

Current Management of the Menopause

Edited by

Christian Lauritzen

John Studd

With a Foreword by

Egon Diczfalusy



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Foreword

*Had I been present at the creation
I would have given some useful hints
For the better ordering of the Universe.*

Alphonso X, the Learned (1252–1284) King of Spain

It is an honour and a privilege to write a foreword to such an important book as this one, but it is also a rather difficult task, particularly if one wishes to resist the temptation of the autumnal mind to draw rapid conclusions about the human condition in a fundamentally uncertain world, where the present is just as uncertain as the future.

When the former Secretary of State of the USA, Dean Acheson, described his years at the Head of the State Department, his book was entitled *Present at the Creation* (1969) in reference to the above epigraph. In a much more modest way, I was also present at the creation of the great revolutions of our time in contraception, reproductive health and gender equity which have changed the world around us and our perception of it. I have also witnessed the biggest of all demographic revolutions in history and could sense the increasing impact of rapidly changing population structures on our social, economical, health and even political infrastructures.

Just 1000 years ago the global population was around 280 million people; today it exceeds 6 billion and the United Nations projects that it may reach 9.3 billion people by the middle of this century. Virtually all of this growth will take place in the less developed regions and the number of people living in the more developed regions is projected to remain unchanged.

The most important demographic change will take place in the population structure of the world, with a rapidly declining number of children and an even more rapidly increasing proportion of elderly people. Between 1950 and 2050 the proportion of the world's children (people aged 14 or less) is projected to decline from 34.3% to 21.0% and that of its elderly population (people aged 60 and over) to increase from 8.2% to 21.1%. During the same period, the proportion of children in Europe is projected to decline from 26.2% to 14% and the elderly population to increase from 13.2% to 46.6%.

The United Nations estimate that today some 335 million elderly women live on our Earth and project that by year 2050 their number will exceed one billion. Of course, projections are always uncertain; however, some of them—like this one—are less uncertain than others, simply because those one billion women are already among us as teenagers or young women. Hence, the overwhelming challenge facing the next generations will be to find imaginative new approaches to the delivery of quality health care which will be affordable in such a brave new world.

If King Alphonso X had lived in the 20th century, perhaps he could have advised us that—in logical terms—a *contraceptive revolution* can hardly exist as a separate idea, without placing it into its wider context of *reproductive health* and that a *revolution in reproductive health* cannot materialize without making major progress in the

achievement of gender equity. Our generation has to learn this in a difficult, sequential manner, 'discovering' each of these ideas as separate concepts. Who knows, perhaps Alphonso X could also have predicted for us that true gender equity may not materialize without also achieving health equity.

In Shakespeare's *Measure for Measure* (Act III, Sc. 1, 1.2) Claudio exclaims, 'The miserable have no other medicine but only hope', and since the dawn of civilization this dictum has applied to the living conditions of the overwhelming majority of human beings. However, there is a change in the air: our generation seems to be the first in history that has dared to think it possible to create a new world on this planet in which medical care may be provided to every human being. For the time being, health equity is still a dream, but a very important one. In fact, dreams are more important than we may think since, as Yates stated, 'in dreams begins responsibility'.

Worldwide life expectancy for women more than doubled over the past two centuries from about 25 to 68 years and it is projected to reach 79 years by the year 2050. However, menopause will still occur at 50 years of age, or so. Hence, when reaching the menopause in the next few decades, one billion women will depend to a considerable extent on the preventive measures, management and advice provided to them by the medical community in general and by the gynaecologists of this world in particular. To enable them to properly do so, access to reliable, up-to-date scientific information will be of paramount importance. Therefore the value of a textbook such as this one cannot be overestimated.

A final reflection: the United Nations project that by the year 2050, women aged 60 and over will constitute 40% of the female population of Europe and 23% of that of the entire world. Hence, it is rather easy to see that the present book will be a most valuable source of information not only to gynaecologists and other members of the medical community, but virtually to everyone involved in the provision of health care to women in general and elderly women in particular.

