Developing Expertise in those Handling Time and Temperature Sensitive Pharmaceutical Products: Applying the Early Phases of a Design Research Methodology

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Abstract: The storage, transportation and distribution of time and temperature sensitive pharmaceutical products such as vaccines and human insulin, within the proper temperature conditions is an important public health concern worldwide. The people responsible for making and handling pharmaceutical products need to have some level of expertise in what they do so they can take actions and make decisions so the products are not negatively affected by temperature. In this paper, we describe a project designed to facilitate the development of expertise through a web-based learning environment. The design research approach and methodology of the study are explained, and the early stages of planning and design are described in detail.

Background and Need

With the increasing development of biotech medicines and the growing use of vaccines, there is a greater concern in how these time and temperature sensitive pharmaceutical products (TTSPP) are transported, stored, and distributed to the end users (Milstien, Kartoğlu, & Zaffran, 2006). If a typical TTSPP is exposed to high temperatures, it can deteriorate, resulting in a lack of effectiveness and an increase in impurities. For many products, like human insulin and certain vaccines, freezing can cause immediate damage to the molecule rendering it inactive. There are individual and public health implications to this: a person’s diabetes may not be controlled if they try to use insulin that was frozen; a national immunization campaign will waste time and money and result in illness and even death if frozen vaccines are used (Ewbank & Gribble, 1993).

To keep these TTSPP at the proper temperatures (typically 2 to 8 degrees centigrade), a cold chain is utilized. A cold chain is the integrated system of equipment (e.g., shipping containers, refrigerators, trucks), procedures, records, and activities used to handle, store, transport, distribute, and monitor time and temperature sensitive products (Afsar & Kartoğlu, 2006; Taylor, 2001). The allusion to a chain is very apt. As with a physical chain, a cold chain is only as strong as its weakest link.

To help ensure that pharmaceutical products are safe, pure, and effective, most nations have specific requirements for the manufacture of drugs and the distribution and handling of drug products. These are known as Good Manufacturing Practices (GMPs) and Good Distribution Practices (GDPs), respectively (FDA, 2010; PIC/S, 2009). Among other things, the GMPs and GDPs require that people involved in manufacturing, testing, handling, and distributing products have education, training, and experience so they can effectively perform their jobs (Vesper, 2001). Put another way, people making or handling pharmaceutical products need to have some level of expertise in what they do.

Expertise is the hallmark of an expert. It includes an in-depth set of knowledge, skills (motor and cognitive), and abilities as well as the ability to determine how to approach a given situation. Dreyfus and Dreyfus quote Aristotle: “the expert ‘straightway’ (sic) does ‘the appropriate thing, at the appropriate time, in the appropriate
way” (Dreyfus & Dreyfus, 2005, p.788). In the context of handling TTSPP, expertise involves more than just knowing the rules and requirements of national authorities. Rather, it requires that people be able to apply those requirements and solve sometimes very complicated, conflict-filled problems in a way that is consistent with the “spirit” of the requirements. This includes identifying potential risks and ways to control and mitigate them. This type of expertise is higher-level thinking as illustrated by Bloom’s Taxonomy (Bloom & Krathwohl, 1956) and its more recent interpretations (Anderson & Krathwohl, 2001).

To help develop this type of expertise in those directly (e.g., vaccine manufacturers, public health professionals) and indirectly (e.g., packaging developers, engineers who design electronic temperature monitoring instruments) involved with pharmaceutical products, the World Health Organization’s Global Learning Opportunities for Vaccine Quality (WHO GLO) (previously called Global Training Network) developed a unique training course, Pharmaceutical Cold Chain Management on Wheels (PCCMoW), that takes 15 carefully selected participants on a bus trip in Turkey where they could make direct observations at the storage, warehousing, distribution and health care facilities that they visited as they physically travel with mentors by bus down the length of the cold chain. Throughout the course, guided observation exercises take place at the visited facilities. Participants are provided with notes and tools to support their critical observations. Participants interact with operational staff and management at these facilities. Presentations and group discussions take place on the bus, in restaurants, and in the open air before and after the visits to the facilities (Vesper, Kartoğlu, Bishara, & Reeves, 2010; WHO, 2005, 2008). Approximately 75 people (as of June 2010) have participated in the PCCMoW course, a very small number compared to the tens of thousands of people world-wide who could benefit from gaining expertise in this field.

