Strategy and Tactics for Pilot Implementation in the ADDIE Model

The ADDIE model is a generic design model. Our focus here will be the role of ADDIE for instructional design projects in Food and Drug Administration (FDA) regulated industry. The model provides guidance at a fairly high level for instructional designers, software engineers, and others as they author and revise training modules or courseware - the learning product. There are several application values of the ADDIE model. First, the model clarifies and standardizes the process of addressing performance gaps in an organization, allowing best practices in instructional design to be identified and implemented. Second, this model is widely utilized in the industry, which facilitates benchmarking of instructional design between organizations. The phases of the ADDIE model are Analyze, Design, Develop, Implement, and Evaluate. These phases are sequential - each depends upon the successful completion of the preceding phase.

The ADDIE model is scalable to all size pharmaceutical, biopharm, and medical device companies. The model can be scaled to various size organizations, and fitted to the particular needs of a specific organization on a case-by-case basis, or by an overall decision. As an example of a particular case, the decision may be made in the Analysis phase to forego the needs analysis of the employees’ skills and dispositions - these attributes may be well-known and documented, requiring no further analysis. Thus management makes the decision to limit the analysis phase to a task analysis.

As another example, management may make the overall decision to forego Pilot Implementation - and the associated Formative Evaluation - and roll out every learning product directly. In this instance, the Implementation phase is followed by Summative Evaluation. In both examples, it is a management decision to save costs by limiting the ADDIE model.

The Analysis phase of the ADDIE model identifies a performance gap, a discrepancy between a standard stipulated in a Standard Operating Procedure (SOP) and some employee performance. A performance gap can be addressed by a learning product, that is, a set of training and assessment materials.

This is followed by the Design phase, where a carefully planned approach to addressing the performance gap is outlined and approved. This planned approach has three components: (1) fitting the proposed learning product into the larger curriculum, (2) outlining the proposed learning product, and (3) securing management approval of the outlined learning product.

If management approves the design, the Development phase comes next, where the learning product - the training materials and the assessment materials - is developed to address the performance gap.

The Implementation phase follows, where the training materials and associated assessment materials are rolled out, on a provisional basis, to ascertain their real-world impact. This is the first of two kinds of implementation - Pilot Implementation or pilot testing - followed by a Formative Evaluation phase; the second kind of implementation is Final Implementation, followed by a Summative Evaluation of the relative cost and benefit of the finalized program to the organization.

Pilot testing of a learning product can add considerable value for an organization. While the learning product - e.g. training module, organizational development program, LMS courseware - is still in the developmental process, not yet approved for final rollout, a pilot can provide significant data about the real-world impact of the product, going well beyond the data that can be inferred from the material that appears on the story-board. The data derived from the pilot can be used to revise and improve the learning product before it is rolled out to the department, site, or entire workforce. This will of course add to the overall cost of module
development, but it is a cost that is well worth incurring.

We review the role of a pilot implementation in the process of developing a learning product, looking initially at strategic issues and then reviewing some tactical issues. First, we consider the relationship between a pilot and the ADDIE design and development model. Next, we compare pilot implementation to other pilot projects in the pharmaceutical industry. Then, we consider a number of conditions that will facilitate or inhibit the implementation of a learning product. Turning to tactical issues, we review how an instructional designer prepares for a pilot implementation of a learning product, conducts a pilot implementation, and finally, evaluates a pilot implementation.

**PILOT IMPLEMENTATION AND ADDIE**

There appears to be some confusion about the meaning of the term “Implement.” We hear folks saying that the “Implementation” phase means that the training module is developed, finalized, and ready to be rolled out. However, this viewpoint gives rise to two questions. First, what then are we to make of the “Evaluation” phase that comes after the Implement phase? Is this to be only a summative evaluation? Does this mean that there is no place in the ADDIE model for formative evaluation? That would be an unduly restrictive view of this generic model.

Second, the ADDIE model is an iterative feedback model, which means that the results of the Evaluation phase are fed back, closing the loop, facilitating further refinement of the learning product. If the evaluation shows that the module has shortcomings, such as lacking clarity, those shortcomings are fed back to the author(s) to be analyzed again. Further design and development efforts follow until the module meets the organization’s needs and standards, but that feature of the model, iterative feedback, strongly suggests that the “Implementation” phase cannot simply be the finalized rollout of the learning product.

