Original Research

A Case Study in Experiential Learning: Pharmaceutical Cold Chain Management on Wheels

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Introduction: *People who handle and regulate temperature-sensitive pharmaceutical products require the knowledge and skills to ensure those products maintain quality, integrity, safety, and efficacy throughout their shelf life. People best acquire such knowledge and skills through "experiential learning" that involves working with other learners and experts.*

Methods: *The World Health Organization developed a weeklong experiential learning event for participants so they could gain experience in how temperature-sensitive products are handled, stored, and distributed throughout the length of the distribution supply chain system. This experiential learning method enabled participants to visit, critically observe, discuss and report on the various components of the cold chain process. An emphasis was placed on team members working together to learn from one another and on several global expert mentors who were available to guide the learning, share their experiences, and respond to questions.*

Results: *The learning event,* Pharmaceutical Cold Chain Management on Wheels*, has been conducted once each year since 2008 in Turkey with participants from the global pharmaceutical industry, health care providers, national regulatory authorities, and suppliers/vendors. Observations made during the course showed that it was consistent with the principles of experiential and social learning theories. Questionnaires and focus groups provided evidence of the value of the learning event and ways to improve it.*

Discussion: *Reflecting the critical elements derived from experiential and social learning theories, five factors contributed to the success of this unique experiential learning event. These factors may also have relevance in other experiential learning courses and, potentially, for experiential e-learning events.*

Key Words: *experiential learning, social learning, pharmaceutical cold chain, handling of pharmaceutical products*

Introduction

Cold Chain Described

Many pharmaceutical products[a] are temperature-sensitive and must be stored and transported at controlled temperatures—for instance, 2 to 8 degrees Centigrade.[1] Exposure to temperatures outside the recommended range can result in damage to the product and cause safety issues or lack of effectiveness.

A "cold chain" is the integrated system of equipment (eg, cold rooms, shipping containers, refrigerators, vehicles), procedures, records, and activities used to handle, store, transport, distribute, and monitor temperature-sensitive products.[2–4] The allusion to a chain is apt. As with a physical chain, a cold chain is only so strong as its weakest link.

People are a critical element of a cold chain. They must correctly execute procedures and take appropriate actions in the event of a problem. Beyond the people directly involved in the cold chain are those who design and develop equipment and devices used in handling pharmaceutical products. Everyone involved must have the appropriate knowledge and skills to perform their jobs, as well as a vision of how the whole handling operation can be maintained and enhanced.

Disclosures: The authors report none.

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• Published online in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/chp.20087

[a] *Pharmaceutical product defined by the World Health Organization:* Any product intended for human use or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals, and vaccines. It does not, however, include medical devices.

The Need for Knowledge and Skills—The Problem

The World Health Organization's Global Learning Opportunities for Vaccine Quality (previously called Global Training Network) recognized the need to develop the knowledge and skills of those involved in the pharmaceutical cold chain. Specifically, the challenge was *how to provide an engaging learning event for manufacturers, health care providers, regulators, and other partners in the supply chain of temperature-sensitive products so they could critically evaluate a pharmaceutical "cold chain" system to ensure the quality, integrity, safety, and efficacy of the pharmaceutical product to the patients.*

Learning Through Experiences with Others—The Solution

Acquiring knowledge and skills from experience is one important method for developing competence in a task, occupation, or profession. Internships, clinical rotations, and practicums are examples of experiential learning, a highly regarded component of adult learning theory.[5] Kolb[6] defined experiential learning as "The process whereby knowledge is created through the transformation of experience. Knowledge results from the combination of grasping and transforming experience." FIGURE 1 depicts Kolb's cycle as modified by Boisot.[7]

These stages form a dynamic learning cycle that a learner can enter at any stage, based on the unique characteristics of the individual.[8] The four stages can be categorized into two sets of activities. First, concrete experience and abstract conceptualization occur when the learner "grasps" experiences. Second, reflective observation and active experimentation allow the learner to transform experience into knowledge and skill.

Experiential learning is categorized into two different types: one which is more personal and informal (eg, learning from experience that one should always read through an e-mail before sending it) and another type that is a designed learning event with situations to which the learner is intentionally exposed. This second type of experiential learning best matches the Pharmaceutical Cold Chain Management on Wheels (PCCMoW) learning event described below.

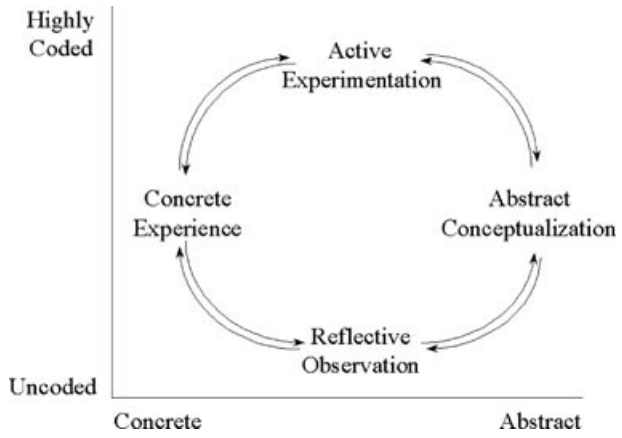

FIGURE 1. Kolb's Learning Cycle (modified by Boisot).

Kolb[6] states, "Experiential learning is not a molecular educational concept but rather is a molar concept describing the central process of human adaptation to the social and physical environment" (p. 171). Social settings in which people interact with others are an essential element in Vygotsky's social learning theory.[9] Two key principles in Vygotsky's model are important in understanding how a person learns. First, there needs to be a more knowledgeable other (MKO)—a person (or other resource, eg, a computer) who knows more or has more advanced skills than the learner. Second, Vygotsky describes a "zone of proximal development" (ZPD) that posits where the learner is at any given point in his or her learning path through which the learner can progress with the support of the MKO.

Kolb's experiential learning and Vygotsky's social learning theories complement each other as the learner builds his or her own mental representation and meaning of experiences. The MKO provides or shapes the experience and guides the learner through the scaffolding as the learner observes and reflects on the experience and creates concepts that are tested and refined in new situations. The MKO can expand the ZPD by guiding the learner through more challenging experiences, so the learner can develop more accurate and robust knowledge.

What might this look like in reality? The PCCMoW course provides an example that applies the concepts of experiential and social learning theory. The PCCMoW course can also be examined in terms of outcomes using a seven-level model developed by Moore et al[10] for assessing and evaluating continuing medical education (CME).

Methods

The developers of the PCCMoW course looked for ways that would be richer and more engaging than a series of illustrated lectures. Specifically, they looked for ways that a group of participants ranging from regulatory authorities to health care providers from around the world could share their knowledge and learn together while working on authentic tasks. Participants represented a variety of roles within the cold chain, such as national regulatory authorities; manufacturing and quality assurance personnel from the pharmaceutical, biopharmaceutical, and vaccine industries; health care professionals who administer temperature-sensitive pharmaceuticals; and others involved in the supply, packaging, distribution, logistics, and cold chain management areas.

Additionally, the intent was to form a learning community that extended beyond the conclusion of the course. Therefore, a password-protected alumni community was developed wherein members cooperate and support each other via e-mail and online discussions as well as at conferences focused on cold-chain topics.

DOI: 10.1002/chp

Enrollment in each PCCMoW course is limited to 15 participants carefully selected by the course director. Three mentors with extensive, comprehensive experience in the international pharmaceutical industry support the participants throughout the course by coaching participants during their assignments, facilitating discussions following presentations, sharing best practices, and guiding the group toward sound conclusions.

The course encourages participants to make direct observations at the storage, warehousing, distribution, and health care delivery facilities that they visit, 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 under the supervision of the mentors. Participants are provided with guidance 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. Turkey was selected as the course venue in part because of the availability of the tour coordinator who arranged the logistics and helped with the extensive planning required.[11–13]

Course Approach

Prior to boarding the bus in Istanbul to begin the 6-day experiential learning opportunity, the 15 participants, 3 mentors, and tour coordinator gathered to meet each other, discuss expectations, and perform a "knowledge check." During this initial meeting, the course mentors provided the general outline that would be used each day during the course:

- An extended tour (2–3 hours) of a facility (eg, pharmaceutical cold storage warehouse, ministry of health storage depot, hospital, primary health care center, pharmacy) including the opportunity to observe, ask questions of facility management and staff, and document their observations and findings
- Small group (5–8 people) discussions about what was seen
- Small group presentations about a defined part of the site (or operations), which included answering 4 questions:
  - What were the facilities/activities observed during the visit?
  - What were some of the strengths of what you saw?
  - What are some areas of enhancement/improvement you would suggest?
  - What are some questions/issues that you would like to discuss?
- Plenary discussions with the whole group

