ABC Project Newsletter Issue n° 4 2009

Ascertaining Barriers for Compliance: policies for safe, effective and cost-effective use of medicines in Europe

HEALTH-F2-2008-223477

The ABC Project is the EU-funded research initiative to improve patient compliance to medication in Europe. The strategic goal of the project is to produce evidence-based policy recommendations for improving patient compliance, and thus raising the effectiveness of medications use by Europeans. Project's findings are expected to help health policymakers to take right decisions in order to minimize the negative impact of non-compliance. ABC Project was launched on January 1, 2009 and will run until December 31, 2011. **www.ABCproject.eu**

The 13th annual European Symposium on Patient Adherence, COMpliance, and Persistence & The European Consensus Meeting on Taxonomy and Terminology of Patient Compliance coordinated by the ABC Project

10th - 11th September 2009, Bangor, Wales, UK

Summary and conclusions

The 13th annual European Symposium on Patient Adherence, COMpliance, and Persistence was held on Thursday, the 10th September 2009 at Bangor University, Wales, UK. This year's symposium constituted a special event as it was the official launch of the newly created non-profit association of the same name, in short ESPACOMP.

The purpose of the association, in which Dr Dyfrig Hughes, President of ESPACOMP, held a welcome speech, is to promote research on patient adherence to drug therapies and to exchange views across Europe.

The symposium was attended by a large number of participants from 14 different countries. Dr. Lars Osterberg was the first recipient of the annual Jean-Michel Métry Memorial Lecture. He gave a keynote presentation on medication adherence: Past, Present and Future. The second keynote presentation was made by Professor Rachel Elliott on the economics of taking medicines: To take or not to take.

A panel of European speakers presented national and international initiatives to improve adherence in ambulatory patients, followed by 10 contributed papers of outstanding scientific quality. The program and slides are available from www.ESPACOMP.eu.

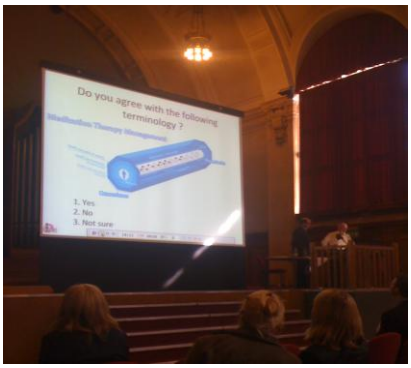
On September 11th, 2009, the EU-funded project entitled "Ascertaining Barriers for Compliance: policies for safe, effective and cost-effective use of medicines in Europe (ABC)" coordinated the European consensus meeting on the taxonomy and terminology of patient compliance. This meeting was chaired by Dr. Jeffrey Aronson, President of the British Pharmacological Society. Dr. Heather Waterman introduced the session with a talk on concordance and Dr. Bernard Vrijens presented the work performed as part of the first work package of the ABC project. There were many fruitful interactions between the participants. A proposal for a sound taxonomy was introduced and further discussed by Drs. Robert Vander Stichele and Lars Osterberg.

The consensus draft document has been posted on the web for further open discussions at **http://wiki.espacomp.eu/** The objective is to reach a final document by the end of 2009.

We are looking forward to the next ESPACOMP meeting in Lodz, Poland, on the 16th & 17th of September, 2010.