Indeed, the “Implementation” phase of the ADDIE model includes pilot implementation as well as final implementation. As Gillis and Beauchemin have put it, “The term ‘pilot’ warns everyone to expect some adjustments. […] Revisions and modifications make even the best training programs more effective, and evaluating the pilot reveals potential program improvements.” The notion that the phase is a “pilot” of the learning product, rather than a finalized rollout, highlights the iterative feature of the model.

Thus the ADDIE model should be conceptualized as having two paths out of the Development phase. One path leads to pilot implementation, followed by formative evaluation, from which a feedback loop allows further analysis, design, and development. At some point, determined by management, the learning product is judged to be ready for the other path. It then moves to final implementation, followed by summative evaluation. (See Figure 1).

In this article we will focus on the place of pilot implementations in the development process.

**PILOT PROJECTS IN THE PHARMACEUTICAL INDUSTRY**

In the pharmaceutical industry we have a well-known example of a pilot activity that illuminates the relationship between the (Pilot) Implementation phase and the rest of the ADDIE model. That is the transition between laboratory research and development and the rest of the ADDIE model. That is the transition between laboratory research and development, and commercial manufacturing.

When a pharmaceutical company has discovered a promising product in the R&D laboratory, it goes into a development phase. The company subjects the product to clinical trials to determine its safety and efficacy. If it is deemed safe and efficacious, it is a candidate for commercial manufacture and marketing. The question is: how does the company move from the scale of laboratory production, perhaps
several ounces of product in total, to the commercial scale of thousands or millions of units of product? This is where the pilot project fits in.\(^8\)

The company pilots the manufacture of the product, as a transition from the laboratory scale to the commercial scale. The pilot has a number of outcomes, four of which are particularly important:

- It demonstrates the feasibility of the scale-up in general.
- It demonstrates the validity and reliability of the particular process selected for the pilot.
- It generates parametric product and process data for commercial manufacturing.
- It provides data for budgeting, planning and scheduling of subsequent manufacturing.

Each of these outcomes may prove positive or negative for the future of the product. As examples of negative outcomes: the scale-up may not prove feasible, the particular process may be unreliable, there may be off-spec findings during scale-up, and the process may not be economically feasible.

The relationship between the (Pilot) Implementation phase and the rest of the ADDIE model is similar. When a pharmaceutical company has discovered a promising solution to a training gap, it goes into a development phase. The company assigns an instructional design team to take the promising solution and develop it into a draft training module. If the training module seems to be efficacious, in terms of face validity and peer-review, for example, it becomes a candidate for department-wide, site-wide, or even corporate-wide rollout. The question is: how will the company move from the instructional designer’s desktop and storyboard to the whole workforce? This is where the pilot implementation fits in.

The company pilots the training module, as a transition to the entire workforce. The pilot has several outcomes. It shows whether or not the promising solution can be scaled up in general. The pilot shows the validity and reliability of the specific interpersonal and institutional process selected for the pilot (or perhaps it shows unreliability). It generates process and outcome data that may be important for the finalized learning product. And it provides data on cost and scheduling considerations that should be taken into account in the wider rollout.

There are two basic possibilities for the pilot implementation of a learning product, depending upon two kinds of participants in the pilot. These participants involve end-users on the one hand, and training and development peers on the other. End-user testing intends to assess how representatives of the target audience interface with the learning product that has been developed for them. The peer inspection subjects the learning product to a review for consistency with design standards and program logic;\(^9\) it also can identify problems such as repetition, overtaxing of memory, etc.

These two possibilities may disclose different kinds of problems with the learning product. End-user testing can find problems that are overlooked by peer inspection; likewise, peer inspection methods can find problems that are overlooked by user testing. In many cases, the best results can often be achieved by combining the two approaches.\(^10\)

**CONDITIONS FACILITATING IMPLEMENTATION**

There are specific conditions that facilitate the pilot implementation, and eventual rollout, of a learning product. The absence of these conditions can inhibit the implementation and rollout. We should ensure that these conditions are present for our pilot implementation.

Donald Ely has discussed eight conditions.\(^11\) There must be the following:

- A dissatisfaction with the status quo - things could be better
- Sufficient knowledge and skills on the part of those who would implement the learning product
- Adequate resources
- Time - as Ely puts it: “Good time; Company time; Paid time.”
- Rewards or incentives for participants
- The expectation and encouragement of participation in decision-making about the implementation
- Commitment by those who are involved
- Evident leadership

Ely points out that this list of conditions has been validated, and can be used to develop a checklist for the implementation project. But, he cautions, they must not be viewed as formulas or rules; they should be subject to local conditions.
Moreover, there can be a profound political aspect - either pro or con - to an implementation effort. As Carol Weiss has expressed it, “This is because policies and programs are proposed, defined, debated, enacted, and funded through political processes, and in implementation they remain subject to pressures both supportive and hostile.”

