Reviewer's report

Title: The use of risk sharing tools for post adoption surveillance of a non-pharmacological technology in routine practice: results from a one year experience

Version: 4 Date: 1 August 2012

Reviewer: I?aki Gutierrez

Major Compulsory Revisions

The authors are unable to explain how they have been able to measure feasibility of the schemes used. They haven't analysed the costs of implementing the action, the resources needed to perform similar schemes in other context or even in their context and the way they have reached to the conclusion that the scheme is feasible to be applied. Would it be necessary to have funds to perform the analysis? What are the needs to implement the surveillance system? How this could interact with routine practice.

The introduction of the article is not totally acceptable. The authors admit the technology assessed and used for the SRCs is a probed technology in clinical practice and supported with high quality evidence RCTs. They also included the citation of one Cochrane systematic review (SR) to support their statement. The conclusions of that SR are not totally alligned with the statement of the introduction. In fact the SR conclude that there is a need to probe external validity of the technology:

"NRT appears to be a safe and effective intervention for the treatment of chronic non-specific LBP. The efficacy is less clear for sub-acute LBP. However, these results are limited to three trials conducted by a small number of specifically trained and experienced clinicians, in a limited geographical location. No data are available on the ease and time-frame needed to achieve that level of expertise. RCTs by other practitioners, in other locations, that replicate the effects reported in this review are needed before recommending a broader practice."

The authors should modify the introduction accordingly and alligned with the conclusions of the systematic review.

The authors also included in the introduction that the European clinical guidelines recommend the use of NRT in Low Back Pain (LBP). This reviewer has performed a research on the Spanish National Clearing House and the International Guidelines Clearing House (NGC) and no other guideline recommend this technology in routine practice for LBP. It has also needed to be
said that the European Guideline on LBP was published in 2006. No updated
guideline is available. According to this, this reviewer recommends that they
should carefully take into account that they could not include this statement in the
introduction. In fact, Guideline producers do not consider guidelines that are
older than 3 years without updating or in updating process.

American or other European evidence based guidelines do not consider even
NRT in their recommendations on LBP.

The authors should also bring to the audience in a paragraph both in discussion
and introduction the different existing regulatory frameworks for drugs and
devices/procedures in Europe that justifies the need for SRC and coverage with
evidence schemes. It is more important in our context than in other nations in the
worlds such as USA or Australia where regulatory frameworks are more tight and
the implementation of devices and procedures in routine practice is much more
difficult.

The authors should discuss how they have reached to the standards used in the
SRC. The process is of high interest for the audience and even more important
than even the results, because this is one of the first reported experiences in
SRC on medical devices in the world. It is so important to define who establish
the standards, how the process was, who define the levels to be reached,...
What was the role of the Balearic Island Health Service?

It has been recently published in Spain with the active participation of all the
Spanish HTA agencies, a document on how and when post-introduction
observation of health technologies should be established. They haven't included
this in the introduction not even discussed in the discussion section. This
document will be used as a methodological framework for SRC by the Spanish
Ministry of Health.

Varela Lema L, Ruano Ravina A, Cerdá Mota T, Blasco Amaro JA, Gutiérrez
Ibarluzea I, Ibargoien Roteta N, et al. Post-introduction Observation of Health
Technologies. A methodological guideline. Abridged version. Quality Plan for the
HTA Reports: avalia-t No. 2007/02.

Available in: http://www.sergas.es/docs/Avalia-t/Post-introObs.pdf

The discussion is poor in general and focused on the research performed by the
group. It should diminish the number of autocitations and include and discuss
articles as those proposed below or some others available in general databases:

Walker S, Sculpher M, Claxton K, Palmer S. Coverage with evidence
development, only in research, risk sharing, or patient access scheme? A

Pre-coverage assessments of new hospital interventions on austria: methodology


The authors include in the abstract and the methods that the study is a prospective cohort evaluation. They should include that it is a prospective cohort evaluation without comparison group, so it is in reality a pre-post prospective case series study.

The authors should include how they have reached to define subacute, chronic and extremely chronic pain and why they have grouped the results of local pain in Table 2a for NP, TP and LBP. In other LBP guidelines the definition of acute, subacute and chronic pain are different.

It is also of interest to the audience how the clauses of the contract and the prices were established.

Minor Essential Revisions

Table 2b column on proportion of patients... should be deleted because it doesn't include further interesting data. Authors should consider deleting Tables 2b and 2c because the information is already on the results section.

The authors should consider reducing the number of autocitation, in some cases the cite didn't support the piece of information included in the text.

The authors should also discussed why Quality of Life validated scales weren't used to analyse the effectiveness of the technology and included in the Contract agreement, on the other hand the authors use a well described and validated scale for the measurement of disability as it is the Roland-Morris questionnaire. But they did not discuss why they didn’t use another validated scale to measure disability as it is the Oswestry Dissably Questionnaire that has a Spanish Version.

Taking into account that it is a surgical procedure, they should also discuss the number of adverse events reported (up to 4.2%).

Second paragraph of discussion section:

The authors state that through RCT data on effectiveness could be obtained. This statement should be change to data on efficacy. Data on effectiveness are
obtained in real practice.

The authors should discuss not only the internal validity of this study but the feasibility and external validity of similar schemes.

Discretionary Revisions

The authors establish that the units and the professionals were certified following professional standards by the Spanish Association of NR. The external validity of this certifications is lacking because, it is provided at the Spanish context and it is not recognized as an official certification by the Spanish Ministry of Health. The authors should clarify briefly this point. It is true that the process of certification is well established and according to professional standards, nevertheless the audience should be aware of it.

Taking into account that it is an observational study, the way biases have been tried to be avoided should be discussed in depth.

Some English expressions should be edited by a native English speaker.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests'