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Ergonomics in Design: The Quarterly of Human Factors Applications 2013 21: 19
DOI: 10.1177/1064804613497957

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What is This?
Adherence Engineering: A New Approach to Increasing Adherence to Protocols

By Frank A. Drews

FEATURE AT A GLANCE:
Checklists, with their goal to increase adherence to protocols, are gaining popularity in health care despite some serious limitations. Here I present adherence engineering (AE), a conceptual framework that aims to increase adherence to protocols. AE provides guidance for the development of equipment that supports the successful completion of structured tasks. An example of how AE principles might be implemented is shown in the context of a clinical task in health care. Nonadherence to protocol when performing this task can have severe consequences for patient safety. The application of AE has the potential to improve human performance in a wide range of contexts.

KEYWORDS:
health care, protocols, checklists, adherence engineering

Hum an error and violations of procedures are present in most human activities. Although recent research has focused mostly on the reduction of human error, relatively little attention has been given to the issues concerning protocol violations. In this article, I present the theoretical framework of adherence engineering (AE), which aims to reduce violations of or nonadherence to protocols. This framework is exemplified in health care, but given the correct conditions, AE can be applied in many other domains as well.

NONADHERENCE IN HEALTH CARE
One example that illustrates the challenges of reducing protocol nonadherence in health care settings is provider hand hygiene. Hand hygiene is a critical component of patient safety; its goals are to prevent infection and reduce the spread of antimicrobial-resistant bacteria (Sax, Uckay, Richet, Allegranzi, & Pittet, 2007). Unfortunately, health care workers continue to fail to adhere to hand hygiene procedures despite clear evidence that such procedures are beneficial. For example, according to recent estimates, hand hygiene in health care settings is performed on only half the occasions when it is necessary (Larson et al., 2005; Pittet, 2001).

Despite significant efforts to improve hand hygiene adherence at the international (World Health Organization, 2009) and national (Centers for Disease Control, 2002) levels, health providers’ adherence to correct hand washing is well below optimal (Jarvis, 1996; Lankford et al., 2003; Pittet, Mourouga, & Perneger, 1999). In addition to training efforts to improve adherence (Sax et al., 2007), other strategies are being used to improve hand hygiene, among them, the use of checklists.

CHECKLISTS ARE ONLY A PARTIAL SOLUTION
Checklists and protocols are used in a wide range of domains as cognitive aids to provide support in completing a task (Boorman, 2001; Hart & Owen, 2005; Helmreich, 2000). Both checklists and protocols structure the steps of a task as a list, thus simplifying the conceptualization and recall of steps in the task (Morrow, Leirer, Andrassy, Hier, & Menard, 1998) and standardizing performance (Gurses et al., 2008). Checklists and protocols aim to increase the consistency of behavior and replace idiosyncratic behaviors with best practices. They have demonstrated their effectiveness in error prevention (Boorman, 2001; Hart & Owen, 2005; Helmreich, 2000).

Consequently, checklists and protocols have been advocated in health care as tools for reducing health care–acquired infections (HAIs; Boorman, 2001; Harrahill & Bartkus, 1990; Hart & Owen, 2005; Helmreich, 2000). Currently, checklist use is considered best practice in many contexts. For example, checklists have been strongly advocated for enhancing patient safety (Gawande, 2009; Hales & Pronovost, 2006; Singh et al., 2009) on the basis of the argument that checklists support task completion accuracy by enhancing memory and performance (Norman, 1991).

Among the benefits of checklist is that when used, they reduce the likelihood that steps in a procedure will be omitted. For example, some estimate that 50% or more of human errors in task completion are a result of omissions (Hobbs, 1997; Reason, 1995; Reason & Hobbs, 2003). However, the
successful implementation of checklists requires overcoming substantial systemic barriers (e.g., physicians’ reluctance to use checklists; Bosk, Dixon-Woods, Goeschel, & Pronovost, 2009; Degani & Wiener, 1993; Vats et al., 2010). In addition, checklists can be problematic because they can lead to the omission of task steps, require dual-tasking (monitoring the checklist while performing the work), and create checklist fatigue (Degani & Wiener, 1993). Additional obstacles to the implementation of checklists include inadequate staffing for independent assessment of adherence (DeLucia, Ott, & Palmieri, 2009), a suboptimal safety culture that rejects checklists or listed steps (Bosk et al., 2009; Durso & Drews, 2010; Helmreich, 2000), and the attitude that checklists undermine clinical expertise and interfere with autonomy of individuals (Bosk et al., 2009).

