected role in commercializing any intellectual property (IP) resulting from the federally sponsored research. Due diligence clauses and expectations should be outlined for the university TTO in the final grant to ensure that the federally funded intellectual property generated is actively shopped to potential licensing companies.

Prior to the official award of the grant from the federal agency, negotiations with the university's TTO office should include how, and under what terms, resultant IP will be licensed by the university. Because the university's research is federally funded, there is an expectation that resultant IP will make its way to the commercial marketplace for the benefit of taxpayers who have funded that research. General guidelines for royalty rates and licensing expectations should be covered prior to the financial award of the grant to the university.

Researchers and or inventors should understand that the grant award has key deliverables that need to be accomplished. The granting agency should make the researcher aware that his or her deliverables for the grant are not finished when they have completed their publications and prototype. It remains incumbent upon researchers to assist in licensing any resultant IP from their research, which means being available for consultation, providing adequate information to their TTO, and continuing to work on the prototype so that it is presented in the best light to potential licensing companies.

Researchers should interject consumer input early in the design process and when finalizing the pre-production prototype. Even large manufacturers of mainstream consumer products make product design decisions without factoring in the needs, wants and expectations of the full range of end consumers. This process leads to ineffective products in the marketplace, new product failures and product abandonment. Failure rates for new product introductions vary by industry, but they generally range from 30% to 90%. Many of these failures can be traced to a point early in the product design process where significant consumer or device-user information was not collected and or not analyzed.

The AT industry has faced the same complaints for decades. The medical model of rehabilitation service provision readily substituted clinical requirements for user requirements. Failing to involve consumers with disabilities in every aspect of product design and development results in products that fail to meet consumer expectations and fail to deliver the required functional capabilities.

When a TTO contacts prospective licensing companies, it should be familiar in advance with the (a) companies they contact, (b) industry or industries those companies operate in, and (c) major players in those industries. Examples of questions to guide research in this area are: Which innovators seek to compete with industry leaders? What and when are the industry trade shows? How do companies in this industry introduce new products? And What are these companies' product development cycles?

Once a TTO makes contact with a licensing company, TTO personnel should attempt to meet multiple people within that organization. This not only builds relationships. It helps mitigate the negative effects of corporate personnel turnover in that multiple people at the licensing company will be familiar with the TTO and the invention under discussion.

The TTO must know enough about the industry to present an invention at the most opportune time. Missing a corporate product development window can stall a project within a corporation for up to a year. Prior to a TTO's contact with a potential licensing company, a TTO should outline the terms and conditions it will seek from the company in order to alleviate any possible negotiation delays. For example, in the wheeled mobility industry, new product introductions revolve around a trade show called Medtrade. A TTO must know when companies seek new products and when they will invest in developing the product or technology that needs licensing.

Timing and correct terminology are extremely important in licensing an invention. Certain terms and methods, in our experience, increase the likelihood of successfully licensing prototype devices. It's important to keep in mind that corporations are motivated by lower product cost, increased profit, and increased market share. Given that, our work has revealed four guidelines for approaching and engaging companies in negotiations to persuade mainstream consumer product manufacturers to add usability and accessibility features to the next generation of their products now: (a) what to say and what not to say; (b) which buzz terms turn off your corporate audience and which pique interest; (c) how to say it, and know how to address the corporate audience; and (d) when to say it.

For example, corporations know millions of Baby Boomers are rapidly approaching their senior years, and they wish to increase market share among this population. Aging, affluent Baby Boomers, who are tech savvy and receptive to product advancements, are changing the traditional consumer market for the elderly. For example, knowing the corporate attitude towards UD, the authors have found it beneficial to speak of TD rather than UD when making presentations to company executives. TD, a term coined by Dr. James Pirkl, is a knowledge-based design strategy that produces products, packages, graphics, and environments that accommodate physical and sensory impairments associated with human aging and which limit independence. TD products are designed to be used by people of all ages and ability levels. TD piques the interest of corporations trying to tap into the aging Baby Boomer market.

A licensing company should use detailed invention information packages or commercialization packages to evaluate the potential invention opportunity. Commercialization package elements include: (a) a listing of relevant product manufacturers; (b) in-depth literature on competing products; (c) literature for technical references; (d) standards and regulations; (e) consumer input through focus groups to determine possible product enhancements and priority ranking of characteristics; (f) technical analysis detailing device characteristics, technical feasibility, and

product enhancements; (g) market analysis with a competing product matrix, benchmarking competing products versus the submitted device's characteristics; (h) identification of the target market and distribution channels; (i) supporting documentation in the way of CAD drawings, pictures, or graphics; and (j) virtual product matrix.

Product Life Cycle

The life cycle of a product has various stages. For the purpose of this paper we will focus on the initial product launch. At this stage, the researcher has little control over the end product unless the licensing company allows the TTO to place due diligence milestones for the company into the license agreement. The product has gone into production and has been launched into the marketplace by the licensing company and the onus is now on the company to make the product introduction successful.

Barriers Encountered After the Product Critical Event

1. Even upon licensing an invention, AT companies may lack sufficient corporate resources to bring many new products to market. Once the invention is licensed, the licensee may encounter unforeseen cost barriers.
2. Once an agreement to license exists, delays inside the licensing organization (related to engineering, product design or financing) can postpone the new product introduction.
3. Inadequate quality control on production of the final product can result in a high failure rate of the product or low consumer acceptance of the product.
4. If a company fails to adequately advertise and promote a new product, the product's life cycle may be short.
5. Pricing is extremely important. If the company overprices the initial offering of the product in an attempt to recoup molding costs quickly, the product may not sell; it may be overpriced compared to its competition.
6. Too many features and functions can increase manufacturing costs and subsequent retail price, thereby placing it at a competitive disadvantage.
7. If the manufacturer bundles two products into one, it may negatively affect sales.

Carriers to Nullify the Barriers Following the Product Critical Event

1. The only carrier and standard practice that can nullify the barriers listed above are applied at the time of licensing. The university TTO should strive to select a licensing company that has a history of successful AT product launches and one that agrees to include certain due diligence clauses in the license agreement.

Summary

Many early steps in the product development process are the same whether they are performed by a corporation or by a university researcher. Significant permutations in the process occur after the prototype event. Once the prototype step is reached, there are many possible branches to follow for commercialization. In this paper, the path we chose was that of a federally funded university researcher attempting to commercialize an invention through his or her university's TT office.

When a barrier is identified, the researcher or TTO must seek a carrier, or standard practice, to overcome the barrier. If the barrier is an internal policy or procedure, the researcher

and his or her institution must enact corrective measures or rewrite policy. A researcher, and his or her institution, can seek answers or carriers from technology transfer literature or the PDMA.

Conclusions

The authors have served as TT brokers for the last 14 years. In the process we have established a high level of credibility with all stakeholders from researchers to manufacturers to consumers. This allows us to build upon our collaborations with AT and mainstream product manufacturers and to successfully navigate potential barriers to the successful TT of inventions. Knowledge gained from research and practice has helped us to identify barriers to successful TT and to craft carriers and standard practices that would ensure our relative success. University-based technology brokers can apply these same lessons to establish relationships in industries where their faculty members generate inventions.

In this paper we have identified significant barriers to TT and the subsequent carriers to overcome those barriers. However, a key carrier we didn't elaborate on is due diligence. If a researcher or TTO performs the tasks needed to initiate a carrier well, the barrier will be overcome. If the researcher and TTO do not perform well, or at all, the barrier will impede commercialization.

In many cases, successful implementation of a carrier requires significant patience and persistence. For example, if a market doesn't yet exist for a product, a researcher may cultivate a market. Or, if a sales track record for a product doesn't exist, but is needed to license the product, the researcher can make a short production run, sell the product on the internet, and gather data to present the business case to a licensing entity.

Having described a range of carriers to barriers, the authors realize that some barriers exist that researchers, or their organizations, can't overcome. Undeveloped technology and technology that is currently too costly present formidable barriers that may only be resolved with the passage of time. However, technology costs have a way of decreasing, and new opportunities or applications reveal themselves, creating new options for bringing inventions to market.

In the end, for successful technology transfer to take place, researchers and their organizations need not only due diligence, patience, and persistence, but also sufficient time and resources to execute the needed implementations of carriers. And, by the way, a little luck helps too!

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Beyond Technology Transfer: Quality of Life Impacts from R&D Outcomes

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Abstract

This paper presents methodology and findings from three product efficacy studies that verify the quality of life benefits resulting from prior research, development, and transfer activities. The paper then discusses key lessons learned with implications for product evaluation practice. The studies assessed the quality of three assistive technology (AT) products transferred to market by the University at Buffalo's Rehabilitation Engineering Research Center on Technology Transfer (T^2RERC) and their value to consumers with disabilities. The purpose was to focus on outcome evaluation and seek evidence of effectiveness for the transfer process. Findings showed differences among the three products regarding their impact on end users in terms of satisfaction with product quality and product acceptance. The product most successful on all quality and value indicators was an automatic jar opener designed for persons with limited hand function. The other two–a computer software product designed to facilitate mouse pointer use by persons with limited hand function or with low vision, and a voice interactive thermostat, designed for persons with total or partial visual impairment–were less successful. They showed mixed results. Not many consumers were satisfied with the technical quality or usability of the latter two products. Of the two, the thermostat was slightly better accepted and valued by users. Differences in impact were found to follow from differences in the way evaluation information was utilized by the three product development processes. A case is made for systematic and timely use of evaluation throughout the development process in shaping a product of quality and value, in the context of the intended end users of AT.

Key words: Outcomes Research, Assistive Technology, Product Evaluation, Technology Transfer, Efficacy Assessment, Quality of Life

The T^2RERC at the University at Buffalo, in partnership with the Western New York Independent Living (WNY-IL), has been seeking to improve the quality of life for persons with disabilities bringing new and improved technologies and products to market. Applying and perfecting a systematic process (Lane, 1999) over its three cycles of funding from the National Institute on Disability and Rehabilitation Research (NIDRR), the T^2RERC has transferred to date over 50 technologies and products into the AT market. The development of an operational model and its demonstrated success in accomplishing technology transfer (TT) were acknowledged by experts at the State of the Science Conference held by the T^2RERC in 2003 at the conclusion of its second cycle of funding (Lane, 2003). As Lane reports, their responses about how to advance the field of TT to the point of establishing it as an academic discipline emphasized the need to first establish TT as a formal process through continued research. The need for

studies about existing models using longitudinal data was pointed out, as was the importance of continued study of the T²RERC model in other contexts and in comparative settings.

As it pursued the study of the model into its third cycle of operation, the T²RERC recognized that an extended evaluation of the model addressing its long term outcomes, as established in the NIDRR long-range plan, was in order. Accomplishing transfers evaluates only part of T²RERC's mission. It means outcomes have been achieved as intended in the form of transferred products, using a systematic transfer process. At that point, some critical questions remain unanswered: In what ways does the new product provide beneficial impacts on the quality of life of people with disabilities? To what extent do the transferred products represent improvements over existing devices that were already available in the marketplace? These questions point to a need for research "…devoted to systematic efficacy trials aimed at demonstrating how well the technologies being developed actually work" as opposed to 'letting the market-place decide' (Fuhrer, 2002, p. 13). The implied concern is about a product's impact on users, which includes product efficacy and through it, the validity or worth (Joint Committee on Standards for Educational Evaluation, 1994) of the T²RERC's transfer effort.

Following up on outcomes from its TT process, the T²RERC undertook an in-depth study of the efficacy of three selected products transferred by the center. This paper reports on this series of three studies comparing and contrasting key findings about beneficial impacts on users.

As conceptualized by Lane (Lane, 1999; Lane, Leahy, Bauer, & Stone, 2008), the transfer effort relates to the movement of technology 'from mind to market.' The T²RERC intervenes in the path of TT, at appropriate points between the 'idea/concept' stage and the final product stage, facilitating its entry into the marketplace as a commercialized product. Whether this intervention is accomplished through a demand-pull (Bauer, 2003), supply-push (Leahy, 2003), or corporate collaboration strategy (Leahy, 2005), the goal is to develop a new AT product designed to better meet the functional needs of users with disabilities, that is, better in relation to existing options currently available in the marketplace.

The product's ability to improve the user's functional capability is evidence of its value to the user and hence supports the value of the process that transferred the product. All three outcome evaluation studies presented here assessed the AT products' efficacy with focus on the intended beneficiaries – people with disabilities. In doing so, they do in fact seek the 'proof of the pudding' for the effectiveness of the T²RERC's transfer process in the context of the sponsor's mission to improve the quality of life for persons with disabilities.

In this article we present the rationale that guided the efficacy study for three products. We then present the three cases, describing the method and results for each. In doing so, we focus on a limited number of key variables common to the three cases. At the end, we summarize, compare, and contrast the three cases, draw conclusions from the overall experience, and end with a discussion of lessons learned and future directions. A summary of the T²RERC intervention into the development process of the three products is included in a later section, while full reports of individual case studies are addressed in our Resource Guide (Stone, Lockett & Usiak, 2009).

Rationale and Guiding Concepts

Efficacy as Quality and Value

Efficacy is a term used in product development practice. As a synonym of effectiveness it has been commonly used as something 'having an effect' and therefore useful or valuable, as well as something 'working well' and therefore meritorious and possessing quality. The U.S. English dictionary and thesaurus equivalents as per MSN Encarta are: "effectiveness or the ability to produce the desired result" (Microsoft, 2009a); and "effectiveness, efficiency, usefulness, worth and value" (Microsoft, 2009b). These equivalents reinforce both of the common usages, suggesting that efficacy is a global term that includes both the quality and value aspects of something being evaluated. In evaluation literature the concepts of *quality* and *value* are roughly equivalent to a product's *merit* and *worth*, the terms used to define evaluation (Joint Committee on Standards for Educational Evaluation, 1994; Scriven, 1991).

In the specific context of products devised for enhancing the functional capabilities of people with disabilities, we understand efficacy as impacting and improving their functional capabilities and independent living. This perspective ties the value of a product to consumer perception of quality and value, as well as to consumer satisfaction about how well individual needs are met. Ideally the products will meet the consumer's quality and value requirements, leading to long term use of the product to enhance daily living and independent functioning.

Each study assessed the quality and value of the transferred device in focus and sought to determine whether the device was an improvement over existing alternatives. In controlled onsite trials, the new product was compared to other products present in the marketplace at the time of transfer and was expected to offer equivalent functional benefits. In home trials, consumers also compared the new product to alternative strategies they had previously used for accomplishing the same function without the new product. Each study also assessed the value of the new product to the consumer through acceptance and use or disuse of the product over a 4- to 6-month timeframe, as well as through the consumer's response to an opportunity to acquire the product.

Evaluation's Role in Technology Transfer

Systematic evaluation is a major component of the T^{2}RERC's transfer effort. Careful evaluation helps steward transfer efforts through each step of the process, from the initial idea to new product in the marketplace. In particular, primary and secondary market research (Malhotra, 1999) captures and provides consumer and market needs. Consumer evaluations in two successive focus group interviews capture and provide features for evolving prototype versions. New product development and commercialization is the goal of the evaluation, and the principles of product evaluation are the most relevant.

Product evaluation is the most mature sector within the field of evaluation (Scriven, 1991). The concepts of *formative* and *summative* evaluations widely used in systems development and program evaluation contexts owe their origins to the principles of product development (Scriven, 1973). Tied directly to product quality and often also to value, efficacy is the focus of all product development. Quality assurance is an essential part of the product development cycle, and value is often a simultaneous concern in optimizing the product's quality. Evaluation enlightens the entire process of product development, stepping in before product conceptualization and offering guidance

through prototype design and construction to final product manufacturing. Formative evaluation includes iterating cycles of testing of the prototype/product against its quality standard, followed by continuous product improvement.

Summative evaluation of the final product version assesses it against desired quality and checks its readiness for final distribution. Formative evaluation shapes the product's quality; summative evaluation verifies if the quality is at par with what was expected. The above mentioned concepts are embedded in Figure 1.

Figure 1 describes the systems approach to product development. This is our specific product development version adapted from a generalized model applicable to any system development, the CIPP (context, input, process, and product) model of evaluation proposed by Stufflebeam and colleagues (Stufflebeam & Shinkfield, 2007; Worthen & Sanders, 1973). The four types of evaluations in this model capture useful data to respectively inform four successive management decisions of design, structure, implementation, and product recycling. Need provides the basis for designing a relevant system (or product), input information makes it feasible to put together, process evaluation enables optimal implementation, and product evaluation helps improve the output to optimal quality. Evaluation thus enlightens the development process. Used beyond the process, it provides post-commercialization guidance.

Issues of quality and value are routinely addressed by professional product developers, whether as part of their technical quality control routine or in their consumer satisfaction assessments and marketing surveys. Such evaluations tend to be isolated and conducted at specific stages of the product's development and commercialization, rather than systematically span the entire development cycle as shown in Figure 1. Yet, in order to maximize evaluation's potential to enhance a product's quality and value to the intended end user, it is

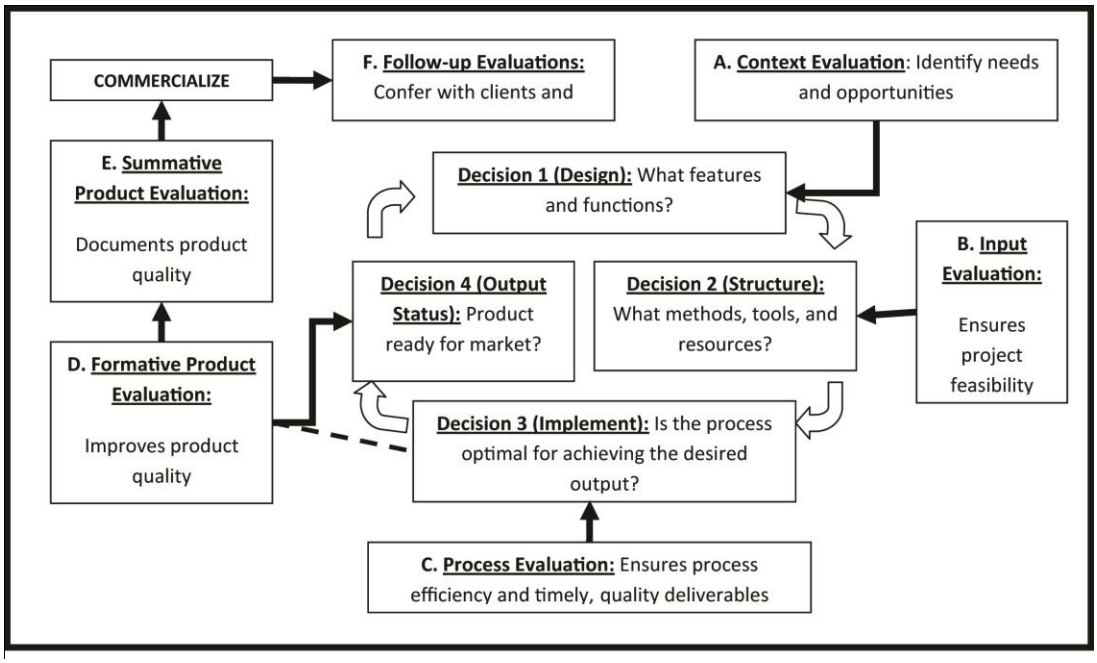

Figure 1. Evaluation enlightens development.

crucial that it occur continuously at all stages of product development and contribute to enlightened management decisions. It is easy to see from the diagram how a pro-active approach where consumer and market needs drive design priorities is superior to an after-commercialization satisfaction survey that may be too late to act upon. Likewise, if formative evaluations (Scriven, 1973) are to be valuable in perfecting product quality, they should not only be iterative but also timely, with all iterations occurring before the product is commercialized. Ideally, a summative evaluation should also occur before commercialization and document product effectiveness, including in real-life situations. This can be difficult, given practical constraints on time, finances, and personnel expertise in the industry sector. Each of these constraints has impeded the utilization of evaluation to its maximum potential with consequences such as poor product quality, product languishing in market, or users abandoning products.

The T^{2}RERC's transfer effort bases its rationale on the Product Development Institute's Stage-Gate® framework (www.prod-dev.com; Kahn, Castellion, & Griffin, 2005), the roadmap for driving new products from idea to launch successfully and efficiently. Used by most major companies today, it brings a management rather than an academic perspective to new product development. Although less explicit and detailed as the CIPP model, the T^{2}RERC roadmap emphasizes evaluation with sufficient concurrence and overlap with the CIPP concepts.

The T^{2}RERC's information capture starts at the pre-design stage and spans the entire path from concept to prototype to product and, if needed, to post commercialization. Consumer and market needs guide the redesign of prototype with the relevant AT features. Consumers then evaluate the prototype in iterative focus groups and surveys and the prototype is refined before licensing to the manufacturer (Stone, 2003). Summative evaluation of the final product is usually limited to pre-production. Full-blown summative evaluations before product commercialization are hard to incorporate into corporate realities. All the same, evaluation is a key contributor to shaping the product as desired by the T^{2}RERC technology transfer process. The quality and value of a transferred product as captured by the efficacy studies is directly tied to this role of evaluation.

Designer and Consumer Perspectives in Measuring Quality and Value

Product designers and developers are a primary group interested in product quality, as are consumers and their advocates who have an equal stake in a product's performance. A review of product evaluation literature reveals interest from both stakeholder groups expressed in different terms. Usability is often the designer expressed product quality, viewed as the optimal match of device features/functions to user characteristics (Green & Jordan, 1999). In an extended view, Popovic (1999) considers it best incorporated during the design process. It is considered best to design with users rather than designing for users, to avoid problems in the user-product interactive interfaces. The concept of usability evolved in the study of human-computer interaction, but has now broadly transcended into the world of consumer electronics (Han, Yun, Kwahk, & Hong, 2001) and home appliances (Rich, Sidner, Lesh, Garland, Booth, & Chimani, 2006). It is often considered as a reflection of the product's ergonomic quality (Babbar, Behara, & White, 2002; Dzida, 1995).

As per the International Standards Organization (1998) definition, usability of day-to-day products would determine how

consumers can interact with them to successfully complete a task in relation to the effort, time and accuracy involved in using them. This approach includes considerations of both effectiveness and efficiency.

From the consumer perspective, quality standards are tied to a product's ability to meet users' expectations. Some consumer-perceived attributes of usability may include a product's ease of use, comfort in use, safety, and reliability. Whereas a designer might view 'meeting user expectations' as an end, or the result of selecting and arranging the desirable product features and functions, the consumer might consider it the starting point or a necessary condition for accepting and using the product to full satisfaction. In this sense, a product's usability and acceptance in consumers' eyes are important indicators for efficacy evaluation. Batavia and Hammer (1990) proposed a preliminary standard set of 17 consumer-expressed quality criteria that could be applied to AT devices and products as measures of their usability. These 17 consumer-expressed criteria were later refined and reduced to 10 by the T^{2}RERC's consumer ideal product study (Lane et al., 1997; Stone et al., 2009). These 10 consumer-expressed criteria are: (a) effectiveness, (b) durability, (c) reliability, (d) safety, (e) comfort, (f) learnability, (g) maintenance/ reparability, (h) portability, (i) operability, and (j) affordability.

In addition to usability, success of consumer products also depends on factors such as technical excellence, functionality, cost, and after-sales customer support (Babbar et al., 2002; Dumas & Redish, 1994; Han et al., 2001). From a consumer perspective technical excellence in design and manufacturing of a product is manifested through factors such as product's appeal or aesthetics, durability, cost and customer support.

Involving consumers in product design has been central to many concepts ranging from the well-known Universal Design (Center for Universal Design, 2007; Story, Mueller, & Montoya-Weiss, 2002; Trace Center, 2003), Design-for-all (Design for All Foundation, n.d.), Trans-generational Design (Pirkl, 1991) to the recently coined Nana-technology (Carle as cited by Jennings, 2006). Although these concepts may have their own subtleties with respect to definition, principles, cultural, and geographic significance, their commonality is in terms of their goal to facilitate the usability of products for all users regardless of their abilities or disabilities.

The above considerations guided the efficacy assessment in all three case studies. Efficacy indicators were defined using designer expertise and consumer experience, as described later in the methods section. Our approach was to combine designer insight about helping people achieve the operational objectives for which they are responsible, with the consumer's desire to use AT to fulfill life's roles (Rouse, 1991). Three examples of designer-expressed indicators of usability (International Standards Organization, 1998; Jordan, 1998) are: (a) effectiveness (i.e., the extent to which a goal or task is achieved); (b) efficiency (i.e., the amount of effort required to accomplish a goal); and (c) satisfaction (i.e., the level of comfort the user feels when using a product and how acceptable the product is to users as a vehicle for achieving their goals).

Taken together, the T^{2}RERC consumer criteria and the designer principles for usability by all represent a fairly comprehensive basis for evaluating a new product's efficacy.

Focus of the Study: Three AT Products Transferred by the T^{2}RERC

The following summarizes key characteristics of the three products assessed by the efficacy study, and salient points of the T^{2}RERC development and support activity that led to

their transfer. Among the dozens of transfers by the T²RERC, the impact of these three products on persons with disabilities was of unique interest. The Lids Off™ represented the best-case scenario in the sense that the transfer process involving the T²RERC's intervention and the company's use of its support very closely followed the transfer model. The product was a big success in the marketplace in terms of sales volume, although it was a universally designed product, not targeting specific disabilities. The Point Smart on the other hand, did not represent the best case in terms of T²RERC's full intervention but did target persons with specific disabilities. The Kelvin thermostat was of interest because of its focus on sensory impairment (persons with blindness), an especially challenging area in T²RERC's experience in terms of responding to accessibility issues. All the same, each company's internal capabilities and constraints influenced their ability to apply the T²RERC's input in their device development. These decisions determined the extent to which the finished product incorporated the features and functions identified by the consumer and/or designer criteria. These points are discussed in the final section of the paper.

Lids-Off™, Automated Jar Opener by Black & Decker

Lids-Off™ is an electrical household appliance manufactured by the Applica division of Black & Decker. It is designed to assist with the task of opening jars, especially useful for consumers with limited hand function. The device uses a motor driven gear system that uniquely grips and breaks the vacuum seal on a jar to unscrew its lid. It is a table top model that allows also for one handed use.

The T²RERC actively facilitated the design, development, and commercialization of Lids-Off™. We provided primary and secondary market research information as well as formative evaluation (Boxes A and D in Figure 1) of the developing prototype. This included (a) desirable functions and features captured through consumer focus groups reacting to the initial prototype, and (b) step-wise input for refining consecutive prototype versions through focus groups and surveys. Market evaluation data including purchase value and intent to purchase enriched the company's commercialization perspective. However, our support by way of summative evaluation (Box E, Figure 1) before commercialization was limited to informal estimates due to the company's time lines and practical constraints. Also, post commercialization evaluations (Box F, Figure 1) were not part of the support. The several hundred thousand units of the product that were sold in the first year of its launch was possibly the pay-off of this collaborative process. More details of the collaboration on the development of Lids-Off™ from its crude prototype are described in Arthanat, Stone, and Usiak (in press).

Point Smart, Mouse Driver Software by Info Grip

Point Smart by Info Grip (2003) is mouse driver enhancement software designed to make any computer pointing device accessible for users with physical limitations, such as poor motor control or visual impairments. Point Smart works with different computer access hardware such as trackballs, a pen mouse, and other AT devices, including augmentative alternative communication (AAC). Its accessible features enable the user to navigate the pointer over the computer screen with minimal touch, or exertion, on the mouse hardware. It makes it easy to control the direction and speed of the mouse cursor and its positioning on the target.

Point Smart was conceptualized by a graduate student at the RERC on Wheeled Mobility at the University at Pittsburgh. The T²RERC

collaborated with him for its manufacturing and launching into the marketplace, with permission from the University at Pittsburgh Technology Transfer Office, the intellectual owners of the design and prototype. After review by Info Grip, a manufacturer and distributor of software products, the prototype interfaces were redesigned and its use was extended to include Windows® 95, 98, 2000, and XP operating systems, before it was released into the market. The T²RERC advised on the development of the product and shared in the development costs. It facilitated the design, development, and commercialization less actively than it did in the case of Lids-Off™. However, Info Grip was receptive of all the T²RERC's recommendations. The prototype was quite advanced and beyond the design (Box A in Figure 1) stage, making it too late for primary and secondary market research information, or for systematic formative evaluation. Unfortunately therefore, the product was brought to market without formal and systematic consumer involvement. Aside from T²RERC's monetary support for making the product compatible with newer operating systems, all T²RERC's evaluative support was informal. Practical constraints further caused the product to be launched to market before all technical limitations could be resolved. Also, as with Lids Off™, formal summative evaluation and follow-up evaluation were not provided by the T²RERC.

Kelvin, Voice-Interactive Thermostat by Action Talking Products

Kelvin is a voice-interactive, fully programmable thermostat designed for visually impaired consumers. It is manufactured by Action Talking Products, LLC (2008) for Innotech Systems, Inc. and distributed by Independent Living Aids. Users can operate it by pushing its buttons, all of which talk. Or, once users program the thermostat, it responds to voice commands – to lower or raise the temperature at specific times of day; or to adjust the temperature at set intervals over long periods like weekends or vacations. It can control both heating and cooling.

The T²RERC's intervention into the development and transfer of the Kelvin was similar to its involvement in the case of the Lids-Off™ jar opener. Systematic evaluative support was provided through consumer and market evaluation data for the prototype design and formative evaluation phases. Consumer-desired functions and features were identified through initial consumer focus groups and used in the development phase of Kelvin. However, follow-up focus groups were not conducted until after Kelvin was brought to market. Revision: Although post-developmental evaluation (summative evaluation of final product) was part of the T²RERC intervention, not all key features suggested by consumers were included in Innotech's alterations to Kelvin. The post-commercialized Kelvin, therefore, lacked these features. Another important difference between Lids-Off™ and Kelvin was in the production phase. Both devices were produced overseas, but Black and Decker owned the manufacturing plant and had direct control over its manufacturing protocols, where as Innotech outsourced its operations, tying Kelvin to the quality controls used by the outside manufacturer.

Evaluative Questions

The purpose of the T²RERC efficacy study was to investigate the quality (merit) and value (worth) of the project's transferred products, based on how well they met the needs of end-users with disabilities, the project's ultimate beneficiaries. Two main questions drove the study.

Table 1
Lids-Off™ Study Participant Distribution by Functional Limitation, Age, and Gender

Functional Limitation	*n*	*%*	Age group	*n*	*%*	Gender	*n*	*%*
Paralysis	12	24	25 – 34	3	6	Male	10	20
Weakness	47	94	35 – 44	9	18	Female	40	80
Tightness or Cramping	33	66	45 – 54	12	24			
Tremors	11	22	55 – 64	23	46			
Lack of Control	24	48	65 – 75	3	6			
Absence of Extremity	1	2						
Joint Restriction	33	66						
Swelling	16	32						
Fatigue	41	82						
Pain	37	74						
Total	50		Total	50	100	Total	50	100

1. How do products transferred through T²RERC compare in *quality*, with other products and or methods available to consumers with disabilities at the time of transfer?
2. To what extent do users with disabilities value the products transferred through the T²RERC, compared to alternatives available to them at the time of transfer?

The questions directed the methodology for studying the efficacy of the three products mentioned earlier. We next present and discuss the method and results, case by case. As mentioned earlier, we present findings selectively focused on key indicators of quality and value that were common to all three products under study. We then follow it by discussing contrasts and commonalities. For additional discussion of aspects unique to each study readers are referred to Stone et al. (2009). Findings were also appropriately synthesized and fed back to the respective manufacturers for product improvement.

Case One: The Lids-Off™ Automated Jar Opener

The Lids-Off™ study was the front runner of the efficacy study series. It helped us learn about both the efficacy of Lids-Off™ and the effectiveness of the transfer process. By piloting our proposed methodological framework, it also provided a master plan for the two subsequent studies on Point Smart and on Kelvin, so that iteration of procedures helped improve and consolidate the methodology itself. Contextual adaptations of the methodology are addressed separately under each case.

Method

Procedures

Described below are the procedures followed in the Lids-Off™ study for sampling, data collection, and data analysis.

Sampling. Lids Off targeted consumers with limited hand control. Sampling was purposive. As consumers with disability were the 'experts,' evaluating the device for merit and worth, we sought to maximize, in a limited participant sample, both the variety of functional needs (vis-à-vis jar opening) as well as related consumer experience. Physical impairments with upper extremity limitations and discomfort were included while excluding cognitive limitations that interfered with the ability to judge and report on device performance. The heterogeneity and the relatively small size of the target disability population drove the final sample size. From an initial sample pool of more than 100

qualified individuals, we were able to form a random sample of 50 satisfying all the purposive criteria.

Table 1 shows the distribution of the sample of 50 participants by functional limitation as well as by age and gender. The sample covered a variety of disabilities, such as spinal cord injury and multiple sclerosis, and the majority had arthritis.

As the table shows, weakness, fatigue and pain in hand mainly characterizes this group. There were more female participants than male participants. Participants' ages ranged from 25 to 75. The median age was 55, with 48% younger than 55 and 52% older.

Data collection design. The study was conducted in three distinct phases. Phase I defined indicators of quality and value, which then directed the design of instruments for data collection. Data was collected in Phases 2 and 3, following a quasi-experimental design (Campbell & Stanley, 1963), with participants evaluating the device in two situations through onsite and home trials as described below.

Onsite trials. In a randomized, post-test only design for repeated measures, the participant consumers evaluated the Lids-Off™ against a competing product on given indicators in systematic hands-on trials of both products. The competing product was an under-the-cabinet mountable device we identified as the marketplace competitor at the time the Lids-Off™ was brought to market, which we omit naming. Each user tried the Lids-Off™ and its competitor in a pre- determined, randomized sequence. They performed a standardized set of tasks, opening five different jars of varying sizes and combinations of weights, sizes, jar materials, and lid materials. In order to minimize participant learning from device to device during the trials, we randomly assigned participants to the product testing sequence. Participants gave detailed evaluative feedback on each task, using questionnaires that were provided in accessible formats. Trained observers recorded their performance on separate sheets. Additionally, as participants exited, they were interviewed for comparative evaluation of the test product against its competitor. They were also asked to assess (estimate) the product's (monetary) value and share their purchase intent. Sessions were video recorded to facilitate post-trial measurements of task completion time and other analyses.

Home trials. Participants who tried the device in their homes were asked to give evaluative feedback, comparing it to similar devices and or methods (critical competitors) that they had used or were familiar with. The duration of the trial period was six months. Longitudinal data was collected over the first two months in a series of six weekly measures that consisted of participant ratings and comments on given indicators. Additionally, participants also gave feedback at the beginning (Day 1) and after two months. Changes in participant perceptions of quality were tracked by repeating questions across questionnaires on key indicators. Changes in participants' acceptance of the product and its value were tracked by asking participants to share their purchase intent, first at the onsite interview and again at the interview at the end of two months of home trial. Further, by letting participants voluntarily use the device with no obligation for formal feedback during the remaining months, and by questioning them later, we measured the extent of participants' use or non-use of the product during that period. Finally, at the end of the study, participants were offered the opportunity to purchase the product in exchange for part of the compensation due to them. This opportunity to purchase was a quantifiable measure par excellence for

assessing the real value of the product to the user.

Indicators. Rather than deriving indicators solely based on theory, we identified indicators through actual empirical observations of consumers performing device-related tasks (opening jars). This was done in Phase I. Seven consumers who customarily used a variety of methods to accomplish the jar opening task were interviewed in their homes and were observed and videotaped as they performed the task. The video-recordings were submitted to task analyses by a team of designers and clinicians, who extracted problem statements pointing to indicators. These designer perceptions, together with consumer perceptions, served as criteria when defining final indicators. We tabulated and distributed them in a two-dimensional matrix, with the universal design (UD) guidelines as one dimension and the T^2RERC device evaluation criteria as the other, both discussed earlier. This Indicator Matrix gave us a framework in which to map specific indicators of product quality and value reflecting designer and consumer perspectives. This matrix was refined over the course of the three case studies. As a tool for organizing indicators for efficacy assessment it marks an outcome from the overall experience.

The final set of quality indicators included effectiveness and efficiency measures, usability measures (i.e., ease of use, comfort, operability and learnability), and product-specific measures such as durability. Value indicators addressed the relevance and or benefits to users, including: (a) satisfaction and benefits perceived from actual use, (b) device use or abandonment, (c) purchase intent, and (d) response to purchase opportunity. The indicators, identified thus, generated instruments that guided the next two phases.

Instruments. We distributed the indicators appropriately over instruments for measuring consumer-perceived quality and value both under controlled conditions (onsite trials) and under free and natural conditions at home over an extended period. Besides protocols and scripts for trial-administration, the onsite trial instruments included: (a) two separate questionnaires for consumers to record evaluations of the device and its marketplace competitor, (b) exit interviews with consumers to elicit comparison of the two devices, and (c) two separate questionnaires for observers to record objective assessments of consumer trials of the two devices. Home trial instruments included (a) initial questionnaire on Day 1 to capture consumer's first impressions and learnability data; (b) weekly questionnaires for consumers to record evaluations of the device against other known alternatives; (c) comprehensive consumer questionnaire at the end of two months (EOT); and (d) two telephone interviews, one halfway through the home trial and the other at the end of the study. Purchase intent and value questions were part of all instruments through onsite and home trials, and of the home trial telephone interviews. We followed this up with an actual offer of the device for purchase at the very end of the study, in order to assess product acceptance and how much the consumer really valued the product. Consumers also answered questions about frequency of use and abandonment at this time.

Data analyses. Both descriptive and inferential analytical techniques were used as appropriate. We used percentages for description and supplementary content analyses to interpret narrated consumer comments, purchase intent and use/abandonment data. ANOVA and paired t-tests were performed for statistical inference for comparative analyses between Lids-Off™ and its onsite competitor as well as for weekly trend analyses of home trial data.

As for judgment standards, we found no previous benchmarks for 'acceptable levels of impact,' theoretical or practical. In other words, how good the results on quality and value have to be in order for Lids-Off™ to be considered a 'worthy' transfer? In a sense, Lids-Off™ was selected for our pilot study because it was a best-case scenario; we let the results speak and enlighten us about such a standard – if and how far the product of such a scenario can go to achieve its potential.

Results

We present findings focused on select key variables common among the Lids-Off™ study and the other two cases. Also, we focus on descriptive and qualitative data in order to provide in-depth views of each context and to explain how the three cases differ. Some analyses reported in Stone et al. (2009) are excluded here.

Sample Size and Attrition

The original sample of 50 completed onsite trials of the Lids-Off™ and continued to home trials. Three participants dropped out subsequently leaving a sample population of 47 and a dropout rate of 6% – the lowest of all three studies.

Indicators and the Indicator Matrix: Two Related Outcomes

The indicators of quality and value for evaluating the Lids-Off™ were derived in Phase I by observing consumers as they performed jar opening tasks. Table 2 shows the number of indicators distributed along two dimensions of an Indicator Matrix, with designer and consumer perspective criteria for

Table 2
Indicator Distribution by Designer and Consumer Perspectives in the Lids-Off™ Study

		T²RERC CRITERIA FOR DEVICE EVALUATION*											
		Effectiveness	Durability	Portability	Operability	Maintenance/ Repairability	Comfort	Reliability	Safety	Learnability	Affordability	Other	Total
UNIVERSAL DESIGN PRINCIPLES**	Equitable	18	3		8	3	8	3	3		3	8	57
	Flexible	27		12	27	6	22		3		2		99
	Simple and intuitive				5		1			1			7
	Perceptive information				4								4
	Error tolerant	2			9		4		14		5	1	35
	Low physical effort	8			22		5					1	36
	Appropriate size and space				13	2	1						16
	Total	55	3	12	88	11	41	3	20	1	10	10	254

*Lane et al. (1997)
** The Center for Universal Design (2002)

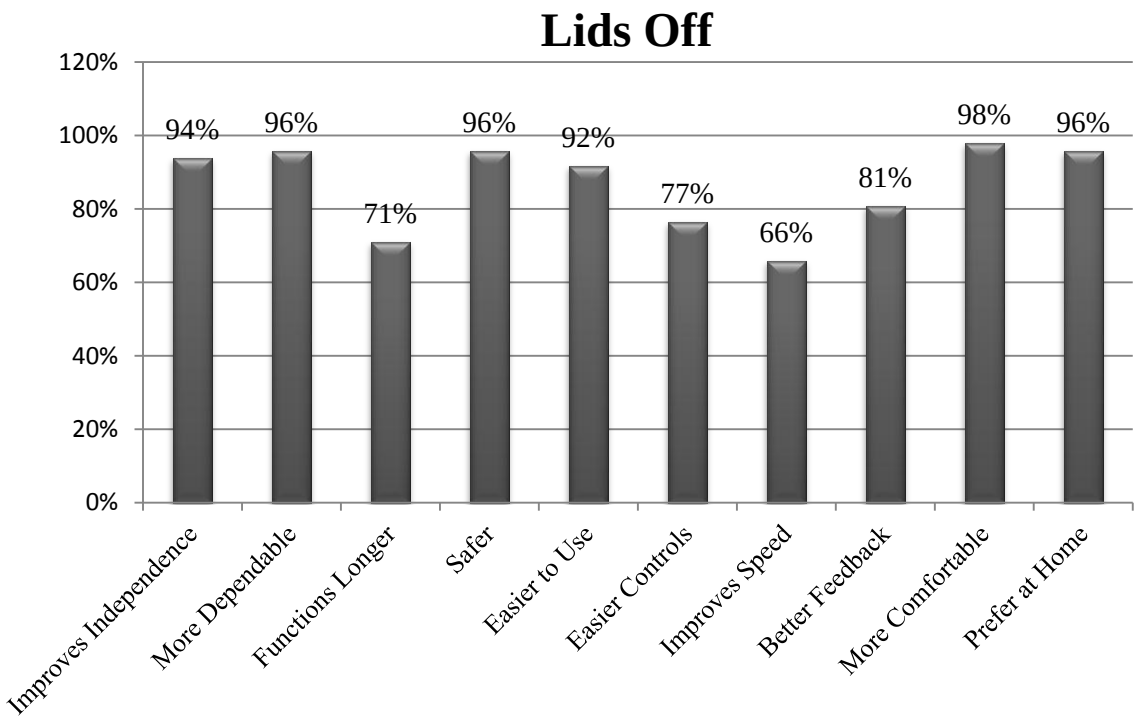

Figure 2. Percentage of participants who preferred Lids-Off™ over its competitor.

the two dimensions. The clustering pattern (distribution) of the indicators across the cells was a rough guide to generating items for instruments and observation protocols for the onsite and home trials with proper weights. For example, effectiveness, operability, and comfort demanded greater weight.

We reiterate that as the front runner of the study series and pilot experience, the Lids-Off™ case was an opportunity to improve and develop the methodological components. The Indicator Matrix in Table 2 developed and refined as a framework for organizing and consolidating efficacy indicators was a useful, although secondary, outcome from the studies; it provided the master template for subsequent studies.

