PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Diabetes and cardiovascular disease risk screening model in community pharmacies in a developing primary healthcare system: feasibility study.
AUTHORS	Alzubaidi, Hamzah; Chandir, Subhash; Hasan, Sanah; McNamara, Kevin; Cox, Rachele; Krass, Ines

VERSION 1 – REVIEW

REVIEWER	David Wright University of East Anglia United Kingdom
REVIEW RETURNED	20-May-2019

GENERAL COMMENTS	This is a nice, well worked and timely with some interesting findings As a feasibility study however I suggest that the focus of the abstract and paper should be more on the feasibility aspects rather than the main findings which are based on a selected sample who may not be representative of such a service over a longer time period. Whilst it is really pleasing to see the content of community pharmacist training provided it would help to have the method of delivery and time taken also stated. It seems that not many patients went to their GP as a result of the pharmacist's recommendations which is a major finding as this represents both a waste of resources and failure to persuade the patient to act on the results. This brings into question the quality of the training with respect to how results and risk are presented. This finding is an important discussion point and should be reflected in the abstract. How was intervention/screening fidelity tested i.e. how do we know whether the pharmacists followed the protocol? What was the dose and reach of the intervention. Within the methods I think that it is important to state clearly what equipment was used for testing BP and HBA1C with stated sensitivity and specificity. The problem with point of care tests is that they do not have the sensitivity and specificity of laboratory based equipment and hence the need to refer to the medical practice for confirmation. How did the community pharmacists calibrate their equipment and was training provided on this?

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	Please state in the method that a researcher followed up patients for feedback. Also state whether the researcher was a pharmacist and if the patient was aware of this when providing feedback. If the community pharmacist did the recruitment and this again may not reflect a real service where patients usually present themselves and therefore some recognition of this in the discussion is required. The selection by a community pharmacist also probably explains the higher rates of identification as I am guessing they were more likely to only approach individuals who were overweight. There is too much focus on the proportions of patients identified with different parameters and comparison between males and females or different age groups (Both of which are largely irrelevant for the purposes of a feasibility study and should be removed). The 95% CIs will be wide on such results and the results are presented such that the reader is expected to assume that they are a good estimate of what would be found from a scaled up service. I am not convinced that this is appropriate from a feasibility study which probably has significant selection bias. The question is whether the service is feasible not how effective is it? At this stage I am more interested in proportion of patients approached and proportion consented and recruitment rate per pharmacy i.e. if I wanted to perform a larger study how long would it take me to reach the required sample size. I would also like to know what the distribution of patients was between chains and multiples. There is nothing in the results to support this statement in the discussion: Several pharmacy and pharmacist-levels factors at selected pharmacies contributed to the success of implementing pharmacist-delivered screening, these include: (i) the necessary infrastructure (such as sufficient/appropriate space) to accommodate the screening service, (ii) motivation of pharmacist to learn about and perform the screening, (iii) high volume and greater variability in clientele. The discussion is very brief and does not consider what has been learned from this study, does not adequately consider strengths and limitations and is too focused on trying to justify what was done rather than what should be done if the service was to be rolled out. The authors have not discussed: 1) Development of the pathway and why this is different to approaches used in different countries 2) Effectiveness of the training 3) The fact that patients have not gone to their Dr even when told to do so and what this means for service efficiency 4) The fact that neither pharmacist or doctor views were obtained 5) The distribution of patients across the different pharmacies, chains and multiples

REVIEWER	Rosa Sicari Institute of Clinical Physiology

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	Italy
REVIEW RETURNED	31-May-2019

GENERAL COMMENTS	The present study was designed to assess the feasibility of a screening model via pharmacies in UAE. The study is interesting because it is conducted in an area where, apparently, there is no attention to an healthy lifestyle. Then, the study is mostly aimed at arising the awareness of the population on this issue. There are several problems in the design of the study that should be addressed. 1. How the questionnaire was administered? Was this a special program? How the sample was selected? Was this done only on a voluntary basis? 2. Who was in charge when the patient should seek physician's advice? 3. There is no measure on how this approach with increase of awareness on a healthy lifestyle is reflected in a change of individual risk factors. 4. The discussion is long and unfocused and should be more focused on the social organization of risk reduction. How to intervene in order to modify risk profile 5. Moreover, there are no data on the outcome of those who sought physician's advice.

