Reviewer’s report

Title: The association between improved quality diabetes indicators, health outcomes and costs: towards constructing a “business case” for quality of diabetes care- a time series study.

Version: 1 Date: 24 July 2014

Reviewer: Sima Djalali

Reviewer’s report:

Overall impression of the study:

The objective of the study is clearly defined. However, the discussion and conclusions drawn from the results as well as title and abstract do not fit well to the objective.

Declared objectives of the study are:

1) investigation of the relationship between improvement in selected measures of diabetes (type 2) care and patients’ health outcomes
2) to estimate the effect of improved performance on direct medical cost.

Providing the base for a “business case” is not a declared objective of the paper and the introduction does not allude to any potential business case.

Moreover, the results are to insufficient to be used for serious business case development. Business case development in health care is very complex, but the present study provides nothing but a single estimate of potential cost savings. It is an exaggeration to state that the "result (...) is a preliminary pivotal for proving such a business case" (Discussion section, paragraph 12).

Nevertheless, title and abstract of the paper take up this issue and suggest that a business case has been developed and that important conclusions for international health care systems other than the MHS system could be derived. The latter suggestion relies on a single phrase of the conclusion-section of the paper, saying: “In health care systems with relatively low member turnover, this finding presents an important milestone linking quality and cost, helping to construct the business case approach to quality”. It is not defined in any way what a “health care systems with relatively low member turnover” is and why the results of the present study should be representative of these systems and not of others. The conclusion section and the abstract suggest that the findings of the study are generalizable but this conclusion is without any foundation.

In sum, the conclusions are not adequately supported by the data.

The data themselves are another issue: Superficial, fragmentary and misleading descriptions of the methods and results make evaluations of their soundness and appropriateness of measures difficult.

Even though the “Methods” section is well structured (Setting, Focus of analysis,
Study population, Data source, Quality indicator Definitions, Statistical Analysis), methods are not well described and many questions arise:

- The calculation of cost savings was obviously based on a price list published by the Israeli Ministry of Health. The price list is neither referenced nor described in detail. What kinds of cost (direct cost, indirect cost…) were actually included in order to determine the costs of a hospitalization day? How much was a hospitalization day assumed to be? Did prices change during the observation period or were they assumed to be stable?
- What led to the expectation that improved control in 2009 had an effect on hospitalization at least until 2012?
- In order to estimate the effect on death “data on death event from the years 2010-2012 were added” (Statistical analysis, paragraph 3). Where were these data taken from?
- Some statistical tests are obviously used, but not described in the “Methods” section. For instance, Table 2 presents results of “linear regression models for curve fit”, but such models are not described in the “Methods” section.
- Why a Poisson regression model is used in addition to GEE models?
- What is meant with “Global and Dynamic GEE models”?
- The description of statistical methods is not consistent with the description of the results. For instance, the “Methods” section enumerates three different statistical methods that were used: Poisson regression, global GEE models and dynamic GEE models. However, the text of the “Results” section describes no results of the Poisson regression. Only table 3 presents results of the Poisson regression, but the text referring to table 3 describes results of the global GEE model.

Concerning the description of results, further questions arise:

- According to the methods section, patients who were diagnosed during the study period were included. This raises the question concerning the mean period of observation of patients. This important information about the study population’s baseline characteristics is lacking.
- A description of the outcome variables’ distribution is lacking. How many hospitalization days/ED visits were counted per year in total and in average per patient? How were outliers handled? How many death events were counted?
- Models for HBA1c testing and ED visits did not reach statistical significance, but the respective results of statistical analysis are not displayed.

Some limitations of the study are stated. However, linguistic problems impair comprehensibility.

- “(3) One can argue that improved health outcomes and reduced cost result from other factors, such as diabetes co-morbidities, such as cardiovascular disease and personal characteristics and life-style. MHS internal data shows that from 2003 to 2009, the proportion of adult members with any cardiovascular disease
It is not clear how diabetes co-morbidities should improve outcomes. Maybe the authors mean “the treatment of co-morbidities”? The proportion of adults with any cardiovascular disease is not interesting, given the fact that cardiovascular disease is a chronic condition. Provided that the number of patients in the MHS Diabetes registry has been more or less stable (actually we cannot know that, because the authors don’t provide any information about that), the number of patients with cardiovascular co-morbidities will always be stable, too. What’s interesting, is the question whether patients are (successfully) treated for their co-morbidities or not?

