Big Data and Machine Learning in Organ Donation and Transplantation

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INTRODUCTION

Big Data and Machine Learning in Organ Donation and Transplantation

Machine learning is a branch of artificial intelligence and computer science that is increasingly being applied to both medical research and clinical practice, including aspects of organ donation and transplantation. Machine learning uses large data sets to identify patterns and to refine predictive algorithms based on those patterns. Ideally, these algorithms will help to support clinical decision-making and to allow for health care that is more precisely tailored and effective.

A wide range of potential applications of machine learning exists for organ donation and transplantation, including early identification of donors, supporting patients in deciding when to proceed with transplantation, improved prognostication and prediction of rejection, and improvements to the algorithms that match donated organs with potential recipients.

Of course, there are also critiques and concerns. There are concerns around how machine learning will fit into clinical decision making and organ allocation processes, the ethics of using it in organ donation and transplantation and questions of transparency and explainability when it is used.

MACHINE LEARNING FOR EARLY IDENTIFICATION OF POTENTIAL DONORS?

Potential organ donors are sometimes missed, which means that families are not approached (or are approached too late) and the opportunity for donation may be lost. One possible application of machine learning is to refine a tool to enable early identification of potential donors. Such technologies could be helpful in more remote areas where such occurrences are rare, or in fast paced environments where the risk of overlooking a potential donor is higher. It remains uncertain if machine learning can be used reliably for early identification of potential donors. Researchers are working to build models that could identify patients who are more likely to be potential organ donors. These models require sophisticated analysis of large amounts of data and have the potential to:

- Enable insights to be drawn from information that is currently ignored;
- Extract new information from patient-related data such as images, vital signs and waveforms; and
- Help with tasks such as screening patients. (1)

Machine learning is not yet being used for the early identification of donors in a clinical setting. One important component in the ethical use of this technique is the careful separation maintained between the active clinical care of the patient and the question of organ donation. This separation aims to ensure that the care of patients is not affected by the possibility of organ donation.

MACHINE LEARNING AND CLINICAL DECISION-MAKING IN ORGAN DONATION AND TRANSPLANTATION

Machine learning may also be used by transplant candidates and their clinicians in assessing whether a patient should accept a transplant offer or await one that offers a better long-term prognosis because it is a better match or of better quality. Not all patients are able to wait, but some can – such as those whose organ function can be supported (e.g. by dialysis). There are risks associated with waiting, which makes the decision faced by patients and their doctors a difficult one.

SHOULD A PATIENT ACCEPT A KIDNEY OR KEEP WAITING FOR A DIFFERENT ONE?

Choosing to accept or refuse an organ from a medically complex donor is up to the patient. It is the patient's decision to accept or refuse an organ, based on information received from their care team.

- "Medically complex donors" are those who have risk features that are associated with lower long term graft survival (e.g. older age, stroke as the cause of death) which may lead the patient to question accepting the organ. (2)

HOW CAN MACHINE LEARNING HELP IN THESE SCENARIOS?

A model that integrates machine learning can be used as a decision support tool, to help answer difficult questions associated with medically complex donors. These tools are not built for organ allocation, but rather, as a support tool in the decision-making process.

Decision support tools use machine learning to estimate survival if the current offer is accepted, based on donor and recipient characteristics to predict overall graft survival. This information, along with estimates of the likely delay until a superior transplant opportunity is likely to arise, may assist the decision to accept or reject the offer. However, these support tools should not replace clinical judgment.