To address some of the limitations associated with checklists and protocols currently employed in health care, using a human factors–based approach, it is necessary to analyze the issues that contribute to nonadherence and provide guidance for the development of approaches that will increase patient safety. One such approach was recently developed at the Center for Human Factors in Patient Safety. Here I present this conceptual framework by outlining a number of basic assumptions related to human operators and applying these assumptions to derive a set of principles aimed at increasing adherence to protocols.

## Adherence Engineering

AE, a new conceptual framework developed by the Center for Human Factors in Patient Safety, complements the training perspective put forth by Sax (Sax et al., 2007) to increase protocol adherence. AE provides a solution for situations in which training and human factors engineering are potentially limited in their success. Previous work applying human factors engineering demonstrates that simplifying task requirements for users through improved device designs reduces design-induced error and increases device usability. For example, work on improving the usability of blood glucose meters (Rogers, Mykityshyn, Campbell, & Fisk, 2001) and infusion pumps (Lin, Vicente, & Boyle, 2001) demonstrates the success of this approach. However, this work is limited to the usability of single devices, whereas AE focuses on tasks that involve multiple devices and for which protocol adherence is essential. Therefore, AE is best applied to situations in which traditional human factors engineering of the tasks and equipment is insufficient to guarantee protocol adherence.

At the core of AE is the assumption that some aspects of behavior are shaped externally and that behavior-shaping factors can be used to increase protocol adherence. Overall, seven principles provide the basis for AE (see Table 1):

(a) Deliberately create object affordance (a quality of an object/environment allows the performance of an action; Norman, 1988).
(b) Provide task-intrinsic guidance (the task guides the user on how to perform it).
(c) Implement nudging (provide optimized choices; Thaler & Sunstein, 2008).

### Table 1. Adherence Engineering Principles, Implementation Goals, and Implementation

<table>
<thead>
<tr>
<th>Principle</th>
<th>Goal</th>
<th>Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affordances</td>
<td>Make use intuitive</td>
<td>Tabs to open kit, visibility of flaps of pockets</td>
</tr>
<tr>
<td>Task-intrinsic guidance</td>
<td>Provide structure and preview of task sequence</td>
<td>Sequential order of pockets; when multiple items, then additional information about sequence of use</td>
</tr>
<tr>
<td>Nudging</td>
<td>Support adherence by suggesting desirable actions/excluding undesirable actions</td>
<td>Providing hand gel in pockets, providing pen to remind to date the dressing</td>
</tr>
<tr>
<td>Smart defaults</td>
<td>Help select desirable actions/material to perform activity</td>
<td>Selection of materials that if used follow best practices [StatLock, bio patch, site scrub, chlorhexidine scrub]</td>
</tr>
<tr>
<td>Feedback</td>
<td>Allow easy resumption and assessment of current performance</td>
<td>Pockets are empty after completion of step, supporting resumption</td>
</tr>
<tr>
<td>Minimizing cognitive effort</td>
<td>Support the execution of a task by reducing the required cognitive resources</td>
<td>Chunking of related activities, icons and labels as reminders, structured sequence, reduction in planning needs for procedure, elimination of potential for omission</td>
</tr>
<tr>
<td>Minimizing physical effort</td>
<td>Make adherence convenient</td>
<td>Reduction of walking requirements [e.g., to hand gel dispenser, supplies room to pick up missing items]; no repeated need to get forgotten materials</td>
</tr>
</tbody>
</table>
(d) Select and implement smart defaults (provide default values that are commonly used; Johnson & Goldstein, 2003).
(e) Provide feedback (Durso & Drews, 2010; Norman, 1988).
(f) Reduce cognitive effort (Fiske & Taylor 1984; Tversky & Kahneman, 1974) required when performing the task.
(f) Reduce physical effort required when performing the task.

AE aims to positively affect behavior, for example, through the design of equipment as a “checklist in action” (Bakdash & Drews, 2012), which can help overcome some of the limitations that are intrinsic to checklists. In essence, through the design of equipment that minimizes effort, reduces physical activity, and lessens required cognition in the direction of protocol adherence, adherence to protocols and best practices can be increased while simultaneously minimizing the opportunity for violations.

**AE IN ACTION: CENTRAL-LINE DRESSING CHANGE**

A central line is a type of catheter typically inserted in the arm or neck of a severely ill patient or a patient requiring aggressive or long-term pharmaceutical therapy (e.g., high-dose antibiotics or chemotherapy that can damage or destroy smaller vasculature if administered with a peripheral IV). The central line terminates near the heart and is highly effective for direct infusion of medications and fluids while also facilitating blood draws.

With a central line, the greatest risk to patients is a systemic infection caused by the accumulation of pathogens colonizing the interior or exterior of the line and then spreading throughout the body (Pronovost et al., 2006). In the United States annually, up to 250,000 patients develop a central-line–associated bloodstream infection (CLABSI). Mortality occurs in up to 20% of infections (Klevens et al., 2007; Richards, Edwards, Culver, & Gaynes, 2000), and the cost to the health care system is in excess of $25,000 per episode (Laupland, Lee, Gregson, & Manns, 2006).