Another feature of the course was a mid-course questionnaire, conducted on day 4 of the 6-day course. This multiple-choice assessment was completed by the participants while traveling on the bus. The intent of the assessment was to provide a starting point for a one-on-one discussion that each participant had with a mentor to ensure understanding; it was not a test to determine whether the participant "passed" the course. The mid-course questionnaire enabled mentors to clarify any confusion as well as emphasize the critical messages. This approach helped ensure that nothing remained unanswered or unclear—something that cannot be achieved in end-course questionnaires or assessments.

The course was evaluated using:

- A feedback form that allowed participants to provide written comments
- A focus group session in which each participant, mentor, and tour coordinator was invited to share what the experience meant to him or her
- Follow-up online questionnaires

Results

The PCCMoW course exhibits many attributes of experiential and social learning, consistent with the work of Kolb and Vygotsky. In Kolb's four-stage model, learners may enter the process at any point,[14,15] in part based on the individual's learning style. For simplicity, we will enter the process at the Concrete Experience stage.

Concrete Experience

One way that the learner "grasps" experience is by using his or her senses to absorb what he or she is experiencing. TABLE 1 illustrates a typical day in the course. In the

TABLE 1. Typical Agenda for the PCCMoW Course

Time	Activity
8:00–8:30	Warm-up Program for the day
8:30–9:00	Board bus and travel to Provincial Health Directorate Vaccine Storage facility
9:00–9:30	Meeting with Provincial Health Director
9:30–11:30	Tour of Provincial Health Directorate Vaccine Storage facility and work in groups (storage area, temperature monitoring, distribution, and transport)
11:30–12:00	Departure/travel to lunch
12:00–13:00	Lunch with representatives of local pharmacies and provincial pharmacy board
13:00–16:00	Small groups (4 participants and mentor/travel coordinator) visit local pharmacies
16:00–21:00	Travel time (1 hour); preparation of small group presentations (2 hours), small group presentations and discussion (2 hours) Evaluation of the day
21:00	Check-in at hotel
21:00	Dinner at hotel

