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Incorporating risk assessment into the formative evaluation of an authentic e-learning program

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Abstract

This paper describes the use of two different risk assessment strategies during the design and development of a complex authentic task-based e-learning program developed by the World Health Organization (WHO). The first strategy involved the use of expert reviewers and the second strategy employed the engagement of a risk assessment expert facilitator. This approach enabled the WHO design team to identify risks in advance and employ control and mitigation strategies to eliminate or reduce the risks that were revealed by the two risk assessments.

Introduction

Risk assessment and risk management processes are used in numerous industries and professions with the purpose of providing information to stakeholders for data-supported, proactive decision making on how to best use resources to prevent the occurrence of unwanted events, and—should such events occur—to protect assets of value (ISO, 2009; Vesper, 2006). Despite the usefulness of risk assessment in articulating potentially problematic events and their consequent possible accommodation, such assessments are rarely performed in design and development of e-learning environments even though significant risks may exist that may affect the implementation and ultimate effectiveness of the e-learning.

In a study of information technology (IT) projects and their associated risks, IT professionals were interviewed to determine how IT risks were managed in their projects and to rank 27 IT risks in terms of importance (Baccarini, Salm & Love, 2004). The top five risks were: personnel shortfalls, unreasonable project schedule and budget, unrealistic expectations, incomplete requirements and a diminished window of opportunity due to late delivery of software. Risk reduction was used, with the prime strategies focusing on project management—rather than technical processes—to manage risk. While e-learning environments have inherent (and easily predicted) risks such as data security, data loss and technology failure, more subtle risks related to learning activities and assessment can create critical obstacles for students engaged in e-learning. These risks are compounded when e-learners in different countries and different cultures must collaborate online. Because e-learning environments that incorporate complex and authentic activities

Practitioner Notes

What is already known about this topic

- Risk assessment and risk management are processes that are used to proactively identify what might go wrong in a project, and consequently define the ways to control and mitigate the possible risks.
- Formative evaluation aims to improve acceptance, success and impact of e-learning programs; it can be carried out in a number of ways during both the design and the development of a learning solution.

What this paper adds

- Risk assessment has not been widely applied during the design and development of complex e-learning programs. This paper shows how formalized risk assessment can be incorporated into formative evaluation of an e-learning solution.
- Examples of two specific risk assessment methods that have utility in formative evaluation are described.

Implications for practice and/or policy

- Formative evaluation is more effective when formalized risk assessment and risk management are included.
- The risk assessment process can enhance the implementation and increase the effectiveness of an e-learning solution.

are relatively new (Herrington, Reeves & Oliver, 2010), there is scarce accumulation of such experience. Nonetheless, there are strategies and approaches that can be used to guide the formative evaluation of risk, as described in this paper.

In presenting how risk assessments were used as part of a formative evaluation strategy for a unique e-learning program, this paper describes the overall risk assessment and risk management processes. Additionally, the paper elaborates on how two specific risk assessment approaches were applied and the results of their application.

Risk assessment and risk management

Risk assessment has been defined as the "overall process of risk identification, risk analysis, and risk evaluation" (ISO, 2009, p. 4). In performing a risk assessment, five basic questions are addressed (Kaplan & Garrick, 1981).

1. What can go wrong?
2. How bad can it get?
3. How could it happen?
4. How likely is it to happen?
5. Should we try to do something about this?

Having found answers to these questions, one can then move into risk management, which is defined as "coordinated activities to direct and control an organization with regard to risk" (ISO, 2009, p. 2) where three further questions are answered:

1. What can be done to control, mitigate or prepare for the risk?
2. How can we communicate the risks and proposed actions to stakeholders?
3. How can we determine if the risks or the assumptions used in determining them have changed?

