A randomized clinical trial of real-time decision support during the evaluation of abdominal organ offers

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OBJECTIVE

Design and conduct a randomized clinical trial to test the efficacy of real-time clinical decision support for abdominal organ offers.

INTRODUCTION

Organ transplantation is a cost and clinically effective treatment for patients suffering from end-stage organ failure. According to the Organ Preservation Alliance, one in three deaths in the US might be prevented by an organ transplant. One limitation on organ transplantation is the onerous and disorganized assessment of an organ offer to determine donor/recipient match quality. Real-time clinical decision support (CDS) with artificial intelligence may significantly increase access, increase quality, and reduce the time and cost of organ transplantation.

METHODOLOGY

Procurement and transplant team members utilized a dedicated mobile application for communicating during the organ offer process. The study is conducted with a year-long, three-arm, open-label, randomized clinical trial at multiple leading transplant centers in the USA. The mobile application was enhanced with two different implementations of CDS, static and dynamic. Static CDS consisted of a prediction environment that was unchanged throughout the trial.

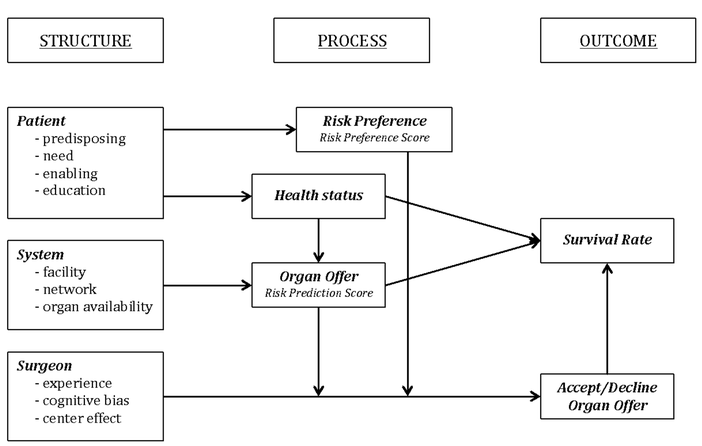

Figure 1. Conceptual framework of the organ offer decision.

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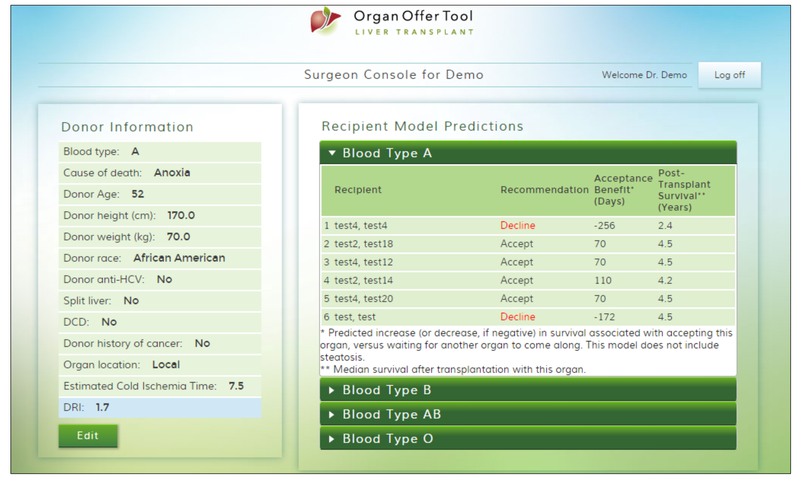

Figure 2. Web-based CDS tool.

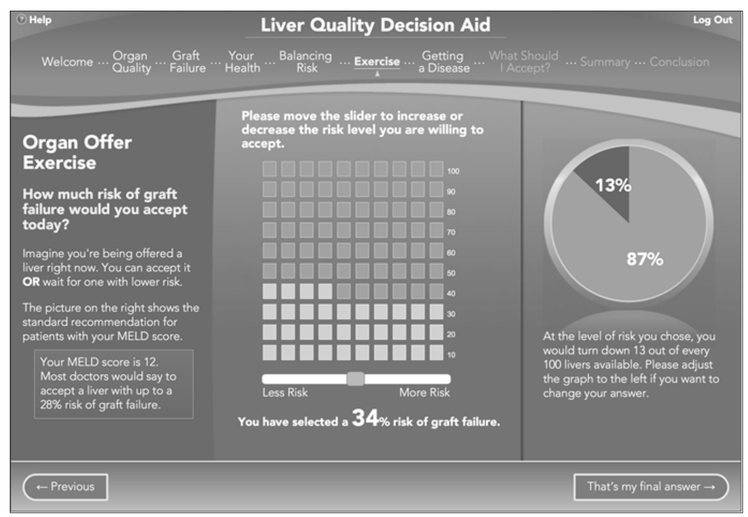

Figure 3. Patient risk preference tool.

