Vaccine 35 (2017) 2243–2251

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Experiential and authentic learning approaches in vaccine management ☆

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ARTICLE INFO

Keywords:
Vaccine management
Experiential learning
Authentic learning
E-learning

ABSTRACT

A high level of concern is placed on the storage, handling, transportation, and distribution of vaccines and other pharmaceutical products, particularly those that are time and temperature sensitive. While active and passive cooling equipment and monitoring devices are important, it is the various personnel responsible for executing and writing procedures, designing and operating systems, and investigating problems and helping prevent them who are paramount in establishing and maintaining a "cold chain" for time and temperature sensitive pharmaceutical products (TTSPPs). These professionals must possess the required competencies, knowledge, skills and abilities so they can effectively perform these activities with appropriate levels of expertise. These are complex tasks that require the development of higher cognitive skills that cannot be adequately addressed through professional development opportunities based on simple information delivery and content acquisition. This paper describes two unique learning solutions (one on a bus called the "wheels course" and the other online called "e-learning") that have been developed by WHO Global Learning Opportunities (WHO/GLO) to provide participants with opportunities not just to learn about cold chain systems or vaccine management, but, rather, to develop high levels of expertise in their respective fields through experiential and authentic learning activities. In these interactive learning environments, participants have opportunities to address real-life situations in contexts similar to what they may face in their own work environments and develop solutions and critical thinking skills they can apply when they return to their jobs. This paper further delineates the managerial and operational vaccine management functions encompassed in these two unique learning environments. The paper also describes the alignment of the objectives addressed in the "wheels course" and the e-learning version with effective vaccine management (EVM) criteria as prescribed by WHO. The paper concludes with an example of a real world product developed by course graduates (specifically a decision tree that is now used by some national programmes). These types of products, valuable in their own right, often emerge when learning environments based on authentic learning principles are designed and implemented as they were by WHO/GLO.

1. Introduction

Many pharmaceutical products including vaccines are time and temperature sensitive and must be stored and transported at controlled temperatures [1]. The increasing portfolio of vaccines and other biotech medicines dictate more effective and efficient operation of complex supply chains. Personnel who handle time and temperature sensitive pharmaceutical products (TTSPPs) must accommodate their different characteristics; all are sensitive to high temperatures and some highly sensitive to freezing. The recent focus on efficiency has led to increased interest in merging multiple disease-specific supply chains, such as vaccines, maternal and child health medicines, and family planning products, into one integrated supply chain [2,3]. Although quantification, procurement, and requisition/ordering for products in this integrated supply chain may represent challenges due to very different quantification, demand-planning, procurement mechanisms and processes, the storage and transport of TTSPPs present tremendous opportunities for integration.

The variety of products contained in temperature controlled supply chain is immense and is further complicated by each product having its own stability budget. A stability budget considers long term, accelerated, and stress temperature exposure, as well as temperature cycling studies to determine the amount of time

☆ Open Access provided for this article by PATH.

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http://dx.doi.org/10.1016/j.vaccine.2016.11.104
0264-410X/

out of storage that a drug product may experience without any significant risk to its quality [4]. The stability budget of a product is also considered critical when it comes to access issues such as where cold chain availability is problematic as well as in hard-to-reach geographical areas and in war conditions [4]. To keep these TTSPPs at appropriate temperatures to ensure their quality, a cold chain is designed and implemented as an integrated system of equipment, procedures, records, and activities [5].

When we speak of "pharmaceutical/vaccine product quality", there is much more that needs to be considered aside from the development, approval and manufacturing aspects - product quality must be viewed in terms of the patient or consumer of the product. All products spend considerable periods of time at storage facilities, in transport between warehouses, at hospitals, pharmacies, health centres and even within the homes of end-users. Therefore just offering a "quality" product to the market is not enough. The product's quality must be maintained throughout its life until it is consumed [6]. The legal requirements for distribution and handling of TTSPPs are known as good storage and distribution practices (GSP/GDP) [7–10]. These requirements require that personnel who handle and distribute pharmaceutical products have the education, training and experience required to perform their jobs effectively. In short, they must have expertise. This makes people the most critical element in a cold chain process.

