



Patient Empowerment – a New Paradigm in Disease Management?

European Parliament

Brussels – Room PHS 4B001

Tuesday 2 March 2010

9.00 – 15.30 o'clock

Background of the ELSC

The European Life Science Circle (ELSC) was launched in 2006 by Dr. Jorgo Chatzimarkakis, Member of the European Parliament to facilitate the dialogue with interested stakeholders on relevant issues in the context of life science and pharmaceuticals.

Participants

- Members of the European Parliament
- Representatives of the European Commission and the EU Member States
- Stakeholder organisations including patients and health professionals associations
- Pharmaceutical and life science industries



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European Life Science Circle – 2 March 2010

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Dr. Jorgo Chatzimarkakis

Member of the European Parliament

Dr. Jorgo Chatzimarkakis MEP is a member of the European Parliament Committee on Industry, Research and Energy (ITRE) and of the Committee on Budgetary Control (CONT). He is also a Substitute on the Committee for Environment, Public Health and Food Safety (ENVI). He was already elected Member of the European Parliament for the German Liberal Party (FDP) in 2004.

Dr. Chatzimarkakis has been actively involved in developing directives on a wide range of subjects, most notably innovation issues (CIP) as well as education and research policies (EIT). In the 6th term of the European Parliament, he was Rapporteur for the Competitiveness and Innovation Framework Programme.

Since 2006 Dr. Chatzimarkakis is member of the Pharmaceutical Forum, a high level group designed to provide a political mandate for relevant public health issues. He launched the European Life Science Circle (ELSC), a platform to discuss relevant issues in the context of life sciences and pharmaceuticals.

In 2009 Mr Chatzimarkakis was re-elected into the European Parliament and became Chairman of the EP-Delegation for the former Yugoslav Republic of Macedonia (FYROM). Additionally, he became Vice-President of the World Hellenic Inter-Parliamentary Association (WHIA).

Jorgo Chatzimarkakis studied agriculture and political sciences in Bonn and Oxford and holds a PhD in political science.

Background of the Meeting

Empowering chronic patients to take responsibility for the day to day management of their disease is believed to significantly enhance the medical outcome. Patients who are empowered to act self-responsibly may also contribute to lowering the costs of health care by avoiding costly and potentially life-threatening complications and co-morbidities. Case in point: cardiovascular- and kidney diseases, diabetes and asthma, common chronic diseases in Europe. How can patients influence the course of their disease? And how can health systems use patient empowerment to improve the medical and economic outcome of their disease management?

I would like to invite you to our European Life Sciences Circle on March 2, 2010 in the European Parliament to discuss:

“Is patient empowerment a new paradigm in disease management?”

Dr. Jorgo Chatzimarkakis, MEP



David C. Klonoff, M.D., F.A.C.P.

Clinical Professor of Medicine, U.C. San Francisco
 Editor-in-Chief, Journal of Diabetes Science and Technology (in PubMed)
 Medical Director, Diabetes Research Institute
 Mills-Peninsula Health Services
 San Mateo, California
 USA

David C. Klonoff, M.D., F.A.C.P. is an endocrinologist who is working to apply science and engineering to fight diabetes. He is a Clinical Professor of Medicine at UC San Francisco and the Medical Director of the Dorothy L. and James E. Frank Diabetes Research Institute of Mills-Peninsula Health Services in San Mateo, California.

He is interested in clinical pharmacology, drug delivery technology, analyte measurement, and computerized data management. Dr. Klonoff is the Founding Editor-in-Chief of Journal of Diabetes Science and Technology, which is in PubMed and is the world's first peer-reviewed purely electronic diabetes journal. This journal is published by the non-profit organization that Dr. Klonoff also founded, Diabetes Technology Society. The organization is devoted to the development and use of new products to help people with diabetes.

Dr. Klonoff has authored over 100 publications. He has chaired or served on grant review panels for National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), National Aeronautics & Space Administration (NASA), Juvenile Diabetes Research Foundation International (JDRFI) and the Governments of Singapore and Hong Kong.