DOI: 10.1002/chp

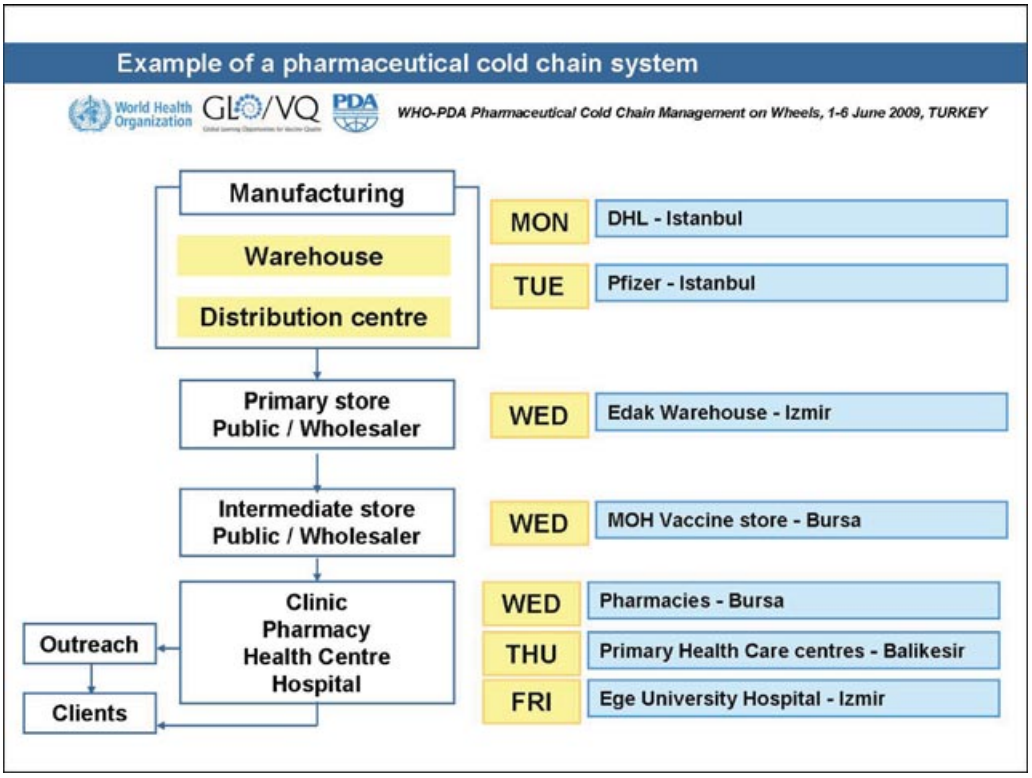

FIGURE 2. Example of the Pharmaceutical Cold Chain System Visited During the Pharmaceutical Cold Chain Management on Wheels Course in Turkey.

PCCMoW, participants had a variety of concrete experiences at different locations identified in FIGURE 2, some planned by the course developer and others that were serendipitous. For example, participants:

- Felt a 2–8-degree Centigrade room's cold environment
- Saw how shipping boxes were packed with ice/cold packs to keep the pharmaceutical products at the proper temperature
- Heard alarms indicating that a cold room was warmer than its specified temperature because of a door being left open for an extended time
- Touched ice packs that were properly "conditioned" prior to their use.

Reflective Observation

Here the learner transforms the concrete experience and finds meaning. After a visit to a facility, the PCCMoW learners would work in small groups and prepare a presentation on what they had seen. They would describe their experiences using images (from photos they had taken or simple diagrams) and words (written on PowerPoint slides or spoken). Using the collective knowledge of the small group, the participants identified areas of strength (what they saw that they felt worked well) and areas potentially in need of improvement. The small groups also listed questions or issues to be discussed.

Abstract Conceptualization

Here, inductive reasoning is used to create "rules" that can be applied in other situations. Because of the varied backgrounds of the participants, many of them had specific interests and questions that they wanted to have addressed. For example, participants saw a temperature-monitoring device made by one firm but they might use a similar device made by a different firm. Would the devices monitor and record the temperature data in the same way? Was the data equally reliable and trustworthy?

Active Experimentation

Using the rules (ie, concepts) that had been created, the learner applies or experiments with them in a different situation. If the experiment confirms the rule, the learner can try it in other contexts; if the experiment fails to confirm the rule, the learner uses this information to correct, revise, or refine, the concept. In the PCCMoW course, experimentation took place in different ways. As different sites were visited, the learners were observed asking more specific, critical questions—here, experimentation overlapped with the concrete experience stage discussed above.

Another way experimentation was used was with new situations that were hypothetical to the group. These "what if" questions were raised by the learners out of general curiosity or because of situations from their own professional experiences. At other times, a mentor would present a situation

DOI: 10.1002/chp

and ask, "How would you handle this?" The mentors tried to show that in many situations there was not one absolute right answer, but several solutions that could be used, given the available resources and constraints.

Another lens for viewing the PCCMoW is provided by the social learning theory of Lev Vygotsky,[9] which explains the causal relationship between social interaction and the cognitive development of learners. As noted above, two primary constructs within this theory are the ZPD (zone of proximal development) and the MKO (more knowledgeable other).

Zone of Proximal Development

Vygotsky[9,p.86] defined this as the distance between the actual development level as determined by independent problem solving and the level of potential development as determined through problem solving under adult guidance or in collaboration with more capable peers.

Understanding the development level (or, more specifically in this case, the knowledge level) of the participants as they arrived at the PCCMoW course was important to the mentors so they could best meet their needs. An anonymous pre-course questionnaire—35 true/false questions—was given on the first day and scored; the results were used to generate a histogram on a flip chart while another mentor discussed the answers. The histogram showed where the group had the most knowledge and where there were gaps. The pre-course questionnaire also served as a preview of the course content and whetted the participants' appetite for learning.

Another aspect of the ZPD—how it can expand or shift as the learners gain more knowledge and skills—was observed in how the learners experimented with the concepts they generated. They asked more sophisticated and relevant questions during the site visits later in the week. Serendipitously, the sites visited earlier in the week had more modern, elaborate systems for controlling and monitoring temperature than some sites visited later in the week. This was an opportunity for the learners to "compare and contrast" what they had seen and what they were seeing.

More Knowledgeable Other

A learner's progression through the ZPD is "under adult guidance or in collaboration with more capable peers," (ie, a more knowledge other, or MKO). The MKO supports and guides the learner to expanded knowledge and skills.

