**Four Models to Guide Projects Intending Technology-based Innovation Outcomes**

**Overview**

The successful creation of technology-based innovations requires detailed planning, implementation and management. University faculty and small business ventures often lack sufficient expertise in all required phases of scientific research, engineering development and industrial production. Four evidence-based models now exist to support project’s intending the generate standards/guidelines; tools/instruments; freeware or commercial products.

**Introduction**

Many organizations attempt to create technology-based innovations. While large established corporations have established procedures and specialized staff, small business entrepreneurs and academic faculty typically lack both. These smaller scale endeavors may have strong engineering capabilities, or a track record of a scholarship, but they typically lack both. Further, neither has experience with the planning, implementation and management of projects that may involve long term efforts, as well as downstream resource commitments from established businesses.

Achieving successful outcomes in the marketplace is very challenging and infrequent even for mainstream products and services. The field of Assistive Technology faces additional barriers of small markets, diffuse customers and limited reimbursement. Compound these barriers with limited experience, and it is clear why despite decades of sustained funding, there are few successful outcomes from small business ventures or university-based projects.

The authors created a model based on best practices drawn from industry and academia called the Need to Knowledge (NtK) Model [1, 2]. The name has two meanings. One meaning is that the NtK model contains the information a project *‘needs to know’* in order to plan, implement and manage a project. The other meaning is that the NtK model is constructed to begin with defining and validating an unmet *need* before commencing to create and apply new *knowledge*.

This initial Need to Knowledge Model focused on the methods and metrics necessary for scientific research, engineering development and industrial production to combine in the generation of an innovation in the form of a commercial product. That is a hardware-based device intended for manufacture, distribution and sale in the competitive marketplace.

People who began to use the original NtK Model offered feedback about the structure and content that was integrated under the goal of continuous improvement. However not all feedback concerned this model or its intended use. Instead, people explained that many of their intended technology-based outcomes were not commercial hardware products. Instead, many projects expected to generate hardware for use in fabrication or measurement. Others were focused on writing new software applications. Still others were engaged with national or international bodies on the creation or revision of standards of practice.

All three of these non-commercial or non-hardware outcomes could apply parts of the original NtK Model, or were forced to adapt the NtK Model to their own context. Neither option represented an ideal solution given our mission of generating the models, methods and metrics to improve technology-based innovation outcomes.

As a result of this feedback, the authors dedicated part of the past three years on the design and documentation of multiple variations to the original NtK Model, with each representing the unique pathway for creating the desired outcome.

Three NtK Model Variants

A retrospective study of a dozen Rehabilitation Engineering Research Centers previously funded in the United States, showed that technology-based or technology-oriented project could be classified into four categories of intended outcomes [3].

1) Industry Standards & Clinical Guidelines;

2) Fabrication Tools & Laboratory Instruments:

3) Software Applications;

4) Commercial Hardware Products.

This prior study was reconciled to a review of literature reporting outcomes for projects funded in North American, Europe and Asia. The results showed that the four categories did encompass all envisioned outputs. The original NtK Model addressed the fourth category (Commercial Hardware Products), so this effort addressed the generation of NtK Model variants to address the remaining three categories of potential project outcomes.

*NtK Model for Standards/Guidelines* - This version of the NtK Model is to guide the creation and deployment ofIndustry Standards or Clinical Guidelines as a project output -- a defined solution to a validated problem. Standards/Guidelines encompass the written documentation of practices, methods, processes or criteria that are adopted as convention by a governing body, regulatory agency or professional practice group, through formal directives, voluntary compliance or generally accepted norms. Industry Standards codify the requirement and specifications for delivering consistent quality in materials, products and processes. Clinical Guidelines codify the characteristics and procedures for delivering consistent quality in treatments and services.

Transforming project outputs into outcomes adopted by external stakeholders requires a high level of collaboration from the outset between the project’s leaders and the appropriate national or international governing body.

*NtK Model for Instrument/Tool* – This version of the NtK Model guides the creation and deployment of an Instrument/Tool project output, which are *not* intended for mass production in the commercial marketplace. Hardware means any device comprised in whole or in part of tangible bio-electro-mechanical components. Instrument/Tool means an implement designed to perform a specific function in a valid and reliable manner. An Instrument is used for data collection, storage, analysis, management or monitoring, while a Tool is used to measure, manipulate or fabricate any type of material.

*NtK Model for Freeware* – This version of the NtK Model is a guide for the creation and deployment of a project output (a defined solution to a defined problem), in the form of freely available computer code or instructions, not intended for mass production and distribution in the commercial marketplace. The "free" in Freeware means there is no or low cost to cost to acquire the ware (product or service). Freeware encompasses both operational software applications (Apps) and Do-It-Yourself (DIY) user instruction kits. The Freeware category is the exclusive domain of electronic offerings with no transmission of tangible materials.