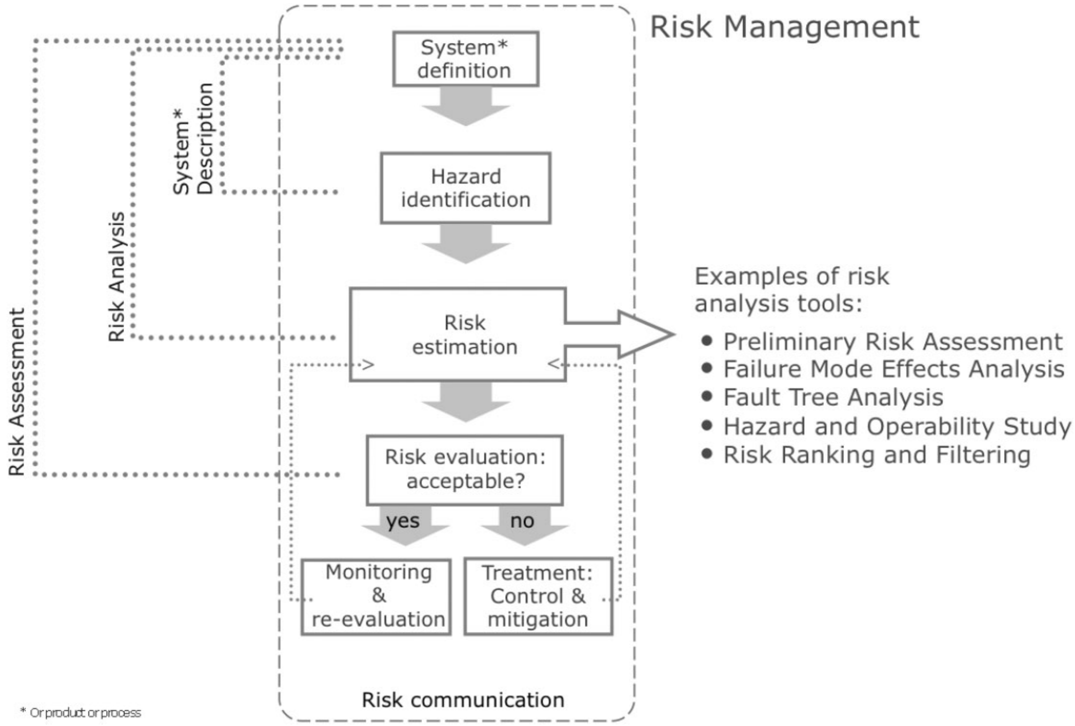

Figure 1: Typical process for risk assessment and risk management (Vesper, 2006)

These questions are typically addressed across a series of phases, using well-defined methods and tools to document the process and results. Figure 1 shows a conceptual diagram of a typical risk assessment and risk management process.

In the first step, the system (or product or process) under study is described or defined. In the second step, hazards—defined as sources of harm—are identified, which typically answers Kaplan and Garrick's (1981) questions, "What can go wrong?," "How bad can it get?" and "How could it happen?" Risk estimates are then made based on the likelihood of occurrence and the impact of the unwanted event.

After answering the three initial questions, the risk is evaluated to determine if action needs to be taken and in what priority. In some cases, the risks are low and they simply need to be periodically reviewed and monitored to ensure that the conditions and assumptions have not changed. If the risks are high, some type of risk treatment in the form of control and mitigation is taken. Communication to stakeholders and documentation of the activities, decisions and results are performed followed by establishing and implementing a plan to monitor and periodically review the risks and assumptions made during the initial assessment.

Risk estimation can be performed using a variety of strategies and tools (such as those illustrated in the right section of Figure 1). Some tools are very basic and may be informal, for example, simply asking "What if?" questions. Other tools, such as *fault tree analysis* (FTA) and *failure mode effects analysis* (FMEA), are highly structured and well defined (Stamatis, 2003; Vesely, Goldberg, Roberts, & Haasl, 1981). Certain tools are optimized to help identify hazards—hazard analysis or hierarchical holographic modeling—while others such as *hazard analysis and critical control points* go through the entire risk assessment and risk management process (Vesper, 2006).

