# Training Decay in Simulated-Use Studies: Research-Based Time Rationales

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## Abstract

A literature review was conducted on the topic of cognitive memory decay as it applies to training decay in simulated-use studies on medical devices for FDA submission. Today, it stands that training decay may be necessary for the testing of medical devices that may not be used immediately or frequently used after training. The use of training decay is meant to more realistically test these devices. When a device might be used very rarely or potentially never, the use of only an hour of memory decay may not allow for the accurate measure of user performance. This poster will look at current research and study logistics to provide rationale for training decay periods.
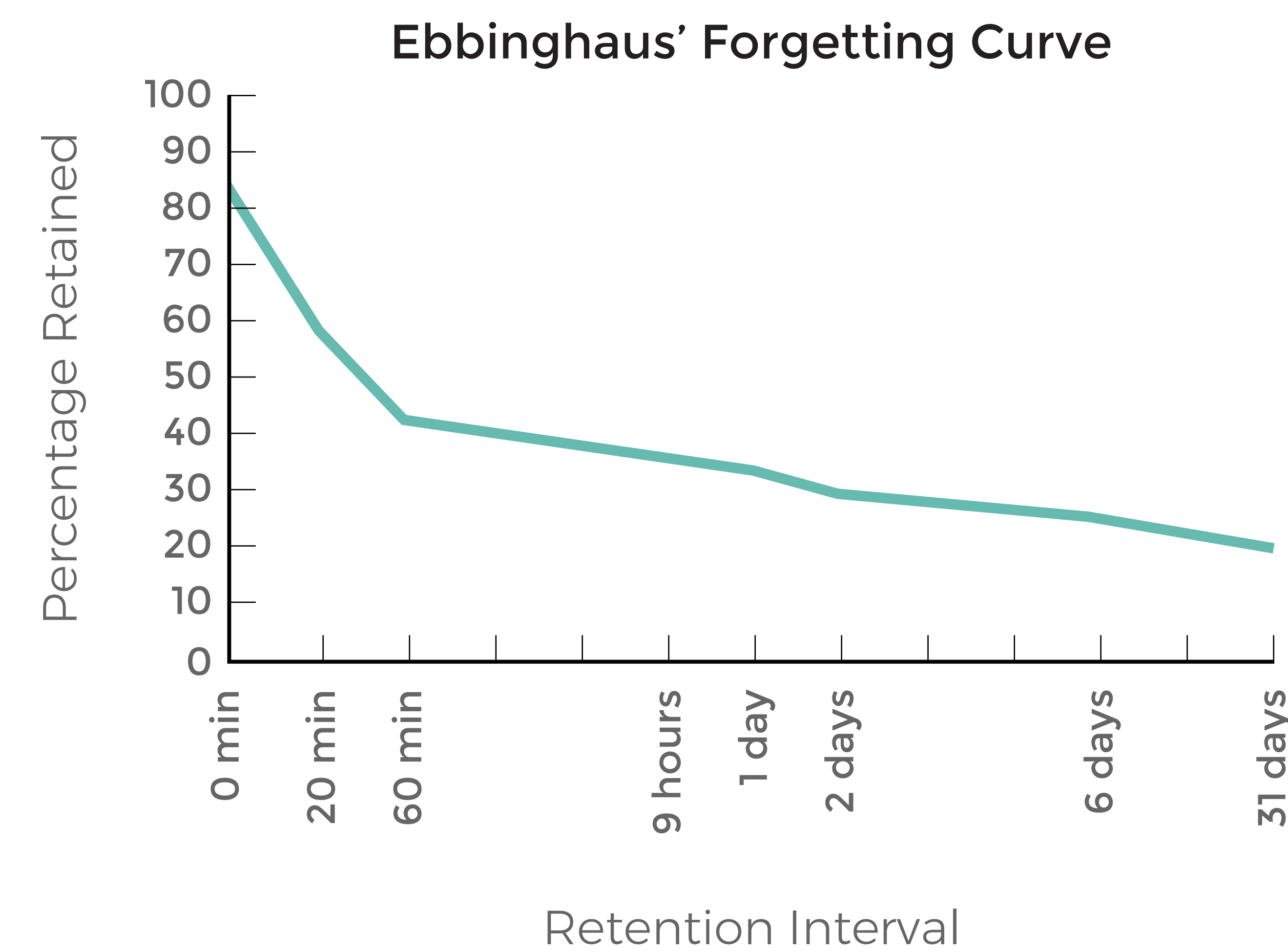
## Introduction