Continuous lifelong learning is crucial for professionals who wish to maintain, upgrade and expand their expertise [11]. The importance of offering professional development opportunities for staff is widely recognised across sectors [12]. Increasingly, professional development programmes and courses are offered online. However, the intended outcomes of professional development, online or otherwise, are not always attained and the competencies, skills, knowledge and abilities that the professional development was set out to enhance are all too frequently not transferred into professional practice [12–14]. Moreover, online professional development programmes are often seen as being better suited for transmitting theoretical content rather than supporting the development of practical skills [15,16]. In order for professional development programmes to lead to sustainable professional growth and transfer of learning, both offline (typical leader-led courses) and online learning environments should prepare the learner to "... draw on a range of resources and to adapt learning to complex and ill-structured workplace problems" [17], rather than simply promote memorising and regurgitating factual knowledge.

2. Developing expertise in vaccine management

Expertise is the hallmark of an expert. It includes an in-depth set of knowledge, cognitive and motor skills, as well as the analytical ability to determine how to approach a given situation. Dreyfus and Dreyfus [18] quoted Aristotle in saying that the expert straight away does "the appropriate thing, at the appropriate time, in the appropriate way". In the context of handling TTSPPs, 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 consistent with both the letter and the spirit of the requirements.

People involved in distribution, storage, and transportation of supply chains perform a range of activities as described in their job descriptions. Those in operations typically execute procedures and tasks. Professionals in quality and management functions develop, optimize, and monitor system functioning. To identify the best ways of providing opportunities to develop the appropriate knowledge and skills for different jobs requires learning professionals to define the specific competencies required to successfully perform a job. Broadly speaking, those who develop and improve systems require a higher-level set of cognitive skills than those who must consistently and flawlessly execute procedures, an activity that must not be depreciated. Fig. 1 shows examples of competencies for two different groups involved with TTSPPs and how they align with Bloom's revised taxonomy [19,20]. The discussion that follows presents specific technical guidelines/requirements and how they relate to Bloom's taxonomy.

Table 1 lists operational and managerial vaccine management functions as prescribed by the World Health Organization (WHO) [21].

These functions are incorporated into the WHO effective vaccine management (EVM) assessment tool that assesses vaccine management functions through a systematic sampling in a country against nine high-level global criteria [22]:

1. Pre-shipment and arrival procedures ensure that every shipment from the vaccine manufacturer reaches the receiving store in satisfactory condition and with correct paperwork.
2. All vaccines and diluents are stored and distributed within WHO-recommended temperature ranges.

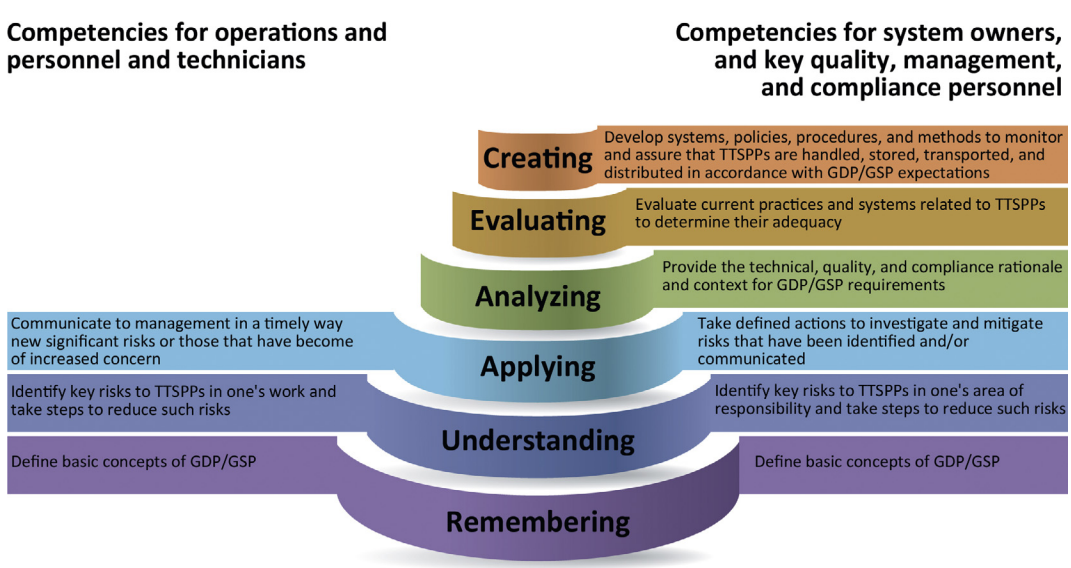

Fig. 1. Competencies and learning taxonomy.

Table 1
Operational and managerial vaccine management functions (WHO).

Operational vaccine management functions	Managerial vaccine management functions
• Carrying out deliveries in consultation with the management • Sorting of vaccines and immunization-related equipment as appropriate • Updating stock records (individual stock sheets per batch) • Monitoring storage temperatures and other conditions as appropriate • Conducting first-level maintenance of cold chain equipment • Informing management of any apparent problems	• Identifying and estimating needs for vaccines and immunization-related equipment in accordance with programme plans and projections • Coordination, preparation and ordering vaccines and injection equipment in a timely fashion • Overseeing systems for optimal use and maintenance of major cold chain equipment and transportation • Establishing standard operating guidelines for the clearance and receipt of vaccines and immunization-related equipment, including completion of Vaccine Arrival Reports • Receiving vaccines and handling of stocks; Clearing vouchers and relevant documentation required for the requisition and distribution of vaccines and immunization-related equipment to lower levels to ensure that adequate quantities have been delivered and can be referenced • Providing technical support to provincial and district level managers • Report-writing and record-keeping of archived documents • The operational functions of vaccine management include • Carrying out deliveries in consultation with the management • Sorting of vaccines and immunization-related equipment as appropriate • Updating stock records (individual stock sheets per batch) • Monitoring storage temperatures and other conditions as appropriate • Conducting first-level maintenance of cold chain equipment • Informing management of any apparent problems

3. Cold storage, dry storage and transport capacity is sufficient to accommodate all vaccines and supplies needed for the programme.
4. Buildings, cold chain equipment and transport systems enable the vaccine and consumables supply chain to function effectively.
5. Maintenance of buildings, cold chain equipment and vehicles is satisfactory.
6. Stock management systems and procedures are effective.
7. Distribution between each level in the supply chain is effective.
8. Appropriate vaccine management policies are adopted and implemented.
9. Information systems and supportive management functions are satisfactory.

Since the introduction of the EVM assessment between 2009 and 2014, a total of 82 assessments have been conducted globally while 21% of these assessments were reassessments [23]. In these assessments, a broad range of performance scores was observed in each criterion at each level, except storage capacity that had a median score above 80%. The availability of appropriate vaccine management policies was also scored relatively high at each level of the supply chain. Temperature monitoring at the national level, maintenance at lower levels, vaccine distribution at all levels, and stock management at lower levels were found to be the weakest areas.

All these vaccine management related performances correspond to higher level of cognitive skills in Bloom's taxonomy (analysis, evaluation and creating). Compared to the lower level cognitive skills (remembering, understanding, and applying) questioned by the EVM assessment tool, higher level cognitive skills are found to be more problematic. Thus, it appears that knowing something (remembering and understanding) is not enough to put it into practice; staff handling TTSPPs require high level cognitive skills and an overall mental model of vaccine management activities in order to analyse, synthesize and evaluate the complex situations to make sound decisions. For example, in the 2009–2014 analysis, the percentage of storekeepers and health workers knowing which vaccines on the schedule can be damaged by freezing was found to be very high (83% at lower level, and over 94% in upper levels). Similarly, health workers knowing how to read a vaccine vial monitor (VVM) was found to be over 90% at all levels [23]. However, these scores do not correspond to the ability to conduct necessary analysis, synthesis and evaluation to come to a decision under critical and complex conditions.

Traditional education and training methods applied to meeting the challenge of vaccine management have rarely been sufficient because they do not reflect the last fifty years of advances in learning theory and design [24]. For example, higher level cognitive skills are best developed when learners engage in solving complex, challenging problems rather than passively attending to messages transmitted by instructors or media [25]. Further, authentic learning principles [26] clearly demonstrate that knowledge and skills should be learned in contexts as much like the real- world situations in which the knowledge and skills will eventually be applied if the learning is not to be inert. In addition, transfer of learning from one context to another is very difficult and, therefore, learners must be given ample opportunities to apply their knowledge and skills in multiple contexts and domains, a process fostered by learning design practices derived from experiential learning theory [27].

3. Global learning opportunities and authenticity

WHO Global Learning Opportunities (called Global Training Network then) between 2004 and 2006 offered vaccine store management and vaccine management courses for selected staff from countries where effective vaccine store management (EVSM) assessments and vaccine management (VM) assessments were conducted [28,29]. As a second step, course graduates were offered the opportunity to attend a vaccine management on wheels course that enables 15 participants with three mentors to travel down the cold chain on a bus [30]. In 2007 the course was extended to cover integrated supply chain and involved representatives as participants from the pharmaceutical, biopharmaceutical sector as well as national regulatory authorities [31]. The "wheels 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 wheels 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 [32].

Table 2
Alignment of Pharmaceutical cold chain management on wheels and authentic e-learning course objectives and EVM criteria.

Objective	Wheels	e-learning	EVM criterion
Define 25 basic terms important in handling time and temperature sensitive pharmaceutical products.		■	All
Identify the major operational components in a pharmaceutical cold chain	■		All
Illustrate the inputs, activities, and outputs of each operational component of a pharmaceutical cold chain	■		All
Given a situation, propose recommendations to improve compliance with "good distribution practice" (GDP) guidelines.	■	■	All
Given a cold storage facility, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP and "good storage practice" (GSP) guidelines	■		3, 4, 5
Given a nonconformance in the transport of pharmaceutical product, analyze data to identify the cause, potential impact to the product, and formulate preventive measures.		■	7
Given a list of elements that could be in a quality agreement, justify five elements you consider to be most beneficial.	■	■	6
Given an example of an operational component in a pharmaceutical cold chain, differentiate the practices as to whether or not they reduce risks.		■	All
Given a situation, select the appropriate methods and materials for packaging and shipping cold chain products to minimize risk	■		7
Given a mode of transportation, identify hazards, and assess and identify methods to control the risks to pharma, biopharma, and vaccine products that are consistent with GDP.	■	■	7

Table 2 (*continued*)

Given a cold chain operation, evaluate which risks require a contingency plan in line with GDP/GSP.			2, 3, 4, 6, 7
Given a stock situation with different vaccines, various expiry periods and batches and VVM status, decide which products to be dispatched against a requisition order.			3, 6, 7
Create a decision tree for dispatch of vaccines involving all relevant factors.			6, 7
Develop an action plan for the successful implementation of a policy change in in-country vaccine distribution.			8
Conduct a risk assessment for a given risk question related to temperature monitoring of temperature-sensitive pharmaceutical products in a storage facility.			6
Given a mode of distribution in the last mile, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP.			7
Assess and control the risks to pharma, biopharma, and vaccine products in a given power cut situation.			3, 4, 5, 6
Given a list of risks and control options, prioritize which risks to reduce first.			All
Compare the advantages and disadvantages of a min-max thermometer to other temperature monitoring devices used in the last mile.			2
Given a situation, select the appropriate methods and materials to monitor temperature and/or humidity for cold chain products to obtain necessary data for making decisions			2
Given a specific temperature monitoring strategy, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP/GSP			2, 7
Examine and assess documents and records that support a cold-chain process consistent with GDP/GSP			1, 6

(*continued on next page*)

Table 2 (*continued*)