He was named best endocrinologist in San Mateo County by Bay Area Consumer Checkbook.

Dr. Klonoff founded the Diabetes Technology Meeting (the second largest scientific diabetes meeting in the US) and the Clinical Diabetes Technology Meeting. He is currently Chair of the Endocrine Society Task Force on Continuous Glucose Monitor Clinical Guidelines, and Chair of the Coalition for Clinical Research: Self Monitoring of Blood Glucose (SMBG); a member of the Diabetes Mellitus Interagency Coordinating Committee Subgroup on Bioengineering Technologies and the Subgroup on Resources and Infrastructure; and a member of the International Working Group SMBG (Self-Monitoring Blood Glucose).

Suggestions for enhanced transparency and efficacy – the benefit of health measures using the example of Diabetes Management

Self monitoring of blood glucose (SMBG) empowers patients with diabetes by providing them with vital information. Diabetes is a disease of elevated blood glucose levels due to a deficiency of insulin or inadequate insulin action. If treatment is insufficient, then the result will be persistently elevated blood glucose levels and if the treatment is excessive, then the result will be depressed blood glucose levels. Both outcomes can be dangerous. SMBG is the most established, accurate, and practical method for patients to know – and act upon, if necessary – their own blood glucose levels.

SMBG also facilitates treatment adjustments in response to abnormal glucose levels; educates patients about the effects of foods, exercise, and other factors; and motivates healthy behavior. These properties of SMBG result in this intervention leading to patient empowerment.

The current status of SMBG is that this practice is an established tool for improving glucose control in type 1 diabetes and insulin-treated type 2 diabetes. Its proper use in non-insulin-treated type 2 diabetes is being studied. This intervention works best when patients and physicians use the information to make treatment decisions.

In November 2008 the Coalition for Clinical Research-SMBG issued a report identifying critical elements of a proper clinical trial of SMBG in type 2 diabetes. They concluded that: 1) subjects and caregivers must use the SMBG monitoring results properly – specific behavior by both parties is critical; 2) controls must not be exposed to the SMBG intervention to prevent a washout effect – avoiding contamination is critical; and 3) current literature inadequately addresses the performance of SMBG in non-insulin-treated type 2 diabetes.

The Accu-Chek 360° View Outcome Study is the first of a new generation of randomized controlled trials which will follow the recommendations of the CCR-SMBG for trial design. This cluster-randomized 12-month trial for subjects with non-insulin-treated type 2 diabetes will compare a structured protocol response to out-of-range SMBG values with usual care. Interim data at 6 months were released in September, 2009. There was a statistically significant increase in healthcare provider-prescribed changes in lifestyle and medications. Subjects experienced a statistically significant improvement in HbA_{1c} levels, various timed blood glucose levels, and mood. It is expected that additional studies of structured SMBG interventions for this group of patients will follow if funding will be available to support these studies.

In conclusion, SMBG is an effective intervention to improve outcomes in type 2 diabetes. This practice provides uniquely valuable information for patients to control their blood glucose levels. SMBG empowers self-management by educating, motivating, and protecting patients. Proper use of this intervention requires that healthcare professionals provide a structured response to the results.



Prof. Dr. Stephan Martin

Medical Director of the West-German Centre of Diabetes and Health
Sana Hospitals Düsseldorf
Düsseldorf
Germany

Professor Dr. Stephan Martin is the Medical Director of the West-German Diabetes and Health Centre Düsseldorf, and also Associate Professor at the German Diabetes Research Institute at Heinrich-Heine University in Düsseldorf, Germany.

Professor Martin studied at the University of Düsseldorf and received his Medical Degree with his dissertation in 1990 and his habilitation in 1997. From 1990 to 1992 he completed a Postdoctoral Fellowship in the Centre for Blood Research in the Harvard Medical School in Boston, USA.

In 2003 he received the distinction as special professor at Heinrich-Heine University in Düsseldorf, Germany.