The role of the PCCMoW mentors as MKOs went beyond the sharing of information; they helped develop the participants' critical thinking skills. The mentors worked to facilitate a learning environment in which everyone could learn from each other: mentors learning from the other participants, mentors from mentors, participants from participants. Having participants with a mix of backgrounds, experiences, and professional roles contributed to a rich fabric that supported mutual learning. Having mentors who modeled the "everyone is always learning" philosophy contributed as well.

An important question that a stakeholder—a participant's supervisor, a funder, the course organizer—might ask is, "Did participating in the course lead to improved outcomes in the handling of temperature sensitive pharmaceutical products?" To address this question, a model described by Moore et al[10] is illustrated in TABLE 2 with a definition of each step and a description of data captured from the course.

Taken together, these levels provide compelling, although incomplete, evidence of the overall value of the learning event. Of particular interest was how participants used (or didn't use) the information gained during the learning event. TABLE 3 shows the questions that were asked of participants after their completion of the 2008 and 2009 courses, and some specific ways that they applied their new knowledge and skills in their work.

Discussion

Critical Success Factors

The evaluation of this unique course confirmed the importance of five factors. Some were related specifically to experiential learning (factors 2 and 3); others were derived from the previous experience of the developers of the course (factors 1, 4 and 5).

Factor 1: A rich learning space where experiences could happen. Without access to the venues and the hospitality of our hosts, the course would not have been possible. The doors to facilities and opportunities were opened to the learners, in part, due to the reputation of the sponsoring organizations. Full access to the venues was granted because of the strong case the program director could make to sites: Sharing their facilities and practices would have an important public health impact on the participants and in their professional roles in their countries. Additionally, each site received feedback on what the participants saw, helping the site benchmark its operations and make enhancements as it saw fit.

Factor 2: A safe space for learners, mentors, and other participants. Having a learning environment that is safe and inclusive for a diverse set of learners is important to both the individual learner and the learning community.[16] The more diverse a community, the more complex this becomes.

It was also important for the people at the sites that were visited to feel comfortable and safe with respect to the information they provided. The storage facilities, health centers, governmental bodies, hospitals, and pharmacies were generously made available to the group; the course mentors did not want anything to embarrass or harm those who opened their doors to the learners. For this reason, learners and mentors agreed that only positive feedback be given at the site; any critical comments would be discussed and filtered by the course mentors and provided back to the site appropriately by the mentors.

DOI: 10.1002/chp

TABLE 2. Comparison of Expanded CME Framework with Assessment and Evaluation Data from PCCMoW Course (based on Moore et al., 2009)

Level	Description	How this was used in the PCCMoW Course
Level 1—Participation	The number of those participating in learning event	Attendance in events throughout course
Level 2—Satisfaction	The degree to which the expectations of the participants about the setting and delivery of the learning event were met	Completed feedback survey form
Level 3A—Learning: Declarative knowledge	The degree to which participants can state *what* the learning event intended for them to know	Pre-/post-test Successful completion of mid-course questionnaire and discussion with mentor
Level 3B—Learning: Procedural knowledge	The degree to which participants state *how* to do what the learning event intended them to know how to do	Not used in course
Level 4—Competence	The degree to which participants *show* in an educational setting how to do what the learning event intended them to be able to do	Observation by mentors of presentations by participants Observation by mentors of findings (positive and negative) and ways to improve/enhance a situation
Level 5—Performance	The degree to which participants do what the learning event intended them to be able to do in their work or practice	Questionnaire requesting self-reporting of specific examples of how each participant has applied what he or she learned in the course
Level 6—Patient Health	The degree to which the health status of patients improves due to changes in the work or practice behavior of the participants	Not used in this course
Level 7—Community Health	The degree to which the health status of a community of patients changes due to changes in the work or practice of the participants	Not used in this course

Factor 3: A learning environment that encouraged critical thinking skills, inquiry, and understanding for everyone. A frequent answer to many technical and regulatory/compliance questions in the pharmaceutical industry is, "It depends." Effort was made by the mentors not to give an answer; rather, questions were often reframed or reworded by the mentors and given back to the learners for them to examine from multiple viewpoints, to consider risk (and the costs/benefits of various options) and the broader context of the issue. By not being given answers, the learners had to think through the rationale for certain requirements by keeping the local situation and public health consequences in mind. This was done not to challenge participants, but to help them succeed in finding solutions/answers.

In some cases after a discussion, the mentors would admit that they were also working to answer similar questions and that all of the group—participants and mentors—were continually learning because of new and different situations and challenges. (Indeed, participants commented on this: they had never seen "teachers" willing to admit that they were learning from their "students" and the experiences they were sharing together.)

Factor 4: Attention to details and logistics. One of the biggest compliments that a professional (in any field) can receive is, "You make it look so easy." That illusion comes through countless hours of planning, preparing, and attending to details, options, and contingencies in advance. The PCCMoW course credits the near flawless execution to WHO administrative staff and the onsite tour coordinator.

Factor 5: People want to have fun. Having a variety of experiences contributes to the richness of experiential learning. Even though it meant longer days (sometimes not checking into the hotel until 10:00 P.M.) the PCCMoW course developers recognized that for the participants to be able to put their observations into a meaningful context, they needed to understand the local culture to a greater extent than first-time visitors to Turkey would normally have. Therefore, they

TABLE 3. Post-Course Survey Questions, Responses, and Examples

Question	Response (*n*/total)	Examples provided by respondents (description of respondent)
Has your participation in the course had an impact on your organization or its stakeholders?	YES (14/19) NO (5/19) (1 skipped question)	"I learned a lot about the way our clients are working. We discussed these topics internally and we are still trying to implement some of the ideas into the development of our new products." (Engineer of temperature monitoring equipment) "I was asked by my boss to develop a cold chain assurance procedure." (National Authority drug inspector)
Have you been able to use and apply the knowledge and skills you acquired during the PCCMoW course in your work?	YES (18/20) NO (2/20)	"I have been using and applying the knowledge and skills I acquired during the PCCMoW course when inspecting/assessing the wholesalers, especially for the performance of pharmaceutical cold chain system." (National Authority drug inspector) "I presented a project to improve the way of temperature monitoring in the pharmaceutical refrigerators, starting with my institution." (National Authority vaccine application reviewer)
Can you identify one or two specific things that you are doing differently as a result of the course and what you learned?	YES (14/20) NO (5/20) (1 skipped question)	"I can inspect based on risk management and product risk on vaccine handling." (National Authority inspector) "I calculate carefully the cold space before asking for other vaccine quantities." (Local public health official)

Note: Respondents include participants from 2008 and 2009 PCCMoW courses. 27 persons received surveys; 20 people responded.

incorporated experiences related to the food, art, music, and history of Turkey into the course.

Conclusion

In examining the PCCMoW course, we see that its design and execution include the four aspects of experiential learning identified by Kolb and two important elements of social learning described by Vygotsky. We found some evidence that course participants were able to apply the knowledge and skills they acquired during the course in their jobs and practices. We identified 5 critical success factors necessary for an effective experiential learning course. Participant feedback indicates that a well-designed and executed experiential learning event can make an indelible mark on the participants.

This information can be used as criteria when evaluating existing experiential learning events sponsored by WHO and when creating other experiential learning events. WHO has had requests for providing the PCCMoW in other regions and for potentially thousands of learners. The work presented here is currently being used to assess the requirements for designing and producing new technology assisted/virtual versions of this experiential learning environment.

Lessons for Practice

- Rich and varied learning spaces are essential for experiential learning.
- Learning spaces that are safe for expressing original ideas and opinions for learners, mentors, and other participants are important, particularly in multicultural learning events.
- Mentors or instructors who use critical thinking skills and continual learning as part of what they do are powerful role models for all learners.
- Preparation and attention to details cannot be over-emphasized for the success of a learning event.
- An experiential learning event is enhanced when the participants have opportunities to engage with the broader context and culture surrounding the experience.

DOI: 10.1002/chp

Conflict of Interest Statement

James Vesper is the president of LearningPlus Inc., and participated in the 2009 PCCMoW course as mentor; he is an advisor to WHO's Global Learning Opportunities for Vaccine Quality. Ümit Kartoğlu works as a scientist at the WHO and is the PCCMoW course designer, course director, and mentor. Rafik Bishara is the chairperson of the PCCIG of the PDA and participated in the course as mentor in 2008 and 2009. Thomas Reeves is a professor of learning, design and technology at the University of Georgia and had no direct participation in the course; he is an advisor to WHO's Global Learning Opportunities for Vaccine Quality.

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