Chapter 7
Ethical and Regulatory Challenges of Emerging Health Technologies

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ABSTRACT

The advances in biotechnology and computer and data sciences opened the way for innovative approaches to human healthcare. Meanwhile, they created many ethical and regulatory dilemmas such as pervasive global inequalities and security and risk to data privacy. The assessment of health technology is a systematic multidisciplinary process that aims to examine the benefits and risks associated with its use including medical, social, economic, and ethical impacts. It is used to inform policy and optimize decision-making. The advance of technology is creating significant challenges to healthcare regulators who strive to balance patient safety to fostering innovation. The FDA and EMA are modernizing their regulatory approaches to foster innovation in digital technology and improve safety and applicability to patients. On the other hand, data analytic technologies have been introduced into regulatory decision processes.

INTRODUCTION

The un-precedent power implied to humans with the aid of technology is transforming many of our life decisions, mostly for the better. Unless responsibly applied, the worse could also happen. The advances appearing in many biotechnology sciences such as genomics, neuroscience, synthetic biology, and nanoscience combined with the rapid developments in computer and data analytics allowed innovative approaches to human health care. On the other hand, the increasing complexity of ethical issues associated with modern health technology has created some novel challenges.

The need for specialized expertise and wider scope of analysis derived a new subfield of ethics termed technology ethics or "techno-ethics" which deals with the framing of principles and methods to guide technology implementation and use.

DOI: 10.4018/978-1-7998-8467-5.ch007

Common areas of techno-ethics include access right, intellectual property (IP) and privacy rights protection, environmental safety and reservation, human health and safety, technology predictability, transparency, and accountability (Spacey, 2016).

Health care is a major field of technology advancement involving a wide spectrum of issues such as medications, devices, innovative therapy, reproduction, personalized medicine, etc., and is associated with an increasing number of ethical dilemmas.

This chapter will review the main categories of health technologies and their potential ethical challenges, assessment methods, and related regulatory aspects.

BACKGROUND

The "Health Technology" term was defined in the 6Th World Health Assembly (2021) as: "the application of organized knowledge and skills within the sort of devices, medicines, vaccines, procedures, and systems developed to unravel ill health and improve quality of lives". (WHO, 2021)

The assessment of health technologies is a multidisciplinary process that systematically examines evidence about their various impacts including medical, social, economic, and ethical aspects. A comprehensive assessment requires knowledge and experience beyond the scope of ethical analysis including awareness of the spectrum and principles of the technology and the related impacts on all stakeholders. Transparency, freedom from bias, and robustness are essential qualities to ensure the validity of the assessment (www.eunethta.eu)

In the next sections, the spectrum of health technology, its ethical and regulatory challenges, assessment frameworks, and regulations will be discussed.

1. The Definition and Spectrum of Health Technology

The term 'health technology' encompasses a wide range of interventions, used for disease prevention, diagnosis, and treatment as well as rehabilitation and long-term care. In other words, it includes interventions intended to promote individual and population health.

It also applies to other broad applications such as restructuring of the health service through standardization or reallocation of resources.

Health technology can be categorized according to its type and intended use into:

1. Physical agents such as drugs and biologics e.g., vaccines and gene and cell products, devices and supplies e.g., cardiac pacemaker, implants, and magnetic resonance imaging (MRI) scanner, and procedures both medical and surgical
2. Public health programs e.g., newborn screening and immunization
3. Support Service e.g., clinical laboratory, blood bank, electronic health record system, telemedicine, and drug formulary
4. Organizational and managerial systems e.g., medication adherence program and alternative health care

Some applications combine more than one category e.g., drugs and devices (Lauritsen 2009) such as the positron emission tomography (PET) used with radiopharmaceuticals.