Identify work practices that contribute or reduce risks to a cold-chain worker's health and safety			8
Given a video of someone performing a shake test, evaluate the process followed, the results obtained, and justify whether the vials can be used.			2, 6, 8
Conduct a shake test to decide whether a given freeze-sensitive vaccine has been affected by freezing.			2, 6, 8
Create a report on the results of a shake test.			2, 6, 8
Given two different scenarios of temperature exposure, expiry date, VVM status and opened/unopened multi dose vials, judge whether the vaccines are suitable for use.			2, 4, 6, 8
Given a client, conduct critical analysis of the cold chain management system and make recommendations to improve the performance of the system in line with GDP/GSPs.			All

Shaded cells indicate whether the mentioned objective is part of that particular course.

However, budgetary and logistical considerations limit WHO GLO to offering the experiential wheels course just once a year with only 15 participants. A way of opening up this experiential learning opportunity to more professionals around the world was deemed desirable, and thus in 2010, the very same course was redesigned as an authentic e-learning course and has been offered online since 2012 [33]. During this time, WHO GLO has conducted this conversion of the wheels course to e-learning as an educational design research study that has pursued the twofold goals of developing a more effective approach to e-learning and identifying reusable design principles for future projects of this kind [33].

The wheels course is based on experiential and social learning theories as defined by Kolb and Vygotsky, respectively [27,34]. Experiential learning can be defined as a direct encounter with the phenomena being studied rather than merely thinking about it or only considering the possibility of doing something about it [35]. Kolb described experiential learning as being an iterative four-phased activity consisting of concrete experience, reflective observation, abstract conceptualization, and active experimentation [27]. A learner can join the process at any of the four phases.

Social learning involves learning from others, particularly by observation of role models [36] that can include both those who make mistakes (negative role models, such as novices) and those who are experts in a field (positive role models) – individuals that Vygotsky [34] identified as "more knowledgeable others". In the pharmaceutical cold chain management (PCCM) course, activities that foster learning by doing (e.g., identifying risks and controls in a drug distribution center) are prevalent, supported by three expert mentors who serve as the more knowledgeable others.

The GLO/EPELA (Extensio et Progressio Authentic e-Learning) e-learning course is based on authentic learning principles [26]. One such principle maintains that authentic tasks should be ill-defined to the point that learners must figure out the specific actions needed to complete such tasks rather than simply applying existing rules to do so. These tasks should ideally be anchored in a context that approximates the complexity of the real world. For example, in the online PCCM course, learners work in teams to solve real world problems (e.g., a regional storage facility's only refrigerated truck breaks down during distribution). Another principle of authentic learning is that authentic tasks should require learners to investigate and accomplish them over a sustained period of time. In the online pharmaceutical cold chain management course, three member teams of learners spend the last five weeks of the twelve-week course collaborating to prepare recommendations for solutions to the real world vaccine management challenges submitted to the course by the public health ministry of a specific country. A third principle maintains that authentic tasks should allow competing solutions and diversity of outcomes. In the online PCCM course, most of the solutions generated by the teams of learners are subjected to expert, peer, and self-review rather than "graded" using a predefined scoring scheme. While some solutions are clearly better than others, creativity is encouraged and there is no penalty for being "wrong," but feedback is provided so that learners can improve their solutions to complex problems.

The GLO wheels and the e-learning courses differ greatly from other courses in the field of vaccine management offered by other organizations. There are no theoretical sessions in the wheels