Risk assessments of this nature are rarely performed in a detailed way during the design and development of e-learning environments. Goodyear (1997) mentions conducting a risk assessment during the *identifying learner requirements* phase of instructional design, but does not specify how this should be done. Ideally, key evaluation functions can address potential problem areas prior to development, particularly during the initial conceptualization phases such as *review* and *needs assessment* (Reeves & Hedberg, 2003). However, as described below, we have found that it is during the *formative evaluation* phase that the most benefit can be achieved through risk assessment.

Formative evaluation

Evaluation "provides information to make decisions about a product or process that is being investigated" (Phillips, McNaught & Kennedy, 2012, p. 15). Evaluation is often characterized as being used for formative (ie, finding ways to improve something) or summative purposes (ie, making decisions about something's value) (Reeves & Hedberg, 2003). In reality, an evaluation will often provide information that fits into both of these categories.

If evaluation is driven by the need to make decisions, then questions must be asked and answered in order to have a rational basis for making those decisions (Reeves & Hedberg, 2003). A number of questions can be asked depending on the intended decision to be made, the stage of the life cycle of the project and the intended stakeholders most qualified to answer the question (eg, participants, supervisors or facilitators). Such questions, answers and decisions guide the development of the project.

In the project described in this study, multiple iterations of formative evaluation were conducted as part of a multi-year long design-based research project (Reeves, Herrington & Oliver, 2005). In conducting a formative evaluation, a variety of methods can be employed that vary in the types of data collected (quantitative or qualitative), technical sophistication, type of researcher/participant contact (eg, interviews or e-mailed questionnaires), the specific questions addressed and the number of people who would be contributing data. At different points in a design-based research study, the researcher/evaluator needs to ask, "What do we need to know now?" (McKenney & Reeves, 2012, p. 133), and then determine the best way to collect the relevant data. Multiple methods provide a richer understanding but also help to cross-validate the results. In this specific study, two different risk assessment strategies were incorporated into the formative evaluation, as described in more detail below.

Risk assessment in formative evaluation in the literature

There is limited literature on risk assessment in relation to formative evaluation and no model could readily be used or adapted for the purpose of analyzing risk in the e-learning course described in this paper. Lynch and Roecker (2007) recommended using risk assessment as part of an evaluation, and presented a simple form to collect data that could be used in such an assessment. Similarly, Benson and Brack (2010), in their planning guide for online learning and assessment, noted that an important administrative function in planning an online assessment was the completion of a risk assessment of four components: (1) student support factors (such as access and equity issues), (2) technical issues (such as access to hardware and software, bandwidth, etc), (3) authentication (such as cheating, collusion, plagiarism, etc) and (4) consideration of the instructor's administrative skills (such as ability to use software, manage online grading, copyright, etc). However, while these descriptions were helpful, no appropriate model or framework of risk assessment was provided. As our project aimed to develop a complex online authentic learning environment involving a community of international learners, risk assessment strategies needed to be custom-built, as described below.