REVIEWER	Nicole Lowres Heart Research Institute
REVIEW RETURNED	17-Jun-2019

GENERAL COMMENTS	This paper describes the development and testing of a new cardiovascular risk assessment service for delivery in the United Arab Emirates. The authors describe the development phase well. I have some questions as per below on the assessment and description of feasibility. Feasibility of a screening program should consider the extent to which the protocol was followed, and what were the limiting factors. I think this is important in the context of this paper. The paper has a lot of results/information on describing the CV risk profile of the screened population, which is interesting, but does not entirely reflect on the feasibility of the screening service. 1. Is it correct that over 6 months, across 12 pharmacies only 115 people were screened? This would equate to approximately 1-2 people screened per month in a pharmacy. Or about 10 people per pharmacy over the whole time? The numbers screened should be considered when assessing the feasibility of this service. 1 -2 per month does not seem like a lot of people screened. 2. How much time did it take for the pharmacist to do the screen/ give the lifestyle information? This is also important information to detail in relation to feasibility. Did the pharmacists have to pre book appointments or was it walk-in? 3. The majority of people screened had also seen their treating physician at least 3 times during the year. Were the treating physicians already aware of the CV risk diagnosis? Were they already receiving treatment for this? 4. How many people declined to be screened and what reasons did they give reasons for declining? Again these are factors in relation to feasibility for the program (this could be presented in a flow chart)

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	5. Did the pharmacists report the reasons (barriers) to screening? That is, why they only screened about 1-2 people per month. This will inform feasibility too. 6. Was there a lot of variation in the numbers screened between the different pharmacies? If so were there any factors that seemed to facilitate a better outcome in the pharmacies that screened more people? 7. Only 24.3% sought follow-up with a physician – this seems to suggest that the follow up pathway for participants needs some consideration for improvements. Should be mentioned in the limitations and discussion 8. How could a better follow-up rate be achieved? 9. The discussion and limitations section should explore factors related to Improving numbers screened and follow-up rates Other: 10. United Arab Emirates (UAE) needs to be spelt out in full on first use in abstract and main text 11. Text states 120 screened (plus 5 not eligible) and abstract states 115 screened. If they were not eligible, then the number screened in the text should state 115 – you could add the numbers approached and not eligible and declined screening in a flow chart to better show the feasibility and acceptability of this service

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

1. As a feasibility study however I suggest that the focus of the abstract and paper should be more on the feasibility aspects rather than the main findings which are based on a selected sample who may not be representative of such a service over a longer time period. Whilst it is really pleasing to see the content of community pharmacist training provided it would help to have the method of delivery and time taken also stated.

It seems that not many patients went to their GP as a result of the pharmacist's recommendations which is a major finding as this represents both a waste of resources and failure to persuade the patient to act on the results. This brings into question the quality of the training with respect to how results and risk are presented. This finding is an important discussion point and should be reflected in the abstract.

Authors' response #1: Authors are very grateful for insightful comments of reviewer. His comments helped us focusing the manuscript more on the feasibility and address the question whether the diabetes and CVD risk screening service is feasible rather than how effective is it – please see amended result section. As suggested, the method of training delivery and time taken have been added to the methods – please see line 201 of amended main text (with track changes). The focus of the results in the abstract is now on feasibility data and not on clinical parameters. Study limitation section has been amended and expanded with a detailed description of the following Participant Selection Potential Bias, Generalizability, Follow up with Physicians did not occur and Short follow-up time with Patients, and Factors related to Improving numbers screened and follow-up rates. We think that this research is best to be viewed as an iterative part of gradual system change. As such, we determined that it is feasible to implement a screening intervention that appears to activate patients to seek further management and testing. We did identify that there is no clear primary care system for prevention in operation.

2. How was intervention/screening fidelity tested i.e. how do we know whether the pharmacists followed the protocol? What was the dose and reach of the intervention.

Authors' response #2: We agree with reviewer #1 on importance of implementation fidelity. As suggested, results of measurement of adherence to the intervention (content, coverage, frequency,

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and duration) have been added to the results section. Please see result section lines 321-341 (of amended text with track changes).
We have designed a specific form for pharmacists to complete after each screening with the intention to gather data on the implementation fidelity and measure the degree to which the screening model was delivered in the community pharmacies as intended. For every participant screened, the pharmacists completed a checklist that covered all key aspects of the screening encounter. The checklist included items asking about the timing of screening - whether the screening was done immediately following recruitment or by appointment. In addition, number of visits needed to complete screening, which major test/assessment categories were completed, tests/assessments that were omitted with justification, duration of testing, points covered during counselling based on study protocol, whether participant was referred, and duration of counselling. Most items on the checklist were yes/no or multiple-choice questions and a few open-ended questions were used to allow pharmacists to justify deviations from the protocol (if any). Pharmacists were instructed to complete the checklist immediately following the screening encounter to minimize recall bias.
3. Within the methods I think that it is important to state clearly, what equipment was used for testing BP and HBA1C with stated sensitivity and specificity. The problem with point of care tests is that they do not have the sensitivity and specificity of laboratory based equipment and hence the need to refer to the medical practice for confirmation.
Authors' response #3: We agree with the reviewer and to acknowledge this point, the following paragraph (highlighted in bold) has been added to the method under 'Data collection and risk factor assessment' section, lines 245-247 (of amended text with track changes).

