Informed treatment decisions: Adherence management to optimize patient outcomes in chronic diseases

General information

Venue
The conference takes place at the:

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Inform ed treatm ent decisions: Adherence m anagem ent to optim ize patient outcom es in chronic diseases

Serono Sym posia International Foundation conference on:

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Aim of the m eeting
The im pact of non-adherence to treatm ent varies across chronic diseases, with higher morbidity and mortality being observed in patients who do not adhere to the standard therapies. The World Health Organization states that the consequences of non-adherence are clinically relevant, and that health benefit would be obtained by improving adherence to existing treatments. The issue of adherence is complex and involves many elements including factors related to the disease, the patient, the environmental and the therapies. This educational program has been developed to discuss problems and to find solutions to improve adherence to long term treatment with a multidisciplinary approach. During this conference, leading international experts in different disciplines (neurology, endocrinology, epidemiology, etc) will present the benefits and barriers to adherence and discuss the solutions that may increase adherence to long term therapy.

Learning objectives
After attending this conference, the participants will have an updated knowledge on:
• Role of adherence in medical practice
• Barriers and solutions to improving adherence in multiple sclerosis
• Barriers and solutions to improving adherence in diabetes
• Tools to improve adherence
• Understand all involved stakeholders’ roles and opportunities

Target audience
This educational activity is designed for endocrinologists, neurologists, internists, geriatricians involved and/or interested in the optimization of adherence in patients with chronic diseases as diabetes and multiple sclerosis

Accreditation
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The conference “Inform ed treatm ent decisions: Adherence m anagem ent to optim ize patient outcom es in chronic diseases” (27-28 January, 2012 - Rome, Italy) is designated for a maximum of 6 (six) hours of European CME credits (ECMEC). Each medical specialist should claim only those credits that he/she actually spent in the educational activity. EACCME® credits are recognized by the American Medical Association towards the Physician’s Recognition Award (PRA). To convert EACCME® credit to AMA PRA category 1 credit, please contact the AMA.

This program “Inform ed treatm ent decisions: Adherence m anagem ent to optim ize patient outcom es in chronic diseases” (27-28 January, 2012 - Rome, Italy) has been submitted for CME accreditation from the Italian Ministry of Health.

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K. "Vish" Viswanath
Harvard School of Public Health
Dana-Farber Cancer Institute
Dana-Farber/Harvard Cancer Center
Boston, MA, USA
Friday - 27 January, 2012

12.30 Welcome lunch

14.00 Serono Symposia International Foundation (SSIF) opening
   G. Comi (Italy)

14.10 Welcome and Introduction
   M. Trojano (Italy)

Adherence in medical practice, barriers and benefits

Chairmen: M. Trojano (Italy) - S. Del Prato (Italy)

14.15 L1 The role of adherence in medicine
   L. Osterberg (USA)

14.45 L2 Barriers to long term therapies
   C. Pozzilli (Italy)

15.15 L3 Adherence in multiple sclerosis, clinical benefits and difficulties
   J. Sastre-Garriga (Spain)

15.45 Coffee break

16.00 L4 Adherences in Diabetes Mellitus, endpoints and difficulties
   C. Day (UK)

16.30 L5 Tools to improve patients' compliance: examples in real practice
   A. Lugaresi (Italy)

17.00 Discussion

17.30 End of the first day

Saturday - 28 January, 2012

Suggestions to Improve Adherence to Treatment

Chairmen: M. Trojano (Italy) - S. Del Prato (Italy)

08.30 L6 The clinician perspective
   G. Comi (Italy)

09.00 L7 The scientist perspective
   P. SW Davies (Australia)

09.30 L8 Psychologist’s role
   D. Langdon (UK)

10.00 L9 Nurse’s role
   J. Poirier (Canada)

10.30 Coffee break

11.00 L10 Cost for non adherence
   M. Salas (USA)

11.30 L11 The research in children
   J. Dahlgren (Sweden)

12.00 L12 Mass media’s role
   K. Viswanath (USA)

12.30 Discussion

12.45 Closing remarks
   S. Del Prato (Italy)

13.00 End of the workshop and closing lunch
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- **Caroline Day**
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- **K. “Vish” Viswanath**
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Abstracts
In order to understand medication adherence and communicate effectively, one must first understand the terminology used in the adherence literature. The consensus group on taxonomy/terminology (The ABC Project Team, see www.ABCproject.eu) recently published the terminology commonly used to describe deviations of assigned treatment recommendations in ambulatory patients:

**Medication Adherence** is the process by which patients take their medications as prescribed and is composed of **initiation**, **execution**, and **discontinuation**.

- **Initiation** occurs when the patient takes the first dose of a prescribed medication.
- **Discontinuation** occurs when the patient stops taking the prescribed medication.
- **Execution** is the extent to which a patient’s actual dosing corresponds to the prescribed dosing regimen, from initiation until discontinuation.
- **Persistence** is the length of time between initiation and discontinuation.

Approximately half of patients prescribed medications for chronic diseases will drop out of treatment within about 6 months, and of those who continue with treatment, typical rates of adherence are about 50% to 60%. There is no standard for what is considered adequate adherence as this depends on the drug being used and disease being treated. One should always consider the possibility of nonadherence as it is difficult to identify, and there are no good predictors of it.

Microelectronic monitors that record the time and date when pill containers are opened have given us a rich understanding of medication taking behavior for a variety of chronic illnesses. Most medication nonadherence consists of patients who completely stop their treatment altogether (nonpersistence). Patterns of medication taking behavior appear to be quite similar regardless of the chronic disease being treated and regardless of the severity of the disease. Providers should be alert to the possibility of noncompliance in all patients, but particularly in a patient who is not responding to therapy.

When a drug is initially prescribed, providers should elicit their patient’s attitude about taking medications and whether the patient feels that s/he can follow the regimen. It is important for a provider to understand whether a patient is agreeable to the therapy before sending him or her out with a prescription.

Finally, patients should be encouraged to develop their own medication-taking system that works for them. These approaches should be individualized with patients in a collaborative approach to empower them to achieve optimal adherence. Providers should ask patients at every visit about how they are taking their medications and encourage them to use a selected time, location, and/or activity cue that fits their daily routine. When faced with a patient in follow-up who has not responded to a given therapy, a clinician must decide whether to continue the current regimen, supplement it, attenuate it, or stop it altogether. If medication adherence is not taken into consideration, the busy clinician will miss an important opportunity to optimize medication treatment through attempts at improving adherence.
Interferons (IFNs) were the first disease-modifying drugs (DMD) to be approved for the treatment of multiple sclerosis (MS). Other DMDs become available later on as Glatiramer acetate (GA). All these agents have distinct mechanisms of action, doses, and modes of application, efficacy, and adverse event profiles. However, a common problem of all the DMDs is the adherence to the treatment. Adherence is significantly influenced by disease related factors such as disability, illness duration, depression and quality of life. Testing the differences in demographic and disease characteristics between adherent and non-adherent the following factors negatively influence adherence: older age of the patients, secondary progressive MS, a longer duration of MS disease, a higher EDSS score and a lower score on quality of life measures. Moreover, among other factors should be mention the family support, therapeutic expectations and education level. Psychological coping also has proved to be crucially important for adjusting to the adaptive demands of chronic diseases, and in the last few years it has received growing interest in MS. Factors related to therapy are to be considered in order to improve treatment adherence, which is essential to maximize treatment benefit and to ensure cost-effectiveness. may benefit from supportive measures to enhance adherence.

