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Experiential and authentic learning approaches in vaccine management $^{\diamond}$

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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.

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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

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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







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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 hardto-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.

Competencies for operations and

2. Developing expertise in vaccine management

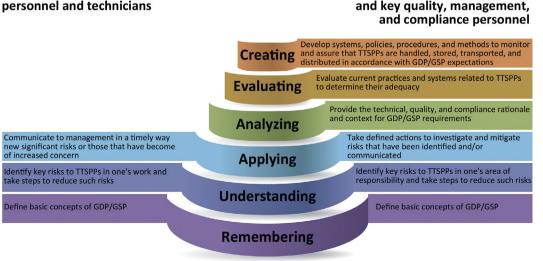
Expertise is the hallmark of an expert. It includes an in-depth set of knowledge, cognitive and motor skills, as well as the analytical ability to determine how to approach a given situation. Dreyfus and Dreyfus [18] quoted Aristotle in saying that the expert straight away does "the appropriate thing, 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.



Competencies for system owners, and key quality, management,

Fig. 1. Competencies and learning taxonomy.

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