All NtK Models share three core principles: First, the problem and solution set must be defined in the context of an underlying unmet need. Second, this unmet need must be validated by the stakeholders who are expected to benefit from the project’s outcomes. Third, these targeted stakeholders must be directly involved from the beginning and through to the delivery of outcomes to society. These principles are grounded in the disability advocate’s simply mandate: *“Nothing about me, without me.”*

**Methods**

Document process elements for each NtK Model Variant.

The original NtK Model relied heavily on best practices for new product development, as documented by the international Product Development Managers Association (PDMA). Lacking any similar structure for the three variant outcomes, the project team conducted a scoping review of literature concerning each one.

The most structured information available through publications addressed the creation of industry standards or clinical guidelines. However, the majority of that information was tailored to the context of individual industry trade associations (e.g., electrical, mechanical), specific standards bodies (e.g., ISO, ANSI), or application contexts (e.g., medical interventions). The project team transformed those context-dependent details into more generalizable language.

There is a fair amount of information on the process of authoring Freeware. However, the field of Freeware appears driven by a supply push mentality, concerned mainly with getting the software code written and posted in application stores (e.g., Apple or Android). Published material has little to say about downstream requirements to access stakeholder input, secure feedback on application performance, and to assess the competitive advantage over existing options. There is little pre-deployment concern over level of interest and uptake, or in metrics to track either. It seems that projects intending to generate Freeware with beneficial impacts on targeted stakeholders, must impose their own rigor on the assessment of users, markets and metrics.

There was little generic information documenting the creation of fabrication tools or data collection instruments, especially for projects concerning uptake and use by external stakeholders. As with standards and guidelines, most published materials focused on a specific topic or context, so this information also had to be generalized for use by projects addressing a variety of topics or contexts.

Despite the divergent amount of available material, and the need to adapt the content for this purpose, there was sufficient documentation to roughly demarcate the critical activities and decisions required to achieve each of the three intended outcomes. For example, the available information for the three outcomes could be loosely organized into the three phases, similar to those comprising the three phases within the original NtK Model for commercial products:

* First, a scientific research phase to collect or discover all knowledge deemed necessary to implement the project at a conceptual level.
* Second, an engineering development phase to transform this concept into a practical form for testing and refinement.
* Third, an industrial production phase in a manner of speaking to transform the prototype into a final version of whatever functional output each project intends to deliver for use by others.

Treat original NtK Model as framework for Variants.

With the rough outline of the required activities and decisions in place for all three variant processes, the next step was to consider if the original NtK Model could serve as the framework for the variant models.

The original NtK Model has been presented and published in multiple venues and vetted through application by dozens of projects, organization and agencies around the world. The Stage/Gate structure works for projects linking multiple methods and actors across an array of activities requiring flexibility in cause and effect. It is important for users to keep in mind that each Stage/Gate and the subordinate activities are modular – not sequential – in nature, so they can be transposed, iterated and re-visited, despite the linear appearance.

Another important attribute is that the original NtK Model is grounded in peer-reviewed literature from both academic and industry sources dating back to 1985. Further, it contains a set of nearly one hundred tools useful for conducting technical, business and market analyses.

The project reviewed the contents of the original NtK Model, and incorporated feedback from users when considering its relevance to the three other types of project outcomes to be modeled in this subsequent effort.

The project had three options for structuring the Variant NtK Models:

a) Pattern closely after Commercial version with narrative revisions.

b) Create three different and parallel models, one for each type of outcome.

c) Create a hybrid model with all sharing common elements with divergence where required by processes.

Initial draft versions of the three variant models demonstrated that they were too divergent in latter stage/gate activity to consider Option A, without imposing artificial similarities. At the same time, the draft variant models were too similar to the original version in their early stage/gate activity to consider Option B, without imposing artificial distinctions or excessive redundancy. As a result, the three variant models were all constructed as hybrids -- Option C.

All three variant models share the same Stage activity and Gate decisions with the original model through the entire Research Phase (Stages/Gates 1 – 3), leading to the generation of new knowledge in the state of conceptual discoveries. They also share the early Stage activity within the Development Phase (Stage 4), where the initial business plan is authored, and where the concepts are first transformed into demonstrations of proof in practical prototype form.

The three variant models begin to diverge from the original NtK Model – and from each other – in the latter Stage activity and the subsequent Gate decisions occurring at the end of Stage 4. They continue to diverge throughout Stages/Gates 5 and 6 where all three variant models end.

The three variant models collapse the original Development Phase consisting of three Stages/Gates (previously 4 through 6) into two Stages/Gates (now 4 and 5), simply because the variant outputs do not require the extensive and iterative testing which is required for the creation of commercial products.