User Assessments of Product Quality

We present below assessments of the product's quality by the participants.

Compared to Marketplace Competitor (Onsite Trials)

As described earlier, participants evaluated Lids-Off™ at the onsite trials against a power-assisted jar opener, mountable under the cabinet. Participants opened five food jars that included a variety of jar and lid types, using each device in the determined sequence. At the exit interview after the trials, participants' comparative evaluations of 'device-versus-competitor' were captured. Figure 2 shows these results on eight key indicators. For each indicator shown on the X-axis, the corresponding column in the figure shows the percentage of participant-users who preferred Lids-Off™ over its competitor.

As the figure shows, the percentages overwhelmingly favor (66%-98%) Lids-Off™ on most indicators. Consumers judged the device superior to the other product in improving functional independence.

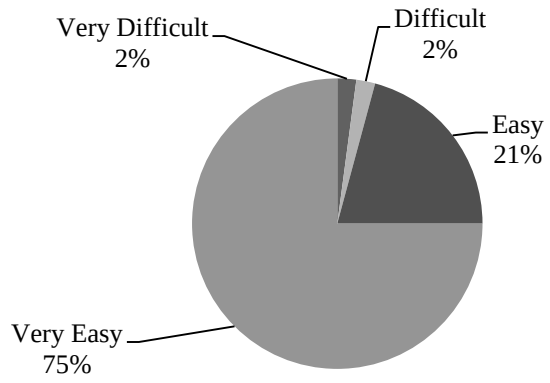

Figure 3. Ease of use of Lids-Off™ operating instructions: User perception on Day 1.

Participants generally deemed it safer, easier, more comfortable to use, and more dependable. Many found it faster and they preferred it for use at home.

Compared to Critical Competitors at Home

The following results include participant assessments over the home-trial period including Day 1 and after two months of use.

On Day 1. Learnability of a product (instructions, setting up) is an important indicator for disability populations challenged for independent operation. We measured this on Day 1 after Lids-Off™ was set up at home. (We point out that participants did have some, but not total, learning from onsite trial). Figure 3 presents user evaluations of its intuitiveness and its learnability through the instructions manual. This simple circle graph shows the percentage distribution of people who rated the manual of operating instructions easy or difficult on a five-point

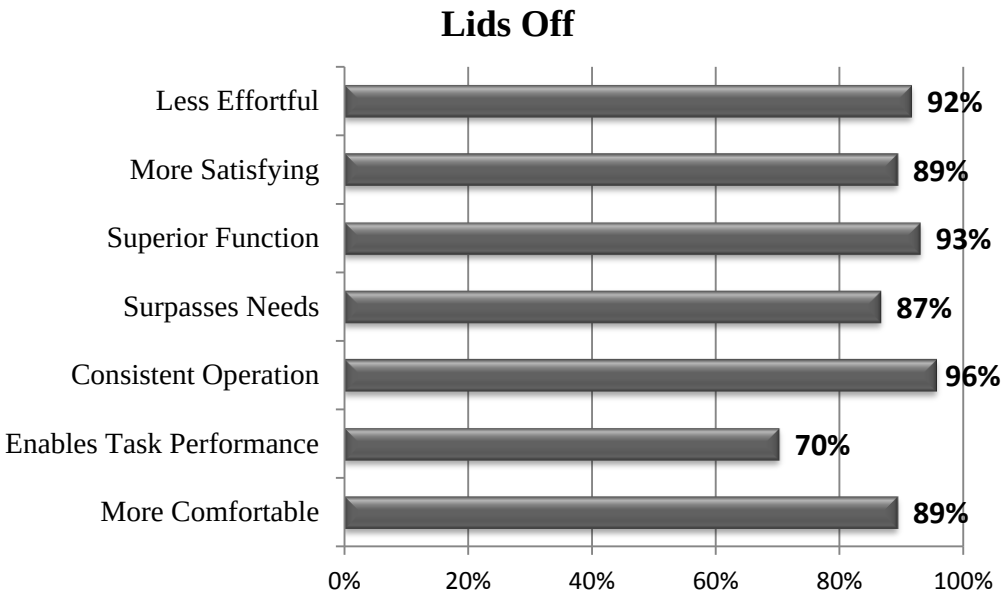

Figure 4. User judgment of Lids-Off™ quality relative to competitors (at two months).

scale. The legend shows the five specific scale points color coded, while the graph shows the corresponding percentage of people who rated Lids-Off™ at levels of easiness from very easy to very difficult.

As we can see, learning to operate Lids-Off™ operation was not very challenging. Learning was considered easy to very easy by 96%, with only 4% considering it difficult or very difficult. We point out that the instructions manual was simplified by its physical design, which was relatively straightforward and intuitive–unlike the other two devices that had complex interfaces to contend with for operation.

After two months of home use. Figure 4 shows user perceptions of Lids-Off™ quality at the end of two months of home trial. For seven selected indicators, it presents the percentage of participants that had 'positive' perceptions, i.e., those who rated at the higher end of the five-point scale (e.g., 4 or 5).

The figure shows positive ratings to be consistently high, ranging from 70% to 96% across all indicators. Participants showed a clear liking for Lids-Off™ over other alternatives they had used or known. They found it consistent in operation, functionally superior, less effortful, more comfortable and more satisfying. As many as 87% of the participants acknowledged that it surpassed their needs.

Over the home-trial period. Figure 5 compares user perceptions between the beginning (Day1) and after two months of home trials on three key indicators. These are 'independent use' (user can operate device without assistance), 'ease of use' of the device, and 'device for me' (device fits user needs). When measured as before-and-after changes in user perceptions over the seven-week trial period, they measure impact of the devices on users' functional capabilities. Perceptions are presented in the graph as percentages of positive ratings, i.e., 4 or 5 on the five- point rating scale. The X-axis shows the three indicators, with paired columns of percentages of positive ratings for each indicator, one for Day 1 and the other after two months of use.

Figure 5 shows overwhelmingly high percentages (84% to 98%) in terms of user perception of quality of Lids-Off™, and consistently so from beginning to end. The apparently small increase or change is explained by higher beginning levels. The highest change (9%) was in accepting the device as 'a fit to their needs.' Figure 6 corroborates the above results, through the

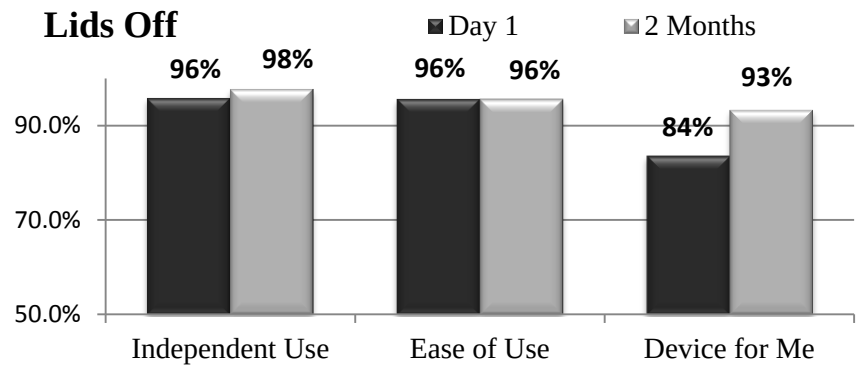

Figure 5. Change in user perception of Lids-Off™ quality over two months.

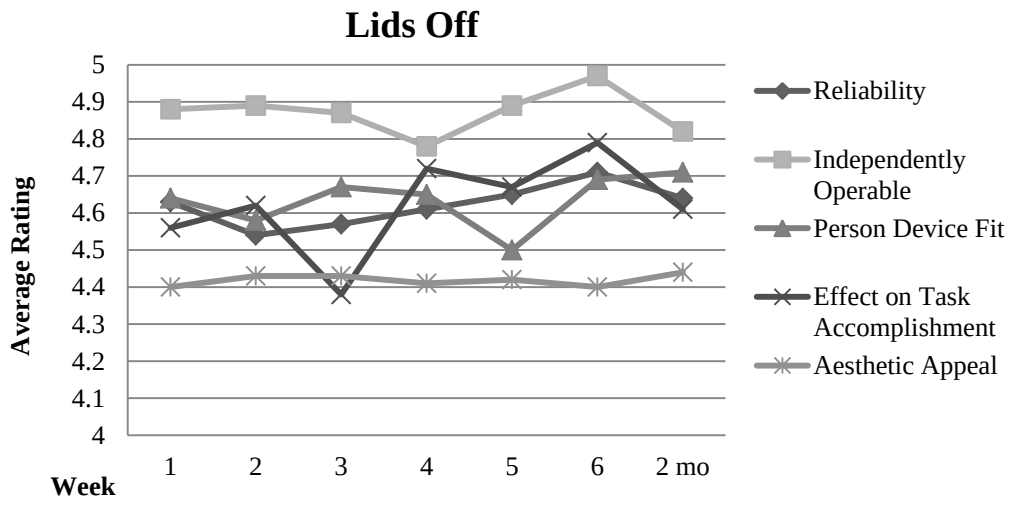

Figure 6. User perception of Lids-Off™'s quality over home trial: Weekly trend.

weekly trend of user perceptions of quality over the home trial period. The graphs in the figure trace the mean ratings on five important indicators – reliability, independent operability, person-device fit, task accomplishment, and aesthetic appeal. Ratings on Lids-Off™ were generally high (4.5 to 5.0) from beginning to end, with slight increases on all indicators.

Product Value to User: Acceptance, Use and Purchase

The foregoing section reported Lids Off™ as a success in terms of user satisfaction relative to its merit. To what extent did they consider it relevant to their needs? What was the level of acceptance of the product for own use? How much did they value it as a result of their experience?

Product Acceptance

Product acceptance was high for Lids-Off™. Only three participants dropped out of the study during the home trials, and they did so for reasons unrelated to device usability or value. Additionally, participant comments at the end of two months of home use (see Table 3) point to satisfaction with features that are key to usability (reliability, ease of use) and their dissatisfaction is limited to storage and accommodation (size and cord length)

Table 3
Participant Perceptions of Device Usability: After Two Months of Home Use

Feature most liked by participants	*n*
Ease of use	24
Portability	5
Aesthetic appeal	5
Reliability	10
Features least liked by participants	***n***
Incompatible with working/storing environment; is too big for narrow counter spaces;	7
cord is too short for plugged-in storage on counter spaces	3

Table 4
Use and Abandonment of Lids-Off™ by Study Participants

Frequency of use	*n*	%
Every Time	23	49
Most of the Time	13	28
Some of the Time	7	15
Rarely	2	4
Very Rarely	2	4
Never	NA	NA
Total- end of home trial	47	100
Drop outs/Missing	3	6

concerns.

To explain their preferences, participants added comments such as: "Lightweight, easy to move," "Worked every time," and "Attractive machine." On the other hand, participant comments related to features least liked included: "Electrical cord too short. Limits area where it can be used," "Short cord. A bit cumbersome," and "It's too big; takes up too much space. I can't keep it plugged in at all times because it's too big for my counter," "Its large size. Cord does not plug into Lids-Off™ itself."

Product Use

The use and abandonment data from Table 4 below attest to the acceptance of Lids-Off™ by its users, and corroborate the foregoing results. During the latter four months of home trial period when participants had no obligation to give feedback to the study, they continued to use the device as shown in this table. Only 8% (four people) used it rarely, and no one said 'never.' The reasons mentioned for rare use included: (a) "Did not work well for me;" (b) inconvenience with cord; (c) disability status fluctuation; (d) getting help in opening jars; (e) "small kitchen; hard to move device around;" and (f) "I really don't know."

Product Purchase

As mentioned earlier, the purchase

Table 5
Purchase Intent vs. Purchase Decision by Participants in Lids-Off™ Study

Situation	Question	Would buy the product		Total
		n	***%***	
Onsite Trial Exit Interview	*Which one would you buy? – Product or its Competitor?*	46	92	50
Mid-Home Trial (2 months)	*Likely to trade part of study compensation to buy product?*	35	70	50
Mid-Home Trial (2 months)	*Would you buy your original device again?*	29	58	50
End of Study (6 months)	Actual Decision to Buy	37	79	47

opportunity we posed to consumers at the very end of the study as part of the compensation due to them was intended to assess the value of the product to the user. We fixed the purchase price at half its market value, a fair price for a 'used' device. Table 5 tracks participants' purchase trend over the course of the study – from intent to actual decision.

As shown in Table 5, 50 people started the Lids-Off™ study, 47 completed it, of whom 37 chose to purchase the product, giving up part ($15-half the retail price) of the total compensation ($200) due to them. The Lids-Off™ seems to have offered 'value' to nearly 80% of users that completed the study.

Case Two: The Point Smart Mouse Driver Software

Method

Procedures

The procedures described under the Lids-Off™ study guided the study of efficacy of the Point Smart software as well. Within the intended uniformity however, contextual adaptations of procedures introduced some variations as described below.

Sampling

Point Smart was aimed at consumers with limited hand control and/or low vision. As with Lids-Off™, sampling was purposive. The priority was to maximize consumer experience and to assemble a sample population with a variety of functional needs that demanded the use of a better mouse for navigating the computer screen. The target disability population was more heterogeneous and smaller. The final sample size was 32. Disabilities ranged from arthritis to diabetes to spinal cord injury; one individual had an added difficulty of having no voice. Table 6 shows the sample distribution by functional limitation, as well as by age and gender.

As can be seen, twice as many participants had motor difficulties as had visual problems. Participants' limitations required them to use mouseware accessories to access the Point Smart software on the computer, therefore requiring complex hardware interfaces as well. Eighteen individuals used a standard mouse; others used a trackball (*n*=9), touchpad (*n*=2), joy stick (*n*=1), pen mouse (*n*=1) and Dynabeam/Dynavox (*n*=1). The logistics of enabling complex hardware interfaces were therefore unique to the Point Smart study. There were more female participants than male participants in the sample. The age range was 18-70 and median age 49.

Data Collection Design

Following the design for Lids-Off™, data was collected in Phases 2 and 3, after identifying indicators and building instruments in Phase 1. The basic quasi-experimental design was

Table 6
Point Smart Study Sample Distribution by Functional Limitation, Age, and Gender

Functional Limitation	*n*	%	Age Group	*n*	%	Gender	*n*	%
Hand control	26	81	18 – 24	5	16	Male	13	41
Visual difficulties	15	47	25 – 34	3	9	Female	19	59
			35 – 44	5	16			
			45 – 54	7	22			
			55 – 70	12	37			
Total	32		Total	32	100	Total	32	100

followed with slight modifications.

Onsite trials. One variation in design was dispensing with random assignment of participants to the product testing sequence, which did not make sense in the case of Point Smart. All participants came with prior knowledge of Microsoft®'s mouse software, which made it the competing software by default. There was new learning on the Point Smart software but not on the Microsoft® mouse software. All participants thus tried the Microsoft® software first and then the Point Smart. We planned an additional measurement of participant performance with the Point Smart at the end of the home trial. Assuming possible learning only on the Point Smart, we took the difference between first (Microsoft®) and third (Point Smart) performances as a measure of comparative efficacy, while the difference between the second and the third (both Point Smart) gave us an absolute measure of efficacy based on pre-post gains. Another variation was the use of an additional instrument for the measurements. The Compass Assessment Software designed by Koester Performance Research (2002), a software program that was also brought to market by Info Grip, measures eight point-and-click skills of computer interaction necessary for tasks such as text composition, web navigation and electronic communication, and configuring and customizing tests for the user. Its speed and accuracy data gave us the needed time-per-task data, which dispensed the need for video recording of the onsite trials. A third variation regarded the set-up of onsite trial sessions. Several logistical provisions became necessary in order to accommodate different disability groups with motor and sensory (visual and communication) impairments. Participants came with their own accessible mouse hardware (foot-operated, pen mouse, head mouse, augmentative communication devices, and others). Computer settings had to be customized for onsite clinical trials and also pre-determined and prescribed for later home trials. A clinician expert worked with us at these trials to configure support systems and assist observing researchers. All the same, as with Lids-Off™, participants: (a) performed the same standard tasks–web browsing, emailing, and simple word processing–using each software program; (b) participants gave feedback on questionnaires and on exit interviews; and meanwhile (c) observers recorded their performances as well.

Home trials. As in the case of Lids-Off™, participants performed tasks of their choice using Point Smart and gave weekly feedback on questionnaires on their use of the software. They also gave feedback on Day 1 and at two months. Quality and Value questions were repeated across questionnaires and interviews. Unlike the Lids-Off™ case however, Phase 3 lasted only four months, given the tedious nature of the tasks and participants' energy levels. Monitoring and tracking logistics was complex. Interacting with the Point Smart software through special mouse accessories at home required special support systems and equipment. Computer platform and system compatibility was a concern, and occasional technical assistance by Info Grip became necessary. Compatibility with computer hardware (for example, a laptop) and assistive/adaptive mouse hardware such as foot operated mouse, and others was also an issue.

Indicators and instruments. Procedures were the same as with Lids-Off™. In Phase One, six persons with disability were interviewed at home for extraction of indicators. Onsite trials and over-the-home trials followed the same design as for Lids-Off™, with corresponding consumer questionnaires, observer questionnaires, and interviews. Participants also had the opportunity to purchase the software at the end, in exchange

for part of the monetary compensation due to them.

Data analyses. Both descriptive and inferential techniques were used. Additionally, individual by individual analyses were initiated and are underway (Stone et al., 2009), not reported in this article.

As we had no previous benchmarks for measuring 'acceptable levels of impact,' we were guided by the results of our pilot study on Lids-Off™ in interpreting from the results whether Point Smart was a 'worthy' transfer. In a sense, Lids-Off™ set the practical standard as to the heights to which a transfer can reach in achieving quality and value for the consumer.

Results

We reiterate that findings are focused on select key variables that the Point Smart study has in common with the other two cases. Additionally, we will focus on descriptive and qualitative data in order to capture context-specific information that can explain its differences from the other two cases.

Sample Size and Attrition

Of the 32 participants who initiated the study as per the previous table, only 25 completed the home trials. This is a drop-out of 72%, which is more than the attrition in the Lids-Off™ study. Several withdrawals were due to incompatible computer hardware. We next present findings on participant assessment of the quality of the Point Smart based on onsite trials and home use.

User Assessments of Product Quality

We present below assessments of Point Smart's quality by the participants.

Compared to Marketplace Competitor (Onsite Trials)

As mentioned earlier, participants compared Point Smart with the Microsoft® mouse software at onsite trials, performing the given set of standardized tasks. The exit interview after the trials captured the participants' comparative evaluations of Point Smart vis-a-vis Microsoft® software. Figure 7 shows these results on the same eight key indicators selected for Lids-Off™ reporting. The indicators are shown on the X axis, and the corresponding columns show the percentage

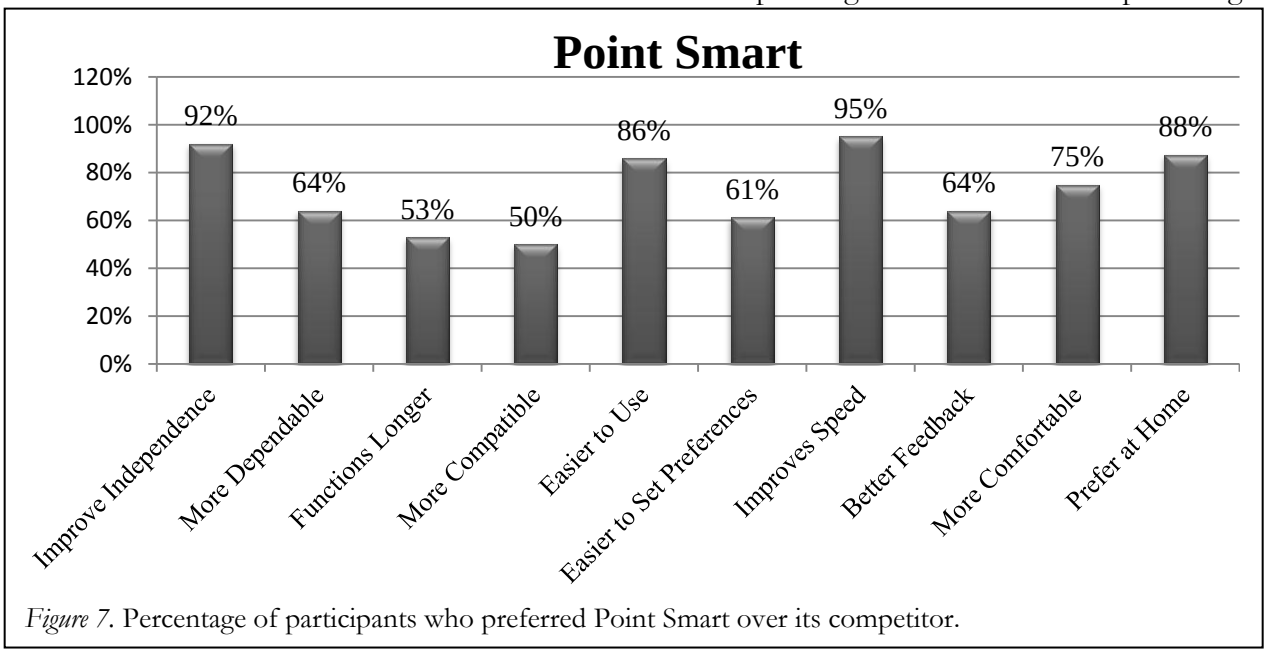

Figure 7. Percentage of participants who preferred Point Smart over its competitor.

