



NORTH-HOLLAND

Risks of Future Drugs: A Danish Expert Delphi

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ABSTRACT

This study adopts the prospective perspective in an attempt to explore and define the risks of future drugs. The use of the Delphi method in this study is substantiated by its psychological, financial, and (in the case of the pharmaceutical field) relevant advantages. This study is one of the first Delphi studies to fully utilize Internet (also referred to as the worldwide web [www]) *html* technology to collect and process data. The two rounds of questionnaires seek both qualitative and quantitative data through Likert-scale questions with mandatory open-ended questions for argumentation. Thirty (round 1) and 22 (round 2) top-level experts drawn from all of the pharmaceutical research and development organizations in Denmark participated. This study concludes that risks of future drugs expand and develop beyond our existing assessment and perception mechanisms. They have the ability to transform side effects from the traditional individual physical level to a societal level with economic, political, and ethical consequences. The study identifies several serious bottlenecks in drug discovery and development in the future; paradigm conflicts and, more important, the assessment of risks associated with future drugs need new and alternative methods and assessment procedures. This is essential in order to capture and cope with the unseen and new side effects that the emergence of the “informational paradigm” within the field of drugs will undoubtedly bring about. © 2001 Elsevier Science Inc.

Introduction

At the *fin de siècle*, we are facing what has been called the “second medical revolution” [1, 2], which includes an entirely new generation of drugs¹ [3, 4, 5, 6]. Drews [7] argues that, after having developed within the “chemical paradigm,” drug research is now under the influence of a radically different approach, the “informational paradigm.” The term “informational” refers to the information provided by our genes. In

¹ Drugs can be defined as natural compounds, chemical compounds, and genetic compounds used to cure, relieve, or prevent illnesses and diseases or/and symptoms of diseases [76] (modified by Møldrup and Morgall).

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that respect, modern drug discovery and development is on a journey that is moving deeper into the secrets of the human being. This journey draws parallels to the “first medical revolution” from nature compounds to the chemical paradigm as primary drug approach. We now know that this “first medical revolution” produced risks: we only have to mention the Thalidomide scandal. As a result, drug discovery and development dramatically changed away from an euphoric belief in chemical structures, once it was learned that chemistry can also cause harm to human beings. Today, the “second medical revolution” may produce new types of risks and harm in the future. We had to learn from our mistakes in the first medical revolution and look deeper into the future of risks. Therefore our concern in this study is with the unseen and new side effects that the emergence of the informational paradigm within the field of drugs will undoubtedly bring about [8].

Objective

This study attempts to explore and define the risks² of future drugs through an expert perspective. We adopt a prospective approach in order to track and keep up with the changing characteristics of new drugs [9].

Method

THE DELPHI METHOD

The Delphi method is perhaps the best known prospective research method in use today [10]. It aims to collect and distill knowledge from a group of experts by means of a series of questionnaires based on a structured process with controlled opinion feedback [11]. According to Lang [12], the development of the Delphi method had its main genesis in two major findings:

1. The “MacGregor effect,” saying that predictions made by a group of individuals are more likely to be right than predictions made by the same individuals working alone (based on findings made by Douglas MacGregor in 1936 [13]).
2. The follow-the-leader bias of face-to-face meetings [14].

The first experiment using a Delphi-style technique was carried out in 1948 in order to predict the winners of horse races and thus optimize betting [10]. In the 1950s, the first attempt to make the Delphi method match scientific standards was made by Dalkey and Helmer [15] at the RAND corporation. Beginning with a number of RAND reports [15–20] and the Dalkey Memorandum of the Delphi method in 1969 [21], the method has received intensive attention in numerous books and journal articles [22], of which Linstone & Turoff [23], Sackman [24], Delbecq et al. [25], Goldschmidt [26] and Adler & Ziglio [27] are the most important. It must be borne in mind that there are significant differences between current practice and the original concept [28–30]. Variants are conventional Delphi [15], policy Delphi [31, 32], and decision-making Delphi [10, 30].

In a broad sense, the Delphi method is a specialized methodology for technology assessment. According to Cuhls and Kuwahara [33], it is based on a heuristic method of scientific problem solving. The classical repertoire of technology assessment can be

² The notion of *risks* in this context is adopted from the theoretical framework of Ulrich Beck’s Risk Society [79]: risk is defined as being induced and socially constructed technological artefacts as introduced. Risks are globalized due to their global impact, invisible to individuals—and sometimes even to social perception—as a consequence of their non-objective nature. This again leads to the understanding that risks of modernity are the projected dangers of the future.

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