• “(4) with the lack of a control group, the effect of the improvement in the quality indicators on outcomes and cost could be measured.” (Discussion section, paragraph 15)

If it could be validly measured without control group, why should someone demand a control group? Or could it NOT be measured? If it could not be measured, all the results of the study must be questioned.

Major Compulsory Revisions:
1) Resolve inconsistencies between objectives, discussion and conclusions; either drop the “Business Case” subject and reframe discussion and conclusions or point out:
   - the clear definition of the terms “Business Case” and “Health system with low enrollee turnover”
   - which stakeholders of a health system would benefit from such a “Business Case”
   - what else besides the results of the study, would be necessary to develop such a “Business Case”
   - why and under which circumstances the results of the study are generalizable

2) Adapt abstract and title according to 1)

3) Reference and describe the price list of the Israeli Ministry of Health in detail. Point out:
   - What kinds of cost (direct cost, indirect cost…) were included in order to determine the costs of a hospitalization day?
   - How much was a hospitalization day?
   - Did prices change during the observation period?

4) Point out what led to the expectation that improved HbA1c control in 2009 had an effect on hospitalization at least until 2012

5) Where were data on death events between 2010 and 2012 taken from?

6) Add a complete description of all statistical analyses used in this study to the
Method section.

7) Point out why Poisson regression model was used in addition to GEE models.

8) Define what is meant with “Global and Dynamic GEE models” and why they were used.

9) Resolve inconsistencies between text (Results section paragraph 3) and contents of Table 3.

10) Add a description of the period of observation per patient to the description of the study population’s baseline characteristics (at least mean/standard deviation).

11) Describe the distribution of outcome variables, at least:
- How many hospitalization days/ED visits were counted per year in total and in average per patient?
- How were outliers handled?
- How many death events were counted?

12) Display results of statistical analyses concerning HbA1c testing and ED visits.

13) State more precisely what is meant by “One can argue that improved health outcomes and reduced cost result from other factors, such as diabetes co-morbidities, such as cardiovascular disease and personal characteristics and life-style. MHS internal data shows that from 2003 to 2009, the proportion of adult members with any cardiovascular disease has been stable.” (Discussion section, paragraph 15)

14) State more precisely what is meant by “with the lack of a control group, the effect of the improvement in the quality indicators on outcomes and cost could be measured.” (Discussion section, paragraph 15)

Minor Essential Revisions:

1) Table 3): Add explanation of the abbreviation S.E. (standard error)
2) Table 6): Add explanation of the abbreviation NIS (New Israeli Shequel)
3) Check orthography: “The quality of health care has drawn increasing attention form health care systems during the last two decades” (Background section, paragraph 1)
4) Check grammar: “In 2004, MHS implemented a "Performance Measurement System" (PMS) that help focus the organization’s attention on selected clinical domains including diabetes care.” (Background section, paragraph 3)
5) Decide whether to use “data” as singular or plural word and use it consistently: “For this task data on death event from the years 2010-2012 were added.” (Statistical Analysis section, paragraph 4); “Although data on hospitalizations specifically related to diabetes are not
available, crude national figures indicate a steady increase in hospitalization days between 2000 and 2010 (22).” (Discussion section, paragraph 6);

“Data from the United Kingdom has shown that the mortality risk among patients with type 2 diabetes is 1.6 times higher than that of the general population (24).” (Discussion section, paragraph 9);

“MHS internal data shows that from 2003 to 2009, the proportion of adult members with any cardiovascular disease has been stable.” (Discussion section, paragraph 15);

6) Avoid using abbreviations of verbs (can’t instead of cannot):

“hence, the data can’t be appropriately used to substantiate returns on investments in quality.” (Discussion section, paragraph 15)

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests