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The Need to Knowledge Model: A Roadmap to Successful Outputs for NIDRR Grantees

Jennifer L. Flagg, BS & Michelle Lockett, MBA

This issue of FOCUS presents the Need to Knowledge (NtK) Model for new product development. The model was designed to encompass all activities from inception of a project through post-launch evaluation to paint a complete picture of the research, development, and production processes. This technical brief explains the details related to the model's stages and gates, while also introducing four specific opportunities to employ knowledge translation techniques.

After a yearlong literature review, the University at Buffalo's Center on Knowledge Translation for Technology Transfer (KT4TT) has unveiled a new product development model designed to show researchers and product developers the ins and outs of bringing new devices and services to market. Encompassing all activities from inception of a project through post-launch evaluation, the model paints a complete picture of the research, development, and production processes. It also offers step-by-step guidance regarding what actions should be considered throughout the life cycle of a project (Center on KT4TT, 2010).

The Center coined the name "Need to Knowledge" (NtK) Model because it identifies unmet needs that lead to the generation of knowledge in the form of a research discovery, prototype invention, or product innovation. Regardless of the state of the intended technology-based output, unmet consumer needs drive all work. The model blends best practices from *The PDMA Handbook of New Product Development*, 2nd ed. (Kahn, Castellion, & Griffin, 2005), Campbell and Stanley's research process (1963), and Ian Graham et al.'s Knowledge to Action (KTA) Model (2006) for knowledge translation.

The NtK Model employs a stage-gate framework. There are limitations to the stage-gate approach; however, it is favorable to apply a simple model rather than neglect planning for the many complex options that arise throughout the new product development process. In the words of Carl Jude Schramm (2008), "It is better to travel an illuminated path toward future economic progress than to stumble in an unlit direction" (p. 9). Within the stage-gate framework, the model is segmented into three broad phases of activity and nine discrete stages. The three broad phases—Discovery, Invention, and Innovation—represent the unique

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outputs that result from research, development, and production activities (Lane & Flagg, 2010). The nine discrete stages span from defining the initial problem and solution through a final post-launch review, and each of the nine stages is followed by a decision point, or "gate." These gates provide opportunities for evaluation, where critical choices determine whether to move a project forward or abandon it. Evaluation criteria employed at each gate will differ as an investigator moves through the new product development process.

Every stage contains a series of steps and associated tips that offer more detail regarding the activities to complete at that time. Steps and tips are supported by findings from the literature that substantiate the model. These findings also provide additional guidance regarding models, methods, and measures that may be helpful when attempting to perform a step. The remainder of this *FOCUS* Technical Brief presents screen shots from the online version of the model and systematically walks through the stages, steps, and tips in the model. Decision gates and possible courses of action are identified, as are opportunities for knowledge translation. Findings are currently undergoing a secondary analysis and will be explored in a future *FOCUS* Technical Brief.

The NtK Model is the first of its kind to operationalize knowledge translation (KT) activities for new product development, and therefore requires some explanation. Knowledge translation has historically focused on interactions between researchers and knowledge users to ensure that scientific research knowledge is put into practice (CIHR, 2004). Working definitions of knowledge translation involve the collection, quality appraisal, synthesis, and adaptation of knowledge generated via research methods into forms that are relevant to their target audiences (National Center for the Dissemination of Disability Research, 2005). However, in the context of new product or service creation, knowledge translation involves the transition of knowledge between three states—discovery, invention, or innovation—each being the output of distinct method-based processes. The state-based knowledge is then communicated for use by any number of stakeholders (consumers, clinicians and care providers, policy makers, brokers, other researchers, or manufacturers) relevant to that knowledge state. There are four specific instances in which adaptations of the formal KTA Model will be particularly useful, each instance occurring at the end of a phase, when the knowledge-state outputs may be handed off to others to carry them through the remainder of the process. These instances and adapted models are described in more detail within this technical brief at Gates 3, 6, and 7.

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Step-by-Step: Using the Model

Phase I: Research Activities Generate Discovery Outputs

Figure 1 provides a screen shot of Stage 1 of the Need to Knowledge Model, which is available on the Center on KT4TT's Web site:
kt4tt.buffalo.edu/knowledgebase/model.php

The model can be condensed by clicking on the "Hide All" links found under the Steps and Tips column headings. A link for "Supporting Evidence" is displayed after every stage and all supported steps and tips. When this link is selected, a new web page will appear displaying primary and secondary literature findings relevant to that specific stage, step or tip. Navigation tips for the online model will be the topic of an upcoming webcast scheduled for September 29, 2010. Visit the NCDDR to stay informed about webcast dates and times at **www.ncddr.org/webcasts/index.html**

As shown in Figure 1, Stage 1 (Define Problem and Solution) of the NtK Model involves defining a problem and a solution, with steps revolving around

Figure 1: Screen Shot of Discovery Phase, Stage 1/Gate 1

Stage/Gate	Steps Hide all	Tips Hide all
Discovery Phase		
Stage 1: Define Problem and Solution [Supporting Evidence] Pill crusher example  	• 1.1 Opportunity for KT: Assess needs for device or service with input from relevant stakeholders from the six knowledge user (KU) groups. [Supporting Evidence] • 1.2 Identify a problem (need). Identify audience for solution. Identify context for both. [Supporting Evidence] • 1.3 Propose plausible solution (goal) to problem in the form of a device or service. [Supporting Evidence] • 1.4 Determine scope of project (role); output as conceptual discovery, prototype invention or device/service innovation? [Supporting Evidence] • 1.5 Consider path to market. [Supporting Evidence]	• Limit disclosure of information regarding solution and document all original thinking related to solution). [Supporting Evidence] • Scope of project determines segments of KT4TT model involved with research generating discovery, development generating invention and production generating innovation level outputs. [Supporting Evidence] • Consider resources, timelines, and partners when defining path to market. [Supporting Evidence]
Gate 1: Idea Screen. PI decides to either terminate or move forward with project to develop solution to problem. [Supporting Evidence]		

planning activities. The first step requires meeting with relevant individuals and organizations to identify unmet needs. Ideally, these discussions will include stakeholders from each of six knowledge user groups: consumers, clinicians, manufacturers, brokers, policy makers, and other researchers. At this stage, investigators should be cautious to limit the amount and type of information disclosed, and will benefit from documenting all original ideas. After identifying unmet needs, the next step is to define a specific focus area consisting of a problem to solve, an interested target audience, and its related context. The third step is to propose a solution to the problem in the form of a device or service. It is important to note that although some investigators may not intend to be involved in activities subsequent to the research phase, they should be mindful of the eventual goal of their work—to have their research-based knowledge used by relevant stakeholders.

The last two steps in Stage 1 involve making significant decisions regarding the device or service's path to market; the investigators' roles in the project; and the resources, timelines, and partners that will help move the project toward commercialization. This stage also is the first opportunity to consider whether new research-generated knowledge is needed to solve the identified problem. A more in-depth review of whether the project requires producing new research-based knowledge versus moving existing knowledge directly into development or production will take place at Gate 2.

After Stage 1, the NtK Model provides the first decision point, or gate. At Gate 1 (Idea Screen), investigators determine whether they have interest in pursuing a solution to the identified problem, and whether doing so will be feasible in light of potential resource availability. If there is a go decision made at Gate 1, then the project moves on to Stage 2. The remainder of Phase I (Stage 2, Gate 2, Stage 3, and Gate 3) is not graphically represented in this document but can be viewed on the KT4TT website previously mentioned.

Stage 2 (Scoping) involves exploratory work that validates the innovativeness of the solution and its value to the target market. Having conceptualized a solution to a problem that meets the needs expressed in Stage 1, the investigators should now define the innovation opportunity. Relevant questions include the following: Will the solution use an existing technology in a new way? Will it require developing a new technology? Should it be introduced as a radical innovation or through incremental changes? While pondering these questions, investigators should also consider the positioning strategy of the device or service. Pertinent questions may include the following: What products are currently used by the target population to meet this need? With what brand names will my device or service be competing? What aspect or feature of this device or service will attract potential customers?

After defining the innovation opportunity and reaching a basic understanding of the device or service's positioning strategy, the next step is to assess the idea from market, business, and technical perspectives. Stakeholders should be involved in these preliminary valuability assessments to ensure that input is gathered from a wide range of backgrounds. The market assessment should include a clear picture of the device's or service's value proposition. This assessment involves considering potential price and performance options. In addition, serious consideration should be given to the amount of time required to reach the marketplace—and if the proposed device or service will still have value for consumers by the time it becomes commercially available. The business assessment should review internal factors that might affect the success or failure of the project. A "SWOT" analysis is often conducted at this time to assess an organization's Strengths, Weaknesses, Opportunities, and Threats in relation to the project. Finally, the technical assessment should consider whether the device or service is technically feasible, and whether the organization or its collaborators have the capabilities to produce it. Following the valuability assessments, barriers should be assessed to identify potential roadblocks that may be overcome or obviated by additional preliminary work.

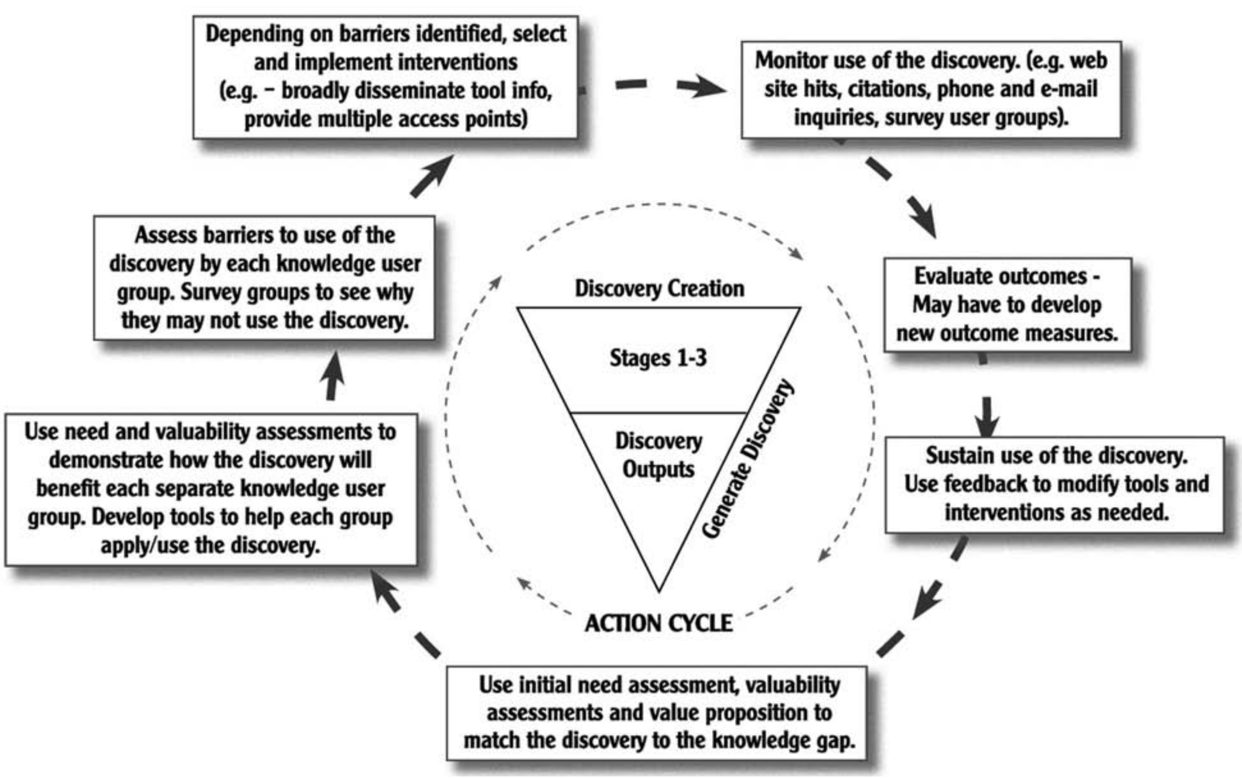
The market assessment should include a clear picture of the device or service's value proposition. This assessment involves considering potential price and performance options. In addition, serious consideration should be given to the amount of time required to reach the marketplace—and if the proposed device or service will still have value for consumers by the time it becomes commercially available.

Gate 2 (Second Screen) provides an opportunity to review the findings from the valuability assessments and potential barriers. If the assessments are unfavorable, the project may be terminated before further resources are invested. If the assessments demonstrate viability of the project, it may move forward in one of two directions: either toward research or toward development activity. The proposed solution may require the generation of new research-based knowledge prior to initiating any development activities. In this case, investigators should proceed to Stage 3 to conduct research and generate research-based discoveries. However, projects often move directly to the development phase because no new research-based knowledge is required.

Research-based knowledge lending to the solution may have been produced through prior research activities, or may simply not be required to effectively meet consumer needs. Investigators should weigh these decisions carefully to avoid spending precious resources on unnecessary stages and steps. Depending on the decisions made, this gate may be an appropriate time to begin developing grant proposals to acquire project funding. The work conducted in Stages 1 and 2 offers a solid platform upon which to base the proposal, and the beginning steps in Stage 3 will provide additional detail for any proposed research activities.

Stage 3 (Conduct Research and Generate Research-Based Findings) consists of formal research activities. The first step in this process is assembling a transdisciplinary team with the necessary research expertise, such as topic experts and individuals with knowledge of research methods and statistics. Next steps will involve defining the purpose of the research and filling "knowledge gaps," which are bits of unknown but needed information. To fill such gaps, investigators must choose a particular research methodology. At this point, there should be enough information to finalize any grant proposals intended to fund this part of the project. Once funding is acquired, the research can begin. Conducting the research may include recruiting research participants, collecting and analyzing data, as well as monitoring and refinement activities. Once the study is complete, the next step is to disseminate the new knowledge from the conclusions and findings. However, care should be taken when disclosing research results at this stage. Publishing pertinent information could start a time bar that may affect the organization's ability to patent its research discoveries and, thus, influence competition (Leahy, 2009).

Figure 2: Discovery Outputs



Adapted from: Graham et al., 2006

After Stage 3 is complete, the project team proceeds to Gate 3 (Begin Invention Phase?), which provides the first opportunity to employ knowledge translation techniques using the modified KTA Model. At Gate 3, the team considers whether the research discovery has merit. If it does and the team decides to move on to development activities, they may immediately proceed to Stage 4. However, they may decide not to move on to Stage 4 for two possible reasons; 1) the research did not produce fruitful results or 2) the project investigator did not intend to go past the research phase. In both situations, Knowledge Translation should be used to effectively communicate the research findings. This will enable them to share lessons learned from situation number 1 or to progress toward the commercialization of a device or service in situation number 2. In both of these instances, KT activities can help ensure that time is not wasted duplicating prior work or stumbling over barriers that could have been prevented or overcome. Figure 2 depicts knowledge translation activities for discovery outputs using Graham et al.'s KTA Model (2006).

A good place to begin the knowledge translation process is by taking stock of what information has already been collected and developed in relation to the project. The valuability assessments can be particularly helpful when persuading another entity to take on a project. Depending on the project's goals, this may also be a good time to survey potential knowledge users to determine how they see the discovery fitting into their context. For example, is the potential knowledge user a manufacturer, who might proceed to develop an invention? Or another researcher, who might like to conduct further research on the discovery? Conducting an assessment of barriers that potential knowledge users may encounter when trying to apply the knowledge can help to develop mitigating strategies that either party can apply. If the project team identifies significant barriers to use, it may consider implementing interventions to ease the process of adoption and the use of the knowledge.

After disseminating the knowledge via multiple forms of media, the project team may consider monitoring uptake and use. In addition to traditional mechanisms such as surveys, phone calls, and e-mail inquiries, a variety of software is available to track Web site usage and downloads. When making follow-up contact, teams should solicit feedback and take it into account. They should seek evidence of usage, which can be particularly helpful when reporting results to funding agencies. Additionally, both positive and negative feedback can be used to help shape future efforts and encourage sustained use of the knowledge. A Table for Discovery Outputs on the Center on KT4TT's Web site details the types of knowledge that may interest the six knowledge user groups, provides suggestions on how to reach each knowledge user group, and anticipates knowledge translation outcomes. The table is available at: **kt4tt.buffalo.edu/knowledgebase/discoverytable.php**

After disseminating the knowledge via multiple forms of media, the project team may consider monitoring uptake and use. In addition to traditional mechanisms such as surveys, phone calls, and e-mail inquiries, a variety of software is available to track Web site usage and downloads.

Phase II: Development Activities Generate Invention Outputs

Figure 3 displays a screen shot of Stage 4, the first stage of the Invention Phase of the NtK Model. Please note that some tips have been purposely excluded in this graphic due to document size constraints. The entire list of tips can be viewed on the KT4TT website. Stage 4 (Build Business Case and Establish Development Plans) consists of a wide range of activities, the first of which is identifying key co-development partners, including both external partners and internal teams. After identifying a group of potential external partners, the project team should assess their fit with the project's needs. In particular, the team should consider an organization's capabilities, resources, and past track record. Once the project team has selected external partners, it can establish formal relationships via contracts. Depending on the project, these contracts may include confidentiality agreements, terms of intellectual property ownership, and scope-of-work

Figure 3: Screen Shot of Invention Phase, Stage 4/Gate 4

Stage/Gate	Steps Hide all	Tips Hide all
Invention Phase		
Stage 4: Build Business Case and Establish Development Plans [Supporting Evidence]	• 4.1 Seek key co-development partners. [Supporting Evidence] • 4.2 Propose draft solution. [Supporting Evidence] • 4.3 Outline preliminary business case. [Supporting Evidence]	• Conduct more detailed marketing, technical and consumer assessments based on refined idea for application of discovery. [Supporting Evidence]
	• 4.4 Implement IP strategy in collaboration with technology transfer office or patent attorney. [Supporting Evidence]	• Discuss IP protection options with technology transfer office/patent attorney.
	• 4.5 Assess regulatory, and reimbursement requirements. [Supporting Evidence]	• Develop understanding of design, pricing, and timing implications of requirements imposed by FCC,FDA (510k), HIPPA, Medicare/Medicaid, etc.
	• 4.6 Opportunity for KT: Initiate key co-development practices. [Supporting Evidence]	• Identify and assess external partners. • •
	• 4.7 Assess resource needs and availability. [Supporting Evidence] • 4.8 Develop implementation plan. [Supporting Evidence]	• Review needs for staffing, funding, and time. [Supporting Evidence] • Identify potential distribution outlets.
	• 4.9 Secure resources for development. [Supporting Evidence]	• Obtain funding from SBIR (Phase II) grant or investors.
	• 4.10 Allocate adequate resources. [Supporting Evidence]	• Budget adequate time, money, and expertise. [Supporting Evidence]
	• 4.11 Gather, analyze and prioritize customer needs. [Supporting Evidence]	• Conduct alpha focus groups. [Supporting Evidence]
	• 4.12 Identify device/service features and specifications in light of production capabilities and component costs. [Supporting Evidence]	• External partners and/or internal staff consider feasibility of future mass production of device/delivery of service, and estimate cost versus target price range. • •
	• 4.13 Complete business case. [Supporting Evidence]	• Reconcile preliminary business case with remainder of development plans.
Gate 4: Implement Development Plan? PI or partner considers if the business case has been validated. If yes, move to stage 5. If no, terminate or reiterate. [Supporting Evidence]		

agreements. The project team should also evaluate its internal resources to ensure that staff, funding, equipment, and facilities will be available as needed.

Once the team is in place, members should collaborate to propose a draft solution to the unmet needs that leverages the new (or existing) knowledge. The team should then develop a business case around the solution, which may consist of more detailed versions of the valuability assessments. As more variables are solidified, these assessments can be performed in greater detail. At this stage, the organization should give serious consideration to the project's strategy for handling intellectual property. If the organization is based at a university, it may have a technology transfer office at its disposal that can provide helpful guidance and insight with this process. Options such as patenting and trademarks, as well as plans for licensing or manufacturing a device, should be touched upon in such discussions.

Additionally, many products—particularly medical and assistive technology devices—must comply with a variety of regulations. Paying close attention to requirements set forth by Medicare/Medicaid and the Veteran's Administration, for example, can help secure reimbursement by health insurance providers for a specific device or service making the product more appealing or available to consumers. The Federal Communications Commission, Food and Drug Administration, and Underwriters Laboratory also may impose regulations, depending on the device or service to be produced. Contacting these organizations early to ensure compliance will only serve to speed the manufacturing and sales processes at later stages.

Organizations often use implementation plans to sketch out and track the detailed tasks that will lead to meeting the project's objective. As such, the plan will consider all of the remaining aspects of commercialization from prototype development through distribution. Specifically, the plan should include information regarding the role of partners, timelines, resource allocations, and distribution plans.

The bulk of work performed in Stage 4 can be leveraged when developing grant proposals to obtain additional funding for a project. For example, U.S.-owned small businesses employing fewer than 500 people are eligible to compete for Small Business Innovation Research (SBIR) grant funding. These grants provide $75,000 to $100,000 to prove feasibility of a concept (Phase I), and subsequently offer awards of $500,000 to $750,000 to harden a product and ready it for commercialization (Phase II). At this stage, a Phase I or Phase II grant could be appropriate depending on the state of the technology being developed. However, to receive Phase II funding, an investigator must have successfully completed a Phase I project.

Regardless of the specific phase, the valuability assessments will be particularly helpful when shaping the specific aims, significance, and background sections of an SBIR proposal. Additionally, the implementation plan, partner agreements, intellectual property strategy, and information regarding regulatory requirements all provide key details to shape the work/research plan. Once funding has been acquired—through grant funds, investors, or the organization's own cash flow—the monies should be budgeted appropriately to ensure that finances are available to complete all aspects of the project.

The majority of Stage 4 focuses on business planning activities. Once those aspects have been considered and funding is in place, it is time to begin thinking about the actual device or service under development. To identify the functions and features that should be offered, the project team must first attempt to understand customer needs. Focus groups are often used in new product development as a tool for obtaining and prioritizing such information. Alpha focus groups, in particular, are a way to conceptualize desired product specifications prior to prototype development. Often, this step will entail a discussion to identify desired functions and features followed by a vote to rank the priority of each function and feature.

The project team can then use the consumer-identified product specifications to begin developing a preliminary bill of materials (PBOM) that identifies component costs. The team may have to make difficult decisions, such as trading off desired features to maintain a target price range and to accommodate lead-time realities, which can affect the ability of an organization to produce cost-effective devices and services. Finally, to complete Stage 4, the team reconciles the business case with the new development plans in light of the newly gathered consumer specifications and estimated PBOM.

Gate 4 (Implement Development Plan?) asks the project team to consider if it has validated the business case sufficiently to implement the development plan. Note that as one moves through the new product development process, costs associated with each stage begin to rise significantly. These escalating costs lead to higher levels of risk, and top management may now become more heavily involved in decision-making. The outcome of this gate may be more favorable if the project team had worked to enlist the support of top management early on in the process. However, both the project team and top management should carefully evaluate the entire scenario to ensure that the device or service has a high likelihood of success in the marketplace. Wasting funds on unwanted or poorly conceived products does not benefit anyone. The next stages in the NtK model (Stages 5 and 6) are not graphically shown in this document but are described below.

Field-testing helps ensure that the product will function as intended under these real-world conditions. A few helpful guides developed by the Rehabilitation Engineering Research Center on Technology Transfer are available from the Center on KT4TT upon request.

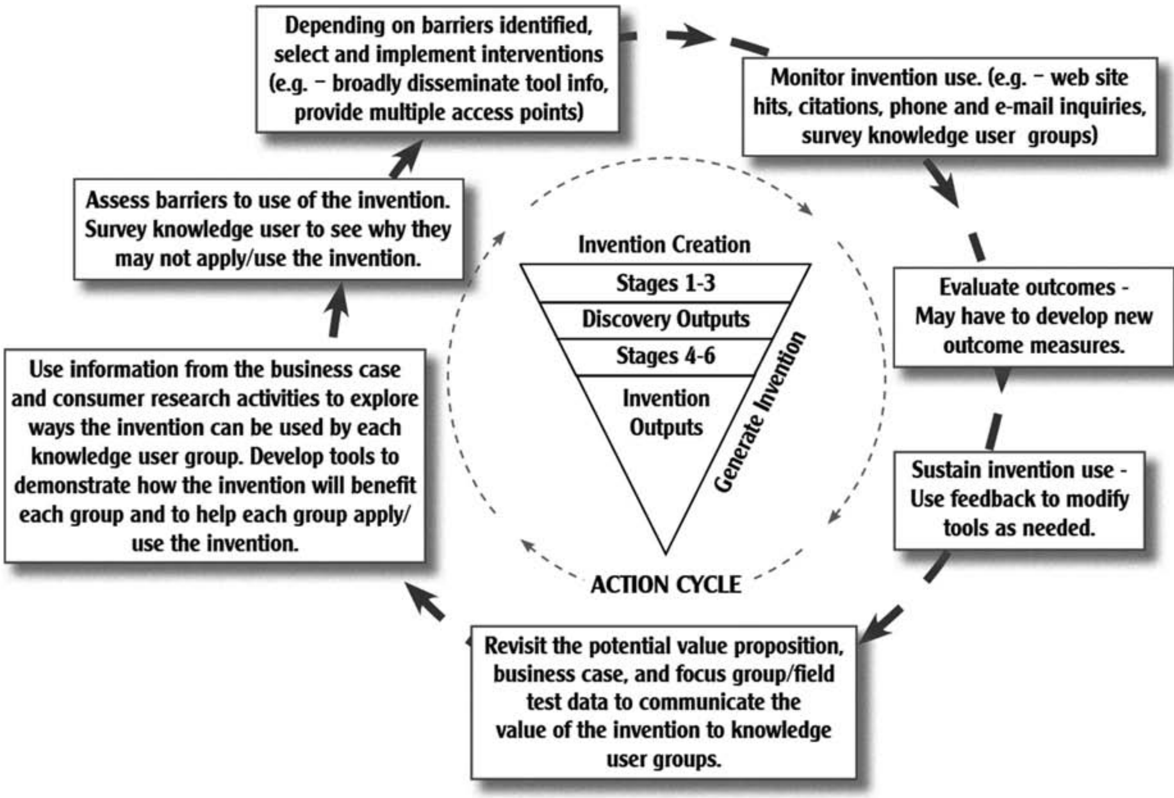
The first step of Stage 5 (Implement Development Plan) is to develop an alpha prototype. Prototypes may be static models that demonstrate size, placement of controls, and the feel of a device. Alternatively, they may be rough versions of a working device—intended to demonstrate functionality rather than form. Both types of prototypes can be helpful for different purposes, although a working version close to its final form is ideal in most cases. Bench testing is often used to confirm that a prototype is functioning properly, and provides input to guide modifications before presenting the prototype to consumers. While testing the prototype, the project team should consider barriers to its use for end users, as well as barriers to development for those stakeholders who may be involved in the supply chain.

Upon reaching Gate 5 (Go to Beta Testing?), the project team should determine if the prototype is likely to solve the problem previously identified in Stage 1. If the answer is yes, then the pertinent question becomes whether the organization should spend the money and resources to beta test the device or service. Once again, as we see the necessary funding levels increasing, top management may be more heavily involved in this decision point.

Stage 6 (Testing and Validation) revolves around testing the prototype models to prepare them to become hardened, store-ready devices or services. This stage is often kicked off with beta focus groups, where the consumers who had participated in the alpha focus groups examine the prototype and indicate how closely it matches their previously stated desires. Ideally, consumers will validate the current design of the prototype. However, if they are not yet satisfied with the prototype's design or function, additional refinements may be made. The developer should take great care in refining the product at this stage—conducting sufficient tests to ensure that the product functions as expected. Bugs and glitches will only sour the field-testing group and may negatively skew results leading to an unfavorable review. In such instances, it is often not the product that the consumers dislike but the problems they encounter while using it. However, in their reviews, consumers are not likely to separate their distaste for the device's problems from their opinion of the device overall.

Once the prototype has been thoroughly bench-tested for functionality, field-testing activities may commence. It is preferable to have the prototype resemble the future product as closely as possible to ensure that field-testing results will be valid for the commercial version. Field-testing frequently involves the use of a product in its intended setting—using a diabetes monitoring system or thermostat within one's home, trying out a whiteboard in a classroom or office environment, or testing a gas-pumping device on one's car at a gas station. Factors such as air quality, temperature, precipitation, available lighting, or level

Figure 4: Invention Outputs



Adapted from: Graham et al., 2006

of ambient noise can all have a significant impact on the functioning of a device.

Field-testing helps ensure that the product will function as intended under these real-world conditions. A few helpful guides developed by the Rehabilitation Engineering Research Center on Technology Transfer are available from the Center on KT4TT upon request, including *A Primary Market Research Training Module* (Flagg, Bauer, & Stone, 2009) and *A Resource Guide to Evaluation in the Context of New Product Development* (Stone, Lockett, & Usiak, 2009). These documents contain a wealth of information regarding focus groups, surveys, and field-testing, including protocols, rationales, and tips and tricks. Upon receiving feedback from the field-testing activities, the developer may want to refine the prototype one last time prior to ramping up manufacturing. At this juncture, the prototype becomes "hardened," and specifications are finalized.

Gate 6 (Go to Production Planning?) asks if the prototype invention demonstrates sufficient value to move on to the production planning stage. Again, the project team is faced with a major decision point that involves much greater resource commitments than previous stages. The team and upper-level management should carefully review the results from lab and field-testing to make certain the project is indeed worthy of such commitments. If the team determines that the project should not move forward, or if the project team's role has ended, knowledge translation techniques (see Figure 4) can be employed to move the product from the invention state out to the marketplace, where it will become a commercially available innovation.

The majority of the KT activities in Figure 4 mirror those from the initial opportunity for knowledge translation at the end of the Discovery phase (Stages 1–3). The suggested steps are still based upon the KTA Model (Graham et al., 2006); however, they leverage the newly available information to sell the invention to outside parties. Again, we suggest the team revisit the value proposition and business case to demonstrate the need for the invention and

Figure 5: Screen Shot of Innovation Phase, Stage 7/Gate 7

Stage/Gate	**Steps** Hide all	**Tips** Hide all
Innovation Phase		
Stage 7: Production Planning and Preparation [Supporting Evidence]	• 7.1 Draft preliminary bill of materials. [Supporting Evidence]	• Create assembly structure overview. • Detail parts; assess and plan for required lead times. • Maintain the preliminary bill of materials (BOM).
	• 7.2 Develop materials plan. [Supporting Evidence]	• Utilize materials requirements planning system.
	• 7.3 Estimate market needs and costs for production. [Supporting Evidence] • 7.4 Develop production and capacity plan. [Supporting Evidence]	• Develop detailed list of manufacturing operations (aka routers).
	• 7.5 Plan and schedule engineering. [Supporting Evidence]	• Add engineering design to BOM as lowest level item. • •
	• 7.6 Plan and schedule tool and process design. [Supporting Evidence]	• Identify need of new tooling or manufacturing processes. • •
	• 7.7 Review costs using preliminary BOM. [Supporting Evidence]	
	• 7.8 Review IP protection and obtain final approval from regulatory and reimbursement bodies- if needed. [Supporting Evidence]	• Begin 510(k) premarket approval with FDA- if needed- to demonstrate that the device is safe and effective.
	• 7.9 Finalize distribution logistics. [Supporting Evidence]	
	• 7.10 Finalize marketing and sales activities. [Supporting Evidence]	• Choose name for device/service. [Supporting Evidence] • •
	• 7.11 Develop post-launch evaluation plan.	
	• 7.12 Initiate trial or limited production runs. [Supporting Evidence]	
	• 7.13 Test market or trial sell. [Supporting Evidence]	
Gate 7: Go to Launch? PI or partner determines if production plans should be implemented through a launch of the device/ service into the marketplace. [Supporting Evidence]		

its associated business opportunity. Additionally, focus group data (alpha and beta) as well as bench testing and field-testing results can be used to underscore the invention's strengths. Weaknesses can also be pointed out to brokers or manufacturers to demonstrate what work remains to be done prior to moving forward with the production planning phase.

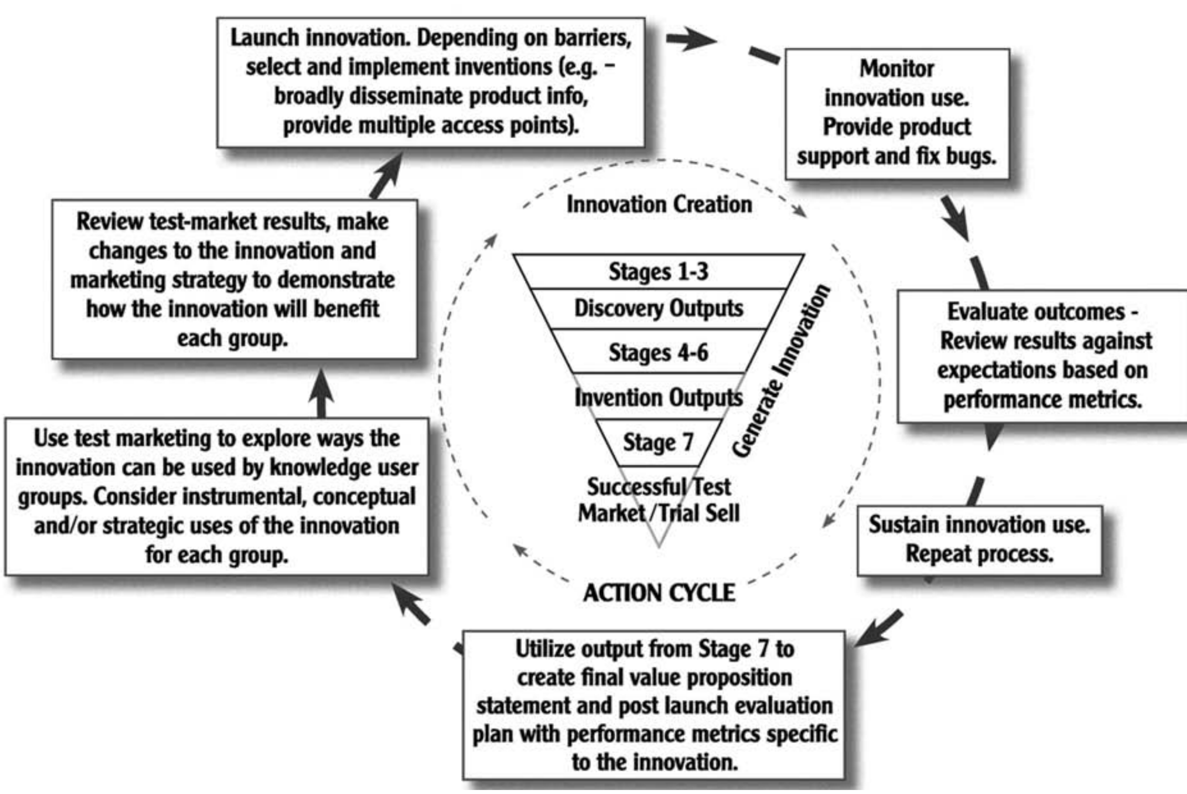
An Invention Outputs table that highlights what information to share with each knowledge user group, how to reach them, and anticipated outcomes is available at: **kt4tt.buffalo.edu/knowledgebase/inventiontable.php**

Barriers to use should again be assessed, and tools and interventions developed to help the various knowledge user groups overcome those barriers. The project team should track use of the invention for reporting purposes, when appropriate, a step that may involve the development of new outcome measures. To sustain use of the invention, feedback should be regularly solicited and used to modify the tools and interventions as appropriate.

