Center for Biologics Evaluation and Research

CBER is the Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER protects and advances public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

According to the US Food and Drug Administration Center for Biologics Evaluation and Research, Healthcare systems have been experiencing blood transfusion overuse. To minimize the overuse of blood product transfusions, a proprietary artificial intelligence (AI)-based blood utilization calculator (BUC) was developed and integrated into a US hospital's electronic health record. Despite the promising performance of the BUC, this technology remains underused in the clinical setting.

A study aimed to explore how clinicians perceived this AI-based decision support system and, consequently, understand the factors hindering BUC use.

They interviewed 10 clinicians (BUC users) until the data saturation point was reached. The interviews were conducted over a web-based platform and were recorded. The audiovisual recordings were then anonymously transcribed verbatim. They used an inductive-deductive thematic analysis to analyze the transcripts, which involved applying predetermined themes to the data (deductive) and consecutively identifying new themes as they emerged in the data (inductive).

They identified the following two themes: (1) workload and usability and (2) clinical decision-making. Clinicians acknowledged the ease of use and usefulness of the BUC for the general inpatient population. The clinicians also found the BUC to be useful in making decisions related to blood transfusion. However, some clinicians found the technology to be confusing due to inconsistent automation across different blood work processes.

This study highlights that analytical efficacy alone does not ensure technology use or acceptance. The overall system's design, user perception, and users' knowledge of the technology are equally important and necessary (limitations, functionality, purpose, and scope). Therefore, the effective integration of AI-based decision support systems, such as the BUC, mandates multidisciplinary engagement, ensuring the adequate initial and recurrent training of AI users while maintaining high analytical efficacy and validity. As a final takeaway, the design of AI systems that are made to perform specific tasks must be self-explanatory, so that the users can easily understand how and when to use the technology. Using any technology on a population for whom it was not initially designed will hinder user perception and the technology's use [1)].

1)
Choudhury A, Asan O, Medow JE. Clinicians' Perceptions of an Artificial Intelligence-Based Blood Utilization Calculator: Qualitative Exploratory Study. JMIR Hum Factors. 2022 Oct 31;9(4):e38411. doi: 10.2196/38411. PMID: 36315238.