"Pharmacists also reninded at-risk individuals that point-of-care tests may not have the same sensitivity and specificity of laboratory based equipment and hence the need to refer to the medical practice for confirmation."
In addition, below is a detailed description of the accuracy of the POC devices for reviewer kind consideration:
The cobas b 101 is an in vitro diagnostic test system designed to quantitatively determine the % hemoglobin A1c (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) and Lipid panel in human capillary. The system is intended for professional use in a clinical laboratory setting, or point of care (PoC) locations. With the following measurement ranges:
HbA1c:
20 - 130 mmol/mol (IFCC) or 4–14 % (DCCT/NGSP)
Lipid:
CHOL: 50–500 mg/dL or 1.28–12.95 mmol/L
TRIGL: 45–650 mg/dL or 0.50–7.35 mmol/L
HDL-CHOL: 15–100 mg/dL or 0.38–2.60 mmol/L
Authors contacted the manufacture (Roche diagnostics) and asked for a specific information on the sensitivity and specificity of Cobas 101 b dual system cobas 101b. Roche provided the following information on the precision of the device:
"The precision of measuring Hemoglobin A1c was determined using controls in a CLSI EP5-A2 protocol. Whole blood samples were measured using a modified CLSI protocol in 5 series of 4 replicates in one day. A comparison of results was obtained with 3 different lots of the cobas b 101 HbA1c test on the cobas b 101 instrument with the cobas c 501 analyzer using Tina-quant Hemoglobin-A1c-Gen.-3-reagent. Measurements were performed by using capillary blood on the cobas b 101 instruments and EDTA whole blood samples on the cobas cobas c 501. A representative lot showed the following result. Sample size (n) for precision determination was 62. Mean difference = 0.19 % HbA1c, 95 % of all differences obtained were between - 0.24 % HbA1c to + 0.62 % HbA1c. The sample concentrations were between 4.7 and 9.3 % HbA1c."
For blood pressure Omron device: All Omron blood pressure monitors are clinically proven accurate. They are clinically validated to be within the following:

- Blood pressure: within +/- 3 mgHg or 2 percent

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- Pulse: within +/- 5 percent of reading.

This meets or exceeds the AAMI (Association of Medical Instrumentation) standards.

4. How did the community pharmacists calibrate their equipment and was training provided on this?

Authors' response #4: The manufacturer's recommendations regarding calibration and quality control of the POC testing devices were followed. A product specialist conducted two sessions to train the study's field team on the correct use of the devices and the recommended measures for quality control. As per the product specialist's recommendations, the research associates performed an optical calibration and a quality control test for each of the HbA1c and lipid panel measuring capabilities of all devices prior to sending them out to the participating pharmacies and at the 3-month time point from the start of the implementation phase. Pharmacists were instructed to immediately inform the research associates of any issues or suspicions they had regarding the operation of the devices. Pharmacists did not face issues regarding the validity and reliability of test results at any point during the implementation phase. However, issues regarding finger prick technique were resolved with the help of the product specialist.

5. Please state in the method that a researcher followed up patients for feedback. Also state whether the researcher was a pharmacist and if the patient was aware of this when providing feedback.

Authors' response #5: We thank reviewer 1 for pointing out this important methodological consideration. To address reviewer's comment, we changed the method section slightly. Please see amended main text lines 257 & 258, and lines 268 – 270 (of main text with track changes).

6. If the community pharmacist did the recruitment and this again may not reflect a real service where patients usually present themselves and therefore some recognition of this in the discussion is required. The selection by a community pharmacist also probably explains the higher rates of identification as I am guessing they were more likely to only approach individuals who were overweight.

Authors' response #6: The point is well made; however, we do believe that this does nevertheless reflect a real service. Until screening becomes known and accepted as a community pharmacy service in UAE, the most likely pathway to uptake of screening in community pharmacy in the UAE is by direct invitation from a pharmacist. It is also likely to yield more individuals at high risk and in need of further testing and diagnosis. This has also been the case in other screening trials (Krass et al 2007, CARS trial). Once such service becomes established it is likely that consumers may request it themselves in response to advertising, posters in the pharmacy etc. There is too much focus on the proportions of patients identified with different parameters and comparison between males and females or different age groups (Both of which are largely irrelevant for the purposes of a feasibility study and should be removed). The 95% CIs will be wide on such results and the results are presented such that the reader is expected to assume that they are a good estimate of what would be found from a scaled up service. I am not convinced that this is appropriate from a feasibility study which probably has significant selection bias. The question is whether the service is feasible not how effective is it?

Authors' response #7: We agree with reviewer. As suggested, Table 2 that focus on the proportions of patients identified with different parameters and comparison between males and females or different age groups has been removed. We introduced results about implementation fidelity. Please see results of amended main text limes 315-335 (main text with track changes).

8. At this stage I am more interested in proportion of patients approached and proportion consented and recruitment rate per pharmacy i.e. if I wanted to perform a larger study how long would it take me to reach the required sample size. I would also like to know what the distribution of patients was between chains and multiples.

