MID Frail

JANUARY 2014

Welcome to the latest issue of the MID-Frail newsletter!

This essential reading brings you a round-up of news on the latest events in this exciting pan-European study on diabetes in older people. In this issue…

- Study Status
- Partner's Contribution
- The Protocol Manuscript

Happy New Year!

Niche wishes every MID-Frail partner a very successful 2014!

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Study Status

The New Year started excellently for MID-Frail with the first patients being enrolled into the study. This happened in Spain where there are two active sites and three patients have been enrolled so far. With this, a crucial study milestone has been achieved.

A special thank you to Drs Castro and Manzarbeitia and congratulations to the team at the Hospital de Getafe.

MID-Frail is also progressing in other countries, with several sites close to recruiting their first patient. The Czech Republic is leading the way with Investigator and initiation meetings completed at all trial sites. Four sites are now actively recruiting and six patients have been screened and found eligible; other sites are expected to start recruitment soon. In Belgium and Italy, all documents required by ethics have been collected and will be submitted for review very soon. In Germany, the protocol submission has been made to the relevant authorities (for the main study and the GeneFrail sub-study) and it is expected that approval will be granted once we have provided the committee with some additional information.

In France, the Sensole sub-study has been approved by the ethics committee and the initiation meeting is expected to take place this month. Clarifications have been requested by the ethics committee for the main protocol and other sub-studies and so ethics review is ongoing. Finally, in the United Kingdom, ethics approval has been granted for the main study and now all that remains to be approved is the local R&D agreements following submission of the R&D and Study Site Information forms.

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Partner's Contribution

Towards the end of last year, Néboa Zozaya and Juan Oliva from the Universidad de Castilla-La Mancha volunteered to write an instructional article for this newsletter on the economic impact of diabetes and the importance of getting an accurate estimate of the size of the costs.

We are delighted that the MID-Frail partners see this newsletter as an effective means of sharing relevant study information and want to thank Néboa and Juan for their contribution. We would also like to take the opportunity to thank Olga Laosa for facilitating this process.

The economic impact of diabetes mellitus and the importance of measuring costs properly

by Néboa Zozaya and Juan Oliva, on behalf of the UCLM Team

Diabetes mellitus (DM) is a chronic disease with a significant economic impact on society. This paper aims to highlight the magnitude of this economic impact, the different costs associated with DM, and why it is so important to measure accurately all the relevant costs.

It was estimated that over 220 million people worldwide had DM in 2010[1], 33 million of whom in the EU[2]. In addition, the incidence of this chronic disease is expected to increase substantially during the next decades. DM is associated with serious complications and many comorbidities, which have significant costs. For instance, individuals with DM are, on average, three times more likely to be hospitalized than non-diabetic individuals, with heart-related complications being the main cause of hospitalization[1]. Some

studies showed that direct healthcare expenditures for individuals with DM can be more than two-fold higher than that in individuals without DM[3].

A real world estimation of the economic burden of DM needs to take into account not only healthcare costs but also other social costs associated with this disease (see Chart 1). These include:

- Direct healthcare costs: usually refers to the costs of treating the disease directly (e.g., medicine consumption, visits to the general practitioner and to health specialists, etc.) and for treatment of associated complications (e.g., hospitalizations, laboratory tests, etc.). It also comprises the cost of educational programs.
- Direct – non-healthcare – costs: these are related to care, which can be formal (social services provided by professionals) or informal (non-paid care provided by relatives and friends of the patient). It can also include the time and costs incurred in transport to and from the health center or care provider.
- Indirect costs: include loss of labour productivity caused by disease morbidity (disability, sick leave, early retirement) and/or premature death from the disease.

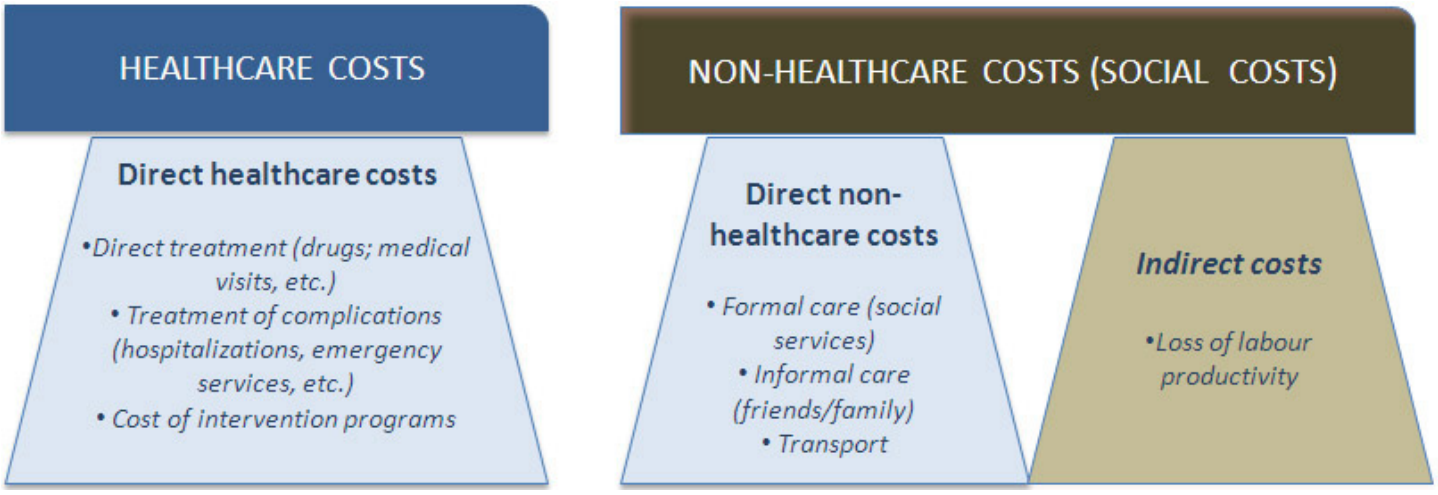

Chart 1. Economic burden of disease

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To establish the actual financial burden of DM on society, it may be necessary to distinguish between the costs of DM and the costs of people with DM. In the first case, we would consider only the healthcare and social costs directly attributable to DM and the complications related to the disease. But there are other healthcare and social costs. These indirect costs of disease are recognised as being more difficult to identify and measure. This is the case for costs created by other health problems that have a link to DM (e.g., vascular problems). Furthermore, DM can lead to longer hospitalization times in individuals who have the disease but were hospitalized for a non-associated health problem.

Some studies have attempted to measure these three types of direct healthcare costs and obtained the following results: 23% of the costs were attributable to direct treatment of DM and 50% to treatment of complications. The remaining 27% were identified as resource used to treat excess medical costs incurred by healthcare services in the treatment of comorbidities associated with diabetes[3].

The American Diabetes Association estimated that in the US the total cost of DM in 2007 was $174 billion ($245 billion in 2012), with direct healthcare costs standing for two thirds of the total costs and indirect costs for the remaining one third[3]. Other studies found differences in the figures for indirect costs among European countries (24% of the total diabetes costs in Norway[4], 30% in Spain[5]; 59% in the UK[6]). In other areas, including the evaluation of formal and informal care of people with DM, there is much less information available, especially when compared with other diabetes-related conditions such as stroke or ischemic heart attacks.

Several studies attempted to estimate the global economic burden of DM, but obtained very different results. This high variability was most likely a consequence of several influencing factors including epidemiological differences between countries, efficiency in the development of the different health systems, marked differences between unitary prices of medicines and use of resources, and methodological differences between studies.

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In this context, we believe that the MID-Frail Study set an ambitious objective: to measure and value direct healthcare costs of people with DM, as well as costs related to formal and informal care. Our analysis will take place on data from subjects on both the intervention and control arms of the study. This initiative is the first that aims to determine economic costs related to elderly pre-frail and frail people with DM across the European Union following the exact same methodology. This will undoubtedly facilitate future comparisons.

In order for anyone to be able to estimate the real global burden of DM, it is essential to identify and accurately measure every single resource expenditure (healthcare, social service or informal care). Substantial differences exist among the healthcare systems, the long-term care programs, and the role played by the family as care providers in the countries included in this project.[7] Therefore, one of our major challenges will be to capture a thorough picture of health and social resource expenditure associated with the treatment and care of the study subjects for each of the participant countries. It will only be possible to achieve this if each of the countries involved in the MID-Frail study provides precise, detailed and up-to-date information on resource use, unit costs and treatment pathways.

Without any doubt, the complexity of the challenge suggests that this task will not be easy. However, the potential of the results that can be obtained, both in scientific and social terms, make the effort worthwhile. The MID-Frail study setting provides the unique situation where this may be possible.

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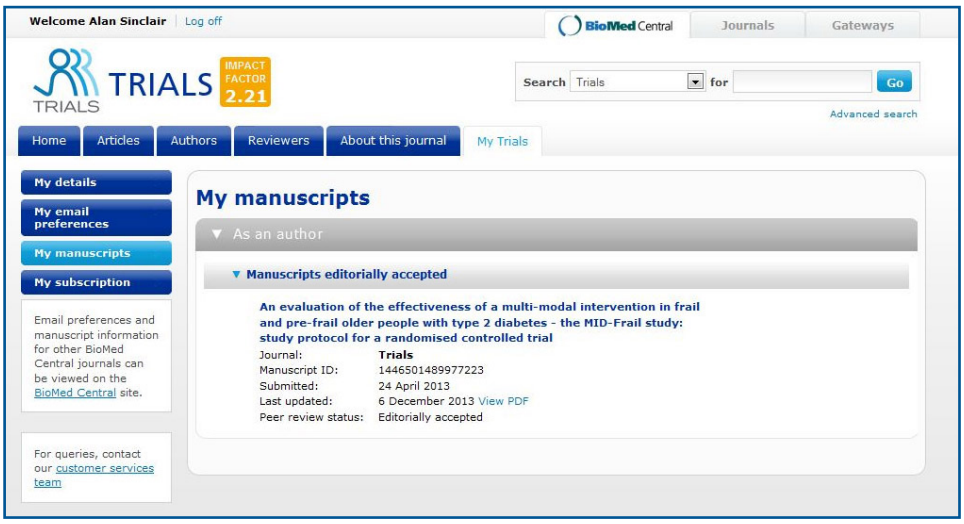
The Protocol Manuscript

We are very pleased to announce that the manuscript describing the rationale behind the MID-Frail study and its methodology (the protocol manuscript) has been accepted for publication by Trials.

The manuscript is entitled "An evaluation of the effectiveness of a multi-modal intervention in frail and pre-frail older people with type 2 diabetes – the MID-Frail study: study protocol for a randomised controlled trial" and will be published in the next couple of months. We would hope that you would all agree that this represents another MID-Frail milestone that has been achieved. Once published, this manuscript will contribute significantly to the dissemination of the study within the medical/scientific community. We encourage you to tell as many people as possible about the publication. It is also the case that the protocol manuscript will be an important reference for any future MID-Frail-related publications. Well done to the team!



Isabelle Bourdel-Marchasson (Université Bordeaux Segalen) will also be displaying a poster on our study at the Société Francophone du Diabète in March 2014, and will be giving an presentation on MID-Frail at the 10ème Congrès International Francophone de Gérontologie et Gériatrie in May.

We will take this opportunity to remind you that we are keen to help you with any other MID-Frail publications and/or presentations you may be planning. Also, please let us know every time you present the study at a congress/conference and send us a copy of the abstract/poster/oral presentation you did. We need to keep track of every single study-related communication but we will not be able to do this without your help. Thank you.

KEEP UP TO DATE

Keep up to date on all that is happening in MID-Frail: watch out for the next regular issue of MID-Frail News.

Website: **www.midfrail-study.org** Facebook: **MID-Frail Clinical Study**

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