Author's response to reviews

Title: Glucose testing and insufficient follow-up of abnormal results: a cohort study

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

Thank you very much for your thoughtful review of our study, entitled “Glucose testing and recognition of incident diabetes: a cohort study” (MS #1981819568982438). Below please find the comments of your reviewers and our responses.

REVIEWER #1:

General comments:

1. The authors find that only a small part of abnormal (diabetic) values actually were taken action on. This is very new for me, and I think that this result should be more focused at in the title, as well as in the discussion. For example, a discussion about reasons for lacking follow-up will be very interesting.

The title has been changed to “Glucose testing and insufficient follow-up of abnormal results: a cohort study.”

We also added a discussion about potential reasons for lacking follow-up (page 12):
“...There are several reasons why physicians may not act upon abnormal values: they may not have seen the values, may not have recognized their importance, or may have been giving their attention to competing demands. Indeed, a study that surveyed physicians about test result management in general found that only 52% of respondents reported keeping a record of tests that they had ordered and 83% acknowledged delays in recognizing and acting upon abnormal results, saying that they had reviewed at least 1 test result in the last 2 months that they “wished they had seen earlier” [17].

Major compulsory revisions:

2. One major task for the authors will be to give a more detailed description of the target population, and the flow of persons selected and excluded. It is by now very hard to understand from which population the 621 reviewed medical records come from.
We revised our methods and results sections to make our sampling strategy clearer. In doing so, we also present our sample size and power calculation to show why reviewing 621 medical records was needed.

The revised methods read: “We generated electronically a list of patients who had an initial visit in 1999 with a full-time attending physician (i.e. one who spent ≥80% effort on patient care per week). The rationale for restricting our sample to those with initial, or first, visits was that initial visits often have more complete data for diabetes risk factors, including family history. The alternative approach of tracing existing patients back to their initial visits was considered less feasible (due to transitions from paper to electronic medical records) and more prone to errors in data collection. We randomly sampled from the list of initial visits and reviewed medical records until we found at least 300 patients who met our inclusion criteria: we required that patients have at least 2 additional visits by the end of 2002, and we excluded patients who were younger than 20 years of age, had known diabetes at the initial visit, or were pregnant at any time during the study period. Our target sample size, based on a prior study of self-reported diabetes screening [5], provided 80% power to determine a 15% absolute difference between the rate of glucose testing among patients with 0-1 risk factors and the rate of glucose testing among patients with 2 or more risk factors [9]” (page 4).

The revised results read: “Our electronic search identified 3543 patients as having initial visits in 1999 with full-time attending physicians. We reviewed medical records for 621 (18%) of these patients, in order to find 301 who met criteria for inclusion. The other 320 (52%) were excluded for the following reasons: did not actually have an initial visit in 1999 (n = 27), did not have 2 additional visits before the end of 2002 (n = 250), age under 20 years (n = 7), known diabetes at the initial visit (n = 19), pregnancy (n = 10) and missing medical records (n = 7)” (page 8).

3. **What does “initial visit” mean? It is used twice in the patient characteristics paragraph, in a way that makes the selection procedure not transferable. The possibility of selection bias has as well to be discussed.**

An initial visit is the first visit a patient makes to the practice. We revised our methods both to define an “initial visit” and to provide the rationale for focusing on it: “The rationale for restricting our sample to those with initial, or first, visits was that initial visits often have more complete data for diabetes risk factors, including family history. The alternative approach of tracing existing patients back to their initial visits was considered less feasible (due to transitions from paper to electronic medical records) and more prone to errors in data collection” (page 4).

We also acknowledge the possible selection bias in the discussion section: “Fifth, patients who came for initial visits in 1999 may vary from patients who only came for subsequent visits that year” (page 13).

4. **It would be useful to know the distribution of number of glucose tests per patient. Normally, this kind of distribution is not normal but skewed against zero. It can be**
questioned if the chosen logistic regression method is the most appropriate in a situation with a non-normal distribution.

We added more information about the distribution of tests per patient to the results section: “The number of tests per patient ranged from 0 to 10, with a mean of 1.9 tests (median 2 tests) per patient” (page 9).

Our rationale for dichotomizing testing (0 tests vs. ≥1 test) was that we were interested in the clinical question of determining which patient characteristics were associated with getting tested (or not). This clinical question was one of the objectives of the research and did not depend on the underlying distribution of the testing variable. In order to make this clearer, we changed “glucose testing” to “any glucose testing” in the statement of our secondary objectives: “Our secondary objectives were to determine which patient characteristics are associated with any glucose testing and to determine whether the practice patterns observed resemble national guidelines” (page 3).

Discretionary revisions

5. Concerning the title I find that it could be catchier, by focusing at the insufficient follow-up of abnormal glucose values. If the authors chose to change the main object of the manuscript, the abstract has to follow this.

As above, the title has been changed to “Glucose testing and insufficient follow-up of abnormal results: a cohort study.”

We modified the background section of the abstract for consistency: “Our objectives were to measure the rate, the predictors and the results of glucose testing in primary care, including rates of follow-up for abnormal values.” The rest of the abstract and manuscript already cover both glucose testing and rates of follow-up for abnormal results.