Authors' response #8: We thank reviewer for his insightful comment. Participant recruitment rate was variable among the 12 participating pharmacies. At the very early stages of the implementation phase, three pharmacists withdrew. The subsequent recruitment and training of replacement pharmacists was time consuming. In one case, pharmacist withdrawal necessitated the withdrawal of

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the site and a new pharmacy had to be recruited. Point-of-care devices arrived in two instalments, which led along with the attrition to only six of the 12 sites continuously screening participants throughout the feasibility assessment period. To account for time lost between withdrawal of a pharmacist and recruitment and training of a replacement pharmacist, we conducted a new analysis that only considered the time from on-site training (i.e., start of participant recruitment) until the date of withdrawal (for pharmacists who withdrew) or end date of feasibility phase (for pharmacists who did not withdraw) for each pharmacist. This method determined that, in total, all pharmacies screened participants for 1011 pharmacy-days, or 33.7 pharmacy-months, and that the recruitment rate across all pharmacies was 3.6 participants per pharmacy-month. Recruitment rates ranged from 1.6 to 6.6 participants per month among individual pharmacies.
We believe that the judgement of the time needed to recruit participants for a larger study based on this feasibility data would be imprecise and could easily lead to an overestimation of time required to reach the required sample size for several reasons. These include: initial steep learning for participating pharmacists - this was the very first time in which pharmacists in the UAE had provided health-screening service, and initial lack of support from pharmacy management. More importantly, the sensitivity evaluation phase that followed the feasibility phase, pharmacists were able to increase their recruitment rate significantly. Pharmacists were able to screen 454 additional participants in the period from May through October 2018 (the total is 569 – 115 in feasibility + 454 in sensitivity). The results obtained in the sensitivity evaluation phase are being collected/analysed.
On a separate note, the investigators planned to recruit independent pharmacies; however, several attempts to do so were unsuccessful due to rarity of independent pharmacies in the UAE relative to chains and refusal of approached pharmacists and/or owners to take-part. All recruited pharmacies throughout the study belonged to pharmacy chains. To clarify this, we have corrected the methods in main text, and 'independent pharmacies' were removed. Please see line 202 (method section, under section 'study setting and participants' of main text with track changes). At initial phase, we planned to document proportion of patients approached and proportion consented and record reason(s) for refusal to screen (if any), however, pharmacists reported that this would be an added work and preferred not to do it sadly we acknowledged this in the limitation section – please see line

9. There is nothing in the results to support this statement in the discussion:
<i>Several pharmacy and pharmacist-levels factors at selected pharmacies contributed to the success of implementing pharmacist-delivered screening, these include: (i) the necessary infrastructure (such as sufficient/appropriate space) to accommodate the screening service, (ii) motivation of pharmacist to learn about and perform the screening, (iii) high volume and greater variability in clientele.
Authors' response #9: As suggested and to support the above mentioned statement, a description of pharmacies was introduced in the result section lines 311 & 313, and also very briefly in method section line 207 – please see main text.
10. The discussion is very brief and does not consider what has been learned from this study, does not adequately consider strengths and limitations and is too focused on trying to justify what was done rather than what should be done if the service was to be rolled out.
The authors have not discussed:
1) Development of the pathway and why this is different to approaches used in different countries
2) Effectiveness of the training
3) The fact that patients have not gone to their Dr even when told to do so and what this means for service efficiency
4) The fact that neither pharmacist or doctor views were obtained
5) The distribution of patients across the different pharmacies, chains and multiples
Authors' response: Thank you for the valuable comment. We have expanded the study limitations (Lines 409 - 436) and factors related to Improving numbers screened and follow-up rates are now described in detail (please see lines 414 - 420) of amended main text with track changes. In-depth interviews with participating pharmacists are planned at the end of the trial to obtain their views and

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perceptions of the screening services, barriers and facilitators, and how best to rollout this service in the future. Physician views, however, are not obtained in this feasibility trail because the follow-up with physicians on uptake of referral and physician action on the results of the screening were determined by participants as per expert panel recommendation. Future studies should evaluate strategies to establish closer links between community pharmacy and physicians in primary care, creating structured referral pathways and emphasis on inter-professional coordination between pharmacists and physician.

Reviewer 2:

The present study was designed to assess the feasibility of a screening model via pharmacies in UAE. The study is interesting because it is conducted in an area where, apparently, there is no attention to an healthy lifestyle. Then, the study is mostly aimed at arising the awareness of the population on this issue. There are several problems in the design of the study that should be addressed.

Authors' response #1: Thank you for positive feedback and raising these questions. For Q1, we have mentioned in line 225 "To document the screening process, participating pharmacists completed brief paper-based records of each screening undertaken". For the second part of the question, we have mentioned under "Phase 1: Formative Phase" section that this entire program was developed based on an international screening model (CARS). For the third part, in the line 215 (main text with track changes), we have revised to clarify the recruitment process and voluntary participation process. The participants could self-volunteer or the pharmacists could invite them to participate, while informed consent was obtained to all eligible individuals after pre-screening.