The e-learning course being developed

With the increasing development of biotech medicines and the growing use of vaccines, there is a greater concern as to how these time- and temperature-sensitive pharmaceutical products (TTSPPs) are transported, stored and distributed to the end-users (Milstien, Kartoğlu & Zaffran, 2006). Exposure to high temperatures can cause a drug to deteriorate, resulting in a lack of effectiveness and an increase in impurities. For other products, like human insulin and certain vaccines, freezing can cause immediate damage to the molecule, rendering it inactive. In both situations, there are individual and public health implications (Ewbank & Gribble, 1993). To keep these TTSPPs at the proper temperatures (typically 2 to 8 degrees centigrade), a cold chain is utilized. A *cold chain* is the integrated system of equipment (eg, shipping containers, refrigerators, trucks), procedures, records and activities used to handle, store, transport, distribute and monitor time- and temperature-sensitive products (Afsar & Kartoğlu, 2006). 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 develop the knowledge and problem-solving skills of people directly (eg, vaccine manufacturers, public health professionals) and indirectly (eg, packaging developers, engineers who design electronic temperature monitoring instruments) involved with pharmaceutical products, the World Health Organization's Global Learning Opportunities for Vaccine Quality created an e-learning course based on a unique experiential learning event, Pharmaceutical Cold Chain Management on Wheels (PCCMoW). This annual PCCMoW event takes fifteen carefully selected participants on an actual weeklong bus trip in Turkey during which they can make direct observations at the storage, warehousing, distribution and health care facilities they visit as they physically travel with mentors down the length of the cold chain (Vesper, Kartoğlu, Bishara & Reeves, 2010; WHO, 2005, 2008). Because of logistical constraints, this experiential learning opportunity can be offered only once a year to just 15 participants.

By contrast, the 12-week e-learning course we have designed provides a virtual bus trip to learners, making extensive use of video and photographs, and a variety of authentic learning tasks (Herrington, 1997; Herrington, Reeves & Oliver, 2006; Herrington *et al*, 2010), which the learners complete online as individuals or in small groups. A key reason for developing the e-learning course was to allow many more vaccine professionals to learn about handling TTSPPs than was possible in the annual physical bus trip. This kind of immersive and authentic web-based journey is substantially different in design, pedagogy and implementation to most e-learning courses, and so it was important to assess the risks associated with such an approach.

Method

Risk assessments were conducted in the first two iterations of formative evaluation of the virtual learning environment. The initial formative evaluation focused on visual design, interface design and instructional design. It was performed independently by two expert instructional designers and one expert graphic designer. All had extensive experience designing e-learning courses for adults in the health care and pharmaceutical industries. Each expert was asked to employ risk-based thinking and create risk scores that would be used to prioritize their proposed changes to the e-learning course.

The second risk assessment was conducted during the second formative evaluation by the project's learning consultant together with three people who were involved in developing the course and who would be the mentors during implementation of the e-learning course. This formative evaluation examined a working "alpha" version of the course and focused on implementation issues. In contrast to the first risk assessment, which was performed individually by the expert evaluators in isolation, the second assessment was conducted in a group setting and facilitated by a researcher who had extensive experience in risk assessment and risk management.

The risk assessment and risk management process
Before starting a risk assessment, it is essential to clearly define what is being assessed. This can be done by a written description, flowchart or diagram (ICH, 2005). For this project, the scope of the risk assessment included:

- the e-learning application,
- technological infrastructure enabling the use of the application, and
- all participants in the course (including the learners and the facilitators/mentors).

One other critical, but often overlooked, element is clearly defining the "risk question" that the risk assessment is meant to answer (Vesper, 2006). This is consistent with Reeves and Hedberg's (2003) key reason for conducting a formative evaluation: answering questions that can be used to make decisions about development and refinement of a prototype program. Examples of risk questions used include:

1 What are the IT/technology risks associated with this e-learning project?
2 What are the risks related to the community of learners due to inappropriate communication?
3 What are all the risks that could arise when using this e-learning program in different countries?

As can be seen in these examples, risk questions can define the scope of the risk assessment from very specific (eg, risk question 2) to very broad (eg, risk question 3).

Identifying hazards
It is important to distinguish between *hazards*—the source of harm—and *risks*—the combination of the likelihood of the occurrence of the unwanted event resulting in the harm and the impact of that harm (ICH, 2005). When beginning a risk assessment, one first needs to identify the hazards using one of a variety of methods. A brainstorming activity can be used, for instance, by asking the simple question, "What might go wrong?" Another approach (and the one that was used in the second assessment described above) is hierarchical holographic modeling (Haimes, Kaplan & Lambert, 2002) where, for example, participants first list success scenarios that are desired conditions or outcomes of the e-learning course, such as, "learners can successfully access the e-learning on any computer running standard web browsers (eg, Safari, Internet Explorer, Chrome)."