Phase III: Production Activities Generate Innovation Outputs

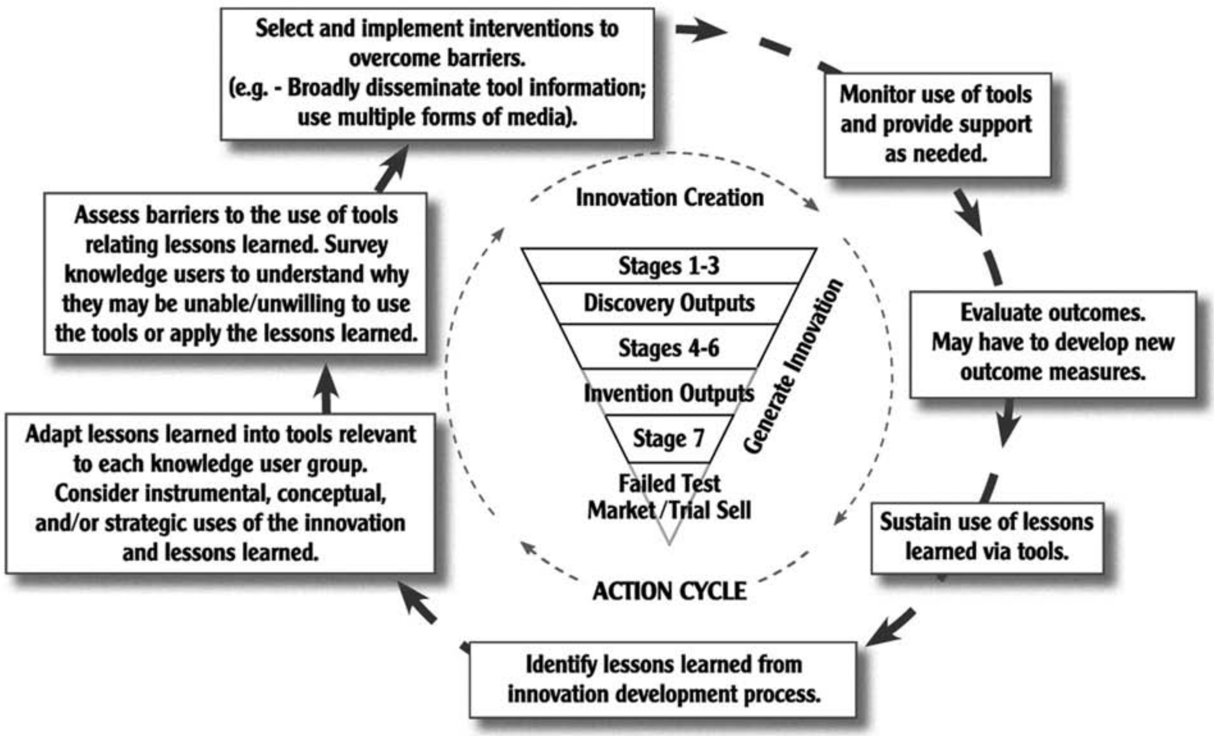
As displayed in Figure 5 (see p. 11), Stage 7 (Production Planning and Preparation) primarily involves logistics issues, beginning with the development of a preliminary bill of materials (PBOM). First, the team lays out an assembly structure overview, which lists all assemblies and sub-assemblies. All known components are then identified for each assembly and sub-assembly. Although the complete list of parts may not be known until later in this stage, the PBOM forecasts the type and quantity of needed parts while also highlighting areas in need of development. Attention should be paid to the quality of the specified materials and their associated costs. The assembly structure and required lead times, as well as suitable alternatives, are also examined at this stage to ensure that raw materials will be available as needed to seamlessly carry out production activities. Material requirements planning (MRP) software is often utilized to streamline this process and to ensure that all critical components are accounted for. By quickly identifying

Figure 6: Successful Test Market Innovation Outputs



Adapted from: Graham et al., 2006

Figure 7: Failed Test Market Innovation Outputs



Adapted from: Graham et al., 2006

specific requirements for the remaining unknown components, MRP systems help to speed component and supplier identification. Throughout this stage, the PBOM should be maintained in preparation for a formal release prior to manufacturing.

The next step is to estimate costs for production by using routers, which are descriptions and time estimates for all aspects of the manufacturing process. The team should create routers not only for assembly but also for any outstanding engineering work to be completed, as well as tool and process design work. Engineering, tool, and process design needs are typically added to the PBOM at this point as well to ensure that staff are not overburdened and will be available to meet project commitments. While taking into account the capabilities of the available manufacturing facilities and equipment, the team should estimate the needs for labor, additional equipment, and machinery. All the information gathered during this stage can then be used to estimate costs and ensure a smooth transition to production. However, a few pre-production steps still remain.

At this stage, the team should re-examine intellectual property issues, reimbursement policies, and regulatory requirements to ensure that all necessary protections and assurances are in place. In some instances, approval will not be granted until later in this stage when the initial trial run units are available for evaluation. After overcoming any hurdles to obtaining reimbursement for a device or service, the team should finalize the marketing, sales, and rollout strategy as well as the distribution plans.

Although the project team had likely contacted potential distribution partners early on in the process, the team should now negotiate final terms and solidify agreements. User manuals, packaging, and a name for the product should also be addressed during this stage. In addition, the team can develop a post-launch evaluation plan to mark progress following trial sell activities as well as during the full-scale rollout. This plan can offer guidance and appropriate strategies for moving forward depending on levels of customer awareness, interest, and use of the innovation. Finally, the project is ready for a trial production run and test marketing activities.

