Author's response to reviews

Title: CoDiab-VD: protocol of a prospective population-based cohort study on diabetes care in Switzerland

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Author's response to reviews: see over
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Dear Dr Morrey,

We thank you for the opportunity to submit a revised manuscript to BMC Health Services Research (MS: 6424121291200885). We have carefully examined the comments made by the reviewer. We addressed them point-by-point, fully with responses and changes in the manuscript as detailed in the accompanying text.

We believe that the changes we have made based on the reviewer’s comments have greatly improved the quality of our manuscript.

We thank you again for your suggestions and consideration of this resubmission.

Sincerely yours,

Emilie Zürcher, PhD
A. Editorial Request

1. CONSORT checklist

*Please include your completed CONSORT checklist as an additional file.*

Please find enclosed as an additional file an up-to-date version of the CONSORT checklist.

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B. Reviewer 1 (Miranda Schram)

**Major Compulsory Revisions**

1. *In the method section, the description of the extensive patients’ questionnaire is not well structured. Could the authors find a way to structure and clarify this section, as they did for example in the description of the treating physicians’ questionnaire? We would advise to allocate section headings to the different areas they identified. Moreover, the comprehensive description of answer categories could be moved to the supplemental materials.*

We have modified the patients’ questionnaire section to clarify and simplify the information. As suggested by the reviewer, the description of answer categories was deleted from the text and moved in a table (Additional file 1). In addition, Table 1 was slightly modified in order to follow the order of the presentation of this section’s elements.

The Patients questionnaire section now reads as follows (modified parts are underlined):

**“Patients’ questionnaire**

The baseline questionnaire was designed to encompass several aspects of disease, care and life of people living with diabetes. It targeted the following areas: diabetes status, diabetes management and quality of care, health-related quality of life (HRQoL) and quality of life (QoL), health services utilisation, health status and health habits, self-management activities and support, socio-demographics. An overview of all variables collected is shown in Table 1, and a comprehensive description of corresponding questionnaires and answer categories is provided in the Additional file 1.

**Selection of indicators**

(...)

**Primary outcomes: processes and outcomes quality of care indicators**

We considered as primary outcomes all usually recommended diabetes processes-of-care indicators, as well as the following outcomes of care indicators: HbA1C levels, as an intermediary outcome associated with future development of diabetes complications [12-14], HRQoL and QoL as measured using a generic tool (SF-12) [15] and a diabetes-specific quality-of-life tool (Audit of Diabetes-Dependent Quality of Life 19 – ADDQoL) [16], and patient assessment of chronic care, i.e. how care is congruent with the Chronic Care Model (PACIC) [17, 18].
Exposure variables

In the 2012 baseline questionnaire, we also added a small number of questions regarding knowledge and participation in the few activities proposed that year by the PcD. These questions were only asked to patients recruited in 2012 in order to describe possible differences in terms of exposition to, and awareness of, the PcD because patients were recruited over two different time periods.

Other variables of interest

The other variables of interest considered in the baseline questionnaire are briefly described thereafter; more details are provided in Table 1 and Additional file 1.

- Diabetes characteristics and related complications;
- Medication adherence using the Morisky medication adherence questionnaire [19];
- Healthcare utilisation within the past 12 months: ambulatory care visits, emergency visits, hospitalisation, home care services, domestic home support;
- Care foregone because of costs;
- Health status and health habits: anthropometric measures (weight and height allowing the calculation of the body mass index (BMI)), smoking status, alcohol consumption using the AUDIT-C questionnaire [20], levels of physical activity using questions from the Swiss Health Survey [21], depression screening using two validated questions [22] and comorbidities;
- Self-management activities and support measures: home glucose self-monitoring, HbA1C knowledge, participation in diabetes education classes, membership of the local diabetes association (Association Vaudoise du Diabète – AVD), knowledge of the “Diabetes Passport” (a small booklet with data, information and reminders) and if it was known, whether it was used;
- “Self-efficacy” measure, which was developed de novo because available instruments were either not appropriate from our point of view, or too long or did not have a French version. We were interested in exploring how easy/difficult it was for patients to manage their diabetes, overall, and also specifically regarding the daily management of physical activity, medication and diet;
- Level and source of information about diabetes;
- Support and satisfaction from the healthcare team or from the members of the social network, if any;
- Overall satisfaction with current care and care recommendation to others;
- Patients’ socio-demographic characteristics: age, gender, nationality, place of residence, marital status, family size, education, employment, household income and insurance status.”

2. The authors describe their study as a population-based cohort study. However, participation rates are low, out of the 1341 patients that were eligible for participation in 2011 and 2012, 519 patients participated in the study. Finally, patients data from the physician was available for 271 patients, which is 20.2% of the eligible patients. This raises serious questions whether this sample is population based, and whether the results of the study are generalizable to the average patient with diabetes living in the canton of Vaud.