The impact of educative programs, injection devises and nurses on adherence to DMD treatment has been recently investigated showing that the use of supportive elements such as autoinjector devices and nurses have a strong influence on the adherence to therapy. However, further studies to assess the impact of programs of patient support to improve the adherence are needed at the light of new emerging therapy for the management of MS patients.
Evidence coming from clinical trials has clearly demonstrated the benefit of immunomodulatory therapies in MS. It is also clear that present therapies are only moderately effective and not without side effects whereas mode of administration is still cumbersome for a number of patients; these factors impact on adherence to treatment, which may render the therapeutic efforts futile. Several studies have shown that most drop-outs from treatment tend to occur in the early phases of therapy so especial care needs to be taken when patients start their immunomodulatory therapy in order to avoid treatment discontinuation. Available evidence suggests that individualized care is an important factor to keep drop-out rates low; in this regard, management of side effects of therapies is crucial, as it is responsible for almost a half of all discontinuations. Another important factor related to treatment discontinuation seems to be perceived lack of efficacy as a consequence of wrong expectations about treatment effects; therefore, adequate setting of expectations about therapy is crucial from outset of treatment with disease-modifying drugs. Side effects profile of IFNbeta preparations and Glatiramer Acetate are not entirely overlapping. In the case of IFNbeta preparations, it is especially important to manage flu-like symptoms at onset of therapy. Several strategies can be implemented to diminish patient discomfort, such as gradual dose increase and anti-inflammatory therapy administration schemes. Other side effects such as injection site reactions, flushing and laboratory abnormalities also need to be closely monitored. Nurse-led patient education at onset of therapy may be helpful to manage patients’ expectations from therapy and to anticipate and diminish the impact of side effects on adherence to treatment. Clinical daily practice individualized monitoring of treatment adherence with proactive side effects and management schemes together with adequate setting of expectations about treatment efficacy are therefore highly recommended if clinical trials efficacy results are to be met in our clinics.
Type 2 diabetes mellitus is a progressive endocrine and metabolic disorder requiring lifestyle modification and a range of medications to lower glycaemia, reduce vascular risk and address diabetes-associated complications. Additionally these patients, who are generally older, may be prescribed drugs to treat ailments not related to diabetes eg pain killers. Several agents are available which lower blood glucose via different mechanisms of action, and the progressive nature of type 2 diabetes generally requires that more than a single lesion is targeted. Even with the current armamentarium of effective agents <50% of people with type 2 diabetes achieve HbA1c <7% (53mmol/mol) and up to two thirds die prematurely of cardiovascular disease. Since these medicines have proven efficacy better glycaemic control would be expected - but only if the prescribed medicines are taken. Over the past decade more attention has been paid to adherence as a likely reason for poor responses to treatment. Inadequate adherence has been defined as collecting <80% of prescribed medicines. It has been reported that about one-third of patients on oral antidiabetic medicines do not achieve adequate adherence. Factors which reduce adherence include clinical inertia, complex dosing regimens, polypharmacy, safety issues, educational status, socioeconomic factors as well as diabetes education, beliefs and social support of the patient. Consideration will be given to investigating adherence in diabetes, lessons learned, challenges identified and strategies employed to help improve adherence.
It has already been underlined that poor adherence to treatment represents one of the main causes of treatment failure. Although actual or perceived lack of efficacy is probably the main cause of treatment discontinuation or poor adherence, other factors directly connected to drug intake are also relevant and need to be addressed. One of the most challenging issues in long term adherence to injectables is represented by the difficulties encountered by patients just at the time of administering the drug. Even care-givers often find this moment demanding, especially when the patient is a child. In the world of Multiple Sclerosis, Diabetes and low statural growth it is particularly relevant to overcome not only needle phobia but also psychological difficulties in self-administering the drug. Forgetfulness is often reported by patients as one of the main causes of missed injections and probably needs to be investigated in depth as, behind forgetfulness we might find reasons hard to confess to the treating physician or nurse. In the last years several mechanic or electronic devices have been devised to help patients to be compliant. In several customer satisfaction questionnaires or observational studies it appears clear that innovation, beyond the appeal of "new" versus "old", actually provides technical improvements, such as thinner needles, programmable depth of injection or speed of needle insertion/retraction and drug delivery, rendering self-injection less distressing. Among injection devices for Multiple Sclerosis patients one of the most attractive is an electronic device with several important characteristics among which: ease of use, totally hidden needle, pre-programmed tachyphylaxis scheme, alarm to remind patients the appropriate time of injection and injection log. The injection log allows assessment of the actual number of injections performed and discussion with the patient of consequences of poor adherence. A recent study, performed in Italy, the Bridge study, has demonstrated that the device, together with medical and nurse advice, has reduced the anxiety connected with treatment, leading to a very good adherence in the short term (12-wk) and very good persistence in treatment after more than 1 yr, confirming that the main causes of early treatment interruption are due to unrealistic expectations and apparently little every-day problems such as injection site reaction and flu-like syndrome. Similar devices are used with the growth hormone, helping parents to administer therapy to their children.
As with all chronic diseases, adherence to prescribed medication is essential for achieving optimal patient outcomes. Most current Multiple Sclerosis (MS) therapies are self-administered or administered by a care-giver in the home, so the success of treatment is partly dependent on the patient adhering to the prescribed regimen. For the clinician it is important to know whether the patient is taking their medication – if a treatment appears to be failing, poor adherence should be ruled out before a therapy change is considered. Accurate assessment of the true level of treatment adherence is difficult – currently there is only one injection device for MS therapy that accurately records data on drug administration. Otherwise, assessment of adherence is largely reliant on retrospective patient reporting. Therefore, fostering a trusting relationship with the patient can help the care-giving team obtain a true picture of adherence and address any issues that arise. As there are many factors that contribute to poor adherence in patients with MS, several strategies can be employed to promote adherence. Patient education on the importance of treatment and treatment adherence is vital – because MS therapy is basically preventative, it is important that patients who are in remission are made aware of the possible consequences of not taking their medication. Treatment fatigue is also common with chronic therapy, and again education and support from the healthcare team can help a patient maintain their regimen. Treatment tolerability can affect adherence and patients can be educated on how to prevent and manage side effects to make therapy less burdensome. Use of injection devices can improve tolerability and convenience of self-injection, although it is important to remember that poor adherence is not limited to injected therapies. Through an open and honest dialogue between the clinician and the patient, improved outcomes can be achieved through optimized adherence.
In the area of informed treatment decisions relating to adherence management in chronic diseases the scientist has at least two key roles and thus should bring at least two perspectives to this field. Firstly, they need to seek the evidence that adherence matters in term of outcomes in chronic diseases. Obviously the level of evidence and its availability will vary depending upon the disease itself. For example, significant non adherence to treatment for diabetes can have major short term effects on the individual including death, whilst non adherence to growth hormone treatment in children has few acute effects. Moreover, the accurate assessment of adherence to treatment can be difficult in many cases with no real tool being ideal and many having significant flaws.