### What is Training Decay?
• Training decay (or learning decay) is described as the falling-off of knowledge that occurs between training and the first time you use that training. In Usability Testing, training decay plays a key role in simulating real-world learning decay such as when learning to use a medical device before first use.

### Ebbinghaus' Forgetting Curve
• The Ebbinghaus Forgetting Curve (named after Hermann Ebbinghaus) describes the decrease in ability of the brain to retain memory over time. The theory is that humans start losing the memory of learned knowledge over time unless the learned knowledge is consciously reviewed time and time again.
• According to Ebbinghaus' experiments, the individual can expect to retain less than half of the learned information after the first hour. The first hour represents the most dramatic decrease in retained information. After this point, the decrease becomes less drastic as the curve begins to level out.
• After 24 hours, the individual only retains 1/3 of the information learned and after 31 days, the number drops to 1/5.
• Beyond 31 days, the curve levels out, representing an insignificant decrease of retention from that point on.

### Ebbinghaus' Forgetting Curve

Y-axis: Percentage Retained (0–100)
X-axis: Retention Interval (0 min, 20 min, 60 min, 9 hours, 1 day, 2 days, 6 days, 31 days)

## Current Training Decay Guidance

**FDA HF Guidance 2016 (page 25)**
• "In some cases, giving the participants a break of an hour (e.g., a 'lunch break') is acceptable."
• "In other cases, a gap of one or more days would be appropriate, particularly if it is necessary to evaluate training decay as a source of use-related risk."

**HF Studies and Related Clinical Study Considerations in Combination Product D&D Draft 2016 (page 8)**
• "The protocol should justify the interval to simulate the training decay."
• "Simulate the training decay by separating the training and simulated use testing by several hours or days."