In this formative evaluation, the evaluation team first brainstormed success scenarios by specifying what would be necessary for a successful e-learning Pharmaceutical Cold Chain Management course (e-PCCM). The team then identified actions, events or situations—the hazards—that could prevent or interfere with a successful e-PCCM deployment. The list was then condensed based on those hazards that were considered most relevant, and then discussed further using a preliminary risk assessment (PRA) tool as described below.

Determining the risks
A PRA can be used early on in a project when minimal information is available, or as a screening tool to identify risks that need to be examined more critically using other tools, such as FTA or FMEA (Vesper, 2006). For the purposes of this evaluation, it was decided that the PRA alone would provide an appropriate level of detail of the risks so that actions could be taken to control or mitigate those risks deemed significant. For each of the hazards, specific questions were asked in order to help determine the risk. These included:

- *What are the potential negative impacts to the learners and the desired course outcomes?* Answers to this question provided examples of the consequences or harm should the hazard be expressed.
- *What could cause this unwanted event to occur?* Here, the team identified the hazard scenario.

These data were summarized in a table and the team estimated the likelihood that the hazard would be expressed resulting in the harm, using a scale of low-medium-high (1-2-3 respectively).

In a similar way, the impact was estimated, again using a scale of low-medium-high (1-2-3). Multiplying these two numbers resulted in a risk score—the higher the number, the more risk considered to be present.

The last step of risk assessment is risk evaluation: deciding on and prioritizing the risks that need to be reduced. Generally, priority is given to the high or medium risks that can be addressed through control and mitigation. Other, low-level risks might be attended to as well if the benefits are likely to outweigh the risk-reduction cost.

Reducing the risks through "treatment"

Risk treatment (ISO, 2009) involves two key concepts: control and mitigation. Control is aimed at *preventing* an unwanted event from occurring in the first place; the focus is on reducing the likelihood by targeting the root and contributing causes of an unwanted event. Mitigation assumes an unwanted event may occur but aims at *protecting* the "thing of value" (CSA, 2002). For example, one cannot totally prevent a server crash at a hosting site, but one can take protective measures should this happen. Whenever possible, it is recommended to use multiple-risk treatment approaches, which have a "layering" of control and mitigation actions that are tied to the different causes or mechanisms that were identified. These layers result in a more robust solution should the hazard be expressed. For each of the risks that were identified, the team created a risk treatment plan.

Using the general risk assessment and risk management method described above, the design team members were able to systematically and proactively identify risks and determine various ways to reduce them. These are presented in the following section.

Results and discussion

Risk assessment by expert evaluators

In the project's first risk assessment conducted by the expert evaluators, a tool common in engineering and the pharmaceutical industry—FMEA—was used by adapting a data collection table. In performing an FMEA on a design, different design elements are identified, and each design element is examined in turn. For this evaluation, three such elements were considered: visual design, interface design and instructional design. The expert evaluators were provided with detailed descriptions of the course and the intended audience along with drawings and screen shots of user interfaces proposed by the e-learning course design team; each risk was ranked and prioritized based on a risk score using a worksheet as shown in Figure 2. This risk score was created by assigning values from a defined scale and computing (1) the perceived severity of the negative impact and (2) the perceived likelihood that a hazard would be expressed. Based on relative risk ratings, priorities and recommendations for improvement were instituted.

Based on the written comments of the expert reviewers, the team completed the FMEA (see Figure 3) by adding risk items if they met the following criteria:

1 There was a clear consensus by the experts (two of two, or three of three experts) OR
2 There was a split in expert opinion (two of three) OR
3 The observation was supported with comments/observations elsewhere in a different expert reviewer's worksheet.

