Adherence to treatment in chronic diseases: focusing on diabetes, growth disorders and multiple sclerosis
Rome, Italy - 5-6 April 2013
General information

Venue
The conference takes place at the:

**NH Vittorio Veneto**
Corso D’Italia, 1
00198 Rome

Language
The official language of the conference is English.

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Adherence to treatment in chronic diseases: focusing on diabetes, growth disorders and multiple sclerosis

Serono Symposia International Foundation conference on:

Adherence to treatment in chronic diseases: focusing on diabetes, growth disorders and multiple sclerosis
Rome, Italy - 5-6 April 2013

Aims of the conference
Adherence to treatment is a critical factor associated with the efficacy of managing chronic diseases, its rate being only about 50% in developed countries and causing poor healthcare outcomes, in terms of higher morbidity and mortality, and increased overall healthcare costs due to more complications, hospitalizations and procedures. Main reasons for a poor adherence are: a low patient income and socio-cultural level, a multiple drug regimen, a psychological burden from the disease, and a costly healthcare insurance system.

Diabetes and growth disorders in the field of endocrinology as well as multiple sclerosis in the one of neurology are major chronic conditions deeply affected by a low rate of adherence to treatment in reason mainly of complex and expensive therapeutic regimens, often with injective drugs, an elevated mental distress associated to the long-life treatments, and the occurrence of secondary invalidating and chronic complications.

Serono Symposia International Foundation is honoured to organize the second live educational meeting entitled "Adherence to treatment in chronic diseases: focusing on diabetes, growth disorders and multiple sclerosis" to continue its tradition in supporting patient care through a dedicated medical education for healthcare professionals.

This live educational meeting aims to discuss the main aspects and recent achievements in managing the different aspects of the adherence to treatment in chronic conditions, such as diabetes, growth disorders and multiple sclerosis, and it will also provide learners with best solutions for optimizing patient care in their daily clinical practice.

Learning objectives
After attending this live educational conference, learners will be able to:

- Evaluate the main obstacles and consequences of poor adherence in major chronic diseases, including social and economical issues
- Recognize all involved stakeholders’ roles and identify available opportunities to get better adherence
- Recognize barriers and solutions for improving adherence in patients with diabetes, growth disorders and multiple sclerosis
- Assess the psychological burden and consequences of diabetes, growth deficits and multiple sclerosis on the adherence to treatment
- Appraise the benefits of new technologies to administer and monitor therapies for diabetes, growth disorders and multiple sclerosis

Target audience
Endocrinologists, diabetologists, neurologists, and all other healthcare professionals involved in the management of diabetes, growth disorders and multiple sclerosis, including psychologists, nurses and also general practitioners (GPs).

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Accreditation
Serono Symposia International Foundation [www.seronosymposia.org] is accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) to provide the following CME activity for medical specialists. The EACCME® is an institution of the European Union of Medical Specialists (UEMS), www.uems.net
The CME conference on “Adherence to treatment in chronic diseases: focusing on diabetes, growth disorders and multiple sclerosis” held in Rome, Italy on 5-6 April 2013, 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 (AMA) towards the Physician’s Recognition Award (PRA). To convert EACCME® credit to AMA PRA category 1 credit, please contact the AMA.

This live educational conference on “Adherence to treatment in chronic diseases: focusing on diabetes, growth disorders and multiple sclerosis” held in Rome, Italy on 5-6 April 2013, has been submitted for CME accreditation from the Italian Ministry of Health.

We value your opinion!
We are continually trying to develop and improve our educational initiatives to provide you with cutting-edge learning activities. During this live educational meeting you will be asked to answer a real time survey and after this educational event you will be receiving an online survey to help us to better tailor our future educational initiatives.
We thank you for participating!

follow us on twitter http://twitter.com/SSIF_Neurology#adherence
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Institute of Experimental Neurology
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**Jaakko Tuomilehto**  
Department of Public Health  
University of Helsinki  
Helsinki, Finland  
and  
Center for Vascular Prevention  
Danube University Krems  
Krems, Austria
Friday - 5 April