The second role that a scientist can have is to attempt to evaluate the degree to which variability in adherence to treatment has an effect on the degree of variability in outcomes. Thus we are attempting to answer two questions; does poor adherence matter and how much does it matter?

This presentation will address both these perspectives with data and evidence drawn primarily from the literature relating to growth hormone treatment in childhood.
Many psychological variables have been demonstrated to affect adherence. These include illness beliefs, construal of illness severity, mood, self-efficacy, health literacy, and injection phobia. Psychologists can assess these aspects of a patient’s illness experience, identify actual or potential hurdles to adherence, and address them to support and facilitate adherence. Interventions could include a cognitive behavioral therapy (CBT) approach, education or mindfulness.

Psychological principles can also be adopted by other professionals to promote adherence, for example pharmacists. Patients with multiple pathologies pose particular challenges with regard to adherence and structured programmes to support adherence with dedicated professional time can be beneficial. E-health programmes show initial promise in supporting adherence.

References:
Adherence to MS therapies is a challenge for healthcare professionals such as neurologists and MS nurses. Since these treatments are not a cure, patients skip doses or simply stop treatment. In addition, the Zamboni procedure CCSVI (liberation treatment) has added to this challenge because many patients think this is a cure.

We, as nurses, have to adopt strategies to encourage long term adherence. At our MS clinic (CHUM, University of Montreal), we focus on the partnership between the patient and our team of neurologists and nurses. We think that patients should be well informed and involved in treatment selection which consequently, has a direct impact on adherence. We will discuss how we work together at the CHUM MS clinic. Last but not least, as an MS nurse, what tips and advise we give to patients to help manage their side effects and increase adherence.
Adherence is a key area of research because of its impact on clinical outcomes, disease progression, and hospitalizations. Non-adherence to treatment increases costs of care, reduces productivity and impacts the overall public health. Improving adherence to medications is an important factor to reach the magnitude of benefits demonstrated in clinical trials. Despite the advances in clinical research and pharmacologic therapies, mainly in chronic diseases, adherence to treatment (pharmacological and non-pharmacological) remains an issue. Multiple studies have shown that on average patients adhere to chronic treatments from 50% to 60% of medications prescribed. Furthermore, it has been estimated that there are approximately 125,000 deaths per year and 33%-69% of medication-related hospital admissions in the United States because of non-adherence to medications.