With this background, we can now see the challenge: How can WHO develop the expertise of thousands of people world-wide who are involved, directly and indirectly, in the handling, storage, and distribution of time and temperature sensitive pharmaceutical products in a time- and cost-effective way?

**Goal and Potential Benefits of the Project**

Consistent with the purpose of design research, specifically, that it “integrates the development of solutions to practical problems in learning environments with the identification of reusable design principles” (Herrington, McKenney, Reeves, & Oliver, 2007, p. 4089), this project sets out to:

- Develop the expertise of those involved with time and temperature sensitive pharmaceutical products using a technology-based solution; and
- Acquire insights in how expertise is developed through applying concepts from cognitive apprenticeship, authentic learning, communities of practice, and communities of learners that can be used to create new – and novel – design principles for future designers.

While the intensive experience of the *Pharmaceutical Cold Chain Management on Wheels* (PCCMoW) is very effective for a small group, providing a technology-based learning opportunity for large numbers of people to develop and enhance their expertise will strengthen the cold chain and contribute to positive public health outcomes. This project is anticipated to provide educational benefits to the users of the learning solution, and, if successful, result in health benefits for those who would use TTSPP. The educational benefits for the learners would include:

- Being actively engaged in the learning process with mentors and other participants
- Acquiring insights into how experts make judgments and decisions
- Experiencing a very different approach to learning (i.e., authentic tasks and communities of practice) and identifying opportunities where they could apply these models in their own practices
- Building relationships with other participants and mentors that will contribute to a vibrant and productive ongoing community of practice.
Some specific health benefits that are anticipated as expertise is developed in those involved with TTSSP include:

- Sharing of problems (so they can be avoided), and best practices (so they can be considered and embraced)
- Reducing exposure of TTSSP to detrimental conditions resulting in less waste of medicines, vaccines, and money.

Additionally, in keeping with the goals of educational design research, this study will:

- Confirm and expand on existing design principles and identify others that can be used to more efficiently create additional technology-based learning solutions for the WHO
- Identify additional design principles that learning solution designers can apply in related contexts in the future.

A key “deliverable” or outcome from this research will be a pedagogical approach to address the problem, such as a set of technology-based learning modules and environments that will develop the expertise of those directly and indirectly involved in the storage and movement of TTSSP. Additionally, the learning solution will include practices to enhance the learner’s sense of “community” and help build a community of practice where participants move from a peripheral role to a more fully participative one. This learning solution will be used by WHO as it builds a world-wide network of TTSSP expertise.

A second deliverable or outcome will be a set of design principles, as discussed below. The design principles that were identified and used in creating the technology-based learning modules will be confirmed, rejected, or modified based on the experiences of study participants and expert practitioners and the findings of the research iterations. Additional design principles will be identified and discussed. Together, these principles will be shared with the WHO advisors for consideration as future technology-based learning solutions are developed covering other topics. These design principles will also be communicated more broadly through publications and presentations.

**Design Research Approach and Methodology**

The research approach to be used is design research (Kelly, Lesh, & Baek, 2008; van den Akker, Gravemeijer, McKenney, & Nieveen, 2006) (also known as design-based research, and design experiments). Barab and Squire (2004) define design research as: “a series of approaches, with the intent of producing new theories, artifacts, and practices that account for and potentially impact learning and teaching in naturalistic settings” (p. 2). While other research models exist, design research, and more specifically educational design research, was selected because it:

- Focuses on broad-based complex educational problems
- Requires collaboration between researchers and those directly involved with the problem of interest
- Integrates known and hypothetical design principles and technology in achieving a solution
- Utilizes rigorous and reflective inquiry to test and refine innovative learning designs and identify new design principles
- Involves improvement of the design through evaluation
- Contributes to both theoretical understanding while solving real world problems (Herrington, Reeves, & Oliver, 2010 p. 176).

Following the design research model will result in a theory-informed, needs-based practical solution to a problem that has real-life impact, specifically, the problem of helping people to handle TTSSP in ways that ensure those products maintain quality, safety, purity, and efficacy throughout their shelf-life.
The design research model that will be used consists of four phases. Figure 1 shows the phases and how they inter-relate as depicted by Reeves (2006).