12.30 Welcome lunch

14.00 Serono Symposia International Foundation (SSIF) opening and introduction
  G. Comi (Italy) and M. Cappa (Italy)

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<td>Targeting therapeutic goal</td>
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<td>L. Osterberg (USA)</td>
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<td>L2: 14.45</td>
<td>Burden to healthcare systems</td>
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<td>L. Terranova (Norway)</td>
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<td>L3: 15.15</td>
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<td>R.B. Haynes (Canada)</td>
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<td>C. Pozzilli (Italy)</td>
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17.45 End of the day
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<td>J.E. Chaplin (Sweden)</td>
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The following faculty provided information regarding significant commercial relationships and/or discussions of investigational or non-EMEA/FDA approved (off-label) uses of drugs:

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<tr>
<th>Faculty Name</th>
<th>Conflict of Interest Details</th>
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<tbody>
<tr>
<td>Patrizia Borboni</td>
<td>Declared no potential conflict of interest.</td>
</tr>
<tr>
<td>Marco Cappa</td>
<td>Declared receipt of honoraria or consultation fees from Ipsen, Merck Serono, Pfizer, Novonordisk.</td>
</tr>
<tr>
<td>Dawn Carle</td>
<td>Declared receipt of honoraria or consultation fees from SSIF.</td>
</tr>
<tr>
<td>John Eric Chaplin</td>
<td>Declared receipt of grants and contracts from the Swedish National Research Bodies and receipt of honoraria or consultation fees from Pfizer.</td>
</tr>
<tr>
<td>Giancarlo Comi</td>
<td>Declared receipt of honoraria or consultation fees from SSIF, Novartis, Teva, Sanofi Aventis, Genzyme, Merck Serono, Bayer and Actelion.</td>
</tr>
<tr>
<td>Peter S.W. Davies</td>
<td>Declared no potential conflict of interest.</td>
</tr>
<tr>
<td>R. Brian Haynes</td>
<td>Declared no potential conflict of interest.</td>
</tr>
<tr>
<td>Stephan Herpertz</td>
<td>Declared receipt of grants and contracts from Diabetes and Depression Study, DAF-Study ISCRTN 89333241, BMBF 05K60505. He declared receipt of honoraria or consultation fees from Lilly Germany. He declared also to be member of Ge4mab Association of Eating Disorders.</td>
</tr>
<tr>
<td>Alessandra Lugaresi</td>
<td>Declared receipt of grants or contracts and honoraria or consultation fees from Bayer Schering, Biogen Idec, Merck Serono, Novartis, Sanofi Aventis, Teva. She declared also to be member of the advisory board or board of directions or other similar groups of Bayer Schering, Merck Serono, Biogen Idec.</td>
</tr>
<tr>
<td>Dawn Langdon</td>
<td>Declared receipt of grants and contracts from Bayer Healthcare. She declared receipt of honoraria or consultation fees from Bayer Healthcare, SSIF, Biogen Idec, Merck Serono. She declared her participation in company sponsored speaker’s bureau: Bayer Healthcare, SSIF, Biogen Idec, Merck Serono.</td>
</tr>
<tr>
<td>Lars Osterberg</td>
<td>Declared receipt of grants or contracts from Macy Foundation.</td>
</tr>
<tr>
<td>Francesco Patti</td>
<td>Declared receipt of honoraria or consultation fees from Bayer, Biogen, Merck Serono, Novartis, Teva. He is member of the advisory board or board of directions or other similar groups of Bayer, Biogen, Merck Serono, Novartis, Sanofi Aventis.</td>
</tr>
<tr>
<td>Carlo Pozzilli</td>
<td>Declared receipt of grants and contracts from Merck Serono, Biogen, Novartis, Sanofi Aventis. Bayer and receipt of honoraria or consultation fees from Merck Serono, Biogen, Teva, Sanofi Aventis e Bayer.</td>
</tr>
<tr>
<td>Jaume Sastre-Garriga</td>
<td>Declared his participation in a company sponsored speaker’s bureau: Novartis, SSIF, Teva, Genzyme.</td>
</tr>
<tr>
<td>Orly Tamir</td>
<td>Declared no potential conflict of interest.</td>
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<tr>
<td>Lorenzo Terranova</td>
<td>Declared receipt of grants and contracts from Quintiles.</td>
</tr>
<tr>
<td>Jaakko Tuomilehto</td>
<td>Declared receipt of grants and contracts from MSD, Servier, Sanofi-Aventis. He is also stakeholder of Orion Pharma.</td>
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Abstracts
Medication Adherence is the process by which patients take their medications as prescribed and is composed of initiation, implementation, 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. Implementation 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.