OBSTACLES TO IMPLEMENTATION

There is also a series of obstacles to implementation. Abt Associates has identified a number of these; of particular interest to us are the following three obstacles:

- Disappearing training intervention
- Variable implementation
- Shifting training audience

Disappearing training intervention

The training intervention is the trainer’s execution of a script.14 This script is executed (or performed) by the trainer(s) in specified training facilities, within allocated space and allotted time, and employing requisite training materials. It is performed for a specific group of trainees. The training intervention disappears when the trainer fails - for any number of reasons - to perform the script within that space and time, for those trainees. The trainer might not be proficient in performing the script, resulting in a clumsy performance; the trainer might not have physical access to the script, resulting in an impromptu performance; the trainees might be inattentive or asleep, etc. In any case, should the training intervention disappear, there is no predictor of interest for the subsequent trainee performance.15

Variable implementation

The trainer performance of the script must be relatively standardized across trainers, facilities, times, and trainees. The word “standardized” is critical here: standardization implies standards, or criteria for the performance. The training intervention becomes (unacceptably) variable when the performance deviates from those standards. On the one hand, the criteria will be set by management; on the other hand, the trainer’s preparation must include an assessment of the relevant scripted tasks, as judged by a supervisor or as indicated on some business-process met-ric. In the case of team-led training events, it will include both individual level and group level (training team) elements. In the absence of such standards and criteria, as Gamse, et al., have pointed out, “if no impact were to be found, it would be impossible to know if it was because of a failure of implementation, a failure of [the training design], or both.”

Shifting training audience

There are obstacles to implementation on the trainee side as well. Employees are transferred or reassigned and are no longer part of the training audience. Curriculums and individual training plans (ITPs) change and the training is no longer relevant to the employee’s work assignments. This attrition and change has an obvious effect on implementation of training modules and the assessment of sustainability of training. Gamse, et al., have commented that it is not so much “that such changes create a bias between groups;” they go on that what is especially “problematic is that the changes create noise or unknown variation against which it is difficult to detect [program] impact.”

These three obstacles are listed in order of increasing seriousness. The disappearance of the training intervention can be addressed and perhaps controlled by a suitable train-the-trainer program, a remediation that is within the scope of the Training Department. Likewise the variability of implementation can be remedied by well-known quality control measures, which are within the scope of the Quality Assurance Department. The problem of shifting training audiences is less tractable, since it is directly caused by the business needs of the organization.

With those strategic considerations in mind, let us turn to some tactical issues. Based on our own experience with pilot projects, we will review how to prepare for, conduct, and evaluate a pilot implementation.

PREPARING FOR A PILOT IMPLEMENTATION

Preparing for a pilot implementation has seven steps. The first step is to review all relevant material that has been developed so far, including any pertinent SOPs, the training materials, the trainee assessment materials, and the evaluation materials. It is important to distinguish between trainee assessments that measure the trainee skill acquisition, and
the evaluation measures of the training module’s adequacy in terms of some set of institutional standards. Just as the organizational or institutional purpose of a training module should not be confused with its behavioral objectives, so evaluation should not be confused with assessment. The two are, of course, related - trainee success will contribute to program adequacy - but the two are, nonetheless, distinct.

Next, we should prepare a plan for the pilot, sometimes called an Execution Plan. We can turn to the Training Outline for a brief overview of the module. This is the brief, one- or two-page outline that lists the name and course number of the module, identifies the training audience, indicates how the module fits in the larger curriculum, lists the behavioral objectives, indicates the delivery modality, the anticipated duration of the training session, identifies the assessment materials, etc. In addition to the information derived from the Training Outline, the plan should sketch the various roles and responsibilities for the preparation, execution, and evaluation of the pilot implementation.

This plan will indicate the extent to which end-user testing, and peer inspection, will be involved. Once the plan is ready, it is important to get management approval of the plan for the pilot.

Our third step is to prepare a checklist for the pilot implementation. As with any well-planned training event, it is hard to imagine too much detail in the checklist. Better the checklist should be overly detailed than to realize at the last minute, with the participants coming in the door, that we have neglected some critical factor. Once we have developed a comprehensive checklist, this can provide a template for subsequent pilots.