![Design-Based Research](image)

**Figure 1:** Four-phased design research model (Reeves, 2006, p. 59).

In creating the learning solution that will help develop expertise of those handling TTSPP, a rapid prototyping method (Tripp & Bichelmeier, 1990) will be used that is integrated with robust formative evaluation methods as described by Reeves and Hedberg (2003) and Laurel (2003). Rapid prototyping methods are based upon solving problems in ways similar to that done by software application developers and architects. Rapid prototyping can involve low-cost, rapidly-developed prototypes – sometimes using hand-drawn sketches or Power Point® slides – that are created, initially using some (but limited) information. Using feedback from the designers, experts, and potential users, versions are developed, improved upon, and then re-developed, in multiple iterations (Gustafson & Branch, 1997) gaining in sophistication and becoming closer to the final product.

Rapid prototyping is significantly different from the ADDIE (Analysis, Design, Development, Implement, Evaluate) instructional design model that is still prevalent in producing courses used in the pharmaceutical industry. ADDIE is often portrayed as linear (see Welty, 2008) and without internal iterations with improvements (McKenney & van den Akker, 2005).

Dorsey, Goodrum, and Schwen (1997) provide information on how to do a version of rapid prototyping they called rapid collaborative prototyping because of the involvement of the users. After the stakeholders/users have been identified and they have established a relationship and an understanding of the basic problem and goal, they start a series of iterative design cycles, moving through each of five levels. Dorsey et al’s method complements Tripp and Bichelmeier’s approach by providing a more detailed description of the process. Both models involve users throughout various stages of the design/development/prototyping process. Laurel (2003), and Reeves and Hedberg (2003) provide extensive guidance in terms of various methods that can be used during the prototyping process such as expert reviews, heuristics evaluation, user observations, usability testing, alpha, beta, field-testing, and so forth.

**Who is Involved?**

Developing the online **Pharmaceutical Cold Chain Management on Wheels** requires a team approach. In keeping with the collaborative and consultative nature of design research, participants will include:

- **Project sponsor.** The sponsor of this project is the primary “customer” who wants to create a useful solution to address the needs discussed above. The sponsor will secure funding and arrange for resources that will be used in creating the solution.
- **Practitioners.** Practitioners are those who have experience and expertise in the area of interest. In this project, practitioners would include experts who work in the pharmaceutical industry, have contributed to writing regulations and guidelines on handling TTSPPs, and packaging engineers. These people will be providing the learning content and its context.
• Developers/production personnel. Graphic artists, videographers, developers, and programmers will be involved in creating and executing the “look and feel” of the program using storyboards.

• Expert reviewers. Instructional designers, e-learning developers, graphic designers, and subject matter experts who will perform a formative evaluation on sketches and paper documents.

• Learners/participants. People who will use prototypes (alpha review) and the initial or “pilot” version (beta review) of the e-learning solution. They will be representative of the larger audience who would use this material. They will be asked to use and help evaluate the e-learning as discussed below.

• Instructional design consultant. An experienced instructional designer with expertise in e-learning and evaluation strategies will be collaborating as a consulting advisor on this project. (He is also the local supervisor to the researcher.)

• Researcher (PhD candidate). The researcher will contribute throughout the design, development, evaluation, and implementation of this project consistent with the design research methodological approach discussed below, and will be in a position will conduct a design research study to address the problem issue.

Design Research Phase 1: Analysis of the problem

Aligned with Phase 1 of the design research model in Figure 1, the steps described by Herrington, et al. (2010) are being used as a guide in executing the design research model. In this phase, the following steps were completed:

A. Identification of the problem
B. Researchers and practitioners clarify problem and goals
C. Initial literature review
D. Creation of research questions

Researcher observation provides some insight into the process, and each of these steps are described in more detail below:

A. Identification of the problem

Awareness of problems related to cold chain and the handling of TTSSPP has grown dramatically in the past several years. New requirements and expectations are being discussed and issued (WHO, 2010); shipping and drug companies are seeing what failures mean and cost (Loh, 2009). Discussions with experts in the field and the project sponsor clearly identified a gap that needed to be filled, specifically, an effective means was needed to educate and train greatly increased numbers of personnel involved in handling of TTSSPP.