In a similar fashion, the original Production Phase consisting of three Stages/Gates (previously 7 through 9), is collapsed into one Stage/Gate sequent (now only 6). The variant outputs do not require the same extensive array of materials, tools and processes required for the generation and deployment of mass quantities of commercial products.

In the case of Standards or Guidelines there is simply no tangible output. In the case of Tools or Instruments offered through this process, they will likely be adapted prior to use by external stakeholders independent of the original creative source, so limited time and effort is called for prior to offering externally.

Populate Models with substantiating literature and relevant analytic tools.

Much of the literature and tools underlying the NtK Model for Commercial Products remained relevant for the three variant models, because the activities and decisions for Stages 1 through 4 are similar, and much of the Commercial Product activity under Stages 7 through 9, is absent or drastically curtailed for the other outputs.

At the same time, there was indeed literature unique to activities and decisions within each model, so those citations were added, as well as excerpts drawn to reflect guidance concerning best practices and overcoming barriers to progress. The specific citations and excerpts were added where appropriate.

There were few new technical, market or customer analysis tools to add, since those appropriate for commercial products in the competitive marketplace already covered every possible type of analysis. There were documents generated by various professional societies concerning the creation of industry standards and clinical guidelines, which some analytic elements. These were included under the literature citations since they were not offering formal validated tools per se.

Circulate Draft Variants for review by external experts.

The project team completed the three draft NtK Model variants in Fall 2015. The subsequent eighteen months were dedicated to obtaining external reviews of the draft content. These reviews enlisted input from experts in each of the three output areas, as well as individuals with experience spanning more than one output. University faculty, small business entrepreneurs, corporate executives, government employees, clinicians and consumers were all engaged in this review process.

As the draft variant models evolved, they were also presented at professional conference forums in the areas of assistive technology, transportation, communication, technology transfer and Science, Technology and Innovation Policy. Stakeholder input was solicited and added from each of these forums during the same timeframe.

By Winter 2016, the project team observed diminishing returns from continued external feedback. That is, the comments were converging on issues already addressed, or were more focused on what was right and useful about the NtK Model variants, than about what needed to be added or revised. At that point the variant models were deemed ready for public dissemination.

There are plans to update the broader reference literature underlying all four NtK Models, to incorporate additional work published between 2011 and 2016.

**Results**

The Need to Knowledge (NtK) Model is now available for download, reference and use in all four versions:

1. Commercial Products version;

2. Freeware version;

3. Instruments/Tools version;

4. Standards/Guidelines version.

Each version contains all of the elements deemed necessary to plan, implement and manage a project intending to generate the specified outcome. All four versions of the NtK Model are currently available on the project’s website [4]: <http://sphhp.buffalo.edu/cat/kt4tt/best-practices/need-to-knowledge-ntk-model.html>

**Discussion**

The four NtK Models will remain works in process, with the content updated as new literature, analytic tools and case examples arise for inclusion. The project’s chief task ahead is to disseminate the content and provide technical support to users. A parallel project is creating an on-line instructional tool to facilitate understanding and application.

The three NtK Model variants each exhibit areas of unique emphasis for accomplishing the intended outcomes.

Lead Role for External Organizations – This is a unique emphasis for projects intending to generate Industry Standards or Clinical Guidelines. Such projects must first identify the target professional group, governing body and/or regulatory agency, along with their evaluation criteria and evidence requirements. They then must tailor the project and subordinate their own role to these external organization’s requirements, since they are the final arbiters of the decision to transform project outputs into societal outcomes.

Lack of Defined Customer – This is a hallmark of projects generating Fabrication Tools or Laboratory Instruments, because most such projects design, build and test them for internal use within their own scientific research or engineering development projects. These projects face a unique challenge to identify external stakeholders and successfully offer this internal output for their adoption and use.

Implications of Output Sub-Categories – Experts in the field identified that there are five sub-categories within the broader category of Freeware outputs. There are three categories of Software applications: No Cost (Free); Low Fee; On-going fee (Freemium). And there are two categories of Do It Yourself instructions or kits: No Cost (Free) and Low Fee. Each of these five output categories involves different activities at various points in the generation process.

**Conclusion**

Agency’s sponsoring technology-oriented innovation projects, proposal reviewers and project managers, should all recognize that the historical lack of outcomes from innovation-oriented projects, is due to several factors. First, even under optimal conditions no project is guaranteed that their outputs will be adopted and used by stakeholders. Second, the processes involved are complex and fraught with barriers, which further decreases the odds of success. Third, managers need to recognize what they need to know but don’t, and engage the missing expertise, or they jeopardize even the slim odds of eventual success. The NtK Models can raise awareness about all three factors.

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