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Preface

At a time when doubts and criticisms concerning the real benefit and the justification of peri-to-postmenopausal estrogen-progestogen substitution, especially of long-term primary prevention, is widely questioned in the name of evidence-based medicine, it is pertinent to summarize the established facts in a critical authoritative monograph. Such a summary should formulate the experiences of competent critical experts on a correct, successful and low-risk management of menopausal women. These experiences are often in contrast to experimental, largely artificial, interventional studies, which are far from practice. An answer must be given and a firm stance must be taken concerning the undoubtable value and benefits of estrogen and hormone replacement therapies (ERT and HRT, respectively) against current disinformation. In this regard, the postmenopausal women affected must be heard.

Not all observational and epidemiological trials, and not all results of account reports dealing with treatment results, are invalid in the light of evidence testing. Some of them have, because of their proximity to practice, their careful design, conscientious performance and perfect plausibility, a strong degree of credibility and must be ranked high in the score of evidence. Many good data and identical positive results of a great number of critical scientists must not be rated low.

We do not intend to regress behind the welcome progress marked by the establishing of evidence-based medicine. However, the danger exists that controlled trials are now widely accepted without the necessary criticism. There is a tendency, originating from poorly planned and conducted randomized controlled trials, which are very construed and unrealistic, that physicians, statisticians, internists, commissions, governmental authorities and health insurance companies draw consequences and conclusions concerning ERT and HRT which are premature and inappropriate. Such examples can regrettably already be given such as following publication of the Heart and Estrogen/progestin Replacement Study (HERS) and the Women's Health Initiative (WHI) study.

The results of these studies were, against all scientific rules (and against the authors' and commenting scientists' wishes) by some self-appointed experts and the lay press, unduly generalized and considered to be valid for all estrogen and progestogens, all doses and all forms of application, whether arranged sequentially or combined, given orally or by the different parenteral ways. This is against the basic rules of science, with the gravest of faults made when results are interpreted to reach conclusions which are not supported by the data. Experience teaches that the latest published results are not always the final truth.

The ad hoc comments of recognized experts and commissions have stated that the WHI study was faulty in design and management, used a badly suited combined preparation, and that the value of ERT/HRT for treatment of climacteric complaints as well as for some aims of primary prevention is valuable and unchanged. Treatment

according to the established rules will, as demonstrated in innumerable account reports and epidemiological studies, not cause substantial side-effects.

Substitution with estrogens and progestogens during menopause will probably become of even greater importance in the future. Biochemical innovations and the development of selective estrogen receptor modulators (SERMs), designer hormones, phytoestrogens and new methods of application will open a wide promising field of new possibilities of individualized treatment and of substitution without unwanted side-effects. The prospective risk assessment will probably be improved by genetic tools, which will influence indications, contraindications and the mode of medication.

This monograph is intended to bring together the contemporary knowledge on the management of the menopause. It aims to give the scientist state-of-the-art information to guide where to go with his/her research. For the gynecologist and the practitioner a guide for his/her practice and for the counseling of menopausal patients when they consider ERT/HRT is given.

The science of estrogens, menopause and its management owes research from the United States a lot of data and knowledge. However, many wrong points were also followed from those results. Many problems and questions are posed differently in Europe. Therefore, this book intends to describe mainly European facts, views, possibilities of menopausal management, problems, conclusions and solutions.

It is a hard task to bring together so many known scientists who are swamped with work, and to make them deliver their contributions. The editors have to thank all authors for their cooperation and for sharing their knowledge and expertise with the readers of this publication.

Our publishers, Martin Dunitz, have been very patient, understanding and professional in their assistance. We sincerely thank Robert Peden, Commissioning Editor, and Maire Harris, Development Editor, for their valuable help in all stages of collecting and editing our book.

One of the most important and still unsolved problems is the missing conversion of scientific facts and knowledge into daily work. We hope that this monograph will provide the interested reader with the desired information on all aspects of the menopause and will give him/her a solid standpoint to find his/her individual attitude. May the book help to attain orientation in the sometimes overwhelming amount of information, and to acquire the knowledge which the therapist has to transfer into his/her medical practice for the benefit of his/her patients.

*C Lauritzen
J Studd*

After the Women's Health Initiative and Million Women Study

John Studd and Christian Lauritzen

Introduction

- **Recent adverse publicity**
- **HERS study**
- **Women's Health Initiative study**
- **NAMS response**
- **Breast cancer**
- **The Million Women Study**
- **Current advice for hormonal replacement therapy prescribing**
- **References**