B. Researchers and practitioners clarify problem and goals

A day-long meeting with the sponsor, lead graphic designer, consultant, and researcher was held in September 2010 to discuss the problem in more detail and find ideas for the proposed learning solution. While not a formal needs analysis, the discussions focused on identifying and characterizing the audience and sharing ideas and expectations for what the solution might look like. Several different models and metaphors had been discussed earlier in the process but there had been no real agreement on which model to pursue. For example, one early option was to have a completely self-contained, asynchronous e-learning solution. At this meeting, the decision was to use a learning model that was more academically oriented using a learning tool similar to Blackboard®, but at the same time, have some learning materials (e.g., overview videos, printed documents) that would be available to other interested persons who were not full participants in the course.

In discussing the course goals, it was evident that some preliminary learning objectives would be useful. Learning objectives from the physical PCCMoW bus course were examined, but it was clear that they needed to be revised to better fit the technology and the vision of the stakeholders. Table 1 shows some of the original bus course objectives and the preliminary learning objectives (that are subject to change as the design research work continues). As the team considered the objectives, they intentionally re-wrote them to so they would be higher
order, that is, more connected to the taxonomic levels of analyzing, evaluating, and creating (Anderson & Krathwohl, 2001).

Table 1: Comparison of some objectives from the actual physical course to the proposed virtual online course

<table>
<thead>
<tr>
<th>Learning Objectives for Physical Bus Course</th>
<th>Tentative Learning Objectives for Online Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identify the major operational components in a pharmaceutical cold chain</td>
<td>• Identify the major operational components in a pharmaceutical cold chain</td>
</tr>
<tr>
<td>• Discuss the concepts of “good distribution practice” (GDP) and what GDP includes</td>
<td>• Identify deficiencies in given situations using the “good distribution practice” (GDP) guidelines</td>
</tr>
<tr>
<td>• Describe the inputs, activities, and outputs of each operational component of a pharmaceutical cold chain</td>
<td>• Illustrate the inputs, activities, and outputs of each operational component of a pharmaceutical cold chain</td>
</tr>
<tr>
<td>• Discuss the role of quality agreements, what they contain, and how they are used in cold-chain operations</td>
<td>• Develop a quality agreement that is appropriate to a given situation</td>
</tr>
<tr>
<td>• Discuss the risks to pharma/biopharma/vaccine products that can occur during each cold chain operational phase</td>
<td>• Given a cold storage facility, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP</td>
</tr>
<tr>
<td>• ...</td>
<td>• Given a mode of transportation, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP</td>
</tr>
</tbody>
</table>

C. Initial Literature Review
A literature review was conducted to, among other things, identify several theoretical underpinnings that would inform the proposed learning solution. Four theories that were of most interest were: cognitive apprenticeship, authentic learning, communities of practice, and communities of learners, all of which have a common foundation in experiential learning, social learning, and situated learning. Together, these theories help us understand how a person gains expertise and becomes an expert.

D. Creation of Research Questions
Given the real-life problem presented above, that is, that a large number of people worldwide need knowledge and skills that they can apply in strengthening the “cold chain” used for the handling and transport of TTSP, the primary research question and four secondary questions were identified as a result of the Phase 1 activities:

Primary:
• In what ways can a technology-based solution be used to facilitate the development of expertise of those involved in the distribution and handling of time/temperature-sensitive pharmaceutical products?

Secondary:
• In what ways can a “community of learners” be established and enhanced when the participants are in different physical locations and of different cultures?
• In what ways can a technological-based learning solution contribute to “learning to become”, just not “learning about”, particularly when the learners have very different roles and responsibilities?
• What are the factors that enable a technology-based learning solution and the affordances they provide, to “mirror” an existing, experiential learning event and improve on that event?
• What are the factors that contribute to successfully using a rapid prototyping model for instructional design when the design team and stakeholders are working virtually, that is, separated in locations and time zones?
The first two secondary research questions have roots in the theories of community of learners and cognitive apprenticeship, respectively. The third is used to examine how technologies can be creatively used in taking a very highly interactive and all-involving event and recasting it in very different approach that participants would experience in a very different way. The final secondary question is aimed at better understanding the process that the design/development team uses as they produce the learning solution.