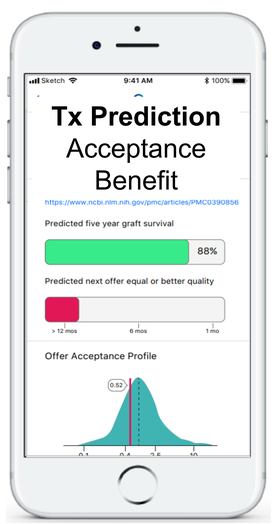

Figure 4. Mobile CDS tool.

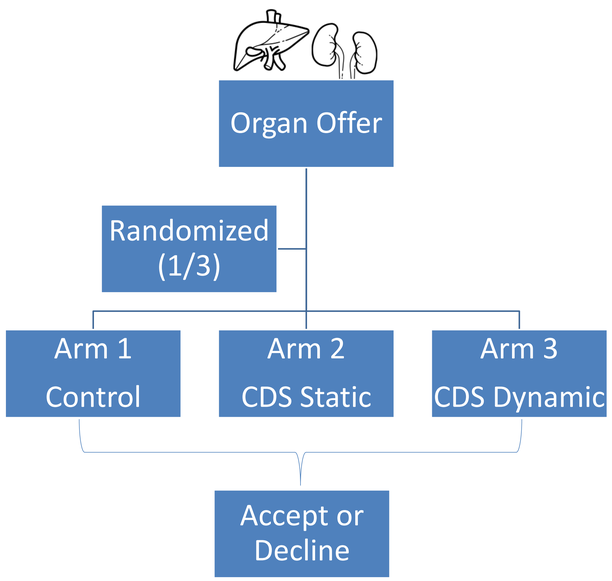

Figure 5. Illustration of the clinical trial design.

Validated Models

The CDS leverages previously validated algorithms and models was an important control for this study. Models that have already demonstrated their clinical effectiveness for prediction of transplant outcomes can be tested independently of a clinical trial.

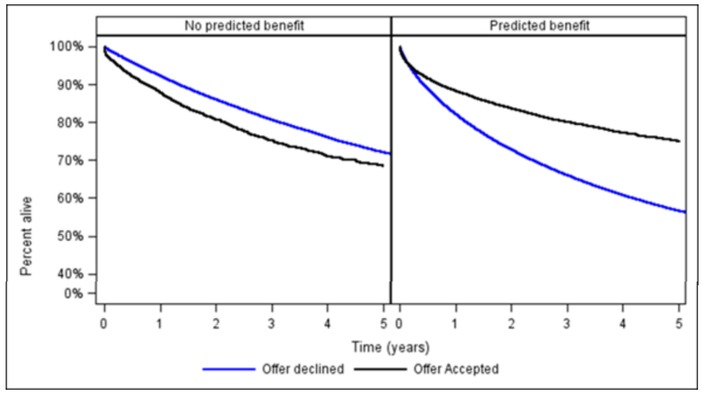

Figure 6. Highlights from previous work (Volk, et al. 2014) validated an acceptance benefit algorithm for deceased donor liver offers. This algorithm is implemented within the clinical trial.

The investigating team has received early indications of satisfaction and perceived enhancement of medical decisions from directors and surgical leaders at participating centers. This study is ongoing and IRB approval was obtained summer 2019.

DISCUSSION

Clinical decision support used during organ offer evaluations may provide clinical professionals an improved basis for making critical decisions in real time. Instant access to clinically relevant information augmented by validated algorithms will change the way professionals make decisions about whether to transplant deceased donor organs into specific patients during the organ offering and allocation processes. The company, OmniLife,[1] deploys mobile apps equipped with real-time tools used for clinical decision support purposes. This research and the company are supported by the NIH.[4]