Even if the final sample of participating patients appears “low” compared to the estimated number of eligible patients, it remains within ranges of participation to similar studies/surveys. In addition, the comparison of a few common variables of the participants included in our cohort study and of patients with diabetes included in a population-based study performed in the same canton/region, did not differ significantly. Finally, participating pharmacies were located throughout the canton and recruited patients from different geographical areas. We are therefore confident that our sample is representative of the targeted population and that the results are generalizable to patients fulfilling our inclusion/exclusion criteria and willing to participate in a study/survey.
3. **The authors state that recruitment through community pharmacies results in a sample of patients that is probably more representative. However, characteristics of non-participants were not available. Therefore, it is difficult to make statements about representativeness of the sample. We would advise the authors to collect this information, or elaborate on the limitation the lack of this information means.**

Since comments 2) and 3) are related, please read below and see also response to previous comment 2).

It was not possible to consider asking pharmacists to collect information about non-participants because of time and organisation constraints, and this information could not be collected afterwards because contact details were not collected for the same reasons. Therefore to verify the representativeness of our sample of patients, we compared a few characteristics of the participants with those of another population-based study conducted in the same region, and found that both samples had close characteristics.

We have modified the discussion paragraph referring to the representativeness of the population as follows (modified sections are underlined):

“One of our study design’s strength is the recruitment through community pharmacies [11], which allowed us to obtain a sample probably more representative of the population of patients with diabetes than a recruitment through medical practices or hospitals. In fact, we hypothesized that this method would limit the selection of patients on the basis of the level of care received, this information not being available to pharmacists. However, this hypothesis could not be confirmed by a comparison of participants’ and non-participants’ characteristics because data on non-participants could not be collected. Elements in favour of an acceptable representativeness are the fact that our study participants did not differ significantly from participants with diabetes of another population-based study conducted in the same region, regarding a few common characteristics (age, gender, education, smoking status, BMI) (P. Marques-Vidal, personal communication). The minor differences probably stemmed from the fact that the population of the latter cohort were limited to a narrower age range (35-75). Another positive aspect of the cohort CoDiab-VD is the fact that we collected at baseline, and plan to collect in the future, a broad range of quality indicators that include not only commonly considered processes-of-care but also a variety of patient-reported outcomes. In fact, the latter encompass different aspects of diabetes and diabetes care that are important to patients but nevertheless often neglected despite the fact that they represent important measures to take into account when wishing to capture the complexity of the quality of diabetes care [24-26].”

**Minor Essential Revisions**

4. **Methods, last sentence of the sixth paragraph; “Twelve patients with diabetes pre-tested the questionnaire.” – Could the authors elaborate on what happened with this pre-test?**

In order to clarify this point we wrote a distinct section for the pretest, which reads as follows:

“**Pretest of the questionnaire**

Before the recruitment, we pretested the questionnaire among 12 patients with diabetes to ensure the understanding and acceptability of the instructions and of the questions, as well as to measure the completion time of the questionnaire as a whole.”
5. Methods, eighth paragraph: Description of the development of the follow-up questionnaires; the process of development is not clear.

We have clarified this paragraph, which now reads as follows:

“Follow-up

Follow-up process

(...)

Because of time constraints and overall limited participation to research projects, treating physicians will be contacted every two years only.

Follow-up questionnaires

The core of the follow-up patients’ questionnaires will be similar to the baseline questionnaire, particularly with regard to the questions targeting primary outcomes, healthcare utilisation, health status and health habits as well as to the questions assessing knowledge and participation to PcD projects. According to the needs and specific interests of the PcD, new questions or thematic modules will be added to the follow-up questionnaires. In 2013 for example, a module on diabetic foot, as well as the Stanford self efficacy questionnaire and a health literacy question were added. In order to keep a questionnaire of a reasonable length, questions representing variables other than primary outcomes may be removed momentarily from the follow-up questionnaire.

The physicians’ questionnaire will be similar to the baseline one.”

6. Discussion; “The number of patients recruited is below the sample size calculated.” We would like the authors to clarify and calculate whether the number of participants is still large enough to detect an absolute change of HbA1C of 0.5%.

The current sample size (n=519 at baseline) is largely enough to detect an absolute change of HbA1C of 0.5% (power above 99%). The text has been modified accordingly.

“The cohort CoDiab-VD is, however, subject to several limitations. First, the number of patients recruited is below the sample size calculated (inclusion of 519 participants instead of the planned 600). However, because of a greater number of clusters (pharmacies) than expected and a conservative sample size calculation, the precision around point estimates was nevertheless acceptable. This sample size is also large enough (power > 90%) to detect an absolute change of HbA1C of 0.5%, a PCS or MCS change of 5 points, a PACIC change of 0.3, or an absolute change of process of care of 10%.”