

# Preface

This book grew from my PhD dissertation. I wanted to write about a topic that was cutting edge and would be applicable for several years. I had been thinking about the ethics of predictive genetic testing (PGT), particularly direct-to-consumer testing, for a while. Eventually I decided that even though I had heard some stories about predictive testing ending badly, I could not clearly say that the testing was unethical. Then I started to evaluate what was troubling in regards to PGT. Especially in the cases that did not turn out well, it seemed that one of the main issues was a lack of understanding. I believe PGT can be a great tool for medicine, but if there is a lack of understanding about the test, potential treatments, or long-term outcomes, then there is the potential for significant harm. While considering these issues, I remembered a plenary speaker in one of the American Society for Bioethics & Humanities conferences addressing future issues and concerns for bioethicists. One of the issues discussed was informed consent. After considering PGT some more, I decided that a more robust discussion on informed consent and PGT could prove valuable to the areas of bioethics, genetic testing, and genetic counseling research.

After doing some more research I decided that a revised model of informed consent would be more appropriate for PGT, since there are some characteristics that differentiate PGT from other types of testing. These characteristics are: the difficulty in understanding genetic risks and probabilities; the problem of treatment options for diagnosed genetic traits; and the concern with family-related genetic information. All three of these characteristics are incorporated into a revised model of informed consent for PGT.

This book focuses on four components: comprehension, disclosure, voluntariness, and patient safety. First, PGT involves a risk analysis of the related probabilities that can be complicated for patients to comprehend. This point develops the importance of understanding in the current model. Second, there are complex treatment options, including no treatment for some diseases, that require genetic counseling to select an appropriate option. This point develops the importance of disclosure in the current model. Third, PGT involves family-related information with accompanying implications that can compromise voluntariness. This third point develops the importance of avoiding coercion of both the patient and the patient's family when information is presented. Fourth, the revised model of consent

requires an additional component to the traditionally recognized three components (comprehension, disclosure, voluntariness): the culture of patient safety. That is, the revised model of consent enhances the traditional components of consent within a medical culture that emphasizes patient safety.

While the first chapter goes into more depth about the purpose and distinctiveness of the book, I did not find many books that addressed specific issues of informed consent that arise from PGT. None of the literature has merged the current components of consent (understanding, disclosure, and voluntariness) with the distinguishing characteristics of PGT. I believe this book's thesis is distinctive, because it establishes a revised model by aligning the three distinguishing characteristics of PGT with the three widely recognized components in the current model.

In the book, I explain what PGT is, address several misconceptions of genetic risks and probabilities, evaluate the idea of treatment options or the lack of treatment options, and call attention to some family-related issues due to genetics. There is also a very in-depth history of informed consent from both a clinical and research standpoint. I discuss how the current components of consent arose, and then compare and contrast the current model with the revised model of consent for PGT. At the end, I apply the revised model of informed consent to direct-to-consumer genetic testing and pleiotropic genetic testing.

While this book focuses on proposing a revised model of informed consent, I believe it can also be useful for those interested in genetic testing both personally and professionally. This book addresses some important questions people need to consider before participating in PGT. I also feel that the points raised in this book can promote increased dialogue among health professionals about how the requirement of informed consent for PGT can be met both legally and ethically.

I would like to acknowledge Dr. Gerard Magill, my advisor during the dissertation process. Dr. Magill always offered extremely helpful comments and was a wise and generous mentor.



<http://www.springer.com/978-3-319-17415-0>

Informed Consent in Predictive Genetic Testing  
A Revised Model

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2015, VII, 232 p., Hardcover

ISBN: 978-3-319-17415-0