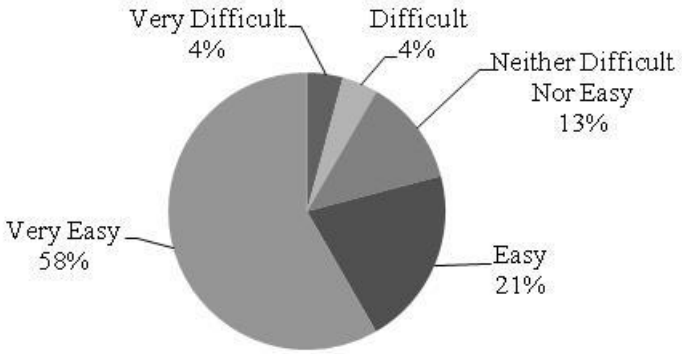

Figure 8. Ease of use of Point Smart's operating instructions: User perceptions on Day 1.

of participant users who preferred the Point Smart over its competitor.

Figure 7 shows that over half (50%–95%) of the participants preferred the Point Smart over its competitor on these indicators, a positive result in favor of Point Smart. A major proportion (95%) rated Point Smart superior to its competitor Microsoft on speed improvement. This is a meaningful finding for the Point Smart user population, considering their need of for multiple accessory interfaces for functional independence, which potentially inhibit speed.

Compared to Critical Competitors at Home

The following results include participant assessments over the home-trial period,

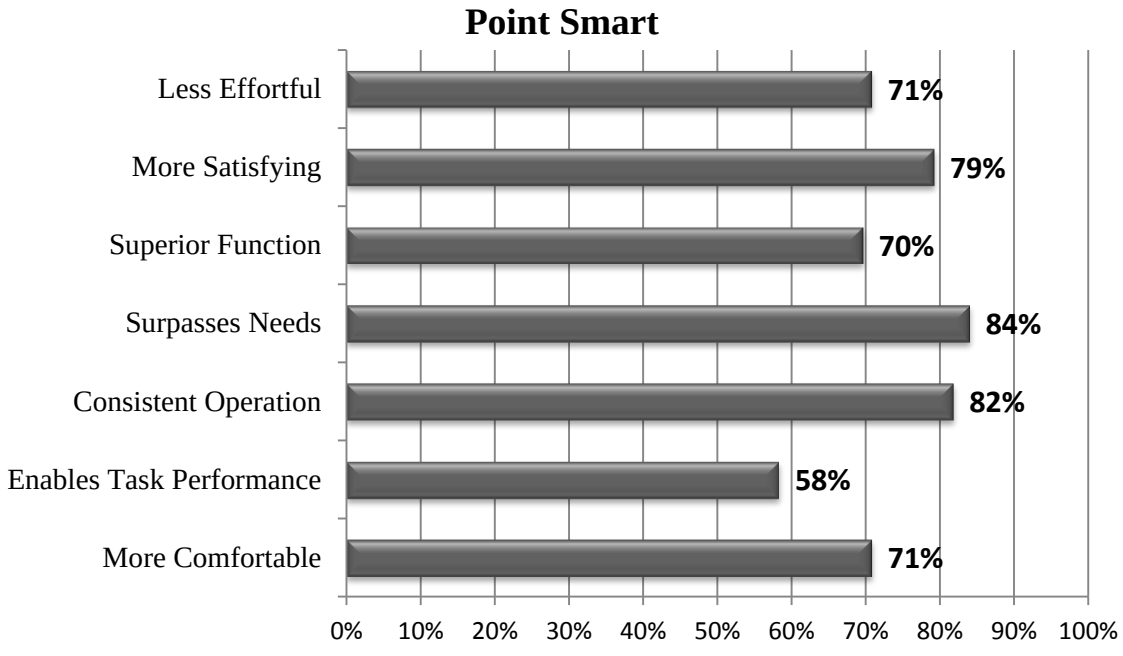

Figure 9. Point Smart's quality relative to alternatives: User assessment at two months.

including Day 1 and after two months of use.

On Day 1. Figure 8 captures Point Smart's learnability and intuitiveness soon after it was set up at home. The circle graph shows participants' evaluations of the operating instructions manual on ease of use, distributing percentages of people who rated the manual easy or difficult on a five-point scale. The legend shows color codes for the five specific points of the scale, while the graph shows the corresponding percentage of ratings at levels of easiness from 'very easy' to 'very difficult.'

More than three-quarters of the sample (79%) considered the Point Smart 'easy' to learn. On the other hand, 8% found it difficult to very difficult. These results are not surprising, considering that Info Grip provided a standard manual of instructions, downloadable from its website, for use by all of its customers. Ironically, this defeated the purpose for those users who could not navigate computer screens for downloading tasks, for which they were seeking Point Smart in the first place. Stabilizing the mouse cursor on the screen was a challenge for this population, and basic tasks like placing it on a desired icon, or a word or a letter needed help. Alternative (print or other) versions would have been more appropriate.

After two months of home use. Figure 9 shows user assessments of Point Smart's quality at the end of two months of home trial. For the seven indicators, it presents the percentage of positive perceptions, i.e., ratings at the higher end of the five point rating scale (e.g., 4 or 5).

Figure 9 shows moderate ratings ranging from 58% to 84% on the indicators presented. Notably, Point Smart earned the satisfaction of as many as 84% of its target sample who acknowledged it as 'surpassing their needs.' Interestingly though, less than 50% were willing to buy the Point Smart at this point. In open comments, many reported frustration with unresolved technical problems, inconsistent performance, and hardware compatibility issues.

Over the home trial period. Figure 10 compares user assessments of Point Smart between the beginning (Day 1) and after two months of home trials, on three key indicators– 'independent use' (i.e., user can operate device without assistance), 'ease of use' of the device, and 'device for me' (device fits user needs). Viewed as before-and-after changes in user

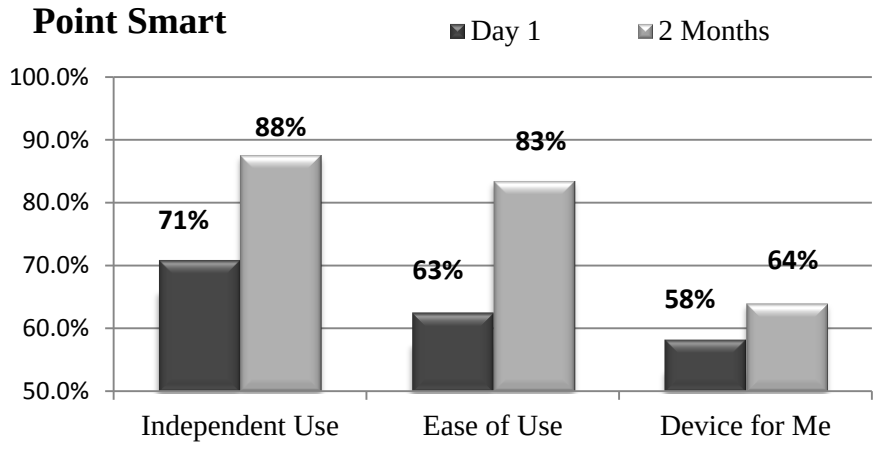

Figure 10. Change in user perception of Point Smart's quality over two months.

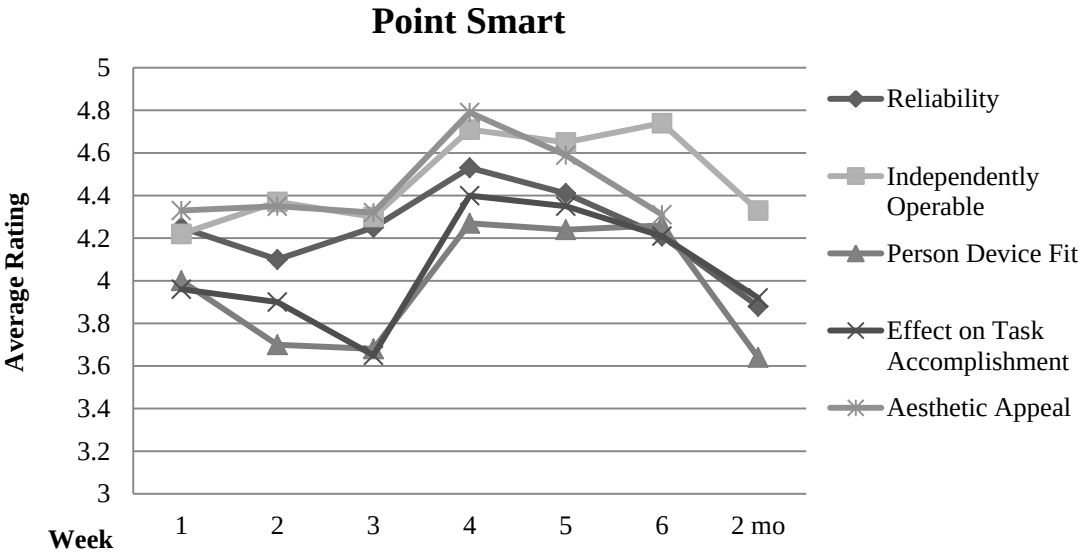

Figure 11. Participant perception of Point Smart's quality over home trial: Weekly trend.

perceptions over the seven-week trial period, they measured device impact on users' functional capabilities. Percentages presented in the graph are of positive ratings, i.e., 4 or 5 on the five-point rating scale. The X axis shows the three indicators, with paired columns of percentages of positive ratings for each indicator, one for Day 1 and the other after 2 months of use.

As shown in Figure 10, ratings were not too low on Day 1 (58%-71 %) and they increased on all three counts. Gains were 20% (from 63 to 83%) on 'ease of use' and 17% (from 71 to 88%) on 'independent use.' Note however, that only 64% elected to characterize it as a 'device for me' in the end, with only an 8% change during the trial period. Point Smart did not reach a high level of acceptance by users after two months of home use.

Figure 11 shows the weekly trend of user perceptions of quality over the home trial period and corroborates the above results. The graphs trace mean ratings on five important indicators–reliability, independent operability, person-device fit, task accomplishment, and aesthetic appeal. Ratings started out high (4.0 to 4.5) on all indicators. Most showed an initial increase but declined after Week 4. Note in particular the oscillating ratings on person-device fit, which dropped to 3.5 in the end, while ratings were relatively higher on independent operability.

Product Value to User: Acceptance, Use, and Purchase

The following results address participants' acceptance, use, and purchase of Point Smart.

Product Acceptance

Dropouts and the reasons for them fairly indicate a product's acceptance during home trial. Seven out of the 32 initial participants (22%) dropped out of the Point Smart study during the home trials. The reasons were partly related to hardware interface issues and partly to do with their dissatisfaction with Point Smart's usability. On one hand, it was incompatible with some computer platforms or mouse hardware (touch pad, pen mouse). On the other hand, features that made it uniquely accessible–such as 'button gravity'

and 'automatic direction control'–did not always work reliably.

Participant perceptions of Point Smart's usability in responses to the end-of-two-months questionnaire corroborate foregoing difficulties and disappointments. On one hand they pointed out three features that they liked most: wrap-around (n=12); large, bright pointer (n=8); and drag-and-drop (n= 4). Participants' comments that attest to these preferences included: "Wrap around, animated pointer and gravity;" "wrap around function and the intelligent cursor positioning;" and "the larger pointer and the bright green color of the pointer."

On the other hand, participants pointed out five features that they liked the least: the gravity feature (*n*=3); the wrap-around feature (*n*=3); the automatic direction control and enable button gravity feature (*n*=1); automatic cursor positioning (*n*=1); and increased crashes (comment that occurred frequently throughout the questionnaire). Comments that attest to these perceptions included: "Crashing software, not letting me use the tablet and trackball at the same time;" "Automatic direction control and enable button gravity function;"and "Automatic cursor positioning and speed control."

Although the foregoing issues do not explain cases of earlier dropouts, they shed light on general problems and probable sources of dissatisfaction with the device. Point Smart's acceptance level was not overwhelmingly high. Consistency of operation was an issue, and there was discrepancy between promise and delivery of features advertised; showed it did not reach its potential and made it less acceptable than expected.

Product Use

The foregoing explains the data presented in Table 7 on use and abandonment of Point Smart.

These data points relate to voluntary use in the last phase of home trials, when participants had no obligation to give feedback to the study. About 73% continued to use the device every time or most of the time. About 14% used it rarely or 'never.' Comments related to rare use included: "Wasn't working;" "Not sure why it wasn't working." Considering the reported difficulties, these results are not surprising.

Product Purchase

The purchase opportunity posed to consumers at the end of the study asked them to exchange part of the compensation ($50 out of $150) due to them. Table 8 presents

Table 7
Use and Abandonment of Point Smart by Study Participants

Frequency of Use	*n*	%
Every Time	11	50
Most of the Time	5	23
Some of the Time	3	14
Rarely	NA	NA
Very Rarely	1	5
Never	2	9
Total- end of home trial	22	100
Drop outs/Missing	10	31

Table 8
Purchase Intent vs. Purchase Decision by Participants in the Point Smart Study

Situation	Question	Would buy the product		Total
		n	***%***	
Onsite Trial Exit Interview	*Which one would you buy? – Product or its Competitor?*	23	72	32
Mid-Home Trial (2 months)	*Likely to trade part of study compensation to buy product?*	12	48	25
Mid-Home Trial (2 months)	*Would you buy your original device again?*	11	44	25
End of Study (6 months)	Actual Decision to Buy	7	28	25

the number participants who considered the product to be of value or relevance to them; it shows the trend of purchase intent over the course of the study and their actual decisions of whether to purchase at the end.

As shown in Table 8, 32 people started the Point Smart study. Purchase intent dropped from 72% to 48% (nearly half) by midway through the home trial. While 25 people completed the study, only seven of them chose to purchase the product in the end. This represents acknowledgement of real value only by 28% of users that completed the study, or 22% of the entire sample.

Case Three: The Kelvin Interactive Thermostat

Method

Procedures

The Kelvin efficacy study followed essentially the same procedures described under the Lids-Off™ except for contextual adaptations that were made as in the case of the Point Smart.

Sampling

Kelvin study participants were visually impaired and included individuals with low vision (legally blind) and those who were totally blind. Table 9 below shows the sample distribution by functional limitation, as well as by age and gender. Sampling was purposive, with the priority placed on maximizing consumer experience and the variety of functional needs that demanded the use of non-visual sensory interaction for accessibility. The sample size was 48 and included legally and totally blind individuals who reported that they were in charge of operating thermostats in their residence. There were more female participants than male participants. The age range was 25-86 and the median age was 58. The mix of younger and older persons around the median age was fairly even.

Data Collection Design

Data was collected in Phases 2 and 3 following the basic procedure, after identifying indicators and building instruments in Phase 1. The basic quasi-experimental design was followed and modifications were minimal.

Table 9
Kelvin Study Sample Distribution by Functional Limitation, Age, and Gender

Functional Limitation	*n*	%	Age Group	*n*	%	Gender	*n*	%
Low Vision / Legally		58			4			35
Blind	28		25 – 34	2		Male	17	
Totally Blind	20	42	35 – 44	4	8	Female	31	65
			45 – 54	14	29			
			55 – 64	12	25			
			65 – 74	9	19			
			75 – 86	7	15			
Total	48	100	Total	48	100		48	100

Onsite trials. A talking thermostat with functionality and features similar to Kelvin was the marketplace competitor selected for onsite performance comparisons. Targeted to blind users, it was designed to talk to users although it could not receive their voice input as Kelvin did. Onsite trial participants performed five specific tasks using each thermostat's command functions/features: reading room temperature, changing the temperature setting, setting the time, setting the day, and programming the device for weekday and weekend temperatures. Participants were randomly assigned to the product testing sequence. They gave feedback on questionnaires as well as through the exit interview. Observers recorded their performance as well. Video recording was not necessary for the Kelvin study since time was recorded through direct observation using stopwatches. The trial logistics had their own complexities due to each individual's need to 'understand' if not totally 'learn' the programming feature of each thermostat before performing the tasks.

Home trials. The home trial lasted six months. Participants used the Kelvin thermostat either for air conditioning or heating, depending on the time of the year each started the use. Participants performed the needed tasks of their choice using Kelvin, completed weekly feedback questionnaires on their use of the software. They also gave feedback on Day 1 and at two months. Quality and value questions were repeated across questionnaires and interviews. Monitoring and tracking logistics was complex. The Kelvin thermostat needed installation expertise assisting the consumers as home furnaces and circuitry needs varied. Skilled external technical assistance became necessary, introducing delays in individual home trial start dates.

Indicators and instruments. Six persons with disabilities were interviewed at home in Phase One for extraction of indicators. Onsite trials and home trials used consumer questionnaires, observer questionnaires, as well as interviews generated by these indicators and structured after the other two studies. Participants also had the opportunity to purchase the thermostat at the end in exchange for part of the compensation due to them for participating in the study.

Data Analyses

Both descriptive and inferential techniques were used. In the absence of previous benchmarks for 'acceptable levels of impact,' we were again guided by the results of our pilot study on Lids-Off™ in order to judge whether Kelvin was a 'worthy' transfer or not. For our purposes, Lids-Off™ had set the practical standard as to the heights to which a transfer can go in achieving quality and value for the consumer.

Results

As with the preceding cases, this section will address the select key variables common to the three cases. Also, we will focus on descriptive and qualitative data in order to capture context specific information that can explain differences among the three cases.

Sample Size and Attrition

Though participants had interface issues with the use of Kelvin, these did not ensue from participant use of accessories, but rather from device incompatibility with users' furnaces. Of the 48 participants who initiated the study (see Table 9), only 25 completed home trials. This represents a 48% drop out, which is almost half the initial sample, representing the highest attrition of all three studies. Interestingly, 11 of the 48 who finished the clinical trials did not even start the home trials, for various reasons (installation not authorized by residential management, previous knowledge of device, incompatible furnaces such as electric or wood burning, and personal reason). Of the 37 who started the home trials, technical quality and usability reasons lost 12 people within two months. In all, 25 people completed home trial.

User Assessments of Product Quality

The following sections present assessments of Kelvin's quality by the participants.

Compared to Marketplace Competitor (Onsite Trials)

We recall that participants gave comparative evaluations of device-versus- competitor at the exit interview of the onsite trials. Figure 12 shows these results for Kelvin using the eight reference indicators earlier presented with the other two studies.

The columns in Figure 12 show the percentage of participants who judged Kelvin superior to its competitor on the corresponding indicators along the X-axis. Kelvin fared rather poorly on all indicators,

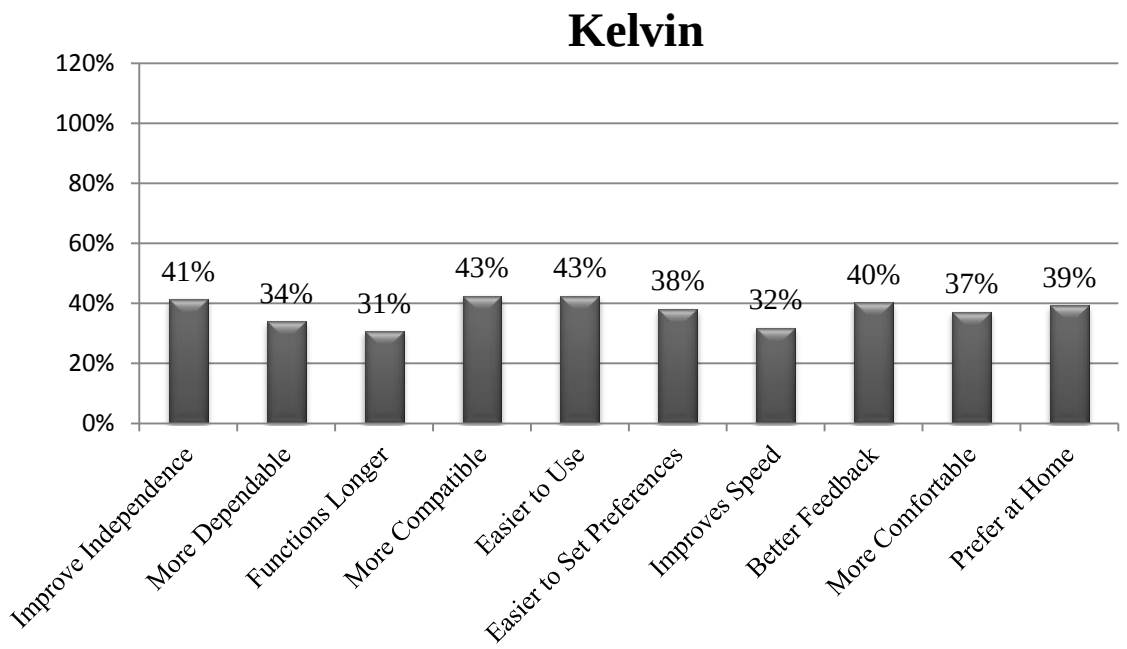

Figure 12. Percentage of participants who preferred Kelvin over its competitor.