2. Who was in charge when the patient should seek physician's advice?

Authors' response #2: The objective of the study was to adapt and evaluate the feasibility of the pharmacy screening model. As described under section "Feasibility assessment", study outcomes were the proportion of screened participants identified with CVD or diabetes risk. Study pharmacist did generate the referrals; however, whether or not at-risk patients consulted a physician was beyond the scope of this study.

3. There is no measure on how this approach with increase of awareness on a healthy lifestyle is reflected in a change of individual risk factors.

Authors' response #3: Our study aimed at early identification of CVD and diabetes risk through a pharmacy-based screening model. The interventions to raise aware of health life-style, treat the disease or delay the progression were beyond the scope of the study. However, we have briefly described changes in lifestyle/adoption of a healthier lifestyle by participants as a result of pharmacists counseling in lines 344-346.

4. The discussion is long and unfocused and should be more focused on the social organization of risk reduction. How to intervene in order to modify risk profile

Authors' response #4: We think that this research should be viewed as an iterative part of gradual system change. As such, we determined that it is feasible to implement a screening intervention that appears to activate patients to seek further management and testing. We did identify that there is no clear primary care system for prevention in operation.

5. Moreover, there are no data on the outcome of those who sought physician's advice.

Authors' response #5: As mentioned in our response to the second comment, the primary outcome was the screening of the participants for CVD and diabetes risk. We did attempt to capture the uptake of referral, which is described in result section lines 356 – 366 (main text with track changes). We have also outlined the practical difficulties of obtaining objective post-referral data, which is identified as a limitation.

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Reviewer: 3
This paper describes the development and testing of a new cardiovascular risk assessment service for delivery in the United Arab Emirates. The authors describe the development phase well. I have some questions as per below on the assessment and description of feasibility. Feasibility of a screening program should consider the extent to which the protocol was followed, and what were the limiting factors. I think this is important in the context of this paper. The paper has a lot of results/information on describing the CV risk profile of the screened population, which is interesting, but does not entirely reflect on the feasibility of the screening service.
Authors' response: Authors are grateful for positive feedback and views, and for brilliant comments. We have now re-focused the manuscript more on feasibility rather than addressing how effective the services was! A detailed description of 'implementation fidelity' is now provided – Please see results lines 321-341 (main text with track changes). In addition, the focus of the results in the abstract is now on feasibility data and not on clinical parameters. Please see amended abstract.
1. Is it correct that over 6 months, across 12 pharmacies only 115 people were screened? This would equate to approximately 1-2 people screened per month in a pharmacy. Or about 10 people per pharmacy over the whole time? The numbers screened should be considered when assessing the feasibility of this service. 1 -2 per month does not seem like a lot of people screened.
Authors' response #1: The feasibility assessment period lasted from mid-December 2017 to early May 2018, five months in total. As mentioned above, pharmacist attrition led to only six pharmacies out of the 12 continuously screening participants. For initial period of the feasibility phase, participating pharmacists had to overcome challenges of offering this new health service (this was the very first health-screening program through community pharmacy in the UAE) with their high workload and inadequate support from colleagues and staff.
To account for time lost between withdrawal of a pharmacist and recruitment and training of a replacement pharmacist, we conducted a new analysis that only considered the time from on-site training (i.e., start of participant recruitment) until the date of withdrawal (for pharmacists who withdrew) or end date of feasibility phase (for pharmacists who did not withdraw) for each pharmacist. This method determined that, in total, all pharmacies screened participants for 1011 pharmacy-days, or 33.7 pharmacy-months, and that the recruitment rate across all pharmacies was 3.6 participants/pharmacy-month. Recruitment rates varied among individual pharmacies, ranging from 1.6 to 6.6 participants/month. Prior commencement of this study, the feasibility phase was thought to last for 2 months, which meant that on average, each pharmacy was supposed to screen five participants per month to achieve the sample size of 120. This goal (of five participants per month) was clearly communicated and emphasized to pharmacists when obtaining their signed consents. However, the unforeseen withdrawal of some pharmacists and the challenges that faced the other pharmacists necessitated lengthening the feasibility phase. Despite this, the authors believe that judgement of the time needed to recruit participants for a larger study based on this feasibility data would be premature and lead to an overestimation given the involved circumstances - the participating pharmacists had a steep learning curve during the feasibility assessment phase. More importantly pertaining to this point, during the sensitivity evaluation phase that followed the feasibility phase, most pharmacists were able to increase their recruitment rate leading to the completed screening of 454 additional participants in the period from May through October 2018 (the total was 569 by the end of the study). The results of the sensitivity evaluation phase are being analysed.