From 1996 to 2003, Prof. Martin gained several qualifications, i.e. the Specialization for Internal Medicine and Diabetology and the Specialization for Endocrinology. The Association for Immunology including qualification for autoimmunity diagnostics gathered Prof. Martin in 2003.

Professor Martin received numerous research prizes over the last 15 years, the most recent ones of which were the Ernst-Friedrich-Pfeiffer-Prize of the Deutsche Diabetes-Gesellschaft and the Jühling-Prize of the Anna Wunderlich-Stiftung both in 2002 as well as the Bloomfield Award, of the American Academy of Continuing Medical Education.

Successfully empowering people with type 2 diabetes – findings from the observational study ROSSO in Praxi

During the past years world wide dramatic changes in lifestyle have occurred. Automation of the working processes, computer use in working and leisure time in addition to overfeeding have affected the human health more dramatically than expected. These are the causes for lifestyle diseases as diabetes mellitus type 2, hypertension or hyperlipidaemia. The numbers of persons affected by type 2 diabetes mellitus has grown dramatically around the world. Due to the fact that the mentioned lifestyle diseases are strongly associated and represent cardiovascular risk factors, diabetes is expected to account for 11 % of all deaths in the 20–79 age group in 2010 (IDF Diabetes Atlas / Fourth Edition).

There are different strategies to treat type 2 diabetes: using a pharmacological approach or motivate the people to change their lifestyle. Because elevated glucose levels are asymptomatic the self measurement of blood glucose (SMBG) is an essential factor for the self management of type 2 diabetes. SMBG also affects long-term outcome in type 2 diabetes as it has been shown recently in the ROSSO study.

There are no guidelines how to use SMBG to improve metabolic control. Therefore we have developed a 12-week lifestyle intervention ROSSO-in-praxi and analysed the impact of measurement of pre- and postprandial glucose on cardiovascular risk factors. 327 participants with type 2 diabetes (81 %) completed the program and significantly reduced postprandial glucose values. Furthermore these participants improved quality of diet and physical activity, accompanied by an increase of >2,300 steps/day. Participants significantly reduced weight, BMI, waist circumference, blood glucose, blood pressure, LDL cholesterol and HbA_{1c} (which is the average blood glucose concentration over the previous three months), accompanied by increased physical and mental health and reduced depression measurements. Weight loss was significantly associated with overall improvements of glucometabolic and health parameters and mean reduction of 0.05 % HbA_{1c}/kg.

In conclusion, behaviour changes that reduce postprandial glucose values are associated with improvement of other cardiovascular risk factors. Therefore, measurement of blood glucose is expected to be more effective in preventing cardiovascular diseases in type 2 diabetes than specific pharmacological treatment.



Mike Meyhoff

Protestant Pastor and Vocational School Teacher
Rheine
Germany

Mr Meyhoff teaches religious education at a vocational college in North Rhine-Westphalia, Germany. He is married and has two children at the age of nine and seven.

In the context of a health check in the summer of 2004 Mike Meyhoff got the diagnosis of type 2 diabetes.

In 2008, he successfully participated in the practical implementation study “Become Germany’s most active person with Type 2 Diabetes” organized by the German “EigenInitiative” and the West-German Diabetes and Health Centre.

Managing life with type 2 diabetes

My name is Mike Meyhoff and I am a protestant pastor and vocational college teacher. In 2004, after an annual medical check-up, I have been diagnosed with Type 2 Diabetes. I had some problems with my blood pressure and my weight was too high. For me, this news was a real shock and I had visions of the long term consequences of diabetes such as amputation and blindness.

After several unsuccessful trials to keep my diabetes under control, I volunteered for the study “Become Germany’s most active person with Type 2 Diabetes” initiated by the German “Eigeninitiative” and conducted by Prof. Stephan Martin and the West-German Centre of Diabetes and Health, Düsseldorf.

With the help of a guidance booklet, appropriate education and support via regular telephone calls I was highly motivated to change my situation actively by adopting a healthy diet, increasing the amount of physical activities and monitoring my blood glucose levels on a regular basis. My medical parameters like weight and blood glucose level became exceedingly better within the 12 weeks of study duration. My personal sportive high point was to accomplish a half marathon without special training.