REVIEWER #2:

Major compulsory revisions:

1. The study was based on 301 patients, which had together contact to 19 different primary care physicians. Only 57% saw their own primary care physician for every visit. The 19 physicians may be different with respect to their interest in diabetes screening and their individual emphasis on follow-up of routine lab tests. The authors adjusted for continuity of physician care in multivariate models (OR 1.4; 95% CI 0.7-2.8). However, it would be interesting to see if results for follow-up of glucose tests are different when restricting to all patients with continuous follow-up by the same physician.
We added the suggested sensitivity analysis to the methods section: “When calculating rates of follow-up for abnormal values, we conducted a sensitivity analysis to assess the effect of continuity, restricting the sample to only those who had all visits with the same physician.” (page 6). We then provide the results in the results section: “Patients were more likely to have some follow-up action for a glucose value ≥110 mg/dl if every visit was with the patient’s primary care physician (69% follow-up rate) than if at least 1 visit was with a covering physician (14% follow-up rate; p=0.02)” (pages 9-10). We also comment on the potential implications of this in the discussion: “That follow-up rates were higher for patients who had all visits with the same primary care physician is intriguing but based on a relatively small sample size and warrants replication in larger studies” (page 12).

2. The vast majority of glucose tests (90%) were part of the routine lab investigation in new patients. The authors reported that physicians documented in only 3% that patients were fasting. Given that 97% were non-fasting (random) blood glucose values, other cut-offs should be used, as recommended by the ADA (e.g. diabetes: equal or above 200 mg/dl).

To clarify, the ADA defines diabetes as a fasting plasma glucose ≥126 mg/dl if the patient is asymptomatic and a random plasma glucose ≥200 mg/dl if the patient has symptoms of diabetes (polyuria or polydipsia). Thus, 200 mg/dl is not an ADA cutoff for asymptomatic patients. We specifically list when patients were reported to have polyuria or polydipsia and separate them from our calculations of rates of follow-up for abnormal values among asymptomatic patients (pages 9).

We also revised our methods section to include our rationale for considering glucose values <200 be potentially abnormal: “If glucose values were random or were not documented as fasting, we still considered values in these ranges to be potentially abnormal, because they should trigger repeat testing to confirm that a patient’s fasting values are in the normal range.” (page 6).

Minor essential revisions:

3. Socioeconomic factors are known to have an impact on the prevalence of (undiagnosed) diabetes and on health care use. Therefore, a more detailed description of the practice background population should be given. Readers outside the U.S. may not know if a proportion of 41% patients of minority ethnicity is above the American average or not.

We added to the discussion the proportion of ethnic minorities in the U.S. overall: “We included an ethnically diverse patient population, with a proportion of ethnic minorities (41%) similar to that in the U.S. overall (37%) [18]” (page 13).

4. The authors should comment on the validity of the exclusion criteria “patients with known diabetes.” Obviously, this was based on the initial visit only. Is it
conceivable, that a prevalent diabetes may not have been recorded at the first visit in a substantial number of patients?

We added this potential limitation to the discussion: “Sixth, it is possible that some patients with known diabetes did not report their condition at the initial visit, although this is unlikely because only 1 patient was diagnosed with diabetes – based on an abnormal glucose – after the initial visit; most patients diagnosed with diabetes were diagnosed after subsequent visits” (page 13).

5. **There was no continuity criteria for subsequent visits except that patients should have at least 2 other visits by the end of 2002. Thus, in an extreme situation, a patient may have been seen by the physician in January 1999 and December 2002 only. Is it possible, that patients may have been additionally treated outside the practice (for diabetes) over the study period?**

We specifically looked for any documentation of this, and we added this methodology to the manuscript: “If a primary care physician documented that a patient had been diagnosed with diabetes by an outside physician or during a hospitalization since the last visit, we counted that as a diagnosis and did not require the primary care physician to do further diagnostic testing” (page 5). However, if the primary care physician did not know of the outside diagnosis or did not document it, it would not have been captured by our study. The limitation regarding documentation is in the discussion section: “Finally, as in all studies that examine medical records, some results were dependent on what physicians documented…” (page 13).

**Discretionary revisions:**

6. **The authors stated that patients were followed up for at least 3 years in order to be consistent with the screening interval recommended by the ADA. However, the ADA recommended this diabetes screening interval beginning at age 45 years. The average age in the present study was 40 (SD 14) years.**

There is no consensus on the proper screening interval. The rationale behind the ADA screening interval is their estimate that diabetes is unlikely to develop and cause serious complications within 3 years of a previously negative test result. The ADA also argues that “testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more…risk factors” [2]. We designed the study with a 3-year observation period to maximize the likelihood that we would capture any glucose testing for a patient. We added this additional rationale to the methods section: “Thus, most patients were followed for at least 3 years, a strategy which is consistent with the screening interval recommended by the ADA [2] and which was chosen to maximize the study’s ability to capture glucose testing for patients” (page 5). Note that the regression analyses count patients as being tested if they had 1 or more glucose ordered; we do not over-count patients who were tested more than once.
Thank you for your consideration of this revised manuscript. We look forward to hearing from you.

Sincerely,

Lisa M. Kern, MD, MPH