2. How much time did it take for the pharmacist to do the screen/ give the lifestyle information? This is also important information to detail in relation to feasibility. Did the pharmacists have to pre book appointments or was it walk-in?
Authors' response #2: We thank reviewer for her insightful. We have added data on the screening encounters and intervention fidelity as documented by participating pharmacists. On average, assessments lasted 27 ± 9.4 minutes and post-assessment counseling lasted 11.6 ± 6.5 minutes.

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More details regarding the assessment of intervention fidelity can be found in the methods and results sections of amended main text.
Pharmacists screened participants both either by pre-booked appointment or on-the-spot (walk-in) according to: (1) patients' preference, (2) pharmacists judgement of how each participant's screening can be best incorporated into their work schedules and foot traffic in the pharmacy at the time of recruitment.

3. The majority of people screened had also seen their treating physician at least 3 times during the year. Were the treating physicians already aware of the CV risk diagnosis? Were they already receiving treatment for this?
Authors' response #3: This point is well made. We incorporated the following exclusion criteria to minimize the potential for patients with managed CVD risk: (1) Previous diagnosis of diabetes or CVD and (2) Use of medications for treatment of diabetes, hypertension or any other CVD at the time of screening. Hence, we have avoided inclusion of all or most high-risk patients who are clearly being actively managed. While for the Australian CARS study researchers were very mindful not to interrupt established therapeutic relationships for prevention, there was general agreement from local experts as to the relatively disorganized state of preventative and primary care in UAE. We felt that it might be inappropriate to make any assumptions of coordinated and ongoing monitoring in this context for untreated individuals, even when a participant felt that their physician might be aware. There was no evidence of problems relating to this during the feasibility study.

4. How many people declined to be screened and what reasons did they give reasons for declining? Again these are factors in relation to feasibility for the program (this could be presented in a flow chart)
Authors' response #4: At initial phase, we planned to document proportion of patients approached and proportion consented and record reason(s) for refusal to screen (if any), however, pharmacists reported that this would be an added work and preferred not to do it sadly. We acknowledged this in the limitation section – please see lines 426-429 (main text with track changes).

5. Did the pharmacists report the reasons (barriers) to screening? That is, why they only screened about 1-2 people per month. This will inform feasibility too.
Authors' response #5: Please see our response above to your comment 1. In-depth interviews with participating pharmacists are planned at the end of the trial to obtain their views and perceptions of the screening services, barriers and facilitators, and how best to rollout this service in the future.

6. Was there a lot of variation in the numbers screened between the different pharmacies? If so were there any factors that seemed to facilitate a better outcome in the pharmacies that screened more people?
Authors' response #6: Authors are grateful for this insightful comment. There was variation in the recruitment rate among the different pharmacies, ranging from 1.6 to 6.6 participants/month – we provided a detailed description above. Reviewer #1 also made a comment on this regard, please refer to our response to reviewer #1 comment #8. Compared with usual/lower recruiting pharmacists, those with the highest recruitment rates reported increased managerial support, were slightly more excited about embracing the identity of 'healthcare provider', those who used multiple recruitment strategies, and those who were located in busier pharmacies where there was a high need and demand for the screening service.

7. Only 24.3% sought follow-up with a physician – this seems to suggest that the follow up pathway for participants needs some consideration for improvements. Should be mentioned in the limitations and discussion

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Authors' response #7: We agree with reviewer, and we appreciate the insightful comment. As suggested, the follow up pathways could/should be improved. Lines 413 & 414 (of amended text with track changes) the following text has been added:
"To optimize the health impacts of a screening service a more effective referral pathway will need to be established in further discussions between pharmacists and physicians.
8. How could a better follow-up rate be achieved?
Authors' response #8: We thank reviewer 1 for pointing out this important issue. We have added the following paragraph on how better uptake of screening and follow-up rate can be achieved, please see main text lines 414-420 (of amended text with track changes).
Better uptake of screening may have been achieved with training of other staff of the pharmacy to aid in recruitment. A focused advertising campaign, including advertorials in local media may also have boosted uptake. A better follow-up rate may have been achieved if the pharmacist him/herself followed up screened participants several weeks after the referral was given. In this follow-up, the pharmacist could check if at-risk screened individuals had taken up the referral or prompt them to act upon it if they had yet done so. It may also have been helpful to send a copy of the referral directly to the referred individual's nominated physician.

9. The discussion and limitations section should explore factors related to Improving numbers screened and follow-up rates
Authors' response #9: We have addressed this comment; please see above (response to 8)

Other:
10. United Arab Emirates (UAE) needs to be spelt out in full on first use in abstract and main text
Authors' response 10: As suggested United Arab Emirates (UAE) needs to be spelt out in full on first use in abstract and main text, please see lines 55 and 127 (of amended text with track changes).
11. Text states 120 screened (plus 5 not eligible) and abstract states 115 screened. If they were not eligible, then the number screened in the text should state 115 – you could add the numbers approached and not eligible and declined screening in a flow chart to better show the feasibility and acceptability of this service.
Authors' response #11: Just to clarify, a total 120 participants were screened, and five participants were excluded for not meeting study criteria, so the total number was 115. Please see lines 314 & 315 (of amended text with track changes).