Changing my lifestyle, monitoring my blood glucose and becoming able to self-manage my disease really prevented me from being switched on insulin therapy and made a big contribution to my quality of life.



Dr. Stephanie Stock

MD, PhD, health economist (ebs)
Köln Institute for Health Economics and Clinical Epidemiology
The University Hospital of Cologne (AÖR)
Cologne
Germany

Stephanie Stock is a physician and health economist and senior lecturer at the Institute of Health Economics and Clinical Epidemiology of the university of Cologne where she has been involved in health care reforms targeting the improvement of quality and coordination of care for chronically ill. Her studies have been published in journals such as “Health Affairs” and “Health Policy”.

Other areas of research include patient information as basis for individualized treatment in oncology, cost-effectiveness – analyses and cost of illness studies for chronic diseases such as diabetes. Stephanie Stock has been a Harkness/Robert-Bosch Fellow in 2007/2008 at the University of Pennsylvania where she examined new models of physician – nursing collaboration and strategies for implementing best practice in home healthcare. She studied medicine at the university of Ulm and at Tuft’s Medical School, Boston, USA and earned her degree in health economics from the European Business School.

The German Disease Management Programme and Patient Outcome

Depression, COPD, diabetes and asthma are ranked among the top ten causes for years lived with disabilities (YLD) for high income countries in the global burden of disease report. For the year 2025 the WHO estimates an expected 300 million people worldwide to suffer from diabetes. Chronic diseases not only pose a significant clinical challenge for healthcare systems but also put substantial pressure on the financing of healthcare. The German Statutory Health Insurance (SHI) for example, spends roughly 14.2% of total healthcare costs to care for patients with diabetes.

Disease Management programs help coordinate and guide care for chronically ill. “German-style” Disease Management Programs were implemented in a nationwide roll-out in 2002. Presently, more than 5 million insured are enrolled in over 13,000 programs for the diagnoses “Diabetes Mellitus type 1 and 2”, “Asthma”, “COPD”, “Breast Cancer” and “Coronary Artery Disease”. The explicit goal of the programs is “to enhance coordination of care and to improve quality of care for chronically ill”. To ensure this, a number of quality assurance measures are in place including evidence-based treatment recommendations and continuing medical education.

Results of the first preliminary evaluations are encouraging. A study of the AOK (German Insurance Company) found that the mortality rates were lower for people with diabetes enrolled in the programs compared to their matched peers in regular care. Besides medical outcomes patient satisfaction with care in the programs is an important outcome which could be shown in a study of the BARMER sickness fund to be higher in the programs compared to routine care.

Despite these encouraging results a main challenge of the programs will be to what extent they will be able to engage patients in the self-management of their disease to enable them to limit the impact of the disease on their quality of life as much as possible. An important prerequisite for patients is to have information, knowledge, skills and confidence to manage their disease if they are to play a central role in the self-management of their disease. However, there remains yet quite a bit to be done to enable patients not just to engage in self-management but to play a central role.



Jim Furniss

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Jim Furniss is Director, Global Market Access Strategy, at Bridgehead International Ltd and heads a practice advising pharmaceutical and medical device companies on pricing, reimbursement and market access issues for healthcare products in European and global markets.

Jim was educated at Churchill College, Cambridge and worked for over twenty years in the UK Department of Health in a number of administrative, policy and management posts. From 1991 to 1997 he was head of the Pharmaceutical Industry Branch in the Department of Health, responsible for the Government's relations with the pharmaceutical industry, and the operation of the Pharmaceutical Price Regulation Scheme (PPRS). This included working with the ABPI to develop the first guidelines on the use of pharmacoeconomics in the UK. He also represented the UK at the European Commission on pharmaceutical issues. In that capacity he gained a detailed understanding of the pricing and reimbursement structures in the other Member States of the European Union, and of the political context within which they operate. He can bring to his work a first-hand experience of the payer perspective and an unrivalled range of contacts in the payer community.