Based on the established rating and scoring rubric, the five issues of highest concern for the reviewers (along with the risk score; 25 being maximum risk possible) were the following:

- Look and feel of the visual design (15)
- User controls/navigation (12)
- Time to complete course exceeding the expectations that were set (9)
- Interface design (9)
- Progress indicators (6)

Failure Mode Effects Analysis (FMEA)
Reviewer name:

Project:

Risk Question: **Date:**

Step #5

Risk ID #	Failure Mode	Failure Effect	Failure Mechanism	Extent of Failure	Severity of Consequence	RPN (E x S)	Suggested improvements
	What could fail?	*What could happen if it fails?*	*What could cause it to fail,* ***WHERE SPECIFICALLY -***	*What is the likelihood that the failure occurs and has this effect? (See 1-3 rating scale.)*	*How significant is the impact? (See 1-5 rating scale.)*	*(calculated)*	*What could be done to prevent the failure*

Figure 2: A modified failure mode effects analysis (FMEA) template used to collect and display data

As can be seen in the list of issues above, none of the salient issues involved the instructional design that was used in developing the course, or in the authentic activities and solutions incorporated into it. All five issues were documented, analyzed in more depth and discussed with the project sponsor and design team members prior to continuing to develop the course. Changes that were implemented by the design team in prototype version of the course included a visual design and color palette that were more "corporate" than the original illustrated style design, user interface and controls that were more simple and consistent, and the provision of progress and completion indicators.

Risk assessment by mentor team

Based on the experience in the first risk assessment, it was decided to conduct additional risk assessment using a team approach. In doing so, the team identified the success criteria of an e-learning course that included factors such as effective communication, participants, mentors, IT, future-proofing and evaluation. The question asked to stimulate the brainstorming was "what are the contributors to a successful e-learning course on handling time- and temperature-sensitive pharmaceutical products?" The answers became the basis for categories from which subcategories were identified that gave more specific, detailed information. Based on these categories and their subcategories shown in Figure 4, team members then brainstormed situations or events that might prevent or interfere in achieving the success criteria. These were the hazards that were further analyzed using a PRA as shown in Figure 5. Included in the analysis were an identification of the harm or impact of the unwanted event (Figure 5, column 3) and what could cause or contribute to the occurrence of the unwanted event (Figure 5, column 4).

Team members then rated the harm and likelihood of occurrence for each hazard using a predefined scale. Risks were then evaluated and prioritized based on the multiplied harm and likelihood ratings. For each of the risks identified as critical, the team prepared a risk treatment plan. In some cases, it included providing information to the participants such as recommendations for browsers that tested favorably. An example of an identified risk is that certain governments do not allow access to the Internet because of censorship restrictions. In such countries, learners would not have access to web-based video material for the course. A mitigation plan was established to pre-produce DVDs of the video segments and send them by DHL courier to the course participants

Failure Mode Effects Analysis (FMEA)
Reviewer name: ***(Composite of all expert reviewers)***

Project: ***Formative evaluation, 1***
Risk Question: ***What are the risks in the early designs of the e-PCCM course that could reduce user acceptance and the success of the course?***

Risk ID #	Failure Mode	Failure Effect	Failure Mechanism	Extent of Failure	Severity of Consequence	RPN (E x S)
	What could fail?	*What could happen if it fails?*	*What could cause it to fail, WHERE SPECIFICALLY?*	*What is the likelihood that the failure occurs and has this effect? (See 1-3 rating scale.)*	*How significant is the impact? (See 1-5 rating scale.)*	*(calculated)*
1	Look and feel of the visual design	· Perceived disconnect between content and visuals · Expectations of learners not met	· Illustrative style used · Colors · Design not consistent with how users' eyes move over image	**3**	**3**	**9**
2	Interface design	· Steep learning curve · Unnecessarily high cognitive load on learners · Effort being put on an aspect of using the tool that has no relevance to learning/content · Learner frustration	· Complexity of menus · Large number of options · Difficult to use	**3**	**5**	**15**
3	User controls/ navigation	· Extra errors in moving through program · Extra time to recover from errors · Extra cognitive load · Learner frustration	· Inconsistency in screen-to-screen and program navigation · No "home" button · Movements, patterns are not consistent with other "typical" interfaces; not consistent between screens	**3**	**4**	**12**
4	Time to complete course exceeded beyond the expectations that were set	· Not completing assignments · Not completing assignments in a timely way · Team issues/conflicts · Learner frustration · Mentor frustration	· Too much material · Activities taking learners longer than planned	**3**	**3**	**9**