VERSION 2 – REVIEW

REVIEWER	David Wright University of East Anglia England
REVIEW RETURNED	20-Aug-2019

GENERAL COMMENTS	This a locally novel service evaluation which is well presented in this publication. The background covers the literature sufficiently well, however some comment regarding sensitivity and specificity of point of care tests is required as this explains the need for patients to go to their doctor for a confirmatory test using systems with greater quality assurance. If that is not the case then again this requires stating. With a focus on the technical aspects of the service the research team failed to involve patients in the service design with respect to enhancing access, acceptability and patient engagement with recommendations. This is a major flaw. All of these problems are

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	demonstrated by the results which found that pharmacists largely actively recruited patients and those who were recommended to visit their doctor largely failed to do so. This requires more consideration within the discussion as this is a regular failing of researchers setting up services of this nature i.e. forgetting to include the service recipient in the design of the service. It is interesting that patients which hypertension were excluded as this is in isolation is a known risk factor for diabetes. I am unsure as to why tests were performed regarding risk/age and gender as these relationships are well documented, the risk factors are non-modifiable and this is not an objective of the study. The lack of UAE born participants in the study sample is very interesting and some discussion regarding this finding is required. Couple of typos 'no obtained' and 'one average' - 'not obtained' and 'on average' The discussion is too positive given the fact that many patients did not go to see their doctor - this represents a significant waste of resource unless it is the patient who is paying for the service. I question whether pharmacists would continue to provide this service for the six dollars offered and what exactly it would require for them to either charge for this or provide this with government funding. Only when this is known can we start to determine whether such a service is likely to represent value for money. Some commentary on this is required. The reasons for lack of follow up by patients are provided as given facts when they are largely supposition. It may just be that the patient perception of the pharmacist ability to make such judgements is low and without some extensive qualitative work this will remain unknown. The researchers take a very paternal view of healthcare i.e. it is the relationship between the pharmacist and doctor which requires resolution without any consideration of the patient at the centre of this. This is further consolidated by the view that if the pharmacist was able to follow up this would make the patient more likely to comply. Again all supposition. These are all ideas which require exploration and testing and the discussion requires moderation to better represent what is known and what is not. I am unsure as to what a larger sensitivity study is?

REVIEWER	Rosa Sicari CNR, Institute of Clinical Physiology, Pisa, Italy
REVIEW RETURNED	07-Aug-2019

GENERAL COMMENTS	Authors have addressed all the issues raised by this reviewer and responded appropriately.

VERSION 2 – AUTHOR RESPONSE

1. This a locally novel service evaluation which is well presented in this publication.

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Authors' response: We thank the reviewer for his positive feedback.

2. The background covers the literature sufficiently well, however some comment regarding sensitivity and specificity of point of care tests is required as this explains the need for patients to go to their doctor for a confirmatory test using systems with greater quality assurance. If that is not the case then again this requires stating.

Authors' response: We had already commented on sensitivity and specificity of POC, and stated that pharmacists explained the need for patients to go to their doctor for a confirmatory test in the method section.

"Pharmacists also reminded at-risk individuals that point-of-care tests may not have the same sensitivity and specificity as laboratory based equipment and hence the need to refer to the medical practice for confirmation."

3. With a focus on the technical aspects of the service, the research team failed to involve patients in the service design with respect to enhancing access, acceptability and patient engagement with recommendations. This is a major flaw. All of these problems are demonstrated by the results which found that pharmacists largely actively recruited patients and those who were recommended to visit their doctor largely failed to do so. This requires more consideration within the discussion as this is a regular failing of researchers setting up services of this nature i.e. forgetting to include the service recipient in the design of the service.

Authors' response: We acknowledge that the focus of this trial was on determining feasibility from a health service perspective. However, it seems relevant to point out that the original CARS model, which we adapted, did engage with a diverse range of Australian consumers (n=46) before study design completion to support model acceptability and patient engagement. This included 20 Arabic speaking migrants, 10 male and 10 female in separate focus groups facilitated by the lead investigator HA, to explore various aspects of a pharmacy screening service from a culturally and linguistically diverse consumer perspective. This process established the generally acceptable parameters for a pharmacist-delivered service from the perspective of Middle Eastern adults, arguably validated by the strong satisfaction with the intervention reported in patient surveys. In these focus groups, there were a number of comments suggesting greater confidence and trust in Arabic pharmacists and pharmacy systems than their Australian counterparts. What this process missed was consumer guidance regarding their specific support needs in the context of this model being operated within the UAE health system. We have relied on health professionals and experts for guidance on this because of the complexity of the health system, absence of primary care, and the novelty of the intervention, which required a significant level of insight and extensive engagement to determine a model that might work. We fully acknowledge that we need to engage UAE consumers further before scaling up this intervention and have added a statement to this effect in the Discussion.