The cost-benefit relation of patient empowerment in the management of type 2 diabetes: evidence from three European countries

The effective management of type 2 diabetes is complex, but of critical importance. Self monitoring of blood glucose (SMBG) has been shown to improve management and outcome, particularly by reducing the risk of complications; and to help patients to modify their lifestyle and improve their management of the disease. As healthcare resources are limited and increasingly under pressure, it is important to know whether the benefits of SMBG outweigh the additional costs. Health Technology Assessment (HTA) is a widely accepted methodology to inform healthcare decision makers and budget holders how to make decisions about the most effective use of scarce resources.

For people with type 2 diabetes on oral antidiabetic drugs (OADs) (but not on insulin) controversy remains regarding the value of SMBG. While most studies have shown clinical improvement, the magnitude of that improvement has not always been cost effective in all analyzed populations. This presentation reviews three recent health economic studies in three European countries – the Czech Republic, Spain and Germany – undertaken as part of the (retrospective) observational study ROSSO. These studies assess the costs of complications and treatment in patients performing SMBG and those who did not. In each case they could demonstrate that the overall costs (including the complication related costs) of treatment are lower in patients using SMBG. In case of the German analysis, which assessed additionally an alternative approach using surrogate parameters like HbA_{1c}, blood pressure and lipid levels, the outcome of the ROSSO study was confirmed. These studies support other analyses which suggest that SMBG is not only effective in improving the management of type 2 diabetes; SMBG is also a cost effective (and in some circumstances even cost saving) therapeutic element in diabetes care and should be more widely adopted.



Lina Buzermaniene

EFA board member
President of the Lithuanian Council of Asthma Clubs
Panevezys
Lithuania

Lina Buzermaniene is a board member of the European Federation of Allergy and Airway Diseases Patients Associations (EFA) since June 2009, President of Lithuanian Council of Asthma Clubs since 2007, Vice-president of Lithuanian Council of Asthma Clubs 2003–2006 as well as President of Panevezys asthmatic community children section since 1999. In addition, she is editor-in-chief of the patients asthma website www.astmainfo.lt.

Lina Buzermaniene has more than 16 years experience living with asthma and allergy in family: her son has asthma, allergic rhinitis and atopic dermatitis. A lot of her spare time she is working on input for patient education. She has been chair of the organizing committee of the national world asthma day events since 2004 and conferences *Asthma at school*.

Lina Buzermaniene is a librarian by education and graduated from Vilnius university in 1993. Currently, she works part-time in Panevezys County Public Library and as a freelance Lithuanian language reviser/proofreader for a few national and international translation bureaus. She is an internet resources lecturer for the national project „Libraries for Innovation“ (2008–2001; strengthening, in essence, information competence of public libraries' staff) and running a professional blog for librarians.

Learn to live with Chronic Respiratory Diseases

The European Federation of Allergy and Airway Diseases Patients Associations (EFA) is a European network of national patient organizations that was founded in 1991 and which represents 21 country and 31 member organizations. In total, there are over 500,000 patient and carer members in EFA member organizations. One of the main goals of EFA is the empowerment of patients and member organizations.

Continuous education of patients is still very important. There is a lack of formal education in many countries and we expect great work to be done by our member organizations working with patient peer-support groups. There are many discussions worldwide how to determine the most effective way to deliver patient education. Behavioural changes must be implemented. To get there we must show the patients the advantages of self-empowerment.

EFA faces few challenges: capacities of patient organizations in different member countries are very different. Another remarkable challenge are languages problems. There are great tools such as the material from the *Learn to live with asthma* campaign from which we just saw the little video. Nevertheless, we have to find ways how to use them the most effective way in countries where the larger part of population is not able to communicate in English. At the same time we have to meet the expectations of organizations which have better capabilities and to work on the main tasks of our organization: the reduction of the frequency and severity of allergies, Asthma and COPD; the minimization of societal implications; the improvement of the health-related quality of life of patients; the verification of full citizenship of people with these conditions; the pursuit of equal health opportunities in the field of allergy and airways across Europe.