Central-line insertion practices have been targeted as contributing to CLABSI, and some successful interventions (Pronovost et al., 2006) have reduced the infection rates significantly. However, an area that has received relatively little attention for its contribution to CLABSI is dressing maintenance activities. This situation is similar to that in other industries in which maintenance activities are underresearched (Reason & Hobbs, 2003) and often do not receive the attention they deserve as an additional source of performance breakdown.

Central-line dressing maintenance (CLDM) involves antiseptic cleaning around the catheter insertion site and catheter hub, including the replacement of dressings and needless injection sites (NIS). CLDM is performed at least once a week or more frequently as needed. When performed correctly, CLDM greatly reduces pathogens, prevents their accumulation, and results in a significant reduction in CLABSI risk (Mermel, 2000; O’Grady et al., 2002). However, when CLDM is performed by inexperienced personnel, infection rates are nearly three times higher than when it is performed by experienced nurses (Alonso-Echanove et al., 2003). This difference can be attributed partly to lack of adherence to CLDM best practices.

In addition to the experience level of the person performing the procedure, other important external and internal factors influence CLDM performance. Nurses operate in a stressful environment, which can negatively affect cognition (DeLucia et al., 2009; Drews, Musters, & Samore, 2008; Parker & Coiera, 2000). Because of shift work, nurses frequently experience fatigue (Krueger, 1989), which has a negative impact on performance. In addition, multitasking or task switching is often required (because of frequent interruptions), which also impairs performance (Grundgeiger & Sanderson, 2009; Grundgeiger, Sanderson, MacDougall, & Venkatesh, 2010).

Thus, the designer of a medical device used by nurses in general, and a CLDM kit more specifically, needs to acknowledge and address the presence of these adverse conditions and their potential impact on task performance. Overall, such an approach is consistent with more recent attempts to increase the resilience of a system (see Hollnagel, 2011; Hollnagel, Woods, & Leveson, 2006).

Typically, clinical performance in the context of CLDM depends heavily on “knowledge in the head” (Norman, 1988). Most often, nurses must collect as many as 27 items prior to a CLDM procedure. Based on a conservative omission rate of 1% per item, the overall likelihood of omitting at least one item equals 23%. This situation can produce adverse consequences for patient safety, given that the procedure needs to be interrupted to retrieve the missing item, or the nurse might improvise to compensate for the missing equipment. In both cases, protocol adherence is compromised.

Commercially available CLDM kits assemble the most commonly used items into “jumble kits.” One of the most salient features of these jumble kits is that they have no internal structure. The items are included together in a bag or tray. In addition, given that each hospital has its own protocol for performing CLDM, these kits require supplementation with additional required items based on each hospital’s policy.

Another important limitation of currently available kits is that they do not offer information on the specific steps to be performed during CLDM or the correct sequence of steps. A nurse needs to recall these steps from memory while performing the task. This reliance on memory and cognition potentially has negative implications for patient safety because missing and suboptimally performed steps are associated with increased infection risk (Mermel, 2000; O’Grady et al., 2002).

Given the complexity of the procedure and increased reliance on less experienced personnel to perform CLDM, a
CLDM kit that applies the principles of AE provides a good test case of the applicability of the AE framework. In the next section, I describe the development of a CLDM kit that is designed to increase protocol adherence.

**TASK ANALYSIS AND PROTOTYPE DEVELOPMENT**

A task analysis (Shepherd & Stammers, 2005) combined with a clinical protocol analysis identified the steps required to perform CLDM (i.e., dressing change and NIS device change) based on the best-practice standards in place at a 121-bed tertiary care facility located in the mountain states (i.e., Mountain West) of the United States. The task analysis revealed that performing CLDM entails substantial cognitive demand with a high reliance on memory during preparation and execution. For example, compliance with the best-practice standards requires a nurse to collect 27 items from the supplies room in preparation for performing the task (Figure 1). After successful collection of the supplies, nurses are required to perform 15 individual steps and 26 substeps to be in adherence with the protocol.