Next, we must schedule room(s) in the case of classroom training, or work station(s) and equipment in the case of Structured On-the-Job Training (SOJT) sessions. When scheduling, try to get the same room, work station, or equipment that would be used in any other training event.

Fifth, we must prepare all required materials for the pilot session, including training materials, safety materials, and process materials. These materials can be listed on the comprehensive checklist, and can be ignored (N/Ad) if not needed.

Training materials include:
- Flip charts and markers
- Handouts for trainees
- Job aids
- Placards
- PowerPoint® slides
- Script for trainers
- Transparencies
- White board and markers

Safety materials include:
- Job Safety Analysis (JSA)
- Material Safety Data Sheet (MSDS)
- Personal Protective Equipment (PPE)

Process materials include:
- Equipment
- Controls (make sure the switches work, etc.)
- Instruments
- Utilities (make sure the water runs when you open the tap, etc.)

The sixth preparatory step is to review the set of end-users, the target audience for the learning product. Who is in the scope of this training? Ensure coverage of all significant groups within the scope. This means including differing technical skill levels; different cultural, language, and ethnic groups; different sites and facilities; differing tenures - some new hires, some old timers, etc. It is important to estimate the percentage of invitees that will actually be attendees; that estimate will ensure you have enough participants attending the pilot to provide reliable and credible data on outcomes and process. The estimate of invitees who will actually attend will depend upon your experience, or the experience of your training and development peers. Then you can assemble the list of invitees, and again be sure to get management approval. Each attendee’s manager will need to approve participation.

The final preparatory step is to send invitations to the pilot session. Invitations should be sent to each participant (trainee), as well as to your training and development peers. Inviting your peers is a courteous collegial gesture, and these attendees can provide peer evaluations of the session that the participants may not be prepared to do. The invitation should include a brief overview of the module indicating that this is a pilot; be sure to mention that training credit in the employee training history will depend on extent of
revisions that are required. If minor revisions are called for, training credit can be given for the session. If major revisions are needed, attendance can be noted but credit cannot be given, since the revised module that will ultimately be rolled out will not be the same as the pilot module.

**CONDUCTING A PILOT IMPLEMENTATION**

Conducting a pilot implementation has eight steps. When the day and time of the pilot session arrive, use your checklist to make sure that everything is in place and ready to go. Welcome the end-user trainees and your training and development peers. Indicate again that this is a pilot implementation; repeat that credit to the participants’ ITPs will depend upon the extent of revisions that are needed. Even if credit cannot be given because major revisions are called for, the trainees’ participation in the development of this module will be noted and appreciated. Discuss the logistics of this facility, where the water fountains, coffee machines, and restrooms are located, etc. Address relevant Emergency Response Plans, fire escape routes, etc.

The second step in conducting the pilot is to distribute the training materials, and indicate criteria for success – 80%, 100% or whatever. The preliminary knowledge check, if applicable, should then be administered.

The third step is to explain the content of the pilot module. This is an opportunity to present the “science” of the process; it is more than a sequence of tasks. Present the behavioral objectives for the module. It is worth repeating that adults learn best when they have crystal clear expectations about their projects; hence we always use behavioral objectives. Invite questions or concerns from the participants (trainees), and specify the feedback process. Stress that you welcome feedback; that the main purpose of a pilot implementation is to elicit feedback for program improvement. Specify how the participants should make their feedback – whether they should interact immediately with the trainer(s) when they have an issue, or they should note the issue for later discussion.

In either case, every issue should be recorded for later attention. Also, mention that they will be called upon to evaluate the pilot session before they leave - we will return to this point in the next section.

The fourth step is to move through the module, section by section, task by task. For each section and task, discuss the purpose of the task; the importance of the task; when and where to perform the activity; and the expected results of correct performance and the potential results of incorrect performance. Highlight critical safety points for each task (as needed); also highlight key Good Manufacturing Practice (GMP) points for each task (as needed). Then invite questions or concerns. It perhaps goes without saying that training and development peers should hold their questions and concerns for a post-session debriefing. The author has seen training sessions where the peers raise questions while the trainees are present, and it can be quite disruptive. On the one hand, the trainees can be confused by the different “spins” on the training material. On the other hand, the exchange between training and development peers can suggest that there is dissention within the training unit.

