



# Introduction

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## Overview

There is an acute need to address the organ shortage today. Stated bluntly, the demand for human organ transplantation greatly exceeds the available supply from both living and deceased donors. Policy solutions, such as presumed consent, have been attempted in different jurisdictions globally with varying results. Iran has turned to a paid kidney donation model. However, much of the world is hesitant to take such steps and the impact of how these steps affect supply are inconclusive. Alternative sources of organs are needed, and xenotransplantation—the cross-species transplantation of organs—is one potential solution.

This book comes at an opportune time when recent studies on xenotransplantation have been performed in the United States in 2021 and 2022. More studies and even formal clinical trials are set to begin. Because of this, the need for clarity regarding ethical, regulatory, and social issues is imperative.

This book seeks to fill a gap in the literature on ethical, regulatory, and social implications of xenotransplantation. Leading thinkers on these issues globally have been sought and contributed to this work with the hope of providing some clarity to

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pressing questions and further the conversation. To this end, the book proceeds in four parts, each of which is briefly described here.

In Part I: Ethical Aspects, many of the ethical aspects of xenotransplantation are covered. The ethical aspects of xenotransplantation have been enumerated by many authors for at least the past three decades. As we move closer to clinical trials, addressing these issues have become more pressing. Trevor Stammers begins the section with a chapter on allotransplantation ethics. In order to understand some of the issues present in xenotransplantation it is important to have a grounding in the larger field of transplant ethics, which Stammers provides. Mariachiara Tallachini discusses the role of public involvement in xenotransplantation and *why* the public's involvement is important. Following this, Potter and White provide a clinical ethics chapter, which is the only publication to date that takes this focus in regard to xenotransplantation. Pediatric ethics issues are then discussed by Padilla, Maxwell, and Hurst. In Chap. 6, Hurst discusses some philosophical intricacies of xenotransplantation and participant informed consent. Martine Rothblatt, chairperson and CEO of United Therapeutics, writes of geoethical concerns in Chap. 7. Lastly, the section concludes with a chapter on animal ethics by Tanja Opiressnig and Patrick Halbur.

Part II on regulatory aspects covers laws and regulations that will have to take place before xenotransplantation occurs in various parts of the world. Although many countries are involved and/or are interested in advancing or adopting xenotransplantation, it finds itself in different stages across the world. The requirements and expectations for its outcomes and use hold different implications based on varying country laws and the need to be socially and culturally sensitive to the population of each country. Part II describes the regulations, laws and the history of the considerations that have taken place in the United States, Europe, Japan and China.

Part III: Religious Aspects examines xenotransplantation through the lens of various religious traditions. Hurst and colleagues begin the section with a chapter on Protestant and Catholic viewpoints, presenting a summary of the empirical and theological writings from Protestantism and Catholicism toward xenotransplantation. Sunni and Shia Islam have distinct chapters in order to parse differences in how the two branches of Islam think through xenotransplantation. Bedzow provides insight on how Judaism may approach xenotransplantation. The section closes with a chapter on Hinduism.

As the experimental work in xenotransplantation moves closer to clinical trials and perhaps to clinical application as a therapeutic option, the question of the social factors associated with it have become more pertinent and in need of closer examination. This is the purpose of Part IV: Social Aspects. In allotransplantation the most important social question has always been how to deal with the inadequate number of donors compared to those in need of a donor organ. The psychosocial assessment of the potential transplant candidate has figured prominently. Patient follow-up was important, but not as critical as making sure the patient accepted for transplantation was the best candidate that would maximize the use of a scarce societal resource. This does not suggest that candidate assessment will be any less important with xenotransplantation, but rather that it is only one part of a much

more complex process. A process will entail who receives a xenograft, the number of times the patient may be transplanted, how the choice of human versus pig source influences the selection process, and the individual patient, family and social milieu reaction to a non-human donor.

In an attempt to explore the numerous avenues associated with this complex process, we have attempted to present the latest knowledge and understanding about what may be involved from a broad definition of what *social* really means. The works included do not focus solely on psychosocial factors as classically defined, but rather encompasses a broader, more inclusive consideration of the term. The book raises social concerns not only related to the individual but also societal concerns such as forced isolation and the possibility of zoonosis.

Our hope is that this edited volume provides a comprehensive viewpoint on the ethical, regulatory, and social implications of xenotransplantation. Some of the issues discussed in this context are perennial issues that have been discussed over the past several decades, while other content we believe is completely novel to this volume. Many of the chapters are written by recognized researchers and practitioners in their fields who are privy to the most up-to-date information. Since this is a rapidly moving field, we are also cognizant that what may be the most up-to-date information at time of press may quickly be surpassed. This is likely to be true of the regulatory environments in which xenotransplantation will be tested in trials and become a clinical option, whereas we believe the remainder of the content will remain relevant for much longer.