**IEC-62366-1 2015 (page 27)**
• "An appropriate wait time might be needed between the training and the rest of the Summative Evaluation to allow for representative learning decay."
• "If user training is a risk control measure and is expected prior to use, that training needs to be received and an appropriate elapsed time to accommodate for learning decay needs to occur."
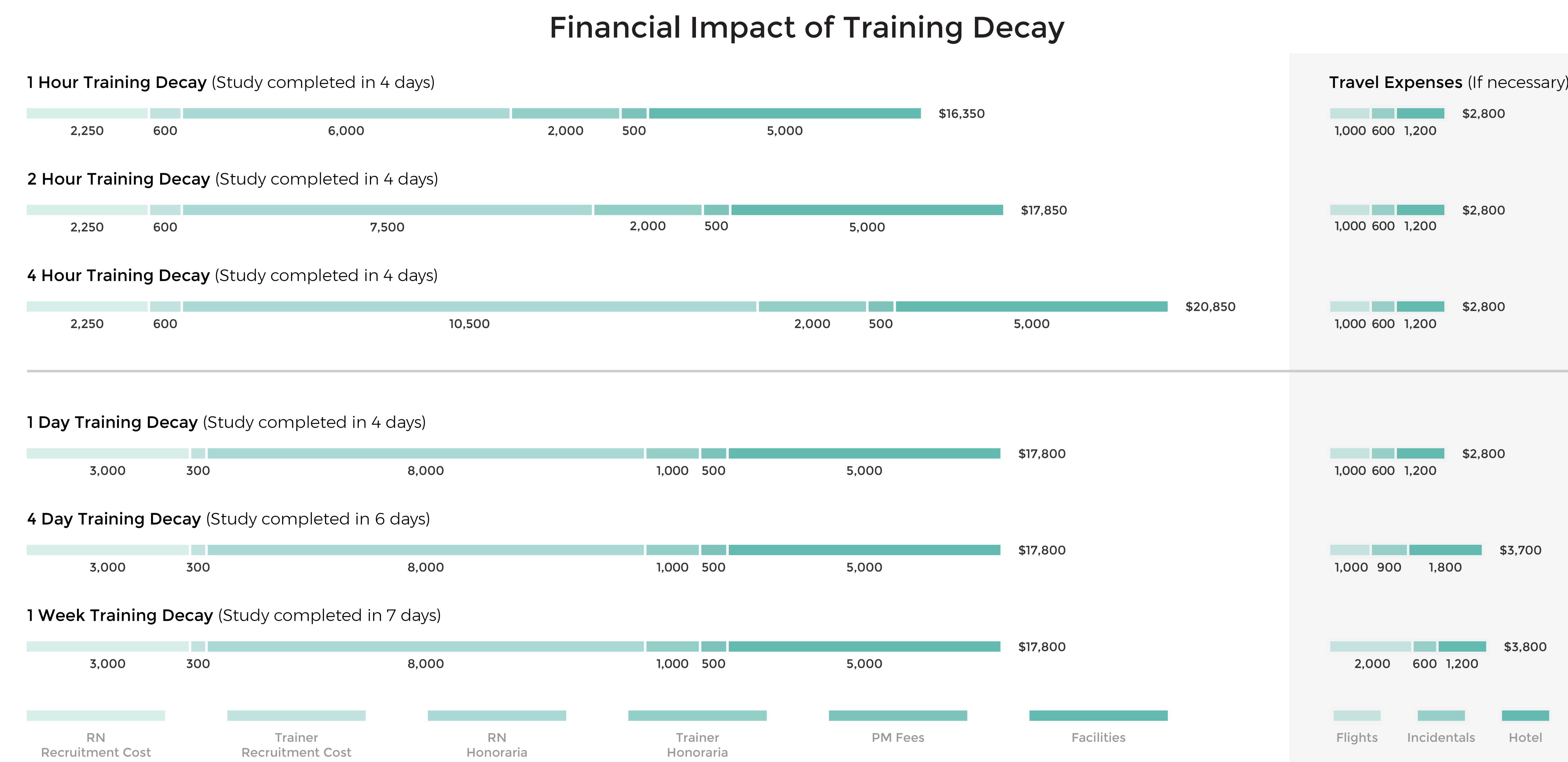
## Discussions

As discussed in Shannon Clark's research on training decay, understanding the complexity of a medical device and the frequency of its use may provide direction for certain lengths of training decay (i.e. the higher the complexity and lower the frequency of use, the longer the training decay). Another factor she mentions has to do with the type of cognitive/motor skills that are needed to complete specific tasks (i.e. the more skill needed to complete a task requires a longer training decay). Further research into these items may lead to a clearer picture when rationalizing the training decay used in a study.

Naomi Cherne and Patricia Anderson of Core Human Factors Inc detailed their experiences with determining the appropriate amount of training decay for specific studies. They offered a recommendation that states "decay periods should span overnight when products are not expected to be particularly memorable or forgettable. For products that are expected to be more memorable, considerations can be presented as a rationale for same-day training and testing. For products that are expected to be more forgettable, those expectations can drive a rationale for a multiple-day decay period" (Cherna, 2018).

Until the current guidances and standards are revised, companies look to research (such as above) to create guidance for safe and efficient lengths of training decay. A same-day training decay for usability studies limits the abundant external considerations (e.g. recruitment, travel, cost, etc.) that affect a decay that spans over multiple days. However, if training is used as a risk mitigation, establishing an appropriate length of training decay, early on in the planning, will help accommodate those considerations.