The economic impact of non-adherence is important. The total cost estimates for non-adherence range from $100 billion to $300 billion each year and include both direct and indirect costs. Studies in diabetes have shown that annual related costs for patient with sustained glycemic control are 32% lower than costs of patients not reaching the target blood-glucose levels (US $1171 vs. $1540 per patient), and those costs increased at three years at US$23,873 and US$26,408, respectively. Other studies have shown that there is a direct impact of medication non-adherence on total diabetes medical costs. For diabetic patients at 80%-100% adherence, the total medical costs have been estimated of approximately US$4,000 compared to US$9,000 for patients at 1% to 19% adherence. Although, the costs of medications have increased, compliant patients with their therapies have a reduction on medical costs thus the total costs of care are reduced. Therefore, interventions to improve patient adherence with their medications will have an important economic impact on the health care system.
The presentation aims to give an overview of the literature concerning adherence management in chronic diseases as well as in health care. Detailed data from pediatric studies in all fields such as hormonal medication, antibiotics, cancer treatment as well as self-care with insulin and lifestyle treatment in diabetes, obesity or malnutrition is presented.

For example, it has been well-known since several decades, that injection frequency of growth hormone is associated to optimal growth response. One study has shown that as much as 31% of height velocity was lost if more than 15 injections per month were missed compared to a maximum of 15 injections per month. Surprisingly, this was the case in as much as one forth of the studied patients.

Hindmarsh et al. showed time ago that non-adherence for growth hormone was found in 20% of patients and intermittent adherence was as common as in one other third of the patients. The same numbers are also found in diabetic children, with long-lasting impairment of health and increased risk for cardio-vascular disease in adult age. Similarly, if an infant with congenital hypothyroidism is not treated properly with hormonal substitution, the impact on cognitive function can not be underestimated.

Published data about factors known to influence parental adherence as well as patient adherence are carefully explored and based on this a future more optimal management in the clinical settings suggested.
According to the 2011 United Nations summit, Non-Communicable Diseases (NCDs) are responsible for 63% of deaths, killing 36 million people annually, with 9 million of them under the age of 60. The summit called for a concerted global action encompassing a range of risk factors and disease conditions to stem the tide of disease and death. Much is already known about prevention and management of chronic diseases such as cardiovascular diseases, diabetes, cancers and chronic respiratory diseases and many success stories abound. Morbidity and mortality due to chronic diseases can be contained if patients adhere to guidelines and recommendations. Many factors influence adherence and mass media, broadly defined, is one of them.

Media’s role in adherence may take three forms. First, media indirectly integrate people into social and cultural expectations and beliefs about health behavior through messages whose health focus may be only incidental -- as in entertainment. Second, the mass media also provide basic information about health that may influence people, or be used by them, to think differently about health, or to solve specific health problems -- as in news about newly-discovered ways to cure or prevent disease and improve health. Third, mass media may be used collaboratively by public health specialists and media gatekeepers seeking to re-define and change social and cultural expectations, beliefs, public policy about health behavior, and health behavior itself.

The role of media has become even more critical with the proliferation of information delivery platforms such as the Internet and other information and communication technologies (ICT) such mobile phones and consumer informatics. While the ICTs may complicate adherence management, many trials are also being conducted to make effective use of ICTs to promote adherence.

This presentation will review the role of mass media, defined broadly, in adherence management and the challenges and opportunities presented by new information and communication technologies. It will end with the contention that an empirical and analytical understanding of both functional and dysfunctional roles of media, combined with strategic use of ICTs, present us with unprecedented opportunities to improving adherence among patients.