Reviewer's report

Title: Comparison of two methods for assessing diabetes risk in a pharmacy setting in Australia

Version: 3 Date: 4 September 2014

Reviewer: James Dunbar

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Major Compulsory Revisions

This paper adds some very relevant insights to what is feasible in pharmacy, and the potential of pharmacy screening have a population-level impact. However, there are several methodological issues that need to be resolved and more clearly explained. There are some fundamental uncertainties and ambiguities in its current state.

58 Background

Several background issues appear to be discussed and described in excess length. Consider briefer accounts in this section.

90 It’s important to note that Krass et al did not have access to AUSDRisk at the time of their study. To say that ‘the tick test used in this study was not a comprehensive diabetes risk assessment’ is perhaps misleading, given it was based on NHMRC guidance at the time.

Methods

Can the authors clearly state the trial design? Is this a controlled trial or an observational study?

Please define the criteria for (patient) ‘participants’, it’s not directly stated. From Figure 1, it seems that anybody ‘who registered in the KYN pilot Program’ was included. More detail is required. What was the eligible age range? Did they have to complete a BP check etc?

138 ‘In keeping with Australian clinical guideline recommendations for BP[26] and diabetes (www.diabetesaustralia.com.au/Understanding-Diabetes/Are-You-at-Risk) at the time this study was designed, participants were classified as ‘high risk’ of diabetes if they had an AUSDRISK score (12+) and or RBGT (> 5.6 mmol/l) and or high BP (>140/90mmHg).’

This sentence suggests that a person only could be considered high risk of diabetes on the basis of BP>140/90 mmHg alone. I don’t think it is advocated in either of the references provided, is there an error in this statement? Table 2 definitions suggest this is not what the authors meant.

179 Feasibility of implementation in pharmacy
Details are lacking regarding the interview methods - how many pharmacies were sought, how was sample size determined, and how were pharmacies selected?

186 ‘One member of staff from each pharmacy was interviewed, and depending on time availability, not all questions were asked.’

Please provide further confirmation around the participants – did they have to be pharmacists or pharmacy assistants, have a certain level of involvement with KYN, or did anybody suffice? The interview questions require some level of familiarity with the local implementation. I see in line 284 (results) that respondents were either a pharmacist or pharmacist assistant. Was this a pre-requisite or just how things panned out.

196 ‘The coding was verified independently by two researchers (AH and TP) to ensure the interpretation and meaning of the data was maintained’.

Please clarify if coding of interviews was undertaken by both of these researchers, or undertaken by one and verified by the other. The statement above is somewhat ambiguous. And how was any disagreement reconciled?

Figure 1 – when did you define an AUSDRISK as ‘completed’. Many patients (esp. males aged over 65) would not have to complete the test to know that they had more than 12 points. Is it possible that enough had been done to justify not completing the form, but as screen had been performed. Or did the pharmacists simply record whenever they found an eligible patient?

The authors should clarify if this is a randomised controlled trial or an observational study. You say that pharmacies were randomly allocated to an intervention. However, pharmacies were allowed to switch groups if they liked (and 10 did – Figure 1). Why were they given this option, and why did you not analyse as intention to treat? It is very interesting to note that most pharmacies appear to prefer use of the RBGT and swapping was in this direction. I am concerned the ten swappers might have been particularly enthusiastic participants. This is heightened by the fact that there were 55.5 participants per pharmacy in the RBGT group (3494/63) vs 35.5 (1989/56) registered pharmacy in the BP/AUSDRisk group. It is not truly randomised if the swapping pharmacies are included, and analysis is performed as-treated rather than ITT analysis.

Results
Figure 1 – I think it needs to be indicated either in Figure 1 or in the text how many people in Group 1 and 2 actually received their respective (dual/single) diabetes screening assessments as intended? In line 132 the authors clearly indicate that the Group 1 pharmacies provided BP testing and both risk diabetes risk assessments. In Figure 1, it identified that 38% and 40% received RBGT and AUSDRISK respectively. How many got both tests?

229 ‘Participants attending Group 1 pharmacies were more likely to complete AUSDRISK (40%) than participants attending Group 2 pharmacies (34%, p<0.05).’

I wonder if this statement has the potential to be misleading. There was a higher
proportion of people with diabetes in Group 2 (16% vs 11%) which might explain most or all of this difference. Would it be more appropriate to quote the proportion of eligible participants (i.e. without diabetes) receiving the screen?