Founders of the ESPACOMP association

Bangor University, ESPACOMP2009



The consensus meeting coordinated by the ABC ESPACOMP2009

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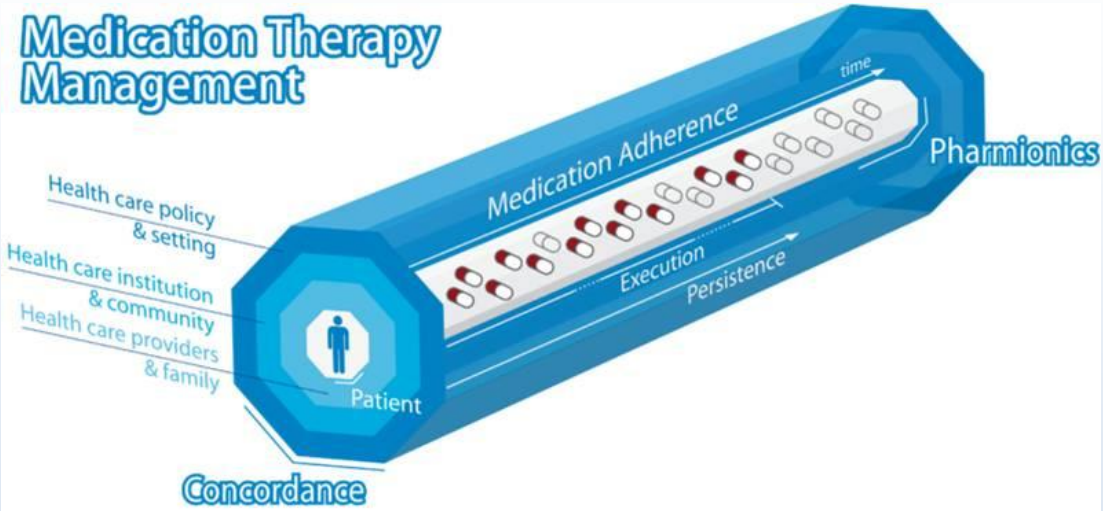
European consensus on taxonomy/terminology used in the field of deviations from recommended treatment in ambulatory pharmacotherapy was proposed by ABC Project team

To learn more and share some of your thoughts and opinions on this important topic with the wider public, please visit http://wiki.espacomp.eu/



Graphical representation of the proposed theoretical model of taxonomy/terminology used in the field of deviations from recommended treatment in ambulatory pharmacotherapy

Using microchips for patient prescription compliance

A novel technology in the area of patient compliance and adherence to medication, implemented by the major global healthcare company, has been presented recently. Below is the excerpt from the article available online:

"The company is testing a new technology […] that inserts a tiny microchip into each pill swallowed and sends a reminder to patients by text message if they fail to adhere to their doctor's prescribed orders. Early tests of the system, which broadcasts from the chip in the pills to a receiver on the patient's shoulder, are encouraging. In 20 test patients on the drug Diovan, a blood pressure medication, Novartis reports compliance was improved 30-80% over six months.

[...] While the results are still quite preliminary, it shows promise for having an impact in long-term chronic conditions like hypertension and diabetes, which are often the toughest for improving patient compliance.

But perhaps what's most encouraging of all is the emphasis Novartis seems to be placing on tackling the patient compliance conundrum in general. In a recent report from the Financial Times*, Joe Jimenez, head of pharmaceuticals at Novartis, said he was close to appointing a "compliance czar" to oversee a wide range of other partnerships and programs to strengthen the appropriate use of medicines." (Lisa Roner, Setting the bar, www.social.eyeforpharma.com, 6 Oct 2009)*

Commentary by the ABC project team member:

Prof. John Urquhart, Pharmionic Systems Ltd.:

Including a microchip in each tablet raises a toxicity question that can only be answered by use-experience. But first it is useful to ask: what do we know *a priori*? Here's what.

First, indigestible solid objects, e.g. seeds, can obstruct a colonic diverticulum. Second, the older the patient, the greater the prevalence of colonic diverticuli. Third, an obstructed diverticulum readily forms an abscess – a surgical emergency. Fourth, a few abscesses arising from diverticular obstruction can discredit an otherwise good product, especially when surgical photos show the solid object lodged in the entrance to the diverticulum, with the abscess beyond. This scenario occurred in the 1980's with a certain type of dosage form that left an indigestible outer coating. Photographs showed the product's name printed on the tablet coating, lodged in an abscessed diverticulum. It's a low incidence but high impact situation.

The emergency surgery involves excision of the affected segment of colon. That is a complicated undertaking, usually a 2-step procedure – the first to excise the abscessed segment of colon and create a temporary colostomy; the second puts things back together again. The details are beyond our scope here. Suffice it to say that it is moderately high risk surgery, particularly in the elderly.

