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BOOK REVIEW

André Pieter den Exter. Health Care Law-making in Central and Eastern Europe. Review of a Legal-theoretical Model. Antwerp-Oxford-New York: Intersentia; 2002. 371 pages; ISBN 9050952534; price: €87.50.

Field of medicine: Health law, health policy.

Format: Paperback.

Audience: Health lawyers and health care policy-makers interested in legal reforms in Central-Eastern European health care systems, including the "European Union (EU) law approximation process."

Purpose: Reviewing a model of health care law-making in transitional countries. Such a legal model should strengthen health care system reforms.

Contents: This book examines the relevance of a theoretical model of health care law-making and focuses on three countries in Central and Eastern Europe, including the Czech Republic, Hungary, and Poland. Confronted with the legacy of the ancient regime, these countries initiated major health reforms. Inspired by pre-war "Bismarckian" experience, these countries shifted away from a "socialist" model towards a more "market-oriented" health care system. From a legal perspective, this change of system imposed on the government the need for drastic reforms of their national legal framework. The most prominent example has been the introduction of health insurance legislation, establishing a compulsory health insurance scheme based on the notion of solidarity. In addition to, or prior to, these health care insurance reforms, the legislature introduced massive privatization of health care services.

The first part of the book deals with these legal changes, which have been highly problematic. Criticism concerns the role of the legislator and the quality of legislation. To strengthen decision-making in reforming health care legislation in Central and Eastern Europe, the author developed a theoretical model of law-making. Such a theoretical model should rationalize the law-making activity and provide a normative framework to guide and review changes in the field of health care legislation. The model represents an analytical series of considerations to facilitate explication of the complexity of law-making. The underlying rational concept is based on normative and instrumental functions of law-making in health care. These functions are based on primordial values of health (care) law, such as the right to health care and individual self-determination (patient autonomy). Both unique principles of health care law, embedded and elaborated in various international legal documents, constitute a major source of the normative framework. They entail understanding the essential concepts, instruments and strategies of health care rights in State parties concerned, and means by which these rights can be realized, notably, by adopting legislation.

The definition of legislation has been considered in terms of functions of health care law, encompassing a broad scope of health care law: public health, the organization and financing of health care services, quality control, and patients rights. These functions of health care law (or "law-jobs") provide a conceptual frame of instruments that, imbedded in international law, substantiate the legislative activity. Apart from structuring the legislative activity, the relevance of this model to transitional countries concerns the interaction between (conflicting) legal and policy values. The approach to systematically introduce incremental changes reveals the classical dilemma between guaranteeing patients' rights (e.g., access to health care) versus cost containment policy measures (e.g., introducing market elements). To solve this dilemma, the conceptual framework of health care law functions as guiding normative standard, whereas the consecutive stages of law-making structure and systematize the diffuse process of decision-making. As such, it provides the legislature with an intellectual instrument aimed at rationalizing the legislative reform activity and process.

In part two, the author uses this theoretical model to examine the current law-making practice in health care. Case study review made clear that initial legal reforms were primarily focused on health insurance reforms and modernizing the health care delivery structure by revising the Health Care Act. Apart from the Czech Republic, the modernization of the organizational structure of the health care system through the Health Care Act preceded the enactment of health insurance legislation. This could explain the serious nature of the problems observed in establishing a social health insurance system in the Czech Republic. With the purchaser-provider split and the subsequent shift towards contractual relationships between purchasers, providers, and patients, traditional organizational structures and planning mechanisms became rather obsolete. By focusing on health insurance, the Czech legislature underestimated the necessary coherence between financing and other organizational and planning reforms.

In terms of the legislative process, the analytical approach confirmed the poor quality of the legislation. This concerns both the drafting process and the outcomes. As in most countries in transition, the legislative activity suffers from major shortcomings. The "pathology of law-making" became manifest by the various symptoms of "legislative malnutrition". Major problems with existing legal norms can be derived from the absence or inadequacies in legislative planning or agenda setting. Where a strategic plan is absent, the legislative activity is prone to personal interests. This planning activity has been further hampered by the frequent changes of Ministers of Health, observed in all the selected countries. The author concludes that the consequent *ad hoc* approach of drafting legal norms did not contribute to the quality of legislation in terms of guaranteeing fundamental rights or realizing and legitimizing socio-economic objectives.