PRACTICAL CONSIDERATIONS FOR USING MACHINE LEARNING IN CLINICAL DECISION-MAKING

- The data produced by machine learning should be interpreted with caution. The underlying models may be unable to shed light on the real contribution of a given factor, or show how changing a variable will affect the output. It is unclear whether the accuracy of some models is reproducible in groups with different characteristics.
- Although machine learning can make accurate predictions, healthcare professionals will need to interpret this information in light of the patient's individual characteristics, condition and expectations, and assist the patient to use it to make informed decisions. (3)
- Machine learning outputs may be difficult to interpret or understand. Other existing statistical models created from regression analyses (e.g. the MELD score, which is used to identify the severity of end-stage liver disease for the purpose of liver transplant allocation) may still offer more interpretable decision-making rules that can be used in the clinical setting. (4)

MACHINE LEARNING AND PAIRED KIDNEY EXCHANGE

Paired kidney exchange is a process where kidneys are exchanged between two or more incompatible pairs so that recipients in the different pairs receive a more compatible kidney. (5) Paired kidney exchange can lead to twice as many successful transplants and reduces the match failure rate for highly sensitized recipients by up to 45%. The use of machine learning can improve this process by incorporating other complex parameters that are not considered in manual matching.

MACHINE LEARNING, ETHICS AND ORGAN ALLOCATION

In some organizations, organ allocation is completed by employing a scoring formula that awards points to candidates based on numerous different criteria such as wait time, medical urgency, proximity to the donor, and so on. Machine learning may be able to improve the allocation of organs and may help to identify the short-term prognosis or stage of disease in order to properly identify urgency. (6)

If moral objectives and limitations are considered at the beginning of the model design process, machine learning can be used in a way that improves efficiency without jeopardizing ethical principles. It is essential to develop models and processes that balance all objectives, including ethical considerations, from the start. If ethical issues are not considered at the outset, these models could lead to problematic outcomes such as discrimination in the organ donation process. (7) These models must strike a balance across several objectives like efficiency, ethics, and fairness so that patients are not discriminated against based on factors including race, age, sex, or geographical location.

ETHICAL QUESTIONS AND CONCERNS SURROUNDING MACHINE LEARNING IN ODT

The use of machine learning in ODT raises several important ethical questions, including:

- **Acceptability:** Is using machine learning in this context acceptable in our society; is it acceptable to the public, to families and to healthcare providers?

- **Quality of data:** Will the data collected end up helping or hurting if it is not representative of the entire population? Will the model lead to discrimination in the healthcare system? These algorithms may not have global applicability and are often best suited to predicting outcomes based on data sets from which they were originally derived. Incomplete data sets used to train machine learning systems may cause potentially biased outcomes. (8)

- **Sourcing of data:** Where do researchers source the data required to build the algorithms? Do patients need to provide informed consent for their data to be used in a data set?

- **Validating the model:** After building and validating the machine learning model, how will we know when it is good enough to use? What are the standards of validation?

- **Impact on clinical decision making:** To what extent do these systems change the balance of discretion of a physician? Will physicians require informed consent to use a model on a patient? Alternatively, can patients opt out of the use of these systems in their care? Are physicians obliged to use these systems if the AI models are considered more accurate?

- **Oversight and accountability:** How will liability, regulation and mistakes be addressed? Is it a hospital, a federal agency, or a group of patients who decides when machine learning is to be used? How will liability for machine learning based systems be addressed and who is responsible for mistakes? Who should be responsible for regulating these tools in healthcare? How do we ensure there is equitable access to these models and that there is broad dissemination? We must ensure that those who contributed to the model will receive the benefit.

TRANSPARENCY, INTERPRETABILITY, EXPLAINABILITY, AND WHY IT SHOULD MATTER

Patient autonomy is a critical value in health care, and this is reflected in the requirement that patients give informed consent to treatment. In order to give informed consent, patients must understand the risks and benefits of treatment alternatives, and they must also understand the reasons for treatment recommendations.

The use of machine learning in healthcare decisions may lead to several challenges, including the ability to interpret or explain decisions:

- To what degree can the output be understood by the doctor and patient? Will the model be transparent enough to be interpreted, or is the machine learning model sufficiently complex that approximate explanations of how the model functions must be developed after the fact to try to understand the output? (9)

- The accuracy of machine learning may come at a cost of losing "explainability" – to both patients and clinicians – on how the technology works. Some models work in ways that are unknown to the creator, and cannot be explained to patients or doctors using them; this issue is commonly referred to as "the black box issue." (10)

- What is the appropriate amount of disclosure to the public that a model is being used?

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