Test market results are reviewed at Gate 7 (Go to Launch?), where the primary question is should this innovation be launched? Regardless of the answer, knowledge translation activities can be utilized to help progress the implementation of the new knowledge, whether it be a product innovation or lessons learned from an unsuccessful test market activity. When the test market/trial sell activities are successful, KT activities mirror Stages 8 (Launch) and 9 (Post-Launch Review) of the new product development process. In this case, KT for Stage 8 will commence by making minor modifications to the innovation based on consumer input. Then, the value of the innovation can be demonstrated to all stakeholder groups, and full-scale rollout can begin, as depicted in Figure 6 (see p. 12).

The Innovation Outputs table that examines ways to reach stakeholders is available at: **kt4tt.buffalo.edu/knowledgebase/innovationtable.php**

If the test market/trial sell activities were not successful, and the project team elects to discontinue work on the project, a different set of KT activities can be employed (see Figure 7). First, the team should identify lessons learned throughout the product development process. They may then consider adapting those lessons into tools that can help other stakeholders make better use of the innovation. Simultaneously, the team may consider barriers to use of the innovation and develop tools to help stakeholders overcome or avoid obstacles to use. Broad dissemination strategies can then be employed to ensure that the innovation reaches as many stakeholders as possible. Use of the tools and innovation can then be monitored, and the dissemination strategy adjusted as needed. Outcomes should periodically be evaluated so that lessons can be learned to help sustain the use of the tools and innovation.

In the case where the test market/trial sell activities were successful, the innovation is ready to move on to Stage 8 (Launch). After implementing the rollout, the team should monitor awareness and use of the innovation. Technical, marketing, and sales support will likely be required at this time as well as help to uncover unforeseen problems that may be corrected with minor adjustments to various strategies. In particular, the team should troubleshoot and correct any technical problems before they have a negative impact on the innovation's image. After a predetermined amount of time, Gate 8 (Post-Production Assessment) calls for a review of the product's performance in the marketplace. This process will use the evaluation plan developed in Stage 7 and help determine if and when an innovation should be removed from the marketplace.

When Gate 8 results in a decision to continue production, Stage 9 (Post-Launch Review) offers an additional opportunity for continued evaluation. This stage involves maintaining production, monitoring, and support, and may also include conducting efficacy studies to determine how well an innovation is meeting consumer needs in the real world. Problems should continue to be corrected, and performance milestones observed. Finally, upon reaching the end of an innovation's life cycle, Gate 9 (Terminate Production) asks if production should be continued or terminated. Products and services inevitably reach maturity or become obsolete at some point in time. When this occurs, production should cease, although monitoring and support may continue until doing so becomes impractical for the organization.

Discussion

It is the hope of the Center on KT4TT that the Need to Knowledge Model provides researchers and developers with a comprehensive understanding of the steps involved in new product or service creation. Often, a team consisting of many divergent individuals brings a product through the various stages, and each team member may not have a complete picture of what the other members bring to the table. Ensuring that all members of a team share a common understanding of the rigors of the process not only provides them with an appreciation for the other members' work but also enhances the quality of the outputs.

The Center on KT4TT welcomes all comments and questions regarding the Need to Knowledge Model and its associated knowledge base findings. A link for "Comments, Questions, Suggestions?" is provided just above the Model, on the Need to Knowledge Model Web page: **http://kt4tt.buffalo.edu/knowledgebase/model.php**

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KT4TT

The 5-year **Center on Knowledge Translation for Technology Transfer (KT4TT)** project (http://kt4tt.buffalo.edu) was awarded to the University at Buffalo (SUNY), Center for Assistive Technology (CAT) on October 1, 2008. SEDL and Western New York Independent Living, Inc., are partners in the project. SEDL's role focuses on utilization-oriented methods of dissemination, training, and technical assistance to effectively communicate with knowledge producers and knowledge users. This *FOCUS* Technical Brief is a product of the SEDL-KT4TT partnership.

The project focuses on three key outcomes:

- *Improved understanding* of the barriers preventing successful knowledge translation for technology transfer and ways to overcome the barriers
- *Advanced knowledge* of best models, methods, and measures of knowledge translation and technology transfer for achieving outcomes
- *Increased utilization* of these validated best practices by NIDRR's technology-oriented grantees

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Address Correspondence

Jennifer L. Flagg
Project Director – Research Project 1
Center on Knowledge Translation for Technology Transfer
100 Sylvan Parkway, Suite 400
Amherst, NY 14228
716-204-8606
Fax: 716-204-8610
e-mail: jlflagg@buffalo.edu

Authors

Jennifer L. Flagg holds a Bachelor of Science degree in Business Administration and Management, with a concentration in Marketing from the State University of New York at Buffalo. Since 2001, Jennifer has worked in the field of technology transfer. She collaborates with technology-focused NIDRR grantees and applicants, as well as assistive technology consumers, to transfer new technologies for people with disabilities into the marketplace. Ms. Flagg is responsible for the execution of Research Project 1 for the Center on KT4TT, and she led the review of knowledge translation literature.

Michelle Lockett holds a BA in Psychology from Ithaca College, NY and MBA from Canisius College, NY. Michelle began working with the RERC on Technology Transfer as the Consumer Testing Coordinator for the WNY Independent Living Project in 2005, where she was responsible for recruiting consumers and coordinating other logistical aspects of focus groups. Within the KT4TT, she is involved with instrument development, and conducting and analyzing intervention studies. She also maintains the consumer and knowledge databases. Michelle previously worked as a Market Research Analyst in the newspaper industry (Buffalo News) and the retail food industry (Tops Markets, LLC). She also has experience as a Customer Relationship Marketing Manager for Tops Markets.

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NCDDR's scope of work focuses on developing systems for applying rigorous standards of evidence in describing, assessing, and disseminating outcomes from research and development sponsored by NIDRR. The NCDDR promotes movement of disability research results into evidence-based instruments such as systematic reviews as well as consumer-oriented information systems and applications.