The results of the aforementioned analysis, in addition to the outcomes from discussions with nurse-expert members of the infusion team, fed into the development of a CLDM kit prototype. The prototype design process included implementation of AE principles. Examples of principle implementation include the following:

1. **Object affordance**: There is visible indication of how and where to open the kit packaging, how to unfold the kit without contaminating the sterile field, and how and where to open the individual item pockets.
2. **Task-intrinsic guidance**: Pockets with individual components are arranged in sequence of use based on CLDM best practice.
3. **Nudging**: Only equipment that is identified as part of the best-practice procedure is provided; other equipment is excluded.
4. **Smart defaults**: The correct number of NIS kits for the most frequently used catheter (dual lumen) is included.
5. **Feedback**: Empty pockets and used items indicate previously performed steps.
6. **Cognitive effort reduction**: The instructions are grouped as chunks, with individual steps illustrated by icons.
7. **Physical effort reduction**: Hand sanitizer is included in the kit in small pouches, obviating the need to walk repeatedly to the wall dispenser to perform correct hand sanitization.

To support easier and faster retrieval from memory of the steps required to conduct a CLDM, the procedure was grouped into three phases: preparation, sterile field, and NIS change. These phases facilitate memory chunking. The guidance sheet included in the kit shows the phases (Figure 2) and summarizes the steps within each phase using icons and brief instructions. Colored visual cues and physical location within the kit indicate the order of use of each item and

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**JUMBLE PACKS**

So-called jumble packs are often used in health care and many other contexts (assembly of furniture, toys, etc.) to support users by supplying them with all or most of the materials required for a task (often an assembly task) in one or several pouches. The items are presented in an unstructured format; that is, without an indication of their sequence of use. Because of the lack of structure, a jumble pack fails to provide feedback as to which stage of a procedure a user has reached. In addition, jumble packs typically do not provide guidance to the user on how to perform a task, although if the expectation is that the user has not performed the task, often some kind of verbal or graphical instruction is also offered.

Among the challenges of using jumble packs is that the contents of these kits often need to be sorted prior to performing the task. If this sorting is not done, delays while performing the task often occur because of the time required to locate the target items. The overall amount of search time for an item increases as a function of the overall number of items included; thus, there is a limit as to how many items can be included. Finally, similarity of items may increase search time and create confusion and error in task performance.

Unfortunately, custom-made jumble packs in health care are frequently incomplete, requiring the collection of additional items. The consequence is that users often forget to collect these additional items, forcing them to interrupt a procedure or to improvise (i.e., violate procedures).
reinforce steps within each phase by providing components in sequence from left to right. Each item pocket is labeled and provides visual cues to facilitate ease of use and promote best-practice standards (Figure 3).

**USER FEEDBACK**

During the initial assessment phase, 12 nurses used the kits for CLDM procedures for two weeks. The feedback provided at the end of this phase was overwhelmingly positive. Nurses
commented on the ease with which they were able to perform the procedure when using the kit, how the kit supported them in recovering from interruptions, and how having all required items for the procedure in the kit reduced their workload. A good summary is found in the following feedback: "I liked the way that everything was in order so I knew which step to take next. I also liked the instructions and that everything I needed was in the kit." Other positive comments focused on the time savings while using the kit and the fact that the kit helped nurses to perform the task better. However, nurses also provided critical feedback. Consistently, they felt that the kit needed to be smaller so that it would not take as much space in the patient room, where surface space comes at a premium.

The overwhelmingly positive feedback from nurses who used the kit supports the view that AE can provide a useful framework for the development of tools that increase procedural adherence. However, in addition to subjective user feedback, another test of AE is to collect performance and adherence data. The results of a study assessing protocol adherence before and after introduction of the CLDM kit indicate a significant increase in protocol adherence (Drews et al., 2013). Thus, the implementation of AE principles in the design of equipment can have a significant impact on clinical performance.

**CONCLUSIONS**

The CLDM kit described in this article provides an example of adherence engineering as implemented in a health care setting to promote and increase clinician adherence to best practices. AE is intended to support practitioners in following protocols and checklists nonintrusively, therefore facilitating adherence without imposing additional task demands.

The AE approach is complementary to commonly used training approaches that are implemented to improve the reliability of human performance. However, whereas training provides knowledge “in the head” that serves to internally control practitioner behavior, AE provides external guidance. In the past, emphasis has been put on training to improve protocol adherence, but with fewer resources directed toward training currently, an alternative is needed. Thus, a combination of training and AE is likely to succeed when each individually may fail.

By implementing AE principles for equipment used to perform protocol-driven tasks, it is possible not only to increase adherence to protocols but also to improve overall safety and reliability of behavior. By focusing on our ability to externally guide behavior, we can make a significant contribution toward the reduction of human error and violations. In health care, such reduction translates into an increase in patient safety, an increase in effectiveness, and a reduction in costs of health care delivery.

**REFERENCES**


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This work is the result of the commitment and dedication of all the past and current members of the Center for Human Factors in Patient Safety at the George E. Wahlen VA Medical Center Salt Lake City, Utah.

The views expressed in this article are those of the author(s) and do not necessarily represent the views of the Department of Veterans Affairs.

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