Figure 3: Completed failure mode effects analysis (FMEA) based on input of expert reviewers during initial formative evaluation

upon request. Because of the risk assessment and preparations that were made, when a participant in the course advised that he or she was not able to access the videos because of a government restriction, a DVD was shipped and arrived within 2 days, allowing him or her to continue with the course with little disruption.

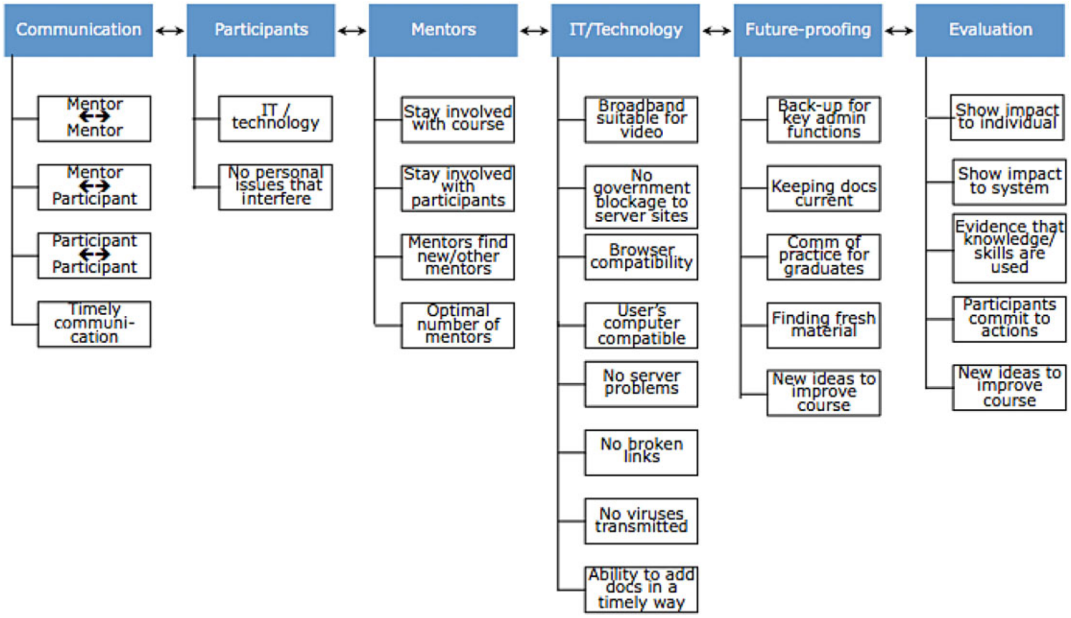

Figure 4: Contributors to a successful e-learning course shown using a hierarchical holographic model (after Haimes et al*, 2002). IT, information technology*

Preliminary Risk Analysis Worksheet
Item analyzed: e-PCCM Course (18 Feb 13 version)
Risk analysis project: Formative evaluation
Risk Question: What are the risks of a TECHNOLOGY RELATED issue with the e-PCCM course?