### Financial Impact of Training Decay

**1 Hour Training Decay** (Study completed in 4 days): 2,250 | 600 | 6,000 | 2,000 | 500 | 5,000 — $16,350. Travel Expenses (If necessary): 1,000 | 600 | 1,200 — $2,800

**2 Hour Training Decay** (Study completed in 4 days): 2,250 | 600 | 7,500 | 2,000 | 500 | 5,000 — $17,850. Travel Expenses: 1,000 | 600 | 1,200 — $2,800

**4 Hour Training Decay** (Study completed in 4 days): 2,250 | 600 | 10,500 | 2,000 | 500 | 5,000 — $20,850. Travel Expenses: 1,000 | 600 | 1,200 — $2,800

**1 Day Training Decay** (Study completed in 4 days): 3,000 | 300 | 8,000 | 1,000 | 500 | 5,000 — $17,800. Travel Expenses: 1,000 | 600 | 1,200 — $2,800

**4 Day Training Decay** (Study completed in 6 days): 3,000 | 300 | 8,000 | 1,000 | 500 | 5,000 — $17,800. Travel Expenses: 1,000 | 900 | 1,800 — $3,700

**1 Week Training Decay** (Study completed in 7 days): 3,000 | 300 | 8,000 | 1,000 | 500 | 5,000 — $17,800. Travel Expenses: 2,000 | 600 | 1,200 — $3,800

Categories: RN Recruitment Cost, Trainer Recruitment Cost, RN Honoraria, Trainer Honoraria, PM Fees, Facilities, Flights, Incidentals, Hotel

To visualize these considerations, the graph above details the financial impact that various training decay times have on a Usability Validation Study conducted by two researchers. This study was created with the following assumptions: 15 participants, RN and Training Recruitment Costs = $150/participant, Trainer Honoraria = $500/Day, RN Honoraria = $100/hr +1 additional hour of travel costs (Same-Day Training) or 2 additional hours of travel costs (Multi-day Training), Facilities = $1250/Day, Project Management Fees = $500, an additional 30% of participants were recruited for Multi-Day Training, Flights = $1000/Trip, Incidentals = $150/Day, and Accommodations = $300/Night

## Decay Considerations (24+ Hours)

**Recruiting:**
• Recruiting specialty surgeons from around the country may reduce the sponsor's ability to recruit from diverse institutions.
• For products with unique user populations, training decay may reduce the sponsor's ability to recruit as many users (Clark, 2016).
    • Training Decay introduces self-selection bias (Clark, 2016).
    • Participants that require a lengthy commute are less likely to participate if they need to return at a later date.
    • More participants are needed to be recruited to offset the poor retention rates.
• Increased lead time needed for successful recruits.

**Team Evaluation:**
• When evaluating a team of participants at once (e.g. an Operating Room Team), difficultly may arise to ensure that the same participants return.
    • As a result, needing to mix teams (i.e. one participant is unable to return) may introduce study artifacts (Clark, 2016).

**Traveling for the Usability Study:**
• Extra costs associated with keeping researchers present for an extended period of time.
• Conducting a usability study at a conference.
    • Unable to retain the same participants due to time constraints.

**Cost:**
• Lower than same-day training that spans more than 1 hour of decay.
• Higher compensation given to participants that travel to the testing site more than once.
• Low fair market values might decrease the likelihood that a clinician would participate in a study that spans over multiple sessions.

## Conclusion

Based on current common practices, research, and planning logistics, a training decay of less than one day, down to one hour, offers the most significant decay in retention. This range can become the new standard for devices that might not be used frequently after training. However, further research is needed to develop a clearer understanding of which decay times are too long (ergo diminishing returns) and which ones are not long enough. In the meantime, the best practice may be to approach the determination of appropriate training decay for a usability study by addressing it the same way other elements of the study are designed. First, understand how the training is performed in the real world and then determine what is the appropriate level of fidelity for the simulated context of use in order to inform a valid test.

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