Patients who are prescribed medications for chronic diseases have typical rates of adherence of about 50% to 60% at one year. There is no agreed standard for what constitutes “adequate adherence”, and therapeutic sufficiency depends on the drug being used and disease being treated. For example, rates of greater than 95% adherence are considered mandatory by some experts in the treatment of patients with HIV, while the treatment of other diseases, such as hypertension or hyperlipidemia, might not require such strict compliance for an acceptable therapeutic benefit. Medication adherence is often thought of as a dichotomous variable, but in reality, patients will have varying patterns of medication-taking behavior. Adherence rates will range from 0% to over 100% (with some patients will taking more than the prescribed amount of medications).

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 nonadherence in all patients, but particularly in a patient who is not responding to therapy.

A number of interventions to improve medication adherence have been attempted with varying results, but the successful methods are multifaceted, expensive, and are not always practical for routine implementation in the clinical setting. Given the frequency in which poor medication adherence contributes to increased health care costs and poor health outcomes, health care providers need to be well educated how to maximize medication adherence in their patients. 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. Effective communication skills are essential for providers to maximize medication adherence in their patients, and a patient centered approach to medication prescribing using shared decision making is most effective. Health care providers should evaluate their health care environment from the patients’ perspective, looking for changes that can be made to remove barriers to medication adherence. A critical look at our health care system and making changes to optimize patients’ adherence to therapy is essential so full advantage can be garnered from the effective pharmaceuticals that have been developed.
Adherence to the therapies by patients could depend on many different factors. Literature has well investigated costs and inefficiencies both afflicting the healthcare systems and the society. Aim of each healthcare system would be to reduce the no-adherence by patients to the therapies. Adherence (or not adherence) is quite often due to the conditions/choices of the patients. Many studies have analyzed reasons connected to clinical or/and psychological reactions by patients to a therapy. Moreover, there are some “macro” (or system) factors that are able to determine the access of the patient to the therapies, and practically to influence the adherence to the therapies (cultural backgrounds, copayment systems, ...). The aim of the lecture is to examine some of these “macro” factors, giving some burdens for the healthcare system and trying to find some policy suggestions.
Low adherence to prescribed medical regimens is a ubiquitous problem. Typical adherence rates are about fifty percent for medications and are much lower for lifestyle prescriptions and other more behaviourally demanding regimens. In addition, many patients with medical problems do not seek care or drop out of care prematurely. Although highly accurate measures of low adherence are lacking for many regimens in usual clinical practice, simple measures, such as directly asking patients and watching for appointment nonattendance and treatment nonresponse, will detect most problems. Improving adherence to long-term regimens requires combinations of information about the regimen, counseling about the importance of adherence and how to organize medication taking, reminders about appointments and adherence, rewards and recognition of the patient’s efforts to follow the regimen, and enlisting social support from family and friends. Successful interventions for long-term regimens are all labour intensive but ultimately can be cost effective.
In diabetes, optimal management is extremely challenging and necessitates ongoing patient motivation, cooperation and self-discipline. These could be difficult to achieve, mainly due to the required changes in various aspects of the patient’s daily life and desired lifestyle. Thus, the effort to reach and maintain disease control imposes a quandary on the individual patient due to the required behavioral changes. Optimizing this balance is a critical goal for both patients and health care providers, and a meaningful step toward its achievement is identifying and addressing perceptions and difficulties associated with the management of treatment modalities. The need to consider parameters subjective to the patient is highlighted particularly in light of the relatively generous arsenal of therapeutic options currently available, which allows a selection among comparable technologies in terms of their clinical effectiveness.

The Patient-Perceived Difficulty in Diabetes Treatment Scale is a brief, treatment-focused instrument that assists in identifying potential barriers in adherence to ongoing treatments and to new treatment options. This instrument allows pinpointing specific perceptions of particular treatment attributes, in a way that can be used to facilitate decisions over therapeutics and to support an improved match of modality to a patient profile.

A cross-sectional study we conducted among 714 type 2 diabetic patients throughout Israel revealed that quality of life was not impaired with the stepwise addition of oral hypoglycemic agents, irrespective of the degree of glycemic control. An insulin-based alternative was consistently associated with a higher perception of difficulty related to pain and to cost of treatment, and with lower overall quality of life when compared with either 1-, 2-, and 3-oral regimens. We conclude that from the patients’ perspective, oral therapy is the preferable strategy for attaining treatment goals. If early insulin treatment is considered, physicians should address specific diabetes-treatment characteristics in order to promote improved quality of life and disease control.

Ideally, improved metabolic control should not occur at the expense of an adverse effect on well-being in order to promote and maintain the patient’s compliance with treatment protocol. A better understanding of the trade-off between different treatments and quality of life and patient-perceived difficulties is expected to facilitate an optimal match of treatment modality to patient profile and define optimal strategies in care.
Type 2 diabetes (T2D) is resulted from a lack of physical activity and unhealthy diet. The genetic factors may modify effects of lifestyle factors. Although diet and physical activity in principle may reverse elevated blood glucose and lower the risk of complications in T2D, data are limited to prove the efficacy of lifestyle management in T2D. Yet, the potential is huge, since the vast majority of T2D patients are obese and sedentary. In people with impaired glucose tolerance intensive diet and physical activity counseling reduces the progression to T2D dramatically as shown by several trials.

Dietary interventions recommended by the EASD Diabetes and Nutrition Study Group (DNSG) are less prescriptive than some earlier advice. They acknowledge that several dietary patterns can be adopted, and emphasize that appropriate intakes of total energy and a diet in which fruits, vegetables, wholegrain cereals, and low-fat protein sources predominate are more important than the precise proportions of total energy provided by the major macronutrients. It is also considered that salt intake should be restricted.

It has been suggested there is no benefit in a high-protein over a high-carbohydrate diet in T2D. Specific dietary recommendations include limiting saturated and trans-fats and alcohol intake, monitoring carbohydrate consumption, and increasing dietary fibre. Routine supplementation with vitamins E and C and carotene is not advised because of lack of evidence of efficacy and concern related to long-term safety. Omega-3 fatty acid supplementation does not reduce cardiovascular (CVD) events in T2D. Coffee and tea drinking seems to lower CVD risk in people with T2D.

For those who prefer a higher intake of fat, a Mediterranean-type diet is perfectly acceptable provided the fat sources are derived primarily from monounsaturated oils as shown by the PREDIMED study using virgin olive oil. The guidelines take cultural practices and personal preferences into account and the diversity of options should encourage adherence.

Physical activity is important in the prevention of the development of T2D in people with IGT and, and for the control of glycaemia and related CVD complications. Aerobic and resistance training improve insulin action and plasma glucose, lipids, blood pressure, and cardiovascular risk. Regular exercise is necessary for continuing benefit. Regular moderate to vigorous physical activity can reduce the risk of CVD events by 20-30% in people with T2D.

Little is known about the best way to promote physical activity. Data from a number of trials support the need for reinforcement of physical activity by healthcare workers in people with T2D. Systematic reviews found that structured aerobic exercise or resistance exercise reduced the HbA1c value by about 0.6% in T2D. Since a decrease of 1% in HbA1c is associated with a 15–20% decrease in CVD events and a 37% reduction in microvascular complications, long-term exercise regimens should decrease vascular complications. Combined aerobic and resistance training has a more favourable impact on HbA1c than aerobic or resistance training alone. In a recent meta-analysis of 23 studies, structured exercise training was associated with a 0.7% fall in HbA1c compared with controls. Structured exercise of >150 min/week was associated with a fall in HbA1c of 0.9%, while <150 min/week was associated with a fall in HbA1c of 0.4%. Overall, interventions of physical activity advice were associated with lower HbA1c levels only when combined with dietary advice e.g. walking after a meal lowers post-prandial glucose excursions.
Children receiving growth hormone therapy have the best growth results when they have good adherence, but adherence rates are often low. Adherence has been difficult to measure and it is often done indirectly. Poor adherence may be caused by various factors, affecting both the children and their families. The key reasons for adherence difficulties are psychological, emotional, everyday problems and technical handling issues of the drug delivery device. Correspondingly a broad range of strategies to improve adherence to hormonal therapy often revolve around counseling and education, not just for the patient but also for the family giving care. This presentation is intended as an analysis of strategies which could help, in clinical practice, to overcome poor adherence to growth hormone therapy in children. Although many factors impact on adherence, there are some crucial point to which a physician should be particularly alert, such as history of poor attendance at consultations. Moreover describes factors associated with non-adherence and how most barriers to good adherence can be overcome by maintaining a good relationship with the children and their families, and delivering useful and clear education and training soon after diagnosis. Managed care organizations face several challenges in providing rhGH therapy, including deciding who is most likely to benefit from treatment and when to discontinue treatment if the benefits appear to level off.
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.
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 IFN beta preparations and GA are not entirely overlapping. In the case of IFN beta 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.
Interferon beta was the first disease-modifying drug (DMD) to be approved for the treatment of multiple sclerosis (MS). Other first line DMDs such as the Glatiramer Acetate, or second line treatments as Natalizumab or Fingolimod have been more recently introduced in the market. As more treatments have become available, the rate of patients switching between them has increased. 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. Patients with MS, particularly those who have already switched from one therapy to another, may benefit from supportive measures to enhance adherence. Adherence is also significantly influenced by disease related factors such as disability, illness duration, depression and quality of life. Psychological coping 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. However, few studies tried to identify coping strategies during therapy initiation which may allow customized support and improve treatment adherence.

