

## Impact of Human Factors on Clinical Protocol Performance: A Proposed Assessment Framework and Case Examples

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### Abstract

#### **Background:**

Hyperglycemia is prevalent in critical care and tight control can save lives. Current ad-hoc clinical protocols require significant clinical effort and can often produce highly variable results. Thus, tight control remains elusive as there is not enough understanding of the relationship between control performance and protocol design, particularly with regard to how a given protocol is implemented.

#### **Methods:**

This article examines the role of human factors and how individuals relate to technological protocols in clinical settings. The study consists of an overall brief review that is used to create a first graphical representation of the impact of human factors in clinical medical protocol implementations. This initial framework is examined in the context of two similar, but different, case studies—the specialized relative insulin and nutrition tables glycemic control protocol and the TREAT system for antibiotic selection.

#### **Results:**

A graphical framework relating the human factors impact on medical protocol implementation is created. This framework describes the primary impacts on performance as resulting from clinical burden and protocol transparency. Their primary effect is on compliance with the protocol, which directly affects performance and outcome, particularly in long-term studies versus short pilot studies.

#### **Summary:**

Compliance is a key element in obtaining the best clinical outcome that a given protocol can provide. The issues that most affect compliance are quite often unrelated to the patient or treatment, but are a function of the protocol design and its ability to integrate (by its design) into a given clinical setting. A framework for examining these issues in design and in post-hoc assessment is therefore proposed and examined in two brief case studies.

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**Abbreviations:** (ICU) intensive care unit, (IIT) intensive insulin therapy, (SPRINT) specialized relative insulin and nutrition tables

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