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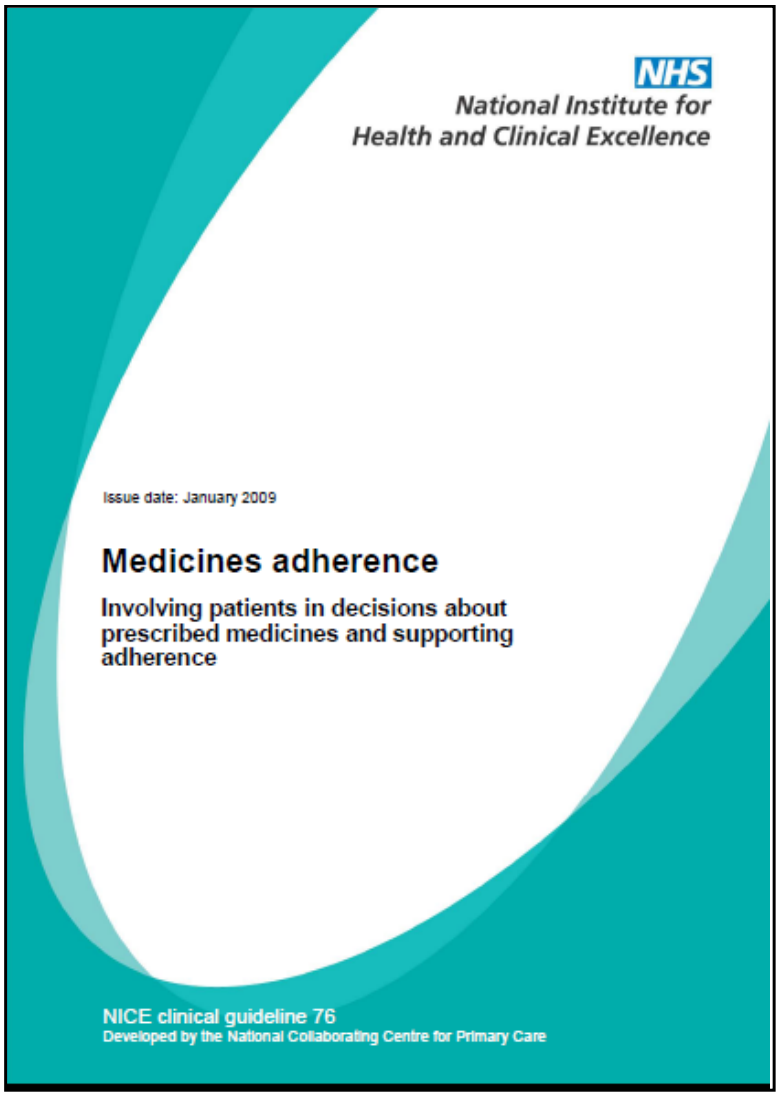
For the microchip in every tablet, the key question is: what does one gain vs alternatives? The answer comes from enough use-experience to gain reliable estimates of the product's benefits and risks.

What is the added value of getting a dose-by-dose assurance of tablet ingestion? The established alternative is electronic medication-event monitoring, which is an indirect method based on automatically recorded package opening times. These recorded times have turned out to be very robust indicators that the prescribed dose was ingested within a negligible interval after the recorded time of package opening. This validation comes from the close agreement between directly measured and computer-projected concentrations of drug in plasma, with the projections based on package-opening times plus the assumption that that the patient prescribed dose at the automatically recorded times. The error rate is less than 2%. Other such studies are underway. Over 350,000 patients have used the indirect method without harm.

Dose-by-dose validation of ingestion has one major usage: directly-observed therapy for tuberculosis, wherein patients come to the TB clinic 3-4 times per week to be observed by clinic staff swallowing their drugs. This method has made revolutionary improvements in the treatment of ambulatory TB patients. It could be referred to as "directly-encouraged therapy", which, though apt, may be politically incorrect. Encouragement can be provided by clinic staff; microchips can report status but cannot effect closure.



Dr Wendy Clyne, Medicines Partnership Programme, NCP Plus, Keele University

NICE Guideline on medicines adherence

The National Institute for Health and Clinical Excellence (NICE) in England published its first guideline on medicines adherence earlier this year. The guideline (see http://www.nice.org.uk/CG76) makes recommendations about how healthcare professionals can help patients to make informed decisions about treatment by facilitating the involvement of patients in the decision to prescribe, and support patients to adhere to medicines they have been prescribed.

The guideline covers the following:

- Patient involvement in decisions about medicines (communication, increasing patient involvement, understanding the patient's beliefs, knowledge and concerns about medicines, providing information)
- Supporting adherence (assessing adherence, interventions to increase adherence)
- Reviewing medicines
- Communication between healthcare professionals

The guidance represents the view of the Guideline Development Group appointed by NICE, of which I was a member. Healthcare professionals in England and Wales are expected to take NICE guidelines into account when exercising their clinical judgment. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient.

Local healthcare commissioners are responsible for the implementation of the guideline (as with all guidelines that NICE produces). The costing statement that accompanies the guideline will be of much interest to healthcare commissioners: NICE state that up to £4 billion of the NHS drugs bill may not be used correctly.

It is hoped that implementation of the guideline will lead to both more cost-effective health care and better health outcomes for patients.

A responsibility to adhere to become law

Earlier this year, the Minister for Health launched a constitution for the National Health Service (NHS) in England. The document, which is subject to Parliamentary approval, is effectively a bill of rights for the health service. It sets out rights to which patients, public and staff are entitled, and pledges which the NHS is committed to achieve, together with responsibilities which the public, patients and staff owe to one another.

Among nine responsibilities of patients (and the public) is the following:

"You should follow the course of treatment which you have agreed, and talk to your clinician if you find this difficult."

Interestingly, this is in the context of helping "[the NHS] work effectively, and to ensure resources are used responsibly", and not to promote better health for individuals, though arguably both amount to the same thing.

Should the constitution be approved, it represents a unique situation where patients have a legal responsibility to adhere to treatments. How this is to be policed (if at all) is unclear - the health secretary, Alan Johnson, is quoted as saying that this is not intended to be used to bully patients who do not adhere.

www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093442.pdf

NHS

THE NHS CONSTITUTION

the NHS belongs to us all

for England
21 January 2009

Patients and the public – your responsibilities | 9

2b. Patients and the public – your responsibilities

The NHS belongs to all of us. There are things that we can all do for ourselves and for one another to help it work effectively, and to ensure resources are used responsibly:

You should recognise that you can make a significant contribution to your own, and your family's, good health and well-being, and take some personal responsibility for it.

You should register with a GP practice – the main point of access to NHS care.

You should treat NHS staff and other patients with respect and recognise that causing a nuisance or disturbance on NHS premises could result in prosecution.

You should provide accurate information about your health, condition and status.

You should keep appointments, or cancel within reasonable time. Receiving treatment within the maximum waiting times may be compromised unless you do.

You should follow the course of treatment which you have agreed, and talk to your clinician if you find this difficult.

You should participate in important public health programmes such as vaccination.

You should ensure that those closest to you are aware of your wishes about organ donation.

You should give feedback – both positive and negative – about the treatment and care you have received, including any adverse reactions you may have had.

ABC at 15th WONCA Conference 16-19.09.2009 Basel, Switzerland

On 17th September 2009, during the 15th **Wonca** (World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physians) Conference in Basel, the ABC project researchers delivered a workshop "How can a busy physician help patients take prescribed medicines correctly?." It was conducted by Ass. Prof. Przemyslaw Kardas MD, PhD and Dr Bernard Vrijens, PhD who presented major issues related to compliance. Presenters' words were illustrated with humorous scenes depicting situations from family doctor's practice. Please visit ABC Project website soon to see a video with this event.

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