



Top Six Educational Principles for Designing an Effective REMS

Nanci Mayer-Mihalski

May 2009

FDA now expects pharmaceutical companies to measure and track the effectiveness of REMS programs. Pharmaceutical companies need to demonstrate that education and other interventions actually achieve levels of understanding and behavioral compliance in healthcare providers and patients. This requires educational techniques that are able to achieve unprecedented levels of effectiveness and behavior change.

The following principles were synthesized from meetings with education experts, the CME Congress, and reviews of both the medical education and adult learning literature to identify what comprises effective educational methods resulting in establishing appropriate behaviors:

Principle #1: Use adult learning principles as the foundation for the design and implementation of a medical education program.

The information presented in the program must address the learners' personal needs and be relevant to their situation. Their individual learning styles need to be taken into consideration for the program to be effective. For example, some people learn better by reading (visual learner) while others learn by listening (auditory learner). Others learn by a combination of these styles.

Principle #2: Design active (versus passive) learning interventions.

The participants must be guided through the learning process by facilitating rather than instructing. Didactic lectures need to be either replaced or enhanced with interactive discussion groups. The more interactive the sessions are, the more the learner will retain and put the learnings into practice. In fact, the learner should "do" rather than just participate in order to transfer the learning into action.

Principle #3: Use blended learning methodology.

Blended learning provides varied, multiple interventions that address different individual learning styles. Utilizing multiple, complementary types of interventions and media can increase the retention rates of the learner. For example, offering a visual presentation and auditory information addresses the learning preferences of visual and auditory learners; doing both can be mutually reinforcing.

Principle #4: Incorporate problem-based learning /simulation into the program design.

Problem-based learning (PBL) consists of carefully designed clinical problems that demand the acquisition and application of critical knowledge, problem solving skills, independent learning strategies, and team participation skills. PBL applies a universal approach to solving problems or meeting challenges that are encountered in everyday practices.

Simulated training provides a virtual environment where participants can experience real-life situations without risking injury to people. This method has been widely applied in the aeronautics industry (e.g., flight simulators). It enables participants to experience low-frequency, high-risk events that they might never experience day-to-day in their practice. Simulation also incorporates direct performance feedback, enabling participants to make the appropriate adjustments necessary to rectify potential errors.

Principle # 5: Utilize several reinforcement strategies to enhance the learning.

Programs facilitated by local opinion leaders should be incorporated into the learning intervention. The learning intervention itself can be an outreach visit by a local opinion leader.

Audit and feedback can be used prior to a learning intervention where results of a chart review are presented and the clinical performance of the physician is compared to that of his peers. Audit and feedback can also be used to assess the results of the learning intervention.

Other reinforcement strategies such as reminders or follow-up surveys, can be used after the intervention has occurred. The key is to use more than one reinforcement strategy as part of the intervention or program.

Principle #6: Evaluate learning effectiveness using “Kirkpatrick’s Model Levels One through Four” .

Participants need to complete a pre- and post-test to assess the knowledge and skills they have acquired as a result of participating in the learning intervention. To effectively change behavior, participants also need to complete an action plan or commitment to change instrument which allows the learner to reflect on what they just learned and to think about how they will apply it.

Action plans, widely used in corporate training programs, and commitment to change instruments are beginning to be used in medical education. These techniques are similar and based on both the cognitive and emotional aspects of the learning process.

Follow-up surveys should be sent out at various intervals after the learning intervention has occurred to discover the extent of durable behavioral change.

Note: These principles can be applied to continuing education for pharmacists, nurses and other health professionals.