The country analysis made clear that, by following the iterative stages of the analytical model, the legal decision-making process can be structured and systematized. This enabled the examination and review of the arguments for legal decision-making with the outcomes described. Simultaneously, the classification in clusters of health care law enabled the identification of the main regulatory changes and relevant problems. Moreover, it allowed the analysis of these results within the conceptual framework of health care law and making suggestions for improvement based on this analysis. The (relative) success of this approach, in terms of comprehensiveness and effectiveness, confirmed the relevance of the analytical model to the legislative practice, ie, to rationalize the legislative activity.

In part three, the author addresses an extremely important issue: the relevance of the analytical model when preparing accession countries for EU membership. Therefore, he incorporated the principles of European Community (EC) law relevant to the health acquis. In such a manner, the conceptual model defines and analyses the alignment of EC (health) law. Moreover, it enables to draw some conclusions concerning the current stage of the "law approximation process".

Paving the way for enlargement, acceding countries will have to consider both public health problems and health-related issues. Adoption of the EC health acquis first requires substantial efforts to adopt the public health "flanking" policy measures based on article 152 and the EC internal market provisions.

More significant, however, are the possible effects of legislation governing the intra-Community trade on national health care legislation. Transposing EC internal market provisions appeared a main force behind the health acquis imposing regulatory convergence of health care systems. Developments, such as the introduction of competition among social health insurance funds, deregulation, increased patients mobility, and health professionals crossing borders, will strengthen the role of EC law on candidate countries' health care systems.

The topics most relevant to health and health systems appeared to be the free movement of persons and services, competition, consumer protection, pharmaceuticals and medical devices, social security, and health and safety at work. The impact of relevant treaty provisions and secondary legislation varies substantially and is often left unrecognized as such. Less known is the impact of free movement of persons and services on the health care sector by means of recent rulings from the European Court.

By such an impact analysis, the author makes clear that EC competition rules could influence social insurance reforms when considering the introduction of market elements in the social health insurance scheme. Some accession countries (Czech Republic, Poland) already introduced or are considering the introduction of additional private health insurance or competition among social health insurance funds. Apart from EC competition rules, it means that a wide range of Court rulings interpreting these provisions may become applicable. The widespread privatization of certain health care services will further increase the impact of EC competition law. In this respect, the public procurement rules for applicable health services will impose contracting authorities, such as health insurance funds, to revise their contract award procedures without discriminating between EU services providers.

Evaluation of (preliminary) outcomes showed that the accession countries, Hungary in particular, made considerable progress in adopting the acquis. Although the public health acquis caused relatively minor legal problems, more difficulties have been observed with incorporating internal market provisions, in terms of both setting legal norms and adequate implementation mechanisms. Newly emerging concepts, such as non-discrimination of non-nationals, the free movement principles, public procurement, and data protection rules, influence various health care sectors, as well as the health system itself. The exact consequences, however, are still highly debated and have been complicated by the latest Court rulings extending the scope of Community law to the organization and financing of health care systems. For candidate member states, the observed omissions in law approximation and the complexity of law reforms mean continuous aligning of their domestic legal framework. To support that process, the theoretical approach enabled the identification and analysis of relevant communitarian concepts. As such, the analytical model has confirmed its practical value as an explanatory, guiding, and steering instrument for both processing and transposing the Community law, promoting rational decision-making in the approximation of laws process.