**Design Research Phase 2: Development of solutions**

Again, with the steps described by Herrington, et al. (2010) as a guide, work continues in Phase 2 (Figure 2) through the following activities:

A. Creation of draft design principles
B. Consideration of implementation technologies and technological affordances
C. Design and development of the prototype learning environment and solution

**A. Creation of draft design principles**

Draft design principles are created to inform the design of a solution to the problem. These principles will be based on the consultations with practitioners, and theory and literature. Table 2 presents a tentative (incomplete) list, based on the relevant theories, that illustrates the form of draft principles for two of the four theories of interest.

**Table 2:** Examples of draft design principles for two of the theories of interest to be used in the proposed solution

<table>
<thead>
<tr>
<th>No.</th>
<th>Draft Design Principle</th>
<th>Source/Reference</th>
<th>Meaning</th>
<th>How this will be used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Anchor and index knowledge in the context in which the learning occurs.</td>
<td>(Ghefaili, 2003) (Brown, et al., 1989) (Hansman, 2001)</td>
<td>Learners need to acquire the knowledge and skills in a “real life” environment.</td>
<td>Ensure the relevance of the content can be seen by all participants (i.e., have something for everyone).</td>
</tr>
<tr>
<td>2</td>
<td>Design the learning solution so that there are “increasingly complex micro-worlds” (ICMs) where a learner can succeed in developing a skill.</td>
<td>(Burton, Brown, &amp; Fischer, 1984)</td>
<td>Structure the learning solution with “scaffolding” and support so the learner feels challenged without being overwhelmed.</td>
<td>Alter the virtual environment, equipment, and specifications of what is to be performed.</td>
</tr>
</tbody>
</table>

**Authentic learning:** when learners are engaged in an inventive and realistic task that provides opportunities for complex collaborative activities (Herrington, et al., 2010, p.1)

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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Include authentic activities that are the “ordinary practices of the culture” or community.</td>
<td>(Brown, et al., 1989, p. 34)</td>
<td>It is important to understand the culture, its practices, and requirements when creating the authentic learning activities.</td>
<td>Identify these practices when designing the learning solution; include them in the learning solution.</td>
</tr>
<tr>
<td>2</td>
<td>Avoid making problem solving as explicit as possible.</td>
<td>(Brown, et al., 1989)</td>
<td>The paths that people use when solving a challenging problem can result in learning even if the problem isn’t successfully addressed.</td>
<td>Present problems with some level of ambiguity and that can be solved with different approaches.</td>
</tr>
</tbody>
</table>
B. Consideration of implementation technologies and technological affordances

Initial discussions have been conducted with the WHO project sponsor and design team members and will continue as the project evolves. Availability of technology (i.e., desk or laptop computers), internet connectivity, and available bandwidth issues that need to be considered in the proposed solution. Because of the rapid evolution of world-wide IT infrastructure, current limitations may affect implementation (i.e., timing of who participates in the learning solution) not its design.

C. Design and development of the prototype learning environment and solution

The activities conducted to date in Phases 1 and 2 will inform the design of a prototype learning environment to enable larger numbers of relevant people to gain expertise in all aspects of handling and storing time/temperature sensitive pharmaceutical products. This design and development work is continuing at the time of writing.

Phases 3 and 4: Implementation and evaluation in iterative cycles, and creation of design principles

The first formative evaluation that will be performed will be done by experts who will review drawings, design documents, and other “paper-based” sketches. Using a protocol to guide them, they will provide the design team and developers information so they can make the decisions about the early designs and take the appropriate actions.

Once the web-based learning environment is created (and formatively evaluated) according to the draft design principles established in Phase 2, prototypes of the program will be implemented with the target group of health professionals. Data will be collected to review and evaluate the approach, and it will be revised and implemented in a second iteration according to the findings of that research that will result in the “pilot” version of the course. Finally, in Phase 4, after all iterations are complete, design principles will again be offered, this time in a sharable form to be published and to help inform the design of learning environments in other contexts and fields.

Conclusion

This paper describes the use of a design research approach to investigate a significant public health issue. The incorrect handing of time/temperature sensitive pharmaceutical products has the potential to impact negatively on the lives of hundreds of people. One negligent act in the chain of events—that takes a vaccine from the point of manufacture to the location where it will be administered—has the capacity to undo the correct handling of every other person in the chain. The design research approach enables this necessary development of expertise to be studied in context, retaining all the complexity of the real-life situation and delivering the benefits of design principles to inform others of the solution.

References