4. It is interesting that patients which hypertension were excluded as this is in isolation is a known risk factor for diabetes.

Authors' response: Thank you for raising this interesting point, which we also deliberated upon during model design. First, let us clarify that people with hypertension were not excluded per se; they were only excluded if they were being treated with medication. The reason for their exclusion was that the Framingham equation upon which the CVD risk score is based, was derived from 'free living' individuals who were not receiving medication – therefore the score is not validated for these individuals who are being treated with medication. As a 'first ever' trial of its kind in UAE, we thought it was important not to compromise the validity of the screening approach. It was an option to include these individuals and screen only for diabetes and not CVD risk. However, at this feasibility/proof of concept stage it was more important not to complicate the intervention and not to risk a reduction in the number of participants with CVD risk screening data. Ultimately we agree with the reviewer

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sentiment expressed that people with treated hypertension should not be excluded from a rolled out program, but we had sound reasons for not introducing it at this stage.

5. I am unsure as to why tests were performed regarding risk/age and gender as these relationships are well documented, the risk factors are non-modifiable and this is not an objective of the study.

Authors' response: We agree with the reviewer regarding data on the relationship between risk factors and age/gender, hence, this data has been removed.

6. The lack of UAE born participants in the study sample is very interesting and some discussion regarding this finding is required.

Authors' response: There were four participants born in the UAE with Emirati nationality, and these were grouped with 'others'. We would like to clarify that expatriates born in UAE are not entitled to UAE citizenship (Emirati nationality). Furthermore, Emirati citizens have different health coverage schemes than expats. In our efficacy trial phase, we recruited 20 participants born in the UAE. We plan to discuss this when we finish data analysis of the second phase (efficacy trial).

7. Couple of typos 'no obtained' and 'one average' - 'not obtained' and 'on average'

Authors' response: The typos have been corrected; please see lines 325 and 330

8. The discussion is too positive given the fact that many patients did not go to see their doctor - this represents a significant waste of resource unless it is the patient who is paying for the service.

Authors' response: Considering the complexity in preventive and primary healthcare services/setting in the UAE, for any screening service to sustain, the receiver of the service would be expected to pay for the service. Hence, it would be either voluntarily up-taken or requested by the participant.

9. I question whether pharmacists would continue to provide this service for the six dollars offered and what exactly it would require them to either charge for this or provide this with government funding. Only when this is known can we start to determine whether such a service is likely to represent value for money. Some commentary on this is required.

Authors' response: To address reviewer's insightful comment, we added to the following paragraph to the Discussion section: "The six-dollar per participant was an incentive for the pharmacists to engage in the study, and it was not based on a calculation of what an actual service would cost. This would eventually need to be negotiated with government and private insurance based on local practices and reported economic studies related to screening services. At this point, this was not the scope of this study."

10. The reasons for lack of follow up by patients are provided as given facts when they are largely supposition. It may just be that the patient perception of the pharmacist ability to make such judgements is low and without some extensive qualitative work this will remain unknown.

Authors' response: We agree with the reviewer, and the following paragraph about participant perceptions was added in the Discussion.

"It could also have been that participants still questioned the validity of the risk screening process carried out in community pharmacies, and that they may have taken the results more seriously had the assessment been carried out in a clinic or a more traditional care setting. Patient and physician reservations about services being provided in community pharmacies have been reported in the

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literature. In the UAE, reasons cited for this included doubt about pharmacist competence to provide the services, a business image rather than a healthcare image of community pharmacy that prevails in the country, little privacy in the pharmacy setting and lack of effective collaboration between pharmacists and physicians. For community pharmacies to be an acceptable setting for providing screening services in the UAE, the service model in the pharmacy will need to assure minimum expectations of patients including patient privacy and properly trained pharmacists."

11. The researchers take a very paternal view of healthcare i.e. it is the relationship between the pharmacist and doctor, which requires resolution without any consideration of the patient at the centre of this. This is further consolidated by the view that if the pharmacist was able to follow up this would make the patient more likely to comply. Again all supposition. These are all ideas, which require exploration and testing, and the discussion requires moderation to better represent what is known and what is not.

Authors' response: The Discussion has been modified to delete unjustified suppositions, provide reference citations of ideas and arguments raised, and to include possible explanations of participant behavior post screening. (Please see modified Discussion).

12. I am unsure as to what a larger sensitivity study is?

Authors' response: 'sensitivity' was deleted, and the phrase now reads 'This feasibility study was continued into a larger scale to evaluate the efficacy of pharmacist-delivered screening in identifying the proportion of screened participants identified as having high diabetes and/or CVD risk in the UAE'

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