Highlights: Although the research focuses on three countries, I am convinced that this model is also relevant to other countries in Central and Eastern Europe since the analyzed health care systems were "only" selected as illustrative cases, explaining the relevance of the analytical model. The author explains his choice by the fact that these countries in particular appeared to have a leading role in health

care system reforms. He emphasized the introduction of market elements in health care, both in terms of providing health services and purchasing health care. Consequently, manifested legal problems are more urgent than in less developed health care systems in this region. In the latter, countries have only recently introduced the concept of social health insurance or are still considering similar reforms and the privatization of outpatient health services (Bulgaria, Romania, and the Ukraine). In these countries, the emphasis of future reforms will be, *inter alia*, on strengthening the purchaser-provider split (selective contracting) and safeguarding patients' rights. In this respect, these countries could benefit from the described experience.

Limitations: Although these findings confirm a common need to increase the rationality of law-making, the practical value of the developed model for Central and Eastern European countries can be questioned. In particular, the rationality notion of law-making has certain limitations since the *extent* of rationality is highly determined by non-legal factors. Still, the originality and in-depth analysis make it a unique and indispensable handbook for anyone interested in health care system reforms in Central and Eastern Europe that, as far as I know, has no competitors in the European hemisphere.

Herbert Hermans

McKee M, Healy J, editors. Hospitals in a Changing Europe. Buckingham-Philadelphia: Open University Press; 2002. 295 pages; ISBN 0-335-20928-9 (paperback); price: US$34.95.

Field of medicine: Public health.

Format: Paperback.

Audience: Health managers, policy-makers, physicians, academics, and students interested in public health.

Purpose: To encourage research in the role of modern hospitals in a rapidly changing environment and influences that these changes have on their most important functions; patient care, teaching and research, employment, and health system support. The authors' intention was to introduce policy-makers to some very important issues in hospital care today and prompt them to ponder how to improve the quality, accessibility, and efficiency of hospital practice within a limited budget in their own region.

Content: The book consists of four parts and 15 chapters. The first part consists of four chapters and deals with hospitals in general, explaining the meaning of the hospital in a health care system. Chapter 1 lists reasons why hospitals must make some mandatory adjustments to deal with the problems like public expectations, aging of population, new technologies, and changing patterns of disease, to mention just a few. The authors also showed that the term "hospital" can cover very different structures and that, despite the fact that hospitals spend more than 50% of the health care budget, there is a general lack of research in hospital performance. Chapter 2 describes how the role of the hospital changed over time and deals with excessive hospital capacity and differences between Eastern and Western Europe, such as number of beds, length of hospital stay, patient admission, and bed occupancy rate. Nursing home is recognized as a facility that should take over the function of a hospital where long-stay patients are concerned. Chapter 3 describes the most influential pressures for change, such as changes in demography, in patterns of disease, in public expectations, in new technology and clinical knowledge, in financial pressures, and internationalization of health systems. Chapter 4 investigates the role of the hospital and its functions in the past two decades and what changes can be expected.

Part Two has 5 chapters and deals with external pressures upon hospitals. In chapter 5, authors consider the relationship and interface between hospitals and other health care services, and discuss what services, now provided by hospital, could be provided by other facilities. Chapter 6 explores the optimum hospital scale, the advantages and pitfalls of bigger hospitals, and their optimal distribution. Investing in hospitals is the main issue of Chapter 7. Changes require investment in facilities, people, and knowledge. Governments are responsible for specifying, monitoring, and rewarding investments, so that they lead to the improvement of hospital performance. Chapter 8 deals with changes in hospital payment system in transitional countries and consequences of these changes to their overall health care system. Different models of payment, such as fee for service, payment per day and per case, global budget and capitation, are represented, including the main problems of their use in transition countries. Chapter 9 discusses why changes in hospital's external environment, such as government, owners, purchasers, and consumers, did not cause the expected changes in organizational hospital structure and thus better performance. The study is based on the experience of eleven transitional countries, including Croatia.

Part Three of the book deals with internal strategies for change. Chapter 10 explores which standards are required and what changes have to be done in fa-

cilities, working staff, hospital culture, and especially clinical governance for high quality health care. Chapter 11 discusses major problems that hospital staff have to deal with. They are faced with decentralization and employment flexibility, skill mix, skill substitution, and hospital reorganization accompanied with shortage of skilled staff. Chapter 12 deals with the introduction of new technologies into hospitals. Accent is on who and under what criteria makes decisions about use of new technologies. The main issues of Chapters 13 and 14 are educational, financial, and other interventions taken to improve clinical effectiveness, and the role of hospital organization and culture in achievement of high hospital outcomes.

Part Four offers the general conclusion of the issues discussed in the book.

Highlights: This book offers exhaustive description of hospitals development and precisely describes the most important hospital components. Emphasis is put on changes that can be done to improve hospital outcomes in the future. Every chapter ends with a lenghty list of references, where the reader can find detailed information on the background of the topics.

Dragan Soldo

MedCalc®. Version 7.0.0.2. MedCalc Software: Mariakerke (Belgium), 2002; price: US$199.00

MedCalc® is a statistical package particularly suitable for various analytical procedures commonly used in biomedical research. A careful reader of the *Croatian Medical Journal* might remember that we published a review of this program five years ago (1). Due to physicians' growing interest in statistics and the development of the software, we decided to provide an insight into the latest MedCalc version.

MedCalc has more than moderate hardware requirements: IBM-compatible AT-computer with 80486 processor (or better), at least 8 MB of RAM, and 4 MB of free space on the hard disk. It will work fine under any Microsoft Windows-based operative system: Windows 95, 98, Windows Me, NT, Windows 2000, XP or later.

The easiest way to get the program is to download it from the manufacturer's website *(http://www.medcalc.be)*. Since the installation file is less than 1.5 MB, the download will be quick, even with the slow connection. After the installation, the user is asked to either enter the product key (product keys are purchased online) or to run the program in the demo mode. Demo is fully operational, although it has some limitations and is restricted to 25 sessions.

MedCalc's interface resembles most spreadsheet calculators. In addition, the program is "intuitive" and very user-friendly. Most users will get around easily and become familiar with MedCalc without using manual or help file. New data can be either typed directly into the spreadsheet or imported. MedCalc supports most commonly used data files: text files, Microsoft Excel files (versions 2.1 and higher), and SPSS files (however, that feature requires a valid SPSS license). MedCalc will even import data files created by DBase, Lotus123, and compatible programs. It is also compatible with other similar applications, so it is possible to copy the data from Excel and paste them into the MedCalc. The data entry feature that I find particularly useful is that MedCalc automatically recognizes the textual input and highlights it blue.

The statistics menu offers summary statistics, distribution plots, and various univariate statistical tests, both parametric and nonparametric. The multivariate techniques are represented by two-way analysis of variance, multiple regression, and logistic regression (up to six independent variables each). The particularly interesting feature of the statistics menu is the scatter diagram with the regression line. A rather common problem associated with the regression graphs is the extrapolation (2). This problem is sometimes generated by defaults imposed of the statistical package – the program draws the line beyond the observation points. Fortunately, regression graphs generated by MedCalc do not have this problem. In addition, MedCalc enables the user to include the 95% confidence interval (CI) of the regression line and 95% CI of the prediction in the graph.

The scientists involved in biomedical research will highly appreciate the last three options in the statistics menu – reference interval, method comparison, and receiver operating characteristics (ROC) curve analysis. Reference interval is an option intended for the calculation of reference (or normal) range of biochemical tests. The user can chose from 90%, 95%, or 99% reference interval. Method comparison option offers four tests – Bland & Altman plot, mountain plot, Passing & Bablock regression, and inter-rater agreement (kappa statistic). I find the method comparison options particularly important. The most frequent methodologic error in comparison studies is the use of Pearson's r (3). Although Pearson's r is well established in certain fields (psychiatry and clinical psychology, for example) its use should be discouraged (Douglas Altman, personal communication). The data measured in quantitative scales should be compared using one of the first three methods mentioned above. For data in nominal or ordinal

scale, kappa or weighted kappa statistic should be used, respectively. The last option in the statistic menu deals with various aspects of the diagnostic tests. The researcher can use two graphical methods to analyze the accuracy of the diagnostic test, ie, ROC curve and a complimentary approach – interactive dot diagram. In addition, it is also possible to compare two ROC curves and calculate the predictive values of the diagnostic test.