Prof. Dr. A. A. Kaptein

Professor for Medical Psychology,
LUMC
Leiden
The Netherlands

Adrian A. Kaptein studied at the University of Leiden, the Netherlands, and received his degree in Psychology, Clinical Psychology and Swedish in 1977 followed by Visiting Scholarships in Canada, the United States and New Zealand.

As Professor in Psychology applied to Medicine at the Leiden University Medical Centre (LUMC) he has a focus on respiratory disorders since 2005. He describes his professional inspiration as follows:

“I am fascinated by the responses of patients – and the determinants of these responses – to their physical complaints and illnesses. These responses turn out to be associated not so much with ‘objective’ medical characteristics but rather with psychosocial characteristics. This implies that interventions aimed at those psychosocial characteristics affect the course of the complaints and illnesses. The way patients make sense of complaints and illnesses can be examined by studying the illness perceptions of patients: the subjective and idiosyncratic cognitions of patients about complaints and illnesses. Self-management by patients with chronic respiratory disorders and other chronic somatic disorders is the area of application of my research, which also translates into my teaching of medical psychology to medical students.”

He published some 300 papers, edited some 10 books, is a former President of the European Health Psychology Society (EHPS), and Editor-in-Chief of *Psychology & Health* (1992–2000). He is a Fellow of the International Association of Applied Psychology (IAAP).

Patient empowerment in the treatment of kidney and asthma diseases

Asthma and chronic kidney disease are two chronic physical illnesses, with a relatively high and a relatively low prevalence, respectively. Their medical backgrounds are hugely different; their similarities regarding self-management are impressive.

Asthma and chronic kidney disease require a major contribution of the affected patients in managing the symptoms, the medical and pharmacological treatment, and the psychological, and social consequences. Patient empowerment, therefore, has great potential in living better with these conditions.

The presentation will review the functional, psychological, and social consequences of asthma. Next, self-management of asthma will be discussed, where the results of high quality studies demonstrate that self-management improves patient empowerment and, thereby, outcomes in various domains. This goes for young children, adolescents, adults, and older patients with asthma.

A similar line of reasoning will be followed in discussing the consequences for quality of life in patients with chronic kidney disease. The tremendously complex and burdensome tasks associated with living with chronic kidney disease will be reviewed, as will self-management skills that help in these tasks. Self-management of chronic kidney disease has positive effects on quality of life, psychological status and social consequences.

The implications for health care providers, partners, and society at large will be highlighted. The traditional patient education model is compared with the self-management model, with its ramifications for patients, partners, physicians, and the public. It will be concluded that patient empowerment is good for all.



Dr. Per Åke Zillén

Dentist
Saltsjö-Boo
Sweden

Dr. Per Åke Zillén is a dentist and transplanted chronic kidney disease patient. He is the retired Executive Director of the FDI World Dental Federation.

Empowerment and self-management in kidney diseases – from a patient’s perspective

The management of chronic diseases in general and chronic kidney disease (CKD) in particular is to a considerable extent based on self-management, as the treatment, in almost all its parts, has to be carried out on a daily basis. While the treatment is planned by health care professionals and then discussed and agreed with the patient, the actual treatment almost entirely has to be carried through by the patient him- or herself. In fact, in respect of prevention and slowing of CKD, there is no real alternative to self-management. Quite simply, effective self-management is a prerequisite for treatment success. In this context, the responsibility for the care is shared between health care staff and patients in a rather different and non-traditional way.

To make effective self-management possible, the patients – preferably together with their intimates or families – need to be empowered through proper educational programmes, focused on learning, motivation and improved health behaviour. Well organised, such education may prove to be a worth while investment with a good return, both in respect of health and finance – for the society as well as for the individuals.

Thus, the terms empowerment and self-management represent the two perspectives of the intersection between health professionals and patients. Effectively utilized, empowered, well informed, well motivated and well behaved self-managing individuals can be the best – maybe even the only – way of combating CKD as well as other chronic diseases.

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