	Step #1	*Step #2*	*Step #3*	*Step #4a*	*Step #4b*	*Step #4c*	*Step #5*
Risk ID #	**Unwanted Event/ Hazard**	**Consequences / Harm**	**Contributing Causes**	**Likelihood of Occurrence**	**Severity of Consequence**	**Risk Score**	**Possible Additional Controls/Actions**
	What could happen?	*What is the potential negative impacts to patient, product, regulatory status, other things of value?*	*What could cause this unwanted event to happen?*	*What is the likelihood that the event & the harm will occur? (rating scale)*	*What is the impact of this consequence? (rating scale)*	*(calculated)*	*What might be done to reduce the likelihood and/or severity?*
1	Incompatibility of browser with website	> Limited access to sections of course > No access to parts of pages	> Set-up of browser > Internal browser thing > Coding issue	1	3	**3**	1) Recommendations of browsers NOT to use 2) Determine cause of problem if possible 3) Tell what browers are supported
2	Bandwidth issue (user side)	> User can't get timely access to videos, docs	> Local provider bandwidth issue	2	3	**6**	1) Send out DVD of videos and docs
3	Government (of participant) blocks server sites (e.g., VIMEO)	> User can't get any access to videos, documents, or course	> Local political issues	2	3	**6**	1) Send out DVD (via express shipment e.g., DHL) 2) Have mirrored alternative sites for videos, etc 3) Make videos available as downloads (e.g. DROPBOX or Yousendit) 4) Inform participants of the possibilty; have them communicate to mentors if there is a problem
4	DVDs/downloads get distributed to others	> Information (e.g., imbedded poor practices) gets distributed and used out-of-correct-context	> Information not controlled (e.g., via streaming)	1	3	**3**	1) Have mirrrored sites available for videos whenever possible 2) Put notice on DVD 3) Have participant agree not to transfer to others
5	Server problems or outages – at host sites (host server, VIMEO	> Non-availability of site and resources when needed by participant	> Crashes – unplanned outages > Planned outages (e.g., for maintenance)	1	2	**2**	1) Find out about site's contingency plans 2) Communicate planned outages with participants in advance 3) Mirror materials on other hosting sites

Figure 5: Section from a preliminary risk analysis worksheet

Conclusion

This paper has described how the formal use of risk assessment and risk management techniques was successfully integrated into the formative evaluation process used in developing a complex e-learning program. By using standard risk assessment tools that have been used in other industries and endeavors, risks were proactively identified and prioritized. Results were then used by the designers and developers to make changes at an early stage in the course when modifications were relatively simple and less costly. Additionally, performing a broadly scoped risk assessment with the facilitators/instructors prior to starting the course identified potential impediments to a successful implementation and execution. Various scenarios could be hypothesized, discussed, evaluated and—if deemed significant—controlled or mitigated.

Beyond identifying and reducing risks, the risk assessment process in this project had the benefit of increasing communication between course developers, design team members and facilitators/instructors. Sharing information helped all parties have a richer understanding of the goals of the project, the purpose of each course element and ways design features could be optimized to benefit learners. Furthermore, specific hazard identification and risk assessment tools, such as FMEA, PRA and holographic hierarchical modeling, were found to be flexible and easily adapted within the context of the formative evaluation stages of a design-based research study.

Risk management of educational information and communication technology projects is an essential process (Baccarini *et al*, 2004) and yet it is not routinely practiced in the development of computer-based environments. This paper has described some key benefits of incorporating risk assessment in the development phase of a complex web-based learning environment—processes that may hopefully become more widespread and routine in future developments throughout the sector.

Statements on open data, ethics and conflict of interest

Open data statement

The data used in the expert FMEA and team HHM and PRA are contained in the PhD thesis by the primary author, entitled, *Developing Expertise of those Handling Temperature-Sensitive Pharmaceutical Products Using E-Learning: A Design Research Study.* The thesis is available online at: http://researchrepository.murdoch.edu.au/24443/.

Ethical declaration

This research was conducted with the approval and oversight of the Murdoch University (Perth, Western Australia) Ethics Committee.

Conflicts of interest statement

There are no conflicts of interest between the research described in this paper and any of the authors.

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