On the other hand, several programs have been studied to improve adherence by Pharmaceutical company making several services and products available to patients. They include:

1) the availability of an experienced specialist nurse from the beginning of therapy and throughout ongoing stages of therapy under the supervision of the treating physician

2) New autoinjectors devices for patients to become familiar with self-administration and to show the potential reduction in the rate of adverse events associated with subcutaneous injection which might contribute to improved treatment adherence.

3) Websites which provided MS news services latest developments with treatments or latest news on MS. It also enabled exchange with the MS community and provided resources to manage the condition.
Abstract not in hand at the time of printing.
Diabetes Control and Complications Trial (DCCT) demonstrated that tight glycemic control in diabetic patients is essential to delay the progression of microvascular complications. Intensive glucose monitoring and intensive insulin therapy are essential to obtain optimal glycemic control. The introduction of continuous glucose monitoring systems (CGMS) represents an advanced technology in management of diabetes. JDRF trial compared the efficacy of self monitoring blood glucose (SMBG) to that of CGMS, demonstrating that intensive use of CGMS reduces HbA1c, hypoglycaemic events and glucose variability.

Near-normal glucose control is achieved by intensive insulin therapy both using multiple daily insulin injections or continuous subcutaneous insulin infusion (CSII). CSII associated to real time continuous glucose monitoring (sensor-augmented insulin pump), is the gold standard in diabetes treatment, demonstrating a beneficial effect on overall glucose control, with a reduced risk of hypoglycaemic events. CSII also improves quality of life but it requires strong patient motivation from one hand and accurate selection of patients from the other hand. The recent developed feature of automatic insulin suspension in sensor augmented insulin pump during targeted level of hypoglycaemia represents the first step toward the goal of an automated insulin delivery system to treat diabetes.
In recent years a number of differing electronic and mechanical devices have been developed that have the aim of making the administration of growth hormone (GH) simpler, less painful and safer. Such advantages may also have an affect on adherence to treatment that is often thought to be poor in some children being given GH for a variety of conditions. The more advanced devices are able to record the time of administration, the actual dose given and other information that might be used to assess adherence. Thus, these devices might be useful tools for addressing the issue of the affect of adherence on growth outcomes. Whilst such data and evidence are a little way off, there have been data published and presented that reports on levels of adherence measured over time that suggest, at least in children given GH, levels of adherence falls over time and in some cases the poor adherence is likely to be having an affect on growth. This phenomenon seems to occur even when patients are aware that their adherence to therapy is being monitored.

This presentation will focus on the reasons for poor adherence to GH therapy during childhood and the emerging data relating to levels of adherence that have been reported using electronic injecting and monitoring devices. There will also be discussion on how knowledge of adherence data and adherence patterning might be used to improve adherence and hence growth outcomes in children.
In the past years the awareness of the crucial role of adherence in the treatment of chronic conditions such as Multiple Sclerosis (MS) has increased. It is now universally recognized 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 and solved. One of the most challenging issues in long term adherence to injectable first line treatments for MS 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 MS, similarly to in Diabetes and growth hormone deficiency, 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. This needs to be thoroughly investigated as forgetfulness might represent a soft way, for the patient, to communicate to the treating physician or nurse poor adherence caused by other, not declared, reasons. 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. A recent study, performed in Italy, the Bridge study, and its extension phase, the River study, have demonstrated that the electronic device, together with medical and nurse advice, has reduced, in the first 3 months of treatment, treatment related anxiety, leading to a very good adherence in the short term (12-wk) and very good persistence in treatment after more than 1 yr, although adherence decreased significantly after the first 3 months. The main causes of early treatment interruption are due to unrealistic expectations and apparently small every-day problems such as injection site reaction and flu-like syndrome. Perceived efficacy has a crucial role in the ensuing phases.
In dealing with Multiple Sclerosis - the best possible strategy is adhering the managing the disease modifying therapies (DMT). The nurse’s role is crucial at every step of this process - from educating, decision making, support, follow up and assisting the patients with their ongoing understanding of their disease process and the changes throughout. This lecture will take a close look the reasoning behind early treatment, reluctance to start treatment, why patients stop taking their medications, and some solutions on how to overcome nonadherence.
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 CBT approach, education or mindfulness.

Electronic injection devices allow discussion of adherence to be based on objective data about medication use. Structured support programmes can improve patient adherence. 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.

E-health programmes show initial promise in supporting adherence.

References:
Over the last decade our research specially focused on the comorbidity of diabetes mellitus, 1. eating disorders (EDs) and 2. depression. With regard to diabetes and comorbid EDs we were specially interested in the prevalence of both full blown EDs and subclinical EDs in diabetic patients with special consideration of metabolic control and diabetic lesions. Considering depression in diabetes we performed a multicenter randomized control trial comparing cognitive behavioural therapy and sertraline in patients with depression and poorly controlled diabetes.

Prevalence rates of bulimia nervosa and especially subclinical EDs seem to be higher in young women suffering from type 1 diabetes compared to non-diabetic women. Up to 24% of adolescent girls with type 1 diabetes suffer from a clinical or subclinical ED compared to only 12% without diabetes (Jones et al. 2000). “Insulin purging” is a frequent practice of withholding insulin as a way to lose weight in diabetic patients both with and without an ED. 60% of young women with comorbid diabetes and an ED and 30% of diabetic women without an ED practice this devastating counterregulatory measure. The comorbidity of diabetes and EDs bears considerable risks for poor metabolic control and diabetic lesions. The risk of retinopathy is increased by the factor of five in comorbid patients. Especially insulin purging is a serious risk factor for nephropathy.

To compare the efficacy of diabetes-specific cognitive behavioral group therapy (CBT) vs. sertraline (SER) in patients with poorly controlled diabetes and depression we recently performed a multicentre randomised controlled trial comparing CBT vs. SER in 251 patients with type1 or type 2 diabetes with HbA1c values >7.5%. After 12 weeks of therapy, only the treatment-responders [50% reduction in the Hamilton Depression Rating Scale, HAMD) were included in the one-year phase. Diabetological treatment as usual was given to both groups. CBT-responders received no further treatment, while SER-responders received a sustained SER regimen. Group differences in HbA1c (primary outcome) and HAMD (secondary outcome) between 1-year follow-up and baseline were analysed controlling for baseline values. Subgroup analyses were conducted for type of diabetes. After 12 weeks 115 (45.8%) patients responded to the treatments (CBT 53, SER 62). In the 1-year follow-up the HbA1c changed from 9.3±1.6 to 9.2±1.7 after CBT and from 9.2±1.4 to 9.4±1.4 under SER with no significant treatment difference (p= 0.129). HAMD scores improved significantly after CBT from 18.0±4.6 to 7.8±6.5 and from 18.9±5.1 to 5.5±5.7 under SER (p=0.020). Subgroup analyses revealed significant differences within the CBT group regarding HbA1c (difference 0.73) favoring type 2 diabetes (HbA1c reduction : -0.40 vs. +0.32 for type1, p=0.0036). Both treatments showed considerable and sustained reduction of depression with a small but statistically significant advantage of sertraline. However, no substantial improvement could be obtained for glycemic control independently of the type of treatment.
There is substantial evidence that patients are often not adherent to their medical advice. Although estimations vary and information on non-compliance is difficult to obtain, evidence from studies of pediatric growth hormone treatment indicate that compliance is not always optimal. It is clear that improvements in patient compliance can be made which will have a substantial effect not only on adult height achieved and the possibility improved quality of life in the long-term but also on consultation time and medical resources.