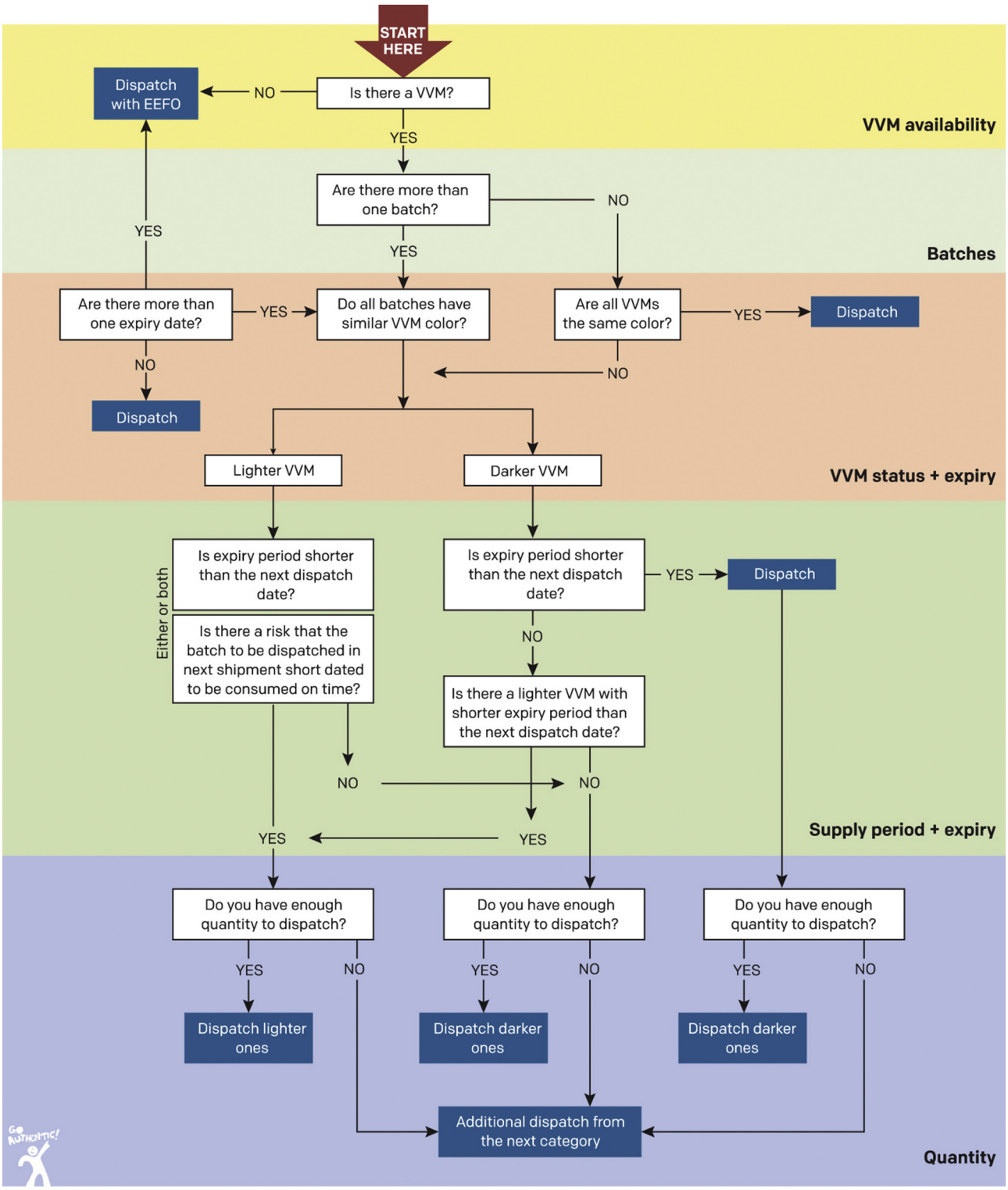

Fig. 2. Using VVMs for dispatching vaccines (EPELA/Kartoglu).

course and "mentors do not lecture others." Instead, possible solutions to problems discovered through facility visits are discussed at length together. The e-learning course is also unique in that it is not a typical "me and the computer screen" course; there is always a human face that supports participants whenever they need help and encouragement. Research has shown that feedback is the most important factor in any type of learning [24]. In addition, GLO e-learning courses mimic the real world through authentic context and tasks, none of the problems are presented in a "prescribed" manner, each task forces participants to find additional information to solve the problem [26]. Assessment is mainly embedded in the authentic tasks, but we also see what the participants are learning by how they comment on other reports, how they reflect on their experience in diaries, how they express themselves through Flipgrid videos [37], how they raise issues or contribute to ongoing discussions. We even see how they engage in fun

learning activities such as a "scavenger hunt" where participants are given situations to photograph and post them in a blog [38]. The infusion of rigorous individual and group authentic assessments may be the most distinguishing feature that sets GLO/EPELA courses apart from other forms of e-learning [26].