The fifth step is to demonstrate each task (as needed). This will be particularly important in SOJT sessions. Also in SOJT sessions, allow the trainee to practice; record the trainee’s progress through the sequence of tasks. It is important to track trainee progress on an explicitly non-GMP progress form. Since trainee progress will only be on part of the module - representing part of a SOP - that progress cannot be recorded on a controlled (GMP) form. The non-GMP progress form can be disposed of after the module is completed, after the session is duly recorded on a controlled training tracking form.

While the trainees are progressing through the sequence of tasks, provide assistance as needed - while the trainee prepares for independent performance (for SOJT), and while the trainee prepares for an assessment (for a classroom module).

In the case of SOJT, after the session is completed, allow independent performance by the trainee. Observe the trainee perform each task safely, correctly, and without any coaching from the trainer.

When the independent performance is completed, or when the classroom session is completed, assess each trainee’s performance. Utilize the appropriate GMP assessment form, and assess independent performance (for SOJT); assess knowledge transfer (for a classroom module).

The final step in conducting the pilot session is to record the completion of the module. Use the training tracking form, which as we have noted is a GMP form.
Once the pilot session is completed, it is time to evaluate the adequacy of the training module, propose revisions as needed, and prepare a report to management.

**EVALUATING A PILOT IMPLEMENTATION**

Evaluating a pilot implementation has six steps. The first step is to invite the end-user trainees to evaluate the pilot module. Explain the evaluation process, and how the evaluations will be used in feedback for program improvement. Use explicitly non-GMP evaluation forms. Since at this point we are evaluating a work in progress, the training module that is under development, not yet approved - there should be no record of that progress on a controlled (GMP) form. Sometimes “sticky notes” - clearly not controlled documents, can be used to record the trainees’ evaluations. The non-GMP evaluation forms can be disposed of after the module is completed and approved. Collect the evaluations from the trainees as they depart the room.

The second step is to collect evaluations of the session and the module from your training and development peers. This can be done by a face-to-face debriefing or, again, by the use of an explicitly non-GMP evaluation form.

The third step is to review all the evaluations of the module and the pilot session.

Then, prepare an evaluation report summarizing the evaluations; consider making revisions to the learning product. Propose needed revisions to the module, and get management approval of these revisions. As Gillis and Beauchemin have put it, “Revisions may include incorporating new material to help the program meet its objectives or changing the objectives themselves based on trainees’ or managers’ input. Changes must support specific, measurable objectives.” In light of the seriousness of the needed revisions, determine the appropriate training credit for participants.

The fifth step is to dispose of all non-GMP evaluation forms.

The last step is to submit the training tracking form for appropriate credit to each participant’s ITP.

**CONCLUSION**

The well-executed pilot implementation of a learning product can add considerable value for an organization, providing significant data about the real-world impact of the product. This data can go well beyond what can be inferred from the material that appears on the story-board. The data from the pilot implementation can be used to revise and improve the learning product - as part of a formative evaluation - before it is finalized and rolled out.

**ENDNOTES**

1. There are some slight variations in the terms applied to the phases of the ADDIE model. For instance, with reference to medical devices, the FDA has used the term “establish” to encompass three of the phases, “define,” “document,” and “implement;” see 21 CFR 820.3(k). Similarly, critics of the ADDIE model occasionally refer to the implementation phase as the “Instruct” phase of the model. See Jack Gordon and Ron Zemke, “The Attack on ISD: Have we got Instructional Design all wrong?” Training, Vol. 37, No. 4 (April 2000), p. 42.


11. Donald P Ely, “Conditions that Facilitate the Implementation of Educational...


Gamse et al. (op cit) give the example of an educational intervention which intended to compare two methods of training school personnel: some were trained by university staff, while others were trained by utilizing a videotape series developed by the same university. The evaluators soon discovered that few schools had ordered the videotapes, and those that did, weren’t using them appropriately. Hence that arm of the intervention had “disappeared.”

Gamse et al. (op cit), p. 156.

Gamse et al. (op cit), p. 157.

See Welty, “The ‘Design’ Phase of the ADDIE Model” (op cit.), pp. 64-73.


As Annie Koh has put it, “you need to segment the people in the company by functions and give them what they need to get the job done;” see “Rolling Out Major IT Projects,” Business Times Singapore (02 Aug 2007).

Gillis and Beauchemin, “The Ideal Rep” (op. cit.), p. 60; also David Gallop, K. Beauchemin and M. Gillis, “Competency-based Training Program Design,” (op. cit.), p. 244 on “Refining.”


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