The graphs menu offers basic graphical displays of the data: box-and-whiskers plot, dot plot, bar chart, and line chart. Furthermore, MedCalc is focused on graphical methods unavoidable the biomedical research – Kaplan-Meier survival curve, control chart, and serial measurements polygon. In addition to drawing the Kaplan-Meier curve, it can calculate the hazard ratio and compare two survival curves using the logrank test. The control chart option will provide a quality control graph. These graphs may be very useful in clinical laboratories to plot the variation of a particular measurement over the time. If sequential measurements of a single variable need to be analyzed (e.g., oral glucose tolerance test), the serial measurements polygon should be considered. Furthermore, this option can be used to summarize the data using several measures – maximum value or area under the curve.

The tests menu is another great feature of the MedCalc software. It provides several tests for the analysis of summarized data, such as comparison of the data reported in the literature without the access to the raw data. I use this option to check the statistical analysis in manuscripts submitted to the *Croatian Medical Journal*. Two tests that our readers will definitively like are the test for one mean and the chi-square test. The test for one mean is used to test the hypothesis that a sample mean differs from a particular value. For example, this option can be used to see if the sample mean differs from the population mean. I think that many would agree that it is usually very difficult to perform the simplest of the statistical tests, ie, chi-square test, using a statistical software package. Statistical packages usually require the raw data entered into a spreadsheet in a particular fashion. This "particular fashion" is often not intuitive at all and the whole testing procedure gets very frustrating. On the other hand, MedCalc allows you simply to enter your previously tabulated data into the table in a dialog box. The results of a chi-square test are just a click away. MedCalc can handle contingency tables of up to nine rows and six columns, which I find more than sufficient for most purposes. Finally, the tests menu could be used to calculate the odds ratio.

Many people seeking statistical advice ask for a sample size (4). MedCalc's sample menu is specially designed to help them with this problem. The supported tests are single mean or single proportion, two means or two proportions, and correlation coefficient. Basically, the user has to decide on the p-level – the power of the study (MedCalc's default is 90%) – and has to have an idea on the difference that she or he would like to detect. The program will do the rest.

Readers already familiar with MedCalc might want to know what is new in the version 7. Since 1996 (version 4), several improvements have been made. I would like to point out the following: reference interval analysis, survival analysis can now compare up to six survival curves, mountain plot, Passing & Bablok regression, clustered multiple comparison or multiple variable graphs (used for the comparison of subgroups), logistic regression, and sample size calculation for correlation coefficient. Furthermore, a variety of spreadsheet functions is now available.

In addition, it is worth mentioning that an excellent program manual accompanies the MedCalc. The manual is much more than a step-by-step guide through the program. It also provides tips and advice on selection of appropriate statistical method and interpretation of statistical analysis. The manual, in the form of an e-book, can be downloaded free-of-charge from the manufacturer's website.

Although MedCalc is a fine product, it has two minor limitations. First, it is not possible to remove the borders of the plot area from the graph. Second, the manufacturers should consider adding an option that would enable the user to include symbols in the graph (e.g., various symbols used to indicate the statistical significance).

To summarize, MedCalc is an excellent statistical program and I sincerely recommend it to everyone dealing with biomedical statistics – from a Ph.D. student to head of department. Additionally, I can recommend it to editors and reviewers of biomedical journals. MedCalc is easy to master, simple to use, and fully equipped to perform a wide spectrum of statistical procedures. Last but not least, it is cheap and can beat any competitor in the terms of cost-benefit ratio.

Ivan Krešimir Lukić

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3 Campbell JM, Machin D. Medical statistics: a commonsense approach. 3rd edition. Chichester (UK): John Wiley & Sons, Ltd.; 1999.

4 Ingelfinger JA, Mosteller F, Thibodeau LA, Ware JH. Biostatistics in clinical medicine. 3rd edition. New York (NY): McGraw-Hill, Inc.; 1994.