234 ‘Overall 1,969 participants without a reported history of diabetes had an AUSDRISK assessment undertaken.’

Why is this total less to the 1385+638 quoted in Figure 1, did some people with diabetes get tested using AUSDRISK?

236 ‘There was a tendency for older people to have higher AUSDRISK scores (p<0.001).’

I wonder if this statement is necessary. Given that age is such a major contributor to the score it would be surprising to find otherwise.

253 ‘Participants attending Group 1 participants’.

Consider rephrasing ‘Participants attending Group 1 pharmacies’.

253 ‘Participants attending Group 1 participants with a high AUSDRISK score were less likely to be recommended to see their general practitioner for further assessment compared to participants attending Group 2 pharmacies (Group 1: 63%, Group 2: 71%, p<0.05).’

Please clarify if these Group 1 participants include all AUSDRISK screenings, or just those AUSDRISK screenings that did not have an additional RBGT.

260 ‘Group 1 pharmacies were less likely to be recommended to see their general practitioner for further assessment (high BP 37%, high AUSDRISK score 37% and high RBGT 34%) if they were at ‘high risk’ of CVD compared to participants attending Group 2 pharmacies (High BP 28%, high AUSDRISK score 29%).’

First – I think you have the wrong numbers in brackets (compared with Table 2) or else the Group 1 rates are higher, referral is more likely in this group. I think it should be 100% minus the numbers in brackets? Second – table two suggests that Group 1 referred 49% overall, compared with 33% overall for group 2. Given your definition of high risk, isn’t this the key statistic for referral rates, not that for individual tests? It is essential that the authors present the referral rates within each group as a proportion of the number with one or more referral criteria. It is worth conducting a statistical test. (Table 2). I find the current statement misleading – Group 1 conducted an extra test and referred more people overall, but the text for the Results ignore this.

267 ‘About one third of participants (369/1,121) were identified at high risk of diabetes (defined as high AUSDRISK and high RBGT).’

Minor note - this definition is at odds with the definition for high risk of diabetes used in the methods (starting on line 138). Please clarify if line 138 is in fact correct.

Discussion

311 ‘The AUSDRISK tool was more acceptable to staff, less costly and resulted in greater numbers of general practitioner referrals.’
See my comments about line 260 above also. The authors need to bear in mind that their design set out to compare one test vs. two, and not AUSDRISK vs RBGT. They have made several inappropriate comparisons to this effect in the results section. Overall, Group 1 had substantially more referrals than Group 2, per pharmacy and overall, cost-effectiveness is a more important consideration than cost – CE has not been established here. Given the increased testing and referral in Group 1 it is even possible that overall program cost per case identification is lower in Group 1 despite RBGT costs. It might be that conducting two tests instead of one, and having more patients, also created a perception of having less time – so the claim that AUSDRISK is more acceptable than RBGT is questionable. Is it possible that it is simply more acceptable than the combined testing.

318 ‘This is the first large study to use the AUSDRISK tool in a pharmacy setting in Australia.’

The Melbourne Diabetes Prevention Study (BMC Public Health 2012, 12:806) has also used pharmacy screening with the AUSDRISK study.

326 ‘Recently, a health promotion program at the Australia India Friendship Fair used the AUSDRISK tool to assess the risk of diabetes in 136 people [32].’

I don’t understand the relevance of this sentence.

357 ‘Even though Group 1 had greater participation, the participants in Group 2 were more likely to be recommended to follow-up with a general practitioner.’

Again, this statement misinterprets the findings. (See line 260 comments). 49% of Group 1 vs 33% of Group 2 were referred, AND there were more patients recruited to Group 1.

I think there are several further limitations that the authors may need to address in their discussion:
- AUSDRISK is perhaps an unreliable outcome measure
- Giving pharmacies the ability to swap groups effectively makes this a non-randomised study
- This study was not designed to differentiate between AUSDRISK and RBGT, but draws very strong conclusions to this effect in its findings.
- There is a low uptake of diabetes risk screening in both groups of pharmacies (<50%) regardless of group, and this is not particularly well explained.
- Pharmacist recommendations are a proxy outcome for actual GP attendance and detection of undiagnosed diabetes, or Life! participation.

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

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
Chief Investigator A - Melbourne Diabetes Prevention Study.
No financial interests.