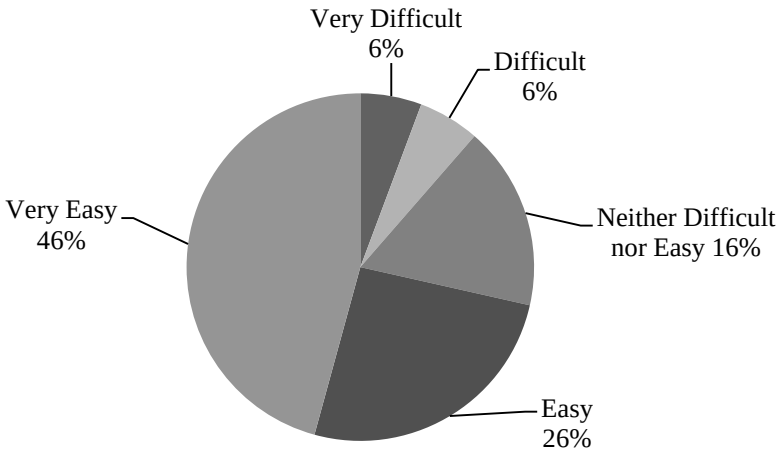

Figure 13. Ease of use of Kelvin's operating instructions: User perception on Day 1.

with less than 50% of the participants (32%-43%) acknowledging it to be superior to the other product on any indicator.

Compared to Critical Competitors at Home

The following results include participant assessments over the home-trial period including Day 1 and after two months of use.

On Day 1. Participants received audio manuals (on cassettes and CDs) as part of Kelvin's installation for trials at home. Considering the importance of Kelvin's programmable feature to blind users living alone, learnability of these manuals was critical to its use, which we measured on Day 1 after the installation. Figure 13 presents user evaluations of Kelvin's intuitiveness and learnability based on the instruction manuals. This simple circle graph shows the percentage distribution of people who rated the manual of operating instructions easy or difficult on a five-point scale. The legend shows the five specific scale points color coded, while the graph shows the corresponding percentage of people who rated Kelvin at levels from 'very easy' to 'very difficult.'

As we can see, Kelvin was considered easy to very easy to learn by 72%. However, as much as 12% of participants considered it 'difficult' or 'very difficult.' Participant comments did not speak highly to its learnability, and pointed to the instructions being difficult to learn from. This is not surprising because Kelvin's target users were persons with blindness that greatly depended on non-visual manuals. Kelvin came with standard print versions, and made CD and audio instructions available only upon request. Large print manuals and Braille versions preferred by some were not an option (later supplied by the study at request).

After two months of home use. Figure 14 shows user perceptions of Kelvin's quality at the end of two months of home trial. For the seven selected indicators, it presents the percentage of positive perceptions by participants, i.e., participant ratings at the higher end of the five-point rating scale (e.g., 4 or 5).

Figure 14 shows moderately positive ratings for Kelvin (59%-77%) in relation to alternative devices they had known and used. In particular, 77% judged it consistent in operation, 70% found it 'enabled task performance' and 73% found it 'functionally

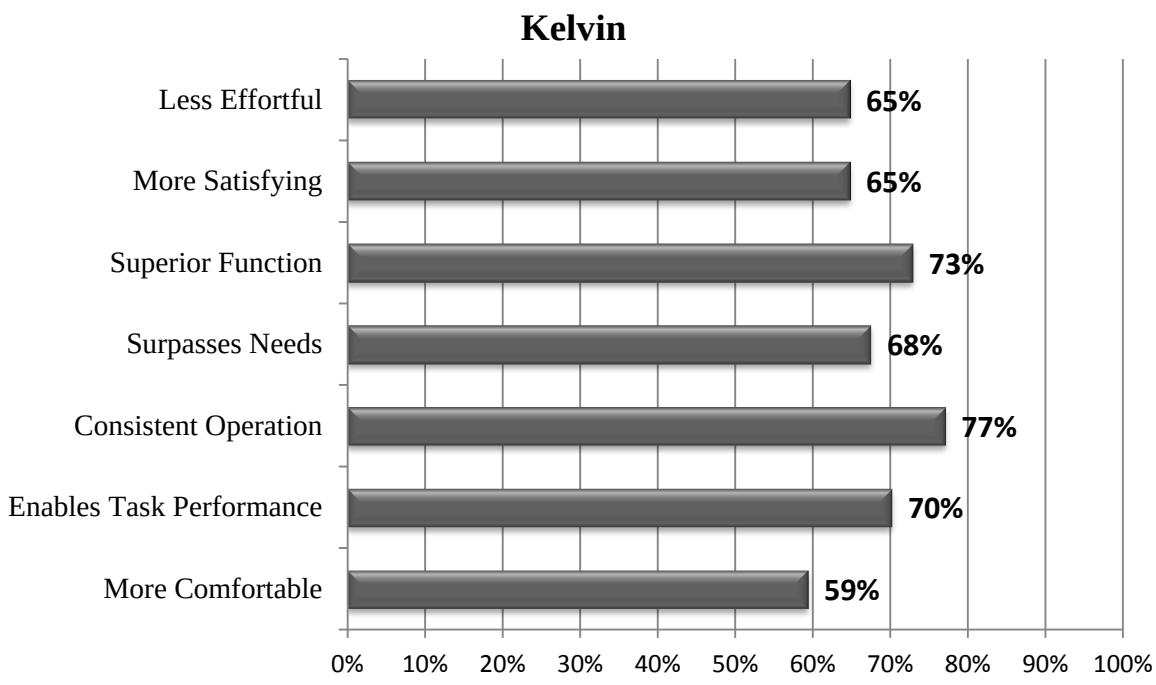

Figure 14. User perception of Kelvin's quality relative to competitors (at two months).

superior.' This is an intriguing finding in light of lower ratings on other counts, considering that these are blind users. One thing that uniquely distinguishes the Kelvin from equivalent devices in the market is its voice input recognition feature.

Over the home trial period. Figure 15 compares user perceptions between the beginning (Day 1) and the end of two months of home trials on three key indicators: 'independent use' (user can operate device without assistance), 'ease of use' of the device, and 'device for me' (device fits user needs). These are before-and-after changes in user perceptions over the seven-week trial period and a measure of Kelvin's impact on users' functional capabilities. Perceptions are presented in the graph as percentages of positive ratings, i.e., scores of 4 or 5 on the five-point rating scale. The X-axis shows the three indicators, with paired columns of percentages of positive ratings for each indicator, one for Day 1 and the other after two months of use.

Figure 15 shows mixed results for Kelvin. Ratings started out reasonably high on all three indicators (70%-80%). On Day 1, 78% recognized its potential to impact their independent functioning, with 9% more joining them at the end. However, the number of people who thought it was easy to use actually decreased during the period (from 80% to 70%). Also, there was no difference regarding it being a good fit (device for me) before and after the period (70% both times). In light of the high percentage (89%) that found it enabled independent use it is not surprising that as many as 70% continued to accept the device as a fit, despite declining perception in its ease of use.

Figure 16 summarizes the weekly trend of participant ratings on the five key indicators common to the three studies. Ratings were moderately high from beginning to end ranging between 4.0 and 4.5. They did drop slightly on all indicators towards the end, while the decreasing trend on person-device fit reversed itself by the end. This

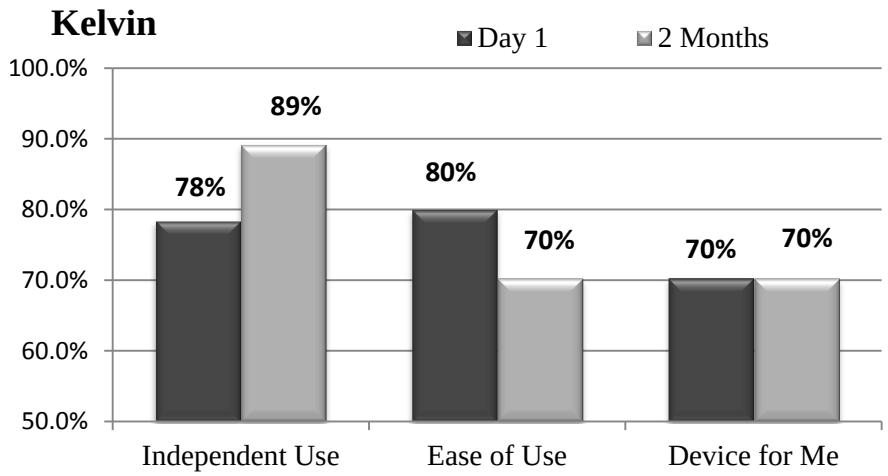

Figure 15. Change of user perception of Kelvin's quality over two months of home trial.

corroborates findings from the previous section.

Product Value to User: Acceptance, Use and Purchase

The following results address the participants' acceptance, use, and purchase of the Kelvin thermostat.

Product Acceptance

The foregoing section reported mixed findings relative to Kelvin's success in terms of user satisfaction. On one hand, as many as 23 people (48%) dropped out of the home trials, but on the other hand, early drop outs (n=11) were for reasons other than dissatisfaction with quality (logistical/installation issues). The question of acceptance and use addresses the remaining

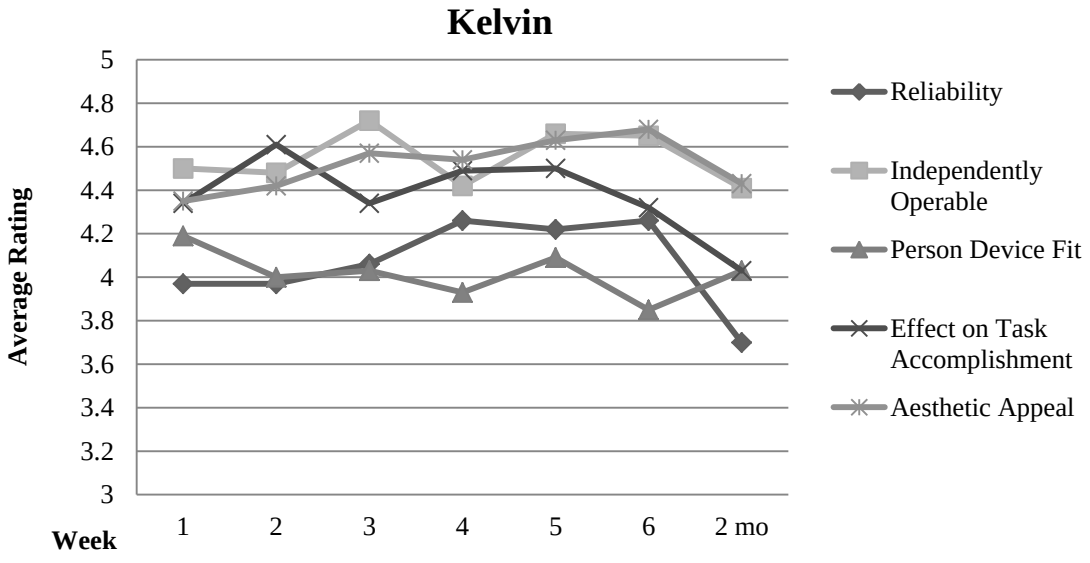

Figure16. Participant perception of Kelvin's Quality over home trial: Weekly trend.

Table 10
Participant Perceptions of Kelvin's Usability: End-of-2-Month Responses

Most liked features	*n*	*%*
The clear voice commands	16	64
Person's ability to check the temperature and time	12	48
Least liked features		
The talking feature was too sensitive	6	
Some of the buttons were too small or difficult to operate for other reasons	7	

37, including 12 who dropped out for quality reasons, as we shall see later, and 13 who completed the study. To what extent did they consider Kelvin relevant to their needs and acceptable for their own use?

Kelvin did not fare very well on product acceptance. Both technical quality and usability issues surfaced as early as the onsite trials and continued into the home trials: buttons were hard to push and were too small and inaccessible for blind user reading. Ironically, the voice activation feature was both a positive and a negative feature. It would respond to the voice of the user, but it would also annoyingly respond to any or all noise in the environment.

Table 10 captures participant comments about their likes and dislikes of the 25 persons at the end of the home trials.

As noted, acceptance varied among the 25 participants. The device worked for some but not for others. Its key features (voice interaction and temperature setting) satisfied 12-16 persons while frustrating 6-7 others who also had difficulty operating it. Those who reported their preferred features offered comments such as: "It does reflect vocally what the settings are. Like the voice activation;" "Independence it provides. Like the availability of voice, repeats things if one

Table 11
Purchase Intent vs. Purchase Decision by Participants in Kelvin Study

Situation	Question	Total	Would buy the product	
			n	*%*
Onsite Trial Exit Interview	*Which one would you buy? – Product or its Competitor?*	48	18	38
Mid-Home Trial (2 months)	*Likely to trade part of study compensation to buy product?*	37	18	49
Mid-Home Trial (2 months)	*Would you buy your original device again?*	37	9	24
			Bought the product	
			n	*%*
End of Study (6 months)	*Actual Decision to Buy*	25	12	48

could not understand;" "Gives you room temp and time;" and "The voice is very good. The program works well."

Comments corresponding to frustrating features included: "When it talks unprompted. The programming buttons are all the same shape, make them different shape;" "It keeps going off when you are talking to someone and it doesn't always do what you tell it to do;" and "Programming; buttons are too small and the sensitivity."

Product Use

During the final four months of the home-trial period (when use was voluntary) it was redundant to ask the use and abandonment question, "How often did you use?" There was no new programming and the 'using' activities were minimal–checking temperature and reporting malfunction if any.

Product Purchase

As with the other two studies, a purchase opportunity was posed to the 25 participants at the very end of the study for purchasing Kelvin giving up $65 (half the market value) from the compensation amount ($150) owed to them. Table 11 presents the trend of participants over the course of the study–in terms of purchase intent and actual purchase decision at the end.

As shown in Table 11, 48 people started the study, 25 completed it. However, only 12 of them chose to purchase the product. This represents only 25% of the total sample. Interestingly, this also represents about half (48%) the people who tried it out to the end, to whom Kelvin seems to have offered 'value.' Interestingly, they were divided in their reasons for acceptance/rejection. Table 12 below summarizes the reasons why participants did (n=12) or did not (n=13) buy Kelvin as per the telephone interview at the end of the study.

Table 12 lists the reasons acknowledged by the 12 participants who bought Kelvin and by the 13 who did not. Their comments

Table 12
Reasons for Buying/Not Buying Kelvin

Is this the reason you bought Kelvin?	*n*	*Is this the reason you did not buy Kelvin?*	*n*
Had confidence in Kelvin's ability to perform accurately.	10	Had no confidence in its ability to perform accurately.	7
Had confidence in the Kelvin's ability to perform consistently.	10	Had no confidence in its ability to perform consistently.	5
Kelvin's voice was easy to understand.	11	Didn't like the voice	1
Found Kelvin programming reliable.	9	Programming too difficult.	5
Frequently used the hands free feature of Kelvin	7	Controls were too difficult to understand.	4
Buttons and controls were easy to locate.	11	Buttons were too hard to push.	1
Maintenance of Kelvin was simple and easy.	8	Pushing the buttons was too painful on fingers.	0
The display screen was easy to read	1	Did not trust its safety in the house	2
Total who bought	12	Total who did not buy	13

corroborate the earlier findings (see Table 10) on acceptance of Kelvin. Beyond the comments, participants volunteered additional reasons beyond what is listed in Table 12. One person reported that a family member did not like the thermostat; some participants claimed they either needed the money or that the price was too much (*n*=4); some reported that the thermostat talked too much, was too sensitive, or that its voice went off at will (e.g., multiple sounds in the house triggered it; *n*=3); some pointed to its inconsistency, saying that it wouldn't maintain temperature settings (e.g., while set at 68 degrees, the temp rose to 70), that it worked inconsistently, that it was totally inaccurate, that its clock kept gaining time, or that it failed to respond to voice commands (*n*=3). Some commented on the buttons, pointing out that they were too small with small print, that they required too much additional AT to read, or that they were too difficult to manipulate because of eyesight (*n*=2).

Summary and Discussion

We summarize and discuss below findings from the three case studies of efficacy assessment presented in the previous section. The methodology used for evaluating quality and value was uniform and systematic for all three products. Results, however, varied with respect to consumer satisfaction and acceptance of the products, as tied to product functionality and features.

Lids-Off™ was liked by an overwhelming number of participants, and it received high ratings on all indicators of technical quality and usability from beginning to end. At the onsite trial, it was clearly rated superior to its marketplace competitor. At home trials, most found it intuitive and learnable. After two months of home use, most gave it high ratings and considered it to be consistent, comfortable, and effortless to operate; most found it both satisfying and said that it surpassed their needs. Seventy percent (70%) considered it enabling. Over 90% embraced the device as a fit for their needs. The product was a success in terms of quality, relative to both market place and critical competitors. In evaluative terms it showed merit. Additionally, it showed worth or value to its consumers. The study had the lowest dropout rate. Users accepted it as a fit for their needs. Most (92%) used it voluntarily during the optional feedback period during home trials. Nearly three-quarters (74%) chose to buy it at the end. Technical quality or usability was rarely mentioned as a factor by those who chose not to purchase it. Money was an issue in isolated cases, but overall the product seems to have been considered cost-effective. Lids-Off™ was a success in that it showed both merit (quality) and worth (value) for this disability population.

The Point Smart software was less successful than Lids-Off™, with mixed results on efficacy. In onsite trials it was preferred to its competitor (Microsoft), although not as overwhelmingly as Lids-Off™. It held great promise and was preferred to its competitor (88%). At home, it was fairly learnable, with just 8% finding it to be difficult. Initially, a good number (70% to 84%) found it consistent in operation, functionally superior, less effortful, more comfortable, and more satisfying than other alternatives. It even ran close to Lids-Off™ regarding 'surpassing needs' of the disability population in question. But it was less an 'enabler' than either Lids-Off™ or the Kelvin, and notably, only 64% embraced it as a fit for their needs. Rating trends declined after four weeks on several usability indicators and on person-device fit. Thus, Point Smart showed dubious merit and its initially positive user perceptions suggest the product's underachieved potential. The product also showed dubious worth or value. Over two months of home use, there was a decline (from 72% to 50%) in participants' willingness to buy the product. During the

optional home-use period, more people (14%) abandoned its voluntary use than did participants in the Lids-Off™ study. Interest in the product declined, with only 22% buying the product at the end.

In terms of cost effectiveness, it is difficult to relate the low purchase numbers to the software's affordability because a confounding factor was its vulnerability of duplication from the trial CD version. At any rate, user comments that supported the declining ratings and declining purchase intent suggested that the effectiveness did not outweigh the cost, at least for those for whom the product worked. In conclusion, although Point Smart was considered to be more effective than its competitor at onsite trials, the home trials clearly showed it did not reach the height of its potential in terms of merit and worth. It was not effective enough to be valuable to most participants.

The Kelvin thermostat was also less successful than Lids-Off™ and showed mixed results. Unlike Lids-Off™ and Point Smart, it was not a big success at the onsite trials. Less than one-third (15%-34%) of participants regarded Kelvin as more favorable than its formidable competitor, based on all indicators. At home, it was less learnable due to inaccessible instructions manual, as with Point Smart. Interestingly however, usability ratings shifted upward by the end of two months, with over two-thirds of participants favorably disposed to Kelvin's use. They reported that it surpassed their needs and rated it highly based on usability indicators, with over 80% attesting to its consistency of operation. It was even perceived to be as enabling (70%) as Lids-Off™. However, trends in perceptions from beginning to end were mixed, rising to 89% from 71% on its independent use while falling to 70% from 80% on ease of use. In all, 70% steadily embraced Kelvin from beginning to end as a 'person-device fit.' This compares favorably with results for Point Smart (64%), which suggests that Kelvin did work for more persons in its sample. While Kelvin was 'less effective' than its competing product (onsite trials), it was effective for 70% of those who persisted with it at home. One thing that uniquely distinguishes Kelvin from equivalent devices in the market is its voice input recognition feature.

User purchase behavior was interesting in the case of Kelvin. Only 25% bought it at the end. The drop-out rate was highest for Kelvin due to usability issues and malfunctioning units, but almost half (48%) of the remaining people bought the device, suggesting that it was valued by those for whom it worked. This did not happen in the case of Point Smart, where only 28% of the remaining participants bought it. Both Kelvin and Point Smart were less affordable than Lids-Off™ in terms of absolute dollar value, but more consumers decided to buy Kelvin as compared to Point Smart. This suggests that Kelvin's effectiveness outweighed its cost for more people. It seemed more 'needed' and 'valued.' In conclusion, although Kelvin was not 'more effective' than the chosen competitor, it appealed to a good proportion over the home trial in absolute terms and was valued by about half of participants. Its merit and worth did not reach the heights of the Lids-Off™, but it fared slightly better than Point Smart.

In summary, Lids-Off™ came out successfully both on quality and value counts, whereas Point Smart and Kelvin were less so on both counts. Neither Point Smart nor Kelvin reached their potentials in terms of quality and in terms of acceptance by the user group studied. Point Smart started out well but its perceived quality and value declined in users' eyes over the study period. Kelvin started with unfavorable user perceptions, but it was more appreciated in real-life trials. It was perceived as promising, however only by a limited few who valued it. What can we

conclude about their efficacy? What factors explain their apparent lack of success with the participant group as a whole? What does this say about the effectiveness of the T²RERC intervention? What are the lessons to the intervention process?

Similar Method, Unique Contexts

At this point in evaluating the three devices, context becomes important. Despite that similar methods were used, contextual differences among the three cases make it difficult to generalize across them. First, product uniqueness and individual corporate realities affected the degree of the T²RERC's intervention and the company's use of the intervention. Second, logistics affected the implementation of the efficacy study itself although same methods guided them. These points are considered below.

Differences in Design Challenges

Each of the three products was unique in design because of the functional needs of the different populations they targeted. While the T²RERC intervened for an 'inclusive' redesign of each of the three prototypes, the three products initially targeted different markets. Lids-Off™ is a home appliance targeted to mainstream buyers, while Point Smart and Kelvin more directly targeted persons with disabilities. As AT products, the last two had more challenging accessibility issues with which to contend. These stemmed from complexity involved in operating them and dependency on hardware and system interfaces. They did not reach the same height, either on quality or on value, as Lids-Off™, whose clear championship in this respect and successful sales volume lend support to an effective intervention by the T²RERC in its development.

Recognizing that AT outcomes are functions of person-device compatibility, it may be argued that a subject-by-subject analysis of the findings is a more valid way of inferring products' benefits to users, rather than evaluating products based on analysis of group data as we did. Such analyses might shed a different light on these results, and we are currently analyzing for differential effectiveness based on functional needs. However, user comments suggest that technical issues and software operability were more of a problem than device incompatibility. Besides, our onsite trials design in this study did permit direct observation of individual performance, and home trials permitted individual tracking of each consumer's experience with the product use. The general frustration reported by participants, our informal observation of the context of product use, as well as the history of the product development reveal that there is more to the difference in impact than appears on the surface.

Differences in the T²RERC Intervention

None of the three prototypes originally targeted the disability market exclusively before the T²RERC intervened. However, both the Lids-Off™ and the Kelvin got the benefit of the full systematic evaluation input from the T²RERC, from the design stage through successive prototype evaluations. Meanwhile the Point Smart case was an exception to our typical intervention. As described earlier, support to Info Grip came at a much later stage of development. Opportunities for timely capture of input for its design were missed. Practical constraints further hastened the product to market before all technical refinements were fully in place. Support was thus not ideal for Point Smart. The repercussions of this difference in evaluative input showed its effect on the levels of quality level and acceptance of Point Smart. Users recognized promise, were impressed with its usability, but were frustrated at the barriers to its full use.

Installation issues, instructional manual quality, and hardware and software compatibility issues made technical assistance crucial for Point Smart. While Info Grip has been very receptive to feedback from the efficacy study and is bringing out its next version of Point Smart, Black and Decker has brought a line of products into the market and requested our continued support.

Differences in Information Use by Developer

Although very similar support was provided both to Kelvin and Lids-Off™ during development, there was a difference in how the two companies used our evaluation information. Whereas Lids-Off™ took all key recommendations, the post-commercialized Kelvin did not incorporate some key features identified in the focus groups, including contrasting or light-up buttons, backlit displays, enlarged lettering on digital displays and switches, and a carbon monoxide detector among others. This was a difference in the use of the evaluative information provided to the two companies. Also, as pointed out earlier in the background section, the production of Kelvin was outsourced and there were quality control issues in the production processes. Kelvin needed technical support during home trials due to malfunctioning units that resulted from production flaws. Such differences were important factors in the final outcome of how each product impacted user perception of quality, and consequently its acceptance.

Differences in Study Implementation

Iterating case studies represent 'real-world' formative evaluations. They can be very valuable for developing best practices in research methods by illuminating how methods need tailoring to contexts. Device and user individualities dictated variations in test protocols in the case of the three efficacy studies. As mentioned earlier, a clinician expert had to work with the Point Smart study participants at the onsite trials, pretesting and configuring the device with each mouse type, and guiding home trial set-ups. Pre-screening tests on computers were needed in recruiting participants for the Point Smart in order to identify true functional limitation. Additionally, unforeseen complications with product operation had logistical implications for the Point Smart and the Kelvin home trials, thus requiring frequent technical support by the respective companies. In contrast to these two studies, the Lids-Off™ was an almost seamless study.

Conclusions and Lessons

In light of the foregoing, conclusions are more straightforward about the relative efficacy of the three products than they are about the effectiveness of the T^{2}RERC's intervention. It is easy to see that Lids-Off™ was a success in terms of its benefit to its end users whereas Point Smart and Kelvin were only partially beneficial. As for the T^{2}RERC's transfer process, the Lids-Off™ case lends evidence to its effectiveness, and one could argue that it would have been just as effective in the other two cases, had those contextual difficulties been surmountable to the point of being 'best-case scenarios.' One could also argue however, that realities are more often far from being best-case scenarios, and there is need to further improve the T^{2}RERC process so it responds to such challenging realities. Indeed, the contrasting cases in this study hold lessons that might lead to improving the transfer process and shedding light on future technology transfer.

Developing Products for Optimal User Benefits: Lessons and Implications

The study of efficacy of its transferred products was a response of the T^{2}RERC to the issue raised in its 2003 conference about advancing the state of the science and practice

of technology transfer through continued study of its model. While previous evidence on successful transfers attested to the merit of the model, the product efficacy studies sought evidence of the model's worth in terms of benefits from its outcomes to end users. In discussion here is the extent to which the studies provided such evidence and in what ways the experience was an enlightened step toward advancing theory and practice of technology transfer.

Technology transfer has long been present in business and industry practice as part of New Product Development (NPD) through Stage-Gate and similar models (Kahn et al., 2005). In academic circles, interest in technology transfer stems from a desire, at least in theory, to link research to NPD through university technology transfer offices that act as bridges to the marketplace. Policy makers have increasing expectations in terms of linkages to new product development from the research projects they approve for funding. Linked to return on investment, there is a growing recognition of the need for knowledge translation (Canadian Institutes of Health Research, 2004; Sudsawad, 2007) resulting in an awareness for the need for transdisciplinary or Mode 2 research (Gibbons et al., 1994; Nowotny, Scott, & Gibbons, 2001) as well as attempts at its operationalization (MacLean, MacIntosh, & Grant, 2002; Savory, 2006). In this context, academic- industry partnerships have been recognized as important for advancement of theory and practice in technology transfer, and paradigms have been attempted (Arvantis, Kubli, & Woerter, 2008; Renault, Cope, Dix, & Hersey, 2008; Sharif & Baark, 2008; Vaajakallio, Vehmas, Keinonen, & Mattelmaki, 2008). Current thinking seems to point to the wisdom of academic and industry collaborations involving joint research and development work.

In light of the above, this article deliberately uses an academic framework (the CIPP model) to integrate and interpret the T^{2}RERC experience with product efficacy assessment. In effect, it layers an academic perspective over the business model (the Stage-Gate model for NPD) that guided the T^{2}RERC in its product development support. This should allow for imperfections in both models–one theoretical and the other practical–to surface as repercussions from the case studies, with lessons for the academic and industry partners who try to deliver new products of quality and value.

Our experience through the challenges from these contextual differences led to three important lessons. They go beyond the T^{2}RERC and the partnering companies to include academic researchers or knowledge brokers and their corporate partners, and they clarify questions about the realities of collaborative models.

Lesson 1: Consumer Input

Consumer input is fundamental to ensuring the quality and value of a product in development. The timing of the input is key–it should be captured prior to (re)design, during prototype improvement, and at the end of the development process. All three product developers recognized the value of the consumer input in shaping their product after our feedback from the efficacy study, if not earlier.

Lesson 2: Product Quality

A business partner's (or company's) commitment to product quality is as important for success as the academic research partner's (T^{2}RERC's in this case). Both Kelvin and Lids-Off™ received standard evaluative support from us, but the product developers used the information differently. Kelvin's diminished value for the consumer can be explained by its omission of important features as well as by its choice to

outsource operations, thereby investing less on quality assurance and production control.

Lesson 3: Customer Support

It is difficult to achieve product value without adequate post-commercialization support to the consumer in the use of the product. Involving the consumer in development may yield the desired product; commitment to quality by both partners may enhance its appeal and value; but unless a manufacturer or vendor renders the product viable for use, consumers will be unable to certify and accept it as right for their needs. As mentioned earlier, both Point Smart and Kelvin were complex to install and operate. Consumer learning and appreciation of these products depended heavily on the availability and effectiveness of accessible versions of instructional manuals. This is a lesson to both partners–the (academic partner/broker), T^{2}RERC, should address this during development of the new product; and the company should build this support into its marketing plans.

In summary, the differing case contexts partly explain differential findings in the efficacy of the three products. Lids-Off™ encountered the optimal conditions for achieving desired product quality and value levels, i.e., the T^{2}RERC's systematic and timely evaluative support and Black and Decker's incorporation of the recommended functions and features into the product. Kelvin, which did poorly on quality and value, was a case of complete and timely input by the T^{2}RERC but limited corporate commitment to quality and product support. Point Smart was the least valued by its users in spite of its perceived potential, and it was also the case with the least optimal conditions under which to achieve its potential. The case study suggests that while the T^{2}RERC successfully brought a new product of quality and value to the market place, the corporate partner had an equally significant role in achieving this outcome. In this sense, the intervention into the prototype is in fact a joint effort between the academic-researcher/knowledge-broker (the T^{2}RERC) and the business partner. Effectiveness and impact cannot be achieved without equal commitment.

Implications for Practice

Academic and corporate partners are each stakeholders in a collaborative product development process, and the above lessons hold implications for them both. First, *involving consumers during (rather than after) the development process is important*. Corporate requests for support need to be timely. On the other hand, academic support teams should work within the company's product development schedules and deadlines.

Second, *evaluation information is only as good as follow-up decisions to improve product*. It should be recognized that the academic role is to enlighten through evaluation, but improvement decisions are a direct corporate concern. Also, commitment to improving quality includes minimizing production flaws through *maintaining control over operations flow*. Practical constraints can make a huge difference in the final design of the product, and smaller companies face a bigger disadvantage than larger companies in commercializing their products with the quality that the product deserves. The Kelvin thermostat might well have suffered the consequences of outsourcing by bidding. Included among the user dissatisfaction comments is the poor quality material that diminishes accessibility to the touch-dependent blind user.

Third, accessibility is key to an AT product's usability, and the importance of post-commercialization product support cannot be minimized. Those responsible for the technology transfer intervention (the T^{2}RERC

/academic broker) should make sure that product manuals are part of their evaluations, so that the product is learnable and can be independently put into operation by consumers. Accessible manuals and technical support to user cannot be overlooked as something obvious that production will take care of. As examples, Point Smart's instructions were web-based, and the user needed Point Smart to access them. Similarly, large print and Braille version options would make the Kelvin thermostat more accessible to blind users.

In general, the efficacy studies suggest that academic-corporate collaborations have great potential for developing products of quality and value, provided there is appropriate use of evaluation as a tool for achieving this. Evaluations are important, not only for what we learn from them, but also for what we learn about them. In this article, we have used the CIPP systems approach as the framework for analyzing how adequately evaluation was utilized in the development and commercialization of the three devices studied. In theory, this approach should maximize evaluation's potential for achieving optimal benefits to product users. The cases illustrate the value of each step in this approach. All the same, through these cases, we have also come to realize the challenges of translating theory into practice. Challenges to this task posed by business-world realities are often greater than the academic world realizes. While there is awareness of the need to make mainstream products more inclusive, it is yet to be recognized that this has implications for effort both by industry and academia. Each of these two sectors has developed its own specialized knowledge and expertise, but unfortunately each has done so mostly in isolation from the other. It is time that the two worked hand-in-hand to develop working frameworks, offering models that do exactly what models should – represent reality. Perhaps this is the best lesson that we have learned from the efficacy studies.

It is important to note that such efficacy studies are realistically only performed once all of the prior research and development outputs are achieved and all transfer and commercialization are accomplished. One cannot know how a new product will meet the needs of intended customers until they use the product and compare their experience with it to other products/methods for accomplishing the same tasks. The study shows that one can optimize the effort to meet customer needs by integrating the relevant design and consumer criteria from the earliest stages of development. Beginning with that end in mind is the best means to ensure that new products do indeed contribute to the quality of life for persons with disabilities.

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Technology Transfer and Technology Transfer Intermediaries

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Abstract

A standard and comprehensive model is needed to evaluate and compare technology transfer systems and the stakeholders within these systems. The principle systems considered include federal laboratories, U.S. universities, the rehabilitation engineering research centers (RERCs), and large small business innovation research programs. An earlier model accounts for technology transfer activities, events, stakeholders, and resource providers (Lane, 1999). This model is augmented to account for dynamic aspects of technology transfer (transfer efficiency, transfer latency) and scale (micro-, macro-). The critical role of technology transfer intermediaries is emphasized. Examples pertaining to the assistive technology industry are used to illustrate important concepts and issues. The technology transfer model with extensions is applied to the four technology transfer systems. Major studies pertaining to the technology transfer performance of: large small business innovation research programs, the federal laboratory system, the U.S. Department of Education RERCs, and U.S. universities are reviewed. Study outcomes are examined in terms of a uniform and comprehensive technology transfer model. Conclusions are drawn regarding the evaluation of program performance. The need for a uniform and comprehensive technology transfer model is demonstrated by showing inconsistencies within and between research study outcomes for major technology transfer systems. Barriers that prevent the full and optimal use of these programs by the assistive technology industry are discussed. The authors conclude that technology transfer from the public to private sector is a major and critical economic driver. Large federal programs, which are generally established through legislation, facilitate and structure the technology transfer efforts of federally funded entities. Effective program oversight and good public policy requires systematic program evaluation in reference to a standard and complete technology transfer model. Identifying and promoting best practices for technology transfer intermediaries requires that the technology transfer model encompass both the macro (systems) and micro (stakeholders within systems) scale.

Key words: Technology Transfer, Demand Pull, Supply Push, Assistive Technology Devices, Transfer Latency, Transfer Efficiency

Technology Transfer and Technology Transfer Intermediaries

The Rehabilitation Engineering Research Center on Technology Transfer (T^2RERC) funded by the U.S. Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR) completed its third five-year funding cycle in September 2008. The T^2RERC conducted research to advance the state-of-the-art for technology transfer while also practicing technology transfer to facilitate technology development, transfer, and product commercialization benefitting elders and people with disabilities.

Technology transfer (TT) is an emerging field. As such, in both research and practice, ad hoc

and borrowed terminology is employed for TT activities, stakeholders, and events. In 1999, a detailed TT model was published that addressed many of these shortcomings (Lane, 1999). In this paper we suggest how that model might be extended, and we provide a rationale for doing so. We propose terminology and concepts for *transfer efficiency*, *transfer latency*, *transfer context*, *push* and *pull* transfer strategies, and *transfer scale*. To illustrate terminology and concepts, examples are presented with reference to familiar TT programs and activities. These examples illustrate the somewhat disjointed manner in which TT programs are currently evaluated.

Readers who will benefit from this paper include TT intermediaries and resource providers, managers and evaluators of TT programs, members of the TT research community, and other stakeholders who participate in TT activities.

Events, Activities, and Stakeholders: Definitions and Examples

Events and Activities

A comprehensive and extensible model and language is required in order to discuss TT clearly and accurately. The model and language should also provide a framework for evaluation and research. Lane's 1999 paper provided an excellent model and vocabulary upon which this paper will expand. Figure 1 captures many of the key elements of this model. For example, within the figure, bounded areas represent *activities*, which include Technology Applications, Technology Research and Development (R&D), Product R&D, and Product Commercialization. These activities are carried out by various *stakeholders*, who include Technology Producers (TP), Technology Consumers (TC), Product Producers (PP), and Product Consumers (PC). Resource Providers facilitate TT activities in various ways throughout the entire TT process. Activity outputs are called

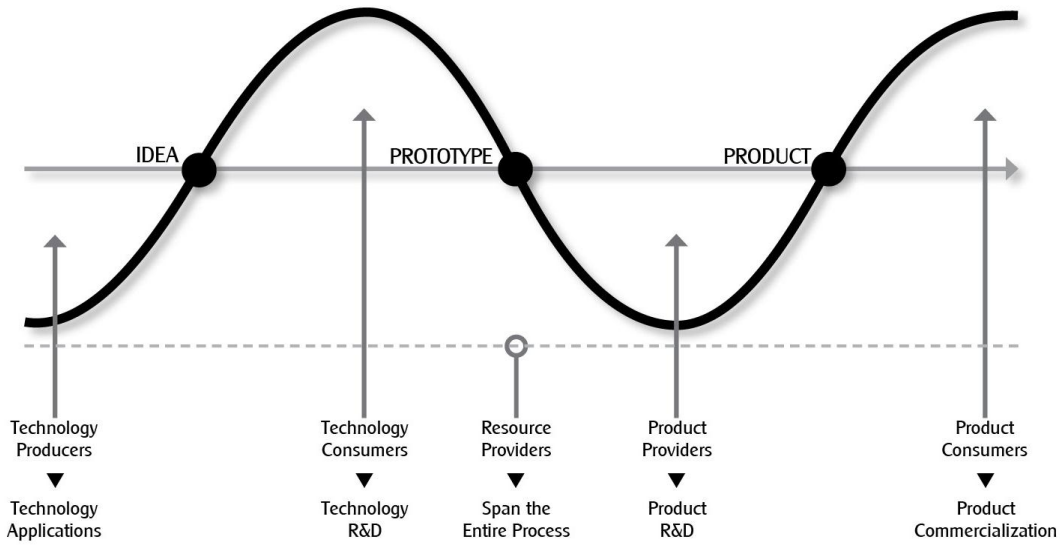

Figure 1. Technology transfer model. Source: Lane, J. (1999). Understanding technology transfer. Assistive Technology, 11(1), p. 15. Used with permission.

critical events, which include idea, proof of concept prototype, and product. These outputs serve as inputs to subsequent activities. Activities above the horizontal midline are generally visible, or public, while activities below the midline are generally hidden, or confidential and proprietary.

The reader can understand TT conceptually by 'walking along' the midline of Figure 1 from left to right. Technology-related activity is on left side of the model, and product-related activity is on the right side of the model. The technology-to-product transition occurs around the midpoint (prototype event). Table 1 presents the activities and critical

Table 1
Technology Transfer Model: Critical Events and Activities

Event/Activity Name	Event/Activity Description	Event/Activity Exemplar
Technology Applications	Theoretical and basic research activities leading up to conceptualized idea.	Eye gaze technology was explored by the U.S. Air Force as a way to enable Vietnam fighter pilots to track, point, and shoot at a target without using their hands.
Idea Event	Point in time when a new or novel application is recognized for a new or novel technology.	LC Technologies founders formed the company to develop a commercial eye gaze product. At the time they saw value in using the product for people with disabilities, but they had no viable prototype.
Technology Research	Applied research activities leading up to proven concept prototype.	All image processing and pattern recognition code was rewritten to enable the system to recognize eye features. When completed, the unit was two to three times more accurate and precise than before.
Prototype Event	Point in time when a new or novel application is embodied as a working prototype that demonstrates the proof of concept.	The first unit ran on a 286 computer and sold for almost $50,000. The unit was functional, but the price was far too high for commercial success.
Product Development	Market research, design, and development activities leading up to 'production-ready' product that also includes other features and functions wanted by customers.	Further refinement of the system focused on improved pointing accuracy and increasing tolerance to: ambient infrared light, inter-user differences, and head motion.
Product Event	Point when a working prototype is refined; includes other necessary features and functions and is ready for manufacture, distribution, and sale.	Solving many previously encountered technical problems lowered the price sufficiently to enter the marketplace. Current units sell for $7,250 to $10,500.
Product Commercialization	Production, distribution, marketing, and sales of the product to customers.	The Eye Gaze Edge Communication System is available through LC Technologies, Inc and a network of dealers. Refinements to the system are ongoing.

Source: D. Cleveland (personal communication, October 31, 2008)

events of the TT process as experienced by one company, LC Technologies, Inc. in the development and commercialization of their eye gaze mouse emulator.

Stakeholders

Typical TT stakeholders are listed in Table 2. Citing examples of TPs and PPs and PCs is relatively straightforward. However *Resource Providers* encompass a wide range of actors whose resources may be leveraged throughout the entire TT process. Examples of Resource Providers include: (a) government and private entities that fund research, development, production, marketing and distribution activities; (b) government and private third-party payers that fund product purchases and create market demand; (c) TT intermediaries that facilitate a range of activities including market research, grant development, brokering, and technical support; and (d) government entities that shape and implement TT policy.

Table 2
TT Model: Stakeholders

Stakeholder Group Name	Members of Stakeholder Group
Technology producers	Universities and federal laboratories (public sector), corporate laboratories, and independent inventors (private sector)
Technology consumers	Manufacturers (private sector) and government agencies (public sector)
Product producers	Manufacturers (private sector)
Product consumers	Primary (end-users) and secondary consumers (individuals who buy and recommend or service providers)
Resource providers	Government agencies (grants, contracts, public insurance), private insurance companies (reimbursement), TT intermediaries (brokers), venture capitalists and angel investors (private investment)

There are many examples of resource providers with greater or lesser relevance to the four TT activities. Setting aside the risks of overgeneralization, the following examples suggest the continuum of roles played by Resource Providers.

1. Federal agencies provide extramural grants to university faculty to conduct basic research. Basic research usually takes place under *Technology Applications* prior to the Idea event and before market demand and business opportunities are readily apparent.
2. Large federal agencies provide Small Business Innovation Research (SBIR) grants to small U.S. businesses and in 2005 these grants totaled more than $1.85 billion (Wessner, 2008). Across agencies, multi-phase SBIR grants vary greatly in size. However, the combined Phase I and Phase II grants frequently exceed $1 million. Phase I grants typically fund *Technology Research* leading up to the Proof-of-Concept Prototype Event, while Phase II grants typically fund *Product Development* activities after the Proof-of-Concept Prototype event and leading up to the Proof-of-Product Event.

3. Angel investors (AIs) pool resources from one to a few affluent individuals to offer second-round funding to (typically) high-growth start-up companies. Company owners generally wish to maintain their controlling equity positions but turn to AIs when they have exhausted, or do not wish to further pursue funding from friends or family. Additionally, other mechanisms such as SBIR grants are not always suitable because of timing, risk, or funding level issues. AIs tend to be risk-tolerant, and may fund late stage *Technology Research* and early *Product Development* activities. Typical AI funding ranges from $250,000 to $1 million. Return on a successful investment ranges from 10 times to 30 times the original AI investment over a five- to seven-year period (Wiltbank & Boeker, 2007). AIs recoup their investments through exit strategies such as initial public offerings (IPO) and business acquisitions.
4. Venture capitalists (VCs) pool resources from private investors, investment banks, and institutional investors; they typically make investments of $1 million to $2 million. VCs are often less risk-tolerant than angel investors, and they generally fund 'later stage' *Product Development* activities up to the Proof-of-Product event. VCs often prefer to invest in established companies entering a phase of rapid growth. However, VC funding is also sought by high-risk, high-reward tech companies that do not qualify for standard bank loans. In return for taking on high-risk, VCs may ask to own controlling equity positions in these companies, guide business plan development, or to have input on decisions regarding management practices, staffing, development, and production. VCs typically employ a '2 and 20 formula' whereby the VC receives 2% of the committed capital plus 20% (or more) of the company's net profits on an annual basis. By employing this (or similar formulas), VCs typically recover their initial investment over three to seven years. VCs then generate profits through exit strategies that include IPO and business acquisition.
5. TT intermediaries (TTIs) are the most diverse group of Resource Providers. They offer various assistances to the stakeholders associated with *Technology Research*, *Product Development* and *Product Commercialization* activities. Examples of TTIs include university TTOs, federal laboratory ORTAs, and other federally funded brokers such as the T^2RERC. It is common for TTI to draw upon the capabilities of other resource providers. For example, a university TTO might help a university researcher to obtain SBIR funding to support further research and development.

Figure 2 maps Resource Providers against their likely involvement within the TT model. Although Resource Providers are typically involved during portions of the process indicated by the horizontal dotted lines, there will occasionally be instances that fall outside of the norm.

Extending the TT Model

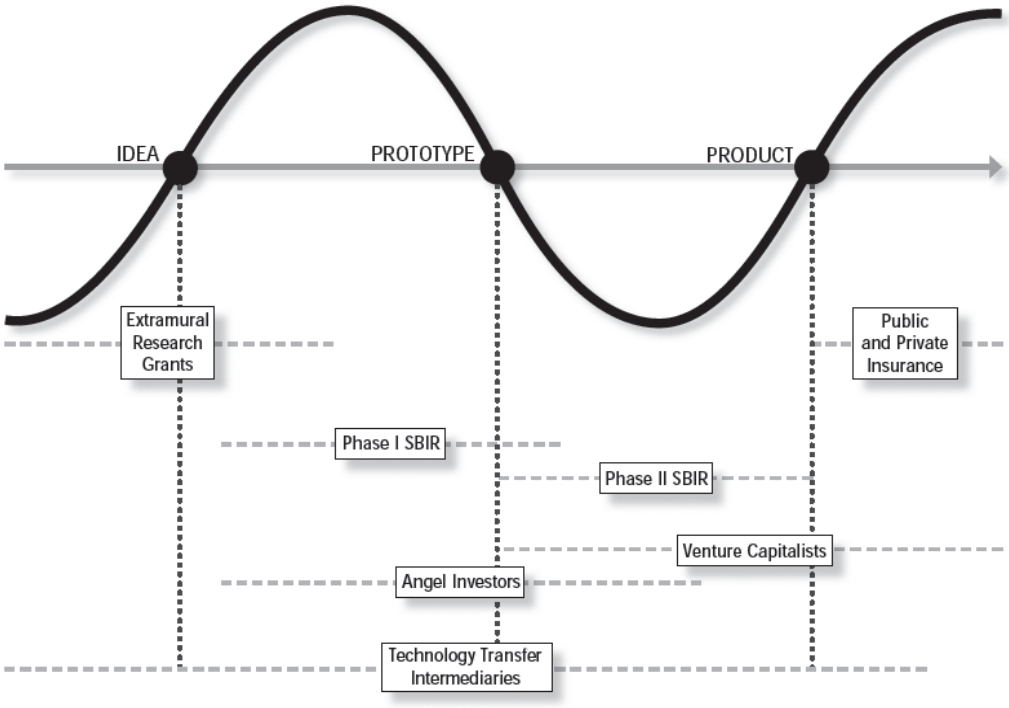

Figure 2. Technology transfer Resource Providers.

Lane's model, while excellent, has focused delivering information on static TT concepts, including: (a) what happens within an activity; who participates in an activity; (b) which Resource Providers support the activity; (c) what event terminates an activity; and (d) what forces might initiate TT. Equally important, however, are concepts and language to describe the dynamic processes of TT and the facilitating roles of TT intermediaries. It is also important to examine TT activities at different scales, recognizing that normative outcomes determined from aggregate measures are likely to obscure both the successful and the unsuccessful practices of individual TT intermediaries. We begin our extension of the model with terminology and examples of new concepts.

Concepts and Terminology

1. *Innovation*--In TT, an idea is transformed from proof-of-concept prototype, to proof-of-product and finally to a commercial product. According to the Merriam-Webster Online Dictionary (2008), an innovation is "2: a new idea, method or device." Throughout the remainder of this article, *innovation* will be used to represent ideas through their subsequent transformations to become commercial products.
2. *Context*--This refers to the various environments in which TT occurs. *Technology Applications*, *Technology Research*, and *Product Research* activities that transform innovations take place in different contexts, including public sector labs and universities, private sector companies, and in the domains of independent inventors. For example, an idea might result from research conducted at a university (context) to be published in a technical journal (purpose). A proof-of-concept prototype might result from research conducted in a federal

laboratory (context) and be patented to facilitate future licensing opportunities (purpose). A proof-of-product might result from production research carried out by a manufacturer (context) as a precursor to introducing a commercial product (purpose).

3. *Transfer Mechanism*--This mediates the movement of an innovation from a source context to a destination context. For example, a journal paper could mediate the movement of an innovation from a university to a manufacturer. A license agreement could mediate the movement of an innovation from a federal lab or university to a manufacturer.
4. *Technology Transfer*--This is the movement (via a TT mechanism) of an innovation (idea, method or device) from a source (original context and purpose) to a destination (new context and purpose). For example, prototype software developed by university researchers (context) for user-friendly creation of keystroke macros is patented and licensed (movement or transfer mechanism) to a private sector manufacturer (new context) for use in a software product that allows blind individuals to independently create screen reader macros (new purpose). A federal lab (context) develops technical expertise and capacity in the area of nanotechnology fabrication (purpose); a cooperative research and development agreement (movement or transfer mechanism) is entered into with a private sector manufacturer (new context), to collaboratively develop a novel refreshable Braille cell (new purpose).

Throughout the remainder of this article, we'll often employ these terms to discuss the dynamic aspects of TT. In the following section the critical role of TT intermediaries is discussed. TT intermediaries employ some combination of push transfer strategies and pull transfer strategies. These strategies facilitate progress and transformation of an innovation from idea to commercial product.

Push Transfer Strategies

Push transfer strategies start by identifying one or more innovations (initiator) from an independent inventor, university, federal lab, company outside of core industry, etc. Then a manufacturer or federal agency (destination) is made aware of the innovation, associated market need, and business opportunity, and the innovation is transferred (via some transfer mechanism) from source to destination.

For example, the T^{2}RERC Case study project (T^{2}RERC, n.d.b) examined 78 development projects being conducted by 11 RERCs previously funded by NIDRR. RERCs must transfer their research knowledge to the private sector to facilitate the development of new products benefitting people with disabilities. RERCs have historically used push transfer protocols, which is to say that basic research precedes market research, product development, and product commercialization. Each RERC proposed a certain number of development projects, which in principle should result in prototypes. RERCs are usually university-based and TT offices (TTOs) serve as their TT intermediaries. In principle, TTOs help to license RERC-based patents (sometimes embodied as prototypes) to manufacturers who subsequently develop new or improved products based on these prototypes. The Transfer Achievement Index (TAI) of RERCs that began five-year funding cycles in 1998, 1999, or 2000 was defined as the number of actual transfers divided by the number of proposed transfers for any given RERC. For the 11 RERCs that qualified for the study, the average TAI was 25%. TAI

scores for individual RERCs ranged from 10% to 100% (Lane, 2007).

Although the average of the 11 RERCs showed fairly low TT efficiency, two RERCs had TAI scores of 100%. These exceptional performances suggest that most of the RERCs studied were employing sub-optimal push transfer strategies, which could be improved to achieve a higher TAI, as demonstrated by the top performers.

This study is especially significant to AT manufacturers, given that the RERC system is the premier federally funded research program pertaining to disability and AT. A low transfer efficiency implies that the RERC system may not provide full and optimal benefits to the AT manufacturers or the disability markets that they serve. (However, a more recent and complete study is needed.)

Pull Transfer Strategies

In contrast, pull transfer strategies start by identifying one or more market needs (initiator). Then a manufacturer or federal agency (destination) is made aware of the market need and wants to fill this need; an innovation that addresses this need is sought and identified (source); and the innovation is transferred (via some transfer mechanism) from source to destination.

For example, the SBIR program was established under the Small Business Innovation Development Act of 1982 (SBIR Act; P.L. 97-219) and most recently reauthorized in September 30, 2008, as the Small Business Reauthorization Act of 2000 (P.L. 106-554). The SBIR Act requires that large federal agencies with extramural research budgets of at least $100 million designate 2.5% of these funds for grants to small U.S. businesses. Basic requirements to participate in an SBIR program stipulate the business must be U.S.-based, U.S.-owned (at least 51%), and U.S.-operated. Also, the principle investigator must be employed by the business; the business must have fewer than 500 employees; and the business must be a 'for profit' entity. For practical purposes, SBIR grants allow small businesses to pursue high-risk, (often) small-market product development.

SBIR programs have two funded phases. SBIR Phase I completion typically results in a proof-of-concept prototype. SBIR Phase II completion typically results in substantial progress towards a proof-of-product plus establishment of commercial viability. In this way, SBIR granting agencies are resource providers who target funding to small businesses for high-risk technology research activities (Phase I awards) and product research activities (Phase II awards).

SBIR programs are all *demand pull* strategies of two sorts; non-acquisition-based (e.g., U.S. Department of Education [USDE], National Institutes of Health [NIH], National Science Foundation [NSF]) or acquisition-based (e.g., Department of Defense [DOD], National Aeronautics and Space Administration [NASA]) programs. In *non-acquisition-based programs*, manufacturers identify a market need and business opportunity and compete for SBIR grants to support the development of technology solutions. In *acquisition-based* SBIR programs, the federal agency has a specific technology need and typically serves as the primary market for the technology solution. In this case, the federal agency is often the primary 'market' and knows its technological need prior to solicitation of proposals from manufacturers to develop technology solutions.

The Department of Commerce (DOC; 2003) published a study (the 'DOC study') of 359 responding AT manufacturers, 98% (349 businesses) of which were businesses eligible to apply for SBIR awards. Of those

businesses, only 52 companies (15%) applied for SBIR funding. A T²RERC study evaluated five acquisition-based SBIR programs (NIH, NSF, USDE, Department of Transportation [DOT], U.S. Department of Agriculture [USDA]) for the period 1996 through 2005. Another study conducted at the T²RERC found for the period 1996 through 2005 that AT companies received 663 Phase I awards totaling $67 million and 328 Phase II awards totaling $201 million (Bauer & Arthanat, n.d.).

Another study shows that firms obtaining Phase II SBIR awards are very likely to obtain follow-on funding (e.g., angel investors, venture capitalists, and additional SBIR awards) (Wessner, 2008). If these results generalize to AT manufacturers, it is likely that AT firms that regularly utilize SBIR program resources gain a significant advantage over their competitors.

Transfer Efficiency and Transfer Latency

Up until this point, we have discussed the TT model, defined related terms and provided examples of various TT strategies. *Transfer efficiency* and *transfer latency* are useful concepts with which to consider TT outcomes. In particular, the effective intervention by TT intermediaries should increase transfer efficiency and or decrease transfer latency.

Transfer Efficiency

Transfer efficiency can readily be tied to critical events such as the likelihood that an idea will result in a commercial product, or the likelihood that a proof-of-concept prototype will result in a commercial product. Examples of transfer efficiency include the ratio of commercial products (or technology licenses) to patents as a measure of transfer efficiency for a university TTO, or federal lab Offices of Research and Technology Applications (ORTA). Transfer efficiency provides a useful basis for comparison between two or more TTI or between TT systems.

For example, a study published by the National Research Council (NRC; Wessner, 2008) evaluated the five largest SBIR programs; they are administrated by DOD, NIH, Department of Energy (DOE), NASA, and the NSF. The NRC study employed stratified random sampling that included 20% of Phase II recipients from each agency. Data is reported for various timeframes between the years 1983 and 2005. The typical culmination of a Phase I award is a proof-of-concept prototype. Phase II awards typically culminate in substantial progress toward proof-of-product and the establishment of commercial viability.

For study respondents receiving Phase II awards, 47% led to marketed products, 19% were expected to produce marketed products, while 5% of projects were still in development. The remaining 29% failed to reach the market. In addition, 43% of Phase II awardees received additional non-SBIR investment averaging about $1.54 million; 54% received one or more related Phase I SBIR awards; and 40% received one or more related Phase II awards (Wessner, 2008).

High transfer efficiencies and follow-on funding opportunities should make SBIR grants extremely attractive to AT manufacturers. For these five SBIR programs, the NRC study suggests a transfer efficiency of at least 49% and at most 71% when the small business has won both a Phase I award (for proof-of-concept prototype development) and Phase II award (for proof-of-product development and establishing commercial potential). Leveraging initial Phase I and Phase II awards to obtain follow-on funding is undoubtedly critical to successful product development and commercialization.

Two considerations temper the NRC study results. Survey methodology removed award recipients (and their awards) if: they were out of business (*n*=25), lacked an email address (*n*=893), or had defunct email addresses (*n*=500). From the 6,408 firms in the sample, 4,523 firms (71%) had working email addresses, and 1,916 (42%) of the firms responded. It is a reasonable conjecture that firms without working email addresses (which may even signify that the company is no longer in business) did not introduce commercial products consequent to receiving Phase II SBIR awards. It is also reasonable to conjecture that firms that *did* respond to the survey were more likely to have introduced a commercial product than contacted firms who *did not* respond. If either or both of these conjectures were supported, then the excellent transfer efficiencies (49% minimum to 71% maximum) obtained for the five SBIR programs would be upwardly biased.

It should also be determined whether AT manufacturers pursue SBIR grants from acquisition-based SBIR programs (such as DOD, NASA, and portions of the DOE) or non-acquisition-based SBIR programs (such as NIH, NSF, and portions of the DOE). Agencies with acquisition-based SBIR programs often serve as the primary market for commercial products consequent to their SBIR Phase II grants. As a consequence, it is reasonable to conjecture that transfer efficiency for acquisition-based SBIR programs will be higher than the transfer efficiency of non-acquisition-based SBIR programs.

Transfer Latency

Transfer latency can also be tied to critical events such as (a) the time required for an idea to result in a commercial product, or (b) the time required for a proof-of-concept prototype to result in a commercial product. An example of transfer latency is the average time between the issuance of a university patents (proof-of-product event) and the resulting commercial product. Transfer latency also provides a useful basis for comparison between two or more TTIs or between TT systems.

For example, in 2006, patent applications were filed for more than 60% of university invention disclosures (Association of University Technology Managers, 2007). There are significant latencies from invention disclosure to patent application, from patent application to patent issuance, and from patent issuance to license. In fact, most patented technologies are never licensed (Government Accounting Office, 1998).

An old study estimated the latency from technology license to the introduction of a commercial product (when successful) to be eight years (Ditzel, 1991). Survey results of university TTO and industry technology licensees found that licensed technologies require further development (asserted by 88% of TTO respondents and 84% of industry respondents) and that licensed technologies are no more than proof-of-concept (asserted by 45% of TTO respondents and 44% of industry respondents). Industry respondents to the survey indicated that for 40% of technology licenses university inventors assisted further development (Thursby & Thursby, 2002). A large portion of university technologies are licensed through exclusive and non-exclusive agreements to start-up companies (16.7%) or existing small companies (50.7%). These results should encourage AT manufacturers who are predominantly small businesses (Association of University Technology Managers, 2007).

Transfer latency for university technologies has two logical phases. The first phase comprises roughly the period from technology disclosure through technology licensing. University TTO activities can

greatly shorten or lengthen this first latency through services to faculty and potential licensees. The second phase comprises roughly the period from technology licensing to product commercialization. A university TTO can support a manufacturer's product development through faculty consulting, contracted research and development, industry and university consortia, etc. University TTOs that effectively support product development will increase the rate of product commercialization and shorten the second latency.

Macro and Micro Perspectives on TT

Thus far we have described the dynamic aspects of TT, push and pull transfer strategies, and their impact on TT efficiency and latency. TT can and should also be viewed at large (macro) and small (micro) scales. A large-scale view pertains to the activities and performance for entire systems or large portions thereof. A small-scale view takes into account the activities and performance of individual actors within these systems. For example, a federal laboratory system might comprise all Department of Energy labs and its associated offices of research and technology applications (ORTA), Federal Laboratory Consortium (FLC) for TT contractors, and manufacturing partners. System actors include individual labs, ORTA, FLC contractors, and manufacturers.

Macro Scale

In analogy to macroeconomics, TT, at a macro-scale examines aggregate activities that are common to large TT systems. Aggregate data is used to construct system-level models, to identify trends, and to make forecasts. In terms of the TT model, aggregate activities can often be associated with critical events (idea, proof-of-concept prototypes, proof-of-product, commercial products).

For example, many public and private entities collect and analyze macro-level data pertaining to universities, federal laboratories, and SBIR programs. These entities include the U.S. Congress' General Accountability Office, the DOC, SBIR, the NRC, and professional organizations such as the Association of University Technology Managers (AUTM).

AUTM annually surveys its membership, which includes TT offices of U.S. research universities, hospitals, and institutes. From each TT office AUTM collects information regarding the amount of funding revenues, type of funding revenues (public or private). It also gathers data on the number of disclosures, patent applications filed, patents granted, intellectual properties licensed, equity positions taken, and revenues generated. Survey data provides a basis for macro evaluation of relative and aggregate transfer efficiencies and transfer latencies for U.S. universities.

The 2006 AUTM Survey found that TTOs at research universities comprised 85% (n=161 of 190) of survey respondents. Some universities had two or more TT offices (e.g., at medical centers). As a consequence, the 161 TTOs are part of 116 U.S. universities, and these 116 universities comprise 84% of U.S. universities receiving $20 million or more in research funding (Lombardi, Capaldi, & Abbey, 2007). In 2006, AUTM reported that 161 university TTOs executed 4,192 licenses or options (n=1,622 exclusive; n=2,570 non-exclusive) with startups (n=698), small companies (n=2,127), and large companies (n=1,327). To refill the technology licensing pipeline, TTOs reviewed 18,874 technology disclosures, prepared and filed 11,622 patent applications, and were awarded 3,255 new patents. Total revenue for research was $45.4 billion in 2006. From 1997 to 2006 industry grants and contracts accounted for 8% of all university research revenue, peaking at 10% in 1999 and tapering off to 7% for 2003 through

2006. Federal, state, and other sources account for the bulk of research revenue, with federal grants averaging about 65% of the total for the period 1997 through 2006. For the fiscal year 2005-2006, university licensing accounted for $1.3 billion in revenue generation for the universities themselves (AUTM, 2007).

Firms licensing university technologies often invest substantially in infrastructure and staffing in order to carry out development activities. Induced investment is especially great for start-up firms and to a somewhat lesser extent, pre-existing small businesses. Firms must also pay universities for technology use, according to the terms of their licensing agreements. An MIT study estimated the ratio of induced investment to licensing revenue to be 24:1 (Pressman et al., 1995).

The breadth of macro-level information obscures that university TTOs often focus their efforts on revenue generation and the transfer of 'homerun' technologies. It is still a common practice for many university TTOs to patent and subsequently make available for licensing only those technologies they feel likely to generate significant revenues. This narrow perspective fails to account for licensing's much greater impact (a ratio of 24:1) in the private sector, or the broad mandate that federally sponsored research should benefit society (Table 2). The Bayh-Dole Act of 1980 also encourages "maximum participation of small business firms." A narrow university policy to maximize TT revenue (licensing, equity buyouts) is likely to be in direct conflict with this sub-objective. Specifically, the Bayh-Dole Act notes:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area. (Title 35, Part II, Chapter 18, § 200 Policy and Objective)

In addition to university resources, the private sector (AT manufacturers) can tap into federal laboratories through Cooperative Research and Development Agreements (CRADA) or contracted research. CRADAs were first created under the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal TT Act of 1986 (Federal Laboratory Consortium, 2006). There are two types of CRADAs. For *cost-shared* CRADAs the government owns the original intellectual property (IP) and the firm wishes to co-develop commercial applications that are based on this IP. For *cost-in* CRADAs the firm owns the original IP and wishes to co-develop commercial applications. In both cases, firms gain access to and leverage the federal laboratory's extensive technical infrastructure and expertise. The firm and government normally share joint-ownership

of any new IP produced under either CRADA. The firm retains exclusive rights to use the new IP for commercial applications. The federal agency has rights to use the new IP for internal use and cannot sub-license the new IP to another commercial partner (T^2RERC, 2005).

CRADAs generally apply when new IP is likely to address an agency's mission-critical needs. The firm pays for work carried out under the CRADA at a negotiated rate. From a lab's perspective, the negotiated rate is impacted by the value of the original IP (for cost-in CRADAs), the new IP developed under the CRADA (shared or cost-in) and the firm's technical contribution. Under contract research, the federal laboratory simply carries out research activities as specified by the firm. The firm retains ownership of any old or new IP and pays for all work carried out by the federal laboratory. Negotiated rates for contract research are likely to be higher than negotiated rates for CRADAs because contract research does not address mission-critical needs, there is no joint ownership of new IP, and the lab does all of the work.