In many traditional e-learning courses, technology is used as a platform through which content is delivered to the participants and participants in turn submit simple assignments or take quizzes to demonstrate their understanding of this delivered content. Traditionally, in this type of "learning from technology" approach, technology is controlled and provided by the teacher [24]. Learning WITH technology, as applied in our courses, is vastly different. In this approach, technology is placed in the hands of the participants to be used as cognitive tools for complex tasks. In this approach participants use technology as a tool for solving problems, constructing knowledge, creating meaningful products and collaborating with each other [24]. Authentic learning encompasses a "learning with technology" approach, thus differentiating our programmes from many other e-learning approaches.

4. Alignment of course elements with EVM

Though encompassing a broader field than only vaccines, both the wheels and the e-learning courses are well aligned with overall EVM criteria. Table 2 presents the alignments between the objectives of each course and each EVM criterion.

As seen in Table 2, both courses focus on the "risk management" approaches in analysing the operational and management functions of a pharmaceutical cold chain system to help participants build a robust mental model of the system.

5. The side products yielded by the courses

In both courses, there are a series of side products that are produced by participants such as decision trees, detailed processes and flow-charts. Most of these are then refined by the mentors and shared back with the group. This reflects the authentic learning principle that authentic tasks should encourage the development of polished products that are valuable in their own right rather than an exercise or sub-step in preparation for something else [26]. Ideally these products should contribute to the profession of which the learners are a part or even society at large. Fig. 2 is an example of just such a side product refined by the mentors in the e-learning course (this decision tree is now used by some national programmes initiated by the course graduates):

6. Conclusion

For vaccines and other medicines to be safe, pure, effective, and available to those needing them, a high level of concern is being placed on the storage, handling, transportation, and distribution of these products, particularly those that are time and temperature sensitive. While active and passive cooling equipment and monitoring devices are important, it is the various personnel who execute and write procedures, design and operate systems, and investigate problems and help prevent them who need to have the required knowledge and skills so they can effectively perform these activities. In two unique learning solutions developed by WHO/GLO, participants have the opportunity of not just learning about cold chain systems or vaccine management, but, rather, learning to become specialists in these fields through experiential and authentic learning. In this process, participants have the opportunity to address real-life situations in contexts similar to what they may face in their own work environments and develop solutions and critical thinking skills they can apply when they return to their jobs.

Interviews conducted with the participants after the completion of the courses indicate that the authentic learning approach and especially engaging in the authentic learning tasks had a beneficial impact on the professional learning of the participants. Several participants emphasised the realism of the tasks, the opportunity to collaborate with colleagues and the support from the mentors as key factors for a successful learning experience. These aspects also differentiated the programmes from a more traditional, content-oriented approach to professional development. In the words of one eLearning course participant, it was "...different from other e-learning courses which are, you know, more theoretical. In this we have both: theory and real practice". The authentic learning approach also contributed to a high level of learner engagement. Several participants reported that the nature of the tasks challenged them and encouraged them to do their very best. The skills and knowledge learned in the programmes have also been transferred into practice in several ways. Not only are the products created during the courses in use in real work environments, but participants have also described improved decision-making, improved contingency planning, increased self-confidence and trust in one's ability to perform new tasks, as well as a strengthened professional identity. These findings suggest that the authentic learning approach can be effective in developing the higher cognitive skills: analysing, evaluating and creating.

All professionals who have graduated from the e-learning programmes described in this paper are now using the skills, knowledge and authentic products created in the programmes in their own professional contexts. These people also continue to be supported through a post-course mentoring programme, ensuring successful learning transfer and continuous professional learning. This professional learning in turn can directly benefit the communities through improved outreach services and increased accessibility and coverage of immunization programmes. As one of the participants concluded: "more children can be vaccinated now".

Conflicts of interest

None.

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