As part of the EU RESPECT project, which carried out investigations across Europe of participation in pediatric clinical trials, adherence issues in short stature were investigated. Although barriers to adherence have often been described in terms of practical aspects such as difficult-to-use devices and forgetting to take one’s medicine, these issues rarely emerged from the research. The RESPECT project found that several other themes emerged, which included a lack of understanding about the importance of keeping to the medical regimen and active non-compliance based on privately held health strategies which were not shared with the medical team. These strategies were rational and based on their knowledge and beliefs about the condition. Medical regimens were evaluated against convenience, perceived benefits, worries about side-effects and the opinions of others.

The RESPECT project identified a number of factors which modified compliance. These were related to the patient or family’s trust in the doctor or medical profession, and the belief in flexible strategies for health. In addition, a number of internal and external factors could be identified. Internal factors included: perception of short stature; beliefs about the importance of short stature in their social environment; beliefs about the risks and effectiveness of treatment; perceptions of personal sensitivity to injections; and background beliefs and attitudes towards medical treatment. External factors included: opinions of friends and significant others; the influence of the media and the immediate and background culture; health-care policies and costs of treatment; and the social support received by the patient or family.

Health care is seen as an increasingly negotiated activity as patients gain more knowledge and access to reliable and detailed information. In order to foster collaboration, information has to be not only tailored to the abilities of the child and the parents but treatment decisions need to be made in a participatory manner, taking into account the beliefs of the patient or family and their health strategies. This, person-centred approach incorporates the patient’s needs into the treatment planning process, and an empowerment model emerges. This model is based on four elements: self-determination through active involvement; transparency of treatment options; cooperation and mutual respect; knowledge and access to information.

In this presentation, the challenges of a participatory process will be explored. Non-adherence should not be seen as a patient problem and we need to make sure that the doctor can provide information and effective treatments while fulfilling the patient’s needs if compliance is to be achieved.
Poor treatment adherence is problematic in many therapy areas, including multiple sclerosis (MS). Several immunomodulatory drugs are available for the treatment of MS, all of which require frequent parenteral administration. Current first-line therapies are two formulations of interferon (IFN) beta-1a, one of IFN beta-1b, and one of glatiramer acetate. Discontinuation of treatment is common, particularly in the first few months after initiation. Although the true effect of poor adherence to MS therapy is not known, it is likely to lead to a fall in treatment efficacy. Many factors influence a patient’s adherence to treatment, including the patient’s MS subtype and disability level, cognitive impairment resulting from MS, depressive mood, perceived lack of efficacy of the prescribed medication, and adverse events associated with MS therapy. Cognitive impairment and depressive mood affect up to 50% of patients suffering from MS. It was shown that cognitive impairment and depression are driven by specific either white or grey matter lesions occurring and accumulating at brain level. A large amount of data seem to indicate a common pathologic basis of cognitive impairment and depression in MS and a specific reciprocal interaction between these syndromes. Maximizing adherence to MS therapies to improve a patient’s chance of gaining the full benefit from their treatment is an important therapeutic goal. Patient education is of paramount importance in achieving this, as a patient’s commitment to a therapeutic regimen may well depend on their understanding of their condition, their need for treatment, and the potential benefits of treatment.

It was reported that disease modifying drugs can protect patients to develop cognitive impairment. There exist controversial data on the effects of disease modifying drugs on depression. Several data showed that interferons can worsen depressive mood; fewer and more recent data do not confirm these results.

As with other chronic diseases such as cancer and diabetes, nonadherence and poor adherence to therapy are common in MS, and improving adherence should be recognized as an important treatment goal in its own right. While suboptimal adherence to MS therapies remains a problem, adherence can be enhanced by various strategies. Hopefully, the new oral drugs recently approved and introduced in the market to treat MS patients could exhibit higher adherence rates than previously reported and seem to not have any detrimental effect on depressive mood. It is also expected that the effects of such drugs on brain atrophy could improve mood disturbances and cognitive performing. Nonetheless new technology and new devices can reduce the burden of adverse venets and increase the adherence rate to injectable therapies.
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