Data is lacking, however it is likely that few AT manufacturers have worked with federal laboratories through CRADAs or contract research (DOC, 2003). As a potential explanation, original IP owned by an AT manufacturer, or new IP developed under a CRADA for this manufacturer, is unlikely to address an agency's mission-critical needs. An AT manufacturer's expertise in applied research for product development is unlikely to be valued by federal laboratories whose focus is basic research. As a consequence, federal labs are likely to have little interest in working with AT manufacturers and negotiated rates for CRADAs or contract research are likely to be high.

In principle, technology licensing provides another avenue for firms to access technologies developed in the federal laboratory system. The Federal Laboratory Consortium (FLC) Locator Service is the principle gateway to laboratory technologies. In using the FLC Locator Service, firms are asked to provide background information and to describe their technology needs. Full and detailed disclosure helps to narrow the search and to ensure that whatever technologies are found closely match the firm's described needs. The Locator Service and federal laboratory ORTA treat each firm's requests as proprietary and confidential (Federal Laboratory Consortium, n.d.).

The FLC Locator Service is an excellent resource for all manufacturers. However, laboratory technologies generally need additional research before an application idea can be embodied as a proof-of-concept prototype (proof of product, commercial product). The originating laboratory is likely to have the expertise and capacity (including the scientist who conducted the research) to assist the firm. However, this assistance can only be obtained through CRADAs or contracts. The drawbacks for these mechanisms, especially for small businesses, have already been outlined.

Micro Scale

In analogy with microeconomics, TT at the micro level looks at activities of individual actors within a TT system. Activities are considered for their impact on that actor's TT performance. In terms of the TT model, individual activities often lead to intermediate outcomes consequent to major events. For example, prior to a technology patent being issued a TTO might solicit technology disclosures, screen technologies (patent searches, public benefit, commercial potential, etc.) and prepare patent applications. Examination of intermediate outcomes and how they are achieved can indicate why the

performances of individual TTIs are exceptional or unexceptional.

For example, data gathered from the AUTM 2006 Annual Survey suggests that the University of Minnesota is a leader in both research and TT outcomes. According to this survey, in 2006 the University of Minnesota ranked fifth in license royalties ($57 million), twenty-sixth in new patents issued (n=28), ninth in new licenses and options (n=83), and fifteenth in research expenditures ($594 million). Given the relative success of the University of Minnesota, other university TTO might benefit from their insights pertaining to effective TT strategies (Association of University Technology Managers, 2007).

At the AUTM 2006 Annual Meeting, the University of Minnesota presented their findings on TT activities most valued by manufactures. In rank order manufacturers valued: (a) access to undergraduate students, (b) access to graduate students, (c) faculty consulting, (d) continuing educational opportunities, (e) university-industry consortia, (f) industry-sponsored research, and (g) technology licensing (Sommerstad, 2006).

Interestingly, undergraduate and graduate student placements and continuing education help manufacturers to assimilate new knowledge and build capacity for research and development. Industry-university consortia, faculty consulting, and industry-sponsored research are demand-side strategies, which is to say that manufacturers identify market needs and business opportunities *before* establishing university collaborations to develop technology solutions. In each case, intellectual property rights, licensing, non-disclosure, and delayed publication can be negotiated between the manufacturer and university up front. Technology licensing, a supply-side strategy, was least valued by manufacturers.

Erik Sander, then at the University of Florida, wrote an excellent overview pertaining to industry and or university research centers (Sander, 2000 September). In this overview, he argues that manufacturers benefit from participation in industry and or university partnerships through (a) their access to bright energetic students, (b) gaining early looks at emerging research and technologies, (c) leveraging of industrial investments, (d) faculty mentoring, (e) access to the university research infrastructure, (f) capacity building through industrial-academic researcher networks, and (g) obtaining favorable intellectual property rights as a center participant. Many USDE-funded RERCs and the NSF funded Quality of Life Technology [Engineering Research] Center conduct collaborative research and development activities with AT manufacturers (Quality of Life Technology Center, n.d.).

Industry and or university collaborations allow university faculty and students to work closely with practicing engineers and scientists solving real world technical problems while exposing them to the culture and constraints of business. Collaborations enrich the students' educational experience and help to prepare them for future employment in the private sector. Collaborations also provide a practical education to faculty, enhance course curriculums, and serve as catalysts for future research and grants.

University TTOs must understand and be responsive to the cultures and values of both business and academe. At some risk of overgeneralization, firms conduct applied R&D to develop products and services; they protect knowledge through non-disclosure, patents, trade secrets, and copyrights; they generate revenue through sales, service contracts, and warranties; and they operate with tightly structured management, organization, scheduling, and timeframes. Firms differ in their resources, R&D capacity,

product portfolios and markets, aggressiveness developing new and improved products, interest in technologies from external origins, use of SBIR and other funding sources, and use of sub-contractors.

Academes (a) conduct basic research to develop new knowledge; (b) disclose knowledge through journal publications and conferences; (c) acquire revenue through grants; (d) mentor, train, and educate students; and (e) operate within loosely structured management, organization, scheduling, and timeframes. Faculty tenure and promotion is often tied to research publications, teaching, grantsmanship, and service rather than technology disclosure, patenting, licensing, or revenue.

To bridge the gap in values and cultures between the private sector and academe, TTO activities must be responsive, transparent, accessible, efficient, consistent, fair, and professional from the perspective of both manufacturers and academe. A university and its TTO might increase faculty awareness of business culture and TT processes and policies through education and training. A university and TTO may also adopt strategies to foster entrepreneurship, tie tenure and promotion to technology disclosure, patenting, and licensing, and reward faculty through license revenue sharing. Universities might strive to optimize their combined TT (licensing, equity buyouts) and research (state, federal, and industry) revenues rather than treating them as separate and independent.

During its 2003-to-2008 funding cycle, the T²RERC conducted three TT projects to facilitate product development and commercialization, benefiting persons with disabilities and elders. A qualitative comparison of the Demand Pull project, the Supply Push project and the Corporate Collaboration project is presented in Table 3.

It is useful to compare these projects. Both the Demand Pull and Corporate Collaboration projects employ demand transfer strategies. Demand transfer strategies can be compared to discharging a rifle. If you chose your target well and aim carefully, you have a high likelihood of hitting your target.

The Demand Pull project has long transfer latency with somewhat lower transfer efficiency. As explanation the Demand Pull project (typically) works with innovations 'leftward' on the TT model with many barriers to overcome. The (typical) small companies participating in the Demand Pull project have limited resources with which to overcome these barriers. In many cases, the T²RERC co-developed SBIR grants with these firms to help overcome these barriers.

The Corporate Collaboration project works

Table 3
Comparison of T²RERC TT Projects

Project	Technology Status (source)	Transfer Strategy	Technology Source	Technology Destination	Transfer Latency	Transfer Efficiency	Exemplar Technologies
Demand Pull	*Technology Research* to early *Product Research*	Pull	federal labs, universities, small companies	AT small company	Long (~3-4 yrs)	Mid	VisiPrint print management software, PowerCheq™ battery string equalizer
Supply Push	*Product Research*	Push	Independent inventors, small companies	AT small company	Mid (~2-3 yrs)	Low	Strong Arm™ Cane, Bumpa Coloring Book
Corporate Collaboration	late *Product Research*	Pull	knowledge transfer from T²RERC	collaborating large corporation	Short (~1 yr)	High	Black & Decker Jar Opener

with large corporations developing innovations already very close to the marketplace and with few barriers to overcome. The collaborating corporations (typically) have tremendous resources with which to overcome barriers and commercialize products. In addition, large corporations in highly competitive markets will (typically) have shorter product development cycles than small companies serving less competitive AT markets.

The Supply Push project used a supply transfer strategy, which can be compared to a shotgun approach. You aim at *likely targets* and fire. In terms of an analogy to a shotgun, some of your shot will hit the target, but much of the buckshot is likely to fly astray of the target. The term likely targets is critical. TTI very familiar with their corporate partners, their markets, technology needs, product portfolios, capacities, and inclinations will be much better at identifying likely targets. Such was the case with the Supply Push project. This project had the lowest transfer efficiency and intermediate transfer latency. As an explanation, the Supply Push project (typically) worked with innovations at a proof-of-product, or more 'rightward,' stage of development.

The effectiveness of the T^{2}RERC as a TT intermediary derived from a number of factors. However, the most influential of these factors was the project personnel's broad knowledge and experience related to development and commercialization activities. First, the team employed its marketing expertise to conduct primary market research using interviews, focus groups, and surveys. It also applied this expertise to perform secondary market research by analyzing competing products, markets, demographics, legislation, and reimbursement. Second, the team utilized engineering skills to apply customer-centered, universal and transgenerational design principles while engaging in collaborative product development. Finally, business management skills were called upon for brokering activities such as negotiations, contract development, and licensing.

Primary market research (i.e., focus groups, panels) was conducted in a state-of-the-art facility at the Western New York Independent Living (WNYIL) center. WNYIL facilitated sampling and recruitment by maintaining a large database comprised of elderly people and people with diverse disabilities. Several personnel were expert in scripting, running, and analyzing data derived from panels and focus groups. Primary market research was integral to customer-centered design and subsequent product validation.

Customer-centered design (CCD) is a best practice. It entails involving consumers in all phases of product definition, design, development, evaluation, and marketing. CCD maximizes commercial potential by helping to ensure that products are well designed, properly priced, and that they serve broad markets. CCD reduces design iteration, saving the manufacturer time, resources, and costs during product development. CCD was commonly used in the Supply Push and Corporate Collaboration projects.

The Demand Pull project transferred technology solutions to AT manufacturers to address critical market needs. Comprehensive primary and secondary market research was conducted to identify critical needs. That research was subsequently compiled into industry profiles — on learning disabilities, wheeled mobility and low vision and blindness — and published online (T^{2}RERC, n.d.c). Demand Pull project personnel also co-wrote about a half-dozen funded SBIR proposals with partner manufacturers. Funding from SBIR grant awards helped (and is helping) to bring several AT products to market.

Project personnel were members of major trade and professional associations and participated in their annual conferences, including Assistive Technology Industry Association, MedTrade, International Seating Symposium, American Academy of Audiology, and the Rehabilitation Engineering and Assistive Technology Society of North America. Membership and participation helped personnel to maintain awareness of emerging technologies, products and markets, and to build an extensive network of responsive contacts.

Project personnel were also members of, or participated in, the annual conferences of the AUTM, FLC (national, regional), and the TT Society. Here membership and participation also provided an opportunity to acquire and to disseminate TT knowledge and practices.

As a TTI, the T^{2}RERC made micro-level adaptations to address the specific needs of its transfer partners. For example, AT manufacturers underutilize primary market research and CCD in product design, development, testing, validating, and marketing. Both AT manufacturers and mainstream manufacturers lack access to people with disabilities. In the U.S., published primary and secondary research pertaining to disability markets and industries is fragmentary and or costly to obtain. This dearth of data stultifies private sector innovation, new product development, and the ability to attract investment. AT manufacturers underutilize SBIR grants to fund product development. Mainstream manufacturers have not taken full advantage of transgenerational design as a strategy by which to broaden, deepen and retain markets. Finally, AT manufacturers underutilize universities and federal laboratories as technology sources (DOC, 2003). The three T^{2}RERC transfer projects were conceived and refined to address these gaps and needs (T^{2}RERC, n.d.a.).

Outcomes and Benefits

This article reviews Lane's TT model. A case study (LC Technologies Eye Gaze System) demonstrates model concepts that include critical events, activities, stakeholders, and resource providers. TT intermediaries and resource providers play central roles as facilitators to TT processes. Examples of TTIs (*with principle activity impacted*) include federal granting agencies (*Technology Applications*), agencies administrating small business innovation research grants (*Technology Research*, *Product Research*), angel investors (*Product Research*), and venture capitalists (late *Product Research to Product Commercialization*).

This model does not address the dynamic aspects of TT, which relate to transfer efficiency and transfer latency, transfer scale (micro, macro); nor does it fully develop the role of TTI. Lane views demand pull and supply push as forces that initiate TT activities. The current paper proposes that TT intermediaries employ demand pull strategies or supply push strategies to *facilitate* TT activities.

Working definitions were given to common terminology including: innovation, context (source, destination), and transfer mechanisms. Using this terminology, TT was defined as the movement of an innovation from a source context to a destination context via some transfer mechanism. Major concepts discussed include transfer efficiency, transfer latency, push transfer and pull transfer strategies (employed by TTI) and micro- and macro- scales. AT-related examples were used to illustrate important concepts.

Studies have been conducted to evaluate large and important TT systems (U.S. universities, federal laboratories, small business innovation development programs and RERCs). In these studies, transfer efficiency was discussed for universities (AUTM, 2007) and SBIR

programs (Wessner, 2008, DOC, 2003) and transfer rate was discussed for universities (Pressman & et al., 1995; T²RERC, n.d.d).

TT was also examined at different scales. Discussions around the studies by AUTM, NRC, MIT, and RERC all focused on macro-scale issues. Discussions around the University of Minnesota Pulse Survey of manufacturer interests and T²RERC project descriptions focused on micro-scale issues.

Data gathered and analyzed in macro-scale studies does not address or substitute for a clear understanding and practice pertaining to micro-scale issues. The AUTM (2007) study presented aggregate data on intermediate outcomes (disclosures, patent applications), the proof-of-concept event (patents granted) and intermediate outcomes subsequent to patenting (exclusive, non-exclusive licensing). However, it is unclear what percentage of licenses result in proof-of-products or commercial products. Economic impacts (product sales, induced investment) are also unclear. Data regarding the average latency from disclosure to patent application, patent application to patent, or patent to license are lacking.

The MIT (Pressman et al., 1995) study suggested that induced investment (ratio of private investment to licensing revenues) consequent to university technology licensing is 24-to-1. However, the AUTM (2007) study neglects the broader economic and social impact of transfer activities (as required under the Bayh-Dole Act). Instead it focuses on revenue generation (primarily) as a consequence of licensing and equity buy-outs. In particular, firms serving small disability markets may not fully benefit from university licensing activities.

A number of strategies might be adopted to balance a university's narrow interests against society's broader interests. Here are a few examples. Universities could reduce or eliminate license royalties (and other fees and payments) for small market technologies. Patent applications could be filed for all novel (screened for due diligence) technology disclosures. This suggestion is not particularly radical, given that more than 62% of university technology disclosures currently result in patent applications. A 'timer' could be employed whereby intellectual property rights are waived back to the inventor if a technology is not licensed in some reasonable period. Societal metrics could be employed to justify transfer policies and practices. State and local revenue sharing might reward universities for positive economic outcomes consequent to their TT activities (and fund subsequent efforts). Universities could adopt metrics that emphasize both total research revenue and industry-based research revenue. Public legislation could require university TT performance be judged (at least in part) against economic impact.

The MIT study (Pressman et al., 1995) discussed transfer latency in terms of the average age of MIT technology licenses. The average MIT technology license was about four years old while product commercialization was expected to take about eight years. In general, university TTOs should adopt and be rewarded for practices that both maximize transfer efficiency and minimize transfer latencies (pre- and post-patent). To shorten post-transfer latencies, universities should adopt policies and practices to support (by speeding and reducing costs of) the licensee's efforts to develop (new) proof of concepts and proof of products. The University of Minnesota Pulse Survey and subsequent discussion of industry and university research centers identified (exemplar) services and support sought by manufacturers.

The RERC study (T²RERC, n.d.b) showed that USDE-funded Rehabilitation

Engineering Research Centers (sample of 11 former centers studied) have low transfer efficiencies. Most RERCs are university-based and TTOs serve as their TT intermediaries. RERCs typically conduct their research, development, and utilization activities in a linear and dependent sequence (a push transfer strategy). These activities normally correspond to needs (technology, service, diagnostic) identified for small disability markets.

RERCs have a five-year funding cycle and utilization activities normally take place in the last year or two of the cycle. With an average post-transfer latency of eight years from a university technology license to the consequent commercial product, one should expect to find (and does find) little evidence for successful utilization. A TTO can exacerbate low transfer efficiency several ways. It may fail to provide outreach or support to their faculty; it may allow (or cause) long pre-patent and pre-license latencies; its transfer strategies may be inflexible or too narrow; and it may demonstrate an exclusive, or predominant, focus on 'homerun' technologies.

RERCs should be a critical knowledge resource, a research and development partner and a technology source for AT manufacturers. To improve transfer efficiency and reduce transfer latency, five strategies might be employed. First, universities should not receive RERC awards until they commit to expedite the transfer of RERC generated intellectual property. The USDE should gain this concession at the grant award site visit.

Second, RERCs should abandon the 'normal' research, development, and utilization sequence. Instead, utilization (market needs, business interest) should be established prior to conducting research and development activities (a pull transfer strategy).

Third, AT manufacturers should be partners on all research and development projects whose intended outcomes are transfer and utilization. AT manufacturers should be active and significant partners from project inception (during proposal development and thereafter), help to establish project objectives, collaborate on research and development activities, and serve as the primary and preferred technology licensee.

Fourth, RERCs should negotiate with their TTOs while preparing their grant proposals. The proposal should include a summary of the negotiations, and it should specify how intellectual property will be handled subsequent to the grant award. In particular, the IP rights and licensing terms and conditions for partner manufacturers should be addressed.

Fifth, RERCs should be required, or strongly encouraged, to work closely and intensively with the Disability Rehabilitation Research Project on Knowledge Translation for TT (Center on KT for TT). The center embodies, and will extend, the micro-level knowledge, experience, and practices of the former and successful RERC on Technology Transfer, which operated over two five year cycles from 1998 to 2003 and 2003 to 2008 (T^2RERC, n.d.e).

The NRC study (Pressman & et al, 1995) evaluated the five largest SBIR programs (DOD, NIH, NASA, DOE, and NSF). Transfer efficiency was stated in terms of the number of commercial products consequent to Phase II grants. The NRC study found a very high transfer efficiency of 49% (minimum) to 71% (maximum) for the five agencies studied. Significant follow-on funding was also consequent to receipt of a Phase II SBIR grant. The NRC study provided the status (ongoing research, discontinued, sales expected, sales not expected, and sales) for technologies

developed with SBIR funding and sales revenues generated.

The NRC study did not provide the average transfer latency from firms' receipt of a Phase I or II SBIR awards to the introduction of commercial products. The NRC study did not classify SBIR awards by type of technology being developed. Sampling biases may have skewed transfer efficiency upward. Firms without a working email address (30%) and their awards were not included in the study. Firms with working email addresses had (only) a 42% response rate. As a consequence, the strong positive findings of the NRC study are somewhat weakened and it is unclear whether findings generalize to AT manufacturers and industries.

The federal laboratory system should be another important knowledge resource, research and development partner, and technology source for AT manufacturers. The FLC locator service is an excellent means by which AT manufacturers can find or pursue development of needed technology. The principle mechanisms available to AT manufacturers include technology licensing, cooperative research, and development agreements and contracts. It is likely that most work carried out by federal laboratories with, or for, AT manufacturers will be through cost-in CRADAs or contracts.

Further study is needed to gauge interactions between AT manufacturers and the federal laboratory system. Future studies may attempt to answer questions such as these: From which federal agencies do AT manufacturers license technologies? With which federal agencies do AT manufacturers enter into CRADAs (cost-in, cost-shared) and contracts? What types of technologies are licensed or developed (requires a classification system)? What factors (barriers, facilitators) influence AT manufacturers licensing, CRADAs, and contract decisions? What factors influence the terms and conditions of CRADAs and contracts?

Most of the studies considered in this paper addressed (albeit incompletely) the macro-performance of large TT systems. However, TTI activities take place at a micro-scale. In order to evaluate the impact of TTI activities on TT outcomes, it is necessary to expand the resolution of the current TT model. The new Disability Rehabilitation Research Project on KT for TT is working to address this need. Specifically, the DRRP is overlaying and synchronizing the Product Development and Management Association (PDMA) product development model to the TT framework. The Product Development and Management Association (PDMA):

> . . . is the premier global advocate for product development and management professionals. Our mission is to improve the effectiveness of individuals and organizations in product development and management. This is accomplished by providing resources for professional development, information, collaboration and promotion of new product development and management. (PDMA, 2010, para 1)

The *PDMA Handbook of New Product Development* embodies the state of the art (Kahn, 2004). The KT for TT is formally mapping carriers, barriers, and best practices to the individual (micro-level) steps of the PDMA model. This work was made publicly available in late 2009 through an online database (http://kt4tt.buffalo.edu/) that is accessible to AT manufactures, TT intermediaries, and other relevant stakeholders.

Finally, where TT processes are concerned, TT intermediaries should be active experts

and facilitators, rather than passive benefactors of TT outcomes. For example, stakeholders served by university TT offices include faculty, students, the university, businesses, the community, and society. However, most stakeholder interests are grossly ignored by applying performance metrics that are narrowly focused on return-on-investment from research dollars. Community, state, and national resources have created university and federal laboratory infrastructures. Scientists working in these institutions are the creators of intellectual property and educators of future members of the workforce. Businesses are the consumers of intellectual property, creators of products, employers and engines of the economy. As a consequence, communities, states, the nation, scientists, students, and business are all critical stakeholders. TT intermediaries have a responsibility to recognize the criticality of these stakeholders and facilitate TT in manner that is maximally responsive to their interests. New and re-enacted TT legislation might reflect these priorities and require the use of more appropriate metrics by universities, federal laboratories, and other covered entities.

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